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THE RISKY BUSINESS OF LIFESTYLE GENETIC TESTING: PROTECTING AGAINST HARMFUL DISCLOSURE OF GENETIC INFORMATION

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INTRODUCTION

THE PERFECT GIFT FOR THE GENETIC AGE. Testing of your unique DNA is now available, easy to do, and usable. For the first time, advanced genetic tests can be ordered together at great savings.

People can now order nutritional, ancestry and drug reaction DNA tests without going to their doctor, most samples can be collected at home using a cotton cheek swab.

LEAD A BETTER LIFE BY LEARNING ABOUT YOUR INDIVIDUAL DNA MAKEUP.¹

Nutrigenetics—the “newly developing science of how a person’s diet interacts with his or her genotype to influence the balance between health and disease”²—promises an easier way to escape the consequences of unhealthy lifestyles. The technological and scientific advances of nutrigenetic testing imply that the future is here, but unfortunately the legal protections are not. This deficit of legal safeguards leaves anybody who wants to take advantage of the potential of nutrigenetics vulnerable to considerable risks, including psychological harms and identity crises caused by a misunderstanding of, or unwanted exposure to, genetic information, stigma and discrimination arising from harmful third-party release of the genetic information, and violation of privacy, equal protection, and potentially even loss of property interests.

Yet with more than half of Americans classified as overweight or obese³—many of whom face incentives or even pressures from employers or insurance companies to improve their health and diet—it is no longer just a fringe of health conscious Americans seeking high-tech

¹ Health & DNA, Predictive Genetic Testing, <http://www.healthanddna.com/publicindex.html> (last visited Nov. 8, 2007) (emphasis omitted).

² Nola M. Ries & Timothy Caulfield, *First Pharmacogenomics, Next Nutrigenomics: Genohype or Genohealthy?*, 46 JURIMETRICS J. 281, 282 (2006) (quoting Janis S. Fidler & Craig H. Warden, *Dietary Fat and Genotype: Toward Individualized Prescriptions for Lifestyle Changes*, 81 AM J. CLINICAL NUTRITION 1255, 1255 (2005)). The ultimate goal of nutrigenetics and nutrigenomics is to optimize health through the personalization of diet. See David M. Mutch et al., *Nutrigenomics and Nutrigenetics: The Emerging Faces of Nutrition*, 19 FASEB J. 1602, 1602 (2005). Nutrigenomics is the study of the sequence, function and interactions of genes and nutrition. *Id.* at 1603–04. Nutrigenetics, on the other hand is the study of how hereditary factors affect a particular individual’s responses to nutrition. *Id.* at 1604. For the purposes of this Article, the differences are unimportant.

³ About one-third of Americans over the age of twenty are overweight, and nearly another third are obese. See National Center for Health Statistics, *Prevalence of Overweight and Obesity Among Adults: United States, 1992–2002*, <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/obese/obse99.htm> (last visited Nov. 8, 2007).

solutions. Many of those same people—both those who are already facing health problems and those seeking to avoid them—are among the majority of American consumers who prefer self-treatment options to seeing a doctor.⁴ The “perfect gift for the genetic age” that genetic testing purportedly offers thus captures a large and receptive audience, particularly given its promises of “[s]elf knowledge [that] leads to self empowerment and self improvement.”⁵ Under the heading “Nutritional Genetics: Personalized Nutritional and Lifestyle Recommendations from the Genetic Age,” the benefits one may expect are said to include:

Reduced cravings caused by nutrients missing from your diet.
Optimize the health and durability of your skin, hair and bones.
Harmonize your diet and life-style with your genome by learning about genetically related risk factors to the big three diseases—heart disease, cancer, and diabetes, that your diet can influence.
Easier compliance with your self-improvement program because personalized advice lets you know that what you are doing is based on your unique needs and will be effective.⁶

Most importantly, this nutrigenetic report promises “[a]dvice that lasts a lifetime because your genes are not a fad.”⁷ Although the lofty promises offered sound much like a dramatization or hypothetical scenario, the quoted text comes from a website currently offering nutrigenetic testing.⁸ What the website does not disclose are the myriad problems—including legal problems—potentially posed by ordering this information that will likely last a lifetime.

The enthusiasm for nutrigenetics may obfuscate the unusual problems surrounding protection of genetic information particularly in a market context. The gravest concern is one of control—upon providing genetic material for lifestyle genetic testing, an individual has little command over who has access to the results. And unregulated access can have devastating

⁴ Michael Johnsen, *Do-It-Yourself Diagnostics*, DRUG STORE NEWS, Oct. 24, 2005, at 19 (discussing the target market and various nutrigenetic test products).

⁵ Health & DNA, *supra* note 1 (emphasis added).

⁶ Health & DNA, Genetic Nutrition Analysis, <http://www.healthanddna.com/nutrigeneticstest.html> (last visited Nov. 8, 2007).

⁷ *Id.*

⁸ *Id.*

effects. Even if the raw genetic information merely is sent back directly to the individual, serious misinterpretation concerns arise due to lack of counseling; in extreme cases, for example, individuals have interpreted genetic information as a death sentence leading to severe psychological trauma and even suicide. Perhaps even more alarming is the release of the genetic test results or genetic materials to third parties to whom the individual never intended to impart the information or material. Release of genetic information to unknown third parties may be a path fraught with peril. The ramifications of such third-party release not only raises considerable liberty concerns—from privacy and equal protection to perhaps even property rights issues, but can also result in significant damage that cannot be undone, such as stigma and discrimination not only against the customer but all the blood relatives who carry some of the same DNA.

Current regulations and safeguards inadequately address the significant legal problems posed even by accurate genetic information, because they fail to sufficiently consider who may obtain the information, including the bearers of the genetic information themselves. To better protect genetic information, courts should recognize an individual's right to control personal genetic information, and Congress should expand existing and proposed legislation to protect information obtained through nutrigenetic and other lifestyle genetic testing. Such legislation should incorporate nutrigenetic and other nonpathologic⁹ testing within its scope and mandate safeguards preventing the numerous legal problems raised, but also allow relevant information to be obtained by individuals and individually authorized third parties. A double-masking system, which separates the raw genetic data from derived information before passing it on to consumers, can achieve this by supporting individuals' rights to control access to genetic information while also protecting individuals from unwanted, potentially harmful information.

⁹ This Article terms traditional testing of genetic variants for disease prediction or diagnosis as “pathologic genetic testing.” Pathologic genetic testing stands in contrast to “lifestyle” or “nonpathologic” genetic testing, which looks for interactions between diet and genes, to maximize quality of life and avoid disease.

This Article starts by surveying the current environment of genetic testing. Following a brief description of nutrigenetics, Part I provides a broad picture of the conditions bolstering the imminent rise of nutrigenetics, and then focuses on the current environment of genetic testing. These macro- and micro-snapshots contrast the various benefits and dangers of nutrigenetics in a currently inadequate regulatory and statutory regime. Part II explains why nutrigenetic testing poses even greater risks than traditional pathologic genetic testing, focusing on the difference in both the scope of testing and the change of setting in which nutrigenetics takes place—a marketplace rather than a doctor's office. Part III briefly overviews traditional problems posed by the disclosure of inaccurate information and highlights unique problems associated with the disclosure of accurate genetic information. Part IV considers the key issue of who should (or should not) have access to and control over genetic information. This analysis focuses primarily on the legal (and to a lesser extent medical) problems of providing genetic information to individuals and other interested parties, as well as the legal problems of not allowing them access.

Against this backdrop, Part V examines and illuminates the deficiencies of previous proposals, legislative and regulatory efforts to protect genetic information, and pending congressional legislation. Juxtaposed against these shortcomings, Part VI describes the benefits of a double-masking model, emphasizing the need to separate the information derived from genetic information from the genetic information itself. Finally, this Part sets forth statutory provisions that Congress should pass to protect genetic information.

I. WEIGHTY PROBLEMS OPEN THE DOOR FOR NUTRIGENETICS' POPULARITY

The last two decades gave rise to exponential increases in the number of obese and overweight individuals around the world, and particularly in the United States.¹⁰ Indeed, the obesity epidemic is expected to result in more than fifty percent of the U.S. population being classified as obese by 2020.¹¹ In addition to individual health consequences, the individual and aggregate economic effects are already significant. Medical costs, for example, continue to rise in the face of expensive treatments that ameliorate, but do not cure, obesity-related diseases.¹² As the costs are only expected to rise, government spending projections forecast an enormous proportion devoted to health care.¹³

Against this background, nutrigenetics provides a beacon of hope. The ultimate goal of nutrigenetics is to provide personally tailored dietary and lifestyle recommendations based on an individual's genetic makeup. This holds tremendous promise for individuals seeking to improve

¹⁰ See Centers for Disease Control and Prevention, Obesity Trends Among U.S. Adults Between 1985 and 2006 slide 4, http://www.cdc.gov/nccdphp/dnpa/obesity/trend/maps/obesity_trends_2006.pdf (last visited Nov. 8, 2007) (providing U.S. data).

¹¹ See International Union of Nutritional Sciences, The Global Challenge of Obesity and the International Obesity Task Force fig.3, <http://www.iuns.org/features/obesity/tabfig.htm> (last visited Nov. 8, 2007). "Currently, about 119 million, or 64.5%, of US adults are either overweight or obese," and by 2008, "73% of US adults could be overweight or obese." *US People Getting Fatter, Fast*, BBC NEWS, Aug. 25, 2005, <http://news.bbc.co.uk/2/hi/health/4183086.stm>; see also Michael S. Rosenwald, *Why America Has to Be Fat*, WASH. POST, Jan. 22, 2006, at F1 ("Much of the long-term financial burden for obesity will fall on the shoulders of U.S. corporations, which already fork out billions of dollars a year in sick time and insurance costs related to obesity illnesses, and on American taxpayers, through their contributions for programs such as Medicare and Medicaid. What's more, shorter lifespans will more quickly take millions of educated people out of the workforce.").

¹² There are more than thirty obesity related diseases, such as cardiovascular disease, various cancers, clinical disorders, and exceptional complications of injuries and infections following trauma. See Richard Thatcher, *The Political Economy of the "War on Fat"*, CANADIAN DIMENSION, May/June 2004, at 30.

¹³ Cf. Facts on Health Care Costs, <http://www.nhc.org/facts/1007%20updates/cost.pdf>; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-510R, THE NATION'S LONG-TERM FISCAL OUTLOOK 7 (2007), available at <http://www.gao.gov/new.items/d07510r.pdf> ("Although Social Security is a major part of the fiscal challenge, it is far from our biggest challenge. Spending on the major federal health programs (i.e., Medicare and Medicaid) represents a much larger and faster growing problem. . . . Over the past several decades, health care spending on average has grown much faster than the economy, absorbing increasing shares of the Nation's resources, and this rapid growth is projected to continue. For this reason and others, rising health care costs pose a fiscal challenge not just to the federal budget but to American business and our society as a whole."). That is not to say that people are not attempting to address health and weight issues. In fact, the weight-loss industry has been booming. See Mike Adams, *U.S. Weight Loss Market Worth \$46.3 Billion in 2004—Forecast to Reach \$61 Billion by 2008*, NEWS TARGET, MAR. 30, 2005, <http://www.newstarget.com/z006133.html>.

the quality of their lives, and offers a remedy to employers, insurers, and governments facing the tremendous negative economic effects of the obesity epidemic and soaring health care costs.¹⁴ At the same time, commercial entities are eager to exploit the nutrigenetics market.¹⁵ What makes nutrigenetics particularly attractive to businesses is the apparent lack of built-in market limitations.¹⁶ Before delving further into what distinguishes nutrigenetics from other types of genetic testing, however, it is important broadly to understand genetic testing.

1. Introduction to Genetic Testing

Genetic testing involves examining deoxyribonucleic acid (DNA) from an individual's blood, tissues, or bodily fluids for variations in the individual's genes.¹⁷ Although scientists initially believed that one gene regulated one particular function (or dysfunction) scientific advances have shed light on this oversimplification.¹⁸ Scientific understanding has evolved to recognize that one gene can code for multiple proteins, and multiple genes can affect coding of a single protein. In other words, single genetic variances may affect more than one condition, and for many conditions, more than one gene plays a role.¹⁹ For years, genetic testing has involved

¹⁴ "Most experts expect that the real-world application of nutrigenomics, or personalized nutrition, will result in significant cost savings for consumers, employers, government and third-party insurance providers through its effects on disease prevention." Amy Paturel, *Does Your Diet Fit Your Genes?*, IDEA FITNESS J., Mar. 2006, at 52, 55, available at <http://www.dswfitness.com/products/index.cfm?action=oqcdetail&productID=690>.

¹⁵ *Cf. id.* at 58 ("The potential market for nutrigenomics products is bound to be huge. In fact, the *Nutrition Business Journal* projects that sales within the nutrigenomics industry could one day reach \$20 billion.").

¹⁶ Ries & Caulfield, *supra* note 2, at 284 (contrasting the open-ended opportunities offered by nutrigenomics with pharmacogenomics, which may actually limit the market by more accurately identifying individuals who would benefit from a given drug).

¹⁷ Susan M. Denbo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?*, 43 AM. BUS. L.J. 561, 567-68 (2006) (noting that genetic tests may also involve biochemical tests looking for the presence or absence of key proteins whose production is directed by specific genes).

¹⁸ There are numerous genes linked to known single-gene diseases, which have already been identified. Yet multi-gene diseases are far more complicated to identify. Robert A. Curley, Jr. & Lisa M. Caperna, *The Brave New World Is Here: Privacy Issues and the Human Genome Project*, 70 DEF. COUNS. J. 22, 26 (2003) ("Because each errant gene makes only a small contribution to [multi-gene] diseases, it has no obvious pattern of inheritance and its presence is hard to find among the natural variations in DNA sequence.").

¹⁹ In the mid-1990s, it was found that leptin is linked to appetite control. Claims followed that we could now change appetite. Instead, scientists found that not only were there more than one genetic variant linked to appetite control,

diagnostic, screening, and predictive tests looking for disease.²⁰ Nonpathologic testing, however, is now becoming increasingly available, and expectations of future demand for such nonpathologic tests are high.²¹ Nutrigenetic testing is an emerging area of nonpathologic genetic testing that looks at the influence of interactions between diet and genotypes on health and disease.²²

Pathologic and nonpathologic testing hold opportunities for improving quality of life, and for providing economic benefits both to individuals and society at large. These tests also pose numerous legal and other dangers that are inadequately addressed by the current regulatory and statutory regime. A passing familiarity with the state of the genetic testing industry illuminates these dangers.

The market for genetic testing is increasing at a rate of thirty percent annually.²³ At the same time, the number of genes being tested is increasing exponentially.²⁴ Though the tests are

but that leptin in particular also had functions in body temperature regulation and fertility. Interrupting the function of the gene therefore did not have isolated effects. See Raja Mishra, *Appetite Control: Scientists Still Search for a Pill to Turn Off Hunger; A Decade After Learning How the Body Signals Fullness*, BOSTON GLOBE, Jul. 11, 2005, at C1. (“A decade ago . . . the world found out about the appetite-controlling hormone leptin Ten years later, though, obesity remains as vexing as ever and there’s nothing remotely resembling a silver bullet.”).

²⁰ Diagnostic tests look for confirmation of a diagnosis, explaining existing health problems. Screening tests seek to determine whether an individual is a carrier of a disease. Predictive testing, on the other hand, forecasts disease susceptibility, though it does not establish severity of the condition, age of onset, or even if that onset will ever definitively occur. Denbo, *supra* note 17, at 568–70.

²¹ See Peter J. Gillies, *Nutrigenomics: The Rubicon of Molecular Nutrition*, 103 J. AM. DIETETIC ASS’N S50, S50 (Supp. 2003) (noting that recent consumer insight surveys “forecast that 33% of US consumers may be collecting and acting upon nutrigenomic information by 2010”).

²² Other examples of nonpathologic tests include ancestry tests, prenatal sex selection, and predictive athlete testing. See, e.g., Alexander van Voorhees, *Truth in Testing Laws: A Shot in the Arm for Designer Gene Tests*, 16 HEALTH MATRIX 797, 798–99 (2006) (describing athletic testing as testing genes that implicate an array of specific athletic abilities).

²³ There are currently 1154 genetics and prenatal diagnostic clinics and 616 laboratories testing for 1478 diseases. GeneTests Homepage, <http://www.genetests.org> (last visited Nov. 3, 2007).

²⁴ Many laboratories are using microarrays—semiconductors containing hundreds of thousands of tiny wells each designed to react to, and thereby identify, particular genetic variants when liquefied human cells are poured over it. Sometimes called “biochips” or “genechips,” microarrays are also like computer processing chips in that they are becoming exponentially more powerful while also becoming less expensive. See Free Online Encyclopedia, Micro Array Definition, <http://computing-dictionary.thefreedictionary.com/micro%20array> (last visited Nov. 8, 2007). Genechips offer continually greater numbers of microarrays in their products, with 100K and 500K array sets commonly offered, see Affymetrix – Products – GeneChip Arrays <http://www.affymetrix.com/products/arrays/index.affx> (last visited Dec. 18, 2007), and the newest products as of

evolving and the market expanding, the form of transmitted information generally remains the same. Clients are provided either the *raw* genetic information—the particular genetic variants accompanied with a brief global summary explaining what the genetic information means, or the *derived* genetic information, which consists of only the meaning of genetic information, and *not* the specific genetic variants. Derived information provides only the specific information the person sought, whereas raw genetic information reveals the genetic variation, which is interpreted to extract the information sought. For example, if a person requests a genetic test to find out whether her bone health might be compromised, the derived genetic information would simply indicate an increased need for vitamin D. The raw genetic information, by contrast, would be that she carries the taq1 variation of the VDR gene, which implies not only the higher vitamin D requirement but also possibly an increased risk of osteoporosis, cancer and other dire health conditions. Current practice is to provide the individual with such raw genetic information.²⁵ The distinction between raw and derived genetic information is critical because the significant problems resulting from disclosure—particularly of nutrigenetic test information—primarily arise in the context of raw genetic information, and would be significantly mitigated by disclosing only derived genetic information.

II. NUTRIGENETICS: SUPER-SIZED, WITH DRIVE-THROUGH EASE

The scope and context of nutrigenetics heightens the risk of information disclosure. First, nutrigenetic testing evaluates a much greater range of variations than traditional pathologic testing. In the context of diseases, genetic testing is generally narrow because patients go to their

December 2007 offering more than one million genetic markers tested in one array. *See* Affymetrix, Genome-Wide Human SNP Array 6.0, http://www.affymetrix.com/products/arrays/specific/genome_wide_snp6/genome_wide_snp_6.affx (last visited Dec. 18, 2007).

²⁵ *See infra* Part III.

healthcare provider with a very specific inquiry. In the narrowest cases, for example, patients may want to know whether they have the specific genetic variant for Huntington's disease or inherited forms of BRCA, the breast cancer gene. In broader cases, a patient may seek genetic testing to explain multiple miscarriages, in which case the healthcare provider may order a menu of tests to examine the various different genetic variations related to fertility or pregnancy problems. Even in the latter case, however, the number of specific variations examined is still quite small.²⁶

Nutrigenetics is considerably different. Nutrigenetic tests do not seek any single or handful of genetic variants; instead, these tests look for a large number of different variations that appear to interact with diet and lifestyle. Thus, the test itself is exponentially broader. Testing for more variations is also becoming cheaper, particularly as the capacity to do so increases exponentially. Accordingly, testing companies already have incentives to create broad, multipurpose tests that analyze thousands of genetic variations. The testing companies would then filter out the information relevant to the particular test and pass it on to the individual.²⁷ This is easier than creating a different test depending on the individual profile, or even creating different tests for subgroups based on age and sex, where entirely different genetic variations are

²⁶ Tests taken by women may look for changes in chromosome structure or number and changes in the Fragile X region of the X chromosome. Men may take tests to look for changes in chromosome structure or number, missing regions on the Y chromosome (also called Y deletion), and changes in the cystic fibrosis gene.

²⁷ There is great skepticism among scientists and experts regarding the value of any information currently delivered to customers by nutrigenetic testing services, due to the lack of scientific validation supporting their health claims and recommendations. *See* GOV'T ACCOUNTABILITY OFFICE, GAO-06-977T, NUTRIGENIC TESTING: TESTS PURCHASED FROM FOUR WEB SITES MISLEAD CONSUMERS 5-7 (2006) (testimony of Gregory Kultz, Managing Director Forensic Audis and Special Investigations), *available at* <http://www.gao.gov/new.items/d06977t.pdf> [hereinafter GAO INVESTIGATION]. Despite the lack of current scientific support, "[w]ith further advances in science, nutrigenetic tests . . . may in the future be valid, allowing consumers to use DNA-based analysis to make diet and lifestyle changes that will actually prevent the development of disease." *Id.* at 22.

relevant.²⁸ The enormously larger dimensions of these tests therefore mean that there is much more genetic information at play in the context of nutrigenetic testing.²⁹

Second, nutrigenetics changes the context of genetic testing dramatically. Pathologic genetic testing looking for Alzheimer's disease, breast cancer, or prenatal diagnostics for Down Syndrome are firmly grounded in the medical context, which provides a structured framework. Prior to testing, patients go to their doctor's office or to a genetic counselor, where the trained practitioner advises them of the risks, implications, and meaning of tests. The health professional can also highlight limitations of the tests and explain why the patient may not want to undergo the test. If the patient chooses to proceed, the professional obtains consent and sends the patient's specimen to federally certified laboratories. The doctor then receives a test report with the genetic variations and often a global interpretation (essentially a short summary saying that these results point to a specific probability of the tested disease or condition, for example). The patient returns for an intensive, detail-oriented session, where the professional explains the findings of the tests and the risks of proceeding based on this information. If patients insist, they will be given a copy of the report with the raw genetic information and the global evaluation.

Nutrigenetics radically shifts the context from a supportive healthcare environment to the commercial marketplace,³⁰ thereby turning the patient into a consumer acquiring the information

²⁸ Gender, pregnancy status, age, and other variables affect which genetic variants are pertinent to a particular individual.

²⁹ Pharmacogenomics represents a type of intermediate position, because it involves testing for a wider number of genetic variations that may influence how a particular drug will affect an individual. Even this type of genetic testing, however, is much narrower in scope than nutrigenomics. It should be noted that whereas traditional pathologic genetic testing focused on a handful or fewer genetic variants, attempts are being made to test for greater numbers of genetic variants in this area as well.

³⁰ Although much of healthcare is also privatized, the goal of healthcare professionals is beneficence—to do what is best for the patient while respecting patient autonomy. By contrast, the primary goal of business is to make money or, at least, increase value.

from profit-driven direct-to-consumer services.³¹ The likelihood of information being inaccurate may increase substantially in the commercial context, as it is unclear whether many of the regulations currently covering genetic testing even apply in this situation.³² Motivated by the prospect of profit, the incentive for these commercial entities to offer questionable or unproven tests is high.³³ In fact, the Government Accountability Office (GAO) has already exposed numerous websites offering nutrigenetic testing as scams based on the inaccurate information they provided.³⁴

This contextual change further amplifies the dangers present even when results are accurate. People already treat nutritional and lifestyle decisions more casually than more concrete medical decisions, such as testing for genetic diseases or prenatal testing. Recommendations concerning how much coffee to drink are not considered life altering to the same extent as finding out whether one has the genetic variation for Huntington's disease, or whether one's fetus has Down Syndrome. The marketplace setting further diminishes the weightiness of the decision. You just swab a cotton stick in your mouth, put it in an envelope,

³¹ Some have suggested that there are various factors that have recently changed the doctor-patient relationship from one grounded in hierarchy and trust to "one grounded in the presumption that physician and patient should relate to each other as autonomous individuals." Janet L. Dolgin, *The Evolution of the "Patient": Shifts in Attitudes About Consent, Genetic Information, and Commercialization in Health Care*, 34 HOFSTRA L. REV. 137, 138 (2005); see also Neil A. Holtzman, *FDA and the Regulation of Genetic Tests*, 41 JURIMETRICS J. 53, 56 (2000) ("The dramatic change in providers of genetic tests over the last 10 to 20 years emphasizes the inadequacy of the current system."); David C. Bonnin, Note, *The Need for Increased Oversight of Genetic Testing: A Detailed Look at the Genetic Testing Process*, 4 HOUS. J. HEALTH L. & POL'Y 149, 170–72 (2003) (discussing patient physician interaction).

³² *Infra* Part V.

³³ See Holtzman, *supra* note 31, at 56 ("Relying for information on the very parties who have the most to benefit from praising the test . . . leaves a great deal to be desired. The need for objective information on the soundness of the tests being purveyed is therefore greatest with respect to commercial services marketing tests broadly to physicians and the public."). Rebuffing critics who argue that many tests are unproven, unnecessary or even quackery, some commercial genetic testing companies contend that "it is a matter of judgment when a test has been sufficiently validated, and that consumers have the right to information 'This is really all about consumer choice at the end of the day.'" Andrew Pollack, *The Wide, Wild World of Genetic Testing*, N.Y. TIMES, Sept. 12, 2006, at G4.

³⁴ See GAO INVESTIGATION, *supra* note 27 at 5–7 (discussing investigation of several nutrigenetic direct-to-consumer websites that provided vague and scientifically unsupported recommendations to consumers).

and wait to hear whether you should stay away from coffee.³⁵ There is no pre-test counseling to explain the implications and limitations of the test, or personalized explanation of why you may not want to have the testing done. On the contrary; the commercial testing services have incentive to hype their test to persuade the consumer to buy it.³⁶

After convincing the consumer to order the test, and analyzing the genetic material received, the testing service sends the test results directly to the consumer. As one nutrigenetic service explains: “Once your diet, lifestyle and genes have been analyzed, we’ll send you a confidential personalized Action Plan telling you how to match your diet and lifestyle to your genes.”³⁷ This report includes a “health profile” providing the raw genetic information.³⁸ A sample table provided by one website lists the genes analyzed, their role in a particular health function, the particular genetic variation screened for, whether the variation was found in this particular individual’s gene, the percentage of the population that has the genetic variation, and then answers yes or no to whether the result suggests an impact on bone health.³⁹

Thus, the individual receives a lengthy report listing many genetic variations. Although the genetic variations may only be linked to certain health issues at present, media reports describe almost daily advances indicating new correlations between genetic variants and innumerable conditions. An individual, hearing about such a new finding, could easily check whether the nutrigenetic report they have received lists a variant mentioned in the media report.

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³⁵ *Cf. id.* at 2.

³⁶ In the medical context, there is no such institutional incentive because the patient will be treated at the institution regardless of which genetic variant, if any, is found to be implicated.

³⁷ MyCellf Online, Learn More About the MyCellf Program, <http://www.mycellf.com/learn-more.aspx> (last visited Dec. 19, 2007).

³⁸ *Id.* (listing specific genetic variants in table form in the sample report).

³⁹ *Id.*

⁴⁰ The word “gene” entered in the Google news search engine, <http://www.news.google.com/>, April 4, 2007, for example, yielded various news articles concerning new links found between diseases and genetic variants, with the name of the variant clearly listed. *Cf.* Miranda Hitti, *Osteoarthritis Linked to Gene Mutation*, WEBMD MEDICAL

Based on the ostensibly innocuous nature of the information sought, in combination with the ease with which such information may be obtained, individuals are more likely to seek direct genetic testing for nutrigenetic purposes than for pharmacogenomic⁴¹ or pathologic genetic testing.⁴² In this context, then, the heightened need to control access to this information becomes plain.

III. EVEN IF IT'S RIGHT, IT MAY BE WRONG: PROBLEMS OF DISCLOSING INACCURATE AND ACCURATE GENETIC INFORMATION

When information is a commercial product, concerns that the information may be inaccurate naturally arise, and governmental regulations generally focus on this concern. The ultimate goal of regulators is to make sure that information is accurate – that there is no fraud, misrepresentation, or product defect. Genetic testing, including nutrigenetic testing, is no exception. What differentiates it from other testing, however, are the significant problems posed by *accurate* genetic information.⁴³

NEWS, Mar. 27, 2007, <http://www.webmd.com/osteoarthritis/news/20070327/osteoarthritis-linked-to-gene-mutation> (“Variations in the GDF5 gene were more common in the osteoarthritis patients than in the people without osteoarthritis.”); Roxanne Khamsi, *Common Gene Mutation Linked to Tripled Stroke Risk*, NEW SCIENTIST, Mar. 27, 2007, <http://www.newscientist.com/article/dn11469.html> (“[A] tiny change in the *HFE* gene, known as the H63D defect, appears to cause excessive iron uptake from the blood into cells . . . [and] some people may develop liver cirrhosis late in life as a result.”); Roxanne Khamsi, *Faulty Body Clock May Cause Mania*, NEW SCIENTIST, Mar. 20, 2007, <http://www.newscientist.com/article/dn11415.html> (“Mice with a gene mutation that disrupts their sleep cycles show signs of hyperactivity and addictive tendencies, a new study reveals. Researchers say that such ‘manic’ behaviour displayed by the animals bolsters the theory that glitches in the body’s internal clock can cause psychiatric illnesses such as bipolar disorder.”).

⁴¹ Pharmacogenomics looks at the interactions of pharmaceutical drugs with specific genetic variants.

“Pharmacogenomics holds the promise that drugs might one day be tailor-made for individuals and adapted to each person’s own genetic makeup. Environment, diet, age, lifestyle, and state of health all can influence a person’s response to medicines, but understanding an individual’s genetic makeup is thought to be the key to creating personalized drugs with greater efficacy and safety.” Human Genome Project Information, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/pharma.shtml (last visited Oct. 31, 2007).

⁴² See Ries & Caulfield, *supra* note 2, at 284 (explaining that there is no market limitation, and that nutrigenetics is more likely to have daily relevance on individual’s daily lifestyle choices).

⁴³ All medical information poses potential risks. The difference with genetic data, however, is that it holds exponentially more information, including future information of conditions not yet manifest (and that may never become manifest). On top of that, it also holds information that does not yet have meaning, but that once discovered may reveal significant personal information.

Even if regulators could ensure that information generated by genetic tests is accurate, concerns arise that are perhaps even greater than those relating to inaccurate information. Thus, different protections are needed than those sufficing for other types of products. To more sharply highlight the distinctive problems arising in the context of genetic (including nutrigenetic) testing, this part therefore separates the issues into (1) typical problems of inaccurate information and (2) the unique problem of accurate information.⁴⁴

1. Inaccurate Information Problems

A defective product is one that cannot be used for the purposes intended, or is made dangerous as a result of a flaw or imperfection. Information inaccuracy in the context of genetic testing is a type of product defect, where the inaccuracy itself is the problem. Inaccuracy couched in false promises of accuracy defrauds consumers.⁴⁵ Furthermore, inaccurate genetic information raises serious safety concerns.⁴⁶ It may lead to misdiagnoses and inappropriate

⁴⁴ See *supra* text accompanying notes 24–25 discussing the difference between raw and derived genetic information.

⁴⁵ GAO INVESTIGATION, *supra* note 27, at 2 (describing its investigation into the legitimacy of nutrigenetic tests as stemming from Congressional “concerns that the companies marketing this type of test may be misleading consumers by providing inaccurate information”).

⁴⁶ See Gail H. Javitt & Kathy Hudson, *Public Health at Risk: Failures in Oversight of Genetic Testing Laboratories*, Genetics & Public Policy Center 17 (Sep. 2006),

<http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf> (listing various examples where genetic test inaccuracies had serious consequences). The following incident provides an example of the adverse consequences that can result from inaccurate genetic testing:

A young woman who experienced several episodes of deep vein thrombosis (blood clots) was tested for the factor V Leiden genetic mutation, which is associated with an increased risk of blood clots. The laboratory indicated she had the mutation. Over the course of several years, two other laboratories reported that she was negative for the mutation. Based on these reports indicating she did not have the mutation, and seeking to conceive a child, she began to take a fertility drug known to increase the risk of blood clots. Two months later she experienced extensive blood clots. A fourth genetic test indicated she had the mutation. A case report reviewing this incident determined that the woman did in fact have the mutation and cited laboratory error (sample misidentification, test failure, incorrect interpretation, or clerical error) as possible reasons for the false negative results by two of the four laboratories.

Id.

recommendations with considerable health implications.⁴⁷ As one recent report explained, “an inaccurate test result can lead to ill-informed decisions with tragic consequences, and to wasted healthcare resources.”⁴⁸ At this nascent stage, the primary concerns regarding nutrigenetics are that the genetic tests provide evaluations and recommendations that are so vague as to be virtually worthless.⁴⁹

Genetic information inaccuracies arise for various reasons, including poor quality control of the tests themselves, inadequate scientific evidence supporting the tests,⁵⁰ and outright scams.⁵¹ Numerous safeguards work to mitigate these problems in the context of pathologic genetic testing. Those tests are generally performed in a doctor’s office, allowing the physicians to serve as one layer of protection. Because usually just one (or very few) genetic variants are assessed, the health professionals administering the tests are generally more knowledgeable as to the level of confidence one should have in these findings. The laboratories doing this type of testing are subject to federal regulations,⁵² which afford assurances of analytical validity for the limited number of analyzed markers, thereby offering a certain degree of protection to ensure that tests are reliable. Moreover, the discussion spurred by the Human Genome Project⁵³ about genetic information concerns focused attention and academic discussion on pathologic genetic testing, thereby providing another layer of protection.

⁴⁷ See e.g., *id.* (“Accurate genetic test results are critical to diagnosis, prognosis, safe and effective treatment, and disease prevention. Genetic tests can lead to profound life-altering decisions, such as the decision to undergo surgery, undertake chemotherapy, discontinue a medication, or to become pregnant or continue a pregnancy.”).

⁴⁸ *Id.* at 6.

⁴⁹ GAO INVESTIGATION, *supra* note 27, at 5 (“The results we received from all the tests we purchased mislead the consumer by making health-related predictions that are medically unproven and so ambiguous that they do not provide meaningful information to consumers.”).

⁵⁰ Holtzman, *supra* note 31, at 54 (explaining that “[l]ack of [clinical] validation is of particular concern for tests of genetic susceptibility to common, complex [conditions] in healthy people”).

⁵¹ See generally GAO INVESTIGATION, *supra* note 27.

⁵² See the discussion of Clinical Laboratory Improvement Amendments (CLIA), *infra* Part V.

⁵³ The Human Genome Project began in 1990 as an international effort sponsored by the U.S. government with the goal of “determin[ing] the complete sequence of the 3 billion DNA subunits, identify[ing] all human genes, and mak[ing] them accessible for further biological study.” Human Genome Project Information, Frequently Asked Questions, http://www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml (last visited Oct. 31, 2007).

Nutrigenetics differs significantly because of its commercial context and the more casual atmosphere in which information transfer occurs. This may convey the false impression that nutrigenetic testing is a relatively trivial undertaking. Additionally, the number of genetic variants assessed increases dramatically compared to traditional pathologic testing, as the exponentially larger volume strains already tight oversight resources and requires experts to become proficient in not just a hundred or so genetic variants, but hundreds of thousands. At the same time, online testing of any sort largely removes the safeguard previously provided by the interaction with a healthcare professional.⁵⁴

2. Accurate Information Problems

Unlike the situation concerning inaccuracy, accurate information itself is not the problem. Rather, accurate information is hazardous in that it gives rise to other problems, specifically those of misinterpretation, self-overdisclosure, and harmful third party disclosure.

Misinterpretation includes both misperceptions and misunderstandings of what the data means, even if the data are accurate. Genetic determinism, the idea that what is written in your genes is an inevitable and inescapable fate, is one of the most deleterious forms of misunderstandings.⁵⁵ Genetic determinism can, on one hand, give people the incorrect idea that because they do not have a particular gene, they have *carte blanche* and need not make conscientious lifestyle choices. On the other hand, genetic determinism may lead people with a particular genetic variant to see disease manifestation as inevitable, even though it may never occur. Unfortunately, the reports about genetics in the media and in popular culture have

⁵⁴ Cf. Curley & Caperna, *supra* note 18 (discussing present protections in place to safeguard privacy of genetic information and arguing that genetic information warrants greater protections than other types of personal information).

⁵⁵ See MATT RIDLEY, *GENOME: THE AUTOBIOGRAPHY OF A SPECIES IN 23 CHAPTERS* 86 (1999).

strongly reinforced this fallacious notion of genetic determinism.⁵⁶ Lack of adequate counseling by a licensed health professional further heightens the danger of individuals being misled, or misinterpreting what test results mean. Yet the direct-to-consumer nutrigenetic testing often does not ensure such counseling.⁵⁷

Further problems manifest when an individual receives more information than they bargained for or wanted. Individuals receiving unwanted or potentially harmful excess information can be termed “self-overdisclosure.” In the context of genetics, self-overdisclosure is significant because the information can gain additional meaning as scientific developments progress. Additional meaning denotes not only greater understanding of the connection between a genetic variant and the tested-for condition, but even more importantly, new correlations between the same genetic variant and other, unrelated conditions—including pathologic conditions. For example, in the early 1980s, researchers testing for APO-E (thought to correlate innocuously to blood cholesterol levels) disclosed to the patients the rare gene they possessed. Shortly thereafter, it was found that APOE is also a predictor for Alzheimer’s disease.⁵⁸

Finally, even if an individual properly understands the genetic test results or gets only the bargained-for results, unauthorized or unanticipated third party disclosure still poses problems.⁵⁹ Particularly in the context of nutrigenetic testing, even third party disclosure that is not illicit can have detrimental effects further down the line. Discrimination against the individual—for example, by employers, insurance companies, or family members—is one of the greatest

⁵⁶ See generally DOROTHY NELKIN & SUSAN LINDEE, *THE DNA MYSTIQUE: THE GENE AS A CULTURAL ICON* (2004) (examining diverse intersections between current social issues and ideas about genetic determinism).

⁵⁷ Some services offer post-testing counseling for an additional (and usually large) fee.

⁵⁸ See James R. Burke & Alan D. Roses, *Genetics of Alzheimer's Disease*, 25–26 *INT’L J. NEUROLOGY* 41, 41–49 (1991–1992).

⁵⁹ See Part IV.

concerns.⁶⁰ Although the same troubles arise in the context of inaccurate information, the point is that these problems persist even if inaccuracy is eliminated. In fact, a higher degree of confidence that the information is accurate may actually exacerbate the prevalence of genetic discrimination, as well as the problems associated with misinterpretation.⁶¹

The difference between accurate and inaccurate information is not merely semantic; recognizing the difference between accurate and inaccurate information is critical to legislative and judicial efforts to protect individuals' autonomy and genetic privacy because the legislative and regulatory responses differ based on the type of information involved. As shall be illustrated, the current legal protections for genetic information are incoherent, at least in part because of the different approaches to accurate versus inaccurate information.

3. Comparing Approaches to Accurate and Inaccurate Information

Inaccurate information problems are the traditional purview of regulatory agencies, such as the Federal Trade Commission (FTC) and the Food & Drug Administration (FDA).⁶² For inaccurate information, the problem exists instantly—something went wrong before the consumer even received the information; the product itself was defective. Although still insufficient, approaches to inaccurate information take the form of statutory requirements and practical efforts by federal agencies focused on addressing these instantaneous inaccurate information problems.

⁶⁰ See Jared A. Feldman & Richard J. Katz, Note, *Genetic Testing & Discrimination in Employment: Recommending a Uniform Approach*, 19 HOFSTRA LAB. & EMP. L.J. 389 (2002). It is often difficult to recognize—much less prove—that discrimination has occurred, yet “public concerns about the possible misuse of their genetic information by insurers and employers have been documented.” The Threat of Genetic Discrimination to the Promise of Personalized Medicine: Testimony Before the U.S. House Subcomm. on Health, Comm. on Ways and Means, 110th Cong., 1st Sess. 4 (2007) (testimony of Francis S. Collins, Director of the National Human Genome Research Institute, National Institutes of Health), available at <http://waysandmeans.house.gov/Media/pdf/110/3-14-07/CollinsTestimony.pdf>.

⁶¹ See Anny Huang, *FDA Regulation of Genetic Testing: Institutional Reluctance and Public Guardianship*, 53 FOOD & DRUG L.J. 555, 568 (1998) (describing the “dangerous information” that genetic data presents).

⁶² Cf. *infra* Part V (examining the current regulatory regime).

Approaches to preventing accurate information problems, including misinterpretation, third party disclosure, and self-overdisclosure, are less concrete both in terms of their enforceability and applicability. Ethical guidelines of medical associations, which are not legally binding and not applicable to commercial services,⁶³ comprise much of the extant protections. One explanation for the lack of concrete regulation and legislation is that the problems of accurate information disclosure are themselves significantly more remote and abstract than inaccurate information problems. Even if genetic information gets out to third parties, the effects may not be immediately apparent or even immediately harmful—the harm may not actually occur until some remote point in the future, for example, when the information is the basis for discrimination.⁶⁴

Furthermore, unlike the concrete product defect that inaccurate information represents, the precise violation regarding accurate information is more nebulous. For example, although it would appear that unwarranted disclosure of accurate genetic information implicates loss of privacy, continuing debates over whether genetic information implicates privacy or property rights⁶⁵ creating uncertainty as to both what harms may be claimed and what constitutes an appropriate remedy.⁶⁶ Moreover, accurate information problems are not as readily apparent or

⁶³ There are also some state laws that attempt to address select accurate information issues, such as employer or insurance discrimination, but these laws leave open many gaps. *See infra* Part V.

⁶⁴ *See* Ronald M. Green & A. Mathew Thomas, *DNA: Five Distinguishing Features for Policy Analysis*, 11 HARV. J. L. & TECH. 571, 572–73 (1998) (describing informational risks, including psychological risks and economic risks, such as discrimination in employment, medical insurance, and life insurance).

⁶⁵ *Compare* Mary J. Hildebrand et al., *Toward a Unified Approach to Protection of Genetic Information*, 22 BIOTECH L. REV. 602 (2003) (focusing primarily on the issue of whether genetic information should be categorized as falling under a privacy or property, arguing that property provides additional protections lacking under privacy rights) *with* Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 746 (2004) (arguing that genetic information should be regarded as a privacy interest rather than a property interest, because property disaggregates the person into parts, whereas privacy contemplates a holistic view of the person).

⁶⁶ For example, if genetic information is a property right, the claim may be conversion or misappropriation. If the right violated is a privacy right, the claim may merely be breach of duty to obtain informed consent. In *Moore v. Regents of University*, the court rejected the property claim and denied the plaintiff's claim to profits made from his tissue. *Moore v. Regents of Univ.*, 793 P.2d 479, 497 (Cal. 1990). The court did find a breach of fiduciary duty and

easily identifiable. Some legislators failing to see the problems posed by accurate genetic information actually deride proposed anti-genetic discrimination legislation as “a solution in search of a problem.”⁶⁷

Given the problems generated by both accurate and inaccurate information, genetic information requires special protections. The best form of protection is to secure individuals’ rights to control their personal genetic information without forcing exposure to unwanted, potentially harmful information, or allowing exposure to raw genetic or pathological information without appropriate counseling. Yet various other players also want to control, or at least access, the information, and allowing or prohibiting disclosure to those parties presents an array of legal issues.

IV. INDECENT DISCLOSURE: INFORMATION ACCESS AND CONTROL

Both accurate and inaccurate nutrigenetic information pose serious potential hazards given the lack of effective regulation to prevent inaccuracies, and the even greater lack of legislation dealing with disclosure of accurate genetic information. The key to dealing with these problems revolves around access to information from nutrigenetic tests.⁶⁸ Aside from the individual seeking the test, other parties also want this information. This section examines these stakeholders and their reasons for wanting the information, as well as the effects and legal issues involved in providing or proscribing that access. Regardless of the interested party examined, the dominant theme is the individual’s loss of control.

lack of informed consent. *Id.* Thus, “[c]onceivably, through property rights, an individual could be provided with a series of rights regarding the control, possession, and transferability of his genetic information that are unavailable through privacy legislation.” Hildebrand et al., *supra* note 65, at 604.

⁶⁷ Louise McIntosh Slaughter, *Genetic Testing and Discrimination: How Private Is Your Information?*, 17 STAN. L. & POL’Y REV. 67, 69 (2006).

⁶⁸ The same can be said about genetic information, and the proposal later presented could also be applied to other forms of genetic testing. The contextual changes surrounding nutrigenetics, as described in Part II, make this arguably more critical in the context of nutrigenetics.

1. Patient/Consumer: The Individual

An individual may seek nutrigenetic testing for numerous reasons: to improve quality of life, to reduce health care costs, or just to follow the latest trend. Whatever the reason, “[i]t is axiomatic that a person who has been tested for one or more genetic conditions has a significant interest in knowing and determining what happens to the resulting information.”⁶⁹ As a Ninth Circuit judge recently put it, DNA does far more than merely identify a person: “DNA stores and reveals massive amounts of personal, private data about that individual, and the advance of science promises to make stored DNA only more revealing in time.”⁷⁰

Yet unrestricted access to nutrigenetic information, even to the individuals themselves, raises previously mentioned problems of misunderstanding and harmful disclosure. Particularly in light of the lack of pre- and post-test counseling in the context of nutrigenetics,⁷¹ misinterpretation is a strong possibility.⁷² When unwanted information emerges from these reports, it may reinforce deterministic views.⁷³ In addition, “[r]eleasing test results to lay consumers, who are not educated in such matters as genetic testing or qualified to understand the information contained therein poses inherent psychological dangers.”⁷⁴ Of course, not all genetic information is dangerous – much genetic information is itself harmless, and not the type that would be used for discrimination (such as eye color or lactose intolerance). The problem is that

⁶⁹ Graeme T. Laurie, *Challenging Medical-Legal Norms: The Role of Autonomy, Confidentiality, and Privacy in Protecting Individual and Familial Group Rights in Genetic Information*, 22 J. LEGAL MED. 1, 8 (2001).

⁷⁰ *United States v. Kincaid*, 379 F.3d 813, 842 n.3 (9th Cir. 2004) (Gould, J., concurring).

⁷¹ See *supra* text accompanying notes 36, 57.

⁷² See *supra* text accompanying notes 55–56.

⁷³ *Id.*

⁷⁴ See Allen C. Nunnally, Note, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in the New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, 345 (2002); see also ADEAR Center, Alzheimer’s Disease Genetics Fact Sheet 11 (2004), http://www.nia.nih.gov/NR/rdonlyres/3C4B634E-A2D8-4415-927F-4B79BEC47EA6/2377/Alzheimers_Disease_Genetics_Fact_Sheet.pdf (“Since the results of APOE testing can be hard to understand, and more importantly, devastating to those tested, the NIA and the Alzheimer’s Association recommend that research volunteers and their families receive genetic counseling before and after testing, if they have the option of learning the results. People who learn through testing that they have an increased risk of getting AD may experience emotional distress and depression about the future, because there is not yet an effective way to prevent or cure the disease.”).

with the large number of genetic variants being tested and discovery of new correlations of a particular genetic variant, one cannot know whether the information received will remain innocuous or will be imputed meaning making it dangerous.

In some cases, this may lead to serious identity issues, or even suicide.⁷⁵ Even if consumers grapple with the implications of the information, they may be placed in the difficult position of either having to lie or having to face potential discrimination from employers and insurers asking for any genetic testing results received by the individual.⁷⁶ There may also be concerns about the implications for family members, particularly those who share the same DNA. Family members may have an interest in the genetic information for their own personal health. Yet, for some, “the prospect of knowing genetic information elicits feelings of anxiety and can even cause family ties to become strained when family members do not want to know the information.”⁷⁷ Use of one family member's DNA has been employed to identify, through forensic databanks, a relative who committed a crime,⁷⁸ and to deny insurance.⁷⁹

As a result of these fears, many individuals have forgone testing even though it could lengthen and improve their quality of life.⁸⁰ Even those individuals wanting to improve their

⁷⁵ Suter, *supra* note 65, at 775. “[M]any individuals suffer from depression after learning that they have the Huntington disease (“HD”) allele; some have even committed suicide.” Not surprisingly, many who were at risk and discover they do not carry the mutation feel liberated. But, after having lived with a sense of being at risk, some have difficulty adjusting to the knowledge that they will not develop HD.” *Id.* (citations omitted).

⁷⁶ See Laurie, *supra* note 69, at 2 (“At first blush, the most obvious interest focuses on knowing genetic information, and, on this basis, arguments for a ‘right to know’ are frequently founded. However, the potential existence of a ‘right not to know’ genetic information, which may protect both personal and familial interests, also merits analysis.”).

⁷⁷ Richard L. Furman, Jr., Comment, *Genetic Test Results and the Duty to Disclose: Can Medical Researchers Control Liability?*, 23 SEATTLE U. L. REV. 391, 414 (1999); see also Green & Thomas, *supra* note 64, at 580–84; Laurie, *supra* note 69, at 9–15.

⁷⁸ Frederick R. Bieber et al., *Finding Criminals Through DNA of Their Relatives*, 312 SCIENCE 1315, 1315 (2006) (describing how a man was linked to a crime after DNA found at the crime was matched to his nephew's sample in a forensic databank).

⁷⁹ Slaughter, *supra* note 67, at 70 (“In 2000, Mrs. Jolene Hollar of Arizona was turned down by two life insurance companies because her family had a history of Huntington's disease. Mrs. Hollar herself had not been tested for the gene.”).

⁸⁰ See Slaughter, *supra* note 67, at 72.

lifestyle with genetically-tailored recommendations have important reasons to want *not* to know anything beyond the specific information requested.

Given these critical concerns, the safest option may be to prohibit individuals from obtaining nutrigenetic tests, or perhaps to allow only a licensed professional to decide whether the person adequately understands the implications before a test may be ordered. Yet such paternalism seems diametrically opposed to the individual liberty valued by American society, and implicates autonomy and self-determination issues.⁸¹ Preventing individuals from obtaining nutrigenetic information also has various legal implications. Restrictions on obtaining one's genetic information may arguably amount to unconstitutional infringement of substantive due process rights.⁸² In fact, the Ninth Circuit asserted that “[o]ne can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.”⁸³ Such restrictions on obtaining personal genetic information may also implicate property rights. Four states have statutes saying that genetic information is personal property. As a result, impeding access to that information may potentially constitute a taking.⁸⁴

In sum, nutrigenetic testing involves balancing the desire to encourage individuals to obtain health benefits from their genetic information while protecting them from unwanted overexposure and unnecessary disclosure to third parties. Given that genetic information “relates to them and can affect their lives in profound ways,” individuals have “a very strong claim to

⁸¹ See Laurie, *supra* note 69, at 3–4 (discussing individual's interest in personal genomic information).

⁸² See Berrie Rebecca Goldman, *Pharmacogenomics: Privacy in the Era of Personalized Medicine*, 4 NW. J. TECH. & INTELL. PROP. 83, 83 (2005) (“The issue of privacy arises as a result of the inherently personal nature of each individual's genetic makeup. 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.”); Van Voorhees, *supra* note 22, at 799 (“Obtaining personal health information may implicate important aspects of privacy and autonomy, and there may be social and individual benefits to being able to plan.”).

⁸³ *Norman-Bloodsaw v. Lawrence Berkeley Lab.*, 135 F.3d 1260, 1269 (9th Cir. 1998).

⁸⁴ For an in depth discussion of whether genetic information should be seen as a privacy or property right, see Suter, *supra* note 65.

control the circumstances in which this information is generated and to determine what happens to the information subsequently.”⁸⁵

2. Commercial Testing Services

Companies that provide commercial nutrigenetic testing services have an obvious interest in obtaining genetic information—the nutrigenetic information is the product they sell to consumers. Yet their interest does not end upon completing the testing and sending back the results. Companies providing genetic testing also have a strong interest in *retaining* the genetic information and any personal information of the individual who supplied the sample. By storing this information in databases, a company can continue developing new services by exploiting the larger sample sizes to find new correlations relevant to nutritional recommendations. Thus, companies simultaneously make money from the services provided and obtain samples to improve the services they offer.⁸⁶

Allowing commercial test providers access to raw genetic information gives rise to several concerns.⁸⁷ Once the individual sends off her genetic sample, she has little control over who else will have access to it. Much like an email, the initial recipient may forward the information to others. Some internet genetic testing services, for example, apparently sell the

⁸⁵ Laurie, *supra* note 69, at 9.

⁸⁶ Many companies are currently more interested in obtaining research participants than in selling those individuals their products, but are having difficulty recruiting research participants because potential participants fear their information will end up being used for discriminatory purposes. At the same time, “[p]armacogenomics requires the examination of large numbers of genetic profiles for success.” Goldman, *supra* note 82, at 84. While there is not much information on nascent nutrigenetic testing companies, pharmaceutical companies have the same interests with regard to the information provided and gained by pharmacogenetic testing. Thus, pharmaceutical companies shed light on those of nutrigenetic testing companies as well.

⁸⁷ One issue, for example, concerns how the information will be classified. If this information is obtained through direct-to-consumer services for purely nutritional purposes, is it still considered medical information protected by federal or state laws such as HIPAA? It is beyond the scope of this article to explore these issues in greater detail, but it is important to understand the broad extent of legal questions and dangers that arise absent adequate protections.

genetic information they obtain to research institutions.⁸⁸ These services may also store the DNA or the test information to create genetic databases themselves. The key here is loss of control and the resulting harm to individuals.

Companies engage in these practices without the knowledge of the individual, thereby implicating informed consent issues. In the medical context, courts hold that doctors have a duty to disclose their financial interests, but this is based on the idea that a doctor has a fiduciary duty to a patient.⁸⁹ A court may have more trouble finding such a duty in an arms-length commercial transaction. Moreover, the private sector, which is focused solely on its own financial gain,⁹⁰ is more likely to “misuse this sensitive information in times of economic crises, such as selling it in the event of bankruptcy.”⁹¹

In many instances, consumers of genetic testing products are not informed that their information was passed on or sold to third parties, or used for purposes other than to provide the product ordered. Even in instances where the commercial service provides a disclaimer, whether the consumer actually understood the implications of that consent is unclear.⁹² Unintended use issues are particularly alarming given not only the large number of genetic variants being

⁸⁸ Ries & Caulfield, *supra* note 2, at 292.

⁸⁹ *See, e.g.*, Moore v. Regents of Univ., 793 P.2d 479, 485 (Cal. 1990).

⁹⁰ DAVID G. EPSTEIN ET AL., BUSINESS STRUCTURES 2 (2d ed. 2007) (asserting that the primary purpose of a business is to create value, which is often done by making money).

⁹¹ Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 12 (2006). For example:

[A]bsent sufficient restrictions and guidelines for the storage of genetic information, each commercial company is free to choose the level of security placed on the genetic information it collects and stores. As a result, we are witnessing incoherency in the manner in which sensitive information is stored and handled, a phenomenon that not only undermines the privacy interests of the research subjects, but is also claimed to create difficulties in the conduct of genetic research. The growing control that private commercial companies have over medical and genetic information and material; the lack of sufficient safeguards in place to protect personal privacy; and potential partnerships between the public and the private sectors that bestow additional power to the hands of the private sector, all intensify the threat to personal autonomy and genetic privacy.

Id.

⁹² *See* Ries & Caulfield, *supra* note 2, at 292.

tested,⁹³ but the permanence of genetic test results and the effect on others, such as family members who share the same DNA. The genetic testing website quoted earlier portrayed nutrigenetic information as “last[ing] a lifetime,”⁹⁴ but actually the unique longevity of DNA “creates the possibility of long-term and even transgenerational harms for persons.”⁹⁵ Genetic information continually gains meaning, as more and more associations between genes and various conditions are discovered. Yet even though exponential growth in genetic knowledge may reveal information individuals do not want themselves—much less revealed to others—to know, it is not easy to withdraw that information.⁹⁶

Proscribing these commercial entities from obtaining genetic material and offering their services raises a different set of problems. Restricting the marketing of these tests, for example, implicates First Amendment rights.⁹⁷ Because the Supreme Court extended First Amendment protections to commercial speech, marketing restrictions may infringe that First Amendment protection.⁹⁸ Another difficulty is that limiting market players potentially hampers general access to the tests.⁹⁹ The problem becomes even greater when considering researchers, who are not purely profit driven, but also seeking to make scientific advances.

⁹³ See *supra* text accompanying note 24.

⁹⁴ Health & DNA. *supra* note 6.

⁹⁵ Green & Thomas, *supra* note 64, at 577. “Over thirty states already authorize banking of DNA data in DNA ‘databanks’ or ‘libraries.’” *Id.* at 578. But, “the capacity for DNA to generate personal information about specific individuals, such as disease possibilities, goes beyond identification and suggests a much greater threat to individual autonomy,” including Fourth Amendment implications. *Id.*

⁹⁶ See Green & Thomas, *supra* note 64, at 577–78.

⁹⁷ See Gail Javitt et al., *Direct-to-Consumer Genetic Tests, Government Oversight, and the First Amendment: What the Government Can (and Can’t) Do to Protect the Public’s Health*, 57 OKLA. L. REV. 251, 273 (2004).

⁹⁸ Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748 (1976) (voiding a state statute that declared advertising of prescription drug prices by a licensed pharmacist to be unprofessional conduct, and holding that even speech that only communicates a message proposing a commercial transaction is socially valuable and entitled to protection).

⁹⁹ Cf. Goldman, *supra* note 82, at 90–99 (looking at privacy issues arising from pharmacogenetic databases, discussing benefits to all of pharmacogenomic database and need for insurance companies to access genetic info).

3. Researchers/Biobanks

Researchers and biobanks constitute another category of interested players. Studies of large cohorts linking genetic information to details about dietary habits and lifestyle factors are “key to unlocking the details of how genetics and environmental exposures, including nutrition, interact.”¹⁰⁰ Though public good may motivate much of these efforts, the information is again used for purposes never intended by the individual ordering a nutrigenetic test.¹⁰¹ Moreover, individuals may find it incredibly challenging to withhold or withdraw consent for future use. Once researchers have the information, preventing them from using it can be very difficult. Again, the main problem is loss of control.

Societal benefits of allowing researchers and biobanks access to genetic information may be lost if this access were proscribed. Researchers argue that genetic information, coupled with the personal information provided, is needed for meaningful results. Yet the ability of researchers to access personal information about specific individuals suggests much greater threats to individual autonomy.¹⁰² The resulting implication is that this creates a conflict of interests between the need for research and the right to individual autonomy.¹⁰³ This view, however, overlooks important aligned interests—the researcher actually benefits by protecting individual genetic autonomy. Concern about lack of control not only harms patients who forego

¹⁰⁰ Ries & Caulfield, *supra* note 2, at 286.

¹⁰¹ Stefan Eriksson & Gert Helgesson, *Potential Harms, Anonymization, and the Right to Withdraw Consent to Biobank Research*, 13 EUR. J. OF HUMAN GENETICS 1071, 1072 (2005) (noting that risks of biobank research are “usually tied to sensitive information ending up in the wrong hands and being used to the disadvantage of a person”; noting arguments that “insurance companies and employers could come to use genetic information to discriminate against people with certain genetic dispositions”).

¹⁰² Indeed, federal regulations have recognized this threat to a certain extent, requiring informed consent in many instances when the information is identifiable; nevertheless, the gaps create too great a threat to render these statutes sufficient. *See infra* Part V.1.

¹⁰³ Goldman, *supra* note 82, at 90–99.

potentially beneficial testing, but also hurts research.¹⁰⁴ Currently, many researchers face significant problems in recruiting study participants, as people are unwilling to participate in studies for fear that such participation may lead to third party disclosure, resulting in discrimination and other negative effects. Protecting individuals' autonomy over access to their genetic information therefore can be mutually beneficial: alleviating patients' concerns by eliminating the main reason they currently refuse to participate in genetic research conducted by academic or commercial researchers.

4. Physicians/Health Care Providers

Health professionals use genetic information to gain a fuller understanding of their patients.¹⁰⁵ Issues concerning the individual's loss of control, similar to those arising in the context of research institutions, surface when the physician uses the information for research without patient approval.¹⁰⁶ A separate issue, however, appears when a doctor is compelled to disclose the information to third parties. Medical information on file with a doctor must often be disclosed to insurers, for example. When the employer is also the insurance provider, there are further concerns that information will be disclosed to the employer.

There is precedent to suggest that physicians in some circumstances may be obligated to reveal the information to family members.¹⁰⁷ In not doing so, physicians may face liability for

¹⁰⁴ Slaughter, *supra* note 67, at 72; *see also* Genomics and Personalized Medicine Act, S. 3822, 109th Cong. § 8(1) (2006) (“[I]n order for personalized medicine to advance and achieve success in both reducing the burden of disease and reducing health care costs, strong privacy protections, including protections against genetic discrimination, must be enacted and implemented . . .”).

¹⁰⁵ A healthcare provider may order a genetic test on a patient to “identify[] the potential for genetic disease, test[] embryos for genetic defects, establish[] or confirm[] diagnoses, determine if there is a potential for future increased disease risk, or determin[e] medication responses.” Douglas A. Grimm, *FDA, CLIA, or a “Reasonable Combination of Both”: Toward Increased Regulatory Oversight of Genetic Testing*, 41 U.S.F. L. REV. 107, 110–11 (2006).

¹⁰⁶ Often, the health professional is also a researcher, but this section divorces that role because the issues surrounding researchers have already been addressed.

¹⁰⁷ *See* Denbo, *supra* note 17, at 580; Furman, *supra* note 77, at 403–04 (discussing duty of physicians to disclose genetic test results in clinical and research setting and concluding that duty to disclose depends on whether a plaintiff's claim is based in tort, contract, or property).

failing to meet their duty to warn. In *Safer v. Estate of Pack*,¹⁰⁸ for example, the New Jersey appellate court recognized “a physician’s duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition.” The court explained that “[i]n terms of foreseeability especially, there is no essential difference between the type of genetic threat at issue here and the menace of infection, contagion or a threat of physical harm.”¹⁰⁹ In a case of first impression, the Supreme Court of Minnesota recently followed the lead of the *Safer* court by accepting the plaintiff’s argument that a physician’s duty to warn others of a patient’s genetic disorder arises from the foreseeability of injury, even if a physician-patient relationship cannot be established.¹¹⁰

While the courts grapple with these issues, problems of not allowing physicians access to genetic information become evident. First, if physicians do not have access to genetic information, important protections may be lost for the patient. Health professionals provide an important safeguard function in interpreting and protecting the data, and explaining the actual ramifications. Second, physicians may be liable to the patient if they do not consult genetic information, for example, before prescribing medications.¹¹¹ In fact, some recent articles have

¹⁰⁸ *Safer v. Estate of Pack*, 677 A.2d 1188, 1192 (N.J. 1996). The traditional rule was that doctors have a legal duty only to the patient, but courts expanded the duty to third parties in situations involving the protection of public health or community at large.

¹⁰⁹ *Id.* It is worth noting again that not all genetic information is the same—much lifestyle information is itself harmless, and would not be used for discrimination. The problem is that with the large number of genetic variants being tested and discovery of additional correlations to a particular genetic variant, one cannot know whether the information received will remain innocuous or will be imputed meaning making it the dangerous type discussed in *Safer*.

¹¹⁰ *Molloy v. Meier*, 679 N.W.2d 711, 716–17 (Minn. 2004) (citing numerous other cases finding liability for failing to provide genetic information to family members); *see also Pate v. Threlkel*, 661 So. 2d 278 (Fla. 1995) (holding unanimously that a physician has a duty to warn a third party about a genetically inherited disease).

¹¹¹ *Furman*, *supra* note 77, at 423–29 (discussing duty of physicians to disclose genetic test results in clinical and research setting, concluding that duty to disclose depends on whether a plaintiff’s claim is based in tort, contract, or property).

suggested the increasing likelihood of doctor liability for failing to test for genetic variations may be an impetus for increasing the progress of pharmacogenetics, for example.¹¹²

While many of these problems remained dormant in the context of pathologic genetic testing, nutrigenetic testing has changed everything—pushing privacy issues from the relative safety of the doctor’s office to the market place, and moving to an exponentially larger magnitude of testing that brings with it exponentially greater room for misinterpretation, discrimination through release to third parties, and self-overdisclosure. Regulations, on the other hand, thus far remain unchanged.

V. NOT GETTING WHAT WE NEED: LIMITS OF CURRENT REGULATIONS & PREVIOUS PROPOSALS

Inaccurate and accurate information disclosure problems, coupled with the numerous parties who seek to exploit genetic information, pose significant hazards. Yet as genetic testing expanded exponentially over the last decade, regulatory and legislative efforts never gained momentum and today remain woefully inadequate. Current regulatory efforts, where they do exist, do not protect against many of the problems posed by genetic information generally. Nor are the current proposals, both by academics and before Congress, sufficient to prevent the opening of the Pandora’s Box presented by nutrigenetic testing.

1. The Current Regulatory Regime

Calls for increased oversight of genetic tests have been made for nearly a decade, yet federal and state regulation remains patchy at best. The Secretary’s Advisory Committee on Genetic Testing (SACGT) set forth its findings nearly seven years ago that “[b]ased on the

¹¹² Kristen Choo, *Personalized Prescriptions: Legal Actions Will Help Determine the Success of Using Genetics to Improve Drug Treatments*, 92 ABA J. 42, 46 (2006) (arguing that doctors are most likely to be liable when failure to test for a genetic variation results in harm to a patient).

rapidly evolving nature of genetic tests, their anticipated widespread use, and extensive concerns expressed by the public about their potential for misuse or misinterpretation, additional oversight is warranted for all genetic tests.”¹¹³ Yet FDA regulation, the Clinical Laboratory Improvement Amendments, Health Insurance Portability and Accountability Act of 1996 (HIPAA),¹¹⁴ and state legislation have all been unsuccessful in providing adequate safeguards.

Federal Agencies

Oversight of all laboratory tests and their components falls within the purview of the Food & Drug Administration (FDA), pursuant to the Federal Food, Drug and Cosmetic Act.¹¹⁵ Some authors suggest that the FDA is in the best position to protect the public from genetic test problems, and that the profound dangers of genetic information “warrant the public delegating the resources and mandate to the FDA to ensure that the troubling issues and agonizing choices occasioned by genetic testing are not compounded by poorly developed or even misleading information.”¹¹⁶

¹¹³ NAT’L INSTS. OF HEALTH, SEC’Y’S ADVISORY COMM. ON GENETIC TESTING (SACGT), ENHANCING THE OVERSIGHT OF GENETIC TESTING: RECOMMENDATIONS OF THE SACGT ix (2000), available at http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf [hereinafter *SACGT Report*]. However, there are ongoing debates about whether “genetic exceptionalism”—the idea that genetic information warrants special attention—is warranted. See generally, e.g., Mark A. Rothstein, *Genetic Exceptionalism & Legislative Pragmatism*, 35 HASTINGS CENTER REP. 27, 30 (2005) (arguing that “[g]enetic-specific laws . . . reinforce the stigma of genetic disorders . . . by treating them differently from nongenetic conditions . . . and ignor[ing] the underlying social problems that genetic privacy and discrimination exemplify”); Sonia M. Suter, *The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U. L.Q. 669 (2001) (arguing that genetic information should not be treated differently from other health information because discrimination should not be allowed for any health information). The SACGT report came to the conclusion that special protections are warranted in certain contexts. *SACGT Report, supra*, at 28–31. Either way, this Article argues it should be afforded heightened protections at least until the debate is resolved. The permanency and longevity of genetic information makes it virtually impossible to get released genetic information back into the proverbial genie bottle.

¹¹⁴ Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 29 U.S.C. and 42 U.S.C.).

¹¹⁵ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331–360m (2000); Bonnin, *supra* note 31, at 159 (discussing marketplace for genetic testing and the current regulatory scheme governing each step of the process).

¹¹⁶ Huang, *supra* note 61, at 558.

Despite its arguably broad powers to act in the area,¹¹⁷ current FDA regulation of genetic testing is minimal. Though there are “genetic tests available for close to 1000 diseases or conditions . . . only about a dozen genetic tests have been reviewed and approved . . . to ensure their safety and effectiveness.”¹¹⁸ Furthermore, FDA regulation is incoherent and vacillating. For example, the FDA deems genetic testing *kits*—classified as medical devices—subject to pre-market approval, yet genetic testing *services* (including nutrigenetic testing) are not.¹¹⁹ In fact, “[c]linical laboratories that plan to market tests as services and that have not received federal funds are under no requirement to consult [independent review boards (IRB)] . . . [and] few have sought IRB approval or consulted the FDA.”¹²⁰ Because nutrigenetics is not testing for the presence of a single marker, but rather involves complex evaluation of numerous different genetic variants, nutrigenetic test kits are unlikely to be offered any time soon. At present, nutrigenetics remains a genetic testing service and thus part of the market which the FDA has barely acknowledged, much less regulated. Overall, FDA policy and statements indicate an unwillingness to regulate genetic testing services, whether because of lack of political will or lack of resources.¹²¹ Even if the unwillingness or inability of the FDA to regulate genetic testing services were overcome, real concerns remain regarding the FDA’s “competence to address the complex social issues attached to genetic testing which go beyond mere product performance concerns.”¹²²

¹¹⁷ *But see* Javitt, Stanley & Hudson, *supra* note 97, at 273 (arguing that the FDA does not have clear jurisdiction to regulate the manner in which laboratories tests are sold or provided to patients).

¹¹⁸ GAO INVESTIGATION, *supra* note 27, at 1.

¹¹⁹ Holtzman, *supra* note 31, at 53–54 (discussing the SACGT’s proposals for increased FDA regulation of genetic tests, not just those marketed as kits, and asserting that the proposal is viable).

¹²⁰ *Id.* at 59.

¹²¹ “FDA has maintained that it lacks the resources to extend its full power to regulate devices to genetic tests marketed as services.” *Id.* at 61.

¹²² Bonnin, *supra* note 31, at 162. Product performance concerns would fall under what this Article terms inaccurate information problems, while complex social issues were described in the section on accurate information problems. *See supra* Part II.

Another proposed candidate for regulating genetic testing services is the Federal Trade Commission (FTC)¹²³ because its mandate under the Federal Trade Commission Act is to prevent “unfair or deceptive acts or practices in or affecting commerce.”¹²⁴ Effectively addressing the combination of accurate and inaccurate information problems presented is virtually impossible given the limitations on the FTC (and other federal regulatory agencies). The mandate of these agencies is generally confined to addressing inaccurate information problems. Accurate nutrigenetic information does not fall within the purview of unfair or deceptive business transactions.

Yet, neither the resources of these agencies, nor legislative support for ensuring that genetic information is at least accurate, reach that far. Fully addressing these myriad problems through federal regulatory agencies would require vigilance, resources, and concerted interagency efforts, as well as legislation recognizing and addressing the problems inherent in nutrigenetic information. Unfortunately, legislation currently underpinning much of the existing regulatory framework is sparse and often not focused on the overarching problems.

Federal Laws

Although several federal laws touch on genetic information issues, “this patchwork of laws and interpretations, untested in the courts, does not adequately address the unique issues surrounding the specific use of genetic information.”¹²⁵ First, the Clinical Laboratory Improvement Amendments (CLIA) of 1988¹²⁶ establish minimum quality levels in laboratory testing practices. Although CLIA may theoretically extend to federal oversight of DNA

¹²³ Javitt, Stanley, Hudson, *supra* note 117, at 274 (noting that “some critics recommend that . . . the FTC regulate advertising for genetic testing in a manner similar to the regulation of [direct-to-consumer] pharmaceutical advertising”).

¹²⁴ 15 U.S.C. § 45(a) (2000).

¹²⁵ Slaughter, *supra* note 67, at 72.

¹²⁶ Clinical Laboratory Improvement Amendments of 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified in 42 U.S.C. 263a (2000)).

analyses,¹²⁷ in practice there is much room for improvement.¹²⁸ Although various governmental advisory bodies found that “a smooth transition of genetic testing from research to practice” would require “creat[ion of] regulations under CLIA that focused specifically on genetic tests,” CLIA has no specific category or requirements for genetic tests.¹²⁹ Because genetic tests are broadly included as part of all laboratory tests, there are no specific personnel, quality control, or proficiency-testing requirements for the vast majority of genetic tests.¹³⁰ As a result, nutrigenetic tests are “sometimes performed in laboratories that have not been approved under CLIA.”¹³¹ The effect of delays in implementing CLIA, not to mention its gaps, means that “neither healthcare providers nor consumers can be confident in the oversight mechanisms in place to ensure genetic tests are accurate and reliable. While genetic science and genetic technologies have leapt into the 21st century, the agency entrusted with ensuring laboratory quality is stuck in the past.”¹³²

Most importantly in this context, CLIA does not address the serious issues relating to genetic counseling or informed consent. Finally, CLIA arguably does not fit the paradigm of genetic testing because of the huge number of tests involved in nutrigenetics. The 50K to up to 1M tests (analyzing 50,000 to up to 1,000,000 genetic variants for one person) used for

¹²⁷ It has been recognized since 1992 that CLIA could be extended to regulate genetic testing. Slaughter, *supra* note 67.

¹²⁸ Javitt & Hudson, *supra* note 46 (“Although Congress was quite clear in the purpose and requirements of CLIA, HHS’s implementation of CLIA for genetic testing has been inadequate.”). For example, CLIA requires laboratories to prove only *analytical validity* (meaning that the test must properly measure what it purports to measure). There is no requirement for *clinical validity* (that the purported correlation exists) or *clinical utility* (that there is high penetrance—the extent to which the properties controlled by a gene, its phenotype, will be expressed). “Penetrance is the likelihood that a gene will express itself. For example, the BRCA1 gene, which predisposes an individual to breast cancer, is about 85 percent penetrant, while the Huntington’s gene is 100 percent.” Curley & Caperna, *supra* note 18, at 24.

¹²⁹ Javitt & Hudson, *supra* note 46, at 6.

¹³⁰ *Id.*

¹³¹ GAO INVESTIGATION, *supra* note 27, at 2.

¹³² Javitt & Hudson, *supra* note 128, at 19.

pharmacogenetic, ancestry, and other developmental testing are already orders of magnitude higher than what can reasonably be quality-controlled under CLIA.¹³³

Second, HIPAA is frequently cited as a protection in the context of genetic testing. HIPAA provides comprehensive protection to individually-identifiable health information. The statute is not focused on genetic information specifically, but it does provide that genetic information may not be treated as a condition “in the absence of a diagnosis related to such condition.”¹³⁴ Yet this indirect and minimal approach to protecting genetic information is inapposite to deal with the large number of concerns presented by genetic information. The statute is full of gaps that cut down the limited protections afforded. For example,

HIPAA does not require that insurance plans offer coverage for genetic disorders or restrict the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage, but instead prevents an insurance plan from applying the premiums or exclusions on a genetically discriminatory basis. Thus, insurers, subject to any binding state regulations, may continue to consult genetic information in determining eligibility and setting premiums for individual plans. Roughly 23.5 million Americans are enrolled in individual plans, therefore a significant regulatory gap exists.¹³⁵

HIPAA is designed to protect confidentiality of health records generally, and is not focused on the special issues surrounding genetic information. In fact, genetic information is only protected if it falls under the definition of protected health information.¹³⁶ Treating genetic

¹³³ CLIA would look at each of the 50,000 to 1,000,000 tests done in a microarray individually, which takes a long time and does not focus on the most relevant concerns. CLIA cannot obviate the dangers posed by genetic information because its requirements already prove cumbersome when dealing with a fraction of the genetic tests that are done for nutrigenetic purposes. Moreover, it does not address many of the most critical problems, such as accurate information problems.

¹³⁴ 42 U.S.C. § 300gg(b)(1)(B).

¹³⁵ Jennifer S. Geetter, *Coding for Change: The Power of the Human Genome to Transform the American Health Insurance System*, 28 AM. J. L. & MED. 1, 48 (2002) (internal quotation marks and footnote omitted); *see also* Hildebrand et al., *supra* note 65, at 603 (“[HIPAA] does not prohibit rating based on genetic information, nor does it prevent health insurers from disclosing or demanding access to genetic information.”).

¹³⁶ Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164).

information as no different from other health information overlooks that the differences—permanency, effects on relatives, and future information—are precisely why heightened protections for genetic information are needed.

State Legislation

State efforts to provide genetic testing oversight currently share many of the problems of federal regulations. State legislation, however, has made more headway than federal legislative efforts. Seventeen states have prohibited direct consumer access to any laboratory testing. Thirty-one states have genetic privacy laws, forty-seven states have genetic non-discrimination in health insurance laws, and thirty-four states have genetic non-discrimination in employment laws.¹³⁷ Yet these statutes are incomplete even when pieced together, leaving numerous problems unaddressed. First, the state laws are by no means uniform, but contain different definitions of the relevant terms, such as genetic information, genetic tests and discrimination.¹³⁸ Second, the state statutes contain significant gaps which leave genetic information unprotected from exploitation or nefarious purposes. Although some states have implemented measures that indirectly regulate some aspects of genetic testing services—such as quality assurance requirements beyond those mandated by CLIA and genetic counselor licensing requirements—nutrigenetic testing falls largely outside the realm of those regulatory efforts.¹³⁹ Third, despite their good intentions and efforts, none of the state laws afford individuals the autonomy to control fully who gets access to their genetic information. Finally, as jurisdictional issues

¹³⁷ National Conference of State Legislatures, Genetics Laws and Legislative Activity, <http://www.ncsl.org/programs/health/genetics/charts.htm> (last visited Oct. 30, 2007).

¹³⁸ Sheri Mezoff, Note, *Forcing a Square Peg into a Round Hole: The Negative Ramifications of Misaligned Protection for Predisposed Individuals Under the ADA*, 85 B.U. L. REV. 323, 323–24 (2005) (“Judicial decisions on such matters [as protection of genetic information] are case-specific and result in a bewildering patchwork of rights and duties across the United States.”).

¹³⁹ Van Voorhees, *supra* note 22, at 815–16 (explaining, for example, that even though many states have codified definitions of genetic testing to prevent discrimination by insurance companies and employers, “[n]on-pathologic tests fall outside the bounds of these laws”); *see also infra* Part V.2–3.

involving services offered through the internet remain judicially unresolved, even the most stringent state laws may not offer the necessary measures to protect information affecting individuals and their families because whether a web-based genetic testing service is subject to a particular state's jurisdiction remains uncertain.

Even if existing federal and state regulations worked exactly as intended, third party disclosure and self-overdisclosure of genetic information—and nutrigenetic information in particular—give rise to problems that remain overlooked and inadequately addressed by the federal and state governments.

2. Other Proposals

Recognizing the shortcomings of current regulation and legislation, various types of proposals attempt to improve the status quo. These proposals generally revolve around three ideas: (1) an informational, informed consent-based approach; (2) anonymization; or (3) stricter governmental regulations. An assessment of these approaches reveals their shortcomings, particularly in the dynamic setting of nutrigenetic testing with the exponential growth of tests for genetic variants. Many of the proposals are so concerned about impeding researchers' access to information, however, that they fail to recognize the benefits to research. The current unwillingness of people to participate in research studies for fear of third party disclosure can actually be most effectively addressed by protecting the individual's autonomy rights.

Informed Consent Models

Some critics suggest that the “essential challenge of this policy reform is going to be the development of ethically justified consent processes and forms that responsibly balance the ethical obligations to respect subject autonomy and protect privacy with the scientific and

clinical benefits of data release.”¹⁴⁰ Indeed, many genetic information related proposals focus on informed consent,¹⁴¹ which requires the individual to be in possession of relevant facts. Legally, informed consent does not mean that the individual must actually comprehend the information.¹⁴²

To remedy this lack of comprehension, the focus of many informed consent based proposals is to enhance the quality of information to enhance the individual’s comprehension, yielding not only consent, but also informed choice on the part of the individual. Thus, these proposals often address the type of information that should be provided and more effective delivery of that information. One information-based proposal, for example, is modeled on the Truth in Lending Act,¹⁴³ arguing that “[t]he underlying problems of the 1960s consumer credit market are virtually identical to modern concerns about non-pathologic elective genetic testing” and that “[i]n both situations the lack of accurate and understandable information leaves consumers ill-equipped to make very important personal decisions.”

¹⁴⁰ Amy L. McGuire & Richard A. Gibbs, *Meeting the Growing Demands of Genetic Research*, 34 J.L. MED. & ETHICS 809, 811 (2006) (looking at different models of consent, including tiered consent, which allows subjects to “agree to participate in the primary research study and are given several options for data sharing, affording them more control over whether, how, with whom and how much of their data are shared”).

¹⁴¹ Informed consent pervades many academic proposals, and even “[d]espite th[e] lack of regulatory oversight, many federal funding agencies, institutions, and investigators are beginning to recognize the importance of informed consent for data sharing.” McGuire & Gibbs, *supra* note 140, at 811.

¹⁴² The landmark case on informed consent, *Canterbury v. Spence*, set forth that physicians have a duty to reasonably inform a patient about all the risks that may affect the patient’s decision, but that “the physician discharges the duty when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it.” See *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972). As Merryn Ekberg explains:

[P]eople may give consent to a test they do not fully understand the significance of, or to which they have received inadequate, incomplete or inaccurate information. They may give their consent voluntarily, but without understanding the immediate and long term health, social and psychological consequences of the test result, this voluntary consent is not informed consent.

Merryn Ekberg, *Governing the Risks Emerging From the Non-Medical Uses of Genetic Testing*, 3 AUSTL. J. EMERGING TECHS. & SOC’Y, 1, 10 (2005).

¹⁴³ See Van Voorhees, *supra* note 22, at 818–19 (arguing that “[t]he underlying problems of the 1960s consumer credit market are virtually identical to modern concerns about non-pathologic elective genetic testing,” and that “[i]n both situations the lack of accurate and understandable information leaves consumers ill-equipped to make very important personal decisions”).

Many researchers also prefer the informed consent paradigm to other approaches. In fact, informed consent schemes generally allow researchers a great deal of control. As long as the individual originally consented to supplying the sample and the possibility of the sample being used for research, researchers control the genetic information.¹⁴⁴ The focus of these proposals, therefore, is ensuring that initial informed consent was legally adequate. For example, one proposal to safeguard information calls for “a description of the test and a statement of its purpose; a description of the disease(s) or condition(s) for which a test will be conducted; an explanation of the risks of stigma and discrimination; and assurances that the patient’s medical confidentiality will be protected,” except as explicitly stated.¹⁴⁵

Because this approach requires genetic testing services to provide a certain amount of educational material explaining the limitations of the tests, it could alleviate some problems of accurate information relating to misunderstandings, such as misinterpreting the information as determinative or conclusive. Moreover, individuals would at least be aware that information may later be used to discriminate against them before deciding to undergo testing.

The limitations, however, are significant. First, the informed consent paradigm does not prevent discrimination. Instead, it merely warns the individual that discrimination may result. Thus, rather than being protected, the individual is simply discouraged from getting the test. Second, even in the purely medical context—dealing solely with pathologic issues—informed consent is abstruse. Different courts vary widely in their application of informed consent, from the extent of disclosure necessary to the standards by which courts determine whether disclosure

¹⁴⁴ Gunter Bruns & Moshe Wolman, *Morality of the Privacy of Genetic Information: Possible Improvements of Procedures*, 19 MED. & L. 127, 138 (2000) (suggesting that, based on a contributing labor-type theory, genetic donors should have no genetic property rights or rights to control where their genetic information goes but that a board should govern whether the donor’s name will be released to a third party and what information is given to the person).

¹⁴⁵ Bonnin, *supra* note 31, at 172 (quoting Elizabeth B. Cooper, *Testing for Genetic Traits: The Need for a New Legal Doctrine of Informed Consent*, 58 MD. L. REV. 346, 405 (1999)).

was adequate.¹⁴⁶ Courts have, however, largely agreed that there is no fiduciary duty requiring the health professional to disclose risks that may have nonmedical implications, such as economic or social drawbacks.¹⁴⁷ In addition, the health professional's obligation is a duty to disclose, not to ensure that patients fully comprehend what has been disclosed to them.¹⁴⁸

Third, the informed consent model seems ill-suited to the commercial, direct-to-consumer context. Even assuming that regulations could mandate that genetic testing services require that testing providers supply relevant information to patients and subsequently require informed consent agreements to be signed stating that the consumer wants to proceed with the test despite the risks, the result may simply be point-and-click or click-through agreements. Most people do not actually read through these agreements before ordering services through the internet.¹⁴⁹ Whether such click-through forms would be any more effective than currently available click-through contracts in facilitating informed consent is unclear. Thus, despite addressing some of the accurate information concerns, there are still significant problems concerning both accurate and inaccurate genetic information, which the informed consent model fails to address.

Anonymization Models

Anonymization proposals seek to draw on the success of the HIV anonymization model, though case law dealing with anonymization of general medical information highlights significant drawbacks to this approach. Anonymization is premised on the idea that without

¹⁴⁶ See *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) (using an objective patient standard to determine duty to disclose). However, a slight majority of U.S. jurisdiction use the professional standard. PETER DE CRUZ, *COMPARATIVE HEALTHCARE LAW* 6 (2001). Notably, it is unclear what happens to the standard when the patient specifically asks about a certain risk.

¹⁴⁷ See *Arato v. Avedon*, 858 P.2d 598 (Cal. 1993) (asserting that doctors are not responsible for giving information that would affect nonmedical interests, in this case the patient's estate decisions).

¹⁴⁸ *Canterbury*, 464 F.2d at 780.

¹⁴⁹ To see whether people actually read click-through end user license agreements, a provision was inserted into one such agreement offering \$1000 for responding to the message. Only after four months during which 3000 users accepted the agreement did a single person claim the money. See Larry Magid, *It Pays to Read License Agreements*, PC PITSTOP, <http://www.pcpitstop.com/spycheck/eula.asp> (last visited Oct. 30, 2007).

identifying personal information, data does not threaten individual privacy. Data may be anonymous from the outset, or it may later be anonymized at the collection, retention, or disclosure stages.¹⁵⁰ Anonymous AIDS testing creates anonymity from the outset. Unlike confidential testing, where the individual's name is recorded and linked to her test results, anonymous AIDS testing uses code numbers to identify the test—names are never linked to the results.¹⁵¹

Parallels drawn between HIV/AIDS tests and genetic testing suggest that anonymous testing could be successfully extended to genetic testing. Both give rise, for example, to concerns about discrimination and lack of pre- and post-test counseling. Despite these similar concerns, there are significant problems with relying on anonymous testing in the context of nutrigenetics. First, personal information is needed to make nutrigenetic recommendations, whereas this is not required for determining whether an individual is HIV-positive. Second, unlike HIV/AIDS testing, genetic testing involves new genetic relationships constantly being discovered and raises possibilities of later revealing other much more serious conditions. Moreover, when tests are done anonymously they do not become part of an individual's medical record; as a result, physicians may fail to catch serious health concerns.¹⁵²

Another approach more frequently proposed in relation to genetic testing focuses on post-test anonymization. Removing or obfuscating any identifying information is thought to

¹⁵⁰ KHALED EL EMAM, ACCESS TO INFO. & PRIVACY DIV. OF HEALTH CAN., DATA ANONYMIZATION PRACTICES IN CLINICAL RESEARCH 7 (2006), available at <http://www.ehealthinformation.ca/documents/HealthCanadaAnonymizationReport.pdf>.

¹⁵¹ STOP AIDS Project, <http://www.stopaids.org/resources/testing> (last visited Oct. 31, 2007).

¹⁵² A compelling example is the story of a female physician who had genetic tests done under an assumed name for fear that she would lose insurance if she used her real name. Robyn Nicoll, *Long-Term Care Insurance and Genetic Discrimination—Get It While You're Young and Ignorant: An Examination of Current Discriminatory Problems in Long-Term Care Insurance Through the Use of Genetic Information*, 13 ALB. L.J. SCI. & TECH. 751, 752-53 (2003). Subsequently, her radiologist disregarded an abnormal abdominal ultrasound because the genetic tests and the woman's family history were not in the same medical record. *Id.*

sufficiently protect the individual's privacy even if the anonymized data is disclosed.¹⁵³ Based on this idea, for example, federal regulations and international guidelines routinely permit use of anonymous tissue samples in research even without consent of the original donors.¹⁵⁴

The greatest problem of anonymizing genetic information is that “DNA carries so much information that anonymization may be difficult or impossible.”¹⁵⁵ Some argue that an individual's “right to privacy is violated when personal medical information is revealed to an unauthorized third party . . . even if such information is rendered anonymous by the removal of all data relating to the [individual's] identity.”¹⁵⁶ The right to privacy understood in this manner means not only protecting one's identity, but involves “[the] person's ability to control access to information about oneself,”¹⁵⁷ whether or not it is known to be *about* the individual.

Current law, however, fails to provide for individuals' rights to retain autonomous decisionmaking authority over the use of genetic data. Though case law and statutes recognize a right to privacy, the right is significantly limited, extending only to *identifiable* medical information.¹⁵⁸ In fact, federal regulations actually “exempt anonymized samples from the requirements of informed consent . . . [allowing] researchers [to] remove identifiers from existing samples [or data] without seeking consent for their use in data analysis.”¹⁵⁹ Still, some

¹⁵³ El Emam, *supra* note 150, at 3.

¹⁵⁴ See Green & Thomas, *supra* note 64, at 579.

¹⁵⁵ *Id.* at 578.

¹⁵⁶ Yaron F. Dunkel, Note, *Medical Privacy Rights in Anonymous Data: Discussion of Rights in the United Kingdom and the United States in Light of the Source Informatics Case*, 23 LOY. L.A. INT'L & COMP. L. REV. 41, 41 (2001).

¹⁵⁷ *Id.* at 45.

¹⁵⁸ *Id.* at 43-44; see also Bartha Maria Knoppers et al., *Ethical Issues in Secondary Uses of Human Biological Matters from Mass Disasters*, 34 J.L. MED. & ETHICS 352, 355-56 (2006) (emphasizing the movement at the international level to differentiate between data and samples that are anonymized, coded or identified).

¹⁵⁹ Furman, *supra* note 77, at 412; see also Knoppers et al., *supra* note 158, at 357 (“Federal regulations on the protection of human subjects permit the use of existing, anonymized, biological materials without consent for research, as this is not considered research on ‘human subjects.’” (citing 45 C.F.R. 46.101(b)(4) (2006)); *id.* at 358 (noting “a move away from requiring an explicit re-consent for all secondary uses provided other safeguards are in place, such as . . . anonymization”).

researchers argue for greater physician and researcher control over data in biobanks,¹⁶⁰ maintaining that anonymization has limited value in protecting participants’ interests because “[i]t may not decisively cut the link to a specific individual, it prevents the use of samples for purposes such as diagnostics, it may not prevent harms to groups, and it does not rule out wrongdoing.”¹⁶¹ They therefore argue that the right to withdraw consent should be restricted to cases where the donor can present sufficient reasons, with the researchers or biobankers determining whether the reason is “sufficient”—that is, whether researchers believe that the reason is based on “*genuine, deeply felt concerns . . . not based on misconceptions.*”¹⁶²

Many researchers generally disfavor anonymization models because of the limits it places on their ability to make meaningful use of the data. Arguing that research interests are not the inherent problem that genetic information concerns need to address, researchers are often among those that argue instead for stricter governmental regulations to prevent nefarious uses of genetic data without impeding access of researchers who will use the genetic information for medical progress and societal benefits.

Models Focusing on Stricter Regulations

Current regulations do not address many areas of concern regarding genetic testing services.¹⁶³ Despite different ideas as to what the appropriate approach should be, there is

¹⁶⁰ Eriksson & Helgesson, *supra* note 101, at 1071 (arguing that “anonymization should not be an automatically permissible response to requests for withdrawal; nor should a request for withdrawal necessarily stop research on identifiable samples”).

¹⁶¹ *Id.* at 1074.

¹⁶² *Id.* at 1075 (emphases added).

¹⁶³ See text accompanying note 113. See generally Bonnin, *supra* note 31 (providing a detailed examination of regulations supplement at each stage of genetic testing services, from development of the tests and delivery of the product, to physician recommendation and testing of samples).

widespread support outside of the regulatory agencies themselves for stricter regulations.¹⁶⁴ Yet, the shortcomings previously discussed highlight only some of the problems impeding progress in that area. As one commentator put it, “[d]espite this near unanimity [of the SACGT and commentators], the clamor for increased regulation . . . is receiving little attention [from regulators].”¹⁶⁵ Legislative mandates may be more effective in guiding regulatory efforts and clarifying the reach of protections.

3. New Legislative Efforts

Because of the uniformity required to protect individuals’ privacy and autonomy regarding their genetic information, federal legislation is most suited to supply the needed legislative mandate. CLIA, HIPAA and other federal legislation are not adequately focused on genetic information issues to address the problems of accurate and inaccurate information, particularly in the context of nutrigenetics.¹⁶⁶ As one critic and member of Congress contends, “[t]hese laws leave many gaps in protections, which fail to alleviate the public fear of genetic testing, and the ambiguity of current law has resulted in both actual and perceived acts of discrimination leading to an inconsistent application of laws to deal with such grievances.”¹⁶⁷ Despite sluggish progress,¹⁶⁸ some recent congressional efforts attempt to address certain genetic information issues.

¹⁶⁴ Holtzman, *supra* note 31, at 57 (proposing that FDA is best positioned to take on stricter regulation); *see also* Huang, *supra* note 61, at 580–91; Nunnally, *supra* note 74, at 343–45 (discussing SACGT regulation, the role of the FDA, and the need to avoid inhibiting corporate involvement).

¹⁶⁵ Bonnin, *supra* note 31, at 165.

¹⁶⁶ *See supra* Part V.1; *see also* Slaughter, *supra* note 67, at 72–73 (“Several existing federal laws touch upon the issues raised by the use of genetic information, including the Health Insurance Portability and Accountability Act (HIPAA), Executive Order 13145, the Americans with Disabilities Act (ADA), and Title VII of the Civil Rights Act of 1963. However, this patchwork of laws and interpretations, untested in the courts, does not adequately address the unique issues surrounding the specific use of genetic information.”).

¹⁶⁷ Slaughter, *supra* note 67, at 72.

¹⁶⁸ Human Genome Project Information, Genetics Privacy and Legislation, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (“No federal legislation has been passed relating to genetic discrimination in individual insurance coverage or to genetic discrimination in the workplace.”).

The Genetic Information Nondiscrimination Act (GINA) demonstrates continuing efforts by legislators in both the House and Senate to introduce federal genetic information protections.¹⁶⁹ GINA seeks to protect against genetic discrimination both by employers and insurance companies. However, strong opposition by powerful groups, including the U.S. Chamber of Commerce, has blocked the bill from becoming law to date.¹⁷⁰ Despite these impediments, the pending legislation is an important step that should be taken. This legislation alone, however, is insufficient to address the multitude of problems posed by nutrigenetic testing.

First, the proposed legislation originally defined genetic information as “genetic tests of an individual or family member . . . used to predict risk of disease in asymptomatic or undiagnosed individuals.”¹⁷¹ This definition did not reach nutrigenetic testing (or other lifestyle-related genetic testing), which looks for patterns of genes that interact with diet in certain ways but do not look for “disorders” or “diseases.” The 2007 version actually eliminated the clause “used to predict risk of disease in asymptomatic or undiagnosed individuals,” thereby eliminating the language excluding nutrigenetic testing.

Second, the act attempts to ban discrimination by prohibiting insurers and employers from using the information for discriminatory purposes. It does not, however, address the risks of misinterpretation inherent in disclosure to the individual. Nor does it address the stigmatizing effects. Finally, it creates a system that relies on litigation for enforcement. Other than the large

¹⁶⁹ Genetic Information Nondiscrimination Act of 2007, H.R. 493, 110th Cong. (2007) (pending); Genetic Information Nondiscrimination Act of 2007, S. 358, 110th Cong. (2007) (pending). Various iterations of the bill have been introduced. *See* H.R. 1910, 108th Cong. (2003) (referred to committee but never acted upon); S.16, 108th Cong. (2003) (referred to committee but never acted upon); Genetic Information Nondiscrimination Act of 2003, S. 1053, 108th Cong. (2003) (passed 95–0 in Senate as amended, 149 Cong. Rec. S12499 (daily ed. Oct. 14, 2003), but held at the desk in House); Genetic Information Nondiscrimination Act of 2005, S. 306, 109th Cong. (2005) (passed 98–0 in Senate as amended, 151 Cong. Rec. S1595 (daily ed. Feb. 17, 2005), but held at the desk in House). Representative Slaughter introduced the first bill considered in the Senate nearly ten years ago. *See* Slaughter, *supra* note 67, at 67.

¹⁷⁰ *See* Slaughter, *supra* note 67, at 78.

¹⁷¹ S. 1053, 108th Cong. § 201(4) (2003).

costs this can involve, GINA also fails to consider that in many instances employees may not know that they were denied coverage or unemployment due to their genetic profile. Even if the individual suspects genetic discrimination, who carries the burden of proof (does the plaintiff have to show proof of discrimination, or does the defendant have to show that there was no discrimination?) or how a court would assess whether there was discrimination remains unclear. Thus, although the bill is an important step in clearly stating that genetic discrimination is prohibited, it leaves unaddressed problems of misinterpretation and self-overdisclosure, and carries practicality problems.

Another bill, the Genomics and Personalized Medicine Act of 2006 (GPMA),¹⁷² proposes to facilitate the advancement of personalized medicine, and as such seeks to “expand the use of molecular tests and therapeutics, the backbone of personalized medicine.”¹⁷³ Like GINA, this is an important piece of legislation that should be passed, but it too is insufficient to protect genetic information. In fact, in its current form, it seems the bill does not even apply to nutrigenetic information. The bill is focused on pharmacogenomic testing (examining the interactions of *pharmaceutical drugs* with specific genetic variants). In failing to address nutrigenetic testing, the GPMA overlooks that nutrigenetic testing (examining the interactions of *nutrition* with specific genetic variants) poses many of the same problems, as well as the additional problems created by the commercial, direct-to-consumer context.

Second, though the bill purports to “protect[] consumers by reaffirming Congress’ commitment to stopping genetic discrimination and protecting genetic privacy,”¹⁷⁴ the bill is

¹⁷² Genomics and Personalized Medicine Act, S. 3822, 109th Cong. (2006).

¹⁷³ Personalized Medicine Coalition, PMC Member Newsletter, Spring 2006, http://www.personalizedmedicinecoalition.org/membership/newsletter/PMC_Newsletter_2006-Spring.pdf.

¹⁷⁴ Fact Sheet, The Genomics and Personalized Medicine Act of 2006, http://www.personalizedmedicinecoalition.org/sciencepolicy/Genomics_Fact_Sheet_Final.pdf (last visited Oct. 31, 2007).

largely focused on the problems of inaccurate information, rather than on creating protections to also alleviate concerns about accurate information. For example, the bill dictates “direct-to-consumer genetic tests to receive greater scrutiny and regulation.”¹⁷⁵ The concern is thus primarily that of ensuring the accuracy and availability of tests. Consequently, the bill does not address many of the discrimination and self-overdisclosure problems presented by accurate genetic information. Moreover, the bill sets forth relatively few concrete protections, focusing instead on forming advisory panels to further explore the problems.

Finally, the GPMA does not protect the autonomy of the individual to control which third parties may access and use that individual’s genetic data. The legislation therefore does not address the primary concerns preventing individuals from participating in research studies.

Although the proposed federal legislation—both GINA and GPMA—would provide useful protections and should be passed, they leave open gaps posing significant dangers to individuals in the form of discrimination, misinterpretation, and inaccuracies. Moreover, the proposed statutes do not actually reach nutrigenetic testing. Thus, further measures are required to protect individuals’ genetic information from self-overdisclosure or harmful third party disclosure.

VI. A SOLUTION TO PROTECT GENETIC AUTONOMY AND CONTROL

Interest in nutrigenetic testing is rising, but the differences between nutrigenetic and traditional pathologic genetic testing remain unaddressed by previous approaches. The amount of genetic information such tests generate is much larger than traditional genetic tests, but the accuracy and reliability of that information is more questionable than that provided by traditional tests. Problems persist even if the information is accurate, particularly in light of the many

¹⁷⁵ *Id.*

parties interested in the information for very different purposes. Given the problems inherent both in allowing and in proscribing these parties' access, courts and legislators seem stuck between the proverbial Scylla and Charybdis.¹⁷⁶ Current proposals to address the problem all miss the mark or leave wide gaps in protection. Despite the serious and numerous problems faced, however, there is a workable and practical solution.

Individual autonomy over genetic information is the lynchpin to protecting genetic privacy while also maximizing the promise of genetic testing. Given its permanency, reach, and developing meaning, the key to protecting genetic information and preventing the many potentially associated legal problems is to allow individuals to control the information and permit disclosure to authorized third parties. At the same time, individuals themselves must also have protection from the adverse effects of unwanted information. This can be accomplished through a double-masking system that separates the raw genetic information from derived information before giving the information to consumers.¹⁷⁷ Rather than hope that businesses voluntarily adopt such protections, Congress must pass legislation providing a uniform federal requirement to avoid the permanent and devastating effects likely if genetic information, particularly seemingly innocuous nutrigenetic information, is not protected.

1. Double-Masking: A Model to Protect Genetic Autonomy and Privacy

The testing process would start when the individual visits a nutrigenetic website and chooses to obtain testing. The website provides a downloadable program that comes with a unique anonymized number (e.g., 123-456), which is linked to an anonymous electronic

¹⁷⁶ “In classical mythology, Scylla was a horrible six-headed monster who lived on a rock on one side of a narrow strait. Charybdis was a whirlpool on the other side. When ships passed close to Scylla’s rock in order to avoid Charybdis, she would seize and devour their sailors. Aeneas, Jason, and Odysseus all had to pass between Scylla and Charybdis.” E.D. HIRSCH, JR. ET AL., MYTHOLOGY AND FOLKLORE, NEW DICTIONARY OF CULTURAL LITERACY 43 (2002).

¹⁷⁷ The double-masking model was developed by Professor Martin Kohlmeier, and I owe a great debt to him for bringing it to my attention.

mailbox. The individual sends a cheek swab to the testing service with the anonymized number attached. The individual separately pays for the tests and gets a payment authorization code (e.g., UVW-XYZ) that verifies payment for a particular service, but does not retain any of the individual's information. The individual then informs the anonymous electronic mailbox that payment has been made by entering the code. The laboratory receives the swab, checks the mailbox to see if payment was made,¹⁷⁸ conducts the test, and sends the *encrypted* genetic information to the anonymous electronic mailbox identified by the ID number. The individual then downloads a program from the nutrigenetic testing website encoded with the appropriate algorithms based on rules provided by the laboratory. The program requests personal information necessary to answer the query (such as age, sex, pregnancy status, and so forth). Once the individual enters the information, the algorithm creates recommendations based on the specific genetic data.¹⁷⁹ The program runs client-side, which means it runs on the individual's computer rather than on a server or central computer of the nutrigenetic testing website. Thus, personal information can be entered without anyone else, including the nutrigenetic testing provider, knowing or recording it.¹⁸⁰

The individual then receives the derived nutrigenetic information without ever learning which specific gene variants were examined to derive that information. So, the individual not only does not know the raw genetic information underlying the nutrigenetic recommendations, but does not even know what tests were run. The process itself is run through a laboratory, with

¹⁷⁸ Employing widely-used public-private key encryption, the lab can verify payment without knowing customer identity or anonymized number, but just by checking whether their "key" fits. The same technology is used to protect privacy of ATM machine users.

¹⁷⁹ The algorithms themselves would be open to professional review to ensure validity, opening it to the same criticism as any other recommendations or scientific claims.

¹⁸⁰ This is much like tax preparation software, which is downloaded and run client-side, allowing individuals to enter sensitive, personal information on their computer without it becoming stored on some central server. Derived genetic information could be transmitted as updates, just as tax preparation programs can be updated based on new tax laws and regulations. In both tax and nutrigenetic programs, clients can enter all necessary personal information without anyone else knowing it (as long as the client keeps his computer secure).

a certified clinical geneticist who determines which information may be released this way to a patient. The geneticist would ensure that only nonpathologic information is released through the program, leaving release of pathologic information to licensed health care professionals, such as genetic counselors and physicians. So far, all of the privacy problems discussed previously have been avoided because no one has access to both the raw genetic information and the individual's identifying information.

The individual, however, is not prohibited from obtaining further information, including the raw genetic information. To do so, the individual can release the data to a licensed physician or genetic counselor who can provide adequate counseling before giving the information sought, including the raw genetic information. The individual provides the licensed health care provider the code to the license number and the patients' computer URL. The system then verifies that this is a licensed healthcare professional against a database of licensed healthcare providers. If the professional is not in the database, the licensing must be certified and the name added to the database by the system curator before information is released.

Individuals can also authorize the release of the raw genetic information to their physicians for other purposes, and they can be contacted by researchers, biobanks, or other parties interested in using the information. The individuals will never be directly contacted, but can receive research participation requests by periodically checking their anonymous mailbox. This way, individuals can contribute to research efforts but ensure that their information is not transmitted to unauthorized or unwanted sources, such as insurance companies.

The double-masking model provides a relatively straight-forward and practical way to preserve individual autonomy while also allowing the potential personal, medical, and societal

benefits of genetic testing to be realized. Thus, double masking demonstrates that it is not only desirable, but feasible to protect individual autonomy over genetic information.

2. Comparing the Double-Masking System to Previous Proposals

As theoretical issues and technological realities are recognized and incorporated into proposals to protect genetic information from potentially devastating generations of people, the double-masking model offers a relatively simple and workable system that addresses the most critical information concerns—specifically, the accurate information concerns widely unaddressed or inadequately addressed by legislation. One of the greatest strengths of this model is that it incorporates the strongest aspects of the informed consent and anonymization models.

Significantly, double masking does not displace regulatory efforts, but compliments and completes a strong regulatory regime, including the proposed Genetic Information Nondiscrimination Act and Genomic & Personalized Medicine Act. While the particulars of the legislative efforts are worked out and the impact of nutrigenetics and lifestyle genetic testing on genetic information privacy and autonomy becomes clearer, the double masking model provides real protections and obviates many of the legal problems previously highlighted by preventing the irreversible and uncontrolled release of genetic information.

Allowing people to receive genetically tailored recommendations without releasing unwanted information to either the individual or to third parties without further review avoids future legal problems such as insurance or employer discrimination. Autonomy is preserved by providing the option of obtaining the raw genetic information through a licensed physician or genetic counselor, who will provide the necessary background information to avoid, as far as possible, misinterpretation of the data. Yet relying on businesses to voluntarily implement a program that provides these protections is not sufficient. The extreme sensitivity and

permanence of this information necessitates a uniform and mandatory requirement, enacted through Congressional legislation.

3. Legislating Double-Masking Protections

Safeguarding nutrigenetic information requires congressional action, ensuring that no gaps leave individuals vulnerable or afraid to undergo nutrigenetic testing. The double-masking model is currently the best way to protect against self-overdisclosure, harmful disclosure to third parties, and misinterpretation. To broadly account for possible future developments, however, legislation should also be passed to more generally ensure for genetic information autonomy, with provisions mandating the essential functions provided by the double-masking model. Therefore, Congress should pass legislation that (1) protects individuals from self-overdisclosure and (2) gives individuals control over third-party disclosure. The double-masking model could be implemented to satisfy regulations pursuant to the enforcement of that legislation.

A genetic information autonomy act could be framed as a bill to protect individuals' rights to control their genetic information from unwanted or harmful disclosure, thereby encouraging individuals to benefit from genetic testing and participate in structured research of great commercial and public health interest. This recognizes the overlapping interests of both researchers and individuals in supporting this legislation, rather than erroneously portraying individuals' interests as divergent from that of researchers.

The provisions of such a bill should address the three problems that are most overlooked under existing and proposed legislation and regulatory efforts: harmful and unwanted disclosure, misinterpretation, and self-overdisclosure. Three key provisions would address all of these issues:

Section 1. Derived Genetic Information.

Direct-to-consumer genetic testing services shall disclose only derived genetic information directly to individuals except as provided in Section 3, and shall ensure that reverse decoding of the underlying raw genetic data is not readily possible.

Section 2. Raw Genetic Information.

Raw genetic information shall be disclosed to individuals only by a qualified healthcare professional, and only after the individual has given explicit, informed, and uncoerced consent.

Section 3. Third Party Access.

Third parties may obtain access to the information only after receiving explicit, uncoerced, and fully informed authorization from the individual, and may not combine an individual's genetic information from different data sources without the originating individual's explicit, uncoerced, and fully informed consent.

The first provision protects individuals from the harms of receiving information that may later be given meaning completely unrelated to nutrigenetics, and which might have devastating effects on the individual.¹⁸¹ In addition to preventing self-overdisclosure, this provision also encourages consumers and nutrigenetic testing providers to make the most of the promise of genetic testing benefits by allowing the derived genetic information to be readily obtained and transmitted.

The second provision provides a safeguard for mitigating the problem of accurate genetic information leading to misinterpretation, by allowing individuals to obtain raw genetic information, but only through licensed genetic counselors or physicians to whom they have released the information. Because these licensed professionals can explain the risks and reasons why one may want to refrain from learning the raw genetic information, this provision provides another protection against self-overdisclosure. This requirement is a procedural safeguard to protect individual autonomy and the right to obtain personal information while also protecting the privacy right not to know unwanted information.

¹⁸¹ See *supra* note 58 and accompanying text.

Critics may urge that individuals should be able to access their own information directly without going through a licensed healthcare professional. Most people, however, have use only for the derived information, which translates the raw scientific data into actionable information, and would not feel like they were losing much, if anything, by receiving only that form of information in the first place. Furthermore, such restrictions are not novel; just as regulations require a prescription for potentially dangerous medicine, this provision prevents potentially toxic information from reaching customers without proper safeguards.

The third provision addresses the problem of harmful disclosure to third parties. In requiring informed, uncoerced consent by the originating individual, this provision prevents information from being sold or otherwise transmitted to third parties who may use the information for discriminatory or otherwise harmful purposes. Granting the individual control also provides a tremendous tool for research. Guaranteeing that third parties will not be given access without explicit consent from the individual addresses the serious impediment of insufficient study samples that many genetic researchers now face. That is, individual control assuages fears of third party disclosure that currently prevent many people from participating in research.¹⁸²

Although the double masking model and the three provisions recommended to mandate the essential functions of that model are particularly helpful in addressing the heightened concerns in the realm of nutrigenetics, they would be just as appropriate to protect other types of

¹⁸² Various legal issues remain for further consideration, such as whether an insurer can ask for the genetic info, and whether an individual can respond, without negative ramifications, that no genetic information was received, or whether genetic information is discoverable in civil or criminal cases. The GINA sets up important provisions on genetic nondiscrimination that speak to this issue. The appropriate standards and what counts in determining the quality of genetic tests present further issues. On this front, the GPMA contains important provisions seeking to enhance and ensure that the problem of inaccurate information is obviated. Finally, although I proceed on the assumption that the permanence of genetic information warrants special protections, the debate continues. The issue of whether genetic information implicates privacy or property rights also remains in dispute. As long as these questions remain unresolved, the double-masking system will safeguard information that never expires and will likely only provide more deeply personal information as new genetic discoveries are made.

genetic information. Whereas the first two provisions, on derived and raw genetic information, are arguably more important for the commercial context of nutrigenetics than the healthcare context of pathologic genetic testing, the third provision—dealing with third party access—would be particularly helpful in safeguarding all genetic information. Requiring explicit, uncoerced, informed consent by the originating individual before disclosing genetic information to third parties would avoid discrimination concerns while also providing assurances that would encourage individuals to participate in important genetic research, thereby maximizing the public investment in the Human Genome Project.

CONCLUSION

Previous proposals regarding general genetic information protection identified many of the problems that also arise in the context of nutrigenetics. Yet the contextual change from a doctor-patient interaction to a consumer-business exchange places new dimensions on, and heightened urgency to, information problems. In particular, the changed context heightens accurate information problems of misinterpretation and discrimination, which are only exacerbated by the exponentially larger number of genetic variants being tested to provide nutrigenetic recommendations. The current regulations are patchy and insufficient to provide adequate safeguards.

Though previous proposals have sought to address this inadequate system, these proposals not only fail to consider nutrigenetic—or any other nonpathologic genetic—testing, they also fail to protect individual autonomy. In doing so, these proposals fail to recognize that the positive effects of ensuring individual autonomy over genetic information will likely outweigh the drawbacks to research, because it eliminates the greatest impediment to recruiting research subjects. Previous proposals also largely focus solely on discrimination, and fail to

address issues of self-overdisclosure. The double-masking proposal, by contrast, balances the right of control by the individual with the need to protect the individual from adverse effects of unwanted or unrequested information, while also creating a regulatory environment that alleviates fears and thereby encourages participation in research.

Whether or not the legislation covers all genetic testing, or just addresses the particularly critical area of nutrigenetic testing, federal legislation must close the large gaps that currently exist by requiring testing providers to implement procedures that incorporate the essential features of a double-masking model—protection against self-overdisclosure, harmful disclosure to third parties, and misinterpretation. A uniform federal law will obviate disparate treatment of genetic information and different protections regarding genetic information accessed without individuals' consent. Without such a uniform law, there remains significant room for abuses and nutrigenetic information remains a significant risk. Enacting the suggested provisions focusing on derived genetic information, raw genetic information, and third-party access will allow nutrigenetic testing to provide countless benefits to individuals and society.