

PHARMACOGENOMICS AND THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008: LEGISLATION LIMITATIONS AND ITS IMPACT ON PG_x RESEARCH AND CLINICAL OPPORTUNITY

I. INTRODUCTION

Pharmacogenomics (“PG_x”) can be defined as “a science that examines the inherited variations in genes that dictate drug response and explores the ways these variations can be used to predict whether a patient will have a good response to a drug, a bad response to a drug, or no response at all.”¹ To be most effective, PG_x research requires a large population sample with diverse racial, ethnic, and genetic backgrounds.² However, genetic discrimination has become the most commonly cited reason for individuals to forgo voluntary research.³ Through the Genetic Information Nondiscrimination Act of 2008 (“GINA”), Congress has attempted to alleviate this fear by providing a federal law that bans genetic discrimination by employers and insurance companies.⁴

However, the goal of increasing voluntary participation in PG_x research may never fully come to fruition because a lack of research participation likely reaches far beyond the fear of genetic discrimination. Numerous other psychological and social risks, including fears of interference with

1. National Center for Biotechnology Information, Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, <http://www.ncbi.nlm.nih.gov/About/primer/pharm.html> (last visited Mar. 17, 2010).

2. See Gail Henderson et al., *Great Expectations: Views of Genetic Research Participants Regarding Current and Future Genetic Studies*, 10 *GENETICS MED.* 193, 193 (2008).

3. See MICHELE SCHOONMAKER & ERIN D. WILLIAMS, *GENETIC TESTING: SCIENTIFIC BACKGROUND AND NONDISCRIMINATION LEGISLATION* 24 (2006) (noting that “fear caused by the possibility that a job may be lost or insurance may be cancelled—whether real or perceived—is the primary reason individuals refrain from seeking what could be a beneficial genetic test in clinical or research settings”); see generally Genetic Information Nondiscrimination Act of 2008 (GINA), Pub. L. No. 110–223, § 2, 122 Stat. 881 (2008) (to be codified in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.). Congress enacted GINA after being informed about cases of genetic discrimination. GINA, 122 Stat. at 882–83.

4. See generally GINA, 122 Stat. at 881–921. GINA provides uniform federal legislation that establishes basic standards aimed “to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies.” GINA §2, 122 Stat. at 882–83.

familial relationships,⁵ concerns that the individual is better off not knowing the results of the genetic test,⁶ and distrust towards medical research may dissuade individuals from participating in research and clinical opportunities.⁷

While GINA has taken a substantial step forward in protecting individuals from genetic discrimination, and thus calming some of the American public's fears, PGx research will only reach its full potential when other risks are clearly identified and addressed through public education and public participation in the decision-making processes.⁸ For minority participants, community involvement that promotes "engagement, dialogue, and feedback" is one approach to better understand the barriers that influence minority participation in genetic research.⁹ Beyond the protections ensured by GINA, these community programs may also help to advance the emerging scientific field of PGx.

Sections II and III of this comment focus on the science and underlying technology of PGx research, as well as its future goals. These sections also identify several current clinical uses of PGx technology and discuss hurdles PGx faces in the coming years. Section IV discusses the importance of including minority populations in PGx research populations and the controversy surrounding race as a biological classification. Section V illustrates current obstacles of PGx research, including specific instances of genetic discrimination, while section VI addresses failed legislative efforts at combating discrimination. Next, section VII describes pertinent provisions of GINA, the most recent non-discrimination effort. Section VIII analyzes the numerous limitations of GINA, including the legislature's failure to address other obstacles to genetic research participation, especially among minority populations. Finally, section IX explains approaches to addressing the others barriers of genetic and clinical research, all of which share the goal of increasing minority research participation.

This comment attempts to answer two central issues surrounding PGx: First, how does GINA help further the goals of PGx and how is the legislation limited in clinical practice? Second, beyond GINA, what other barriers to genetic research need to be addressed so that the future of PGx can continue to develop in research and clinical application?

5. See SCHOONMAKER & WILLIAMS, *supra* note 3, at 23-24 (noting that, for example, some family members may not want to know the results of paternity tests).

6. See Henderson et al., *supra* note 2, at 196.

7. Barbara A. Noah, *The Participation of Underrepresented Minorities in Clinical Research*, 29 AM. J.L. & MED. 221, 229-31 (2003).

8. See Paul Slovic, *Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield*, 1997 U. CHI. LEGAL F. 59, 95-96 (1997).

9. See Giselle Corbie-Smith et al., *Distrust, Race, and Research*, 162 ARCHIVES INTERNAL MED. 2458, 2462 (2002).

II. PHARMACOGENOMICS: HISTORY AND BASIC SCIENCE

PGx aims to “identify and quantify the association between variations in DNA sequence and variations in the drug response phenotype (i.e. the ‘genotype-phenotype correlation’).”¹⁰ The study of PGx merges the fields of pharmacology, genetics, and human genomics.¹¹ The research goals of PGx are focused on defining drug absorption, drug safety, and drug efficacy for a particular genotype in order to move from the current “one size fits all” standard for prescription drugs, to a more precise “personalized drug” standard.¹² In doing so, the pharmaceutical industry hopes to reduce, if not eliminate, adverse drug reactions (“ADRs”).¹³

The underlying science of PGx, although relatively new to most physicians and patients, has been studied since the early 1900s.¹⁴ In 1902, Archibald Garrod theorized that alcaptonuria was caused by a genetic variation in the metabolic pathway that broke down toxic substances in the body.¹⁵ Later, during World War II, specific drug reactions based on inherited genetic variations were recorded for the first time.¹⁶ Then in 1959 the term “pharmacogenetics” was first used by Fredrich Vogel.¹⁷ Even though the two terms are sometimes used interchangeably in the literature, “*pharmacogenetics* is generally recognized as the study of how individual genetic differences affect drug response [whereas] *pharmacogenomics* encompasses the role of the whole genome in pharmacology and drug design.”¹⁸

10. DEP’T OF HEALTH & HUMAN SERV., SECRETARY’S ADVISORY COMM. ON GENETICS, HEALTH, & SOCIETY, REALIZING THE POTENTIAL OF PHARMACOGENOMICS: OPPORTUNITIES AND CHALLENGES 14 (2008) [hereinafter HHS].

11. *Id.* at 9.

12. O. P. Corrigan, *Pharmacogenetics, Ethical Issues: Review of the Nuffield Council on Bioethics Report*, 31 J. MED. ETHICS 144, 144–45 (2005). See also Lawrence J. Lesko et al., *Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision Making: Report of the First FDA-PWG-PhRMA-DruSafe Workshop*, 43 J. CLINICAL PHARMACOLOGY 342, 343 (2003).

13. Corrigan, *supra* note 12, at 145.

14. See Berrie Rebecca Goldman, *Pharmacogenomics: Privacy in the Era of Personalized Medicine*, 4 NW. J. TECH. & INTELL. PROP. 83, 85 (2005).

15. Penelope K. Manasco & Teresa E. Arledge, *Drug Development Strategies*, in PHARMACOGENOMICS: SOCIAL, ETHICAL, AND CLINICAL DIMENSIONS 83, 89 (Mark A. Rothstein ed., 2003).

16. See Goldman, *supra* note 14, at 86 (noting that during World War II, some soldiers who were treated with an anti-malarial medication developed anemia due to an underlying genetic deficiency of the glucose-6-phosphate dehydrogenase enzyme).

17. Barbara Ann Binzak, *How Pharmacogenomics Will Impact the Federal Regulation of Clinical Trial and the New Drug Approval Process*, 58 FOOD & DRUG L.J. 103, 104 (2003).

18. HHS, *supra* note 10, at 9. Pharmacogenomics can be further defined as “the study of how individual genetic differences affect drug response . . . This definition encompasses

Today, the Human Genome Project ("HGP"), spearheaded by the Department of Energy ("DOE") and the National Institutes of Health ("NIH"), has helped advance the field of PGx through the identification of approximately 25,000 genes in human DNA.¹⁹ "More than 1.4 million single-nucleotide polymorphisms [SNPs] were identified in the initial sequencing of the human genome, with over 60,000 of them in the coding region of genes."²⁰ Individualized PGx information is gathered through comparing an individual's single nucleotide sequence to the nucleotide sequence that was discovered from the HGP to see if the DNA "matches" the normal sequence.²¹ Because SNPs may affect drug-metabolizing enzymes, understanding SNPs will be an important tool in predicting an individual's response to certain medications.²² The ultimate aim is that physicians will use an individual's genotype to determine which drugs and dosages have been shown to be safe and effective through clinical drug trials that utilized PGx data.²³ Likewise, those individuals without the requisite genotype will be able to forgo unnecessary and possibly unsafe treatment.²⁴ PGx aims to bring previously rejected drugs into the market place by making them safe for a genetically targeted population,²⁵ and also to introduce newly formulated drugs that target specific genotypes.²⁶ Therefore, PGx will change the pharmaceutical industry's approaches to drug development, clinical trials, and marketing.²⁷ In return, it is predicted

interindividual genetic differences such as variation in [DNA] sequence, gene expression, and copy number related to an individual's metabolism of drugs (pharmacokinetics) or . . . physiological response to drugs (pharmacodynamics)." *Id.* at 9-10. For the purpose of this comment, pharmacogenomics and pharmacogenetics are used interchangeably and denoted by the short-form PGx.

19. Binzak, *supra* note 17, at 109; William E. Evans & Howard L. McLeod, *Pharmacogenomics—Drug Disposition, Drug Targets, and Side Effects*, 348 *NEW ENG. J. MED.* 538, 538 (2003).

20. Evans & McLeod, *supra* note 19, at 538. See also Binzak, *supra* note 17, at 109.

21. See Binzak, *supra* note 17, at 109.

22. *Id.* at 110.

23. Teresa Kelton, *Pharmacogenomics: The Rediscovery of the Concept of Tailored Drug Therapy and Personalized Medicine*, *HEALTH LAW.*, Jan. 2007, at 1, 3.

24. *Id.*

25. Alan Dove, *Pharmacogenomics Regulations Take Flight*, *DRUG DISCOVERY & DEV.*, Jan. 2006, at 40, 41.

26. See HHS, *supra* note 10, at 28.

27. See Binzak, *supra* note 17, at 113 (discussing that PGx will change the pharmaceutical industry by allowing companies to identify a new drug compound that will interact with a person based on genotype, "saving" drugs that had previously been rejected by the FDA, using diagnostic tests in drug trials for drugs that have already been approved, and performing follow-up trials on specific subpopulations as ADRs are reported).

that PGx could save the industry \$300 million a year and each drug will take two fewer years to develop.²⁸

III. CLINICAL DRUG DEVELOPMENT, PGX RESEARCH, AND CLINICAL OPPORTUNITY

Currently, physicians engage in a “trial and error” approach when determining what drugs to prescribe to their patients.²⁹ The goal is always to find a safe and effective drug; however this goal may be thwarted by side effects and ADRs.³⁰ “Although ADRs can result from a variety of factors, genetic variations of drug-metabolizing enzymes have been highly correlated with ADRs in some instances.”³¹ ADRs pose extreme risks to patients; more than two million serious adverse events occur each year, resulting in more than 135,000 deaths.³² Patients that are hospitalized due to ADRs face an average of 1.7–2.2 days in the hospital and between \$2,000 and \$2,600 in medical care costs.³³ Further, ADRs are the primary reason medications are withdrawn from the market.³⁴

The trial-and-error approach also causes physicians to prescribe an estimated three million incorrect or ineffective medications every year.³⁵ Currently, there is no trial and error drug that is 100 percent safe and effective for use with 100 percent of the population. Partially as a result of ineffectiveness, patients with chronic conditions, for example, often do not follow through with their medication treatment.³⁶

The first step in attempting to curtail the trial and error approach of prescribing medication is to gather PGx data for clinical drug trial participants. During Phase I trials, a small population of healthy individuals are studied to identify their tolerability to investigative drugs, which helps determine associated ADRs and how drugs should be dosed.³⁷ Next, Phase II trials include several hundred to a thousand subjects who have the disease that the investigative drug seeks to treat.³⁸ During this phase, PGx data can be used to identify a correlation between the safety and efficacy of the drug

28. *Id.*

29. Kelton, *supra* note 23, at 1.

30. *Id.*

31. See HHS, *supra* note 10, at 11; see also Biznak, *supra* note 17, at 110 (noting that CYP3A, a drug metabolizing enzyme, is involved in the breakdown of up to fifty percent of clinically therapeutic agents).

32. Kelton, *supra* note 23, at 6.

33. *Id.*

34. HHS, *supra* note 10, at 11.

35. *Id.*

36. *Id.*, at 12-13 (noting that “[h]alf of patients with chronic health conditions discontinue their medications after 1 year”).

37. See Manasco & Arledge, *supra* note 15, at 89.

38. *Id.* at 90.

and the genotypic variations that may explain ineffective or unsafe reactions.³⁹ Further, this type of PGx data can later be used to develop commercial tests that identify the variation in patients.⁴⁰ Finally, during Phase III trials, PGx data can be used to identify more stringent inclusion and exclusion participation criteria.⁴¹ This hopefully will reduce the population size, make the trial more effective (because all of the participants will or will not have the particular genetic variation that reacts with the drug), and decrease research costs. Drugs developed with PGx data will not be 100 percent effective, nor will they have zero incidence of ADRs. However, PGx drugs will be marketed specifically to those patients who have the genotype that reacts to the particular drug, and in doing so, will presumably make drugs on the market more safe and effective.

With regard to drug labeling, by using drug labels to warn patients of risks to specific genotypes and by requiring genetic tests prior to drug treatment, pharmaceutical companies may be able to reduce their liability and avoid lawsuits.⁴² This seems practical given the relative ease of SNP genotyping.⁴³ However, the most recent data indicates that only 121 drug labels (out of 1200 drug labels reviewed) contained pharmacogenomic information.⁴⁴ Even though PGx data is available for seventy-one percent of the top 200 prescribed drugs, only three actually contain package inserts.⁴⁵ Federal law requires that certain information should be included in the indications and usage section of the drug label “[i]f evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population . . .”⁴⁶ or “[i]f specific tests are [needed] for

39. *Id.*

40. *Id.* at 91.

41. *See id.*

42. *See, e.g.,* Binzak, *supra* note 17, at 107 (discussing lawsuits brought against SmithKline Beecham claiming that LYMERix vaccine should have been labeled to indicate a possible ADR for people with the HLA-DR4+ genotype).

43. *See* David J. Wu, *A Pharmacogenomics Standard for FDA Drug Approval: Arbitrary and Capricious or Safe and Effective?*, 23 BIOTECH. L. REP. 733, 738 (2004) (stating an individual’s genotype, and thus any variant SNP, can be determined within “minutes rather than hours or days”).

44. *See* Felix W. Frueh et al., *Pharmacogenomic Biomarker Information in Drug Labels Approved by the United States Food and Drug Administration: Prevalence of Related Drug Use*, 28 PHARMACOTHERAPY 992, 994 (2008).

45. HHS, *supra* note 10, at 76 (citing Issam Zineh et al., *Discordance Between Availability of Pharmacogenetics Studies and Pharmacogenetics-Based Prescribing Information for the Top 200 Drugs*, 40 ANNALS PHARMACOTHERAPY 639, 639 (2006) (stating that “pharmacogenetics data are available in only about 2% of all drug package inserts (PIs) and that less than 1% of PIs have pharmacogenetics data sufficient to guide therapy”).

46. 21 C.F.R. § 201.57(c)(3)(i) (2006).

selection or monitoring of the patients who need the drug."⁴⁷ Undoubtedly, this may include data gathered through PGx research.

Recently, the FDA approved Herceptin®, making it the first drug to be approved based upon PGx data.⁴⁸ It was approved for patients with breast cancer who over-express the HER-2/neu protein.⁴⁹ The label now advises patients to undergo a genetic test prior to taking the medication, "HERCEPTIN should only be used in patients whose tumors have HER2 protein overexpression [sic]."⁵⁰ Ideally, through PGx data, researchers will be able to specifically pinpoint the type of genotypic variations that cause some types of ADRs, and address them on the drug label.

The clinical applications of PGx research in diagnostic testing have thus far been limited.⁵¹

The decision of whether a pharmacogenetic and pharmacogenomic test is necessary prior to dosing will be dependent on many factors, including the following: (1) if safety, the seriousness of the adverse event; (2) if efficacy, the consequences of nonresponse; (3) the incidence of the clinical outcome; (4) the variability in the clearance of the drug; (5) how well an adverse event can be managed . . . (6) need for education of physicians and third-party payers; and (7) feasibility of accessing and using the test in clinical practice.⁵²

Regardless of clinical applications, research on Cytochrome p450 ("CYP450") has already proven to be important.⁵³ CYP450 is a protein that metabolizes more than twenty-five percent of all prescription drugs.⁵⁴ Mutations in the CYP450 genes cause certain drugs to metabolize at drastically different rates.⁵⁵ This results in a less effective and more dangerous drug because some patients will not be able to eliminate the medication, which may become toxic to the body.⁵⁶ On the other hand, if drugs are eliminated from the body too quickly they may not have any physiological response. Consequently, in 2004, the AmpliChip®

47. 21 C.F.R. § 201.57.

48. Kelton, *supra* note 23, at 5.

49. GENENTECH, INC., HERCEPTIN® (2000) (package insert), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm092760.pdf>.

50. *Id.*

51. See HHS, *supra* note 10, at 17.

52. See Lesko, *supra* note 12, at 351.

53. See HHS, *supra* note 10, at 11.

54. See Kelton, *supra* note 23, at 5.

55. *Id.*

56. See Yusuke Nakamura, *Pharmacogenomics and Drug Toxicity*, 359 NEW ENG. J. MED. 856, 857 (2008); Kelton, *supra* note 23, at 5.

Cytochrome p450 Genotyping Screening Test was designed.⁵⁷ The test detects mutations in two CYP450 genes⁵⁸ allowing a physician to determine the right drug dose for the patient based on how the patient's body expresses CYP450.⁵⁹ Over half of all drug labels available with PGx data reference CYP2D6 or CYP2C19.⁶⁰

Particularly, the CYP2D6 enzyme is involved in metabolizing seventy-five percent of all psychotropic drugs.⁶¹ One such drug, risperidone, is poorly metabolized in seven percent of Caucasians and one to two percent of other races.⁶² Such a deficiency, if gone unidentified, can cause severe ADRs.⁶³ An example of this reaction is found in the case of Michael Conroy-Adams, a nine-year old boy who was prescribed Prozac.⁶⁴ Michael had a genetic variation on the CYP2D6 receptor that caused his body to metabolize the drug slowly.⁶⁵ Sadly, this led to a fatal accumulation of toxic substances in his body.⁶⁶ If a genetic test had been done prior to his prescription, instead of during an autopsy, the variant may have been discovered and Michael may still be alive.

Similarly, the CYP2C19 enzyme metabolizes warfarin, a drug prescribed for people at risk for blood clots that works by blocking the Vitamin K pathway.⁶⁷ Individuals whose genotypes are homozygous for the *3 allele of the gene are slow metabolizers of warfarin and do not clear the drug properly.⁶⁸ This results in a toxic buildup of the drug that can lead to an ADR.⁶⁹ Therefore, the identification of the CYP450 gene, its variants, and its associated SNPs, make it clear that genetic tests developed through PGx research can be life-saving.

57. *Id.*

58. *Id.*

59. See generally Wu, *supra* note 43, at 745 (arguing that FDA should require mandatory genetic testing and data submission for CYP450 genes because they are highly polymorphic and metabolize a large percentage of drugs at possibly different rates).

60. See Frueh, *supra* note 44, at 995.

61. See John Bray et al., 15 J. PSYCHIATRIC & MENTAL HEALTH NURSING 357, 358 (2008). CYP450 enzymes are also responsible for metabolizing Adderall®, Coreg®, Effexor®, Inderal®, Paxil®, Prozac®, Strattera®, Toprol®, Tussionex®, and Zofran®. HHS, *supra* note 10, at 11.

62. See Bray, *supra* note 61, at 358.

63. *Id.*

64. Wu, *supra* note 43, at 733.

65. *Id.*

66. *Id.*

67. See Evgeny Krynetskiy & Patrick McDonnell, *Building Individualized Medicine: Prevention of Adverse Reactions to Warfarin Therapy*, 322 J. PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS 427, 428 (2007).

68. HHS, *supra* note 10, at 15.

69. See Krynetskiy & McDonnell, *supra* note 67, at 428.

Another current application of PGx concerns a genetic test that determines whether or not patients have an inherited variation in the enzyme thiopurine methyltransferase ("TPMT") which metabolizes a drug used to treat acute lymphoblastic leukemia in children.⁷⁰ Children who have a germline variation do not metabolize the drug as quickly or effectively as those without the variation.⁷¹ This results in toxic levels of the drug in the bloodstream, inevitably leading to destruction of bone marrow and possibly death.⁷² When children are tested for the TPMT variation, their physicians can better determine the appropriate course of treatment, type of drug, and necessary dosage. Such a test will hopefully result in less pain and suffering for children with acute lymphoblastic leukemia.

The FDA may be partially to blame for the low utilization of PGx research and application. The FDA issued guidance documents for submitting PGx data in investigational new drug applications ("INDs") in March, 2005.⁷³ These guidance documents amount to nothing more than suggestions for the pharmaceutical industry to follow, and as such, are completely voluntary.⁷⁴ If the FDA made PGx data a requirement rather than a recommendation, the pharmaceutical industry would have no choice but to include PGx research in clinical drug trials.⁷⁵ Indirectly, the requirements may result in package inserts, drug labels, and diagnostic genetic tests indicating safety and efficacy based on PGx data. In this regard, some argue that the FDA is not doing enough to keep patients safe even though it possesses the authority to do so.⁷⁶

IV. PGx AND MINORITY POPULATIONS

Throughout drug development, PGx data will be useful in defining the precise genotypes that are likely to respond to specific drugs in a certain way.⁷⁷ Because genetic SNPs can vary between racial groups, a widely diverse population sample during clinical drug trials will be necessary to realize the full potential of PGx.⁷⁸ As discussed with the CYP2D6 enzyme,

70. HHS, *supra* note 10, at 14.

71. *Id.* at 14-15.

72. *Id.*

73. DEP'T OF HEALTH & HUMAN SERV., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: PHARMACOGENOMIC DATA (2005), <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126957.pdf>.

74. *Id.* at 1.

75. See Dove, *supra* note 25, at 42.

76. See Wu, *supra* note 43, at 734.

77. HHS, *supra* note 10, at 23.

78. See Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J.L. MED. & ETHICS 491, 492 (2008) (discussing that genetic variants which appear at a frequency of less than twenty percent in a racial group are likely to

the way in which individuals metabolize a drug can differ widely between racial and ethnic subpopulations, thus affecting drug safety and efficacy.⁷⁹ Since genotypic variation exists between racially and ethnically diverse populations, gathering enough research data to implement population-wide application poses a significant hurdle to PGx research and its application.

BiDil® is a modern example of PGx research benefitting a racially diverse population. BiDil, patented and marketed by NitroMed, was approved by the FDA in 2005 to treat heart disease in African Americans.⁸⁰ BiDil has been in existence in one form or another since 1980, when trials were first conducted on the drug.⁸¹ The drug's medical use was largely discovered by the African-American Heart Failure Trial (A-HeFT), which enrolled 1,050 self-identified African-American participants.⁸² The trial found that the placebo group showed a higher rate of mortality and a lower quality of life.⁸³ BiDil was shown to reduce death rates in heart failure patients by forty-three percent.⁸⁴ Based on this data, NitroMed ended the trial early because it was determined it would be unethical to continue

be contained within that group; Africans have several low-frequency genetic variants and thus, genetic variants are common and contained within the group).

79. See Bray, *supra* note 61, at 358 (discussing that the incidence of poor metabolism of CYP2C19 ranges from fifteen to one hundred percent in certain Asian subgroups and only three to six percent in Caucasians); Vural Ozdemir et al., *Race as a Variable in Pharmacogenomics Science: From Empirical Ethics to Publication Standards*, 18 PHARMACOGENETICS & GENOMICS 837, 837 (2008) (discussing that there is an "unequal distribution of disease-associated alleles for certain recessive disorders such as Tay-Sachs disease and sickle cell anemia among racially defined populations"); HHS, *supra* note 10, at 46 (discussing a Washington, D.C. area study that found two percent of Ashkenazi Jews in the area carried mutations in their BRCA 1 and BRCA 2 genes, conferring an increased risk of breast and ovarian cancer by age 70).

80. Obasogie, *supra* note 78, at 493. See also Stephanie Saul, *F.D.A. Approves a Heart Drug for African Americans*, N.Y. TIMES, June 24, 2005 (discussing that BiDil is thought to work by increasing levels of nitric oxide in the body, which is more often deficient in African Americans, thereby relaxing blood vessels and making it easier for the heart to pump blood), available at www.nytimes.com/2005/06/24/health/24drugs.html?_r=1&scp=1&sq=F.D.A..%20Approves%20a%20Heart%20Drug%20for%20African%20Americans&st=cse.

81. See generally Sharon Hoffmann, "Racially-Tailored" Medicine Unraveled, 55 AM. U. L. REV. 395, 400-01 (2005-06). BiDil consists of a combination of two drugs, hydralazine and isosorbide dinitrate. *Id.* at 400. The first studies on the drugs ran from 1980 to 1991 during the Vasodilator Heart Failure Trials. *Id.* at 401. The trials included black and white participants but did not report racial distinctions in drug response rates. *Id.*

82. Obasogie, *supra* note 78, at 493.

83. *Id.*

84. See Saul, *supra* note 80.

giving the control group a placebo while the other group was benefitting substantially from the drug.⁸⁵

“Race-based medicine,” as it has become known, is not without controversy.⁸⁶ Some social scientists denounce the use of race as a factor for genetic based research. They argue that race-based research lends itself to race stigmatization, stereotyping, and more racial disparity, over forty years after the Civil Rights movement.⁸⁷ Race-based medicines are controversial, with BiDil serving as a prime example.⁸⁸ Generally, critics are concerned that pharmaceutical companies and researchers will begin to use race as a substitute for genotyping and that race will be used as a genetically-based categorization.⁸⁹ Critics argue that such categorization is unfair. “Race, at the continental level, has not been shown to provide a useful categorization of genetic information about the response to drugs, diagnosis, or causes of disease.”⁹⁰ However, as the approval of BiDil has shown, race-based medicine has advantages and therefore needs research participant support in order to further understand genetic differences among races. The effect of such *genetic* research on various races and ethnicities may ensure that medical therapy and PGx will better suit the general population.⁹¹

V. OBSTACLES: CONSENT, PRIVACY, AND GENETIC DISCRIMINATION

PGx faces numerous obstacles in the years and decades that lie ahead. When participants engage in PGx research, they effectively give permission for their genetic information to be used in numerous ways, some of which

85. See Andrew Pollack, *Drug Approved for Heart Failure in Black Patients*, N.Y. TIMES, July 20, 2004, at C1.

86. See Obasogie, *supra* note 78, at 491 (noting that there is a “heated debate in scientific and bioethical communities over when and how race should be used in biomedical research”).

87. See generally Dorothy E. Roberts, *Is Race-Based Medicine Good for Us?: African American Approaches to Race, Biomedicine, and Equality*, 36 J.L. MED. & ETHICS 537, 537 (noting that there are several different approaches to race-based medicine).

88. See generally Hoffman, *supra* note 81, at 405-06 (discussing that critics of BiDil argue that the trial results are not significant because the treatment combination was only studied in self-identified African Americans, and therefore it would be erroneous to conclude that the treatment is effective only in that population).

89. See Saul, *supra* note 80.

90. Richard S. Cooper et al., *Race and Genomics*, 348 NEW ENG. J. MED. 1166, 1168 (2003).

91. See Alastair J.J. Wood, *Racial Differences in the Response to Drugs—Pointers to Genetic Differences*, 344 NEW ENG. J. MED. 1393, 1394-95 (2001) (arguing that genetic differences among racial groups support the use of race-based genetics in medical research and drug therapy).

are not known at the time of consent.⁹² The patient/participant, as with any medical procedure, must give complete informed consent without coercion.⁹³ However, when PGx testing is required for treatment, patients may believe that they have to submit their genetic fingerprint in order to have their medical needs met.⁹⁴ Consenting to genetic research has the potential to forever link participants to the results of the research by way of their genetic profiles. Because people can be easily identified by only a few SNPs, privacy is a continuous issue.⁹⁵ Consent and privacy are implicated even further when a genotyping test implies a risk for future disease, which may lead to unintended consequences, such as stigmatization for the patient and his or her family.⁹⁶

Another commonly cited hurdle to reaching the full potential of PGx is the fear that patients' genetic information will be misused.⁹⁷ Patients may fear that if a genotyping test reveals a genetic disease, they or their family members will be discriminated against by insurance companies and employers.⁹⁸ The effect could be a reluctance to submit to PGx clinical research for drug development and treatment. Historically, some form of genetic discrimination has occurred in the United States since at least the early 1900's. During this time, states enacted laws requiring people with physical and mental handicaps to undergo sterilization so that they were not able to reproduce.⁹⁹ Indiana was the first state to do so in 1907.¹⁰⁰ While states have since enacted laws abolishing and repealing state sterilization laws,¹⁰¹ perceived and actual genetic discrimination persists.

Today, genetic discrimination occurs primarily with employment and medical insurance. For employers, the rationale for such discrimination is simple; not hiring, firing, or not promoting a person with a genetic predisposition to a disease reduces labor and medical expenses.¹⁰²

92. See Corrigan, *supra* note 12, at 146 (noting that patients agree to the participating in the clinical drug trial, a genetic test pertaining to the drug effect, and other genetic tests to be used in future PGx studies).

93. See *id.*

94. See HHS, *supra* note 10, at 42.

95. *Id.* at 41.

96. Wu, *supra* note 43, at 745. See GINA, Pub. L. No. 110-223, § 2, 122 Stat. 881, 882 (2008) (discussing how state-imposed mandatory testing of African Americans for sickle cell disease in the 1970s led to discrimination and fear).

97. GINA § 2, 122 Stat. at 881-82.

98. See Goldman, *supra* note 14, at 83.

99. See GINA § 2, 122 Stat. at 882.

100. GINA § 2, 122 Stat. at 882.

101. GINA § 2, 122 Stat. at 882.

102. See COUNCIL FOR RESPONSIBLE GENETICS, GENETIC DISCRIMINATION: POSITION PAPER (2001) [hereinafter CRG], <http://www.councilforresponsiblegenetics.org/pageDocuments/2R-SW5M2HJ2.pdf>.

Specifically, if the employee becomes sick, he or she is likely to be less productive, absent from work more often, and have higher insurance costs.¹⁰³ Similarly, the insurance industry operates on reducing risk in order to lower benefit payments.¹⁰⁴ Naturally, reducing the number of insureds who have a greater chance of becoming sick in the future is a way for the insurance industry to meet this goal.¹⁰⁵

Americans seem to understand the positive future impact of genetic testing, and particularly, PGx. In 2007, the Genetics and Public Policy Center at John Hopkins University completed a survey highlighting Americans' attitudes toward genetic testing.¹⁰⁶ The survey found that "more than 90 percent support the use of genetic testing by researchers to find new ways to diagnose, prevent or treat diseases."¹⁰⁷ Further, "more than 90 percent of Americans support the use of genetic testing by doctors to identify a person's risk for future disease when there are treatments or medicines available, or to determine the risk of having a bad reaction to a particular medicine."¹⁰⁸ However, eighty-one percent oppose the use of genetic testing by employers "to make decisions about hiring and promotion" and eighty-five percent oppose the use of genetic testing by health insurers "to determine who [sic] to insure or how much to charge."¹⁰⁹ These statements reflect the fear that information can be used adversely by employers and insurance companies, which may result in a decision to forego participating in genetic research and testing.¹¹⁰

Despite assertions that genetic discrimination does not occur, others argue it is a reality and is significantly underreported due, in part, to low utilization of genetic testing, fear of adverse insurance and employment actions, and privacy concerns.¹¹¹ The Council for Responsible Genetics has

103. *Id.*

104. *See id.*

105. *See id.*

106. *See The Genetic Nondiscrimination Act: Hearing on H.R. 493 Before the Subcomm. on Health of the H. Energy and Commerce Comm.*, 110th Cong. 3 (2007) [hereinafter *Hearing*] (testimony of Kathy Hudson, Ph.D., Director, Genetics and Public Policy Center, John Hopkins University).

107. *Id.*

108. *Id.*

109. *Id.* at 5.

110. *See* Lauren J. Sismondo, *GINA, What Could You Do for Me One Day?: The Potential of the Genetic Information Nondiscrimination Act to Protect the American Public*, 21 WASH. U. J.L. & POL'Y 459, 462 (2006) (discussing that fear of misuse of genetic information stems partially from the fact that genetic information is important to "relatives, employers, insurers, researchers, and the government").

111. *See* Karen H. Rothenberg & Sharon F. Terry, *Before It's Too Late—Addressing Fear of Genetic Information*, 297 SCIENCE 196, 196-97 (2002); *see generally* Jill Gaubling, Note, *Race, Sex, and Genetic Discrimination in Insurance: What's Fair?*, 80 CORNELL L. REV. 1646,

documented a wide range of cases of employment and insurance discrimination.¹¹² In one case, a social worker mentioned during an informal conversation at work that her mother died of Huntington's disease and that she had a fifty percent chance of developing the condition.¹¹³ One week later, the social worker was fired from her job even though her performance was well above average.¹¹⁴ With the tremendous amount of personal and sensitive information that can be determined from a genetic test, the importance of protecting patients and research subjects is irrefutable.

While no per se genetic discrimination case has been decided in the United States, several have been filed under various legal theories, and others have implicated such discrimination.¹¹⁵ In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, former employees of a government-run research institute brought a lawsuit under Title VII of the Civil Rights Act and the Americans with Disabilities Act (ADA).¹¹⁶ They alleged several violations arising from employment entrance examination requirements to submit to testing for sickle cell disease, syphilis, and pregnancy.¹¹⁷ In ruling on behalf of the former employees, the court noted that "[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up."¹¹⁸ The court went on to state that the types of information revealed from these tests were more personal than other general medical information and enjoy "the highest expectations of privacy."¹¹⁹ Specifically, the court determined that carrying the sickle cell trait has implications of family history and reproductive decisions, and may not be necessary for a routine physical examination.¹²⁰

1665-66 (1995). Gauling claims that insurers practice "fair discrimination" when they use predictive genetic tests in underwriting because it is the best indication of an insured's expected loss. *Id.* at 1665. For example, any person that tests positive for the Huntington's Disease genetic marker will develop the disease. *Id.* at 1666.

112. CRG, *supra* note 102.

113. *Id.*

114. *Id.* Other cases include: 1) A seven-year-old boy whose genetic test reveals that he has a predisposition to a heart disorder was denied insurance on the basis that the genetic condition qualifies as a preexisting condition; 2) a young boy with Fragile X Syndrome lost his insurance coverage on the basis that his disability represents a preexisting condition; and 3) a woman chose not to undergo a BRAC-1 breast cancer screening because she was afraid that it would jeopardize her chances of getting a promotion. *Id.*

115. See Sismondo, *supra* note 110, at 474-75.

116. *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1264 (9th Cir. 1998).

117. *Id.* at 1264-65.

118. *Id.* at 1269.

119. *Id.* at 1270.

120. *Id.*

Similarly, in *E.E.O.C. v. Burlington Northern and Santa Fe Railway Company*, the Equal Employment Opportunity Commission brought a lawsuit on behalf of current or former Burlington Northern employees alleging genetic discrimination under 42 U.S.C § 12112(d) and § 12203 of Title I of the ADA.¹²¹ The employees who filed suit alleged that they had been forced to submit to a blood test in order to locate a genetic marker for carpal tunnel syndrome.¹²² Further, they alleged that Burlington Northern imposed negative consequences for those employees who refused to submit to the test.¹²³ Burlington Northern agreed to settle and the court ordered that it pay up to \$1,775,000 to the employees.¹²⁴ Burlington Northern also agreed to return the genetic samples to the employees.¹²⁵ Burlington Northern's motive was possibly driven by cost; in the year that the case was filed, Burlington Northern received approximately 125 disability claims from employees for work-related carpal tunnel syndrome.¹²⁶

In addition to a claim under the ADA, the plaintiff in *Fleming v. State University of New York* also alleged a Fourteenth Amendment constitutional claim arguing genetic discrimination in violation of due process protections.¹²⁷ The plaintiff stated that he voluntarily disclosed his sickle cell disease to his supervisor after hospitalization.¹²⁸ Roughly three years later, the plaintiff applied to and was hired by Yuma Regional Medical Center ("Yuma").¹²⁹ During its credentialing process, the plaintiff claims Yuma contacted the plaintiff's supervisors who informed Yuma that the plaintiff had sickle cell disease.¹³⁰ The plaintiff claims Yuma questioned him on his health and asked why he had not disclosed the information to them directly.¹³¹ The plaintiff refused to sign an addendum to his employment contract, and he believes that such an addendum was part of constructive termination.¹³² In finding that the defendants violated the plaintiff's right to

121. *EEOC v. Burlington N. & Santa Fe Ry. Co.*, No. 02-C-0456, 2002 WL 32155386, at *1 (E.D. Wis. 2002).

122. *Id.*

123. *Id.*

124. *Id.* at *2.

125. See *id.* at *3. Burlington Northern agreed to not 1) require its current or former employees to submit to genetic testing, 2) submit previously obtained blood samples for genetic testing, 3) analyze previously obtained genetic samples, 4) use any previously obtained genetic sample, or 5) threaten or take any adverse employment actions because of the legal proceedings. *Id.* at *2-3.

126. *Sismondo*, *supra* note 110, at 475.

127. *Fleming v. State Univ. of N.Y.*, 502 F. Supp. 2d 324, 327 (E.D.N.Y. 2007).

128. *Id.* at 326.

129. *Id.* at 327.

130. *Id.*

131. *Id.*

132. *Fleming v. State Univ. of N.Y.*, 502 F. Supp. 2d 324, 327 (E.D.N.Y. 2007).

privacy under the Fourteenth Amendment, the court noted that sickle cell disease is a "serious medical condition," as it exposed the plaintiff to painful attacks and caused the death of his sister.¹³³ The court further described that knowledge of sickle cell disease "can expose an individual to intolerance," as it has invoked employment and insurance discrimination since the 1970's against sufferers and those who show a genetic predisposition to the disease.¹³⁴ As such, the court held that the plaintiff's right to privacy under the Fourteenth Amendment included the right to confidentiality with regard to his sickle cell disease.¹³⁵

Finally, in *Jones v. Inter-County Imaging Centers*, the plaintiff alleged genetic discrimination under the ADA and state human rights law.¹³⁶ There, the plaintiff claimed that his employer, defendant Inter-County Imaging Center, offered him a full-time promotion but that while he was out on sick leave for sickle cell disease, the defendant informed him that the full-time position had been filled and his previous part-time position had been eliminated.¹³⁷ The plaintiff claimed that the defendant terminated his employment because the Center did not want to continue to pay for the plaintiff's medical costs brought on by sickle cell disease.¹³⁸ While the court ultimately did not reach the issue of genetic discrimination,¹³⁹ the plaintiff's claim amounted to such an assertion.

VI. PRIOR NON-DISCRIMINATION EFFORTS

Throughout the past several decades, there have been numerous attempts to limit genetic discrimination by state and federal legislation. However, such efforts have been anything but comprehensive.¹⁴⁰ By 2008, forty-seven states had enacted laws prohibiting genetic discrimination in health insurance and thirty-five states restricted employers from adversely using the information against employees.¹⁴¹ These laws were limited, however, as they generally only prohibited underwriting for private health insurance and prohibited the use of genetic information for employment

133. *Id.* at 341 (citing *Doe v. City of N.Y.*, 15 F.3d 264, 267 (2d Cir. 1994)).

134. *Id.* at 341, 343.

135. *Id.* The court rejected the plaintiff's ADA claim on grounds that Title II did not apply to employment discrimination. *Id.* at 346.

136. *Jones v. Inter-County Imaging Ctrs.*, 889 F. Supp. 741, 742 (S.D.N.Y. 1995).

137. *Id.*

138. *Id.*

139. *Id.* at 746 (denying the defendants' motion to dismiss for failure to state a claim).

140. See *Sismondo*, *supra* note 110, at 466-67 (noting that President Clinton signed an executive order banning genetic discrimination in employment, but it only applied to federal employees).

141. Mark A. Rothstein, *Putting the Genetic Information Nondiscrimination Act in Context*, 10 *GENETICS MED.* 655, 655 (2008).

decisions.¹⁴² Currently, no state law covers genetic discrimination from employer-sponsored insurance plans,¹⁴³ which combine to provide the largest source of insurance coverage in the country.¹⁴⁴

While the majority of states have laws prohibiting genetic discrimination, they lack uniformity and “vary widely with respect to their approach, application, and level of protection.”¹⁴⁵ For example, North Carolina requires that no “entity shall deny or refuse employment to any person or discharge any person from employment on account of the person’s having requested genetic testing or counseling services, or on the basis of genetic information obtained concerning the person or a member of the person’s family.”¹⁴⁶ Presumably, under North Carolina law it would be permissible for an employer to require genetic testing as long as the information obtained is not used against the employee.¹⁴⁷ There are likely very few appropriate reasons for such a request, and at the very least, the request may amount to breach of privacy and certainly opens the door for genetic discrimination. Even more shocking, Florida has legislation that only protects people with the sickle cell trait.¹⁴⁸ Therefore, a person’s predisposition to cancer—or any other illness whatsoever—would be acceptable grounds for discrimination.

Before GINA, federal law also failed to adequately protect employees and patients from genetic discrimination. In 1996, Congress enacted the Health Insurance Portability and Accountability Act (HIPAA),¹⁴⁹ which amended many provisions of the Employee Retirement Income Security Act of 1974 (ERISA)¹⁵⁰ in order to better protect private health care information

142. *Id.*

143. See Sara Abiola, *The Genetic Information Nondiscrimination Act of 2008: “First Major Civil Rights Bill of the Century” Bars Misuse of Genetic Test Results*, 36 J.L. MED. & ETHICS 856, 857 (2008) (citing National Conference of State Legislatures, *Genetics and Health Insurance State Anti-Discrimination Laws* (2008), <http://www.ncsl.org/IssuesResearch/Health/GeneticNondiscriminationinHealthInsuranceLaws/tabid/14374/Default.aspx>).

144. Abiola, *supra* note 143, at 857 (citing Kaiser Comm’n on Medicaid & the Uninsured, *Health Insurance Coverage in America: 2004 Data Update 10* (2005)).

145. GINA, Pub. L. No. 110-223, § 2, 122 Stat. 881, 882.

146. N.C. GEN. STAT. ANN. § 95-28.1A(a) (LexisNexis 2005).

147. § 95-28.1A(a). The statute does not prohibit employers from requiring genetic testing or otherwise obtaining genetic information.

148. See Fla. Stat. Ann. § 448.075 (West 2006) (prohibiting employers from denying or terminating employment because a person has the sickle-cell trait); § 448.076 (prohibiting mandatory testing or screening for the sickle-cell trait).

149. See Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936, 1936 (1996) (codified in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.).

150. See Employee Retirement and Income Security Act of 1974, Pub. L. 93-406, 88 Stat. 829 (1974) (codified at 29 U.S.C. §§ 1001-1461).

and address genetic discrimination. HIPAA is a federal privacy law prohibiting the disclosure, and limiting the use, of confidential medical information.¹⁵¹ Before GINA, HIPAA regulations stated that “a group health plan . . . may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on . . . [g]enetic information.”¹⁵² This section failed to prohibit the requesting or requiring of genetic tests, and only applied to employer-based group health plans.¹⁵³

HIPAA also prescribes that in the absence of a current medical diagnosis, the predisposition to a disease cannot be considered a preexisting condition for the purpose of determining issues relating to medical insurance. As amended in 2006, “[g]enetic information shall not be treated as a condition . . . in the absence of a diagnosis of the condition related to such information.”¹⁵⁴ Under HIPAA, insurance companies cannot use information in genetic tests to determine eligibility or set premium prices in employer-based or group health plans.¹⁵⁵ However, genetic information could still be used to set premiums and determine eligibility for individually-purchased plans.¹⁵⁶ Further, nothing is mentioned about restrictions placed on employers.¹⁵⁷ Because the provisions of HIPAA have left looming gaps

151. See Goldman, *supra* note 14, at 93 (citing Jeffrey N. Gibbs, *State Regulation of Pharmaceutical Clinical Trials*, 59 Food & Drug L.J. 265, 266 (2004)). HIPAA is an act “[t]o . . . improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.” HIPAA, 110 Stat. 1936.

152. 29 U.S.C. § 1182(a)(1)(F) (2006).

153. See § 1191b(a)(1) (defining a “group health plan” as “an employee welfare benefit plan . . . that . . . provides medical care . . . to employees or their dependents”) (emphasis added).

154. 29 U.S.C. § 1181(b)(1)(B) (2006). Not including this specific exception for genetic information, section 1181(a)(1) states that “a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if – (1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period ending on the enrollment date.” 29 U.S.C. § 1181(a)(1).

155. § 1182(b) (prohibiting group health plans from charging any person a higher premium based on “any health status-related factor,” compared to a “similarly situated individual enrolled in the plan”).

156. Such plans fall outside the scope of the HIPAA protections discussed. See *infra* notes 169 and 172.

157. See generally 29 U.S.C. §§ 1181-82 (applying only to group health plans and “health insurance issuer[s] offering group health insurance coverage”).

in private insurance plans and employment decision regulations, the breadth of this Act does not adequately prevent genetic discrimination.

While the Americans with Disabilities Act (ADA) has been cited in genetic discrimination cases, it was not enacted for that purpose and therefore gives little protection in the workplace. The following excerpt summarizes the influence of the ADA on genetic discrimination:

The ADA states that “[n]o covered entity shall discriminate against a qualified individual with a *disability* because of the *disability* of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment.” Thus, to pursue a genetic discrimination claim under the ADA, genetic traits must fall within the ADA’s definition of disability. To be considered a disability under the ADA, a genetic trait must be “a physical or mental impairment that substantially limits one or more of the major life activities[.] . . . a record of such impairment; or . . . being regarded as having such an impairment.” Since genetic traits tend to cause impairment in the future, the United States Supreme Court has suggested that genetic traits do not sufficiently meet the interpreted requirement that a disability be currently present. Consequently, genetic traits likely fall outside of the ADA’s definition of disability.¹⁵⁸

Because the definition of “disability” requires that impairments have substantial limits on life activities, it would be difficult to prove that an employer acted adversely based on a person’s genetic information without some outward showing of symptoms.¹⁵⁹ Thus, a genetic predisposition to a disease would fall outside of the scope of “disability” and discrimination under the ADA. Similar to HIPAA, the ADA left too much room for “lawful” genetic discrimination and is still too broad to adequately protect employees.¹⁶⁰

Other genetic discrimination claims have been founded under Section 504 of the Rehabilitation Act.¹⁶¹ The Rehabilitation Act states that “[n]o

158. Paul D. Trumble, “Knicker” and Dime Issues: An Unexplored Loophole in New York’s Genetic Discrimination Statute and the Viability of Genetic Testing in the Sports Employment Context, 70 ALB. L. REV. 771, 777 (2007) (internal citations omitted). See also Americans with Disabilities Act, 42 U.S.C. § 12112(a) (2006).

159. Jeremy A. Colby, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 466-67 (1998).

160. See *id.* at 467 (concluding that the ADA offers little protection in the absence of a favorable judicial interpretation). See also, Sismondo, *supra* note 110, at 467 (noting the ADA’s broad language, its failure to expressly cover genetic discrimination, and the absence of any court decision recognizing that it extends to genetic information).

161. See, e.g., Fleming v. State Univ. of N.Y., 502 F. Supp. 2d 324, 334-39 (E.D.N.Y. 2007) (holding that the plaintiff stated a valid claim under section 504 of the Rehabilitation Act after the plaintiff was allegedly constructively terminated after his employer discovered he

otherwise qualified handicapped individual . . . shall, solely by reason of her or his disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."¹⁶² The major limitation of the Rehabilitation Act is obvious; only employees of federally funded institutions or programs are protected from genetic discrimination.¹⁶³

Finally, the Fourteenth Amendment has been used as a vehicle for genetic discrimination claims. Plaintiffs may claim that genetic discrimination is a breach of privacy under the Fourteenth Amendment and hold the defendant liable under 42 U.S.C. § 1983.¹⁶⁴ Section 1983 states that an action can be brought against any "person who, under color of any statute, ordinance, regulation, custom, or usage, of any State . . . subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws."¹⁶⁵ This claim is likely centered on a broad argument of privacy and, similar to the other failed non-discrimination efforts, it is not specific enough to entirely shield against many types of genetic discrimination.

Although state laws, ERISA, HIPAA, the ADA, the Rehabilitation Act, and the Fourteenth Amendment have allowed for some protection against genetic discrimination in employment and the insurance industry, such an inconsistent and broad assembly of legislation has failed to adequately address specific cases of genetic discrimination. Finally, in 2008, Congress responded to earlier legislative short-comings and adopted the Genetic Information Nondiscrimination Act of 2008 as the primary vehicle to combat genetic discrimination.

had sickle cell anemia). See also *supra* notes 127-35 and accompanying text (discussing *Fleming*).

162. Rehabilitation Act of 1973, Pub. L. 93-112, § 504, 87 Stat. 355, 394 (codified at 29 U.S.C. § 794(a) (2006)).

163. See 29 U.S.C. § 794(d) ("The standards used to determine whether this section has been violated in a complaint alleging employment discrimination...shall be the standards applied under...the Americans with Disabilities Act of 1990... as such sections relate to employment."); See also *Fleming*, 502 F.Supp.2d at 334-37 (finding the ADA's prohibition of discrimination based on medical examinations and inquiries applicable in an employment discrimination case under the Rehabilitation Act).

164. See U.S. CONST. amend. XIV, § 1 ("No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.").

165. 42 U.S.C. § 1983 (2006).

VII. THE GENETIC INFORMATION NONDISCRIMINATION ACT OF 2008 (GINA)

Congress has long been aware of genetic discrimination and its negative impact on genetic research participant recruitment.¹⁶⁶ Congresswoman Louise Slaughter (D, NY) introduced the first genetic non-discrimination bill in the 104th Congress in 1995, and similar bills were introduced in the 105th, 106th, 107th, 108th, and 109th Congresses.¹⁶⁷ Finally, after thirteen years, the Genetic Information Nondiscrimination Act of 2008 was signed into law by President Bush on May 21, 2008 during the 110th Congress.¹⁶⁸ The Act brings much needed and anticipated uniformity to the prohibition of genetic discrimination in employment and health insurance. To prohibit discriminatory uses of genetic information in making employment and health insurance decisions, GINA amends previous federal legislation, including ERISA, the Public Health Service Act (PHSA), the Internal Revenue Code of 1986, and Title XVIII of the Social Security Act (SSA).¹⁶⁹ It also seeks consistency with Title VII of the Civil Rights Act of 1964, HIPAA, and the ADA.¹⁷⁰ While GINA provides more consistent and

166. Kathy L. Hudson et al., *Keeping Pace with the Times – The Genetic Information Nondiscrimination Act of 2008*, 358 NEW ENG. J. MED. 2661, 2662 (2008) (quoting cosponsor Senator Ted Kennedy: “Discrimination in health insurance and the fear of potential discrimination threaten both society’s ability to use new genetic technologies to improve human health and the ability to conduct the very research we need to understand, treat, and prevent genetic disease”).

167. H.R. REP. NO. 110-28, pt. 1, at 23 (2007).

168. See GINA, Pub. L. No. 110-233, 122 Stat. 881, 881, 922 (2008).

169. See GINA § 101, 122 Stat. at 883-88 (amending ERISA); § 102, 122 Stat. at 888-96 (amending the PHSA); § 103, 122 Stat. at 896-99 (amending the I.R.C.); § 104, 122 Stat. at 899-903 (amending the SSA). Many provisions of Title I and II look strikingly similar to the consent order/settlement agreement in *EEOC v. Burlington Northern & Santa Fe Railway Co.*, No. 02-C-0456, 2002 WL 32155386, at *3 (E.D. Wis. 2002). There, as part of equitable relief, the court prohibited Burlington Northern from requiring or requesting genetic testing from current or former employees or threatening adverse employment actions based on genetic test results. *Id.*

170. See, e.g., H.R. REP. NO. 110-28, at 35 (“As a guiding principle, [GINA] is designed to extend to individuals in the area of genetic discrimination the same procedures and remedies as are provided under Title VII of the Civil Rights Act of 1964.”). Provisions regarding the confidentiality of genetic information are “intended to be consistent with the ADA’s requirements regarding the maintenance and treatment of medical information.” H.R. REP. NO. 110-28, at 35. H.R. REP. NO. 110-28, at 67 (noting attempts to resolve a conflict between GINA and HIPAA regarding the types of information “that can be permissibly shared between HIPAA covered entities”). See also Civil Rights Act of 1964, Pub. L. 88-352, 78 Stat. 241, 253 (1964) (codified as amended at 42 U.S.C. §§ 2000e-2000e-17 (2006)); HIPAA, Pub. L. 104-191, 110 Stat. 1936, 2073 (1996); Americans with Disabilities Act, 42 U.S.C. §§ 12101-12213 (2006).

universal non-discrimination protection, it does not preempt more protective state genetic non-discrimination legislation.¹⁷¹

GINA is divided into two titles: Title I prohibits discrimination in health insurance and Title II prohibits discrimination in employment. Under Title I, GINA prohibits all health insurers from using genetic information as a means of setting eligibility or premiums, and from requesting or requiring genetic tests.¹⁷² Genetic information with respect to any individual is defined as “information about such individual’s genetic tests, the genetic tests of family members of such individual, and the manifestation of a disease or disorder in family members of such individual.”¹⁷³ Genetic test is defined as “an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.”¹⁷⁴ These provisions include genetic information and testing with respect to the insured’s dependants, or any other first-degree, second-degree, third-degree, or fourth-degree relatives.¹⁷⁵

Title II of GINA restricts employers from using genetic information to make employment decisions and also restricts them from requesting, purchasing, or requiring genetic information about a prospective employee, current employee, or the employee’s family members.¹⁷⁶ These restrictions also apply to employment agencies, labor organizations, and those in charge of job training programs.¹⁷⁷

VIII. LEGISLATION LIMITATIONS AND RACIAL DISPARITY

Unfortunately, the reading of GINA’s plain text may result in unintended consequences. With regard to health insurance, because GINA does not allow health insurers to request or require genetic tests, some individuals may not receive medical coverage and treatment in dangerous situations.¹⁷⁸ Similarly, this same prohibition does not allow health insurers to recommend a genetic test for preventive screening, confirming a medical diagnosis, or

171. See Abiola, *supra* note 143, at 856.

172. GINA, Pub. L. No. 110-233, §§ 101(a)-101(b), 122 Stat. 881, 883-85 (2008). See also *Hearing*, *supra* note 106, at 44 (“The bill would explicitly allow researchers, for the first time, to tell research participants that it is simply against the law for health insurers or employers to use genetic information to discriminate.”).

173. GINA, Pub. L. No. 110-233, § 101(d), 122 Stat. at 885-86.

174. § 101(d), 122 Stat. at 885-86.

175. §§ 101(a)(3), 101(b), 122 Stat. at 883.

176. §§ 202(a)-(b), 122 Stat. at 907.

177. §§ 204-06, 122 Stat. at 910-14.

178. H.R. REP. NO. 110-28, pt. 1, at 66-67 (2007) (giving the example of a patient with hepatitis C: some viral genotypes require longer treatment and unless the health insurer requests a genetic test to determine the genotype, the patient may not receive adequate therapy).

predicting a response to therapy (which consequently is the major goal of PGx).¹⁷⁹ These consequences could become significant obstacles to health insurers' access to medical information, and in effect, patients' access to care.¹⁸⁰ In employment, the minority view of Republicans on the Committee on Education and Labor was that Title II could lead to an increase in frivolous lawsuits against employers due to the availability of punitive and compensatory damages.¹⁸¹ The minority view of the Committee on Energy and Commerce cites a more general problem. Title II, the Committee claims, is too broad and sweeping in that it reaches practically every entity, corporation, foundation, and agency that has contact with employees.¹⁸²

Extending beyond GINA's possible unintended consequences, the legislation has another and likely more crucial limitation in achieving its legislative aim. The purpose of GINA is to "establish[] a national and uniform basic standard . . . to fully protect the public from discrimination and allay their concerns about the potential for discrimination, thereby allowing individuals to take advantage of genetic testing, technologies, research, and new therapies."¹⁸³ The question remains: will GINA encourage and allow individuals to participate in PGx research and clinical opportunity? Likely, GINA has somewhat quelled the genetic discrimination "fear factor" when it comes to patients' decisions about participating in genetic research and having the results attached to them for the rest of their lives. However, in order to gain the full benefits of PGx research and its applications, Congress and the research communities may need to realize that the fear of genetic discrimination is not the only "fear factor" patients and individuals face. Further, with the specific need for genotypically diverse minority populations, there may be a much more significant hurdle to fully realizing the scope of PGx than the fear of genetic discrimination.

While genetic discrimination may be unique to genetic research, it is not the only risk participants and patients associate with general clinical research. Risk is defined as "the chance of injury, damage, or loss"¹⁸⁴ and is mostly subjective, formed through psychological, social, emotional,

179. H.R. REP. NO. 110-28, at 67.

180. H.R. REP. NO. 110-28, at 67.

181. H.R. REP. NO. 110-28, at 67-68.

182. See H.R. REP. NO. 110-28, pt. 3, at 66-67 (2007). "Title II [of GINA] . . . covers employers from the FBI to NASA to laboratories, to State and local governments, to nuclear power plants, to hospitals, and many more. Title II restricts information flow in numerous settings from employers involved in responses to pandemic flu outbreaks, to employers involved in judicial proceedings, to health and safety monitoring, and to employers administering or sponsoring benefits. We cannot today easily imagine all of the circumstances." H.R. REP. NO. 110-28, at 66.

183. GINA, Pub. L. No. 110-233, § 2, 122 Stat. 881, 882-83 (2008).

184. Slovic, *supra* note 8, at 62 (citation omitted).

cultural, and political means.¹⁸⁵ Whether the risk is real or subjective, the fear of such risk is absolutely real, and with respect to genetic research, Americans likely perceive numerous social and psychological risks that go well beyond genetic discrimination.¹⁸⁶ These risks include the fear of learning harmful genetic information about oneself, the risk that the learning genetic information may have a negative impact on genetically related family members, the fear that genetic testing is too risky and confusing, as well as numerous others.¹⁸⁷ Thus, these perceived risks should not be overlooked by the research community as hurdles to furthering genetic research and PGx participation.¹⁸⁸

The receipt of genetic information can be psychologically harmful to research and clinical participants in several ways.¹⁸⁹ Simply learning that one is predisposed to a genetic disease or is certain to become afflicted with a disease in the future can be injurious to one's overall well-being.¹⁹⁰ Such information is likely to cause worry and be emotionally upsetting either because it makes the participant's future uncertain, or because it makes it firmly certain.¹⁹¹ Additionally, a participant's predisposition to certain diseases is measured in probabilities; therefore the prediction will not come to fruition in many cases, causing some to worry that they will waste valuable time and energy worrying for no reason.¹⁹² Some people even report that they would rather just not know about their genetic make-up than learn that they have a genetic predisposition to a certain disease or cancer.¹⁹³

185. See *id.* at 67 ("Recent studies have shown that factors such as gender, race, political worldviews, affiliation, emotional affect, and trust are strongly correlated with risk judgments.").

186. See Schoonmaker & Williams, *supra* note 3, at 22-25 (discussing how genetic information and testing can lead to many undesired outcomes).

187. *Id.* at 23-24 (stating that two additional fears include the fear of being convicted of a crime, and the fear of discovering that the person tested is not actually the biological relative of a family member).

188. See generally Slovic, *supra* note 8, at 60 (discussing that research participants and researchers often have differing views of risk and therefore people are generally not swayed by researchers' recitations of risk statistics).

189. See Henderson et al., *supra* note 2, at 196 (noting that concerns about genetic research included "knowing too much," "knowing what conditions we [have to face]," "realizing there is no treatment or prevention," and "worrying").

190. See DEP'T OF HEALTH & HUMAN SERV., Office for Human Research Protections, Institutional Review Board Guidebook, Chapter V, http://www.hhs.gov/ohrp/irb/irb_chapter5ii.htm#h12 (last visited March 12, 2010).

191. See *id.*

192. See *id.*

193. See Henderson et al., *supra* note 2, at 196.

Family plays a definite role in genetic research risk. A recent literature review of studies found that people with a family history of a genetic disease consented to participate in genetic research at lower overall rates.¹⁹⁴ Logically, the lower consent rate may correspond to the participants' fears of learning genetic information about themselves. Learning one's own predisposition to a disease, genotype variation, or disease marker can be equally detrimental to family members' well-being, especially if the genetic information can be inherited.¹⁹⁵

Because of the significant importance of including ethnically and racially diverse groups in PGx research, it is crucial to understand the unique perceived risks that these populations face in genetic research. This importance stems from the fact that minority populations are often underrepresented in clinical drug trials compared to the surrounding community.¹⁹⁶ One researcher found that out of thirteen studies of drug efficacy and safety of hypertensive drugs, only eight had at least one African American.¹⁹⁷ Making participation even more difficult is that as a group, African Americans have been found to have less positive views about genetic research than Caucasians.¹⁹⁸ Several empirical studies have supported that African-American and ethnic minorities are less likely to consent to genetic testing.¹⁹⁹ In one study, as compared to whites, African-American and Hispanic participants reported significantly higher levels of

194. Rene Sterling, et al., *Public Willingness to Participate in and Public Opinions About Genetic Variation Research: A Review of the Literature*, 96 AM. J. PUB. HEALTH 1971, 1976 (2006).

195. See SCHOONMAKER & WILLIAMS, *supra* note 3, at 23-24.

196. Noah, *supra* note 7, at 225-26 (discussing that in a 1989 analysis of clinical trials, African Americans were underrepresented in twenty-three out of thirty-five clinical trials for which racial data was available).

197. *Id.* at 226.

198. Henderson et al., *supra* note 2, at 196; see generally Slovic, *supra* note 8, at 76 (discussing that, compared with white males, "nonwhite men see the world as more dangerous because in many ways they are more vulnerable, because they benefit less from many of its technologies and institutions, and because they have less power and control over what happens in their communities and their lives").

199. See, e.g., Hillary R. Bogner et al., *Personal Characteristics of Older Primary Care Patients Who Provide a Buccal Swab for Apolipoprotein E Testing and Banking of Genetic Material: The Spectrum Study*, 7 CMTY. GENETICS 202, 207 (2004) (finding that "patients 80 years and older and African-Americans were less likely to provide a buccal swab than other older patients"; Geraldine M. McQuillan et al., *Consent for Genetic Research in a General Population: The NHANES Experience*, 5 GENETICS MED. 35, 37 (2003) (finding that the lowest consent rates for genetic research were provided by non-Hispanic blacks); Patricia G. Moorman et al., *Racial Differences in Enrollment in a Cancer Genetics Registry*, 13 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1349, 1349 (2004) (finding much lower enrollment rates for African-American women in a cancer genetics registry).

fear of racial discrimination than European Americans.²⁰⁰ The same study showed that African Americans reported a higher percentage of concern of unequal economic access to benefits.²⁰¹ Also, a smaller percentage of African Americans named the prevention and treatment of disease as a perceived benefit of genetic research.²⁰²

Trust is likely one of the most important risk barrier between African-American participants and genetic research. According to a recent survey, the rate of mistrust among African Americans as compared to whites is staggering. A survey population comprised of 527 African Americans and 382 whites was polled to examine racial differences regarding distrust of research and the medical community, wherein "distrust" was defined as "lack of agreement with a statement of trust."²⁰³ The survey revealed that African Americans are less likely to trust that their physician would fully describe research participation, less likely to believe that they could freely ask their physician questions, more likely to disagree that their physician would not ask them to participate in research if the physician thought there was harm, more likely to believe that their physician exposed them to unnecessary harm, and more likely to believe that someone like them would be used as a guinea pig without his or her consent.²⁰⁴ The results also showed that a higher percentage of African-American participants believed that physicians have prescribed medication or given them treatment as a way of experimenting on them without their consent.²⁰⁵ The authors of the study concluded that past and present racial experiences may contribute significantly to African Americans' mistrust of the medical and research community.²⁰⁶

There are several reasons for African Americans' mistrust of medicine and research, many of which seemingly stem from historically unequal treatment. Slaves were sometimes forced into roles as research subjects so

200. Benjamin R. Bates et al., *Warranted Concerns, Warranted Outlooks: A Focus Group Study of Public Understandings of Genetic Research*, 60 SOC. SCI. & MED. 331, 335 (2005) ("Participants were 58 African Americans, 26 European Americans, and 7 Hispanics.").

201. *Id.* at 336. 11.5% of African Americans were concerned about unequal economic access to benefits, as compared to 8.6% of European-Americans and 3.8% of Hispanic-Americans. *Id.*

202. *Id.* at 339. Only 67% of African Americans reported that the prevention and treatment of genetic diseases is a benefit to genetic research, while 81.8% of European-Americans reported the same. *Id.*

203. See Corbie-Smith et al., *supra* note 9, at 2459.

204. *Id.* at 2460. See also Giselle Corbie-Smith et al., *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 J. GEN. INTERNAL MED. 537, 539-40 (1999) [hereinafter *Attitudes and Beliefs*] (discussing that African-American participants to another survey reported fear of being used as "guinea pigs" and "being experimented on").

205. See Corbie-Smith et al., *supra* note 9, at 2460.

206. See *id.* at 2462.

that researchers could study sunstroke, surgical techniques, and postmortem dissection.²⁰⁷ Further, the infamous Tuskegee study has helped continue the trend of mistrust in recent decades.²⁰⁸ Even though some potential African-American research participants have inaccurate knowledge about the study, many have nonetheless referenced the study as a reason for researcher mistrust.²⁰⁹ Regardless of the accuracy of their beliefs, their version of the study is what they believe to be “real.”²¹⁰ Some African Americans even believe that a government conspiracy was to blame for the results of the Tuskegee study and that such a conspiracy exists to this day and is responsible for introducing HIV into the African-American community.²¹¹ Even more daunting for PGx research in particular is that African Americans report the highest levels of mistrust in studies and trials involving the collection of DNA.²¹²

State legislation has also helped fuel historical mistrust. In the 1970’s, some states enacted laws requiring African Americans to undergo genetic tests indicating markers for sickle cell anemia.²¹³ Such laws heightened racial discrimination and scrutiny.²¹⁴ Whatever the reason may be for mistrust among various African-American communities and individuals, without trust, no level of communication between researchers and African-American participants may be adequate for research recruitment. In other words, if the African-American participant does not trust the research and medical community, he or she may not trust the researchers’ positive assertions about genetic research, its benefits, or its minimal risk, and therefore may not participate.

Other risks and barriers to minority recruitment for genetic research exist and should not be ignored. Such factors include financial barriers, attitudes of treating physicians, pharmaceutical company involvement, and health illiteracy.²¹⁵ Further, while it is not a perceived risk per se, a certain barrier

207. Noah, *supra* note 7, at 229.

208. See *id.* at 229-30. Participants of the study included 400 African Americans who were believed to have syphilis. The study was designed to investigate the natural development of the disease over time. When the study began in the 1930s, there was no known cure for syphilis. However, once penicillin was discovered to be an effective treatment, the investigators failed to inform the study participants that there was a cure. *Id.*

209. See *Attitudes and Beliefs*, *supra* note 204, at 543.

210. *Id.*

211. Noah, *supra* note 7, at 230.

212. See Cathrine Hoyo, *Barriers and Strategies for Sustained Participation of African-American Men in Cohort Studies*, 13 *ETHNICITY & DISEASE* 470, 472 (2003).

213. GINA, Pub. L. No. 110-233, § 2, 122 Stat. 881, 882 (2008) (codified at 26 U.S.C., 29 U.S.C. § 2000ff).

214. § 2, 122 Stat. at 882. In response, Congress passed the National Sickle Cell Anemia Control Act, Pub. L. No. 92-294, 86 Stat. 136-39 (1972).

215. See Noah, *supra* note 7, at 226-28.

to African-American research participation is lack of scientific and medical understanding.²¹⁶ Unfortunately, this barrier is confounded by the presumption that race is correlated with lower socio-economic status and education, both of which correlate with lower health status.²¹⁷

IX. ADDRESSING RACIAL DISPARITIES IN PGX RESEARCH AND CLINICAL OPPORTUNITY

In order for PGx to reach its full potential, African-American populations must be included in clinical drug trials so that the link between race and genetic variation can be better understood. Only then can this population benefit from the clinical applications of PGx research. In order for this to occur, however, more focus must be placed on identifying risks important to the specific study population, and on educating the public about risks and their truthful relation to genetic research. While numerous methods for achieving this goal have been suggested, many scholars support some form of "community-based review" as a useful vehicle for public education.²¹⁸ Community review involves aspects of "community approval, group consent, communal discourse, and other methods of consulting with communities about the potential implications of genetic research."²¹⁹

From the researchers' perspective, community involvement will help form a long-term relationship and allow researchers to better understand risks facing the research participants.²²⁰ Specifically, constructive dialogue can identify both perceptions of PGx and the public's willingness to participate in clinical research.²²¹ Such a dialogue has begun with regard to African Americans' views on ways to improve participation in research.²²² Participants of the dialogue "expressed the need for more honest and respectful communication from physicians and other research personnel, and the importance of providing complete information about risk and benefits of research."²²³ The participants of this survey also suggested it would be beneficial to have time to research the study implications on their own and talk to family and friends about such implications.²²⁴ Further suggestions included more education and promotion of awareness of the

216. *Id.* at 228.

217. *Id.* at 229.

218. See e.g., Richard R. Sharp & Morris W. Foster, *Involving Study Populations in the Review of Genetic Research*, 28 J.L. MED. & ETHICS 41, 42 (2000).

219. *Id.* (noting that "[i]n its least demanding form, community review could be little more than informal dialogue between researchers and members of the study population").

220. *Id.*

221. See HHS, *supra* note 10, at 8.

222. See *Attitudes and Beliefs*, *supra* note 204, at 541.

223. *Id.*

224. *Id.*

purpose of research.²²⁵ Once researchers fully understand the cultural values and perceived risks and attitudes toward genetic research, they can create community-tailored recruitment strategies and research designs.

Because researcher and physician mistrust is one of the most cited barriers to minority research participation, establishing cultural trust must be a primary objective of community review. Researcher knowledge and participant mistrust are inevitably intertwined, and as such, building trust should include all facets of community involvement, such as engagement, dialogue, and feedback.²²⁶ Based on information from African-American participants, one study suggested identifying civil organizations in the community, the head of which could operate as a “gate keeper” between the researcher and possible participants.²²⁷ In this model, “clusters” of participants would be identified within the civic organizations and the gatekeeper of the organization would approach individuals in the cluster about research participation.²²⁸ Recommended civic organizations included churches, fraternity and sorority organizations at Historically Black Colleges and Universities (HBCU), Partners Against Crime, various women’s organizations, and the American Legion.²²⁹ The study also suggested that African-American trust would increase if the researchers themselves were African American.²³⁰

Researchers should be cautious, however, not to offend or alienate minority participants, as differing experiences have left many African Americans vulnerable. In opening a community dialogue, researchers should be careful not to label individuals as belonging to a particular group or base their discussions on an assumption that all members of the group have the same concerns and beliefs.²³¹ Additionally, researchers should ensure that any conversations take the form of a dialogue, such that there is the ability for questions and answers, as opposed to a monologue where the researcher gives a convoluted “presentation” of research benefits and risks.²³² With such careful consideration and assessment, genetic research participation risks and barriers can be identified and addressed in order that PGx can bring safe and effective medicine to the entire American population.

225. *Id.* at 542.

226. See Corbie-Smith et al., *supra* note 9, at 2462.

227. Hoyo, *supra* note 212, at 473.

228. See *id.*

229. See *id.* at 473-74.

230. *Id.* at 474.

231. See Noah, *supra* note 7, at 230-31.

232. See *id.*

X. CONCLUSION

Researchers, pharmaceutical companies, and scholars agree that PGx has the potential to greatly impact the future of medicine by producing safe, efficient, and cost-effective drugs. With continued increases in research participation and public interest among diverse racial, ethnic, and genetic backgrounds, the long-term goals of PGx research will likely be exceeded. GINA has certainly allowed research to continue its forward progress by alleviating or reducing participants' fears of genetic discrimination by insurance companies and employers. This federal law was greatly needed to add consistency to fragmented state laws and give more severe penalties to those employers and insurers who discriminate against research participants.

However, the failure of legislation to recognize the numerous other psychological and social risks associated with genetic research in the African-American community will thwart the forward progress of PGx research and implementation. While GINA has taken a substantial step forward in eliminating genetic discrimination and thus calming some of the American public's fears, PGx research will only reach its full clinical potential when other risks are clearly identified and addressed through various forms of community review and involvement.

AMANDA TESSMER*

* J.D. Candidate, Saint Louis University School of Law, 2010; B.A. with honors in Biology and Psychology, *magna cum laude*, 2007. I would like to thank my faculty advisor, Jesse Goldner, as well as Professor Elizabeth Pendo and Amy Sanders for their assistance with this article.