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Patient-Tailored Medicine, Part One: The Impact of Race and Genetics on Medicine

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Patient-Tailored Medicine, Part Two: Personalized Medicine and the Legal Landscape

The idea of publishing an article on personalized medicine and healthcare disparities among minority populations had its genesis with the American Health Lawyers Association's Advisory Council on Racial and Ethnic Diversity. This two-part article was supported by the Association's Public Interest initiative and written by Jeffrey P. Braff, Biswajit Chatterjee, Meredith Hochman, Jessica Kennington, Chandana Kolavala, Katherine Layman, Corrine Parver, Chelsea S. Rice, Myra C. Selby, John R. Washlick, and Rebecca Wolf. The authors' biographical statements appear on the following page.

ABSTRACT: In Part One, the authors addressed the relevance of genetic information, and how race and genetics have affected and may impact the development of medicines, pharmacogenomics, and personalized medicine in the United States.* Part Two examines current and proposed federal and state laws and regulations intended to protect individuals from the misuse of genetic information, including uses that discriminate based on genetic predispositions. This Part next explores the potential for litigation against both manufacturers and providers, as well as potential defenses. The authors also discuss legal issues relating to research that relies on the use of genetic information.

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* Am. Health Lawyers Ass'n's Advisory Council on Racial & Ethnic Diversity, *Patient-Tailored Medicine, Part One: The Impact of Race and Genetics on Medicine*, J. HEALTH & LIFE SCI. L. 1 (Oct. 2008) [hereinafter *Patient-Tailored Medicine, Part One*].

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PATIENT-TAILORED MEDICINE, PART TWO

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Introduction

Personalized medicine uses new methods in molecular analysis to better manage a patient’s disease, or predisposition toward a disease. The goal is to achieve optimal medical outcomes by helping physicians and patients choose patient-specific disease management approaches based on a patient’s genetic profile. Such approaches may include genetic screening programs that more precisely diagnose diseases and their sub-types, or that help physicians select the type and dose of medication best tailored for a certain group of patients.¹ Even now, personalized medicine is affecting the way in which physicians treat patients. For instance, molecular testing is being used to identify those breast cancer and colon cancer patients likely to benefit from new treatments, and patients newly diagnosed with early stage invasive breast cancer are being tested for the likelihood of recurrence.²

As described in Part One of this series,³ the importance of studying and mapping the human genome is beyond question. Data on human genetic variations helps scientists to understand human origins, susceptibility to illness, and genetic causes of disease. Unfortunately, history has been marked by destructive episodes of genetic research and attempts at “ethnic cleansing” that make it crucial to consider

1 Personalized Med. Coal., *Personalized Medicine 101*, available at www.personalizedmedicinecoalition.org/sciencepolicy/personalmed-101_overview.php [hereinafter *Personalized Medicine 101*].

2 *Id.*

3 *Patient-Tailored Medicine, Part One*, at 1.

the ethical and social implications of research in genomics, especially research on human genetic variation.⁴ Thus, an analysis of ethical, legal, and social implications should be an integral component of genetic research undertakings, with the participation of scientists who can anticipate and monitor the full range of possible applications of the research from the earliest stages.⁵ This issue is so important that the U.S. Department of Energy's (DOE) Human Genome Program, which oversees the Human Genome Project (HGP), devoted three percent of its annual HGP budget toward studying the ethical, legal, and social issues surrounding the availability of genetic information.⁶

Some of the most troubling ethical questions related to advancing genetic knowledge and the ensuing development of personalized medicine arise out of issues related to justice and equity.⁷ As discussed in Part One, raced-based differences in medicine⁸ and inequity in clinical trials for personalized medicine are ways in which unequal access between people of different races can be perpetuated. While experts note that race-based determination of medical treatment is temporary, and a precursor to treatment that is determined person-by-person,⁹ the current method of racial classification in medicine provides unequal access between Caucasians and African-Americans.

Ultimately, the answer may lie in science rather than law. To prevent racial inequities in personalized medicine, Peterson-Iyer advises mis-equating race with genotype.¹⁰ Rather than conducting race-based clinical trials, she recommends that studies focus on the genotype of study participants. Not only would this draw focus away from individuals' arbitrary race classifications, but it likely would provide more accurate results. Race-based genetic similarities are present only for individuals whose recent ancestors are from the same area of the world.¹¹ For example, study participants in the African-American Heart Failure Trial (A-HeFT), in which 1,050 self-identified African-Americans participated,¹² likely had ancestors from different regions

4 See Mildred K. Cho & Pamela Sankar, *Forensic Genetics and Ethical, Legal and Social Implications Beyond the Clinic*, 36 *NATURE GENETICS* 58 (2004).

5 *Id.*

6 Humane Genome Project Info., *Minorities, Race, and Genomics*, www.ornl.gov/sci/techresources/Human_Genome/elsi/minorities.shtml (last visited Sept. 25, 2008).

7 Karen Peterson-Iyer, *Pharmacogenomics, Ethics, and Public Policy*, 18 *KENNEDY INST. ETHICS J.* 35, 38 (2008) [hereinafter *Peterson-Iyer*].

8 *Id.* at 41.

9 Jonathan Kahn, *How a Drug Becomes "Ethnic": Law, Commerce, and the Production of Racial Categories in Medicine*, 4 *YALE J. HEALTH POL'Y L. & ETHICS* 101, 128 (2004).

10 *Peterson-Iyer*, at 52.

11 Hua Tang et al., *Genetic Structure, Self-Identified Race/Ethnicity, and Confounding in Case-Control Association Studies*, 76 *AM. J. HUM. GENETICS* 268, 269–70 (2005).

12 Anne L. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 *NEW ENG. J. MED.* 2049 (2004).

of the world. Race is not a biological factor, but rather a “social or cultural construct.”¹³ Race is a “pernicious concept that has been used to suggest that human beings can be divided into subspecies, some of which are morally, intellectually, and physically inferior to others.”¹⁴ All things considered, a race-based classification in medicine is a crude and inadequate way to assign particular medical treatments, and may fail to treat patients properly.¹⁵

Because of these significant issues, the *Journal of Health & Life Sciences Law* features this two-part series on the topic of personalized or “patient-tailored medicine.” In Part One, the authors addressed the relevance of genetic information, and how race and genetics have affected and may impact the development of medicines, pharmacogenomics, and personalized medicine in the United States.¹⁶ Part Two examines current and proposed federal and state laws and regulations intended to protect individuals from the misuse of genetic information, including uses that discriminate based on genetic predispositions. This Part next explores the potential for litigation against both manufacturers and providers, as well as potential defenses. The authors also discuss legal issues relating to research that relies on the use of genetic information. In sum, this Part examines the significant legal and ethical issues facing the future of personalized medicine that tailors patient clinical therapies based on the results of genetic testing.

Federal Legal Landscape

Federal laws specifically addressing personalized medicine are a relatively new topic of discussion. Even before Congress enacted laws aimed specifically against genetic discrimination, some commentators interpreted other non-discrimination laws to include genetic discrimination. These include the Health Insurance and Portability Act of 1996 (HIPAA), the American with Disabilities Act (ADA) of 1990, and Title VII of the Civil Rights Act of 1964. Other laws and pronouncements address the use of genetic information more directly, such as the Genetic Information Nondiscrimination Act (GINA) and a 2000 Executive Order prohibiting use of federal employees’ genetic information in employment decisions.¹⁷ The Food and Drug Administration (FDA)

13 INST. OF MED., THE UNEQUAL BURDEN OF CANCER: AN ASSESSMENT OF NIH RESEARCH AND PROGRAMS FOR ETHNIC MINORITIES AND THE MEDICALLY UNDERSERVED 38 (M. Alfred Haynes & Brian D. Smedley eds. 1999).

14 Sharona Hoffman, “Racially-Tailored” Medicine Unraveled, 55 AM. U. L. REV. 395, 409 (2005) [hereinafter “Racially-Tailored” Medicine].

15 M. Gregg Bloche, *Race-Based Therapeutics*, 351 NEW ENG. J. MED. 2035, 2036 (2004).

16 *Patient-Tailored Medicine, Part One*.

17 Human Genome Project Info., Genetics Privacy and Legislation: GINA Becomes Law May 2008, www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (last visited June 5, 2008) [hereinafter *GINA Becomes Law*].

plays a key role in advancing personalized medicine, conducting discussions, and convening debate about the implications for drug development and regulatory review. Questions include issues such as how narrowly clinical trials should be designed and whether efficacy is defined in different ways for different genetic subgroups.¹⁸ The federal government faces issues related to the reimbursement and payment of personalized medicines as well. Public and private payers will have new and complex questions, such as whether therapies should be reimbursed only for those patients who are identified as likely to respond to treatment.¹⁹ The following sections explore these issues.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 provides, among other things, for the portability of health insurance by ensuring that individuals who change health coverage do not have new employment-related coverage denied or restricted on the basis of preexisting conditions.²⁰ Before the Genetic Information Nondiscrimination Act was passed in 2008, HIPAA was the only federal law that directly addressed genetic discrimination.²¹ The portion of HIPAA addressing portability of health insurance (HIPAA Portability Rule) prohibits insurers who provide health coverage for a group of fifty or more individuals from denying an applicant for health reasons, including reasons related to genetic information.²² (The HIPAA Privacy Rule, also part of the HIPAA legislation enacted in 1996, will be addressed below under Privacy protections and issues for providers.) HIPAA also limits exclusions for preexisting conditions in group health plans to twelve months, and it prohibits exclusions if an individual was covered previously for that condition for at least twelve months.²³

The HIPAA Portability Rule was the first federal law to address use of genetic information in the health insurance context. It prohibits group health plans and group health insurers from imposing a preexisting condition exclusion on the basis of genetic information unless there is an actual diagnosis of the condition related to the genetic information.²⁴ HIPAA also prohibits establishing eligibility requirements for any individual based on genetic information or other health-status factors. Health insurers in the small-group market, employers with between two and fifty employees, may not refuse to issue a policy on the basis of the

18 *Personalized Medicine* 101.

19 *Id.*

20 29 U.S.C. § 1181; 42 U.S.C. § 300gg; 26 U.S.C. § 9801.

21 *GINA Becomes Law*.

22 29 U.S.C. §§ 1181, 1002(7); 42 U.S.C. § 300gg; 26 U.S.C. § 9801.

23 *GINA Becomes Law*.

24 29 U.S.C. § 1181(b)(1)(B); 42 U.S.C. § 300gg(b)(1)(B); 26 U.S.C. § 9801(b)(1)(B).

genetic information of any enrollee or any potential enrollee.²⁵ Insurers in both the small and large group markets may not refuse to renew a policy based on genetic information about an enrollee or a potential enrollee.²⁶

Nonetheless, the HIPAA Portability Rule was narrowly drawn. As noted in a report commissioned by the Secretary's Advisory Committee on Genetics, Health, and Society, "HIPAA does not restrict a group health plan or issuer from requesting, purchasing, or otherwise obtaining genetic information about an individual or [from] requiring an individual to submit to a genetic test as a condition of coverage..."²⁷ Nor does it prohibit the group health plan or issuer from charging all members of the group higher premiums based on the information obtained.²⁸

Further, HIPAA does not prohibit employers from refusing to offer health coverage as part of their benefits package. In addition, the applicability of the preexisting condition exclusion and nondiscrimination provisions do not apply to individual health insurance policies, very small plans, retiree-only coverage, and self-insured non-Federal government plans.²⁹ Lastly, the HIPAA Portability provisions do not address the issues raised by gathering and using genetic information in the workplace outside the health insurance context.³⁰

ADA

The Americans with Disabilities Act prohibits employment, public services, public accommodations, and communications discrimination against individuals with disabilities.³¹ Although Title I of the ADA, enforced by the Equal Employment Opportunity Commission (EEOC), does not explicitly address genetic information, it does provide some protection against disability-related genetic discrimination in the workplace.³²

25 45 C.F.R. § 146.150.

26 *Id.* § 146.152.

27 Robert B. Lanman, OFFICE OF BIOTECH. ACTIVITIES, NAT'L INSTS. OF HEALTH, AN ANALYSIS OF THE ADEQUACY OF CURRENT LAW IN PROTECTING AGAINST GENETIC DISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT: A REPORT COMMISSIONED BY THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY i (2005), available at http://oba.od.nih.gov/oba/sacghs/reports/legal_analysis_May2005.pdf [hereinafter SACGHS REPORT].

28 *Id.* GINA does prohibit this, however, as discussed below.

29 Interim Final Rules for Nondiscrimination in Health Coverage in the Group Market, 66 Fed. Reg. 1378, 1379 (Jan. 8, 2001); see also Marisa Anne Pagnattaro, *Genetic Discrimination and the Workplace: Employee's Right to Privacy v. Employer's Need to Know*, 39 AM. BUS. L.J. 139, 166–67 (2001).

30 See SACGHS REPORT, at 4.

31 42 U.S.C. §§ 12101–12213.

32 *GINA Becomes Law*.

The ADA defines the term “disability” with respect to an individual as a person having:

- (A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;
- (B) a record of such an impairment; or
- (C) being regarded as having such impairment.³³

Although this language does not reference genetic traits, congressional debates in 1990 touched on the issue; however, Congress apparently left it in the hands of the EEOC.³⁴ In March 1995, the EEOC issued an interpretation of the ADA that states: “Entities that discriminate on the basis of genetic predisposition are regarding the individuals as having impairments, and such individuals are covered by the ADA.”³⁵ This interpretation constitutes policy guidance that “does not have the same legal binding effect on a court as a statute or regulation....”³⁶ Because the interpretation has yet to be tested in the legal arena, it remains simply interpretive policy guidance.³⁷

Title III of the Americans with Disabilities Act applies to private businesses, and provides that no individual shall be discriminated against on the basis of disability in the full enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation. However, the United States Circuit Court of Appeals has found that this nondiscrimination provision does not apply to insurance policies.³⁸

Finally, the “safe harbor provision” of the ADA, which provides that the ADA’s provisions must not be interpreted to prohibit or restrict an insurer from underwriting risks, classifying risks, or administering risks consistent with state law, has been construed in favor of insurers.³⁹

33 42 U.S.C. § 12102(2)(A)–(C).

34 Nancy Lee Jones & Amanda K. Sarata, CRS REPORT FOR CONGRESS—GENETIC INFORMATION: LEGAL ISSUES RELATING TO DISCRIMINATION AND PRIVACY 1 (Mar. 10, 2008), *available at* http://assets.opencrs.com/rpts/RL30006_20080310.pdf [hereinafter CRS REPORT].

35 *GINA Becomes Law*.

36 *Id.*

37 *See, e.g.,* United States v. Utah Construction & Mining Co., 384 U.S. 394, 422 (1966) (preclusion principles apply to administrative proceedings [only] when the administrative agency in the first action was “acting in a judicial capacity” and the parties had an adequate opportunity to present their case); Christensen v. Harris County, 529 U.S. 576, 587 (2000) (agency interpretations contained in policy statements, agency manuals, and enforcement guidelines all lack the force of law).

38 SACGHS REPORT, at 5–6.

39 *Id.* at 6.

Title VII of the Civil Rights Act of 1964

Title VII of the Civil Rights Act prohibits all private employers with 15 or more workers, labor organizations, employment agencies, and federal, state, and municipal government employers from discriminating on the basis of race, color, religion, sex, and national origin.⁴⁰ The statute does not specifically address discrimination based on genetic discrimination, but Title VII may protect against discrimination on the basis of an individual's genetic makeup if that discrimination disproportionately impacts individuals belonging to a protected class. For example, if an employer refuses to hire an individual who is a carrier of the genetic mutation for Tay-Sachs disease, it is arguable that the employer is discriminating against persons with an Eastern European Jewish ethnic background, which would constitute prohibited disparate impact on the basis of national origin.⁴¹ However, protection is available only where an employer engages in discrimination based on a genetic trait substantially related to a particular race or ethnic group, and there have been only a few diseases where such a strong relationship has been proven.⁴²

The Genetic Information Nondiscrimination Act

It is difficult to imagine information more personal or more private than a person's genetic makeup... If Congress fails to make sure that genetic information is used only for legitimate purposes, we may well squander the vast potential of genetic research to improve the nation's health.⁴³

These words were spoken by Massachusetts Senator Edward Kennedy on January 22, 2007, in his introductory remarks to the Senate regarding the Genetic Information Nondiscrimination Act. On May 21, 2008—13 years after the legislation was initially introduced—Senator Kennedy's words and concerns were implemented into law when President Bush signed GINA.⁴⁴

Congress had been attempting to pass federal protections against genetic discrimination for over a decade. Although GINA passed overwhelmingly, there had been ongoing debates over the need for such

40 42 U.S.C. § 2000e-e17; 42 U.S.C. § 2000e(b).

41 SACGHS REPORT.

42 *GINA Becomes Law*.

43 Introductory Remarks of Senator Edward Kennedy (D-MA) on the Genetic Information Nondiscrimination Act 1, 1–2 (Jan. 22, 2007), available at www.geneticalliance.org/ksc_assets/publicpolicy/gina_remarks_kennedy.pdf.

44 Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (2008) [hereinafter *GINA*]. GINA becomes effective in November 2009.

federal legislation.⁴⁵ Opponents noted that more than forty states prohibited genetic discrimination in health insurance, and more than thirty states prohibited genetic discrimination in the workplace. They also argued that the HIPAA Portability Rule and the ADA provided sufficient protection from genetic discrimination, making GINA superfluous legislation. According to GINA's opponents, ample safeguards already were in place to prevent genetic discrimination.⁴⁶

Despite these efforts, the law passed by an overwhelming majority in the House of Representatives (414–1) and unanimously in the Senate. The law amends Title VII, HIPAA, the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, the Internal Revenue Code of 1986 (IRC), and Title XVIII (Medicare) of the Social Security Act, which collectively apply to group health plans with any number of participants and health insurance issuers underwriting the plans' benefits.⁴⁷ Further, GINA applies to issuers of health insurance policies in the individual markets,⁴⁸ as well as to issuers of "Medi-Gap" insurance policies, which supplement health coverage available under the Medicare program.⁴⁹ The net result is that virtually all health insurers are subject to GINA's nondiscrimination prohibition. Significantly, because GINA does not preempt existing state laws, counsel must continue to identify state laws that offer greater protections.⁵⁰ GINA's preemption provision does not override state laws that provide equal or greater protection against genetic discrimination, and this likely will complicate compliance because of differing state and federal standards.⁵¹

GINA fills in many of the perceived gaps in protection under HIPAA. In addition to defining "genetic information" broadly,⁵² GINA addresses discrimination in the workplace as well as in the health insurance arena. Not only does it prohibit both employers and group health plans from discriminating on the basis of "genetic information,"⁵³ it also limits the ability of employers and group health plans to collect genetic information.⁵⁴

45 *GINA Becomes Law*.

46 *Id.*

47 29 U.S.C. § 1182(e); 26 U.S.C. § 9801(e); 42 U.S.C. § 300gg-1(b). See Marian Waldmann et al., *New Federal Law Regulates Collection and Use of Genetic Information by Employers and Group Health Plans*, 7 BNA PRIVACY & SECURITY L. REP. 764–69, May 19, 2008 [hereinafter *BNA*].

48 42 U.S.C. § 300gg-51.

49 GINA, tit. 1, § 104.

50 *Id.*, tit. 2, § 209(3).

51 Kevin P. McGowan, *Employer Advocates Remain Wary of New Bias Law's Potential Effects*, BNA DAILY LABOR REPORT No. 99 (May 22, 2008).

52 GINA, tit. 1 §§ 101(6), 102(d)(4)(16), 103(d)(7), 104(3)(B); *id.* tit. 2 § 201(4).

53 See *id.* tit. 1 §§ 101(a), 102(a); *id.* tit. 2 § 202(a).

54 *Id.* tit. 1 §§ 101(b), 102(d); *id.* tit. 2 § 202(b).

GINA expands Title VII by imposing broad restrictions on the collection, use, and disclosure of genetic information in the employment context.⁵⁵ GINA applies to all employers, employment agencies, labor organizations, and joint labor-management committees subject to Title VII, and defines “genetic information” as not only the genetic tests of employees and their family members, but also any “manifestation of a disease or disorder” in the employee’s family members.⁵⁶ Further, the statute defines “family member” very expansively; it includes not only the employee’s dependents, but also relatives of the employee, or of the employee’s dependents, from the first to the fourth degree.⁵⁷ In other words, information about the employee’s father, grandfather, great-grandfather, and great-great-grandfather would constitute genetic information for purposes of GINA.

GINA imposes three principal restrictions on employers with respect to genetic information. First, employers cannot discriminate in the terms or conditions of employment based upon genetic information.⁵⁸ Second, employers may not retaliate against an employee who opposes genetic discrimination.⁵⁹ Third, except in certain situations described below, employers cannot collect genetic information about an employee, or an employee’s family member, whether by request, mandatory disclosure, or purchase from a third party.⁶⁰

The restriction on collecting genetic information has several exceptions. GINA allows employers to request or require disclosure of a family member’s genetic information, including manifested diseases or disorders, to comply with the Family and Medical Leave Act and with state family and medical leave laws.⁶¹ In addition, employers may offer “genetic services” as an employee benefit. To qualify, an employee must provide prior, voluntary, and written authorization for disclosure of genetic information to the service provider.⁶²

GINA incorporates Title VII provisions with respect to enforcement. For instance, employees must exhaust all administrative remedies before filing a lawsuit, and damages are subject to the same restrictions

55 The DOE Human Genome Project observed that genetic predisposition or conditions can lead to workplace discrimination, even in cases where workers are healthy and unlikely to develop a disease, or where the genetic condition has no effect on the ability to perform work. *GINA Becomes Law*.

56 GINA, tit. 1, § 101(a), (d).

57 *Id.* § 101(d)(5).

58 GINA, tit. 2, § 202(a)(1).

59 *Id.* § 207(f).

60 *Id.* § 202(b).

61 *Id.* § 202(b)(3).

62 *Id.* § 202(b)(2)(B).

as under Title VII.⁶³ However, unlike Title VII, GINA does not permit claims to be brought on a disparate impact theory.⁶⁴

GINA prohibits insurance companies from discriminating against individuals based on information derived from genetic tests.⁶⁵ Group health plans and insurance issuers cannot adjust contribution amounts or premiums for the group based on the genetic information of any plan participant. GINA prohibits insurance providers from requesting or requiring that individuals or their family members undergo genetic tests and from requesting, requiring, or purchasing genetic information for underwriting purposes or prior to an individual's enrollment.

Despite the expansive scope of GINA's discrimination provisions relating to health insurance, neither GINA nor any other federal law addresses discrimination with respect to other insurance products, including life insurance, disability insurance, and long-term care insurance. Questions that arise include:

1. Whether insurance companies may require applicants to disclose genetic testing information;
2. Whether applicants are required to disclose genetic testing information on an application; and
3. Whether genetic testing information may be used for underwriting purposes or for denying coverage.

There are differing opinions as to the potential for discrimination in the life insurance industry. Some argue that it would be more actuarially fair for insurers to have access to genetic testing results, while others argue that having the test results would not make a significant difference. A medical director of an insurance company posed the question, "[I]s it more 'fair' to require low-risk individuals to make what is in effect an involuntary and non-tax-deductible donation to help fund death benefits of others at a higher risk?"⁶⁶

In reality, the use of genetic information in life insurance underwriting is not a novel concept. Life insurers generally ask applicants about their family medical history, revealing genetic information as defined under GINA.⁶⁷ In fact, a positive test result might have a negligible impact on premiums or eligibility, because the insurance company would have taken the predisposition into account through the family history

63 *Id.* § 207(a).

64 *Id.* § 208(a).

65 *Id.* § 102(a)(1).

66 William Nowlan, *A Rational View of Insurance and Genetic Discrimination*, 297 *Sci.* 195 (2002).

67 Yann Joly et al., *Genetic Information and Life Insurance: A "Real" Risk?*, 11 *EUR. J. HUM. GENETICS* 561 (2003).

questionnaire.⁶⁸ Of course, a positive test result more specifically identifies an individual's genetic risk factors than would a family history.

The passage of GINA represents progress in the protection of genetic testing and personalized medicine and, while it is not perfect, it provides a number of safeguards, such as protecting individuals who have a genetic predisposition or have been diagnosed with a disease.⁶⁹ Further, by prohibiting insurers and employers from requiring genetic tests and using genetic information to discriminate, GINA provides the groundwork for additional federal and local protections against genetic discrimination and supports the use of personalized medicine.

Executive Order protecting federal employees

On February 8, 2000, President Clinton signed an Executive Order prohibiting every federal department and agency from using genetic information in any hiring or promotion action.⁷⁰ This Executive Order, endorsed by the American Medical Association, American College of Medical Genetics, National Society of Genetic Counselors, and the Genetic Alliance:

- Prohibits federal employers from requiring or requesting genetic tests as a condition of being hired or receiving benefits. Employers cannot request or require employees to undergo genetic tests to evaluate an employee's ability to perform his or her job.
- Prohibits federal employers from using protected genetic information to classify employees in a manner that deprives them of advancement opportunities. Employers cannot deny employees promotions or overseas posts because of a genetic predisposition for certain illnesses.
- Provides strong privacy protections for any genetic information used for medical treatment and research. Obtaining or disclosing genetic information about employees or potential employees is prohibited, except when necessary to provide medical treatment to employees, ensure workplace health and safety, or provide occupational and health researchers access to data. In every case where genetic information about employees is obtained, it will be subject to all federal and state privacy protections.

68 Mark A. Rothstein & Mary R. Anderlik, *What Is Genetic Discrimination, and When and How Can It Be Prevented?*, 5 *GENETICS MED.* 354 (2001).

69 H.R. 493, S. 358.

70 Exec. Order, *To Prohibit Discrimination in Federal Employment Based on Genetic Information* (Feb. 8, 2000), available at www.opm.gov/pressrel/2000/genetic_eo.htm.

Food and Drug Administration

Although personalized medicine is an exciting phenomenon that has the potential of revolutionizing medicine, many obstacles remain.⁷¹ As discussed in detail in Part One of this series, clinical trials for drug safety and effectiveness often fail to include minority participants. According to FDA, participation of African-Americans in clinical trials declined from 12 to 6% from 1995 to 1999.⁷² As a result of this lack of participation, much is unknown about the way in which an individual of an under-included ethnic background will react to certain medications. This prevents FDA from accurately providing information about the efficacy, safety, and usage of drugs for those populations. As a result, when physicians prescribe drugs to underrepresented populations it is often difficult for them to know how effective or harmful a particular drug will be to a particular individual.⁷³

As described in detail in Part One of this series,⁷⁴ FDA's recent involvement with personalized medicine was demonstrated in the African-American Heart Failure Trial (A-HeFT). In 2005, BiDil was approved by FDA for treating heart failure in African-Americans based on the results of the A-HeFT trial. This was the first time that FDA approved a therapy for a specific racial group. A number of scientific and policy concerns have arisen as a result,⁷⁵ notably that the "differential drug response" has not been sufficiently tested. The FDA responded that its approval of BiDil to treat heart failure in African-American patients, but not white patients, was scientifically reasonable and data-based.⁷⁶ From a policy point of view, the approval suggests that racially specific drugs might be at least part of the solution to the problem of racial disparities in health in the United States, thereby minimizing the broad public health issues associated with disparities and socio-economic status.

Treatment for HIV disease may provide another opportunity for personalized medicine. Discoveries of anti-HIV drugs have brought the potential armamentarium of treatments to more than twenty agents in four drug groups.⁷⁷ A number of studies dealing with anti-HIV drugs

71 Neal Learner, *The Promise of Personalized Medicine Is Exciting, but Barriers Remain, Along with Questions About How to Achieve ROI*, AIS HEALTH, May 16, 2008, available at www.aishealth.com/Bnow/hbd051608.html [hereinafter *Promise of Personalized Medicine*].

72 Vivek K. Murthy et al., *Participation in Cancer Clinical Trials: Race-, Sex-, and Age-Based Disparities*, 291 JAMA 2720 (2004).

73 *Promise of Personalized Medicine*, at 5.

74 *Patient-Tailored Medicine, Part One*, at 29, 30.

75 Kirsten Bibbins-Domingo & Alicia Fernandez, *BiDil for Heart Failure in Black Patients: Implications of the U.S. Food and Drug Administration Approval*, 146 ANNALS INTERNAL MED. 52 (2007).

76 Robert Temple & Norman L. Stockbridge, *BiDil for Heart Failure in Black Patients: The U.S. Food and Drug Administration Perspective*, 146 ANNALS INTERNAL MED. 57 (2007).

77 Tim R. Cressey & Marc Lallemand, *Pharmacogenetics of Antiretroviral Drugs for the Treatment of HIV-Infected Patients: An Update*, 7 INFECTION, GENETICS & EVOLUTION 333-42 (2007).

have indicated that genetic polymorphisms (*polymorphisms* are genetic variants that appear in at least one percent of a population) may play a role in both toxicity and response to treatment,⁷⁸ but only one study specifically designed to test this hypothesis has been carried out with anti-HIV drugs. In that study, it was shown that there are race/ethnic-specific differences in plasma lipid levels.⁷⁹

Thus, for moral and policy reasons, the FDA has recognized the need to foster race-based therapies. Significantly, the FDA advisory committee asserted that a major rationale for approving BiDil was the “moral[] imperative” to remedy long-standing and “significant health disparities among blacks.”⁸⁰ African-Americans and other racial and ethnic minorities suffer disproportionately from heart disease, cancer, diabetes, and HIV.⁸¹ All of these groups suffer unique healthcare disparities that could be remedied by tailored therapies.⁸²

Centers for Medicare and Medicaid Services and Medicare Part D

In addition to treatment difficulties that result from a paucity of information about minority populations’ reactions to particular medications, cost concerns arise. As innovations make possible more extensive treatment on an individual basis than ever before, health financing systems fail to address the rising costs of personalized medicine, particularly for minority populations.

In policies related to medical treatments, particularly pharmaceuticals, cost and quality of healthcare are inextricably linked. In the past several years, Congress has enacted significant bills related to drug payments for Medicare beneficiaries that may affect the ability of minorities to access patient-tailored medicine. On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act,⁸³ a prescription drug benefit for Medicare beneficiaries. This legislation prohibited the Medicare program from bargaining with pharmaceutical companies to lower the prices of prescription drugs. Under the 2003 law, private prescription drug plans (PDPs) rather than government agencies became responsible for mod-

78 *Id.*

79 Andrea S. Foulkes et al., *Associations Among Race/Ethnicity, ApoC-III Genotypes, and Lipids in HIV-1-Infected Individuals on Antiretroviral Therapy*, 3 PLoS MED. e52 (2006). For a more detailed explanation, see *Patient-Tailored Medicine, Part One*, at 29, 30.

80 Sandra Soo-Jin Lee, *Racializing Drug Design: Implications of Pharmacogenomics for Health Disparities*, 95 AM. J. PUB. HEALTH 2133, 2137 (2005).

81 See generally Michael B. Losow, *Personalized Medicine & Race-Based Drug Development: Addressing Minority Health Care Disparities in an Ethically Charged Area*, 20 ST. JOHN’S J. LEGAL COMMENT. 15, 16–17 (2005).

82 *Id.*

83 Medicare Prescription Drug, Improvement, & Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

erating drug plans.⁸⁴ The prices that PDPs establish directly affect the costs that Medicare beneficiaries—and taxpayers, who pay for three-fourths of Medicare Part D—incur.⁸⁵

Under the Medicare Part D benefit, use of preferred drug lists (PDLs) is a rapidly expanding phenomenon⁸⁶ in which providers attempt to save money on prescription drugs by providing only “preferred” medications. While individuals with private health insurance may enjoy more personalized care in pharmaceutical treatment, restrictive formularies and PDLs may cause difficulties for individuals from minority groups who receive Medicare, Medicaid, and other health insurance.⁸⁷ Studies have shown that the use of PDLs often can result in negative health outcomes.⁸⁸ Minority populations likely will feel these negative effects more profoundly than their non-minority counterparts.⁸⁹ Because clinical trials often fail to include representation of minority groups, there tends to be a paucity of clinical trial data about the efficacy of drug treatments for these populations. Due to this lack of information, physicians would need greater latitude to determine the best course of treatment for minority patients.

Governments generally choose to contain costs rather than spend necessary funds to ensure that minority patients receive the best treatment.⁹⁰ As a result, minority populations, the individuals who would benefit most from personal health assessments, are least likely to receive individualized care. Even if drugs are designed to address the unique medical needs of minority populations, individuals likely will not have access to specialized medications, as it is unlikely that Medicare Part D will cover the high costs of unique drugs. Medicare Part D provides:

If a Part D plan sponsor maintains a formulary tier in which it places very high cost and unique items, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.⁹¹

84 42 U.S.C. § 1395w-111. See Gary A. Puckrein et al., NAT’L MINORITY HEALTH MONTH FOUND., DRUG PRICES AND THE EMERGING MAJORITY: SHOULD GOVERNMENT NEGOTIATE DRUG PRICES? 3, *available at* www.nmhmf.org/issuebrief.pdf [hereinafter DRUG PRICES AND THE EMERGING MAJORITY].

85 *Id.* at iv.

86 In 2003, 29 states had obtained legislative approval to institute a preferred drug list (PDL). Mary Kay Owens, NAT’L PHARM. COUNCIL, STATE MEDICAID PROGRAM ISSUES: PREFERRED DRUG LISTS 1 (2004), *available at* www.npcnow.org/resources/PDFs/PDLbrief.pdf.

87 DRUG PRICES AND THE EMERGING MAJORITY.

88 Matthew M. Murawski & Tamer Abdelgawad, *Exploration of the Impact of Preferred Drug Lists on Hospital and Physician Visits and the Costs to Medicaid*, 11 AM. J. MANAGED CARE SP35 (2005).

89 Alvin Headen & Neal Masia, *Exploring the Potential Link Between Medicaid Access Restrictions, Physician Location, and Health Disparities*, 11 AM. J. MANAGED CARE SP21 (2005).

90 DRUG PRICES AND THE EMERGING MAJORITY.

91 42 C.F.R. § 423.578(a)(7). See Pi-Yi Mayo, *Medicare Part D*, HOUSTON LAW., May/June 2006, *available at* www.thehoustonlawyer.com/aa_may06/page22.htm.

Failing to address the unique health needs of minorities not only will affect disadvantaged individuals negatively, but also will affect the entire American population negatively in the long run. Minority populations tend to receive health treatment later in the disease progression than their non-minority counterparts. As a result, when minorities do receive treatment, the financial cost may be much greater.⁹² Thus, from a societal perspective, treatment at a later stage puts a much greater strain on the health system. While disadvantaged populations will “bear the immediate burden of those decisions,”⁹³ ultimately the entire population will be affected by inequities in treatment and disparate understanding of the health needs of minority populations.

Despite potential drawbacks and cost-containment concerns, personalized medicine has the potential of improving drug delivery and optimizing spending on pharmaceuticals. According to Robert Epstein, M.D., Chief Medical Officer at Medico Health Solutions:

We think it is one of the key ways to manage drug expenditures in the near future. Because you can move beyond the debate of unit costs to who is really supposed to be taking the drugs, and who is really going to benefit from it, and who is really going to have a bad side effect. If you can take those cuts out, using science, you’re going to definitely save money and improve effectiveness.⁹⁴

If personalized medicine does, in fact, improve efficiency and improve spending for drug treatments, then initial increases in drug costs will be worth the investment in the long run.

State Legislative Landscape

States have a patchwork of genetic-information nondiscrimination laws, none of them comprehensive.⁹⁵ State laws differ in coverage, protections afforded, and enforcement mechanisms.⁹⁶ In 1991, Wisconsin became the first state to enact a comprehensive law prohibiting discrimination based on genetic test results. Currently, at least 34 states and the District of Columbia have enacted laws prohibiting some form of

92 Kristi V. Mizelle, STUDENT NATIONAL MEDICAL ASSOCIATION: MINORITY HEALTH DISPARITIES POSITIONS STATEMENT (2002), available at www.snma.org/downloads/snma_minority_health_disparities.pdf.

93 DRUG PRICES AND THE EMERGING MAJORITY, at ii.

94 Neal Learner, *The Promise of Personalized Medicine Is Exciting, but Barriers Remain, Along with Questions About How to Achieve ROI*, AIS HEALTH, May 16, 2008, available at www.aishealth.com/Bnow/hbd051608.html.

95 More information on state-specific genetics bills is available from the National Conference of State Legislatures at www.ncsl.org/programs/health/genetics/geneticsDB.cfm.

96 See CRS REPORT.

genetic discrimination in employment.⁹⁷ Although the scope and function of these laws vary widely, they all prohibit discrimination based on the results of genetic tests. Many extend the protections to inherited characteristics, including family history and family member test results. Most states restrict employers from accessing genetic information; some prohibit employers from requesting, requiring, and obtaining genetic information or test results, albeit with exceptions for situations such as identifying individuals who may be a safety risk in the workplace.⁹⁸

Some states extend protections against genetic discrimination to healthcare and other contexts. Massachusetts, Pennsylvania, Rhode Island, and Texas explicitly prohibit medical facilities from providing discriminatory medical treatment. Other states have Patients' Bills of Rights that "prohibit race discrimination in health care," or prohibit discrimination in distribution of state services.

Forty-seven states have enacted laws pertaining to the use of genetic information in health insurance.⁹⁹ These states generally prohibit

- using genetic information to determine eligibility,
- using genetic information to set premiums for risk selection and risk classification,
- requiring genetic testing of applicants, or
- disclosing genetic information without consent.¹⁰⁰

However, state laws do not govern the use of genetic information in employer-sponsored health benefit plans, which are exempt from state insurance laws due to ERISA preemption.¹⁰¹ As it has been estimated that more than one-third of the employed insured population is insured through self-funded plans, the ERISA exemption significantly limits the application of these state laws.¹⁰²

Fewer states have enacted laws restricting the use of genetic information in life, disability, and long-term care insurance. For example, only seven states prohibit genetic discrimination in life insurance without actu-

97 These states include Arizona, Arkansas, California, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Oregon, Rhode Island, South Dakota, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin. See NCSL, State Genetics Employment Laws, available at www.ncsl.org/programs/health/genetics/ndiscrim.htm (last visited Oct. 30, 2008).

98 *Id.*

99 NCSL, Genetics and Health Insurance State Anti-Discrimination Laws, available at www.ncsl.org/programs/health/genetics/ndishlth.htm (last visited Oct. 30, 2008).

100 *Id.*

101 29 U.S.C. §§ 1001–1145.

102 CRS REPORT, at 21 (citing Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need for Reform*, 270 SCI. 391 (1995) and Karen H. Rothenberg, *Genetic Information and Health Insurance: State Legislative Approaches*, 23 J. L. MED. & ETHICS 312 (1995)).

arial justification.¹⁰³ Three states also prohibit genetic discrimination in disability insurance without actuarial justification.¹⁰⁴ Only three states prohibit genetic discrimination in disability and long-term care insurance.¹⁰⁵

Some commentators believe that before personalized medicine can be fully realized, there is a need for new regulatory approaches and stronger patient privacy protection laws.¹⁰⁶ However, despite the differing state approaches to genetic discrimination, GINA goes a long way—as it was intended to do—in providing a federal floor of protection against discrimination to allow personalized medicine to continue to evolve.

Litigation Challenges and Trends

This section describes manufacturer and provider liabilities, litigation risks, and protections when dealing with patient-tailored medicines.

Manufacturers' risks

Roadblocks and impediments on the path toward personalized medicine continue to persist. Personalized medicine represents only a very small portion of the healthcare sector, where “blockbuster drugs” are still defined as \$1-billion-a-year sellers that target the largest number of patients with a disease. Thus, tailoring drugs to particular individuals poses a challenge to traditional pharmaceutical companies by suggesting that new drugs will target smaller populations.¹⁰⁷ This focus on genetic information raises numerous cost and ethical concerns, which may create new risks of liability for manufacturers.

Inadequate warning liability

In the most common type of tort suit against pharmaceutical manufacturers, the plaintiff asserts a drug company is liable for failing to warn consumers of dangers that the company itself should have foreseen and disclosed.¹⁰⁸ Personalized medicine would subject manufacturers

103 The seven states are Arizona, Maine, Maryland, Massachusetts, Montana, New Jersey, and New Mexico. See NCSL, Genetics and Life, Disability and Long-term Care Insurance, available at www.ncsl.org/programs/health/genetics/ndislife.htm (last visited Oct. 30, 2008).

104 The states are Arizona, Maine, and New Jersey. *Id.*

105 These states are Massachusetts, Montana, and New Mexico. *Id.*

106 Jacqueline Risher, *Personalized Medicine: The Promise and Realities of Healthcare Tailored to You*, SUITE101.COM, June 22, 2008, http://healthfieldmedicare.suite101.com/article.cfm/personalized_medicine (last visited Nov. 3, 2008).

107 Rick Mullin, *Armed with the Decoded Human Genome, Drug Researchers and Clinicians Are Working to Close the Gap Between Patient and Therapy*, 86 CHEMICAL & ENGINEERING NEWS 17 (2008), available at <http://pubs.acs.org/cen/coverstory/86/8606cover.html>.

108 Bernard J. Garbutt & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 FOOD & DRUG L.J. 269 (2003) [hereinafter *Recent Developments in Pharmaceutical Products Liability Law*].

to heightened duties to disclose risks to consumers, and to provide clear instructions to providers.

In an environment of patient-tailored medicines, manufacturers of race/ethnicity-based therapies would be expected to know the risks peculiar to the differentiated populations for which they develop and market pharmaceuticals. Thus, a “manufacturer may face liability if [clinical] data show that certain genotypes are more susceptible to adverse side effects to a drug that is subsequently marketed without adequate genetic warnings.”¹⁰⁹

The basic premise of race/ethnicity-based therapies is that they are safer and more effective than other drugs for particular genomic populations. In the past, courts did not recognize inadequate warning claims by hypersensitive individuals and small groups because a manufacturer could not have known of those rare risks. Pharmacogenomic research changes that rationale.¹¹⁰ Now, courts are more likely to impose greater duties upon manufacturers to warn consumers of risks revealed by advances in pharmacogenomic research. For example, a class action suit involving the manufacturer of LYMERix, a lyme disease vaccine, alleged that the drug manufacturer should have known about peculiar risks presented by the drug for only 30 percent of the population. Rather than fight in court, the manufacturer agreed to a settlement and withdrew the vaccine.¹¹¹

The history of healthcare disparities in the United States, discussed in Part One of this series, may contribute to expanded liability as well. Race-based therapies likely will result in increased litigation for inadequate warnings, precisely because the therapies are targeted toward populations that traditionally have been victims of discrimination; it is logical to expect that because victims of racism are more likely to be apprehensive, they will be more determined to prevent future racial discrimination. Manufacturers of these therapies would be prudent to ensure as full a level of disclosure of knowable risks as possible to minimize potential litigation from the consumers of those therapies. On the other hand, failure to adequately apprise consumers of unique race-based risks could open drug manufacturers not only to an initial wave of litigation from injured consumers, but also to subsequent waves of litigation from the compounding effect of negative public relations based upon charges of exploitation of vulnerable populations.

109 *Id.*

110 Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 *JURIMETRICS J.* 1, 25–26 (2002).

111 Gary E. Marchant, *Personalized Medicine and the Law*, 44 *ARIZ. ATT'Y* 12, 16 (2007).

Design defect liability

Personalized medical care may create a greater likelihood of more successful and frequent design defect claims. Personalized medicine and associated genetic screening tests would create a consumer expectation that the drugs are designed for individual use. The more effective personalized medicine becomes, the more purchasers will perceive their care to be on the cutting edge of pharmaceuticals.¹¹² If manufacturers know about the benefits of the drugs for a particular population, they will be expected to know the risks as well.¹¹³

On the other hand, tailored therapies may face fewer liabilities related to design defects, based on a risk-utility balancing test that considers consumer expectations.¹¹⁴ That is, if a tailored therapy is demonstrated to be particularly safe and effective for use by a particular subgroup of the population, it would present a lower risk of liability (even though it would cause adverse side effects in the general population). Targeted therapies would

- pose lower risks to targeted demographics than drugs designed for the general population,
- have higher utility due to increased effectiveness for that subgroup, and
- engender “reasonable” consumer expectations that the tailored therapy be only as safe and effective as current market alternatives.

Breach of implied warranty

While plaintiffs’ product liability claims based on a drug’s failure to be effective generally have not been successful, in patient-tailored medicine, there are compelling rationales for courts to find merit in claims based on the implied warranty of fitness for a particular purpose. A key reason for this shift is the policy goal of assuring that race-based therapies and other pharmacogenomic medicines meet expectations of being safer than other drugs for the populations to which they advertise. From a legal perspective, race-based therapies will meet the two elements of the warranty of fitness for a particular purpose: (1) The seller will have knowledge of the consumer’s reasons for purchase (the drugs will actually be developed for specific genotypes with specific

112 Barbara J. Evans, *What Will it Take to Reap the Clinical Benefits of Pharmacogenomics?*, 61 *FOOD & DRUG L.J.* 753, 792 (2006) (comparing the difference between designing pharmacogenomic drugs and traditional drugs to that between a “jet” and a “propeller biplane”) [hereinafter *Clinical Benefits of Pharmacogenomics*].

113 *Id.*

114 Ellen Wertheimer, *The Biter Bit: Unknowable Dangers, The Third Restatement, and the Reinstatement of Liability Without Fault*, 70 *BROOK. L. REV.* 889, 925 (2005).

health problems); and (2) The consumer will rely on the seller's representation, both implicit and otherwise, that the drug is effective as marketed (especially due to the perception that these drugs are more targeted than traditional drugs).¹¹⁵

Informed consent of research subjects

There may be potential liability for manufacturers who do not fully inform racial and ethnic minority research subjects that they are being used to test a commercially viable, race-based drug. As discussed in detail in Part One of this series, the Tuskegee syphilis experiments created a level of distrust towards clinical research by African-Americans that exists to this day.¹¹⁶ Given this history, race-based medicine researchers who do not disclose significant dangers to their participants likely would face punitive damages for recklessly endangering the safety of minority participants.

“Currently, the states are almost evenly split between two types of standards for informed consent—the physician-based standard, effective in [twenty-five] states, and the patient-based standard, effective in [twenty-three] states and the District of Columbia.”¹¹⁷ Under both standards, in the treatment context, physicians have a duty to inform the patient of all “risks, benefits, and alternatives to treatment” that a patient needs to make a decision about his or her course of treatment, if any, but the two standards for satisfying that duty are distinct.¹¹⁸ Under the physician-based standard, a physician must provide informed consent to a patient “in the same manner that a ‘reasonably prudent practitioner’ in the field would.”¹¹⁹ The patient-centered standard of disclosure requires that information be provided to the patient in the manner that “a ‘reasonable patient’ would attach significance to in making a treatment decision.”¹²⁰ The modern, or emerging, standard for informed consent is the patient-centered standard.¹²¹

Because race-based pharmacogenomic drugs will be on the cutting edge of scientific knowledge, it will be difficult for personalized medicine researchers to draft informed consent disclosures that adequately identify material risks—but they must do so under both approaches. This could result in a blanket permission for genetic research, which

115 Wayne M. Serra, *Ensuring the Safety of Genotech Drugs Through Implied Warranty Theory*, 23 AM. J.L. & MED. 363, 380–81 (1997).

116 “Racially-Tailored” Medicine, at 426–27.

117 Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 430 (2006).

118 *Id.*

119 *Id.* (citing *Tashman v. Gibbs*, 556 S.E.2d 772, 777 (Va. 2002)).

120 *Id.*

121 *Clinical Benefits of Pharmacogenomics*, at 772.

generally is considered morally problematic.¹²² However, to the degree that jurisdictions with physician-based standards of informed consent are more reluctant to impose liability upon physician researchers of tailored therapies, researchers and their employing manufacturers may find it advantageous to conduct research from those jurisdictions.

Race-based tailored therapy manufacturers also should ensure that subjects are fully informed of the commercial potential of any successful outcomes. In a landmark 1990 California case, *Moore v. Regents of the University of California*,¹²³ the Supreme Court of California imposed a duty upon a physician researcher to disclose potentially conflicting economic and research interests, citing the physician's fiduciary duty to reveal all material facts relevant to the patient's decision.¹²⁴ The *Moore* court also held out the possibility that private companies could be liable under a vicarious liability theory, such as *respondeat superior*, for the inadequate disclosure of commercial interests to the research subject by failing to disclose that the physician researcher was paid by the manufacturer.¹²⁵ For a broader discussion of genetic research, see **Research and Patient-Tailored Medicine**, beginning on page 36.

Defenses available to manufacturers

Although there are policy justifications for compensating consumers of race-based therapies for personal injuries, there is an even greater countervailing need to improve racial minorities' access to drugs. Until manufacturers of race-based therapies demonstrate sound business models that can pass on liability costs, courts should be careful not to impose crushing awards for technologically innovative drugs. It remains to be seen whether race-based therapies will prove to be profitable ventures in the short term. For example, BiDil's initial sales projections of \$130 million per year never materialized. The drug produced revenues of \$12 million in 2006, over ten times less than the goal.¹²⁶ As a result, BiDil's manufacturer, NitroMed, has discontinued marketing, though it will continue to produce the drug.¹²⁷ The following sections explore possible defenses for the manufacturers of patient-tailored medicines.

122 Richard R. Sharp, *The Evolution of Predictive Genetic Testing: Deciphering Gene-Environment Interactions*, 41 JURIMETRICS J. 145, 160 (2001).

123 *Moore v. Regents of the Univ. of Cal.*, 51 Cal. 3d 120, 133 (1990).

124 *Id.* at 131–33.

125 *Id.* at 133.

126 David Armstrong, *Nitromed Halts Marketing of Drug*, WALL ST. J., Jan. 16, 2008, at D8.

127 *Id.*

FDA preemption

There is a strong possibility that FDA regulation will preempt the entire field of pharmaceutical personal injury litigation. In 2008, in *Riegel v. Medtronic*,¹²⁸ the U.S. Supreme Court recognized FDA preemption of suits against defective medical devices. The majority opinion rejected any state-level liability exposure for defective medical devices that are FDA approved.¹²⁹ *Medtronic* was resolved based on express preemption provisions of the applicable federal statute at issue in the case, i.e., the Medical Device Amendments of 1976.¹³⁰ Justice Scalia, writing for the majority, seemed to favor broad FDA preemption of state common law tort liability, going so far as to express reservations about allowing FDA to define parameters for narrowing the scope of preemption.¹³¹ The court's rationale demonstrates the Supreme Court's current attitude towards FDA preemption in general and is equally applicable to FDA preemption of pharmaceutical litigation.

However, the Supreme Court has not issued a definitive decision on whether FDA approval should preempt all state-level personal injury litigation against pharmaceutical manufacturers.¹³² The Court will decide the issue in the landmark case of *Wyeth v. Levine*,¹³³ argued in November 2008, and possibly preempt the entire area of personal injury lawsuits for pharmaceuticals—even though the majority of lower courts have been unreceptive to FDA preemption of state-level personal injury claims.¹³⁴

Courts could become instruments of redistributive justice, forcing innovative pharmaceutical products like race-based therapies to exit the market. On the other hand, court decisions could set back advancements in the health of Americans by depressing sales in tailored therapies. The absence of state tort ramifications could encourage risk-averse companies to enter the pharmacogenomics market.

128 *Riegel v. Medtronic*, 128 S. Ct. 999 (2008). See Linda Greenhouse et al., *Justices Shield Medical Devices from Lawsuits*, N.Y. TIMES, Feb. 21, 2008, at 1, available at www.nytimes.com/2008/02/21/washington/21device.html [hereinafter *Justices Shield Medical Devices*]. See also Biswajit Chatterjee, *Washington Update: Court Rules in Favor of FDA Preemption in Medical Devices*, 2 HEALTH L. & POL'Y 94 (2008) [hereinafter *Washington Update*].

129 *Justices Shield Medical Devices*. See also *Washington Update*.

130 Christen L. Young, *Agency Preemption Inputs in Riegel v. Medtronic*, YALE L.J. (online companion), July 9, 2008, available at <http://yalelawjournal.org/2008/07/09/young.html>.

131 *Id.*

132 *Warner-Lambert v. Kent*, No. 06-1498, 1 (U.S. Mar. 3, 2008), available at www.supremecourtus.gov/opinions/07pdf/06-1498.pdf; see also *Washington Update*.

133 *Wyeth v. Levine*, 2006 VT 107 (2006), cert. granted, 128 S. Ct. 1118 (2008) (oral argument Nov. 3, 2008). Docket available at www.supremecourtus.gov/docket/06-1249.htm. See also Gardiner Harris, *Court Considers Protecting Drug Makers From Lawsuits*, N.Y. TIMES, Feb. 26, 2008, at 1, available at www.nytimes.com/2008/02/26/washington/26drug.html [hereinafter *Protecting Drug Makers From Lawsuits*]; see also *Washington Update*.

134 *Protecting Drug Makers From Lawsuits*; see also *Washington Update*.

Learned intermediary doctrine

Regardless of the outcome on the preemption argument, other avenues to mitigate liability remain. A prime pharmaceutical company defense against litigation has been the learned intermediary doctrine, which undoubtedly will be relied upon in litigation against pharmacogenomic drug manufacturers. To date, most personalized medicines have been prescription drugs, thereby especially necessitating the doctrine's application.

The learned intermediary doctrine absolves the manufacturer of the duty for adequate warnings as long as the company gives direct and adequate warnings to the physician, because the physician has specialized knowledge, prescribes the medicines, and advises the patient of appropriate medications.¹³⁵ While most jurisdictions recognize the learned intermediary defense, there is an evolving trend among a minority of jurisdictions to reject the defense, or to provide exceptions, when the manufacturer issues direct-to-consumer (DTC) advertising.¹³⁶

In *Perez v. Wyeth Laboratories*,¹³⁷ for example, New Jersey's Supreme Court in 1999 recognized an exception, finding that the underpinnings of the learned intermediary doctrine had been chipped away by the prevalence of pharmaceutical companies advertising directly to consumers, effectively bypassing and negating the traditional physician-patient treatment relationship.¹³⁸ In 2007, West Virginia's Supreme Court followed suit and expanded the *Perez* holding, rejecting outright the learned intermediary doctrine in any situation, largely because of DTC ads.¹³⁹

Key premises of the learned intermediary doctrine will be inapplicable to tailored therapies. A physician will not be acting as a "learned intermediary" to nearly the same extent with pharmacogenomic drugs because both drug makers and patients will rely less on physicians, and more on manufacturers, to make determinations about whether a drug should be prescribed.¹⁴⁰ It is likely that manufacturers

135 *Recent Developments in Pharmaceutical Products Liability Law*, at 272–73.

136 *Id.* at 275.

137 *Perez v. Wyeth Labs.*, 734 A.2d 1245 (1999).

138 *Recent Developments in Pharmaceutical Products Liability Law*, at 273–75.

139 *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007). See Nixon Peabody LLP, *West Virginia Supreme Court of Appeals Declines to Adopt Learned Intermediary Doctrine in Prescription Drug Failure-to-Warn Case*, PHARMACEUTICAL, MED. DEVICE & LIFE SCIS. ALERT (July 2007), available at www.nixonpeabody.com/linked_media/publications/JulyAlert.pdf; see also Drug & Device Law, *In Defense of the Learned Intermediary Rule*, <http://druganddevicelaw.blogspot.com/2007/07/in-defense-of-learned-intermediary-rule.html> (July 6, 2007).

140 Timothy A. Pratt & John F. Kuckelman, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising of Prescription Drugs*, at 7, www.thefederation.org/documents/pratt.htm (last visited Mar. 30, 2008) [hereinafter *The Learned Intermediary*].

of tailored therapies will engage heavily in DTC marketing to specific population subgroups¹⁴¹—that is, to the self-identified persons of particular races, ethnicities, and subgroups that a given tailored therapy are designed to help. The manufacturers, rather than physicians, will have the pharmacogenomic research basis to tailor warnings to specific subgroups.¹⁴²

Nonetheless, four main rationales for the learned intermediary defense continue today:

[1] prescription drugs remain complex and a physician must act as a learned intermediary in the process of prescribing a drug;

[2]...physicians remain in a superior position to convey meaningful information to individual patients;

[3]... even though a manufacturer can communicate with patients through advertising, a manufacturer cannot effectively tailor warnings specifically for individual patients... and

[4] requiring a manufacturer to warn a consumer directly imposes the manufacturer into the patient-physician relationship.¹⁴³

Thus, as for off-label drugs, the learned intermediary doctrine may continue to be an especially apt defense to pharmacogenomic drug manufacturer liability, as these manufacturers could better shift the burdens for proper prescription upon the physician. Off-label use of ordinary pharmaceuticals is a commonly accepted practice in which physicians prescribe drugs to untested subgroups or for untested uses not originally approved by FDA.¹⁴⁴ A traditional drug that fails to mention use for a given subpopulation does not necessarily mean that the drug is unsafe or ineffective.¹⁴⁵ For personalized medicines, however, physicians may risk malpractice claims for off-label drug recommendations when adverse side effects occur—off-label use for unapproved population groups of pharmacogenomic drugs could connote that the nonindicated use would be unsafe or ineffective.¹⁴⁶ “For genetically targeted therapies, the lack of an approved indication in labeling may be “with prejudice,” i.e., it may mean, “this use may be bad,” rather

141 Alix Weisfeld, *How Much Intellectual Property Do the Newest (and Coolest) Biotechnologies Get Internationally?*, 6 CHI. J. INT'L L. 833, 836 (2005).

142 *The Learned Intermediary*, at 7.

143 *Id.*

144 *Clinical Benefits of Pharmacogenomics*, at 783.

145 *Id.*

146 *Id.* at 784.

than merely “this use was never tested.”¹⁴⁷ As such, physicians should tread a careful path in prescribing racially, ethnically, or sex-targeted drugs to untested subgroups, and manufacturers should monitor the application of the learned intermediary defense in the context of patient-tailored drug therapies.

Provider risks

Use of patient-tailored prescription drugs may create a unique set of challenges for physicians. Physicians may be subject to malpractice liability for side effects associated with generic use of race-based medicines. Physicians might be placed in the uncomfortable situation in which they need to discern a particular individual’s racial background by asking a series of probing questions. Further, physicians might be subject to malpractice liability for failing to refer a patient to a genetic counselor for race-based medicines. Ultimately, physicians may be forced to confront privacy issues in attempts to provide a particular patient with the best treatment possible, given that individual’s racial and ethnic background.

Off-label prescription of pharmacogenomic drugs

Even though generic use, in which physicians prescribe drugs to untested subgroups or for untested uses not approved by FDA, of ordinary pharmaceuticals is a commonly accepted practice, physicians could be subject to malpractice liability for generic uses of race-based medicines when adverse side effects occur.¹⁴⁸ For conventional pharmaceuticals, the failure of the drug label to mention its safety for a given racial group does not mean that the drug is unsafe or ineffective for that group.¹⁴⁹ However, for patient-tailored therapies, generic use could constitute experimental treatment.¹⁵⁰ This could be a concern for physicians when patients request a prescription for a specific racially targeted therapy, or when a physician wishes to ensure that only persons of appropriate genotypes are recommended for tailored therapies. For example, it would not appear to make sense to recommend BiDil to Caucasian patients when it is targeted to self-identified African-Americans.

As a result, physicians could be placed in the awkward position of having to discern subtle differences in race and ethnicity. Physicians could face claims for violation of anti-discrimination mandates if they base prescription decisions for race-based medicines upon their sub-

¹⁴⁷ *Id.*

¹⁴⁸ *Id.* at 783.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

jective perceptions of a patient's racial or ethnic identity.¹⁵¹ Interracial individuals also could be problematic for physicians' prescription decisions. Physicians may be forced to find objective means to make such decisions. Besides pharmacogenomic tests, another avenue of determining if a race-based treatment is appropriate for an individual would be to conduct probing and detailed questioning of the individual's ethnic ancestry.¹⁵² A more scientific alternative solution for ascertaining ethnic identity would be to order a haplotype test to ascertain a patient's geographic ancestry.¹⁵³

Failure to refer and conduct screenings

Physicians also may be subject to malpractice liability for failing to refer a candidate for race-based medicines to genetic counselors.¹⁵⁴ Because physicians would be expected to guide their patients in the use of innovative pharmacogenomic medicines, physicians could be held liable for inappropriately relying on race as the sole proxy for a genetic profile.¹⁵⁵ This could result in inappropriately denying a treatment to persons of another racial group than that targeted by a racially tailored therapy, but who have the same "genetic variant."¹⁵⁶ Relying on race as a proxy also could cause physicians to provide the treatment inappropriately to persons of the targeted racial group, even though some members of that race would not have the assumed genetic profile.¹⁵⁷ This risk raises an associated need for physicians to provide pharmacogenomic screening tests to ascertain the suitability of patients for any race-based medicines.¹⁵⁸

Privacy protections and issues for providers

The Director of the National Institutes of Health (NIH), Elias A. Zerhouni, M.D., stated that "comprehensive, genomics-based health care will become the norm, with individualized preventive medicine and early detection of illnesses."¹⁵⁹ Privacy and control of personalized medicine information will be one of the most significant issues facing

151 "Racially-Tailored" Medicine, at 449.

152 *Id.*

153 See Jonathan Kahn, *Race-ing Patients/Patenting Race: An Emerging Political Geography of Intellectual Property in Biotechnology*, 92 IOWA L. REV. 353, 382-83 (2007). Haplotyping is a tool for determining geographic ancestry based on an individual's DNA matched against an international database, the International HapMap Project.

154 *Id.*

155 NUFFIELD COUNCIL ON BIOETHICS, PHARMACOGENETICS: ETHICAL ISSUES 42 (2003), available at www.nuffieldbioethics.org/fileLibrary/pdf/pharmacogenetics_report.pdf.

156 *Id.*

157 *Id.*

158 *Clinical Benefits of Pharmacogenomics*, at 792.

159 Press Release, NIH, NIH Seeks Input on Proposed Repository for Genetic Information (Aug. 30, 2006), available at www.nih.gov/news/pr/aug2006/od-30.htm.

providers in the years to come. As discussed above, while state and federal lawmakers have begun to address these issues, current laws are inconsistent in their protection of genetic information.

The privacy and security regulations promulgated under the HIPAA Privacy Rule provide a federal floor of protection for “protected health information” (PHI).¹⁶⁰ This would include genetic testing and personalized medicine data if that information were created or received by a healthcare provider, health plan, or healthcare clearing house.¹⁶¹ However, PHI does not include information created or received by other entities, such as employers or insurance companies. Under GINA, however, employers are required to apply the same privacy protections for “genetic information” as are applicable to medical information protected under HIPAA and the ADA.¹⁶² In addition, GINA mandates that genetic information falls within HIPAA’s definition of “protected health information” and must be treated as such when in the plan’s or insurer’s possession.¹⁶³

In general, the HIPAA Privacy Rule requires that an individual authorize the use and disclosure of his or her PHI.¹⁶⁴ Despite this seemingly expansive protection—as described in the Notice of Privacy Practices providers and insurers are required to provide to patients—there are broad exceptions where individual authorization is not required, including uses and disclosures for treatment, payment, and healthcare operations.¹⁶⁵ In addition, there is a long list of situations where authorization is not required because of public policy considerations (e.g., abuse or neglect, public emergencies, regulatory oversight, etc.).¹⁶⁶ Thus, broad exceptions for use and disclosure of PHI without individual authorization result in the protections offered to patients by the HIPAA Privacy Rule being somewhat illusory.

Before the implementation of the HIPAA Privacy Rule, many states had enacted laws to provide protection for the confidentiality of genetic testing information. In general, these laws give more protection to PHI than the HIPAA Privacy Rule, which preempts only state

160 42 U.S.C. § 1320; 45 C.F.R. §§ 160, 164. HIPAA contains two different sections relevant to a discussion of genetic information: one addressing non-discrimination in the health insurance context (42 U.S.C. §§ 300gg et. seq.) and the other addressing privacy of PHI (42 U.S.C. § 1320; 45 C.F.R. §§ 160, 164). The non-discrimination provisions are discussed above under Federal Legal Landscape, HIPAA.

161 45 C.F.R. § 160.103.

162 GINA, tit. 2, § 206.

163 GINA, tit. 1, § 105(a).

164 45 C.F.R. § 164.508(a)(1). HIPAA does not provide individuals who suffer damages as a result of any unlawful use or disclosure of PHI a private cause of action against the covered entity.

165 *Id.* § 164.506(a).

166 *Id.* § 164.512(a)-(l).

laws that give less protection to PHI.¹⁶⁷ Thus, evaluating the interaction of the HIPAA Privacy Rule with state laws is critical to understanding the privacy protection of genetic information.

In general, state laws make an individual's authorization a prerequisite for disclosing genetic information, even where the HIPAA Privacy Rule would not require authorization.¹⁶⁸ While a fifty-state survey is beyond the scope of this article, it is noteworthy that twenty-seven states require an individual's consent for the disclosure of genetic testing information.¹⁶⁹ In addition, some states require individual authorization for activities such as retaining genetic information and performing genetic tests.¹⁷⁰ Although states frequently carve out exceptions for situations such as confirmation of paternity, identification of deceased persons, and criminal investigations and prosecutions, these exceptions are far more limited than under the HIPAA Privacy Rule. As a result, states that offer protection of genetic information truly give the individual the ability to control access to that information. Even so, that protection—and its scope—is inconsistent from state to state. As a result, the strength of a state's laws protecting genetic information likely will determine how willing patients are to disclose that information, and providers who collect or use genetic information will need to closely follow restrictions applicable in their jurisdictions.

Privacy and the duty to warn

Every state recognizes a common law or statutory right to privacy.¹⁷¹ Generally, geneticists are prohibited from disclosing a patient's medical genetic information without the patient's written authorization.¹⁷² An exception exists for medical geneticists to disclose PHI to a patient's friends and family members so that they may assist in the patient's care.¹⁷³ However, this exception does not allow a medical geneticist

167 45 C.F.R. § 160.203.

168 The scope of "genetic information" is defined differently in various states. Oregon, for example, defines "genetic information" to include information about blood relatives while California's statute refers to "genetic characteristics," defined as a scientifically identifiable gene or chromosome that is known to be a cause of a disease or disorder. See OR. REV. STAT. § 192.531(11); CAL. INS. CODE § 10147(b).

169 These states include Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Minnesota, Missouri, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, South Carolina, Texas, Vermont, Virginia and Washington. See Nat'l Conference of State Legislatures, *State Genetic Summary Table on Privacy Laws*, www.ncsl.org/programs/health/genetics/prt.htm (last visited Nov. 1, 2008).

170 *Id.*

171 Amy L. McGuire & Richard A. Gibbs, *Currents in Contemporary Ethics: Meeting the Growing Demands of Genetic Research*, 34 J.L. MED. & ETHICS 809, 809 (citing Standards for the Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462–829 (2000)).

172 Laura J. Cole & Lynn D. Fleisher, *Update on HIPAA Privacy: Are You Ready?*, 5 GENETICS IN MED. 183, 186 (2003).

173 *Id.*

operating under the HIPAA Privacy Rule to disclose PHI to benefit the patient's family members.¹⁷⁴

The HIPAA Privacy Rule allows medical geneticists to disclose information to prevent a "serious and imminent threat to the health or safety of a person or the public."¹⁷⁵ From an ethical standpoint, a physician's duty to warn requires the "availability of medical interventions to reduce the risk of developing a disease or to lessen the ensuing harm."¹⁷⁶ For infectious diseases, for example, New York requires that a doctor warn a third party "when the service performed on behalf of the patient necessarily implicate[d] protection of... other identified persons foreseeably at risk because of [the] relationship with the patient, whom the doctor knows or should know may suffer harm by relying on prudent performance of th[e] medical service."¹⁷⁷ However, "[i]t is questionable whether the uncertain probability of a future genetic disease constitutes an imminent harm or a threat to the public interest."¹⁷⁸ The American Society of Clinical Oncology suggests that "federal requirements to justify a breach of confidentiality are [not] met by genetic syndromes of cancer predisposition."¹⁷⁹

There are varying successes in reducing a predisposition toward disease with the use of genetic information. For example, women with BRCA mutations—gene mutations that may determine a woman's likelihood of developing breast or ovarian cancer¹⁸⁰—can reduce their risk of developing breast or ovarian cancer by 75 percent if they undergo surgical removal of the ovaries and fallopian tubes after childbearing.¹⁸¹ Some studies suggest that screening and prevention in hereditary breast, colon, and thyroid cancers is efficacious.¹⁸² Other genetic diseases, such as phenylketonuria, can be prevented through such means as dietary modification.¹⁸³ However, there are minimal or no medical interventions for some genetic disorders, such as Huntington disease and Alzheimer's disease.¹⁸⁴ Less than one percent of physicians believe

174 *Id.*

175 45 C.F.R. § 164.512(i).

176 Kenneth Offit et al., *The "Duty to Warn" a Patient's Family Members About Hereditary Disease Risks*, 292 JAMA 1469, 1470 (2004) [hereinafter *Duty to Warn*].

177 *Tenuto v. Lederle Lab.*, 687 N.E.2d 1300, 1303 (N.Y. 1997).

178 *Duty to Warn*, at 1471.

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

180 Mary-Claire King et al., *Tamoxifen and Breast Cancer Incidence Among Women with Inherited Mutations in BRCA1 and BRCA2*, 18 J. AM. MED. ASS'N. 2251 (2001).

181 *Duty to Warn*, at 1470 (citing Noah D. Kauff et al., *Risk-Reducing Salpingo-oophorectomy in Women with a BRCA1 or BRCA2 Mutation*, 347 NEW ENG. J. MED. 1609 (2002)).

182 *Id.* (internal citations omitted).

183 *Id.* (citing Wylie Burke et al., *Genetic Test Evaluation: Information Needs of Clinicians, Policy Makers, and the Public*, 156 AM. J. EPIDEMIOLOGY 311 (2002)).

184 *Id.*

that it is ethical to breach patient confidentiality when no medical intervention exists.¹⁸⁵

State courts hint that providers may be obligated in some instances to share genetic test results with a patient's at-risk relatives.¹⁸⁶ In *Safer v. Estate of Pack*, a daughter sued the estate of her father's physician for failing to warn her about the risk of familial adenomatous polyposis,¹⁸⁷ a condition that leads to colon cancer by 40 years of age.¹⁸⁸ Her father's physician diagnosed her father with the disease 30 years prior to her diagnosis of advanced colorectal cancer.¹⁸⁹ Had she been informed of the risk, she claimed, she would have had a prophylactic colectomy in her late teen years.¹⁹⁰ Although this New Jersey court ultimately decided against the daughter based on evidence that she had colorectal screening at age 10, the court stated that the doctor's duty to warn relatives is not always fulfilled by informing the patient about the genetic nature of the disease.¹⁹¹ Physicians must take reasonable steps to ensure that at-risk family members receive the warning.¹⁹² One commentator worries that this duty might overburden some physicians, because it is difficult to locate family members of patients who are unwilling to share the news of their increased risk themselves.¹⁹³

In *Pate v. Threlkel*, a daughter filed suit in Florida against her mother's physician because he did not warn her of her elevated risk of hereditary thyroid cancer.¹⁹⁴ If physicians recognized this condition early, she argued, they could have intervened by removing her thyroid gland and treating her with hormones.¹⁹⁵ The mother's physician never informed the mother that she needed to tell her daughter about the elevated cancer risk.¹⁹⁶ The Supreme Court of Florida held that the physician had a duty to inform the mother of the daughter's risk; it held that privity was irrelevant, because the standard of care was intended to benefit the children.¹⁹⁷

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

186 Lawrence O. Gostin & James G. Hodge, *Genetic Privacy and the Law: An End to Genetics Exceptionalism*, 40 JURIMETRICS J. 21, 35 (1999).

187 *Safer v. Estate of Pack*, 677 A.2d 1181 (N.J. Super. Ct. 1996).

188 *Id.*

189 *Id.*

190 *Id.*

191 *Id.*

192 *Id.*

193 *Duty to Warn*, at 1471.

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

195 *Id.*

196 *Id.*

197 *Id.*

Because of the potential implication of genetic information for parents, siblings, and children, some commentators suggest that patients who undergo genetic testing should designate recipients of genetic information to enable physicians to contact family members about elevated risk potentials safely and easily, even if the patient has died before development of a test.¹⁹⁸ It is foreseeable that genetic tests will become much more accurate in determining an individual's predisposition to certain diseases, providing a compelling reason for disclosure to at-risk family members. In addition, more preventive measures with proven efficacy will be developed, increasing the likelihood that a judge will find a duty to warn third parties of test results. A potential negative externality to disclosure to at-risk family members will be the loss of study participants, but it would be wise for providers to seek consent to family-member disclosures proactively.

In general, a physician's duty to warn is discretionary.¹⁹⁹ A Presidential Commission established several conditions for a physician to breach confidentiality ethically by disclosing information to a patient's relatives. Three of the conditions are:

- (1) the high likelihood of harm if the relative were not warned,
- (2) the identifiability of the relative, and
- (3) the notion that the harm resulting from failure to disclose would outweigh the harm resulting from disclosure.²⁰⁰

Professional societies have expressed the opinion that physicians should advise patients about the usefulness of conveying genetic test results to at-risk family members. The American Medical Association's Council on Ethical and Judicial Affairs considered a proposal that physicians should provide a "genetic *Miranda* warning" before conducting a genetic test.²⁰¹ This proposal would have required physicians to inform patients of situations in which the physicians would feel compelled to breach confidentiality by informing at-risk family

198 Annette R. Patterson et al., *Custodianship of Genetic Information: Clinical Challenges and Professional Responsibility*, 23 J. CLINICAL ONCOLOGY 2100, 2102 (2005).

199 *Duty to Warn*, at 1471.

200 *Id.* (citing Am. Soc'y of Human Genetics Social Issues Subcomm. on Familial Disclosure, *ASHG Statement: Professional Disclosure of Familial Genetic Information*, 62 AM. J. HUMAN GENETICS 474 (1998); NAT'L INFO. RES. ON ETHICS & HUMAN GENETICS, SCREENING AND COUNSELING FOR GENETIC CONDITIONS: THE ETHICAL, SOCIAL, AND LEGAL IMPLICATIONS OF GENETIC SCREENING, COUNSELING, AND EDUCATION PROGRAMS 1 (1983), available at www.bioethics.gov/reports/past_commissions/geneticscreening.pdf; COMM. ON ASSESSING GENETIC RISKS, INST. OF MED., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (1994)).

201 *Duty to Warn*, at 1471.

members about elevated genetic predispositions.²⁰² After deliberation, the council decided to suggest that physicians should inform patients about the “circumstances under which they would expect patients to notify biological relatives of the availability of information related to the risk of disease.”²⁰³ Similarly, the American Society of Clinical Oncology suggests that physicians should “remind patients of the importance of communicating test results to family members....”²⁰⁴ It is the American Society of Clinical Oncology’s position that informing their patients of the risk discharges the physicians’ duty to warn.²⁰⁵

Research and Patient-Tailored Medicine

As discussed above, until the clinical research emphasis shifts from participants’ racial and ethnic backgrounds toward individuals’ genetic make-up, researchers should make efforts to include minority populations in trials to ensure equal benefit among different races. In addition to including minority participants, researchers may promote equal representation of minority groups by including experts from minority groups in the research and review process and by including minorities in institutional review boards.²⁰⁶ For instance, researchers from minority groups could evaluate DNA databanks to ensure that minority populations are adequately represented in the research.²⁰⁷

“Biobanks,” which store and analyze human tissue samples, hold tremendous promise for researchers mining tissue samples for genetic information.²⁰⁸ As emerging technology reduces the cost of genetic testing, the number of genome-wide association studies will increase tremendously.²⁰⁹ Although biobanks hold great promise, the American public has concerns about providing genetic samples to biobanks. One concern is the potential that hackers will steal genetic information.²¹⁰ The public also is concerned with genetic codes that contain unobservable, secret information about themselves.²¹¹ Even individuals who do not have concerns about their own genetic information may have concerns about the implications for their parents, siblings, and children

202 Council on Ethical & Judicial Affairs of the Am. Med. Ass’n, CEJA Report 9-A-03, *Disclosure of Familial Risk in Genetic Testing*, 8 GENETIC TESTING 356 (2004).

203 *Id.*

204 ASCO Policy Statement, at 2397.

205 *Id.*

206 *Pharmacogenomics*, at 52–53.

207 Charles Weijer & Paul B. Miller, *Protecting Communities in Pharmacogenetic and Pharmacogenomic Research*, 4 PHARMACOGENOMICS J. 9–16 (2004).

208 Edward J. Janger, *Genetic Information, Privacy and Insolvency*, 33 J.L. MED. & ETHICS 79 (2005).

209 Amy L. McGuire & Richard A. Gibbs, *Meeting the Growing Demands of Genetic Research*, 34 J. L. MED. & ETHICS 809, 810 (2006).

210 Mary L. Durham, *How Research Will Adapt to HIPAA: A View from Within the Healthcare Delivery System*, 28 AM. J.L. & MED. 491, 495 (2002).

211 *Id.*

if their genetic makeups were exposed.²¹² Thus, to assuage potential participants' fears about participation, the informed consent process for biobank donation should explain clearly the privacy protections that will be implemented.

Many donors demand extra protection because genetic information is unique in comparison to other health information:

1. [I]t remains largely stable throughout life;
2. [G]enetic fingerprints are remarkably identifiable;
3. [G]enetic conditions are inherited, and thus genetic information can reveal information about an individual's current family members and future offspring; and
4. [G]enetic information can transcend health status to reveal predispositions and personal characteristics.²¹³

Despite affirmative actions to ensure the privacy of highly sensitive genetic information,²¹⁴ researchers worry that legislatures, in passing statutes that focus on genetic privacy rather than health data privacy in general, will stir unwarranted fear that may discourage individuals from seeking genetic testing.²¹⁵ Although genetic information is unique, concerns about privacy may be explained by the general decline in the public trust of health professionals. Seventy percent of Americans have concerns about disclosing their medical records to researchers,²¹⁶ yet Americans support both ensuring the privacy of their medical records and encouraging medical research.²¹⁷

Federal policy for the protection of human subjects

Which specific protections apply to genetic research depends in part upon whether a study constitutes "human subjects research." The Federal Policy for the Protection of Human Subjects (Common Rule) sets guidelines that researchers must follow when they conduct human subjects research.²¹⁸ The Common Rule defines "research" as any "systematic

212 *Id.*

213 James G. Hodge, Jr., *Ethical Issues Concerning Genetic Testing and Screening in Public Health*, 125C AM. J. MED. GENETICS 66, 69 (2004) (citing NAT'L CONF. OF STATE LEGISLATURES, GENETICS POLICY AND LAW: A REPORT FOR POLICYMAKERS (2001)) [hereinafter *Ethical Issues Concerning Genetic Testing*].

214 Joanne Hustead & Janlori Goldman, *Genetics and Privacy*, 28 AM. J.L. & MED. 285 (2002).

215 *Ethical Issues Concerning Genetic Testing*, at 69.

216 John M. Eisenberg, *Can You Keep a Secret?: Measuring the Performance of Those Entrusted with Personal Health Information*, 16 J. GEN. INTERNAL MED. 132 (2001).

217 George J. Annas, *Medical Privacy and Medical Research—Judging the New Federal Regulations*, 346 NEW ENG. J. MED. 216 (2002) [hereinafter *Judging the New Federal Regulations*].

218 45 C.F.R. § 46.103(a). Researchers must provide the Office of Protection from Research Risks with a satisfactory assurance that their research complies with the Common Rule.

investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”²¹⁹

Of particular interest in the biobank context, the Common Rule states that “[p]rivate information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.”²²⁰ Specifically, the Office for Human Research Protections (OHRP) of HHS takes the position that data are individually identifiable “when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.”²²¹ Thus, it seems likely that genetic research, which depends on identifiable genetic information, would constitute human research.

The OHRP provides a safe harbor, however, for information that cannot be linked. A guidance document states that if the following conditions are met, a study does not constitute human subjects research, because the information is not individually identifiable:

- (1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - (a) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - (b) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

219 45 C.F.R. § 46.102(d).

220 45 C.F.R. § 46.102(f).

221 OFFICE FOR HUMAN RESEARCH PROTS., DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION ON BIOLOGICAL SPECIMENS 3 (2004), *available at* www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf.

- (c) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.²²²

Whether coded or anonymized genetic information is “identifiable PHI” remains unclear. HHS recognizes this issue but has not promulgated any clarifying regulations. Some researchers claim that “de-identified” genotypic data are actually potentially identifiable.²²³ For example, single nucleotide polymorphisms (SNPs), DNA sequence variations between members of the same species, can be used to identify individuals.²²⁴ There are databases of SNP data in the public realm. It is possible that one who has access to individual genetic data might be able to match that data with public SNP data.²²⁵ Once this is done, any previously de-identified information linked to that individual in the public records would become available, severing anonymity.²²⁶ Researchers currently are exploring algorithms called Re-Identification of Data In Trails (REIDIT) to link public genomic data to individual patients using patient location visit patterns.²²⁷

There are some methods that researchers who work with genetic information might use to prevent re-identification. One technique is to change randomly some SNPs for each participant before releasing the genetic information.²²⁸ However, this is not an ideal situation, because researchers would like to use the true and correct genetic information, not data in which “noise” has been introduced. Another method would be to “group SNPs into bins.”²²⁹ By “[d]isregarding exact genomic locations of SNPs[, one] increases the number of records that share the same values....”²³⁰ Some researchers remain skeptical about this approach because “the pattern of binned values is unlikely to match anyone other than the owner of the DNA.”²³¹ In addition, binning would make genetic analysis difficult.²³² Others have suggested encrypting identifying information associated with the genetic information, such as subjects’ names and social security numbers, into pseudonyms.²³³

222 *Id.* at 4.

223 Zhen Lin et al., *Genomic Research and Human Subject Privacy*, 305 *Sci.* 183,183 (2004) [hereinafter *Genomic Research*].

224 *Id.*

225 *Id.*

226 *Id.*

227 Bradley Malin & Latanya Sweeney, *How (Not) to Protect Genomic Data Privacy in a Distributed Network: Using Trail Re-Identification to Evaluate and Design Anonymity Protection Systems*, 37 *J. BIOMEDICAL INFORMATICS* 179 (2004) [hereinafter *Using Trail Re-Identification*].

228 *Id.* (citing Leon Willenborg & Ton de Waal, *ELEMENTS OF STATISTICAL DISCLOSURE CONTROL* (2001)).

229 *Genomic Research*, at 183.

230 *Id.*

231 *Id.*

232 *Id.*

233 *Using Trail Re-Identification*, at 179.

Where the Common Rule does apply, it contemplates the protection of privacy of participants in research studies. The relevant section of the Common Rule states:

In order to approve research covered by this policy, the IRB shall determine that... [w]hen appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.²³⁴

In addition, the Common Rule mandates that subjects receive “[a] statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained[.]”²³⁵ Further, if asked, researchers should be able to explain to the subjects how their information will be protected.²³⁶

To ensure potential research participants are informed adequately about the risks and benefits of taking part in genetic clinical studies, researchers must obtain participants’ informed consent.²³⁷ The basic components of this process include disclosing the study’s purpose, the benefits as well as the risks, and the roles of the participants in the study.²³⁸ See the earlier section, *Informed consent of research subjects*, on pages 24 and 25, for a discussion of related manufacturer liabilities.

As discussed above, clinical studies, especially human genetic research studies, based on homogenous samplings will be biased in their applicability if race and ethnicity are not taken into consideration.²³⁹ Bias occurs in many clinical studies, partially because many racial or ethnic minorities do not wish or are not asked to participate as research subjects. If racial or ethnic minorities do participate, researchers must be sensitive to issues that may arise if minority participants may not understand the purpose or potential risks and benefits involved in research, whether due to cross-cultural issues, low literacy rates, lack of access to healthcare, lack of education, or other factors.²⁴⁰

234 45 C.F.R. § 46.111(a), (a)(7).

235 *Id.* § 46.116(a)(5).

236 *Id.*

237 Nat’l Human Genome Research Inst., *Informed Consent*, www.genome.gov/10002332 (last visited Sept. 28, 2008).

238 Christen Brownlee, Johns Hopkins Med. Insts., *Study Into Informed Consent for Clinical Trials*, *MED. NEWS TODAY*, Jan. 14, 2008, www.medicalnewstoday.com/articles/93839.php (last visited Sept. 26, 2008).

239 Kjersti Aagaard-Tillery et al., *Sample Bias Among Women with Retained DNA Samples for Future Genetic Studies*, 1 *OBSTETRICS & GYNECOLOGY* 1115, 1116 (2006). See also *Patient-Tailored Medicine, Part One*, and the earlier discussion of the role of the Food and Drug Administration.

240 See Gordon Gong et al., *Ethical, Legal and Social Issues of Genetic Studies with African Immigrants as Research Subjects*, 100 *J. NAT’L MED. ASS’N* 1073, 1076 (2008).

The HIPAA Privacy Rule and research

The HIPAA Privacy Rule was not adopted either to encourage or discourage research.²⁴¹ The Privacy Rule strives “to strike a balance by minimizing the privacy risks of research participants, while not impeding the conduct of vital national and international research.”²⁴²

The advancement of medical knowledge through research requires access to medical information.²⁴³ In accordance with the Common Rule, research protocols and consent forms must be reviewed by an institutional review board (IRB).²⁴⁴ Researchers must receive authorization to obtain medical records for each individual genetic research project; however, because authorizations cannot be re-used, a new consent to use medical records must be obtained for each project.²⁴⁵ The HIPAA Privacy Rules provide that valid written authorizations to release PHI must include:

- (i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
- (ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
- (iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
- (iv) A description of each purpose of the requested use or disclosure. The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
- (v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement “end of the research study,” “none,” or similar language is sufficient if the authorization is for a use or disclosure of protected

241 *Judging the New Federal Regulations*, at 216.

242 Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 14,775, 14,793 (Mar. 27, 2002) (to be codified at 45 C.F.R. pts. 160, 164).

243 Jennifer Kulynych & David Korn, *Use and Disclosure of Health Information in Genetic Research: Weighing the Impact of the New Federal Medical Privacy Rule*, 28 AM. J.L. & MED. 309, 310 (2002) (citing Amitai Etzioni, *THE LIMITS OF PRIVACY* 152 (1999)).

244 45 C.F.R. § 46; *Judging the New Federal Regulations*, at 216–17 (2002).

245 45 C.F.R. § 46; Lynn S. Muller & Dominick L. Flarey, *Genetic Research Implications*, 9 LIPPINCOTT'S CASE MGMT. 45 (2004).

health information for research, including for the creation and maintenance of a research database or research repository.

- (vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.²⁴⁶

Sharing information between researchers

Anecdotal evidence suggests that the HIPAA Privacy Rule impedes sharing of information between researchers. For instance, in a Johns Hopkins genetics study on prostate cancer covering 14 institutions, the institutions refused to combine data into a centralized database of genetic data for family members. Such a database could have been used to search for cancer susceptibility genes across hospitals, but in refusing to do so, the hospitals cited HIPAA Privacy Rule concerns.²⁴⁷ Instead, each institution conducts its own analysis and shares a summary with the other researchers.²⁴⁸ In such situations, each institution makes its own decision whether to participate—HIPAA is the floor of protection.

In any case, researchers must inform their subjects about opportunities to share genetic information among researchers, and must explain the risks and benefits from their participation.²⁴⁹ In addition, study participants must be given the opportunity to refuse participation in the research.²⁵⁰

Conclusion

Although personalized medicine is an exciting new phenomenon that has the potential of revolutionizing medicine in the coming years, there are many obstacles.²⁵¹ In the present regulatory, healthcare industry, and societal climate, clinical trials for drug safety and effectiveness often fail to include minority participants. As a result, much remains unknown about the way in which an individual of a particular race, ethnic background, or genotype will react to certain medications. There is a longstanding need in America to remedy disparities

246 45 C.F.R. § 164.508(c)(1)(i)–(vi).

247 Jocelyn Kaiser, *Privacy Rule Creates Bottleneck for U.S. Biomedical Researchers*, 305 Sci. 168, 169 (2004).

248 *Id.*

249 Amy L. McGuire & Richard A. Gibbs, *Meeting the Growing Demands of Genetic Research*, 34 J. L. MED. & ETHICS 809 (2006).

250 *Id.*

251 *Promise of Personalized Medicine*.

in healthcare access for minorities. As a corollary, there is a compelling moral and ethical argument that race-based therapies must be protected by the courts from excessive legal burdens so that the United States can achieve greater equality in the healthcare system by fostering the growth of both new and existing race-based therapies.

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