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Pharmacogenomics: A Brave New World in Designer Drugs.

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PHARMACOGENOMICS: A BRAVE NEW WORLD IN DESIGNER DRUGS*

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* The title alludes to Aldous Huxley's dystopia in *Brave New World.* ALDOUS HUXLEY, BRAVE NEW WORLD (1932). In his novel, science has become the panacea for many of society's ills; thus, its techniques and philosophies have been applied to every facet of human life. Eugenics has triumphed to the point where babies, according to the needs of society, are "decanted." *See generally id.* (describing the "decanting" process; this author sees it as homologous to baking and animal husbandry). Although a rather controlled and emotionless vision of the future, Huxley portrays the ills of science and technology in his society with the underlying themes of community, identity, and stability. *Id.* at 1 (referring to the motto for Huxley's utopian World State: "Community, Identity, Stability"). Just as this comment inquires into those ills that may destroy mankind, it also explores how science, specifically in the field of pharmacogenomics, may improve the caliber of human beings.

† St. Mary's School of Law, Candidate for J.D, May 2003. St. Edward's University, B.S., Biology, May 1998. I would like to thank God for giving me the strength and perseverance to complete this comment. To my parents, Daniel and Norma, and brother, Neil Edward, thank you for your love and guidance. To my sister, Diane, thank you for your encouragement, support, and input – especially all things scientific. To *The Scholar* Team who worked on my comment, thank you for your suggestions. They were greatly appreciated. For their guidance in drafting and editing, I would like to thank my editors, Jon Michael Hayes and Yvette Aguilar, who made this publication possible through their hard work. Finally, many thanks to Platz and Strausse for their friendship, encouragement, and insanity.

PART I: INTRODUCTION

"Biology will become an engine of transformation of our society. . . Instead of guessing how we differ one from another, we will understand and be able to tailor our life experiences to our inheritance. We will also be able, to some extent, to control that inheritance."[1] However, this engine is a double-edge sword.

> [W]e have our stability to think of. We don't want to change. Every change is a menace to stability. That's another reason why we're so chary of applying new inventions. Every discovery in pure science is potentially subversive; even science must sometimes be treated as a possible enemy. Yes, even science.[2]

Thus, we have this engine, which has far-reaching and limitless possibilities to enhance mankind's standard of living and understanding of life. Yet, it opens the door for exclusion through distinctions, which are drawn from our genetic predispositions.[3] These exclusions, based on purported behavioral dispositions and anticipated health risks, are commonly associated with particular races or ethnic groups.[4]

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1. Ralph Brave, *Governing the Genome*, NATION, Dec. 10, 2001, at 18, 18 (quoting Cal Tech president and Nobelist David Baltimore from his preface to the published human genome sequence).

2. ALDOUS HUXLEY, BRAVE NEW WORLD 231 (1932).

3. Dorothy Nelkin, *A Brief History of the Political Work of Genetics*, 42 JURIMETRICS J. 121, 122 (2002). Mutations, which are changes in the sequences of the genes' chemistry, account for diseases characteristic in particular populations. *Id.*; *see also* STEDMAN'S MEDICAL DICTIONARY 1166 (27th ed. 2000) [hereinafter STEDMAN'S].

4. Nelkin, *supra* note 3, at 122. For example, population stereotypes have historically played a role in immigration legislation. *Id.* at 131. In response to anti-immigration rhetoric claiming potential immigrants as biologically inferior, intrinsically unhealthy, and potentially draining on public services, Congress passed the Immigration Act of 1924, which restricted immigration from Central, Eastern and Southern Europe. Immigration Act of

This comment will explore the double-edged sword of biology, particularly in the field of pharmacogenomics. Pharmacogenomics uses the knowledge that ethnic variation plays a part in human drug responses, thereby creating the need for population-specific research to study this effect of genetic diversity on human responses to drugs and other chemical substances.[5] Part I addresses preliminary issues, which include a discussion of scientific terminology and theories pertinent to this comment, as well as an overview of pharmacogenomics. Part II delves into the historical and sociological perspectives pertinent to this issue. Part III reviews particular state and federal laws relating to genetic testing and information. This section includes an application of current laws to pharmacogenomics. Part IV proposes a uniform law to alleviate people's fear of potential discrimination. The abstractness of science to the general public evokes a fear that even the decoded human genome cannot alleviate without the regulations and protections afforded by the law.

A. *Laying the Foundation*

The Human Genome Project (HGP)[6] sought to demystify the human genetic make-up by mapping and sequencing the genes on the human DNA.[7] One of the goals for the Human Genome Project was to determine the gene associated with specific physiological functions.[8] As a re-

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1924, ch. 190, 43 stat. 153 (repealed 1952); Nelkin, *supra* note 3, at 131. Although the Immigration Act of 1924 has been repealed, similar arguments have resurfaced among anti-immigration groups. Nelkin, *supra* note 3, at 131.

5. *See* Wendell W. Weber, *Scientific Rationales for Population-Specific Genetic Research: Pharmacogenetics in Indigenous Peoples*, 42 JURIMETRICS J. 141, 141-43 (2002).

6. J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304, 1305 (2001). The modern history of DNA sequencing began in 1977 when the technology was developed to determine an organism's genetic sequence and when the first human gene was isolated and sequenced. *Id.* In 1985, scientists finally presented the first formal proposal for a project to determine the human genome's complete nucleotide sequence. *Id.* Though an international endeavor, the United States did not officially initiate its own HGP until 1990. *Id.* The United States created its HGP under the direction of the National Institutes of Health and the United States Department of Energy. *Id.* Although the penultimate goal was to decode the human genome, the HGP sought to ultimately understand current scientific and medical mysteries (e.g., the interplay between heredity and environment, human evolution, causation of diseases). *Id. See generally* Leslie Roberts, *Controversial From the Start*, 291 SCI. 1182 (2001) (outlining chronologically the researchers, who contributed to and furthered the HGP mission, and their achievements).

7. ERIC S. GRACE, BIOTECHNOLOGY UNZIPPED: PROMISES AND REALITIES 69 (1997); *see* Anita LaFrance Allen, *Genetic Testing, Nature, and Trust*, 27 SETON HALL L. REV. 887, 887 (1997); Michael R. Costa, Note, *Genetic Testing: International Strategies to Prevent Potential Discrimination in Insurance Risk Classification*, 20 SUFFOLK TRANSNAT'L L. REV. 109, 113 (1996).

8. Allen, *supra* note 7, at 887.

sult of this endeavor, a technological revolution, specifically in biotechnology, occurred.[9] Issues regarding benefits, risks, and regulation arose with this revolution. The HGP also created new fields within biotechnology.[10]

The discovery of the double-helix model of deoxyribonucleic acid (DNA) in 1953 by Watson and Crick marked the beginning of this era of modern biotechnology.[11] By the 1970s, scientists were able to isolate a given piece of DNA, which in turn led to the development of genetic engineering, also called recombinant DNA technology. Recombinant DNA technology involves the process of gene splicing, that is, the combination of heterologous DNA pieces for the purpose of cloning, analysis, and design of potential genetic therapeutics, thereby revolutionizing modern biotechnology with its ability to alter genetic material.[12] Recombinant DNA technology transformed food production,[13] industry,[14] and

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9. *See generally* JEREMY RIFKIN, THE BIOTECH CENTURY: HARNESSING THE GENE AND REMAKING THE WORLD (1998) (analyzing how the new genetic engineering technologies have revolutionized biotechnology).

10. Biotechnology is the industrial use of "biological materials to create products for the benefits of human beings." SUSAN ALDRIDGE, THE THREAD OF LIFE: THE STORY OF GENES AND GENETIC ENGINEERING 185 (1996); Louis Levine, *Biotechnology*, *in* MICROSOFT ENCARTA ONLINE ENCYCLOPEDIA, *at* http://encarta.msn.com/encnet/refpages/RefArticle.aspx?refid=761575885 (last visited Sept. 27, 2002). This field applies the techniques of biochemistry, biophysics, cellular biology, and molecular biology to address practical issues related to agriculture, the environment, and human beings. STEDMAN'S, *supra* note 3, at 207. It uses genetic technologies, like recombinant DNA, to produce useful molecules, or to alter biologic processes in order to enhance some desired property. *Id.* Its history dates back to about 5000 B.C. in the area of food production and medicine. *See* ALDRIDGE, *supra*, at 185 (discussing the fermentation of fruits and grains to make wine, beer, and spirits and describing the use of Penicillin by Egyptians who placed moldy bread on infected wounds); Levine, *supra* (growing maize in Mexico). Thus, the major application of biotechnology had been in the field of agriculture, where for over 10,000 years humanity has engaged in such biotechnological activities as animal husbandry and plant breeding. TABITHA M. POWLEDGE, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES, NATIONAL INSTITUTE OF HEALTH, GENETIC BASICS 52 (2001). Now, however, the term "biotechnology" generally refers to a scientific approach to produce living organisms with new traits (e.g., cloning, recombinant DNA, molecular biology, genomic sequencing). *See id.*

11. GRACE, *supra* note 7, at 16; *Timeline: A History of the Human Genome Project*, 291 SCI. 1195, 1195 (Leslie Roberts ed., 2001) [hereinafter *Timeline*]; Levine, *supra* note 10.

12. Levine, *supra* note 10; *Genetic Engineering*, *in* MICROSOFT ENCARTA ONLINE ENCYCLOPEDIA, *at* http://encarta.msn.com/encnet/refpages/RefArticle.aspx?refid=761557775 (last visited Sept. 27, 2002). In other words, recombinant DNA is altered DNA resulting from the insertion, through biologic, chemical, or enzymatic means, of a partial or whole sequence of DNA not originally present in the original DNA chain. STEDMAN'S, *supra* note 3, at 476.

13. Philip L. Bereano, *Some Environmental and Ethical Considerations of Genetically Engineered Plants and Foods*, *in* CHANGING NATURE'S COURSE: THE ETHICAL CHAL-

medicine.[15] With advances in areas such as recombinant DNA technology, combinatorial chemistry, and molecular biology, 1997 saw the emergence of pharmacogenomics.[16]

1. The Scientific Background

In order to understand the concepts underlying pharmacogenomics, a basic understanding of the human genome is in order. The human genome template varies slightly among individuals due to minute variations from single nucleotide polymorphisms (SNPs).[17] Twenty-three pairs of chromosomes are collectively known as the "human genome."[18] DNA strands, which make up these chromosomes, have building blocks consisting of four different bases: adenine, thymine, cytosine, and guanine.[19] These bases, combined with a phosphate and sugar group, create a unit called a "nucleotide," which is the DNA's fundamental component.[20] Random mutations – harmful, good, and neutral – commonly occur during DNA replication. It is this combination of alleles – "the alternative forms of a gene" – that makes each individual unique.[21] Therefore, polymorphisms are the variations within the DNA sequence of a popula-

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LENGE OF BIOTECHNOLOGY 27, 29 (Gerhold K. Becker ed., 1996) (explaining how the use of recombinant bovine growth hormone in cows increased milk production).

14. *Genetic Engineering*, *supra* note 12 (discussing how genetically altered microbes are used to break down garbage and petroleum products in industrial waste). *See generally* ALDRIDGE, *supra* note 10, at 232-36 (identifying the use of biotechnology in various industries).

15. *See* George P Smith, II & Thaddeus J. Burns, *Genetic Determinism or Genetic Discrimination*, 11 J. CONTEMP. HEALTH L. & POL'Y 23, 33 (1994) [hereinafter Smith & Burns] (explaining how, in medicine, gene therapy is used to replace deficient genes). *See generally* ALDRIDGE, *supra* note 10, at 187-92 (describing biotechnology's impact on drugs, vaccines, and antibodies); *Genetic Engineering*, *supra* note 12 (discussing other uses of biotechnology in medicine).

16. *See* Ian J. Mehr, *Pharmacogenomics and Industry Change*, 9 APPLIED CLINICAL TRIALS 34 (2000). Pharmacogenomics relates to the genetic determination of variations in response to drugs in humans or laboratory organisms. STEDMAN'S, *supra* note 3, at 1360.

17. Marc Wortman, *Medicine Gets Personal*, 104 TECH. REV. 72, 72-73 (2001); *Medicine Made to Match Genetic Profile*, DRUG WEEK, Mar. 9, 2001, at 3 [hereinafter *Medicine Made to Match*].

18. Lee M. Silver, *The Meaning of Genes and "Genetic Rights,"* 40 JURIMETRICS J. 9, 13 (1999).

19. GRACE, *supra* note 7, at 16-17; Robert Snedden, *The Challenge of Pharmacogenetics and Pharmacogenomics*, 9 NEW GENETICS & SOCIETY 145, 156 (2000).

20. GRACE, *supra* note 7, at 25; NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES, NATIONAL INSTITUTE OF HEALTH, THE CHEMISTRY OF HEALTH 7-8 (2000); NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES, NATIONAL INSTITUTE OF HEALTH, THE STRUCTURES OF LIFE 12-13 (2000) [hereinafter STRUCTURES OF LIFE]; POWLEDGE, *supra* note 10, at 52.

21. Silver, *supra* note 18, at 13.

tion.[22] The single nucleotide polymorphisms, which are variations in single base pairs, are the small genetic mutations in the DNA.[23] These random mutations occur to create, within a population, the greatest source of variability.[24]

This genetic diversity, specifically in genes coding for metabolic pathways affecting metabolism, contributes to the differing drug responses in individuals and subpopulations.[25] Although genetics contributes to 85% of an individual's reaction to drugs, pharmaceutical companies design and market drugs to all patients.[26] Pharmacogenomics hopes to counter this broad-spectrum approach by gearing drugs to specific patient populations.[27]

2. An Introduction to Pharmacogenomics

Pharmaco*genetics* is a combination of pharmacology and genetics.[28] Its objective is to personalize medicine through safer and more effective drugs tailored to an individual's unique genetic code.[29] Pharmaco*genomics* merges pharmaco*genetics* with genomic technology to achieve this

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22. *Timeline*, *supra* note 11, at 1195.

23. *Id.*; *Medicine Made to Match*, *supra* note 17, at 3-4.

24. ALDRIDGE, *supra* note 10, at 245; *Timeline*, *supra* note 11, at 1195; Beth Schachter, *Pharming the Genome*, HMS BEAGLE: THE BIOMED MAGAZINE, Oct. 30, 1998, *available at* http://www.nasw.org/users/bschachter/Pharming.html (last visited Oct. 24, 2002).

25. Wortman, *supra* note 17, at 72; Snedden, *supra* note 19, at 148; *Medicine Made to Match*, *supra* note 17, at 3; Cynthia Robbins-Roth, *Tailor-Made Drugs*, FORBES, July 6, 1998, at 172. Genes do not operate in a vacuum; rather, they interact with other genes, their gene products, and gene products. Leena Peltonen & Victor A. McKusick, *Dissecting Human Disease in the Postgenomic Era*, 291 SCI. 1224, 1226 (2001). This operation results in symptoms varying among patients with the same disease. *Id.*

26. Snedden, *supra* note 19, at 147. *See generally* Wortman, *supra* note 17 (discussing how pharmaceutical companies will transition from the "one size fits all" drugs to personalized medicine); Leah E. Perry, *How Pharmacogenomics Will Change Drug Marketing*, DRUG TOPICS, May 7, 2001, at 70 (comparing the present market of blockbuster drugs with the future trend toward narrow spectrum drugs). Other factors, aside from genetic influences affecting a person's reaction to medication, include the expressed symptoms to the disease, the progression of the disease, the "presence of any concurrent disease conditions or concomitant use of other medication, and tolerance of potential side effects." Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients' Genetic Profiles*, 43 JURIMETRICS 1, 2 (2002); *see also* Alun McCarthy, *Pharmacogenetics: Implications for Drug Development, Patients and Society*, 9 NEW GENETICS & SOCIETY 135, 138 (2000) (listing the "amount and rate of medicine absorption [and] rate of drug metabolism and elimination" as other factors influencing a patient's response to medication).

27. Snedden, *supra* note 19, at 147; *see* Wortman, *supra* note 17, at 74, 78; Perry, *supra* note 26, at 70.

28. Snedden, *supra* note 19, at 145.

29. *Id.*; *Medicine Made to Match*, *supra* note 17, at 3.

goal.[30] It uses genetic technology to understand how a patient's DNA interacts with a drug.[31]

With this emerging field of pharmacogenomics comes possible benefits and potentially problematic issues. Benefits include improving drug effectiveness,[32] reducing adverse drug reactions,[33] determining which drugs will work optimally for patients,[34] and allowing continued use of drugs that may work for one subpopulation but not another.[35] Issues include the potential misuse of genetic information for healthcare and employment, the effect on large pharmaceutical companies who rely on "blockbuster drugs,"[36] and the international and domestic regulation of pharmacogenomics. The issues of genetic determinism and genetic discrimination must also be considered.[37]

As previously stated, pharmacogenomics seeks to design drugs for specific individuals or subpopulations. Pharmacogenetic traits are linked to ethnicity.[38] For example, genetic variation in the production of the en-

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30. Snedden, *supra* note 19, at 146.

31. *See* Robbins-Roth, *supra* note 25, at 172; Gary Stix, *Personal Pills*, 279 SCI. AM. 17, 17-18 (1998); *Journal Debuts Theme Issue on Pharmacogenetics, Pharmacogenomics*, GENOMICS & GENETICS WEEKLY, Feb. 2, 2001, at 10 [hereinafter *Journal Debuts Theme*].

32. *See* Cinda Becker, *The DNA Rx: Advances in Genetics Give Physicians Ability to Tailor Drugs to Patients' Unique Makeup*, MODERN HEALTHCARE, Aug. 28, 2000, at 24; William E. Evans & Mary V. Relling, *Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics*, 286 SCI. 487, 487 (1999); Robert McCarthy, *Can Drug Industry Hold on Until Pharmacogenomics Move In?*, DRUG TOPICS, Apr. 17, 2000, at 27.

33. *See* Becker, *supra* note 32, at 24; McCarthy, *supra* note 32, at 27.

34. *See* Evans & Relling, *supra* note 32, at 487; *Get Set for Pharmacogenomics*, APPLIED GENETICS NEWS, Aug. 1, 1997 (LEXIS, Applied Genetic News, Drug Discovery); *The Right Medicine: Pharmacogenomics Could Revolutionize the Pharmaceutical Industry*, MED AD NEWS, June 1, 1999, at 3 [hereinafter *The Right Medicine*].

35. Snedden, *supra* note 19, at 149; Wortman, *supra* note 17, at 72; *Journal Debuts Theme*, *supra* note 31, at 10; Robbins-Roth, *supra* note 25, at 172.

36. Definitions of a blockbuster drug varies, but they are generally broad-spectrum drugs that treat large patient populations. *See* Perry, *supra* note 26, at 70; *see also* Mae Thamer et al., *A Cross-National Comparison of Orphan Drug Policies: Implications for the U.S. Orphan Drug Act*, 23 J. HEALTH POL. POL'Y & L. 265, 270 (1998) (stating "[p]roposed regulations for the FDA's generic drug program define blockbuster drugs as those with a market above $50 million a year").

37. Lori B. Andrews, *A Conceptual Framework for Genetic Policy: Comparing the Medical, Public Health, and Fundamental Rights Models*, 79 WASH. U. L.Q. 221, 258-67 (2001); Silver, *supra* note 18, at 17; Snedden, *supra* note 19, at 149. *See generally* Tara L. Rachinsky, *Genetic Testing: Toward a Comprehensive Policy to Prevent Genetic Discrimination in the Workplace*, 2 U. PA. J. LAB. & EMP. L. 575 (2000) (discussing genetic discrimination in the workplace).

38. Snedden, *supra* note 19, at 145. For example, sickle cell disease is common among those of African descent while cystic fibrosis often affects those of northern European descent. STRUCTURES OF LIFE, *supra* note 20, at 6. Other examples of racial differences in responses to chemicals include studies showing (1) the more pronounced effects of atro-

zymes involved in the metabolism of alcohol, namely ADH (aldehyde dehydrogenase) and ACDH (alcohol dehydrogenase) enzymes, are more common in Asians, particularly in the Japanese.[39] Hence, a difference in alcohol tolerance exists between Caucasian and Asian populations.[40] However, does the determination of traits like alcohol sensitivity contribute to the idea of genetic determinism and genetic discrimination? Although genes correlate to specific physiological functions, they do not explain everything, because genes work in conjunction with environmental and behavioral factors.[41]

For example, recombinant DNA technology has allowed scientists to trace human ancestry from the maternally inherited mitochondrial DNA to the paternally inherited Y chromosome.[42] The scientists' comparison of present day populations confirms a common ancestry originating in Africa and documents how the African gene pool had the most variation in the world.[43] Additionally, scientists have discovered how individuals in the same population, even in small or isolated areas, have a greater percentage of genetic variation than persons from different continents.[44] Hence, individuals in homogenous groups, who possess superficially similar traits, are more different from each other than if genetically compared with an individual outside their race.[45] Yet, despite the discovery of a common ancestry in Africa, individuals persist in using race and ethnicity to differentiate human populations.[46] From the scientific perspective, the stereotypical features associated with race merely reflect allelic combina-

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pine among blacks than whites; (2) the more pronounced dilatory effects of cocaine and pseudoephedrine on the eyes of Chinese and Caucasians than on blacks; and (3) the better resistance by blacks to skin blistering from exposure to mustard gas than by whites. Weber, *supra* note 5, at 142.

39. *Medicine Made to Match*, *supra* note 17, at 3; Snedden, *supra* note 19, at 156.

40. *Medicine Made to Match*, *supra* note 17, at 3; Snedden, *supra* note 19, at 156. Although genes contribute to the variance in people's susceptibility to diseases, certain genes can make people resistant or vulnerable to a disease. Peltonen & McKusick, *supra* note 25, at 1226-27. The same variance can be said about people's response to medication. A single gene, a compilation of genes, or a person's diet and environment may govern the body's reaction. POWLEDGE, *supra* note 10, at 52. Pharmacogenomics will use the information from genome sequencing to predict how individuals respond to medications. *Id.*

41. Robbins-Roth, *supra* note 25, at 172; Wortman, *supra* note 17, at 72-75.

42. Kelly Owens & Mary-Claire King, *Genomic Views of Human History*, 286 SCI. 451, 451 (1999).

43. *Id.*; Svante Pääbo, *The Human Genome and Our View of Ourselves*, 291 SCI. 1219, 1219 (2001).

44. Owens & King, *supra* note 42, at 452 (stating the human genetic diversity among individuals in different continents is 10% while the genetic variation is 80% among individuals in the same population); Pääbo, *supra* note 43, at 1220.

45. Owens & King, *supra* note 42, at 453.

46. Pääbo, *supra* note 43, at 1219.

tions.[47] Therefore, scientists hypothesize that since minute genetic mutations determine superficial traits, such as hair color, skin color, hair texture, and facial traits, the environment (e.g., climate) is a reasonable cause for the variation in those traits.[48]

Another argument parallels the following:

> We've called the human genome the blueprint, the Holy Grail, all sorts of things. It's a parts list. If I gave you the parts lists for the Boeing 777 and it has 100,000 parts, I don't think you could screw it together, and you certainly wouldn't understand why it flew.[49]

In other words, the Human Genome Project seeks to determine the complete nucleotide sequence of the human genome – deciphering every adenine (A), thymine (T), cytosine (C) and guanine (G).[50] Although many of these nucleotide sequences consist of non-coding DNA,[51] an understanding of the genome with these individual pieces of information alone cannot be made without looking at the totality of the information. This misunderstanding is further exacerbated by the misconstrued ideas perpetuated by the media. For example, media fervor is given to scientific reports purporting to have discovered the "genes for" certain traits such as aggression[52] and homosexuality.[53] These journalists, however, only add to society's misconception of genetic information by incorrectly suggesting the mere presence of a gene corresponds to the manifestation of a trait or disorder.[54]

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47. *Id.* at 1220.

48. Owens & King, *supra* note 42, at 453.

49. *Timeline*, *supra* note 11, at 1198 (quoting a portion of Eric Lander's address before the Millennium Evening at the White House, (Oct. 14, 1999)).

50. Roberts, *supra* note 6, at 1183; Venter et. al., *supra* note 6, at 1305. Nucleotides are the building blocks of RNA (ribonucleic acid) and DNA. They include a base (A, T, C, or G – the written alphabet of the DNA code), a phosphate molecule, and a sugar molecule (ribose in RNA and deoxyribose in DNA). POWLEDGE, *supra* note 10, at 3.

51. Non-coding DNA consists of bases that do not code for genes. ROBERT F. WEAVER & PHILIP W. HEDRICK, GENETICS 269-70 (2d ed. 1992); STEDMAN'S, *supra* note 3, at 918; POWLEDGE, *supra* note 10, at 12; *see also* Gretchen Vogel, *Objection #2: Why Sequence the Junk?* 291 SCI. 1184, 1184 (2001) (explaining how the human genome has more non-coding DNA than any other animal).

52. Peter McGuffin et al., *Toward Behavioral Genomics*, 291 SCI. 1232, 1232 (2001). The behavioral trait of aggression has been identified in a mutation reported in the X-linked *MAO A* gene. *Id.*

53. *Id.* Linkage has been reported at the X-linked marker locus on "sib pairs" for male homosexuality. *Id.*

54. *See id.* Not all genes are "genetic" although genes are involved in all diseases. POWLEDGE, *supra* note 10, at 55. Diseases caused by single gene mutations are common. GREGORY STOCK, REDESIGNING HUMANS: OUR INEVITABLE GENETIC FUTURE 43 (2002). Examples of these single gene mutations include Lesch-Nyhan syndrome, which is an X-linked inheritance that leads to mental retardation and self-mutilation of fingers and lips

The misconception that harboring certain genes will manifest into specific traits or disorders leads people to fear third parties will abuse publicly disseminated information obtained about an individual's genotype.[55] People fear employers, insurers, and schools may discriminate or stigmatize simply because a person carries traits linked to diseases.[56] However, this type of discrimination has the similar invidious effect of delegating the person into a suspect classification, like sex.[57]

If persons experiencing genetic discrimination are "suspect," then these people carrying certain traits or disorders are afforded special protection. But what is "suspect classification?" The Supreme Court of the United States distinguishes suspect classification from non-suspect classification by asking whether the trait bears any relation to the individual's ability to "perform or contribute to society."[58] Take, for example, alcohol addiction. Although a person may have the propensity for this disease, a genetic predisposition to it does not necessarily determine whether or not the individual will abuse alcohol.[59] Additionally, carriers of diseases, like sickle cell anemia, do not necessarily develop the symptoms.[60] Hence, the sequences of one's genes does not necessarily determine whether or not the trait will be expressed.

This thought of genetic discrimination conjures up a myriad of other issues. One such issue is eugenics, which carries the shadow of negative eugenics from the Nazi racist genocide.[61] Also under the umbrella of eugenics is positive eugenics, or the power to reengineer the human spe-

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by biting; Tay-Sachs disease, which leads to early neural degeneration, then to a failure to develop motor skills, and eventually to death; and Werner's syndrome, which manifests premature aging. STEDMAN'S, *supra* note 3, at 521, 1939, 1771; STOCK, *supra*, at 43. However, a combination of genetic and environmental factors influence complex disorders such as asthma, arthritis, most cancers, diabetes, heart disease, and mental disorders that are common diseases killing millions of people. *See* POWLEDGE, *supra* note 10, at 55. *See generally* Peltonen & McKusick, *supra* note 25 (comparing the genetic background of monogenic diseases and complex disorders).

55. *See* Mary Z. Pelias & Nathan J. Markward, *The Human Genome Project and Public Perception: Truth and Consequences*, 49 EMORY L.J. 837, 840-41 (2000) (highlighting the factors contributing to the public perception of genetics as mysterious and threatening); Smith & Burns, *supra* note 15, at 25 (concluding how advancements in DNA technology and screening techniques create potential abuse by state and private entities).

56. *See* Pelias & Markward, *supra* note 55, at 840-41; Silver, *supra* note 18, at 17; Smith & Burns, *supra* note 15, at 30.

57. *See* Smith & Burns, *supra* note 15, at 45, n.118.

58. Frontiero v. Richardson, 411 U.S. 677, 686-87 (1973); *see* Smith & Burns, *supra* note 15, at 45.

59. *See generally* Silver, *supra* note 18 (disclosing the high likelihood of genetic discrimination despite the fact people can overcome their genetic instincts).

60. Smith & Burns, *supra* note 15, at 45 n.118.

61. Pelias & Markward, *supra* note 55, at 855-56.

cies.[62] Another issue is the determination of the genetically less fortunate. Who are these people facing discrimination simply because they carry a gene expressing a certain trait or disorder and are thus labeled the "genetically less fortunate?" Existing legislation uses broad sweeping language to define terms such as genetic discrimination and genetic information. Are these terms to include minorities, indigenous peoples, the disabled, the cosmetically imperfect, or the diseased?[63]

Also, one must consider whether the history of scientific discrimination against minority populations in the United States, like the sterilization laws at the turn of the twentieth century,[64] may discourage minorities from taking advantage of the benefits offered by pharmacogenomics.[65] Finally, as the ideas of pharmacogenomics solidify, how will it affect current legislation?[66]

As a new field in biotechnology, pharmacogenomics shares similar social, ethical, medical, and legal concerns related to genetic research. The valuable knowledge and the possible benefits to humanity this field offers keeps pharmacogenomics in the forefront of biotechnology. Yet the pharmaceutical industry and governments are left to resolve issues arising out of people's ethical, legal, medical, and social concerns.

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62. *See id.* at 855-56 (explaining positive eugenics encourage the propagation of survival of the fittest).

63. *See generally* Andrews, *supra* note 37 (exploring how third parties could use a person's genetic information to stigmatize and discriminate against them); Smith & Burns, *supra* note 15, at 35 (describing potential forms of discrimination); Henry T. Greely, *Genotype Discrimination: The Complex Case for Some legislative Protection*, 149 U. PA. L. REV. 1483 (2001) (providing an overview of genetic discrimination and the protections afforded under present statutes).

64. Rifkin, *supra* note 9, at 122. At the beginning of the Twentieth Century, various state laws involuntarily sterilized thousands of American citizens. *Id.* "Confirmed criminals, idiots, imbeciles, and others in state institutions" were manditorially sterilized in order to "weed out the biologically inferior stock" from America. *Id.*

65. *See generally* Andrews, *supra* note 37 (recognizing the potential abuses of genetic information).

66. Take, for example, the Orphan Drug Act. Orphan Drug Act, 21 U.S.C. §§ 360aa-360ee (2001); *see also* Gary A. Pulsinelli, *The Orphan Drug Act: What's Right With It*, 15 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299, 300 (1999) (discussing the history, provisions, and amendments of the Orphan Drug Act). The Orphan Drug Act encourages pharmaceutical companies to develop products for orphan diseases, which affect less than 200,000 persons in the United States. 21 U.S.C. §§ 360aa-360ee; *see also* Snedden, *supra* note 19, at 150 (stating the U.S. Food and Drug Administration created the orphan status – conditions or diseases "afflicting fewer than 200,000 people" – through the Orphan Drug Act to encourage drug pharmaceutical companies to develop drugs for rare diseases); Mignon Fogarty, *Up for Adoption: Pharmacogenomics and the Orphan Drug Law*, (Biomednet Dec. 11, 1998), *available at* http://www.pst.fhg.de/pla/german/info/news/archiv/10021.htm (last visited Feb. 7, 2003).

PART II: HISTORICAL PERSPECTIVE: AN INTRODUCTION TO PHARMACOGENOMICS

"My doctors are claiming that my humanity, my genetic essence, is their invention and their property. They view me as mine from which to extract biological material. I was harvested."[67]

—John Moore

The social and legal issues in pharmacogenomics parallel those found in other fields of genetic engineering, such as cloning,[68] stem cell research,[69] and gene therapy.[70] The root of these issues originates from the genetic information obtained. Its offshoots are people's fears of potential discrimination and the embroilment into privacy issues. These issues also impact the social areas of employment, insurance, and education and the legal concepts of constitutional rights,[71] property rights,[72] and privacy

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67. LORI ANDREWS, THE CLONE AGE 191 (1999) (quoting Moore's reaction to his doctors' actions). In 1976, John Moore sought treatment at the Medical Center of the University of California at Los Angeles for hairy-cell leukemia. *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 480-81 (Cal. 1990); ANDREWS, *supra*, at 191. The doctors, aware of the scientific and commercial value of Moore's cells, removed his spleen. *Moore*, 793 P.2d at 481; ANDREWS, *supra*, at 191. After the splenectomy, they retained Moore's spleen for research purposes: they established a cell line, which they patented, from Moore's cell and earned millions of dollars selling the rights to a biotech company without Moore's consent. *Moore*, 793 P.2d at 481-82; ANDREWS, *supra*, at 191. Moore sued for wrongful conversion alleging his blood and bodily substances were his tangible and personal property – that he owned his body, his tissues, and his own DNA. *Moore*, 793 P.2d at 482; ANDREWS, *supra*, at 191. However, the California Supreme Court disagreed. *See generally Moore*, 793 P.2d 479 (concluding although the actions against Moore were unethical, they are not illegal). The Court held patients must be informed in advance if their tissues are to be used for commercial products or research but denied Moore's claim of property rights over his own body. *Id.*; ANDREWS, *supra*, at 192.

68. *See e.g.,* Rifkin, *supra* note 9, at 110-13 (lamenting the loss of genetic diversity, especially in plants, when replicating and mass producing hardy genes); STOCK, *supra* note 54, at 139-40 (addressing fears such as impoverished genetic constitutions with the diminished biological diversity and viewing cloned individuals as objects not as human beings).

69. *See e.g.,* STOCK, *supra* note 54, at 130-39, 161-65 (discussing how the divisiveness of playing God by enhancing human vulnerability and extending life spans engenders anxiety in many people).

70. *See e.g.*, *id.* at 235 n.146 (providing an example of genetic discrimination in the workplace wherein the employer fired an employee for accumulating high medical expenses while undergoing preventative therapy treatments for Alpha-1, a genetic condition).

71. *See generally* John B. Attanasio, *Science Tests Human Dignity: The Challenges of Genetic Engineering*, 53 SMU L. REV. 455 (2000) (presenting constitutional concepts with regards to genetic engineering); Smith & Burns, *supra* note 15, at 43, 50 (discussing whether genetic discrimination will create a suspect class and whether genetic screening constitutes unreasonable searches and seizures).

rights.[73] What makes pharmacogenomics unique is its use of individuals' genetic makeup to create drugs specifically designed to their genetic tendencies in order to better combat diseases;[74] whereas other genomic fields[75] target a specific gene to inhibit or reduce the disease and its consequences or to over-express a gene that would combat the disease.[76] Since pharmacogenomics seeks to move away from the broad spectrum approach of drug manufacturing toward a narrower spectrum, these designer drugs require the targeting of specific patient subpopulations.[77] Yet, before a discussion on how focusing on the disease, not the patient,

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72. *See generally Moore*, 793 P.2d 479 (rejecting plaintiff's claim that his body tissues, cells, and DNA were his property); D.M., *Will a Smaller Genome Complicate the Patent Chase?*, 291 SCI. 1194, 1194 (2001) (explaining how commercialization of the gene has led to patent fights).

73. Karen Rothenberg et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Challenges*, 275 SCI. 1755, 1755 (1997).

74. Paul Smaglik, *Pharmacogenetics Initiative Galvanizes Public and Private Sectors*, 410 NATURE 393, 393 (2001) (stating the aims of pharmacogenomics is to tailor drug prescriptions to each patient).

75. *See generally* Katheryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproduction*, 8 ALB. L.J. SCI. & TECH. 1 (1997) (discussing the legal implications in creating a cloned human); Gerald Coleman, Comment, *Genetic Engineering: Should Parents Be Allowed to Design Their Children?*, 34 HOW. L.J. 153 (1991) (describing the issues inherent in designing children).

76. Despite the conserved sequence of DNA that connects all of humanity, each individual has a unique genetic makeup that is a result of the combination of parental genes and normal nonlethal mutations occurring at the genetic level. *See generally* POWLEDGE, *supra* note 10 (explaining the science of genetics). This concept defines the uniqueness of pharmacogenomics, whereby drugs are specifically designed to an individual's genetic tendencies. Such an idea is of great importance to both the medical and scientific community, because patient responses to diseases differ on a molecular level. That is, variations in genetic expression and protein interactions affect the binding efficiencies of drugs. *See generally* William A. Haseltine, *Discovering Genes for New Medicines*, 276 SCI. AM. 92 (1997) (explaining gene expression in diseases). In contrast, other genomic fields counteract diseases by combating common motifs present in DNA. That is, certain gene domains common to humanity are targeted with drugs that could either inhibit lethal gene expressions or induce the overexpression of chemopreventive genes. *See generally* French W. Anderson, *Gene Therapy*, 273 SCI. AM. . 124 (1995) (explaining how gene therapy works: by transporting genetic material into the patient either by inserting "a healthy copy of a gene into the. . .[cell] in order to compensate for a defective gene" or to purposely alter a gene); Matthew J. Plunkett & Jonathan A. Ellman, *Combinatorial Chemistry and New Drugs*, 276 SCI. AM. 68 (1997) (discussing the process of combinatorial chemistry wherein compounds are screened for medicinal value); Robert Tijan, *Molecular Machines that Control Genes*, 272 SCI. AM. 54 (1995) (noting how current knowledge of gene regulation can lead to the development of drugs that combat life-threatening diseases by blocking gene expression).

77. WEAVER & HEDRICK, *supra* note 51, at 578; McCarthy, *supra* note 32, at 27; *The Right Medicine*, *supra* note 34, at 3.

can create a conglomerate of social and legal concerns, a look into human history and the genome must first be presented.

A. *The Genome and Human History*

Genetics has the power to reveal the past. For example, mitochondrial DNA (mtDNA) is generally maternally inherited with virtually little recombination between mitochondria.[78] Thus, the assumption is that a common female ancestor exists among individuals with the same type of mtDNA. Also, the Y-chromosome, which is purely paternally inherited, has no recombination on the chromosome's Y-specific region.[79] Yet, like mtDNA, the Y-chromosome offers a gender-specific record of the past.[80]

Phylogenetic techniques[81] in human mtDNA suggest current mtDNA, and therefore humans, descended from a female originating out of Africa some 200,000 years ago.[82] Further analysis shows the African gene pool having more genetic variation than the gene pool outside Africa.[83] Additionally, a greater genetic diversity exists among individuals in the same population rather than among individuals from different continents.[84] A

78. WEAVER & HEDRICK, *supra* note 51, at 578; Owens & King, *supra* note 42, at 451; *see also* BRYAN SYKES, THE SEVEN DAUGHTERS OF EVE 54 (2001) (explaining how mtDNA is maternally inherited).

79. WEAVER & HEDRICK, *supra* note 51, at 53; Owens & King, *supra* note 42, at 451.

80. SYKES, *supra* note 78, at 194 (explaining how mtDNA and the Y chromosome told the same gender specific story of the past).

81. A "phenotype" is the "morphological, biochemical, behavioral, or other properties of an organism." WEAVER & HEDRICK, *supra* note 51, at 633. A "genotype," on the other hand, is the "allelic constitution of a given individual." *Id.* at 628. In other words, the phenotype is the observable characteristics and the genotype is the genetic characteristics. The differences among related species can be measured through these phenotypic and genotypic traits. Using this information, scientists arrange these groups of related populations or species to illustrate ancestral relationships. Scientists use diagrams called phylogenetic trees to show these relationships. WEAVER & HEDRICK, *supra* note 51, at 577. Therefore, phylogenetic techniques are the methods used to create this biological relationship. *Cf.* SYKES, *supra* note 78, at 277 (claiming "genetics tells us very clearly that modern humans had their origins in Africa within the last hundred and fifty thousand years).

82. WEAVER & HEDRICK, *supra* note 51, at 578; ALDRIDGE, *supra* note 10, at 17. *See generally* Pääbo, *supra* note 43 (elucidating how humans are from a global family with common ancestry); Owens & King, supra note 42 (explaining how genomic technology can shed light to history). The tools of genomic analysis have shed light on human history through the analysis of the written record encoded in the DNA. *Id.* at 451. The few genes with the ability to encode visible traits and the Y chromosomal DNA and mitochondrial DNA all have unique inheritance patterns that scientists can use to trace a particular human population back to a common ancestor. Pääbo, *supra* note 43, at 1220. Scientists used current mitochondrial DNA to trace a back to female some 200,000 years ago. WEAVER & HEDRICK, *supra* note 51, at 578.

83. Pääbo, *supra* note 43, at 1219; Owens & King, *supra* note 42, at 452.

84. Owens & King, *supra* note 42, at 453.

possible explanation of mtDNA migration is females historically have a higher migration rate than males.[85] They tend to relocate to their husbands' birthplace and give birth to their children there.[86]

The possibility humans migrated out of Africa belies humanity's concept of race – that each individual belongs to a particular homogenous group. The stereotypical features of race (e.g., skin and hair color) are superficial, because they merely affect the body's exterior and do not indicate other variations within the genome, and are environmentally influenced (e.g., climate affecting skin pigmentation).[87] This genetic perspective of individuals from different races being more related to each other than to persons of the same race shatters the practice of racial classification. If anything, knowledge of the genome should foster compassion. With a mixed gene pool and with everyone carrying at least some deleterious alleles, stigmatizing a particular group based on one's allele is ludicrous.[88] Yet, ethnicity remains a major force in society. The genetic analysis of human populations and the resulting information can lead to abuse.

B. *Genetic Determinism and Discrimination*

Genotyping racial and ethnic groups can backlash because many diseases are racially and ethnically related.[89] For example, Jews are common carriers of Tay-Sachs and Gaucher's disease,[90] Armenians are more prone to Familial Mediterranean Fever disease, and Africans are common carriers of the sickle-cell anemia trait.[91]

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85. *Id.* at 451.

86. *Id.*

87. Pääbo, *supra* note 43, at 1220; Owens & King, *supra* note 42, at 453.

88. Pääbo, *supra* note 43, at 1220.

89. Examples of ethnically related diseases include asthma (among the isolated people of Easter Island, the Brazilian Highlands, and Tristan da Cunha, scientists have found susceptibility genes); Huntington's Disease (prevalent in an island in Venezuela), diabetes (prevalent in Nigeria, Ghana, and among the Pima Indians in Arizona), Alzheimer's (the Cherokee of Oklahoma seem resistant to Alzheimer's), and HTLV, a leukemia-causing virus (the Hagahai of New Guinea are resistant to a leukemia-causing virus, HTLV). Nelkin, *supra* note 3, at 126.

90. *Id.* Tay-Sachs and Gaucher are lysosomal storage diseases. STEDMAN'S, *supra* note 3, at 515, 521. Tay-Sachs can cause a failure in infants to develop motor skills. *Id.* at 521. In the first year, blindness and seizures are evident; within a few years, death occurs. *Id.* Gaucher, on the other hand, is commonly found among people of Ashkenazi Jewish descent. *Id.* at 515. It occurs most severely in infants with characteristics including bone lesions, seizures, and dementia. *Id.*

91. Nelkin, *supra* note 3, at 126; RIFKIN, *supra* note 9, at 163. Sickle cell results in abnormal red blood cells, "which appear in response to a lowering of the partial pressure of oxygen," and is characterized by such manifestations as anemia and chronic leg ulcers and bone deformities. STEDMAN'S, *supra* note 3, at 521. In the 1970s, when scientists

Although DNA sequences supply the instructions to construct a living organism, this "blueprint" does not foretell the organism's success in life,[92] because epigenetic mechanisms will also exert their influence on it. Yet, belief in biological and genetic determinism still exists. These concepts suggest genetics or biology predetermines one's fate.[93] Such ideologies have led to many incidents of positive and negative eugenics around the world.

C. *The Shadow of Eugenics*

"If we could make better humans. . .why shouldn't we?"[94]

—James Watson, Scientist

Sir Francis Galton[95] coined the term "eugenics," which is the process whereby desirable traits in the human gene pool are selected and undesirable traits are eliminated.[96] Positive eugenics involves improving the characteristics of a species or an organism.[97] The current use of genetics

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discovered the sickle-cell anemia trait, many African Americans, specifically carriers of the recessive gene, experienced employment discrimination. RIFKIN, *supra* note 9, at 164; *see, e.g.*, Nelkin, *supra* note 3, at 130 (describing how eight African American employees of the Lawrence Berkeley Laboratory at the University of California were tested, without their knowledge or consent, for the sickle cell mutation). The United States Air Force Academy denied entrance to these carriers under the mistaken belief they would not function in oxygen-reduced environments, because the affected gene was for the blood's oxygen carrying red blood cells, which they assumed would sickle at high atmospheric levels. JERRY E. BISHOP & MICHAEL WALDHOLZ, GENOME 299 (1999) (stating the ban on sickle cell carriers was eventually lifted following medical and public protests of racism); RIFKIN, *supra* note 9, at 164 (claiming other carriers were denied jobs in the chemistry industry in toxic sensitive environments).

92. Barbara R. Jasny & Pamela J. Hines, *Genome Prospecting*, 286 SCI. 443, 443 (1999).

93. Colin S. Diver & Jane Maslow Cohen, *Genophobia: What is Wrong With Genetic Determinism?*, 149 U. PA. L. REV. 1439, 1448 (2001).

94. STOCK, *supra* note 54, at 12.

95. Sir Francis Galton, the cousin of the English biologist and evolutionist Charles Darwin, was also an English scientist. STEDMAN'S, *supra* note 3, at 459, 724; *see also Eugenics, in* GALE ENCYCLOPEDIA OF PSYCHOLOGY (2d ed. 2001) *available at* http://www.findarticles.com/g2699/0001/2699000124/p1/article.jhtml (last visited Oct. 31, 2002). He is known as the founder of eugenics. Leslie Jones, Social Darwinism Revisited, HISTORY TODAY (August 1998), *available at* FindArticles.com, http://www.findarticles.com/m1373/n8_v48/21031902/p1/article.jhtml (last visited Oct. 31, 2002).

96. Lisa Sowle Cahill, *Genetics, Ethics and Social Policy: The State of the Question, in* THE ETHICS OF GENETIC ENGINEERING, at vii, vii (Maureen Junker-Kenny & Lisa Sowle Cahill, eds., 1998); RIFKIN, *supra* note 9, at 116; Smith & Burns, *supra* note 15, at 24 n.9.

97. RIFKIN, *supra* note 9, at 116; Smith & Burns, *supra* note 15, at 25 n.9.

tests,[98] via gene therapy, to apply the information obtained from the Human Genome Project is an example of positive eugenics. Negative eugenics, on the other hand, systematically eliminates undesirable biological traits in organisms or species.[99] Sterilization efforts, selective mating, and the detection and subsequent elimination of "defective" fetuses or embryos are applications of negative eugenics.[100]

During the eugenics movement of the Nazi regime in Germany, religion, ethnicity, and sexual orientation were traits used to identify undesirables.[101] The United States also had its own eugenic past. From the turn of the 1900s until the Great Depression, a number of the American intellectual elite and some people of the white Anglo-Saxon race embraced eugenic ideology.[102] The movement itself was spawned during the first massive wave of immigration into the United States in the 1890s and the growth of inner-city slums.[103] Eugenics reached a peak during World War I with the red scare as some of the white Anglo-Saxon elite became paranoid of losing their social and economic status.[104]

The idea that heredity, not the environment, determines individuals' behaviors and status in society attracted some of the white Anglo-Saxon elite.[105] Thus, they turned to eugenics. Even Alexander Graham Bell stated: "We have learned to apply the laws of heredity so as to modify and improve our breeds of domestic animals. Can the knowledge and experience so gained be available to man, so as to enable him to improve

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98. Genetic tests are being developed for diseases that include cystic fibrosis, breast cancer, colon cancer, Huntington's disease, Tay-Sachs, Duchenne muscular dystrophy, Gaucher, hemophilia, fragile X syndrome, and sickle cell anemia. Edward S. Colub, *Ethical Considerations Arising From Economic Aspects of Human* Genetics, *in* CHANGING NATURE'S COURSE: THE ETHICAL CHALLENGE OF BIOTECHNOLOGY 78 (Gerhold K. Becker & James P. Buchanan, eds., 1996); Eliot Marshall, *The Genome Program's Conscience*, 274 SCI. 448, 448 (1996).

99. RIFKIN, *supra* note 9, at 116; Smith & Burns, *supra* note 15, at 24 n.9.

100. Cahill, *supra* note 96, at vii.

101. Smith & Burns, *supra* note 15, at 25 n.9.

102. RIFKIN, *supra* note 9, at 118.

103. *Id.* Moral, racial, and social issues influenced the American eugenics movement. *Eugenics*, *supra* note 95; *see also* Nelkin, *supra* note 3, at 123 (explaining how immigration authorities argue the "Mediterranean races were intellectually inferior to the Nordic race" because of "their propensity for degeneracy, crime, and congenitally poor health").

104. RIFKIN, *supra* note 9, at 118.

105. *Id.* For example, one of America's foremost geneticist, Charles Davenport, played an active role in the Eugenics movement. Stephen Jay Gould, *The International Brand of the Scarlet (Genetic Aspects of Nomadism)*, NATURAL HISTORY (Mar. 1998), *available at* http://www.findarticles.com/m1134/n2_v107/20485353/p1/article.jhtml (last visited Feb. 7, 2003).

the species to which he himself belongs?"[106] Margaret Sanger, the well-known feminist who fought for birth control programs, also subscribed to the notion that biology influenced the superiority or inferiority among different groups.[107] This belief led to the formation of a significant amount of eugenic societies.[108] They included the American Breeders Association, which set up the first functioning Committee on Eugenics in 1906, and the formation of the Eugenics Committee of the United States in 1922, later renamed the American Eugenics Society.[109]

The United States applied these eugenic concepts in the form of sterilization laws as a tool for weeding out the biologically inferior.[110] In 1907, Indiana became the first state to pass a mandatory sterilization law.[111] Other states passed similar laws in which "confirmed criminals, idiots, imbeciles, and others in state institutions" were manditorially sterilized in order to "weed out the biologically inferior stock" from America.[112] However, most of these state laws have since been overturned.[113]

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106. Bell gave this speech before the American Breeders Association in Washington in 1908. RIFKIN, *supra* note 9, at 121. *Contra* STOCK, *supra* note 54, at 151 (quoting one contemporary view regarding eugenics: "Positive eugenics, any tailoring of an individual's genetic endowment. . .will put us on a slippery slope to the abolition of man").

107. RIFKIN, *supra* note 9, at 121.

108. *Id.* at 119-20.

109. Other eugenics societies in the United States include: The Eugenics Record Office in Cold Spring Harbor, New York, established in 1910, The Galton Society of New York, established after 1910, and The Eugenics Association, formed in 1913. *Id.*

110. *Id.* at 122. The eugenics movement in the United States disproportionately institutionalized and sterilized more women than men. ANDREWS, *supra* note at 67, at 131. In general, victims included people diagnosed with deafness, epilepsy, mental retardation, and psychiatric symptoms. *Eugenics*, *supra* note 95. They were also people of "low moral stature." *Id.* These people included prostitutes, thieves, and unwed mothers. *Id*; *see also* Nelkin, *supra* note 3, at 123 (noting how eugenicists claimed "intelligence, feebleminded-ness, special talents, criminal tendencies, industriousness, pauperism, alcoholism, laziness, poverty, loquacity, harlotry, and vagrancy were all heritable traits distinguishing certain families and groups").

111. RIFKIN, *supra* note 9, at 122; *see Eugenics*, *supra* note 95. *But see* Smith & Burns, *supra* note 15, at 25 n.9 (noting how most states' sterilization laws have been overturned).

112. RIFKIN, *supra* note 9, at 122. Thirty states, between 1907 and 1931, passed sterilization legislation for people considered "feebleminded" or who have criminal tendencies. ANDREWS, *supra* note at 67, at 131. They were informally called "Mississippi appendectomy[ies]," because the recipients were often poor individuals from the South. *Id.* Over 64,000 people received these "appendectomies." *Id.* Some were performed without the people's knowledge or against their will. *Id.* Legislators also created miscegenation laws to prevent interracial marriages. *Eugenics*, *supra* note 95. These compulsory sterilization laws reflected the belief that undesirable traits would proliferate in the dominant populace if individuals of different races were allowed to mix. *Id.*

113. *E.g.*, McKinney v. McKinney, 805 S.W.2d 66, 69 (Ark. 1991) (holding unconstitutional Arkansas's involuntary sterilization laws on mental incompetents because it did not provide sufficient procedural protection); Skinner v. Oklahoma, 316 U.S. 535 (1942) (strik-

The decline in the eugenics movement in the United States occurred after 1924.[114] It met its death with the collapse of the stock market and Hitler's rise to power in 1929.[115] Once Hitler's Third Reich came into power in 1933, the Germans established the Hereditary Health Law[116] as a eugenic sterilization statute.[117] The statute became the first step in the Nazi's mass eugenic program. Scandinavian countries, like Sweden, also had their own eugenic programs. Sweden's sterilization law, which was abolished in 1976, forcibly denied about 100,000 women the right to reproduce.[118] With the new genetic engineering tools having the potential to reengineer man's blueprint, they evoke the specter of these negative eugenics past.

D. *The Nature of Pharmacogenomics*

Nonetheless, pharmacogenomics proposes to elucidate the differences in drug responses by focusing on genetic polymorphisms of drugs metabolizing enzymes.[119] Studies to date show these polymorphisms differ in frequency amid ethnic and racial groups.[120] Take, for example, MC1R, a melanocortin-stimulating hormone receptor gene, which may cause the variations in skin and hair color.[121] Although not a pharmacogenetic polymorphism, it illustrates the relationship between ethnicity and genetics. The amount of melanin, emalanin (brown and black melanins that provide protection against ultraviolet (UV) radiation) and phaeomelanin (red and yellow melanins that may contribute to UV induced skin damage), vary to cause these differences in color.[122] Variations in multiple sites of the MC1R protein are found in over eighty percent of red-headed individuals with fair skin that burns, not tans, and in less than four per-

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ing down the Oklahoma Habitual Criminal Sterilization Act, Okla. Stat. Ann. Tit. 57, § 171 et seq., an involuntary sexual sterilization law for repeat offenders). *But see* Buck v. Bell, 274 U.S. 200 (1927) (setting the precedent for sterilization of the "feebleminded" by upholding the Virginia Sterilization Act ch. 394 (1924)). Approximately 20,000 people were sterilized by the end of the America's eugenics movement. *Eugenics*, *supra* note 95.

114. RIFKIN, *supra* note 9, at 125.

115. *Id.* at 125-26.

116. THE AMERICAN-ISRAELI COOPERATIVE ENTERPRISE, THE JEWISH VIRTUAL LIBRARY, LAW FOR THE PROTECTION OF HEREDITARY HEALTH: THE ATTEMPT TO IMPROVE THE GERMAN ARYAN BREED (JULY 14, 1933), *available at* http://www.us-israel.org/jsource/Holocaust/nurmlaw1.html (2001) (last visited Feb. 7, 2003).

117. RIFKIN, *supra* note 9, at 126-27; Sandro Spinsanti, *Gene Therapy and The Improvement of Human Nature: Ethical Questions, in* THE ETHICS OF GENETIC ENGINEERING 14 (Maureen Junker-Kenny & Lisa Sowle Cahill, eds., 1998).

118. Spinsanti, *supra* note 117, at 14.

119. Evans & Relling, *supra* note 32, at 487.

120. *Id.* at 488.

121. *Id.* at 453.

122. Owens & King, *supra* note 42, at 453.

cent of British or Irish individuals having skin that tans without burning.[123] However, no variations were found among African individuals.[124] Among Asians, amino acid substitutions are common in MC1R.[125]

With the marked diversity in pharmacogenetic polymorphisms, frequency of polymorphisms among racial and ethnic groups dictates the aim of pharmacogenomics: to discover genetic or phenotypic associations to diseases or drug toxicity, race must be considered.[126] By targeting and studying genetic subpopulations, pharmaceuticals can help diagnose diseases and prescribe drugs according to their distinct biological makeup.[127] Despite this seemingly good news, a cloud of "genetic hypochondria" lurks in the background.[128]

PART III: ANALYSIS

A. *Genetics and the Law*

Genes, generally those located on enzymes metabolizing drugs in the liver, intestine, and other organs, are known to influence an individual's reaction to specific drugs.[129] Many of these drug-metabolizing enzymes

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123. *Id.* Variation in the sequence of amino acids occurs in the second transmembrane domain, the first extracellular domain, and the seventh transmembrane domain. *Id.*

124. *Id.* at 453.

125. *Id.*

126. Evans & Relling, *supra* note 32, at 488.

127. *Collaboration Works on Cancer Pharmacogenomics*, CANCER WKLY., Mar. 21, 2000 (LEXIS, Sci. & Tech., Medical & Healthcare); *see* Jasny & Hines, *supra* note 92, at 443 (1999); Perry, *supra* note 26, at 70; *The Right Medicine*, *supra* note 34, at 3. Studies on genetic variations in drug responses based on ethnicity, race, and gender have been conducted. Mark A. Rothstein, Abstract, *Pharmacogenomics and Minority Populations*, NAT'L. INST. OF GEN. MED. SCI. (2001), *available at* http://www.nigms.nih.gov/pharmacogenetics/#ethical_studies (last visited Nov. 22, 2002). For example, studies on drug reactions by Native Americans are currently underway. Paul G. Spicer, Abstract, *The Promises and Pitfalls of Native Genetic Research*, NAT'L. INST. OF GEN. MED. SCI. (2001), *available at* http://www.nigms.nih.gov/pharmacogenetics/index.html (last visited Dec. 20, 2002).

128. Pääbo, *supra* note 43, at 1220.

129. Brian Spear, *Pharmacogenomics: Today, Tomorrow, and Beyond*, 11(2) DRUG BENEFIT TRENDS 53-54 (1999) (access to this article may be obtained through free registration at the Medscape website; on file with author), *available at* http://www.medscape.com (last visited Feb. 7, 2003). Known drug metabolizing enzymes include CYP2D6, which metabolizes many drugs including tricyclic antidepressants, a number of antiarrhythmics, beta-blockers, and neuroleptics; TPMT, which metabolizes azathioprine, a drug that treats leukemia and autoimmune disorders; and CYO2C19, which contributes to the metabolism of anxiolytics and antiulcer medications. Becker, supra note 32, at 24; Peter L. Bullock, *Pharmacogenetics and Its Impact on Drug Development*, 11(1) DRUG BENEFIT TRENDS 53-54 (1999) (access to this article may be obtained through free registration at the Medscape website; on file with author), *available at* http://www.medscape.com (last visited Feb. 7, 2003); Spear, *supra* note 129, at 53-54.

exhibit polymorphic expression[130] that causes adverse drug reactions. The idea that genetic variations in drug-metabolizing enzymes in the liver may cause certain adverse drug reactions first came about in 1957.[131] Two years later, in 1959, the term "pharmacogenomics" was used to describe this relationship between drug therapy and genetic makeup.[132]

The science of pharmacogenomics came about in 1997 as a by-product of the Human Genome Project.[133] Ideas as to how pharmaceuticals could enter the arena of personalized medicine followed. These ideas included obtaining a list from doctors of patients suffering from adverse drug reaction to certain medications and contacting those patients to participate in research studies or identifying the problems in the protein pathways causing the adverse drug reactions through the use of single nucleotide polymorphisms (SNPs).[134]

Despite the potential benefits pharmacogenomic studies may offer,[135] there are risks inherent with this biotechnology breakthrough.[136] Studies assessing the drug responses among individuals of different genotypes and the relevant prevalence of genotypes in populations and subpopulations will reflect how certain traits are linked to ethnicity and gender, while the degree to which other factors (e.g., environmental) interact with

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130. Polymorphism causes the variability in DNA expression. It is a region of DNA containing a difference or change in the base sequence from one individual to another. When these polymorphisms occur in a gene, they may contribute to the difference in the gene's protein product, which may give rise to the disease. *See* OXAGEN LTD. –GLOSSARY OF TERMS, *at* http://www.oxagen.co.uk/pages/media_investors/6/index.html (last visited Feb. 7, 2003).

131. Bullock, *supra* note 129, at 53-54.

132. *Id.*

133. Juan C. Mendible, *Pharmacogenomics: Medicines Tailored Just for You* (Jan. 3, 2000), *at* http://www.suite101.com/article.cfm/4866/31171 (last visited Feb. 7, 2003).

134. *Id.* If the SNP is within a gene, it may indicate the disease and the protein it codes for by marking the location of the gene. *Id.*

135. Spear, *supra* note 129, at 53-54. Potential benefits in pharmacogenomics include: (1) the ability to predict adverse drug reaction, (2) the distribution of proper medication dosages, (3) the ability of patients to get well sooner since the optimal drug will be prescribed at the onset of the therapy, (4) decreased medical costs, and (5) increased understanding of the nature of important diseases, which will lead to new cures. *See id.*; Muin J. Khoury & Jill Morris, *Pharmacogenomics and Public Health: The Promise of Targeted Disease Prevention*, CENTER FOR DISEASE CONTROL, *at* http://www.cdc.gov/genomics/info/factshts/pharmacofs.htm (last visited Feb. 7, 2003).

136. Potential risks in pharmacogenomics include misuse of the genetic information and premature and indiscriminate application of the information. *See* Bullock, *supra* note 129, at 53-54.

genetic factors to influence drug response will focus on individuals' economic status and geographic locale.[137]

Pharmacogenomics studies genetically inherited conditions by focusing largely on genetic polymorphisms in drug metabolizing enzymes[138] in order to understand the differences in drug effects.[139] Yet, the requirement for homogenous samples in studies and the fact that many diseases are gender-[140] and race-[141] based create a genetic profiling that has a potential for misuse, primarily in the insurance and employment arena.

Genetic testing does not guarantee a disease will manifest. Rather, it indicates the likelihood of an individual's susceptibility to a particular disease.[142] The culmination of other factors, not just the mere possession of a gene, influences the disease in its severity, onset, and manifestation.[143] This lack of understanding that a positive identification for a gene does not necessarily equate to the manifestation of a disease may result in in-

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137. Khoury & Morris, *supra* note 135. *See generally* Peltonen & McKusick, *supra* note 25, at 1226 (comparing the genetic background of monogenic diseases and complex disorders).

138. Genes exhibiting genetic polymorphism include dihydropyrimidine dehydrogenase, which is linked to flourouracil neurotoxicity, and thiopurine methyltransferase, which is linked to thiopurine toxicity and efficacy and which increases the risk for second cancers. Evans & Relling, *supra* note 32, at 489 (providing a comprehensive list of genetic polymorphisms influencing drug metabolism).

139. Evans & Relling, *supra* note 32, at 487.

140. Examples of gender-based diseases include those affecting women: Rheumatoid arthritis affects 1.5 million American women. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, SELECTED MEDICINES IN DEVELOPMENT FOR WOMEN, *at* http://www.phrma.org/publications/quickfacts/19.11.2001.312.cfm (last visited Feb. 7, 2003). This year approximately 175,000 new cases of breast cancer will be diagnosed. *Id.* Ovarian cancer, the "silent killer," will kill more than 14,000 American women this year. *Id.* Alzheimer's disease kills twice as many women than men. *Id.*

141. Race based diseases exist for many ethnicities. Take for example the African American population: The death rate for heart disease is higher among African Americans than Caucasians. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, SELECTED MEDICINES IN DEVELOPMENT FOR MAJOR DISEASES AFFECTING AFRICAN AMERICANS, *at* http://www.phrma.org/publications/quickfacts/13.09.2002.548.cfm (last visited Feb. 7, 2003). Since the 1960s, the number of African Americans with diabetes has tripled. *Id.* Glaucoma occurs six to eight times more often among African Americans than among Caucasians. *Id.* African Americans have a 30% greater chance of dying from cancer than Caucasians. *Id.*

142. Kyle G. French, Note, *The Elderly and the Discriminatory Use of Genetic Information*, 5 ELDER L.J. 147, 155 (1997); Paul Steven Miller, *Is There a Pink Slip in My Genes? Genetic Discrimination in the Workplace*, 3 J. HEALTH CARE L. & POL'Y 225, 231 (2000).

143. Miller, *supra* note 142, at 231-32; *e.g.*, BISHOP & WALDHOLZ, *supra* note 91, at 283 (explaining how prenatal tests for diseases, where the victim lives a long but disabled life, detect the presence of the mutation but does not determine the severity of the disease).

surer and employer misinterpretation and misuse of genetic information as well as in people's refusal to take genetic tests for fear of reprisal by employers or insurers.[144]

Although pharmacogenomics examines individuals already exhibiting symptoms of their diseases in order to rectify or ease their conditions, pharmacogenomics also concerns the prevention of diseases (e.g., vaccinations). This framework may appear beneficial and may lack any basis for discrimination by the employer, insurer, and the individual, but the mere fact a genetic profile exists contravenes that idea.[145]

1. State Legislation

"[W]ith genetic tests, insurance companies can virtually eliminate the guesswork in underwriting. They can seek out people who are genetically pure, creating a ghetto of the uninsured, because they will know who is likely to get a particular disease at a particular age."[146]

—J. Brian McCall

The fear that one's genetic profile may be misinterpreted and misused resulted in a flurry of legal protection for genetic privacy.[147] The scope and content of resulting legislative acts vary; however, they tend to implement restrictions on the disclosure or use of genetic information.[148] While disclosure restrictions generally forbid the release or communication of genetic information without an individual's prior consent to third

144. Miller, *supra* note 142, at 232; *cf.* BISHOP & WALDHOLZ, *supra* note 91, at 282 (relating an example of one insurer who agreed to pay for a couple's prenatal test but would subsequently require the parents to abort the child if it was affected, as the insurer was already paying the high health costs related to the couple's first child's illness).

145. Racial and ethnic groups face the prospect of discriminatory genotyping by institutions as scientists uncover and identify those genetic predispositions and traits unique to their group. RIFKIN, *supra* note 9, at 163. Using this genetic information, institutions can segregate, abuse, and discriminate. *Id.* However, preexisting genetic conditions have many uncertainties associated with it. Variables include: (1) the likelihood of becoming symptomatic; (2) the time when the onset may occur; and (3) the degree of severity of a disease, which the individual has no control over and which may be treatable. *Id.* at 161. Despite these facts, a 1996 survey of genetic discrimination in the United States conducted by the Department of Neurobiology and Division of Medical Ethics at Harvard Medical School found the incidence of genetic discrimination growing. *Id.*

146. *Id.* at 162. J. Brian McCall is a Republican insurance executive and state legislator who authored a Texas law banning genetic discrimination by insurers. *Id.*

147. Diver & Cohen, *supra* note 93, at 1443; *see also* ANDREWS, *supra* note 67, at 182-83 (discussing how some genetic testing has led to the loss of jobs or insurance, thereby creating a movement for protection under the law against genetic discrimination).

148. Diver & Cohen, *supra* note 93, at 1444; ANDREWS, *supra* note 67, at 183 (suggesting having the genetic information remain private or stopping the tests until protective laws are enacted).

parties, these same restrictions prevent the use of genetic information to withhold or grant certain privileges or benefits.[149] Insurance and employment are the primary areas where these legislative acts prohibit genetic discrimination. The insurance legislation generally forbids asking and/or using an applicant's genetic information to deny coverage or to assign a higher risk classification.[150] The employment provisions, on the other hand, generally restrict the use of genetic information as the basis for various personnel actions, such as the refusal to hire, the refusal to discharge, the refusal to promote, and the assignment of unfavorable tasks.[151]

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149. *See* Diver & Cohen, *supra* note 93, at 1444. A prohibition on genetic discrimination by insurance companies, government agencies, health care providers, and schools is a form of use restriction. *Id.*

150. *See id. See generally* ALA. CODE § 27-5-13 (2001) (prohibiting the denial of health or disability insurance coverage because an applicant has sickle cell anemia); ALA. CODE § 27-53-2 (2001) (prohibiting health insurers from the use or requirement of genetic testing to determine a predisposition for cancer or to determine insurability, rates, or benefits); COLO. REV. STAT. § 10-3-1104.7 (2001) (providing privacy protection of genetic information and prohibiting the use of genetic information to deny access to insurance); FLA. STAT. ANN. § 626.9707 (West 2000) (prohibiting insurers from refusing insurance or changing to higher rates for individuals with sickle cell anemia); FLA. STAT. ANN. § 760.40 (West 2000) (providing informed consent and privacy protection of genetic information); GA. CODE ANN. §§ 33-54-1 to -8 (2000) (requiring consent prior to genetic testing, providing privacy protection of genetic information, and prohibiting genetic testing unless for therapeutic or diagnostic purposes); MO. ANN. STAT. § 375-1303 (West 2000) (prohibiting the request or requirement of genetic information or genetic testing); N.H. REV. STAT. ANN. ch. 141-H (2000) (prohibiting the consideration of genetic testing); N.C. GEN. STAT. § 58-65-70 (2002) (prohibiting the refusal of health insurance because the individual has the hemoglobin C or sickle cell trait); OR. REV. STAT. § 659A.303 (2001) (prohibiting the use of genetic information to affect insurance coverage and providing for privacy protection and informed consent of genetic information); WIS. STAT. ANN. § 631.89 (West 2000) (prohibiting insurers from using genetic information as leverage against applicants); NATIONAL HUMAN GENOME RESEARCH INSTITUTE, GENETIC INFORMATION AND HEALTH INSRUANCE ENACTED LEGISLATION, Insurance Chart, *available at* http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/insure.htm (last visited Dec. 18, 2002) (listing 39 states and the legislation they have enacted as of September 2000).

151. *See* Diver & Cohen, *supra* note 93, at 1444-45. *See generally* FLA. STAT. ANN. § 448.075 (West 2000) (prohibiting employers from denying employment or discharging employees based on the sickle cell trait); IOWA CODE ANN. § 729.6 (West 1993) (prohibiting employers from requesting genetic testing or conditioning employment on a genetic test); MO. ANN. STAT. § 375.1306 (West 2002) (prohibiting the use of genetic information with regard to employee benefits or rights but allowing its use when the information relates to an employee's ability to perform assigned job tasks); N.H. REV. STAT. ANN. §§ 141-H:1 & -H:3 (1996) (prohibiting employers from using or requiring genetic testing); OR. REV. STAT. § 659.303 (1999) (prohibiting employers from subjecting employees to genetic screening); R.I. GEN. LAWS §§ 28-6.7-1 & 28-6.7-3 (2001) (prohibiting employers from requesting, requiring, selling, or interpreting genetic information); NATIONAL HUMAN GENOME RESEARCH INSTITUTE, GENETIC INFORMATION AND THE WORKPLACE STATE

a. Genetic Laws in General

The scope of state legislation has evolved from early laws prohibiting discrimination based on a few specific genetic conditions (e.g., the trait for sickle cell anemia) to laws offering expanded protection for a wider range of genetic afflictions.[152] While most states prohibit the unauthorized disclosure of genetic information, some states extend these restrictions to certain kinds of employment decisions (e.g., work assignments, promotions, and benefits).[153] As of September 2001, thirty-nine states have some form of legislation addressing the use of genetic information.[154] California, for example, has passed laws prohibiting health insur-

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ENACTED LEGISLATION, Workplace Chart, *at* http://www.genome.gov/page.cfm?pageID=10002339 (last visited Dec. 18, 2002) (listing 24 states and the legislation they have enacted since August 1999).

152. Diver & Cohen, *supra* note 93, at 1443; *see also* N.C. GEN. STAT. § 95-28.1 (2000) (listing the sickle cell and hemoglobin C traits as factors employers cannot use as a basis for employee discharge or refusal to hire); N.J. STAT. ANN. §§ 10:5-5(x) & 10:5-12(a) (West 2001) (forbidding employment discrimination based on atypical hereditary blood or cellular traits); FLA. STAT. ANN. § 448.075 (West 2000) (prohibiting employers from discharging employees or refusing employment based on the sickle cell trait).

153. *See* Diver & Cohen, *supra* note 93, at 1444-45.

154. *See* ALA. CODE §§ 27-53-1 to -4 (2001); ALASKA STAT. §§ 21.54.100, 21.54.110 (Michie 2000); ARIZ. REV. STAT. ANN. §§ 20-448, 20–448.02, 20-1379 (West 2002); ARK. CODE ANN. §§ 23-86-304, 23-86–306 (Michie 2000); CAL. CIV. CODE § 56.17 (Deering Supp. 2002); CAL. HEALTH & SAFETY CODE § 1374.7 (Deering 2002); CAL. INS. CODE §§ 742.405-.407 (Deering Supp. 2002); CAL. INS. CODE §§ 10123.3-.35, 10123.9, 10140, 10140.1, 10143, 10146, 10148-10149.1, 10198.9, 10705 (Deering 1996 & Supp. 2002); COLO. REV. STAT. §§ 10-3-1104.7, 25-1-122.5 (2001); CONN. GEN. STAT. ANN. § 38a-816(19) (West 2001 & Supp. 2002); FLA. STAT. ANN. § 627.4301 (West Supp. 2002); FLA. STAT. ANN. §§ 627.65625, 636.0201, 641.31073, 641.438, 760.40 (West 1997 & Supp. 2002); GA. CODE ANN. §§ 33-54-1 to -8 (1996); HAW. REV. STAT. ANN. §§ 431:10A-118, 432D-26 (Michie 2001); IDAHO CODE §§ 41-2221, -3940, -4708 (Michie 1998); 215 ILL. COMP STAT. 97/20, 97/25 (2002); IND. CODE ANN. § 16-39-5-2 (Michie 1993 & Supp. 2002); IND. CODE ANN. §§ 27-8-26, -1 to -11 (Michie 1999); IOWA CODE ANN. § 729.6 (West 1993); KAN. STAT. ANN. § 40-2259 (2000); LA. REV. STAT. ANN. §§ 22:213.7, :250.3 (West Supp. 2002); LA. REV. STAT. ANN. §§ 40:1299.6, :2210 (West 2001); MONT. CODE ANN. §§ 33-18-206, -22-514, -22-526 (2002); NEB. REV. STAT. § 44-5246.02 (2001); NEV. REV. STAT. §§ 629.101-.201, 689A.417, .545, .585, 689B.069, .420, .550, 689C.193, .198 (2001); N.H. REV. STAT. ANN. §§ 141-H:1 to -H:5 (1996 & Supp. 2002); N.H. REV. STAT. ANN. §§ 420-G:6 to -G:7 (1998 & Supp. 2002); N.J. STAT. ANN. §§ 10:5-5, :5-12 (West 1993 & Supp. 2002); N.J. STAT. ANN. §§ 10:5-43 to -49 (West Supp. 2002); N.J. STAT. ANN. § 17:48-6.18 (West Supp. 2002); N.J. STAT. ANN. § 17:48A-6.11 (West Supp. 2002); N.J. STAT. ANN. §§ 17.48E-15.2, 17B:26-3.2, :27-36.2, :27-57 (West Supp. 2002); N.J. STAT. ANN. § 17B:30-12 (West 1996 & Supp. 2002); N.J. STAT. ANN. § 26:2J-15.1 (West Supp. 2002); N.M. STAT. ANN. §§ 24-21-1 to -7, 59A-23E-11 (Michie 2001); N.Y. EXEC. LAW 296 (McKinney 2001); N.Y. INS. LAW §§ 2612, 3221, 4305 (McKinney 2000 & Supp. 2002); N.C. GEN. STAT. §§ 58-68-30, -35, 95-28.1A (2001); N.D. CENT. CODE §§ 26.1-08-12, 36.4-03.1 (1995); OHIO REV. CODE ANN. §§ 1751.18(D)(6), 1751.65 (West 2002); OHIO REV. CODE ANN. §§ 3901.21(T)(3)(f), 3901.491, 3901.501, 3924.031, 3924.27 (Anderson 2002); OR. REV. STAT. §§ 659A.303,

ers from refusing or canceling benefits or imposing higher rates based upon the presence of certain genetic characteristics.[155] California laws also bar health insurers from refusing benefits or altering terms or conditions on the basis of genetic test results unless the policy is contingent upon testing for particular diseases and the informed consent of the applicant is acquired before screening.[156]

The earliest state legislative efforts aimed at genetic legislation addressed discrimination in the workplace and prohibited unequal treatment based on the possession of particular genetic disorders or traits (e.g., hemoglobin C or sickle cell carriers).[157] Currently, North Carolina and Florida have laws prohibiting employment discrimination against individuals carrying the sickle cell trait.[158]

659A.300, 192.531 - .539, 746.135 (2001); R.I. GEN. LAWS §§ 28-6.7-1 to -4 (2000); S.C. CODE ANN. §§ 28-41-45, 38-71-670, -840, -860 (Law Co-op. 2001); S.D. CODIFIED LAWS §§ 58-17-84, 58-18-45, 58-18B-27 (Michie 2002); TENN. CODE ANN. §§ 56-7-2701 to 7-2708, 56-7-2802 (2000); TEX. LAB. CODE § 21.401-.405 (Vernon 1996 & Supp. 2002); TEX. REV. CIV. STAT. ANN. Art. 9032 (Vernon Supp. 2002); VA. CODE ANN. §§ 32.1-67.1 to -69.2 (Michie 1997); VA. CODE ANN. §§ 38.2-508.4, 38.2-613 (Michie 1999); W. VA. CODE ANN. §§ 33-15-2a(g), -16-1a(j), -16-3k (Michie 2000); WIS. STAT. ANN. §§ 111.372, 631.89, 632.748 (West Supp. 2001); WYO. STAT. ANN. §§ 26-19-107, -306 (Michie 2001).

155. CAL. INS. CODE §§ 10123.3, 10140, 10148, 10149, 11512.95 (Deering 1996 & Supp. 2002); CAL. HEALTH & SAFETY CODE §§ 1374.7, 11512.95 (Deering 2002).

156. CAL. INS. CODE §§ 10148, 10123.3, 10140 (Deering 1996 & Supp. 2002); FLA. STAT. ANN. ch. 448.076 (West 2002); Miller, *supra* note 142, at 259.

157. Miller, *supra* note 142, at 259.

158. N.C. GEN. STAT. § 95-28.1 (2002) (prohibiting employment discrimination against individuals with the hemoglobin C or sickle cell traits); FLA. STAT. ANN. ch. 448.076 (West 2002) (preventing employers from requiring prospective employees to undergo screening for the sickle cell trait); *see* Miller, supra note 142, at 259. Other states with legislation like Florida and North Carolina include Alabama, New Jersey, and New York. ALA. CODE § 27-5-13 (1986); N.J. STAT. ANN. §§ 10:5-5, 10:5-12 (West 1993 & Supp. 2002); N.Y. CIV. RIGHTS LAW § 48-a (McKinney 1992 & Supp. 2002). Louisiana's statute prevents genetic discrimination in the workplace against individuals with the sickle-cell trait. LA. REV. STAT. ANN. § 23:352 (West 1998); *see* Miller, *supra* note 142, at 260. New Jersey's statute proscribes against discrimination for individuals carrying the sickle cell, hemoglobin, thalassemia, Tay-Sachs, and cystic fibrosis traits. N.J. STAT. ANN. § 10:5-12-12 (West 1993); *see* Miller, *supra* note 142, at 260. Finally, New York's statute protects individuals with sickle cell, Tay-Sachs, and the beta-thalassemia traits from discrimination. N.Y. CIV. RIGHTS LAW § 48-a (McKinney 1992); *see* Miller, *supra* note 142, at 260.

New York and New Jersey's general statutes include prohibitions on genetic discrimination in employment practices (i.e., hiring, discharging, and fixing terms and conditions of employment). N.J. STAT. ANN. § 10:5-12 (West 1993 & Supp. 2002); N.Y. EXEC. LAW § 296 (McKinney 2001); *see* Miller, *supra* note 142, at 263. Although New York limits its coverage to asymptomatic genetic characteristics, New Jersey's statute does not. *Compare* N.J. STAT. ANN. § 10:5-12 (West 1993 & Supp. 2002), *with* N.Y. EXEC. LAW § 296 (McKinney 2001) (stating discrimination on the basis of "genetic predisposition or carrier status" is prohibited). *See* Miller, *supra* note 142, at 263.

Some states, like Arizona, Iowa, and New Hampshire, have passed more comprehensive statutes forbidding employers from discriminating against individuals based on the result of genetic tests.[159] Several states provide additional employment protection by barring discrimination on the basis of genetic information obtained not from genetic tests but from other sources.[160] Other states, however, prohibit employers from administering, requiring, or soliciting genetic tests as a condition to employment.[161]

A few states, such as Iowa, New Hampshire, and Wisconsin, forbid employers from requiring their employees to take genetic tests.[162] Iowa, Rhode Island, and Wisconsin broaden this prohibition by prohibiting discrimination against persons who have voluntarily taken genetic tests.[163] Finally, there are states that provide an exception to the confidentiality of genetic information with the employee's consent.[164]

b. Problems With State Laws

Despite the intentions of these state laws, flaws exist: the uninsured, unemployed, and self-insured employers are not generally regulated under these laws.[165] Most of these laws focus on the genetic test, not on the information generated by other sources capable of providing similar information (e.g., medical records or family history).[166] These laws provide inconsistent protection because they vary from broad protection to narrow protection against genetic discrimination.[167]

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159. ARIZ. REV. STAT. ANN. § 41-1463(B) (West 2001); N.H. REV. STAT. ANN. § 141-H:3I(a) (2001); N.Y. CIV. RIGHTS LAW § 48-a (McKinney 1992); WIS. STAT. ANN. § 111.372(1)(a) (West 2000); Miller, *supra* note 142, at 260.

160. Miller, *supra* note 142, at 261; *e.g.,* N.C. GEN. STAT. § 95-28.1A (2001) (including information from genetic testing or counseling services or from "information obtained concerning the person or a member of the person's family").

161. IOWA CODE ANN. § 729.6.2 (West 1993); N.H. REV. STAT. ANN. § 141-H:3I(a) (1996); N.Y. CIV. RIGHTS LAW § 48-a (McKinney 1992); OR. REV. STAT. § 659A.303(1) (2001); R.I. GEN. LAWS § 28-6.7-1(a)(1) (2000); TEX. LAB. CODE ANN. § 21.402(a)(2) (Vernon 2001 & Supp. 2002); WIS. STAT. ANN. §111.372(1)(a) (West 1999); *see* Miller, *supra* note 142, at 261.

162. IOWA CODE ANN. § 729.6(2) (West 1993); N.H. REV. STAT. ANN. § 141-H:3I(a) (1996); WIS. STAT. ANN. § 111.372(1)(a) (West 1990); *see* Miller, supra note 142, at 261.

163. IOWA CODE ANN. § 729.6(2)(b) (West 1993); R.I. GEN. LAWS § 28-6.7-1(a)(2) (2000); WIS. STAT. ANN. § 111.372(1)(b) (West 2002); Miller, *supra* note 142, at 261.

164. IOWA CODE ANN. § 729.6(7) (West 1993); N.H. REV. STAT. ANN. § 141-H:3(IV) (1996); N.Y. EXEC. LAW § 296(19)(d) (McKinney 2001); WIS. STAT. ANN. § 942.07(3) (West 1996); Miller, *supra* note 142, at 261.

165. *See* Jeremy A. Colby, Note, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 465-67 (1998).

166. *Id.* at 466.

167. *Id.*

Colorado, for example, has four premises by which it regulates the use of genetic information:

(a) Genetic information is the unique property of the individual to whom the information pertains;
(b) [Genetic testing information] may be subject to abuse if disclosed to unauthorized third parties without the willing consent of the individual to whom the information pertains;
(c) To protect individual privacy and to preserve individual autonomy with regard to the individual's genetic information, it is appropriate to limit the use and availability of genetic information;
(d) The intent of this statute is to prevent information derived from the genetic testing from being used to deny access to health are insurance, group disability insurance, or long-term care insurance coverage.[168]

This coverage regulates the use of genetic testing. The Colorado statute characterizes information obtained through genetic testing as privileged and confidential except when used in treatment, diagnosis, or therapy or, when used for other purposes, with the written consent of the person tested.[169] Unfortunately, the statute applies only to entities providing long-term care, group disability, or health insurance but not to self-insured individuals.[170]

In addition, few state laws specifically address the restriction of the dissemination of genetic information in the insurance arena despite requiring the equitable and fair treatment of parties.[171] Before 1986, existing state laws prohibiting genetic discrimination had a narrow scope.[172] Yet, since 1990 with the start of the Human Genome Project, states have expanded their laws to include protections against most genetic conditions.[173]

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168. COLO. REV. STAT. § 10-3-1104.7(1)(a)-(d) (2001); *cf.* Coleman, *supra* note 75, at 161-64 (addressing a state's reasons for preventing gene manipulation in the context of genetically molding or creating a child).

169. COLO. REV. STAT. § 10-3-1104.7(3)(a) (2001).

170. COLO. REV. STAT. § 10-3-1104.7(3)(b) (2001).

171. French, *supra* note 142, at 170-71.

172. *See id.* at 171.

173. CAL. CIV. CODE § 56.17 (Deering Supp. 2002); CAL. INS. CODE §§ 10123.3, 10123.31, 10123.35, 10140, 10140.1, 10143, 10146, 10148, 10149, 10149.1 (Deering 1996 & Supp. 2002); CAL. HEALTH & SAFETY CODE §§ 1374.7, 1374.9 (Deering 2002); COLO. REV. STAT. § 10-3-1104.7 (2001); FLA. STAT. ANN. § 760.40 (West 1997 & Supp. 2002); GA. CODE ANN. §§ 33-54-1 to -8 (1996); MINN. STAT. ANN. § 72A.139 (West 1999); N.H. REV. STAT. ANN. §§ 141-H:1 to :6 (1996 & Supp. 2002); OHIO REV. CODE ANN. § 3901.49 (in effect until Feb. 9, 2004 then to be replaced by § 3901.491), 3901.50 (Anderson 2001); OR. REV. STAT. §§ 192.533, 192.535, 192.537, 192.539, 746.135 (2001); WIS. STAT. ANN. § 631.89

California has one of the strongest genetic testing laws in the United States due to its extensive coverage of genetic characteristics, such as Tay-Sachs trait, Thalassemia trait, sickle cell trait, and X-linked hemophilia.[174] Furthermore, California law prohibits insurance companies from fixing fees or rates based on genetics.[175] Finally, California law requires a written informed consent be obtained from an applicant before insurers can request a genetic test.[176]

In 1992, Wisconsin became the first state "to ban the use of genetic testing" in health insurance underwriting.[177] The Wisconsin statute prohibits the insurer from denying coverage or continued coverage and from increasing insurance premiums on the basis of whether or not a genetic test has been taken or on the results of such tests.[178] Furthermore, the statute forbids requiring or requesting family members "to obtain a genetic test," to reveal such a test was taken, or to give the results of such tests.[179]

Arizona and Montana laws prevent insurance companies from refusing to consider applicants or from fixing rates, terms, or conditions on the basis of genetic discrimination.[180] Such action "constitutes unfair discrimination unless the applicant's medical condition and history and either claims experience or actuarial projections establish that substantial differences in claims are likely to result from the genetic condition."[181] Thus, if insurers provide justification, they can use genetic information in assessing risk.

(West 1995 & Supp. 2001); *see also* French, *supra* note 142, at 171 (noting ten states have passed laws protecting against genetic discrimination since 1990).

174. CAL. INS. CODE § 10143 (Deering 1996); *see also* French, *supra* note 142, at 172 (complimenting California's strong genetic testing).

175. CAL. INS. CODE § 10143 (Deering 1996); *see* French, *supra* note 142, at 171-72 (discussing the regulation of insurance fees and rates in relation to genetics).

176. CAL. INS. CODE § 10148(a) (Deering Supp. 2002).

177. WIS. STAT. ANN. § 631.89 (West 1995 & Supp. 2001); *see* French, *supra* note 142, at 171.

178. WIS. STAT. ANN. § 631.89 (2)(a)–(d) (West 1995 & Supp. 2001); *see* French, *supra* note 142, at 171.

179. WIS. STAT. ANN. § 631.89 (2)(a)–(b) (West 1995 & Supp. 2001); *see* French, *supra* note 142, at 171.

180. ARIZ. REV. STAT. ANN. § 20-448(D) (West 2002); MONT. CODE ANN. § 33-18-206(3) (2002).

181. MONT. CODE ANN. § 33-18-206(4) (2002); *see* ARIZ. REV. STAT. ANN. §§ 20-448(E) & (F) (West 2002).

Florida also requires informed consent.[182] Florida law provides for the person tested to have the exclusive property rights over the results.[183] These results are confidential and cannot be disclosed without the person's consent.[184] A violation of this requirement is a misdemeanor.[185] An entity performing a test must notify the person tested that the information was received and specify how it was used.[186]

The Iowa genetic testing statue defines "genetic testing" as:

> a test of a person's genes, gene products, or chromosomes, for abnormalities or deficiencies, including carrier status, that are linked to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or that demonstrate genetic or chromosomal damage due to environmental factors.[187]

However, this law pertains only to employment-related discrimination.[188] It prohibits employers from requiring a genetic test from current or potential employees and from using genetic information as a term or condition of employment.[189]

New Hampshire also has a sweeping genetic law that prohibits genetic testing as a requirement to conduct business between individuals and their family members.[190] The New Hampshire statute defines "genetic testing" as:

> a test, examination, or analysis which is generally accepted in the scientific and medical communities for the purpose of identifying the presence, absence, or alteration of any gene or chromosome, and any report, interpretation, or evaluation of such a test, examination, or analysis, but excludes any otherwise lawful test, examination, or analysis that is undertaken for the purpose of determining whether an individual meets reasonable functional standards for a specific job or task.[191]

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182. FLA. STAT. ANN. § 760.40 (West 1997 & Supp. 2002).

183. FLA. STAT. ANN. § 760.40(2)(a) (West 1997 & Supp. 2002); *see also* French, *supra* note 142, at 173 (stating Florida provides that genetic tests are the exclusive property of the person tested).

184. FLA. STAT. ANN. § 760.40(2)(a) (West 1997 & Supp. 2002).

185. FLA. STAT. ANN. § 760.40(2)(b) (West 1997 & Supp. 2002); *see also* French, *supra* note 142, at 173.

186. FLA. STAT. ANN. § 760.40(3) (West 1997 & Supp. 2002); *see also* French, *supra* note 142, at 173.

187. IOWA CODE ANN § 729.6(1)(c) (West 1993).

188. *Id.*

189. *Id.*; *see also* French, *supra* note 142, at 173.

190. N.H. REV. STAT. ANN. ch.141-H (1996 & Supp. 2002).

191. N.H. REV. STAT. ANN. § 141-H:1(IV) (1996).

Under the New Hampshire law, health insurers may not ask whether an individual has taken a genetic test, require a genetic test, set rates or benefits on the basis of a genetic test, or condition coverage on the results of genetic testing.[192]

Hailed as the strictest genetic privacy act in the United States,[193] Oregon's law is based on legislative findings that "[t]he improper collection, retention or disclosure of genetic information can lead to significant harm to an individual. . .including stigmatization and discrimination in areas such as employment, education, health care and insurance."[194] Oregon law prohibits a possessor of genetic information from disclosing it, allowing very few exceptions (e.g., specific court order, authorized by state, written consent).[195] The statute also requires anyone who seeks to obtain genetic information from an individual first acquire that individual's informed consent.[196]

These state laws reflect a collective trend toward greater protection in the areas of insurance and employment laws. The breadth of these laws covers the regulation of genetic testing and the protection of genetic information.[197]

2. Federal Laws

Currently no federal statute exists that explicitly addresses genetic discrimination; however, protection against such actions could possibly be inferred from a number of federal laws,[198] such as the American with Disabilities Act (ADA) of 1998,[199] President Clinton's Executive Order[200] prohibiting genetic discrimination in federal employment, and the Health Insurance Portability and Accountability Act (HIPAA) of 1996.[201]

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192. *See* N.H. REV. STAT. ANN. § 141-H:4 (1996).

193. *See* French, *supra* note 142, at 173.

194. OR. REV. STAT. § 192.533(1)(c) (2001).

195. *See generally* OR. REV. STAT. §§ 192.537, -.539 (2001) (listing the exceptions to the disclosure of genetic information).

196. 2001 Or. Laws Ch. 388 (OR. REV. STAT. § 659.710 (1999)).

197. *See* French, *supra* note 142, at 174.

198. *See* Miller, *supra* note 142, at 237.

199. *See* Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12111-12117 (2001) (prohibiting genetic discrimination in the workplace).

200. Exec. Order No. 13,145, 3 C.F.R. 235 (2001), *available at* 42 U.S.C. § 2000e-16.

201. *See* Health Insurance Portability and Accountability Act of 1996, 29 U.S.C. §§ 1181-1183 (2001) (restricting genetic discrimination in the insurance arena).

a. Americans With Disabilities Act of 1990

The ADA prohibits genetic discrimination in the workplace.[202] Although this protection against genetic discrimination is not explicitly stated, Subchapter I of the ADA protects individuals from discrimination on the basis of disability.[203] The Act's broad language covers hiring, discharge, promotion, and other conditions and terms of employment from which discrimination is prohibited.[204] The ADA defines "disability" as a condition in which physical or mental impairments limits substantially a person's performance in a major life activity.[205]

In 1995, the Equal Employment Opportunity Commission (EEOC) issued a guideline interpreting the ADA's application to pre-symptomatic individuals having a genetic predisposition for a disabling condition.[206] The policy guideline states employers violate the ADA when they discriminate against individuals "on the basis of a genetic predisposition to an illness, disease, or other disorder" whether or not the condition has manifested.[207]

Thus, the ADA covers individuals having a history of genetically related disabilities and those individuals who have a predisposition for genetically related illnesses or disabilities that manifests themselves and greatly impairs a major life activity.[208] The ADA also provides other protections: it prohibits the discrimination against individuals who associate with people with disabilities, prohibits hiring practices that injure workers based on their genetic makeup, and protects individuals from discrimination in the workplace who express asymptomatic genetic conditions.[209]

Nevertheless, these interpretations are not binding.[210] They have yet to be tested in the courts.[211] The ADA's definition of "disability" focuses on the *nature* not on the *cause* of an individual's functional limitation.[212]

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202. *See* 42 U.S.C. §§ 12111-12117 (2001).

203. *See* Diver & Cohen, *supra* note 93, at 1450; Miller, *supra* note 142, at 238.

204. *See* Miller, *supra* note 142, at 238.

205. 42 U.S.C. §§ 12111-12117 (2000); Miller, *supra* note 142, at 238.

206. 2 EEOC COMPL. MAN (BNA) § 902:0045 (1995); Miller, *supra* note 142, at 239.

207. Miller, *supra* note 142, at 239.

208. *Id.* at 238-39.

209. *Id.* at 239-41.

210. *See* Diver & Cohen, *supra* note 93, at 1450; Miller, *supra* note 142, at 241.

211. The ADA provides some workplace protections against genetic discrimination but the scope of these protections have yet to be protected in the courts. *See* James M. Jeffords & Tom Daschle, *Political Issues in the Genome Era*, 291 SCI. 1249, 1250 (2001).

212. *See* 42 U.S.C. § 12102(2) (2000).

(2) DISABILITY.—The term "disability" means, with respect to an individual—
(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

Plus, the employer may use and obtain information of the employee's medical history and condition at the placement stage of hiring.[213] For example, in *Olson v. General Electric Astrospace*,[214] Olson alleged his former employer, General Electric, did not hire him because he suffered from depression, multiple personality disorder, and post traumatic stress disorder.[215] Although the employer did not know of Olson's condition, General Electric was aware he suffered from some illness as reported through his performance evaluations.[216] Nonetheless, the Third Circuit Court of Appeals found Olson did not show he was disabled or had a record of impairment.[217]

Additionally, coverage under the ADA requires a physical impairment that *substantially* limits a major life activity.[218] Another problem with the ADA is that it requires employers to make only "reasonable accommodations" for the disabled person to perform the jobs he or she would otherwise not be equipped to perform.[219]

(C) being regarded as having such an impairment.

Id.; *see* Diver & Cohen, *supra* note 93, at 1452.

213. *See id.* at 1450-51.

214. Olson v. General Electric Astrospace, 101 F.3d 947 (3d Cir. 1996).

215. *Olson*, 101 F.3d at 950.

216. *Olson*, 101 F.3d at 954-55. *But see generally* Geraci v. Moody Tottrup Int'l, Inc., 82 F.3d 578 (3d Cir. 1996) (stating the plaintiff offered no evidence that her manager knew she was pregnant in her pregnancy discrimination suit).

217. *Olson*, 101 F.3d at, 952.

218. 42 U.S.C. § 12102 (2) (2001) (stating "[t]he term 'disability' means, with respect to an individual—(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual"); *see* Miller, *supra* note 142, at 243 (explaining the ADA's definition of "disability").

219. 42 U.S.C. § 12112 (2001). The ADA's requirements include the following:

> (a) GENERAL RULE.—No 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.
>
> (b) CONSTRUCTION.—As used in subsection (a), the term "discriminate" includes—
>
> (5)(A) not making reasonable accommodations to the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee, unless such covered entity can demonstrate that the accommodation would impose an undue hardship on the operation of the business of such covered entity; or
>
> (B) denying employment opportunities to a job applicant or employee who is an otherwise qualified individual with a disability, if such denial is based on the need of such covered entity to make reasonable accommodation to the physical or mental impairments of the employee or applicant.

However, not all carriers for certain genetic traits or disorders result in a *physical* impairment that substantially limits a major life activity. For example, in *Murphy v. United Parcel Service Inc.*,[220] the Court ruled hypertension was not a disability under the ADA.[221] On the other hand, the Second Circuit Court of Appeals in *Heyman v. Queens Village Committee for Mental Health for Jamaica Community Adolescent Program, Inc.*,[222] concluded Heyman's employer discriminated against him when he was fired for the physical impairment he developed from his lymphoma.[223]

Furthermore, the ADA authorizes the states to regulate matters relating to insurance and genetic issues.[224] No specific provision mentions genetic discrimination, thereby raising the question of whether "disability" under the ADA covers genetic conditions.[225] The ADA considers only mental or physical impairments that substantially limit a major life activity as disabilities.[226] Thus, if an individual carries a gene for a disease yet

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Id.; see Diver & Cohen, *supra* note 93, at 1450; *see also* 42 U.S.C. § 12111 (8) & (9) (2001). The ADA defined "qualified individual with disability" and "reasonable accommodations" as the following:

> (8) QUALIFIED INDIVIDUAL WITH A DISABILITY.—The term "qualified individual with a disability" means an individual with a disability who, with or without reasonable accommodation, can perform the essential functions of the employment position that such individual holds or desires. For the purposes of this title, consideration shall be given to the employer's judgment as to what functions of a job are essential, and if an employer has prepared a written description before advertising or interviewing applicants for the job, this description shall be considered evidence of the essential functions of the job.
>
> (9) REASONABLE ACCOMMODATION.—The term "reasonable accommodation" may include—
>
> making existing facilities used by employees readily accessible to and usable by individuals with disabilities; and
>
> (B) job restructuring, part-time or modified work schedules, reassignment to a vacant position, acquisition or modification of equipment or devices, appropriate adjustment or modifications of examinations, training materials or policies, the provision of qualified readers or interpreters, and other similar accommodations for individuals with disabilities.

Id.

220. Murphy v. United Parcel Serv. Inc., 527 U.S. 516 (1999).

221. *Murphy*, 527 U.S. at 524.

222. Heyman v. Queens Vill. Comm. For Mental Health for Jamaica Cmty. Adolescent Program, Inc., 198 F.3d 68 (2d Cir. 1999).

223. *Heyman*, 198 F.3d at 73.

224. 42 U.S.C. §§ 12111-12117 (1994).

225. Miller, *supra* note 142, at 238.

226. 29 C.F.R. § 1630.2(g) (2001); Miller, *supra* note 142, at 238-39; Rachinsky, *supra* note 37, 591 (quoting the EEOC guidelines regarding the definition of disability). The ADA defines "disability" as "a physical or mental impairment which substantially limits

to be expressed, coverage under ADA becomes problematic.[227] Prohibition of discrimination against these individuals may not be covered, because the ADA does not directly address this issue.[228] Congress basically constructed the ADA for people with phenotypic disabilities,[229] but with the advent of the Human Genome Project and with the increased understanding of diseases and conditions, a change in either the ADA's definition of "disability" or people's perception of what constitutes a disability must occur.[230]

b. Title VII of the Civil Rights Act

Another federal law that may provide protection against forms of genetic discrimination is Title VII of the Civil Rights Act of 1964,[231] which relates to national origin, race, religion, and gender.[232] Genetic screening is considered to be a facially neutral policy, thus, claims succeeding under the protection of this Act must demonstrate a disparate impact theory.[233] With most genetically related diseases and disorders having yet to disproportionately affect one of Title VII's protected classes, this Act may not provide ample protections against genetic discrimination in the workplace.[234]

c. Health Insurance Portability and Accounting Act of 1996

The Health Insurance Portability and Accounting Act [HIPAA] of 1996,[235] the first federal law addressing genetic discrimination,[236] deals primarily with genetic discrimination in insurance through the restriction of the extent to which health insurance plans can exclude coverage to

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one or more of that person's major life activities." 29 C.F.R. § 1630.2(h) (2001). This term does not include "characteristic predisposition to illness or disease." *Id.*

227. *See* Miller, *supra* note 142, at 238 (stating the ADA does not explicitly mention genetic discrimination).

228. Rachinsky, *supra* note 37, 591-92 (stating there is virtually no case law on point to determine how much protection the ADA provides against genetic discrimination); Colby, *supra* note 165, at 467 (stating without judicial delineation, the ADA offers only limited protection against genetic discrimination). *But see* Miller, *supra* note 142, at 238 (noting several cases in which the ADA covers individuals with genetically related disabilities).

229. Phenotypic disabilities are those that are expressed.

230. *See* Rachinsky, *supra* note 37, 584 (declaring a need to amend the definition of "discrimination" under the act).

231. 42 U.S.C. §§ 2000e – 2000e -16(e) (2001).

232. Miller, *supra* note 142, at 247.

233. *Id.* at 248.

234. *Id.*

235. 29 U.S.C. § 1182(a)(1) (1999).

236. French, *supra* note 142, at 168.

individuals with a genetic predisposition.[237] Without diagnosis, genetic information or susceptibility to genetic disorders cannot constitute a pre-existing condition and cannot be used to limit access to health insurance.[238] Unfortunately, gaps in the protections exist. HIPAA applies only to group health insurance plans.[239] Those individuals who buy insur-

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237. Diver & Cohen, *supra* note 93, at 1449; Jeffords & Daschle, *supra* note 211, at 1250.

238. 29 U.S.C. § 1182(a)(1) (1999). HIPAA's rules on preexisting conditions are as follows:

> (a) Limitation on preexisting condition exclusion period; crediting for periods of previous coverage
> Subject to subsection (d) of this section, 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;
> (2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and
> (3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1) of this section) applicable to the participant or beneficiary as of the enrollment date.
> (b) Definitions
> For purposes of this part—
> (1) Preexisting condition exclusion
> The term "preexisting condition exclusion" means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.
> (B) Treatment of genetic information
> Genetic information shall not be treated as a condition described in subsection (a)(1) of this section in the absence of a diagnosis of the condition related to such information.

Id.; *see* Miller, *supra* note 142, at 255.

239. Health Insurance Portability and Accounting Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (stating in Title XXVII subpart 2 that the provisions are applicable only to health insurance issuers); 42 U.S.C. § 300gg-11 (2000). HIPAA's provisions on group health insurance includes the following:

> (a) Issuance of coverage in the small group market
> (1) In general
> Subject to subsections (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State—
> (A) must accept every small employer (as defined in section 300gg-91(e)(4) of this title) in the State that applies for such coverage; and
> (B) must accept for enrollment under such coverage every eligible individual (as defined in paragraph (2)) who applies for enrollment during the period in

ance outside of employment-based plans (i.e., the individual market) and the unemployed are not covered under HIPAA.[240] Additionally, HIPAA does not prohibit the requirement of or the request for genetic tests by insurers.[241]

Other failures in HIPAA include its inability to address genetic privacy concerns (e.g., the dissemination of genetic information).[242] Secondly, it fails to regulate or prohibit insurers' genetic testing requirements.[243] Finally, it fails to prohibit employer discrimination against people seeking health insurance.[244]

d. President Clinton's Executive Order

Former President Clinton issued Executive Order 13,145 on February 8, 2000, To Prohibit Discrimination in Federal Employment based on Genetic Information (the Genetic Executive Order).[245] Under the Genetic Executive Order, federal agencies and departments cannot discriminate against an applicant for employment, an employee, or former employee with respect to hiring practices (e.g., promotion, discharging, and hiring) and terms of employment (e.g., compensations, conditions, privileges) on the basis of genetic information.[246] The Order also prohibits classification of employees based on protected genetic information.[247] It forbids

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which the individual first becomes eligible to enroll under the terms of the group health plan and may not place any restriction which is inconsistent with section 300gg-1 of this title on an eligible individual being a participant or beneficiary.

(b) Assuring access in the large group market.

Id.; *see* Jeffords & Daschle, *supra* note 211, at 1250.

240. *See* Diver & Cohen, *supra* note 93, at 1449-50; Jeffords & Daschle, *supra* note 211, at 1250; Miller, *supra* note 142, at 255.

241. *See* Jeffords & Daschle, *supra* note 211, at 1250; Miller, *supra* note 142, at 256.

242. Miller, *supra* note 142, at 255-56. *See generally* Diver & Cohen, *supra* note 93 (discussing genetic privacy in the insurance arena); Jeffords & Daschle, *supra* note 211 (stating "the greatest difficulty will be for policy-makers to strike a balance between timely promotion and use of the best genetic research and careful protection of people from genetic discrimination")

243. Miller, *supra* note 142, at 255-56.

244. *Id.*

245. *See* Exec. Order No. 13,145, 3 C.F.R. 235 (2001), *available at* 42 U.S.C. § 2000e-16; Diver & Cohen, *supra* note 93, at 1451; Miller, *supra* note 142, at 248.

246. *See* Jeffords & Daschle, *supra* note 211, at 1250; Miller, *supra* note 142, at 249.

247. *See generally* Exec. Order No. 13,145, 3 C.F.R. 235 (2001) (requiring "[t]he employing department or agency. . .not disclose protected genetic information with respect to an employee, or information about a request for or the receipt of genetic services by an employee" and "[t]he employing department or agency shall not request, require, collect, or purchase protected genetic information with respect to an employee, or information about a request for or the receipt of genetic services by such employee").

the disclosure of genetic information and the requirement or request for genetic testing as a condition of being hired.[248]

Under the Genetic Executive Order, genetic discrimination against federal employees by federal departments and agencies is prohibited *except* during the pre-placement stage where genetic information can be used.[249] Title VII provides for the disclosure of genetic information under limited circumstances: to the individual, the subject of the genetic tests, to a health researcher under certain circumstances, to a court of competent jurisdiction under the order of a subpoena, and to investigating officials of the executive branch acting in compliance with the Genetic Executive Order where the genetic information is relevant to the investigation.[250]

e. Problems With Federal Legislation

Despite the federal legislation, none of it defines the genetic conditions to be protected. Do the genetic conditions include only the well-established, clinically defined diseases? Or, does it also consist of the syndromes and functional incapacities of individuals? Does addictiveness, compulsiveness, or other patterns of behavior factor in the determination of what constitutes "genetic" in genetic discrimination?[251] Finally, these legislations permit adverse treatment of symptomatic individuals but prohibits such treatment against asymptomatic individuals.[252]

As scientific information grows exponentially to outpace the surging social and legal issues, a special genetic legal regime is required. In general, the few existing state restrictions are weak because of the rapid pace of science and the dynamic nature of genetics.[253] Despite stronger federal legislation, a special genetic legal regime is still required. Current legislation is insufficient to provide the afforded protections – they do not explicitly address the regulation and prohibition of genetic information and genetic testing.[254] Although current laws such as HIPAA are steps in the right direction, more is needed in the form of either discrete statutes for discrete problems or a comprehensive uniform act.

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248. *See* Miller, *supra* note 142, at 250.

249. Diver & Cohen, *supra* note 93, at 1451. *See* Miller, *supra* note 142, at 250.

250. *See* Exec. Order No. 13,145, 3 C.F.R. 235 (2001), *available at* 42 U.S.C. § 2000e-16; Miller, *supra* note 142, at 250.

251. *See* Diver & Cohen, *supra* note 93, at 1451.

252. *See id.* at 1452.

253. *See* French, *supra* note 142, at 175.

254. *See id.*

B. *Applicability to Pharmacogenomics*

What makes pharmacogenomics different from other genetic fields is that it uses genetic information to create drugs for specific individuals. Pharmacogenomics attempts to predict when patients experience toxicity or side effects and to reduce adverse drug reactions. Molecular genotyping identifies these poor metabolizers who are predisposed to such suffering.[255] Thus, misuse of genetic information can result. For example, the information can be sold to pharmaceutical companies to pinpoint individuals genetically fit for their drugs. Additionally, the knowledge that diseases and disorders are linked to population groups identified by ethnic categories, economic status, and gender must guide policy makers away from America's eugenic past of sterilization laws.

1. Constitutional Analysis

The Fourteenth Amendment[256] provides no person shall be denied equal protection of the law by any state.[257] Federal classifications (i.e., fundamental rights or suspect classifications) that do not promote a compelling governmental interest violate the Due Process Clause.[258] The Equal Protection Clause guarantees similar individuals be dealt with in a similar manner by the government.[259]

United States v. Carolene Products Co.[260] provides the criteria for which strict scrutiny may be applied:

> Nor need we enquire whether similar considerations enter into the review of statutes directed at particular religious, or national, or racial minorities, whether prejudice against discrete and insular minori-

255. *See* Bullock, *supra* note 129, at 53-54.

256. *See* U.S. CONST. amend. XIV.

257. *See* U.S. CONST. amend. XIV § 1. The Fourteenth Amendment applies to states. *Id.* There is no equal protection clause governing the federal government, but the federal government infers a Fifth Amendment equal protection guarantee through the Due Process Clause. *See* U.S. CONST. amend V.

258. *See generally* Adarand Constructors, Inc. v. Pena, 515 U.S. 200 (1995) (applying the strict scrutiny test to examine even benign uses of race classification); Bolling v. Sharpe, 347 U.S. 497 (1954) (establishing the congruence of the Equal Protection guarantee of the Fifth Amendment).

259. *Cf.* Reed v. Reed, 404 U.S. 71 (1971) (stating sex cannot be the basis for determining whether an individual may be an estate executor). Three standards of review exist in an equal protection analysis: the Rational Relation test (the means the government takes must rationally related to a governmental end to survive), Strict Scrutiny test (provides no deference to the government because the government has to show a compelling interest), and the Intermediate Test (requires the governmental means to have a "substantial relationship" to an "important" governmental interest). *See* JOHN E. NOWAK & RONALD D. ROTUNDA, EDS., CONSTITUTIONAL LAW 639-641(6th ed. 2000).

260. United States v. Carolene Products Co., 304 U.S. 144 (1938).

> ties may be a special condition, which tends seriously to curtail the operation of those political processes ordinarily to be relied upon to protect minorities, and which may call for a correspondingly more searching judicial inquiry.[261]

Can individuals with abnormal genetic traits be considered a suspect class, and therefore guarded under the Equal Protection Clause? The criteria to identify a suspect class include the application of strict scrutiny, as the classification focuses on "immutable characteristics over which individuals identified by such characteristic have no control."[262] Suspect classifications include classifying individuals as members of a racial minority or on the basis of ancestry (national origin).[263] Suspectness is also found in a group's status of being a "discrete and insular minority" and having a group's defining quality of being "immutable."[264] Courts generally focus on the "'stigma' and 'opprobrium'" attached to the membership in a particular group that results in unequal treatment.[265]

In *Frontiero v. Richardson*,[266] the immutable characteristic was sex, which the Court found to be like race and national origin – all "determined solely by the accident of birth."[267] The Court further held:

> [W]hat differentiates sex from such nonsuspect statuses as intelligence or physical disability, and aligns it with the recognized suspect criteria, is that the sex characteristic frequently bears no relation to ability to perform or contribute to society. As a result, statutory distinctions between the sexes often have the effect of invidiously relegating the entire class of females to inferior legal status without regard to the actual capabilities of its individual members.[268]

A similar comparison can be made with genetic predispositions, because the genetic variations among individuals have no relation to their function as members of society.[269] Statutory distinctions on genetic information can have the comparable invidious effect of relegating individuals to an inferior legal status.[270]

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261. *Carolene Products Co.*, 304 U.S. at 152-53 n.4.

262. Smith & Burns, *supra* note 15, at 43-44.

263. Nowak & Rotunda, *supra* note 259, at § 14.3.

264. *Id.* at § 14.3.

265. *See* Smith & Burns, *supra* note 15, at 44 n.116.

266. Frontiero v. Richardson, 411 U.S. 677 (1973) (introducing the concept of possessing an immutable characteristic as a basis for identifying suspect classifications).

267. *Frontiero*, 411 U.S. at 686 (introducing the concept of possessing an immutable characteristic as a basis for identifying suspect classification).

268. *Frontiero*, 411 U.S. at 686-87.

269. Smith & Burns, *supra* note 15, at 45.

270. *Id.*

Until technology exists to change an individual's genetic makeup, individuals possessing genetic defects that do not inhibit their functionality should fall under the protection of suspect classification.[271] The extent to which genetic markers affect one's functionality differs. Although asymptomatic individuals carry a defective gene, they have a higher likelihood of developing the disease.[272] Heterozygous individuals merely carry the genetic information of a disease, which will be passed on to their progeny, and remain asymptomatic.[273] Take, for example, haemophilia: females may carry the gene for haemophilia without experiencing the effect of intense bleeding with even the lightest of bruises, whereas male members of the family exhibit the phenotypical manifestations of the disease. Then, there are those individuals who possess one or more genetic polymorphisms that do not manifest any genetic condition.[274]

Although current legislation is drafted in response to new technology through constraints, moratoria, and prohibitions, they are shortsighted. They close potential avenues of research by prohibiting techniques, by limiting their scope and application to current issues, and by not addressing the application of new techniques.[275] Also, they fail to uniformly address privacy and social issues.

PART IV: PROPOSAL

"O brave new world/ That has such people in it"[276]

Miranda, The Tempest, Act V, Scene I

Pharmacogenomics operates under the assumption that a genetic test has been done and the genetic condition or disease determined is expressed. A uniform law addressing the use, distribution, and application of genetic information may lessen public fear of potential third party discrimination. Such law must also address whether a physical impairment is necessary for protection and whether the genetic information indicating a predisposition to a disease or condition is deemed a pre-existing condition in the absence of a diagnosis based on other medical information of such disease or condition. Defining who regulates the genetic informa-

271. *Id.* at 45-46.
272. *Id.* at 26.
273. *Id.* at 26, 46.
274. *Id.*
275. Bartha Maria Knoppers et al., *Commercialization of Genetic Research and Public Policy*, 286 SCI. 2277, 2277 (1999).
276. The Complete Works of William Shakespeare, *at* http://the-tech.mit.edu/Shakespeare/tempest/tempest.5.1.html (last visited Mar. 27, 2003).

tion, requiring informed consent, and pursuing strict compliance of the law may also alleviate such fears. Uniform definitions in what constitutes genetic discrimination and genetic information through broad language, like the ADA, can guide in the application of nondiscrimination yet still remain malleable in the application of the definitions.

PART V: CONCLUSION

Before designer drugs can become a reality and be used for their intended purpose, the fears of those carrying genes that may be expressed or already express some disorder or disease must be lessened. Maybe the fully decoded human genome will prove that everyone has a predisposition to some sort of abnormality thereby eliminating any logical basis for discrimination. But until humanity accepts the perceived differences among populations as merely superficial, the creation of a comprehensive uniform act that focuses on the distribution and control of genetic information may alleviate people's fears and help bring about the new era of pharmacogenomics.