

BREACHING DOCTOR-PATIENT CONFIDENTIALITY: CONFUSION AMONG PHYSICIANS ABOUT INVOLUNTARY DISCLOSURE OF GENETIC INFORMATION

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I. INTRODUCTION

In the past, genetic tests were primarily used in the context of reproductive health care to determine whether patients would transfer a particular genetically communicable condition to their children.¹ Today, visits to the doctor routinely entail genetic tests that can predict patients' personal susceptibility to an increasing array of serious conditions.² Patients may discover that they are likely to develop a serious condition that will require invasive treatment and extensive monitoring. Some patients will discover that they have a devastating terminal illness such as Huntington's Disease.³ Other patients will discover that they have a higher risk of developing a certain condition, such as breast cancer, that has a higher likelihood of being treated successfully if detected early through

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1. Caryn Lerman et al., *Genetic Testing: Psychological Aspects and Implications*, 70 J. CONSULTING & CLINICAL PSYCHOL. 784, 784 (2002).

2. *Id.*

3. *Huntington's Disease Information Page*, NAT'L INST. NEUROL. DISORDERS & STROKE, <http://www.ninds.nih.gov/disorders/huntington/huntington.htm>, (last updated Aug. 13, 2010). Huntington's Disease ("HD") is a "familial" disease: each child of an HD parent has a fifty-fifty chance of inheriting the HD gene and a person who inherits the HD gene will develop the disease. *Id.* HD causes the "genetically programmed degeneration of brain cells This degeneration causes uncontrolled movements, loss of intellectual faculties, and emotional disturbance." *Id.* As the disease progresses, a patient may have difficulty feeding himself or herself and swallowing; currently, there is no way to stop or reverse the course of HD. *Id.*

careful screening and monitoring.⁴ In addition, because genetic tests reveal susceptibilities to certain conditions not only in the patient, but also in the patient's relatives, timely disclosure of test results to at-risk relatives may be a matter of life and death.⁵ However, patients may not permit disclosure of the genetic results to relatives because of a desire for privacy or estrangement from family members.⁶ In such a situation, the physician faces a difficult choice. This conflict between patient confidentiality and the duty to protect the health or life of a third party is the focus of this Note.

This dilemma can be approached in one of three ways: (1) the physician has no duty to at-risk relatives and therefore does nothing beyond treating the patient; (2) the physician has a duty to warn the patient about the risk to relatives but no duty to warn the relatives themselves; or (3) the physician has either an affirmative duty or mere discretion to warn relatives even when the patient refuses to do so.⁷ Part II of this Note discusses the ethical tradeoffs between these options and the ways in which the tradeoffs of genetic testing differ from those of traditional medical tests. Part III of this Note then summarizes the inconsistent and incomplete ways in which courts, professional medical associations, and state and federal laws currently address this issue, and presents evidence that physicians are confused by the legal framework. Part IV shows that the relevant federal legislation regulating the disclosure of medical information prevents health care providers from following the guidelines suggested in this Note. It then suggests an amendment to this legislation that will achieve a more nuanced balance between patient confidentiality and prevention of harm to third

4. *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, NATIONAL CANCER INSTITUTE, <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Feb. 13, 2012). Note that research suggests that “[a] woman’s risk of developing breast cancer and/or ovarian cancer is greatly increased if she inherits a deleterious (harmful) BRCA1 or BRCA2 mutation.” *Id.* See also, *Breast Cancer Tests: Screening, Diagnosis, and Monitoring*, BREASTCANCER.ORG, <http://www.breastcancer.org/symptoms/testing/types/> (last updated July 8, 2011); *Genetic Testing*, BREASTCANCER.ORG, <http://www.breastcancer.org/symptoms/testing/genetic/> (last updated July 8, 2011).

5. See *Breast Cancer Tests: Screening, Diagnosis, and Monitoring*, *supra* note 4.

6. U.S. 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 44 (1983) [hereinafter U.S. PRESIDENT’S COMM’N].

7. See Kenneth Offit et al., *The “Duty to Warn” a Patient’s Family Members About Hereditary Disease Risks*, 305 J. AM. MED. ASS’N 1469, 1469–72 (2004).

parties. Part V summarizes the arguments set forth in this Note, and addresses a potential future limit to the proposed amendment.

II. BALANCING CONFIDENTIALITY OF PATIENTS' GENETIC INFORMATION AND PROTECTION OF AT-RISK RELATIVES

A physician's professional duty to keep patients' medical information confidential is well established.⁸ Generally, physicians may not disclose any medical information—either revealed by a patient or discovered by a physician in connection with the treatment of a patient—unless a patient expressly consents or a law requires the disclosure.⁹ Most states, for instance, have laws requiring reporting of certain communicable diseases, such as HIV, to the state.¹⁰ The professional duty to maintain confidentiality is intended to encourage patients to seek medical treatment and to give “full and frank” disclosures to their physicians.¹¹ Patients are potentially more likely to be forthcoming with their physicians if their communications will be confidential.¹²

Despite the general duty of confidentiality, some situations require physicians to involuntarily disclose information to prevent harm to a third party. The “duty to warn” in a medical setting originated from the landmark 1976 case of *Tarasoff v. Regents of University of California*.¹³ *Tarasoff* departed from existing law by recognizing that doctors and psychotherapists have a legal duty to protect certain persons endangered by a foreseeable harm.¹⁴ In *Tarasoff*, Prosenjit Poddar killed Tatiana Tarasoff in 1969—two months after Poddar confided his intention to kill Tarasoff to

8. *Patient Confidentiality*, AM. MED. ASS'N, <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/patient-confidentiality.page> (last visited Feb. 26, 2012). The Hippocratic Oath, one of the earliest known sets of guidelines for physicians, addresses confidentiality: “Whatever I may see or learn about people in the course of my work or in my private life which should not be disclosed I will keep to myself and treat in complete confidence . . .” TONY HOPE, *MEDICAL ETHICS: A VERY SHORT INTRODUCTION* 90 (2004) (quoting the Hippocratic Oath).

9. *Patient Confidentiality*, *supra* note 8.

10. See LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 296 (rev. & expanded 2d ed. 2008). See *e.g.*, CAL. HEALTH & SAFETY CODE § 121022(a) (requiring health care providers and laboratories to report cases of HIV).

11. *Id.*

12. *Id.*

13. *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976); Offit et al., *supra* note 7, at 1470.

14. LINDA FARBER POST, JEFFREY BLUSTEIN & NANCY NEVELOFF DUBLER, *HANDBOOK FOR HEALTH CARE ETHICS COMMITTEES* 293 (2007).

his therapist.¹⁵ No one, including the therapist, warned Tarasoff or her family about Poddar's intentions.¹⁶ *Tarasoff* held that a therapist could be found liable for breaching a duty of reasonable care by failing to warn Tarasoff of the potential danger.¹⁷ This landmark decision substantially expanded the scope of the duty to protect third parties.¹⁸

As a result of *Tarasoff*, therapists are required to sacrifice their professional duty to keep patients' information confidential if it conflicts with the court-fashioned legal duty to a third party.¹⁹ *Tarasoff* balanced these two duties by concluding that the "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."²⁰

While *Tarasoff* marked a departure from contemporary law by creating a new duty to third parties, there was some precedent for breaching confidentiality to promote public health.²¹ For example, before *Tarasoff*, most states had existing laws requiring health care providers to report cases of certain communicable diseases to prevent the disease from spreading further.²²

15. *Tarasoff*, 551 P.2d at 339.

16. *Id.* at 340.

17. *Id.* at 348.

18. NEIL F. SHARPE & RONALD F. CARTER, GENETIC TESTING: CARE, CONSENT, AND LIABILITY 403 (2006). *Tarasoff* was superseded in 1985 by California Civil Code § 43.92, which results in potential liability for failure to warn for psychotherapists where "the patient has communicated to the psychotherapist a serious threat of physical violence against a reasonably identifiable victim." CAL. CIV. CODE § 43.92 (Deering 2010). The California Evidence Code defines "psychotherapist" broadly, including physicians working as psychiatrists, licensed psychologists, licensed clinical social workers, and licensed marriage and family therapists, among others. CAL. EVID. CODE § 1010 (Deering 2010).

19. KENNETH S. ABRAHAM, THE FORMS AND FUNCTIONS OF TORT LAW 238 (3d ed. 2007).

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

21. POST, BLUSTEIN & DUBLER, *supra* note 14.

22. *See id.*; Lawrence O. Gostin, Scott Burris & Zita Lazzarini, *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 63 (1999). One example of such a law is section 1603.1(c) of California Health and Safety Code, which provides: "A physician, hospital, or other health care provider shall report all AIDS cases, HIV infections, and viral hepatitis infections, including transfusion-associated cases or infections, to the local health officer with the information required, and within the timeframes established by the department." CAL. HEALTH & SAFETY CODE § 1603.1 (Deering 2010).

The California Supreme Court's holding in *Tarasoff* has led physicians to confront a somewhat similar problem in handling patients' genetic information.²³ A 2004 medical journal article used the following example to illustrate the problem: A forty-year-old woman with a family history of various conditions makes a routine visit to a physician.²⁴ During her first visit, the physician provides the woman with genetic testing.²⁵ Before testing, the physician discusses the potential importance of familial risk notification— notifying family members of any risks discovered from the tests.²⁶ At the patient's follow-up visit, the physician informs her that genetic tests showed that she had inherited the breast cancer 2 susceptibility protein ("BRCA2") gene, which considerably increases her risk of developing breast and ovarian cancer.²⁷ The physician is aware the patient has a sister, and therefore, the sister has a 50 percent chance of having inherited the same BRCA2 mutation.²⁸ Despite the physician's prior warning about the importance of familial risk notification, the patient declines the recommendation that she should share her genetic test results with her sister.²⁹ Instead, the patient requests that this information be kept confidential.³⁰ Does this physician have a legal or ethical obligation to tell the patient's sister that she may have inherited these genetic predispositions?³¹ If the physician does not warn the sister, and the sister later develops breast cancer, does the sister have a valid claim that the physician had an obligation to contact her about her genetic risk?³² This hypothetical illustrates a problem with the duty to warn doctrine in an era of genetic medicine: while a physician generally has a duty to keep a patient's information confidential, should genetic information ever be made available to third parties (such as at-risk relatives) in order to prevent future harm?³³ For physicians, the choices are: (1) they have no duty to at-risk relatives and can treat only their immediate patient; (2) they have a duty only to warn the patient about the risk to relatives; or (3) they have either

23. See SHARPE & CARTER, *supra* note 18, at 403.

24. Offit et al., *supra* note 7, at 1469–70.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.* at 1470.

32. *Id.*

33. See *id.* at 1469–70.

an affirmative duty or the discretion to warn relatives even when the patient refuses to do so.³⁴

A. GENETIC INFORMATION IS DIFFERENT FROM OTHER MEDICAL INFORMATION

A duty to warn in the context of genetic testing differs in key ways from *Tarasoff* and from statutes requiring physicians to report cases of communicable diseases to the state. In *Tarasoff*, the potential harm was the patient's threat of physical violence.³⁵ The court's reasoning implied that when the patient poses the risk, his or her confidentiality must be violated unless the patient can be controlled.³⁶ The reason for allowing a breach of confidentiality in the event of a communicable disease is similar: physicians can—and in many states are required to³⁷—disclose information necessary to prevent the spread of disease.³⁸ In both cases, the threat to public safety originates from the patient; releasing the patient into society without disclosure creates harm. In contrast, a patient who receives genetic information from tests does not pose a risk to the relative, instead “it is the disease gene and ignorance regarding carrier status that pose[s] a risk to the relative.”³⁹

While the source of the harm is distinct in situations with genetic test results as opposed to other medical test results, some of the considerations of disclosure may be similarly motivated. The physician's ability to disclose genetic information is based on the “likelihood of harm in failing to disclose, fairly consistently justifying disclosure for the protection of public health or another's life.”⁴⁰ Similarly, disclosure of genetic information to relatives can sometimes prevent or decrease harm if the information is actionable.⁴¹ Therefore, while the duty to warn in a genetic context is dissimilar in some ways from *Tarasoff* and communicable disease cases, if the rationale is based on preventing harm, as opposed to

34. *See id.* at 1469–72.

35. *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 339 (Cal. 1976).

36. Sonia M. Suter, Note, *Whose Genes Are These Anyway? Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1883 (1993).

37. GOSTIN, *supra* note 10.

38. *Id.* at 1873 (quoting *Simonsen v. Swenson*, 177 N.W. 831, 832 (Neb. 1920) (per curiam)).

39. *Id.* at 1883.

40. *Id.*

41. *Id.*

maintaining a personal right to confidentiality, then disclosure of genetic information can be justified when it “can prevent foreseeable and significant harm.”⁴²

There are other significant differences between genetic tests and traditional medical tests. The most important distinction is that unlike traditional medical tests for conditions such as high blood pressure or glaucoma, genetic tests inherently reveal information about not only the patient, but also about the patient’s biological relatives.⁴³ Genetic tests are different from other diagnostics tests because they provide the potential to predict a variety of susceptibilities to disease and “often indicate[] that other family members are at risk for the same condition.”⁴⁴

In addition, unlike traditional medical tests, genetic tests do not simply seek to diagnose the condition causing a patient ill health, but also predict what conditions the patient, and therefore the patient’s biological relatives, may develop. One such challenge is that “[m]any types of genetic tests may not clearly promote diagnosis, treatment, and cure. They may only provide information about a medical condition that is likely to occur at some time in the future.”⁴⁵ Genetic testing “may fail to predict how severe the medical condition may be, when it will occur, or even, due to reduced penetrance, that it will occur.”⁴⁶

Therefore, while genetic tests reveal risks to relatives, disclosing the results cannot always lead to prevention and effective treatment; many such genetic conditions can only be treated, but not cured. Huntington’s Disease is one such example; it is an incurable genetic condition likely to be passed to children.⁴⁷ However, many people who are at risk for Huntington’s opt not to get tested for the gene.⁴⁸ For those at risk, one benefit of not knowing about the Huntington’s gene is the hope that they do not have it.⁴⁹ After receiving a positive result, the inevitable onset of the disease can lead

42. *Id.*

43. Sara Taub et al., *Managing Familial Risk in Genetic Testing*, 8 GENETIC TESTING 356, 356 (2004).

44. Wylie Burke, *Genetic Testing*, 347 NEW ENG. J. MED. 1867, 1868 (2002).

45. SHARPE & CARTER, *supra* note 18, at 4.

46. *Id.* at 4–5.

47. *Huntington’s Disease Information Page*, *supra* note 3.

48. Huntington Study Group PHAROS Investigators, *At Risk for Huntington Disease*, 63 ARCH. NEUROL. 991, 991 (2006).

49. Amy Harmon, *Facing Life with a Lethal Gene*, N.Y. TIMES, Mar. 18, 2007, at 1.

to life-changing consequences.⁵⁰ This illustrates another difficulty with respect to genetic information: a “right not to know.”⁵¹ A physician may not know whether or not a patient’s relatives want to know the results of a genetic test, making a decision about disclosure to people further than the immediate patient very difficult. Beyond violating the privacy of the patient and the relative’s “right not to know,” disclosure can harm the health of the recipient: studies have shown that knowledge of a medical condition itself can lead to a deterioration of physical health, which is sometimes referred to as the “nocebo” effect.⁵²

Another potential difficulty posed by genetic tests is understanding where to draw the appropriate line for identifying potential relatives. For example, sperm donations are a common means to conceive children.⁵³ These children are at risk for inheriting genetic conditions from the donors.⁵⁴ Though donors are screened at the outset for specific, common testable conditions,⁵⁵ future breakthroughs will implicate genes unknown at the time of the donation. Many individuals donate on the condition that their identity will remain anonymous,⁵⁶ in which case it may be impossible to ever warn such at-risk relatives.

Despite how genetic testing differs from testing for traditional medical conditions, there is an argument that genetic information is not different from other types of confidential medical information. The key question is “whether genetic tests raise novel ethical issues, or whether simply that genetic tests themselves are novel” and therefore decisions about disclosing information related to these tests should be applied “consistently with other

50. *Id.*

51. See generally R. Adorno, *The Right Not to Know: An Autonomy Based Approach*, 30 J. MED. ETHICS 435 (2004).

52. *Id.* at 437; Robert A. Hahn, *The Nocebo Phenomenon: Concept, Evidence, and Implications for Public Health*, 26 PREV. MED., 607, 607 (1997).

53. Barry J. Maron et al., *Implications of Hypertrophic Cardiomyopathy Transmitted by Sperm Donation*, 302 J. AM. MED. ASS’N 1681, 1681 (2009).

54. *Id.*

55. See Kate Snow, *Sperm Donor Gives Rare Genetic Disease to Kids*, ABC NEWS, May 19, 2006, <http://abcnews.go.com/WNT/story?id=1982801&page=1>.

56. Lucy Frith, *Gamete Donation and Anonymity: The Ethical and Legal Debate*, 16 HUM. REPROD. 818, 819 (2001).

disclosures.”⁵⁷ Genetic make-up can be interpreted as one immutable trait, among others, that has always been used by medical professionals.⁵⁸

However, this Note argues that as a result of the many distinguishing characteristics of genetic tests, it is necessary to treat genetic tests differently from other medical tests in the context of the duty to warn. In addition, in 2008 Congress passed federal legislation aimed at preventing genetic discrimination, which this Note discusses in greater detail in Part III.C.⁵⁹ The legislation suggests that society has come to accept genetic information as sufficiently different from other private medical information, and thereby deserving of unique protection.

III. SOURCES OF CONFLICTING AUTHORITIES AND RESULTING CONFUSION

When faced with dilemmas about the duty to warn following genetic tests, physicians have several sources of authority to inform their decision. Unfortunately, these sources are incomplete and inconsistent. While there are a few relevant state cases that address the subject, these cases also come to contradictory results.⁶⁰ Similarly, the recommendations made by different professional medical associations are similarly inconsistent.⁶¹ Finally, state and federal laws that address genetic testing are concerned primarily with disclosures to employers and insurers, creating further difficulties for physicians attempting to apply laws to at-risk relatives.⁶²

A. CONFLICTING STATE CASE LAW

In the 1990s, two important state cases applied the duty to warn to situations involving genetic information. In 1995, in *Pate v. Threlkel* the Florida Supreme Court held that physicians treating patients with hereditary conditions owe a duty of care to at-risk relatives.⁶³ In *Pate*, a woman had received treatment for medullary thyroid carcinoma—a

57. Nick Raithatha & Richard D. Smith, *Disclosures of Genetic Tests for Health Insurance: Is It Ethical Not To?*, 363 LANCET 395, 395 (2004).

58. *Id.*

59. U.S. E.E.O.C., *Background Information for EEOC Final Rule on Title II of the Genetic Information Nondiscrimination Act of 2008*, <http://www.eeoc.gov/laws/regulations/gina-background.cfm>, (last visited Oct. 19, 2011) [hereinafter *GINA Background*].

60. *See infra* Part III.A.

61. *See infra* Part III.B.

62. *See infra* Part III.C.

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

genetically transferable disease.⁶⁴ Three years later, the woman's daughter learned that she also had medullary thyroid carcinoma and subsequently filed a complaint against her mother's physician.⁶⁵ The daughter alleged that the physician knew of the likelihood that her children would inherit the condition, and as a result, the physician had a duty to warn the patient—the plaintiff's mother—that her children should be treated for the disease as well.⁶⁶ The daughter argued that if the physician had warned her mother that her children were at risk to inherit the disease, her mother would have warned her.⁶⁷ The daughter argued that she would have taken preventative action as a result of the warning and her condition would likely have been curable.⁶⁸ While *Pate* found that the physician owed the daughter a duty of care, it held that “in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning *the patient*.”⁶⁹ Thus, the court did not impose a duty upon the doctor to locate and warn a third party.

In 1996, a New Jersey Appellate Court went a step further. In *Safer v. Estate of Pack*, the physician treated the plaintiff's father for multiple polyposis, a hereditary condition that leads to cancer if it is left untreated.⁷⁰ The plaintiff's father died when she was a child, and she never knew about her father's polyposis diagnosis.⁷¹ When the plaintiff was thirty-six years old, however, she was diagnosed with multiple polyposis and cancer.⁷² The plaintiff sued her father's physician after she obtained her father's medical records and learned that he had also suffered from polyposis.⁷³ She argued that the physician knew about the hereditary nature of the disease and was required to warn those at risk.⁷⁴ The court in *Safer* held that a physician has a duty to warn those known to be at risk of avoidable harm from a

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.* at 282 (emphasis added).

70. *Safer v. Estate of Pack*, 677 A.2d 1188, 1189–90 (N.J. Super. Ct. App. Div. 1996). See also *infra* text accompanying notes 162–163 (discussing multiple polyposis and genetic screening).

71. *Id.* at 1190.

72. *Id.*

73. *Id.*

74. *Id.*

genetically transmissible condition.⁷⁵ However, unlike in *Pate*, the court in *Safer* found that solely informing the patient would not automatically satisfy the physician's duty to warn.⁷⁶ The *Safer* court found that a physician must actually locate and warn the potentially-afflicted third party.⁷⁷

Finally, a third state case further expanded duty to warn in the situation of an at-risk relative. In 2004, in *Molloy v. Meier*, the Minnesota Supreme Court held that a physician's duty regarding genetic testing and diagnosis extends beyond the patient to biological parents who "foreseeably" may be harmed by a breach of that duty.⁷⁸ In *Molloy*, the patient was a child who "suffered from a serious disorder that had a high probability of being genetically transmitted and for which a reliable and accepted test was widely available."⁷⁹ The mother of the patient argued that she would not have conceived another child had she been warned of the risk of passing genetic disorders on to her children.⁸⁰ The court found that "[t]he standard of care thus acknowledges that families rely on physicians to communicate a diagnosis of the genetic disorder to the patient's family," and that it is foreseeable that a negligent diagnosis will cause harm to both the patient and the patient's family.⁸¹ The court in *Molloy* found that the physician had a duty to inform the child's mother so that the mother could make fully informed choices about conceiving additional children in light of the children's heightened risk of inheriting a serious disorder.⁸² Those opposed to the decision argue that the ruling "broadens the definition of who is considered the patient in cases involving genetic diseases."⁸³ As a result, doctors face a greatly expanded situation of liability. *Molloy* is another indication that physicians owe a duty not only to the patient, but also to biological relatives who would benefit from genetic disclosure.

75. *Id.* at 1192.

76. *Id.* at 1192-93.

77. *Id.*

78. *Molloy v. Meier*, 679 N.W.2d 711, 719 (Minn. 2004).

79. *Id.*

80. *Id.* at 715.

81. *Id.* at 719.

82. *See id.* at 719.

83. *Genetic Testing Challenges Doctor-Patient Confidentiality*, MSNBC.COM, Sept. 21, 2004, <http://www.msnbc.msn.com/id/6065956/ns/health-genetics>.

B. CONFLICTING RECOMMENDATIONS AND GUIDELINES FROM
PROFESSIONAL MEDICAL ASSOCIATIONS

A number of professional medical associations have also considered this issue and provided recommendations for physicians. For example, the American Medical Association (“AMA”) addresses this issue in their Code of Medical Ethics.⁸⁴

In *Opinion 2.131—Disclosure of Familial Risk in Genetic Testing*, the AMA advises that “[p]hysicians have a professional duty to protect the confidentiality of their patients’ information, including genetic information.”⁸⁵ However, the opinion also found that:

Pre- and post-test counseling must include implications of genetic information for patients’ biological relatives. At the time patients are considering undergoing genetic testing, physicians should discuss with them whether to invite family members to participate in the testing process. Physicians also should identify circumstances under which they would expect patients to notify biological relatives of the availability of information related to risk of disease.⁸⁶

While these guidelines recommend that physicians discuss potential familial consequences with patients undergoing testing (both before and after the test), the guidelines are silent on the subject of whether a physician has the duty or freedom to warn at-risk relatives if the patient does not do so.⁸⁷

In 2003, the American Society of Clinical Oncology (“ASCO”) issued a policy statement update, entitled *Genetic Testing for Cancer Susceptibility*, which concluded that in cases where genetic testing reveals a marker of increased cancer risk for a family, “current case law is underdeveloped and not uniform regarding a physician’s ‘duty to warn’ family members not cared for by that physician.”⁸⁸ ASCO also considered the federal privacy regulations that allow for a breach of confidentiality in

84. See Am. Med. Ass’n, *AMA Code of Ethics: Opinion 2.131—Disclosure of Familial Risk in Genetic Testing* (Dec. 2008), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2131.shtml> [hereinafter AMA, *Opinion 2.131*].

85. *Id.*

86. *Id.*

87. See *id.*

88. Am. Soc’y of Clinical Oncology, *American Society of Clinical Oncology Policy Statement Update: Genetic Testing for Cancer Susceptibility*, 21 J. CLINICAL ONCOL. 2397, 2403 (2003) [hereinafter ASCO, *Policy Statement*].

cases in which it is “necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.”⁸⁹ ASCO observed that even in cases in which there is a high cancer risk, the “maximal (mendelian) probability for a relative to inherit this susceptibility is 50%.”⁹⁰ As a result, ASCO concluded that genetic syndromes of cancer predisposition do not justify a breach of confidentiality under current federal requirements because there is no imminent threat of harm.⁹¹ ASCO also pointed to the conflict between federal and state laws, noting that some states, such as New York, Illinois, and Massachusetts, “prohibit communication of genetic information to anyone without the permission of the person tested.”⁹² Given these discrepancies, ASCO ultimately found that if a physician does have any obligation to at-risk relatives, then these obligations are “best fulfilled by communication of familial risk to the person undergoing testing, emphasizing the importance of sharing this information with family members so that they may also benefit.”⁹³ In contrast to the AMA’s silence as to whether physicians are allowed or obligated to warn at-risk relatives about genetic information, ASCO concludes that genetic risk does not justify a breach of confidentiality by physicians, so physicians are not able to warn at-risk relatives about genetic risk.⁹⁴

Coming to yet another conclusion, in 1998, the American Society of Human Genetics (“ASHG”) prepared a report entitled *Professional Disclosure of Familial Genetic Information*, which focused on the conflict that arises when patients refuse to warn at-risk relatives about relevant genetic information.⁹⁵ The report found that since genetic information is medical information, “albeit with special concerns and implications,” the legal and ethical norm of patient confidentiality should be respected.⁹⁶ ASHG concluded that a physician “may have a privilege to warn at-risk

89. *Id.* (quoting Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 5, 8, 10, 18, 22, 25, 29, 31, 38 & 42 U.S.C.)).

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. Am. Soc’y of Human Genetics Social Issues Subcommittee on Familial Disclosure, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENETICS 474 (1998).

96. *Id.* at 474.

relatives if the harm is serious, imminent, and likely; if prevention or treatment is available; and if the health-care professional, if she or he were in similar circumstances would disclose.”⁹⁷ The report does not elaborate on the circular argument it uses to recommend that a health care professional should disclose where “the health-care professional, if she or he were in similar circumstances, would disclose.”⁹⁸ The report also found that the term “serious” defies an exact definition, and must be determined on a case-by-case basis.⁹⁹ Finally, the report concluded, “[a]t the very least, it is clear that a health-care professional has a positive duty to inform a patient about potential genetic risks to the patient’s relatives.”¹⁰⁰

There are significant differences in the conclusions of state courts and professional medical associations. None of the professional medical associations discussed above impose a duty for physicians to disclose a patient’s genetic information to warn at-risk relatives.¹⁰¹ In contrast, *Safer* states that physicians have a duty to warn at-risk relatives about genetic risk.¹⁰² In addition, at least one association, ASCO, concluded that based on federal privacy regulations, and the uncertainty involved with genetic information, it is never appropriate for physicians to breach confidentiality to warn at-risk relatives.¹⁰³ The only area where the state courts and the professional medical associations agree is that physicians should always inform the patient about the risk to their relatives.

C. CONFLICTING STATE LAWS AIMED AT PREVENTING GENETIC DISCRIMINATION AND THE RESULTING FEDERAL GENETIC INFORMATION NON-DISCRIMINATION ACT

State case law and medical association recommendations are not the only sources of conflicting authority for physicians. Many states have enacted laws specifically governing the disclosure of genetic information.¹⁰⁴ However, the purpose of many of these statutes is to

97. *Id.* at 482.

98. *Id.*

99. *Id.*

100. *Id.*

101. For additional discussion of the differing positions of professional medical societies, see Gregory Katz & Stuart O. Schweitzer, *Implications of Genetic Testing for Health Policy*, 10 *YALE J. HEALTH POL’Y L. & ETHICS* 90, 101–02 (2010).

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

103. ASCO, *Policy Statement*, *supra* note 88.

104. See *Genetic Privacy Laws*, NAT’L CONF. OF STATE LEGS., <http://www.ncsl.org/IssuesResearch/Health/GeneticPrivacyLaws/tabid/14287/Default.aspx>

prevent genetic discrimination by employers or insurance companies.¹⁰⁵ The advancement of genetic technology has spawned fears that the results of a patient's genetic test could be broadly disclosed, resulting in discrimination against the patient.¹⁰⁶ For example, a genetic test predicting the probability of developing a debilitating medical condition creates a clear incentive for discrimination by health insurance companies or employers.¹⁰⁷ Fear of potential genetic discrimination can also harm medical research and public health care.¹⁰⁸ "People may be unwilling to participate in research and to share information about their genetic status with their health care providers or family members"¹⁰⁹ because they fear that this information will be misused. In response to these concerns, and with the increased availability of individual genetic tests, nearly every state enacted laws with the purpose of preventing genetic discrimination in the 1990s and 2000s.¹¹⁰

These various state statutes do not provide adequate guidance for physicians deciding whether or not to warn at-risk relatives because the statutes were written to address the entirely different problem of genetic discrimination. As a result these state laws are not helpful for physicians looking for guidance, and may even complicate matters further. For example, in California, a state law governs the disclosure of genetic test results requested by an insurer.¹¹¹ Section 10149.1(c) of the California Insurance Code provides:

Any person who willfully discloses the results of a test for a genetic characteristic to any third party, in a manner which identifies or provides identifying characteristics of the person to whom the test results apply, except pursuant to a written authorization . . . or except as provided in this

(last updated Jan. 2008); NANCY LEE JONES & AMANDA K. SARATA, CONG. RESEARCH SERV., RL 30006, GENETIC INFORMATION: LEGAL ISSUES RELATING TO DISCRIMINATION AND PRIVACY 20–21 (2008), available at http://assets.opencrs.com/rpts/RL30006_20080310.pdf.

105. Jeffrey S. Morrow, Note: *Insuring Fairness: The Popular Creation of Genetic Antidiscrimination*, 98 GEO. L. J. 215, 220 (2009).

106. Kathy L. Hudson et al. *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 279 SCIENCE 391, 392 (1995).

107. Morrow, *supra* note 105, at 218–19.

108. Hudson et al., *supra* note 106, at 391.

109. *Id.*

110. Morrow, *supra* note 105, at 220 ("[F]orty-seven states enact[ed] some form of statutes identifying genetic information for explicit protection in health insurance contexts.").

111. CAL. INS. CODE § 10149.1(a) (Deering 2010).

article or in Sections 1603.1 and 1603.3 of the Health and Safety Code, shall be assessed a civil penalty in an amount not less than one thousand dollars (\$1,000) and no more than five thousand dollars (\$5,000) plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.¹¹²

Because this section of the California Code applies only to genetic tests requested by an insurer, it does not provide guidance for physicians contemplating disclosure to another individual (a relative) without patient authorization. In contrast to California's approach, New York state law prohibits any disclosure of genetic information without a patient's express consent, even if disclosure is made only to a relative:¹¹³

All records, findings and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test.¹¹⁴

While many state statutes are silent about whether disclosure to other individuals, including relatives, is allowed,¹¹⁵ others, like the New York statute, may be over-protective, and do not afford physicians the option of warning relatives about genetic risk.¹¹⁶

Congress also responded to fears of genetic discrimination by enacting federal legislation.¹¹⁷ The Genetic Information Nondiscrimination Act ("GINA") became law on May 21, 2008.¹¹⁸ GINA prohibits employers from considering genetic information in hiring, employment, or termination,¹¹⁹ and prohibits insurers from using genetic information for group or individual insurance.¹²⁰ GINA's definition of "genetic information" includes information about an individual's or family

112. *Id.* § 10149.1(c).

113. N.Y. CIV. RIGHTS LAW § 79-1 1.(a) (Consol. 2011).

114. *Id.* § 79-1 3.(a).

115. *See* CAL. INS. CODE § 10149.1(c).

116. N.Y. CIV. RIGHTS LAW § 79-1.

117. *GINA Background*, *supra* note 59.

118. Genetic Information Nondiscrimination Act (GINA) of 2008, Pub. L. No. 110-233 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.). *See also* Morrow, *supra* note 105, at 220 ("[T]he Genetic Information Nondiscrimination Act . . . passed both houses of Congress with near unanimity, receiving only one negative vote in the House of Representatives.").

119. 42 U.S.C. § 2000ff. *See also* Morrow, *supra* note 105, at 221.

120. *Id.* § 300gg-53. *See also* Morrow, *supra* note 105, at 221.

member's genetic tests, family medical history, requests for and receipt of genetic services by an individual or a family member, and genetic information about a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology.¹²¹ Under GINA, "genetic information is given full Title VII civil rights protection, alongside race, sex, religion, age, and disability."¹²²

In addition to banning genetic discrimination, GINA aims to promote clinical research and health care delivery.¹²³ Fear of genetic discrimination discourages patients from having genetic test results in their medical records and dissuades patients from taking genetic tests recommended by their health care providers.¹²⁴ Similar fears deter patients from participating in research involving genetic tests. The protections offered by GINA should go far in dispelling such concerns.

However, GINA, like the state genetic information statutes, uses language that is not helpful for physicians attempting to determine whether they have an ability or obligation to warn relatives about genetic risk. In fact, GINA's passage may have come at a price: "[T]he focus on potential genetic discrimination by insurers and employers has come at the cost of other important issues in genetics . . . [N]either medical mal-practice law nor the law of confidentiality (privacy and disclosure laws) are particularly well-suited to the arena of genetics."¹²⁵

D. THE CONFLICTING SOURCES OF AUTHORITY RESULT IN CONFUSION FOR PHYSICIANS ABOUT DUTIES TO THIRD PARTIES WITH RESPECT TO A RELATED PATIENT'S GENETIC INFORMATION

The numerous yet conflicting sources of authority pose a problem for physicians: "The current absence of legal guidance in many areas of potential liability has created roadblocks to effective education and

121. *GINA Background*, *supra* note 59.

122. *Morrow*, *supra* note 105, at 221.

123. Kathy L. Hudson, M.K. Holohan & Francis S. Collins, *Keeping Pace with the Times—The Genetic Information Nondiscrimination Act of 2008*, 358 *NEW ENG. J. MED.* 2661, 2663 (2008) ("Studies have shown the 'fear factor' to be a major obstacle to patient's participation in research studies that involve the collection of genetic information.").

124. *Id.*

125. Lee Black, Jacques Simard & Bartha Maria Knoppers, *Genetic Testing, Physicians and the Law: Will the Tortoise Ever Catch up with the Hare?*, 19 *ANNALS HEALTH L.* 115, 120 (2010).

communication . . . between health professionals and patients.”¹²⁶ The discrepancies in state case law, professional association recommendations, and genetic information antidiscrimination statutes, coupled with uncertainty about whether the inexact probability of a future genetic disease constitutes an imminent threat to a person or the public, have led to confusion over when it is appropriate for physicians to breach confidentiality.¹²⁷

Physicians are confused about what actions, if any, are permissible or required for warning relatives about genetic risk. In 2003, a survey of medical geneticist members of ASHG and the American College of Medical Genetics (“ACMG”) showed that “over two thirds of the surveyed geneticists considered themselves to be responsible for warning the relatives of their patients when discovered to be at-risk for a genetic disease.”¹²⁸ One quarter of the geneticists surveyed reported considering disclosing information to at-risk relatives without patient consent in situations where the patient refused to notify family members.¹²⁹ Additionally, the survey reported:

Upon inquiry into their knowledge of pertaining laws, published recommendations, and institutional guidelines, 66% (146/206) of respondents incorrectly believed federal or state laws exist which regulate disclosure of patient information to at-risk relatives for genetic disease. Similarly, only 38% (78/206) correctly indicated their knowledge of ASHG guidelines, and almost one-third (29%, 60/206) falsely believed the ACMG to have published similar guidelines. Finally, 16% (35/206) had been informed about their institutional policy, which was almost universally described as “impermissible to disclose any patient’s genetic information without patient consent”¹³⁰

In addition to ambiguity about when, if ever, it is appropriate to override a patient’s wishes and breach confidentiality to warn an at-risk relative, physicians also face administrative confusion. In a recent article about genetics and ethical issues, Kenneth Offit, Chief of the Clinical Genetics Service at Memorial Sloan-Kettering Cancer Center, discussed his experience with a breast cancer patient who died before learning about a

126. *Id.*

127. ASCO, *Policy Statement*, *supra* note 88.

128. Katz & Schweitzer, *supra* note 101, at 101.

129. *Id.*

130. Marni J. Falk et al., *Medical Geneticists’ Duty to Warn At-Risk Relatives for Genetic Disease*, 120A AM. J. MED. GENETICS 374, 376 (2003).

genetic mutation linked to her cancer.¹³¹ Since the deceased patient could not inform her own family members about the genetic risk, her physicians felt they needed to tell the patient's daughters about their risk of possessing the mutation.¹³² In an attempt to locate the daughters, Offit contacted the deceased patient's mother about contacting her granddaughters.¹³³ The deceased patient's mother was uncooperative so the granddaughters remained ignorant of their risk until they found a copy of Offit's letter years later after their grandmother had died.¹³⁴ They came to Offit's clinic and "[o]ne daughter tested positive for the mutation and began regular screening."¹³⁵ When Offit offered this story to a group of attorneys as an example of "how he had tried to fulfill his duty to warn," many of the attorneys criticized him for not trying harder to find the daughters.¹³⁶

Physicians' confusion about what they are legally obligated and allowed to do also has led to concerns about physician liability. In 2004, a member of the AMA's Council on Ethical and Judicial Affairs, Dr. Robert Sade, stated, "The frightening aspect . . . is that physicians can be sued whether they do or they don't inform relatives."¹³⁷

IV. ADDRESSING THE BARRIERS TO ACHIEVING A TARGET BALANCE BETWEEN CONFIDENTIALITY AND WARNING AT-RISK RELATIVES

Parts I–III of this Note discussed the general conflict between protecting patient confidentiality and preventing harm to biological relatives in the context of genetic information. Part II discussed the unique characteristics of genetic information in the context of the duty to warn, and concluded that in light of these characteristics, genetic information is different from other types of confidential medical information. Given this conclusion, the documented conflicting authorities, and the resulting confusion discussed in Part III of this Note, the following section turns to

131. Ann Marie Menting, *Dilemmas of Destiny*, HARV. MED. (Autumn 2010), available at <http://harvardmedicine.hms.harvard.edu/magazine/autumn2010/dilemmas.php>.

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.* One lawyer felt that Offit should have hired a private detective and another lawyer said she "would have offered to represent the daughters should they have developed breast cancer before they were notified and elected to sue." *Id.*

137. *Genetic Testing Challenges Doctor-Patient Confidentiality*, *supra* note 83.

current privacy regulations that are relevant to the disclosure of medical information. These regulations stand in the way of achieving a consistent balance between maintaining a patient's confidentiality over genetic information and the ability of physicians to protect third-party at-risk relatives in situations where genetic information may prevent or lessen serious harm. These regulations also do little to alleviate confusion among physicians.

A. FEDERAL REGULATIONS ON THE DISCLOSURE OF MEDICAL INFORMATION

Health care providers, both individual and institutional, are governed by the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule.¹³⁸ The Privacy Rule ("PR") set national standards for the protection of individually identifiable health information.¹³⁹ One of the main goals of the PR was to define and limit the circumstances in which an individual's protected health information may be used or disclosed by health care providers.¹⁴⁰ Noncompliance with this rule can result in civil or criminal penalties for physicians.¹⁴¹ While the rule generally prohibits disclosure, it allows for unauthorized disclosure of a patient's confidential health information for certain "Public Interest and Benefit Activities,"¹⁴² which include disclosures required by law and disclosures that fall under the "Serious Threat to Health or Safety" exception.¹⁴³ This exception provides that physicians "*may* disclose protected health information that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat."¹⁴⁴

138. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191 (codified as amended in scattered sections of 5, 8, 10, 18, 22, 25, 29, 31, 38 & 42 U.S.C.). See also U.S. DEP'T OF HEALTH & HUMAN SERVS., SUMMARY OF THE HIPAA PRIVACY RULE 2 (2003), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

139. *HIPAA Administrative Simplification Statute and Rules*, U.S. DEP'T HEALTH & HUMAN SERVS., <http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html> (last visited Oct. 18, 2011).

140. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 138, at 1.

141. Offit et al., *supra* note 7, at 1471. Accord U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 138, at 17-18.

142. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 138, at 6.

143. *Id.* at 8.

144. *Id.* (emphasis added).

The “Serious Threat to Health or Safety” exception addresses situations like the reporting of new cases of certain communicable diseases.¹⁴⁵ However, unlike infectious diseases, genetic mutations and their concomitant risks are already present (or not present) in the patient, and the immediacy of the harm caused by many genetic predispositions is less clear.¹⁴⁶ This is because the greatest probability that a relative will inherit a dominant trait is 50 percent, and even for those who do inherit a genetic mutation, the risk of developing a serious illness may vary.¹⁴⁷ While many individuals are likely to consider a 50 percent chance of developing cancer to be serious, “[i]t is questionable whether the uncertain probability of a future genetic disease constitutes an *imminent* harm or a *threat to the public interest*.”¹⁴⁸ As a result, HIPAA fails to consider the context of genetics because the HIPAA rules focus on:

[the] level of the potential danger to the third party and the imminence of the threat. This type of narrow focus is common in rules limiting disclosure but does not take into account the nature of the information being protected—in the case of genetic risk information, the fact that it applies to more than one person.¹⁴⁹

In order to guide practitioners in an era of genetic testing, it is necessary to have “[a]n expanded national discussion of the ethical and legal implications of genetic risk notification.”¹⁵⁰

B. PROPOSED SOLUTION: GENETIC INFORMATION DISCLOSURE AMENDMENT TO HIPAA PRIVACY RULE

Part II presented the contradictions and inconsistencies amongst the sources of authority that guide physicians when they are considering whether or not to disclose genetic test results to third parties. Part IV.A demonstrated that HIPAA places further restrictions on physicians disclosing medical information, but since the statute fails to address both genetic tests—which, as demonstrated, are different from the traditional

145. See Offit et al., *supra* note 7, at 1471; ASCO, *Policy Statement*, *supra* note 88, at 2403.

146. Offit et al., *supra* note 7, at 1471.

147. *Id.* (“For example, the risk of breast cancer by 80 years of age for carriers of BRCA2 mutations may be as low as 38%.”).

148. *Id.* (emphasis added).

149. Black, Simard & Knoppers, *supra* note 125, at 118–19.

150. Offit et al., *supra* note 7, at 1472.

medical information that HIPAA protects¹⁵¹—or the duty and privilege to warn, it offers physicians little guidance when addressing the problems raised in this Note. Clear and consistent guidance is necessary and the federal government is in the best position to provide this guidance.

There would be two major benefits from such legislation. First, a federal law would provide a single standard for handling genetic information that applies equally in all situations. As a result, the details of the law could be integrated into medical school curricula, permitting consistent training and instruction about the duties and privileges regarding involuntary disclosure of genetic information. This would not only alleviate confusion about the issue, but also would provide an opportunity for proper training for physicians about how to counsel patients about the familial risks of genetic information. Second, this legislation would decrease unexpected liability for physicians facing this dilemma about disclosure and reassure physicians who fear potential liability. Physicians would no longer find themselves “between a rock and a hard place”¹⁵² when deciding whether they must involuntarily disclose a patient’s information or risk potential harm to an affected third party.

Given the existence of HIPAA, which already governs physicians’ disclosure of patients’ medical information, perhaps the easiest way to create a federal solution is to update HIPAA with an amendment explicitly governing the disclosure of genetic information to family members. HIPAA is an existing law with which physicians are already familiar and HIPAA covers the disclosure of medical information by health care providers, including physicians.¹⁵³ Aside from exceptions explicitly stated in the Act, HIPAA prohibits the disclosure of medical records.¹⁵⁴ As a

151. *See supra* Part II.A.

152. *Genetic Testing Challenges Doctor-Patient Confidentiality*, *supra* note 83.

153. *Fact Sheet: HIPAA Basics: Medical Privacy in the Electronic Age*, PRIVACY RIGHTS CLEARINGHOUSE, <http://www.privacyrights.org/fs/fs8a-hipaa.htm> (last updated June 2011).

154. *Id.* “The Privacy Rule permits use and disclosure of protected health information, without an individual’s authorization or permission, for 12 national priority purposes.” OFFICE FOR CIVIL RIGHTS, SUMMARY OF THE HIPAA PRIVACY RULE 6 (2003), *available at* <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>. Such permitted disclosures include those required by law or court order, disclosures made to protect public health, disclosures made to government authorities regarding victims of abuse, neglect or domestic violence, disclosures made to health oversight agencies, disclosures made for specific law enforcement purposes, disclosures made to decedents, disclosures made in connection with cadaveric organ, eye or tissue donations, disclosures

result, HIPAA implicitly restricts the disclosure of medical records to family members.¹⁵⁵

Such a HIPAA amendment should track the language of the 1983 publication, “A Report on the Ethical, Social, and Legal Implications of Genetic Screening, Counseling, and Education Programs” (“1983 Report”), which was created by the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.¹⁵⁶ The report focused on genetic screening undertaken to uncover an individual’s need for medical care.¹⁵⁷ It found that genetic screening is similar to routine medical tests because the goal is to determine whether care is needed.¹⁵⁸ However, the report also noted an important distinction between individual genetic screening tests and routine medical tests “in that the information produced [by genetic screening] is often relevant to medical decisions by individuals other than the person screened, even when this is not the primary reason for obtaining the information.”¹⁵⁹

The report also examined confidentiality issues stemming from the disclosure of genetic information, particularly focusing on physicians’ disclosure of genetic information to relatives of the patient, “either to advise them that they or their offspring are at risk for genetic disease or to gain information about them for a more accurate diagnosis of the person originally screened.”¹⁶⁰ In this situation, the report concluded, serious harm can be prevented if physicians provide relatives with information that they cannot otherwise obtain.¹⁶¹ To illustrate the problem, the report examined the diagnosis of multiple polyposis of the colon, a genetic condition that is a precursor to cancer and for which early detection and treatment greatly improve the patient’s prognosis.¹⁶² The report notes that the issue is whether the physician who detects the condition should advise others in the family to be screened even if the patient refuses to allow test results to be

made for research purposes, disclosures made to prevent a serious threat to health or safety, disclosures made in connection with essential government functions, and disclosures made in compliance with workers’ compensation laws. *Id.* at 7.

155. *Id.*

156. U.S. PRESIDENT’S COMM’N, *supra* note 6.

157. *Id.* at 3.

158. *Id.*

159. *Id.*

160. *Id.*

161. *Id.* at 42–43.

162. *Id.*

used as a reason to contact relatives.¹⁶³ The report concluded that the appropriateness of involuntary disclosure depends on the specific circumstances surrounding the testing.¹⁶⁴ For example:

The narrowest claim for involuntary disclosure to relatives at increased risk would apply when it is known in advance that a test's results could be uniquely helpful in preventing serious physical harm to relatives of the person tested. In such circumstances prospective screenees should be advised prior to testing of the value of informing at-risk relatives and efforts should be made to elicit their voluntary consent to disclosure. Making access to the test conditional upon prior agreement to disclose information may be justifiable.¹⁶⁵

A difficult case arises when "an advance agreement has not been reached, as when genetic testing produces unexpected information that could benefit a person's relatives."¹⁶⁶ In this case, patients may oppose disclosure because they fear stigmatization by relatives, because they believe their relatives would not want the information, or because they "are estranged from their families and do not want to do anything that might help their relatives or bring them back into contact."¹⁶⁷

The report noted that though it seems that a physician can never override a patient's wishes to breach confidentiality by disclosure to a relative, "[b]oth the law and morality recognize . . . that a professional's primary obligation is in some circumstances subsumed by the need to prevent harm to others."¹⁶⁸ A clear example of this principle is a health care provider's obligation to report communicable diseases; the relevant similarity is that a duty to prevent harm to others may, in some instances, place limits on the professional's duty of confidentiality.¹⁶⁹ The report ultimately made the following recommendation:

A professional's ethical duty of confidentiality to an immediate patient or client can be overridden only if several conditions are satisfied: (1) reasonable efforts to elicit voluntary consent to disclosure have failed; (2)

163. *Id.*

164. *See id.*

165. *Id.* at 43-44 ("Such a policy, however, might deter some people from participating. Consequently, a decision to require consent to disclosure must take into account the harm that might be done or the benefits that might be forgone if some individuals chose not to participate.").

166. *Id.* at 44.

167. *Id.*

168. *Id.*

169. *Id.*

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 identifiable individuals would suffer would be serious; and (4) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.¹⁷⁰

The ethical guidelines recommended in the report outline circumstances in which the Commission believes that it is permissible for a physician to warn at-risk relatives; however, the report did not go as far as to advocate for a legal duty to warn.¹⁷¹

It is important to note that neither the 1983 Report on genetic screening, nor any of the professional medical associations' guidelines, go as far as the New Jersey Court did in *Safer*.¹⁷² None of the associations recommend imposing an affirmative duty on physicians to directly identify, locate, and warn at-risk relatives of the potential harm discovered through genetic testing of a patient. Requiring physicians to locate family members is an incredible burden.¹⁷³ In addition, it would be difficult for physicians to determine when they have sufficiently exhausted their search.¹⁷⁴ How much effort is sufficient before a physician can give up on the search for a long-lost relative who is out of touch with the patient? Fear of liability could cause physicians to spend too much time searching for such relatives. This is an inefficient expenditure of health-care providers' time and other resources, especially since such searches fall far outside of physicians' expertise.

Additionally, an affirmative duty would fail to take into account the full extent of harm a disclosure may cause to the patient. For example, emotional harm and distress could result from any contact with an estranged relative. In addition, forcing doctors to reveal genetic information to at-risk relatives with whom they have no relationship has the potential to compromise the privacy interest of the individual at-risk relative. For example, as discussed more extensively in Part II, there are many situations in which individuals opt not to seek or receive genetic information.¹⁷⁵ In

170. *Id.*

171. Katz & Schweitzer, *supra* note 101, at 102.

172. *See infra* Part III.A (discussing *Safer v. Estate of Pack*, 677 A.2d 1188 (N.J. Super. Ct. App. Div. 1996)).

173. Menting, *supra* note 131.

174. *See id.*

175. *See generally infra* Part II.

these cases, requiring a physician to warn at-risk relatives, with whom they have no prior relationship, may cause harm by infringing on the relative's right not to know about harmful risks.¹⁷⁶

The proposed HIPAA amendment should be modeled on the conclusions from the 1983 Report. While the proposed amendment would not include a duty to for physicians to directly warn at-risk relatives, the HIPAA amendment should make clear that doctors have a duty to inform their patients, both pre- and post-testing, about the potential familial risk that may be associated with genetic tests.¹⁷⁷ In many situations, warning the patient about the seriousness of the risks that are implicated for relatives will likely ensure that the patient passes the warning along to family members. Thus, creating a duty to warn the patient directly is consistent with *Pate's* holding: a duty to warn about the familial risk of genetic testing can be discharged by informing the patient about the potential harm to family members.¹⁷⁸

Finally, the HIPAA amendment should include explicit language allowing physicians to override a patient's desire to keep genetic information confidential in certain situations. Again, this language should track the following recommendations made in the 1983 Report. The proposed amendment to HIPAA would read as follows:

Genetic Information. Covered entities may disclose protected genetic health information to biological relatives of the patient when the following conditions are satisfied: (1) the patient has been properly counseled pre-testing about the potential risk to biological relatives, (2) the patient has been warned post-test about the risk to biological relatives, (3) reasonable efforts to elicit voluntary consent to disclosure have failed, (4) 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, and (5) appropriate precautions are taken to ensure that only the genetic information needed for diagnosis and/or treatment of the disease in question is disclosed.

Therefore, physicians would be allowed a privilege, in certain limited situations, to ensure that the interests of a patient and the patient's relatives

176. See generally Adorno, *supra* note 51.

177. AMA, *Opinion 2.131*, *supra* note 84. The proposed HIPAA amendment will incorporate this aspect of the American Medical Association's *Opinion 2.131* into its language.

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

are best served by disclosing genetic information that may prevent serious and specific harm.

To summarize, the proposed amendment would require physicians, before administering a genetic test, to inform the patient of the conditions under which results would be disclosed to a third party; require physicians, after the test is complete, and if appropriate, to inform the patient of the risk to family members and to urge the patient to inform family members of risk; permit physicians, if conditions (1) through (5) above are met, to contact biological relatives of the patient; and explicitly disclaim a physician's duty to directly inform biological relatives of genetic tests results.

C. APPLICATION OF THIS SOLUTION TO A HYPOTHETICAL PROBLEM

The proposed HIPAA amendment can be applied to Offit's hypothetical (discussed in Part II) about the patient diagnosed with breast cancer mutation BRCA2 (and who was warned before and after the genetic test that the findings might have implications for the patient's relatives).¹⁷⁹ Since this patient was warned pre-test about the potential risks to relatives of hypothetical genetic test results, and has been told post-test that she possesses the genetic mutation that poses a risk for relatives who might also have it, the physician will have met the duty requirements of the proposed HIPAA amendment.

However, if the patient volunteers information that she has a sister from whom she has been estranged for years, and that she has no intention of locating her sister to warn her of the potential risk, the physician is then faced with a problem: the physician knows there is some chance the estranged sister possesses the same mutation, in which case she would benefit from genetic testing and early screening and prevention techniques. After reviewing the law and ethics guidelines, the physician finds no duty to directly warn the sister, but that a physician has the ability to do so. The physician then looks to the additional factors that have been added to HIPAA for guidance. The physician determines that the risk involved here is serious: breast cancer is a life-threatening condition. The physician notes that in this case the harm may be preventable if the sister is warned about the risk of breast cancer before (a) developing breast cancer or (b) exhibiting any symptoms for breast cancer. Clearly the sister will benefit

179. See Offit et al., *supra* note 7, at 1469–70.

from testing for the mutation and undergoing specific screening procedures. Breast cancer cases that are detected early have a better chance of responding well to treatment.¹⁸⁰ Therefore, if this physician wishes to override the patient's wishes and warn the sister, such an action would be permitted under the new amendment.

This approach is not unprecedented. The factors this hypothetical physician will examine are recommended by various medical associations and are included in the AMA medical ethics guidelines.¹⁸¹ However, adding explicit language to a proposed HIPAA amendment offers the advantage of clearly defining physicians' privileges and duties. Without this amendment, physicians must consider conflicting sources of authority, such as *Safer* (seemingly requiring a physician to warn the sister in the above example)¹⁸² and the ASCO guidelines (advising that physicians should never breach confidentiality to warn at-risk relatives).¹⁸³

V. CONCLUSION

The 1983 Report provides a thorough analysis of the legal and ethical problems involved in a new age of genetic medicine. The report recommends that physicians always warn patients about the potential familial risks that may result from genetic tests. The report concludes that physicians do not owe a duty to warn to third-party relatives outside of the doctor-patient relationship. However, the report also concludes that for various public health reasons, there is some benefit to allowing physicians the privilege of breaching patient confidentiality in specific, serious situations for the purpose of preventing or lessening harm.

Influenced by the 1983 Report, medical associations have created similar guidelines and recommendations for physicians faced with the difficult question of whether or not to breach patient confidentiality to prevent or lessen harm to other individuals. However, these recommendations are inconsistent. This problem has been complicated recently by state courts, which have reached conflicting conclusions about what physicians are required to do. Genetic discrimination laws have also

180. *Breast Cancer Tests: Screening, Diagnosis, and Monitoring*, *supra* note 4.

181. *See generally* AMA, *Opinion 2.131*, *supra* note 84.

182. *See Safer v. Estate of Pack*, 677 A.2d 1188, 1192–93 (N.J. Super. Ct. App. Div. 1996).

183. ASCO, *Policy Statement*, *supra* note 88.

increased confusion by creating regulations for the disclosure of genetic information that are not properly tailored to address the problem of a duty to warn. In addition, the situation is further complicated by HIPAA regulations, which govern the disclosure of private medical information, but fail to account for either genetic tests or a duty to warn. HIPAA creates other barriers by requiring that harm be “serious and imminent” in order to justify disclosure. Like the genetic discrimination statutes, the “serious and imminent” language in HIPAA is not properly tailored to address a duty to warn in a genetic context, since genetic information shows only the likelihood (never more than 50 percent) that an at-risk relative might be affected.

At the same time, public concern about genetic discrimination has been rising. In the 1990s and 2000s, many states passed laws specifically tailored to regulating the disclosure of genetic information to prevent genetic discrimination.¹⁸⁴ In 2008, Congress passed federal legislation to prevent genetic discrimination. However, GINA and similar state laws were meant to target employers and insurers.¹⁸⁵ As such, while these laws regulate disclosure, they are not helpful to physicians puzzling over whether there is a duty or a privilege to warn third parties.

The mix of conflicting guidelines from professional associations, inconsistent case law, and related (but not quite on-point) genetic antidiscrimination laws created confusion among physicians who are in relevant positions to warn patients’ relatives of genetic risk. Physicians’ confusion about their rights, duties, and potential liabilities in such situations has been documented.¹⁸⁶ As doctor-patient confidentiality is an important aspect of the relationship between patients and physicians,¹⁸⁷ this confusion presents a problem both to the medical community and to patients, who must have confidence that confidentiality will remain intact unless extreme and necessary circumstances require otherwise.

This Note argues that legislation is needed to provide clear guidance and that the problems of genetic testing are sufficiently unique to require specific legislation to address them. This Note argues that the best solution is to amend the current federal HIPAA privacy rule to include more

184. Morrow, *supra* note 105, at 220.

185. *GINA Background*, *supra* note 59.

186. Falk et al., *supra* note 130, at 376–77.

187. *See Patient Confidentiality*, *supra* note 8.

guidance for physicians regarding duties and privileges with respect to confidentiality and involuntary disclosure of genetic information. Any proposed federal amendment should follow the recommendations made in the 1983 Report. Physicians should have a duty to inform patients about the potential risks to family members before and after testing. Physicians should not, however, have an affirmative duty to directly warn at-risk family members. This would be too administratively burdensome for physicians, and would have unjustified harmful consequences to patient confidentiality issues. However, physicians should have a privilege to warn at-risk relatives if they decide breaching confidentiality is justified.¹⁸⁸ As a result of this privilege, any new or amended federal legislation must address factors and circumstances for physicians to take into account when considering whether a breach of confidentiality is justified. Federal codification of these rules and factors in one specific place will decrease physicians' confusion in this area.

As genetic technology advances, researchers will identify and isolate more genes as indicators or causes of harmful conditions. In 2011, the National Human Genome Research Institute ("NHGRI") published a plan for the future of genomics research in which they noted that while genomics research has already begun to improve diagnostics and treatments in a few specific circumstances, genetics techniques will significantly advance medicine in the next several decades.¹⁸⁹ With dramatic advances in genetic technology, we are likely to see more cases in which physicians are forced to choose between patient confidentiality and the need to protect patients' biological relatives from harm. The legislation proposed in this Note provides a clear reference tool for physicians faced with such a difficult choice, and should encourage the increased use of personalized medicine for everyday health care.

In the future, genetic testing may become so ubiquitous that that most patients are regularly screened for known genetic conditions. As technology advances, genetic tests will become less expensive and more routine. In this event, because most individuals will receive genetic tests, the time gap between a patient's and a relative's genetic tests will decrease. As a result, the problems associated with a duty to warn third parties about

188. U.S. PRESIDENT'S COMM'N, *supra* note 6, at 44.

189. Eric D. Green, Mark S. Guyer & Nat'l Human Genome Research Inst., *Charting a Course for Genomic Medicine from Base Pairs to Bedside*, 470 NATURE 204, 204–06 (2011) (emphasizing that profound advancements cannot be expected for many years).

the results of a patient's genetic tests will become less of an issue, and consequently, the proposed legislation will not hinder physicians, but will simply be less necessary.