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Pharmacogenomics:
Privacy in the Era of Personalized Medicine

Berrie Rebecca Goldman

Pharmacogenomics: Privacy in the Era of Personalized Medicine

Berrie Rebecca Goldman*

I. INTRODUCTION

¶1 Pharmacogenomics is defined as “the use of associations between the effects of drugs and genetic markers to develop genetic tests that can be used to fine-tune patient diagnosis and treatment.”¹ Researchers in the field of pharmacogenomics study genes that produce drug-metabolizing enzymes in the body.² Utilizing an individual’s genetic profile in prescribing medications for various diseases will prevent unwanted side-effects and allow drugs to work more efficiently.³ Pharmacogenomics requires the analysis of an individual’s genetic information and the comparison of that genetic information, along with reactions to specific drugs, to the information and reactions of others to determine which drugs most effectively treat a given disease or condition.⁴ Although pharmacogenomics is not yet widely used, this technology is likely to someday change the way physicians practice medicine and the expectations of patients in seeking treatment. Pharmacogenomics may not only benefit patients by improving physicians’ ability to more accurately provide treatment for diseases and illnesses, but this new technology may potentially affect patients negatively by risking the individual’s right to privacy.

¶2 The issue of privacy arises as a result of the inherently personal nature of each individual’s genetic makeup.⁵ Some people may be reluctant to share this information with physicians and medical researchers, fearing that they or their family members will be discriminated against by insurers if they test positive for a genetic disease.⁶

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¹ STUART M. BROWN, *ESSENTIALS OF MEDICAL GENOMICS* 253 (2003). Pharmacogenetics, a parallel field, involves the study of how genes affect the way people respond to drugs. The difference between pharmacogenomics and pharmacogenetics is slight. Some scientists consider these two fields to be equivalent, and the terms “pharmacogenomics” and “pharmacogenetics” are sometimes used interchangeably. LEON SHARGEL ET AL., *APPLIED BIOPHARMACEUTICS & PHARMACOKINETICS* 355 (2005).

² SHARGEL, *supra* note 1.

³ BROWN, *supra* note 1.

⁴ See B. Michael Silber, *Pharmacogenomics, Biomarkers, and the Promise of Personalized Medicine*, in *PHARMACOGENOMICS* 14 (Werner Kalow et. al. eds., 2001).

⁵ LAURINDA BEEBE HARMAN, *ETHICAL CHALLENGES IN THE MANAGEMENT OF HEALTH INFORMATION* 275 (2001).

⁶ See, e.g., *id.* at 274.

¶3 Each individual has genetic markers, which serve as points of reference.⁷ These markers are DNA or protein sequences that are located on a specific region of a chromosome.⁸ The developing technology behind pharmacogenomics utilizes these genetic markers to evaluate how drugs will react in an individual with a specific genetic profile.⁹ Pharmacogenomics seeks to determine variations in drug responses by monitoring genetic changes (alterations in genotype) or physical changes (alterations in phenotype) in individuals and groups of patients in order to determine the most efficient and least adverse treatment for disease.¹⁰

¶4 Pharmacogenomics, as a way of enabling physicians to better treat their patients, inherently involves comparison and analysis of a large number of genetic profiles.¹¹ In order to best evaluate which course of treatment to follow, and more specifically which drug will work best for a patient's condition, the physician must be able to evaluate other patients' responses to treatment options or drugs available for that condition. To provide the most comprehensive access to genetic profiles, there must be a database containing that information which physicians can access to determine the likelihood of adverse drug reactions, side-effects, and efficacy.¹² Disclosure of this type of personal information inevitably leads to privacy issues, as individuals are concerned about sharing their genetic profiles with the general population.¹³

¶5 This new method of cataloguing and disseminating genetic information is likely to increase the privacy concerns already associated with genetic research and genetic testing.¹⁴ Several studies have shown concern among United States citizens regarding discrimination and loss of privacy as a result of sharing their genetic information, and many cite these concerns as reasons for not participating in medical research studies.¹⁵ Pharmacogenomics requires the examination of large numbers of genetic profiles for success, but individuals will be reluctant to participate unless measures are taken to ensure confidentiality and restrict the possibility of discriminatory uses of genetic information.¹⁶

¶6 This comment will first set forth the technology of pharmacogenomics and its future applicability to medical treatment. Second, it will propose a solution to the privacy issues resulting from the development of a pharmacogenomics database. This comment

⁷ LELAND H. HARTWELL ET AL., GENETICS: FROM GENES TO GENOMES 113 (2000).

⁸ Patricia A. Peyser & Trudy L. Burns, *Approaches to Quantify the Genetic Component of and Identify Genes for Complex Traits*, in HUMAN GENOME EPIDEMIOLOGY: A SCIENTIFIC FOUNDATION FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE 43 (Muin J. Khoury et al. eds., 2004).

⁹ BROWN, *supra* note 1, at 185-86.

¹⁰ SHARGEL, *supra* note 1, at 360.

¹¹ See Silber, *supra* note 4.

¹² *Id.*

¹³ *Id.*; see also HARMAN, *supra* note 5.

¹⁴ See HARMAN, *supra* note 5.

¹⁵ A 1995 Harris Poll found that "86% of those surveyed were concerned that insurers and employers might use genetic information against them." In addition to discrimination in insurance and the workplace, the survey respondents expressed concern regarding the confidentiality of genetic information used for research purposes. In 1997, one-third of the women invited to participate in a study of gene mutations leading to breast cancer declined participation, citing fear of discrimination and loss of confidentiality. *Id.* at 275.

¹⁶ See *id.* at 276.

seeks to create a template for federal legislation protecting an individual's right to privacy in light of the development of pharmacogenomics technology.

The technological development of pharmacogenomics, examined in Part II, requires a database to compare and catalog genetic profiles of individuals suffering from various conditions and undergoing treatment for those conditions.¹⁷ Establishing a database poses issues of confidentiality and privacy, as an individual's information is made available to the public, or at least to specific classes of professionals.¹⁸ The Health Insurance Portability and Accountability Act ("HIPAA") is the current manifestation of federal protection of patient privacy rights in the United States,¹⁹ but this legislation may not be enough to protect individuals with the creation of a pharmacogenomics database containing genetic profiles. Part III analyzes the inadequacies of HIPAA in light of the development of pharmacogenomics and increased usage of genetic databases. Part IV will discuss how federal law may be tailored to balance patient privacy and the dissemination of information for the public good. This comment proposes, as a primary solution to concerns about genetic privacy, federal legislation that expands the scope of HIPAA to specifically protect information compiled in a pharmacogenomics database, in addition to providing incentives for patients to contribute to the public welfare by sharing their genetic profiles.

II. BACKGROUND - PHARMACOGENOMICS: WHAT IS IT AND HOW DOES IT WORK?

A. History of Pharmacogenomics

Pharmacogenomics has been around in some form since the 1930s.²⁰ In 1902, Archibald Garrod first asserted the hypothesis that genetic variations could cause adverse biological reactions when chemical substances were ingested.²¹ He also suggested that enzymes²² were responsible for detoxifying foreign substances, and that some people do not have the ability to eliminate certain foreign substances from the body because they lack enzymes required to break down these materials.²³

The first pharmacogenetic study took place in 1932, when the inability to taste a chemical compound known as phenylthiocarbamide was linked to an autosomal recessive

¹⁷ See Silber, *supra* note 4.

¹⁸ These classes of professionals include physicians and researchers, and may also include insurance companies and employers. See *infra* Part IV.c for a discussion of who should have access to a database created to support pharmacogenomics.

¹⁹ Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

²⁰ David L. Veenstra, *The Interface Between Epidemiology and Pharmacogenomics*, in HUMAN GENOME EPIDEMIOLOGY: A SCIENTIFIC FOUNDATION FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE, *supra* note 8, at 234.

²¹ Laviero Mancinelli et al., *Pharmacogenomics: The Promise of Personalized Medicine*, 2 AAPS J. 1, 3 (2000), available at <http://www.aapspharmsci.org/articles/ps0201/ps020104/ps020104.pdf>. Garrod was a British physician working at St. Bartholomew's Hospital in London during the late 19th and early 20th centuries and is best known for demonstrating that the genetic disorder alkaptonuria results from the recessive allele of an autosomal gene, which he called an "inborn error of metabolism." HARTWELL, *supra* note 7, at 201.

²² An enzyme is defined as a protein within a living organism that increases the rate of speed of a chemical reaction, without being used up during the reaction. KENNETH R. MILLER & JOSEPH LEVINE, BIOLOGY 75 (2000).

²³ Mancinelli, *supra* note 21.

trait.²⁴ An autosome is a chromosome that does not participate in sex determination,²⁵ and therefore refers to all the cells in the body except for sperm and eggs. Recessive traits are described as follows: each person has two genes that code for a particular trait — one is inherited from the mother and one is inherited from the father.²⁶ If a person inherits two different alternative forms of a gene, called alleles, the trait that is expressed physically as a phenotype is the dominant trait, while the one not expressed is a recessive trait.²⁷ Examples of recessive traits include hitchhikers thumb and blue eyes.

¶10 In the 1932 study, participants with two recessive alleles were unable to produce a particular enzyme that allowed them to taste the phenylthiocarbamide chemical.²⁸ This determination that the inability to taste was linked to an autosomal recessive trait demonstrated that certain chemicals react differently depending on genetic predispositions.²⁹

¶11 In the 1940s and 1950s, scientists first began to note “variable drug responses” in people taking various preventive medications.³⁰ Drug reactions based on inherited traits were first recorded during World War II, when some soldiers developed anemia after receiving doses of the anti-malarial drug primaquine.³¹ Later studies confirmed that the anemia was caused by a genetic deficiency of the glucose-6-phosphate dehydrogenase enzyme.³² Similar reactions to succinylcholine and isoniazid were studied, and revealed that deficiencies in enzymes led to an inability to metabolize those drugs.³³ After studying adverse drug reactions to primaquine, succinylcholine, and isoniazid, Arno Moltulsky³⁴ proposed in 1957 that inherited traits may not only lead to adverse drug reactions, but may also affect whether the drugs actually work.³⁵

¶12 In recent decades, further progress has been made in isolating genetic variations in major drug-metabolizing enzymes, including cytochrome P450.³⁶ Scientists first began to study cytochrome P450 when some patients experienced a severe decline in blood pressure while taking debrisoquin, an anti-hypertensive drug. The study revealed that these patients had two recessive alleles for the enzyme, resulting in an inability to

²⁴ *Id.*

²⁵ BROWN, *supra* note 1, at 238.

²⁶ U.S. National Library of Medicine, National Institutes of Health, Department of Health & Human Services, *Help Me Understand Genetics* 11 (February 25, 2005), available at <http://ghr.nlm.nih.gov/dynamicImages/understandGenetics.pdf>.

²⁷ *See id.* at 51-52; HARTWELL, *supra* note 7, at 17, 19.

²⁸ Mancinelli, *supra* note 21.

²⁹ *Id.*

³⁰ The studies performed evaluated individuals taking isoniazid (to prevent tuberculosis), succinylcholine (a muscle relaxant), and the anti-malaria drug primaquine. *See* Veenstra, *supra* note 20.

³¹ Mancinelli, *supra* note 21.

³² *Id.* The United States Army determined that approximately 10% of African Americans have the polymorphic allele of glucose-6-phosphate dehydrogenase, leading to the deficiency causing anemia. BROWN, *supra* note 1, at 186.

³³ Veenstra, *supra* note 20. The studies revealed that reactions to succinylcholine resulted from a deficiency in the N-acetyl transferase enzyme, while reactions to isoniazid resulted from a deficiency in the pseudocholinesterase enzyme.

³⁴ Dr. Motulsky is currently a senior faculty member at the University of Washington, and is continuing his research in human genetics. UW Genome Sciences Faculty, <http://www.gs.washington.edu/faculty/motulsky.htm> (last visited Nov. 1, 2005).

³⁵ Mancinelli, *supra* note 21.

³⁶ Cytochrome P450 is also referred to as CYP2D6. Veenstra, *supra* note 20; Mancinelli, *supra* note 21.

metabolize the drug.³⁷ Approximately ten percent of the population metabolizes cytochrome P450 poorly, experiencing adverse effects and reduced drug uptake when they take drugs in the family of chemicals metabolized by the enzyme.³⁸ The evaluation of cytochrome P450 has led to the identification and characterization of many other drug-metabolizing enzymes.³⁹

¶13 Although pharmacogenomics continues to be a burgeoning field of technology, it is unclear where this new technology will ultimately lead. Currently, research in pharmacogenomics is primarily focused on preventing adverse drug reactions through the analysis of the relationship between drug-metabolizing enzymes and the chemical compounds that those enzymes break down.⁴⁰ In the future, pharmacogenomics may also be used to determine which receptors are best equipped to transport particular chemical compounds into the cell for the purpose of treating a disease or condition.⁴¹ Such an application would allow greater “personalization” of medicine by tailoring drugs to an individual’s genetic profile.⁴² Although evaluating receptor participation in drug uptake is a promising area of research, it is likely that research in the near future will continue to focus on the evaluation of polymorphisms⁴³ in drug-metabolizing enzymes.⁴⁴

B. Example of Pharmacogenomics Applicability: Birth Control Pills

¶14 The research carried out by Garrod, Moltulsky, and others illustrates the importance of genetic factors in determining which drugs will work most effectively and which will cause adverse reactions.⁴⁵ However, pharmacogenomics can also aid people without diseases or enzyme deficiencies. The potential negative effects of oral contraceptives, provides such an example: women who take birth control pills are generally young, healthy individuals looking to prevent pregnancy or regulate hormones for other reasons.⁴⁶ Although taken by healthy individuals, birth control pills may cause severe side-effects including blood clots and stroke, which could lead to death.⁴⁷

¶15 The increasing use of pharmacogenomics will enable physicians to identify risk factors in a woman’s genetic profile, which may be examined in conjunction with

³⁷ Veenstra, *supra* note 20.

³⁸ SHARGEL, *supra* note 1, at 361-363.

³⁹ Veenstra, *supra* note 20.

⁴⁰ SHARGEL, *supra* note 1, at 360.

⁴¹ For an in-depth discussion of the use of receptors in pharmacogenomics, see Wendell W. Weber, *Pharmacogenetics — Receptors*, in PHARMACOGENOMICS, *supra* note 4, at 51.

⁴² Veenstra, *supra* note 20.

⁴³ A polymorphism refers to a change in a nucleotide base at a given position on the genome, “when the frequency of the most common base at that position is [greater than] 99%.” BROWN, *supra* note 1, at 103.

⁴⁴ Lars Noah, *The Coming Pharmacogenomics Revolution: Tailoring Drugs to Fit Patients’ Genetic Profiles*, 43 JURIMETRICS J. 1, 9 (2002).

⁴⁵ See Veenstra, *supra* note 20, at 235.

⁴⁶ See Jan Vandenbroucke, et. al., *Oral Contraceptives and the Risk of Venous Thrombosis*, 344 NEW ENG. J. MED. 1527, 1531-32 (2001).

⁴⁷ Recent studies have indicated that the risk of blood clots, also known as venous thrombosis, increases three to six times for women using oral contraceptives over the risk to those who do not use oral contraceptives. *Id.* at 1527. Litigation against both physicians and pharmaceutical companies has resulted. See *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981); *Spensieri v. Lasky*, 258 A.D.2d 754 (N.Y. 1999); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985).

environmental factors to determine whether the use of birth control pills is likely to result in potentially severe side effects.⁴⁸ Research in this area has already begun. Scientists have recently uncovered a genetic mutation, called Factor V Leiden, that increases a woman's risk of blood clots, especially when paired with oral contraceptives.⁴⁹ Factor V Leiden is a mutation of the Factor V gene, a gene that codes for a glycoprotein circulating in the blood.⁵⁰ This mutation is the most common inherited blood-clotting disorder in the United States, affecting 5% of Caucasians and 1.2% of African-Americans.⁵¹ DNA tests can determine whether an individual is homozygous or heterozygous for the Factor V Leiden mutation,⁵² thus increasing her chances of developing blood clots.⁵³ By using this genetic information, physicians prescribing oral contraceptives may be able to reduce their patients' risk of adverse drug reactions like blood clots and stroke.⁵⁴

C. *Method to the Madness: The Technology Behind Pharmacogenomics*

¶16 Understanding the scientific processes underlying the technology of pharmacogenomics requires a short cell biology lesson. Each living organism has a unique genetic profile comprised of genes that code for the production of proteins.⁵⁵ Proteins known to affect drug metabolism fall into three categories: (1) proteins that degrade or activate chemical compounds; (2) proteins that interact with a target molecule to prevent drugs from binding to a receptor; or (3) proteins that regulate metabolic pathways that affect drug function.⁵⁶

¶17 Some proteins themselves act as receptors, and therefore receive chemical signals from outside the cell.⁵⁷ These proteins transport molecules into and out of cells, thereby regulating which materials are allowed to enter the cell.⁵⁸ Receptors, by virtue of their gate-keeping function, determine which drugs can enter the cell and fight disease.⁵⁹

⁴⁸ See Vandembroucke, *supra* note 48, at 1532.

⁴⁹ Jan P. Vandembroucke et al., *Factor V Leiden, Oral Contraceptives, and Deep Vein Thrombosis*, in HUMAN GENOME EPIDEMIOLOGY: A SCIENTIFIC FOUNDATION FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE, *supra* note 8, at 322.

⁵⁰ *Id.* at 324-325.

⁵¹ MedicineNet.com, <http://www.medterms.com/script/main/art.asp?articlekey=25022> (last visited Oct. 24, 2005). See also Vandembroucke, *supra* note 51, at 326 (prevalence of Factor V Leiden is approximately 5% in Caucasians worldwide, but is virtually absent in African and Asian populations).

⁵² An individual is homozygous for a gene if that individual possesses two identical copies of each gene coding for an expressed trait. An individual has a heterozygous genotype when that person has two different forms of a gene that code for an expressed trait. HARTWELL, *supra* note 7, at 19. The presence of the mutation, either in homozygous (two copies of the mutation) or heterozygous (one copy of the mutation) form, increases the probability that a woman will develop blood clots while taking oral contraceptives. See Vandembroucke, *supra* note 51, at 326.

⁵³ Vandembroucke, *supra* note 51, at 326.

⁵⁴ See Vandembroucke, *supra* note 48, at 1532.

⁵⁵ HARTWELL, *supra* note 7, at G-10.

⁵⁶ BROWN, *supra* note 1, at 186. The drug-metabolizing enzymes discussed *supra* Part II.a fall into the third protein category.

⁵⁷ HARTWELL, *supra* note 7, at 2.

⁵⁸ See ARTHUR M. LESK, INTRODUCTION TO PROTEIN SCIENCE: ARCHITECTURE, FUNCTION AND GENOMICS 25 (2004).

⁵⁹ The genetic sequence that codes for a protein also codes for its shape. Shape is an important feature of a protein, as it is this shape that determines how the protein will function. HARTWELL, *supra* note 7, at 203.

Receptors on the surface of cells vary depending on genotype, as DNA determines the characteristics of proteins.⁶⁰ Because of this variance, people react differently to different medications, as one person's receptors may allow a chemical into the cell while another person's receptors may prevent the cell from absorbing that drug.⁶¹

¶18 In addition to determining which chemicals to allow into the cell, some proteins serve to alter the shape of drug molecules, effectively turning them "on."⁶² Evaluating which genotypes allow chemicals to be turned on, and which keep the drugs "off," will allow physicians to determine the medications that will work for their patients.⁶³ Geneticists can now identify single genetic markers in an individual's genetic profile that code for drug-interaction genes, which will ultimately increase physicians' ability to prescribe the appropriate medication without the risk of side-effects or the possibility of failed treatment.⁶⁴

D. Pharmacogenomics Versus Genetic Testing

¶19 Pharmacogenomics is considerably different from genetic testing because it requires an evaluation of a person's entire genetic profile, not just the presence or absence of single genetic markers.⁶⁵ Genetic testing was previously conducted under the theory that most diseases were monogenic, meaning that one gene caused each disorder.⁶⁶ Now, the general belief has shifted toward the concept of polygenic disorders, where multiple mutated genes contribute to a single disorder.⁶⁷ Due to this shift in theory, genetic testing now involves analyses of multiple portions of the genome, but still does not require analysis of the complete genetic profile.⁶⁸ Although both pharmacogenomics and genetic testing involve comparing genes to determine the likelihood of future disease, only pharmacogenomics compares whole genetic profiles to evaluate drug efficacy and potential adverse reactions.⁶⁹

¶20 The success of the pharmacogenomics technology therefore depends on compiling complete genetic profiles that will allow physicians to compare thousands of single nucleotide polymorphisms ("SNPs")⁷⁰ from one individual with those of another individual.⁷¹ A comparison of these markers across the entire genome will enable physicians and researchers to "screen groups of patients receiving a specific drug and then correlate good and poor drug efficacy and the occurrence of specific side effects

⁶⁰ *Id.* at 2.

⁶¹ See LESK, *supra* note 60.

⁶² National Institutes of Health, *Medicines for You*, available at <http://publications.nigms.nih.gov/medsforyou/MedsForYou.pdf>.

⁶³ *Id.*

⁶⁴ BROWN, *supra* note 1, at 186.

⁶⁵ *Id.*

⁶⁶ SHARGEL, *supra* note 1, at 360.

⁶⁷ *Id.*

⁶⁸ See BROWN, *supra* note 1, at 187-88.

⁶⁹ Silber, *supra* note 4, at 24.

⁷⁰ Single Nucleotide Polymorphisms, also known as SNPs, are defined as "single base pair mutations that appear at frequencies above 1% in the population." BROWN, *supra* note 1, at 257. In plain English, an SNP is one change in the sequence of amino acids that comprise a strand of DNA. SNPs are frequently used to identify genes related to disease. Peyser, *supra* note 8, at 44.

⁷¹ BROWN, *supra* note 1, at 187.

with individual SNP markers.”⁷² As a result of these comparisons, physicians and researchers may determine which genetic markers influence adverse drug reactions and which genetic markers increase drug efficacy.⁷³

III. ANALYSIS

¶21 In the near future, pharmacogenomics is likely to become the standard used by physicians to prescribe medications to their patients.⁷⁴ Prior to the full development of this technology, it is important to consider its privacy implications and what should be done to protect the confidentiality of each patient’s genetic information.⁷⁵ The sections below evaluate the need for a database containing genetic information, the current statutory system for genetic information privacy in the United States, and how the current system should be revised and expanded in order to protect confidentiality of genetic information as pharmacogenomics progresses.

A. *The Pharmacogenomics Database*

¶22 Pharmacogenomics cannot succeed unless a system is developed where a large number of genetic profiles and individual responses to drugs may be compared to evaluate drug efficacy and potential adverse reactions.⁷⁶ The most efficient way to evaluate and compare genetic profiles and individual drug response is to develop a national database containing this information.⁷⁷ However, the development of such a database presents significant issues of privacy and confidentiality. Many patients are concerned that their information may be used without their consent and they will be discriminated against in areas of insurance and employment.⁷⁸

¶23 The key to a beneficial pharmacogenomics program is the development of a database, linking data obtained in the lab with data obtained from patients.⁷⁹ Such a database would enable scientists to compare large numbers of patient profiles and access information gleaned from laboratory research.⁸⁰ Although pharmacogenomics has great potential to revolutionize medicine, if genetic information is kept private, the technology will not succeed.⁸¹

¶24 The current manifestation of a pharmacogenomics database exists in the Pharmacogenomics Knowledge Base (“PharmGKB”), and is funded by the National

⁷² *Id.*

⁷³ *Id.*

⁷⁴ See Darrell L. Ellsworth & Christopher J. O’Donnell, *Emerging Genomic Technologies and Analytic Methods for Population- and Clinic-Based Research*, in HUMAN GENOME EPIDEMIOLOGY: A SCIENTIFIC FOUNDATION FOR USING GENETIC INFORMATION TO IMPROVE HEALTH AND PREVENT DISEASE, *supra* note 8, at 33.

⁷⁵ Silber, *supra* note 4.

⁷⁶ Silber, *supra* note 4.

⁷⁷ *Id.*

⁷⁸ See HARMAN, *supra* note 5, at 274-75; see also *supra* text accompanying note 15.

⁷⁹ Silber, *supra* note 4.

⁸⁰ *Id.*

⁸¹ *Id.*

Institute of General Medical Science, a branch of the National Institutes of Health.⁸² The database is based on a project entitled the Pharmacogenomics Research Network⁸³ and represents a synthesis of studies evaluating the functions of proteins, identifying polymorphisms, and assessing the relationship of genetic variants to clinical drug responses.⁸⁴ The database includes information on a subject's health, including history of disease, physical/physiologic characteristics,⁸⁵ the drugs taken and the response to those drugs, as well as DNA sequences that may play a role in drug metabolism.⁸⁶ PharmGKB currently contains data on 597 genes, sixty drugs, and eighteen diseases.⁸⁷ PharmGKB contains no identifying personal information, and consists of only partial DNA sequences as opposed to full genetic profiles.⁸⁸

¶25 PharmGKB does not contain full genetic profiles, however, and will not be sufficient as pharmacogenomics becomes essential for treating diseases and conditions. Additionally, the fact that PharmGKB does not contain *any* identifying information could pose difficulties. Although anonymity safeguards privacy, including some form of identifying information would allow for notification. Notification may be necessary, or at least desired, as the database grows and increases the number of genetic markers known to affect drug metabolism. Individuals may want to know if the drugs they are taking may be replaced by more effective treatment options. In order for patients to receive the benefits of the database, there must be a way to notify them if information contained in the database suggests the drugs they are taking may be replaced by more effective treatment options.

B. Privacy Concerns

¶26 Developing a database containing genetic profiles poses a significant problem — privacy. Patients may not want to share their genetic profiles for fear that they may be discriminated against by insurance companies, employers, and others.⁸⁹ Similarly, making genetic information available to the public, or at least to a specific segment of the public, namely physicians, marks a decline in patient autonomy.⁹⁰ Patients will not be

⁸² Press Release, National Institutes of Health, NIH Renews Network Focused On How Genes Influence Drug Responses (Sept. 28, 2005) *available at* <http://www.nigms.nih.gov/News/Results/20050928PGRN.htm> (last visited Oct. 24, 2005).

⁸³ The NIH recently announced plans to expand the Pharmacogenomics Research Network over the next five years, and anticipates spending approximately \$150 million on the project. *Id.*

⁸⁴ BROWN, *supra* note 1, at 190.

⁸⁵ Physical characteristics available in the Pharmacogenomics Knowledge Base include height, weight, blood pressure, and other relevant characteristics. Access to the Pharmacogenomics Knowledge Base may be found at <http://www.pharmgkb.org>.

⁸⁶ BROWN, *supra* note 1, at 190.

⁸⁷ These numbers are current as of October 10, 2005. However, the number of genes, drugs, and diseases with primary information available in the PharmGKB database is rapidly expanding. The numbers in each category have almost doubled over the past nine months. Pharmacogenomics Knowledge Base, *at* <http://www.pharmgkb.org/> (last visited October 24, 2005).

⁸⁸ BROWN, *supra* note 1, at 191.

⁸⁹ See HARMAN, *supra* note 5, at 274-75.

⁹⁰ Patient autonomy is a substantive principle of social justice, stating that “each person is in control of his own person, including his body and mind.” This principle is often compared with the principle of beneficence, where “what is best for each person should be accomplished.” These two principles may come into conflict when an individual wants something for himself that others believe is not best for him.

able to decide who has access to their personal information if it is freely accessible in a public database.⁹¹

¶27 There are many other potential public costs of a national genetic database. Individuals will not consider sharing their information if the opportunity cost is too high. It may be difficult to persuade individuals to share their genetic information if they are concerned about the availability of insurance or employment when their profile reveals the potential for genetic disease.⁹² Additionally, individuals, especially older generations, may not clearly understand the technology and therefore may be less likely to participate in such a system.

¶28 One potential comfort to patients is that privacy in pharmacogenomics should not be as much of a concern as privacy in genetic testing.⁹³ Because genetic testing involves identification of potential disease-causing biomarkers, individuals may be understandably concerned about sharing this extremely private information with others.⁹⁴ Pharmacogenomics, however, focuses on responses to medication.⁹⁵ This focus on medication, as opposed to a focus on potential development of diseases, should decrease apprehension regarding the sharing of information, as it is less likely to lead to discrimination in insurance or in the workplace.

¶29 Nonetheless, the privacy concern raises the issue of whether individuals would be willing to share their genetic profiles with others to benefit the public. If a significant percentage of the population were to donate their profiles to a pharmacogenomics database, the likelihood that researchers could successfully link drug responses to specific genetic characteristics would increase exponentially.⁹⁶ On the other hand, if concerns about discrimination and misunderstanding of technology restrict sharing of genetic information, the pharmacogenomics database will ultimately be less efficient.⁹⁷

¶30 Greater participation in the database will ultimately lead to an increased opportunity for research to identify and isolate polymorphisms affecting drug metabolism.⁹⁸ People should be willing to share their information because they and their family members will reap the future benefits of a database indicating which drugs will cause adverse reactions and which drugs will work most effectively for their conditions.

FURROW ET AL., *BIOETHICS: HEALTH CARE LAW AND ETHICS* 229 (2001). This issue is likely to arise in pharmacogenomics when someone declines the use of his profile for privacy reasons, even though it would be in his best interest and the best interest of society to contribute to research that will increase the effectiveness of drugs.

⁹¹ The National Institutes of Health and various research groups have continued to push for public access to genetic information in recent years in order to improve the efficient dissemination of information and advancement of science. For a discussion of public versus private databases, see Adam D. Marks and Karen K. Steinberg, *The Ethics of Access to Online Genetic Databases: Private or Public?*, 3 AM. J. PHARMACOGENOMICS 207 (2002).

⁹² See HARMAN, *supra* note 5.

⁹³ Silber, *supra* note 4, at 24.

⁹⁴ See HARMAN, *supra* note 5, at 274-75.

⁹⁵ Silber, *supra* note 4, at 24.

⁹⁶ See *id.* at 14.

⁹⁷ See Henry T. Greely, *Genotype Discrimination: The Complex Case for Some Legislative Protection*, 149 U. PA. L. REV. 1483, 1501 (2001).

⁹⁸ See Silber, *supra* note 4.

C. *The Current Privacy Standard: HIPAA*

¶31 The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) is the current federal health information privacy law in the United States.⁹⁹ HIPAA protects the confidentiality of a patient’s medical information by limiting its collection, use, and disclosure.¹⁰⁰

¶32 Section 701(b)(1)(B) addresses genetic information. It states that “[g]enetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.”¹⁰¹ Therefore, insurance companies are prohibited from refusing to enroll an individual or charging higher premiums based on information gleaned from that individual’s genetic profile.¹⁰² Under HIPAA § 701(b)(1), insurance companies may only utilize genetic information if there has already been a confirmed diagnosis of disease.¹⁰³

¶33 Although the provisions contained in HIPAA that place strict standards on healthcare providers and insurance companies work well for genetic testing, these standards will not be strong enough to address privacy concerns once a pharmacogenomics database is developed. Pharmacogenomics will require the use of genetic information before a condition has developed because researchers in this field evaluate the interactions of enzymes produced by genes, and not diseases resulting from the presence or absence of such genetic markers.¹⁰⁴ In almost all cases, there will be an “absence of a diagnosis of the condition related”¹⁰⁵ when researchers are using the genetic information to determine which drug is most effective and poses the least risk. Based on these considerations, it is necessary to amend HIPAA to explicitly include genetic databases.

IV. PROPOSED SOLUTION: RECONCILING THE NEED FOR A GENETIC DATABASE WITH AN INDIVIDUAL’S RIGHT TO PRIVACY

¶34 With the continuing concern over genetic privacy and potential discrimination, increased protections must be implemented in order to encourage individuals to

⁹⁹ Pub. L. No. 104-191, 110 Stat. 1936 (1996).

¹⁰⁰ Jeffrey N. Gibbs, *State Regulation of Pharmaceutical Clinical Trials*, 59 FOOD & DRUG L.J. 265, 266 (2004).

¹⁰¹ Section 701(a) provides that insurance companies may exclude coverage for a preexisting condition only under the following circumstances:

(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)) applicable to the participant or beneficiary as of the enrollment date.

§ 701(a)(1-3), 110 Stat. at 1939.

¹⁰² *Id.*; § 701(b)(1)(B), 110 Stat. at 1940.

¹⁰³ *Id.*

¹⁰⁴ See Silber, *supra* note 4, at 24.

¹⁰⁵ Pub. L. No. 104-191 § 701(b)(1)(B), 110 Stat. at 1940.

contribute their genetic information to a pharmacogenomics database.¹⁰⁶ As discussed in Part III.a, comparisons of large numbers of genetic profiles are essential to the success of pharmacogenomics technology.¹⁰⁷ Without some assurance that genetic information will not be used for discriminatory purposes, patients will be understandably reluctant to participate in the collection of data for a pharmacogenomics database.¹⁰⁸ This section will discuss how the current law may be improved to address genetic privacy concerns in pharmacogenomics.

A. Expanding HIPAA: The Need for a New Federal Law (or at least an addition to the old law)

¶35 In order to protect an individual's right to privacy once the pharmacogenomics database becomes a reality, Congress must pass a federal law to supplement HIPAA. The law must be federal — although state law could adequately protect individuals, the database itself must be available nationally in order to improve its efficiency.¹⁰⁹ Uniformity is also necessary to ensure that all individuals contributing to the database are afforded the same protections and benefits under a federal law.¹¹⁰

¶36 Establishing a new federal law to protect privacy concerns involving the pharmacogenomics database poses the question of whether this federal law should preempt state law. HIPAA currently does not preempt state law where the state law provides greater privacy protections.¹¹¹ Allowing more stringent privacy protections provided by state law may limit the amount of available information in a pharmacogenomics database, thereby decreasing the benefit to all who utilize the system. Therefore, such a provision may also reduce the efficiency of the system by limiting the number of people who contribute their profiles to the database. A pharmacogenomics database would be most effective and provide the most material to evaluate drug efficacy and reactions if this proposed federal law preempted state law.¹¹²

B. The Privacy Rule

¶37 When HIPAA was passed in 1996, the statute required the Secretary of Health and Human Services to design standards for its implementation.¹¹³ In compliance with the

¹⁰⁶ See Greely, *supra* note 100, at 1500-01.

¹⁰⁷ See Silber, *supra* note 4, at 14.

¹⁰⁸ See Greely, *supra* note 100, at 1499-1502.

¹⁰⁹ Under HIPAA, states are currently allowed to implement more stringent standards supplementing federal law to protect genetic information without the possibility of preemption. HIPAA IN PRACTICE: THE HEALTH INFORMATION MANAGER'S PERSPECTIVE 8 (American Health Information Management Association ed., 2004).

¹¹⁰ One of the reasons for implementing HIPAA was to ensure uniformity among the states in protecting the confidentiality of health information. Gina Marie Stevens, *A Brief Summary of the HIPAA Medical Privacy Rule*, CRS REPORT FOR CONGRESS RS20934 (2003). Similarly, any addition to current law should represent a federal standard in order to continue uniformity of health information protection throughout the United States.

¹¹¹ HIPAA IN PRACTICE, *supra* note 112.

¹¹² See Greely, *supra* note 100, at 1501.

¹¹³ Pub. L. No. 104-191 § 262, 110 Stat. at 1938.

Administrative Simplification provisions of the Act,¹¹⁴ the Secretary published the *Standards for Privacy of Individually Identifiable Health Information* on December 28, 2000.¹¹⁵ These standards, more commonly referred to as the Privacy Rule, were finalized on August 14, 2002, and required health plan and health care provider compliance by April 13, 2003.¹¹⁶ The Privacy Rule states that HIPAA applies to group health plans covering more than fifty individuals and all health care providers, regardless of size, who transmit health information electronically.¹¹⁷

¶38 The Privacy Rule allows health care providers to disclose information about their patients as long as there is a justification for doing so.¹¹⁸ The Privacy Rule “protects all ‘individually identifiable health information’¹¹⁹ held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper or oral,”¹²⁰ which presumably includes genetic information.

¶39 Although the Privacy Rule offers strong protections against the disclosure of information, the Rule also provides for situations in which disclosure is permissible.¹²¹ Health care providers may disclose information for the “public good” without authorization by the patient.¹²² Under the public good exception, medical information may be disclosed without the patient’s consent to a public health authority for purposes of controlling or monitoring disease, or to government agencies such as the Food and Drug Administration (“FDA”) for evaluation of adverse drug reactions.¹²³ It is this element of unauthorized disclosure that poses difficulties for the level of privacy needed for a successful pharmacogenomics database.

¹¹⁴ *Id.*

¹¹⁵ UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF CIVIL RIGHTS PRIVACY BRIEF: SUMMARY OF THE HIPAA PRIVACY RULE 2 (May 2003), *available at* <http://www.hhs.gov/ocr/privacysummary.pdf>.

¹¹⁶ *Id.* at 2, 18.

¹¹⁷ *Id.* at 2.

¹¹⁸ CAROLYN P. HARTLEY, MLA, CHP & EDWARD D. JONES III, *HIPAA PLAIN & SIMPLE: A COMPLIANCE GUIDE FOR HEALTH CARE PROFESSIONALS* 58 (2004).

¹¹⁹ The Privacy Rule defines “individually identifiable health information” as: (1) information that is “created or received by a health care provider,” and (2) “relates to the past, present, or future physical or mental health or condition of an individual,” or relates to the provision of or payment for health care services by an individual, which identifies or may serve to identify that individual. 45 C.F.R. § 160.103 (2005).

¹²⁰ Privacy Rule, *supra* note 118, at 3.

¹²¹ A health care provider may disclose Protected Health Information (PHI) for the following purposes/situations:

- (1) To the individual when the individual when the information is her own;
- (2) For use in treatment, payment or health care operations of the covered entity;
- (3) When the patient has the opportunity to agree or object to disclosure;
- (4) Disclosure is incidental to a permitted use or disclosure;
- (5) For activities benefiting the public and in the public’s interest; or
- (6) For research, public health, or health care operations (only limited data may be disclosed).

Id. at 4-9. *See* 45 C.F.R. § 164.512 (2005).

¹²² Hartley, *supra* note 121, at 91.

¹²³ HIPAA IN PRACTICE, *supra* note 112, at 149. Additionally, health care providers may disclose information in emergency situations, in cases of work-related illness, and to ensure compliance with OSHA. *Id.*

¶40 The pharmacogenomics database is likely to fall under the “public good” exception to disclosure, thereby reducing an individual’s ability to exclude her information from the database.¹²⁴ The pharmacogenomics database may qualify as a “public good” under any number of circumstances allowing disclosure without the individual’s consent, including disclosure to a public-health authority or the FDA, or disclosure for research purposes.¹²⁵

¶41 Because the pharmacogenomics database will be compiled for the good of the public in preventing adverse reactions and increasing drug efficacy, it is necessary to require informed consent of individuals who wish to include their profiles in the database. As the law stands now, the “public good” exception to confidentiality would allow researchers and compilers to obtain information that individuals desire to keep private.¹²⁶ Therefore, a provision governing the pharmacogenomics database and requiring informed consent must be included in a new federal law in order to protect the individual’s right to privacy.

C. Access to Information Under the Proposed Law

¶42 The current privacy law in the United States, as governed by HIPAA and related provisions promulgated under HIPAA such as the Privacy Rule, must be expanded to specifically address genetic information contained in databases like those required for the success of pharmacogenomics technology. Once these provisions are expanded to protect against unauthorized disclosure of genetic information, access to a pharmacogenomics database must be granted not only to physicians and researchers, but also to insurance companies. This would encourage growth and development of the system while also providing tangible financial benefits to the general public.

¶43 With the development of a new pharmacogenomics database, it is important to determine who will have access to such a database, and codify these restrictions in new legislation. Physicians and researchers would unequivocally require access to the pharmacogenomics database. Physicians must access the database to aid in determining which drugs will cause the fewest side-effects and most effectively treat their patients’ conditions. Researchers must also have the ability to access the database in order to make comparisons of genetic profiles to determine which genes affect drug-metabolizing enzymes.¹²⁷

¶44 Although it seems clear that physicians and researchers must have access to the pharmacogenomics database, other groups may want access as well. Insurance companies are the most problematic of these groups, as discrimination by insurance agencies is one of the most foreseeable improper uses of an individual’s genetic information.¹²⁸

¶45 The argument for not granting access to insurance companies is based on the idea that insurance companies could utilize genetic information to deny coverage or to raise

¹²⁴ For research purposes, a health care provider may release health information without the consent of the patient as long as an institutional review board or privacy board approves a waiver of authorization. There are no other requirements. JANE M. SULLIVAN, HIPAA: A PRACTICAL GUIDE TO THE PRIVACY AND SECURITY OF HEALTH DATA 45 (2004).

¹²⁵ 45 C.F.R. § 164.512 (i-j).

¹²⁶ See SULLIVAN, *supra* note 127.

¹²⁷ See BROWN, *supra* note 1, at 191.

¹²⁸ See Barbara P. Fuller & Kathy Hudson, *Genetic Information*, in HARMAN, *supra* note 5, at 275.

premiums.¹²⁹ However, even HIPAA prohibits insurance companies from using genetic information to evaluate coverage limitations and premiums, unless the patient has been diagnosed with a disease or condition.¹³⁰ The proposed federal statute should follow HIPAA's example in strongly protecting an individual's right to keep genetic information private, especially when applied to the pharmacogenomics database.

¶146 As long as the proposed expansion of HIPAA is applied to information contained in the pharmacogenomics database, there are multiple advantages in allowing insurance companies to gain access to such information. First, allowing access to such a database will ultimately result in lower premium costs for consumers by greatly diminishing the incentive for insurance companies to engage in reverse engineering. Second, providing such access to insurance companies will benefit those companies financially, providing an incentive for the insurance industry to make financial contributions in support of the pharmacogenomics database. Support from the insurance industry should ultimately cause the database to expand more quickly, resulting in tangible benefits to patients sooner rather than later. However, these advantages will only occur if the insurance industry is forbidden from using genetic information to discriminate where the patient has not yet developed a disease or condition.

1. Reducing Consumer Costs by Preventing Reverse Engineering of Genetic Information

¶147 The potential new federal law governing the pharmacogenomics database must include access for insurance companies. If access by insurance companies were restricted, it would likely lead to a sort of "reverse engineering." Reverse engineering typically appears in the context of trade secrets.¹³¹ An individual may purchase a product on the open market, then take it apart to see how it works, thus potentially revealing the trade secrets of the manufacturer.¹³² Reverse engineering may also apply in the context of the pharmacogenomics database. Insurance companies may employ physicians or geneticists to determine the presence or absence of specific genes in an individual's genetic profile based on the treatment prescribed by that individual's physician for a given condition. The insurance companies will waste money trying to determine, which of their customers have the potential for developing costly conditions. Doing so may allow the insurance company to skirt the HIPAA provision preventing disclosure of genetic information, thereby providing an avenue for higher premiums or a denial of coverage.

¶148 Although HIPAA explicitly states that premiums cannot be increased due to non-diagnosed conditions,¹³³ insurance companies may be able to determine genetic markers for specific diseases anyway through reverse engineering. Because of this, insurance companies should have full access to the pharmacogenomics database under the new law, which should retain HIPAA's guard against the misuse of genetic information and

¹²⁹ *Id.* at 274-75.

¹³⁰ Pub. L. No. 104-191 § 701(b)(1)(B), 110 Stat. at 1940.

¹³¹ See ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 66-67 (2003).

¹³² *Id.* at 49.

¹³³ Pub. L. No. 104-191 § 701(b)(1)(B), 110 Stat. at 1940.

expand it to specifically include the pharmacogenomics database. Since HIPAA explicitly states that premiums cannot be increased due to non-diagnosed conditions,¹³⁴ people will not be penalized financially for the possibility that they will develop a genetic disease in the future.

2. Financial Incentives for Insurance Companies Translate into Benefits for the Public

¶49 The development of the pharmacogenomics database will not only help the public, but will also financially benefit the insurance industry. The database, once it is fully-operational, will reduce insurance companies' expenditures. As researchers determine with more accuracy which genes or gene combinations affect drug metabolism, physicians will be able to provide treatment options with more certainty.¹³⁵ Experimental treatments and drugs, which are customarily more expensive, will be used less frequently, as patients will receive effective initial treatment of their condition. Therefore, insurance companies will not be required to pay for multiple prescriptions or various expensive procedures in an effort to uncover a successful treatment for disease.

¶50 Drug companies are already realizing a decrease in expenditures as a result of pharmacogenomics.¹³⁶ During the early stages of clinical trials, drug companies are comparing genetic profiles of patients in order to determine which individuals react positively to the new drug.¹³⁷ In the later stages of clinical trials, patients are pre-screened to eliminate those individuals that may experience side effects or otherwise react poorly to the drug.¹³⁸ As a result, new drugs may become available that would otherwise be declined due to side effects or lack of effectiveness for a large percentage of the population.¹³⁹ Similarly, insurance companies will ultimately receive a financial benefit because the insured will only receive a particular medication if that individual's genetic profile indicates a high degree of efficacy and a low risk of negative side effects.¹⁴⁰

¶51 Due to the strong financial benefit to insurance companies, it is less likely that insurance companies will take advantage of the pharmacogenomics database by using it to discriminate against their clients. It is possible that the insurance industry may even contribute financially to the initial development of the database, or by providing incentives to those covered under their plans who donate their profiles. Since the insurance industry will not benefit from the database until it is well-established, that industry has a strong incentive to encourage the development of the pharmacogenomics database.

¹³⁴ *Id.*

¹³⁵ See BROWN, *supra* note 1, at 185.

¹³⁶ See, e.g., *id.* at 188 (suggesting the strong possibility for future benefits).

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.* at 185.

V. CONCLUSION

¶52 Pharmacogenomics will forever alter the way that physicians, patients, and the general public perceive genetic information. In the near future, the expansion of pharmacogenomics will result in patients' contribution of their genetic profiles to a database, enabling both themselves and the public to reap the benefits of a system that will most effectively distribute pharmaceuticals for treatment of all types of diseases and conditions. Individuals will want to use the system in order to reduce the risk of unwanted side-effects and adverse drug reactions, as well as to increase the effectiveness of medications necessary to treat disease or relieve symptoms.

¶53 The current manifestation of a pharmacogenomics database, PharmGKB, will probably not be sufficient to provide adequate comparisons of genetic profiles because (quick synopsis). The new database, or modification to the existing PharmGKB database, must include entire genetic profiles, as most conditions and enzyme deficiencies reducing drug metabolism are now thought to be based in more than one gene.¹⁴¹

¶54 It remains to be seen how the logistics of developing a new pharmacogenomics database will work out. The National Institutes of Health is the most likely candidate to run the database, as it has experience in the area of managing genetic databases with the Human Genome Project. Other issues that need to be addressed include funding for the project, creation of software, and whether to require licensing of software.

¶55 New legislation must be passed to enhance the privacy laws already in place. This legislation must be federal and must include specific provisions for databases containing genetic material, as well as for collection, use, and distribution of information derived from an individual's genetic profile.¹⁴² Databases of genetic material need not be protected more than other types of health information,¹⁴³ but genetic information contained in databases must be expressly protected by federal legislation in order to ensure privacy rights. New legislation should also include provisions requiring informed consent, as information collected for the pharmacogenomics database may be susceptible to the public good exception to the existing HIPAA Privacy Rule. As individuals must have the ability to decide whether to include their genetic information in the pharmacogenomics database, informed consent must be required under the new law to prevent disclosure without the individual's consent.

¶56 The change in legislation must precede the changing technology in order to create the most efficient and beneficial pharmacogenomics system. A new law governing the pharmacogenomics database need not be dramatically different from current privacy laws in the United States. The scope of current law simply must be expanded to include patients' rights to prevent their information from being publicly available on such a database, and to require informed consent under all circumstances. The law should also include a provision encouraging individuals to register their genetic profiles on the database, as the greater the number of people who contribute, the more likely that the database will be a successful medical tool.

¹⁴¹ SHARGEL, *supra* note 1, at 360.

¹⁴² See Silber, *supra* note 4, at 14 (discussing the need for a comprehensive database).

¹⁴³ Fuller, *supra* note 131, at 276.