

Genetic Testing: Balancing Preventative Medicine with Privacy and Nondiscrimination

JONATHAN HSU*

Abstract: Genetic testing promises to provide patients with substantial benefits through early diagnosis, preventative medicine, and individualized treatments. It also promises to reduce the overall societal cost of healthcare. Yet, use of genetic testing also poses significant privacy and discrimination concerns, particularly in the context of health insurance coverage. Current legislation and regulatory schemes do not effectively balance these competing interests. This Note examines these shortcomings, and suggests that future legislative and regulatory efforts should not impose a single standard on all genetic tests. Rather, permitted uses of genetic test results by insurers should depend on the statistical predictive value of the particular test at issue.

I. INTRODUCTION

Current state and federal legislative schemes regulate genetic information much in the same way the Health Insurance Portability and Accountability Act (“HIPAA”) regulates other individually identifiable health information—by simply limiting the disclosure and use of certain categories of information. This approach is ineffective because genetic testing is more complex than other medical tests that generate individually identifiable health information. With genetic tests, statistical confidence levels vary greatly from test-to-test, and

* Jonathan Hsu is a Juris Doctor candidate, expected May 2011, at The Ohio State University Moritz College of Law. Jonathan received a Bachelor of Science from Cornell University in 2007 in Biological Engineering. Jonathan would like to thank my father, Jason Hsu, a professor of statistics at The Ohio State University, for his excellent support and assistance in identifying the statistical issues relevant to this note.

some genetic tests therefore pose a significantly greater risk of inaccurate results than others. Inaccurate information about risk for disease could unfairly affect an individual's insurance coverage, while accurate information could improve care and reduce costs through effective preventative medicine and early detection. Balancing these interests will therefore require future genetic privacy and nondiscrimination legislation to go beyond the traditional HIPAA approach to health information regulation, and acknowledge the differences between the types of tests generating the information in addition to placing limitations on the information's disclosure and use.

This Note first addresses the deceptively simple question, "what is genetic testing?" Most are familiar with genetic fingerprinting (as seen on the television show "CSI"), and might even be familiar with early genetic tests such as the test for Huntington's disease. However, genetic testing has become a vastly more complex industry. Today, genetic tests claim to reveal everything from a patient's risk for cancer to the likelihood he or she will respond to a particular drug.

The next part of this Note discusses the various concerns over the use of genetic information. Popular fear of genetic testing stems from concerns that doctors and scientists lack a thorough understanding of genetics and that inaccurate information could be used to discriminate. It also stems, significantly, from an almost metaphysical sense of identity that many individuals attach to their genetic code.

The third and fourth parts of this Note outline the current legal landscape of genetic privacy and nondiscrimination and its shortcomings. Of the various shortcomings, the most fundamental is that the current genetic privacy and nondiscrimination laws do not take into account the wide variety of genetic tests, and thus do not address significant differences in statistical reliability.

Finally, this Note proposes three principles that should guide future legislative efforts. First, genetic tests sold directly to consumers should fall within the HIPAA privacy rule. Second, permitted uses of genetic test results by insurers should depend on whether the test has been approved by the FDA. And third, elevated protection of genetic information due to its association with individual identity should remain within the realm of state property law.

II. WHAT IS "GENETIC TESTING?"

Like many aspects of medicine and biotechnology, the meaning of the phrase "genetic testing" has changed dramatically over the last several years. Most people are familiar with some basic forms of

genetic testing. Forensic scientists and prosecutors, for example, have used DNA fingerprinting to identify and convict defendants in criminal cases in the United States since 1987.¹ However, in recent years, genetic testing has advanced at a remarkable rate. At least in theory, scientists and doctors can now use genetic tests to conduct clinical diagnoses, evaluate a patient's likely response to a particular drug, and even predict an individual's risk for future disease.² As this part explains, these different types of tests often function in vastly different ways. This leads to great disparity in statistical confidence from test-to-test, and helps explain, in part, why genetic privacy and nondiscrimination legislation has been largely ineffective thus far. This part examines the three broad categories into which the vast majority of modern genetic tests fall: (1) diagnostic, (2) non-diagnostic, and (3) pharmacogenomic.

A. DIAGNOSTIC GENETIC TESTING

Widespread "genetic testing" for the purpose of clinical diagnosis began in 1963 when Dr. Robert Guthrie developed a test to screen newborns for phenylketonuria ("PKU").³ PKU is a genetic disorder caused by a mutation to the PAH gene.⁴ The PAH gene codes for the production of the enzyme phenylalanine hydroxylase, which metabolizes (i.e., breaks down) phenylalanine present in an individual's diet.⁵ Mutations to the PAH gene severely reduce the activity of the enzyme phenylalanine hydroxylase, without which phenylalanine levels build up to toxic levels in the blood and other tissues of PKU patients.⁶ The Guthrie test screened for elevated

¹ Michelle Hibbert, *DNA Databanks: Law Enforcement's Greatest Surveillance Tool?*, 34 WAKE FOREST L. REV. 767, 773 (1999) (noting that in 1987, Tommie Lee Andrews became the first American to be convicted in a case that utilized DNA evidence).

² The Universe of Genetic Testing, <http://www.labtestsonline.org/understanding/features/genetics.html> (last visited Apr. 17, 2011).

³ Genetic Testing Report – Appendix 5, <http://www.genome.gov/10002397> (last visited Apr. 17, 2011).

⁴ Phenylketonuria, <http://ghr.nlm.nih.gov/condition=phenylketonuria> (last visited Apr. 17, 2011).

⁵ *Id.*

⁶ *Id.*

phenylalanine levels to detect the disease, but did not directly detect mutations in the patients' PAH gene sequence.⁷

After the initial success of the Guthrie test for PKU, other success stories followed. Scientists soon developed tests for the diagnosis of sickle cell disease and Tay-Sachs disease. As with PKU, mutations to single genes cause sickle cell disease and Tay-Sachs disease.⁸ And like the Guthrie test for PKU, these tests detected abnormalities in each gene's metabolites (i.e., the enzymes and proteins the gene codes for) rather than mutations in the genetic sequence itself.⁹ The genetic test developed to confirm the presence of Huntington's disease did test for a particular genetic sequence as opposed to the protein for which the sequence codes.¹⁰ But again, as with the other diseases subject to early genetic diagnostic tests, a mutation to a single gene causes Huntington's disease.¹¹

However, scientists soon discovered that unlike PKU, sickle cell disease, Tay-Sachs disease, and Huntington's disease, the vast majority of genetic diseases bear "gene signatures" consisting of numerous genes.¹² Further, they discovered that mutations to these genes most often operate merely to increase one's risk for a disease or

⁷ Robert Guthrie & Ada Susi, *A Simple Phenylalanine Method for Detecting Phenylketonuria in Large Populations of Newborn Infants*, 32 *PEDIATRICS* 338, 342 (1963).

⁸ Sickle cell disease, <http://ghr.nlm.nih.gov/condition=sicklecelldisease> (last visited Apr. 17, 2011) (Sickle Cell Anemia is caused by mutations to the HBB gene); Tay-Sachs disease, <http://ghr.nlm.nih.gov/condition=taysachsdisease> (last visited Apr. 17, 2011) (Tay-Sachs disease is caused by mutations to the HEXA gene).

⁹ Sickle Cell Test, <http://www.nlm.nih.gov/medlineplus/ency/article/003666.htm> (last visited Apr. 17, 2011) (A sickle cell test looks for the presence or absence of abnormal hemoglobin in the blood that causes sickle cell anemia); Tay-Sachs Disease, <http://www.nlm.nih.gov/medlineplus/ency/article/001417.htm> (last visited Apr. 17, 2011) (Additional tests may include ... Enzyme analysis of blood or body tissue for hexosaminidase levels).

¹⁰ Learning About Huntington's Disease, <http://www.genome.gov/10001215> (last visited Apr. 17, 2011).

¹¹ *Id.*

¹² See SNPs: Variations on a Theme, <http://www.ncbi.nlm.nih.gov/About/primer/snps.html> (last visited Apr. 17, 2011) (Many common diseases in humans are not caused by a genetic variation within a single gene but are influenced by complex interactions among multiple genes as well as environmental and lifestyle factors).

disorder rather than to conclusively cause it.¹³ While a large proportion of recent genetic research therefore focuses on risk assessment as opposed to clinical diagnosis, some genetic predisposition for disease is nonetheless so great that the predisposition is itself considered a disease,¹⁴ warranting prophylactic measures by the patient.¹⁵

Tests for severe genetic predisposition would fall within the Food & Drug Administration's ("FDA") definition of *in vitro* diagnostics tests (subjecting them to FDA regulation) due to the prophylactic measures doctors may recommend as a result of the patient's diagnosis of a severe genetic predisposition for the disease.¹⁶ However, most such tests are "laboratory developed tests" ("LDTs"),¹⁷ over which the FDA has traditionally declined to exercise regulatory authority. The LDT exemption—also known as the "home brew" or "in-house" exemption—allows for the sale of diagnostic tests that are both manufactured and performed by the same laboratory with generally little FDA regulation.¹⁸ While the FDA has jurisdiction over LDTs,¹⁹ it has traditionally regulated only those LDTs that use "analyte specific reagents" ("ASRs") under its *in vitro* diagnostic device regulatory scheme.²⁰ Further, only LDTs that use Class II or Class III

¹³ *Id.*

¹⁴ See *Katskee v. Blue Cross/Blue Shield of Nebraska*, 515 N.W.2d 645, 653 (Neb. 1994) (characterizing breast-ovarian carcinoma syndrome as an illness because patients diagnosed with the syndrome have at least a 50 percent chance of developing breast and/or ovarian cancer).

¹⁵ Genetic Basis of Cancer Syndromes, <http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=cmed6&part=A4561> (last visited Apr. 17, 2011).

¹⁶ See 21 C.F.R. § 809.3(a) ("In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae.").

¹⁷ See Genetic Testing, <http://www.genome.gov/10002335> (last visited Apr. 17, 2011).

¹⁸ *Id.* (... [T]he FDA does not regulate "home brew" tests, that is, tests that are both manufactured and performed by the same laboratory.").

¹⁹ See Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 62 Fed. Reg. 62243, 62249 (Nov. 21, 1997) (codified at 21 C.F.R. Parts 809 and 864).

²⁰ FOOD & DRUG ADMIN., *IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS* (July 26, 2007), at 7-8, *available at*

ASRs²¹ require pre-market approval or clearance.²² Few genetic tests fall within this category.²³ Notably, the BRCA1/BRCA2 testing for the predisposition to breast cancer falls within the LDT exemption, as Myriad Genetics in Salt Lake City, Utah analyzes all test samples.²⁴

Despite the fact that the majority of tests do not *require* pre-market approval or clearance, several companies marketing modern, sophisticated genetic tests have nonetheless sought and obtained FDA approval. Most notably, Agendia voluntarily sought FDA approval for MammaPrint and obtained it in 2007.²⁵ MammaPrint uses microarray technology to detect abnormal expression levels in a group of seventy genes to aid in the evaluation of a breast cancer patient's risk for metastasis and tumor recurrence.²⁶ Different types of breast cancer respond to treatments differently, and optimal treatment may vary depending on a patient's risk for metastasis and tumor recurrence.²⁷ According to Agendia, MammaPrint aids doctors in evaluating a patient's risk, and thus aids them in tailoring that patient's treatment to her needs.²⁸

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCMo71455.pdf> (last visited Apr. 17, 2011).

²¹ 21 C.F.R. § 864.4020.

²² FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA STAFF COMMERCIALY DISTRIBUTED ANALYTE SPECIFIC REAGENTS (ASRS): FREQUENTLY ASKED QUESTIONS (Sept. 14, 2007), at 6, *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCMo71269.pdf> (last visited Apr. 17, 2011).

²³ See Dan Vorhaus, *Personal Genomics Follows Pathway to Corner Drugstore; Is Regulation Next?*, Genomics Law Report, (May 11, 2011), *available at* <http://www.genomicslawreport.com/index.php/2010/05/11/pathway-walgreens-and-dtc-regulation/> (last visited Apr. 17, 2011) ("Most ASRs are Class I devices ...").

²⁴ Genetic Testing, *supra* note 17.

²⁵ Press Release, U.S. Food & Drug Admin., *FDA Clears Breast Cancer Specific Molecular Prognostic Test* (Feb. 6, 2007), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108836.htm> (last visited Apr. 21, 2011).

²⁶ What You Need to Know about Breast Cancer Recurrence, http://www.agendia.com/pages/questions___answers/142.php (last visited Apr. 17, 2011).

²⁷ *Id.*

²⁸ *Id.*

Nor has FDA approval been limited to tests that characterize the risk of recurrence in patients with a known disease. In 2008, the FDA approved Pathwork Tissue of Origin, a truly diagnostic test in the sense that it identifies the presence of disease whose origin and presence might otherwise be unknown.²⁹ The test uses microarray technology to analyze 1,550 gene expression levels to determine the origin of metastatic cancer.³⁰ Some cancer patients are not diagnosed with cancer until it has metastasized and led to symptoms.³¹ For these patients, Pathwork Tissue of Origin can play an important role in their care by diagnosing the primary cancer (i.e. where the cancer began before spreading throughout the body) and allowing doctors to tailor treatment to that type of cancer.³²

Recently, one company has begun to use microarray technology not to test for genetically complex diseases such as cancer (as in MammaPrint and Pathwork Tissue of Origin), but rather to test for numerous diseases caused by mutations to single genes.³³ The test, known as the Universal Genetic Test, offered by Counsyl, claims to enable prospective parents to test whether they are carriers for over 100 genetic disorders caused by single genes, including PKU, sickle cell and Tay-Sachs.³⁴ Although prospective parents have tested for many of these diseases for several decades, Counsyl differs from previous screening tests in that it is purportedly able to detect over 100 disorders from a single saliva sample.³⁵ Like the BRCA1/BRCA2 test, Counsyl has thus far escaped FDA regulation under the in-house

²⁹ Press Release, U.S. Food & Drug Admin., *FDA Clears Test that Helps Identify Type of Cancer in Tumor Sample* (July 31, 2008), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116931.htm> (last visited Apr. 17, 2011).

³⁰ Federico Monzon et al., *Multicenter Validation of a 1,550-Gene Expression Profile for Identification of Tumor Tissue of Origin*, 27 J. CLIN. ONCOL. 2503, 2503 (2009).

³¹ Metastatic Cancer: Q&A, <http://www.cancer.gov/cancertopics/factsheet/Sites-Types/metastatic> (last visited Apr. 17, 2011).

³² See *id.* (“The choice of treatment generally depends on the type of primary cancer [among other things] ...”).

³³ See Counsyl, <https://www.counsyl.com/> (last visited Apr. 17, 2011); See also Andrew Pollack, *Firm Brings Gene Tests to Masses*, N.Y. TIMES, Jan. 29, 2010, at B1.

³⁴ Pollack, *supra* note 33; See also *Preventable Genetic Diseases Covered by the Universal Genetic Test*, <https://www.counsyl.com/diseases/> (last visited Apr. 17, 2011).

³⁵ Pollack, *supra* note 33.

exception³⁶ despite explicit claims that its test will allow prospective parents to take preventative measures and engage in more effective treatment.³⁷

B. NON-DIAGNOSTIC GENETIC TESTING

As noted above, a diagnostic test is designed both to identify a condition *and* to influence the patient's subsequent medical treatment.³⁸ While the best known genetic tests are diagnostic in nature, an increasing number of companies now market genetic tests whose stated goal is simply to inform individuals of their genetic risks without necessarily influencing decisions about their medical care. Such tests are distinguished from diagnostic tests not only by their purpose, but also in that they are typically requested without physician consultation.³⁹

Although numerous companies offer non-diagnostic genetic tests, deCODE Genetics and 23andMe (a Google-backed company) remain the most well-known. Both companies market genetic tests that claim to inform customers about their genetic risks for numerous diseases.⁴⁰ deCODE and 23andMe sell their tests online, shipping customers a sample collection kit.⁴¹ Customers then either swab the inside of their cheek (as with deCODE) or spit into a test tube (as with 23andMe)

³⁶ See Pollack, *supra* note 33.

³⁷ Early Testing Allows Prevention, <https://www.counsyl.com/learn/prevent-genetic-disease/> (last visited Apr. 17, 2011).

³⁸ 21 C.F.R. § 809.3(a).

³⁹ See Jennifer A. Gniady, Note, *Regulating Direct-to-Consumer Genetic Testing: Protecting the Consumer Without Quashing a Medical Revolution*, 76 FORDHAM L. REV. 2429, 2241-42 (2008) (noting that "diagnostic tests ... are ... more likely to involve a physician or genetic counselor in the course of administering and interpreting the results of the test.").

⁴⁰ See *e.g.*, Genetic Risk for 47 Conditions in One Scan, <http://www.decodeme.com/conditions-covered> (last visited Apr. 17, 2011) (listing conditions covered by deCODE's whole genome scan); See also List of Conditions, <https://www.23andme.com/health/all/> (last visited Apr. 17, 2011) (listing conditions covered by 23andMe's scan).

⁴¹ See About deCODEme, <http://www.decodeme.com/about-decodeme> (last visited Apr. 17, 2011); See also Using Your Personal DNA Test, <https://www.23andme.com/howitworks/> (last visited Apr. 17, 2011).

and ship their sample back to the laboratory for analysis.⁴² Both the deCODE and 23andMe laboratories then use microarrays to analyze the samples for various single nucleotide polymorphisms (“SNPs”) that are associated with the conditions covered by their respective scans.⁴³ Finally, the companies give customers access to a report detailing the SNPs revealed by the laboratory analysis and explaining what the presence of those SNPs might mean for the individual’s risk for disease.⁴⁴ While these companies claim to offer insight into an individual’s genetic risk for various diseases, they are careful to characterize the tests as non-diagnostic in nature.⁴⁵

As with diagnostic genetic tests, the vast majority of non-diagnostic genetic tests have not traditionally required pre-market FDA approval due to the LDT (in-house) exemption. However, as Direct-to-Consumer (“DTC”) genetic tests have become increasingly available to consumers, the FDA has begun to rethink its position on LDTs.⁴⁶ In 2007, the FDA issued proposed draft guidance that would require pre-market approval or clearance for “*in vitro* diagnostic multivariate index assays,” which seek to analyze multiple variables (i.e., multiple genes) to yield a “score” or “index” characterizing a particular patient’s risk.⁴⁷ Then in May 2010, when Walgreens

⁴² *Id.*

⁴³ See SNP Measurement and Risk Calculation, <http://demo.decodeme.com/health-watch/snp-measurement> (last visited Apr. 17, 2011) (Illumina’s bead chip is a type of microarray); See also Our Service: Genotyping Technology, <https://www.23andme.com/more/genotyping/> (last visited Apr. 17, 2011).

⁴⁴ See e.g., Try deCODEme using the Demo User Account, <http://demo.decodeme.com/your-results> (last visited Apr. 17, 2011).

⁴⁵ See e.g., Frequently Asked Questions, <http://www.decodeme.com/faq#interpreting3> (last visited Apr. 17, 2011) (“deCODEme provides information about your genetic risk. It does not make a definitive diagnosis...”); See also Why Can’t 23andMe Diagnose Me?, <https://www.23andme.com/you/faqwin/nodiagnosis/> (last visited Apr. 17, 2011) (“23andMe provides you with genetic information, but does not sequence your entire genome or perform predictive or diagnostic tests.”).

⁴⁶ Rob Stein, Walgreens Won’t Sell Over-the-Counter Genetic Test After FDA Raises Questions, WASH. POST, May 13, 2010, at A02; Press release, *FDA to Host Public Meeting on Oversight of Laboratory-Developed Tests* (June 16, 2010), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm215766.htm> (last visited Apr. 17, 2011).

⁴⁷ FOOD & DRUG ADMIN., *supra* note 20, at 7-8 (“Class II medical devices typically require FDA clearance ... Class III devices require the submission of an application for Premarket Approval ... We believe most IVMIAs will be either class II or III devices ...”).

announced its intention to sell Pathway Genomics' test kit at its stores, the FDA issued a letter stating its belief that the test kit required approval.⁴⁸ One month later, the FDA followed with similar letters to 23andMe, Navigenics, deCODE, Illumina and Knome.⁴⁹ And in July 2010, the FDA held a public meeting to discuss potential changes to the way it oversees LTDs.⁵⁰

C. PHARMACOGENOMICS/ PHARMACOGENETICS

“Pharmacogenomics” and “pharmacogenetics” are essentially interchangeable terms, which the National Center for Biotechnology Information (“NCBI”) defines as the “science that examines the inherited variations in genes that dictate drug response and explores the ways these variations can be used to predict whether a patient will have a good response to a drug, a bad response to a drug, or no response at all.”⁵¹ Rather than using genetics to diagnose, cure or

⁴⁸ Letter from James Woods, Deputy Director, Food and Drug Administration, to James Plante, Founder and CEO, Pathway Genomics Corporation (May 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM211875.pdf> (last visited Apr. 17, 2011).

⁴⁹ Letter from Alberto Gutierrez, Food and Drug Administration, to Anne Wojcicki, President and Co-Founder, 23andMe, Inc. (June 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215240.pdf> (last visited Apr. 17, 2011); Letter from Alberto Gutierrez, Food and Drug Administration, to Vance Vanier, President and CEO, Navigenics (June 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215243.pdf> (last visited Apr. 17, 2011); Letter from Alberto Gutierrez, Food and Drug Administration, to Earl M. Collier, Jr., CEO, deCODE Genetics (June 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215241.pdf> (last visited Apr. 17, 2011); Letter from Alberto Gutierrez, Food and Drug Administration, to Jay T. Flatley, President and CEO, Illumina, Inc. (June 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215242.pdf> (last visited Apr. 17, 2011); Letter from Alberto Gutierrez, Food and Drug Administration, to Jorge Conde, Co-Founder and CEO, Knome, Inc. (June 10, 2010), *available at* <http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM215239.pdf> (last visited Apr. 17, 2011).

⁵⁰ Press release, FDA to Host Public Meeting on Oversight of Laboratory-Developed Tests, *supra* note 46.

⁵¹ Pharmacogenomics Fact Sheet, <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html> (last visited Apr. 17, 2011).

prevent disease, pharmacogenomics seeks to use genetics to explain “the great heterogeneity in the way individuals respond to medication, in terms of both host toxicity and treatment efficacy.”⁵² A pharmacogenomic genetic test, then, seeks to determine a patient’s genotype to aid doctors in selecting an appropriate drug or an appropriate drug dosage.⁵³ The FDA has approved only a limited number of pharmacogenomic tests, with two notable examples being Roche’s AmpliChip and DAKO’s HercepTest.

AmpliChip, like several of the tests discussed above, uses microarray technology to detect mutations in the genes CYP2C19 and CYP2D6.⁵⁴ These genes affect the metabolism of a wide variety of drugs, including antipsychotics, antidepressants, β -blockers, anti-arrhythmic agents and opiates.⁵⁵ By evaluating a patient’s CYP2C19 and CYP2D6 gene expression levels, AmpliChip purports to allow doctors to better tailor treatment to an individual patient.⁵⁶

DAKO’s HercepTest uses an immunohistochemical assay to test for HER2 over-expression.⁵⁷ The HER2 gene codes for a membrane receptor protein associated with cell growth and proliferation.⁵⁸ Over-expression of the HER2 gene creates extra HER2 proteins within the cell membrane, leading to excessive cell growth and/or proliferation.⁵⁹ HercepTest tests for HER2 over-expression by binding staining agents

⁵² William Evans and Mary Relling, *Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics*, 286 SCIENCE 487, 487 (1999).

⁵³ *Id.* at 490-91 (“...automated systems are being developed to determine an individual’s genotype for polymorphic genes that are known to be involved in the pathogenesis of their disease, in the metabolism and disposition of medications, and in the targets of drug therapy. Such diagnostics, which need be performed only once for each battery of genes tested, can then become the blueprint for individualizing drug therapy.”).

⁵⁴ AmpliChip CYP450 Test, <http://www.roche.com/products/product-details.htm?type=product&id=17> (last visited Apr. 17, 2011).

⁵⁵ L. DiAnne Bradford, *CYP2D6 Allele Frequency in European Caucasians, Asians, Africans and Their Descendants*, 3 PHARMACOGENOMICS 229, 229 (2002).

⁵⁶ AmpliChip CYP450 Test, *supra* note 54.

⁵⁷ HercepTest™ Interpretation Manual, *available at* http://www.dako.com/us/index/knowledgecenter/kc_publications/kc_publications_interpret/herceptest.htm (last visited Apr. 17, 2011), at 3.

⁵⁸ *Id.* at 5.

⁵⁹ *Id.*

to HER2 proteins, allowing the user to evaluate the expression level of HER2 based on an imaging analysis of the stained tumor tissue.⁶⁰ The drug Herceptin works by blocking HER2 protein activity, and is thus thought to be effective only in patients whose cancer is related to HER2 over-expression.⁶¹ Doctors can therefore use HercepTest as an aid in determining which patients are likely to benefit from Herceptin use.⁶²

As noted above, however, FDA-approved pharmacogenomic tests such as Amplichip and HercepTest remain the exception rather than the rule. As with diagnostic genetic testing, a majority of pharmacogenomic test vendors have taken advantage of the “in-house” exemption and have escaped nearly all FDA regulation. For example, Ziagen (an antiretroviral medication used in the treatment of HIV, also known as Abacavir) produces a serious adverse event (“SAE”) in approximately 5% of patients.⁶³ An allele (i.e., discrete genetic variant) of the major histocompatibility complex (“MHC”) known as HLA-B*5701 is thought to be associated with these Ziagen-induced SAEs.⁶⁴ A number of laboratories, including LabCorp, now offer an “in-house” pharmacogenetic screening test for the HLA-B*5701 to aid in determining which patients might be likely to have an SAE as a result of taking Ziagen.⁶⁵

A similar example is found in association with the drug Tegretol, an anticonvulsant and specific analgesic for the treatment of

⁶⁰ *Id.* at 7.

⁶¹ See Herceptin Package Insert, available at <http://www.gene.com/gene/products/information/pdf/herceptin-prescribing.pdf> (last visited Apr. 17, 2011), at 6.

⁶² HercepTest Interpretation Manual, *supra* note 57, at 3.

⁶³ Simon Mallal et al., *Association Between Presence of HLA-B*5701, HLA-DR7, and HLA-DQ3 and Hypersensitivity to HIV-1 Reverse-Transcriptase Inhibitor Abacavir*, 359 LANCET 727, 727 (2002).

⁶⁴ *Id.*

⁶⁵ Malorye Allison, *Is Personalized Medicine Finally Arriving?*, 26 NAT. BIOTECHNOL. 509, 514 (2008); Ziagen Package Insert, available at http://us.gsk.com/products/assets/us_ziagen.pdf (last visited Apr. 17, 2011), at 2; HLA-B*5701 Genotyping, available at <https://www.labcorp.com/.EdosPortlet/TestMenuLibrary?libName=File+Library&compName=L1148> (last visited Apr. 17, 2011).

trigeminal neuralgia.⁶⁶ The MHC allele HLA-B*1502 appears to be associated with Tegretol-induced SAEs, at least among Asians.⁶⁷ As with Ziagen, several vendors now offer “in-house” pharmacogenetic screening tests for the HLA-B*1502 allele to aid in determining a patient’s likelihood of experiencing a Tegretol-induced SAE.⁶⁸

III. GENETIC TESTING, PRIVACY AND DISCRIMINATION

Fear of genetic testing is not new. In part, it stems from a long and tragic history of its misunderstanding and misuse. The infamous Nazi physician Josef Mengele engaged in extensive and brutal genetic experimentation for the purpose of “proving” the superiority of the Aryan race.⁶⁹ Even the United States once embraced eugenics and forced sterilization programs.⁷⁰ In his now-infamous opinion in *Buck v. Bell*, Justice Holmes declared that it was desirable to “prevent those who are manifestly unfit from continuing their kind.”⁷¹ The Supreme Court held that the forced sterilization of a mentally retarded woman, whose mother and grandmother were also believed to be mentally retarded, was not a violation of her Constitutional rights.⁷² If genetic science has led us to take such extreme missteps in the past, how are we to know that it will not happen again? It is true that scientists in the early to mid-twentieth century understood much less about genetics than they do today, but our understanding of genetics today is still largely incomplete.

⁶⁶ Tegretol Package Insert, *available at* <http://www.pharma.us.novartis.com/product/pi/pdf/tegretol.pdf> (last visited Apr. 17, 2011), at 2.

⁶⁷ Kheng Seang Lim et al., *Association of HLA-B*1502 Allele and Carbamazepine Induced Severe Adverse Cutaneous Drug Reaction Among Asians*, a Review, 13 NEUROL. ASIA 15, 15 (2008); See also Tegretol Package Insert, *supra* note 66, at 1.

⁶⁸ See, e.g., <https://www.labcorp.com/wps/portal/provider/testmenu> (search “167359”) (last visited Apr. 17, 2011).

⁶⁹ JUDITH T. BAUMEL, THE HOLOCAUST ENCYCLOPEDIA 412 (Walter Laqueur ed., Yale Univ. Press, 1st ed. 2001).

⁷⁰ See *Buck v. Bell*, 274 U.S. 200, 47 S. Ct. 584 (1927).

⁷¹ *Id.* at 207.

⁷² *Id.* at 208.

It is also not only the application of genetic science and technology to humans that creates fear. The 1990s and early 2000s saw an intense backlash against so-called “frankenfood” (i.e., genetically engineered food).⁷³ Although the use of recombinant DNA technology in crop development did not fundamentally differ from what plant breeders and farmers had practiced for millennia through selective breeding, many nonetheless perceived it as unfamiliar and unnatural.⁷⁴ This unfamiliarity-based fear is likewise not a new phenomenon.⁷⁵ Although in some ways, genetic engineering was actually *more* precise and predictable than traditional selection techniques because of its ability to introduce a single new gene at a time,⁷⁶ many people still perceived genetically engineered foods as less safe than foods produced using more traditional techniques.⁷⁷

Thus, our concern over genetic privacy and nondiscrimination stems from two distinct sources. First, it stems from a concern that scientists’ and doctors’ understanding of genetic science is incomplete. And second, it stems from a concern that as a society, we lack sufficient safeguards to prevent the discriminatory use of genetic information, whether flawed or not.

These concerns manifest themselves in a number of scenarios. For example, perhaps an employer could test prospective employees and reject those likely to develop a complex—and expensive to treat—disease. Or perhaps a prospective spouse could test his or her partner to evaluate the other’s “genetic potential” before committing to marriage. Yet, the most pressing genetic privacy and nondiscrimination anxiety for the typical individual (and the subject of this note) occurs in the context of applying genetic testing to health insurance.⁷⁸

⁷³ See Henry I. Miller & Gregory Conko, *The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution* (Praeger Publishers 2004).

⁷⁴ *Id.* at 19, 22.

⁷⁵ *Id.* at 27 (“There is a cartoon that depicts prehistoric cave dwellers gathered around a campfire, when a lookout peering into the distance shouts a warning: ‘Quick, put it out; here comes the anti-fire activists!’”).

⁷⁶ *Id.* at 6.

⁷⁷ *Id.* at 19.

⁷⁸ NANCY LEE JONES AND AMANDA K. SARATA, *GENETIC INFORMATION: LEGAL ISSUES RELATING TO DISCRIMINATION AND PRIVACY* 4 (Comm. Print 2008).

Insurance companies have long set premiums on the basis of statistical risk (though, as discussed in greater detail below, this will change beginning in 2014), and they argue that the use of genetic information is important because it allows them to more accurately assess a policy holder's risk and more accurately set premiums.⁷⁹ Further, such information is also potentially of extreme importance to policy holders themselves because prophylactic or preventative measures may be available upon discovering one's genetic predisposition to a particular disease,⁸⁰ and because pharmacogenomic testing may allow doctors to choose a treatment or determine a dosage more effectively.⁸¹ And for society as a whole, such preventative measures and personalized medicine may also be a means to significantly reducing overall health care costs.⁸²

Yet, in spite of these potential benefits, most individuals feel some level of discomfort in giving their insurers (or employers) full access to their genetic information. For example, when one employer began to discuss implementing a genetic screening test to identify workers likely to contract chronic beryllium disease, union officials vehemently expressed their displeasure.⁸³ They argued that employees would be unable to obtain health insurance and would be discriminated against by other employers in the future.⁸⁴ Prior to the passage of health care reform laws in 2010, a report compiled for Congress also found that "68 percent agree that insurers would do everything possible to use genetic information to deny health coverage."⁸⁵ Individual cases asserting actual discrimination on the basis of genetic testing are rare,

⁷⁹ Elaine Draper, *The Screening of America: The Social and Legal Framework of Employers' Use of Genetic Information*, 20 BERKLEY J. EMP. & LAB. L. 286, 289 (1999).

⁸⁰ See Genetic Basis of Cancer Syndromes, *supra* note 15; See also Kasparian et al., Genetic Testing for Melanoma Risk: A Prospective Cohort Study of Uptake and Outcomes Among Australian Families, 11 GENETICS IN MEDICINE 265 (2009) (observing that those identified as having higher risk for melanoma engaged in more frequent clinical skin examinations).

⁸¹ See Evans & Relling, *supra* note 52.

⁸² Monte Malach & W.J. Baumol, Opportunities for the Cost Reduction of Medical Care, 34 J. COMMUNITY HEALTH 255, 255 (2009).

⁸³ Diane Lewis, *Under a Genetic Cloud: The Benefits of DNA Testing Come with a Potential for Abuse*, THE BOSTON GLOBE, Aug. 14, 1994, at A1.

⁸⁴ *Id.*

⁸⁵ Jones & Sarata, *supra* note 78, at 4.

but the Council for Responsible Genetics does cite some examples, including a healthy seven-year-old child who was denied health insurance coverage because genetic tests claimed to reveal a predisposition for heart disease.⁸⁶

Concern over insurer use of genetic information generally falls into four categories. First, there is a fear that insurers could use genetic information to discriminate unfairly in setting premiums or denying coverage. The vast majority of genetic disorders are caused by complex interactions among numerous genes and numerous environmental factors.⁸⁷ Thus, an adverse genetic test result may not reflect an individual's *actual* risk of developing symptoms requiring medical treatment. In other words, the concern is that insurers may not fully understand the *true* statistical significance of a particular test result. Further, because genetic traits often fall along ethnic lines, there is a fear that insurance companies could use genetic information as a pretext for racial discrimination.

Second, both the law and society generally favor differentiating individuals on the basis of "lifestyle choices" rather than immutable characteristics.⁸⁸ For example, illegal drug use is generally regarded as an acceptable basis for differentiation.⁸⁹ However, it is now widely accepted that some individuals are more susceptible to addiction than others.⁹⁰ Thus, there is concern that insurers could use genetic testing to discriminate against those who, for example, have never used illegal drugs or smoked, but who are nonetheless genetically predisposed to addiction.

Third, pharmacogenomic tests may reveal that a patient is unlikely to respond favorably to a particular treatment or may be particularly likely to have severe side-effects. Therefore, it is possible that insurance companies will deny some patients coverage for such treatments. In the context of terminal patients for whom experimental

⁸⁶ CENTER FOR RESPONSIBLE GENETICS, GENETIC DISCRIMINATION: POSITION PAPER, available at <http://www.councilforresponsiblegenetics.org/pageDocuments/2RSW5M2HJ2.pdf> (last visited, Apr. 17, 2011).

⁸⁷ SNPs: Variations on a Theme, *supra* note 12.

⁸⁸ Draper, *supra* note 79, at 306-07.

⁸⁹ *Id.*

⁹⁰ See Peter Kalivas, *Predisposition to Addiction: Pharmacokinetics, Pharmacodynamics, and Brain Circuitry*, 160 AM. J. PSYCHIATRY 1, 1 (2003).

treatments often offer the only hope, there is a concern—and a lively ongoing debate—about the fairness of such decisions.⁹¹

Finally, even beyond concerns over the technology and its applications, there is the feeling that genetic information is uniquely personal. One commentator has referred to an individual's genetic code as a "coded future diary."⁹² Others have observed that today, "DNA appears in popular culture as a soul-like entity."⁹³ Walter Gilbert, who pioneered methods for sequencing DNA, stated that understanding one's genetic code is "the ultimate answer to the commandment 'Know thyself.'"⁹⁴ Even those who seek to debunk the idea of "DNA as soul," and who argue against elevating legal protections for genetic information beyond that of other health information, nonetheless acknowledge the existence of such sensitivities.⁹⁵

Thus, legislative and regulatory efforts to control genetic privacy must balance the interest in cost-reduction and preventative medicine against the interest in avoiding discriminatory insurance practices. And as if balancing those interests was not difficult enough, legislators must also recognize that genetic information can be intensely personal in a way that other forms of health information generally are not.

IV. THE LEGAL FRAMEWORK OF GENETIC PRIVACY AND NONDISCRIMINATION

Until recently, federal legislation pertaining explicitly to genetic information did not exist. Issues of genetic privacy and nondiscrimination were dealt with only indirectly under HIPAA and the Americans with Disabilities Act ("ADA"). Part of the American

⁹¹ NUFFIELD COUNCIL ON BIOETHICS, PHARMACOGENETICS: ETHICAL ISSUES 60, available at <http://nuffieldbioethics.org/sites/default/files/Pharmacogenetics%20Report.pdf>.

⁹² George J. Annas, *Privacy Rules for DNA Databanks: Protecting Coded 'Future Diaries,'* 270 J. AM. MED. ASS'N, 2346 (1993).

⁹³ Hugh Miller, *DNA Blueprints, Personhood, and Genetic Privacy*, 8 HEALTH MATRIX 179, 181, quoting DOROTHY NELKIN & M. SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* 41 (W. H. Freeman 1995).

⁹⁴ JERRY E. BISHOP & MICHAEL WALDHOLZ, *GENOME: THE STORY OF THE MOST ASTONISHING SCIENTIFIC ADVENTURE OF OUR TIME* 218 (Touchstone Books 1991) (quoting Walter Gilbert).

⁹⁵ Miller, *supra* note 93.

Recovery and Reinvestment Act (“ARRA”) directed the Department of Health and Human Services (“HHS”) and the Federal Trade Commission (“FTC”) to conduct a study on privacy issues pertaining to vendors of “personal health records” (“PHRs”) *and related entities* (which arguably includes vendors of genetic tests).⁹⁶ The ARRA also required the FTC to issue an interim health breach notification rule.⁹⁷ Although some groups submitted comments recommending the inclusion of genetic test vendors under the proposed rule’s definition of PHR vendors,⁹⁸ the FTC’s final notification rule made no mention of genetic data or genetic test vendors.⁹⁹ However, in October of 2009, HHS issued proposed modifications to the HIPAA Privacy Rule pursuant to the Genetic Information Nondiscrimination Act of 2008 (“GINA”).¹⁰⁰ These modifications explicitly included genetic information in the Privacy Rule’s definition of “health information”¹⁰¹ and became the first explicit federal regulations for genetic privacy and nondiscrimination.

Then, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act (“PPACA”). PPACA provided for sweeping reform of the health care insurance industry. Among its many provisions, beginning January 1, 2014, PPACA will prohibit insurers from determining eligibility on the basis of genetic information¹⁰² and will prohibit insurers from charging differential premium rates except on the basis of family structure, geography,

⁹⁶ American Recover and Reinvestment Act of 2009, Pub. L. No. 111-5, § 13424, 123 Stat. 277-78 (2009) (codified at 42 U.S.C. § 17953).

⁹⁷ *Id.*

⁹⁸ See, e.g., Letter from Ashley Katz, Coalition for Patient Privacy Rights, to Cora Tung Han & Maneesha Mithal, Fed. Trade Comm’n, at 3, *available at* <http://www.ftc.gov/os/comments/healthinfobreach/541358-00113.pdf> (last visited Apr. 17, 2011).

⁹⁹ Health Breach Notification Rule, 74 Fed. Reg. 42,962 (Aug. 25, 2009) (to be codified at 16 C.F.R. pt. 318).

¹⁰⁰ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, 74 Fed. Reg. 51,698, 51,698 (proposed Oct. 7, 2009) (to be codified at 45 C.F.R. pt. 160 & 164).

¹⁰¹ *Id.* at 51,700.

¹⁰² Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 2705(a), 124 Stat. 156 (2010) (effective Jan. 1, 2014).

actuarial value, tobacco use, participation in a health promotion program, and age.¹⁰³

An increasing number of states have also passed laws addressing genetic privacy and nondiscrimination. State genetic privacy laws vary widely in scope. They include provisions that require patient access to genetic information, that require patient consent in a variety of scenarios before disclosure, that define genetic information as personal property, and that provide civil remedies for breaches of genetic privacy.¹⁰⁴ State genetic nondiscrimination laws likewise vary in scope. Some such laws include provisions that variously prohibit insurers from using genetic information to establish eligibility and/or for risk assessment, as well as from requiring policy holders to undergo genetic testing.¹⁰⁵

A. FEDERAL LAW

1. AMERICANS WITH DISABILITIES ACT OF 1990

The general rule under the ADA states, “No *covered entity* shall discriminate against a qualified individual on the basis of disability...”¹⁰⁶ However, a “covered entity” is defined only as “an employer, employment agency, labor organization, or joint labor-management committee.”¹⁰⁷ Thus, while there is some debate as to whether a genetic disorder constitutes a “disability” under the ADA,¹⁰⁸

¹⁰³ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2701(a), 124 Stat. 155 (2010) (effective Jan. 1, 2014).

¹⁰⁴ Genetic Privacy Laws, <http://www.ncsl.org/IssuesResearch/Health/GeneticPrivacyLaws/tabid/14287/Default.aspx> (last visited Apr. 17, 2011).

¹⁰⁵ Genetic Nondiscrimination in Health Insurance Laws, <http://www.ncsl.org/IssuesResearch/Health/GeneticNondiscriminationinHealthInsuranceLaws/tabid/14374/Default.aspx> (last visited Apr. 17, 2011).

¹⁰⁶ Americans with Disabilities Act of 1990, 42 U.S.C. § 12112(a) (2009) (emphasis added).

¹⁰⁷ Americans with Disabilities Act of 1990, 42 U.S.C. § 12111(2) (2009).

¹⁰⁸ See Frances Miller & Philip Huvos, *Genetic Blueprints, Employer Cost-Cutting, and the Americans with Disabilities Act*, 46 ADMIN. L. REV. 369 (1994); See also EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, SECTION 902 DEFINITION OF THE TERM DISABILITY (1995), available at <http://www.eeoc.gov/policy/docs/902cm.html> (last visited Apr. 17, 2011) (“... ‘disability’ applies to individuals who are subjected to discrimination on

none of the ADA's provisions apply directly to either insurers or vendors of genetic tests. Furthermore, the ADA explicitly exempts insurance risk underwriting from its scope.¹⁰⁹

Nonetheless, the ADA is still somewhat relevant in the context of health insurance because many employers offer health insurance as an employment benefit.¹¹⁰ The ADA's prohibition on disability-based discrimination by employers does extend to employer-provided health insurance.¹¹¹ However, the Equal Employment Opportunity Commission ("EEOC") has stated that a distinction is *not* "disability-based discrimination" if "it is a broad distinction which applies to a multitude of dissimilar conditions" and "it constrains both individuals with and individuals without disabilities."¹¹² A broad distinction on the basis of "genetic disorders" would clearly apply to a multitude of dissimilar conditions. Also, as discussed above, many predispositions for disease are not themselves considered diseases, and are therefore likely not "disabilities" under the ADA.¹¹³ Even though some genetic disorders *are* likely "disabilities" under the ADA, and even though the ADA prohibits disability-based discrimination in employer-provided health insurance, it is thus unclear whether using a broad range of genetic information to underwrite employer-provided health insurance would violate the ADA.

2. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

HIPAA addresses genetic information in a number of ways. As applied directly to insurers, it limits the ways in which *group health plans*¹¹⁴ may use genetic information. HIPAA states that "[g]enetic

the basis of genetic information relating to illness, disease, or other disorders....Those individuals, therefore, are covered by the third part of the definition of 'disability.'").

¹⁰⁹ Americans with Disabilities Act of 1990, 42 U.S.C. § 12201(c) (2009).

¹¹⁰ See Miller & Huvos, *supra* note 108, at 381-83.

¹¹¹ See EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, COMPLIANCE MANUAL, CHAPTER 3: EMPLOYEE BENEFITS (2000), available at <http://www.eeoc.gov/policy/docs/benefits.html> (last visited Apr. 17, 2011).

¹¹² *Id.*

¹¹³ See SECTION 902 DEFINITION OF THE TERM DISABILITY, *supra* note 108.

¹¹⁴ HIPAA directly addresses only "group health plans," defined as "an employee welfare benefit plan to the extent that the plan provides medical care ... to employees or their

information shall not be treated as a [pre-existing condition] in the absence of a diagnosis of the condition related to such information.”¹¹⁵ This is important because under HIPAA, group health insurance plans may exclude pre-existing conditions from coverage for up to twelve months, provided that the participant received treatment, care, or advice within six months prior to enrollment.¹¹⁶ Additionally, HIPAA prohibits group health insurance plans from using “health status-related factors,” including genetic information,¹¹⁷ to determine a particular participant’s eligibility¹¹⁸ or to set differing premiums among similarly situated individuals.¹¹⁹

As applied to certain “covered entities,” HIPAA also limits the circumstances under which “protected health information” may be disclosed. Under the HIPAA Privacy Rule, a “covered entity” is defined as “[a] health plan,” “[a] health care clearinghouse,” “[a] health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter,” or business associates of another covered entity.¹²⁰ Some vendors who supply genetic tests through doctors and hospitals—such as Myriad Genetics—are clearly at least business associates of covered entities.¹²¹ However, DTC genetic test vendors—such as 23andMe—do not fall under definition of “covered entity,” as most DTC genetic test vendors are careful to characterize their services as non-diagnostic.¹²²

dependents ... directly or through insurance, reimbursement, or otherwise.” 29 U.S.C. § 1186(a)(1) (2009).

¹¹⁵ Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1181(b)(1)(B) (2009).

¹¹⁶ *Id.* § 1181(a) (2009).

¹¹⁷ *Id.* § 1182(a)(1)(F) (2009).

¹¹⁸ *Id.* § 1182(a)(1) (2009).

¹¹⁹ *Id.* § 1182(b)(1) (2009).

¹²⁰ 45 C.F.R. §§ 160.102 & 160.103.

¹²¹ See Reimbursement Continued, http://www.myriadtests.com/index.php?page_id=314 (last visited Apr. 17, 2011).

¹²² See Lawrence Moore & Emily Sherlock, *Federal Privacy Regulation and the Financially Troubled DTC Genomics Company*, Genomics Law Report, <http://www.genomicslawreport.com/index.php/2009/10/27/federal-privacy-regulation-and-the-financially-troubled-dtc-genomics-company/> (Oct. 27, 2009) (last visited Apr. 17, 2011); See also Why Can’t 23andMe Diagnose Me?, *supra* note 45; 45 C.F.R. § 160.103 (defining “health care” to include “Preventive, diagnostic, therapeutic, rehabilitative,

If an entity is a “covered entity,” it may not disclose “protected health information” without the patient’s authorization, except as required or permitted by the HIPAA Privacy Rule.¹²³ “Protected health information” is defined as “individually identifiable health information,”¹²⁴ which the HHS has considered as including genetic information even though it is not explicitly stated in the regulations.¹²⁵ Permitted disclosures are those disclosures to the individual or those disclosures for the purpose of “treatment, payment, or health care operations.”¹²⁶ Significantly, “health care operations” are defined broadly, and explicitly include insurance underwriting and risk assessment.¹²⁷

3. AMERICAN RECOVERY AND REINVESTMENT ACT

The ARRA—better known as the Stimulus Bill—required the HHS and FTC to conduct a study on privacy, security, and breach-notification requirements for “personal health record” (“PHR”) vendors and their related entities.¹²⁸ It also required the FTC to issue an interim health breach notification rule.¹²⁹ In April 2009, the FTC released its proposed health breach notification rule, and solicited comments from the public.¹³⁰ The proposed rule made no mention of genetic information.

“Personal health records” are generally understood to be “electronically accessible records of patient health care information

maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body.”).

¹²³ 45 C.F.R. § 164.502.

¹²⁴ 45 C.F.R. § 160.103.

¹²⁵ Does the HIPAA Privacy Rule protect genetic information?, <http://www.hhs.gov/hipaafaq/about/354.html> (last visited Apr. 17, 2011).

¹²⁶ 45 C.F.R. § 164.502

¹²⁷ 45 C.F.R. § 164.501

¹²⁸ American Recover and Reinvestment Act of 2009, *supra* note 96.

¹²⁹ *Id.*

¹³⁰ Proposed Health Breach Notification Rule, 74 Fed. Reg. 17,914 (proposed Apr. 20, 2009) (to be codified at 16 C.F.R. pt. 318).

that can be maintained by the patient . . . [and] may include medical histories, prescription histories, and lab results that patients can give to their providers.”¹³¹ As one comment submitted by the Coalition for Patient Privacy Rights observed, DTC genetic test vendors often provide patients with online access to their test results, and could therefore be deemed PHR vendors within the meaning of the health breach notification rule.¹³² However, this comment was the only one of 129 comments received to suggest the inclusion of DTC genetic test vendors, and the final interim health breach notification made no mention of genetic information.¹³³ While the HHS and FTC study could ultimately conclude that PHR vendors should include DTC genetic test vendors, the exclusion of DTC vendors from the FTC’s interim rule makes it unlikely.¹³⁴

4. GENETIC INFORMATION NONDISCRIMINATION ACT

GINA required the HHS Secretary to modify the HIPAA Privacy Rule such that “[g]enetic information shall be treated as health information.”¹³⁵ GINA imposed a May 2009 deadline for the Secretary to make these modifications.¹³⁶ However, perhaps because of the pending health breach notification rule discussed above, HHS did not release its proposed rule implementing the modifications until October 2009.¹³⁷ While the proposed rule states that genetic information has long been included under the Privacy Rule, the proposed rule explicitly adds “genetic information” to the Privacy Rule’s definition of “protected health information.”¹³⁸

¹³¹ DANIEL R. LEVINSON, DEP’T OF HEALTH AND HUMAN SERVICES, OEI-02-06-00270, STATE MEDICAID AGENCIES’ INITIATIVES ON HEALTH INFORMATION TECHNOLOGY AND HEALTH INFORMATION EXCHANGE (Aug. 2007), at 2, *available at* <http://oig.hhs.gov/oei/reports/oei-02-06-00270.pdf> (last visited Apr. 17, 2011).

¹³² Katz, *supra* note 98, at 3.

¹³³ Final Health Breach Notification Rule, *supra* note 99.

¹³⁴ Moore & Sherlock, *supra* note 122.

¹³⁵ Genetic Information Nondiscrimination Act, 42 U.S.C. § 1320d-9 (2009).

¹³⁶ Genetic Information Nondiscrimination Act, 42 U.S.C. § 2000ff-10 (2009).

¹³⁷ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,700.

¹³⁸ *Id.*

The proposed rule goes on to define “genetic information” to include an individual’s genetic tests.¹³⁹ “Genetic test” is defined as “an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.”¹⁴⁰ However, under GINA, “genetic test” excludes tests that are “directly related to a manifested disease, disorder, or pathological condition.”¹⁴¹ The proposed rule further clarifies that the term “manifested” applies when non-genetic clinical symptoms can be observed and the disease can be diagnosed on the basis of those non-genetic symptoms.¹⁴² Thus, for example, although breast-ovarian carcinoma syndrome (severe predisposition for breast or ovarian cancer) can be considered a disease itself,¹⁴³ GINA does not consider the disease “manifested” until the patient can be diagnosed with breast cancer on the basis of non-genetic clinical symptoms. Identical tests could be both included and excluded under the definition of “genetic test” depending on the clinical progression of the patient’s disease. The rule cites the test for Huntington’s disease,¹⁴⁴ which *would* be a “genetic test” until the disease manifests clinical symptoms. At that point, the same test, used merely to *confirm* the diagnosis, would *not* be a “genetic test.”¹⁴⁵

Also, while GINA and the accompanying HHS regulations do clarify what genetic information is protected under HIPAA, GINA does not affect the definition of “covered entities,” nor is it clear whether it significantly affects the information’s permitted uses.¹⁴⁶ Notably, this means that DTC genetic test vendors are still likely outside the scope of the HIPAA privacy rule.¹⁴⁷ Further, it is unclear to

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 51,701.

¹⁴² *Id.* at 51,702.

¹⁴³ See *Katskee*, *supra* note 14.

¹⁴⁴ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,702.

¹⁴⁵ *Id.*

¹⁴⁶ Moore & Sherlock, *supra* note 122.

¹⁴⁷ Moore & Sherlock, *supra* note 122.

what extent, if at all, GINA affects the ability of insurers to use genetic information for underwriting or risk assessment purposes.¹⁴⁸

5. PATIENT PROTECTION AND AFFORDABLE CARE ACT

PPACA extends and strengthens several HIPAA provisions relevant to genetic privacy and nondiscrimination. First, it prohibits *all* insurers from determining eligibility on the basis of “health status-related factors” including genetic information.¹⁴⁹ HIPAA’s equivalent provision applied only to “group health plans.”¹⁵⁰ Second, it prohibits *all* insurers from setting differential premium rates except on the basis of family structure, geography, actuarial value, tobacco use, participation in a health promotion program, and age.¹⁵¹ HIPAA prohibited only differential premiums among “similarly situated individuals,” and applied only to “group health plans.”¹⁵² And third, PPACA prohibits all pre-existing condition exclusions.¹⁵³ HIPAA allowed certain pre-existing condition exclusions for up to twelve months.¹⁵⁴

Thus far, HHS has issued only a limited interim rule pursuant to PPACA. The interim rule does not define “genetic information” or explicitly specify how genetic information will be treated with respect to “pre-existing conditions.” However, the PPACA provision regarding pre-existing conditions simply modifies its HIPAA counterpart, and the interim rule generally adopts HIPAA’s definition of “pre-existing

¹⁴⁸ See HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,702-05.

¹⁴⁹ Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 2705(a), 124 Stat. 156 (2010) (effective Jan. 1, 2014) (“A group health plan *and* a health insurance issuer offering group or individual health insurance coverage...”).

¹⁵⁰ Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1182(a)(1) (2009) (“...a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan...”).

¹⁵¹ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2701(a), 124 Stat. 155 (2010) (effective Jan. 1, 2014).

¹⁵² Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1182(b)(1) (2009).

¹⁵³ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2704(a), 124 Stat. 154 (2010) (effective Jan. 1, 2014).

¹⁵⁴ Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1181(a) (2009).

condition.”¹⁵⁵ Thus, it seems likely that the final rule will follow HIPAA, which states that genetic information shall not be treated as a pre-existing condition “in the absence of a diagnosis of the condition related to such information.”¹⁵⁶ Similarly, although PPACA does not explicitly define “genetic information,” it seems likely that HHS will ultimately adopt a similar definition to that in the rule promulgated pursuant to GINA.¹⁵⁷

B. STATE LAW

An increasing number of states have also passed laws pertaining to genetic information. These laws generally fall within two categories: (1) laws pertaining to genetic privacy, and (2) laws pertaining to genetic nondiscrimination. As discussed below, however, the scope of these state laws varies greatly.

1. STATE GENETIC PRIVACY LAWS

Only four states require that patients be given access to their genetic information upon request. Delaware law states that “[a]n individual promptly upon request, may inspect, request correction of and obtain genetic information from the records of that individual.”¹⁵⁸

Meanwhile, twenty-nine states have passed laws that require patient consent before various actions are taken with respect to genetic information.¹⁵⁹ Of these twenty-nine states, twelve have laws requiring patient consent before a genetic test may be performed.¹⁶⁰

¹⁵⁵ Requirements for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections, 75 Fed. Reg. 37,188 (proposed June 28, 2010) (to be codified at 45 C.F.R. parts 144, 146, and 147).

¹⁵⁶ Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1181(b)(1)(B) (2009).

¹⁵⁷ See HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,700.

¹⁵⁸ DEL. CODE ANN.16, § 1223 (2009).

¹⁵⁹ See Genetic Privacy Laws, <http://www.ncsl.org/IssuesResearch/Health/GeneticPrivacyLaws/tabid/14287/Default.aspx> (last visited Apr. 17, 2011).

¹⁶⁰ See *id.*

For example, New York Civil Rights Law states, “No person shall perform a genetic test on a biological sample taken from an individual without the prior written informed consent of such individual...”¹⁶¹

Seven states also have laws requiring patient consent to access or retain genetic information.¹⁶² For example, Minnesota law provides that genetic information “may be used only for purposes to which the individual has given written informed consent [and] may be stored only for a period of time to which the individual has given written informed consent.”¹⁶³ Finally, twenty-seven states have laws that require patient consent prior to the disclosure of genetic information.¹⁶⁴ For example, the New York Civil Rights Law provides that genetic information “shall not be released to any person or organization not specifically authorized by the individual subject of the test.”¹⁶⁵

Five states have passed laws that actually define genetic information as personal property.¹⁶⁶ For example, Colorado law states: “Genetic information is the unique property of the individual to whom the information pertains.”¹⁶⁷ These laws, in particular, appear to recognize the soul-like ability of genetic information to define one’s self.

Finally, nineteen states provide specific civil or criminal penalties for violations of genetic privacy provisions.¹⁶⁸ For example, Alaska law creates a private right of action up to \$5,000 for breaches of genetic privacy resulting in no monetary gain for the violating party and up to \$100,000 for breaches that do result in monetary gain.¹⁶⁹

¹⁶¹ N.Y. CIV. RIGHTS LAW § 79-l(2) (2009).

¹⁶² See Genetic Privacy Law, *supra* note 159.

¹⁶³ MINN. STAT. § 13.386 (2009).

¹⁶⁴ See Genetic Privacy Law, *supra* note 159.

¹⁶⁵ N.Y. CIV. RIGHTS LAW § 79-L (2009).

¹⁶⁶ See Genetic Privacy Law, *supra* note 159.

¹⁶⁷ COLO. REV. STAT. §§ 10-3-1104.6 & 10-3-1104.7 (2009).

¹⁶⁸ See Genetic Privacy Law, *supra* note 159.

¹⁶⁹ ALASKA STAT. § 18.13.020 (2009).

2. STATE GENETIC NONDISCRIMINATION LAWS

All but four states have passed some form of law that prohibits insurers from establishing eligibility rules on the basis of genetic information.¹⁷⁰ However, the laws vary in which types of insurers—group or individual—are covered. For example, Alaska, Iowa, South Dakota and Wyoming's antidiscrimination laws apply only to group insurers; while Hawaii, Nebraska and West Virginia's nondiscrimination laws apply only to individual insurers.¹⁷¹ Laws from the other thirty-nine states apply to both individual and group health insurance companies.¹⁷² For example, Ohio prohibits insurers from considering "any information obtained from genetic screening or testing in processing an application for coverage for health care services under an individual or group policy, contract, or agreement or in determining insurability under such a policy, contract, or agreement."¹⁷³

Additionally, twenty-seven states have laws that prohibit insurers from requiring genetic testing or requiring access to genetic information.¹⁷⁴ For example, the California Insurance Code states: "No insurer shall require a test for the presence of a genetic characteristic for the purpose of determining insurability other than for those policies that are contingent on review or testing for other diseases or medical conditions."¹⁷⁵

Finally, all but six states have laws that prohibit insurers from using genetic information for risk selection or risk classification purposes, at least under some circumstances.¹⁷⁶ For example, New Hampshire law states that health insurers shall not:

¹⁷⁰ See Genetic Privacy Law, *supra* note 159.

¹⁷¹ Genetic Nondiscrimination in Health Insurance Laws, *supra* note 108.

¹⁷² See Genetic Privacy Law, *supra* note 159.

¹⁷³ OHIO REV. CODE § 1751.65 (2009).

¹⁷⁴ See Genetic Privacy Law, *supra* note 159.

¹⁷⁵ CAL. INS. CODE § 10148 (2009).

¹⁷⁶ See Genetic Privacy Law, *supra* note 159.

Consider in the determination of rates or any other aspect of health insurance coverage or health care benefits provided to an individual whether an individual or a member of the individual's family has undergone genetic testing or the results of the testing, if undergone by the individual or a member of the individual's family.¹⁷⁷

Thus, while a large majority of states have passed at least some form of law pertaining to either genetic privacy or genetic nondiscrimination, their scopes vary greatly from state to state. Further, these state laws follow similar approaches to federal law—namely HIPAA, as modified by GINA—in that they seek to limit the use and disclosure of “genetic information.”

V. SHORTCOMINGS OF THE CURRENT LEGAL FRAMEWORK OF GENETIC PRIVACY AND NONDISCRIMINATION

GINA was hailed as a triumph. Yet, even in the wake of GINA and PPACA, the legal framework of genetic privacy and nondiscrimination remains muddled, and some of the most pressing concerns remain unresolved. First, DTC genetic test vendors remain outside the scope of the HIPAA Privacy Rule. Second, because PPACA does not (yet) define “genetic information,” permitted uses of genetic information by insurers remain inconsistent and unclear. And third, most importantly, both federal and state genetic privacy and nondiscrimination laws continue to ignore differences in the predictive value of various genetic tests. While GINA does attempt to address this issue in its definition of “genetic test” (which, as discussed above, will also likely apply to PPACA), it fails to do so in a statistically meaningful way. Assuming PPACA adopts GINA’s definition of “genetic information,” it will likely prohibit most uses of genetic test results by insurers. And in so doing, it will remove an important incentive insurers had to cover the cost of genetic testing.

A. DIRECT-TO-CONSUMER GENETIC TEST VENDORS REMAIN OUTSIDE THE SCOPE OF THE HIPAA PRIVACY RULE

As several commentators have observed, DTC genetic test vendors likely remain outside the scope of the HIPAA Privacy Rule because

¹⁷⁷ N.H. REV. STAT. § 141-H:4 (2009).

GINA did not modify the definition of “covered entity.”¹⁷⁸ The web sites of the two major players in the DTC genetic testing industry—23andMe and deCODE—make no mention of HIPAA.¹⁷⁹ Of the DTC genetic test vendors surveyed for this note, only Counsyl has attempted to comply with the HIPAA Privacy Rule and GINA.¹⁸⁰ However, Counsyl differs significantly from other DTC genetic test vendors in two important ways. First, it explicitly characterizes its services as diagnostic.¹⁸¹ Second, it offers its services both directly to consumers *and through doctors*.¹⁸² Thus, Counsyl is almost certainly a “covered entity” under HIPAA/GINA as either a “health care provider” itself (because it offers diagnostic services) or a business associate of other health care providers (because it offers its services through doctors).

This continued exclusion of DTC genetic test vendors from scope of the HIPAA Privacy Rules is problematic because of their increasing popularity and the misleading advertising practices engaged in by some vendors. A number of DTC genetic test vendors suggest that their services are *more* protective of a customer’s privacy *because* the test is not ordered through a doctor and would not be part of one’s medical record.¹⁸³ Additionally, as deCODE’s recent bankruptcy

¹⁷⁸ Moore & Sherlock, *supra* note 122.

¹⁷⁹ Privacy Statement, <https://www.23andme.com/about/privacy/> (last visited Apr. 17, 2011); deCODE Genetics, <http://www.decode.com/company/terms.php#privacy> (last visited Apr. 17, 2011).

¹⁸⁰ Your Privacy, <https://www.counsyl.com/about/privacy/> (last visited Apr. 17, 2011).

¹⁸¹ Early Testing Allows Prevention, <https://www.counsyl.com/learn/prevent-genetic-disease/> (last visited Apr. 17, 2011).

¹⁸² The Universal Genetic Test, <https://www.counsyl.com/learn/universal-genetic-test/> (last visited Apr. 17, 2011) (“Get your kit from your local doctor’s office.”).

¹⁸³ Kathy Hudson et al., *ASHG Statement on Direct-to-Consumer Genetic Testing in the United States*, 81 AM. J. HUMAN GENETICS 635, 636 (2007); *See, e.g.*, Tera Eerkes, *The Scary Truth About Your Genetic Information* (Sept. 4, 2008), <http://www.genedream.net/wordpress/?p=12> (last visited Apr. 17, 2011) (“Don’t let someone take your genetic info (even if it’s anonymized) and sell it to other people, EVER...Don’t let someone take your genetic info and use it for research they won’t happily tell you about...Don’t let someone take your genetic information and use it for anything unless they promise that you can have it back whenever you want it. I can’t name names, but these three things are big No-Nos, and they are also things that several personal genetic testing companies are currently doing. Obviously, QTrait doesn’t do this.”); *See also* Brandon Keim, *Genetic Protections Skimp on Privacy, Says Gene Tester*, *Wired Science*, <http://www.wired.com/wiredscience/2008/05/genetic-protect/> (May 23, 2008, 08:13 EDT) (last visited Apr. 17, 2011).

demonstrates, the exclusion of DTC genetic test vendors from HIPAA makes it unclear what control a customer would have over his or her genetic information if a DTC genetic vendor goes bankrupt.¹⁸⁴

B. PERMITTED USES OF GENETIC INFORMATION BY INSURERS REMAIN INCONSISTENT AND UNCLEAR

As discussed above, federal protections against genetic discrimination by insurers have historically been limited. HIPAA did prohibit excluding pre-existing genetic disorders from coverage after twelve months, but pre-existing conditions were defined narrowly and the exclusion was permitted for twelve months.¹⁸⁵ Although GINA clarified “genetic information,” it did little to affect its permitted uses. Further, HIPAA applied only to group insurers and did not protect those seeking coverage in the individual health insurance market.

Beginning in 2014, PPACA will indeed prohibit *all* insurers from determining eligibility on the basis of genetic information and, generally, from setting differential premiums.¹⁸⁶ PPACA will also prohibit all pre-existing condition exclusions.¹⁸⁷ However, PPACA does not define “genetic information.” And although PPACA will likely adopt GINA’s definition of the term, it is therefore still somewhat unclear exactly what information insurers may consider in determining eligibility. For example, PPACA specifically allows insurers to set differential premiums on the basis of tobacco use.¹⁸⁸ Yet, studies have shown that genetic factors may predispose some individuals to addiction to tobacco.¹⁸⁹ If a policy holder both uses tobacco *and* possesses a gene that predisposes him or her to continued addiction, it may thus be somewhat unclear whether the

¹⁸⁴ Dan Vorhaus, *deCODE Declares. Now What?*, Genomics Law Report, <http://www.genomicslawreport.com/index.php/2009/11/17/decode-declares-now-what/> (Nov. 17, 2009) (last visited Apr. 17, 2011).

¹⁸⁵ Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. § 1181(a) (2009).

¹⁸⁶ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2701(a), 124 Stat. 155 (2010) (effective Jan. 1, 2014).

¹⁸⁷ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2704(a), 124 Stat. 154 (2010) (effective Jan. 1, 2014).

¹⁸⁸ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 2701(a)(1)(A)(iv), 124 Stat. 155 (2010) (effective Jan. 1, 2014).

¹⁸⁹ Kalivas, *supra* note 91.

insurer could set a higher premium on the basis of his or her tobacco use.

Further, PPACA does not address whether severe genetic predisposition for a particular disease constitutes a “pre-existing condition.” Thus, it is unclear whether insurers must cover prophylactic care for an individual who, for example, tested positive for a mutation to BRCA1 or BRCA2 prior to enrolling in the plan. Accordingly, at least until HHS promulgates further rules (and even then, until 2014), genetic privacy and nondiscrimination protections remain largely a function of state law.

At the state level, the scope of protection varies widely. Alabama, for example, prohibits only the use of genetic test results revealing a predisposition for cancer.¹⁹⁰ Other states prohibit such a broad scope of genetic information uses that their prohibitions are impracticable. For example, New Hampshire prohibits the consideration of genetic test results in “any ... aspect of health insurance coverage....”¹⁹¹ However, a “genetic test” is defined as “a test, examination, or analysis, which is generally accepted in the scientific and medical communities for the purpose of identifying the presence, absence, or alteration of any gene or chromosome.”¹⁹² Because genetic disorders are, by definition, caused by genetic abnormalities, this definition of “genetic test” includes *diagnostic* as well as predictive tests. It is difficult to imagine that insurers would never be able to consider, under any circumstances, whether a policy holder *currently* manifests cancer. Further, this is not traditionally what is meant by genetic discrimination.¹⁹³

Moreover, such heavy-handed genetic privacy and nondiscrimination laws can conflict with other medically sound objectives. Minnesota’s genetic privacy law requires patient consent prior to the use, storage, or dissemination of genetic information.¹⁹⁴

¹⁹⁰ ALA. CODE § 27-53-2 (2009).

¹⁹¹ N.H. REV. STAT. § 141-H:4 (2009).

¹⁹² N.H. REV. STAT. § 141-H:1 (2009).

¹⁹³ Michael S. Yesley, *Protecting Genetic Difference*, 13 BERKELEY TECH. L.J. 653, 662 (1998) (“It is important to note that whether genetic information is defined narrowly or broadly in the laws barring genetic discrimination, the term generally does not include information about expressed, or existing, genetic disorders. The quintessential feature of genetic discrimination is the use of genetic information about an asymptomatic person. If the disorder related to a genetic characteristic has occurred, discrimination based on the disorder may be unfair but is not customarily considered ‘genetic discrimination.’”).

¹⁹⁴ MINN. STAT. § 13.386 (2009).

Like New Hampshire discussed above, Minnesota defines “genetic information” extremely broadly:

(a) "Genetic information" means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of:

(1) the individual's biological information or specimen;
or

(2) the biological information or specimen of a person to whom the individual is related.

(b) "Genetic information" also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual or the individual's family members.¹⁹⁵

However, as the plaintiffs' claims in *Bearder, et. al. v. State of Minnesota*¹⁹⁶ demonstrate, this law's broad and heavy-handed protection is potentially inconsistent with another Minnesota statute, which requires newborn screening for certain inherited diseases, including PKU.¹⁹⁷ Newborn screening for PKU has long been considered justified given the severe consequences of the disease and the accuracy of its test.¹⁹⁸ Thus, heavy-handed genetic privacy/nondiscrimination statutes and over-broad definitions of genetic information are not only impracticable for insurers, but could also interfere with legitimate and scientifically sound medical objectives.

¹⁹⁵ *Id.*

¹⁹⁶ 788 N.W.2d 144, 144 (Minn. Ct. App. 2010) (Plaintiffs claim “that respondents' collection, retention, use, or dissemination of appellant-children's blood in conjunction with a state-mandated newborn screening program violated their ... rights [under the state's genetic privacy act, among other things]”).

¹⁹⁷ MINN. STAT. § 144.125 (2009).

¹⁹⁸ See Screening for phenylketonuria (PKU): U.S. Preventive Service, <http://www.guideline.gov/content.aspx?id=12270> (last visited Apr. 17, 2011) (“The USPSTF recommends screening for phenylketonuria (PKU) in newborns.”).

C. GENETIC PRIVACY AND NONDISCRIMINATION STATUTES DO NOT
ADDRESS DIFFERENCES IN PREDICTIVE VALUE

At the heart of these shortcomings is a failure of genetic nondiscrimination laws to address the differences in statistical predictive values of different genetic tests. It may be true that all genetic discrimination raises at least some concerns. For example, allowing insurers to set higher premiums for those with greater risk for disease on the basis of *accurate* genetic information could potentially increase societal costs through decreased use of preventative medicine and early treatment if such individuals are unable to afford adequate insurance. However, the greatest threat of genetic discrimination centers on the risk that individuals could be categorized on the basis of an *inaccurate* assessment of their risk for the future manifestation of clinically symptomatic disease.¹⁹⁹

Several commentators have observed that, to the extent genetic information can *accurately* predict a particular individual's risk for disease, consideration of genetic information by insurers is natural and even desirable. Time Magazine contributor Michael Kinsley states:

The very appealing notion that genetic discrimination is unfair looks especially odd in the context of insurance. The idea of insurance is to protect against the unexpected or unlikely. Forbidding insurers to take predictable risks into account when choosing whom to insure and how much to charge is asking them to behave irrationally and make bets they are sure to lose. Not insuring people who are likely to get cancer, or charging them more, isn't evil. It's rational behavior. Of course, we outlaw a lot of behavior that would be rational if it weren't against the law. But the skeptics who say this is a step on the way to universal health care actually understate the case. To truly apply the appealing principle that people should not be discriminated against because of their genes would be a leveling experiment, like something out of Stalinist Russia or China's Cultural Revolution.²⁰⁰

¹⁹⁹ See Yesley, *supra* note 193, at 662.

²⁰⁰ Michael Kinsley, *Inherited Properties*, TIME, May 19, 2008, at 56.

Similarly, Eric Rakowski, a professor at the U.C. Berkley School of Law, argues that parents who choose to give birth to “genetically disadvantaged” children in spite of undesirable test results *should* incur greater liability “because they could not fairly push the cost of their choices off on other members of the insurance pool.”²⁰¹ Others have observed that our society generally accepts placing increased costs and burdens on those who suffer from obesity, a condition that is, at least in part, hereditary.²⁰²

Thus, what is often lost from the discussion on genetic discrimination is that genetic discrimination itself is not necessarily what is to be avoided; it is *unfair* genetic discrimination. As Kinsley observes, setting insurance premiums on the basis of risk is clearly not new or undesirable. The fear of genetic discrimination should therefore largely center on the (probably justified) fear that genetic tests may be *inaccurate* in their reflection of risk.

In that regard, genetic tests do present a more complicated statistical problem than conventional medical tests. A conventional medical test generally contains only one level of statistical risk analysis: how likely the observed trait (i.e., cholesterol level, blood pressure, etc.) is to cause the associated disease. The accuracy of the test in measuring the observed trait is generally high, or at least well understood. Genetic tests introduce a second, and often overlooked, layer of statistical analysis to the problem. Not only must one determine the degree of correlation between the observed genetic mutation and the disease, but one must also determine whether the test results accurately reflect the genotype of the patient.

GINA does recognize that different genetic tests have different “predictive power.”²⁰³ However, “predictive value” has a particular statistical meaning that GINA’s modifications to the HIPAA Privacy Rule do not reflect. In determining whether an observed genotype actually exists in the patient, statisticians refer to “positive predictive value” (“PPV”) and “negative predictive value” (“NPV”).²⁰⁴ PPV, the percentage of positive test results that are true positives, is defined as follows:

²⁰¹ Eric Rakowski, *Who Should Pay for Bad Genes?*, 90 CAL. L. REV. 1345, 1345 (2002).

²⁰² See e.g., Sayward Byrd, *Civil Rights and the “Twinkie” Tax: The 900-Pound Gorilla in the War on Obesity*, 65 LA. L. REV. 303 (2005).

²⁰³ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,702.

²⁰⁴ Interview with Jason Hsu, Professor of Statistics, The Ohio State University, in Columbus, Ohio (Feb. 6, 2010).

$$\frac{(Sensitivity)(Prevalence)}{(Sensitivity)(Prevalence) + (1 - specificity)(1 - prevalence)}$$

NPV, the percentage of negative test results that are true negatives, is defined as follows:

$$\frac{(Specificity)(1 - prevalence)}{(Specificity)(1 - prevalence) + (Prevalence)(1 - sensitivity)}$$

“Sensitivity” is the proportion of people with the target condition who have a positive test result, and “specificity” is the proportion of people without the target condition who have a negative test result.²⁰⁵ “Prevalence” refers to the percentage of the population affected with a particular disease at a given time.²⁰⁶ Significantly, *prevalence* is relevant in both the PPV and NPV equations. Even if a given genetic test has extremely high sensitivity and specificity, the test may have poor positive predictive value (i.e., the test will produce a high percentage of false positives) if the prevalence of the particular genotype is extremely low.

For example, Counsyl claims 99.9% sensitivity and specificity.²⁰⁷ One of the diseases tested, Achromatopsia, occurs in approximately 1 in 33,000 Americans.²⁰⁸ While 99.9 % sensitivity and specificity would seem excellent, the prevalence of 1 in 33,000 leads to a PPV of only approximately 0.0294. This means that *33 out of 34 positive test results for Achromatopsia will be false positives.*

While the PPV and NPV formulas clearly apply regardless of whether a test or disease is genetic or not, genetic disorders are often extremely rare compared to non-genetic disorders, and additional testing to confirm a genetic diagnosis is often not immediately

²⁰⁵ Glossary of EBM Terms, <http://ktclearinghouse.ca/cebmglossary> (last visited Apr. 12, 2011).

²⁰⁶ Merriam Webster's Online Medical Dictionary, <http://www.merriam-webster.com/medical/prevalence> (last visited Apr. 17, 2011).

²⁰⁷ Prescribed at Yale Fertility Center, <https://www.counsyl.com/learn/reliable/> (last visited Apr. 17, 2011).

²⁰⁸ Achromatopsia, <https://www.counsyl.com/diseases/achromatopsia/> (last visited Apr. 17, 2011).

available. Because low prevalence leads to poor PPVs and high false positive rates, false positives are particularly problematic for genetic tests. Although GINA acknowledges differing “predictive power,” it fails to take into account the challenge presented by varying PPVs of genetic testing in a statistically meaningful way.

Similarly, even aside from the risk of inaccurate genotyping, possessing a particular genetic variant associated with a disease does not necessarily lead to the manifestation of clinical symptoms. As the HHS interpretation of GINA recognizes: “In some cases, an individual may have a genetic variant for a disease and yet never develop the disease. In other cases, the presence of a genetic variant means that the individual will eventually develop the disease.”²⁰⁹ While this observation is a step in the right direction compared to previous federal and state approaches, it still fails to articulate precisely the particular concern over genetic discrimination in the insurance context.

As with all risk factors for non-genetic disease, the concern over genetic discrimination in the insurance context should center on whether the risk can be accurately characterized, not whether the risk is 100% or less.²¹⁰ GINA’s classification of genetic tests on the basis of their temporal relation to the manifestation of clinical symptoms thus mischaracterizes the concern.²¹¹ Moreover, GINA does not even accomplish its “100% versus less than 100% distinction” with precision. One example cited—the test for Huntington’s disease—is considered a “genetic test” (and thus treated as possessing suspect predictive power) when it is administered prior to the onset of clinical symptoms. Yet, an individual with the tested-for genetic variant *will invariably* develop the disease later in life.²¹²

²⁰⁹ HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,702.

²¹⁰ See Kinsley, *supra* note 200.

²¹¹ The manifested/un-manifested distinction makes significantly more sense in the employment context. There, one might be concerned if an employer refuses to hire an individual who has a predisposition for—but does not yet possess symptoms of—a condition that would prevent the individual from performing his or her job. See Chai Feldblum, Commissioner, Equal Emp. Opp. Comm’n, Remarks at Cornell University, Implementing the Genetic Information Nondiscrimination Act: A Public Policy Forum (Feb. 1, 2011).

²¹² HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information, *supra* note 100, at 51,702.

This is not to suggest that a more effective classification system for tests necessarily exists. Quite the opposite is true. It is extremely challenging to classify the accuracy of a genetic test's analysis of patient risk on the basis of the type of test. The possession of some genetic variants—such as those leading to PKU or Huntington's disease—predicts future manifestations of clinical symptoms with a high degree of statistical certainty. Other genetic variants, on the other hand, do not. Even mutations to BRCA1 and BRCA2, which strongly correlate with breast and ovarian cancer, do not definitively predict the eventual development of breast cancer because cancer is a complex interaction of many genes and environmental factors.²¹³ Not surprisingly, the correlations between the mutations for which some DTC vendors test and the future manifestation of clinical symptoms are largely unknown.²¹⁴ It is also worth noting that test accuracy is not necessarily a function of the complexity of the genetic mechanism involved. For example, MammaPrint, which tests a seventy-gene group, has been shown to predict the recurrence of breast cancer with a sufficiently high degree of statistical confidence to be clinically useful, as evidenced by its FDA approval.²¹⁵

Just as it is difficult to characterize the accuracy of a genetic test on the basis of the type of gene(s) it tests, the type of technology used also does not necessarily indicate the results' reliability. MammaPrint, 23andMe, and Counsyl all use similar microarray technology.²¹⁶ Yet, MammaPrint has been approved by the FDA, while little evidence exists to validate the reliability of 23andMe.

This is perhaps best explained by the empirical methods that scientists use to search for genes associated with complex diseases. As discussed above, most genetic disorders are caused by complex interactions between numerous genes and environmental factors.²¹⁷

²¹³ See BRCA1 and BRCA2: Cancer Risk and Genetic Testing, <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Apr. 17, 2011).

²¹⁴ U.S. FED. TRADE COMM'N, AT-HOME GENETIC TESTS: A HEALTHY DOSE OF SKEPTICISM MAY BE THE BEST PRESCRIPTION (July 2006), at 2-3, available at <http://www.ftc.gov/bcp/edu/pubs/consumer/health/heo02.pdf> (last visited Apr. 17, 2011).

²¹⁵ U.S. Food & Drug Admin., *FDA Clears Breast Cancer Specific Molecular Prognostic Test*, *supra* note 25.

²¹⁶ Our Service: Genotyping Technology, *supra* note 43; Breast Cancer Test Leverages Advances Made by Human Genome Project, http://www.agendia.com/pages/microarray_technology/41.php (last visited Apr. 17, 2011).

²¹⁷ SNPs: Variations on a Theme, *supra* note 12.

To determine which genes are associated with a particular disease, scientists often use microarrays to detect differences in gene expression levels between normal and diseased tissue.²¹⁸ Microarrays can perform this analysis on thousands of genes at one time.²¹⁹ However, this technique has been observed to produce inconsistent results, with “gene signatures” for the same disease that often do not overlap between independent studies.²²⁰ Without independent validation of a particular “gene signature,” it is difficult to confirm correlations observed in any particular study.

In contrast to the “empirical” methods employed by MammaPrint and 23andMe to identify the relevant genes, Counsyl tests only for diseases caused by (or primarily caused by) well-known mutations to single genes. Thus, it is potentially more reliable than other microarray-based genetic tests because less empirical methods are used to identify the relevant genes. However, because Counsyl has not released any of its data, its claims of accuracy are impossible to validate.²²¹

To some extent, PPACA reduces this classification problem with its sweeping prohibition of differential premiums. However, when this prohibition becomes effective in 2014, it will also remove much of the incentive insurers currently have to cover the cost of genetic testing. Although genetic testing may, in the long run, reduce overall health care costs, most genetic testing would do so only indirectly.²²² Without *direct* cost-reduction through either more accurate risk assessment or preventative measures, insurers will lack an incentive to cover the often substantial cost of genetic testing. Also, it is worth noting that while PPACA will require insurers to cover “preventive services,”²²³ it essentially defines “preventive services” as those with a U.S.

²¹⁸ Microarrays Factsheet, <http://www.ncbi.nlm.nih.gov/About/primer/microarrays.html> (last visited Apr. 17, 2011).

²¹⁹ *Id.*

²²⁰ Jason Hsu, et al., *Statistically Designing Microarrays and Microarray Experiments to Enhance Sensitivity and Specificity*, 8 BRIEFINGS IN BIOINFORMATICS 22, 22 (2007).

²²¹ Pollack, *supra* note 33.

²²² See e.g., Genetic Basis of Cancer Syndromes, *supra* note 15; Kasparian, *supra* note 80; Evans & Relling, *supra* note 52.

²²³ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 1302(b)(1)(I), 124 Stat. 164 (2010) (effective Jan. 1, 2014).

Preventive Services Task Force (“USPSTF”) grade of A or B.²²⁴ The USPSTF has not addressed most genetic testing procedures; it even recommends BRCA1/BRCA2 testing, which is relatively well understood compared to other genetic tests, *only* for those with a history of breast cancer.²²⁵ Thus, it is unlikely that the USPSTF will recommend—and accordingly, that insurers will be required to cover—other, less well understood genetic tests.

VI. RECOMMENDATIONS FOR FUTURE APPROACHES TO GENETIC PRIVACY AND NONDISCRIMINATION

Future legislative and regulatory efforts to address genetic privacy and nondiscrimination should at least include DTC genetic test vendors within their scope. However, for legislative and regulatory schemes to truly address the complex problem of genetic privacy and nondiscrimination effectively, they must ultimately move beyond the traditional HIPAA approach, which simply limits the disclosure and use of certain categories of information. Future efforts should focus on providing privacy and nondiscrimination protections that reflect the different statistical positive and negative predictive values of *particular* tests. Such a regulatory scheme would require that genetic test vendors actually disclose statistical data and would require greater statistical expertise within the governmental agencies tasked with oversight. Because the FDA already possesses such expertise through its current regulation of drugs and certain medical diagnostics, future genetic privacy and nondiscrimination schemes should therefore take into account whether the test is FDA-approved. Finally, additional protections for genetic information that seek to address its “soul-like” quality should remain primarily a matter of state law.

A. DIRECT-TO-CONSUMER GENETIC TEST VENDORS SHOULD BE SUBJECT TO HEALTH PRIVACY LAWS

Of the shortcomings of the current legal framework for genetic privacy and nondiscrimination, perhaps the simplest to rectify is the

²²⁴ Patient Protection and Affordable Care Act 2010, Pub. L. No. 111-148, § 4104(a), 124 Stat. 557 (2010) (effective Jan. 1, 2011).

²²⁵ Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement, *available at* <http://www.ahrq.gov/clinic/uspstf05/brcagen/brcagenrs.pdf> (last visited Apr. 17, 2011).

exclusion of DTC genetic test vendors from the HIPAA Privacy Rule. For example, the definition of “health care” could be amended to read as follows:

Preventive, diagnostic, *genotyping*, *phenotyping*, *genetic sequencing*, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body...²²⁶

Such language would bring DTC genetic test vendors—who offer genotyping, phenotyping, and genetic sequencing services—under HIPAA’s definition of “health care provider,” and thus under its definition of “covered entity.”²²⁷ This would close what has been a major gap in genetic privacy legislation,²²⁸ and would also more accurately reflect consumers’ understanding of their DTC genetic test results.²²⁹ Even DTC genetic test vendors themselves appear to agree that patients often misinterpret their test results as medically significant information, as evidenced by their advice to seek genetic counseling.²³⁰

²²⁶ Cf. 45 C.F.R. § 160.103 (proposed amendments emphasized).

²²⁷ See 45 C.F.R. §§ 160.102 & 160.103.

²²⁸ Moore & Sherlock, *supra* note 122.

²²⁹ Shane Green and Mike Spear, *Getting Personal with DNA: From Genome to Me-Ome*, 11 VIRTUAL MENTOR 714, 717-18 (2009) (The article details how Mike, a 23andMe, deCODE, and SNPedia customer, changed his behavior after receiving his genetic test results. Mike sought the advice of his doctor and committed to regular eye testing after tests uncovered a supposed increased risk for age-related macular degeneration and statin-related SAEs.).

²³⁰ Genetic Counselors Facilitate Your Practice, http://www.navigenics.com/visitor/for_physicians/our_services/genetic_counseling/ (last visited Apr. 17, 2011); FAQ, <http://www.decodeme.com/faq> (“We also offer free genetic counseling through our network of certified genetic counselors.”) (last visited Apr. 17, 2011); Genetic Testing for Carrier Status, Disease Risk and Drug Response, <https://www.23andme.com/health/carrier/> (“23andMe health reports include where to look for more information, support group contacts, and links to genetic counseling resources.”) (last visited Apr. 17, 2011).

B. GENETIC PRIVACY AND NONDISCRIMINATION LEGISLATIVE AND REGULATORY SCHEMES SHOULD REFLECT THE DIFFERING STATISTICAL CONFIDENCE LEVELS OF DIFFERENT TESTS

The more complex legislative and regulatory problem is the great variation in statistical confidence levels between particular tests. As discussed above, the multiple layers of statistical analysis make it difficult to separate genetic tests into clean categories that lend themselves to similar statistical reliability. While the entities currently tasked with oversight—the non-FDA portions of HHS and the FTC—lack the statistical expertise to evaluate tests on a test-by-test basis, the FDA has long performed this function with respect to drugs, medical devices and procedures.

Therefore, future privacy legislation and regulation should take FDA approval status into account in determining the level of privacy and nondiscrimination protection afforded to the patient. Even the FDA's 501(k) Premarket Notification Program, under which the majority of genetic tests are approved,²³¹ requires an applicant to demonstrate that its test is safe and effective, even if only as compared to similar existing FDA-approved tests.²³² Allowing insurers to consider genetic information produced by FDA-approved tests, while prohibiting insurers from considering information produced by non-FDA-approved tests, would afford policy holders some level of confidence that insurers would base eligibility and premium decisions only on *accurate* genetic information and simultaneously maintain a significant incentive for insurers to cover the tests' costs. This would also disincentivize use of the "in-house" exemption by test manufacturers, which the FDA recognizes has been problematic in the area of complex genetic tests,²³³ because insurers would likely stop

²³¹ CAROL A. HOLLAND, ASS'N. FOR MOLECULAR PATHOLOGY, FDA-CLEARED/APPROVED MOLECULAR DIAGNOSTIC TESTS, *available at* <http://www.amp.org/FDATable/FDATable.doc> (last visited Apr. 17, 2011).

²³² *See generally* Food & Drug Admin., Overview of IVD Regulation, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm123682.htm> (last visited Apr. 17, 2011).

²³³ FOOD & DRUG ADMIN., IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS (July 2007), at 7-8, *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCMO71455.pdf> (last visited Apr. 17, 2011).

reimbursing policy-holders for the genetic tests whose results they could not consider.²³⁴

Notably, FDA approval under 501(k) also generally involves reporting sensitivity, specificity, and *positive and negative predictive values*.²³⁵ Because patients often overlook positive and negative predictive values in evaluating the reliability of a test, particularly when presented with apparently excellent sensitivity and specificity data, this requirement could well lead to more rational patient responses to test results. While certainly not every patient would read or understand the information, at least such information would be available. Currently, such information is either only available through calculation or is not available at all.

C. ADDITIONAL PROTECTIONS FOR GENETIC INFORMATION SHOULD REMAIN IN THE REALM OF STATE LAW

A number of commentators have observed that elevating genetic information to a “soul-like” expression of one’s personal identity is problematic, at least within the context of federal law.²³⁶ Nonetheless, for some, genetic information is deeply personal in a way that extends beyond other health information.²³⁷ For these individuals, genes are as much intrinsic to their sense of self as their face, their physical features, and their voice.²³⁸ How (or should) this “soul-like” quality of DNA influence the legal framework of genetic privacy and nondiscrimination? I suggest that it should be addressed primarily at the state level.

In many ways, fundamental privacy rights (as opposed to the primarily practical ones discussed above) resemble property rights in that they involve an inherent right to exclude others from making use

²³⁴ Cf. Covered by Insurance, <https://www.counsyl.com/learn/free-with-insurance/> (last visited Apr. 17, 2011).

²³⁵ FOOD & DRUG ADMIN., STATISTICAL GUIDANCE ON REPORTING RESULTS FROM STUDIES EVALUATING DIAGNOSTIC TESTS (Mar. 2007), at 7-8, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071287.pdf> (last visited Apr. 17, 2011).

²³⁶ See Miller, *supra* note 93.

²³⁷ See *id.*

²³⁸ See *id.*

of a particular thing.²³⁹ Thus, to invoke DNA as a “soul-like” entity would be to treat it, in a sense, as personal property.²⁴⁰ However, just as society’s conception of property rights almost certainly varies greatly from state to state,²⁴¹ not all individuals view their DNA as equivalent to their soul.

Given that the “soul-like” quality of DNA is probably not universally accepted across the country, it therefore seems unlikely and unwise to incorporate such consideration into *federal* law. Instead, the limited scope of *state* law appears the more appropriate venue.²⁴² Moreover, treatment of genetic information as essentially personal property should not be incorporated into privacy and nondiscrimination law, but would instead be more properly addressed under property law. This has, of course, already happened to an extent.²⁴³ However, as the federal legal landscape for genetic privacy and nondiscrimination clears, states considering additional protections for genetic information should understand that some of the desire for such increased protection likely stems not from concerns about discrimination, but rather from a sense that, at least for some individuals, genetic information is an important part of their self-identity.

VII. CONCLUSION

The increasing complexity of genetic tests has rendered the traditional HIPAA-based approach to genetic privacy and nondiscrimination ineffective. First, the direct-to-consumer genetic testing phenomenon has left a large gap in the scope of genetic privacy

²³⁹ See *id.*, at 186-87.

²⁴⁰ See *e.g.*, COLO. REV. STAT. §§ 10-3-1104.6(1)(a) & 10-3-1104.7(1)(a) (2009) (defining genetic information as personal property).

²⁴¹ See Hon. Jeffrey S. Sutton, *Why Teach – And Why Study – State Constitutional Law*, 34 OKLA. CITY U.L. REV. 165, 174 (“Does anyone doubt that...the Montana Supreme Court might look at property rights differently from other States or the United States Supreme Court?”).

²⁴² See *id.*, at 173 (“In some settings, the challenge of imposing a constitutional solution on the whole country at once will increase the likelihood that federal constitutional law will be underenforced or that a ‘federalism discount’ will be applied to the right. State courts face no such problem in construing their own constitutions.”).

²⁴³ *E.g.*, ALASKA STAT. § 18.13.010(A)(2); COLO. REV. STAT. § 10-3-1104.7(1)(A); FLA STAT. § 760.40(2)(A); GA. CODE ANN. § 33-54-1(1); LA REV. STAT. ANN. § 22:1023(E).

protections. HIPAA's Privacy Rule should explicitly cover such entities.

Second, the fear that inaccurate genetic test results will lead to unfair discrimination by health insurers is justified, but blunt, heavy-handed approaches to defining protected "genetic information" do not reflect wide variation in the statistical reliability of particular genetic tests. Because such differences are difficult, if not impossible, to categorize, a new approach to genetic privacy and nondiscrimination should emerge. Incorporating the FDA approach to efficacy that already exists for other medical diagnostics into genetic privacy and nondiscrimination schemes would likely address these concerns in a meaningful way.

Finally, many individuals perceive that they have an ownership interest in their DNA because DNA, in a way, exemplifies their self-identity. However, the protection of this perceived interest does not fit well within federal privacy law. Instead, any such additional protections for genetic information should fall within a regime of property law and remain in control of the states.

