
NOTE

Warning Third Parties of Genetic Risks in the Era of Personalized Medicine

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INTRODUCTION

In recent years, genetic testing technology has undergone drastic improvements, far surpassing its predicted capabilities and potential applications.¹ Testing methods are also evolving, moving from clinical laboratories to direct-to-consumer (“DTC”) technologies like testing kits supplied by private companies.² Consumers can now purchase genetic testing services without any input from healthcare professionals.³ DTC kits reflect a general trend of modern healthcare: a “personalized medicine” approach that focuses on patients’ specific needs and tailors treatments to individual genetic profiles.⁴ Some commentators have even speculated that DTC tests may “displace clinicians as the primary providers of genetic information related to health”⁵ Initial research, however, suggests that DTC tests have not diminished the role of physicians.⁶ On the contrary, genetic information from DTC tests generally leads consumers to seek greater physician involvement in applying genetics to healthcare.⁷

At the same time, various governmental entities, including the FDA, have begun to regulate DTC tests in response to health, safety, and policy concerns.⁸ The current regulatory system is still in its early stages, and commentators have pointed out the need for a more cohesive and comprehensive framework.⁹ But this momentum toward

¹ See, e.g., Francis S. Collins & Victor A. McKusick, *Implications of the Human Genome Project for Medical Science*, 285 JAMA 540, 540-44 (2001) (theorizing that by 2010, “predictive genetic tests will be available for . . . a dozen common conditions”); *Genetic Testing: How It Is Used for Healthcare*, NAT’L INST. HEALTH (Oct. 2010), available at [http://www.report.nih.gov/NIHfactsheets/Pdfs/GeneticTesting-HowItIsUsedForHealthcare\(NHGRI\).pdf](http://www.report.nih.gov/NIHfactsheets/Pdfs/GeneticTesting-HowItIsUsedForHealthcare(NHGRI).pdf) (as of October 2010, “over 500 laboratories” supplied genetic testing for “over 2,000 rare and common conditions” for diagnostic, predictive, pre-symptomatic, carrier screening, pharmacogenetic, prenatal/pre-implantation/newborn screening, and research purposes).

² See Morris W. Foster & Richard R. Sharp, *Out of Sequence: How Consumer Genomics Could Displace Clinical Genetics*, 9 NATURE REVIEWS GENETICS 419, 419 (2008).

³ Pascal Borry et al., *Where Are You Going, Where Have You Been: A Recent History of the Direct-to-Consumer Genetic Testing Market*, 1 J. COMMUNITY GENETICS 101, 101 (2010).

⁴ See Gary E. Marchant, *Personalized Medicine and the Law*, 44 ARIZ. ATT’Y, Oct. 2007, at 12, 13.

⁵ Foster & Sharp, *supra* note 2.

⁶ See Borry et al., *supra* note 3, at 103.

⁷ See David J. Kaufman et al., *Risky Business: Risk Perception and the Use of Medical Services Among Customers of DTC Personal Genetic Testing*, 21 J. GENETIC COUNSELING 413, 417 (2012).

⁸ Stephanie Bair, *Direct-to-Consumer Genetic Testing: Learning from the Past and Looking Toward the Future*, 67 FOOD & DRUG L.J. 413, 426, 429-31 (2012).

⁹ See, e.g., *id.* at 426-27.

regulation has not diminished the influences of DTC testing;¹⁰ if anything, it has accelerated the integration of DTC companies into more legitimate, traditional healthcare systems.¹¹

In response to the pressures of developing regulation, as well as consumers' desire for physician involvement, DTC companies are starting to include healthcare professionals in their business models.¹² While the law mandates this shift for some companies, the decision is voluntary for others.¹³ For example, certain companies voluntarily require a physician's order to obtain testing services, or send test results to physicians for interpretation.¹⁴ Involved physicians may then become responsible for patients' healthcare decisions, if patients made those decisions in response to genetic test results.¹⁵

Many physicians already report that patients are actively asking about DTC tests, or actually bringing in their test results, and in many circumstances the results end up affecting their healthcare decisions.¹⁶ But physicians are ill-suited to take on this "gatekeeper" role over use of genetic information in healthcare, for several reasons.¹⁷ First, many physicians lack adequate education, training, or experience to recommend genetic testing, interpret test results, or answer patients' questions.¹⁸ Second, even among experienced physicians, clinically useful interpretations of genetic information are highly subjective and

¹⁰ See, e.g., Julie Steenhuysen, *US FDA Sends Letter to DNA4Life Over Consumer Genetic Tests*, REUTERS (Nov. 9, 2015, 1:46 PM), <http://www.reuters.com/article/2015/11/09/us-usa-genetics-dna4life-fda-idUSKCN0SY1US20151109#jMkVhHAs7vfMvvYB.97> (after the FDA ordered 23andMe's DTC test off the market in 2013, the company simply re-launched its service with a more limited number of genetic tests, which still triggers concerns that consumers may use those tests to make decisions about their medical care).

¹¹ See, e.g., Alice Park, *Genetic Testing Company 23andMe Finds New Revenue with Big Pharma*, TIME (Jan. 8, 2015), <http://time.com/3660174/23andme-big-pharma/> (after the FDA shut down 23andMe's DTC service, the company entered a \$10 million partnership with Genentech, a biotech giant that will use 23andMe's database to develop drugs to treat Parkinson's disease).

¹² See Borry et al., *supra* note 3, at 103-04.

¹³ See Kathryn Schleckser, Note, *Physician Participation in Direct-to-Consumer Genetic Testing: Pragmatism or Paternalism?*, 26 HARV. J.L. & TECH. 695, 710 (2013).

¹⁴ See, e.g., Borry et al., *supra* note 3, at 103-04.

¹⁵ See *infra* Part II.

¹⁶ See Katherine Kolor et al., Letter to the Editor, *Health Care Provider and Consumer Awareness, Perceptions, and Use of Direct-to-Consumer Personal Genomic Tests, United States, 2008*, 11 GENETICS MED. 595, 595 (2009); Rita Rubin, *Most Doctors Are Behind the Learning Curve on Genetic Tests*, USA TODAY, http://usatoday30.usatoday.com/yourlife/health/medical/2010-10-25-genetics24_cv_n.htm (last updated Oct. 24, 2010).

¹⁷ See Borry et al., *supra* note 3, at 104.

¹⁸ See Schleckser, *supra* note 13, at 724-25.

differ between individuals; there is often no “best” or most correct course of action.¹⁹ Although medical care in general may involve some subjectivity or variation in preferences between professionals and patients, personalized medicine uniquely exacerbates this problem because it deals with risks and propensities rather than actual conditions. For example, the standards of care for well-established medical practices like the administration of antibiotic prophylaxis for most surgical procedures are relatively uncontroversial, since they are predicated on reliable data and their outcomes conducive to objective interpretation.²⁰ In contrast, personalized medicine represents a new and uncertain frontier where even well-known associations, e.g., between the BRCA1 and BRCA2 genes and inherited breast cancer, do not indicate the same medical decisions for all patients or healthcare professionals.²¹ Thus, a patient’s individual preferences, from risk aversion to religious beliefs, and not the physician’s input or expertise, are often the primary determinants of healthcare decisions based on genetic information.²²

¹⁹ See Morris W. Foster et al., *Evaluating the Utility of Personal Genomic Information*, 11 GENETICS MED. 570, 570-74 (2009) (noting that “multiple factors are involved in assessing a test’s clinical utility”).

²⁰ See, e.g., Alan R. Salkind & Kavitha C. Rao, *Antibiotic Prophylaxis to Prevent Surgical Site Infections*, 83 AM. FAM. PHYSICIAN 585 (2011) (primary care physicians should be familiar with the recommendations of national organizations, including the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention, regarding administration of antibiotic prophylaxis for surgical patients); Ronald K. Woods & E. Patchen Dellinger, *Current Guidelines for Antibiotic Prophylaxis of Surgical Wounds*, 57 AM. FAM. PHYSICIAN 2731 (1998) (antibiotic prophylaxis reduces the incidence of surgical wound infection and is uniformly recommended for virtually all procedures); Deverick J. Anderson & Daniel J. Sexton, *Antimicrobial Prophylaxis for Prevention of Surgical Site Infection in Adults*, UPTODATE, <http://www.uptodate.com/contents/antimicrobial-prophylaxis-for-prevention-of-surgical-site-infection-in-adults> (last updated Aug. 1, 2014) (“The efficacy of antibiotic prophylaxis for reducing [surgical site infection] has been clearly established.”).

²¹ See, e.g., Francois Eisinger, *Prophylactic Mastectomy: Ethical Issues*, 81–82 BRITISH MED. BULL. 7 (2007) (arguing that prophylactic mastectomy in response to testing for the BRCA genes should be an at least partially ethical question, rather than a purely medical one); Sandhya Pruthi et al., *Identification and Management of Women with BRCA Mutations or Hereditary Predisposition for Breast and Ovarian Cancer*, 85 MAYO CLINIC PROC. 1111 (2010) (noting that there are no established or consistent definitions for what constitutes “high risk” of breast or ovarian cancer, and recommending multidisciplinary rather than purely medical management strategies for BRCA carriers); Charles Bankhead, *Universal BRCA Testing Slammed as Too Costly, Inefficient — But BRCA1 Discoverer Disagrees*, MEDPAGE TODAY (Sept. 3, 2015), <http://www.medpagetoday.com/Genetics/GeneticTesting/53396> (summarizing a debate over whether universal BRCA testing is even a good idea).

²² See Foster et al., *supra* note 19 (“[W]here the clinical implications of a genetic

Physicians in such “gatekeeper” roles nevertheless face expansive risk of liability. In recent years, plaintiffs have filed suits against physicians stemming from the use of genetic technology under a number of legal theories.²³ The evolution of physician liability in response to genetic technology has generally followed common law doctrines.²⁴ Thus, to hold physicians liable for novel causes of action, courts generally rely on two types of analysis. First, courts may determine that, due to policy considerations, a physician’s professional duty encompasses certain actions with respect to genetic technology.²⁵ Second, they may find that a physician breached his duty by failing to meet an applicable standard of care.²⁶ The trend of recent cases has been both to expand the scope of physician duty, and to raise the standard of care for physicians in using genetic technology and practicing personalized medicine.²⁷

This Note will focus on the recent judicial expansion of physician liability, and its justifications under prevailing common law doctrines. Specifically, this Note will analyze influential case law holding physicians liable for failing to warn third parties²⁸ of genetic risks (i.e., genetically inheritable diseases or predispositions to such diseases). Part I discusses the evolution of physician duty and the standard of care as they apply generally to malpractice suits.²⁹ Part II analyzes various courts’ rationales for expanding liability in the context of genetic testing, and argues that they are inconsistent with traditional legal principles.³⁰ Part III assesses the impacts of this expansion of physician liability, and argues that it is undesirable as a policy

test are ambiguous, the preferences of individual patients often shape a physician’s perceptions of a test’s utility and guide decisions to pursue clinical genetic testing.”).

²³ See *infra* Part II. It is also worth noting that physicians are not the only ones caught up in these new theories of liability. See, e.g., Turna Ray, *Lawsuit in Hawaii Against Plavix Sponsors Alleges Burden Is on Pharma to Market PGx Information*, GENOMEWEB (Apr. 16, 2014), <https://www.genomeweb.com/clinical-genomics/lawsuit-hawaii-against-plavix-sponsors-alleges-burden-pharma-market-pgx-informat> (analyzing a recent lawsuit which takes on the issue of whether drug makers can be liable for failing to affirmatively warn consumers — i.e., going beyond ordinary labeling — that certain genetic markers can limit or negate their responses to specific drugs).

²⁴ See *infra* Part I.

²⁵ See *infra* Part I.A.

²⁶ See *infra* Part I.B.

²⁷ See *infra* Part I.

²⁸ Unless otherwise specified, “third party” means someone with whom a medical provider does *not* have an established physician-patient relationship.

²⁹ See *infra* Part I.

³⁰ See *infra* Part II.

matter.³¹ Part IV concludes that, in the genetic testing context, responsible dissemination of public information and improved training for medical professionals are preferable to judicial expansion of physician liability for both legal and policy reasons.³²

I. LEGAL PRINCIPLES OF PHYSICIAN LIABILITY

Ordinary actors have a duty to exercise reasonable care when their conduct risks causing physical harm to others.³³ But medical professionals cannot simply be held to this general duty because what constitutes “reasonable care” in the complex, highly specialized medical field is not easily understandable to lay persons.³⁴ Rather, medical professionals owe their patients a duty to exercise *customary* care, as reflected through other similar, reasonably diligent practitioners in the profession.³⁵

A. Evolution of Physician Duty

To determine whether a duty exists between a plaintiff and defendant, courts must decide whether the plaintiff’s interests are entitled to legal protection from the defendant’s conduct.³⁶ Courts answer this question by considering the totality of all relevant policy considerations.³⁷ Absent overriding policy concerns, the most important factor in determining the existence of duty is foreseeability of risk.³⁸ Specifically, a defendant has a legal duty to use “ordinary care and skill” to avoid creating a foreseeable danger of injury to another person.³⁹ As a general rule, however, no one owes a duty to “control the conduct of another” or “warn those endangered by such conduct.”⁴⁰ Under this traditional rationale, “physicians have no responsibility to anybody except patients with whom they’ve entered

³¹ See *infra* Part III.

³² See *infra* Part IV.

³³ RESTATEMENT (THIRD) OF TORTS § 7 (2010).

³⁴ See *id.* cmt. a.

³⁵ See *id.*

³⁶ See *Dillon v. Legg*, 441 P.2d 912, 916 (Cal. 1968).

³⁷ See *id.*

³⁸ See *id.* at 920 (“The obligation turns on whether the offending conduct foreseeably involved unreasonably great risk of harm to the interests of someone other than the actor.” (internal quotation marks omitted)).

³⁹ See *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 342 (Cal. 1976).

⁴⁰ *Id.* at 343 (internal citations omitted); RESTATEMENT (SECOND) OF TORTS § 315 (1965).

into a professional doctor-patient relationship.”⁴¹ Thus, in general, physicians owe a duty only to their direct patients, not to third parties.

In the landmark case of *Tarasoff v. Regents of the University of California*,⁴² the court articulated a body of exceptions carved out from the general no-duty rule, specifically applicable to healthcare providers.⁴³ Because of the “special relation” between patients and certain healthcare providers, the court decided that public policy concerns may cause the latter to owe affirmative duties to some third parties.⁴⁴ For example, hospitals “must exercise reasonable care to control the behavior of a patient which may endanger other persons.”⁴⁵ Doctors must “warn a patient if the patient’s condition or medication renders certain conduct, such as driving a car, dangerous to others.”⁴⁶ Therapists must warn a patient’s threatened victim when the exercise of reasonable care requires them to do so.⁴⁷ And physicians not only must detect contagious diseases; after diagnosis, they also owe a duty to warn a patient’s immediate family members of the risk of infection.⁴⁸ In all of these circumstances, courts have found that healthcare professionals owe a duty to third parties to take some affirmative action because of overriding policy considerations.⁴⁹

B. Evolution of the Standard of Care

The critical inquiry in determining breach of a legal duty is whether a physician’s actions fell below the prevailing standard of care, i.e., what a reasonably prudent physician in a similar community would have done.⁵⁰ Thus, in traditional medical malpractice actions, “there

⁴¹ Gary E. Marchant et al., *Physician Liability: The Next Big Thing for Personalized Medicine?*, 8 PERSONALIZED MED. 457, 461 (2011) [hereinafter *Next Big Thing*].

⁴² *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334.

⁴³ See W. Jonathan Cardi, *A Pluralistic Analysis of the Therapist/Physician Duty to Warn Third Parties*, 44 WAKE FOREST L. REV. 877, 877-78 (2009); Angela Liang, Note, *The Argument Against a Physician’s Duty to Warn for Genetic Diseases: The Conflicts Created by Safer v. Estate of Pack*, 1 J. HEALTH CARE L. & POL’Y 437, 439 (1998).

⁴⁴ See *Tarasoff*, 551 P.2d at 343.

⁴⁵ *Id.*

⁴⁶ *Id.* at 343-44.

⁴⁷ *Id.* at 347.

⁴⁸ See *Hofmann v. Blackmon*, 241 So. 2d 752, 753 (Fla. Dist. Ct. App. 1970); *Wojcik v. Aluminum Co. of Am.*, 183 N.Y.S.2d 351, 357-58 (Sup. Ct. 1959) (“Such a risk is within the range of probability and apprehension of an ordinarily prudent person.”).

⁴⁹ See *Tarasoff*, 551 P.2d at 347; *Hofmann*, 241 So. 2d at 753; *Wojcik*, 183 N.Y.S.2d at 357-58.

⁵⁰ See *Burke v. Scaggs*, 867 A.2d 213, 217 (D.C. Ct. App. 2005); RESTATEMENT

are three elements a plaintiff must show to establish a prima facie case: (1) the applicable standard of care; (2) a deviation from that standard of care by the defendant; and (3) a causal relationship between *that deviation* and the plaintiff's injury.⁵¹ Such cases often turn on where the court looks to find the applicable standard of care — i.e., what constitutes “members of the medical profession” and “similar circumstances.”⁵² Traditionally, courts have applied the “locality rule,” which compared the defendant's actions with the customary practices of other comparable practitioners within the same local medical community.⁵³ The locality rule accounted for the fact that, traditionally, what a reasonable practitioner would do varied according to the level of technology and general expertise in the local medical community.⁵⁴

A national standard of care, under which physicians are judged against similar practitioners not only in their locality but rather across the nation, is steadily replacing the locality rule.⁵⁵ There are several factors driving this shift. One is the system of national accreditation for healthcare providers, which standardizes medical education throughout the country and generally reduces disparities between the skills of practitioners in different regions.⁵⁶ Another is improvements in transportation, which allow most physicians to access adequate or even excellent hospital facilities.⁵⁷ And advanced modes of communication permit physicians, regardless of location, to keep abreast of recent developments in medical technology and practices.⁵⁸ In short, because of nationally standardized education and advanced information technology, courts have concluded that physicians have no excuse not to exercise the same degree of care and skill as

(SECOND) OF TORTS § 299A (1965).

⁵¹ *Burke*, 867 A.2d at 217 (emphasis added) (internal citations omitted).

⁵² See *Morrison v. MacNamara*, 407 A.2d 555, 561 (D.C. Ct. App. 1979) (“In medical malpractice . . . the duty of care is generally formulated as that degree of reasonable care and skill expected of members of the medical profession under the same or similar circumstances.”).

⁵³ See *id.* at 561; JAMES BUCHWALTER ET AL., 17 MICHIGAN CIVIL JURISPRUDENCE: MEDICINE & SURGERY § 137 (2015); Marchant et al., *Next Big Thing*, *supra* note 41, at 459.

⁵⁴ See *MacNamara*, 407 A.2d at 561; see also Marchant et al., *Next Big Thing*, *supra* note 41, at 459 (describing current events in the locality rule).

⁵⁵ See Marchant et al., *Next Big Thing*, *supra* note 41, at 459.

⁵⁶ See *MacNamara*, 407 A.2d at 563.

⁵⁷ See *Paintiff v. City of Parkersburg*, 345 S.E.2d 564, 566 (W. Va. 1986).

⁵⁸ See *id.*

reasonably competent practitioners in similar circumstances, regardless of geographic location.⁵⁹

Courts consider several factors when determining the standard of care, including, *inter alia*, “advances in the profession, availability of facilities, specialization or general practice, proximity of specialists and special facilities”⁶⁰ The law holds physicians to a higher standard of care than it does the normal reasonably prudent person because of physicians’ specialized knowledge and skills, but traditionally tempers that burden by permitting the medical profession to set its own standards of reasonable conduct.⁶¹ As a result, in most medical malpractice cases, expert witnesses must explain the often technical and complex guidelines of the medical profession for the courts.⁶²

II. LIABILITY IN THE WAKE OF GENETIC TECHNOLOGY

In light of new genetic technologies, commentators have called for expansion of physician duty to include the use of genetic information in healthcare.⁶³ However, case law analyzing a physician’s duty to warn third parties of genetic risks remains sparse.⁶⁴ *Pate v. Threlkel*⁶⁵ and *Safer v. Estate of Pack*⁶⁶ are two prominent cases that have held physicians can be liable for not warning third parties of genetic risks.⁶⁷ Both are explored below.

⁵⁹ See, e.g., *MacNamara*, 407 A.2d at 563; *Vergara v. Doan*, 593 N.E.2d 185, 186-87 (Ind. 1992); *Shilkret v. Annapolis Emergency Hosp. Ass’n*, 349 A.2d 245, 253 (Md. 1975); *Wickliffe v. Sunrise Hosp., Inc.*, 706 P.2d 1383, 1387-88 (Nev. 1985); *King v. Williams*, 279 S.E.2d 618, 620 (S.C. 1981); *Paintiff*, 345 S.E.2d at 566.

⁶⁰ *Shilkret*, 349 A.2d at 253.

⁶¹ *Robbins v. Footer*, 553 F.2d 123, 126 (D.C. Cir. 1977).

⁶² *Id.* at 126-27. There is, however, a “common knowledge exception” to the expert testimony requirement, which applies in straightforward medical malpractice cases where the conduct at issue is fully comprehensible to laypersons without any medical training or background (e.g., if a dentist extracts the wrong tooth or a surgeon leaves a device inside the patient’s body). See generally Joseph H. King, *The Common Knowledge Exception to the Expert Testimony Requirement for Establishing the Standard of Care in Medical Malpractice*, 59 ALA. L. REV. 51 (2007) (discussing the common knowledge exception).

⁶³ See, e.g., Jeffrey W. Burnett, Comment, *A Physician’s Duty to Warn a Patient’s Relatives of a Patient’s Genetically Inheritable Disease*, 36 HOUS. L. REV. 559, 581-82 (1999).

⁶⁴ See *id.* at 569.

⁶⁵ *Pate v. Threlkel*, 661 So. 2d 278 (Fla. 1995).

⁶⁶ 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

⁶⁷ See, e.g., Kenneth Offit et al., *The “Duty to Warn” a Patient’s Family Members About Hereditary Disease Risks*, 292 JAMA 1469, 1470-71 (2004).

A. *Pate v. Threlkel*

In 1990, Heidi Pate discovered that she had medullary thyroid carcinoma, a genetically inheritable disease.⁶⁸ Because Pate's mother had been treated for the same disease in 1987, Pate and her husband filed suit against her mother's physicians, alleging the physicians knew or should have known of the likelihood that their patient's children would inherit the disease.⁶⁹ The complaint depended on, *inter alia*, an allegation that the physicians owed a duty to warn Pate's mother that her children should be tested for the disease.⁷⁰

In its analysis of physician duty, the Supreme Court of Florida decided two issues. First, the court held "that a duty exists if the . . . standard of care requires a reasonably prudent health care provider to warn [their] patient of the genetically transferable nature of the condition for which the physician was treating the patient."⁷¹ Second, the court found that the "prevailing standard of care was obviously developed for the benefit of the patient's children as well as the patient."⁷² Comparing the patient's children to "identified third party beneficiaries" in "other professional relationships,"⁷³ the court concluded that children "fall within the zone of foreseeable risk" and held that the physician's duty to warn a patient of genetic risks extends to a patient's children.⁷⁴ Thus, under *Pate*, a physician's duty extends to reasonably identifiable third parties with foreseeable genetic risks, so long as the third parties benefit from the physician's duty to a direct patient.⁷⁵

The posture and rationale in *Pate*, however, do not support judicial expansion of physician duty to include a duty to warn third parties of genetic risks. First, the *Pate* court made its decision without the guidance of medical expertise to provide the applicable standard of care because the Supreme Court of Florida took the case on appeal from a motion to dismiss.⁷⁶ This required the court to assume as true the plaintiff's allegations that, under the "prevailing standard of care," the physicians "were under a duty to warn [plaintiff's mother] of the

⁶⁸ *Pate*, 661 So. 2d at 279.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.* at 280.

⁷² *Id.* at 282.

⁷³ *Id.* at 281.

⁷⁴ *Id.* at 282.

⁷⁵ *Id.*

⁷⁶ *See id.* at 281.

importance of testing her children . . .”⁷⁷ Without the “required expert medical authority” to support this alleged standard of care, *Pate* cannot have any bearing on the *actual* standard of care, except perhaps to say that more evidence (e.g., a battle of the experts) is necessary.⁷⁸

Second, even assuming *arguendo* that warning third parties of genetic risks is standard practice within the medical profession, it is not, as the *Pate* court claims, obvious that this standard aims to specifically protect patients’ children.⁷⁹ Because all biologically related persons share genetic risks, the technically foreseeable third parties that share risks with a single patient extend far beyond the patient’s children.⁸⁰ But, as the *Pate* court implicitly recognized, a concept of foreseeable victims that encompasses all biological relatives is not a realistically workable basis for a duty to warn.⁸¹ Even aside from the impracticality, such a broad duty to warn would seriously compromise the physician’s traditional duty of confidentiality to direct patients.⁸² Thus, the mere *foreseeability* of the genetic risk to a patient’s children cannot provide a sufficient basis for a legal duty.

The *Pate* court attempted to bolster this rationale by comparing a patient’s children to the intended beneficiaries of a will.⁸³ This reasoning would make the patient analogous to the drafting attorney’s client. But the analogy suggests that the patient’s wishes, rather than the medical community, should inform the physician’s standard of care. This suggestion conflicts with established jurisprudence that the medical community is responsible for developing the standard of care.⁸⁴ But suppose the point of the *Pate* court’s analogy is that, like

⁷⁷ *Id.*

⁷⁸ *See id.*

⁷⁹ *See id.* at 282.

⁸⁰ *See generally Genetic Risk*, GENETIC SCI. LEARNING CTR., <http://learn.genetics.utah.edu/content/history/geneticrisk/> (last visited Mar. 8, 2016) (explaining that predicting genetically inherited disease is a complex and uncertain process that tries to account for a complete family medical history, including any known relatives and potentially extensive family data); *What Does It Mean if a Disorder Seems to Run in My Family?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/inheritance/runsinfamily> (last visited Mar. 8, 2016) (explaining that a genetic professional will “ask about the health of people from several generations of the family” in determining “whether a disorder has a genetic component”).

⁸¹ *See Pate*, 661 So. 2d at 282 (admitting that “[t]o require the physician to seek out and warn various members of the patient’s family would often be difficult or impractical and would place too heavy a burden upon the physician”).

⁸² *See id.* (“In most instances the physician is prohibited from disclosing the patient’s medical condition to others except with the patient’s permission.”).

⁸³ *See id.* at 281.

⁸⁴ *See supra* Part I.B.

the attorney drafting a will, a physician must respect the patient's wishes to care for their children.⁸⁵ This rationale would still be flawed because, like the foreseeability justification, it is overbroad. Every hypothetical patient would ostensibly prefer their physician to be responsible for taking care of their children as well — not just for genetic risks, but for their healthcare in general.⁸⁶ But unlike will-drafting attorneys, whose clients solicit their services specifically for the purpose of protecting third party beneficiaries, physicians traditionally enter a professional relationship with no one except their direct patients.⁸⁷ It would be both inconsistent with the nature of the medical profession, and unwise as a matter of policy, to extend the legal duties of physicians to third parties just because patients would like such duties to exist.⁸⁸

The *Pate* court was careful to put a wedge in the slippery slopes of both its foreseeability analysis and its duty rationale. The court specifically held that “in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient.”⁸⁹ This limitation substantially mitigates the issues discussed above because it maintains the *scope* of physician duty, in the sense that physicians are still only responsible for their actions with respect to their *direct* patients.

⁸⁵ See *Pate*, 661 So. 2d at 281.

⁸⁶ See, e.g., Kathryn Taaffe Young et al., *Listening to Parents: A National Survey of Parents with Young Children*, 152 ARCHIVES PEDIATRICS & ADOLESCENT MED. 255 (1998) (parents reported physically healthy children, but still wanted pediatricians to give more support and information on child-rearing, even though child-rearing is not a traditional pediatric field and pediatricians are rarely trained in it).

⁸⁷ Cf. *supra* Part I.A.

⁸⁸ Patients, especially consumers influenced by DTC advertising, overly influencing physician conduct has been a dangerous trend in other fields. See generally John B. McKinlay et al., *Effects of Patient Medication Requests on Physician Prescribing Behavior: Results of a Factorial Experiment*, 52 MED. CARE 294 (2014) (more patients are requesting prescriptions because of public influences like DTC advertising; such requests substantially affect physicians' prescribing decisions, even when they have medical concerns about the requested medications); Pamela Moore, *How to Say No to Patients*, PHYSICIANS PRAC. (Oct. 1, 2009), <http://www.physicianspractice.com/articles/how-say-no-patients> (explaining some reasons why physicians might need to refuse patient wishes, but have a hard time doing so); Kevin B. O'Reilly, *Patient Satisfaction: When a Doctor's Judgment Risks a Poor Rating*, AM. MED. NEWS (Nov. 26, 2012), <http://www.amednews.com/article/20121126/profession/311269934/4/> (discussing how physicians deal with patients who demand inappropriate care).

⁸⁹ See *Pate*, 661 So. 2d at 282 (noting that the issue was “not encompassed by the certified question,” but stressing that, “in light of [its] holding,” it is important that physicians only need to warn patients).

But even if the message of *Pate*'s holding is only that physicians should warn direct patients of their children's genetic risks, it would still be problematic. General practitioners often lack the specific education, training, and experience required to identify and assess such risks and interpret their implications for healthcare decisions.⁹⁰ And the holding aside, the *Pate* court's rationale is problematic because it sets a precedent for expanding physician liability on dubious legal and policy grounds.

B. Safer v. Estate of Pack

Less than a year after the *Pate* decision, the Superior Court of New Jersey also recognized a physician's duty to warn third parties of genetic risks.⁹¹ The underlying facts in that case were similar to *Pate*'s. The plaintiff, Donna Safer, suffered from multiple polyposis, a hereditary condition.⁹² Her father, who had died approximately 26 years before her diagnosis, had been treated for the same condition.⁹³ She filed a complaint against her father's physician's estate, alleging that the physician owed a duty to warn "those at risk" of inheriting the condition so that they could benefit from early examination, monitoring, detection, and treatment that could improve their prognosis.⁹⁴

Unlike the *Pate* court, the *Safer* court authorized a broader scope of potential liability by relying on foreseeability of harm to third parties as the rationale for finding duty.⁹⁵ The court found "no essential

⁹⁰ Compared to specialists like, for example, medical geneticists or genetic counselors. See, e.g., Alan E. Guttmacher et al., *Educating Health-Care Professionals About Genetics and Genomics*, 8 NATURE REV. GENETICS 151, 154-55 (2007) (discussing the need to improve education of healthcare professionals in genetics and genomics, and observing uncertainties among primary care providers as to the clinical utility of genetic technologies); Susanne B. Haga et al., *Primary Care Physicians' Knowledge of and Experience with Pharmacogenetic Testing*, 82 CLINICAL GENETICS 388, 391 (2012) (although primary care providers will likely become major users of pharmacogenetic testing in the future, many do not currently feel well-informed about, or comfortable ordering, pharmacogenetic tests); Karen J. Hofman et al., *Physicians' Knowledge of Genetics and Genetic Tests*, 68 ACADEMIC MED. 625, 630-32 (1993) (finding substantial variation and notable deficiencies in knowledge of genetics and genetic tests among general physicians, especially compared to genetics specialists, and discussing the importance of further physician education to prepare for increasingly available genetic tests).

⁹¹ See *Safer v. Estate of Pack*, 677 A.2d 1188, 1191 (N.J. Super. Ct. App. Div. 1996).

⁹² *Id.* at 1190.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.* at 1192.

difference between” genetic threats “and the menace of infection, contagion or a threat of physical harm” because “[t]he individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning.”⁹⁶ Moreover, the court did not limit the duty to warn to a patient’s children, but extended it to “members of the immediate family.”⁹⁷ And perhaps most importantly, even though its rationale shared and worsened the problematic implications of *Pate*’s, the *Safer* court declined to follow *Pate*’s holding that this new physician duty could be satisfied by warning the patient.⁹⁸

In addition to rejecting this practical limitation on an expansive new realm of potential liability, the *Safer* court expressly declined to say “how, precisely, [this] duty is to be discharged . . . except to require that reasonable steps be taken to assure that the information reaches those likely to be affected or is made available for their benefit.”⁹⁹ The court further compounded this broad language, declaring that “the underlying rationale of our rules of law on foreseeability” is “heretofore held to be specifically applicable in professional negligence cases involving genetic torts.”¹⁰⁰ While admitting that such an “overly broad and general application of the physician’s duty to warn might lead to confusion, conflict or unfairness in many types of circumstances,” the court was “confident that the duty to warn of avertible risk from genetic causes, by definition a matter of familial concern, is sufficiently narrow to serve the interests of justice.”¹⁰¹

Safer thus magnified the problems with *Pate*’s rationale. Unlike the specific potential victim envisioned in *Tarasoff*, “victims” of genetic risks are neither specific nor readily identifiable even though they are easily foreseeable as a *group* — in the sense that all biological relatives “foreseeably” share genetic risks. But the *Safer* court explicitly disregarded this important distinction. More problematic for physicians, the *Safer* court ignored the practical challenges of trying to adhere to such a broad and vague standard of care; the court’s “confident” stance that the duty was “sufficiently narrow” and could be satisfied by “reasonable,” undefined actions offers little guidance to medical practitioners.¹⁰² Unlike *Pate*’s rationale, however, much of

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *See id.*

¹⁰¹ *Id.*

¹⁰² *See id.* (elucidating the *Safer* standard); *infra* Part III.A (discussing emerging

Safer's relied on cases where physicians who negligently failed to diagnose contagious diseases were liable for the injury to victims who subsequently contracted those diseases from the physician's patient.¹⁰³

Such reliance was misplaced for several reasons. Unlike patients with "contagious diseases or violent behavior, a patient with a genetic defect does not pose a risk to family members or other members of society."¹⁰⁴ *Tarasoff's* principle that "privilege ends where the public peril begins," echoed by the court in *Safer*, is inapplicable to genetic risks because there simply is no public peril.¹⁰⁵ Relatives of patients with genetic risks have no chance of *becoming* carriers; rather, they only have a chance of finding out that they *already are* carriers.¹⁰⁶ Patients with contagious diseases or violent propensities can harm others, whether by exposing them to infection or by assaulting them, but patients with adverse genetics do not put others at risk merely by carrying those genes (except perhaps through procreation).¹⁰⁷

Of course, early detection, diagnosis and treatment may prevent some harm to carriers.¹⁰⁸ But physicians, who have no power to control the genetic makeup of another human being, do not actually *cause* the harmful consequences of certain genes. They might arguably cause harm in the sense that they knowingly failed to improve a third party's chances at optimal healthcare decisions.¹⁰⁹ But to extend physician duty this way would conflate *preventing harm* to third parties with *optimizing healthcare* for third parties. The distinction between a disease and a genetic risk or propensity is also relevant here. Even assuming that a patient's genetic information could be interpreted unambiguously to infer a serious risk (which it often cannot),¹¹⁰ the question of what constitutes appropriate diagnosis and treatment for genetic risks is a complex one that often has no *right* or

problems faced by physicians working with genetic technologies).

¹⁰³ See *Safer*, 677 A.2d at 1192.

¹⁰⁴ Liang, *supra* note 43, at 452-53.

¹⁰⁵ See *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 347 (Cal. 1976); *Safer*, 677 A.2d at 1192.

¹⁰⁶ Sonia M. Suter, *Whose Genes Are These Anyway? Familial Conflicts Over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1881 (1993).

¹⁰⁷ *Id.*

¹⁰⁸ See *id.* at 1882.

¹⁰⁹ See Burnett, *supra* note 63, at 568 (rejecting the distinction between genetic risks and contagious diseases because "a third party already suffering from a contagious disease would nevertheless benefit from a warning, not because it would prevent the third party from contracting the disease, but because early detection could prevent unnecessary harm").

¹¹⁰ See, e.g., *supra* note 21 and accompanying text.

best answers.¹¹¹ Both on its face, and as specifically applied to decisions to warn of genetic risks, a physician duty to give optimal healthcare to third parties is untenable. It also exacerbates the danger in medical malpractice cases of, as one physician put it, equating “standard of care” to “best practice.”¹¹²

Besides departing from traditional principles for extending physician liability, the contagious disease analogy has another flaw: the relative threat of harm. What more concerns courts in cases involving contagious diseases is not *treating* already infected parties but, rather, preventing the *spread* of such diseases, which can pose a serious threat to public health.¹¹³ Looking to traditional examples of serious threats to public health, it is clear that the danger of potentially subpar measures in response to genetic risks pales in comparison to the danger of epidemics and pandemics.¹¹⁴

This distinction is significant for two reasons. First, the public policy interests that compel courts to hold that physicians owe a duty to warn third parties of contagious diseases simply do not weigh as strongly in favor of expanding that duty to include genetic risks. Second, the special “last line of defense” role of physicians against the spread of contagious diseases, similar to therapists against the actions of dangerous patients, is inapplicable to genetic risks.¹¹⁵ Responsibility for optimizing third party healthcare in response to preexisting, inherent genetic risks places physicians, not in a last line of defense, but in a first line of attack. Such an expansion of liability is especially unnecessary given that the third parties ostensibly have their *own* primary physicians, who are more appropriately responsible for

¹¹¹ See *infra* Part III.A.

¹¹² See Shadowfax, *Medical Malpractice: Equating Standard of Care to Best Practice*, KEVINMD.COM (Jan. 8, 2013), <http://www.kevinmd.com/blog/2013/01/medical-malpractice-equating-standard-care-practice.html>.

¹¹³ See Suter, *supra* note 106, at 1875-76.

¹¹⁴ Compare *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) (“early monitoring of those at risk can effectively avert some of the more serious consequences a person with multiple polyposis might otherwise experience”) with, e.g., *2014 Ebola Outbreak in West Africa*, CDC, <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/index.html> (last visited Mar. 10, 2016) (providing case counts and other key information on the 2014 Ebola outbreak); *Ebola Virus Disease*, WHO, <http://www.who.int/csr/don/archive/disease/ebola/en/> (last visited Mar. 10, 2016) (tracking the numerous countries, across multiple continents, touched by the 2014 Ebola outbreak); *The Five Deadliest Outbreaks and Pandemics in History*, ROBERT WOOD JOHNSON FOUNDATION (Dec. 16, 2013, 1:28 PM), http://www.rwjf.org/en/culture-of-health/2013/12/the_five_deadliest.html (summarizing famous outbreaks of disease and pandemics).

¹¹⁵ See *Cardi*, *supra* note 43, at 883.

optimizing their direct patients' healthcare. In short, the expansive duty proposed in *Safer* is not an innocuous step in a long line of analogous cases, but a deviation from established legal doctrine that also runs counter to sound public policy.

III. IMPACT ON THE MEDICAL PROFESSION

A. *The Effects of Expanding Physician Liability*

A recent study identified over 50 cases in which patients sued health professionals for some sort of alleged negligence in recommending, conducting, or reporting genetic test results.¹¹⁶ Physicians were held liable for, *inter alia*, “not taking an adequate family history; failing to recommend the right kind of testing; not referring the patient for genetic counseling; interpreting a test result incorrectly or in an untimely fashion; not recommending the right risk-mitigation strategies; and failing to disclose test results to family members who may be at risk for a hereditary illness.”¹¹⁷

Physicians heavily involved at critical junctions of the genetic testing process are thus the most vulnerable group for lawsuits related to genetic technologies in a rapidly changing landscape for personalized medicine.¹¹⁸ The magnitude of problems raised by such legal trends far exceeds the small number of recent lawsuits.¹¹⁹ As Professor Gary E. Marchant points out, “doctrinal shifts in medical malpractice liability[,] including the demise of the locality rule and the increased prominence of the reasonableness standard, all contribute to the potential for impending liability risk for physicians.”¹²⁰ Moreover, while new trends of litigation may start slow, they typically pick up momentum and become very difficult to stem later on.¹²¹

B. *Demands and Expectations*

The most fundamental problem with overly expansive physician liability is that even reasonably prudent physicians are simply ill-

¹¹⁶ Turna Ray, *Study Finds Docs Could Face Greater Malpractice Risk in Personalized Rx Era*, ARIZ. ST. U. (June 27, 2011), https://web.law.asu.edu/Portals/31/Marchant_Lindor_genomeweb_June.pdf [hereinafter *Greater Malpractice Risk*].

¹¹⁷ *Id.*

¹¹⁸ See *supra* INTRODUCTION.

¹¹⁹ See Marchant et al., *Next Big Thing*, *supra* note 41, at 457, 464-65.

¹²⁰ *Id.* at 464.

¹²¹ *Id.*

suited to take on such responsibilities.¹²² Most medical professionals today possess only “limited knowledge of genetics.”¹²³ Extensive training in genetics, genetic testing, and the implications of genetic information for clinical practice is not included in the ordinary course of formal medical education.¹²⁴ New genetic tests, including DTC kits, have “far outpaced the ability of doctors — who typically have little training in genetics — to figure out what to do with them.”¹²⁵ Specialized physicians and geneticists acknowledge that genetic information is becoming integral to mainstream medicine, but worry that the medical professionals practicing today are simply not ready to handle the change.¹²⁶

Even among healthcare professionals who are up-to-date and well-trained on the uses of new genetic technologies, there is little consensus on how to use it.¹²⁷ Genetic information is, after all, just raw data with no intrinsic normative information; its implications for patient care are entirely dependent on the interpretations of medical professionals.¹²⁸ When patients sue doctors for malpractice related to such interpretations, the outcomes are often not an accurate reflection of some existing standard of care in the medical community, but a product of selected expert opinions and uncertain juror responses.¹²⁹

¹²² See Turna Ray, *Physicians’ Genomics Knowledge, Basic Skills Still Barrier to Adoption, Study Finds*, GENOMEWEB (Sept. 17, 2014), <https://www.genomeweb.com/clinical-genomics/physicians-genomics-knowledge-basic-skills-still-barrier-adoption-study-finds>.

¹²³ See Marchant et al., *Next Big Thing*, *supra* note 41, at 461.

¹²⁴ See Rubin, *supra* note 16 (stating that doctors who are trained and specialize in genetics are the exception, not the norm); Aimee Tucker Williams & Hope Northrup, *Who Are Geneticists and Genetic Counselors?*, TUBEROUS SCLEROSIS ALLIANCE, <http://www.tsalliance.org/documents/Who%20are%20Geneticists%20and%20Genetic%20Counselors.pdf> (last revised Oct. 17, 2005) (summarizing the special education, testing, and certification process for physicians to specialize in the clinical practice of medical genetics; as of 2005 there were only slightly more than 1,000 physicians board-certified to practice clinical medical genetics in the United States).

¹²⁵ Rubin, *supra* note 16.

¹²⁶ See *id.*

¹²⁷ See Marchant et al., *Next Big Thing*, *supra* note 41, at 459-60.

¹²⁸ See Rubin, *supra* note 16. In addition to being more complex and subjective than, say, lab tests for high blood pressure or sepsis, genetic testing has greater potential to trigger long-term consequences for the emotional, social, and psychological well-being of patients and their families. See, e.g., Robert C. Green & Alan H. Beggs, *Genome Sequence-Based Screening for Childhood Risk and Newborn Illness*, in *The BabySeq Project*, GENOMES2PEOPLE, <http://www.genomes2people.org/babyseqproject/> (last visited Mar. 10, 2016).

¹²⁹ See Marchant et al., *Next Big Thing*, *supra* note 41, at 459 (noting that experts’ opinions differ widely on the proper application (if any) of personalized medicine and that “disparities in the genetics proficiencies of practicing physicians” can “be

Medical malpractice suits' reliance on expert testimony aggravates the problem because there is significant uncertainty and disagreement, even among leading experts in the field, about which genetic technologies are ready for use and how to apply them.¹³⁰ Any party to such a suit could thus easily put on experts with opinions that are advantageous to their cases, but in no way reflect any consensus within the medical profession. While this risk may generally be present in any trial involving expert witnesses, it is especially dangerous in a developing field as novel, complex, and potentially groundbreaking as personalized medicine.

The fact-finding duties of lay jurors also add to the problem, because jurors are the same patients and consumers who have unrealistic expectations for the consistency, utility, and objectivity of genetic medicine in practice.¹³¹ These public expectations "play a major role in setting the standard of care and may influence jurors to hold physicians liable for failing to understand and use these highly publicized genetic technologies."¹³² In short, in the current legal and social climate, many courts and jurors may hold physicians liable for failing to understand new technologies that are outside the scope of their training and experience.¹³³ This is especially problematic when these physicians' actions did not directly affect their ability to serve their *own* patients, but rather the well-being of third parties, extending the legal doctrine well beyond the traditional bounds of liability.¹³⁴

exploited by deft plaintiffs' lawyers").

¹³⁰ See *id.*; see also David Polin, *Qualification of Medical Expert Witness*, 33 AM. JUR. 2D PROOF OF FACTS 179, § 3 (1983) ("As a general rule, expert evidence is essential to support an action for malpractice against a physician . . . [and] 'conclusive as to the proof of the prevailing standard of skill and learning'").

¹³¹ See Marchant et al., *Next Big Thing*, *supra* note 41, at 460 ("While the medical community has been slow to adopt new genetic technologies, public expectations for personalized care have been fueled by fantastical accounts of futuristic medicine in best-selling novels, popular television shows, magazine covers and some news accounts of direct-to-consumer genetic testing services."); see also Austin Frakt & Aaron E. Carroll, *Can This Treatment Help Me? There's a Statistic for That*, N.Y. TIMES (Jan. 26, 2015), <http://www.nytimes.com/2015/01/27/upshot/can-this-treatment-help-me-theres-a-statistic-for-that.html> (explaining the limitations of targeted treatments, the long road ahead for developing effective personalized medicine, and why the public needs a better understanding of the capabilities of modern therapies).

¹³² See Marchant et al., *Next Big Thing*, *supra* note 41, at 460; see also Rubin, *supra* note 16 (showing that, in a survey of "more than 10,000 doctors, only 10% said they felt adequately informed and trained to use genetic testing in making choices about medications").

¹³³ See Ray, *Greater Malpractice Risk*, *supra* note 116.

¹³⁴ See *supra* Part I.A.

C. *Physicians and Courts: Goals and Perspectives*

In the midst of so much uncertainty about the outcomes of such malpractice lawsuits, physicians' and courts' perspectives on these issues have diverged. From the courts' perspective, two prongs guide the issue of physician liability: where proposed liability would fit within existing torts law frameworks and what policy consideration should factor into the legal analysis.¹³⁵ This approach, however, fails to account for the unique effects of genetic technology on professional guidelines within the medical community.¹³⁶ While courts may comfortably hold physicians to a national standard of care for noncontroversial, unambiguous treatments like insulin and antibiotics,¹³⁷ these treatments are simply not comparable to the nuanced and highly disputed applications of new genetic technologies. What is routine in a leading medical facility with state-of-the-art testing labs and experienced geneticists may be extraordinary, even unknown, to the everyday practitioner who is nonetheless a reasonably prudent and competent physician.¹³⁸ And given that even expert opinions vary on how to understand or use new genetic technologies, ordinary practitioners are unlikely to find comprehensive guidance from literature or academia, as the court suggested in *Paintiff v. City of Parkersburg*.¹³⁹

The message conveyed by recent litigation is essentially that “[c]ourts are willing to require the use and understanding of genetic information even before the medical community itself is ready and able to do so.”¹⁴⁰ In the context of personalized medicine, a one-size-fits-all national standard of care may be premature — not because of disparate education or prohibitive communication barriers, but because of inadequate knowledge, consensus, and experience on a new and complex topic.¹⁴¹ Attempting to distill an accurate standard of care from conflicted experts and layman jurors in such a situation is unrealistic

¹³⁵ See *supra* Part I.A.

¹³⁶ For example, genetic technologies have given rise to many new topics in the AMA policy guidelines. See, e.g., *Genetic Testing*, AMA, <http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/related-policy-topics/genetic-testing.page?> (last visited Mar. 10, 2016) (summarizing some medical applications of genetic technology and the roles of genetic counselors).

¹³⁷ See *Paintiff v. City of Parkersburg*, 345 S.E.2d 564, 566-67 (W. Va. 1986).

¹³⁸ See Ray, *Greater Malpractice Risk*, *supra* note 116.

¹³⁹ See *Paintiff*, 345 S.E.2d at 567.

¹⁴⁰ See Ray, *Greater Malpractice Risk*, *supra* note 116.

¹⁴¹ See *id.*

and contrary to the legal principle that the medical community — not jurors — should develop medical standards of care.¹⁴²

Even if we viewed *Safer* as a temporary standard of care that would yield to any future medical consensus, that limitation would provide little comfort to practitioners today. Physicians need guidance in their everyday practices, and look to both medical professional guidelines¹⁴³ and legal precedents for that guidance.¹⁴⁴ Inconsistencies between the two are bound to lead to widespread confusion, and the legal standard will eventually inform the medical guidelines until they converge into a new unified standard, albeit one that could easily change following a contrary decision. For example, in the years since *Pate* and *Safer*, the American Medical Association's journals have published several "Virtual Mentor" pieces on the duty to warn third parties of genetic risks.¹⁴⁵ Each piece specifically cited both *Pate* and *Safer* in its

¹⁴² See *supra* Part I.B.

¹⁴³ See generally *Education Center*, AMA, <http://www.ama-assn.org/ama/pub/education-careers/education-center.page> (last visited Mar. 10, 2016) (offering physicians credit for staying up-to-date on standard education topics in medicine); *Medical Ethics*, AMA, <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics.page?> (last visited Mar. 10, 2016) (summarizing ethical policies and ethical issues in medicine "that practicing physicians are likely to encounter in their training and daily practice").

¹⁴⁴ See generally Jeffrey D. Brunken, *Ten Simple Ways Physicians Can Avoid a Malpractice Suit*, PHYSICIANS PRAC. (July 29, 2012), <http://www.physicianspractice.com/blog/ten-simple-ways-physicians-can-avoid-malpractice-suit> (offering advice on avoiding non-medical mistakes that put "[e]ven the best physicians" at risk of lawsuits "on an almost daily basis"); Susan Kreimer, *Six Ways Physicians Can Prevent Patient Injury and Avoid Lawsuits*, MED. ECON. (Dec. 10, 2013), <http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/injury/six-ways-physicians-can-prevent-patient-injury-and-avoid-lawsu?page=full> (advising physicians on risk management strategies); *Legal Issues for Physicians*, AMA, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics.page?> (last visited Mar. 10, 2016) (offering guidance for physicians to "stay up to date on legal issues that could affect them and their medical practice"); Madelyn Young, *Avoid Lawsuits: How to Be a Malpractice-Free Practice*, POWER YOUR PRAC., <http://www.poweryourpractice.com/practice-management/avoid-lawsuits-how-to-be-a-malpractice-free-practice/> (last visited Mar. 10, 2016) (advising physicians on practicing defensive medicine).

¹⁴⁵ See Shawneequa Callier & Rachel Simpson, *Genetic Diseases and the Duty to Disclose*, 14 AM. MED. ASS'N J. ETHICS 640, 641-42 (2012); Anne-Marie Labege & Wylie Burke, *Duty to Warn At-Risk Family Members of Genetic Disease*, 11 AM. MED. ASS'N J. ETHICS 656, 657-58 (2009); Faith Lagay, *A Physician's Role in Informing Family Members of Genetic Risk*, 7 AM. MED. ASS'N J. ETHICS (2005), available at <http://journalofethics.ama-assn.org/2005/06/pdf/hlaw1-0506.pdf>; Kristin E. Schleiter, *A Physician's Duty to Warn Third Parties of Hereditary Risk*, 11 AM. MED. ASS'N J. ETHICS 697, 697-99 (2009).

analysis.¹⁴⁶ Some advised physicians to take the actions suggested by the *Pate* and *Safer* courts, reflecting the ability of case law to influence the medical community, even though the latter is supposed to determine standards of care for physicians.¹⁴⁷ Essentially, by allowing jurors to set the standard of care, courts have reversed the proper and respective roles of the legal standard and the medical community's consensus.

Furthermore, the influence of such decisions on medical guidelines has effectively transposed jurisdictionally dependent legal uncertainties into the medical standard, threatening a return to the uncertainty of the locality rule. For example, some Virtual Mentor pieces have implicitly disagreed with *Pate* and *Safer*. One such piece noted that in the decade since *Pate* and *Safer*, concerned physicians have been asking the professional community which opinion, if any, they should follow.¹⁴⁸ Legal and bioethics scholars have, meanwhile, taken a conservative approach to the issue that favors preserving patient confidentiality over the duty to warn third parties, and no more recent court cases for failure to warn third parties of genetic risks have come to light to clarify the issue.¹⁴⁹ Moreover, the piece claims,

The *representative thinking of the medical community* is expressed in the AMA's *Code of Medical Ethics* The overriding message of this guideline is that "physicians have a professional duty to protect the confidentiality of their patients' information, including genetic information." . . . The AMA's position on the primacy of patient confidentiality . . . is *shared by most physicians and ethicists in the field*¹⁵⁰

Another Virtual Mentor piece noted that "[i]n the wake of *Pate* and *Safer*, the American Society of Human Genetics ("ASHG") published a policy paper that reaffirmed the general rule of confidentiality . . . [and] favor[ed] discretion on the part of physicians in disclosing information about genetically transferable conditions to those at risk for developing them."¹⁵¹ According to at least some commentators, it seems, *Pate* and *Safer* may have prompted the medical community to

¹⁴⁶ See Callier & Simpson, *supra* note 145, at 641-42; Laberge & Burke, *supra* note 145, at 657-58; Lagay, *supra* note 145; Schleiter, *supra* note 145, at 697-99.

¹⁴⁷ See Callier & Simpson, *supra* note 145, at 641-42; Laberge & Burke, *supra* note 145, at 657-58.

¹⁴⁸ See Lagay, *supra* note 145.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* (emphasis added).

¹⁵¹ Schleiter, *supra* note 145, at 699.

expedite developing an actual standard of care for warning third parties of genetic risks. But if so, the developing standard is certainly *not* the one promulgated by *Pate* and *Safer*. Even professional guidelines that recommend disclosure to third parties in some situations still emphasize that it should be up to the physician's professional judgment, not compelled by a court of law.¹⁵² These growing gaps between the positions of courts and the medical community exemplify why courts should be wary of introducing liability risks that may prevent healthcare professionals from developing medically sound standards in the wake of new technology.¹⁵³

IV. SOLUTIONS

A. *Training to Practice Personalized Medicine*

Healthcare professionals like physicians already have some options to pursue specialized training in genetics. For example, certification with the American Board of Medical Genetics and Genomics involves education on “the interaction between genes and health.”¹⁵⁴ Certified professionals, or medical geneticists, “are trained to evaluate, diagnose, manage, treat and counsel individuals of all ages with hereditary disorders.”¹⁵⁵ A physician must train for two to four years to receive this certification.¹⁵⁶ In addition to this particular certification, various other training options are available for different specialties in medical genetics, from lab work to applied healthcare.¹⁵⁷ Yet, despite the availability of such education, there is a definite

¹⁵² See *id.*

¹⁵³ See, e.g., *McKenzie v. Hawai'i Permanente Med. Grp., Inc.*, 47 P.3d 1209, 1216 (Haw. 2002) (noting that “individual treatment decisions are best left to patients and their physicians”); *Wilschinsky v. Medina*, 775 P.2d 713, 718 (N.M. 1989) (concluding that the court “cannot intrude on the medical profession's own careful balancing of treatment and risk. . . . [because] [w]here doctors are bound to administer to the sick and take an oath to that effect, they should not be asked to weigh notions of liability in their already complex universe of patient care.”); see also *Lester ex rel. Mavrogenis v. Hall*, 970 P.2d 590, 593-94 (N.M. 1998) (recognizing that, while courts are empowered to recognize new legal duties for healthcare providers, that power should be used sparingly).

¹⁵⁴ See *Medical Genetics and Genomics*, ABMS, <http://www.certificationmatters.org/abms-member-boards/medical-genetics.aspx> (last visited Mar. 10, 2016).

¹⁵⁵ See *id.*

¹⁵⁶ See *id.*

¹⁵⁷ See *Training Options*, ABMGG, http://www.abmgg.org/pages/training_options.shtml (last updated Dec. 15, 2014).

shortage of physician-geneticists in the United States.¹⁵⁸ Currently, leaders in the emerging field of personalized medicine tend to be practitioners in more traditional specialties, like oncology, where there is strong demand for groundbreaking treatments.¹⁵⁹

In the future, it will be up to a combination of the medical profession, patient demand, and public support to increase the number of physicians and healthcare professionals seeking further education in genetics and personalized medicine. Medical schools and continuing education sources could provide both information and encouragement to prospective candidates.¹⁶⁰ Meanwhile, more readily available public information could help patients learn about their options, and encourage them to seek out professionals properly certified in personalized medicine.¹⁶¹ For their part, DTC companies should focus on recruiting certified specialists to consult with consumers on the implications of their genetic information, even though the number of specialists available will be limited at first.¹⁶²

Of course, there must be a way for physicians who do not wish to pursue specialization to still avoid liability for “malpractice” of personalized medicine.¹⁶³ One simple measure for such physicians

¹⁵⁸ See *Shortage of Physician-Geneticists in the United States*, PERS. GENOME, <http://thepersonalgenome.com/2007/12/shortage-of-geneticists-in-the-united-states/> (last updated Jan. 2, 2007).

¹⁵⁹ See, e.g., *Local Doctor a Leader in ‘Precision Medicine,’* WOAI (Feb. 3, 2015, 2:00 PM), <http://www.woai.com/articles/woai-local-news-sponsored-by-five-119078/local-doctor-a-leader-in-precision-13216662/> (identifying pediatric oncologist as a “leader in the emerging field of Precision Medicine”).

¹⁶⁰ See, e.g., *A Sample Workshop: Encouraging Doctors to Be Deaf-Friendly*, NAT’L ASS’N DEAF (July 10, 2010), <http://nad.org/blogs/taylor-mayer/sample-workshop-encouraging-doctors-be-deaf-friendly> (providing an example of how medical schools could offer such information and encourage doctors to train in cultural sensitivity).

¹⁶¹ Modern consumers and patients already show tremendous interest and initiative in seeking out publicly available healthcare information. See, e.g., R.J.W. Cline & K.M. Haynes, *Consumer Health Information Seeking on the Internet: The State of the Art*, 16 HEALTH EDUC. RES. 671, 672-74 (2001) (describing the increase in consumer health-information seeking on the internet); Carolyn Crane Cutilli, *Seeking Health Information: What Sources Do Your Patients Use?*, 29 ORTHOPAEDIC NURSING 214, 218 (2010) (describing various ways that patients obtain health information to supplement what they get from healthcare providers).

¹⁶² See *supra* note 157 and accompanying text.

¹⁶³ See generally Anupam B. Jena et al., *Malpractice Risk According to Physician Specialty*, 365 NEW ENG. J. MED. 629 (2011) (showing substantial variations in the medical malpractice risks faced by different specialties); David M. Studdert et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 2609, 2610 (2005) (listing certain specialties, like neurosurgery and radiology, as especially affected by high and rising liability costs).

could be to make it abundantly clear that they are not specialists. Accordingly, physicians and healthcare professionals who do not wish to pursue specialization in personalized medicine should be educated on the importance of referring patients to specialists when appropriate.¹⁶⁴ To put it in torts terms, only truly qualified specialists in personalized medicine should hold themselves out as such to patients.¹⁶⁵

B. Potential Problems for Patients/Consumers

If courts decline to hold that physicians must warn any defined group of third parties of genetic risks based on patient information, at least four problems may arise. First, third parties may be more vulnerable to harms, without recourse through courts of law. This arguably imposes an undesirable burden on third parties as a policy matter, as the public is potentially assuming the risk of suboptimal healthcare.

Second, the medical community may have insufficient incentive to develop a standard of care for personalized medicine. After all, if practitioners are not liable in the absence of an applicable standard of care, then the absence of any such standard, whether for patients or for third parties, is desirable for physicians. The burden on patients and consumers is thus compounded by physicians' desire to avoid increased liability.

Third, letting physicians dodge liability by avoiding a standard of care may encourage ignorance in medical practice. One clear example demonstrating that society does not tolerate such opportunistic ignorance is pain management.¹⁶⁶ If a method exists anywhere — no matter how few practitioners are skilled in it, or what facilities it may require — that can better alleviate pain, then a physician has a duty to inform their patient of that option and either provide the treatment, or refer the patient to someone who can.¹⁶⁷ Likewise, the nationwide lack of education and training in personalized medicine should perhaps not excuse physicians from a duty to perform it well. After all, it would be

¹⁶⁴ See Barbara Starfield et al., *Primary Care and Genetic Services: Health Care in Evolution*, 12 EUR. J. PUB. HEALTH 51, 55-56 (2002).

¹⁶⁵ See, e.g., *Orcutt v. Miller*, 595 P.2d 1191, 1195 (Nev. 1979) (stating that specialists are held to the standard of care expected of a reasonably competent practitioner in the *same* specialty).

¹⁶⁶ Like personalized medicine, pain management is a field in which physicians are often under-educated. See Ben A. Rich, *A Prescription for the Pain: The Emerging Standard of Care for Pain Management*, 26 WM. MITCHELL L. REV. 1, 14-17 (2000).

¹⁶⁷ See *id.* at 31-32.

absurd if medical professionals could categorically escape liability by uniformly adhering to subpar policies in education, training, and practice.¹⁶⁸

Fourth, in declining to extend physicians' legal duty to third parties in the context of personalized medicine, courts may, to some extent, accept the idea that preventing harm is distinguished from optimizing healthcare.¹⁶⁹ This may appear incongruous with some older legal positions on simpler medical problems involving genetic diagnostics — namely, wrongful birth actions.¹⁷⁰ It is worth noting that wrongful birth remains a fairly controversial concept; only about half of all jurisdictions in the United States have recognized such actions, usually on the basis that the parents of a child with congenital defects have been deprived of a reproductive choice through physician negligence.¹⁷¹ But assuming *arguendo* that wrongful birth actions are justified, such cases appear to exemplify situations in which physicians did not cause genetic defects, but were nonetheless held liable for the consequences of such defects.¹⁷²

C. Responding to Problems for Patients/Consumers

We can address the first two problems simultaneously. The danger of third parties becoming victims of malpractice without recourse depends on what society considers malpractice. Rejecting an affirmative duty to warn certain third parties of genetic risks is not allowing physicians to get away with malpractice; failing to give such a warning simply does not constitute malpractice under traditional tort law.¹⁷³ This view does not abandon the interests of third parties, leaving them ignorant of genetic risks to which a physician's direct patient may be privy. After all, every "third party" to one physician is presumably the "patient" of another physician. Put simply, the

¹⁶⁸ See *id.* at 72-73.

¹⁶⁹ See *supra* notes 108–10 and accompanying text.

¹⁷⁰ Wrongful birth actions are brought by parents and allege that a physician failed to prospectively advise them of the risks of having a child with congenital defects. See *Wrongful Birth-Action*, BLACK'S LAW DICTIONARY (10th ed. 2014).

¹⁷¹ See Amy Lynn Sorrel, *Judging Genetic Risks: Physicians Often Caught Between What Patients Want and What Science Offers*, AM. MED. NEWS (Nov. 10, 2008), <http://www.amednews.com/article/20081110/profession/311109973/4/>; see also Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149, 152 (1992) (describing the nature of wrongful birth actions).

¹⁷² See *supra* notes 108–10 and accompanying text.

¹⁷³ See *supra* Part II.

responsibility for any given individual's personalized medicine should rest with *that individual's physician*, rather than with other physicians.¹⁷⁴

Furthermore, public awareness of, and demand for, personalized medicine has been increasing steadily and will only continue to increase as DTC tests become more prevalent and better regulated.¹⁷⁵ DTC kits exemplify how popular media, consumer advertisements, and general public sentiment are turning in favor of personalized medicine.¹⁷⁶ This public demand could incentivize the medical community, as physicians who cannot meet patient demands for personalized medicine will have reason to become specialists.¹⁷⁷ And as patients and consumers take the initiative in moving towards personalized medicine, courts could find liability for negligent practice without having to define a group of third parties to whom physicians owe a duty. General physicians, for example, could be liable for negligent misrepresentation or a negligent failure to refer a patient to appropriate specialists.¹⁷⁸ Developing the basic understanding that only genetic specialists should attempt to practice personalized medicine would probably go quicker than properly training physicians to become specialists.¹⁷⁹

Finally, even if cutting back on physician liability for failure to warn third parties of genetic risks puts an additional burden on the public, it is arguably a good thing. Society generally benefits from increasing patient access to, and participation in, personalized medicine that utilizes a wide spectrum of available genetic technology.¹⁸⁰ Instead of

¹⁷⁴ See *supra* Part II.B.

¹⁷⁵ See *supra* INTRODUCTION.

¹⁷⁶ See *id.*

¹⁷⁷ See Rubin, *supra* note 16 (mentioning a \$600,000 grant to develop a genomic medicine college because “[p]hysicians don’t want to be trumped in their knowledge by the patient . . . they need to be in the leading front of knowledge”).

¹⁷⁸ See, e.g., *Steele v. United States*, 463 F. Supp. 321, 330 (D. Alaska 1978) (holding that a physician who failed to inform a patient’s parents of the need for a specialist and failed to refer the patient to a specialist breached the standard of care); *Larsen v. Yelle*, 246 N.W.2d 841, 845 (Minn. 1976) (concluding that a physician’s failure to refer a patient to a specialist may establish negligence if the failure caused the patient’s injury); *Wacker v. St. Francis Med. Ctr.*, 413 S.W.3d 37, 39 (Mo. Ct. App. 2013) (holding that a physician’s negligent failure to refer a patient to a specialist violated the standard of care).

¹⁷⁹ See generally Charles J. Epstein, *Medical Geneticists in the 21st Century*, 7 GENETICS MED. 375, 378 (2005) (explaining that proper training of “medical geneticists” among physicians would be a difficult and probably time-consuming process).

¹⁸⁰ See EUR. ALLIANCE FOR PERSONALISED MED., INNOVATION AND PATIENT ACCESS TO

imposing more liability on physicians, federal and state governments could focus on disseminating information that encourages citizens to take the initiative in improving their own healthcare with personalized medicine. With both patients and physicians motivated to increase their participation in the shift towards personalized medicine, the quality of healthcare overall can improve.

Personalized medicine is, moreover, distinguishable from pain management. The latter has a clear end: the improvement of suffering. The constant problem of personalized medicine, however, is that there is no clear set of answers that will fit every patient.¹⁸¹ In many situations, perhaps the measure of competent and reasonable medical practice is simply *considering* all the appropriate factors and approaching the decision in the right way. The actual healthcare decisions that result can — and perhaps should, given the individuality of patients — vary from case to case, to a far greater degree than with pain management.¹⁸² The importance of this distinction is that even if courts should expect all physicians to achieve a certain outcome in traditional fields, e.g., managing pain, it may still be inappropriate for courts to mandate specific professional decisions in the field of personalized medicine.

Lastly, prenatal screening for congenital defects, the subject of wrongful birth actions, is also distinguishable from personalized medicine. First, the serious congenital defects involved in wrongful birth actions are considerably better understood than the myriad genetic factors contemplated by personalized medicine.¹⁸³ Moreover, the only plaintiffs in wrongful birth actions are parents who entered into a physician-patient relationship with the defendant physician *specifically* for the purpose of prenatal care.¹⁸⁴ In other words, the plaintiffs are the physician's *direct patients*, not third parties. To hold that physicians owe a duty to such plaintiffs is generally consistent

PERSONALISED MEDICINE 4-7 (2013), available at http://euapm.eu/pdf/EAPM_REPORT_on_Innovation_and_Patient_Access_to_Personalised_Medicine.pdf.

¹⁸¹ See Foster, *supra* note 19, at 570.

¹⁸² See *id.*

¹⁸³ Congenital defects that can result in serious medical problems, such as lifelong disability, are well-defined and affect only approximately three to four percent of newborns in the United States. See *Congenital Abnormalities*, AM. ACAD. OF PEDIATRICS, <http://www.healthychildren.org/English/health-issues/conditions/developmental-disabilities/Pages/Congenital-Abnormalities.aspx> (last updated Nov. 21, 2015); *Update on Overall Prevalence of Major Birth Defects — Atlanta, Georgia, 1978–2005*, CDC (Jan. 11, 2008), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a2.htm>.

¹⁸⁴ See *supra* notes 171–72 and accompanying text.

with traditional legal principles.¹⁸⁵ Wrongful birth actions may seem superficially comparable to actions like the ones in *Pate* and *Safer*, in the sense that they all tend to arise from situations involving genetic risks.¹⁸⁶ But wrongful birth actions focus, not on background issues of genetic diagnostics, but rather on whether physicians breached a legal duty to their direct patients by depriving them of a meaningful reproductive choice.¹⁸⁷ That question is fundamentally distinct from the novel issues presented by personalized medicine.

As a final point of consideration, it is worth reiterating that the expansion of physician duty to third parties in the context of personalized medicine triggers a unique problem: it comes into direct conflict with the older, more well-established duty of physician-patient confidentiality.¹⁸⁸ From a policy perspective, even if the four issues discussed above were evenly balanced, this tension would at least indicate caution and skepticism toward, if not outright rejection of, a physician's duty to warn third parties of genetic risks.

CONCLUSION

Due to our increasing knowledge of genomics and the increasing integration of genetic information into patients' healthcare decisions, personalized medicine is likely the future norm of healthcare.¹⁸⁹ The push for advanced medical treatments informed by genomics is gaining momentum on multiple fronts, both in the United States and abroad.¹⁹⁰ During this transitional period, however, cases that attempt to expand traditional malpractice liability for physicians in genetic

¹⁸⁵ See *supra* Part I.A.

¹⁸⁶ See *supra* Part II.

¹⁸⁷ See *supra* notes 171–72 and accompanying text.

¹⁸⁸ See *supra* notes 150–52.

¹⁸⁹ See *supra* INTRODUCTION.

¹⁹⁰ See, e.g., OFFICE OF MGMT. & BUDGET, BUDGET OF THE U.S. GOVERNMENT, FISCAL YEAR 2016, at 19 (2015), available at <http://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/budget.pdf> (the Obama Administration's Precision Medicine Initiative); Sharon Begley & Toni Clarke, *Obama's 'Precision Medicine' Plan to Boost Research, but Faces Hurdles*, REUTERS (Jan. 28, 2015, 1:07 AM), <http://www.reuters.com/article/2015/01/28/us-health-precisionmedicine-idUSKBN0L10D720150128> (providing a survey of President Obama's Precision Medicine Initiative, which gave "a much-needed boost to research in the field"); Rosetta Genomics Ltd., *Rosetta Genomics Announces Key Patent Allowances in U.S. and Europe*, MARKETWATCH (Feb. 17, 2015, 8:15 AM), <http://www.marketwatch.com/story/rosetta-genomics-announces-key-patent-allowances-in-us-and-europe-2015-02-17> (showing that, shortly after President Obama announced the United States' Precision Medicine Initiative, a leading developer of diagnostic genomics obtained key patents for genetically-based cancer therapeutics).

testing contexts may inappropriately promulgate a premature standard of care for the medical community.¹⁹¹ The development of the applicable standard of care should be up to healthcare professionals and experts who are familiar with the specialized knowledge and background involved, especially in a field as complex and nuanced as personalized medicine.¹⁹²

The healthcare field is already integrating specialized training and education options into the medical profession. However, public demand — partially fueled by unrealistic expectations and encouraged by DTC companies — currently exceeds the supply of genetic specialists in both number and depth of knowledge.¹⁹³ Both public education and DTC companies can significantly reduce this problematic gap by distributing more accurate information that does not mislead patients and consumers. And the medical profession can encourage physicians and healthcare professionals to pursue further training, or to refer patients to genetic specialists for personalized medicine. Through these combined efforts, we can more accurately define appropriate standards of care for both “medical geneticist” physicians and traditional general physicians.

¹⁹¹ See *supra* Part II.

¹⁹² See *supra* Part III.C.

¹⁹³ See Rubin, *supra* note 16.