UCSD UNDERGRADUATE LAW REVIEW

EUGENE KONG

Balancing Acts: Navigating the Ethical and Legal Challenges of Genomic Medicine in Healthcare

ABSTRACT. This paper delves into the intricate relationship between the evolving field of genomic medicine and healthcare providers' legal and ethical responsibilities, with a particular focus on the duty to warn in the context of genetic risks. Through a critical examination of landmark cases such as *Pate v. Threlkel* and *Safer v. Estate of Pack*, this study underscores the expanding scope of healthcare providers' duties to include not just the patient but potentially at-risk family members as well. It highlights the legal, ethical, and practical challenges that arise when balancing patient confidentiality with the need to prevent harm through the disclosure of genetic information. The descriptive portion of the paper outlines the current legal precedents and the ambiguity surrounding healthcare providers' responsibilities. The prescriptive portion proposes the establishment of comprehensive, clear guidelines to support healthcare providers, particularly genomic counselors, in navigating these complexities. This includes recommendations for policy changes and the development of protocols that respect patient autonomy while addressing the preventive potential of genomic medicine. Through an analysis of legal frameworks and ethical considerations, this paper argues for a nuanced approach that equitably balances individual rights with the collective good, ultimately advocating for a future where genomic medicine is integrated into patient care in an ethically responsible and legally sound manner.

AUTHOR. Eugene, a Bioinformatics major at UC San Diego, is on a path to becoming an MD/JD with a focus on the confluence of technology, law, and medicine. He is passionate about integrating these disciplines to innovate ethically in healthcare. In his leisure time, Eugene enjoys coding, outdoor adventures, and moments with his cat, Winnie. He aspires to shape future healthcare policies and practices amidst biotechnological advancements. Eugene would like to thank Irene Swan from Klinedinst PC, primary editor Shyam Kulkarni, and the rest of the Undergraduate Law Review Board at UCSD for their exceptional guidance throughout the 2023-24 cycle.

INTRODUCTION

The year is 2050. Personalized medicine has revolutionized the healthcare landscape, offering cures for cancer, allergies, diseases, and genetic defects through advanced genomic therapies. This remarkable future, once full of promise, now teeters on the brink of jeopardy. Legal entanglements and unclear standards of care have and will continue to plunge genomic medicine into a crisis, creating a future that could potentially become a barren wasteland devoid of the life-saving potential these technologies hold. Burdened by the fear of litigation under unfair legal expectations, doctors will be increasingly hesitant to utilize genomic therapies, thereby stalling medical progress. Data from the Harvard Medical School in 2011 found that 75 percent of all physicians in low-risk specialties faced a medical malpractice claim, while 99 percent of all physicians in high-risk specialties faced a medical malpractice claim.[1] While most of these do not go to trial, the palpable fear that pervades the medical community following the initiation of a lawsuit cannot be overlooked. The mere possibility of facing legal action can incite a profound psychological toll on physicians, and a range of emotional responses ranging from outrage and shock to profound anxiety and dread about the personal and financial ramifications.[2]

This initial reaction triggers a cascade of stress-related symptoms that can persist throughout the arduous litigation process. Over 95% of physicians report experiencing significant emotional distress during these times, which is not just a transient state but a constant headspace that can deeply impact their professional and personal lives.[3] This can then materially manifest into symptoms of major depressive disorder (with a prevalence of 27%-39%), adjustment disorder (20%-53%), and even the onset or exacerbation of physical illnesses (2%-15%).[4] The specter of malpractice suits looms large, casting a shadow over their practice, influencing medical decisions, and fostering a climate of fear and uncertainty. As these practices become more ingrained, they feed into a dangerous negative feedback loop, where the fear of being sued drives medical decisions, potentially leading to suboptimal patient outcomes and, in the worst cases, contributing to the very incidents of harm they aim to avoid.

---

[1]Anupam B. Jena et al., *Malpractice risk according to physician speciality*, 365 N Engl J Med. 629, 629-630 (2011) (Data for medical malpractice between low risk and high risk specialties).

[2] Sara C. Charles, *Coping with a medical malpractice suit*, 174 West J.M. 55, 55-56 (2001) (Data showing physicians report experiencing significant emotional distress during malpractice cases).

[3] *Id.* at. 55.

[4] *Id.* at. 55.

The world of medicine is about to be thrust into danger levels unforeseen as we venture towards perfecting genomic therapies. This situation has emerged because the legal framework surrounding the standard of care in genomic medicine lacks clarity and adaptability. As medical advancements outpace legal reforms, healthcare providers find themselves navigating a minefield of potential legal challenges without a clear path forward. The ambiguity in legal standards not only stifles innovation but also undermines patient trust and access to cutting-edge treatments essential for combating complex genetic diseases.

In the realm of medical malpractice, proving negligence hinges on the failure to adhere to the "standard of care," a purely legal concept that serves as the cornerstone of tort law in this context.[5] This principle varies from state to state yet generally orbits around a common understanding of "best practices" in medicine. For instance, California's definition suggests a medical practitioner is negligent if they don't apply the same level of "skill, knowledge, and care that other reasonably careful practitioners would in comparable situations.[6] In other words, doctors are negligent if they fail to adhere to reasonable practices.

Already, we see a glaring issue. The concept of the "standard of care" in medical malpractice, as demonstrated by California's legal definition, presents a paradox that is both baffling and profoundly concerning. Entrusting the interpretation of such a critical and complex concept of normal medical practices to juries, who are laypersons in the field of medicine, borders on the absurd. The expectation that jurors can determine the appropriate level of medical skill, knowledge, and care based solely on expert testimony underscores a glaring disconnect between legal procedures and the nuanced realities of medical practice. This reliance on non-experts to make such specialized determinations undermines the integrity of medical malpractice litigation and exposes the legal system's inadequacies in addressing the intricacies of healthcare.
Let’s examine key court cases that have set precedent throughout the history of medical malpractice to see how the revolving door of “standard of care” actually plays out.

[5] Donna Vanderpool, *The Standard of Care*, 18 Innov. C.N. 50, 50-51 (2021) (Proving that standard of care is a legal concept).
[6] Jud. Council of Cal. Civ. Jury Instr., No. 501 (2024).

I. THE STANDARD OF CARE

One of the first major, confusing, and dangerous precedents for medical malpractice came from the Washington Supreme Court in 1975.

A. Helling v. Carey

In the landmark case of *Helling v. Carey*, the Washington Supreme Court grappled with the vexing question of whether standard medical practices, specifically within the realm of ophthalmology, sufficiently protect patients from rare but severe conditions like glaucoma in individuals under 40. At the heart of the dispute was Barbara Helling, a patient who suffered significant vision loss due to undiagnosed glaucoma despite seeking care from Dr. Thomas F. Carey and Dr. Robert C. Laughlin. For years, Helling's deteriorating condition went undetected under the defendants' care because they adhered to the prevailing medical wisdom that deemed routine pressure tests for glaucoma unnecessary for patients under the age of 40. It was not until her vision was irreversibly damaged that a pressure test was finally conducted, revealing the glaucoma that had been insidiously eroding her sight.[7]

The court's ruling in *Helling v. Carey* marked a critical pivot, as it boldly deviated from the established norms governing medical malpractice. In a departure from the principle that a physician's adherence to common practices shields them from negligence, the court found the defendants liable for Helling's vision loss. Although the court agreed in its majority opinion that the likelihood of contracting glaucoma was 1 out of 25,000 persons under the age of 40, the justices nevertheless decided that the rarity of glaucoma in younger patients did not absolve the ophthalmologists of the responsibility to perform a simple, yet potentially lifesaving, pressure test.[8] This decision undeniably casts a long shadow, setting a precedent that could compel medical professionals to transcend the boundaries of standard care to mitigate even the most remote risks. While well-intentioned in its effort to prioritize patient safety over customary practices, the ruling introduces a precarious ambiguity into the legal expectations of medical care. It suggests a shift towards an almost prescient standard of care, wherein medical practitioners might be held liable for not preventing conditions

[7] Helling v. Carey, 83 Wash. 2d 514, 514-522 (1974).
[8] *Id*. at. 517.

that the prevailing medical standards deem exceedingly unlikely to occur, even if that likelihood is 0.004%.[9]

In *Helling v. Carey*, the concurring opinions, particularly that of Justice Utter, echoed the majority's stance but underscored a crucial nuance: the potential for a heightened duty of care beyond the established norms of the medical profession. Justice Utter's concurrence emphasized that in cases where a simple, non-invasive, and definitive test exists for a potentially severe disease like glaucoma, which can be easily missed until it causes irreversible damage, the legal system should consider imposing a duty on physicians to conduct such tests even if the profession's standard does not require it.[10] This perspective suggests that the law might need to impose higher expectations on medical practitioners in certain situations to prevent avoidable patient harm.

This approach essentially raises the bar for what is considered reasonable care in specific medical scenarios, distinguishing between what a "great" physician and a "reasonable" physician might do. A great physician, always erring on the side of caution, might conduct the glaucoma test proactively, recognizing the catastrophic consequences of the disease if left undetected, despite its rarity among patients under 40. On the other hand, a reasonable physician, adhering strictly to the prevailing standards of the profession, might opt not to perform the test. The concurring opinion in *Helling v. Carey* signals a judicial willingness to reevaluate and potentially elevate the standard of care in medicine, advocating for a shift towards practices that prioritize patient safety even when they exceed current professional norms. This redefinition challenges physicians to not only meet the standard practices of their field but to *surpass* them when the stakes involve significant, preventable risks to patient health. Granted, patients should expect the best possible care they can get with respect to their physician. However, the question is not “Does the patient get the best possible care?” Rather, the question in the context of medical malpractice is simply, “was the care reasonable?.”

If this case was a one-off scenario that did not bleed into the realm of modern medicine, society might be able to breathe a sigh of relief. Alas, this is not the case, as we examine the next case study from the Twelfth Judicial Circuit of Florida.

[9] *Id.* at. 517.
[10] *Id.* at. 520.

B. Wagner v. Shoffner

One of the court cases that highlights this expansionary nature of the standard of care in genomic medicine is in *Wagner v. Shoffner*. Plaintiffs E. John Wagner II and Rosetta F. Barrett-Wagner experienced the heartbreaking loss of their previous two children to a rare unknown disease. In their pursuit of a healthy child, they sought the expertise of Dr. John M. Shoffner, who advised on the prospects of utilizing in vitro fertilization (IVF), a modern technique that combines sperm and egg in a laboratory dish,[11] with a donor egg and Mr. Wagner's sperm. Despite these consultations and the tragic similarity in the developmental problems faced by their children conceived naturally, the third child also exhibited the same genetic complications, leading to another devastating loss for the Wagner family. The Wagner family's legal action against Dr. Shoffner hinged on the assertion of negligence — that he failed to properly advise them of the risks involved in using Mr. Wagner's sperm for IVF, which led to the birth of another child with the same genetic disease.[12]

Analyzing the factual and procedural background of the court reveals interesting information. According to the official court opinion document,

> Dr. Shoffner was negligent as follows: Dr. Shoffner breached duties owed to the Wagners by...advising the Wagners that using a donor egg and Mr. Wagner's sperm in an in vitro procedure would replicate the same risk as the general population of conceiving a child with the same genetic defect as their first two children.[13]

Specifically, the court agreed that Dr. Shoffner breached the standard of care by failing to address the potential risk that carrying on with IVF would result in.[14] However, the genetic mutation (which turned out to be a rare disease called Alper Syndrome) had not been diagnosed yet prior to the birth of the third child with IVF, and there was no allegation in the motions provided by the plaintiffs that the doctor had any way to define the specific disease. Moreover, it was no fault of the physician to begin with. The donor egg turned out to also have the rare disease by unfortunate coincidence, not Mr. Wagner's sperm, and the chance of a known carrier parent

---

[11] Yale Medicine, *In Vitro Fertilization (IVF)*, www.yalemedicine.org/conditions/ivf.
[12] Wagner v. Shoffner, No. 2009, Fla. Cir. LEXIS 2020 (D.Mass. Mar.29, 2010).
[13] *Id.* at. 11.
[14] *Id.* at. 12.

passing on the disease in IVF was 1 in 1000.[15]

This case brings up the familiar debate brought to light in *Helling v. Carey*, where the legal system's imposition of a standard of care exceeds the expectations established by medical practice.[16] Much like in *Helling*, the question arose of whether the duty of care should require extraordinary measures, particularly in areas dominated by uncertainty and evolving knowledge. The Wagner case exemplifies a dangerous expansion of physicians' liability, where medical professionals are expected to provide assurances against incredibly unlikely risks — in this instance, the transmission of a rare genetic mutation with a likelihood of less than 0.1%.[17] This expectation to predict and prevent near-improbable outcomes places an onerous and arguably unjust burden on physicians who operate within the realms of current medical understanding and technology.

This is just the tip of the iceberg. Numerous cases have placed extraordinary burdens on physicians, who must take into account near-impossible circumstances and maintain a reasonable, well-balanced standard of care. As oxymoronic as this sounds, this is the status quo of the physician landscape and ecosystem that the law has bred in the past few decades. As genomic and medicinal technology continues to improve, the premise that changes will occur naturally without any drastic changes is naive at best and destructive at worst.

Here is the chain of events that lies ahead: new technologies and therapeutics are discovered and invented to improve health. Doctors, in turn, adopt this technology to help with patient treatment, only to be bombarded with changing standards and unreasonable expectations.

II. A CHANGING GOAL POST

A. Duty of Care

Another facet of proving medical malpractice is the "duty of care." In essence, the plaintiff must prove that a duty between the physician and the patient was neglected in the action that breached the standard of care. But even this definition is vague and expansive.

---

[15] Gary E. Merchant, and Rachel A. Lindor, *Genomic Malpractice: An Emerging Tide or Gentle Ripple*, 73 Food and Drug L.R. 1, 1-37 (2018) (Explanation of chance of a known carrier parent passing).
[16] *Helling*, 83 Wash. at. 517.
[17] *Id.* at. 34.

The Tarasoff case, formally known as *Tarasoff v. Regents of the University of California*, is a landmark legal case that significantly impacted the field of psychology, the principles of patient confidentiality, and the scope of duty of care in the United States. The case arose from a tragic event that occurred in the mid-1970s.

Prosenjit Poddar, a student at the University of California, Berkeley, developed a deep affection for Tatiana Tarasoff, a fellow student. After Tarasoff rejected Poddar's romantic advances, Poddar sought psychological treatment at the university's health service and was seen by a psychologist. During therapy sessions, Poddar expressed a desire to kill Tarasoff. Concerned by the threat, the psychologist informed his superior and campus police. Based on the psychologist's recommendation, the police briefly detained Poddar but released him after he appeared rational and promised not to harm Tarasoff.[18] The psychologist's superior decided against further action, including failing to notify Tarasoff or her family of the threat.

Poddar's threats were not idle; after being released, he eventually located Tarasoff, who had been abroad, and fatally stabbed her. Tarasoff's parents sued the university, its health service employees, and the police for failing to warn their daughter about the threat against her life. The case eventually reached the California Supreme Court, which issued a ruling with profound implications for the duty of care and confidentiality in therapeutic settings. The court held that mental health professionals have a duty to protect individuals who are being threatened with bodily harm by a patient.[19] This duty may require the professional to take reasonable steps to notify the intended victim and the police or take whatever steps are reasonably necessary under the circumstances. This ruling established the principle widely known as the "duty to warn," marking a significant exception to the rule of patient-therapist confidentiality. The decision underscored the idea that the protection of potential victims from harm outweighs the patient's right to confidentiality in situations where there is a foreseeable risk of serious harm to an identifiable individual.

At first glance, this seems to have nothing to do with genomic medicine. But imagine a scenario where a genetic counselor discovers through testing that a patient carries a gene for a highly aggressive form of cancer, which not only affects the patient but also has a high probability of being passed on to their children. The implications of the Tarasoff ruling, when applied to such a scenario, become intriguing and complex. Just as the court decided that the duty to protect extends beyond the therapist-patient

[18] Tarasoff v. Regents of the University of California, 17 Cal. 3d 425, 430-464 (1976).
[19] *Id.* at. 439.

relationship in cases of imminent physical harm, one could argue that a similar duty might extend to healthcare professionals in the realm of genetic counseling. This could mean that genetic counselors, and potentially other healthcare providers involved in genomic medicine, might have an ethical and possibly legal obligation to warn the patient and potentially at-risk family members about genetic conditions that could have serious health implications.

This duty to warn, adapted from the Tarasoff decision, could require healthcare professionals to navigate the delicate balance between confidentiality and the obligation to prevent harm. In genomic medicine, this balance is particularly challenging due to the hereditary nature of the information involved. Similarly to disclosing confidential information as a therapist, a geneticist disclosing genetic information to family members without the patient's consent could violate the patient's privacy and autonomy. However, withholding this information could potentially lead to preventable harm if at-risk family members remain unaware of their susceptibility to serious genetic conditions.

B. What Does a Physician Do?

In fact, one need not imagine a hypothetical scenario where a physician's duty to warn extends beyond the patient to their immediate family in the context of genomic medicine; the *Safer v. Estate of Pack* case provides a concrete example. This case centered around the genetic condition familial adenomatous polyposis, a precursor to metastatic colon cancer.[20] The plaintiff argued that knowledge of her risk for developing this condition, which was known to the physician treating her mother, could have led to preventative measures, potentially saving her from the disease's most severe consequences.[21] In a landmark ruling, the New Jersey Appellate Court expanded the traditional boundaries of medical responsibility by acknowledging that the implications of genetic conditions do not stop with the patient but ripple through their biological relatives. Now, physicians could be liable for failing to warn close genetic relatives of a disease carrier of their likelihood of carrying the disease. By challenging the narrow interpretation of a physician's duty to warn, this case underscored the necessity of considering the familial nature of genetic conditions in medical practice.

---

[20] Peyman Dinarvand et al., *Familial Adenomatous Polyposis Syndrome*, 143 Arch Pathol. L.Med. 1382, 1382-1383 (2019) (Explaining Familial Adenomatous Polyposis).

[21] Safer v. Estate of Pack, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996).

The implications of the *Safer* ruling are profound and far-reaching. First and foremost, it signals a shift towards a more inclusive understanding of patient care, where the patient's health is seen in the context of their broader biological connections. This approach recognizes the unique nature of genetic information as something that is shared among relatives and, therefore, of potential significance to family members' health. It challenges the medical community to consider how best to manage this information, balancing the need for confidentiality and respect for the patient's autonomy with the potential benefits of sharing lifesaving information with at-risk family members. However, as highlighted in Safer v. Estate of Pack, the expansion of the duty to warn also introduces a host of ethical, legal, and practical challenges. The primary concern is the ambiguity surrounding how physicians should navigate these expanded responsibilities. Due to cases like *Safer v. Estate of Pack,* physicians may be uncertain about their legal obligations and the best practices for protecting their patients and their families from harm. In other words, physicians are now caught in a dilemma. Doctors may be bound by doctor-patient confidentiality but simultaneously obligated to share life-saving information with family members to thwart the prospect of being sued. This uncertainty could lead to inconsistencies in care and potentially hinder the effective use of genetic information in preventing disease.

The pressing demand for clarity and guidance in the evolving domain of genomic medicine cannot be overstated. As we stand on the cusp of a new era in healthcare, where the potential for genetic information to save lives and prevent disease is immense, the burden placed on physicians, especially genomic counselors, is unfair and unsustainable. These professionals are tasked with navigating an intricate maze of ethical, legal, and medical challenges without a compass. The landmark cases of *Helling, Wagner*, *Tarasoff*, and *Safer* have peeled back the layers of the profound complexities and responsibilities that healthcare providers face, particularly when genetic risks extend beyond the individual to affect family members and even the broader public.

This situation presents a glaring injustice. Expecting healthcare providers to shoulder these responsibilities—with the current lack of clear, comprehensive guidelines—places them in an impossible position. They are forced to make decisions that have far-reaching implications for patient confidentiality, familial rights, and preventive healthcare, all while navigating the murky waters of evolving legal expectations and ethical considerations. The absence of standardized protocols

endangers patient and family welfare and exposes healthcare providers to potential legal liabilities and ethical quandaries.

III. SOLUTIONS

A. Case by Case?

A joint paper from Yale University and the University of Washington argues that, in light of all the issues with the standard of care, the legal system should completely abolish the standard of care. They argue that because of the vagueness of the definition, that medical malpractice cases should instead be weighed on a cost-benefit criterion.[22] In their paper, they argue to restructure the juror instructions to simply decide whether or not the actions were justifiable, based on whether the action of claimed negligence was more likely to benefit or harm the patient. The jury would be tasked with determining if the doctor undertook "risk-creating conduct," a term that would be used to describe any unjustifiable action taken by the physician in question.[23]

This paper agrees that the standard of care definition is deeply flawed. It is unreasonably burdensome on jurors who are presented with a barrage of complex medical information. While it may be true that in a perfect world, simply doing a cost-risk analysis of each case may be the best course of action, it is simply not feasible and realistic in our current court-case system.

Analyzing each case without any pure precedent, set standard, or legal background already established will prove to be a nightmare for both sides. Not only will each case be hyper-specific to its own context, but the extreme confusion of the medical world will only be heightened by the fact that each conduct and piece of medical information will need to be explained in depth in order for the jury to come to a correct conclusion. In fact, we have already seen what happens when the law becomes too complex. In 1982, the US Supreme Court began to realize that the specific nature of patent law was becoming too extreme for generalist judges. So, it created the United States Court of Appeals for the Federal Circuit to gain jurisdiction to hear appeals in patent cases.[24] If we continue to move in this direction, the legal system will eventually

[22] Lawrence H. Brenner et al., *Beyond the Standard of Care: A New Model to Judge Medical Negligence*, 470 Clinical OR.R. 1357, 1357-1364 (2012) (Discussing the vagueness of standard of care).
[23] *Id*. at. 1359.
[24] Timothy B. Lee, *Specialist Patent Courts Are Part of the Problem*, Forbes, Aug. 19, 2011, at 1.

have to create another federal circuit court for the sole purpose of examining appeals from highly complicated medical malpractice cases. This would not only cost tens of millions of dollars to legislate and implement but also be highly inefficient due to the long proceeding nature of each case.

Moreover, weighing each action on a cost-benefit criterion opens the door for inconsistent rulings and unpredictability in the courtroom. What could be considered a "benefit" to one's interpretation of the standard could be also considered a cost to another. A simple cost-benefit analysis still leaves room for ambiguity and subjectivity. The Oxford Journal of Law underscores the necessity for precedent in the rule of law for three main reasons: stability, reliability, and equality.[25] This approach to precedent does not imply that past rulings regarding the standard of care are infallible or must be followed without question. Instead, it simply suggests that these earlier decisions provide a valuable reference point for reflection and guidance.[26] Without it, the legal system risks becoming a labyrinth of subjective decisions, where similar cases might receive vastly different judgments based on the presiding judges.

While flawed, a standard of care, or any standard for that matter, allows for a structured legal framework within which similar cases can be evaluated against established benchmarks, reducing the potential for arbitrary decisions. Without it, each case would essentially start from scratch, forcing courts to reinvent the wheel with every new trial, which is preposterous considering lives are at stake.

B. One Size Fits All?

In order to solve the standard of care problem, the legal system needs to adopt a multifaceted approach. Keeping the concept of the standard of care will be necessary, but substantial changes will be needed to ensure the system works effectively. A paper from the University of British Columbia in 2022 describes a potential workflow for genomic and personalized medicine.[27] While not "official guidelines of care," these instructions could help govern what physicians should be expected to do when applying personalized medicine. Nevertheless, the instructions are complex. In fact, the complete workflow instructions consist of 31 steps, each with various branching

[25] Sebastian Lewis, *Precedent and the Rule of Law*, 41 Oxford J. Legal S. 873, 874-875 (2021) (Importance of necessity for precedent in the rule of law).
[26] Lewis, *supra*, at 873-874.
[27] Julia Handra et al., *The Practice of Genomic Medicine: A delineation of the process and its governing principles*, 9 Frontier M. 1, 1-13 (2023) (A modified legal approach to standard of care).

paths of possible situations.[28] Under these guidelines, the standard of care would be, in essence, a set of tasks. For example, the first few steps of the potential standard of personalized medicine are identifying the problem, assessing the patient, and deciding whether to undergo genetic counseling. From there, the doctor would answer a series of yes-no questions, collect samples, and run tests, depending on the situation.[29] Thus, the solution proposed by this paper, if legislated and accepted, would be to take existing procedures and workflows and define them as the official standard of care.

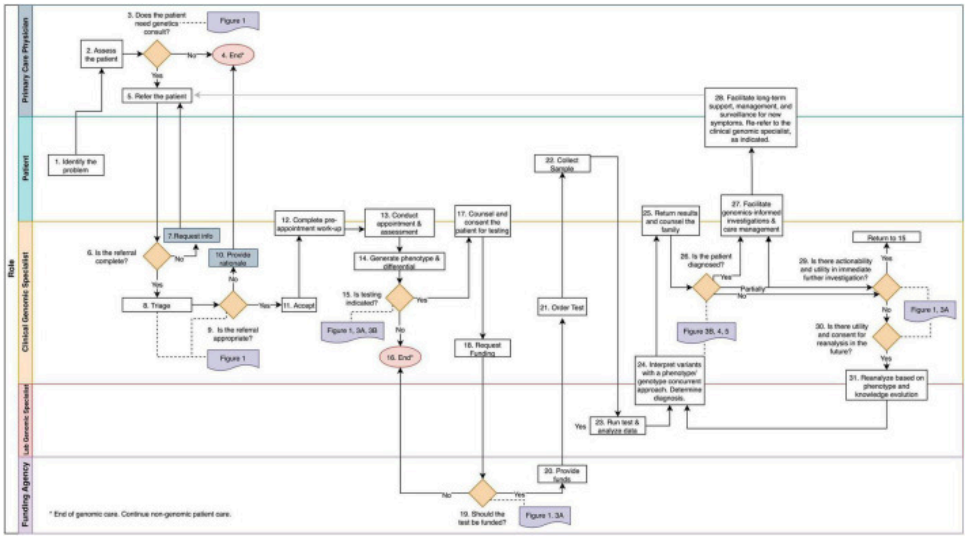

Figure 1: The University of British Columbia Genomic Medicine Standard.[30]

There are some merits to defining the legal standard of care as a complete roadmap. For one, it eliminates the vagueness surrounding the concept of the standard of care by providing clear and actionable steps for healthcare providers to follow. This would significantly reduce the risk of malpractice claims by establishing actual concrete expectations for both practitioners and patients. Having a structured approach is the missing piece of the puzzle for the legal system in medical malpractice. While the University of British Columbia's roadmap might not be the Holy Grail, a collaboration of international leaders in medicine developing decision trees to become legal standards of care could be the future of the legal system.

[28] *Id.* at. 8.

[29] *Id.* at. 1-4.

[30] *Id.* at. 4.

Most importantly, a well-defined roadmap would make it easier for jurors to understand and evaluate medical malpractice cases. Currently, the vague notion of a standard of care can lead to confusion and subjective interpretations. Jurors, who often lack medical expertise, must rely on expert testimonies to grasp what constitutes appropriate care, which can vary significantly between cases. By contrast, a detailed roadmap offers a clear, step-by-step guide that jurors can reference directly. This concrete framework allows them to see whether a healthcare provider adhered to the prescribed steps or deviated from them. In practice, this means that during a trial, jurors could be presented with the specific steps outlined in the roadmap, making it straightforward to determine if a doctor broke a step or failed to follow a particular procedure. This clarity reduces ambiguity and helps ensure more consistent and objective judgments. It shifts the focus from interpreting complex medical standards to simply checking compliance with established guidelines. Consequently, the decision-making process becomes more transparent and accessible, enhancing the fairness and reliability of verdicts in medical malpractice cases.

However, there are some potential drawbacks to this approach. Firstly, there could arise legal situations not specified in the proposed roadmap. As coherent and comprehensive as these standards try to be, there will inevitably be some exceptions and rare cases that would force courts to adhere to their own interpretations. Moreover, in the medical spectrum, the complexity and specificity of a detailed, step-by-step standard of care could potentially lead to rigidity in medical practice. Medicine is an art as much as it is a science, requiring practitioners to exercise judgment and adapt to the unique circumstances of each patient. A highly detailed standard might limit this flexibility by forcing physicians to adhere to a prescribed path even when their professional judgment suggests an alternative approach might be better.

Thus, to bolster this system, an ongoing committee of genomic medicine should be established as well. On the off-chance that some scenario arises that justifies an exception to the predominantly followed standard of care, this committee would address the evolving nature of medical science and offer a reputable definition of what the best practice should have been. This would be imperative particularly in the advancing field of genomics, which is characterized by rapid discoveries and technological advancements. An entity, akin to the prowess of the American Heart Association (AHA) or the American College of Cardiology (ACC), but with a laser focus on the rapidly advancing field of genomics, would be crucial in order for doctors to adapt to any roadmap or decision standard of care. Furthermore, experts in this field

would be far better equipped to answer complex questions about what best practices in genomics should be, as opposed to leaving such critical decisions to laymen jurors who are given instructions to determine what the genomic standard of care is.[31]

In fact, the same paper by Yale and the University of Washington that called for the abolition of the standard of care advocates for a committee in the replacement of the standard of care.[32] But the two do not have to be mutually exclusive. It is entirely possible for both to exist in any status quo, harmonizing the traditional principles of medical care with the groundbreaking potential of genomic insights. The proposed committee could function not as a replacement, but as a pivotal enhancement, enriching the standard of care with the nuanced, personalized approaches enabled by genomic medicine. This would still allow structure and guidelines for the legal system, while still allowing doctors the freedom to improve medicine based on approvals from the committee.

Furthermore, such a committee would create comprehensive guidelines detailing when and how doctors should communicate genetic risks to patients and their families. In cases involving rare genetic diseases or conditions with significant hereditary implications, this framework would help physicians determine the appropriate course of action. By clearly defining the circumstances under which family notification is necessary, the committee would ensure that doctors are not left to make these critical decisions in isolation, thereby reducing the risk of legal repercussions and improving patient care. This approach would offer a balanced solution to the "duty of care" issue, respecting patient confidentiality while acknowledging the ethical responsibility to inform at-risk relatives, ultimately strengthening the standard of care in genomic medicine.

Addressing the perennial debate of misdiagnosis or failure to diagnose, the combined guidelines of the committee and the roadmap would introduce a new layer of clarity and precision to the process. With genomic medicine's potential to predict and diagnose diseases with unprecedented accuracy, the committee would offer a clear framework for integrating these capabilities into standard practice. And with respect to the probability, added extra layers of decision-making could be introduced into the workflow when necessary. This clarity would not only aid in the accurate diagnosis of diseases but also in preemptively identifying at-risk individuals, thereby shifting the paradigm from vagueness to clarity.

---

[31] Judicial Council of California Civil Jury Instructions, No. 501 (2024).

[32] Brenner et al., *supra* note 22, at . 1361.

Moreover, the establishment of this committee addresses the fundamental issue of duty and responsibility in the medical field. By providing a detailed roadmap that incorporates genomic data into patient care, the committee delineates the responsibilities of healthcare providers in this new era. This roadmap would outline who has the duty to perform genomic testing, interpret its results, and take action based on those findings, thereby clarifying the expectations placed on medical professionals. Such guidelines ensure that both the medical community and the patients understand the roles and responsibilities in genomic medicine, fostering a transparent, trust-based relationship.

Should disputes arise, whether they pertain to the failure in diagnosing a genetic condition or the misinterpretation of genomic data, the committee would serve as the arbiter, offering a specialized, informed perspective. This not only streamlines the resolution process but also ensures that decisions are made with the utmost respect for the latest scientific knowledge and ethical considerations. The committee's existence would significantly reduce the ambiguities that currently complicate legal evaluations of medical negligence, offering a clear, authoritative source of guidance on the appropriate use of genomics in patient care.

In essence, this committee wouldn't just solve existing issues—it would preemptively address future challenges, ensuring that as genomic medicine evolves, so too does our approach to integrating it into patient care. It offers a dynamic, evolving framework that respects the complexities of genetic science while honoring the foundational principles of medical practice. This approach promises not just to adapt to the future of healthcare but to actively shape it, ensuring that every advancement in genomics translates into tangible benefits for patients worldwide.

CONCLUSION

As we stand on the precipice of a new frontier in healthcare, defined by the incredible potential of genomic medicine, the imperative to navigate this landscape with both precision and foresight has never been more critical. The establishment of a dedicated committee for genomic medicine, as proposed in this paper, represents not just a step but a leap towards realizing the full promise of genomic insights in transforming patient care. By integrating a comprehensive roadmap with the nuanced, personalized approaches enabled by genomic medicine, we chart a course towards a future where the clarity and precision of care are not just ideals but realities.

The solution outlined herein—marrying the traditional with the innovative through the formation of an authoritative genomic committee—addresses the core challenges that have long plagued the healthcare system: the vagueness of the standard of care and the dire consequences of misdiagnosis or failure to diagnose. This approach promises to usher in an era of healthcare that is not only more accurate but also more equitable. It envisions a world where advancements in genomic medicine are accessible to all, irrespective of socioeconomic status or geographic location, closing the gaps that have historically divided healthcare experiences and outcomes.

Moreover, this committee's role as an arbiter in disputes and its capacity to offer a specialized, informed perspective on the use of genomics in patient care illuminate the path towards a more just and accountable healthcare system. By reducing ambiguities and providing clear guidelines, it ensures that every decision made by healthcare providers is informed by the latest scientific knowledge and ethical considerations, thereby safeguarding the interests of patients and their families.

The significance of this proposed solution extends beyond the immediate benefits of improved diagnostic accuracy and patient care; it lays the groundwork for a healthcare system that is adaptable, resilient, and prepared to integrate future scientific discoveries. As genomic medicine continues to evolve, this committee will serve as the cornerstone of a dynamic framework that can accommodate new knowledge and technologies, ensuring that the healthcare system remains at the cutting edge of medical science.

In essence, the solutions proposed in this paper are not just about addressing current challenges; they are about reimagining the future of healthcare. They underscore the importance of foresight, collaboration, and ethical consideration in harnessing the transformative power of genomic medicine. As we move forward, the integration of these solutions into the healthcare landscape promises not just to change lives but to save them, heralding a new era of medical care that is as compassionate as it is innovative. This is the future of healthcare—a future where every discovery brings us one step closer to a world where the full potential of genomic medicine is realized for the benefit of all.