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**Genetics Research and Privacy: Balancing the
Scientific Advancement of Genetics Research with
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Identifiable Genetic Information**

Frank E. Ferruggia Jr.

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Introduction

Advances in genetics research are extremely important in the treatment and diagnosis of disease.¹ Technological innovations provide researchers with the means to sequence entire genomes and publicly disseminate the data through private and public genetic databases.² However, genetic research has raised some ethical and legal concerns.³ Specifically, the increase in access to genetic information has threatened the genetic privacy of individuals who either directly or indirectly participate in genetics research.⁴

Genetic information is considered highly sensitive and private for several reasons.⁵ Access to an individual's genetic information will disclose that person's traits, disease patterns, and family history.⁶ Consequently, if this information is disclosed to the wrong person, that person could gain access into an individual's future, past, and present.⁷ Critics of the availability of genetic information believe that it will be used unfairly in employment practices.⁸ A discouraging genetic makeup could reduce employment prospects or even cause an employer to deny an employee insurance coverage based on genetic information received.⁹ The availability of genetic research may also be used by insurance providers in making coverage decisions.¹⁰

In response to the aforementioned privacy concerns of genetic research, federal legislation has been developed and amended.¹¹ Congress recently enacted the Genetic Information and

¹ Kristie Sosnowski, *Genetic Research: Are More Limitations Needed in the Field*, 15 J.L. & HEALTH 121, 136 (2001).

² Sarah Fendrick, *The Role of Privacy Law in Genetic Research*, 4 J.L. & POL'Y FOR INFO. SOC'Y 803, 804 (2008).

³ Sosnowski, *supra* note 1, at 136.

⁴ Fendrick, *supra* note 2, at 804.

⁵ Sosnowski, *supra* note 1, at 136.

⁶ *Id.* at 137.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.* at 139.

Nondiscrimination Act of 2008 (hereinafter “GINA”) to restrict the use of genetic information by insurance and health care providers and in employment practices.¹² Also, the Health Insurance Portability and Accountability Act of 1996 (hereinafter “HIPAA”), was enacted to ensure the fair use of genetic information by insurance providers¹³ and to preserve the confidentiality of an individual’s protected health information.¹⁴ However, the incomprehensive nature of the federal legislation has prompted states to enact laws that address the privacy concerns of genetic research.¹⁵

This article first provides a basic understanding of genetic testing and research of human tissue samples. Next, this article will provide an overview of the major federal legislation, GINA and HIPAA, which have been passed in an effort to remedy the privacy concerns of genetics research. Furthermore, the article will discuss whether the states have adequately supplemented the federal legislation. This article will primarily focus on New Jersey and New York law as it will be argued that other states should adopt a similar statutory framework in order to establish more uniform and stringent laws on the use and disclosure of genetics research. Finally, this article will propose solutions to effectively address the individual privacy concerns of genetics research while still allowing for the scientific advancement of genetics research in order to benefit humanity.

I. Genetic Tests and their Administration

A genetic test has generally been as defined as the analysis performed on human deoxyribonucleic acid (hereinafter “DNA”), ribonucleic acid (hereinafter “RNA”), genes and/or

¹² *Id.*

¹³ *Id.* at 140.

¹⁴ Elizabeth Hutton & Devin Barry, *Privacy in Review: Developments in HIPAA*, 1 J.L. & POL’Y FOR INFO. SOC’Y 347, 347 (2004).

¹⁵ Fendrick, *supra* note 2, at 804.

chromosomes in order to detect heritable and acquired genotypes, mutations, phenotypes, or karyotypes that cause or are likely to cause a specific disease or condition.¹⁶ A genetic test also is the analysis of human proteins and certain metabolites, which are predominantly used to detect heritable or acquired genotypes, mutations, or phenotypes.¹⁷

Specifically, there are two general types of health-related genetic tests: diagnostic and predictive.¹⁸ Diagnostic tests are used to identify the presence or absence of a disease.¹⁹ In contrast, predictive genetic tests are used to predict whether an individual will develop a genetic disorder in the future before any signs or symptoms are manifested.²⁰ Early diagnosis and treatment of severe genetic diseases lead many to believe that the benefits of genetics testing and research outweigh the risks,²¹ such as discrimination by employers and/or health insurance providers if an individual's genetic information is distributed without their knowledge.²²

For example, if a tissue provider learns through genetics research that she carries the gene for Huntington's disease, then breaches of confidentiality may be detrimental to the interests of that tissue provider.²³ If third parties, such as an insurance provider or employers gain access to this information, they may find ways to refuse, limit, or terminate that individual's insurance, employment, or other opportunities.²⁴ Also, genetic material identifies not only the individuals

¹⁶ Laren E. Nuffort, *The Genetic Information Nondiscrimination Act of 2008: Raising a Shield to Genetic Discrimination in Employment and Health Insurance*, 21 no. 5 HEALTH LAW 1, 5 (2009).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ Sosnowski, *supra* note 1, at 133.

²² *Id.* at 137.

²³ Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 130 (2009).

²⁴ *Id.*

who provide it, but close family members as well.²⁵ Thus, not only do consenting tissue providers have a stake in the confidentiality of their genetic information, but so do their genetic relatives.²⁶ Consequently, genetic information that is disclosed to an unauthorized source, such as insurance providers or employers, raise substantial privacy concerns.²⁷

Traditionally, researchers have taken a number of steps to protect the confidentiality of tissue providers.²⁸ Specifically, tissue samples may be coded, meaning that they are assigned a number that corresponds to a secret file containing identifying information.²⁹ Thus, identifying information for a particular tissue sample can only be obtained with access to a decoding program or database.³⁰

Moreover, researchers and institutions may “anonymize” tissue samples, a process designed to completely and permanently separate the sample from identifying information.³¹ However, with emerging technology, it is unclear whether true anonymization can ever be achieved.³² DNA is as individually identifying as a fingerprint, and thus any individual cell could be traced back to its source.³³

On the other hand, society has a profound interest in promoting genetics research using human tissue in order to advance scientific development.³⁴ In particular, societal interests may include facilitating researcher access to research materials, incentivizing investment in high

²⁵ *Id.* at 132.

²⁶ *Id.*

²⁷ Sosnowski, *supra* note 1, at 133.

²⁸ Ram, *supra* note 23, at 131.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.* at 132.

³³ *Id.*

³⁴ *Id.* at 137.

quality research, and ensuring that research is conducted in a responsible and ethical matter.³⁵ Simple and inexpensive access to the raw materials of research is critical to promoting investment in science and medicine.³⁶ However, if the interests of research participants are inadequately protected, then potential tissue providers will simply refuse to participate in genetics research.³⁷ Therefore, the scientific advancement of genetics research should be balanced with the protection of individual privacy interests.³⁸

II. Overview of Federal Legislation

A. Health Insurance Portability and Accountability Act of 1996

The HIPAA Privacy Rule is the first federal law to protect health information created or received by health care providers and health plans.³⁹ Specifically, as applied only to “covered entities,” HIPAA limits the circumstances under which “protected health information” may be disclosed.⁴⁰ If an entity is a “covered entity,” it may not disclose “protected health information” except as required or permitted by HIPAA.⁴¹ The Privacy Rule of HIPAA requires covered entities to adhere to a “minimum necessary” standard when disclosing protected health information.⁴² The “minimum necessary” standard provides that when disclosing protected health information, a covered entity must make “reasonable efforts to limit protected health

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.* at 176.

³⁸ *Id.* at 138.

³⁹ Joanne L. Husted & Janlori Goldman, *Genetics and Privacy*, 28 AM. J.L. & MED. 285, 289 (2002).

⁴⁰ Jonathan Hsu, *Genetic Testing: Balancing Preventive Medicine with Privacy and Nondiscrimination*, 6 J.L. & POL’Y FOR INFO. SOC’Y 557, 577 (2011).

⁴¹ 45 C.F.R. § 164.502 (2013).

⁴² *Id.* at § 164.502(b).

information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.”⁴³

A “covered entity” is defined as “a health plan,” “a health care clearinghouse,” “a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter,”⁴⁴ or a “business associate” of another covered entity.⁴⁵ A “health plan” is any plan that pays for health care services such as Medicare, Medicaid, any state or federal health plan, private health plans, and employer self-funded health plans.⁴⁶ Health maintenance organizations also fall within the contours of a “health plan.”⁴⁷ Additionally, a “health care clearinghouse” is any entity that compiles health care information,⁴⁸ such as computer data processing centers and billing companies, which aggregate and process computerized health information.⁴⁹ Moreover, a “health care provider” is anyone who furnishes, bills, or is paid for healthcare in the normal course of business, such as doctors, nurses, therapists, hospitals, medical technicians, nursing homes, rehabilitation centers, psychologists, pharmacists, and therapists.⁵⁰ Finally, “business associates” of a covered entity are those individuals and entities, such as lawyers, accountants, or certain vendors, that are required to have access to and knowledge of “protected health information,” must also abide by HIPAA’s requirements.⁵¹

⁴³ *Id.* at § 164.502(b)(1).

⁴⁴ *Id.* at § 160.102; 42 U.S.C. § 1320d-1 (1996).

⁴⁵ 45 C.F.R. at § 160.103.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*; 42 U.S.C. at § 1320d(3).

⁵⁰ 45 C.F.R. at § 160.103.

⁵¹ *Id.*

Furthermore, “protected health information” (hereinafter “PHI”) is broadly defined under HIPAA as “individually identifiable health information,”⁵² which does not explicitly include genetic information.⁵³ However, the U.S. Department of Health and Human Services (hereinafter “HHS”) has clarified that “genetic information” is covered as “PHI” under the Privacy Rule.⁵⁴ Every covered entity is obligated to protect the confidentiality of individually identifiable information.⁵⁵ Permitted disclosures of PHI are those disclosures to the individual or those disclosures for the purpose of “treatment, payment, or health care operations.”⁵⁶ A covered entity may also disclose PHI to the extent as required by law.⁵⁷ Only covered entities are required to comply with the HIPAA privacy regulations, whereas non-covered entities, such as research laboratories, are not required to comply.⁵⁸ Therefore, genetic information used in research is afforded the same protection under HIPAA as other health care information only if the researcher is characterized as a “covered entity.”⁵⁹

In 2013, HHS released final regulations expanding privacy rights for patients and others under the Privacy Rule of HIPAA.⁶⁰ The regulations expand many of the requirements to business associates of entities that receive protected health information, such as contractors and subcontractors.⁶¹ Ostensibly, some of the largest breaches reported to the HHS have involved

⁵² *Id.* (“Protected health information means individually identifiable health information that is: (i) transmitted by electronic media; maintained in electronic media; or transmitted or maintained in any other form or medium.” *Id.*)

⁵³ *Id.*

⁵⁴ U.S. Department of Health & Human Services, *Health Information Privacy*, March 14, 2006, available at http://www.hhs.gov/ocr/privacy/hipaa/faq/protected_health_information/354.html (last visited at April 5, 2013).

⁵⁵ 45 C.F.R. at § 164.502(a).

⁵⁶ *Id.*

⁵⁷ *Id.* at § 164.512(a)(1).

⁵⁸ Fendrick, *supra* note 2, at 808.

⁵⁹ *Id.* at 809.

⁶⁰ U.S. Department of Health & Human Services, *News Release*, Jan. 17, 2013, available at <http://www.hhs.gov/news/press/2013pres/01/20130117b.html> (last visited at April 5, 2013).

⁶¹ *Id.*

business associates.⁶² Consequently, penalties are increased for noncompliance based on the level of negligence with a maximum penalty of \$1.5 million per violation.⁶³ Also, individual rights are expanded in important ways.⁶⁴ Patients can ask for a copy of their electronic medical record in an electronic form.⁶⁵ When individuals pay by cash they can instruct their provider not to share information about their treatment with their health plan.⁶⁶ There are also limits on how information is used and disclosed for marketing and fundraising purposes and prohibits the sale of an individuals' health information without their permission.⁶⁷

Moreover, HIPAA addresses the concerns associated with the use of genetic information by insurance providers.⁶⁸ HIPAA provides that “genetic information shall not be treated as a [pre-existing] condition in the absence of a diagnosis of the condition related to such information.”⁶⁹ Also, HIPAA precludes insurance providers offering a group health insurance plan from requiring an individual to pay a higher premium than those similarly situated, based solely on the individual's health information, which includes genetic information.⁷⁰ In essence, HIPAA prohibits insurers from using genetic information to deny or limit health insurance coverage.⁷¹

On the other hand, there are many ways that insurers can obtain and adversely use genetic information that are not precluded by HIPAA.⁷² For example, insurers in the group market may charge an entire group of any size more than another group because of the genetic information of

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Sosnowski, *supra* note 1, at 144; 29 U.S.C. § 1182(a)(1)(F) (2008).

⁶⁹ 29 U.S.C. § 1181(b)(1)(B).

⁷⁰ *Id.* at § 1881(b)(3)(A).

⁷¹ Sosnowski, *supra* note 1, at 145.

⁷² Husted, *supra* note 39, at 292.

one individual in the group.⁷³ Also, insurers may request, require, purchase or otherwise collect an applicant's genetic information in the group and individual markets.⁷⁴ Furthermore, insurers in the group market may refuse to cover an entire group because of the genetic information of one individual in the group.⁷⁵

Additionally, employers may learn about the health status and medical conditions of their employees and dependents, in various ways.⁷⁶ One important source of this information is medical examinations required by employers.⁷⁷ Research demonstrates that employers use results from medical examinations when making decisions about hiring, placement, retention, and dismissal.⁷⁸ Another important avenue for collection of medical information is through health claims submitted to employer-sponsored health plans.⁷⁹ All of the ways in which employers may obtain health information could result in employers obtaining genetic information.⁸⁰ An employer that provides health care services to its employees may be a "health care provider" that is required to comply with the HIPAA regulations.⁸¹ Under HIPAA, only employees involved in plan administration would have access to PHI.⁸² Although its protections are substantial, HIPAA does not prevent genetic discrimination by employers.⁸³

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 293.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 291.

⁸² 45 C.F.R. § 164.504(f)(2)(iii).

⁸³ Hutton, *supra* note 14, at 368.

Therefore, a substantial inadequacy of the HIPAA regulations is its failure to reach all people or entities that have access to PHI,⁸⁴ such as tissue banks or researchers.⁸⁵ Also, while HIPAA addresses certain genetic discrimination practices, it was not created for the sole purpose of preventing genetic discrimination.⁸⁶ Because HIPAA sets a federal floor of privacy protections,⁸⁷ state laws that are less protective of privacy are preempted.⁸⁸

B. Genetic Information and Nondiscrimination Act of 2008

GINA amended a variety of federal statutes, including HIPAA, in order to limit health insurers' use of genetic information in making decisions about plan enrollment and in adjusting premiums.⁸⁹ It also regulates how employers may use and store genetic information.⁹⁰ Pursuant to GINA, "genetic information" is defined as the following: "(i) the individual's genetic tests; (ii) the genetic tests of family members of such individual; and (iii) the manifestation of a disease or disorder in family members of such individual,"⁹¹ which does not include sex or age.⁹²

A "genetic test" pursuant to GINA is defined as "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes."⁹³ But there are exceptions that provide that a genetic test is not "an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes,"⁹⁴ or "an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or

⁸⁴ *Id.*

⁸⁵ Christina Strong et. al., *Healthcare Privacy laws- Covered Entities*, 2012 § 10:6 (2012).

⁸⁶ Hutton, *supra* note 14, at 376.

⁸⁷ Husted, *supra* note 39, at 292.

⁸⁸ *Id.* at 293.

⁸⁹ 29 U.S.C. § 1182(b)(1).

⁹⁰ 42 U.S.C. § 2000ff-1(a) (2008).

⁹¹ *Id.* at § 2000ff(4).

⁹² *Id.* at § 2000ff(4)(C).

⁹³ *Id.* at § 2000ff(7).

⁹⁴ *Id.* at § 2000ff(7)(B); *Id.* at § 300gg-91(17)(B)(i).

pathological condition.”⁹⁵ These definitions under GINA do not provide much guidance as to the types of tests considered genetic.⁹⁶

Specifically, Title I of GINA amended HIPAA in order to prevent group health plans and group health insurance issuers from setting group premium or contribution amounts on the basis of genetic information.⁹⁷ Additionally, GINA prohibits plans and issuers from requesting or requiring an individual to undergo genetic tests, and prohibits a plan from collecting genetic information (including family history) prior to or in connection with enrollment,⁹⁸ or for underwriting purposes.⁹⁹ Under GINA, underwriting purposes include rules for determination of eligibility for benefits and the computation of premium and contribution amounts.¹⁰⁰ In other words, plans or issuers are generally prohibited from offering rewards in return for completing a health risk assessment that requests genetic information, including family medical history.¹⁰¹ An exception will allow genetic testing to be requested, but not required, for research purposes when certain conditions are satisfied.¹⁰²

On the other hand, there are some examples where a health insurance plan may obtain or use genetic information that are permitted under GINA.¹⁰³ First, a health insurance plan may recommend to an individual that he or she may want to undergo a genetic test for purposes of disease management or prevention.¹⁰⁴ However, the health insurance plan may only recommend

⁹⁵ *Id.* at § 300gg-91(17)(B)(ii).

⁹⁶ Mark A. Rothstein, *GINA, the ADA, and Genetic Discrimination in Employment*, 36 J.L. MED & ETHICS 837, 838 (2008).

⁹⁷ 26 U.S.C. § 9802(b)(3) (2008).

⁹⁸ *Id.* at § 9802(d)(2).

⁹⁹ *Id.* at § 9802(d)(1).

¹⁰⁰ *Id.* at § 9832(d)(10).

¹⁰¹ Eric N. Miller, *The Genetic Information Nondiscrimination Act of 2008*, 2015, 2016 (2013).

¹⁰² 26 U.S.C. § 9802(c)(4).

¹⁰³ Nuffort, *supra* note 16, at 15.

¹⁰⁴ *Id.*

the genetic test to the individual; it cannot request or require that the test be taken.¹⁰⁵ Also, when certain conditions are satisfied, health insurance plans may request that an individual undergo a genetic test for research purposes.¹⁰⁶

Moreover, Title II of GINA amended HIPAA in order to prohibit private employers, state and federal governmental entities, labor organizations, employment agencies, and joint labor-management committees from discriminating against an employee based on genetic information.¹⁰⁷ An employer engages in an unlawful employment practice if the employer requests, requires, or purchases the genetic information of an employee or family member of that employee.¹⁰⁸

However, there are certain exceptions to this prohibition.¹⁰⁹ First, an employer who inadvertently requests or requires an employee's medical history or an employee's family members' medical history has not committed a violation.¹¹⁰ Second, an employer can offer health or genetic services whereby an employee gives prior, knowing, voluntary, and written authorization, and only the employee or employee's family member and a licensed health care professional receive the results.¹¹¹ This information may be available only for purposes of such services and cannot be disclosed to the employer except in aggregate terms that do not disclose the employee's identity.¹¹² Third, an employer may request or require family medical history

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ 42 U.S.C. § 2000ff-1(2).

¹⁰⁸ *Id.* at § 2000ff-1(b).

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at § 2000ff-1(b)(1).

¹¹¹ *Id.* at § 2000ff-1(b)(2)(B).

¹¹² *Id.* at § 2000ff-1(b)(2)(C).

from the employee in order to comply with state family or medical leave laws.¹¹³ Finally, an employer is permitted to purchase publicly available documents of family medical history.¹¹⁴

Accordingly, GINA provides that unlawful employment practices include failing to hire, discharging, or otherwise affecting a term, condition, or privilege of employment resulting from genetic information received.¹¹⁵ It also prevents an employer from limiting, segregating, or classifying employees, or tending to deprive them of employment opportunities on the basis of genetic information.¹¹⁶ Also, in the event that an employer does obtain access to an individual's genetic information, such information must be kept on separate forms and in separate medical files.¹¹⁷ The information must be treated as confidential medical records of the employee.¹¹⁸

A major concern for both employers and insurers is GINA's overly broad definition of "genetic test."¹¹⁹ The health care industry has recommended that the definition of "genetic test" be limited to predictive testing performed on asymptomatic or undiagnosed individuals for the purpose of assessing the risk of future diseases; because the industry was concerned that the broad definition of "genetic test" would force employers to offer health plan coverage for all treatments for genetically related conditions.¹²⁰ Also, the broad definition of "genetic test" may increase the number of GINA-based lawsuits.¹²¹ However, Congress did not adopt the health industry's recommendation.¹²²

¹¹³ *Id.* at § 2000ff-1(b)(3).

¹¹⁴ *Id.* at § 2000ff-1(b)(4).

¹¹⁵ 42 U.S.C. § 2000ff-1(a)(1).

¹¹⁶ *Id.* at § 2000ff-1(a)(2).

¹¹⁷ *Id.* at § 2000ff-5(a).

¹¹⁸ *Id.*

¹¹⁹ Stephen E. Trimboli & Marissa B. Ruggiero, *Navigating the Genetic Information Nondiscrimination Act of 2008*, 24, 27 (2011).

¹²⁰ *Id.* at 27.

¹²¹ *Id.*

¹²² *Id.* at 28.

For example, in a recent case, the U.S. District Court for the Western District of North Carolina held that the plaintiff failed to state a cognizable claim pursuant to Title II of GINA.¹²³ The plaintiff alleged that he was rejected from employment because of his failure to pass initial screening tests.¹²⁴ However, the court held that there were no allegations that the employer asked for or obtained the plaintiff's genetic information.¹²⁵ Also, the court held that even if the employer did obtain the plaintiff's genetic information, the facts did not suggest that such information was used to discriminate against the plaintiff.¹²⁶

Furthermore, the U.S. District Court for the Southern District of Florida dismissed plaintiff's complaint without prejudice because it failed to allege that the defendant required him to take a genetic test, that the defendant had otherwise obtained the plaintiff's genetic information, or that the defendant had discovered specific genetic information that caused it to deny employment to the plaintiff.¹²⁷ There was also an issue as to the timing of the alleged discrimination.¹²⁸ Any alleged violations taking place prior to Nov. 21, 2009, predate the effective date of Title II of GINA, and thus are not actionable.¹²⁹

One of the purposes of GINA was to reconcile the various state laws that had been adopted on the issue of genetic discrimination and establish a "national and uniform basic standard."¹³⁰ However, if that was truly Congress' intent, one would expect Congress to preempt the legislation in this area.¹³¹ Instead, Title II of GINA expressly provides that its provisions cannot

¹²³ Bullock v. Spherion, No. 3:10-cv-465, 2011 WL 1869933, at *4 (W.D.N.C., May 16, 2011).

¹²⁴ *Id.* at *1.

¹²⁵ *Id.* at *6.

¹²⁶ *Id.*

¹²⁷ Citron v. Niche Media/Ocean Drive Magazine, No. 10-24014- CIV, 2011 WL 381939, at *2 (S.D. Fla. Feb. 2, 2011).

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881, § 2(5) (2008).

¹³¹ Trimboli, *supra* note 119, at 28.

be construed to “limit the rights or protections of individuals under any other Federal or State statute that provides equal or greater protection.”¹³² This provision seems inconsistent with the stated intention of creating a uniform national standard.¹³³ Because of varying state laws and the rapid development of genetic science, there may be unintended consequences that arise from Congress’ inability to accurately predict future results subsequent to GINA’s adoption¹³⁴

C. Synthesis

A substantial inadequacy of HIPAA is its inability to reach all entities or persons that have access to an individual’s PHI. HIPAA applies only to “covered entities” that have access to an individual’s PHI, which include “genetic information.” Thus, entities such as certain research laboratories and tissue banks do not have to comply with HIPAA’s regulations and may freely disclose an individual’s identifiable genetic information to an unauthorized source, such as employers and/or health care providers. Also, while HIPAA creates some restrictions on the use of an individual’s PHI, it was not created for the sole purpose of preventing discrimination by employers and/or health care providers.

On the other hand, GINA amended HIPAA in order to preclude discriminatory conduct by employers and/or health insurance providers if they gain access to individual’s PHI. However, while GINA improved the anti-discriminatory provisions of HIPAA, it does not prevent certain entities, such as research laboratories or tissue banks, from disclosing an individual’s identifiable genetic information to third parties without authorization.

¹³² 42 U.S.C. § 2000ff-8(1).

¹³³ Trimboli, *supra* note 119, at 28.

¹³⁴ *Id.* at 27.

Therefore, federal legislation allows certain researchers and tissue banks to freely disclose to a third party an individual's PHI, including identifiable genetic information, without authorization. Consequently, employers and/or health care providers are still able to gain access to an individual's PHI through researchers or tissue banks and possibly make discriminatory judgments based on this information. Because of the incomprehensive nature of federal legislation, the states have implemented laws to effectively address these privacy concerns of genetics research.

III. Overview of State Legislation

A. "Genetic Information" and "Genetic Test"

Inadequate federal legislation with regard to an individual's genetic information has prompted states to pass laws that impose higher standards.¹³⁵ State protections of genetic information do not mirror one another, and thus vary widely in their capabilities.¹³⁶ Many states have passed legislation that place restrictions on what constitutes a genetic test and place limits on the collection and disclosure of genetic information.¹³⁷ These restrictions have varying effects on genetic research, which depend on the definitions of "genetic information" and "genetic tests" and how broadly these terms are defined in the legislation.¹³⁸ Consequently, the variety of definitions generates difficulty in determining the information that should be protected.¹³⁹

¹³⁵ Fendrick, *supra* note 2, at 812.

¹³⁶ Nuffort, *supra* note 16, at 9.

¹³⁷ Fendrick, *supra* note 2, at 812.

¹³⁸ *Id.*

¹³⁹ Michael S. Yesley, *Protecting Genetic Difference*, 13 BERKELEY TECH. L.J. 653, 661 (1998).

Accordingly, state legislation that narrowly defines “genetic information” may be easier to implement, but may not provide sufficient protection.¹⁴⁰ For example, Massachusetts provides that genetic information “shall not include any information about an identifiable person that is taken: (1) as a biopsy, autopsy, or clinical specimen solely for the purpose of conducting an immediate clinical or diagnostic test that is not a test of DNA, RNA, mitochondrial DNA, chromosomes or proteins.”¹⁴¹ Therefore, Massachusetts distinguishes between research and clinical data.¹⁴²

In contrast, some states use broad definitions of “genetic test” that do not exclude certain research from their scope, which may restrict the ability of researchers to use tissue samples.¹⁴³ For example, “genetic test” is defined in Louisiana as “any test for determining the presence or absence of genetic characteristics in an individual, including tests of nucleic acids, such as DNA, RNA, and mitochondrial DNA, chromosomes, or proteins in order to diagnose or identify a genetic characteristic or that detects genotypes, mutation, or chromosomal changes.”¹⁴⁴

On the other hand, many statutes contain language similar to that found in Nebraska, which excludes from the definition of “genetic test” any activities undertaken as part of biomedical research: “Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.”¹⁴⁵

¹⁴⁰ *Id.* at 660.

¹⁴¹ Mass. Gen. Laws Ann. Ch. 111 § 70G(a)(1) (2000).

¹⁴² *Id.*

¹⁴³ *See, e.g.* LA. Rev. Stat. Ann. § 22:213.7(A)(9)(a) (2003).

¹⁴⁴ *Id.*

¹⁴⁵ Neb. Rev. Stat. § 77-5519 (2012).

B. Informed Consent

Some states require informed consent from the individual providing the genetic material before the information and/or material can be disclosed for research purposes.¹⁴⁶ Within a number of states requiring informed consent, specific provisions are included that regulate the retention and future use of blood and tissue samples.¹⁴⁷ Specifically, Delaware, Nevada, New York, New Jersey, and Oregon have laws requiring researchers to obtain individual informed consent in order to retain “genetic information.”¹⁴⁸

For example, in New Jersey genetic privacy is regulated pursuant to New Jersey’s Genetic Privacy Act.¹⁴⁹ The act prevents employers and insurance companies from discriminating against individuals on the basis of their genetic information.¹⁵⁰ “Genetic information” is defined as the “information about genes, gene products or inherited characteristics that may derive from an individual or family member.”¹⁵¹ The act protects genetic privacy by mandating that genetic information be destroyed after completion of the research project unless individual consent is obtained to retain the sample.¹⁵²

Similarly, New York protects the confidentiality of records of genetic tests.¹⁵³ New York law imposes stringent requirements for informed consent and retention of samples for limited periods, but the law permits the research on anonymous samples, pursuant to a research protocol

¹⁴⁶ Yesley, *supra* note 139, at 660.

¹⁴⁷ *Id.*

¹⁴⁸ Del. Code Ann. tit. 16, § 1202 (2012); Nev. Rev. Stat. § 629.161 (2007); N.Y. Civil Rights Law § 79-1(2)(a) (McKinney 2002); N.J. Stat. Ann. § 10:5-46 (1996); Or. Rev. Stat. § 192.535 (West 2009).

¹⁴⁹ N.J. Stat. Ann. § 10:5-43 (1996).

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at § 10:5-5.

¹⁵² *Id.* at § 10:5-46; see Mich. Comp. Laws § 333.17520(2) (2000) (Michigan also requires that informed consent incorporate a statement of future use of the sample and specify who will have access to the sample). However, most states only require informed consent for use of genetic data in research if the genetic material is identifiable and can be linked to an individual. See, e.g. Ark. Code Ann. § 20-35-103(c)(1) (2001).

¹⁵³ N.Y. Civil Rights Law § 79-1 (McKinney 2002).

approved by an institutional review board (hereinafter “IRB”), when the identity of the individuals is protected.¹⁵⁴ In general, New York prohibits the conduct of “genetic tests” without the prior written informed consent of the individual.¹⁵⁵ A “genetic test” is defined as:

...Any laboratory test of human DNA, chromosomes, genes, or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disability in the individual or the individual’s offspring; such term shall also include DNA profile analysis. ‘Genetic test’ shall not be deemed to include any test of blood or other medically prescribed test in routine use that has been or may be hereafter found to be associated with a genetic variation unless conducted purposely to identify such genetic variation.¹⁵⁶

According to the New York statute, valid informed consent must be obtained prior to a “genetic test.”¹⁵⁷ Specific elements must be incorporated into the informed consent form, which include the following: a general description of each specific disease or condition that will be tested, the level of certainty that a positive test result for that disease or condition serves as a predictor of such disease, the name of the person or categories of persons or organizations to whom the test results may be disclosed, and a statement that no tests other than those authorized shall be performed on the biological sample.¹⁵⁸

For clinical genetic tests, the informed consent must provide that the sample shall be destroyed at the end of the testing process, or not more than sixty days after the sample was taken, unless a longer period of retention is expressly authorized in the consent.¹⁵⁹ New York law requires individual authorization for sample retention for up to ten years if no genetic testing

¹⁵⁴ *Id.* at § 79-1(9)(a).

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at § 79-1 (a).

¹⁵⁷ *Id.* at § 79-1(2)(a).

¹⁵⁸ *Id.* at § 79-1(2)(b).

¹⁵⁹ *Id.* at § 79-1(2)(b)(7).

is performed; however, informed consent must be obtained prior to the conduct of genetic tests.¹⁶⁰

On the other hand, for research (rather than for clinical purposes), New York law provides that samples may be used without individual informed consent when IRB approval of the research protocol is given, as long as the identity of the individual has been removed, the results are not linked to the person, and no information relating to the identity of the individual is disclosed.¹⁶¹ Therefore, for the purposes of compliance with the New York law, the samples and data may be used as proposed, as long as IRB approval is obtained, and the information regarding individual identities is protected.¹⁶²

Moreover, individual ownership of “genetic information” has been declared by four states: Colorado, Florida, Georgia, and Louisiana.¹⁶³ However, of the four states that declare that genetic information is “owned” by the individual, three of them (Colorado, Georgia, and Louisiana) permit the use of “genetic information” for research purposes when the identity of the individual is not disclosed.¹⁶⁴ Thus, while these provisions appear restrictive, they permit the use and retention of genetic information for research purposes when the data are anonymous.¹⁶⁵

Finally, Michigan and Nebraska also have identical statutes for the conduct of “genetic tests,” which impose a strict requirement to obtain informed consent from individuals that incorporates a statement of future uses of the sample and who will have access to the sample.¹⁶⁶

¹⁶⁰ *Id.* at § 79-1(9)(e)(10).

¹⁶¹ *Id.* at § 79-1(9)(a).

¹⁶² *Id.*

¹⁶³ Col. Rev. Stat. § 10-3-1104.7 (2009); Fla. Stat. § 760.40(2)(a) (2009); Ga. Code Ann. § 33-54-1 (2012); La. Rev. Stat. Ann. § 22:213.7(E) (2012).

¹⁶⁴ Col. Rev. Stat. at § 33-54-1(2)(b)(5); Ga. Code Ann. at § 33-54-6; La. Rev. Stat. Ann. at § 22:213.7(D)(4).

¹⁶⁵ *Id.*

¹⁶⁶ Mich. Comp. Laws at § 333.17520(2); Neb. Rev. Stat. § 71-551(1) (2012).

Both states permit research without informed consent when research is conducted pursuant to federal regulations.¹⁶⁷ Similarly, South Carolina imposes strict limits on the conduct of genetic tests for clinical purposes, but permits the use of samples and information for research purposes when patient identities are not disclosed.¹⁶⁸

C. Synthesis

A noteworthy addition to the federal legislation has been the states' broad definition of "genetic information" or "genetic test" in conjunction with a comprehensive informed consent procedure prior to any genetic testing/research. A broad definition of "genetic information" or "genetic test" places most research within the scope of the statute.

Furthermore, a comprehensive informed consent procedure restricts the use and disclosure of an individual's identifiable genetic information. Generally, the informed consent form requests information from the research participant regarding future use of the genetic sample, such as permissible disclosures to third parties. Specifically, New York mandates that informed consent must be obtained prior to any "genetic test." Similarly, in New Jersey, all "genetic information" must be destroyed after genetics research and/or genetic testing, unless the individual participant provides otherwise. This ensures that an individual's identifiable genetic information is not being released to an unauthorized third party after the research and/or testing has been completed.

Therefore, when the data of a genetic sample is not anonymous, certain states have adequately protected the unauthorized disclosure of an individual's "genetic information" through an informed consent procedure prior to genetics research and/or testing. A

¹⁶⁷ *Id.*

¹⁶⁸ S.C. Code Ann. § 38-93-40(A) (2010).

comprehensive informed consent procedure ensures that an individual's identifiable genetic information is not released to an unauthorized third party, thus preserving that individual's genetic privacy.

IV. Proposed Recommendations to Preclude Unauthorized Disclosure of an Individual's Identifiable Genetic Information

Although genetics research provides invaluable information in the study and treatment of diseases, there is a substantial privacy concern with respect to an individual's identifiable genetic information following the completion of genetics research and/or testing. There are certain research entities that are not regulated by federal or state law and pose a threat to an individual's genetic privacy by freely disseminating an individual's identifiable "genetic information" without authorization.

Specifically, in order to address the ongoing privacy concerns of genetics research, the following recommendations are proposed: (1) HIPAA should be amended to mandate that any person or entity with access to an individual's PHI must comply with HIPAA's privacy regulations; (2) a majority of states should adopt a statutory framework similar to New Jersey and New York law, which include informed consent provisions, in order to preclude the unauthorized disclosure of an individual's identifiable genetic information; or (3) Congress should preempt the entire field on this matter in order to establish more uniformity. These changes will reach a balance that protects an individual's genetic privacy while still allowing for the scientific advancement of genetics research to progress for the benefit of humanity.

First, HIPAA could be amended to mandate that any person or entity with access to an individual's PHI must comply with the HIPAA privacy regulations. Most research laboratories

or tissue banks do not fall within the definition of a “covered entity.” This amendment would regulate those certain research laboratories or tissue banks that do genetics research/testing or any other person that has access to an individual’s identifying “genetic information.” Thus, if a research laboratory has done genetics research or testing, that research laboratory can only disclose that individual’s identifying “genetic information” to the individual research participant, or those necessary disclosures for the purpose of “treatment, payment, or health care operations.” This amendment to HIPAA would ensure that confidentiality of an individual’s identifying genetic information is preserved and only used or disclosed as needed.

Next, the states could adopt a statutory framework similar to New Jersey and New York in order to preclude the unauthorized disclosure of an individual’s identifiable genetic information. New Jersey mandates that unless the research participant authorizes otherwise, an individual’s genetic information must be destroyed after the completion of genetic research or testing. Also, New York mandates that informed consent must be obtained prior to any “genetic test.” The informed consent requests information with regard to future use of the genetic sample, such as authorized disclosures. Furthermore, New York suggests a longer retention of genetic information if anonymity is preserved along with IRB approval. Therefore, so long as there is no identifying link between the sample and the research participant, then a longer retention of the sample could be permissible. Adopting a similar statutory framework will ensure that an individual’s identifiable genetic information is not freely disseminated to unauthorized third parties, such as employers and/or health care providers.

Finally, another option to precluding the unauthorized disclosure of an individual’s identifiable genetic information could be for Congress to preempt the entire area of law on this particular matter. HIPAA could be amended as the first proposal suggests to mandate that any

person or entity with access to an individual's PHI must comply with the HIPAA privacy regulations. Moreover, HIPAA could also be amended to incorporate similar informed consent provisions as noted in the second proposal. As a result, there would be more uniformity on the type of conduct that is regulated. This would establish a more "national and uniform basic standard," as originally intended by Congress, and ensure the confidentiality of an individual's identifiable genetic information is preserved. More uniformity is necessary in order to create less confusion on the type of conduct that is regulated.

Although the proposed amendments to HIPAA may establish more uniformity it is likely not a practicable recommendation. It would probably take Congress many years to amend a federal statute, such as HIPAA. In order to effectively regulate research laboratories and tissue banks, the states will probably have to continue to take the initiative by establishing comprehensive informed consent procedures prior to any "genetic test." A comprehensive informed consent procedure will ensure that an individual's identifiable genetic information is not disclosed to an unauthorized third party, such as employers and/or health insurance providers. Also, expanding the definition of what constitutes a "genetic test" will ensure that certain research laboratories and tissue banks are properly regulated.

V. Conclusion

Genetics research is critical to the study and treatment of diseases; however, there is a substantial privacy concern with respect to an individual's identifiable genetic information after the research and/or testing has been completed. Certain research laboratories or other entities not covered under federal or state legislation may freely disseminate an individual's identifiable genetic information to third parties, which could result in various types of discrimination by employers and/or health insurance providers. The aforementioned proposals would preserve the confidentiality of an individual's identifiable genetic information while still allowing for the scientific advancement of genetics research in order to benefit humanity.