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The Future of Genetic Testing and the Legal and Ethical Implications of ENCODE

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INTRODUCTION

Advancements in genetics research are rapidly transforming the fields of personalized medicine and population research. These developments will introduce a wide range of difficult bioethical issues and raise many yet unaddressed legal concerns. On September 5, 2012, *Nature*, *Cell*, *Science*, *Genome Research*, and other scientific journals released a coordinated publication of thirty articles detailing the groundbreaking findings of The Encyclopedia of DNA Elements (ENCODE) consortium.¹ The ENCODE consortium represents new research that for the first time confirms that over eighty percent of our DNA which was once thought of as “junk” with no function actually plays a “critical role in controlling how cells, tissue, and organs behave.”² These portions of the genome, once disregarded as non-protein-coding DNA (ncDNA) are now being described as genetic “switches” that may lead to many discoveries about disease.³

Imagine a patient walking into his physician’s office, handing the physician a memory stick and saying: “Here, look at all 3.2 billion base pairs of my DNA and tell me exactly what is wrong with my cancer and how you are going to treat it.” According to Dr. George Sledge Jr., a past president of the American Society of Clinical Oncology, this scenario could become a reality in as few as two to three years.⁴ Advancements in the field of genetic testing will change clinical practices and patient expectations, which will shift boundaries of medical malpractice

¹ Sara Huston Katsanis, *Encode, CODIS, and the Urgent Need to Focus on What is Scientifically and Legally Relevant to the DNA Fingerprinting Debate* (Oct. 12, 2012), <http://www.genomicslawreport.com/index.php/2012/09/21/encode-codis-and-the-urgent-need-to-focus-on-what-is-scientifically-and-legally-relevant-to-the-dna-fingerprinting-debate/#more-6839>.

² Jennifer Lynch, *Mew Research on Junk DNA Raises Questions on Eve of Crucial Court Hearing*, Electronic Frontier Foundation (Sept. 11, 2012), <https://www.eff.org/deeplinks/2012/09/new-research-on-junk-dna-raises-questions>.

³ *Id.*

⁴ Damian McNamara, *Oncologists Learn how to Use Patients’ Complex Genomic Data*, NY Genome Center (Oct. 1, 2012), nygenome.org/blog.

law, expand the meaning of informed consent, and present new challenges in bioethics and privacy.

Although there is much to be gained from learning more about individual genomes, genetic information can reveal highly sensitive personal information such as medical history, familial relationships, predisposition for disease, and possibly even behavioral tendencies.⁵ The government has already recognized the potential gains from genetic testing, as well as the concerns that individuals might have about the confidentiality of their genetic information.⁶ The Genetic Information Nondiscrimination Act was enacted to address these concerns and promote genetic testing.⁷ It is likely that GINA and other protective privacy measures will encourage more individuals to undergo genetic testing.

As more about the human genome is revealed and more patients choose to undergo genetic testing, it is increasingly important to develop professional guidelines and recommendations that take into account new genetic discoveries and testing techniques. In order to provide an argument in support of the further development of professional guidelines, this paper will consist of four sections. Section I will discuss the background of genetic testing, the Human Genome Project and the ENCODE Consortium. Section II will explore the legal issues surrounding genetic testing and discuss the implications that increased genetic testing will have on the doctrines of medical malpractice and informed consent. This section will also discuss how the law will be challenged by rapidly developing advancements such as the ability to detect

⁵ Lynch, *supra* note 2.

⁶ Jennifer Wagner, *Alabama's "Genetic Information Privacy Act" and the Ongoing Need for Personal Genomics Leadership* (Feb. 16, 2012), <http://www.genomicslawreport.com/index.php/2012/02/16/alabamas-genetic-information-privacy-act-the-ongoing-need-for-personal-genomics-leadership/#more-6448>.

⁷ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008) (prohibiting discrimination on the basis of genetic information with respect to health insurance and employment).

genetic “switches.” Section III will examine the unique legal and bioethical concerns that arise from the interplay between patient privacy and the duty to warn third parties of genetic diseases. Finally, Section IV will conclude that in order to promote the advancement of personalized medicine, it will be important to increase genetics education and establish professional guidelines that recognize advancements made in whole genome sequencing while preserving patient confidentiality.

I. ENCODE: THE NEW FRONTIER OF GENETIC TESTING

Technological innovation has made genetic testing more accessible and an increasing number of individuals now have the opportunity to access and interpret their own genetic information.⁸ The price of sequencing an entire human genome is dropping rapidly and it may soon cost a consumer only \$1,000 for an entire genetic blueprint.⁹ This genetic blueprint can reveal predispositions to cancer, diabetes, and even psychiatric conditions.¹⁰ The cost of sequencing the entire genome, consisting of more than 20,000 genes and 6 billion DNA building blocks, will soon be less than that to perform individual tests for cancer or metabolic disease.¹¹

Whole genome sequencing has already made promising developments in the field of targeted gene therapy.¹² In 2009, the Memorial Sloan Kettering Cancer Center conducted a phase II trial of the kidney cancer drug Everolimus on patients with bladder cancer.¹³ Although the trial was unsuccessful overall, one patient (Patient X) responded remarkably well to the drug and

⁸ Wagner, *supra* note 6.

⁹ Amy Gutman, *Privacy and whole genome sequencing*, The Great Debate (Oct. 11, 2012), <http://blogs.reuters.com/great-debate/2012/10/11/privacy-and-whole-genome-sequencing/>.

¹⁰ *Id.*

¹¹ *Id.*

¹² Christie Rizk, *Sequencing Brings Useful Results from ‘Failed’ Drug Trial* (Oct 22, 2012), <http://nygenome.org/blog/sequencing-brings-useful-results-failed-drug-trial>.

¹³ Rizk, *supra* note 12.

went into complete remission.¹⁴ The researchers then used array-based tools to perform a targeted search of the Patient X's tumor DNA for mutations and variations.¹⁵ When that did not produce significant results, they sequenced the tumor's entire genome to detect potential biomarkers.¹⁶ This whole genome sequencing revealed that there were indeed two mutations unique to Patient X.¹⁷ Upon referencing previous studies, scientists discovered that one of these mutations had been shown to sensitize patients to the same protein that is targeted by Everolimus, likely deducing the source of Patient X's positive response.¹⁸ Scientists believe that experiments in this vein can continue to identify previously undetected subtypes of disease that can then be targeted and treated through personalized therapies.¹⁹

Whole genome sequencing will likely increasingly be used as a discovery platform.²⁰ Namely, the federal government spent \$288 million to support development of the Encyclopedia of DNA Elements (ENCODE), an international research collaboration that follows up on and supplements the Human Genome Project (HGP).²¹ The goal of the HGP, an international, collaborative research program jointly managed by the U.S. Department of Energy and the National Institutes of Health, was to map and sequence the genes of the human body.²² In 2003, the HGP was successfully completed.²³ ENCODE now aims to provide a deeper understanding of the "functional" elements of the genome and serve as a catalog of these segments.²⁴

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ Brendan Maher, *ENCODE: The Human Encyclopedia* (Sept. 5, 2012), <http://www.nature.com/news/encode-the-human-encyclopaedia-1.11312>.

²² National Human Genome Research Institution, *An Overview of the Human Genome Project*, (Feb. 15, 2006), <http://www.genome.gov/12011238> [hereinafter NHGRI, HGP Overview].

²³ NHGRI, HGP Overview, *supra* note 22.

²⁴ *Id.*

One of ENCODE's most ground-breaking discoveries is that certain non-protein coding regions serve much larger functions than previously thought.²⁵ So far, four million switches, also called transcription factors or "regulatory genes," have been discovered.²⁶ Study results found that regulatory genes are responsible for common diseases such as Crohn's disease and about 17 major different types of cancer.²⁷ Gaining understanding of these networks of genetic switches may prove to provide new targets for drug therapy and greatly expand personalized medicine.²⁸ Namely, genome-based research will eventually allow scientists to develop highly effective diagnostic tests to better understand the health needs of people based on their unique genetic make-ups, and to design personalized treatments for diseases.²⁹

Laboratories and clinicians will benefit from collaborating to understand the relationships between sequence variations and health conditions within the context of ENCODE's findings. Clinical decisionmakers will be also need to take these findings into account in order to avoid inappropriate recommendations that may cause patient harm.³⁰ As data on current practices on genetics reporting and its impact on health outcomes continues to accumulate, it will be important to survey these practices and how they link to patient outcomes. These new discoveries will reshape the boundaries of medicine and should be taken into account when addressing legal and bioethical quandaries that will inevitably arise as genetic testing becomes more prevalent.

II. THE CHANGING LANDSCAPE OF LIABILITY

²⁵ *Id.*

²⁶ Dan Vergana, Researchers: "Junk" DNA plays major role in disease (Dec. 5, 2012), <http://usatoday30.usatoday.com/news/health/story/2012-09-05/junk-dna-disease/57604346/1?csp=34news>.

²⁷ *Id.*

²⁸ *Id.*

²⁹ NHGRI, *supra* note 22.

³⁰ *U.S. system of Oversight of Genetic Testing* (Dec. 1, 2012), http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf.

The possibility of linking DNA variations with health conditions will result in unprecedented ways to predict and treat diseases.³¹ In a pilot study Mike Snyder, the head of the Center for Genomics and Personalized Medicine and Stanford University, decided to sequence his own genome in order to demonstrate the capabilities of personal genomics.³² Snyder explained that he wanted to sequence his DNA to see if it would predict conditions that he might be at risk for, particularly those that were not evident from his family history.³³ The sequencing revealed that the seemingly healthy Snyder was at high risk for type 2 diabetes.³⁴ Snyder stated that he believed that the early detection would allow him to manage the risk through diet and increased exercise, thereby mitigating an otherwise debilitating disease.³⁵

Although advancements in whole genome research will play a role in making medicine more preventative, personalized and effective, there are significant gaps in the U.S. system of genetic testing oversight that can lead to harms.³⁶ Further, customs in the genomics industry are not yet fully developed.³⁷ As genetic testing continues to grow exponentially, the number of qualified clinical geneticists and genetic counselors is unlikely to meet the demand, and an increasing amount of general physicians may be expected to offer, interpret and convey genetic tests results.³⁸ Thus, increased validation and acceptance of genetic testing in clinical practice

³¹ Gutman, *supra* note 9.

³² Joyce Gramza, *Stanford Researcher Predicted his Own Diabetes with Genome Study*, NY Genome Center (Oct. 30, 2012), <http://nygenome.org/blog/stanford-researcher-predicted-his-own-diabetes-genome-study>.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*; Presidential Commission for the Study of Bioethical Issues, *Privacy and Progress in Whole Genome Sequencing* (Currently there are no state or federal laws exist to address whole genome sequence data comprehensively).

³⁷ Wagner, *supra* note 6.

³⁸ *Id.*

could result in a challenging time for physicians.³⁹ Physicians will be at the forefront of genetics medicine and may be faced with changing forms of liability for medical malpractice, lack of informed consent, and the legal duty to warn.

1. Medical Malpractice: Standard of Care

As physicians incorporate genetic services into their practice, the framework for analyzing medical malpractice cases will change. Medical malpractice claims are based on negligence⁴⁰ and must include a duty owed by the physician to his patient, a breach of that duty, causation, and damages.⁴¹ The physician-patient duty is unique in that it is upheld if the physician meets the required standard of care.⁴² Generally, the standard of care is measured by the level of care demonstrated by other physicians in the same field in terms of skill, knowledge and care.⁴³

Genetics knowledge, skills, and abilities vary greatly across the discipline, making it difficult to make standard of care determinations. In a survey of six allied healthcare training programs, 78 percent of graduates reported that they received marginal to no instruction on genetics knowledge and skills.⁴⁴ However, even though they had minimal levels of genetics education, these professionals were still responsible for providing clinical services relevant to genetics, such as taking family genetic histories and counseling patients on the genetic basis for the disorders.⁴⁵ As the personal genomics industry grows, it will be important for primary care

³⁹Michael J. Donovan, *Legal Issues Stemming from the Advancement of Pharmogenomics*, 14 UCLA J.L. & TECH. 1 (2010).

⁴⁰Dan B. Dobbs, *The Law of Torts* 631 (2000).

⁴¹*Id.*

⁴²Restatement (Second) of Torts § 299A (1965).

⁴³*Id.*

⁴⁴Christianson, C.A., McWalter, K.M., and Warren, N.S. *Assessment of allied health graduates' preparation to integrate genetic knowledge and skills into clinical practice*. 34 *Journal of Allied Health* 138 (2005).

⁴⁵*Id.*

providers to equip themselves with the necessary knowledge and skills to assess patients' situations. The wide range of genetics care providers, ranging from geneticists who have medical degrees to laboratory technicians, implies that some types of providers may be more qualified than others depending on the nature of the test and the complexity of the condition at issue.⁴⁶

Currently, the American Medical Association (AMA) predicts that only ten percent of physicians possess the requisite knowledge to use genetic testing.⁴⁷ Due to the low percentage of general physicians who genetic testing services, it may be difficult to establish a standard of care that would give rise to liability for failure to administer genetic testing services.⁴⁸ However, as more genetic tests for common chronic disorders become incorporated into primary practice, even health care professionals who do not have specialized training in genetics may be held to the same standard of care as clinical geneticists. This may impose general practitioners with a heightened standard of care and resulting malpractice cases that they are not prepared to prevent.

This issue is compounded by the fact that patients may be more confident in their primary physicians' ability to convey genetic services than statistics should currently suggest.⁴⁹ The AMA reported in a survey that over 60 percent of respondents would choose their primary care doctor as their first consultant on genetic disorders.⁵⁰ In addition, about 80 percent reported feeling "very confident" or "somewhat confident" that their primary care provider could advise them or their family members about risk for developing inherited cancer, counsel them about

⁴⁶ Secretary's Advisory Committee on Genetics, Health, and Society, *Coverage and Reimbursement of Genetic Tests and Services* (April 3, 2008.), http://www4.od.nih.gov/oba/sacghs/reports/CR_report.pdf.

⁴⁷ Melissa Healy, *Doctors Untrained to Utilize Genetic Testing*, L.A. Times, Oct. 24, 2009, at A19 (stating that only 13% of physicians administer pharmacogenomic tests).

⁴⁸ *Id.*

⁴⁹ Donovan, *supra* note 39.

⁵⁰ American Medical Association, *Genetic Testing. A Study of Consumer Attitudes*, Chicago: Survey Center (June 1, 2001), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1071428/>.

available genetic tests, and interpret results from the test.⁵¹ However, a separate study conducted by the National Cancer Institute concluded that only 40 percent of primary care physicians and 57 percent of tertiary care physicians felt that they were qualified to recommend genetic testing for cancer susceptibility to their patients.⁵²

Studies have shown that the level of genetics knowledge of the primary care provider greatly determines willingness to offer genetic testing and services.⁵³ Attitudes and acceptance of testing are also dependent on complex balancing tests of the benefits, risks, and costs of genetic testing.⁵⁴ Notably, providers will be faced with the challenge of constantly maintaining knowledge of what tests are currently available, and how accurate and valid the tests are.⁵⁵ The burden of attaining rapidly changing knowledge about genetics, including new findings that come from ENCODE, may prove to be a deterrent for providers who do not wish to incur liability for care related to genetic services.⁵⁶

Further, even if a physician purports not to offer genetics services, plaintiffs may still succeed in bringing a case under the current standard of care. According to the Restatement (Second) of Torts, “[i]n determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account, but are not controlling where a reasonable man [or woman] would follow them.”⁵⁷ For example, if there is sufficient knowledge in the medical community that a certain set of gene mutations cause a particular

⁵¹ AMA, *supra* note 50.

⁵² Geller, G., Tambor, E.S., Bernhardt, B.A., Chase, G.A., Hofman, K. J., Faden, R.R., & Holtzman, N.A., *Physicians’ attitudes toward disclosure of genetic information to third parties*, 21 J. L. MED. & ETHICS 238 (1993).

⁵³ *Id.*

⁵⁴ Secretary’s Advisory Committee on Genetics, Health, and Society, *Coverage and Reimbursement of Genetic Tests and Services* (April 3, 2008), http://www4.od.nih.gov/oba/sacghs/reports/CR_report.pdf.

⁵⁵ *Id.*

⁵⁶ Hofman, K.J., Tambor, E.S., Chase, G.A., Geller, G., Faden R.R., & Holtzman, N.A., *Physicians’ knowledge of genetics and genetic tests*, 68 ACADEMIC MEDICINE 625 (1993).

⁵⁷ Restatement (Second) of Torts § 299A (1965).

disease to develop, and the physician does not follow up with a patient whose medical records show these gene mutations which in turn lead to that patient's injuries, the physician could face liability under this standard.⁵⁸ The physician may argue that due to his limited background in genetics related care, medical custom would not dictate him to follow up with his patient regarding the predicted disease.⁵⁹

However, if a reasonable person, given the prominence of the predictive test, would have conducted follow up care, medical custom may not prescribe the outcome.⁶⁰ This reasonable person objective standard has been applied by at least one court in a medical malpractice setting.⁶¹ In *Helling v. Carey*, the court stated that although an early glaucoma detection technique using air puffs tests was not in routine use by ophthalmologists, the court could impose liability for breaching the standard of care.⁶² The court stated that "irrespective of its disregard by the standards of the ophthalmology profession, it is the duty of the courts to say what is required to protect patients."⁶³ Under this same reasoning, the lifesaving potential of genetic testing and follow up care could lead courts to impose liability for physicians who fail to utilize available testing and care.

Physicians who do choose to offer genetic testing services will be exposed to even more forms of liability. For example, they could be held liable for an incorrect interpretation of test results and for recommending a suitable course of treatment or drug therapy. Further, physicians will have to consider the fact that simply revealing genetic information to patients could have

⁵⁸ Donovan, *supra* note 39.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974) (en banc), superseded by statute, Wash. Rev. Code Ann. § 4.24.290 (West 2010).

⁶² *Id.*

⁶³ *Id.*

unexpected effects on the patients' psyche.⁶⁴ To prevent these situations, it will be crucial for physicians to establish obtain informed consent with patients before engaging in genetics services.

2. *Lack of Informed Consent as Liability*

The theory of informed consent raises significant areas of liability for physicians. The need for informed consent is based in the principles of autonomy and self-determination and recognizes the patient's desire to decide which tests and procedures to undergo.⁶⁵ In order to establish informed consent liability, an injured patient must show that his physician failed to disclose all information pertinent to the test or procedure, including benefits, risks, and alternatives.⁶⁶ The patient must also establish by a preponderance of evidence that if the patient had received all of the pertinent information, he would have chosen an alternative means of treatment.⁶⁷ As applied to genetic testing, the injured patient might allege that, if given all the relevant information about undergoing a certain treatment plan, the patient would have asked for a genetic test to determine whether he would be negatively impacted by the treatment, and would have either avoided the treatment altogether or undertaken a alternative means of treatment.⁶⁸

Similar to other medical malpractice claims, claims for lack of informed consent may be evaluated under the "reasonable practitioner" standard, which states that the plaintiff must establish what a reasonable physician would disclose to his patient, prove that his own physician failed to disclose than information, and then show that he was harmed by this lack of

⁶⁴ Donovan, *supra* note 39.

⁶⁵ Richard A. Heinemann, *Pushing the Limits of Informed Consent: Johnson v. Kookemor and Physician-Specific Disclosure*, 1997 WIS. L. REV. 1079, 1081-82 (1997) (quoting *Schlondorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *abrogated by Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957).

⁶⁶ Dan B. Dobbs, *The Law of Torts* 631 (2000).

⁶⁷ *Id.*

⁶⁸ Donovan, *supra* note 39.

disclosure.⁶⁹ This standard, which has been relatively easy to meet due to the limited practice of genetic testing, may shift as genetic testing becomes more widespread.⁷⁰ Further, some states hold physicians to an informed consent standard according to what a “reasonable patient” would need to know to make an informed decision.⁷¹ This patient-centered approach dictates that “the test for determining whether a particular peril must be divulged is its materiality to the patient's decision,” and that “all risks potentially affecting the decision must be unmasked.”⁷² Under this standard, patients who bring a cause of action for a physician’s failure to provide a genetic test would be required to show that a test was commercially available that would provide results that would dictate the patient’s course of action.⁷³ However, if there was no test commercially available, then the information would not be considered materially relevant.⁷⁴ Advancements in genetic testing techniques such as the ENCODE findings will increase the number, power, and accuracy of genetic tests, necessitating clear informed consent and communication between physicians and patients.⁷⁵

As findings from ENCODE and similar whole genome sequencing projects begin to disseminate throughout the medical community, physicians may increasingly be held liable for failure to provide genetic tests or failure to properly interpret those tests.⁷⁶ In order to avoid liability, doctors may find it necessary to learn about these techniques and incorporate them in to their practice.⁷⁷ Finally, physicians who do engage in genetic testing services will be faced with a

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ Heinemann, *supra* note 65.

⁷² *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir. 1972) (citing Jon R. Waltz & Thomas W. Scheuneman, *Informed Consent to Therapy*, 64NW. U. L. REV., 628, 639-41 (1970).

⁷³ Donovan, *supra* note 39.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

challenging legal and bioethical issue that pushes the boundaries of confidentiality and the physician-patient relationship: the duty to warn.

III. THE DUTY TO WARN: INCREASING TENSION BETWEEN PATIENT CONFIDENTIALITY AND AVERTING HARM

1. Legal Duty to Warn

Genetic testing presents the unique problem of not only identifying the risk for disease for patients but also for family members who may not be receiving care from the physician providing the test.⁷⁸ Most medical professional organizations take the policy position that physicians should actively encourage patients with inherited diseases to inform their at-risk family members.⁷⁹ Certain hereditary diseases, such as breast cancer, have mutations that can be easily detected. Predictive tests, or susceptibility tests, include those for breast and ovarian cancer, colon cancer, and Alzheimer's disease.⁸⁰ In the case of breast cancer, mutations in BRCA1 and BRCA2 are highly associated with increased risk for both breast and ovarian cancer.⁸¹ Patients who test positive for mutations may elect for cancer prophylaxis or even take preventative measures such as mastectomies.⁸² However, patients who choose to take preventive measures for themselves may not want to reveal this sensitive information to family members.⁸³

Depending on the jurisdiction, the hereditary nature of genetic traits creates a unique situation for physicians who offer genetic testing to their patients but do not share test results

⁷⁸ American College of Physicians Ethics Manual Sixth Edition, (Oct. 2, 2012), http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#genetic-test.

⁷⁹ *Id.*

⁸⁰ Tara L. Rachinsky, *Genetic Testing: Toward a Comprehensive Policy to Prevent Genetic Discrimination in the Workplace*, 2 U. PA. J. LAB. & EMP. L. 575, 581 (2000).

⁸¹ Anne-Marie Laberge, *Duty to Warn At-Risk Family Members of Genetic disease*, Virtual Mentor (Sept. 2009), <http://virtualmentor.ama-assn.org/2009/09/ccas1-0909.html>.

⁸² *Id.*

⁸³ *Id.*

with the patients' close relatives. For instance, in Florida⁸⁴ and New Jersey,⁸⁵ physicians have the duty to inform patients that they should warn close relatives if genetic testing reveals harmful genotypes.⁸⁶ New Jersey courts have gone even further to say that warning the patient may not be enough, indicating that physicians may be required to give patients' relatives direct warnings with whom they may have no physician-patient relationship.⁸⁷

The physicians' legal duty to warn was established in *Tarasoff v. Regents of the University of California*.⁸⁸ In *Tarasoff*, a woman was murdered by a man who was obsessed with her after he had shared his intention to kill her with his psychotherapist.⁸⁹ The court held that a physician has a duty to warn if 1) he has a special relationship with either the person who may cause harm or the potential victim, 2) the person at risk is identifiable, and 3) the harm is foreseeable and serious.⁹⁰ The *Tarasoff* duty to warn identifiable individuals at risk of harm is significant for physicians in the context of genetic testing because genetic test results may identify potential risk of harm for patients' relatives.⁹¹ Particularly, case law has suggested that physicians may have a duty to disclose genetic information to families of patients when related individuals may need it to make informed reproductive choices⁹² or when they are genetically susceptible to potentially harmful genetic traits demonstrated in the physician's patient.⁹³

⁸⁴ *Pate v. Threlkel*, 661 So.2d 278, 279, 282 (Fla. 1995).

⁸⁵ *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) (quoting *Schroeder v. Perkel*, 432 A.2d 834, 839 (N.J. 1981)).

⁸⁶ *Id.*

⁸⁷ *Id.* at 1192-93.

⁸⁸ *Tarasoff v. Regents of Univ. of California*, 17 Cal. 3d 425, 551 P.2d 334 (1976).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Sonia M. Suter, *Whose Genes Are These Anyway? Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1877-78 (1993).

⁹² *See Lininger v. Eisenbaum*, 764 P.2d 1202 (Colo. 1988); *Molloy v. Meier*, 679 N.W.2d 711 (Minn. 2004); *Schroeder v. Perkel*, 432 A.2d 834 (N.J. 1981).

⁹³ *See Pate*, 661 So. 2d at 278; *Safer* 715 A.2d at 363.

For example, In *Pate v. Threkel*,⁹⁴ Heidi Pate, the adult daughter of a woman who had thyroid carcinoma, a genetically inheritable disease, sued her mother's physician for medical malpractice after she developed the same disease three years after her mother's treatment was completed.⁹⁵ Her complaint stated that her mother's physician knew or should have known that the disease was hereditary and that the physician had a duty to warn her mother that her that her children should be tested for the disease.⁹⁶ Further, she alleged that if her mother had been warned, she would have had her children tested, and that if Pate had been tested at that time, she would have taken preventive action and could have cured her condition.⁹⁷

The Florida court ruled that the physician did have a duty to warn Pate's mother due to the genetically transferable nature of her disease,⁹⁸ and that this duty should run to the "intended beneficiary of the prevailing standard of care."⁹⁹ As the patient's child, the court said, Pate was an intended beneficiary of her mother's care, and the lack of a direct physician-patient relationship did not "foreclose liability if a duty of care [was] otherwise established."¹⁰⁰ Thus, in cases in which the prevailing standard of care creates a duty that is intended to benefit identifiable third parties, then the physician's duty extends to those third parties.¹⁰¹ However, the court was careful to note that the physician was not required to personally warn the patient's children.¹⁰² Their duty would be satisfied "in any circumstances in which the physician has a duty to warn of a genetically transferable disease," by warning the patient."¹⁰³

⁹⁴ *Pate*, 661 So. 2d at 278.

⁹⁵ *Id.* at 279.

⁹⁶ *Id.* at 279-280.

⁹⁷ *Id.* at 280-281.

⁹⁸ *Id.* at 281.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.* at 282.

¹⁰³ *Id.*

In a similar New Jersey case, *Safer v. Estate of Pack*, a patient diagnosed with a hereditary form of colon cancer brought a malpractice claim against the estate of the physician who had treated her father thirty-four years earlier, alleging that the doctor had breached his duty to warn her that she was at risk of developing the hereditary disease.¹⁰⁴ Although there was no direct physician-patient relationship, the court stated that a doctor had a duty to warn those “known to be at risk of avoidable harm from a genetically transmissible condition,”¹⁰⁵ and postured that there was no “essential difference” between protecting third parties from contagious disease or physical harm and protecting them from potential genetic disease.¹⁰⁶ In certain situations, “[t]he individual or group at risk is easily identified, and substantial future harm may be averted or minimized by a timely and effective warning.”¹⁰⁷ Notably, unlike the *Pate* court, the *Safer* court did not assert that a physician satisfies his duty to warn of avoidable risks by informing only the patient of the disease’s hereditary nature.¹⁰⁸ Rather, the court stated that duty to warn can be discharged, especially with respect to at-risk children, if reasonable steps are taken to assure those most likely to be affected are given the proper information.¹⁰⁹ Finally, while the court recognized that there was a potential conflict between its stated duty to warn and physician-patient confidentiality, it elected not to resolve that issue.¹¹⁰

2. Ethical Duty to Warn- The Importance of Maintaining Patient Confidentiality

The tension between physicians’ duty to warn third parties of genetic disease through familial risk and the duty to respect their patients’ confidentiality is a difficult conflict with ethical implications. Genetic test results may impact individuals and their families with

¹⁰⁴ *Safer*, A.2d at 11188.

¹⁰⁵ *Id.* at 1192.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 1193.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 1192.

¹¹⁰ *Id.* at 1192-93.

implications for obtaining insurance and employment and affect decisions pertaining to childbearing, diet, and physical activities.¹¹¹ Specifically, “genetic predestination” is a theory that may significantly alter the lives of those who learn the results of their genetic tests.¹¹² As genetic testing becomes more common and whole genome sequencing is able to reveal more accurate results about an individual’s health, physicians need maintain their primary obligations of promoting the best interests of their patients.¹¹³ However, physicians should also make best efforts to cooperate with the patient in informing at-risk family members or obtain consent to inform them.¹¹⁴

According to the National Human Genome Research Institute (NHGRI), due to the complexity of the decision about whether to be tested for genetic disease, it is recommended that those considering undergoing testing first consult with genetic counselors who are trained to “help individuals and families weigh the scientific, emotional, and ethical considerations” that may impact their decision.¹¹⁵ In fact, as the amount of genetic information resulting from the HGP and ENCODE increases, physicians may soon have the professional responsibility to ensure that their patients receive genetic counseling in appropriate cases.¹¹⁶ Physicians who offer genetics services may be expected to assess the risk of a genetic disorder by researching and evaluating family history and medical records, interpreting the results of genetic tests and medical data, and explaining possible treatments, preventive measures, and reproductive options.¹¹⁷ In addition, they may need to weigh the medical, social, and ethical decisions

¹¹¹ *Safer*, A.2d at 1192.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ NHGRI, *supra* note 22.

¹¹⁶ Jeri E. Reutenauer, *Medical Malpractice Liability in the Era of Genetic Susceptibility Testing*, 19 QUINNIPIAC L. REV. 539, 549 (2000).

¹¹⁷ NHGRI, *supra* note 22.

surrounding genetic testing, provide support and information relevant to the decision, counsel or refer individuals and their families to support services, and serve as patient advocates.¹¹⁸ As physicians who perform genetic tests are faced with rising standards of care, they must carefully consider their ethical obligations to their patients, patients' families, and society as a whole.

Significant bioethical concerns, such as the duty to preserve confidentiality of medical information, will emerge as genetic testing becomes more predictive. This duty, which is rooted in respect for the patient's autonomy, dictates that physicians must maintain the confidentiality of their patients' genetic information and abide by best-practices to avoid potentially unauthorized or inappropriate disclosure of patients' genetic data.¹¹⁹ Patients may not want to share results with family members for fear of backlash or concern, and this should be taken into account even when potential of risk to family members is high.

The duty to warn, which is based the principles of beneficence and nonmaleficence, supports the disclosure of relevant genetic information to family members who might be affected.¹²⁰ The principle of justice recommends that family members have the right to the same access to testing and options to reduce risk as patients who receive tests.¹²¹ Disclosure of genetic test results may greatly benefit family members by giving them necessary access to surveillance and preventative therapies that could reduce the risk of developing the disease.¹²² Nondisclosure may actually harm at-risk relatives who might develop the familial condition without their knowledge.¹²³ In addition, delayed diagnosis could limit treatment options and curability.

Professional associations, such as the AMA, have recognized that while physicians must protect

¹¹⁸ NHGRI, *supra* note 22.

¹¹⁹ *Id.*

¹²⁰ Heinemann, *supra* note 65.

¹²¹ *Id.*

¹²² *Id.*

¹²³ Laberge, *supra* note 81.

the confidentiality of patient disclosures and information, “countervailing societal interests” may justify the breach of confidentiality.¹²⁴ Disclosure may be justified particularly when the at-risk relative is identifiable, the genetic disorder is highly likely to be present, the disorder is treatable or preventable, and medically accepted standards indicate that early monitoring will reduce the genetic risk.¹²⁵ Under all circumstances, the harm that would result from failure to disclose should outweigh the harm that may result from the disclosure.¹²⁶

The reasons for this ethical position are significant. First, the physicians’ duty to protect patient confidentiality, especially with respect to highly sensitive health conditions, is stronger than the duty to warn family members with whom no physician-patient relationship has been established.¹²⁷ Although third parties may stand to benefit from being informed of their relatives’ genetic test results, the development of whole genome sequencing and increased genetic testing supports an emphasis on respect for patient autonomy. Namely, disclosure to third parties without the patient’s consent should only be recommended in exceptional situations where it is the last resort.¹²⁸ As genetic testing becomes more common among the patient population, it is less likely that relatives will be harmed by the failure of their relatives’ physician to warn them of possible risk, making it less crucial for that physician to extend the duty to warn.

Ideally, individuals should be able to have complete control their genetic information and its dissemination. To this end, physicians should strive to work with patients to obtain informed

¹²⁴AMA, *Principles of Medical Ethics, Preamble Part IV* (June 17, 2001), <http://www.ama-assn.org/ama/pub/category/2512.html>.

¹²⁵Lori B. Andrews, *Assessing Genetic Risks: Implications for Health and Social Policy*, The National Academies Press (April 1, 1994), (Specifically, it allows confidentiality to be breached when: (1) attempts to elicit voluntary disclosure fail; (2) there is a high probability of irreversible or fatal harm to the relative; (3) the disclosure of the information will prevent harm; (4) the disclosure is limited to the information necessary for diagnosis or treatment of the relative; and (5) there is no other reasonable way to avert the harm).

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

consent and to cooperate in the responsible disclosure of test results to family members. Thus, it will be crucial to thoroughly counsel patients about the possible consequences of genetic testing, its limitations, implications for family members, and the right to protect the confidentiality of the information prior to undergoing genetic testing. The patient's response to pre-test counseling and willingness to include family members in the testing progress should alert health care providers to potential communication problems within the patient's family.

On the other hand, decisions to disclose to at-risk family members must also consider respect for the autonomy of those family members and the "right not to know" about a relative's genetic information.¹²⁹ There are a number of potentially negative implications from sharing genetic test results with at-risk relatives. In addition to possible discrimination, the disclosure that one is genetically predisposed to or a carrier for a disease may cause devastating psychological and emotional damage.¹³⁰ This may be particularly true for condition such as Huntington's disease, when there is no cure for the disease and its onset is a virtual certainty.¹³¹ Testing may also cause familial division if some members protest the test itself because they do not want to open an investigation into the family's genetic reality.¹³² For these reasons, health care providers should not inform at-risk relatives of a patient's genetic test results without first determining whether the relative would like to learn the information.¹³³ However, an exception may be made when the patient is a minor and the potentially at-risk relatives are the child's biological parents, because the parents may need this information to make informed decisions

¹²⁹Susan M. Denbo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to A Patient's Biological Relatives?*, 43 AM. BUS. L.J. 561, 597 (2006).

¹³⁰ Stewart A. Laidlaw et al., *Genetic Testing and Human Subjects in Research*, 24 WHITTIER L. REV. 454, 460 (2002).

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

about their child's medical care and it may help parents make informed reproductive decisions.¹³⁴

Finally, when considering the duty to warn, physicians must assess the accuracy of the genetic test in question and avoid using tests that have not been evaluated for safety and effectiveness. Even if the genetic test generally provides accurate results for single-gene disorders, it might have significantly weaker predictive power for multifactorial disorders.¹³⁵ Heart disease, diabetes, most cancers, and Alzheimer's disease are examples of multifactorial disorders whose mutations often do not guarantee the onset of disease because they result from the interaction of multiple genes and environmental factors.¹³⁶ The discoveries from ENCODE, and further knowledge about genetic switches, will likely shed light on the development of multifactorial disorders and hopefully increase the accuracy of predictive tests. Increasing accuracy may be able to provide at-risk relatives with clinically relevant information and enable them to take meaningful action to avoid future harm.

The increase in the amount of genetic information available has led to the call for, and adoption of, new legislation on both state and federal levels to protect the confidentiality of genetic information and prevent discrimination based on genetic information in employment and health insurance contexts.¹³⁷ However, there is no legislation that specifically speaks to the duty of health care providers to disclose genetic information about their patients to the relatives of

¹³⁴ Denbo, *supra* note 129 at 597.

¹³⁵ NHGRI, *supra* note 22.

¹³⁶ *Id.*

¹³⁷ Forty-one states have enacted laws regulating genetic discrimination in health insurance and thirty-one states have enacted legislation addressing genetic discrimination in the workplace. For a searchable database of the federal and state laws pertaining to “privacy of genetic information/confidentiality; informed consent; insurance and employment discrimination; genetic testing and counseling; and commercialization and patenting,” see NHGRI, Policy and Legis. Database, www.genome.gov/PolicyEthics/LegDatabase/pubsearch.cfm.

those patients.¹³⁸ There is a need to enact a consistent floor of privacy protections covering whole genome sequence data and to prohibit unauthorized whole genome sequencing without full informed consent. In addition to preserving patient privacy and confidentiality, many other steps need to be taken in order to ensure that the medical field is able to progress by allowing genetic testing and whole genome sequencing to fully advance. Until legislatures establish clear guidelines regarding a physician's duty to warn relatives of their possible genetic risk, physicians may benefit from increased education and the creation of policies and guidelines in a professional code of conduct that recognizes current advancements in genetics medicine.

IV. RECOMMENDATIONS: INCREASED EDUCATION AND UNIFORM STANDARDS

Newly emerging genetic discoveries and testing techniques such as whole genome sequencing are likely to be accompanied by an onslaught of litigation previously unseen by physicians and courts. Presently, the majority of physicians is not adequately trained and educated about advancements in genetic research and may be unaware of legal consequences. Currently, no state or federal laws exist to address whole genome sequence data comprehensively, while specific laws designed to protect genetic information in general typically address where the data is collected and by whom, but may or may not offer protection.¹³⁹ In order to assist the medical community to adopt these valuable new resources, as well as to provide courts with a suggested standard of care, it will be important to incentivize increased genetics education and a set of uniform medical practice guidelines.

1. Increased Education

¹³⁸ L.J. Deftos, *Genomic Torts: The Law of the Future--The Duty of Physicians to Disclose the Presence of a Genetic Disease to the Relatives of Their Patients with the Disease*, 32 U.S.F. L. REV. 105, 131 (1997).

¹³⁹ Presidential Commission for the Study of Bioethical Issues, *Privacy and Progress in Whole Genome Sequencing* (Oct. 1, 2012), <http://bioethics.gov/cms/sites/default/files/PrivacyProgress508.pdf>.

In order to adapt to the changing field of medicine and for patients to benefit from scientific advancements, physicians will need to become better educated and trained in the field of genetic testing. Currently, primary care physicians are not adequately prepared to assume responsibility for their patients' genetic services. For example, in a survey of 124 primary care physicians, twenty percent were unaware that a predisposition to breast cancer could be determined by a genetic test.¹⁴⁰ Another survey about primary care physicians' knowledge about genetic testing for colon cancer found that the physicians' incorrect interpretation of the test results would have led them to provide their patients with inaccurate information in 31.6% of the cases.¹⁴¹ These studies demonstrate what may happen as genetic tests become available for public use before physicians are properly trained in when and how to use them. If physicians have the duty to disclose genetic information to their patients, they will either have to undertake the testing themselves or refer to experts who can.¹⁴² Thus, it is clear that physicians need to become more familiar with the capabilities of genetic testing to advise their patients or risks or to refer them for genetics services.

In order to assure that physicians receive adequate education and training, it will be crucial for more genetics teaching to be included in medical schools, residency programs, and medical board exams. It may be beneficial for physicians to obtain certifications to require demonstration of sufficient knowledge in genetics prior to providing genetically based health care. Hospitals and health management organizations should require competence in the field of genetics a prerequisite to allowing them to provide genetic counseling or testing. Particularly in the context of managed care systems, primary care physicians occupy roles as the “gatekeepers”

¹⁴⁰ Neil A. Holtzman & Michael S. Watson, National Human Genome Research Institute, *Promoting Safe and Effective Genetic Testing in the United States: Final Report of the Task Force on Genetic Testing* (Sept. 1997), <http://www.genome.gov/10001733>.

¹⁴¹ *Id.*

¹⁴² Ian Hoffman, *Experts Discuss Dilemmas in Genetic Testing*, Albuquerque J., July 26, 1997, at 1.

of their patients' medical care and may be increasingly called on to interpret genetic test results for their patients.¹⁴³ Moreover, as science reveals more about the origins of multifactorial disorders, the number of individuals potentially at risk for the development of these disorders will increase, and initial genetic risk assessments may become an expected standard in primary care medicine.¹⁴⁴ Thus, there must be increased efforts to promote health professional education and access to information about advancements in genetics medicine. Although transitioning into this new realm will be challenging, new methods of genetic testing through early detection, prevention, and treatment, will benefit doctors, patients, and the health care of the nation.

2. *Professional Guidelines*

As new advancements in genetics are made, medical and legal communities must recognize their responsibilities to inform themselves of current developments and to create appropriate standards so that patients receive quality care. This may be accomplished by the creation of a regularly updated set of professional guidelines that may be used to guide enforcement to maintain the integrity of genetic testing. These guidelines should survey the current state of how physicians are using genetic testing in clinical practice and provide anticipatory recommendations on how to incorporate new techniques.

Promulgated guidelines should include what specific genetic tests should be designated as the “standard of care” and under what circumstances.¹⁴⁵ For instance, the American Society of Clinical Oncology has already promulgated guidelines recognizing that cancer specialists may not currently be fully informed of the range of issues that are involved in genetic testing for

¹⁴³ Barbara A. Noah, *The Managed Care Dilemma: Can Theories of Tort Liability Adapt to the Realities of Cost Containment?*, 48 MERCER L. REV. 1219, 1225 (1997).

¹⁴⁴ Michael J. Malinowski & Robin J.R. Blatt, *Commercialization of Genetic Testing Services: The FDA, Market Forces, and Biological Tarot Cards*, 71 TUL. L. REV. 1211, 1245-46 (1997)

¹⁴⁵ See Statement of the American Society of Clinical Oncology, *Genetic Testing for Cancer Susceptibility*, 14 J. CLINICAL ONCOLOGY 1730 (1996) [hereinafter Statement of the American Society of Clinical Oncology].

cancer risk.¹⁴⁶ Medical professionals, especially those who work in genetic specialties, need to publish similar established standards of care.¹⁴⁷ The development of practice guidelines and protocols for testing will help physicians by providing a reference for the changing standard of care and serve as strategies for patient management and clinical decision making.

In addition to helping physicians with decision making in patient care management, courts may benefit from having these practice guidelines in malpractice litigation as a reference to the current standard of care. The U.S. tort system may allow compliance or noncompliance with these guidelines to support malpractice claims or defenses. This will help promote efficiency and uniformity and reduce wasteful litigation that may deter physicians from incorporating genetic counseling and testing into their practices. These guidelines may also be used for patient education and could possibly lower the risk of physician liability by resolving ambiguity as to the governing standard. Genetic malpractice actions may force physicians either to overuse genetic diagnostic testing to defend against genetic malpractice suits or to avoid genetic services altogether by making blanket referrals.¹⁴⁸ Without such policies and guidelines physicians may fear litigation and may not be able act responsibly, leaving courts with the burden of determining when a duty exists.

While new medical practice guidelines may increase physician sophistication and improve the quality of American health care, their promulgation will likely be met with some resistance from the medical community. Established guidelines will also not guarantee consistent results from courts. Compliance with medical practice guidelines does not assure that a court will find that a physician is not liable for malpractice. Rather, “[o]nce admitted into evidence, a practice guideline does not constitute a predetermined standard of care that a court is obligated to

¹⁴⁶ See Statement of the American Society of Clinical Oncology, *supra* note 145.

¹⁴⁷ Andrews, *supra* note 125.

¹⁴⁸ Reutenauer, *supra* note 116.

apply.”¹⁴⁹ From there, the court may consider other evidence regarding what the standard should be, and it may stray from the practice guidelines if it finds that other evidence about the standard is more persuasive.¹⁵⁰ Although medical practice guidelines may not definitely establish the standard of care, they will become a necessary resource for courts to work from and a valuable reference particularly if it is periodically updated to include significant new advancements.

3. Incorporation of Electronic Health Records

Finally, providers may also adopt and improve genetic testing practices by incorporating a system of “interoperable, clinically useful genetic laboratory test data and analytical tools into electronic health records to support clinical decisionmaking for the health care provider and the patient.”¹⁵¹ Electronic health records may support maximal benefits from genetic tests by tracking family history and provide an efficient means of delivering genetic test results. Although the Genetic Information Nondiscrimination Act (GINA) prohibits health insurers and employers to discriminate on the basis of genetic information, patients may still have privacy concerns about the incorporation of their genetic information in electronic health records. Thus, physicians should encourage their patients to undergo testing by fully explaining existing privacy protections and available remedies.

CONCLUSION

Whole genome sequencing and findings from ENCODE will make genetic testing more accurate and powerfully predictive. Increasing availability and enforced privacy protections will likely encourage more patients to undergo genetic testing. The ability to target and prevent diseases through personalized medicine will prove to be an invaluable tool that will benefit

¹⁴⁹ Edward B. Hirschfeld, Office of the General Counsel: *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886 (1991).

¹⁵⁰ *Id.*

¹⁵¹ Department of Health and Human Services, Health Information Technology, Personalized Health Care Workgroup (April 4, 2008), <http://www.hhs.gov/healthit/ahic/healthcare>.

physicians, patients, and the health care of the nation. Physicians liability for medical malpractice provides justice for harmed patients and may promote the advancement and proliferation of genetic testing. On the other hand, physician fear of frivolous lawsuits and the burden of acquiring a vast and unfamiliar body of knowledge may discourage physicians from engaging in these valuable new practices. In order to facilitate the growth of genetic testing capabilities, courts should provide relief to a plaintiff only when the physician failed to utilize appropriate care and demonstrated negligence.

In order to meet evolving standards of care, it is important for physicians who conduct genetic tests to obtain the necessary skills and training in pretest and posttest education.¹⁵² Clinicians who meet these qualifications must thoroughly discuss with patients the degree to which particular genetic risk factors correlate with the chance of developing the disease.¹⁵³ Further, physicians should clearly present the risks and benefits of available testing and inform patients of available genetic tests, including whole genome sequencing.¹⁵⁴ If physicians are unsure or unqualified of the services they are offering, they should be responsible for referring their patients for further discussion.¹⁵⁵ Clinicians should also be careful not to undertake testing until all the potential consequences of learning genetic information are thoroughly disclosed to the patient.¹⁵⁶ In this context, it will be important to discuss potential effects of the patient's well-being and that of family members; and the possibility of adverse use by employers, insurers, or other institutions.¹⁵⁷ Finally, if the patient's genetic information reveals a condition that may not be treated or prevented, physicians should be given the right to refrain from revealing the

¹⁵² American College of Physicians Ethics manual Sixth Edition (Oct. 2012), http://www.acponline.org/running_practice/ethics/manual/manual6th.htm#genetic-test.

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

information to individuals other than the patient. Under all circumstances, it will be essential that physicians receive appropriate training and education in genetics, and that patients who undergo testing receive comprehensive genetic counseling.

As physicians are positioned at the forefront of this new realm, they are the most qualified to establish the standard of care in genetic medicine. Thus, it will become imperative for physicians to establish professional guidelines that help courts to set the standard of care and serve as a reference in medical malpractices cases. Setting a baseline for the standard of care will foster the adoption of genetic medicine among physicians and allow courts to apply a uniform standard in medical malpractice cases. Once these standards of care have been established, the medical community must continue to establish and abide by these standards and remain abreast of current developments in genetics. With both the medical and legal communities better prepared for the obstacles that will accompany newly emerging genetic technologies, the genetic revolution can continue to make unprecedented breakthroughs in personalized care.