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CONTROLLING YOUR DNA: PRIVACY CONCERNS IN GENOMIC TESTING AND THE UNCERTAINTY OF FEDERAL REGULATION AND LEGISLATION

Sarah Washburn *

I. INTRODUCTION

The headlines In November 2013, the United States Food and Drug Administration (FDA) issued a “cease and desist” order to the leading direct-to-consumer (DTC) genetic testing company 23andMe.¹ In the warning letter, the FDA cited concerns about the public health consequences of inaccurate test results and drastic measures patients could take due to a false positive or false negative test result.² Though 23andMe has temporarily halted access to health-related genetic testing while it complies with the FDA’s regulatory review process, they remain committed to ensuring consumers have direct access to their health information.³ 23andMe is one of many genetic testing companies with the belief that consumers have the right to access their genetic information and that this information can help people live longer, healthier lives.⁴ Open access to

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¹ Nancy Fliesler, *Direct-to-consumer genetic testing: a case of potential harm*, VECTOR (May 5, 2014), <http://vectorblog.org/2014/05/direct-to-consumer-genetic-testing-a-case-of-potential-harm/>.

² U.S. Food and Drug Administration, *23andMe, Inc. 11/22/13, INSPECTIONS, COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS*, <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm>. [hereinafter Warning Letter] It should be noted that the warning letter points out that the FDA has been diligently working to help 23andMe comply with regulatory requirements regarding safety and effectiveness and obtain marketing authorization but 23andMe has failed to complete the necessary studies and provide additional information requested by the FDA. *Id.* According to the letter, 23andMe has failed to even communicate with the FDA since May, six months prior to the issuance of the warning letter. *Id.*

³ Anne Wojcicki, *An Update Regarding The FDA’s Letter to 23andMe*, 23ANDMEBLOG (Nov. 26, 2013), <http://blog.23andme.com/news/an-update-regarding-the-fdas-letter-to-23andme/>.

⁴ *Id.* Unfortunately many of these companies are no longer pure DTC companies. That is, many of these companies now require physician involvement in order for the consumer to obtain their genetic infor-

genetic information will not only give individuals control over their health, but the research that flows from public genetic information will lead to a healthier society as a whole. Over-reaching regulators and over burdensome regulations will hinder that goal and inhibit potential scientific progress from free and accessible genetic information.

This Comment explores current regulation and proposed legislation within the field of genomic testing at both the federal and state level. It will also explore how such regulation and legislation affects the personalized medicine landscape for both the individual and the American public. I argue for a comprehensive regulatory plan that protects the privacy of genetic testing consumers without hindering an individual's access to their own genetic information, as well as the public accessibility of genetic information for the purposes of scientific and medical advancement. Part II provides an overview on the science of genetics, genomic sequencing, and the current state of personalized medicine, including the explosion in popularity of direct-to-consumer genetic services. Part III explores the current regulatory landscape of DTC genomic testing and access to genomic information for research purposes on both the state and federal level. I then argue that federal legislators and the FDA should assume a limited role in the control of genomic information obtained through open and voluntary consent as to foster innovation and the continued development of personalized medicine.

II. BACKGROUND

Throughout the last Genetic testing involves analyzing DNA, RNA, chromosomes, and proteins to detect minute variations that may be connected to various diseases and other health related issues.⁵ A genetic test can identify the carrier status for inherited disorders and make predictions about disease risk and medication response.⁶ Genetic testing has the potential to be a powerful healthcare tool, but because the basic science behind it is widely misunderstood, its potential may be quashed through overzealous regulation or legislation based on unfounded fears. Under-

mation. These companies include Pathway Genomics, Gene by Gene, and GeneDx, just to name a few. With 23andMe temporarily halting its health-related genetic testing services to consumers in 2013, no pure DTC companies currently exist. *See infra* note 84.

⁵ Jessica Elizabeth Palmer, *Genetic Gatekeepers: Regulating Direct-to-Consumer Genomic Services in an Era of Participatory Medicine*, 67 FOOD DRUG L.J. 475, 478 (2012).

⁶ *Id.* at 476.

standing the science of genetic testing is necessary to recognize both the benefits of and limitations to this probabilistic science.⁷

The Genome

A gene is the basic unit of heredity.⁸ Genes are made up of deoxy-ribonucleic acid (DNA) and serve as instructions for making functional molecules such as ribonucleic acid (RNA) and proteins.⁹ Proteins have many functions within the body including performing chemical reactions and forming the cell's structural components, but they cannot copy themselves.¹⁰ When a cell needs more proteins, it uses the manufacturing instructions coded in DNA.¹¹ The DNA code of a gene is made up of a sequence of individual DNA building blocks, labeled A (adenine), T (thymine), C (cytosine) and G (guanine) – collectively called nucleotides.¹² The sequence of nucleotides within a gene gives the cell instructions on how to manufacture the necessary protein.¹³ Genes can vary in size from a few hundred DNA bases to more than 2 million bases.¹⁴ Genes are packaged tightly into structures called chromosomes.¹⁵ Every cell in the body contains a full set of chromosomes in the nucleus of the cell.¹⁶ A complete set of genes is called a genome.¹⁷ The human genome contains approximately 21,000 genes with three billion pairs of nucleotides.¹⁸ While any two individuals' DNA are 99.9% identical, the variations within the remaining 0.1% are responsible for the diversity among human be-

⁷ Genomic testing is a probabilistic science as compared to a deterministic science. *Id.* That is, a genetic test merely describes the probability of a certain disease risk or medicine response. "Reduced risk is not inconsistent with disease incidence." Kathryn Schleckser, *Physician Participation in Direct-to-Consumer Genetic Testing: Pragmatism or Paternalism?*, 26 HARV. J. LAW & TEC 695, 713-14 (2013). An individual shown to have a decreased risk for a certain type of cancer may nevertheless develop that cancer. *Id.* That does not call into question the validity of the genetic test. *Id.*

⁸ U.S. Nat'l Library of Medicine, *What is a gene?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/gene> (Jan. 11, 2016).

⁹ Nat'l Institute of General Medical Sciences, *Chapter 1: How Genes Work*, THE NEW GENETICS, <http://publications.nigms.nih.gov/thenewgenetics/chapter1.html> (June 9, 2011).

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *What is a gene?*, *supra* note 8.

¹⁵ *Chapter 1: How Genes Work*, *supra* note 9.

¹⁶ *Id.* Every cell normally contains 23 pairs of chromosomes, giving a total of 46 chromosomes per cell. U.S. Nat'l Library of Medicine, *How many chromosomes do people have?*, GENETICS HOME REFERENCE, <http://ghr.nlm.nih.gov/handbook/basics/howmanychromosomes> (Feb. 23, 2015). Eggs, sperm, and red blood cells are the exception. *Chapter 1: How Genes Work*, *supra* note 9.

¹⁷ Palmer, *supra* note 5, at 478.

¹⁸ *Id.*

ings.¹⁹ Although these gene variations are what make each person unique, certain gene variants are associated with specific diseases and conditions.²⁰

Genomic Medicine

Genetic tests involve the analysis of DNA, RNA, chromosomes, or proteins in order to detect variations related to health and disease.²¹ Early advances in genetic medicine involved identification of disorders caused by inherited mutations in single genes such as cystic fibrosis, sickle-cell anemia, and Huntington's disease.²² Huntington's disease is a highly penetrant disorder, meaning that almost all individuals with the mutated gene will eventually develop the disease.²³ Thus, a genetic test for Huntington's disease is highly predictive.²⁴ Other disorders, such as cystic fibrosis, are significantly less penetrant.²⁵ The presence of a mutated gene simply means that there is a possibility of developing a certain disease, but that possibility is dependent on other factors as well including the environment and family history.²⁶

Some of the most common diseases are more complex and are not expressed by a mutation in a single gene.²⁷ Disorders such as heart disease, obesity, addiction, and diabetes are influenced by a complex interplay of genetic and environmental factors.²⁸ To identify the genetic basis for complex common diseases, genetic researchers began to study single nucleotide polymorphism (SNPs).²⁹ The most common form of genetic variation between individuals, SNPs occur about once every 1,000 base pairs.³⁰ SNPs are the 0.1% of base pairs in the genetic code that differ in each individual.³¹ SNPs are only classified as such if the variation occurs

¹⁹ *Id.*

²⁰ Nat'l Human Genome Research Institute, *Regulation of Genetic Tests*, National Institutes of Health, <http://www.genome.gov/10002335> (Sept. 2, 2014).

²¹ Palmer, *supra* note 5, at 478; *Regulation of Genetic Tests*, *supra* note 20.

²² Palmer, *supra* note 5, at 478.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ Palmer, *supra* note 5, at 478.

²⁹ In the scientific community, the acronym "SNPs" is colloquially pronounced "snips". U.S. Nat'l Library of Medicine, *What are single nucleotide polymorphisms (SNPs)?*, GENETIC HOME REFERENCE, (January 4, 2016), <http://ghr.nlm.nih.gov/handbook/genomicresearch/snp>; Palmer, *supra* note 5, at 479.

³⁰ Jeffrey Perkel, *SNP genotyping: six technologies that keyed a revolution*, 5 NATURE METHODS 447 (2008), <http://www.nature.com/nmeth/journal/v5/n5/full/nmeth0508-447.html>.

³¹ Palmer, *supra* note 5, at 479.

in 1% or more of the population; otherwise the variation is a mutation.³² SNPs can serve as landmarks in the search for genes associated with disease, drug response, and observable traits.³³ Because a SNP-based screen can capture most of the genetic variation between individuals, comparing SNP data from many participants allows researchers to uncover small statistical associations between SNPs and various health conditions.³⁴ More than a thousand genetic variants linked to common disorders have been identified in recent years.³⁵

Even though SNPs make up only about one percent of the human genome, SNP-based testing can capture most genetic variation among individuals.³⁶ Genetic tests are used to detect gene variants associated with a specific disease or condition.³⁷ In the clinical setting, genetic tests can be used to determine the genetic cause of a disease, confirm a suspected diagnosis, predict future illness, detect the likelihood of passing on a gene mutation, and predict response to therapy.³⁸ A number of tests have been developed to perform complex analyses of multiple genes for chronic diseases such as heart disease and cancer, or to determine a patient's risk of cancer reoccurrence.³⁹ Genetic tests are also used to screen newborns, fetuses, or embryos used in *in vitro* fertilization for genetic defects.⁴⁰ They also have non-clinical uses such as paternity testing and forensics.⁴¹

Sequencing is the process of determining the exact order of the base pairs in a segment of DNA.⁴² Whole genome sequencing refers to the sequencing of the entire complement of DNA in an individual.⁴³ Unlike SNP genotyping, which captures less than 0.1% of the genome, full genome sequencing is the complete DNA sequence of an individual.⁴⁴ Various techniques are utilized in whole genome sequencing including bacterial artificial chromosome (BAC) based sequencing and more recently next-

³² Perkel, *supra* note 30.

³³ *Id.*

³⁴ Palmer, *supra* note 5, at 479–80.

³⁵ *Id.*

³⁶ *Id.*

³⁷ Regulation of Genetic Tests, *supra* note 20.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Illumina Sequencing Methods, ILLUMINA.COM <http://applications.illumina.com/applications/sequencing.html>; Nat'l Human Genome Research Institute, *The Human Genome Project Completion: Frequently Asked Questions*, NATIONAL INSTITUTES OF HEALTH, (Oct. 30, 2010), <http://www.genome.gov/11006943>.

⁴³ *Id.*

⁴⁴ *Id.*

generation sequencing (NGS).⁴⁵ BAC-based sequencing involves cloning fragmented pieces of DNA in bacteria, amplifying the DNA.⁴⁶ The BAC clones are then cut into still smaller fragments and loaded into a sequencer.⁴⁷ Computational methods are used to reassemble these short sequences into the entire sequence representing the human DNA.⁴⁸ Recent advances in technology led to next-generation sequencing, enabling more rapid sequencing or larger stretches of DNA base pairs spanning entire genomes.⁴⁹ NGS involves identifying bases of a small fragment of DNA from signals emitted as each fragment is resynthesized using a known reference genome.⁵⁰ This process is extended across millions of reactions in parallel.⁵¹

Current Research

The Human Genome Project was a joint venture between the National Institutes of Health (NIH) and the Department of Energy, along with international partners, to sequence all 3 billion base pairs in the human genome.⁵² The Project's goal was to provide researchers with the tools to understand the genetic factors in human disease, paving the way for new strategies in diagnosis, treatment and prevention.⁵³ The completed human sequence is a sort of map, a resource providing a set of detailed information about the structure, organization, and function of the complete set of human genes.⁵⁴ All data generated by the Human Genome Project was made available on the Internet, serving to accelerate the pace of medical discovery around the world.⁵⁵ To date, the Project has fueled the discovery of more than 1,800 disease genes, and at least 350 biotechnology-

⁴⁵ Nat'l Human Genome Research Institute, *supra* note 20; Illumina, *An Introduction to Next-Generation Sequencing Technology*, ILLUMINA.COM, (October 16, 2013), http://www.illumina.com/content/dam/illumina-marketing/documents/products/illumina_sequencing_introduction.pdf.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Illumina, *supra* note 45 at 4.

⁵¹ *Id.*

⁵² See generally, Nat'l Human Genome Research Institute, www.genome.gov; *Human Genome Project*, www.report.nih.gov.

⁵³ *Human Genome Project*, www.report.nih.gov.

⁵⁴ Nat'l Human Genome Research Institute, *An Overview of the Human Genome Project*, NATIONAL INSTITUTES OF HEALTH, (Nov. 8, 2012), <http://www.genome.gov/12011238>.

⁵⁵ *Id.*

based products resulting from the Human Genome Project are currently in clinical trials.⁵⁶

The Personal Genome Project was founded in 2005 and is dedicated to creating public genome, health, and trait data.⁵⁷ While the Human Genome Project used only one anonymous individual for 70% of the final sequence and a number of different individuals for the remaining 30%, the Personal Genome Project aims to recruit as many as 100,000 individuals to contribute genomic sequence data, tissues, and extensive environmental, trait and other information to a publicly accessible and identifiable research database.⁵⁸

There are currently more than 2,000 genetic tests for various human conditions.⁵⁹ These tests enable patients to learn their genetic risks for disease and also help healthcare professionals to diagnose disease.⁶⁰ Having the complete sequence of the human genome is like having an instruction manual to the human body.⁶¹ The more researchers study this manual, the better they can understand human health and disease.⁶² A deeper understanding of disease at the genomic level will lead to a new generation of targeted interventions, including highly effective pharmaceuticals with fewer side effects.⁶³

The Human Genome Project was a thirteen-year and nearly \$3 billion effort.⁶⁴ Today, the price for the sequencing of an entire human genome is under \$5,000 and is continuing to fall.⁶⁵ The NIH and other research institutions are striving to bring the cost of sequencing an individual's genome to \$1,000 or less, increasing the availability of genetic sequencing to consumers.⁶⁶ One private sequencing technology company, Illumina, recently announced that the company would begin producing

⁵⁶ Research Portfolio Online Reporting Tools, *Human Genome Project*, NATIONAL INSTITUTES OF HEALTH, at <https://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx> (Jan. 6, 2015).

⁵⁷ Jeantine E. Lunshof et al., *Personal genomes in progress: from the Human Genome Project to the Personal Genome Project*, DIALOGUES IN CLINICAL NEUROSCIENCE (Mar. 2010), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3181947/>.

⁵⁸ *Id.*

⁵⁹ *Understanding the Human Genome Project – A Fact Sheet*, 8 NIH MEDLINEPLUS 15 (Spring 2013), at <http://www.nlm.nih.gov/medlineplus/magazine/issues/summer13/articles/summer13pg15.html>.

⁶⁰ *Id.*

⁶¹ Nat'l Human Genome Research Institute, *supra* note 42.

⁶² *Id.*

⁶³ *Understanding the Human Genome Project – A Fact Sheet*, *supra* note 59.

⁶⁴ Nat'l Human Genome Research Institute, *supra* note 42; Michael Malecek, *Emerging Trends In Nucleic Acids And Human Genome Work*, LAW 360, (Dec. 18, 2012); Trevor Woodage, *Gatekeepers and Goalposts: The Need for a New Regulatory Paradigm for Whole Genome Sequence Results*, 11 NW. J. TECH. & INTELL. PROP. 1 (2012).

⁶⁵ Malecek, *supra* note 64; Palmer, *supra* note 5, at 483. ("[T]he cost of whole genome sequencing...is expected to dip below the thousand-dollar mark soon").

⁶⁶ See generally, Nat'l Human Genome Research Institute, *supra* note 42.

a new system this year that could sequence the full human genome for less than \$1,000.⁶⁷ Individualized analysis of a personal genome will lead to a powerful tool of preventive medicine.⁶⁸ This new form of personalized health care will reshape preventative and diagnostic care to complement each individual based on his or her unique genetic code.⁶⁹ Full genomic sequencing is not only important to individual patient care, but with the ability to sequence possibly millions of people, researchers will be able to truly understand how gene variants contribute to disease.⁷⁰ This knowledge can then be used to develop more effective treatments and pharmaceuticals.⁷¹

The data researchers currently use comes from people who have provided consent to the use of their genomes for projects such as the Human Genome Project and the Personal Genome Project.⁷² A controversy arises with the use of information paid for personally by individual direct-to-consumer genetic testing consumers. There is a debate on whether such personal genetic information should be available for use in supplemental research and the level of consent that should be required.

Direct-to-Consumer Genomic Testing

With the completion of the Human Genome Project in 2003, the interest in personal genetic information in the United States has increased exponentially.⁷³ It became clear that Americans wanted access to their personal health blueprints, and as the cost of genetic testing plummeted, the direct-to-consumer (DTC) genetics industry emerged to meet this demand.⁷⁴ With several affordable choices available today, consumers can select a DTC provider, order a test kit online, send in a saliva sample, and then wait just a few weeks to gain access to the plethora of information contained in their very own unique genome.⁷⁵

⁶⁷ Erika Check Hayden, *Is the \$1000 genome for real?*, NATURE (Jan. 15, 2014) ("If there was any doubt to if genomics would ever be able to reach the everyday man, at this price point and efficiencies it is absolute certainty." quoting Michael Schatz).

⁶⁸ *Understanding the Human Genome Project – A Fact Sheet*, *supra* note 59.

⁶⁹ Palmer, *supra* note 5, at 481.

⁷⁰ Hayden, *supra* note 67.

⁷¹ *Id.*

⁷² See generally National Human Genome Research Institute, at www.genome.gov; (Jan. 7, 2016); *Human Genome Project*, at www.report.nih.gov. (Feb. 18, 2015).

⁷³ Schleckser, *supra* note 7, at 697.

⁷⁴ *Id.*

⁷⁵ *Id.*

Traditional genetic testing is done through a healthcare provider.⁷⁶ A patient who wants to be tested for disease risks or to determine if he or she is a carrier of a particular gene must see a doctor.⁷⁷ The doctor will determine which tests, if any, are appropriate, collect samples, and send those samples to a laboratory.⁷⁸ The laboratory returns the results to the doctor, who then interprets the results for the patient.⁷⁹ However, DTC tests take the doctor out of the equation and gives control directly to the patient.⁸⁰

To some, most prominently regulation agencies, the absence of the learned intermediary has potentially unsafe consequences, with DTC companies essentially providing unregulated medical diagnoses.⁸¹ Many of the commercial providers primarily market to people seeking to learn about their ancestry, but most of the recent controversy has been on those DTCs that provide health-related genomic services.⁸² The International Society of Genetic Genealogy currently lists twenty-five commercial testing providers.⁸³ Of those twenty-five providers, only two currently list “health” as a purpose for the genetic testing services.⁸⁴ Largely due to the threats of tough regulation, companies that emerged as leaders in the late 2000s such as deCODEme, Navigenics, and Pathway Genomics have widely fallen off the map.⁸⁵ Under pressure by the FDA in 2010, Pathway Genomics and Navigenics quickly eliminated the customers’ ability to order tests without physician involvement.⁸⁶ Then in 2012, both deCODEme and Navigenics

⁷⁶ *Id.* at 698.

⁷⁷ *Id.* at 698-99.

⁷⁸ *Id.*

⁷⁹ *Id.* at 699.

⁸⁰ *Id.*

⁸¹ See *infra* notes 111-16 and accompanying text.

⁸² Palmer, *supra* note 5, at 483.

⁸³ *List of DNA testing companies*, at http://www.isogg.org/wiki/List_of_DNA_testing_companies, (Nov. 11, 2015).

⁸⁴ *Id.* 23andMe and Gene by Gene are the two companies listed with “health” still listed as a function of the company. 23andMe has since ceased offering genetic reports due to FDA intervention. See Warning U.S. FOOD AND DRUG ADMINISTRATION, *supra* note 2. See also Anne Wojcicki, *23andMe Provides An Update Regarding FDA’s Review*, 23ANDEMBLOG (December 5, 2013), <http://blog.23andme.com/news/23andme-provides-an-update-regarding-fdas-review/>; INTERNATIONAL SOCIETY OF GENETIC GENEALOGY WIKI, *supra* note 83; Schleckser, *supra* note 7, at 700.

⁸⁵ Schleckser, *supra* note 7, at 700; see *infra* notes 110-25 and accompanying text.

⁸⁶ Schleckser, *supra* note 7 at 700; See also Dan Vorhaus et al., *DTC Genetic Testing and the FDA: Is There an End in Sight to the Regulatory Uncertainty?*, GENOMES UNZIPPED (June 16, 2011), <http://www.genomesunzipped.org/2011/06/dtc-genetic-testing-and-the-fda-is-there-an-end-in-sight-to-the-regulatory-uncertainty.php#more-3681>; The FDA sent Pathway Genomics a letter in 2010 stating that its Genetic Health Report was a medical device under the Act requiring FDA approval. U.S. Food and Drug Administration, *Letter to Pathway Genomics Corporation Concerning the Pathway Genomics Genetic Health Report*, 5/10/10, MEDICAL DEVICES, <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm211866.htm>. See *infra* note 123.

were acquired by biotech companies and left the DTC market.⁸⁷ As a result, the genetic testing company 23andMe emerged as the undisputed leader in the DTC market.⁸⁸

23andMe offers their genomic testing services for \$99.⁸⁹ Consumers enroll via the website and purchase a DNA kit through the online store.⁹⁰ The 23andMe kit arrives with detailed instructions.⁹¹ Following the instructions, customers spit two milliliters of saliva into a collection tube through an attached funnel.⁹² Closing the lid of the funnel releases the stabilization buffer into the collection tube.⁹³ Then the funnel is removed, a cap attached, and the tube is ready for shipping.⁹⁴ The customer packs her sample into the prepaid box and drops it into a mailbox.⁹⁵

The saliva sample is sent to and processed by a clinical laboratory.⁹⁶ The lab typically genotypes over one million SNPs and then “presents this SNP information to the consumer in the form of a personalized genomic report, which includes disease risk estimates, . . . pharmacogenomic information, carrier status for [select] heritable diseases, and . . . ancestry information.”⁹⁷ 23andMe results are typically available four to six weeks after [the] customer’s kit arrives at the laboratory.⁹⁸ 23andMe provided results for over 200 conditions ranging from earwax type and bitter taste perception to risk for Alzheimer’s disease and multiple sclerosis.⁹⁹

⁸⁷ *Id.*; Pathway Genomics today is still considered a DTC testing company even though it requires physician permission because it provides the information directly to the customer through its web portal. Schleckser, *supra* note 7, at footnote 30.

⁸⁸ *Id.*

⁸⁹ *How it works*, 23ANDME, <https://www.23andme.com/howitworks/>.

⁹⁰ *Id.*

⁹¹ *Providing your saliva sample*, 23ANDME, <https://customer.care.23andme.com/hc/en-us/articles/202904530-Providing-your-saliva-sample>.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ Palmer, *supra* note 5, at 483-84; Schleckser, *supra* note 7, at 701.

⁹⁷ Palmer, *supra* note 5, at 484. It is important to note that direct-to-consumer genetic tests like 23andMe are only examining predetermined locations on the genome – the SNPs – that are associated with particular traits. See Schleckser, *supra* note 7, at 701. In contrast, whole genome sequencing determines the precise sequence of all three billion base pairs in the individual genome. *Id.* Genotyping is currently much more cost effective but does have its disadvantages. *Id.* at 702. Since not all genetic variation takes the form of SNPs, genotyping misses many genetic variants present throughout the genome. *Id.* It cannot detect rare mutations, such as deletions or duplications of DNA, and in some populations, a given SNP may not be an accurate marker for a nearby mutation. See Palmer, *supra* note 5, at 484. As the cost of full genome sequencing continues to fall, genetic tests genotyping only SNPs will fall out of favor but until then the ability to access even a fraction of one’s genetic information for a reasonable price will still be attractive to consumers.

⁹⁸ Schleckser, *supra* note 7, at 701.

⁹⁹ *Id.* at 703; *Health Risks*, 23ANDME, <https://www.23andme.com/you/health/risk/>.

23andMe used only those SNPs that were clinically validated in two or more research studies and agreed to collaborate with other DTC companies to develop a consensus in how to calculate disease risk predictions.¹⁰⁰ Each test listed in the health report is categorized according to the degree of scientific support for the relevant genetic association.¹⁰¹ The tests with the highest confidence are established research reports.¹⁰² They have been involved in multiple studies with over 750 participants or have the consensus of the scientific community.¹⁰³ Tests with less confidence are listed as being in the preliminary research stage and have been involved in one study of more than 750 participants.¹⁰⁴ These tests are based on peer-reviewed findings that have yet to be confirmed by the scientific community.¹⁰⁵ Tests with low confidence are also included and are described as preliminary research with the studies done involving less than 750 participants.¹⁰⁶ Test results are presented graphically and numerically, displaying the customer's risk as a percentage and comparing that risk to the average risk of the population.¹⁰⁷ Similarly, drug response results are listed according to scientific validity and list the customer's sensitivity to each drug compared to the average population.¹⁰⁸ A customer can also download his or her raw data into a text file, which includes each genotype at the approximately one million SNPs tested.¹⁰⁹

Efforts to Regulate DTC Testing

The current state of DTC regulation is messy and unclear.¹¹⁰ Three federal agencies that play a role in the regulation of genetic tests are Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC).¹¹¹ CMS regulates all clinical laboratories performing genetic testing, ensuring their compliance with Clinical Laboratory Improvement Amendments of 1988

¹⁰⁰ Palmer, *supra* note 5, at 485.

¹⁰¹ Schleckser, *supra* note 7, at 703; *Health Risks*, *supra* note 99.

¹⁰² Schleckser, *supra* note 7, at 703.

¹⁰³ *Health Risks*, *supra* note 99.

¹⁰⁴ *Id.*

¹⁰⁵ Schleckser, *supra* note 7, at 703.

¹⁰⁶ *Health Risks*, *supra* note 99.

¹⁰⁷ Schleckser, *supra* note 7, at 703.

¹⁰⁸ *Drug Response*, 23ANDME, https://www.23andme.com/you/health/drug_response/.

¹⁰⁹ Schleckser, *supra* note 7, at 703.

¹¹⁰ *Id.* at 705 ("Regulation of DTC genetic testing is a hodgepodge at best").

¹¹¹ *Id.*; NAT'L HUMAN GENOME RESEARCH INSTITUTE, *supra* note 20. The FTC's authority relates to how genetic tests are advertised. *Id.*

(CLIA).¹¹² The FDA has the broadest authority to regulate genetic tests as medical devices.¹¹³ Under the Federal Food, Drug and Cosmetic Act (the Act), the FDA has the power to review all new medical devices for safety and effectiveness.¹¹⁴ A medical device is defined in section 201(h) of the Act as a device intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.¹¹⁵ The degree of FDA oversight of a genetic test is based on its intended use and the risks posed by an inaccurate test result.¹¹⁶ The agency categorizes medical devices into three separate classes: class I for low risk products, class II for moderate risk products, and class III for tests requiring the greatest level of scrutiny.¹¹⁷ Class III devices require premarket approval by the FDA.¹¹⁸

In 2010, the FDA announced that it planned to regulate genetic testing, citing concerns in the growing separation between the commercial laboratories doing the testing and the physicians ordering the test.¹¹⁹ There were growing concerns that DTC genetic tests were medically unproven, meaningless, and misleading for consumers.¹²⁰ Congress and the Government Accountability Office (GAO) also released reports that voiced concerns on the deceptive practices of DTC genetic tests, referring to the tests as “misleading and of little or not practical use.”¹²¹ That same year,

¹¹² *Id.* Congress passed CLIA in response to concerns about the quality of clinical laboratory testing. Woodage, *supra* note 64, at 4. CLIA allowed CMS and CDC to implement standards for laboratory certification. *Id.* These standards focus on quality control and quality assurance mechanisms with laboratories rather than the concerns about the clinical uses of test results. *Id.*

¹¹³ Regulation of Genetic Tests, *supra* note 20.

¹¹⁴ *Id.*

¹¹⁵ 21 U.S.C. 321(h); FD&C Act 201(h).

¹¹⁶ Regulation of Genetic Tests, *supra* note 20.

¹¹⁷ *Id.*; See also 21 U.S.C. 360c (As device class increases from Class I, to Class II, to Class III, the regulatory controls also increase); *Regulatory Controls*, FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm> (June 26, 2014) (Class I devices are subject to the least regulatory control, and Class III devices are subject to the most stringent regulatory controls. *Id.* An example of a Class I device is a manual toothbrush). Compare with *How to Study and Market Your Device*, FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>, (Feb. 27, 2015) (An example of a Class II device is a non-invasive blood pressure monitors. *Id.* A heart value is classified as a Class III device). *Id.*

¹¹⁸ 21 U.S.C. 360c(a)(1)(C).

¹¹⁹ Regulation of Genetic Tests, *supra* note 20.

¹²⁰ *Id.*

¹²¹ *Id.*; Palmer, *supra* note 5, at 493; (The 2010 report by the GAO is entitled “Direct-to-Consumer Genetic Tests: Misleading Test Results are Further Complicated by Deceptive Marketing and Other Questionable Practices” and identified ten egregious examples of deceptive marketing). Kevin de Leon, *Senate Appropriations Committee Fiscal Summary* (May 20, 2013) http://leginfo.ca.gov/pub/13-14/bill/sen/sb_0201-0250/sb_222_cfa_20130520_092108_sen_comm.html; DIRECT-TO-CONSUMER GENETIC TESTS: Misleading Test Resulting Are Further Complicated by Deceptive Marketing and Other Questionable Prac-

the FDA began sending warning letters to DTC companies, notifying them that their services were medical devices subject to FDA regulation.¹²² The first such letter was sent to Pathway Genomics.¹²³ Pathway had recently announced a marketing partnership with the drugstore chain Walgreens but the letter quickly caused Walgreens to back out and Pathway soon moved to a physician consent based business model.¹²⁴ Twenty letters were sent out in 2010 to DTC testing companies, including 23andMe.¹²⁵

Either in spite of or in defiance to the FDA, 23andMe “pressed on under the shadow of possible regulation” until July 2012 when it decided to seek regulatory approval.¹²⁶ 23andMe announced that it submitted the first set of 510(k) documentation to the FDA.¹²⁷ The application provided, according to 23andMe, a detailed description of the Person Genome Service, extensive data supporting the performance of the technology, and comprehensive discussion of the science supporting the information presented to customers about their genetics and its impact on health.¹²⁸ 23andMe remained committed to the belief that consumers have a fundamental right to their personal genetic data.¹²⁹ Dissatisfied with the lack of cooperation by 23andMe, the FDA reiterated its policy that providing what

tices, U.S. GOVERNMENT ACCOUNTABILITY OFFICE (July 22, 2010), *available at* <http://www.gao.gov/products/GAO-10-847T>.

¹²² Schleckser, *supra* note 7, at 706.

¹²³ Palmer, *supra* note 5, at 493. *See supra* note 86.

¹²⁴ *Id.*

¹²⁵ Schleckser, *supra* note 7, at 706.

¹²⁶ *Id.* at 707.

¹²⁷ *23andMe Takes First Step Toward Clearance*, 23ANDEMBLOG (July 30, 2012), <http://blog.23andme.com/news/23andme-takes-first-step-toward-fda-clearance/>; *See also* Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance. *510(k) Clearances*, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 13, 2015), *at* <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/>; 21 U.S.C. 360(k); FD&C Act 510(k). Anyone who intends to market in the U.S. a Class I, II, or III device for human use, for which a Premarket Approval is not required, must submit a 510(k) submission to the FDA. *Premarket Notifications 510(k)*, U.S. FOOD AND DRUG ADMINISTRATION (Feb. 24, 2014), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm#when>. A 510(k) is a premarket submission made to the FDA to demonstrate that the device is substantially equivalent to another legally marketed device. *Id.* That is, the device to be marketed must be at least as safe and effective as the comparable device currently on the market. *Id.* In the Warning Letter sent to 23andMe, the FDA indicated that the 510(k) mechanism is not appropriate because there are no substantially similar approved tests already on the market. *See* Warning Letter, *supra* note 2; Gary Marchant, *The FDA Could Set Personal Genetics Rights Back Decades*, SLATE (Nov. 26, 2013 12:39 PM), http://www.slate.com/articles/technology/future_tense/2013/11/_23andme_fda_letter_premarket_approval_requirement_could_kill_at_home_genetic.html. The FDA determined the 23andMe must instead seek premarket approval or de novo classification of its tests. *Id.* *What The FDA Decision Means For 23andMe Customers*, *infra* note 147.

¹²⁸ 23andMe Takes First Step Toward Clearance, *supra* note 127.

¹²⁹ *Id.*

looks like disease diagnoses makes 23andMe's service a medical device and thus is subject to FDA approval.¹³⁰ The FDA ordered the company to discontinue marketing the Personal Genome Service.¹³¹

As of December 5, 2013, 23andMe ceased offering new customers access to health-related genetic tests pursuant to an FDA's directive.¹³² Customers who had purchased kits before November 22, 2013 continue to have access to health reports previously provided by 23andMe, but any DNA kits purchased after that date have access only to ancestry-related information and their raw data without interpretation of that data by 23andMe.¹³³ In a letter dated November 22, 2013 the FDA warned 23andMe that the company was marketing its Personal Genome Service without marketing clearance or approval in violation of the Act.¹³⁴ The FDA has classified the Saliva Collection Kit as a medical device within the meaning of the Act because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.¹³⁵ The FDA quotes language from the 23andMe website and says that most of the intended uses for the Personal Genome Service listed on the website, for example health reports providing "health risks," "carrier status," "drug response," and "first step in prevention" that enables users to "take steps toward mitigating serious diseases" are medical device uses under the Act.¹³⁶ These uses require premarket approval from the FDA.¹³⁷ The FDA cites some of these uses as particularly concerning because of the potential health consequences.¹³⁸ In particular the FDA believes that assessments for the BReast CAncer susceptibility gene (BRCA)-related genetic risk and drug responses could lead a patient to take unnecessary drastic measures based on a false positive or fail to recognize an actual risk that may exist based on a false negative.¹³⁹ The FDA says that it has no assurance that the company has analytically or clinically validated the Per-

¹³⁰ *Id.* (The FDA also did not care for 23andMe's plan for an expanded marketing effort, including a planned television ad campaign). Robert Hof, *Seven Months After FDA Slapdown, 23andMe Returns With New Health Report Submission*, FORBES (June 20, 2014), <http://www.forbes.com/sites/roberthof/2014/06/20/seven-months-after-fda-slapdown-23andme-returns-with-new-health-report-submission/>.

¹³¹ Warning Letter, *supra* note 2; Hof, *supra* note 130.

¹³² Wojcicki, *supra* note 84.

¹³³ *Id.* November 22, 2013 is the date of the warning letter sent by the FDA.

¹³⁴ Warning Letter, *supra* note 2.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ Warning Letter, *supra* note 2.

sonal Genome Service for its intended uses and thus must discontinue marketing the PGS until it receives the proper authorization from the agency.¹⁴⁰

The FDA and 23andMe came to an agreement that the genetic testing company could continue to sell the test on the condition that it provided only raw genetic data and ancestry information, not health reports.¹⁴¹ With this discontinuance in service, people have few options to obtain a health report based on their genetic information.¹⁴² In essence, this sort of regulation has caused pure DTC testing to cease to exist.¹⁴³ 23andMe agreed to go through the long and arduous FDA approval process.¹⁴⁴ However, this has been a significant step backward in an individual's control of their genetic information and a step toward FDA regulation of genetic information. The agency's designation of 23andMe's service as a medical device inhibits the consumer from accessing his or her own genetic information without the permission of a learned intermediary.¹⁴⁵ Until 23andMe can gain approval for each of its more than 200 genetic tests, consumers are left with little choice.¹⁴⁶

III. ANALYSIS

The FDA and associated regulatory agencies need to develop a comprehensive regulatory plan that addresses the issues it raises regarding consumer safety and privacy without unnecessarily restricting an individual's right to his personal information and trampling a potentially vastly useful and significant DTC genetic testing market. The first section argues

¹⁴⁰ *Id.*

¹⁴¹ Wojcicki, *supra* note 84

¹⁴² Promethease – Genetic Health Information Alternative, DNAEXPLAINED – GENETIC GENEALOGY (Dec. 30, 2013), <http://dna-explained.com/2013/12/30/promethease-genetic-health-information-alternative/>. (Third parties offering interpretive reports such as Promethease have emerged in the market to fill this new void. At Promethease people can upload the text file obtained from any DTC testing service including 23andMe. They will process the raw data and provide the customer with a report that is available for download from the server).

¹⁴³ Schleckser, *supra* note 7, at 705.

¹⁴⁴ Wojcicki, *supra* note 3.

¹⁴⁵ Schleckser, *supra* note 7, at 707.

¹⁴⁶ Anne Wojcicki, *A Note to Our Customers Regarding the FDA*, 23ANDME BLOG (Dec. 23, 2015), <http://blog.23andme.com/news/a-note-to-our-customers-regarding-the-fda/>. (On February 19, 2015, the FDA granted authorization to 23andMe to market the Bloom Syndrome Carrier Status report, the first such authorization granted to any DTC genetic test. This gives 23andMe a regulatory framework for future submissions. Because 23andMe successfully gained authorization from the agency, it may be able to submit some future submission through the standard 510(k) pathway as opposed to the much more stringent *de novo* review). What The FDA Decision Means For 23andMe Customers, 23ANDME BLOG (Feb. 19, 2015), <http://blog.23andme.com/news/what-the-fda-decision-means-for-23andme-customers/>.

for the necessity of freely accessible genetic information and its benefits to both individual consumers and patients and society as a whole because its promise to transform healthcare as we know it. The next section then explores the concerns about DTC genetic testing put forth by both regulatory agencies and legislators and attempts to explain why many of these concerns are both shortsighted and heavy-handed, largely doing more to stifle the genetic testing industry rather than protect consumers. Nevertheless, valid concerns do exist in the DTC genetic testing landscape that can be addressed in such a way as to both protect consumers and promote scientific innovation, benefiting all of society. Lastly, I argue that the Genomics and Personalized Medicine Act (GPMA), originally introduced in 2006, is a suitable starting point for legislation aiming to protect consumers while expanding and accelerating beneficial genomics research.

The Need For Open Accessibility of Genetic Information

To use whole genome sequencing to uncover changes in DNA that underlie disease, scientists and clinicians need access to whole genome sequence data from many individuals.¹⁴⁷ Continued advances in healthcare depend on large numbers of individuals willing to share their data for research purposes.¹⁴⁸ Additional health and demographic information on each individual further aid researchers in making connections between variations in whole genome sequence data and specific diseases.¹⁴⁹ Public sequencing projects like the Personal Genome Project rely on public participation for their success.¹⁵⁰ The PGP's model is based on open consent and public data access to further human genomic research.¹⁵¹ Data sets and tissue samples from the project are made publicly available with minimal or no access restrictions and can generally be transferred to outside research studies to be utilized by and combined with data from third parties.¹⁵² This organized effect is essential to the success of genomic research.¹⁵³

The DTC genetic testing company 23andMe is not just a place for customers to learn about their own ancestry and genetic predisposition to

¹⁴⁷ Presidential Commission for the Study of Bioethical Issues, Privacy and Progress in Whole Genome Sequencing, page 16 (2012),

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Jeantine E. Lunshof et al., *Personal genomes in progress: from the Human Genome Project to the Personal Genome Project* 12(1) DIALOGUES IN CLINICAL NEUROSCIENCE 47, 47-60 (Mar. 2010).

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

diseases, it has also become one of the largest databases of personal genetics information in the world.¹⁵⁴ 23andMe has a substantial research arm and has done significant medical research with the database of genetic information it has built.¹⁵⁵ They are also able to offer the genetic data of 700,000 people to researchers and pharmaceutical companies to conduct large-scale medical studies that would normally take months or years to solicit enough volunteers.¹⁵⁶ 23andMe offers customers the opportunity to participate in genetic research at the time they purchase the testing kit.¹⁵⁷ 23andMe asserts that its customers who consent to research contribute to over 230 studies.¹⁵⁸ The company has identified hundreds of new genetic associations.¹⁵⁹ The more innocuous include whether a person is likely to sneeze when looking at a bright light or whether a person can smell asparagus in his urine to.¹⁶⁰ More promising research includes the company's recent findings on Parkinson's disease.

A study with more than 10,000 participants has identified two new genetic associations for the disease.¹⁶¹ This led to 23andMe's first patent in May 2012 entitled "Polymorphisms Associated With Parkinson's Disease."¹⁶² The patent relates to the discovery of a variant in the SGK1 gene that may be protective against Parkinson's disease in individuals who carry the rare risk-associated LRRK2 G2019S mutation.¹⁶³ In its announcement of the patent, 23andMe emphasizes its belief that patents should not be used to obstruct research and maintains that obtaining a patent is an important step in ensuring its genetic breakthroughs translate into real-world benefits.¹⁶⁴ Patents are important for biotechnology or pharmaceutical companies as they provide assurance for the large financial investment required in the resource-intensive process of drug development.¹⁶⁵ 23andMe goes on to say that its patent will not prevent other entities from accessing the genetic data or its interpretation specific to its patents.¹⁶⁶ Third parties

¹⁵⁴ Heather Somerville, *23andMe aims to be Google for genetic research*, SAN JOSE MERCURY NEWS Sept. 6, 2014. .

¹⁵⁵ 23andMe, *Get involved in a new way of doing research*, at, <https://www.23andme.com/research/>.

¹⁵⁶ Somerville, *supra* note 154.

¹⁵⁷ 23andMe, *supra* note 155.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ Charles Seife, *23andMe Is Terrifying, but Not for the Reasons the FDA Thinks* (Nov. 27, 2013) at <http://www.scientificamerican.com/article/23andme-is-terrifying-but-not-for-reasons-fda/>.

¹⁶¹ 23andMe, *supra* note 155.

¹⁶² Anne Wojcicki, *Announcing 23andMe's First Patent*, 23ANDMEBLOG (Mar. 28, 2012), at <http://blog.23andme.com/news/announcements/announcing-23andmes-first-patent/>.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

can continue to use the genetic information without licensing fees, furthering their stated belief that meaningful research based genetic information is their primary mission.¹⁶⁷

Concerns in the DTC Genetic Testing Industry

Concerned with the privacy of individual participants, recent state legislation has attempted to curb the wide availability of this information.¹⁶⁸ Several states have attempted to enact legislation pertaining to the privacy of genetic information.¹⁶⁹ For example, the Genetic Information Privacy Act in California proposed by California State Senator Alex Padilla attempts to regulate what DTC companies can and cannot do with the genetic information of its customers.¹⁷⁰ Similar bills have passed in other states, including Illinois, but the range of protections differs from state to state.¹⁷¹ California's proposed bill is of particular interest because there is currently no protection of genetic privacy outside of the health care system and the booming biotech industry in the state is vocal about how this type of legislation could slow the progress of research and clinical trials.¹⁷² The bill addresses concerns over DTC genetic testing companies that allow consumers to submit genetic samples in order to test for genetic disorders, obtain ancestral information, or participate in research studies.¹⁷³

Currently, the federal Health Insurance Portability and Accountability Act (HIPAA) protects the genetic and personal health information of

¹⁶⁷ *Id.*

¹⁶⁸ Jessica Shugart, *California bill would prevent genetic-testing firms from using surreptitiously obtained DNA*, SAN JOSE MERCURY NEWS (May 23, 2013).

¹⁶⁹ *Id.* Over 30 states have some sort of laws in place providing protection against the collection or sharing of genetic data. *Id.* The laws range from protecting the privacy of health-related genetic information to treating all DNA as private property. *Id.* Specifically, 27 states require consent to disclose genetic information. *Genetic Privacy Laws*, National Conference of State Legislatures, <http://www.ncsl.org/research/health/genetic-privacy-laws.aspx> (Jan. 2008). Five states explicitly define genetic information as private property. *Id.* Four states mandate individual access to personal genetic information. *Id.* Nineteen states have established penalties, civil and criminal in some cases both, for violating genetic privacy laws. *Id.*

¹⁷⁰ *Id.*; Senator Kevin de Leon, *Senate Appropriations Committee Fiscal Summary*, Bill Analysis (January 23, 2014); California Senate Bill 222 and Senate Committee Reports, available at http://leginfo.ca.gov/pub/13-14/bill/sen/sb_0201-0250/sb_222_cfa_20140123_091418_sen_comm.html; California Senate Bill 1267 and Senate Committee Reports, Chandi Abeygunawardana, *Governing The Code Of Life: Calif.'s DNA Privacy Bill*, LAW 360 (June 6, 2012).

¹⁷¹ Shugart, *supra* note 168. See also *Genetic Privacy Laws*, *supra* note 169.

¹⁷² Shugart, *supra* note 168; Helen Shen, *California considers DNA privacy law*, NATURE (May 18, 2012), <http://www.nature.com/news/california-considers-dna-privacy-law-1.10677>.

¹⁷³ Kevin de Leon, *Senate Appropriations Committee Fiscal Summary* (May 20, 2013), http://leginfo.ca.gov/pub/13-14/bill/sen/sb_0201-0250/sb_222_cfa_20130520_092108_sen_comm.html.

patients but Senator Padilla maintains that the laws do not protect people against companies outside the health care system.¹⁷⁴ The Senate Appropriations Committee analysis of Senator Padilla's bill cites the GAO report that identifies deceptive marketing practices and misleading test results.¹⁷⁵ If passed, the bill would prohibit any person from "obtaining, analyzing, retaining, or disclosing genetic information without the written authorization of the individual to whom the information pertains" under the threat of civil and criminal penalties.¹⁷⁶ The bill includes exceptions such as for a hospital, laboratory, or physician carrying out court-ordered tests, a licensed health care professional, and any person that is already required to comply with HIPAA.¹⁷⁷ DTC companies are specifically excluded from the exhaustive list of exemptions.¹⁷⁸

The University of California and other major research universities argue that these exceptions do not go far enough and could have a costly and damaging effect on research.¹⁷⁹ The university wrote a formal letter to the California legislature objecting to the bill.¹⁸⁰ Under the proposed legislation, an individual's genetic information may only be used by individuals specifically named on a consent form and only for purposes given on the consent form.¹⁸¹ A genomic dataset could not be re-used in separate experiments or be made available to third-parties for further research.¹⁸² Researchers must either destroy the data after each study or obtain new consent from individual participants, an infeasible task for studies involving thousands of subjects.¹⁸³

Geneticist David Segal, associate director of genomics at the University of California, Davis, believes such requirements could seriously hinder genomic research.¹⁸⁴ By being forced to re-obtain consent, California universities would essentially be barred from doing such large genomic studies.¹⁸⁵ The university estimates the provisions of the bill could increase central research and hospital administrative costs approximately \$40 million per year.¹⁸⁶ The costs result from the increased workload as-

¹⁷⁴ Shugart, *supra* note 168.

¹⁷⁵ Kevin de Leon, *supra* note 170.

¹⁷⁶ *Id.*

¹⁷⁷ Kevin de Leon, *supra* note 173.

¹⁷⁸ *Id.*

¹⁷⁹ Shugart, *supra* note 168.

¹⁸⁰ Shen, *supra* note 172.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ Kevin de Leon, *supra* note 173.

sociated with obtaining authorizations for research not covered by the exceptions enumerated in the bill.¹⁸⁷

The University of California is also concerned that the state's biomedical industry could be put at a distinct competitive disadvantage for public and private research grants.¹⁸⁸ To the extent research involving genomic data could become more difficult to conduct due to the added level of consent, financiers could look to other states with less red tape.¹⁸⁹ A reduction in research grants could result in a loss of millions of dollars in research funding for institutions within the state.¹⁹⁰ Supporters of the bill maintain that the bill does not prevent institutions from doing research and that it simply adds a level of consent but the added level of consent is over-burdensome.¹⁹¹ University of California policies governing human research already require informed consent when using genomic data.¹⁹² Genetic information is also typically identified by number rather than by an individual's name.¹⁹³ Under the bill, even anonymous data would require re-authorization for re-use.¹⁹⁴ The first attempt to pass similar legislation stalled in 2012 in the Appropriations Committee.¹⁹⁵ The new version of the bill was introduced in February 2013 and is currently pending in the Senate.¹⁹⁶

23andMe, a California based company, has similar concerns to the University of California and other research institutions as to the detrimental effects of the genetic privacy bill.¹⁹⁷ 23andMe requires customer consent for research participation.¹⁹⁸ Research participation is an opt-in choice during the kit registration process and customers can opt-out of future research at any time through his account.¹⁹⁹ The consent forms and privacy policy clearly state that its customers' genomic information is used for research by 23andMe and may be disclosed to third parties for outside

¹⁸⁷ *Id.*

¹⁸⁸ Shugart, *supra* note 168; Shen, *supra* note 172.

¹⁸⁹ Kevin de Leon, *supra* note 173.

¹⁹⁰ *Id.*

¹⁹¹ Shen, *supra* note 172.

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ Shugart, *supra* note 168.

¹⁹⁶ S.B. No. 222. Complete Bill History, available at http://leginfo.ca.gov/pub/13-14/bill/sen/sb_0201-0250/sb_222_bill_20140203_history.html; See also Washington State Legislature, at *Overview of the Legislative Process*, <http://www.leg.wa.gov/legislature/Pages/Overview.aspx>. The bill can then be reintroduced and retained in its present position. *Id.* At this time it does not seem that the bill has been reintroduced.

¹⁹⁷ Shugart, *supra* note 168.

¹⁹⁸ See generally Get involved in a new way of doing research, *supra* note 155.

¹⁹⁹ *Id.*

research studies.²⁰⁰ 23andMe explains that basic research consent means that the customer's genetic and self-reported information may be used in an aggregated form, stripped of identifying registration information for peer-reviewed scientific research.²⁰¹ The company may disclose individual-level personal information to a third party only through an additional level of consent given by the customer.²⁰² The customer can choose to have his DNA sample discarded to further ensure his privacy.²⁰³ Customers also have the option of simply receiving their raw genetic data with no analysis.²⁰⁴ They can then take that raw data file to alternative companies such as Promethease.²⁰⁵ Promethease will process the raw data and then the raw data file is deleted within 24 hours of completion of the health report, providing additional security to those that wish to receive their health report but not to share their genetic information.²⁰⁶

Individuals who freely give their consent to companies such as 23andMe or public projects such as the Personal Genome Project and wish to contribute to the beneficial research taking place should not be prohibited from doing so. Senator Padilla cites concerns with specific genetic testing companies that make no attempt to discourage customers from secretly sending in another's genetic sample.²⁰⁷ The Illinois based company EasyDNA encourages customers to send "discreet samples" such as hair, clothing, or cigarette butts when it is not possible to directly obtain sample from the individual to be tested.²⁰⁸ Companies that aim to surreptitiously obtain DNA for nefarious reasons should be prohibited from doing so through regulation but said regulation should not impede those doing beneficial research or hinder individuals' ability to discover and use their own genomic data for their benefit.²⁰⁹ 23andMe requires that the person submitting the DNA sample has legal authorization to do.²¹⁰ Although all consent forms are filled out online, the testing kit requires eight milliliters of saliva.²¹¹ A sample of that size usually takes a customer five to ten minutes to gather, greatly minimizing the likelihood that amount of saliva

²⁰⁰ 23andMe, *Privacy Statement*, (Dec. 7, 2015), <https://www.23andme.com/legal/privacy/>.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ Get involved in a new way of doing research, *supra* note 155; *Promethease privacy*, SNPEDIA, (Mar. 25, 2014), at <http://www.snpedia.com/index.php/Promethease/privacy>

²⁰⁵ *Promethease privacy*, *supra* note 204.

²⁰⁶ *Id.*

²⁰⁷ Shugart, *supra* note 168.

²⁰⁸ *Id.*

²⁰⁹ *Id.* at 3. (discussing research concerns in light of potential regulation).

²¹⁰ *Id.*

²¹¹ *Id.*

could be secretly collected from another. 23andMe does not perform paternity or infidelity testing.²¹² There needs to be a distinction between genetic testing obtained by individuals that wish to gain knowledge about their personal health and predisposition to cancer, diabetes, Parkinson's and a host of other diseases and the more deceitful uses of genetic testing such as paternity testing without consent and "infidelity testing" in which the underwear of an allegedly unfaithful partner is secretly tested for foreign genetic material.²¹³

Immediate Concerns for the DTC Genetic Testing Consumer

Many opponents of public access to personal genetic data, including the FDA, cite concerns about the misuse of this data ranging from the plausible to fanciful.²¹⁴ The FDA in particular is concerned that physicians have been removed from the equation and consumers now have direct access to their genetic information straight from the testing facility.²¹⁵ The FDA believes that marketing directly to consumers can increase the risk to the consumer because of the possibility patients may make a decision that adversely affects their health based on the information received from genetic reports.²¹⁶ This stems from the FDA's patent mistrust of the accuracy of genetic tests being offered to consumers through DTC testing.²¹⁷

The FDA has a legitimate concern in companies making high-risk claims to their customers such as their risk for cancer or their likelihood of responding to a specific drug.²¹⁸ Companies certainly should not be making arbitrary determinations or allowing customers to rely on false or misleading marketing to make consumers believe tests are more reliable than they actually are. However, this concern should not bar consumers from gaining access to their genetic information without the consent of a physician. Rather the FDA, along with the other participating agencies, can alleviate this concern through proper regulation and strict enforcement for

²¹² Shugart, *supra* note 168.

²¹³ *Id.*

²¹⁴ *Direct-to-Consumer Genetic Testing and the Consequences to the Public: Hearing before the Subcomm. on Oversight and Investigations of the Comm. On Energy and Commerce*, 111th Cong., 68-82 (2d Sess. 2010) [hereinafter Prepared Statement by Shuren] (statement of Jeffrey Shuren, M.D., Dir. of the Center for Devices and Radiological Health, Fed. Drug Admin.) (describing the potential effects of direct-to-consumer testing).

²¹⁵ *Id.*

²¹⁶ *Id.* at 79.

²¹⁷ *Id.*

²¹⁸ *Id.*

companies not in compliance. The FDA believes that giving this type of information directly to the consumer can cause the consumer to make a rash decision such as stopping or changing the dose of a medication or continuing an unhealthy lifestyle.²¹⁹ To reach such a conclusion is drastic and farfetched. This is especially clear in the BRCA-related genetic risk example the FDA likes to use in its Warning Letters.²²⁰ The FDA is concerned that consumers that receive a false positive (the genetic test showed the presence of a BRCA1 or BRCA2 genetic mutation that can cause cancer) will take unnecessary measures such as prophylactic mastectomy, chemoprevention or other “morbidity-inducing actions.”²²¹ What the FDA either fails to recognize and conveniently overlooks is that no consumer who learns they do have mutations in either the BRCA1 or BRCA2 genes is going to take “morbidity-inducing actions” without first consulting with a physician. These types of drastic measures must be performed by trained physicians and thus a doctor as an intermediary is still present in the process. A doctor retains the ability to relay information to the patient and advise the patient on the reliability of such tests and the likelihood of false positives. A doctor may even recommended a second test to confirm. There is no reason to assume that a consumer cannot responsibly control his or her health decisions after receiving a genetic report from a DTC genetic testing service.

The report from 23andMe is also informative to the consumer and ensures the consumer understands the limitations of the report.²²² The genetic test from BRCA1 and BRCA2 mutations is listed as an established research report, a test with the highest confidence and support of the scientific community.²²³ However, the report goes on to explain that the BRCA mutations covered in the report are only three of hundreds in the BRCA1 and BRCA2 genes that can cause cancer.²²⁴ The absence of the mutations tested in the 23andMe genetic report does not rule out the possibility of other mutations that increase the risk of the disease.²²⁵ Further, only five to ten percent of breast cancers occur in women with a genetic predisposi-

²¹⁹ *Prepared Statement by Shuren*, *supra* note 214.

²²⁰ Warning Letter, *supra* note 2.

²²¹ *Id.*

²²² *Inherited Conditions, BRCA Cancer Mutations*, 23andMe, at <https://www.23andme.com/you/journal/bcrca/overview/>.

²²³ *Id.*; See *supra* notes 101-03 and accompanying text.

²²⁴ *Id.* 23andMe provides data for only three specific cancer-associated mutations because these three mutations account for 80-90% of all hereditary breast and ovarian cancers cases in people with Ashkenazi Jewish ancestry. *Id.* A powerful predictive tool, about 50-60% of women who have one of these three mutations will develop breast cancer. *Id.*

²²⁵ *Id.* About one in eight women with one of the three mutations will still develop breast cancer.

tion for the disease, usually due to mutation in either the BRCA1 or BRCA2 genes.²²⁶ Many other factors can contribute to the likelihood of developing breast cancer including family history and environmental factors.²²⁷ Given the amount of information 23andMe provides, it is unlikely even a false negative would cause a consumer to fail to take or continue to take preventative measures in his or her healthcare.

Similarly, the FDA's concern with consumers self-managing their prescription medicine based on the drug response assessment is unfounded. Genetic reports on drug responses from 23andMe assess the likelihood of a consumer's sensitivity to certain prescription drugs.²²⁸ For example, the 23andMe genetic report tests an individual's sensitivity to the generic drug warfarin.²²⁹ Warfarin is an anticoagulant used to treat and prevent blood clots.²³⁰ Finding a patient's optimal dose of this life-saving drug is notoriously difficult.²³¹ This kind of genetic information can help a doctor determine the initial dose of the drug.²³² The 23andMe report explains that there are many genetic and non-genetic factors that can affect how the body responds to warfarin.²³³ A doctor takes into account several other factors including age, sex, weight, and diet when selecting the initial dose of warfarin.²³⁴ Throughout the Warfarin Sensitivity Report, 23andMe instructs consumers to continue taking their medication as directed and enunciates that the information should be used in consultation with their physician.²³⁵

23andMe is an example of the way DTC genetic testing services should be run. The model 23andMe established is the model the FDA should emulate when designing regulations for future DTC testing companies. Their reports provide reliable information while responsibly disseminating that information to consumers. The ability of individuals to obtain reports that include over 200 tests for under \$100 is a valuable tool in the

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ 23andMeDrug, *supra* note 108.

²²⁹ 23andMe, Drug Response > Warfarin (Coumadin®) Sensitivity, available at <http://www.23andme.com/you/journal/warfarin/overview/>. An overview of the drug Warfarin (Coumadin®). This test is also based on established research, fully supported by the scientific community.

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.*

²³³ *Id.*

²³⁴ *Id.*

²³⁵ *Id.* ("If you are taking warfarin, keep taking it as directed by your doctor;" "Consult with a healthcare provider about confirming the result of taking appropriate next steps;" "Do not use the information in this report on its own to stop, start, or mark any changes to any current treatment without first consulting a healthcare provider.") *Id.*

continuing healthcare revolution in the United States.²³⁶ The ability for consumers to obtain such valuable information without the requirement of a physician as an intermediary is essential to an individual's ability to be proactive about their own healthcare. Again, these reports are a tool people are using to reclaim control over their health. It is not to say that a learned physician is not an important and vital part of the healthcare process. It is essential that the DTC genetic testing industry work in conjunction with the healthcare community to ensure maximum benefit to society.

Concerns with Public Access to Genetic Information

There are of course risks associated with the publication of an individual's genetic data.²³⁷ Many of these risks can be mitigated through the proper legislation including requiring strict privacy controls and strong security practices. As risks are inherent in society though, some threats will always remain. Both 23andMe and public genome databases like the Personal Genome Project disclose these risks in its consent forms.²³⁸ Risks associated with public disclosure include adverse affects on the employment, insurance and financial well being due to discrimination based on information discovered in a person's genetic data.²³⁹ There is also a possibility of a security breach wherein personal data, not intended to be published, could become public. The possible scenarios for nefarious uses of pubic data are boundless. Like an episode of CSI, some tech savvy offender could take a DNA sequence data and make synthetic DNA to plant at a crime scene, implicating some oblivious participant in the crime.

Though these risks are real and should be addressed by the FDA and other enforcement agencies, they pale in comparison to the benefits of the availability of a large public database for research purposes. Each participate consents to these risks when he or she chooses to sign the consent forms and publically share genetic data. Participants choose to share their personal data in hopes of making meaningful scientific contributions. Because of individual participation, society as a whole reaps the benefits of research and the resulting scientific advancement.

²³⁶ *Health Risks*, *supra* note 99; *How it works*, *supra* note 89.

²³⁷ Harvard Med. Sch., Personal Genome Project (updated Dec. 13, 2011) available at http://www.personalgenomes.org/static/docs/harvard/PGP_Consent_Approved_02212013.pdf; 23andMe, Research Consent Document, <https://www.23andme.com/about/consent/>.

²³⁸ Research Consent Document, *supra* note 237.

²³⁹ *Id.* at 13. (Such a risk has been addressed in the Genetic Information Nondiscriminatory Act (GINA). GINA prohibits individuals from discrimination by health insurers or employers based on genetic information. 42 U.S.C. § 2000ff (2014). The law does not apply to the use of genetic information in all circumstances.

Proposed Legislation Based on the GPMA

While there is a need for appropriate regulation to protect consumers and patients, there is an equally pressing need to avoid creating a system of oversight that would be an obstacle to the continued growth of personalized medicine.²⁴⁰ Encouraging the advancement of genomic research while ensuring individuals are adequately protected from deceptive practices of genomic testing companies through regulation involves a delicate balance. The Genomics and Personalized Medicine Act (GPMA) was originally introduced in 2006 by then-Senator Barack Obama and was re-introduced in 2010 by Congressman Patrick Kennedy.²⁴¹ Though the bill died in committee,²⁴² it was a promising start on regulation that would protect individuals but not stifle innovation. The bill aimed to strike a balance between consumer protection and flexibility for companies and research institutions.²⁴³ The bill's stated purpose was "to secure the promise of personalized medicine for all Americans by expanding and accelerating genomics research and initiatives to improve the accuracy of disease diagnosis, increase the safety of drugs, and identify novel treatments, and for other purposes."²⁴⁴ The bill established an Office of Personalized Healthcare (OPH) within the Department of Health and Human Services (HHS).²⁴⁵ The responsibilities of the OPH include the coordination of cross-agency activities and the collaboration with federal agencies and private entities to implement the GPMA initiatives.²⁴⁶ These initiatives include development of a strategic, long-term plan to advance research and development in personalized medicine and personalized medicine products, and to clarify and simplify the regulation of products used for personalized medicine to ensure that guidelines are consistent.²⁴⁷ The OPH would also recommend a clear delineation between the roles and responsibilities of the FDA and the CMS in regulation and enforcement of prod-

²⁴⁰ Dan Vorhaus, The Genomics and Personalized Medicine Act Returns to Congress, GENOMICS LAW REPORT (August 24, 2010), available at <http://www.genomicslawreport.com/index.php/2010/08/24/the-genomics-and-personalized-medicine-act-returns-to-congress/>.

²⁴¹ *Id.*

²⁴² Presidential Commission for the Study of Bioethical Issues, *supra* note 147.

²⁴³ Vorhaus, *supra* note 240.

²⁴⁴ Genomics and Personalized Medicine Act of 2010, H.R. 5440, 111th Cong. (2D Sess. 2010)2d (May 27, 2010).

²⁴⁵ *Id.* at §101.

²⁴⁶ *Id.*

²⁴⁷ *Id.*

ucts used for personalized medicine, including laboratory-developed tests.²⁴⁸

The GPMA also specifically addresses direct-to-consumer genetic testing.²⁴⁹ The Act directs the CDC to work in conjunction with the FDA and FTC to conduct an analysis of the public health impact of DTC marketing of genetic tests, analyze the validity of claims made in marketing campaigns, and make recommendations to the OPH regarding the protection of the public from potential harm of DTC genomic tests.²⁵⁰ The Act also directs the FDA to collaborate with the FTC to identify and terminate advertising campaigns that make false, misleading, deceptive, or unfair claims regarding the risks or benefits of products used for personalized medicine.²⁵¹

For this current version of the bill to become law, it would likely require extensive revision as personalized medicine and the use of DTC genetic testing has grown exponentially in the last four years. The topic of consent should be addressed in terms of the use of genomic data in future research. The Act should mandate informed consent agreements that allow for future research in advance of clear research objectives but maintain the right of an individual to opt out of the research at any time.²⁵² The FDA should be given clear guidelines as to the scope of its regulatory power and its priorities in the DTC genetic testing realm to ensure that its oversight is not counterproductive to the best interests of individuals and society by hampering research efforts. Unlike in the California Genetic Information Privacy Act, civil and criminal penalties should only be available in situations of intentional testing or use of genetic information without consent and other nefarious uses of genetic testing.

IV. IMPACT

Proper legislation and regulation of DTC genetic testing can help to minimize various privacy concerns while allowing for the use of genetic data to further research in drug therapies, disease prevention, disease

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ See Vorhaus, *supra* note 240 at 3. While this was addressed in the GAO report around the same time as the introduction of the bill, the GAO's investigation is frequently criticized for being an "unscientific snapshot" of the field of genomic testing.

²⁵² *Id.* at 1..H.R. 5440. This language is contained in the GPMA in regard to obtaining consent for a proposed national biobank. A similar consent structure would work well for private biobanks.

treatments and ultimately, to find genetic paths to cures.²⁵³ Last year saw the first use of emergency genome sequencing to aid in direct treatment.²⁵⁴ Fourteen-year-old Joshua Osborn was rushed to the hospital with headaches, fever, and brain swelling so severe he was put in a medically induced coma.²⁵⁵ After weeks of testing and even a brain biopsy, the doctors were no closer to discovering the cause of his illness.²⁵⁶ Then doctors decided they would run one more test using an experimental DNA technology and researchers' newest genomic sequencing technique: next-generation sequencing.²⁵⁷ Doctors prepared samples of Joshua's cerebrospinal fluid and sent the samples to researchers at the University of California, San Francisco for sequencing.²⁵⁸ After two days, the sequencers determined the sequences of three million fragments of DNA present in the boy's samples.²⁵⁹ After removing the human DNA fragments, the remaining DNA was compared to sequencing data from the National Center for Biotechnology Information, an online host of genomic databases worldwide.²⁶⁰ Within just a few hours, the doctors discovered that Joshua's cerebrospinal fluid contained DNA from a potentially lethal bacterium called *Leptospira*.²⁶¹ While extremely difficult to discover, *Leptospira* is easily treated with penicillin and Joshua started to recover almost immediately.²⁶²

Experts in the field are excited about the plethora of possibilities in the field of genomic testing.²⁶³ "Diagnosis is a crucial step in treating illness but can also be the most difficult."²⁶⁴ In many situations, doctors can only guess at a diagnosis based on the symptoms and then run costly and time-consuming tests to determine the cause of the problem.²⁶⁵ Though further research is required, this case study shows DNA sequencing can be

²⁵³ Anne Wojcicki, *A Note To Our Customers About The New Year*, 23ANDMEBLOG (Jan. 12, 2015), at <https://blog.23andme.com/news/announcements/a-note-to-our-customers-about-the-new-year/>.

²⁵⁴ *Top Genetic Findings of 2014*, 23ANDMEBLOG (December 26, 2014), at <http://blog.23andme.com/news/top-genetic-findings-of-2014/>; citing Carl Zimmer, *In a First, Test of DNA Finds Root of Illness*, N.Y. TIMES (June 4, 2014), available at http://www.nytimes.com/2014/06/05/health/in-first-quick-dna-test-diagnoses-a-boys-illness.html?_r=0. See Michael R. Wilson et. al., *Actionable Diagnosis of Neuroleptospirosis by Next-Generation Sequencing*, 370 NEW ENG. J. MED. 2408 (2014).

²⁵⁵ Wilson, *supra* note 254 at 2408.

²⁵⁶ Zimmer, *supra* note 254.

²⁵⁷ *Id.*; See *supra* notes 49-51 and accompanying text.

²⁵⁸ *Id.*

²⁵⁹ *Id.*

²⁶⁰ *Top Genetic Findings of 2014*, *supra* note 254.

²⁶¹ Zimmer, *supra* note 254.

²⁶² *Id.*

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*

an immensely useful tool in diagnostics.²⁶⁶ Instead of performing multiple tests to search for the pathogen, DNA sequencing can reveal the pathogen immediately.²⁶⁷ Whether it is a virus, bacterium, fungus or parasite, just one test is needed.²⁶⁸

This is just one example of the potential impact this may have on the future of genetic testing and research. A Presidential Commission espoused this notion in its whole genome sequencing report stating that “[w]hole genome sequencing offers the promise of tremendous public benefit, and is expected to change substantially our ability to assess risk, diagnose, and treat disease.”²⁶⁹ Scientists predict that whole genome sequencing research will promote a better understanding of the genetic factors that contribute to the overall health of individuals.²⁷⁰ Whole genome sequencing will change how individuals manage their own health through personalized medicine, allowing physicians to tailor treatments and manage the health of individuals based on their genetic profiles.²⁷¹

The research conducted using publically available data also supports scientific entities that advance the common good by increasing economic opportunities.²⁷² The U.S. government invested billions of dollars in the Human Genome Project.²⁷³ This investment has generated \$244 billion in personal income and \$796 billion in overall economic impact.²⁷⁴ Taking data from just 2010, human genome sequencing projects and related research directly and indirectly generated over 300,000 jobs and \$3.7 billion in tax revenue.²⁷⁵ In addition to the vast public benefit of genomic research, the economic impact of promoting scientific innovation is also significant. Ensuring this kind of impact continues to propagate throughout society should be a top priority of United States legislators and regulatory agencies.

V. CONCLUSION

The essence of the GPMA should be preserved: to secure the promise of personalized medicine for all Americans. Regulation that pro-

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ Presidential Commission for the Study of Bioethical Issues, *supra* note 147, at 34.

²⁷⁰ *Id.* at 35.

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *Id.* at 36.

²⁷⁵ *Id.*

motes improving the accuracy of disease diagnosis, increasing the safety of pharmaceuticals, preventing deceptive marketing practices, and ensuring consent is openly and voluntarily given while expanding and accelerating genomics research is in the best interesting of every person and societ