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TRANSFORMING THE PHYSICIAN’S STANDARD OF CARE IN THE CONTEXT OF WHOLE GENOME SEQUENCING TECHNOLOGIES: FINDING GUIDANCE IN BEST PRACTICE STANDARDS

I. INTRODUCTION

Personalized medicine has entered the clinical setting and is complicating the physician-patient relationship. With the advent of new genetic testing technologies, determining whether a physician has a “duty to warn” and a “duty of care” regarding certain genetic dispositions is becoming ever more complex and still remains fundamental to determining whether a physician may be held liable for failing to conform to the standard of care. As history has demonstrated, the risk for medical malpractice litigation increases with the introduction of new information that may affect the clinical relationship.¹

Certain types of genetic testing technologies, such as whole genome sequencing, are a driving force in an overall vision for personalized medicine that delivers information more efficiently and achieves meaningful outcomes for patients via narrow-focused prevention and treatment methods. However, advancements in whole genome sequencing technologies have outpaced a physician’s ability to manage and interpret the voluminous amount of information being generated. As genetic testing technologies become more sophisticated and robust and as they continue generating voluminous amounts of information, the physician’s standard of care will need to transform accordingly to account for the reality of these changes.²

Although “considerable progress has been made in mapping the sequence of the human genome and identifying sources of human genetic variation,”³

1. See Gary E. Marchant & Rachel A. Lindor, *Personalized Medicine and Genetic Malpractice*, 15 *GENETICS MED.* 913, 921 (2013) (stating a probable cause of this increase in litigation involves the presumed connection between the belief that the more a provider is capable of doing, then the more a provider should do, which means that more can go wrong and lead to a lawsuit).

2. Kayte Spector-Bagdady & Elizabeth Pike, *Consuming Genomics: Regulating Direct-to-Consumer Genetic and Genomic Information*, 92 *NEB. L. REV.* 677, 680 (2014) (expressing the view that the reality is concerning for the clinical context because genetic testing has rapidly transitioned from one of discrete testing looking at single genes to large-scale genetic testing (or genomic sequencing), which has shown to return information about many or all of a patient or consumer’s genes, and many of these are still lacking in function or significance).

3. THE COUNCIL ON SCI. & PUB. HEALTH, RESOL. 422, A-05: GENOMIC AND MOLECULAR-BASED PERSONALIZED HEALTH CARE, <http://www.ama-assn.org/ama/pub/advocacy/topics/personalized-medicine.page> (last visited Dec. 19, 2015) [hereinafter RESOL. 422, A-05]. For

there is still a high level of uncertainty pertaining to the genotype-phenotype associations that are generated through whole genome sequencing.⁴ Current medical standards of care do not account for these types of technologies because the threshold has yet to be defined. The specific threshold of concern here involves clinical utility.⁵ Consequently, there is a risk for physicians being held liable for failing to meet an expected standard of care when that standard has yet to be defined. With integration into the health care delivery system still in its infancy and personal genetic information becoming more readily available, genetic testing technologies such as whole genome sequencing pose certain challenges that must properly be addressed if the potential of this form of personalized medicine is to be realized with meaningful utility.⁶ Specifically, the standard of care ethically and legally expected of physicians will need to appropriately transform as the threshold is being defined in the clinical context within the scope of the physician-patient relationship.

While some argue for a more cautious approach to clinical implementation, particularly asserting that genetic testing technologies are still in their infancy and the generated results cannot be interpreted with much clinical utility,⁷ this article argues that despite the considerable amount of uncertainty pertaining to the threshold by which whole genome sequencing information is used with clinical utility, physicians are only one step away from being held accountable and there is a current legal framework by which this standard may begin to take shape. This accountability would only be triggered after physicians receive thorough education that is similar to genetic counselors and is informed by best practice standards, and after the threshold of clinical utility has been more fully defined and met.

Accordingly, this article examines how the physician's standard of care will be shaped by the reality of whole genome sequencing. Part II provides background information to personalized medicine and whole genome

example, "[c]onstruction of genetic maps and the identification of conserved haplotypes promises to assist in the search for genes that convey risk, or protection from, chronic diseases." *Id.*; see also NAT'L HUMAN GENOME RESEARCH INST. AT THE NAT'L INSTS. OF HEALTH, HUMAN GENOME PROJECT (2015), [http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject\(NHGR1\).pdf](http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGR1).pdf).

4. See Isaac S. Kohane et al., *The Incidentalome: A Threat to Genomic Medicine*, 296 [J]AMA 212, 212 (2006).

5. See *infra* Section II.B.1. The threshold necessarily involves the relationship between and among analytic validity and clinical validity, as they relate to clinical utility. *Id.*

6. See, e.g., Matthew J. Westbrook et al., *Mapping the Incidentalome: Estimating Incidental Findings Generated Through Clinical Pharmacogenomics Testing*, 15 GENETICS MED. 325, 325 (2013); see also Kohane et al., *supra* note 4; Amy L. McGuire & Wylie Burke, *An Unwelcome Side Effect of Direct-To-Consumer Personal Genome Testing: Raiding the Medical Commons*, 300 [J]AMA 2669, 2671 (2008).

7. See, e.g., Wylie Burke et al., *Seeking Genomic Knowledge: The Case for Clinical Restraint*, 64 HASTINGS L. J. 1649, 1649 (2013).

sequencing, articulates their promise for the future of health care, and examines certain threshold issues and barriers to its clinical implementation. Part III provides a rule-centric, legal framework by which a standard of care and subsequent liability may take form for physicians with the advent of whole genome sequencing and in consideration of its emerging issues. Part IV considers the aforementioned historical background, the threshold issues and barriers to clinical implementation, and the established legal precedent to offer guidance as to how physicians may best educate themselves, the referential professions in which they may find best practice standards, and the future implications for negligence liability as the current standard of care reacts to and is transformed by whole genome sequencing testing technologies.

This last part offers a new way to contextualize the physician's role in addressing, communicating, and educating patients of their genetic susceptibility for certain diseases, illnesses, and conditions. The proposal is analogous to genetic counselors and is premised upon uncovering those best practices that physicians may take advantage of when faced with a situation where they may not have the requisite knowledge to adequately educate patients and where patients might not comparably respond to seemingly similar genetic information. Clinical utility is the turning point for re-defining and transforming a physician's standard of care as it relates to whole genome sequencing. The bridge between these is premised on a revised "duty to warn," which is based upon a threshold of foreseeability, and adequate education, as informed and guided by best practice standards. Framing the standard of care upon a foreseeability doctrine in the context of whole genome sequencing may allow for meaningful interpretation of those findings generated through the genetic testing technology. Before one may understand the implications of what this means for physicians, patients, and their relationship to one another in the clinical setting, the emerging genomic landscape upon which this discourse takes root needs to be established and illustrated.

II. PARSING THROUGH AND UNDERSTANDING THE EMERGING GENOMIC LANDSCAPE

A. *Background of Personalized Medicine and Whole Genome Sequencing*

Personalized medicine holds promise for the future health and well-being of many patients.⁸ Understanding the human genome through a variety of genetic testing technologies, including whole genome sequencing, is important for better capturing the nature and etiology of disease so that pharmaceutical

8. And President Obama's recent announcement for his "Precision Medicine Initiative" is evidence of a future investment in the advancement in and use of personalized medicine methodologies. WHITE HOUSE, OFFICE OF THE PRESS SEC'Y, FACT SHEET: PRESIDENT OBAMA'S PRECISION MEDICINE INITIATIVE (2015).

drugs and therapies may be directly tailored for each patient's particular genetic makeup.⁹ The availability of information related to the human genome has become more widespread at a reduced cost,¹⁰ and the genetic testing technologies themselves have become more sophisticated, revealing more nuanced information than ever before.¹¹ As such, before engaging in an ethical and legal discourse pertaining to the potential challenges facing physicians on one side of the clinical equation, one must first understand the nature of personalized medicine and whole genome sequencing, and why they offer benefits and pose potential risks for patients and their relationship to their physicians now and in the future.

Personalized medicine is health care that is "informed by each person's unique clinical, genetic and environmental information."¹² Physicians have benefitted greatly from the inclusion of personalized medicine in the clinical setting,¹³ by enabling them to "more easily detect individual differences [] in susceptibility to particular diseases or [] in responses to specific treatments and to then tailor preventive and therapeutic interventions to optimize benefit and minimize harm."¹⁴ An example of how physicians have tailored patient treatment plans is with greater information on the pharmaceutical drug warfarin.¹⁵ Advancements have enabled physicians to better understand when

9. *Policy Perspective on Personalized Medicine*, AM. MED. ASS'N (2013), <http://www.ama-assn.org/ama/pub/advocacy/topics/personalized-medicine.page> [hereinafter *AMA Policy Perspective*]; see also THE COUNCIL ON SCI. & PUB. HEALTH, REPORT 4 (A-10), GENOMIC-BASED PERSONALIZED MEDICINE 1, <https://download.ama-assn.org/resources/doc/csaph/x-pub/a10csaph4-summary.pdf> [hereinafter *CSAPH*].

10. See Spector-Bagdady & Pike, *supra* note 2, at 688; see also SANCY A. LEACHMAN ET AL., EDUCATIONAL BOOK: DIRECT-TO-CONSUMER GENETIC TESTING: PERSONALIZED MEDICINE IN EVOLUTION 34 (2011); Richard R. Sharp, *Downsizing Genomic Medicine: Approaching the Ethical Complexity of Whole-Genome Sequencing by Starting Small*, 13 GENETICS MED. 191, 191 (2011) ("Although the field of genomics has been driven largely by technological innovation, we are rapidly approaching a time when neither capacity nor genotyping costs are limiting factors in the emergence of genomic medicine.").

11. See Sean D. Mooney, *Progress Towards the Integration of Pharmacogenomics in Practice*, 134 HUM. GENETICS 459, 460 (2015).

12. *AMA Policy Perspective*, *supra* note 9, at 2; see also *CSAPH*, *supra* note 9.

13. RESOL. 422, A-05, *supra* note 3, at 1. "The mapping of the human genome [which arguably initiated the movement towards personalized medicine from a pharmacogenomics perspective] coupled with the abilities to measure the function of genes... offers the possibility that a patient's genome can be analyzed in order to choose appropriate diagnostic and therapeutic strategies, including preventative measures." *Id.* These features hold great promise for personalized medicine.

14. *AMA Policy Perspective*, *supra* note 9, at 2.

15. See Guang-Ming Tan et al., *Role of Warfarin Pharmacogenetic Testing in Clinical Practice*, 11 PHARMACOGENOMICS 439, 439 (2010), <http://www.gbcbiotech.com/laboratorio/assets/role-of-warfarin-pharmacogenetic-testing-in-clinical-practice.pdf> ("Variations in two genes, VKORC1 and CYP2C9, have been associated with variation in warfarin metabolism

a particular variation of either one of two genes (VKORC1 and CYP2CP)¹⁶ will cause a patient to be more susceptible to an adverse health event when taking the drug.¹⁷ Personalized medicine's successful implementation into the clinical setting also has potential cost reduction benefits not only to physicians, but also to health care providers, institutions, and the patient.¹⁸

These personalized medicine realizations can be attributed, in part, to the advent of whole genome sequencing, which continues to be a driving force for revealing the nuances of certain genetic variants. Whole genome sequencing is a form of genetic testing technology¹⁹ that measures variation in one's whole DNA sequence.²⁰ As a medical screening tool used by physicians, it strives to identify a disease or marker in patients,²¹ and has demonstrated a considerable amount of value in:

among individuals. Some of this variation includes longer dose stabilization time, higher risk of serious or life-threatening bleeding, and increased risk of other adverse health events. Physicians have been able to utilize pharmacogenetic testing to determine whether a patient will be more or less susceptible to having an adverse event by virtue of having a particular variant on either of the two genes. As a result, physicians may choose to prescribe another drug for the same anticoagulation treatment purpose.”); *see also* RESOL. 422, A-05, *supra* note 3, at 6 (“A hallmark of drug disposition, for example, is large interindividual variability. Such variability is a major reason why patients differ in their responses to standard doses of a drug. A combination of genetic, environmental, and disease-state factors affect drug disposition, with the relative contribution of each, depending on the specific drug and disease.”).

16. *See* Simone Rost et al., *Mutations in VKORC1 Cause Warfarin Resistance and Multiple Coagulation Factor Deficiency Type 2*, 427 NATURE 537, 541 (2004); Ann K. Daly et al., *CYP2CP Polymorphism and Warfarin Dose Requirements* 53 BRIT. J. CLINICAL PHARMACOLOGY 403, 408 (2002).

17. *See* Tan et al., *supra* note 15. For patients with genetic variants of VKORC1 and CYP2CP, there is an increase in the risk of hemorrhage. *Id.*

18. *See, e.g.*, AMA Policy Perspective, *supra* note 9. As with any new technology, costs to hospitals and/or providers substantially increase. *Id.* However, personalized medicine services have the “potential to significantly reduce waste and improve health outcomes by ensuring care is delivered earlier and with treatments that have a higher likelihood of success.” *Id.* The adoption of personalized medicine in the clinical setting also has the potential to reduce overall costs by “shorten[ing] the diagnostic journey for those with rare conditions or diseases.” *Id.*

19. Spector-Bagdady & Pike, *supra* note 2. In a footnote, the authors clarify a distinction between “genetic testing” and “genomic testing” that is important for the scope of this article. *See id.* at 680 n.12 (“[T]he term ‘genomic testing’ [] mean[s] large-scale or whole genome testing (i.e., testing most if not all of a person’s nuclear DNA). The term ‘genetic testing’ can also include whole genome analysis as well as looking at only one or several discrete genes. Therefore, while all genomic testing is also appropriately described as genetic testing, not all genetic testing includes the analysis of enough genes to be considered genomic testing.”). Accordingly, for purposes of this article, whole genome sequencing/testing is synonymous with genomic testing as it directly relates to the physician-patient encounter in the clinical setting.

20. Burke et al., *supra* note 7, at 1650.

21. Mark A. Rothstein, *The Case Against Precipitous, Population-Wide, Whole-Genome Sequencing* 40 J. L. MED. & ETHICS 682, 682 (2012).

elucidating the genetic etiology of rare disorders, in identifying atypical variants in common diseases, in determining pharmacogenomically appropriate drugs and dosages, in performing tumor genome sequencing, and in aiding other clinical applications for the diagnosis and treatment of individuals who are symptomatic or whose family health history places them at substantial risk.²²

Advancements in testing accuracy and information generation²³ have paved the way for whole genome sequencing testing technologies to become more affordable to consumers and more available for widespread use in the clinical setting.²⁴ This reality also brings to light certain fundamental issues facing the physician-patient relationship.²⁵ Whole genome sequencing has allowed for the uncovering of information that was not previously known and, as a result, is not yet understood and cannot be adequately interpreted.²⁶ Recognizing and addressing these issues are central to the successful implementation of

22. *Id.*

23. Robert Pear, *U.S. Introduces New DNA Standard for Ensuring Accuracy of Genetic Tests*, N.Y. TIMES (May 14, 2015), http://www.nytimes.com/2015/05/15/health/new-way-to-ensure-accuracy-of-dna-tests-us-announces.html?_r=0. The National Institute of Standards and Technology, after collaborating with the Food and Drug Administration has made significant strides in developing a standard to ensure the accuracy and reliability of genetic testing technologies. *Id.* By way of “reference materials,” which includes deoxyribonucleic acid (DNA) of a Utah woman of European ancestry, scientists and laboratories may now demonstrate the quality of the DNA sequencing and the confidence in pinpointing specific mutations and devising tailored treatments that may be used in clinical practice for the benefit of patients. *Id.* Health insurance companies recognizing the increased trustworthiness of these genome-based tests may also be more likely to cover them under their plans. *Id.* This standard also benefits federal government regulators by reducing the variance of results among laboratories and thus decreasing the likelihood of wrongful diagnosis and treatment, especially given genetic testing’s growing importance in these clinical decisions. *Id.* Moreover, this technological development is in-step with President Obama’s “Precision Medicine Initiative,” which is aimed at fostering the development and adoption of customized treatments to the benefit of health care providers and their patients. Pear, *supra* note 23.

24. *See generally* Spector-Bagdady & Pike, *supra* note 2 (elaborating on what each direct-to-consumer provider offers to the public). For example, Illumina, Knome, deCODEme, FamilyTreeDNA, 23andMe, and *openSNP*—at one point each offered consumers with the opportunity to access their genetic information at a low-cost. *Id.*

25. *See, e.g.*, AMA Policy Perspective, *supra* note 9. Some of the issues permeating personalized medicine include (1) “well-informed, voluntary consent, including implications for biologically related others and appropriate counseling” and (2) “protection of privacy/confidentiality to prevent unauthorized/inappropriate use of personal genetic information, including constraints on access to information by third parties.” *Id.* at 2.

26. Greer Donley et al., *Prenatal Whole Genome Sequencing: Just Because We Can, Should We?* 42 HASTINGS CTR. REP. 28, 32 (2012), *quoted in* Spector-Bagdady & Pike, *supra* note 2, at 685 (“As technologies for sequencing genetic material increasingly allow for rapid sequencing for large amounts of DNA, our technological capacity for discovering variants outpaces scientific understanding regarding their consequences for individuals.”).

personalized medicine. Potential resolutions to these issues are contingent upon other threshold issues and barriers pertinent to the incorporation of this information in the clinical setting.

B. Threshold Issues with and Barriers to Clinical Implementation

There are many issues and “barriers confront[ing] the development and implementation of genetically based, personalized health care.”²⁷ Among these include: determining the analytic validity, clinical validity, and clinical utility of genetic testing results; patient preferences and behavior, trait variations, and a general lack of education; inadequate genetic education among physicians; and, as argued here, a lack of a defined standard of care upon which physicians may be held accountable in the clinical setting.²⁸

1. Analytic Validity, Clinical Validity, and Clinical Utility

It is generally accepted that rare genetic diseases are considered the context by which genetic testing primarily enters the clinical setting for particular patients.²⁹ The incidence of genetic variations producing a clinical phenotype and disease is extremely rare.³⁰ A genetic variation that is absolutely indicative of a phenotype (i.e., manifestation of a disease) is the huntingtin (HTT) genetic mutation with Huntington’s disease.³¹ The relationship between ordering a genetic test because a patient presents with symptoms potentially indicating Huntington’s disease, that test revealing the specific HTT genetic mutation, and a physician adequately communicating that information in a meaningful way to the patient is the archetypical connection demonstrating analytic validity, clinical validity, and clinical utility.

In addition to the diagnostic testing available to determine if one has or will develop Huntington’s disease, there is a diagnostic assay testing approach used to identify thousands of genes and evaluate the impact of those genes on genetic risks.³² However, it is insufficient for establishing the genetic risks for other diseases, illnesses, or conditions, such as hypertension, diabetes, and

27. RESOL. 422, A-05, *supra* note 3, at 1.

28. *Id.* Other considerations also include the overarching reality that “pharmacogenomics and personalized medicine are being introduced into a fragmented health care system confronted by significant disparities in health status, health care delivery, and access.” *Id.*

29. *Id.* at 3.

30. *Id.*

31. See Francis O. Walker, *Huntington’s Disease*, 369 LANCET 218, 218 (2007); see *infra* Part IV.B. (showing there is more scientific evidence establishing yet another causal relationship similar to that of the HTT mutation and Huntington’s). Evidence suggests that a genetic variation on BRCA causes breast cancer in women. *Id.*

32. RESOL. 422, A-05, *supra* note 3, at 3. This approach is used to identify the genetic risks associated with any number of genetic variations for Mendelian disorder. *Id.*

coronary artery disease.³³ This is due to the fact that the relationship between and among analytic validity, clinical validity, and clinical utility is not firmly established with sufficient evidence. Some evidentiary challenges embedded in and facing genomics include: a lack of comparative outcomes data for genomic applications due to regulatory and reimbursement policies that do not require such studies and their inherent costs; the relative ease of market access for genomic tests, including direct to consumer testing, which makes the lack of evidence more problematic;³⁴ and, a lack of consensus on evidentiary requirements for genomic test evaluation.³⁵ Considering the aforementioned context, a brief overview of analytic validity, clinical validity, and clinical utility and their relationship to each other provides a sufficient foundation upon which one may begin to understand the impact of the challenges associated with whole genome sequencing.

Analytic validity involves the “recognition of a genetic variant [on a particular gene],” specifically by a laboratory.³⁶ Ensuring analytic validity is the first step towards any genetic variant potentially having clinical significance, and this is safeguarded through the regulatory authority of the Clinical Laboratory Improvement Amendments (CLIA).³⁷ CLIA has the responsibility of ensuring that those laboratories performing genetic testing “establish and maintain the accuracy of its testing procedures.”³⁸ Analytic validity is a *necessary* step “toward ensuring clinical validity.”³⁹

Clinical validity is defined as “the accuracy with which a particular finding predicts the presence or absence of the underlying condition.”⁴⁰ The “[l]ikelihood of disease can depend on other genetic, environmental or stochastic factors that have not been, or cannot yet be, determined, leaving a degree of uncertainty.”⁴¹ Clarity and certainty are key determinants for clinical

33. *Id.*

34. *See, e.g.*, SEC’Y ADVISORY COMM’N ON GENETICS, HEALTH, & SOC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES (2008), http://osp.od.nih.gov/sites/default/files/SACGHS_oversight_report.pdf (reporting that there are gaps, for example, in the area of the evidence of clinical validity and utility for most direct-to-consumer genetic tests).

35. Muin J. Khoury et al., *Evidence-Based Classification of Recommendations on Use of Genomic Tests in Clinical Practice: Dealing with Insufficient Evidence*, 12 GENETICS MED. 680, 680 (2010).

36. Spector-Bagdady & Pike, *supra* note 2, at 720-21.

37. *Id.* at 720. CLIA is regulated by The Centers for Medicare & Medicaid Services. *Id.* at 719-20.

38. 42 C.F.R. § 493.801(a)(2)(ii) (2015).

39. Spector-Bagdady & Pike, *supra* note 2, at 721.

40. Shiri Shkedi-Rafid et al., *Defining and Managing Incidental Findings in Genetic and Genomic Practice*, 51 J. MED. GENETICS 715, 718 (2014).

41. *Id.*

validity. Through these determinants, one may better understand the relationship between analytic validity and clinical validity: while analytic validity is the *first* and *necessary* step towards a genetic variant having any potential clinical validity, it is not a *sufficient* step.⁴² However, the more salient issue with whole genome sequencing, similar to other large-scale, genomic tests, still remains rooted in determining clinical validity and clinical utility—the latter of which is of utmost importance and concern for the future of personalized medicine and the roles of physicians in the clinical transformation as a result.

Clinical utility will be the key determinant for a physician's ability to meaningfully educate a patient and provide guidance that satisfies the standard of care, once that standard of care has been defined in the particular context of whole genome sequencing. The threshold of clinical utility has been a focal point, for example, for contention about the disclosure of incidental findings.⁴³ It is in this particular context of incidental findings that a variety of definitions of clinical utility have emerged, which are still nonetheless applicable for this article's purpose. In the broadest sense possible, clinical utility "refers to whether the finding could lead to a medical intervention . . . that could improve health outcomes."⁴⁴ Determining this clinical utility has presented physicians with multiple practical difficulties, including: uncertainties about when and for whom results have clinical utility;⁴⁵ "novel findings not previously described in the literature;"⁴⁶ and personal utility.⁴⁷

42. Spector-Bagdady & Pike, *supra* note 2, at 721. For example, a genetic "test that satisfies the highest analytic standards might nevertheless produce genetic information that is inaccurate if the association between the genetic variation and clinical manifestation of disease is not strong." *Id.*

43. See Shkedi-Rafid et al., *supra* note 40; see also Gary E. Marchant et al., *Physician Liability: The Next Big Thing for Personalized Medicine?* 8 PERSONALIZED MED. 457, 457 (2011). The authors detail the differences in argument. On the one hand, "some experts claim that certain personalized medicine techniques are ready for clinical application today and several leading medical institutions have begun to deploy such techniques." *Id.* On the other hand, others are more skeptical about deployment of personalized medicine because they are not ready for widespread adoption because of uncertainty and disagreement over the clinical utility and validity of certain results. *Id.* at 459.

44. Shkedi-Rafid et al., *supra* note 40, at 716. A medical intervention may include "treatment, risk-reducing surgery and/or surveillance." *Id.* As the authors have argued, "[t]he greater the potential benefit that a medical intervention could provide, the greater the perceived onus to disclose. Potential clinical benefit needs to be weighed against the potential harm of disclosing the [incidental finding] (such as distress and uncertainty) especially if no specific consent has been given at the time of testing." *Id.*

45. *Id.* For example, "[i]nternational guidelines suggest[ing] that children not being tested for adult-onset genetic conditions until there is a medical benefit or until [the children] can decide [themselves] if and when to be tested. By contrast, the ACMG holds that the potential benefits to adult family members outweigh the potential harms of disclosing findings that do not have

While the aforementioned was provided in the context of incidental findings, as those genetic testing results pose a whole host of challenges in and of themselves,⁴⁸ the issue of clinical utility remains important and guiding for clinical implementation and holding physicians to an expected standard of care.⁴⁹ To date, whole genome sequencing (or any other genetic tests) continues to demonstrate the insufficiency of evidence for clinical utility, coupled with other challenges to clinical validity, for their meaningful use in clinical practice.⁵⁰ Some of the evidentiary challenges facing the field of genomics involve lack of information.⁵¹ On the specific issue of the insufficiency of the evidence, some have approached the associated problems by way of analogous methodologies in other medical contexts.⁵² “Shared decision making” has been recommended as one way for physicians to appropriately approach the insufficient evidence issue.⁵³ Other information is

immediate clinical utility for the child, at least in the near future when parents are not likely to otherwise have access to genomic tests.” *Id.* at 716-18.

46. Shkedi-Rafid et al., *supra* note 40, at 718. Evidence for pathogenicity is sometimes not apparent in some findings. Some clarification might be attained via studies of the finding or familial segregation studies. Careful communication is warranted here. *Id.*

47. *Id.* “Some results will lack clinical utility because there are no available medical interventions.” *Id.* However, “individuals could still consider these findings useful to know about because the knowledge would lead them to choose different reproductive options or make lifestyle and health behavior changes.” *Id.* at 719. Disclosure of such results that might not have clinical utility but nevertheless personal utility becomes the issue to be resolved. *Id.*

48. *See, e.g.,* Kohane et al., *supra* note 4.

49. *See* Shkedi-Rafid et al., *supra* note 40. Concerns about the clinical utility of genetic testing results have permeated the clinical setting. “As the genetic code is investigated in more detail, healthcare professionals will need to consider more downstream consequences of testing. [This down streaming] means that testing will be done in settings where clinicians have little experience of genetics/genomics.” *Id.* at 719. Some have expressed concern about whether consumers have been provided adequate information pertaining to findings and the concern has been amplified by consumers receiving results, for example, when consumers receive the results “without an explanation from a clinician or researcher.” *Id.* at 720. “The rise of such testing has also raised concerns about consumers turning to and overburdening the health service to interpret test results not clinically indicated.” *Id.*

50. Houry et al., *supra* note 35, at 680. However, “explicit and quantitative tools can be used in the evaluation of direct and indirect evidence on the utility of genomic [issues],” e.g., a recommendation matrix as proposed by Veenstra et al., which can be developed based on the amount of certainty of the evidence and the assessment of the risk-benefit profile. *See* David L. Veenstra et al., *A Formal Risk-Benefit Framework for Genomic Tests: Facilitating the Appropriate Translation of Genomics into Clinical Practice*, 12 GENETICS MED. 686, 691 (2010).

51. Houry et al., *supra* note 35, at 680.

52. *Id.* at 681.

53. *Id.* This “shared decision making” recommendation has been argued “as an appropriate approach for services for which evidence was insufficient, or the balance of benefits and harms was weakly positive or would vary depending on individual values or preferences.” *Id.* This involves a process in which the patient “(1) understands the risk or seriousness of the disease or

also available to help clinicians with their decision making in this context, which involves the balancing of harms and benefits of a particular genetic testing service.⁵⁴ Nevertheless, progress has been made in developing a methodology to counter the evidentiary challenge of translating genomic discoveries into health benefits,⁵⁵ and proposals have relied upon genetic counseling for guidance in, for example, shared decision-making models.⁵⁶

This progress is clearly being demonstrated in the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group,⁵⁷ which was established “for the purpose of adapting existing evidence review methods to the systematic evaluation of genomic tests and to link scientific evidence to recommendations for the clinical use of genomic tests, thereby addressing the challenges posed by complex and rapidly emerging genomic applications.”⁵⁸ Consequently, improving the “efficiency of a robust, evidence-based recommendation process”⁵⁹ has certain implications.⁶⁰ Categorizing and

condition to be prevented; (2) understands the preventive service, including the risks, benefits, alternatives, and uncertainties; (3) has weighed his or her values regarding the potential benefits and harms associated with the service; (4) and has engaged in decision making at a level at which he or she desires and feels comfortable.” *Id.*

54. *Id.* “The USPSTF . . . provide[d] additional information to clinicians to help with decision making in the context of insufficient information on the balance of harms and benefits of a service [The USPSTF has detailed] four ‘domains’ [of importance]: the potential burden of disease that might be prevented by an effective service, potential harms from such a service, costs—including opportunity costs—of widespread use of the service, and a description of current practice.” *Id.*

55. *E.g., id.* at 680. For example, “The Advisory Committee on Heritable Disorders in Newborns and Children evaluates genomic tests for use in newborn screening panels. The Evaluation of Genomic Applications in Practice and Prevention Working Group (EGAPP) provides an evidence-based assessment of genomic tests and other applications that are in transition from research to clinical and public health practice.” *See also id.* (arguing insufficient evidence facing genomic medicine can be countered by the implementation of evidence-based triaging of genomic applications for specific intended uses in practice). *See generally*, Veenstra et al., *supra* note 50.

56. Khoury et al., *supra* note 35, at 681 (“[W]hen evidence is insufficient, the use of informed or shared decision making is not new to the field of genetics [R]esearch on clinical utility has been limited or entirely lacking, but genetic counseling, using a model similar to that of informed/shared decision making has been effectively used for decades.”); *Id.* at 682 (proposal for “genomic tests [to] be classified on the basis of available direct and indirect evidence into three tiers (implement in routine practice, do not use [because of insufficient evidence], and promote informed decision making). . . . [T]ests should have at least established analytic and clinical validity even though final evidence of clinical utility may not be available.”).

57. *See* EVALUATION OF GENOMIC APPLICATIONS IN PRACTICE AND PREVENTION (EGAPP), <http://www.egappreviews.org/> (last visited June 12, 2015).

58. David L. Veenstra et al., *Improving the Efficiency and Relevance of Evidence-Based Recommendations in the Era of Whole-Genome Sequencing: An EGAPP Methods Update*, 15 GENETICS MED. 14, 14 (2013).

59. *Id.* at 21.

triaging whole genome sequencing results has been more thoroughly investigated and proposed as an effective management tool.⁶¹

2. Patient Preferences, Unique Trait Variations, and Lack of Education

Important considerations for the future success of whole genome sequencing also includes patient preferences and acknowledging their general lack of education. As statistics tend to support, “a significant percentage of the population has low health literacy and a poor understanding (or fear) of science and technology.”⁶² Secondly, uncertainty not only exists for genetic variations and incidence with diseases, illnesses, and conditions for patients generally, but is further complicated if those variations are stratified by sex, age, race, and ethnicity.⁶³ Where there is literature indicating that certain populations of a particular region of the world have an overall risk of developing a particular disease in the presence of a genetic variant, there is just as much literature indicating a protective risk for that same genetic variation given the same parameters of sex, age, race, and ethnicity.⁶⁴ Moreover, there are other studies indicating that genetic variants shown to be linked with a certain illness or disease are no more predictive than the parameters of sex, age, race, and ethnicity, among others, in the first place.⁶⁵

60. Among these implications include the following: First, frameworks and updating, which includes categorizing or triaging whole-genomic results that focus on expert-driven placement of results into individual “bins” to provide guidance for return of results. *See infra* Section IV.D. Second, evidence thresholds and value of future research, which involves the issue of relative evidence threshold for recommending return of results to a patient versus recommending clinical actions based on the result. Third, patient preferences and personal utility, the importance of which involves providing methods for assessing patient preferences with respect to the possible outcomes of genetic and genomic testing. Preferences and their variations need to reflect individuals’ attitudes. *See supra* Section II.B. Lastly, stakeholder engagement because there is an increasing level of interest in stakeholder engagement as a part of the comparative effectiveness research movement, which makes it likely that approaches developed in that field may be useful for groups developing evidence-based recommendations, particularly given the potentially conflicting objectives of guidelines that are expert informed and yet independent. *See infra* Section IV.A.

61. *See generally*, Jonathan S. Berg et al., *Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time*, 13 *GENETICS MED.* 499, 499 (2011).

62. RESOL. 422, A-05, *supra* note 3, at 1.

63. *Id.* at 6.

64. *See, e.g.*, Westbrook et al., *supra* note 6 (providing an empirical assessment of the incidentalome through a systematic review of published articles reporting this data).

65. *See* Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 *FOOD & DRUG L. J.* 475, 482 (2012) (reporting that of the many genetic variants linked to Type 2 diabetes, risk estimation of developing the disease was better predicted by that individuals’ BMI, age, and sex). The lack of determinative causality between genetic variants and development of an illness or disease has led

In the specific context of the physician-patient relationship, which is of a fiduciary nature, patients generally lack the adequate education to make fully informed medical decisions without the aid of physicians.⁶⁶ Assessment of one's own health status is dependent upon, for example, a physician "provid[ing] critical information about [one's] medical well-being" so as to "assist and direct [patients] in choosing necessary medical treatment."⁶⁷ The dependence is enhanced by the uncertainty involving whole genome sequencing information, as it is a sophisticated technology offering information that physicians are not even well-equipped to manage, interpret, and meaningfully use.⁶⁸

3. Lack of Physician Education

As has been articulated up until this point, a central issue permeating the successful implementation of whole genome sequencing into the clinical setting predominantly involves clinical utility. As a direct consequence, physicians face some of the most challenging issues as they are ill-equipped to manage, interpret, and meaningfully advise patients of their test results generated through whole genome sequencing. As some scholars have acknowledged, "almost no clinician is capable of interpreting the comprehensive results of [whole genome sequencing]."⁶⁹ Physicians are not well-versed, educated, or proficient in genetics, genomics, or the interpretation of said testing results.⁷⁰ Moreover, they have expressed concern about their lack of familiarity with genetic tests⁷¹ and, consequently, their lack of

some researchers to conclude that "currently known variants explain too little the risk of disease occurrence to be of clinically useful predictive value." Spector-Bagdady & Pike, *supra* note 2, at 688 (quoting Teri A. Manolio, *Genomewide Association Studies and Assessment of the Risk of Disease*, 363 *NEW ENG. J. MED.* 166, 173 (2010)).

66. See Thomas L. Hafemeister & Selina Spinos, *Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient*, 86 *WASH. U. L. REV.* 1167, 1186 (2009) (explaining where there is an appropriate duty to disclose to avoid or mitigate potential harm in the context of emergent medical risks).

67. *Id.*

68. "This dependence is enhanced by the anxiety that patients typically feel about their health, the vulnerability that they experience from a sickness or injury." *Id.* See generally Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to "Just Say No" if an "Informed" Patient Demands Services that Are Not Medically Indicated*, 39 *SETON HALL L. REV.* 335, 370-73 (2009).

69. Ellen Wright Clayton et al., *Managing Incidental Genomic Findings: Legal Obligations of Clinicians*, 15 *GENETICS MED.* 624, 626 (2013).

70. AMA Policy Perspective, *supra* note 9, at 4.

71. UNITED HEALTH GRP., CTR. FOR HEALTH REFORM & DIAGNOSTICS, WORKING PAPER 7, PERSONALIZED MEDICINE: TRENDS AND PROSPECTS FOR THE NEW SCIENCE OF GENETIC TESTING AND MOLECULAR DIAGNOSTICS 23-24 (2012), <http://www.unitedhealthgroup.com/~media/UHG/PDF/2012/UNH-Working-Paper-7.ashx>; see also UNITED HEALTH GRP., NEW REPORT FINDS GREATER USE OF GENETIC TESTING, BUT HALF OF PHYSICIANS CONCERNED

confidence to deal with “genetic-related issues that arise in the clinical setting,” partly because the voluminous amount of information generated through genetic testing technologies is unmanageable and uninterpretable to be clinically significant for their patients.⁷² As such, physicians have shown concern that they may be prime targets of litigation if faced with a situation involving the integration of personalized medicine in the form of genetic testing results into the clinical setting.⁷³ Adequate education may lessen this concern and minimize the litigation risk.

Reference materials on sequencing analysis might provide a step in the right direction towards educating physicians.⁷⁴ Recognizing that “there are no widely accepted genomic standards or quantitative performance metrics for confidence in variant calling when sequencing genomes,” the National Institute of Standards and Technology has begun developing reference materials intended to enable translation of whole genome sequencing to clinical applications.⁷⁵ These would be widely available for physician utilization in daily clinical practices as use of whole genome sequencing test results become more widespread and available for patients.⁷⁶

Also available for physicians is the genetic test registry (GTR) set up by the National Institutes of Health, which aims at “providing to physicians and other interested stakeholders information about every genetic test’s purpose, methodology, validity, evidence of the test’s usefulness, and laboratory contacts and credentials.”⁷⁷ The GTR represents a key initiative that facilitates

ABOUT THEIR LACK OF FAMILIARITY WITH GENETIC TESTS (Mar. 12, 2012), <http://www.unitedhealthgroup.com/Newsroom/Articles/News/UnitedHealth%20Group/2012/0312GeneticTesting.aspx>.

72. AMA Policy Perspective, *supra* note 9, at 4.

73. Barbara J. Evans, *Finding a Liability-Free Space in Which Personalized Medicine can Bloom*, 82 CLINICAL PHARMACOLOGY & THERAPEUTICS 461, 461 (2007) (“There are two schools of thought how tort liability may affect personalized medicine, *i.e.* whether fear of lawsuits will tend to accelerate progress or slow it down . . . Physicians are concerned that they will be prime targets of litigation. However, business structures for delivering personalized medical services to patients are still evolving and no dominant business model has emerged. The choice of business model(s) can affect the frequency and viability of lawsuits related to pharmacogenetics. If litigation threatens to impede progress, there are ways to structure the ‘personalized medicine business’ to reduce lawsuit risks and promote speedier translation of this promising science.”).

74. AMA Policy Perspective, *supra* note 9, at 5.

75. *Id.*

76. *Id.*

77. *Id.*; see also *Genetic Testing Registry*, OFFICE OF SCI. POLICY, NAT’L INST. OF HEALTH, <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/genetics-health-and-society/gtr> (last visited Dec. 23, 2015). The GTR is a free, centralized, online resource that provides information about the genetic tests available. NIH clinical experts and members from the National Center for Biotechnology Information Board of Scientific Counselors medical genetics working group will be consultants about the content and structure of the GTR. *Id.*

“standardization and access by practicing clinicians to information on genetic testing.”⁷⁸

Considering the aforementioned issues and barriers to clinical implementation, coupled with a sufficient background regarding whole genome sequencing's role in a vision for personalized medicine, the next step in evaluating the standard of care and how it may be transformed is by establishing a legal framework by which this discourse may take root.

III. CURRENT LEGAL FRAMEWORK FOR THE STANDARD OF CARE

Exploring whether legal precedent imposes upon physicians a duty to disclose genetic risks was extensively considered subsequent to Congress' launch of the Human Genome Project in 1989 and even before the project was completed, and its fruits realized, fourteen years later.⁷⁹ To date, a standard of care has not yet been established to account for the reality of whole genome sequencing testing. A beginning point for framing the potential new standard of care likely to emerge involves assessing the fundamental issues of negligence liability as it relates to the standard of care and, more specifically, legal precedent evaluating and holding on issues of foreseeability of imminent danger.

A. *Standard of Care and Negligence Liability*

The “standard of care” for determining a negligence action is defined as the “prevailing professional practice.”⁸⁰ It is “what a reasonable [physician]

78. AMA Policy Perspective, *supra* note 9, at 5-6 (Current Procedural Terminology (CPT) codes will now be incorporated into the GTR, which will aid in building an infrastructure supporting movement towards new genetic discoveries to clinical care and enhance reporting of genetic tests and services.); *see also*, *Genetic Testing Registry*, NAT'L CTR. FOR BIOTECH. INFO., <http://www.ncbi.nlm.nih.gov/gtr> (last visited Dec. 23, 2015). The GTR relies on voluntary submission of genetic test information by providers for the information it makes available online. The information provided includes the test's purpose, methodology, validity, evidence of the test's usefulness, and laboratory contacts and credentials. The website's homepage also provides resource information including those pertaining to molecular genetics, clinical information on genetic conditions, genetics professional listings, and consumer-friendly information about genetic variation and human health.

79. *See, e.g.*, Lori B. Andrews, *Torts and the Double Helix: Malpractice Liability for Failure to Warn of Genetic Risks*, 29 HOUS. L. REV. 149, 151-52, 169 (1992) (articulating that “[t]he sheer magnitude and diversity of genetic information that the Human Genome Project will produce,” and the “current rapid evolution of genetic diagnostic testing,” “raises questions about whether health care professionals are necessarily the most appropriate source” of disclosure predicated on a duty to warn, which is found in “cases recognizing causes of action for wrongful life and wrongful birth, finding [the] duty to warn a patient of newly-discovered risks from previously rendered services, and allowing breaches of confidentiality to protect third parties.”).

80. Amy L. McGuire et al., *Can I Be Sued For That? Liability Risk and the Disclosure of Clinically Significant Genetic Research Findings*, 24 GENOME RES. 719, 720 (2014).

would do under similar circumstances.”⁸¹ Falling below the standard of care is evidenced by a breach of duty owed by the physician to a patient.⁸² Generally, negligence may take the form of either disclosure or nondisclosure. In the context of genetic testing, an action of nondisclosure pertains to that “conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.”⁸³ By contrast, an action of disclosure “must [be done] competently” while being “consistent with standard practice” and “seek[ing] to maximize the analytic and clinical validity of findings.”⁸⁴ Premised on these two negligence bases, there is precedent concerning incidental findings for medical imaging, which might provide a foundation upon which the standard of care may begin to take shape and consequently determine a threshold for liability in the genomic context.⁸⁵

Case law suggests that clinicians may be held liable for failing to disclose incidental findings in the context of medical imaging.⁸⁶ The liability in these cases was generally premised on the assumption that the patients

“would have [been] offered an opportunity to prevent or alter the course of future disease,” if under the applicable standard of care, health care providers

“fail to identify or appreciate the significance of an [incidental finding,] or [if] they [negligently] fail to notify other clinicians and/or the patient of an identified [incidental finding].”⁸⁷

Case law further suggests that the determinative factor for liability was the potential for a result to inform medical interventions aimed at improving the health outcome of the person tested.⁸⁸ It is expected that in addition to negligence-based breach of duty claims, physicians might face the threat of other litigation claims.⁸⁹ Physicians’ options in these other litigation contexts have also been clarified and might be influential as whole genome sequencing

81. *Id.*

82. *Id.* Physicians may be found negligent if all elements are satisfied: duty, breach of duty, causation between the duty and breach of duty, injury as a consequence, and compensable damages for the injury suffered. *Id.*

83. *Id.*

84. *Id.* at 721.

85. Clayton et al., *supra* note 69, at 626-27.

86. *See, e.g.,* Lo v. Burke, 455 S.E.2d 9, 9 (Va. 1995); Davy v. Schiffer, 2008 NY Slip Op 31556(U) (Sup. Ct. June 6, 2008); Durham v. County of Maui, No. 08-00342, 2010 WL 2943358, at *13 (D. Haw. July 28, 2010); Cooper v. Ciccarella, No. 07-2434, 2009 WL 539911, at *6-7 (D. Kan. Mar. 4, 2009); Workman v. O’Bryan, 944 N.E.2d 61, 68 (Ind. App. 2011); Stallworth v. Boren 54 P.3d 923 (Haw. Ct. App. 2002); Riley v. Stone, 900 A.2d 1087 (R.I. 2006); Cifaretto v. Dalton, No. L-476-07 2011 WL 831867 (N.J. Super. Ct. App. Div. Mar. 11, 2011).

87. Clayton et al., *supra* note 69, at 624.

88. *Id.*

89. Marchant et al., *supra* note 43, at 459-61. Some of these other claims include failure to recognize genetic risk, loss of chance, informed consent, and failure to warn. *Id.*

and other personalized medicine techniques are incorporated into clinical care.⁹⁰

B. *Duty to Warn and Foreseeability of Imminent Danger*

Another legal challenge facing the integration of the results generated through whole genome sequencing technologies is that many providers are concerned they will be held liable for failure to address the results generated through such technology.⁹¹ Even though liability claims of this nature would be of first impression in courts of law or equity,⁹² providers have already been held accountable for their failure to warn third parties of their genetic risk for developing a certain illness or disease.⁹³ Before diving into these negligence cases in the Florida Supreme Court and the New Jersey Appellate Court,⁹⁴ one may consider a case determining whether an imminent danger was within the scope of a physician's standard of care. In that case, the California Supreme Court carved out an exception to the strictly-held physician-patient fiduciary relationship in the context of foreseeability. This case set the stage for the subsequent negligence cases in Florida and New Jersey. Using a provider's "duty to warn" as a context for understanding the standard of care as a consequence of the courts' rulings in these cases will provide a beginning framework by which the standard of care may take shape in the genomic context.

1. The *Tarasoff* "Imminent Danger" Rule

In the mid-1970s, the California Supreme Court weighed in on whether a psychologist employed by the University of California could be held liable for failure to warn a third-party of impending danger to that third-party's life.⁹⁵ In

90. *Id.* The case law explains physicians' options are "knowing the information and doing the counseling themselves, or referring the patient to a [more suitable specialist.]" *Id.* See *Findley-Smith v. Smith*, No. 01-07-00360, 2008 WL S25813, at *7 (Tex. App. 2008).

91. See generally Ribhi Hazin et al., *Ethical, Legal, and Social Implications of Incorporating Genomic Information into Electronic Health Records*, 15 *GENETICS MED.* 810, 814-15 (2013). This "failure to address" issue is subsumed under the "duty to warn" standard. *Id.* As Hazin et al. has articulated, the duty to warn needs to be further clarified, and will inevitably be transformed, as physicians gain access to a greater amount of information that can "forecast medical risks." *Id.* A line is distinctively drawn however, between disclosing that information related directly to the patient and that information that might relate to the patient's relatives (emphasis added). *Id.* at 815. HIPAA precludes, in most cases, those warnings given to relatives that overrule objections of the patient. *Id.*

92. See *supra* Section III.A.

93. *Safer v. Pack*, 677 A.2d 1188, 1192-93 (N.J. Super. Ct. App. Div. 1996).

94. These cases illustrate the potential ethical dubiousness of health care providers allegedly failing to meet their duties to warn of patient's children of parents with particular diseases who ended up developing the same disease as their parent.

95. *Tarasoff v. Regents of the Univ. of Cal.*, 551 P.2d 334, 339-40 (Cal. 1976) (en banc).

Tarasoff v. Regents of the University of California, the court held that the psychologist could not escape liability merely upon the fact that the third-party was outside of the privileged relationship.⁹⁶ The psychologist was under a duty to use reasonable care to protect the third-party against *imminent danger* upon learning⁹⁷ of the threat of serious danger to that third-party by the patient within the privileged relationship. Once that threat of imminent danger became present, the duty to warn arose. Considering the nature and context of the case and its particular circumstances, the psychologist may have discharged his duty by warning the third-party of the imminent threat or danger, notifying the police, or taking any reasonable steps necessary given the present circumstances.⁹⁸

In that case, Poddar, a student of the University of California, voluntarily committed himself to psychological help from the defendant's employed psychologist, where he confided in that psychologist his intent to kill Tatiana Tarasoff.⁹⁹ The psychologist notified the campus police, who detained Poddar for a brief period of time before releasing him, claiming that the psychologist's superior directed no further action to be taken given that Poddar was rational and promised not to follow-through with his intent to kill Tarasoff.¹⁰⁰ Upon returning home from studying abroad, Poddar confronted Tarasoff and killed her.¹⁰¹

Pursuant to amendments to the allegations asserted by the plaintiffs,¹⁰² the court concluded that the plaintiffs could state a cause of action against the defendant's psychologist for negligent failure to protect Tarasoff.¹⁰³ The plaintiffs' amendment asserted that their daughter's death "proximately resulted from [the psychologist's] negligent failure to warn" their daughter.¹⁰⁴ In response, the psychologist contended that given the nature and circumstances of the case at hand, he did not owe a duty of care to Tarasoff or her parents and that, "in the absence of such duty, [he was] free to act in careless disregard of [Tarasoff's] life and safety."¹⁰⁵ The court disagreed with this contention.

96. *Id.* at 340.

97. *Id.* (stating that this would need to be based upon the psychologist's professional determination or in accordance with the standards of his profession).

98. *Id.*

99. Daughter of the plaintiff's asserting allegations against the defendant university. *Id.* at 339.

100. *Tarasoff*, 551 P.2d at 339-40.

101. *Id.* at 341.

102. *Id.* at 339-40 (Tarasoff's parents).

103. *Id.* at 342.

104. *Id.*

105. *Tarasoff*, 551 P.2d at 342.

Recognizing *context* as a salient factor in analyzing and making a determination upon the issue, the court set forth a framework of rules and public policy upon which it rendered its decision. First, the court acknowledged that “legal duties are not discoverable facts of nature, but merely conclusory expressions that, in cases of a particular type, liability should be imposed for damage done.”¹⁰⁶ Making an assertion that one does not have liability because one does not have a duty to act in a certain way in the first place begs the question: “whether the plaintiff’s interests are entitled to legal protection against the defendant’s conduct.”¹⁰⁷ The duty formed upon this consideration was premised on considerations of public policy. Articulating the justifications of particular duty standards by courts in preceding cases, the court here recognized the imposition of liability “for [an] injury occasioned to another by his want of ordinary care or skill” when the circumstances have “placed [that person] in such a position with regard to [the other].”¹⁰⁸ The absence of exercising ordinary care and skill in one’s conduct gave rise to the duty to avoid danger that might be caused as a consequence.¹⁰⁹

However, the court diverted on the balancing test set forth in *Merrill v. Buck*.¹¹⁰ Instead, the court firmly asserted that the most important factor to be considered is that of *foreseeability*, which relates to owing a fiduciary duty to those who are foreseeably endangered by one’s conduct, “with respect to all risks which make the conduct unreasonably dangerous.”¹¹¹ However, the court distinguished this generally accepted principle from that which relates to special relationships, such as a relationship that a patient shares with his or her psychologist. The factor distinguished was that liability would only be imposed if the defendant did not control the conduct of another person, or warn of such conduct. The existence of the type of relationship unique to these circumstances did not necessitate the court to determine “whether foreseeability alone is sufficient to create a duty to exercise reasonable care to protect a potential victim of another’s conduct.”¹¹² Courts have carved out an exception premised upon the rule where there are special relationships either to “the person whose conduct needs to be controlled” or “the foreseeable victim of that conduct.”¹¹³

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

110. *Merrill v. Buck*, 375 P.2d 304, 310 (Cal. 1962).

111. *Tarasoff*, 551 P.2d at 342.

112. *Id.* at 343.

113. *Id.*

Upon this exception, the court reasoned that there existed a special relationship that necessitated a duty of care by the psychologist.¹¹⁴ This type of relationship was “sufficient to support the duty to exercise reasonable care to protect others against dangers emanating from [circumstances related to] the patient’s illness.”¹¹⁵ However, the court did recognize important complexities related to making judgments that fall within the “reasonable care” standard in the first place, namely “forecast[ing] whether a patient presents a serious danger of violence.”¹¹⁶ The *reasonableness* of a psychologist’s actions are based upon standards of treatment and practices of that particular specialty, and practitioners are given the freedom to exercise their best judgment without liability.¹¹⁷ Once a determination has been made (or should have been made) under the applicable professional standards that a danger exists to a third-party, then that practitioner “bears a duty to exercise reasonable care to protect the foreseeable victim of that danger.”¹¹⁸ Social policy, not professional expertise, is the guidance for resolving the conflict between a patient’s interests¹¹⁹ and a potential victim.¹²⁰ Therefore, the court held that “public policy favoring protection of the confidential character of patient-psychotherapist communications must yield to the extent to which disclosure is essential to avert danger to others. The protective privilege ends where the public peril begins.”¹²¹

The holding in *Tarasoff* provides a foundation upon which the issue of foreseeability may be discussed in the context of genomic testing generally. Specifically, this context begs the question, as has been posed before: “[A]re genetic risks sufficiently similar to [the] existing exceptions to the requirement

114. *See id.* at 345 (stating that this relationship was similar in nature to that of a physician-patient relationship).

115. *Id.* at 344.

116. *Tarasoff*, 551 P.2d at 345 (acknowledging that psychologists “need only exercise ‘that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of [that professional specialty] under similar circumstances.’”).

117. *Id.*

118. *Id.* However, the decision rendered by each psychologist (or therapist) will be different for each case because of the particular circumstances. *Id.* Thus, the adequacy of that decision will be measured against the traditional negligence standard of the rendition of reasonable care under the circumstances. *Id.*

119. *Id.* at 347. The patient’s interests include having information remain confident in the special relationship. *Id.* This is in accordance with the Principles of Medical Ethics of the American Medical Association (1957): “A physician may not reveal the confidence entrusted to him in the course of medical attendance . . . unless he is required to do so by law or unless it becomes necessary in order to protect the welfare of the individual or of the community.” *Id.*

120. *Id.* The potential victim is one who might be the subject of the patient’s dangerous conduct. *Id.* This is in accordance with the Principles of Medical Ethics of the American Medical Association (1957). *Id.*

121. *Tarasoff*, 551 P.2d at 347.

of confidentiality that they warrant an exception as well?"¹²² The resounding opinion from advisory boards has been "no,"¹²³ but given that these professional opinions only have persuasive authority, one may now turn to two negligence cases determining the issue of failure to warn of genetic risks, which still hold the force of law today.

2. *Pate v. Threlkel*

Relying on the establishment of a foreseeable risk of harm, the Florida Supreme Court in *Pate v. Threlkel* held that a physician's duty to warn was satisfied by informing the patient that her children may have an increased risk of developing a particular illness or disease, but then the patient had a responsibility to warn her children of their potential risk.¹²⁴ In that case, the issue before the Florida Supreme Court was whether a physician owed a duty of care to the children of a patient to warn the patient of the genetically transferable nature of the condition for which the physician is treating the patient.¹²⁵ The plaintiff's¹²⁶ case was comprised of four medical malpractice allegations,¹²⁷ the bases of which rested upon the physician's negligence being a direct and proximate cause of the plaintiff's suffering from advanced medullary thyroid carcinoma.¹²⁸

122. Ellen Wright Clayton, *Ethical, Legal, and Social Implications of Genomic Medicine*, 349 *NEW ENG. J. MED.* 562, 567 (2003).

123. See COMM. ON ASSESSING GENETIC RISKS, *ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY* 22 (Lori B. Andrews et al. eds., 1994); see also B. M. Knoppers et al., *Professional Disclosure of Familial Genetic Information*, 62 *AM. J. HUM. GENETICS* 474, 474 (1998); PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. & BEHAVIORAL RESEARCH, *SCREENING AND COUNSELING FOR GENETIC CONDITIONS: A REPORT ON THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS* 42-45 (1983).

124. *Pate v. Threlkel*, 661 So. 2d 278, 279 (Fla. 1995).

125. *Id.*

126. *Id.* (daughter of physicians' patient who had medullary thyroid carcinoma).

127. *Id.* The four allegations were: (1) the "physicians knew or should have known of the likelihood that [the patient's] children would have inherited the condition genetically;" (2) "the physicians were under a duty to warn [the patient] that her children should be tested for the disease;" (3) "had [the patient] been warned [when the patient was diagnosed and received treatment in 1987 for her medullary thyroid carcinoma], she would have had her children tested at that time;" and (4) "if [the plaintiff] had been tested [at the time her mother had been diagnosed and treated], she would have taken preventative action, and her condition, more likely than not, would have been curable." *Id.*

128. *Id.* The court acknowledged that medullary thyroid carcinoma was a "genetically transferable disease," but the record was devoid of evidence indicating that the parent received a genetic test to confirm. *Id.* Likewise, the patient's daughter argued that had she known of the likelihood of her mother's genetically transferable disease—that of medullary thyroid carcinoma—then she would have sought genetic testing for the disease and could have taken preventive measures in order to potentially cure her of the disease. *Id.*

Finding for the physicians at the district court and appellate levels, the Florida Supreme Court reviewed the physician's argument that the plaintiff had not established a fiduciary physician-patient relationship.¹²⁹ The focus of the court's reasoning was whether there was a duty in the first place.¹³⁰ As provided in *McCain v. Florida Power Corp.*, Florida recognizes that "a legal duty will arise whenever a human endeavor creates a generalized and foreseeable risk of harming others."¹³¹ Finding that the focus on duty was relevant to the case at hand, the Florida Supreme Court narrowed the scope of its reasoning by applying the relevant Florida statute pertaining to the duty owed by health care providers in a medical malpractice case.¹³² The court applied the standard to the case at hand and concluded that "a duty exists if the statutory standard of care requires a reasonably prudent health care provider to warn a patient of the genetically transferable nature of the condition for which the physician was treating the patient."¹³³ Assuming that the plaintiff's factual allegation in the complaint was true and basing its decision upon the fact that the trial court granted a motion for summary judgment in favor of the physicians, the court accepted them, but ordered for them to be determined by the pertinent Florida statute.¹³⁴

The next sub-issue explored by the court involved determining "to whom does the alleged duty to warn [the plaintiff] of the nature of her disease run."¹³⁵ Privity was of significance here given that the duty was predicated upon the patient who was in privity with the physician. However, the rights of third parties had been recognized in the judicial system.¹³⁶ Thus, the fact that the plaintiff was not part of the physician-patient relationship did not foreclose liability for the physician treating the plaintiff's mother if a duty of care was otherwise established.¹³⁷ The court reasoned that the "analysis recognizing that privity is not always needed to establish liability should apply to the professional relationship between a patient's child and a health care provider."¹³⁸

Consequently, the court concluded that "when the prevailing standard of care creates a duty that is obviously for the benefit of certain identified third parties and the physician knows of the existence of those third parties, then the

129. *Pate*, 661 So. 2d at 279-80.

130. *Id.* at 280.

131. *Id.* (quoting *McCain v. Fla. Power Corp.*, 593 So. 2d 500, 503 (Fla. 1992)).

132. *Id.* (citing FLA. STAT. § 766.102 (1989)).

133. *Id.*

134. *Pate*, 661 So. 2d at 281.

135. *Id.*

136. *Id.* (listing cases recognizing third-party rights).

137. *Id.* at 281-82 (citing *Pensacola Exec. House Condo. Ass'n v. Baskerville-Donovan Eng'rs, Inc.*, 566 So. 2d 850, 852-53 (Fla. Dist. Ct. App. 1990)).

138. *Id.* at 282.

physician's duty runs to those third parties."¹³⁹ Extending this conclusion, the Florida Supreme Court further concluded that because the physician was "prohibited from disclosing the patient's medical condition to others except with the patient's permission," then the duty that the health care provider owed to the patient is satisfied when the physician warns the patient.¹⁴⁰ Because there was evidence and case law to support a potential recovery for the plaintiff on the medical malpractice claim, the Florida Supreme Court ultimately concluded that the trial court erred in its dismissal and granting of summary judgment, and remanded the case for further proceedings.¹⁴¹

3. *Safer v. Estate of Pack*

In contrast to *Pate v. Threlkel*, the New Jersey Appellate Court in *Safer v. Estate of Pack* held that a physician's duty to warn extended beyond informing the patient of her genetic risk of developing a particular illness or disease, including the patient's children. In that case, the issues before the New Jersey Appellate Court were: whether a physician had a duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition; whether a physician's duty extended to members of the immediate family of a patient who may be adversely affected by a breach of duty; and whether a physician had breached the duty owed.¹⁴² The plaintiff, who was not a patient of the defendant physician, alleged that the physician should have warned her about her fifty percent risk of having multiple polyposis, which led to metastatic colon cancer.¹⁴³ The plaintiff premised her allegation upon the contention that multiple polyposis was a hereditary condition, that this hereditary nature was known by the physician, and that the physician, having this knowledge, was required by prevailing medical standards to "warn those at risk so that they might have the benefits of early examination, monitoring, detection, and treatment, that would provide opportunity to avoid the most baneful consequences of the condition."¹⁴⁴

The New Jersey Appellate Court challenged the trial court's judgment that the physician had "no legal duty to warn a child of a patient of a genetic risk."¹⁴⁵ The trial court's rationale was premised upon the legal standard that "in order for a [physician] to have a duty to warn, there must be a patient/physician relationship or circumstances requiring the protection of the

139. *Pate*, 661 So. 2d at 282.

140. *Id.*

141. *Id.*

142. *Safer v. Pack*, 677 A.2d 1188, 1189 (N.J. Super. Ct. App. Div. 1996).

143. *Id.* at 1190 (the same cancer the plaintiff developed over twenty-five years after her father died of it).

144. *Id.*

145. *Id.*

public health or the community at large.”¹⁴⁶ *Pate v. Threlkel* was the guiding case for the trial court’s decision, which subsequently affected the appellate court’s acceptance of the asserted factual allegations.¹⁴⁷ The prevailing medical standard included in these allegations was defined as that “standard of care, knowledge, and skill . . . ‘which is ordinarily possessed and exercised in similar situations by the average member of the profession practicing in the field.’”¹⁴⁸ While determining whether the physician’s actions comported with the prevailing medical standard was a matter for the factfinder, determining whether there was a legal duty to act in a certain way was a matter of law.

Likening a genetically transmissible condition to infections, contagions, or threats of physical harm, the court recognized that potential future harm “may be averted or minimized by a timely and effective warning.”¹⁴⁹ Consequently, the court disagreed with the trial court’s ruling that the physician “breached no duty because avoidable harm to [the plaintiff] was not foreseeable.”¹⁵⁰ Relying upon precedent, the court contended that the duty was to be “seen as owed not only to the patient himself but that it also ‘extend[ed] beyond the interests of a patient to members of the immediate family of the patient who may be adversely affected by a breach of that duty.’”¹⁵¹

Thus, the court decided to distinguish itself from the ruling in *Pate v. Threlkel*, holding that “the duty to warn” is not always “satisfied by [simply] informing the patient.”¹⁵² Rather, certain circumstances might necessitate the “physician’s broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease.”¹⁵³ However, similar to the *Pate v. Threlkel* court, the court here decided to remand the case for further proceedings given that there were serious and conflicting medical, social, and legal policies being implicated in the case.¹⁵⁴

146. *Id.*

147. *Safer*, 677 A.2d at 1191 (including the plaintiff’s assertion that the prevailing medical standard “required the physician to warn of the known genetic threat”).

148. *Id.* (quoting *Schueler v. Strelinger*, 204 A.2d 577, 584 (N.J. 1964)).

149. *Id.* at 1192.

150. *Id.* (namely, that the physician’s conduct did not create a “foreseeable zone of risk”).

151. *Id.* (quoting *Schroeder v. Perkel*, 432 A.2d 834, 838 (N.J. 1981)).

152. *Safer*, 677 A.2d at 1192.

153. *Id.* at 1192-93.

154. *Id.* at 1193; see also Sonia M. Suter, *Whose Genes Are These Anyway?: Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1870-72 (1993) (identifying some of these implications); Janet A. Kobrin, *Confidentiality of Genetic Information*, 30 UCLA L. REV. 1283, 1305-06 (1983).

4. Implications for Framing the Standard of Care in the Genomics Context

The aforementioned cases had tremendous implications for the fiduciary role of physicians given that privacy and confidentiality are both fundamental to any physician-patient relationship and now protected by the Health Insurance Portability and Accountability Act (HIPAA).¹⁵⁵ The *Pate* and *Safer* cases in particular are guiding for an analysis as to how they contextualize a new standard of care for physicians with the advent of whole genome sequencing. In those cases, even though the children were not under the direct care of the physician, the courts ruled that a standard of care still applied because of the delicate issue pertaining to genetic information, namely that of foreseeability, as previously established in *Tarasoff*.¹⁵⁶ When the physicians' actions did not conform to the expectations of a standard of care,¹⁵⁷ the courts ruled that the duty to care was breached. This breach of duty was further supported by the fact that the plaintiffs in both cases developed the same illness or disease¹⁵⁸ that their parent had previously developed. Thus, the breach of duty had caused an injury that could have been avoided if the plaintiffs had taken preventive measures.

Pate and *Safer* have been criticized for their legal reasoning and deviation from ethical guidelines.¹⁵⁹ However, they have not yet been overturned and, by common law rule, they may prove persuasive in other states and circuits. Had HIPAA been enacted prior to the courts' rulings, the courts might have held differently. There might not have been a duty owed, and, thus, no breach. Likewise, even though the children suffered *injury* (in the form of suffering from the same illness as their parent) in each of the cases, it might not have been the result of a breach of duty. Medical negligence might not have been the proximate cause of the plaintiffs' injuries of developing the same illness or disease as their parents. Courts ought to use caution when analyzing and applying the reasoning in these cases as they may adversely affect physicians

155. Anne-Marie Laberge & Wylie Burke, *Duty to Warn At-Risk Family Members of Genetic Disease*, 11 AM. MED. ASS'N J. ETHICS 656, 658 (2009). *Tarasoff* was decided in 1976, while *Pate* was decided in 1995, *Safer* was decided in July 1996, and HIPAA was enacted in August 1996. HIPAA allows exceptions to the strict nondisclosure policy in the case of serious and imminent threat to the public or to an identifiable third party when the physician has the capacity to avert the harm. *Id.* However, it is unclear for now whether the threat of cancer associated with hereditary cancer predispositions would fall under this exception. *Id.*

156. *Id.* at 657-58.

157. *Id.* (discussing the failure to warn the patient's children of their foreseeable potential genetic risk.).

158. See *Pate v. Threlkel*, 661 So. 2d 278, 279 (Fla. 1995); *Safer v. Estate of Pack*, 677 A.2d 1188, 1189-1190 (N.J. Super. Ct. App. Div. 1996).

159. Clayton, *supra* note 122, at 567.

in future negligence cases involving a not-yet-defined standard of care as it pertains to whole genome sequencing.

Nevertheless, in the wake of these cases, the issue of disclosure has been taken up by many professional organizations, including the American Society of Human Genetics¹⁶⁰ (ASHG) and the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research,¹⁶¹ which advocate for methodologies allowing disclosure, while others argue disclosure is not warranted to the extent offered by the aforementioned organizations.¹⁶² The articulated cases and consequent responses at the organizational level pertaining to the issues of disclosure, seriousness, foreseeability, probability of harm, and an identifiable medically-accepted standard of care might provide a framework by which a new threshold for a "duty to warn" is created. In order to understand how this novel framework might be structured, one may look to the roles of genetic counselors as an analogy when educating and informing potential parents of their future child's genetic abnormality or mutation.

160. Kristin E. Schleiter, *A Physician's Duty to Warn Third Parties of Hereditary Risk*, 11 AM. MED. ASS'N J. ETHICS 697, 699 (2009) (quoting ASHG's Policy Statement advocating "a two [prong] approach to disclosure that respects confidentiality of genetic information while acknowledging that the information is both individual and familial in nature."). The first prong requires physicians, acting under a standard duty of care, informing patients prior to and following testing about the familial implications of genetic testing. *Id.* This prong preserves the duty of confidentiality. The second prong is triggered once the physician has satisfied the first requirement of warning the patient. The physician may now use discretion in notifying at-risk family members of the patient when four factors are present: "[1] Attempts to encourage disclosure on the part of the patient have failed. [2] The harm is highly likely to occur and is serious and foreseeable. [3] The at-risk relative is identifiable. [4] The disease is preventable, treatable, or medically accepted standards indicate that early monitoring will reduce the genetic risk." *Id.*; see also Mary L. Kovalesky, *To Disclose or Not to Disclose: Determining the Scope and Exercise of a Physician's Duty to Warn Third Parties of Genetically Transmittable Conditions*, 76 U. CIN. L. REV. 1019, 1034 (2008).

161. Schleiter, *supra* note 160, at 699 ("Disclosure without the patient's consent is justified only if: (1) Reasonable efforts to elicit voluntary consent to disclosure have failed; (2) There is a high probability both that harm will occur if the information is withheld and that the disclosed information will actually be used to avert harm; (3) The harm that the identifiable individuals would suffer would be serious; and (4) Appropriate precautions are taken to ensure that only the genetic information needed for diagnosis or treatment of the disease in question is disclosed."); see also AM. MED. ASS'N, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, REPORT 9: A-03, DISCLOSURE OF FAMILIAL RISK IN GENETIC TESTING (2007) [hereinafter REPORT 9: A-03].

162. Schleiter, *supra* note 160, at 699. For example, The AMA Council on Ethical and Judicial Affairs' "Code of Medical Ethics" and the American Society of Clinical Oncology's "Policy Statement on Genetic Testing for Cancer Susceptibility." See REPORT 9: A-03, *supra* note 161. These organizations hold that a physician should address the issue of communicating genetic test results to family members, and is not required to reach out to at-risk family members. *Id.*

IV. FINDING GUIDANCE IN BEST PRACTICE STANDARDS

The aforementioned legal precedent provides an initial framework by which the potential standard of care may take shape. In addition to setting this legal stage, consideration must be lent for those stakeholders likely to be (or that already have been) involved or directly affected by whole genome sequencing. Within the set of evident stakeholders, one may find best practice standards that may be guiding for physicians who will be directly impacted. Genetic counselors, in particular, are a sufficient source for framing the discussion about how physicians may become educated about whole genome sequencing and, consequently, potentially held liable for a standard of care that will inevitably transform as whole genome sequencing takes root in the clinical setting.

A. *Frontline of Stakeholders*

Finding, as detailed above, that patients themselves lack the “expertise required to convert genetic data” into meaningful medical information,¹⁶³ some have posited that there are a considerable number of potential health care professionals who can be in a position to manage, return, and interpret the genetic data. Among these are “molecular and computational biologists, geneticists, pathologists and physicians with exquisite knowledge of the disease and of treatment modalities, research nurses, genetic counselors, and information technology and systems support specialists.”¹⁶⁴

One of the stakeholders identified is already leading the way in interpreting whole genome sequencing testing results. The College of American Pathologists has “launched a concerted effort to position pathologists as an essential leader of the medical team versed in genetic and genomic testing.”¹⁶⁵ Available are online education resources for enhancing their skills and knowledge in “the revolutionary diagnostic and treatment competency area” that is genomic medicine.¹⁶⁶ However, work still needs to be done at the forefront of interpreting and managing the information in the first place. The current need for management and interpretation has not yet been matched as

163. Spector-Bagdady & Pike, *supra* note 2, at 730 (explaining that this conversion involves the diagnosis, curing, mitigation, treatment, or prevention of a disease “in and of itself”).

164. *Id.* (quoting Elaine R. Mardis, *The \$1,000 Genome, the \$100,000 Analysis?*, 2 GENOME MED. 84, 84 (2010)).

165. AMA Policy Perspective, *supra* note 9, at 4.

166. *Genomics and Molecular Medicine Education & Resources*, C. AM. PATHOLOGISTS, http://www.cap.org/web/home/resources/genomics-molecular-medicine-education-resources/genomics-molecular-medicine-tools-resources?_adf.ctrl-state=c54pr7twi_4&_afLoop=281811077566085#%40%3F_afLoop%3D281811077566085%26_adf.ctrl-state%3Db5pthehy4_4 (last visited June 25, 2015) (discussing online courses available include those related to genomics, pharmacogenomics, molecular medicine, next generation sequencing, and genetic/genomics competency).

the information and the testing technologies generating this information have outpaced providers' and pathologists' ability to manage and interpret the data in clinically meaningful ways.¹⁶⁷ Pathologists might be a resource for information about genetic and genomic testing technologies, but the physician will still be at the forefront for the medical care and treatment a patient receives. Physicians are the source of accountability and reliability for patients as patients make medical decisions in their lives.

While pathologists might be in a position to educate themselves about the interpretation of data, the communication and established-relationship with patients is absent. The same can be said of the other stakeholders identified above,¹⁶⁸ with the exception of physicians and genetic counselors. Given that a physician's role has radically changed with the advent of whole genome sequencing technologies, one may observe how physicians may not yet be adequately prepared in their clinical practices to address patient concerns pertaining to the genetic results they receive. Best practice standards might be found in genetic counseling, as genetic counselors have experience and are directly educated for the purposes of managing, interpreting, communicating, and advising patients on their options.

B. Best Practice Standards in Genetic Counseling

Newborn and prenatal screening have already benefitted from the fruits of and advancements in genetic testing technologies,¹⁶⁹ and have become commonplace in the health care setting.¹⁷⁰ The standards by which these genetic tests are carried out and subsequently interpreted and communicated to parents of potential children may provide a framework upon which other genetic test results may be used in a clinically meaningful way, such as infectious and rare diseases. Already, the path has been paved for better

167. *But see* Euan A. Ashley et al., *Clinical Assessment Incorporating a Personal Genome*, 375 LANCET 1525, 1525 (2010); *see also id.* at 1533 (“[It] provides an approach to comprehensive analysis of a human genome in a defined clinical context . . . results of the study provide proof of principle that clinically meaningful information can be derived about disease risk and response to drugs in patients with whole genome sequence data.”)

168. Spector-Bagdady & Pike, *supra* note 2, at 728; *see also id.* at 744 n.435 (“[S]ome scholars . . . have called for researchers to provide research participants access to their raw genetic data to, among other things, give participants the option of their independent analysis.”); Jeantine E. Lunshof et al., *Raw Personal Data: Providing Access*, 343 SCIENCE 373, 374 (2014) (evaluating returning results in different contexts).

169. AMA Policy Perspective, *supra* note 9, at 2.

170. *Id.*; *see also* AM. MED. ASS'N, RE: 21ST CENTURY CURES: EXAMINING THE REGULATION OF LABORATORY-DEVELOPED TESTS 3 (2014), <http://docs.house.gov/meetings/if/if14/20140909/102625/hhr-113-if14-20140909-sd005.pdf> (discussing how “[Laboratory-Developed Tests] providing genetic and next-generation testing and screening have already become common in certain medical specialties. For [example], newborn screening is universal, and carrier, pre-implantation and prenatal testing is commonplace.”).

treatment options and thus better outcomes for patients with Huntington's disease, which is the disease proven to have a 100% accurate genotype-phenotype relationship.¹⁷¹

Hospitals are allocating resources to oncology departments to establish stable infrastructures that will support "widespread adoption of genomic-based testing and treatment" with the hopes of "propel[ing] adoption of personalized medicine as a standard of care in diagnosis, risk assessment and treatment."¹⁷² For example, Vanderbilt University Medical Center clinicians are engaged as part of a core development team with geneticists, informaticists, electronic health record (EHR) experts, pharmacists, pharmacologists, clinical pathologists, and program managers in the Pharmacogenomic Resource for Enhanced Decisions in Care and Treatment (PREDICT) project.¹⁷³ Vanderbilt University is one of a few academic medical centers currently engaged in implementing clinical decision support tools for the practical application and facilitation of genomic information in patient care.¹⁷⁴ As others have argued, these institutions "must play a central role in unleashing the potential of [personalized health care]."¹⁷⁵

In the specific case of breast cancer, it has become well-known that the genotype-phenotype association between this disease and mutations in BRCA¹⁷⁶ is almost as strong as that association for Huntington's disease and

171. See Walker, *supra* note 31, at 225.

172. AMA Policy Perspective, *supra* note 9, at 2.

173. Jill M. Pulley et al., *Operational Implementation of Prospective Genotyping for Personalized Medicine: The Design of the Vanderbilt PREDICT Project*, 92 CLINICAL PHARMACOLOGY THERAPEUTICS 87, 88 (2012).

174. See Andrea Hartzler et al., *Stakeholder Engagement: A Key Component of Integrating Genomic Information into Electronic Health Records*, 15 GENETICS MED. 792, 794-96 (2013), for a discussion on others like Northwestern University, the Mayo Clinic, Marshfield Clinic, and the University of Washington.

175. Geoffrey S. Ginsburg et al., *Academic Medical Centers: Ripe for Rapid-Learning Personalized Health Care*, 3 SCI. TRANSLATIONAL MED., Sept. 21, 2011, at 1. The potential for personalized health care, which relies upon personalized medicine, can be unleashed by academic medical centers because they "act[] as a nexus for discovery, development, and dissemination of tools and clinical health care-delivery models," that can overcome the uncoordinated research environment and disjointed translational-research infrastructure that hinders personalized health care from reaching its expected and meaningful potential. *Id.* Given the resources available and state-of-the-art, robust technological equipment capabilities, academic medical centers may provide opportunities for "train[ing] [the] next generation of MDs in genomics and [personalized health care]" so as to promote literacy in the area and reform medical education to account for the growing body of knowledge in personalized medicine and health care. *Id.* at 1-2.

176. See *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NAT'L CANCER INST. NAT'L INST. HEALTH, (Apr. 1, 2015), <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> [hereinafter NAT'L CANCER INST.].

an HTT genetic mutation.¹⁷⁷ For some, BRCA has become the “gold standard.”¹⁷⁸ Information about the genetic link between a patient having the BRCA1 and BRCA2 variants is strong enough to influence patients with a variant of BRCA to take preventive measures, such as a mastectomy.¹⁷⁹ Genetic testing for these variants are performed on women (and men) if there is a family history of having the variant or a family history of having breast cancer, or some combination thereof.¹⁸⁰ In those cases where the variants are not able to be confirmed in a family member with breast cancer, then physicians are encouraged to suggest that that patient receive genetic counseling and offered the option for genetic testing for the variant.¹⁸¹

Because breast cancer has a tremendous physical and emotional impact on those diagnosed with the disease, a model for genetic counseling has been developed that informs women at risk.¹⁸² This two-level model consists of a threshold evaluation level of the risks associated with BRCA variants and breast cancer, and the genetic counseling level.¹⁸³ The threshold level is one of evaluation by the physicians, who use specific tools to assess the likelihood of a woman developing breast cancer considering the family history.¹⁸⁴ This criteria is premised upon the sensitivity of breast cancer and genetic susceptibility, and the fact that having one of the two BRCA variants is extremely rare in the greater population. Family history, coupled with the genotype-phenotype association provides a strong, sufficient-enough framework upon which physicians may begin to communicate to their patients about the risks of breast cancer and what can be done on a preventive basis.¹⁸⁵ This initiates the genetic counseling level provided from physicians.

177. Agatha M. Gallo et al., *Disclosure of Genetic Information Within Families: How Nurses Can Facilitate Family Communication*, 109 AM. J. NURSING 65, 65-69 (2009).

178. AM. SOC’Y OF CLINICAL ONCOLOGY, <http://am.asco.org/multiplex-genetic-testing-inherited-cancer-future-now>.

179. *Id.*; see also Gary N. McAbee et al., *Physician’s Duty to Warn Third Parties about the Risk of Genetic Diseases*, 102 PEDIATRICS 140, 141 (1998) (“Advances in genetics that permit some individuals to identify their risk for various types of cancer also permit these same individuals to take prophylactic precautions” (e.g., total bilateral mastectomies or oophorectomies in the cases of individuals who are carriers of BRCA1 and BRCA2 genes who are at risk for breast and ovarian cancer)).

180. NAT’L CANCER INST., *supra* note 176.

181. *See id.*

182. *Id.*

183. *Id.*

184. *See id.* These include: breast cancer diagnosed before age 50; cancer in both breasts; both breast and ovarian cancers; multiple breast cancers; two or more primary of BRCA1- or BRCA2-related cancers in a single family member; cases of male breast cancer; and Ashkenazi Jewish ethnicity. *Id.*

185. NAT’L CANCER INST., *supra* note 176.

The genetic counseling women receive includes, in addition to a heredity cancer risk assessment based upon an individual's personal and medical history, information addressing a multitude of factors.¹⁸⁶ The factors have been developed over time and with a greater scientific and medical understanding of the genotype-phenotype relationship with BRCA variants and breast cancer. These developments and growth in understanding have provided for a more sufficient foundation upon which genetic counseling can provide an important avenue for utilizing the genetic information in a clinically meaningful way. This is indicative of and supports the validity and utility of the threshold level of the physician evaluation. Not only does this avoid potential negative consequences in patients who need not become anxious or fearful of developing breast cancer when there is not family history to suggest a susceptibility, but also enables physicians to focus on those who have a greater susceptibility and utilize well the time with those patients informing them of the aforementioned information.

C. How the Standard of Care May Take Shape Through Physician Education

While much literature has been written on the framework by which genomic findings may be translated and returned to participants in the research context, there is a gap pertaining to the same issue in the clinical context. As such, there is an overwhelming lack of preparation for the influx of genetic information among physicians.¹⁸⁷ As has been argued, integrating whole genome sequencing technologies into patient care before "having [] the knowledge base and clinical infrastructure required to support clinical genomic testing" might be premature.¹⁸⁸ If whole genome sequencing is to be fully integrated into patient care and interpreted to the patient's benefit, then prioritization of results through effective communication with the patient and counseling of the patient once results are obtained are essential.¹⁸⁹

186. *Id.* These factors include: "The appropriateness of genetic testing[;] The medical implications of a positive or a negative result;" the potential for ambiguity in the genetic test result; "The possibility that a test result might not be informative[;] The psychological risks and benefits of genetic test results[;] The risk of passing a mutation to children[;] . . . the technical accuracy of the [specific genetic] test(s)" to be performed; and, the options available if the genetic test returns a positive result. *Id.*

187. Marchant & Lindor, *supra* note 1, at 922.

188. Sharp, *supra* note 10, at 191.

189. *Id.* at 192. The author identifies three issue areas that a clinician can, and should, play a key role in resolving. The first involves informed consent: "If [whole genome sequencing (WGS)] is to be integrated successfully into patient care, it is essential to establish that pretest counseling can place patients in a position to make informed choices about genomic risk assessment. Studies that evaluate pretest counseling for multiplexed forms of genetic testing are a critical first step in establishing that it is possible to obtain genuinely informed consent to clinical genomic testing." *Id.* The second involves disclosing results to the patient and preparing for lifelong follow-up in the physician-patient relationship: "the volume of data produced through

Additionally, having sufficient numbers of physicians with specialty training or education in genetics will be necessary if the benefits of the technology are to be fully realized.¹⁹⁰

Despite a discrepancy in the model framework by which physicians may interpret and implement genetic findings into the clinical setting in a meaningful way for their patients, physicians, like researchers and commercial providers, have already been suggested to “routinely make [their patients] aware of the potential for [incidental findings].”¹⁹¹ Putting their patients on notice about this potential presupposes that clinical validity and utility has been established. Once established, in any genomic context, physicians may begin to adapt their practices to a reformed standard of care. The voluminous amount of genomic information and the potential clinical utility of that information will force physicians to seek education and transform their roles from providing not only diagnostic and allopathic medicine, but also counseling. This reformed standard of care may begin to take shape via “clear, credible, evidence-based, and up-to-date clinical guidelines specifying when and where genetic testing can be useful.”¹⁹² These recommendations may be necessary to help guide a

WGS will greatly exceed an individual clinician’s capacity to present all relevant clinical findings that are discovered,” and “clinical judgments will have to be made about the specific results to prioritize in presenting diagnostic results from WGS.” *Id.* Disclosure of results might take the form of future use of utilizing test results previously ascertained but not readily interpretable that are now (in the future) interpretable with greater clinical utility, and “[a]s larger volumes of personal genetic information are produced, it will be important to examine the criteria that patients and clinicians use to assess the value of results from genomic testing.” *Id.* at 192-93. Lastly, bundling of genetic tests may prove to be helpful, as WGS will require “significant departures” from existing standards of care in clinical genetics, it is critical that this new form of testing be introduced with care. Sharp, *supra* note 10, at 192. Although counterintuitive, the author suggests that “the most direct path toward genomic medicine involves being more strategic in developing smaller scale forms of multiplexed genetic testing that offer real-world settings in which to study ethical and practical challenges that will be associated with the use of WGS in patient care.” *Id.* at 193. Until ethical issues (e.g., informed consent and responsible management of genetic information amounts) are addressed, physicians should be hesitant to use WGS for genetic risk assessment. *Id.*

190. Marchant & Lindor, *supra* note 1, at 922. Genetic counselors are also a viable option for taking on this role despite the clinical encounter being different than that of a physician. Currently, the number of genetic counselors and physicians with specialty training in genetics is already inadequate (approximately 3,000 nationwide for each category). *Id.* “[P]roviders will be increasingly confronted with genetic data or opportunities for useful genetic testing but, lacking adequate genetics education and unable to access genetic specialists, may commit the types of diagnostic errors that could lead to liability.” *Id.*

191. Shkedi-Rafid et al., *supra* note 40, at 715; see also PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, ANTICIPATE AND COMMUNICATE: ETHICAL MANAGEMENT OF INCIDENTAL AND SECONDARY FINDINGS IN THE CLINICAL, RESEARCH, AND DIRECT-TO-CONSUMER CONTEXTS (2013), http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf.

192. Marchant & Lindor, *supra* note 1, at 922.

physician's clinical judgment and avoid, or at least provide a "partial shield against," malpractice liability.¹⁹³ As some have held, "understanding where genetic testing might arguably be applicable to individual patients and carefully documenting decisions and the associated rationales for recommending or not recommending genetic testing for each patient" provides for a more nuanced approach.¹⁹⁴

Some studies have even dived as deep as evaluating the roles of genetic counseling from a psychological perspective.¹⁹⁵ In that study, in order to better understand the genetic counselor's role, "risk perception" was important.¹⁹⁶ The study ultimately found that this risk perception was inaccurate because of certain predictors that influence the function or meaning of the process of communication.¹⁹⁷ The takeaway is that the physician, assuming the role of counselor, and the patient, assuming the role of counselee, must recognize how they psychologically orient themselves prior to even beginning the communication process.¹⁹⁸

D. *Confrontation with Information Generated Through Whole Genome Sequencing*

Hypothesizing the future implications that the nature and potential of genetic information will have on the physician-patient relationship, including

193. *Id.* As the authors have asserted: Defensive medicine is not the answer. *Id.* Neither is recommending genetic testing when it is not clinically justified. *Id.*

194. *Id.*

195. See Joel Vos et al., *A Counselee-Oriented Perspective on Risk Communication in Genetic Counseling: Explaining Inaccuracy of the Counselee's Risk Perception Shortly after BRCA 1/2 Test Result Disclosure*, 13 GENETICS MED. 800, 800 (2011). In that study, "genetic counseling" was defined as the "process of helping people understand and adapt to the medical, psychological, and familial implications of genetic contributions to disease," which includes communication of risk information and medical options based on these risks, which are calculated on the basis of a pathogenic mutation DNA test result, or on the basis of pedigree information, in combination with the counselee's cancer history. *Id.*

196. See *id.* Risk perception was important in predicting the impact of genetic counseling: counselee's creation of own perception versus what is actually communicated by counselor. *Id.*

197. See *id.* Risk Perception is inaccurate because of either information-oriented (the function of a process) or counselee-oriented (meaning of a process) predictors. Information-Oriented Predictors focus on "how specific genetic information is communicated by the genetic counselor, how it is received, processed, and reproduced by the counselee, and how these processes are influenced by knowledge-related variables." *Id.* at 800-01. Some of the predictors discussed include "what information is communicated, levels of education and innumeracy, presence of specific information about cancer in relatives and in counselees, and specific cognitive processes regarding the processing of specific information." *Id.* at 801. On the other hand, Counselee-Oriented Predictors focus on "how the genetic information is experienced and fundamentally embedded in the life of the counselee." *Id.* Variable predictors include "the self, existential concerns, and the need for certainty." Vos et al., *supra* note 195, at 800-01.

198. See *supra* Section II.B.

whether the clinical setting will or should be the venue by which genetic information is disclosed to patients, is not a new discourse.¹⁹⁹ Advancements in genetic testing technologies will require collaboration from the various stakeholders, including physicians,²⁰⁰ because “ethical, social, and legal issues will continue to evolve as the technology itself evolves.”²⁰¹ Although the “clinical research enterprise, technologies, and data required to implement genetically-based preventive medicine on a personal basis”²⁰² have not yet been fully realized, the reality of whole genome sequencing has been established and will change the scope of the physician-patient relationship.

The physician’s role in addressing, managing, and advising the patient on the validity and utility of genetic information is contingent upon the physician’s prioritization of the results as they pertain to the patient. First, an effective management method physicians may employ is a binning system.²⁰³ This binning system allows for results to be “triaged,” which provides physicians with a framework by which they may manage, interpret, and communicate information to their patients.²⁰⁴ The specific reporting criteria Berg et al. proposed involves categorizing genotype-phenotype associations into three “bins.”²⁰⁵ The bin with the fewest results having “clinical utility”²⁰⁶ would allow patients and physicians to focus on those most useful to the

199. See Andrews, *supra* note 79, at 184 (“In the future . . . the health care provider/patient relationship may become an obsolete mechanism for transferring the bulk of genetic information. If we as individuals or as a society are to make the best use of the growing genetic information, we must develop a much greater understanding of the nature of genetics and its potential for figuring into our major life decisions.”).

200. AMA Policy Perspective, *supra* note 9, at 5. These advancements “will require a concerted effort on the part of the private and public sector, coupled with enhanced educational efforts.” RESOL. 422, A-05, *supra* note 3.

201. RESOL. 422, A-05, *supra* note 3. It is also important to recognize salient considerations when identifying and articulating the evolution of these ethical, social, and legal issues. These advancements “will require a concerted effort on the part of the private and public sector, coupled with enhanced educational efforts.” *Id.*

202. *Id.*

203. Berg et al., *supra* note 61, at 501; see also Westbrook et al., *supra* note 6, at 6 (citing and discussing benefits and drawbacks of proposals in Berg et al.’s article).

204. Berg et al., *supra* note 61, at 501.

205. *Id.*; see also Westbrook et al., *supra* note 6, at 6. “Bin 1 would contain clinically valid results that also carry clinical utility according to the current literature. Bin 2 would contain clinically valid results that are not considered to be actionable. This bin is further stratified into bins 2A, 2B, and 2C. Bin 2A would hold results that are unlikely to cause distress (such as risks for common diseases) to patients, whereas Bin 2B and 2C would hold results that patients are more likely to find distressing (such as risks for Alzheimer disease or Huntington disease). Bin 3 would contain results with unknown clinical implications and would thus hold the majority of incidental findings.” *Id.*

206. This bin would house results with both clinical validity and utility according to the literature. Westbrook et al., *supra* note 6, at 6.

patient in the clinical and diagnostic setting.²⁰⁷ Management of this bin is important as it will house the fewest and some of the most salient information for the physicians to use in communicating to their patients. As such, the criteria by which this information will get into the bin in the first place will need to be adjusted with the generation of new information as technology becomes more robust, and balanced with each other as some information may be more salient than others given the particular patient.

A physician confronted with whole genome sequencing information may choose to refer the patient to a genetic counselor for further education and clarification as to the meaning of that genomic information. Exercising this option may enable the physician to circumvent ethical and legal ramifications. Not only will improving genomic literacy among physicians prove helpful, but also improving genomic literacy among patients so as to elucidate their expectations and preferences. "To promote patient participation in genomics, the [United States] Department of Health and Human Services launched the Personalized Health Care and Initiative Policy to facilitate patient empowerment through genomics as a central priority of future health care programs."²⁰⁸

For optimal utilization of genomic information in the clinical setting, patients should be aware of the benefits and limitations of genomic testing. Online educational tools are also available for patients to help them better understand how genomics relates to their health. This program communicates educational information to the patient with the hope that the patient takes advantage of it prior to engaging in communication with the patient's provider.²⁰⁹ Regardless of the source, communication still remains key.

E. Future Implications on Potential Negligence Liability

Although literature has been published on negligence issues pertaining to the return of results to research participants and involving whether, under what circumstances, and how results should be returned, the discussion of negligence in the clinical context may take similar form. It is not farfetched to think of negligence actions in the context of returning whole genome sequencing testing results because of the expectation that a physician will be able to interpret the information generated and provide guidance to and for a patient. For these particular instances, negligence may take the form of either nondisclosure or disclosure, in a similar fashion as discussed above.

As has been previously documented, physician behavior tends to be driven by a fear of liability.²¹⁰ As such, some have argued that a physician, acting in

207. Berg et al., *supra* note 61, at 502; Westbrook et al., *supra* note 6, at 6.

208. *See generally* Hazin et al., *supra* note 91, at 811.

209. *See generally id.*

210. McGuire et al., *supra* note 80, at 722.

good faith and using professional expertise to make good, responsible judgments, may have a defense against a negligence claim.²¹¹ Framing this potential in the context of the court rulings on a physician's "duty to warn," defending against disclosure or nondisclosure will turn on the issue of foreseeability, reasonableness, and the relative risk associated with each of the findings. While leaving resolution of these issues to litigation may result in "inconsistency across jurisdictions and court rulings that may not take into account the full complexity of the issue[s],"²¹² precedent might be established if and when a patient believes he or she is owed a duty and the court needs to weigh in on the issue and remedy the alleged wrong.

By contrast, others are concerned, anxious, and skeptical with the growing consensus that returning the results of genomic research will become the standard of care, which has the potential for giving way to malpractice liability premised on negligence-based breach of duty.²¹³ Policy adequately addressing the legal and ethical implications is necessary before the standard of care can be reshaped. Policy will need to specifically address the belief that "[j]ust because research data exists does not always make its clinical use compelling, or even appropriate."²¹⁴

Similar to the context of prenatal screening, liability is expected to be "unpredictable and influential in changing medical practice" as personalized medicine techniques become more widespread in their clinical application.²¹⁵ Interpretation and guidance on genomic testing results remain within the province of the physician in the clinical setting. The burden of interpretation upon which the physician is expected to act has not yet been established. This burden, as it directly relates to the standard of care, might be shaped by (or even take the shape of) certain legal elements such as foreseeability and imminent danger.

The likelihood of developing a certain disease or illness predicated on a particular genetic variant is not yet within the realm of *foreseeability* to the extent that physicians will be held liable for falling below the standard of care. Notwithstanding this lack of foreseeability issue, the standard of care itself has yet to be defined for this particular context. The issue of foreseeability of imminent danger as it relates to developing a particular disease or illness in the

211. *Id.*

212. *Id.*

213. Ellen Wright Clayton & Amy L. McGuire, *The Legal Risks of Returning Results of Genomics Research*, 14 GENETICS MED. 473, 473 (2012). Although this concern involves the threat of liability posed to researchers, the reality of concerns are both applicable and relevant to discussions pertaining to the clinical setting.

214. *Id.* at 474. Here, the authors draw a line between research tests and clinical tests based upon the reasons why those tests are conducted in the first place. Translating research-based results into the clinical setting has ethical implications.

215. Marchant et al., *supra* note 43, at 457.

presence or absence of a particular genetic variant might be analogized to the weak relationship between clinical validity and clinical utility, their respective significance in the clinical setting, and their gatekeeping threshold position for unleashing this information's use for the benefit of patients.

V. CONCLUSION

One of the two central tenets of Western medicine is that physicians should focus on the interests of their patients.²¹⁶ This focus is guided by the standard of care that physicians are expected to perform up to and that patients are expected to receive from their physicians. In the case of genomic medicine and unleashing its potential, determining the patient's interests becomes a challenge as the physician is expected to provide guidance to their patients, but the information pertaining to genomic medicine has yet to be properly defined and rendered clinically useful so that physicians may perform at the standard of care expected. An assumption cannot be made that everyone who has access to genomic information will reap its benefits. Whether people will actually use the test results to alter their behavior in ways that improve health is still uncertain. Some preventive or therapeutic measures are more likely to be pursued than others. But the question still remains: How is a physician expected to suggest preventive or therapeutic measures to patients with this information when the clinical validity and utility has yet to be definitively determined and is constantly changing, and the physician has yet to be properly educated so as to provide clinically meaningful information to the patient, which would also meet the standard of care?

The amount of information that has resulted, and is still to come, has been analogized as a "tidal wave."²¹⁷ Doubt exists as to whether we are paying attention to it.²¹⁸ This article has argued that given the amount of literature, adequate attention has been paid on account of recognizing the voluminous amount of information, the challenges to implementing it effectively in the clinical setting, and the potential for liability threats against physicians for failing to address genomic results with their patients. These challenges will take on a new identity as the standard of care expected of physicians adapts to the reality of whole genome sequencing and its beneficial and detrimental potential. It is not farfetched to hypothesize that a patient receiving this genetic information would expect the physician to interpret and provide guidance for the patient's benefit.

Genetic counselors might be a good resource for patients to consult, but given the inadequate number of counselors available in the United States, this

216. Clayton, *supra* note 122, at 566.

217. *Is Genome Sequencing Surpassing Medical Knowledge?*, NAT'L PUB. RADIO (Oct. 29, 2010), <http://www.npr.org/templates/story/story.php?storyId=130916257>.

218. *Id.*

inadequacy may impede the use of genomic testing in the clinical practice.²¹⁹ It is evident that physicians, specifically primary care physicians, will be on the frontline of using genomic medicine in mainstream care.²²⁰ Although physicians lack the requisite knowledge of genomics needed to provide adequate counseling on the issues,²²¹ there are resources available for physicians to take advantage of and increase their expertise in the area.

Education, management and interpretation skills, and expertise in the area of genomics are important factors for determining the changing scope of a physician's legal duty to address all or at least some of the information generated through whole genome sequencing. This will impact the standard of care permeating throughout the profession. A physician's potential duty as it will be shaped by whole genome sequencing will be more fully realized as physicians find guidance in best practice standards, which will have the effect of enabling physicians with the ability to gain control and to facilitate the clinical dialogue with their patients.

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219. Hazin et al., *supra* note 91, at 811-12. "There are only 3,026 board-certified genetic counselors in the United States, and little effort is under way to expand genetic counseling programs." *Id.* at 811.

220. *Id.* at 812.

221. *Id.* ("The new dimension of genome-informed medical care is likely to further unmask knowledge gaps in this area and increase the frequency of misinterpretations, thereby exposing patients to medical risk.").

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