



# Legal Challenges in Genetics, Including Duty to Warn and Genetic Discrimination

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This review will explore two legal issues in genetic counseling: genetic discrimination and the duty to warn. It emphasizes the complexity and variability of federal and state genetic non-discrimination protections in the United States and how the many gaps in such protections may affect people pursuing genetic testing. The limited law addressing legal obligations genetic counselors owe at-risk relatives likely does not require counselors to warn relatives directly about genetic risks. Whether it permits them to make such disclosures, however, is more uncertain and may depend on the jurisdiction.

## LEGAL ISSUES IN GENETIC COUNSELING

Central to genetic counseling is the collection and sharing of medical and genetic information with clients. Genetic counselors, of course, do more than obtain and share information—they work with clients to help them make informed decisions based on their personal values and life plans. This involves discussions about clients' goals, medical and personal circumstances, family situation, reproductive plans, and, of course, the reason for genetic counseling in the first place. The genetic or genomic information at the center of genetic counseling, therefore, has as much psychological and social as medical value.

Genetic information has social significance in other ways. It can affect how third parties view and treat us. Entities like employers, insurers, mortgage companies, schools, and future part-

ners may find our genetic information relevant, raising issues about who can access our genetic information and how they can use it. In addition, because we share many genetic variants with family members, genetic information that is personally and medically significant to us may be equally consequential to relatives. That raises questions about the legal obligations genetic counselors have toward a client's family members to warn them about genetic risks.

This review explores these two different legal issues, with a focus on the United States. The first section describes genetic nondiscrimination and privacy laws, which mirror laws in many other countries in both their reach and variety. It highlights the scope and limitation of these laws so that genetic counselors can understand how variable these protections are across jurisdictions. Although genetic counselors cannot become experts as to every legal nu-

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ance, they should understand the general legal landscape to help clients consider the implications of obtaining genetic information, as well as the optimal timing and context.

The second section explores cases, statutes, and regulatory law to consider what legal and ethical duties genetic counselors owe a client's relatives. Although the focus is on U.S. law, many of the same principles apply internationally, particularly in Europe. Although a genetic counselor's primary obligation is to her client, she owes certain ethical and legal obligations to the client's relatives. Although there is limited law in this area and some uncertainty about its reach, this section suggests genetic counselors likely have no duty to warn relatives directly. It might, however, be permissible for them to do so in very rare instances.

### Genetic Discrimination—What Is Protected and What Is Not

This section lays out the areas where genetic nondiscrimination and privacy protections exist and where they do not. The goal is to give genetic counselors tools for helping clients understand the implications of undergoing genetic testing or counseling in light of the complex range of U.S. federal and state genetic nondiscrimination and privacy protections. Helping patients navigate this legal landscape is not easy. These legal protections vary considerably from state to state and depend on the context in which genetic information is obtained. Furthermore, there is a tension between the counselor's ethical obligation to ensure that clients understand the limits of privacy and nondiscrimination protections and the danger that overemphasizing these risks may prevent the client from undergoing genetic testing that could be beneficial to their health and well-being.

Worries about genetic discrimination arose not long after the Human Genome Project began when ethics and legal scholars sounded the alarm that employers and insurers might use genetic information to discriminate. Although the threat of genetic discrimination was mostly theoretical in the 1990s, state legislatures began to craft laws to prohibit genetic discrimination,

primarily in employment and health insurance. Combining antidiscrimination features with some genetic privacy features, the state laws varied in many respects: who was proscribed from certain uses of genetic information (antidiscrimination protections), the restrictions on third-party access to genetic information (privacy protections), and the definition of genetic information (Suter 2001).

For over a decade, Congress unsuccessfully attempted to pass legislation to address this patchwork of genetic nondiscrimination and privacy protections. After 13 years of failed attempts, it finally passed the Genetic Information Nondiscrimination Act ("GINA"),<sup>1</sup> which President Bush signed into law in 2008. GINA was not the first federal law prohibiting genetic discrimination. The Health Insurance Portability and Accountability Act had already prohibited genetic discrimination by employer-sponsored group health plans,<sup>2</sup> although these protections were not fully comprehensive and left the individual insurance market untouched.

GINA differs from other antidiscrimination laws in that it was a preemptive measure to prevent future discrimination, rather than a response to historical and pervasive discrimination (Roberts 2010). Congress was also motivated by a concern about the public health and research implications of the public's fear of genetic discrimination, regardless of the prevalence of such discrimination. Specifically, members worried these fears would prevent people from undergoing genetic testing or participating in research (Roberts 2010; Suter 2019). In addition, Congress wanted to remedy the "patchwork of State and Federal laws," which were "confusing and inadequate to protect [the public] from discrimination."<sup>3</sup> For all of these reasons, Congress enacted GINA to "fully protect the public from discrimination."<sup>4</sup> To that end, it defined genetic information more broadly than

<sup>1</sup>Public Law No. 110-233, 122 Stat. 881 (2008) (codified in scattered sections of 26, 29, and 42 U.S. Congress).

<sup>2</sup>29 U.S. Congress §§ 1181-82 (2006), 42 U.S. Congress §§ 3000 gg-41 (2006).

<sup>3</sup>Public Law No. 110-223, § 2(5).

<sup>4</sup>*Id.*



most state laws.<sup>5</sup> Congress also wanted to ensure a minimum level of protections across the United States by making GINA's provisions a floor below which no state could go (Roberts 2010).

GINA achieves its goal of nondiscrimination in health insurance and employment in two ways. First, it prohibits discriminatory *uses* of genetic information. Health insurers cannot make determinations of eligibility and premium rates or create preexisting condition exclusions based on genetic information with respect to group health plans and individual insurance markets.<sup>6</sup> Similarly, employers may not use genetic information to make employment decisions with respect to such matters as hiring, compensation, or conditions of employment.<sup>7</sup> Second, GINA bolsters the nondiscrimination features by prohibiting health insurers<sup>8</sup> (Sarata et al. 2011) and employers (with some exceptions)<sup>9</sup> from *accessing* genetic information through requests or inquiries (Roberts 2015). GINA, therefore, provides an element of federal privacy protection, at least with respect to health insurers and employers.

Although GINA represented progress in proscribing genetic discrimination, in several ways, GINA does not “fully protect the public from discrimination.” First, although its definition of genetic information is broad in including family history (and an expansive conception of family history at that) (Suter 2019), its definition is narrow in another sense. GINA does not cover discriminatory provisions “based on the mani-

festation of a disease or disorder of an individual.”<sup>10</sup> This is consistent with the general consensus that genetic discrimination is problematic when based on a predisposition to, as opposed to manifestation of, an illness (Hall 1999). Yet it is not clear why such a distinction is morally sound. Surely a genetic counseling client's need for health insurance is even greater once a genetic risk develops into disease (Suter 2001). Genetic counseling clients, and perhaps even some genetic counselors, however, may not understand that GINA provides no protections against discrimination based on illness.

Any federal protection against health insurance or employment discrimination based on manifested genetic conditions comes from other laws. For example, the significant health insurance reforms of the Patient Protection and Affordable Care Act of 2010 (“ACA”)<sup>11</sup> protects against health insurance discrimination based on most health factors, including predisposition to disease, a protection that largely overlaps with GINA, and manifestation of a genetic condition, which goes beyond GINA (Sarata et al. 2011).

Although growing public support of the ACA quelled Congressional efforts to repeal the ACA (Everett 2018), the law is once again under attack in the courts. In 2018, 20 state governors and attorneys general challenged the statute's constitutionality, and a federal judge ruled that the ACA's individual mandate was unconstitutional, rendering the entire statute invalid.<sup>12</sup> Legal scholars strongly question the decision, which has been appealed to the Fifth Circuit. In a “highly unusual move,” President Trump's Department of Defense not only failed to defend the federal law (Keith 2018), it asked the federal appeals court to invalidate it (Pear 2019). Unfortunately, recent oral arguments suggest the three-judge panel of the Fifth Circuit is skeptical about the ACA's constitutionality (Goodnough 2019). The case may ultimately end up before

<sup>5</sup>Public Law No. 110-233, §§ 101(d), 102(a)(1)(B), 103(d), 104(b), 201(4)(A)(i)–(iii); 42 U.S. Congress §2000ff(A)(i)–(iii) (defining family history as “the manifestation of a disease or disorder in family members”); GINA could have modified the definition as “the manifestation of an *inheritable* disease or disorder in family members,” but it did not (Suter 2019).

<sup>6</sup>Public Law No. 110-223 § 102. GINA “fortified” existing protections from HIPAA with respect to group plans, but its “main value” was with respect to protections against discrimination in the individual insurance market (Rothstein 2009).

<sup>7</sup>Public Law No. 110-233 § 202(b).

<sup>8</sup>Public Law No. 110-233, §§101-106.

<sup>9</sup>Section 202(b); Genetic Information Nondiscrimination Act, Public Law No. 110-233, § 101(d), 112 Stat. 881, 884-5; § 102 (d)(2)(A), 112 Stat at 896; § 103(d), 122 Stat. at 898-00; § 104(b)(2), 122 Stat. at 901.

<sup>10</sup>Public Law No. 110-233, § 101(1)(3); 29 USCA. § 1182.

<sup>11</sup>Public Law No. 111-48, as modified by the Health Care and Education Reconciliation Act, Public Law No. 111-52.

<sup>12</sup>*Texas v. United States* (340 F. Supp. 579) (E.D. Ark. 2018).

the Supreme Court. Thus, the fate of the ACA, including its protections against preexisting condition exclusions, once again hangs in the balance. Such litigation creates uncertainty about the scope of protections against discrimination based on genetic illness.

In the employment context, The American with Disabilities Act (“ADA”)<sup>13</sup> offers protections for people with manifested genetic conditions if they can show the employer’s allegedly discriminatory action was based on the ADA’s definition of a disability.<sup>14</sup> Unfortunately, some individuals will lie in the uncovered gap between GINA’s and the ADA’s employment nondiscrimination protections. For example, someone in the early stages of a disease would not be protected by GINA, but their mild symptoms or biomarkers might not meet the criteria for ADA protections (Rothstein 2018a). This presents genetic counseling challenges because it is difficult to determine whether someone has demonstrated enough signs of illness to be denied GINA’s protections against employment discrimination, but not enough for the ADA’s protections.

An additional vulnerability with respect to employment discrimination protections involves the regulation of employee wellness programs, which employers offer to encourage healthy behavior in employees to reduce health-care costs (Wieczner 2013). Although GINA prohibits employers from asking employees for genetic information, it allows them to collect such information as part of a wellness program if certain conditions are met. For example, the employee must give “knowing, voluntary, and written authorization,” and the employer can only receive information in an aggregated and unidentifiable form (Sarata et al. 2011). In 2017, some Congressional Representatives introduced a bill to reduce employers’ burdens in implementing wellness programs. One provision

would have allowed employers to collect identifiable medical history (including family history) and genetic tests,<sup>15</sup> which would have undone many of the privacy protections of GINA and the ADA. News of these efforts worried individuals considering genetic testing or counseling. Although the legislative attempts failed, they highlight GINA’s vulnerability to political whims, which can impact public attitudes and fears regarding genetic testing.

Another significant inadequacy of GINA is that, in focusing only on health insurance and employment, it ignores areas in which genetic discrimination may be even more likely. For example, GINA does not address life, long-term care, and disability insurance. Similarly, GINA fails to protect against discriminatory uses of genetic information for mortgages or commercial transactions (Rothstein 2009), admission to schools, etc. Some states have enacted laws prohibiting discrimination in some of these areas, but their protections vary dramatically. The patchwork of legislation here is even sparser than the health insurance and employment laws that motivated GINA’s passage.

To give an example, some state laws prohibit disability and life insurers from discriminating based on genetic information that is not actuarially justified. That means such insurers can underwrite insurance based on genetic information if evidence demonstrates it truly indicates an increased risk for a relevant disability or serious medical condition.<sup>16</sup> In other words, they can charge higher premiums or deny coverage based on genetic predispositions, precisely the type of discrimination people feared with advances in genetics.

Other state laws prohibit certain types of insurers from *requiring* genetic tests, but they do not prohibit the use of *existing* genetic information, for underwriting.<sup>17</sup> This does not pre-

<sup>13</sup>Public Law 101-336.

<sup>14</sup>42 U.S. Congress § 12101 (1) (defining a disability as an “impairment that substantially limits one or more major life activities,” having a “record of such an impairment,” or being “regarded as having such an impairment.”).

<sup>15</sup>H.R. 1313, 115th Congress (2017).

<sup>16</sup>See generally, Genome Statute and Legislation Database Search. *National Human Genome Research Institute*. [https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content\\_type=1&content\\_type\\_id=1&topic=4&topic\\_id=1&source\\_id=1&keyword=&search=Search](https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=4&topic_id=1&source_id=1&keyword=&search=Search).

<sup>17</sup>*Id.*



vent genetic discrimination against clients who have undergone genetic testing, but it avoids their being coerced into testing simply to obtain insurance. With respect to other areas of potential discrimination, the protections are extremely limited or nonexistent. Genetic counseling clients should be aware of such genetic discrimination risks. The challenge, however, is that helping them understand when genetic discrimination is still possible may lead to fears that discourage their pursuit of genetic testing for medical purposes. Genetic counselors can help clients navigate these issues by encouraging them to consider the ideal time for testing. For example, some clients may benefit from seeking such insurance before pursuing genetic testing.

GINA and state genetic nondiscrimination laws also fail to protect against future areas of discrimination that may arise as technologies refine our ability to predict disease risks through indicators other than genetic variants. For example, these statutes do not address, let alone consider, the possibility of third parties using information about epigenetic changes or microbiomes to discriminate. As Professor Rothstein notes, “GINA has been frozen in time for at least ten years” (Rothstein 2009). These limitations will be increasingly relevant in genetic counseling as the scope of information patients obtain expands beyond analysis of genetic variants.

Finally, GINA provides only limited privacy protections. It restricts to some extent the information that health insurers and employers may request or require, but it does not address privacy protections in other realms. The most comprehensive law addressing genetic privacy is the Health Insurance Portability and Privacy Act (HIPAA) Privacy Rule, which protects “identifiable health information”<sup>18</sup> by prohibiting its disclosure without written authorization if such disclosure is not for treatment, payment, or health-care operations.<sup>19</sup> After GINA was enacted, the Privacy Rule was modified to expressly include genetic information within its

protected health information.<sup>20</sup> HIPAA’s federal privacy protections, however, only apply to health-care providers, health plans, health clearing houses, and business associates of these entities.<sup>21</sup> Consequently, genetic privacy protections outside the health-care context depend on the patchwork of state legislation.

Not all states have genetic privacy laws, and those that do vary considerably. Some protect genetic privacy by requiring an individual’s (written and/or informed) consent to perform a genetic test or DNA analysis, to obtain or retain an individual’s genetic information, or to release genetic information to third parties. A few states define genetic information as the individual’s property, although it is not precisely clear what added protections that label offers (Suter 2004). Sometimes these statutes are limited to specific entities such as insurers, employers, and/or schools. Most of these laws create exceptions for activities like diagnosis and treatment, newborn screening, forensics, etc.<sup>22</sup> Although genetic counselors cannot be expected to know the particular privacy protections of every jurisdiction, they can assure patients that information obtained through genetic counseling clinics or other health-care facilities is protected by HIPAA.

As more people seek genetic testing outside the medical context, however, the protections over genetic information will be more limited. GINA, HIPAA, and many state genetic privacy or nondiscrimination statutes simply do not apply in this context. For example, direct-to-con-

<sup>20</sup>Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA rules, 78 Fed. Reg. 5566-01, 5661-62 (Jan. 25, 2013) (noting that prior to enactment of GINA, the Department of Health and Human Services had issued guidance that genetic information was considered protected health information under the Privacy Rule).

<sup>21</sup>45 C.F.R. § 160.103 (2018).

<sup>22</sup>See generally, Genome Statute and Legislation Database Search. *National Human Genome Research Institute*. [https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content\\_type=1&content\\_type\\_id=1&topic=4&topic\\_id=1&source\\_id=1&keyword=&search=Search](https://www.genome.gov/policyethics/legdatabase/pubsearchresult.cfm?content_type=1&content_type_id=1&topic=4&topic_id=1&source_id=1&keyword=&search=Search).

<sup>18</sup>45 C.F.R. § 160.103 (2014).

<sup>19</sup>45 C.F.R. § 164.508 (2013).



sumer (“DTC”) genetic testing companies like 23andMe are not among the four listed entities to which HIPAA applies. GINA is only relevant to DTC genetic testing to the extent it prohibits employers or health insurers from seeking genetic information, including information generated by DTC companies. One’s control over genetic data generated through DTC companies largely depends on their varied practices and policies (Hazel and Sogbogan 2018). Some state laws might grant consumers limited control over this information, but most would not. Moreover, some elements of genetic privacy are virtually impossible to protect as the expansion of DTC genetic testing allows individuals to identify the presence or absence of genetic links in families (Holger 2018). Although such information may not reveal disease propensity, it highlights the limits of our control over our genetic information.

This brief survey of genetic privacy and non-discrimination laws suggests that people contemplating genetic testing should understand the complexity, range, and limits of state and federal protections. Genetic counselors can play a role in emphasizing the variability in protections against discrimination outside of health insurance and employment. They can also indicate that, in many jurisdictions, protections against genetic discrimination in areas like long-term care, life, and disability insurance are limited or nonexistent. Genetic counseling clients should also understand that, once their genetic information is generated, their ability to control third-party access to it might be restricted. Although the greatest protections exist for information generated in the health-care context, they are minimal in the realm of DTC genetic testing.

Genetic counseling clients should also understand that entities other than health insurers and employers who might have an interest in one’s genetic information—life insurers, long-term care insurers, schools, mortgage brokers, etc.—are legally entitled in most jurisdictions to ask individuals whether they or family members have received genetic testing or counseling, and if so what the results are. A failure to answer such questions truthfully would invalidate the

terms of any insurance contract they obtain.<sup>23</sup> Clients should therefore consider not only the personal and medical value of obtaining genetic information, but also the optimal timing based on their plans and needs for other lines of insurance. In some jurisdictions, however, even if one planned to undergo genetic testing after seeking life, disability, or long-term care insurance, these insurers may be legally entitled to make genetic testing a precondition for obtaining insurance.

Asking genetic counselors to address, in general terms, the complicated nature of legal nondiscrimination protections demonstrates how elusive GINA’s goal to eliminate public fears of genetic discrimination may have been. Congress hoped GINA would inspire more people to seek genetic counseling and testing and to participate in genetic research, but helping clients understand its limitations may not offer the sense of security GINA was intended to instill. Nevertheless, such information is necessary to assist clients in making decisions consistent with their values, goals, and life plans.

Even though it is appropriate for genetic counselors to highlight the general gaps and variation in federal and state genetic nondiscrimination and privacy laws, they cannot be expected to become experts about the nuanced variations in protections (or lack thereof) across jurisdictions and the range of contexts in which discrimination might occur. Genetic counselors are increasingly burdened with broadening disclosure obligations as genetic/genomic testing becomes more complex and generates ever larger amounts of information. Furthermore, as more people seek genetic information through DTC companies, we cannot rely solely on genetic counselors to educate the public about the inadequacies of genetic nondiscrimination and privacy protections. Instead, we must develop mechanisms to provide greater awareness of these issues. Not only would that help people

<sup>23</sup>Contract voidable for fraudulent misrepresentation, 6 Couch on Ins. § 82:21 (“where a representation is intentionally false, and calculated to mislead the insurer into issuing the policy, and is material, the policy may be avoided . . .”).

make more informed choices, it would also engage the public in a larger discussion of the proper reach of genetic nondiscrimination laws.

GINA's shortcomings reflect, to a large degree, the lack of political will to go further (Ray 2010; Zhang 2017). Greater public awareness could change the political discourse and perhaps motivate efforts to expand protections against discriminatory uses of genetic and genomic information. As it becomes more difficult to control access to genetic information, privacy protections may prove too weak to prevent genetic discrimination. Instead, we should tighten restrictions on uses of genetic information, which requires a serious debate about the social value of access to things like life, disability, and long-term care insurance. How and where we should draw those lines is too large an issue for this review, but genetic counselors should be part of this conversation.

#### Legal Duty to Warn At-Risk Relatives?

Insurers are not the only third parties interested in a patient's genetic information; biological relatives also have a personal interest in this information. Because genetic information can have significant value to family members, the consensus among professional organizations and ethicists is that genetic counselors should inform patients about the clinical relevance of their genetic information to family members and encourage patients to disclose such information to their relatives (Rothstein 2018b). The thornier question is whether genetic counselors owe a legal duty to those relatives and, if so, what the nature of that duty is, particularly when the patient chooses not to share clinically actionable information with relatives.

Only three legal cases have addressed this issue. Although they involve physicians, their analysis applies to health-care providers, including genetic counselors. The first case, *Pate v. Threlkel*, involved a mother, Marianne New, who was treated for medullary thyroid carcinoma in 1987. New's physicians failed to inform her that the condition was autosomal dominant, posing a risk of cancer to her children. When her daughter, Heidi Pate, was later diagnosed with

the same condition, she sued the physicians, claiming they violated their duty to warn her about the heritable risk. Pate argued that had she been warned, she would have been tested and received preventive treatment.

In its 1995 ruling, the Florida Supreme Court held that physicians owe a duty of care to "identified third parties" in the "zone of foreseeable risk," like New's daughter, if the standard of care requires physicians to warn *patients* about the heritability of the condition. The court reasoned that any such standard of care exists precisely for the benefit of individuals like a patient's children. Nevertheless, the court pointedly narrowed the scope of this obligation, declaring any duty of care to a patient's close relatives "to warn of a genetically transferable disease... will be satisfied by warning the *patient*."<sup>24</sup> The court found that requiring the physician to "seek out and warn" the patient's family "would often be difficult or impractical and would place too heavy a burden upon the physician" and would likely conflict with statutory obligations to protect patient confidentiality.<sup>25</sup>

A few years later, in *Safer v. Estate of Pack*, a New Jersey appellate court faced a similar issue. In the mid-1950s, Dr. Pack treated Robert Batkin for retroperitoneal cancer. Unfortunately, Batkin succumbed to the cancer when his daughter, Donna, was 10 years old. More than 30 years after her father was treated for cancer, newly married Donna Safer was diagnosed with metastatic colorectal cancer. Arguing her cancer resulted from untreated multiple polyposis, which her father had, Safer sued Dr. Pack's estate for failing to warn her father about the hereditary nature of the disease.

Assuming the standard of care required Dr. Pack to warn Safer's father of the "genetic threat" to his children, the New Jersey appellate court had no difficulty concluding a duty was owed to "members of the [patient's] immediate family" facing "an avertable risk from genetic causes." The court did not, however, follow *Pate* in lim-

<sup>24</sup>*Pate v. Threlkel* (661 So. 2d 278, 282) (Fla. 1995) (emphasis added).

<sup>25</sup>*Id.*

iting the scope of the duty to informing the *patient* of the familial risk. Instead, it declared it “may be necessary, at some stage, to resolve a conflict between the physician’s broader duty to warn and his fidelity to an expressed preference of the patient that nothing be said to family members about the details of the disease.”<sup>26</sup>

Although the *Safer* court did not resolve whether “there are or ought to be any limits on physician–patient confidentiality,” the New Jersey legislature did so 5 years later by enacting a genetic privacy statute. The statute prohibits the disclosure of identifiable genetic information without the individual’s written consent,<sup>27</sup> with some exceptions, including to “furnish genetic information relating to a decedent for medical diagnosis of” the decedent’s genetically related relatives.<sup>28</sup> This statute effectively overturned *Safer* (Rothstein 2018b), at least with respect to living patients who have not consented to such disclosures.

The third case, *Molloy v. Meier*, involved the failure to identify the fragile X mutation in Kimberly Molloy’s developmentally delayed daughter and to counsel Molloy about the risk of passing on the mutation to future children. Molloy remarried and had a son with similar disabilities. He was found to carry the fragile X mutation, which ultimately led to identification of the mutation in Molloy’s daughter. The court held that Molloy was owed a duty of care even though she was not a patient because “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.”<sup>29</sup> Unlike *Pate* and *Safer*, however, *Molloy* did not implicate confidentiality issues because Molloy was entitled to her minor child’s medical information. In contrast, the parties alleging the physician had a duty to warn them in *Pate* and *Safer* had no underlying right to the adult patients’ information.

The upshot of this limited case law is that genetic counselors, as health-care providers, owe a duty of care to identifiable, closely related familial members, if a patient’s medical diagnosis or genetic information reveals an “avertable” or foreseeable risk to the relatives. The trickier question concerns the scope of that duty. Would a genetic counselor fulfill it by informing the *client* about the medical implications to family members, as *Pate* decided? Or must a genetic counselor, as *Safer* suggested, sometimes warn the *relative* directly, creating tension between the counselor’s duty of confidentiality to the patient and duty of care to the relative?

In some jurisdictions, state law offers guidance. New Jersey’s privacy law seems to allow a breach of confidentiality only after the patient has died. Florida’s genetic privacy statute, however, consistent with *Pate*, prohibits disclosure of an individual’s genetic analysis without the individuals’ consent, with no exception for decedents.<sup>30</sup> Whether other states set such limits depends on whether they have genetic privacy statutes and their scope.

The HIPAA Privacy Rule is also relevant in prohibiting disclosure of protected health information, including genetic information, without written authorization if such disclosure is not for treatment, payment, or health-care operations. These protections are not absolute, however. The Rule contains 12 exceptions in which an individual’s personal health information can be disclosed without the individual’s authorization.<sup>31</sup> One exception allows unauthorized disclosures “necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public.”<sup>32</sup> The regulatory language describes this exception to “avert a serious threat to health or safety” as consistent with the “duty to warn’ third persons” articulated in *Tarasoff v. Regents of the University of California*.<sup>33</sup> In that case, a therapist’s patient revealed his intention to kill a woman whom he ultimately mur-

<sup>26</sup>*Safer v. Pack* (677 A.2d 1188) (N.J. Super. Ct. App. Div. 1996).

<sup>27</sup>N.J. STAT. ANN. § 10:5-47 (2001).

<sup>28</sup>N.J. STAT. ANN. § 10:5-47 (a)(6) (2001).

<sup>29</sup>*Molloy v. Meier* (679 N.W.2d 711) (Minn. 2004).

<sup>30</sup>FLA. STAT. ANN. § 760.40.

<sup>31</sup>45 C.F.R. § 164.512 (2016).

<sup>32</sup>45 C.F.R. § 164.512(j) (2016).

<sup>33</sup>65 Fed. Reg. 82462, 82538 (Dec. 28, 2000).



dered. The California Supreme Court held that the therapist owed a duty of care to the woman, leaving open the possibility that such a duty might have required warning her directly.<sup>34</sup>

Although differences exist between the third-party risks in *Tarasoff* and in genetics (Suter 1993; King 2000), unauthorized disclosures might be permissible under this Privacy Rule exception if a genetic counselor believes in good faith that (1) the client's genetic information reveals a "serious and imminent threat" to the relative's health, (2) disclosure of this information would be "necessary to prevent or lessen the threat," (3) the relative would be "reasonably able to prevent or lessen the threat," and (4) such disclosure would be consistent with "applicable law and standards of ethical context."<sup>35</sup>

In some genetic counseling scenarios, the second and third elements would apply. If a client's medical information indicates clinically actionable risks to a family member, by definition, the relative could prevent or lessen the risk, meeting the third element. Additionally, if the client declines to share such information with the relative and the relative cannot otherwise learn about the risk, unauthorized disclosures might be necessary to avert the risk, meeting the second element.

In most genetic counseling cases, however, the first and last elements are hard to satisfy. Even when a client's genetic information suggests a high risk to relatives of a serious disease, the risk is rarely *imminent* in the way a homicidal patient's intent to murder might be. Even a 50% risk of inheriting a genetic variant for a serious condition presents less than a 50% risk (unless the variant is fully penetrant) of developing the disease at some undefined point in the future, which does not seem imminent. In certain specialties, genetic counselors may have clients with a heritable condition like arrhythmogenic right ventricular cardiomyopathy, which can pose temporally imminent risks like sudden cardiac death. In the vast majority of genetic counseling situations, however, predic-

tive genetic information does not present an *imminent* risk, failing the first element of the Privacy Rule exception.

Second, even if genetic counselors find themselves in the "rare circumstances" in which the risk seems imminent,<sup>36</sup> HIPAA's regulatory language makes clear it does not "preempt any state law" prohibiting disclosure of protected health information.<sup>37</sup> Thus, in jurisdictions with privacy statutes like Florida's, HIPAA would not override state prohibitions against unauthorized disclosure. Of course, many jurisdictions do not have legal restrictions to limit this exception.

The Privacy Rule exception also requires disclosures to be "consistent with ... ethical standards of conduct." Professional groups (American Society of Clinical Oncology 2003; American Medical Association 2015), including genetic counselors, emphasize the duty of confidentiality. The National Society of Genetic Counselors' Code of Ethics stresses the importance of maintaining the "privacy and security of their client's confidential information and individually identifiable health information, unless released by the client or disclosure is required by law" (National Society of Genetic Counselors). This code of ethics describes no situation in which a genetic counselor must or may disclose information to an at-risk biological relative.

The American Society of Human Genetics (ASHG), however, considers the possibility that genetic counselors *may*, though they are not required to, disclose information to relatives. But it limits permissible disclosures to very narrow circumstances:

... where attempts to encourage disclosure on the part of the patient have failed; where the harm is highly likely to occur and is serious and foreseeable; where the at-risk relative(s) is identifiable; and where either the disease is preventable/treatable or medically accepted standards indicate that early monitoring will reduce the genetic risk (American Society of Human Genetics 1998).

<sup>34</sup>551 P.2d 334 (Cal. 1976).

<sup>35</sup>45 C.F.R. § 164.512(j)(1)(i) (2016).

<sup>36</sup>65 Fed. Reg. 82462-01, 82703 (Dec. 28, 2000).

<sup>37</sup>65 Fed. Reg. 82462-01, 82704 (Dec. 28 2000).



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Although narrow, this exception is slightly broader than HIPAA's exception because it does not require an "imminent" risk.

These different professional statements create uncertainty about whether breaching client confidentiality to warn a relative to "avert a serious threat to health" would be consistent with ethical standards. Such disclosure seems inconsistent with the Genetic Counselors' Code of Ethics, which prohibits breaches of confidentiality not *required* by law. However, if the risk of harm is "highly likely" and "preventable/treatable," it seems consistent with ASHG's policy statement.

Finally, although the original HIPAA Privacy Rule does not explicitly address disclosures of genetic information to family members, the Office for Civil Rights of the Department of Health and Human Services, which enforces the rule, addresses scenarios in which patients' family members want "to identify their own genetic health risks." It states that a health-care provider may share genetic information about the patient "with providers treating family members of the individual . . . , provided the individual has not requested and the health-care provider has not agreed to a restriction on such disclosure."<sup>38</sup> If upheld by courts, this interpretation seems to allow genetic counselors to disclose genetic information concerning a client to family members' *providers* if the patient has not requested, and the genetic counselor has not granted, a request, to restrict disclosure (Rothstein 2018b).

This mix of case, statutory, and regulatory law is clearer in some respects than others. It suggests genetic counselors have a legal duty of care to a client's relatives, if the client's genetic information reveals a "foreseeable risk" to closely related relatives.<sup>39</sup> The limited law suggests that telling the *client* about the risk satisfies the duty. In other words, genetic counselors do not seem to have a legal obligation to warn relatives or their physicians directly and would likely not

risk liability for failing to warn, if they explain the relatives' genetics risks to the patient.

It is less clear, however, whether disclosures to at-risk relatives are legally permissible. If the HIPAA Privacy Rule exception to "avert serious threats to health" applies in the genetics context, it does so rarely: when the health risk is serious and imminent, when disclosure is *necessary*, and when disclosure could avert the risk. Alternatively, under the 2013 interpretations of the Privacy Rule, genetic counselors may sometimes be permitted to share health information about a patient to a relative's health-care *provider* for treatment purposes. Both exceptions only *permit* rather than *require* disclosures, and neither has been tested in court.

In the rare instance when a client chooses not to warn relatives, genetic counselors face an ethical dilemma. On the one hand, disclosure to relatives could help them prevent serious medical harms. The necessity of disclosure to relatives or their patients, however, may depend on the state of technology and access to genetic testing. For example, if whole-genome sequencing becomes more routine, relatives with access to such technology could learn about actionable genetic risks without a genetic counselor having to breach patient confidentiality. Sometimes, however, disclosure might be the only way to avert harm.

On the other hand, clients may be trying to protect relatives. For example, a mother reportedly forbade her married daughters to tell her unmarried daughter about the mother's *BRCA* mutation for fear it could make the unmarried daughter "less marriageable" (Lewin 2000). Breaches of confidentiality could cause various harms, such as embarrassment, impaired family relationships (Rothstein 2018b), stigmatization, or discrimination. Finally, they could lead to distrust of genetic counselors, deterring genetic testing, genetic counseling, or participation in genetics research, the very concerns that motivated GINA and related laws.

For these reasons it is ethically appropriate not to *require* genetic counselors to do more than encourage clients to warn relatives about genetic risks (Rothstein 2018b). Nevertheless, an absolute rule forbidding disclosure to rela-

<sup>38</sup>78 Fed. Reg. 5668 (Jan. 25, 2013).

<sup>39</sup>The case law does not make clear the outer reaches of genetic relatedness for such an obligation to apply.



tives or their physicians raises ethical concerns. Imagine a genetic counseling client with arrhythmogenic right ventricular cardiomyopathy. In trying to cultivate a tough image as a police officer and avoid seeming weak, he refuses to disclose his condition to relatives. His marathon-runner sister would be at great risk of sudden cardiac arrest if she inherited the genetic variant.<sup>40</sup> Should the client's strong interest in confidentiality trump her strong(er) interest in living? Though the genetic counselor likely has no legal obligation to do so, should she be permitted to warn the sister if she cannot persuade her client to do it himself?

The HIPAA interpretation that *permits* a provider to inform a relative's *physician* about genetic risks for treatment purposes might offer the best alternative in these rare scenarios in which serious and imminent risks can only be prevented by disclosure. The genetic counselor could inform the relative's physician, who could recommend genetic tests as part of "routine care" without disclosing information about the genetic counseling client. Although this might prevent some harms the patient seeks to avoid, it puts the provider in the position of keeping secrets, raising other ethical concerns. Sometimes telling the relative, if possible, might be the best way to prevent harm.

If courts agree with the interpretations of HIPAA allowing, in exceedingly rare instances, disclosures to relatives or their physicians to avert serious harms, genetic counselors would have discretion to balance the potential harms of disclosure and nondisclosure. Given that these exceptions depend in part on ethical principles, the genetic counseling community has a role to play in considering whether disclosures are ever ethically permissible in the genetic counseling context and, if so, under what narrow circumstances. Until such cases are litigated, however, the permissibility of disclosures remains uncertain.

<sup>40</sup>This scenario was shared with me by a cardiac genetic counselor.

## CONCLUSION

As we have seen, many legal issues in genetic counseling are unresolved or depend on the jurisdiction. As is often the case, the law remains a few steps behind emerging technologies. Unfortunately, this makes it difficult to predict with certainty how courts will rule when confronted with some of these genetic counseling dilemmas. Because norms within the genetic counseling community influence the law's approach to some of these issues, genetic counselors must remain engaged in the discussions and debates concerning the complex issues genetics and genomics pose.

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