CRITICAL DILEMMAS IN GENETIC TESTING: WHY REGULATIONS TO PROTECT THE CONFIDENTIALITY OF GENETIC INFORMATION SHOULD BE EXPANDED

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I. INTRODUCTION

Deoxyribonucleic acid (DNA) was first analyzed by Watson and Crick in 1953.[1] Due to scientific advances, over 1,000 genetic tests are presently available.[2] The confidentiality of vast amounts of genetic information available today presents multiple scientific and ethical dilemmas.[3] Because of these dilemmas, the law and bioethics have become intimately connected.[4]

The first genetic test ever developed detected Huntington's Disease (HD), a genetic disorder which causes individuals to eventually lose mental and physical control of their bodies.[5] Imagine having a family history of HD and being the parent of an adult child. You decide to undergo genetic testing to see if you carry the HD genetic mutation. The results show that you carry the gene and already have reached the early stages of HD. You

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[1] *See* J.D. Watson & F.H. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 4356 NATURE 737, 737–38, *reprinted in* 160 AM. J. PSYCHIATRY 623, 623 (2003).

[2] Human Genome Project Information: Gene Testing, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml (last visited Apr. 16, 2010) [hereinafter Gene Testing].

[3] *See* Dale Halsey Lea et al., *Ethical Issues in Genetic Testing*, 50 J. MIDWIFERY & WOMEN'S HEALTH 234, 234–37 (2005).

[4] Susan M. Wolf, *Law & Bioethics: From Values to Violence*, 32 J.L. MED. & ETHICS 293, 295 (2004).

[5] EW Almqvist et al., *Psychological Consequences and Predictors of Adverse Events in the First Five Years After Predictive Testing for Huntington's Disease*, 64 CLINICAL GENETICS 300, 300 (2003) (analyzing the distressing psychological effects of undergoing genetic testing for the neurodegenerative disorder known as Huntington's Disease).

tell your adult daughter because she may have inherited the genetic mutation from you. When your daughter applies for health insurance and discloses her family's history of HD, she is denied any coverage until she is genetically tested for the HD mutation and the result is negative. Unfortunately, this discriminatory scenario actually happened to Phil Hardt's daughter.[6]

Numerous regulations have been enacted to prevent genetically-based discrimination and to protect the confidentiality of patients' medical records, including genetic information. However, federal regulations, like the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[7] and the Genetic Information Nondiscrimination Act of 2008 (GINA),[8] have limited applications because they are only relevant in restricted circumstances. While the situation with Phil's daughter applying for generic health insurance would be illegal today under the health insurance non-discrimination provisions of GINA, the same situation is still perfectly legal in multiple other insurance contexts such as long term care or disability insurance. For many people like Terry McCarty, whose wife is a carrier of the HD genetic mutation, the discriminatory denial of long term disability coverage on the basis of merely possessing a HD genetic mutation is even scarier than not having any health insurance at all.[9]

Part II of this article provides a foundation for understanding the science of genetic testing. Part III reviews the dismal patchwork of federal and state regulations for protecting the confidentiality of genetic information. The discussion of the impact of these regulations includes a review of existing survey and vignette studies involving the dilemmas stemming from genetic testing scenarios that many medical professionals are faced with in

[6] SECRETARY'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, DEP'T OF HEALTH & HUMAN SERVS., PUBLIC PERSPECTIVES ON GENETIC DISCRIMINATION: SEPTEMBER 2004–NOVEMBER 2004 23–25 (2004), *available at* http://oba.od.nih.gov/oba/sacghs/reports/Public_Perspectives_GenDiscrim.pdf (collecting written and live testimony from individuals about their experiences with genetic discrimination) [hereinafter PUBLIC PERSPECTIVES].

[7] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936.

[8] Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881.

[9] *See* PUBLIC PERSPECTIVES, *supra* note 6, at 48. McCarty's testified about how his wife's diagnosis will impact their lives and finances given the almost instant industry-wide denial of long term disability coverage for individuals who test positive for HD and the lack of available alternatives or nursing homes willing to care for individuals who eventually develop the debilitating disease. *Id.*

their daily practices and how they report dealing with the issues when they arise. Part IV examines scientific and policy-based concerns associated with genetic testing which demonstrates the need to increase existing confidentiality protections for genetic information. Part V explores the ethical aspects of privacy, autonomy, and the Hippocratic Oath; all of which support extending regulations to protect the confidentiality of genetic information. Part V also responds, using ethics and logic-based arguments, to proponents who seek to dismantle confidentiality protections to allow disclosures of genetic information in many more contexts. This article concludes that the lack of uniformly applicable regulations for protecting the confidentiality of genetic information has created scientific and ethical dilemmas that necessitate more encompassing federal and state policies in the field of genetic testing.

II. SCIENTIFIC ASPECTS OF GENETIC TESTING

Cells are the essential units of all living systems.[10] DNA sequences dictate how cells develop.[11] In humans, DNA is arranged into units of twenty-three pairs of chromosomes with each chromosome containing many genes, "the basic physical and functional units of heredity."[12] Ribonuclic acid (RNA) transmits DNA's code from cells' nuclei to ribosomes so proteins conform to DNA's design.[13] Genomes are the complete set of an organism's DNA.[14]

Genetic testing includes the analysis of DNA to identify sequences associated with diseases.[15] Some genetic traits, like eye color, can be detected from physical appearance. However, other types of genetic traits, those only discoverable by genetic tests, present most of the relevant ethical

[10] Human Genome Project, U.S. Dep't of Energy, *Genomics & Its Impact on Science & Society* (2008), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer2001/primer11.pdf [hereinafter *Genomics*].

[11] *Id.*

[12] *Id.*

[13] Elizabeth Pennisi, *DNA's Cast of Thousands*, 300 SCIENCE 282, 283 (2003); *see also* Cynthia D. Lopez-Beverage, *Should Congress Do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents?*, 10 J. TECH. L. & POL'Y 35, 41–51 (2005) (providing a more in-depth discussion of DNA and RNA).

[14] *Genomics*, *supra* note 10, at 1.

[15] Gene Testing, *supra* note 2.

problems.[16]

Genetic testing is an invaluable tool because information derived from these types of tests facilitates the diagnosis and confirmation of diseases.[17] Such testing provides clues about the probable courses of diseases, including the ability to predict the risk of developing specific diseases in the future.[18] Genetic components exist with respect to every disease or medical disorder from cancer to diabetes.[19] Estimates indicate that each human is predisposed to between five and fifty serious disorders.[20]

Genetic information can be used to help prevent or detect several diseases early enough to effectively manage them.[21] For instance, individuals who test positive for a hereditary nonpolyposis colorectal cancer gene, also known as Lynch syndrome, have a ninety percent lifetime risk of developing one of the cancers associated with that gene.[22] Early detection of a genetic trait with such a high likelihood of developing could be the difference between a painful and premature death and having a substantially full and healthy life. Gaining knowledge about various genetic mutations may also result in the development of new treatments and cures.[23]

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[16] *See* Janet L. Dolgin, *The Evolution of the "Patient:" Shifts in Attitudes About Consent, Genetic Information, and Commercialization in Health Care*, 34 HOFSTRA L. REV. 137, 164–65 (2005).

[17] *Genomics*, *supra* note 10, at 5.

[18] *Id.*

[19] Congresswoman Louise M. Slaughter, Address at the Harvard Graduate School of Arts & Sciences Science Policy Group (Apr. 17, 2009), *in* U.S. FED. NEWS, Apr. 18, 2009, *available at* 2009 WLNR 7265066.

[20] *Id.*

[21] *Id.* However, genetics test results are not necessarily accurate because of the lack of federal regulation of laboratories. *See* Gregorio M. Garcia, *The FDA and Regulation of Genetic Tests: Building Confidence and Promoting Safety*, 48 JURIMETRICS J. 217, 217–18 (2008). Additionally, genetic testing's potential is limited by low clinical sensitivity rates, misinterpretation of results, incomplete knowledge about the effect of genetics on certain disease development, and variables such as environmental factors and the effects of multiple genes interacting. Allison Ito, *Privacy and Genetics: Protecting Genetic Test Results in Hawai'i*, 25 U. HAW. L. REV. 449, 455–56 (2003). *See also infra* notes 155–162 and accompanying text.

[22] Slaughter, *supra* note 19. Some of the known cancers associated with the gene include cancers of the stomach, small intestine, liver, gallbladder ducts, upper urinary tract, brain, skin, and prostate. U.S. National Library of Medicine, Genetics Home Reference, Lynch Syndrome, http://ghr.nlm.nih.gov/condition=lynchsyndrome (last visited Mar. 16, 2010). Additionally, women with the gene have a higher risk of developing cancers of the ovaries and endometrium, the lining of the uterus. *Id.*

[23] Alissa Brownrigg, *Mother Still Knows Best: Cancer-Related Gene Mutations, Familial*

The benefits of genetic testing are overshadowed by the lack of regulations protecting the confidentiality of genetic information. Though theoretically overturned by subsequent legislation including HIPAA, some state courts ruled that physicians have a duty to disclose patients' genetic information to third parties who are the patients' genetic relatives in certain circumstances.[24] Additionally, Americans admit to forgoing genetic testing because of uneasiness about the lack of confidentiality protections for genetic information and how that can cause discrimination in numerous areas of their lives.[25] Therefore, scientific and ethical debates over genetic information obtained from voluntary tests usually surround both whether and to what extent this information should be confidential.

III. THE CURRENT STATUS OF FEDERAL AND STATE GENETIC INFORMATION LAWS

Confidential relations between physicians and patients are important and socially beneficial.[26] To that end, the federal government has attempted to maintain the sanctity of the physician-patient relationship. However, federal regulations are insufficient to protect the confidentiality of genetic information in many cases. Congress, reluctant to pass genetic information legislation with wide-sweeping effects, created narrowly-tailored regulations that only apply in specific situations.[27] As such, the states have

Privacy, and a Physician's Duty to Warn, 26 FORDHAM URB. L.J. 247, 254–60 (1999) (discussing BRCA mutations and the benefits of the genetic tests for the treatment and diagnosis of breast and ovarian cancers).

[24] Pate v. Threlkel, 661 So. 2d 278, 282 (Fla. 1995) (holding that the defendant physician had a duty to warn patient's adult children of genetically transferable condition, medullary thyroid carcinoma, despite lack of privity; however, such a duty was discharged by warning the patient); Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996) (holding that the defendant physician had a duty to warn members of patient's immediate family of genetically transmittable condition, multiple polyposis of the colon, when his patient tested positive for the gene and developed the condition, but not permiting the duty to be satisfied by merely warning the patient to communicate knowledge of the genetic condition to his family). *See also infra* notes 110–127 and accompanying text.

[25] Joanne L. Hustead & Janlori Goldman, *Genetics and Privacy*, 28 AM. J.L. & MED. 285, 285 (2002) (stating that the United States lacks a "coherent policy" for genetic testing and the use of genetic information).

[26] Ralph Ruebner & Leslie Ann Reis, *Hippocrates to HIPAA: A Foundation for a Federal Physician-Patient Privilege*, 77 TEMP. L. REV. 505, 508–09 (2004) (stating that the physician-patient relationship is important for promoting individuals' sense of privacy).

[27] Hustead & Goldman, *supra* note 25, at 288 (analyzing the gaps in HIPAA's application and

been left to fill in the federal voids as they see fit by enacting laws about the confidentiality of genetic information.[28]

A. Federal Genetic Information Laws

1. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The federal government's best privacy protection regulation regarding health information is HIPAA.[29] HIPAA lead to the creation of "The Privacy Rule"[30] to guard patients' health information.[31] The Department of Health and Human Services (HHS) was charged with the task of administering the Privacy Rule.[32] Within the HHS, the Office for Civil Rights has the ultimate responsibility for implementing and enforcing the Privacy Rule.[33] Regrettably, HIPAA and its "Privacy Rule" do not apply to all of the circumstances involving genetic information.[34] HIPAA's protections are limited because the statute's application is targeted at specific entities, information, and situations.[35]

HIPAA only applies to businesses and individuals that meet the statutory definition of covered entities.[36] "Covered entities" include:

Congressional reluctance to fully engage the issue of genetic privacy in legislation).

[28] *See* Ruebner & Reis, *supra* note 26, at 533.

[29] *See id.* at 508.

[30] *See HIPAA Privacy Complaints: What to Expect*, HEALTHCARE REGISTRATION, May 2008, at 1, 6–7. Compliance with HIPAA's Privacy Rule did not become mandatory until April 14, 2003. *Id.*

[31] *See* Ruebner & Reis, *supra* note 26, at 510–11.

[32] Mark A. Rothstein, *Research Privacy Under HIPAA and the Common Rule*, 33 J.L. MED. & ETHICS 154, 158 (2005).

[33] OFFICE FOR CIVIL RIGHTS, U.S. DEP'T OF HEALTH & HUM. SERVS., SUMMARY OF THE HIPAA PRIVACY RULE 1 (2003), *available at* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacy summary.pdf [hereinafter OFFICE FOR CIVIL RIGHTS].

[34] Ito, *supra* note 21, at 459–60 (stating that HIPAA does not address the broad spectrum of privacy and non-discrimination concerns that surround genetic information).

[35] Hustead & Goldman, *supra* note 25, at 288. HIPAA does not directly apply to entities that create or receive health care information, such as pharmaceutical companies, workers' compensation insurers, employers, and many researchers. *Id*. Instead, HIPAA either indirectly regulates entities not specified in federal regulations or does not apply to them at all even though they have access to protected health information. *Id.*

[36] 45 C.F.R. § 160.102 (2009).

(1) health plans, (2) health care clearinghouses, and (3) health care providers transmitting health information electronically in connection with HIPAA-regulated transactions.[37] The term "health plans" encompasses most public and private health plans, whether group or individually sponsored, that provide or pay the cost of medical care.[38] The statute exempts group health plans with less than fifty participants if they are solely administered by the employer.[39] Additionally, certain types of insurance entities like workers' compensation or automobile insurance are exempted from qualifying as covered entities under the health plan provision.[40] "Health care clearinghouses" are entities that "process[] or facilitate[] the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction," or vice versa.[41] Outside billing services are the most common example of a health care clearinghouse.[42] "Health care providers" include providers of medical or health services and other people or organizations furnishing or being paid for health care in the normal course of business.[43]

HIPAA regulates protected health information, which includes genetic information.[44] "Protected health information" is "individually identifiable health information" that is not otherwise exempted.[45] "Individually identifiable health information" is defined as the following:

> [I]nformation that is a subset of health information, including demographic information collected from an individual, and:
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> (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
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> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health

[37] *Id.* § 160.103.

[38] *Id.*

[39] OFFICE FOR CIVIL RIGHTS, *supra* note 33, at 2.

[40] *Id.*

[41] 45 C.F.R. § 160.103.

[42] *See id.*

[43] *Id.* The category of health care providers also includes providers specifically referenced by statute. *See id.*

[44] Ito, *supra* note 21, at 459.

[45] 45 C.F.R. § 160.103.

> care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
>
> (i) That identifies the individual; or
>
> (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.[46]

Under HIPAA, genetic information qualifies as protected health information if it otherwise meets the statutory definition.[47]

HIPAA's privacy protections, in summary, apply when "protected health information" is improperly used or disclosed by a "covered entity."[48] Compliance with HIPAA is voluntary when non-covered entities have control over protected health information and when information is not classified as "protected health information."[49] When compliance with HIPAA is not voluntary, violators are subject to criminal penalties—including fines and imprisonment.[50]

There are many situations where loopholes permit covered entities to properly disclose an individual's genetic information without violating HIPAA. Entities like researchers and genetic test developers can disclose genetic information without individuals' consent.[51] For instance, covered entities are able to avoid HIPAA's disclosure requirements if they explicitly state on consent forms that the research results will not become part of the subject's medical records.[52] Additionally, if certain requirements are met,

[46] *Id.*

[47] Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,621 cmt. & response (Dec. 28, 2000). In response to a comment that genetic information should qualify as protected health information, the Department of Health and Human Services stated that if the information met the statutory requirements for "public health information" it would be protected. *Id.* However, the Department of Health and Human Services refused to specify any particular type of information, including genetic information, in the regulations because "singling out specific types of protected health information for special mention in the regulation text could wrongly imply that other types are not included." *Id.*

[48] Ito, *supra* note 21, at 460.

[49] *Id.* at 460–61.

[50] *See* 42 U.S.C. §§ 1320d-5, -6 (2006).

[51] Hustead & Goldman, *supra* note 25, at 288.

[52] *See* Matthew P. Gordon, *A Legal Duty to Disclose Individual Research Findings to Research Subjects?*, 64 FOOD & DRUG L.J. 225, 232–33 (2009) (discussing the lack of a legal duty for researchers to disclose genetic test results to participants, but also suggesting that such results might end up on research participants' medical records).

covered entities can even disclose protected health information for research purposes without informing individuals who then become unknowing donors.[53] Covered entities can distribute medical information to non-covered entities through agreements where non-covered entities in non-research categories promise to secure the privacy of the data it receives under HIPAA.[54] Additionally, genetic test manufacturers are not required to get consent from sample donors to disclose their genetic information to third parties.[55] Given these and many other examples, HIPAA's privacy protections are limited in scope and application.

2. The Genetic Information Nondiscrimination Act of 2008 (GINA)

HIPAA's continuous inability to fully protect the confidentiality of genetic information finally prompted the federal government to enact GINA over a decade later.[56] In addition to medical contexts, GINA also serves to correct problems with genetic discrimination in employment which are caused by the lack of coverage for this type of discrimination under existing federal regulations.[57] Specifically, while the Americans with Disabilities Act of 1990 (ADA)[58] was made to apply to individuals with symptomatic genetic diseases, it did not appear to protect genetic disease mutation carriers who were pre-symptomatic, asymptomatic, or unaffected by the genetic mutation.[59]

GINA prohibits using genetic tests and the evaluation of genetic information as conditions for obtaining or keeping certain insurance coverage or employment opportunities.[60] GINA applies to both public and

[53] *See* 45 C.F.R. § 164.512(b)(i) (2009).

[54] Daniel Schlein, *New Frontiers for Genetic Privacy Law: The Genetic Information Nondiscrimination Act of 2008*, 19 GEO. MASON U. CIV. RTS. L.J. 311, 340 (2009).

[55] *Efforts to Control Genetic Testing*, 27 BIOTECHNOLOGY L. REP. 315, 315–16 (2008).

[56] Schlein, *supra* note 54, at 339 (discussing how health plans and providers were able to use and disclose plan participants' genetic test results to create guidelines and policy limits for new and existing health insurance contracts and benefits despite HIPAA's restrictions).

[57] William J. McDevitt, *I Dream of GINA: Understanding the Employment Provisions of the Genetic Information Nondiscrimination Act of 2008*, 54 VILL. L. REV. 91, 92 (2009).

[58] Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified at 42 U.S.C. § 12101 (2006)).

[59] McDevitt, *supra* note 57, at 115.

[60] Teneille R. Brown, *Double Helix, Double Standards: Private Matters and Public People*, 11 J. HEALTH CARE L. & POL'Y 295, 329 (2008); *see also Efforts to Control Genetic Testing*,

private employment.[61] Title I of GINA, dealing with insurance coverage, became effective in May of 2009, and Title II of GINA, concerning employment regulations, went into effect in November of 2009.[62]

Many non-geneticists incorrectly believe that the presence of a genetic mutation is an "unalterable prediction that a person will manifest the associated disorder."[63] If a person tests positive for a genetic mutation, there is no guarantee that the person will ever develop that genetic disease.[64] Rather, genetic tests simply reveal the risk that an individual has of developing a specific disease.[65] Misplaced beliefs about the meaning of genetic test results are documented to have caused numerous individuals to forego genetic testing and genetic research participation because of fears that employers and insurance companies would access the information and use it to discriminate against those individuals.[66] Even when genetic tests can avoid premature morbidity, Americans feel so unprotected by genetic information confidentiality regulations that they are willing to decline such testing.[67]

Justified fears of discrimination on the basis of genetic information prompted legislators to enact GINA. The story of genetic discrimination within the employment sector is all too common.[68] Take, for instance, the woman who was fired because her employer found out that she tested positive for a genetically transmitted lung disorder even though she did not actually have the disorder.[69] Even though the woman had submitted herself to prophylactic treatments that would keep her healthy, her employer still felt the need to fire her because she might develop the disease.[70] Others

supra note 55, at 315.

[61] 42 U.S.C.S. § 2000ff(2) (LexisNexis 2008). In the employment context, GINA regulates employers, employment agencies, labor organizations, and training programs. *Id.* §§ 2000ff to ff-11.

[62] Slaughter, *supra* note 19.

[63] Patricia Nemeth & Terry W. Bonnette, *Genetic Discrimination in Employment*, MICH. B.J., Jan. 2009, at 42, 43 (referencing the Senate Committee on Health, Education, Labor, and Pensions' report which helped to secure GINA's enactment).

[64] Slaughter, *supra* note 19.

[65] *Id.*

[66] Nemeth & Bonnette, *supra* note 63, at 43–44.

[67] Slaughter, *supra* note 19.

[68] *See id.*; *see also* PUBLIC PERSPECTIVES, *supra* note 6, at 89.

[69] Slaughter, *supra* note 19 (discussing briefly individuals' personal accounts of genetically-based discrimination).

[70] *Id.*

have been fired because they merely underwent genetic testing, even though the test had not yet been processed.[71]

Worse examples of discrimination exist in cases where an individual has not even tested positive for a known mutation of a genetic disease.[72] For example, a social worker with outstanding performance reviews was fired because of her employer's fears about her family's history of Huntington's Disease.[73] The woman did not even undergo genetic testing before being fired.[74] These examples strongly support and justify the fears of genetic testing that many Americans harbor.

Fears of discrimination likely prompted GINA's very encompassing designation of what constitutes genetic information for purposes of the Act. GINA defines "genetic information" as "with respect to any individual, information about—(i) such 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."[75] This broad definition, however, does not solve the issues surrounding the confidentiality of genetic information in any non-HIPAA context other than in limited employment and insurance situations specified within the statute.

The regulations promulgated in accordance with GINA have not extended HIPAA very far. The Department of Health and Human Services is supposed to revise the relevant privacy regulations under HIPAA to reflect that genetic information qualifies as protected health information.[76] Yet, under HIPAA's privacy regulations, genetic information already is considered to be protected health information.[77] The problem under HIPAA is not the definition of protected health information. Instead, the dilemma stems from the definitions of covered entities and protected health information and the ways that covered entities are able to blatantly violate privacy regulations through various statutorily-created exceptions.

The enforcement and damages provisions applicable to violations of

[71] PUBLIC PERSPECTIVES, *supra* note 6, at 89. Eric Fowler, a genetic counselor, explained how one of his patients was told that she was fired merely because she underwent testing for BRCA mutations. *Id.*

[72] *See supra* note 6 and accompanying text.

[73] PUBLIC PERSPECTIVES, *supra* note 6, at 155 (discussing briefly individuals' personal accounts of genetically-based discrimination).

[74] *Id.*

[75] 42 U.S.C.S. § 2000ff (LexisNexis 2008).

[76] 42 U.S.C.S. § 1320d-9(a).

[77] *See supra* notes 45–47 and accompanying text.

GINA were directly modeled after Title VII of the Civil Rights Act of 1974 and other federal laws meant to prevent and punish employment-based discrimination.[78] GINA's effect on discriminatory employment practices is narrowed by its incorporation of Title VII because Title VII's definition of employer exempts entities not affecting commerce or with fifteen or fewer employees.[79] Individuals who claim that qualifying employers or potential employers discriminated against them are required to file a complaint with the Equal Employment Opportunity Commission (EEOC) before filing suit under GINA.[80] If the employer does not affect commerce or does not have more than fifteen employees, then there is no remedy for employees or potential employees whose genetic information is improperly used by employers or potential employers because such actions are not illegal.[81]

GINA's ability to deter discrimination in employment is also restrained by the drafters' decision to bar lawsuits based upon the theory of disparate impact for at least six years.[82] A Genetic Nondiscrimination Study Commission is supposed to form in May 2014 to "review the developing science of genetics and to make recommendations to Congress regarding whether to provide a disparate impact cause of action" under GINA.[83] Disparate impact refers to a type of discrimination whereby policies that appear neutral on their face actually disproportionately impact a protected class regardless of the intent to discriminate or lack thereof by the policymakers.[84] The exclusion of disparate impact lawsuits is troubling because intentional discrimination based on genetic information is

[78] 42 U.S.C.S § 2000ff-6; Mac B. Greaves & Austin E. Smith, *The New Genetic Information Non-Discrimination Act*, 76 DEF. COUNSEL J. 137, 140 (2009).

[79] 42 U.S.C.S. § 2000e(b).

[80] Greaves & Smith, *supra* note 78, at 140.

[81] 42 U.S.C.S. § 2000e(b).

[82] *Id.* § 2000ff-7.

[83] *Id.* § 2000ff-7(b)

[84] Griggs v. Duke Power Co., 401 U.S. 424, 430 (1971). This groundbreaking case involved a suit brought under Title VII of the Civil Rights Act of 1964 against an employer for racial discrimination. *Id.* at 425–26. Duke Power Company instituted a policy requiring its employees and applicants for employment to have either a high school education or a passing score on a standardized general intelligence test as a condition of employment for job applicants and in order to transfer jobs for existing employees. *Id.* at 427. The result of the policy was that non-white employees and applicants were disproportionately affected even through the policy was not significantly related to successful job performance. *Id.* The United States Supreme Court held that policies with disparate impacts on protected groups in the employment sector violated Title VII. *Id.* at 435.

incredibly difficult to prove.[85] Thus, many individuals will be left with no remedy even if an employer covered by GINA has discriminatory policies.

Despite these enforcement problems, GINA should prevent the misuse of genetic information in a lot of employment and insurances contexts.[86] However, GINA has some additional loopholes that permit genetic information to be shared with employers and other entities. For instance, under the Family and Medical Leave Act of 1993 (FMLA),[87] an employer can potentially gain lawful access to genetic information to certify the health status of an employee who seeks medical leave under FMLA.[88] Additionally, GINA permits employers, subject to some limitations, to require employees or a family member of the employee to submit to regular genetic testing to see the biological effects of toxic substances in the workplace.[89] This practice, called "genetic monitoring," is defined within GINA as the following:

> [T]he periodic examination of employees to evaluate acquired modifications to their genetic material, such as chromosomal damage or evidence of increased occurrence of mutations, that may have developed in the course of employment due to exposure to toxic substances in the workplace, in order to identify, evaluate, and respond to the effects of or control adverse environmental exposures in the workplace.[90]

One of the problems with genetic monitoring and other similar exceptions for employers is that employers will be legally permitted to gather genetic information and may fire employees based upon their genetic information—even though GINA states that information obtained for

[85] Jennifer Girod & Katherine Drabiak, *A Proposal for Comprehensive Biobank Research Laws to Promote Translational Medicine in Indiana*, 5 Ind. Health L. Rev. 217, 225 (2008) (noting that genetic discrimination may occur "through unconscious or unspoken bias").

[86] National Human Genome Research Institute, Genetic Discrimination Fact Sheet: Genetic Information Nondiscrimination Act of 2008, http://www.genome.gov/10002328#6 (last visited Apr. 7, 2020) (stating that GINA does not prevent genetic discrimination against people when they apply for life insurance, long term care insurance, and disability insurance).

[87] Family and Medical Leave Act of 1993, Pub. L. No. 103-3, 107 Stat. 6.

[88] 42 U.S.C.S. § 2000ff-1(b)(3) (LexisNexis 2008).

[89] *Id.* § 2000ff-1(b)(5).

[90] *Id.* § 2000ff(5).

genetic monitoring purposes should not be used in such a manner.[91] Employers will be able to do this because there is no cause of action based on the theory of disparate impact under GINA,[92] and since it is incredibly difficult to prove the actual basis for an employee's termination when the employee must prove intentional discrimination was a factor.[93]

Despite the fact that 2010 is well under way, many employers are still unaware of the requirements that GINA places upon them.[94] Part of the problem with employers' awareness may stem from the lack of the EEOC'srulemaking regarding GINA.[95] The EEOC's new rules to integrate the congressional grant of authority to enforce GINA did not become effective until January 2010, about two months after GINA became effective, even though the initial rule proposal published in May 2009 only generated two comments.[96] One commentator's proposals for changes were "declined . . . because the items . . . dealt with substantive GINA issues beyond the scope" of the rules the EEOC adopted.[97] The EEOC's response to the commentator clarified that the rules they adopted merely integrated terms like "genetic information" and "the Genetic Information Nondiscrimination Act" into the pre-existing rules which referenced Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act of 1990 so that the agency could enforce GINA.[98] These rules, however, did not go to the next level of creating additional substantive rules.[99] The agency has not indicated when it will take the next step in substantive rulemaking regarding GINA. To EEOC's credit, the agency did revise the workplace notice posters that it provides to employers to include GINA's

[91] *See id.* §§ 2000ff-1, ff-7.

[92] *See id.* § 2000ff-7.

[93] Girod & Drabiak, *supra* note 85, at 223–25; Hutson v. McDonnell Douglas Corp., 63 F.3d 771, 781 (8th Cir. 1995).

[94] Kevin McGowan, *Employment Discrimination—Genetic: As Ban on Genetic Bias Takes Effect, Employers Await Final Rule from EEOC*, 78 U.S.L.W. 2323, 2323 (2009) (explaining that attorneys need to educate their clients about GINA so that any necessary changes are made to workplace posters, employee manuals, and forms).

[95] *Id.*

[96] Amendment of Procedural and Administrative Regulations to Include the Genetic Information Nondiscrimination Act of 2008, 74 Fed. Reg. 63,981, 63,981–85 (Dec. 7, 2009) (to be codified at 28 C.F.R. pts. 1601–03, 1607, 1610–11, 1614, 1690).

[97] *Id.* at 63,981–82.

[98] *See id.*

[99] *Id.* at 63,981–85.

new requirements.[100] The posters now incorporate a paragraph outlining how Title II of GINA protects applicants and employees from discrimination based on genetic information.[101]

The multiple lapses in coverage areas, the various exceptions for employers and insurance companies, and the lack of agency action regarding substantive rules undermine GINA's claims of being a broad solution to discrimination on the basis of genetic information within employment and insurance contexts. Additionally, because GINA is limited to insurance and employment situations, it does not protect genetic information in other non-HIPAA regulated areas such as with research studies, pharmaceutical companies, and certain physician-patient relationships.[102] Therefore, states have been left to decide whether they want to fill the confidentiality gaps in the field of genetic information.

B. State Genetic Information Laws

The absence of federal regulations protecting the confidentiality of genetic information has lead to various approaches from the states addressing genetic testing's ethical issues. Regrettably, nine states do not regulate disclosures of genetic information beyond any of HIPAA's requirements.[103] Of the District of Columbia and the forty-one states with some protection of genetic information written into their laws, nineteen states have laws simply relating to specific employment situations,[104] insurance plans,[105] or both.[106] However, the laws in those nineteen states

[100] *Environment: New EEOC Workplace Poster Available*, 78 U.S.L.W. 2275, 2275 (2009).

[101] *See* Equal Employment Opportunity Commission, Equal Employment Opportunity is the Law, http://eeoc.gov/employers/upload/eeoc_self_print_poster.pdf (last visited Apr. 7, 2010).

[102] Hustead & Goldman, *supra* note 25, at 288.

[103] Iowa, Mississippi, Nebraska, North Carolina, North Dakota, Pennsylvania, South Dakota, West Virginia, and Wyoming do not have regulations to prevent the disclosure of genetic information to third parties in any contexts that are not addressed by HIPAA.

[104] The District of Columbia and Kansas, Michigan, and Wisconsin regulate the confidentiality of genetic information solely in the area of employment. D.C. CODE ANN. §§ 2-1401.03, .11 (LexisNexis 2008); KAN. STAT. ANN. § 44-1009 (2000); MICH. COMP. LAWS SERV. § 37.1202 (LexisNexis 2001); WISC. STAT. ANN. § 111.372 (West 2002).

[105] Alabama, Hawaii, Indiana, Kentucky, Maine, Montana, Ohio, and Tennessee protect the confidentiality of genetic information in some, but not all, insurance contexts that are not covered by HIPAA. ALA. CODE §§ 27-53-1, -2 (LexisNexis 2007); HAW. REV. STAT. ANN. §§ 431:10A-118, 432:1-607, 432D-26 (LexisNexis 2008); IND. CODE ANN. §§ 27-8-26-1 to -11 (West 2003); KY. REV. STAT. ANN. § 304.12-085 (LexisNexis 2006); ME. REV. STAT. ANN. tit. 5, §§ 19301–19302 (2002); MONT. CODE ANN. §§ 33-18-901 to -903 (2009); OHIO REV. CODE ANN.

are not unique anymore given that GINA fully went into effect this past November and GINA protects most situations regarding genetic information in the areas of employment and insurance currently covered by those states' laws.[107] Only twenty-two states have laws protecting the confidentiality of genetic information in most employment, insurance, and non-federally regulated contexts.[108] However, multiple states with genetic

§§ 3901.491–.501 (LexisNexis Supp. 2009); TENN. CODE ANN. §§ 56-7-2701 to -2708 (2008). Hawaii may have intended to protect the confidentiality of genetic information in the employment sector, in addition to insurance contexts, but the state's statutes do not explicitly provide for such regulations. *See* HAW. REV. STAT. ANN. §§ 378-1, -2 (LexisNexis 2004 & Supp. 2009). While chapter 378 defines the terms "genetic information" and "genetic test," the section outlining what constitutes unlawful discriminatory practices does not mention either of the terms. *See id.*

[106] States regulating in the areas of both employment and insurance, but not in most areas not covered by HIPAA or GINA, such as research, genetic test companies and pharmaceuticals, and some physician-patient relationships, include Arkansas (genetic research studies are addressed by state statute), California (statute regarding general disclosure of genetic test results is limited to contexts where the insurer requests the genetic test and does not address when the insured requests a genetic test), Connecticut, Idaho, Louisiana (state statutes address pre- and post-natal genetic tests), Maryland, Massachusetts, and Utah. ARK. CODE. ANN. §§ 11-5-401 to -405 (2002); ARK. CODE. ANN. §§ 20-35-101 to -103 (2005); ARK. CODE. ANN. §§ 23-66-320 (2001); CAL. GOV'T CODE § 12940 (West 2005); CAL. INS. CODE §§ 742.405, .407 (West 2005); CAL. INS. CODE §§ 10123.3, 10140, 10143, 10146–10149.1 (West 2005 & Supp. 2010); CONN. GEN. STAT. ANN. § 38a-816 (West Supp. 2009); CONN. GEN. STAT. ANN. § 46a-60 (West 2009); IDAHO CODE ANN. §§ 39-8301 to -8304 (Supp. 2009); IDAHO CODE ANN. §§ 41-1313 (Supp. 2009); LA. REV. STAT. ANN. §§ 22:1061, 22:1063 (2009); LA. REV. STAT. ANN. § 22:1964 (2009); LA. REV. STAT. ANN. §§ 23:302, :368, :369 (Supp. 2010); LA. REV. STAT. ANN. § 40:1299.6 (2008); MD. CODE ANN., INS. §§ 15-1401 to -1407, 18-120, 27-909 (LexisNexis 2006 & Supp. 2009); MD. CODE ANN., STATE GOV'T § 20-601 (LexisNexis 2009); MASS. ANN. LAWS ch. 111, § 70G (LexisNexis 2004); MASS. ANN. LAWS ch. 151B, §§ 1–4 (LexisNexis 1999); MASS. ANN. LAWS ch. 175, §§ 108H, 108I (LexisNexis 2008); MASS. ANN. LAWS ch. 175, § 120E (LexisNexis 2008); MASS. ANN. LAWS ch. 176A, § 3B, ch. 176B, § 5B (LexisNexis 2009); MASS. ANN. LAWS ch. 176G, § 24, ch. 176I, § 4A, ch. 176J, § 1, ch. 176M, § 1 (LexisNexis 2005 & Supp. 2009); UTAH CODE ANN. §§ 26-45-101 to -106 (2007); UTAH CODE ANN. § 31A-22-1602 (Supp. 2009); UTAH CODE ANN. § 34A-11-102 (2009).

[107] *See supra* notes 56–102 and accompanying text. However, there may be a benefit from the overlap between the federal and state laws on these fronts because plaintiffs might have the option to file suit in federal or state court.

[108] Alaska, Arizona, Colorado, Delaware, Florida, Georgia, Illinois, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Oregon, Rhode Island, South Carolina, Texas, Vermont, Virginia, and Washington have regulations to prevent the disclosure of genetic information in most of the situations not covered by HIPAA or other federal regulations, including employment and insurance contexts. ALASKA STAT. §§ 18.13.010–.100 (2008); ARIZ. REV. STAT. ANN. §§ 12-2801 to -2804 (Supp. 2009); ARIZ. REV. STAT. ANN. § 20-448.02 (2002); ARIZ. REV. STAT. ANN. § 41-1463 (2004); COLO. REV. STAT. ANN. §§ 10-3-1101

information regulations further complicate the equation by narrowly or broadly defining the scope of what constitutes "genetic information" for purposes of their statutes.[109]

Individuals considering genetic testing may still fear what state courts might hold regarding the confidentiality of genetic information. Before the enactment of HIPAA, Florida and New Jersey courts had ruled that a physician had a duty to warn a patient's blood relatives when a patient tested positive for genetically transmittable conditions despite the lack of privity between the physician and patient's relatives.[110] Those states subsequently enacted legislation that should have reversed the cases.[111] Moreover, HIPAA theoretically requires a physician to obtain written consent from the patient before disclosing genetic test results to blood relatives.[112]

to -1104.7 (West 2006); DEL. CODE ANN. tit. 16, §§ 1220–1227 (2003); DEL. CODE ANN. tit. 18 § 2317 (1999); DEL. CODE ANN. tit. 19, §§ 710–718 (2005); FLA. STAT. ANN. §§ 627.4301, 627.6419, 641.31071, 760.40 (West 2005 & Supp. 2010); GA. CODE ANN. §§ 33-54-1 to -8 (West 2003); 215 ILL. COMP. STAT. 97/20 (West 2008); 410 ILL. COMP. STAT. 513/1–/50 (West 2005); MINN. STAT. ANN. § 13.386 (West Supp. 2010); MINN. STAT. ANN. § 181.974 (West 2006); MO. ANN. STAT. §§ 375.1300–.1309 (West 2002 & Supp. 2010); NEV. REV. STAT. ANN. §§ 629.101–.201 (West 2007 & Supp. 2009); N.H. REV. STAT. ANN. §§ 141-H:1 to -H:6 (LexisNexis 2006 & Supp. 2009); N.J. STAT. ANN. §§ 10:5-5, -12, -43 to -49 (West 2002 & Supp. 2009); N.M. STAT. ANN. §§ 24-21-1 to -7 (West 2003 & Supp. 2009); N.Y. CIV. RIGHTS LAW § 79-l (Consol. 2001 & Supp. 2009); N.Y. EXEC. LAW § 296 (Consol. 1995 & Supp. 2009); OKLA. STAT. ANN. tit. 36, §§ 3614.1–.4 (West 1999 & Supp. 2009); OR. REV. STAT. §§ 192.531–.549, 659A.300–.306, 746.135 (2009); R.I. GEN. LAWS §§ 27-18-52 to -52.1, 27-20-39.1, 27-41-53 to -53.1 (2008); R.I. GEN. LAWS §§ 28-6.7-1 to -5 (2003); S.C. CODE ANN. §§ 38-93-10 to -60 (2002); Tex. Ins. Code Ann. §§ 546.001–.152 (Vernon 2009); Tex. Lab. Code Ann. §§ 21.401–.405 (Vernon 2006); Tex. Occ. Code Ann. §§ 58.001–.105 (Vernon 2004 & Supp. 2009); VT. STAT. ANN. tit. 18, §§ 9331–9335 (2000); VA. CODE ANN. § 38.2-508.4 (2007); VA. CODE ANN. § 40.1-28.7:1 (2002); WASH. REV. CODE ANN. §§ 70.02.005 to -904 (West 2002 & Supp. 2009).

[109] *See* Schlein, *supra* note 54, at 347–48.

[110] Castillo v. Emergency Med. Assocs., 372 F.3d 643, 648 (4th Cir. 2004) (stating that the physician-patient relationship is established when there is a relationship based on contractual privity, express or implied, where the physician agrees to treat and the patient agrees to be treated); Pate v. Threlkel, 661 So. 2d 278, 281–82 (Fla. 1995); Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996).

[111] FLA. STAT. ANN. § 760.40 (West 2005 & Supp. 2009); N.J. STAT. ANN. §§ 10:5-43 to -49 (West 2002 & Supp. 2009). Additionally, because HIPAA's Privacy Rule became effective in 2003, after these cases were decided, it would likely invalidate each of the cases on privacy grounds.

[112] Gayun Chan-Smutko et al., *Professional Challenges in Cancer Genetic Testing: Who Is the Patient?*, 13 THE ONCOLOGIST 232, 233 (2008).

There is no general legal duty to rescue in the United States.[113] Absent a statutory provision requiring physicians to disclose genetic information test results to patients' blood relatives, health care providers are not under a legal obligation to warn at-risk blood relatives of their patients about genetic conditions they may be predisposed to developing.[114] Yet, courts and commentators argue—among other things—that genetic information has familial implications which make genetic test results "familial property" that blood relatives are entitled to request or be told about by physicians.[115]

Despite current federal and state laws, ambiguity persists about what courts will do in states without laws protecting the confidentiality of genetic information.[116] Additionally, professional medical associations disagree about whether health care providers are required or permitted to disclose genetic information to non-patients.[117] Although HIPAA and subsequent state legislation should have effectively overturned these decisions, they remain close to the center of genetic information disputes regarding confidentiality.[118] The Florida and New Jersey court opinions are examined to illustrate the double-bind that medical providers say they face because of uncertainties surrounding whether there is a duty for physicians to disclose genetic information to patients' blood relatives.[119]

In *Pate v. Threlkel*, Pate, the adult child of a woman being treated for medullary thyroid carcinoma, a genetically transferable disease, was

[113] Soc. Issues Subcomm. on Familial Disclosure, Am. Soc'y of Hum. Genetics, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUM. GENETICS 474, 480 (1998) [hereinafter ASHG].

[114] *Id.*

[115] *Id.* at 476.

[116] Am. Coll. of Obstetricians and Gynecologists, *ACOG Committee Opinion 410: Ethical Issues in Genetic Testing*, June 2008, at 4, *available at* http://www.acog.org/from_home/publications/ethics/co410.pdf; Am. Soc'y of Clinical Oncology, *ASCO Policy Statement Update: Genetic Testing for Cancer Susceptibility*, 21 J. CLINICAL ONCOLOGY 2397, 2403 (2003).

[117] Susan M. Denbo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?*, 43 AM. BUS. L.J. 561, 588–93 (2006) (addressing the various viewpoints from the American Society of Human Genetics, the National Society of Genetic Counselors, the American Medical Association, the American Society of Clinical Oncology and the Institute of Medicine's Committee on Assessing Genetic Risks on whether physicians should disclose genetic test results to biological relatives).

[118] Anne-Marie Laberge & Wylie Burke, *Duty to Warn At-Risk Family Members of Genetic Disease*, 11 Am. Med. Ass'n J. Ethics 656, 658 (September 2009).

[119] *See* Pate v. Threlkel, 661 So. 2d 278, 278 (Fla. 1995); Safer v. Estate of Pack, 677 A.2d 1188, 1188 (N.J. Super. Ct. App. Div. 1996).

diagnosed with the disease three years after her mother began treatment for the disease.[120] Pate argued that the defendant physician should have warned the patient's adult children to get tested for the gene.[121] Florida's Supreme Court held that physicians owe a duty of care to warn a patient's adult children about the genetically transferable nature of conditions for which a physician is treating a patient—despite the lack of privity between the patient's children and the physician.[122]

In *Safer v. Estate of Pack*, Safer's father was diagnosed with colon cancer.[123] Safer filed suit alleging breach of professional duty to warn her about the genetic nature of the cancerous blockage of the colon and multiple polyposis that she eventually developed.[124] New Jersey's Superior Court held that physicians had a duty "to warn of the avertable risk from genetic causes, by definition a matter of familial concern."[125] The court declined to follow *Pate*'s holding that the duty to warn was satisfied by informing the patient that they should tell their genetic relatives about their genetic trait diagnosis.[126]

The lack of federal regulations and the inconsistency with state regulations necessitates the enactment of more encompassing policies to protect the confidentiality of genetic information. Federal and state governments should set minimum levels of informed consent needed for genetic testing, including warnings about when the disclosure of genetic information is permissible. Many states with genetics regulations have failed to regulate beyond the barebones employment and insurance contexts.[127] A stricter floor should be set to require that individuals' genetic information remain confidential until consent for disclosure is given unless scientifically and ethically justifiable statutory exceptions permit disclosure.

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[120] 661 So. 2d at 279.

[121] *Id.*

[122] *Id.* at 281–82 (stating that the duty to warn was satisfied by telling the patient to inform their blood relatives).

[123] 677 A.2d at 1189–90.

[124] *Id.* at 1190.

[125] *Id.* at 1192.

[126] *Id.* Instead, the court held that physicians needed to warn blood relatives directly within certain limitations about their patient's genetic test results. *Id.*

[127] *See generally* Susan M. Wolf & Jeffrey P. Kahn, *Genetic Testing and the Future of Disability Insurance: Ethics, Law & Policy*, 45 J.L. MED. & ETHICS 6 (2007) (discussing how states have widely varying laws regarding genetic testing but that multiple state statutes give more leeway to life insurers than health insurers and that few states even focus on disability insurance).

If individual states desire more stringent regulations, they should remain free to enact them.

C. Studies of Disclosures by Medical Professionals Document the Need to Eliminate Gaps in Current Genetic Information Laws

Few studies have investigated the rate of unauthorized disclosures of genetic information by physicians to patients' blood relatives.[128] The two recent fact-based survey studies were published in 2003.[129] In the pilot study, members of the National Society of Genetic Counselors were asked to respond to a questionnaire with questions ranging from whether they believed a duty existed for genetic counselors to warn "at-risk" relatives, to questions about the counselors' clinical experiences with patients who refused to notify "at-risk" relatives, and the factors or rationale that went into the counselors' decisions about what to do in the face of patient refusals to share genetic test results with blood relatives.[130] A computer program was used to remove all identifying information from the submitted questionnaires so the survey was essentially anonymous.[131] The majority of survey participants, sixty-three percent, believed that genetic counselors had a duty to disclose genetic information to a patient's blood relatives.[132] Of the genetic counselors with a patient who had refused to notify an "at-risk" relative, twenty-one percent reported seriously considering warning the patient's relatives without the patient's consent.[133] One counselor surveyed admitted to having disclosed a patient's test results to a blood relative of the

[128] The limited studies on the issue were mainly conducted or published in early 2003, just before HIPAA's Privacy Rule became effective. *See infra* note 129–143 and accompanying text. Studies do not seem to have been conducted subsequent to HIPAA's enactment even though nothing indicates physicians' beliefs—that caused them to disclose genetic information without patients' consent to blood relatives—have changed or that physicians would be less likely to be honest about their actions and beliefs in anonymous surveys.

[129] *See* R. Beth Dugan et al., *Duty to Warn At-Risk Relatives for Genetic Disease: Genetic Counselors' Clinical Experience*, 119C AM. J. MED. GENETICS 27, 27 (2003); Marni J. Falk et al., *Medical Geneticists' Duty to Warn At-Risk Relatives for Genetic Disease*, 120A AM. J. MED. GENETICS 374, 374 (2003).

[130] *See* Dugan et al., *supra* note 129, at 29. While the term "at-risk" was not explicitly defined in the study, the article implied that it referred to patients' "relatives who are at-risk for carrying the same genetic mutation." *Id.* at 28.

[131] *Id.* at 29.

[132] *Id.* at 29–31 (noting, however, that in response to several hypothetical scenarios, most of those individuals felt that they would not disclose such information).

[133] *Id.* at 31.

patient without having permission.[134] The study noted that as the number of genetic testing opportunities increase, so too will the situations where genetic counselors are faced with the dilemma of disclosing genetic test results to patients' blood relatives.[135]

The group that conducted the pilot study on this issue conducted a follow-up survey of medical geneticists who, at the time of the study, were members of either the American Society of Human Genetics and/or the American College of Medical Genetics.[136] The second survey was intended to identify the factors used by medical geneticists while deciding whether to disclose genetic test results to patients' "at risk" relatives.[137] Two-thirds of the geneticists surveyed stated that they believed there was a duty to warn blood relatives of genetic test results regardless of the absence of permission for such disclosures.[138] Of the medical geneticists faced with the dilemma of whether to disclose patients' information despite having the patients' consent, twenty-five percent admitted to have "seriously considered" disclosing the information.[139] Four of the surveyed geneticists, or nine percent of the geneticists who seriously considered disclosure without consent or who did not answer that survey question, proceeded to notify relatives despite patients' refusals to give permission for the disclosures.[140] Given that some geneticists admitted to unauthorized disclosures of genetic information, it seems likely that there were other geneticists surveyed who had done the same but chose not to admit their actions in the survey.[141]

The factors considered by the individuals who admitted that they proceeded to disclose their patients' information without the patients' consent included: "the magnitude of risk for the relative, whether the

[134] *Id.* at 32 (noting, however, that the situation was unusual because the relative was also a patient of the genetic counselor and the counselor shared the test results in order to prevent the relative patient from undergoing an invasive test to test for the genetic trait).

[135] *Id.* at 34.

[136] Falk et al., *supra* note 129, at 375. Survey data in this study was organized and analyzed between September 2001 and July 2002, during the period when HIPAA's Privacy Rule was not in effect. *Id.*

[137] *Id.*

[138] *Id.*

[139] *Id.* at 376.

[140] *Id.* at 378 (explaining that apparently not all of the geneticists who proceeded, or took steps, to breach confidentiality actually ended up disclosing the test results without the patients' permission).

[141] *Id.*

condition is treatable or manageable, the biological relationship of the patient and relative, whether early monitoring can alter risk, and whether lifestyle changes can alter risk."[142] Additional factors in some, but not all, of those cases involved the ages of the relatives and patients, "the patient's emotional reaction, the emotional relationship of the patient and relative, and whether the relative may be made aware of the disease by other means."[143]

A third relevant study on the issue involved a vignette given to physicians who were members of the New Jersey Association of Osteopathic Physicians and Surgeons.[144] Hypothetical studies have limitations that are not generally present in clinical surveys because they may not accurately reflect how an individual will actually respond when faced with such a situation that involves real people.[145] However, such studies are still valuable because many physicians have not faced the issue yet, so a hypothetical scenario is the best way to gather their opinions. Also, clinical surveys are not error-proof.[146]

The vignette in this study involved a forty-three year old man who was divorced and had three children who were twelve, seventeen, and twenty-two years old.[147] The man was diagnosed as having an inheritable disease that could easily be tested for using a genetic test.[148] Despite the fact that the disease was fatal, and that it caused the early deaths of his father and aunt, he told his physician that he did not want to inform his ex-wife or their children because he was estranged from them all.[149] The compiled questionnaire results showed that the treatable or untreatable nature of the disease was the main factor considered by physicians as to whether to disclose the results without the patient's consent.[150] The physicians

[142] *Id.*

[143] *Id.*

[144] Edmund L. Erde et al., *Patient Confidentiality vs. Disclosure of Inheritable Risk: A Survey-Based Study*, 106 J. AM. OSTEOPATHIC ASS'N 615, 616 (2006).

[145] Dugan et al., *supra* note 129, at 29.

[146] *Id.* at 33 (noting that because clinical surveys are based on the recollection of past experiences, they are subject to recall bias so "the actual number of cases where the conflict of breaking confidentiality and duty to warn at-risk relatives might actually be higher than reported by participants").

[147] Erde, *supra* note 144, at 616.

[148] *Id.* at 616.

[149] *Id.*

[150] *Id.* at 617 (noting that if the disease was untreatable, the survey respondents unanimously

surveyed generally agreed that the man's adult child should be notified of their father's genetic condition.[151] While the physicians also agreed that the twelve-year-old child should not be notified, there was a split as to whether the seventeen-year-old child should be notified.[152] Despite the fact that HIPAA's Privacy Rule would have been effective when this study was published, the authors argued that physicians needed more specific laws to dictate the outcome in moral and legal dilemmas where disclosing genetic information to patients' relatives without their consent could be used to avert potentially life-threatening genetic diseases.[153]

The discussion of the need for more specific laws in post-HIPAA Privacy Rule enactment studies as well as the current confusion regarding the law amongst the various medical associations today strongly suggests the necessity of more encompassing and direct legislation on the issue of the confidentiality of genetic information.[154] At worst, such regulations, with respect to physicians' unauthorized disclosures of genetic information, should help to clarify the law and make physicians feel more confident in their decisions not to notify blood relatives without their patients' consent. At best, new regulations could prevent unauthorized disclosures of genetic information by clearly establishing guidelines, penalties, and enforcement criteria which are lacking in current regulations.

IV. SCIENTIFIC AND POLICY CONCERNS ABOUT GENETIC TESTING JUSTIFY PROTECTING THE CONFIDENTIALITY OF GENETIC INFORMATION

Genetic testing is still a new and emerging science. The accuracy of genetic tests, including the human error factor in reading results, is something of a concern. Moreover, despite the availability of hundreds of genetic tests, there are no medical treatments for many of the testable diseases and conditions that people may be genetically predisposed to developing. If physicians are required or permitted to disclose genetic information to blood relatives or other third parties, they might be liable for damages if the results are inaccurate and someone obtains unnecessary treatments because of reliance on the results. In light of these scientific and

agreed that there was no legal justification for informing any of the patient's relatives).

[151] *Id.* at 617–18.

[152] *Id.*

[153] *Id.* at 620.

[154] Denbo, *supra* note 117, at 588–93.

policy concerns, the evaluation of issues surrounding genetic testing is very relevant to the question of whether state and federal regulations should be extended to protect the confidentiality of genetic information.

A. The (In)Accuracy of Genetic Tests

The current regulatory structure for genetic testing is riddled with fissures that enable genetic testing manufacturers and laboratories to operate without any real standards.[155] No single government entity oversees or regulates genetic testing.[156] Laboratory testing, including the testing of human specimens, is primarily regulated by the Centers for Medicare and Medicaid Services pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).[157]

Most genetic tests enter the marketplace without any type of regulatory review.[158] Despite the highly sensitive and specialized nature of genetic testing, CLIA does not include a specific section for laboratories conducting genetic tests.[159] Laboratories conducting genetic tests are not currently required to verify the accuracy of their tests under any standards, meaning that genetic tests are approved under CLIA "even if there is not a strong connection between the genetic information being tested for and the disease or condition that a positive test is supposed to predict."[160]

The questionable accuracy of genetic tests makes arguments against protecting the confidentiality of genetic information problematic. Information obtained from genetic tests that may be inaccurate because of

[155] *See* Rebecca Antar Novick, *One Step at a Time: Ethical Barriers to Home Genetic Testing and Why the U.S. Health Care System is Not Ready*, 11 N.Y.U. J. LEGIS. & PUB. POL'Y 621, 624 (2008).

[156] *Id.*

[157] *Id*.

[158] Amy L. McGuire & Wylie Burke, *An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing: Raiding the Medical Commons*, 22 J. OF AM. MED. ASS'N 2669, 2670 (2008).

[159] Novick, *supra* note 155, at 626. Thus, genetic tests are not required to meet any specific standards for accuracy, reliability, or clinical validity. Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2440 (2008).

[160] Novick, *supra* note 155, at 626–27; *see also id.* at 629 (concluding that because of the "apparent resistance of the federal agency responsible for CLIA to developing a specialty for genetic tests or making other changes to the relevant laws, it is unlikely that genetic tests will face additional regulation in the foreseeable future").

the lack of industry regulation and oversight cannot be helpful to insurance companies trying to make decisions about premiums, employers using results for whatever supposedly legal purposes they claim to use them for, or blood relatives trying to make life-altering decisions based on the traits of a blood relative who was tested for genetic predispositions. While accurate genetic tests are an invaluable tool to many people, there is an unjustified risk that inaccurate genetic tests may be used to lawfully discriminate against people because of weak government regulations in the areas of confidentiality and genetic test quality control.[161] Such concerns further demonstrate the need for additional regulations with regards to the confidentiality of genetic information.

B. The (Un)Availability or Complications of Prophylactic Treatments

One of the main concerns with genetic testing comes after test results indicate that an individual is genetically predisposed to developing a specific disease. The question "what next?" often arises and can present very complicated dilemmas for physicians and their patients. The amount of prophylactic treatments or measures that should be taken for any given individual, if even available, is a serious concern because merely testing positive for a specific gene when an individual lacks the disease itself does not mean that an individual should undergo any prophylactic treatments. Moreover, given the serious potential for inaccurate and misread genetic tests, because of the lack of regulatory control over the genetic testing industry, people should be wary about undergoing extreme treatments based on the results of a single genetic test. Because of the above concerns, the consequences of not protecting the confidentiality of genetic information can be even more severe for individuals in employment, insurance, and familial contexts.

Some genetic conditions that can currently be detected through genetic testing have neither a cure nor a prophylactic treatment. For instance, Alzheimer's is a disease where genetics plays a significant role.[162] Despite the lack of a cure or prophylactic treatment for Alzheimer's, a genetic test exists that can inform both disease-free and pre-symptomatic individuals whether they are predisposed to developing the disease.[163] If a person

[161] Girod & Drabiak, *supra* note 85, at 223.

[162] Victoria Colliver, *Alzheimer's Trials Make a Dent*, S.F. CHRON., May 8, 2009, at F1.

[163] *See* Kay Lazar, *Alzheimer's Study Finds Parental Link: Patients' Offspring Have Memory*

voluntarily gets a genetic test and the result is positive for a genetic trait that means they are predisposed to a disease which has no cure. They would surely be more distraught than if they did not know about the test result. Regardless of these limitations, some individuals argue that blood relatives have a right to know about the test results; and that both employers and insurance companies deserve access to genetic information so that they can make discriminatory decisions based upon an individual's immutable characteristics—even though making such decisions once the disease actually manifests itself would likely be illegal.

Some genetic conditions that are detectable through genetic testing have prophylactic treatments which present serious risks of complications if used and may not even ultimately prevent the disease from developing. Breast and ovarian cancer genetic testing serves as a very realistic example of the problems associated with prophylactic treatments. Genetic tests for the detection of the BRCA-1 and BRCA-2 genes and their associated mutations help to diagnose individuals' genetic susceptibility to developing breast and ovarian cancers.[164] Myriad Genetics, Inc., launched an enormous direct-to-consumer marketing campaign for its product which detects these mutations.[165] Arguably, as a result of this campaign, prophylactic treatments for breast and ovarian cancers are near the forefront of genetic testing debates.

Once an individual tests positive for a BRCA mutation, there are three leading approaches for responding to the diagnosis: (1) increased detection strategies; (2) chemoprevention; and (3) surgical intervention.[166] Increased detection strategies include undergoing clinical breast examination and self breast examination, annual mammographies, and annual magnetic resonance imaging scans (MRIs).[167] Detection strategies do not constitute

Loss, BOSTON GLOBE, Feb. 19, 2009, at 1.

[164] Nat'l Office of Pub. Health Genomics of the Ctrs. for Disease Control & Prevention, *Fact Sheet on Genetic Testing for Breast and Ovarian Cancer Susceptibility*, http://www.hhs.state.ne.us/hew/owh/docs/FSBreastCancerGeneticTesting.pdf (last visited Apr. 7, 2010) (noting that while between five to ten percent of women in America diagnosed with breast or ovarian cancer have the BRCA-1 and BRCA-2 mutations, many women with the relevant BRCA genes will never develop breast or ovarian cancer).

[165] Ellen Matloff & Arthur Caplan, *Direct to Confusion: Lessons Learned from Marketing BRCA Testing*, AM. J. BIOETHICS, June 2008, at 5, 6.

[166] *See* Susan Sherwin, *BRCA Testing: Ethics Lessons for the New Genetics*, 27 CLINICAL & INVESTIGATIVE MED. 19, 20 (2004).

[167] *See* Karen Lisa Smith & Claudine Isaacs, *Management of Women at Increased Risk for Hereditary Breast Cancer*, 27 BREAST DISEASE 51, 52–55 (2007).

prevention because they merely identify if cancer has already begun to develop and are, therefore, not a prophylactic treatment.[168] However, because such strategies can assist in the early detection of cancer formation, they are recommended for women who have tested positive for BRCA mutations or have family histories of breast cancer.[169]

Chemoprevention is a drug-based therapy option meant to prevent the development of breast and ovarian cancers in BRCA carriers.[170] Chemoprevention usually relies on drugs in the selective estrogen receptor modulators (SERMs) category like Tamoxifen.[171] Studies regarding the effectiveness of Tamoxifen and related drugs at preventing cancer are inconsistent.[172] Most troubling, however, are the side effects of Tamoxifen which include cardiovascular death, stroke, and uterine cancer.[173] As such, the decision about whether to pursue chemoprevention should not be taken lightly by individuals who test positive for BRCA mutations and do not actually have cancer.

The main surgical prevention options for individuals who test positive for BRCA genes are prophylactic bilateral mastectomies (PBM), the removal of the breasts, and prophylactic bilateral salpingo-oophorectomies (PBSO), the removal of the ovaries.[174] PBM has been shown to reduce the risk of developing breast cancer by at least eighty-five percent.[175] Women who undergo PBM may suffer psychological side effects such as changes in body image and sexuality, but women surveyed have not indicated that the surgery diminished their quality of life.[176] PBSO may have similar

[168] *See* Sherwin, *supra* note 166.

[169] *See* Smith & Isaacs, *supra* note 167, at 51, 52.

[170] *See id.* at 56–57.

[171] *See* Michael Fatouros et al., *The Predominant Role of Surgery in the Prevention and New Trends in the Surgical Treatment of Women With BRCA1/2 Mutations*, 15 ANNALS OF SURGICAL ONCOLOGY 21, 25–26 (2008)

[172] *See* Smith & Isaacs, *supra* note 167, at 56–57.

[173] Gordon R. Mitchell & Kelly Happe, *Informed Consent After the Human Genome Project*, 4 RHETORIC & PUB. AFF. 375, 380 (2001).

[174] *See* Michael Fatouros et al., *The Predominant Role of Surgery in the Prevention and New Trends in the Surgical Treatment of Women With BRCA1/2 Mutations*, 15 ANNALS OF SURGICAL ONCOLOGY 21, 23–25 (2008) (providing a detailed discussion of surgical prevention options for women diagnosed with BRCA mutations including the benefits and risks of such surgeries).

[175] *Id.* at 23; *see also* Mitchell & Happe, *supra* note 173, at 380 (noting that PBM does not completely reduce the risk of breast cancer because some potentially cancerous breast tissue remains after the surgery).

[176] Fatouros et al., *supra* note 174, at 23.

psychological effects, and it has been documented as reducing the risk of ovarian cancer by approximately ninety percent and breast cancer by fifty percent.[177] Both surgical options can be extremely invasive,[178] can carry a risk of surgical error and infection as with any surgical procedure, have a chance of morbidity,[179] may not be enough to prevent cancerous growth in the breasts or ovaries,[180] and may increase the risk in BRCA mutation carriers of developing cancer in another organ.[181] Given this knowledge, the risks and benefits of these surgeries must be carefully weighed by individuals considering them, especially when a person is merely a BRCA gene carrier who may never develop breast or ovarian cancer and could unnecessarily be undergoing surgery.

Prophylactic treatments, or the lack thereof, present new complications in the areas of insurance and employment which have not been addressed by GINA or other similar legislation. Insurance carriers might find loopholes to permit them to charge policyholders higher premiums if they develop a medical condition that they knew they were genetically predisposed to develop. For instance, while federal regulations prohibit group health plans and group health insurers from adjusting premiums or contribution amounts for such plans on the basis of genetic information,[182] those same regulations permit premiums to be increased for individuals who manifest a particular disease or disorder.[183] The regulations do not appear to set a cap or limit as to how much insurance costs may be raised if an individual develops a disease or disorder that the individual was genetically predisposed to develop. Thus, if an insured individual refuses to accept prophylactic treatments covered by an insurance policy—even though the individual was diagnosed as being genetically predisposed to the disease or disorder—existing regulations appear to permit insurers to essentially penalize the insured individual for not accepting prophylactic treatments.[184]

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[177] *Id.* at 24.

[178] Bradley C. Nahrstadt & Christina D. Ketcham, *A Primer on Defending Breast Cancer Litigation*, 25 AM. J. TRIAL ADVOC. 451, 459 (2002).

[179] Fatouros et al., *supra* note 174, at 24–25.

[180] *Id.* at 23–25.

[181] *Id.* at 28.

[182] 29 U.S.C.S. § 1182(b)(3)(A) (LexisNexis Supp. 2009).

[183] *Id.* § 1182(b)(3)(B).

[184] Acceptance of treatments does not mean that the treatments were necessarily free of charge to the individual. The individual would likely pay a "co-pay" for the treatments which could be as

Employers, though unlikely, might try to use exceptions under GINA or create spin-offs of bona fide occupational qualification (BFOQ) exceptions to require employees to undergo prophylactic treatments or jeopardize losing their jobs despite the risks associated with such treatments and the reality that an individual might not ever develop a specific illness even though they are genetically predisposed to develop the illness. The District of Columbia already includes a BFOQ exception within its statute that generally prohibits discrimination in the field of employment on the basis of genetic information.[185] While informed consent is required to get the individual's genetic information, nothing in the District of Columbia's Code makes it illegal to refuse to hire or to fire an individual for declining to give their consent in this context if there is a BFOQ which is reasonably necessary for the normal operation of the employer's business or enterprise.[186]

Permitting physicians to disclose genetic test results to patients' blood relatives without the permission of their patients complicates the equation. While a blood relative's genetic test may correctly show that the blood relative has a specific genetic marker that they should be concerned about, this does not mean that the genetic relative also inherited that specific gene or gene mutation.[187] Moreover, if the test was inaccurately processed or interpreted and the blood relative does not undergo their own testing, the relative may rely on completely faulty information in deciding to undergo prophylactic treatments with potentially severe complications.[188] If such testing occurs, the physician might be liable to both the actual patient and the patients' blood relative for damages sustained by the unnecessary treatments, discrimination related to the diagnosis, and psychological trauma from being told of the incorrect diagnosis. There is not yet any case law specific to this kind of liability issue. Given these and other scientific and legal concerns with genetic testing, confidentiality laws should be made to error on the side of caution when it comes to protecting individuals' genetic information.

high as hundreds or thousands of dollars per year depending on the treatments.

[185] D.C. CODE ANN. §§ 2-1401.03 (LexisNexis 2008) (permitting employers, employment agencies, and labor organizations to seek, obtain, and use genetic information to determine the existence of a BFOQ if the employee or potential employee consents in writing).

[186] *See id.*

[187] Slaughter, *supra* note 19.

[188] *See* Ito, *supra* note 21, at 455 (noting that "[g]enetic testing is limited by the uncertainty of disease manifestation, misinterpretation, and low clinical sensitivity rate").

V. ETHICAL ARGUMENTS FOR EXTENDING STATE AND FEDERAL REGULATIONS TO PROTECT THE CONFIDENTIALITY OF GENETIC INFORMATION

There are strong ethical arguments for protecting genetic information even if confidentiality is not absolute.[189] The concepts of privacy, autonomy, and the Hippocratic Oath each call for keeping genetic information confidential. Despite these persuasive arguments, some advocate for mandatory disclosures of genetic information to patients' blood relatives.[190]

A. Privacy and Autonomy

Privacy and autonomy are intimately connected to each other and to the doctrine of informed consent. Informed consent is at the epicenter of medical ethics because society recognizes the importance of autonomy and privacy.[191] Since the law is a key mechanism for establishing standards of ethical conduct, societies should legislatively ensure the confidentiality of genetic information to uphold the principles of privacy and autonomy.[192]

Privacy can mean that an individual has control over personal information, or a state of "nonaccess [sic] to the individual's physical body or psychological person."[193] Privacy is an umbrella concept which

[189] *See* ASHG, *supra* note 113, at 474–76 (1998) (arguing that genetic information should be viewed as a special kind of medical information such that the legal and ethical norms of patient confidentiality should apply to information in most cases); *see also* Andrea Sudell, *To Tell or Not to Tell: The Scope of Physician-Patient Confidentiality When Relatives Are at Risk of Genetic Disease*, 18 J. CONTEMP. HEALTH L. & POL'Y 273, 284–85 (2001) (stating that there are common statutory exceptions to a physician's duty of confidentiality with respect to genetic and medical information such as in cases of contagious disease and child neglect).

[190] *See* Brownrigg, *supra* note 23, at 272–73 (arguing for a balancing test to determine when physicians should disclose the results of genetic tests to non-patient family members); Sudell, *supra* note 189, at 291–92 (arguing for a multi-factored test to require disclosure of patient's genetic information to non-patient family members); *see also* Mary L. Kovalesky, *To Disclose or Not to Disclose: Determining the Scope and Exercise of a Physician's Duty to Warn Third Parties of Genetically Transmissible Conditions*, 76 U. CIN. L. REV. 1019, 1032 (2008) (discussing a New York statute which allowed for disclosure of genetic information absent the consent of the individual who was tested through a court order, noting that one of the considerations was the privacy interests of close relatives of the individual).

[191] Marshall B. Kapp, *Patient Autonomy in the Age of Consumer-Driven Health Care: Informed Consent and Informed Choice*, 28 J. LEGAL MED. 91, 94 (2007).

[192] *Id.* at 91.

[193] Graeme T. Laurie, *Challenging Medical-Legal Norms: The Role of Autonomy,*

encompasses confidentiality and autonomy.[194] Confidentiality includes an expectation that personal information, such as genetic information, will generally not be disclosed without consent from the individual.[195] The disclosures mandated by *Safer*,[196] it has been argued, "eviscerat[ed]" individuals' privacy for the greater significance of the "genetic whole."[197]

Autonomy is the philosophical concept that people should make decisions independently and without external pressure.[198] Respect for autonomy is "paramount in virtually all ethical situations."[199] The concept of autonomy extends to patients' personal health information.[200] Patient autonomy was embodied in the law through informed consent.[201] Despite the importance of autonomy, there is no consensus about the applicability of informed consent requirements to genetic information.[202]

The disclosure of genetic information presents complicated ethical dilemmas since it reveals unique and immutable characteristics which might not otherwise be discovered.[203] Genetic tests are commonly used as predictive diagnosis for hereditary diseases.[204] There is a great potential for harm from disclosure of this information since being labeled as carrying a certain gene may cause stigmatization and discrimination.[205]

In certain circumstances, however, the disclosure of genetic information is ethical. For example, in Alaska, a state with a genetic information non-disclosure statute, statutory exceptions permit disclosures of genetic information: (1) for DNA identification systems for criminals as required by any state's law (2) "for a law enforcement purpose, including the

Confidentiality, & Privacy in Protecting Individual and Familial Group Rights in Genetic Information, 22 J. LEGAL MED. 1, 27 (2001).

[194] Ito, *supra* note 21, at 458.

[195] *Id.* at 458.

[196] Safer v. Estate of Pack, 677 A.2d 1188, 1192 (N.J. Super. Ct. App. Div. 1996); *see also supra* note 24.

[197] Dolgin, *supra* note 16, at 171.

[198] Ito, *supra* note 21, at 457.

[199] Lea et al., *supra* note 3, at 235.

[200] Laurie, *supra* note 193, at 15.

[201] *See id.*; *see also* Denbo, *supra* note 117, at 595.

[202] *See* Denbo, *supra* note 117, at 595–98 (discussing the various options available regarding informed consent).

[203] Hustead & Goldman, *supra* note 25, at 285.

[204] Natalie Ram, *Tiered Consent & the Tyranny of Choice*, 48 JURIMETRICS J. 253, 258–59 (2008).

[205] Ito, *supra* note 21, at 449.

identification of perpetrators and the investigation of crimes and the identification of missing or unidentified persons or deceased individuals," (3) "for determining paternity," (4) "to screen newborns as required by state or federal law," and (5) "for purpose[s] of emergency medical treatment."[206]

The disclosure of genetic information in the first two contexts is ethical since the public interest in solving crime is strong and because of criminals' decreased interest in privacy.[207] The paternity provision is necessary to determine whether someone has a constitutionally protected interest in parenting a child or is responsible for financial obligations with respect to a child.[208] The last two exceptions pertain to medical treatment of individuals who are unable to care for themselves.[209] Public health and medical emergency justifications exist behind those disclosure exceptions.[210]

Absent such compelling instances, violating the principles of autonomy and privacy by disclosing genetic information is unethical. Informed consent for genetic tests should include requirements stating when and why individuals' genetic information may be disclosed.[211] Most states have not addressed the interaction of informed consent and the disclosure of genetic information.[212]

Patients' beliefs that confidentiality will be respected in communications with their physicians about their genetic information are important to successful medical systems. The possibility of unauthorized disclosures may deter patients from undergoing genetic testing because of

[206] ALASKA STAT. § 18.13.010(b) (2008).

[207] *See generally* Laura A. Matejik, *DNA Sampling: Privacy & Police Investigation in a Suspect Society*, 61 ARK. L. REV. 53 (2008) (arguing that the public interest in solving crime is weighed against the reasonable privacy expectations of criminals under the Fourth Amendment of the United States Constitution to determine if, when, and how the government can obtain individuals' DNA).

[208] Mary Beck, *A National Putative Father Registry*, 36 CAP. U. L. REV. 295, 326 (2007).

[209] *See* ALASKA STAT. § 18.13.010(b).

[210] *See generally* R. Rodney Howell, *Immediate Clinical Applications of the New Genetic Technology*, 13 ST. THOMAS L. REV. 945 (2001) (discussing the use of genetic tests to screen newborn infants and whether public health policy arguments should defeat patients' ability to deny informed consent for such tests); *Update: HIPAA Privacy and Security Rules: Tougher Enforcement Expected in 2008*, HEALTHCARE REGISTRATION, Apr. 2008, at 1, 10–11 (discussing the emergency medical treatment exception to the Privacy Rule's requirement that informed consent be obtained before physicians can disclose confidential information).

[211] *See* Lea et al., *supra* note 3, at 235–36; Ito, *supra* note 21, at 457.

[212] *See supra* notes 103–109 and accompanying text.

the absence of trust, an essential ingredient for successful relationships.[213] If genetic test providers disclose that someone is predisposed to a genetically transmittable disease, devastating emotional and psychological harm may result to the individual tested, including discrimination and disruption of family harmony.[214]

When genetic information is disseminated without regard for individuals' wishes, respect for the principles of autonomy and privacy are substantially diminished. Government regulations must set a floor protecting the confidentiality of genetic information to uphold these ethical standards. Regulations should limit the disclosure of genetic information to third parties whether or not there is a physician-patient relationship. Individuals should be given consent statements about the potential uses and disclosures of their genetic information prior to genetic testing. People undergoing genetic testing should consent to the disclosure of their genetic information before any disclosures occur.

B. The Hippocratic Oath

The confidentiality associated with the physician-patient relationship, a staple of the medical field, is rooted in the Hippocratic Oath.[215] The classic version of the Hippocratic Oath includes a promise to "benefit my patients according to my greatest ability and judgment" and to "do no harm or injustice" to them.[216] The Oath also contains a declaration that "[w]hatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private."[217] A modern version of the oath is generally recited at medical school graduations.[218]

Disclosures of genetic information without patients' consent, aside from violating the Hippocratic Oath's promise to keep patient information

[213] Laurie, *supra* note 193, at 29.

[214] Stewart A. Laidlaw et al., *Genetic Testing & Human Subjects in Research*, 24 WHITTIER L. REV. 429, 454–55, 460 (2002).

[215] Ruebner & Reis, *supra* note 26, at 508.

[216] Hippocrates, *The Hippocratic Oath* (Michael North trans., National Library of Medicine, 2002) (400 B.C.), http://www.nlm.nih.gov/hmd/greek/greek_oath.html (last visited Mar. 16, 2010).

[217] *Id.*

[218] Denbo, *supra* note 117, at 572 n.49.

confidential, can harm patients.[219] If patients cannot rely on physicians' compliance with the Oath, patients may forego genetic testing and an important tool for preventing and treating hereditary diseases will be left idle.[220]

Physicians should comply with the spirit of the Hippocratic Oath when considering whether to disclose patients' genetic information. Physicians should not disclose genetic information without patient consent, especially if such disclosure would physically or mentally injure the patient. The survey results for the clinical studies and vignette suggest that many physicians felt obligated to disclose patients' genetic information to blood relatives when certain genetic conditions were involved.[221] However, physicians should not individually and arbitrarily be making such calls on a case-by-case basis because doing so circumvents the confidential basis of the physician-patient relationship and could have deleterious consequences, given the scientific concerns about genetic testing and the lapses in regulations meant to prevent discrimination on the basis of genetic information. Without newer, more encompassing regulations to prevent physicians from disclosing patients' genetic information, the values reflected in the Hippocratic Oath are hollow promises.

C. Responses to Arguments in Favor of Disclosing Genetic Information

Some commentators believe that disclosing genetic information to patients' blood relatives should be mandatory for physicians.[222] They make two main arguments. The first argument is that a duty to disclose genetic information exists under *Tarasoff*.[223] The second assertion is that medical information disclosure exceptions parallel justifications for disclosing

[219] *Id*. at 598 (stating that unauthorized disclosure of genetic information can cause patients to suffer emotional and psychological harm).

[220] *See* Brownrigg, *supra* note 23, at 264–65.

[221] *See supra* notes 128–154 and accompanying text.

[222] Denbo, *supra* note 117, at 591 n.138.

[223] Tarasoff v. Regents of the Univ. of Cal., 551 P.2d 334, 339–40 (Cal. 1976). A psychotherapist employed by a university treated a patient who had confided his intention to kill a readily identifiable female. *Id.* The psychotherapist allegedly requested that the patient be detained by campus police, but the patient was released when he appeared to be rational. *Id.* The physician did not take any further steps to detain the patient and no one notified the victim of the threats to her life. *Id.* at 340.

genetic information to blood relatives.[224] Both contentions are flawed.

1. *Tarasoff* is Inapplicable to the Disclosure of Genetic Information

In *Tarasoff*, California's Supreme Court held that psychotherapists have a duty to warn identifiable third parties when: (1) they have special relationships with the person who may cause the harm, (2) the potential target of the harm is identifiable, and (3) the harm to the victim is imminent and serious.[225] The *Tarasoff* duty to warn has been adopted in other jurisdictions with various modifications.[226]

Tarasoff is inapplicable to ethical debates about disclosing genetic information. The danger in *Tarasoff* stemmed from the fact that a patient violently carried out promises to kill a readily identifiable target.[227] An individual's genes, however, do not harm the individual's relatives.[228] Patients cannot put existing relatives at risk of becoming carriers of genetic mutations.[229] Because the disclosure of genetic information is irrelevant to whether relatives possess a certain gene or known mutations of genes, there is no parallel justification for imposing a *Tarasoff* duty on physicians to disclose genetic information to patients' blood relatives.[230]

[224] ASHG, *supra* note 113, at 475.

[225] *Tarasoff*, 551 P.2d at 343–47.

[226] The duty to warn articulated in *Tarasoff* has been applied in many states with modifications. For instance, some states do not create a duty to warn, but rather permit psychotherapists to warn when there are special relationships between the therapist and the third party. Providence Health Ctr. v. Dowell, 262 S.W.3d 324, 331 (Tex. 2008) (citing Thapar v. Zezulka, 994 S.W.2d 635, 637–39 (Tex. 1999)).

[227] *Tarasoff*, 551 P.2d at 345.

[228] ASHG, *supra* note 113, at 475. There is the potential for genetic tests to be a mode through which reproductive decisions are made. However, if a person wishes to know about a genetic trait before they reproduce, but their relative who has already been tested will not disclose their test results, the author believes that the individual should have genetic tests performed on themselves and on their partner instead of forcing a breach of the individual patient's privacy.

[229] Denbo, *supra* note 117, at 603. The only risk to relatives is that they discover that they carry specific genes. *Id*.

[230] Sudell, *supra* note 189, at 293.

2. General Exceptions to Medical Disclosure Laws Are Not Synonymous with Physicians' Disclosure of Genetic Information to Patients' Relatives

Exceptions to medical disclosure laws for contagious diseases, gunshot wounds, and child abuse are inapplicable to genetic information. Disclosing information about contagious diseases or potential child abuse protects the public and helpless individuals from suffering injury.[231] Genetic traits are not communicable diseases.[232] The presence of genes is not comparable to a gunshot wound or child abuse because those result from a third party's intentional and physical actions. Thus, current exceptions to generic disclosure laws do not provide reasons to permit, much less require, disclosure of genetic information to relatives.

VI. CONCLUSION

The ability to test for hundreds of genetically transmittable diseases marks a medical achievement that comes with moral and legal dilemmas attached.[233] Current confidentiality policies meant to protect genetic information are not enough to prevent unauthorized and discriminatorily-based disclosure requirements of genetic information by public and private entities. Gigantic gaps in federal and state genetic information regulations must be remedied by legislation that improves genetic information confidentiality standards by making regulations more encompassing and by making penalties for violations of these regulations enough to actually deter people from violating them. Scientific problems surrounding the accuracy of genetic tests and the lack of prophylactic treatments for diagnosable genetic diseases are very troubling. While some physicians and relatives may disagree, the ethical theories of autonomy, privacy, and the Hippocratic Oath, which are necessary for the effective functioning of medical systems, are destroyed each time an unauthorized disclosure of genetic information occurs. These important scientific concerns and ethical principles require that society, whether at the federal or state level, enact more encompassing laws to better protect the confidentiality of genetic information.

[231] *See* Denbo, *supra* note 117, at 574–75.

[232] Suddell, *supra* note 189, at 293.

[233] Suddell, *supra* note 189, at 273.