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ARTICLES

THE POTENTIAL IMPACT OF GENETIC SEQUENCING ON THE AMERICAN HEALTH INSURANCE SYSTEM

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I. INTRODUCTION

The ability to sequence individual human genomes holds great promise for a better understanding of disease pathophysiology and susceptibility to disease.¹ One hope is that with an increased understanding of how genetic differences contribute to disease susceptibility, we will be able to identify those individuals at greatest risk. This ability to identify and treat disease at an earlier stage has important implications with respect to the manner in which health insurance delivery can be improved.

With this newly harnessed technology comes enormous responsibility. There is currently a climate of great apprehension that the information contained in the human genome and deciphered by the Human Genome Project (HGP) will be used for ill.² Many fear that the law will be slow to catch up to the science.³

Part II considers the design and implementation of a model for health insurance in which policies are customized to policyholders based on their genetic predisposition to a series of diseases. This model is based on the well established framework of traditional life and health insurance policies. Specifically, it is reliant on the advantages of distributed risks among a population of insured individuals.

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1. 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, 2 (2002); see also Natalie E. Zindorf, Discrimination in the 21st Century: Protecting the Privacy of Genetic Information in Employment and Insurance, 36 TULSA L.J. 703, 703 (2001); NAT'L HUM. GENOME RES. INST. (NIH), DIV. EXTRAMURAL RES., Introduction to the Human Genome Project, at <http://www.genome.gov/page.cfm?pageID=10001772>.

2. Dorothy C. Wertz, *Society and the Not-So-New Genetics: What are We Afraid of? Some Future Predictions from a Social Scientist*, 13 J. CONTEMP. HEALTH L. & POL'Y 299, 300 (1997).

3. See Zindorf, *supra* note 1, at 703.

Although it may not be practical to implement such a model today, it will become increasingly possible to do so as (1) deoxyribonucleic acid (DNA) sequencing technology improves, and (2) enough data is accumulated to accurately assign risk based on genetic polymorphisms. This genetic model has the potential advantage of maximizing profits and minimizing costs as compared to the traditional health insurance model by identifying at risk people early.⁴

Part III then presents a brief survey of the current state of the law. Both the federal and state regulatory responses to genetic advancements have been slow and inadequate. The common law appears even less suited to properly deal with potential problems of discrimination and abuse. All of the legislative and common law solutions are predicated upon the notion that an actual problem has been identified and substantiated, an idea that has been called into question by some authors.⁵

Whatever the ultimate application of genomic sequencing, Part IV offers a brief discussion of the security and privacy aspects that will need to be part of the calculus. Part V concludes with the observation that while this model has theoretical promise, disciplines from diverse sections of society will need to work together to realize the potential for advancement.

II. DESIGN AND IMPLEMENTATION OF A GENETIC SEQUENCING MODEL

A. A Brief History of DNA Sequencing

DNA is a polymer that consists of four different monomers or bases.⁶ The order in which these monomers appear denotes their sequence.⁷ Avery, MacLeod and McCarthy demonstrated in 1944 that DNA was the genetic material comprising all organisms.⁸ Since then, efforts have been made to determine the sequence of a given piece of DNA. Various tedious methods were in place when Maxam and Gilbert described a chemical technique for sequencing DNA in 1977.⁹ This method supplanted previous techniques, and despite its limitations, was

4. See generally Roberta M. Berry, *The Human Genome Project and the End of Insurance*, 7 U. FLA. J.L. & PUB. POL'Y 205, 231-33 (1996).

5. Mark A. Hall, *Legal Rules and Industry Norms: The Impact of Laws Restricting Health Insurers' Use of Genetic Information*, 40 JURIMETRICS J. 93, 98-99 (Fall 1999).

6. Charles Vorndran & Robert L. Florence, *Bioinformatics: Patenting the Bridge Between Information Technology and the Life Sciences*, 42 IDEA 93, 96 (2002).

7. *Id.*

8. Maclyn McCarty, *Discovering Genes are Made of DNA*, available at <http://dx.doi.org/10.1038/nature01398> (last visited May 19, 2003).

9. See generally Allan M. Maxam & Walter Gilbert, *A New Method for Sequencing DNA*, 74 PROC. NAT'L ACAD. SCI. 560 (1977).

beginning to enjoy widespread use when a biological method was introduced later that year by two-time Nobel Laureate Frederick Sanger.¹⁰

Sanger's method can be likened to determining the order of playing cards in a shuffled deck. Consider a large group of individuals who are playing cards. Each player is handed an identically shuffled deck and told to "cut the cards," making note of where they cut the deck and which card was present at that position. No individual player has enough information to determine the order of all of the cards in the deck, but by sharing information, they can infer the order of the cards in the deck. So it is with Sanger sequencing wherein one measures the length of a DNA fragment and the identity of the base at one end.¹¹ When enough fragments have been analyzed, the sequence of the starting material from which the fragments are derived can be determined.

Sanger's method has undergone a number of improvements since its inception and it is the technique used today in modern DNA sequencing instruments.¹² The present instruments can simultaneously determine the sequence of 1,000 contiguous bases of DNA in several hundred samples.¹³ By way of comparison, the human genome consists of approximately three billion bases.¹⁴ These instruments, despite the impressive speed with which they operate cannot resolve billions of contiguous bases and fall short in their ability to sequence a human genome.

A conceptual breakthrough was provided by Craig Venter and Nobel Laureate Hamilton Smith. They proposed what became known as the "shotgun" sequencing approach wherein an entire genome is broken into small fragments.¹⁵ Each of these fragments is sequenced by Sanger's method with automated instrumentation.¹⁶ Then, with the help of a computer, the sequences are re-assembled to construct the original genome sequence.¹⁷ This approach can be likened to randomly fragmenting the alphabet into numerous three letter fragments.

10. See generally Frederick Sanger et al., *DNA Sequencing with Chain-terminating Inhibitors*, 74 PROC. NAT'L ACAD. SCI. 5463 (1977).

11. Brian Huseman, *Taylor v. State, Rule 706, and the DNA Database: Future Directions in DNA Evidence*, 22 OKLA. CITY U. L. REV. 397, 409 (1997).

12. Automated instruments that measure fragment length and base identity have been developed. Additionally, improvements in instrumentation account most significantly for the current state of the art. Lloyd M. Smith, *Product Options Increase in DNA Sequencing Arena*, at http://www.the-scientist.com/yr1988/jul/tools_p23_880725.html.

13. OAK RIDGE NAT'L LABORATORY, DEP'T OF ENERGY, *Overview of the Human Genome Project*, § 1 (1997), at http://www.ornl.gov/TechResources/Human_Genome/publicat/miscpubs/jason/backgrd.html.

14. Vorndran & Florence, *supra* note 6, at 97.

15. See generally J. Craig Venter et al., *Shotgun Sequencing*, 280 SCI. 1540, 1540-42 (1998).

16. Niva Elkin-Koren, *Of Scientific Claims and Proprietary Rights: Lessons from the Dead Sea Scrolls Case*, 38 HOUS. L. REV. 445, 447 (2001).

17. *Id.*

Because each fragment possesses some overlap with another fragment, one can order the individual fragments so as to deduce the sequence of the starting material (e.g., the alphabet).

The shotgun approach was first applied to microbial genomes and subsequently the human genome by Craig Venter and colleagues at Celera Genomics and by the NIH sequencing consortium team led by director Francis S. Collins.¹⁸ The outcome of these efforts was an announcement by then President Clinton on June 26, 2000, that the draft sequence of the human genome had been determined.¹⁹

It is currently impractical to sequence the genomes of several individuals using the shotgun approach because of the time and costs incurred. It is speculated that in order for individual genome sequencing to become common, it must cost less than 1,000 dollars per genome and be completed in less than one week.²⁰ This goal led to the development of a number of new sequencing technologies that differ from Sanger sequencing.²¹ These new methods promise to both increase the throughput and decrease the size of sequencing instrumentation. There is no Moore's law²² equivalent for DNA sequencing speed or power. However, if the past is any predictor, we can expect that in ten to fifteen years it will become practical to sequence individual human genomes.

B. The Traditional Insurance Model

Life insurance by its nature, distributes risk across a population. Although some individuals will pay far less in premiums than the disbursement to their estate, *on average* people will pay more in premiums than the value of their policy.²³ This is how insurers profit. How can this model of life insurance be applied to health insurance?

Consider a large population of individuals who wish to purchase health insurance. Further, assume that there are 100 diseases that account for the majority

18. Michael D. Lemonick, *Gene Mapper: The Bad Boy of Science has Jump-Started a Biological Revolution*, TIME MAGAZINE, *1 (2000), <http://www.time.com/time/poy2000/mag/venter.html>.

19. *Id.*

20. See generally Mark D. Uehling, *Wanted: The \$1,000 Genome*, BIO-IT WORLD NEWS (2002), http://www.bio-itworld.com/news/111202_report1516.html.

21. *Id.*

22. The observation made, that the number of transistors per square inch on integrated circuits had doubled every year since the integrated circuit was invented in 1965 by Gordon Moore, co-founder of Intel. Moore predicted that this trend would continue for the foreseeable future. In subsequent years, the pace slowed down a bit, but data density has doubled approximately every eighteen months, and this is the current definition of Moore's Law, which Moore himself has blessed. Most experts, including Moore himself, expect Moore's Law to hold for at least another two decades.

23. See Kyle D. Logue, *The Current Life Insurance Crisis: How the Law Should Respond*, 32 CUMB. L. REV. 1, 9-10 (2002).

of health care costs and that one's likelihood of developing each of these diseases can be accurately estimated by some combination of a lifestyle questionnaire and genetic testing. Currently, insurance companies develop questionnaires that attempt to identify those at higher or lower risk for any of the 100 diseases based on physical or behavioral parameters and then assign premium payments accordingly. One might, for example, inquire about smoking history, height, weight and family history (a precursor to genetic analysis). They may also include tests such as cholesterol level, blood pressure and HIV infectivity status. This is a relatively crude means of assigning risk compared to genetic testing but it can be effective for certain diseases. When combined with genetic testing, it can be much more predictive.

An insurer might view the risk associated with insuring any large group of individuals as consisting of intrinsic and extrinsic factors. Intrinsic factors might include risk profiles that are overrepresented in the population being insured. For example, a population of Ashkenazi Jews might be at higher risk for Tay-Sachs disease.²⁴ No matter how many individuals in this population are insured, the risk for Tay-Sachs disease will still be higher than in the African-American population. Extrinsic risk refers to environmental factors, including trauma and infectious disease, which occur at some frequency with a near random distribution.

The Capital Asset Pricing Model for which Markowitz, Miller, and Sharpe shared the 1990 Nobel Prize in economics, states that investors must assume more risk if they expect a greater return on their investment.²⁵ We also know that there are ways of diversifying to minimize risk. The important point from an insurer's point of view is how one can diversify their insured population to minimize the risk associated with insuring them. Intrinsic risk can be minimized by insuring a genetically diverse population. If this is not possible based on the geographic region in which an insurer operates, then another insurance company can be enlisted to co-insure the population. The co-insurer helps balance the risk by insuring individuals from a different genetic background.

Returning to the previous example, two companies may operate in geographically distinct regions where there are disproportionately high amounts of Ashkenazi Jews and African-Americans. The incidence of Tay-Sachs disease and

24. Paul J. Edelson, *The Tay-Sachs Disease Screening Program in the U.S. as a Model for the Control of Genetic Disease: An Historical View*, 7 HEALTH MATRIX: J. L. MED. 125, 126 (1997). Tay-Sachs disease is a fatal genetic disorder, occurring primarily in children, which results in progressive destruction of the central nervous system. *Id.* at 125. Symptoms develop approximately six months after birth in the form of recurrent seizures and diminishing mental function. *Id.* Over the course of five years, the infant's motor skills will gradually regress until the child becomes blind, mentally retarded, paralyzed, non-responsive, and eventually the child dies. *Id.*

25. Professor Assar Lindbeck, Presentation of the Bank of Sweden Prize in Economic Sciences in Memory of Alfred Nobel (1990), <http://www.nobel.se/economics/laureates/1990/presentation-speech.html> (last visited May 19, 2003).

Sickle Cell²⁶ disease will tend to be higher in these populations respectively.²⁷ These two companies may elect to enter into a co-insurance agreement in which the policy costs for the two populations are pooled. This prevents either insurer from paying a disproportionate number of claims that are secondary to factors intrinsic to the insured population.

Extrinsic risk can be minimized by insuring larger numbers of individuals. If the incidence of traumatic ankle fracture is 1 in 5,000 and the insured pool consists of 500 people, then the single event in the small pool of individuals can have a significant impact on costs. However, if 5,000 people are insured, the risk is distributed over an additional 4,500 premiums, thereby minimizing the likelihood that a single event will have a significant impact on the economics of the policies.

C. THE THEORETICAL IMPLEMENTATION OF GENOTYPE-GUIDED INSURANCE

1. *Most cases*

Much in the same way that life insurance companies have employed actuaries to calculate the average life span of individuals given certain physical and behavioral characteristics, rapid, whole genome sequencing may enable health insurers to calculate, with unprecedented accuracy, the average amount of health care dollars an individual will use. The association of genetic polymorphisms with disease risk cannot only predict who is most likely to develop a disease but also *when* they are most likely to develop it.

To begin, a risk multiple must be assigned to each individual in the policy group for each disease under consideration. This multiple will be one (1.0) for individuals at average risk, less than one (<1.0) for individuals at below average risk, and greater than one (>1.0) for individuals at elevated risk. The risk multiple increases with the number of genetic risk factors one possesses for a given disease. For example, if ten polymorphisms are examined to predict one's risk for colon cancer, an individual who possesses high risk sequences at four of the markers will be assigned a lower risk multiple than one who possesses seven high risk sequences.

26. Pauline T. Kim, *Genetic Discrimination, Genetic Privacy: Rethinking Employee Protections for a Brave New Workplace*, 96 NW. U. L. REV. 1497, 1513 (2002). Sickle Cell disease is caused by a mutation in the hemoglobin-Beta gene. *Id.* Abnormal hemoglobin molecules stick to one another and form long, rod-like structures which cause red blood cells to become stiff and sickle shape. *Id.* This shape causes red blood cells to pile up, causing blockages and damaging vital organs. *Id.* Individuals with Sickle Cell disease experience lung tissue damage that causes acute chest syndrome, pain episodes, and strokes. *Id.* It also causes damage to the spleen, kidneys, and liver. *See also* NIH, LEARNING ABOUT SICKLE CELL DISEASE, <http://www.genome.gov/page.cfm?pageID=10001219> (last visited May 19, 2003).

27. *See generally* Kim, *supra* note 26.

The risk multiple can then be used to assign each individual to a screening regimen for the disease under consideration. It can also be used to group individuals in a policy so that they are not all at risk for similar diseases (minimizing intrinsic risk in the process). When these screening regimens are distributed over several diseases, one may find that those individuals at risk for disease number one may not be at risk for disease number two, and *vice versa*, which further increases screening efficiency.

Screening regimens are designed with large populations in mind and they take into account overall disease incidence. Consider the American College of Gastroenterology's (ACG) recommendations for colon cancer screening.²⁸ The ACG recommends that all individuals over the age of fifty without significant family history of colon cancer receive an initial colonoscopy and then one colonoscopy every ten years thereafter.²⁹ An alternative to this regimen is annual fecal occult blood tests and sigmoidoscopy every five years.³⁰ While some individuals will be screened too intensively by this regimen and others not intensively enough, on the average, lives will be saved.

Armed with more accurate, genetic risk predictors, we can customize screening regimens to the individual thereby identifying disease at an earlier stage when it can be treated more effectively. The underlying theme is to more wisely spend each health care dollar and, in doing so, create a more efficient insurance policy that leads to better care for individual policyholders, less expensive policy premiums, and greater profits for the insurers.

Take as another example Familial Adenomatous Polyposis (FAP), a genetic disease with an incidence of approximately 1 in 8,000 that invariably results in colon cancer.³¹ Individuals with mutations in the adenomatous polyposis coli gene (APC) account for greater than 95% of FAP cases.³² Individuals with FAP develop thousands of pre-cancerous polyps beginning at sixteen years of age.³³ The treatment for FAP is prophylactic colectomy which is curative.³⁴ In certain instances, disease severity can be estimated from the nature of the individual's APC mutation. FAP is not an especially common disease but it illustrates the point

28. AM. COLL. OF GASTROENTEROLOGY, RECOMMENDATIONS FOR COLORECTAL CANCER PREVENTION, at <http://www.acg.gi.org/patientinfo/cc/patcards.htm> (last visited May 19, 2003).

29. See generally *id.*

30. *Id.* See also Hall et al., *Measuring Medical Practice Patterns: Sources of Evidence From Health Services Research*, 37 WAKE FOREST L. REV. 779, 816 (2002) (citing the 1997 American Cancer Society guidelines for appropriate colon cancer screening, which includes annual fecal occult blood testing with sigmoidoscopy every five years).

31. Cindy Solomon & Randall W. Burt, *Familial Adenomatous Polyposis*, available at <http://www.genetests.org/servlet/access?db=geneclinics&site=gt&id=8888891&key=QKovxra4E1N-e&gry=&fcn=y&fw=aAqQ&filename=/profiles/fap/index.html> (last visited May 19, 2003).

32. See generally *id.*

33. *Id.*

34. *Id.*

well that with advanced genetic knowledge, one can successfully interrupt an otherwise fatal disease process.

A clear distinction must be made between money spent on screening and profit garnered. The amount of money spent on screening by a genetic-based insurer will be no less than that spent by a traditional health insurer. In this respect, the policies are indistinguishable. The difference is that a genetic based insurer will more effectively target their screening so that disease processes are identified earlier when successful intervention is more likely. Successful early intervention is what permits a greater profit because disease is generally much less expensive to treat at an earlier stage than at a later, disseminated stage.

2. *What About Individuals at Known Low Risk?*

One might wonder why those individuals who know they are at average or below average risk for all of the diseases in question want to participate in such a system. While genetic analysis can assign relative risk, it cannot assign absolute risk. Therefore, individuals with a genetic low risk profile may in fact be at higher risk for a given disease based on their lifestyle and/or habits. In addition, when comparing these "average risk" individuals to above average risk individuals, one must be clear that the term "risk" applies only to the specific disease in question. When this analysis is extended to hundreds of different diseases, the number of individuals at average or below average risk for all of the diseases becomes exceedingly small.

3. *Unpreventable and Untreatable Diseases*

An interesting question arises when one considers a disease for which efficient genetic screening exists but no effective prevention or treatments are available. An example is Huntington's Chorea, an autosomal dominant disease, for which genetic tests of nearly 100% accuracy exist but for which no effective treatment or prevention has been identified.³⁵ If an individual tests positive for a mutated Huntington gene then they will develop the disease with nearly 100%

35. Brian R. Gin, *Genetic Discrimination: Huntingtons Disease and the Americans With Disabilities Act*, 97 COLUM. L. REV. 1406, 1414-15 (1997). Huntington's chorea, or Huntington's disease, is a genetic disease in which individuals will not develop symptoms until mid-life. *Id.* Symptoms include an extended period of dementia and loss of body control, with a destruction of memory and speech until the disease results in death. *Id.*

certainty.³⁶ The age at which individuals develop the disease can also be predicted from the Huntington gene structure.³⁷

This is an example of a disease where, because of the age of onset and the lack of treatment and prevention options, an insurer might be tempted either to exclude the insured with this mutation from purchasing a policy, or to exclude the disease in question.

4. Practical Reasons Minimizing the Likelihood of Discrimination

There may be some pecuniary and practical reasons that militate against insurance companies using genetic information to discriminate against “genetically adverse” individuals. As a threshold matter, death is an inevitable event that will likely be the end result of a disease process. Humans all begin their journey in life with a genetic slate that contains several “marks.” These marks are the polymorphisms that predispose us to certain diseases and make us less likely to develop others. It is a genetic truism that none of us start with a perfect slate. From the perspective of an insurer, failure to offer a policy to any individual with some disease predisposition effectively reduces the customer base.

One might be inclined to ask why an insurer would not simply insure the average or below average risk individuals only. If these individuals were the only ones insured, then over 99% of the health insurance buying market have not been sold a product. This is poor business strategy irrespective of what good or service is being provided. These average or below average risk individuals are worth including in a larger insurance pool to better distribute risk. As a practical matter, an approach in which only a minority of customers with average, or below average risk for all of the diseases in the screen are offered policies might well become a public relations nightmare that may generate sufficient public discontent so as to damage the company.

Furthermore, health insurance companies are quite profitable in the *absence* of genetic profiling. It seems unlikely that they would adopt a strategy that might make them more profitable on a customer-by-customer basis but reduce overall profitability by severely constricting that base. Consider also the myriad behavioral and environmental factors that contribute to one’s health. Even if an individual with a “clean slate” could be identified, that person may still amass tremendous health care costs as the result of an accident, drug or alcohol abuse, exposure to an environmental toxin, infectious agent or a poor diet.

36. *Id.*

37. Mahbubul Huq & Michael R. Hayden, *Huntington’s Disease*, *1 (1998), <http://www.genetests.org/servlet/access?db=geneclinics&site=gt&id=8888891&key=EQOhl85elPYMA&gry=&fcn=y&fw=QbCr&filename=/profiles/huntington/index.html>.

A model can be envisioned in which insurance companies are only allowed to access information on those genes which lead to a disease phenotype that can be prevented, and/or treated. A list of these genes would be maintained by the government. To be added to the list, a genetic association would have to withstand the scrutiny of a panel of scientists in much the same way that drugs are granted approval by the Food and Drug Administration (FDA). In this model, the insured population will include, at some low frequency, individuals who have untreatable, fatal diseases that have a relatively early age of onset. Because these individuals are present in the insured population at a low frequency, the cost of their treatment is effectively distributed. This approach necessitates a third party regulator of genetic information (discussed *infra*, in part IV).

III. A BRIEF SURVEY OF THE LEGAL ISSUES

A health insurance model that relies exclusively on free market competition to guard against discrimination would be naïve. In fact, society has recognized as much, as evidenced by the explosion of state and federal regulatory responses to the HGP as well as the proliferation of scholarly commentary on the subject.³⁸ Lawmakers have recognized that using a genetic sequencing model as a tool for enhanced medical underwriting has the potential to tempt insurance companies to discriminate against “risk adverse” individuals.³⁹

In the most general terms, fears about undue discrimination center around concerns that insurance companies might use genetic information to make unfair decisions about insurance coverage, premiums and exclusions.⁴⁰ The mantra goes that insurance companies, if left unchecked, would be tempted to use genetic information about asymptomatic people with genetic predispositions for disease to adversely risk stratify them. The resultant conflict between individual privacy rights and unrestricted access to genetic information raises issues such as: who should have access?; who has the right to such information?; is it a right or an interest?; and how will the information be used?⁴¹

These thorny issues, each with its attendant theoretical risks, have led to several contemporaneous debates over the most equitable way to deal with this risk. One of the most notable threshold debates is over the fundamentally different

38. See discussion *infra* Part III B.

39. Sheryl Stolberg, *Insurance Falls Prey to Genetic Bias*, L.A. TIMES, Mar. 27, 1994, available at 1994 WL 2148771.

40. See Geetter, *supra* note 1, at 2.

41. Nathalie Smith, *The Right to Genetic Privacy? Are We Unlocking the Secrets of the Genome Only to Risk Insurance and Employment Discrimination?*, 2000 UTAH L. REV. 705, 707 (2000).

nature of genetic information. This difference has led many notable scholars in the field of genomics to coin the phrase “genetic exceptionalism.”⁴²

A. Exceptionalism

The corollary to this “exceptional” genetic information is that this information is deserving of its own set of rules.⁴³ However, as at least one critic has noted, “this argument responds well to public fears and tugs at the collective apprehension...the theory is fundamentally flawed and shortsighted.”⁴⁴ Specifically, critics argue that genetic information is no different than other classes of medical information.⁴⁵

They further contend that genetics legislation, though well intentioned, is both over-inclusive and under-inclusive.⁴⁶ The real problem is the risk-taking inherent in medical underwriting, a problem not just specific to genomics but the entire insurance industry process.⁴⁷ The thrust of any new legislation should be aimed at revamping the laws that inadequately protect the more general notions of medical privacy.⁴⁸ Some authors believe that, in the area of insurance, genetic information properly lies in the broader category of confidentiality of the medical record.⁴⁹

B. An Overview of Current Legislative Protections

With continuing advances in genomic technology, state and federal policymakers have responded by addressing the potential for abuse with several rapid generations of genetic legislation.⁵⁰ Most of these laws currently embody this concept of “genetic exceptionalism.”⁵¹

42. See Geetter, *supra* note 1, at 56-57 (“Genetic exceptionalism is the theory that genetic information departs sufficiently radically from other types of genetic information so that the new rules are necessary to govern the collection and dissemination of genetic information.”) (citing the N.Y. Task Force on Life & the Law, *Genetic Testing and Screening in the Age of Genomic Medicine* 97 (2000)).

43. See Geetter, *supra* note 1, at 57.

44. *Id.*

45. Natalie E. Zindorf, *Discrimination in the 21st Century: Protecting the Privacy of Genetic Information in Employment and Insurance*, 36 TULSA L.J. 703, 724 (2001).

46. Sonia M. Suter, *The Allure and Peril of Genetics Exceptionalism: Do We Need Special Genetics Legislation?*, 79 WASH. U.L.Q. 669, 672 (2001). Not all genetic information requires protective legislation, which makes genetics legislation over-inclusive. At the same time, a great deal of other medical information shares many of the features of genetic information that have inspired legislation, which makes it dramatically under-inclusive. *Id.* at 671.

47. See generally Lawrence O. Gostin & James G. Hodge, Jr., *Genetic Privacy and The Law: An End to Genetics Exceptionalism*, 40 JURIMETRICS J. 21 (1999).

48. See Geetter, *supra* note 1, at 2-3.

49. See Zindorff, *supra* note 45, at 724.

50. See Smith, *supra* note 41, at 727-33.

51. See Suter, *supra* note 46, at 727-28.

1. Federal Law

The federal government's first indirect attempt to regulate this area came with the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996.⁵² HIPAA applies primarily to governmental insurance plans (e.g., Medicare and Medicaid), and large and small group health plans,⁵³ but not to the individual health insurance market.⁵⁴

Many of the relevant HIPAA provisions prohibit the covered companies from using either genetic test results or, more broadly, genetic information when making decisions regarding eligibility, premium rate setting and exclusions.⁵⁵ The net effect of these sorts of provisions is to try and limit or eliminate the ability of the insurance companies to use genetic information as a tool for medical underwriting.⁵⁶

Not surprisingly, insurance companies feel that HIPAA's current proscriptions are more than enough to discourage the industry from using genetic information in an unfair manner. They claim that subsequent regulation will overly burden the industry practice of risk selection and add to the already existing confusion.⁵⁷

Critics charge that the federal law allows too many gaps that insurance companies could potentially stride through.⁵⁸ Most importantly, private consumers seeking health insurance in the individual market are not covered.⁵⁹ Another deficiency relates to the possibility for the health insurance company to "pass down" discriminatory practice and thus indirectly obviate HIPAA's protective mandates.⁶⁰ A large insurance carrier can "pass down" discriminatory practices by offering incentive programs to employers to cover low risk individuals, which

52. See Smith, *supra* note 41, at 727-31.

53. 15 U.S.C. §§ 1011-12 (2000).

54. See *id.*

55. See Smith, *supra* note 41, at 729.

56. See Geetter, *supra* note 1, at 47-48.

57. See generally Carol Lee, *Creating A Genetic Underclass: The Potential for Genetic Discrimination by the Health Insurance Industry*, 13 PACE L. REV. 189 (1993).

58. See generally Jennifer Krumm, *Genetic Discrimination: Why Congress Must Ban Genetic Testing in the Workplace*, 23 J. LEGAL MED. 491 (2002), WL 23 JLEGMD 491; see also, e.g., Lisa M. Caperna & Robert A. Curley, Jr., *The Brave New World is Here: Privacy Issues and the Human Genome Project*, 70 DEF. COUNS. J. 22 (2003), WL 70 DEFCEJ 22; Melody Simmons, *A Weekly Checkup on Health Care Costs and Coverage: Managed Care and Genetic Tests*, WASH. POST, July 2, 2002, available at 2002 WL 22785226.

59. 29 U.S.C. § 1182(a) (2000). The new security regulations that became effective 4/21/2003, do little to narrow the regulatory gap. Rather, they pertain more generally to refining some of the security provisions with respect to confidentiality of the electronic medical record. See generally 68 Fed. Reg. (<http://www.gpoaccess.gov/fr/index.html>) (last visited May 19, 2003).

60. See Smith, *supra* note 41, at 731.

includes those without genetic predispositions to disease [under the guise of so-called “health promotion and disease prevention company policies”].⁶¹

Yet another regulatory gap exists as a result of certain HIPAA provisions that allow insurance companies to define the term “eligible individual.”⁶² While other parts of the law try and prohibit outright eligibility exclusions,⁶³ companies are not restricted in the *amount* of insurance that they have to provide individuals with genetic predispositions.⁶⁴

2. State Laws

There are currently some 41 states with laws prohibiting or limiting companies from using genetic information to make coverage decisions.⁶⁵ Many of these states impose an outright ban on the use of genetic information all together.⁶⁶ A few states make a distinction between genetic information and genetic testing.⁶⁷

Those states with statutes that specifically name permitted uses of genetic information are thought to be deficient in allowing companies to circumvent the law. For example, states might specifically ban limiting coverage or adjusting benefits but fail to address topics such as using genetic information to cover premiums.⁶⁸ State statutes also suffer from the same incompleteness of the federal statute in that many do not cover the private sector of the insurance market.⁶⁹

Another perceived problem with the states’ response to this issue has been with state regulation of self insured group plans. These plans are actually considered employee benefits and as such, are governed by the Employment Retirement Income Security Act (ERISA).⁷⁰ Since ERISA pre-empts state

61. *Id.*

62. *Id.*

63. *Id.* at 731-32 (citing another HIPAA provision that notes that insurers are not limited to the *amount* of insurance to be provided. *See* 29 U.S.C. § 1182(a)(2) (2000)).

64. *Id.*

65. NIH, *State Legislation: Genetic Information and Health Insurance*, <http://www.genome.gov/10002338> (last visited May 19, 2003) [hereinafter *State Legislation*].

66. *See generally* Hall, *supra* note 5.

67. *See generally* State Legislation, *supra* note 65. For example, Alabama and Arizona define genetic test whereas California and Colorado more broadly define genetic information. Insurance companies tend to prefer those states with a more narrow proscription against testing, allowing them to still potentially use genetic information. *Id.*

68. *See generally* William F. Mullholland & Ami S. Jaeger, *Genetic Privacy and Discrimination: A Survey of State Legislation*, 39 JURIMETRICS J. 317 (1999).

69. *See generally* Gostin & Hodges Jr., *supra* note 47.

70. ERISA, 29 U.S.C. §§ 1101-1461 (2000).

regulation of employee benefits including health insurance,⁷¹ large-self insured plans may opt to switch to ERISA governed plans to escape state regulation.⁷²

3. *The Courts*

While some writers feel that the courts could handle potential disputes generated in this area,⁷³ most commentators feel that the common law would be too slow to respond to a rapidly changing field and that the courts do not possess adequate technical expertise to handle these types of cases.⁷⁴ Proponents of a legislative solution point to the ability of the legislative branch to delegate to the agencies the power and authority to generate procedures and criteria to address problems as they arise.⁷⁵ The courts could then refine the subtleties of these issues through case law.⁷⁶

C. Has there been any Actual Discrimination?

For some in society, it seems the fear of discrimination is proportional to the speed of genetic sequencing. But is this fear borne out by any empirical evidence? Often times, it seems like technology outpaces the law and the law must “catch up.” In the area of genomics, however, one could argue the opposite is true. While the argument is not a literal one, Shakespeare might have been tempted to wonder if all this sound and fury was much ado about not much.⁷⁷

There have been some claims of genetic discrimination in the area of health insurance although they have been more frequent in the employment sector.⁷⁸

71. See generally *FMC Corp. v. Holiday*, 498 U.S. 52 (2000).

72. Geetter, *supra* note 1, at 46-47, citing Amy Darby, *The Individual, Health Hazardous Lifestyles, Disease and Liability*, 2 DEPAUL J. HEALTH CARE L. 787, 796 (1999) (noting the 20% increase in self-insured plans between 1982 and 1986).

73. See generally Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV. 1037 (1993).

74. See generally Michael M.J. Lin, *Conferring a Federal Property Right in Genetic Material: Stepping into the Future with the Genetic Privacy Act*, 22 AM. J.L. & MED. 109 (1996).

75. Jack F. Williams, *A Regulatory Model for Genetic Testing in Employment*, 40 OKLA. L. REV. 181 (1987).

76. See generally Lin, *supra* note 74.

77. See *Much Ado About Nothing: An Analysis of the Play by Shakespeare*, available at <http://www.theatrehistory.com/british/muchado001.html> (last visited May 19, 2003), originally published in 13 THE DRAMA: ITS HISTORY, LITERATURE AND INFLUENCE ON CIVILIZATION, 167-70 (Alfred Bates ed., London: Historical Pub. Co. 1906).

78. NIH, *Genetic Information and Health Insurance Enacted Legislation*, http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/insure.htm (last visited May 19, 2003).

Since screening is so new and many people avoid it for fear of discrimination, the evidence that it occurs has been largely anecdotal.⁷⁹

For example, stories about parents who are unable to obtain insurance for their children because of a primary hereditary defect⁸⁰ and insurance companies threatening to cancel insurance based on the results of prenatal testing are surfacing with greater frequency.⁸¹ Some commentators believe that the use of genetic information in medical underwriting is occurring.⁸²

The health insurance industry claims that insurers are not conducting genetic testing on individuals as a prerequisite for coverage.⁸³ Insurers argue that current state and federal regulations protecting genetic information makes using genetic information as a prerequisite for coverage unlikely.⁸⁴ This would seem to be supported by an often quoted empiric study done by Professor Mark Hall who found that actual cases of genetic discrimination are at present, very infrequent.⁸⁵

To assess the impact of genetic discrimination laws, Professor Hall conducted a study in seven states, using in-depth questionnaires and extensive interviews with representatives from most of the major health insurers, most of the major medical centers that do clinical genetics work, and insurance agents specializing in health insurance.⁸⁶ He found, from several independent sources, that genetic discrimination by insurers was very low or nonexistent in states with and without these laws, both before the laws were enacted and afterwards.⁸⁷

Insurance regulators, for example, were completely puzzled why this was an issue of public concern. Many complained that “this was a stupid issue” . . . that they felt “frustrated” by having to spend \$250,000 on a task force looking for evidence of genetic discrimination, without finding a single case.⁸⁸ Hall suggests

79. See generally *Genetic Information in the Workplace: Hearing Before the House Comm. on Health, Education, Labor and Pensions*, 106th Cong. (2000) (statement of Francis S. Collins, Director, NIH), available at 2000 WL 1115522.

80. See Catherine Arnst, *Should Bad Genes Rob You of Life or Health Insurance? Rapid Progress in Identifying Genes That Pre-dispose People to Hereditary Diseases Is Starting to Raise a Major Ethical Dilemma*, TORONTO STAR SUNDAY EDITION, Sept. 15, 1991, available at LEXIS, News Group File.

81. See generally, Natalie Anne Stepanuk, *Genetic Information and Third Party Access to Information: New Jersey's Pioneering Legislation as a Model for Federal Privacy Protection of Genetic Information*, 47 CATH. U. L. REV. 1118 (1998).

82. See generally Jon Beckwith & Joseph S. Alper, *Reconsidering Genetic Antidiscrimination Legislation*, 26 J.L. MED. & ETHICS 205 (1998).

83. Press Release, Health Insurance Association of America, *Health Insurance and Genetic Information: Just the Facts*, Please (June 21, 1998), available at <http://www.hiaa.org/search/content.cfm?ContentID=570> (last visited May 19, 2003).

84. See Smith, *supra* note 41, at 724.

85. See Hall, *supra* note 5, at 98.

86. *Id.* at 96.

87. *Id.* at 98.

88. *Id.* at 103.

that these laws, while not currently needed, might help serve as a deterrent for insurance companies and thereby convince the industry that it would not be appropriate or legitimate to use such information.⁸⁹

IV. SECURITY/CONFIDENTIALITY ISSUES

An insurance model based on genetic risk assessment such as the one profiled above, requires that extensive measures be taken to ensure the security and confidentiality of the genetic information obtained. It is likely that from the insured's point of view, all that will be required is a blood sample. However, what happens from the time the sample is obtained to the time a policy is offered is considerably more complicated.

High-throughput DNA sequencing technologies of the future will likely rely on an approach wherein all DNA sequence information is obtained simultaneously. In this setting, it becomes impractical to only sequence certain parts of an individual's genome or only specific genes. Because the entire genome will be sequenced, it is of practical importance that an individual be able to "block" access to certain genetic information. A second practical concern is whether or not sequence information may be obtained locally or off-site. This will depend to a large extent on whether or not the inventors of high-throughput sequencing technology plan to be a service provider or a machine and reagent provider. If the technology exists but the inventors are unwilling to sell the instruments, exploiting sequencing technology could prove problematic to implement.

Whether the DNA sequence information is obtained at the insurance company or at a contractor's facility, this is the first link in a chain of persons and corporations who have access to the insured's genetic information. Each option has its theoretical benefits and liabilities. If the sequence information is obtained locally at the insurance company, then the number of persons with access to the information is reduced because a contractor is not involved. However, by obtaining the sequence information itself, the insurance company will have access to information that a prospective policy holder may not want them to have. Employing a third-party contractor to obtain the sequence information can potentially guarantee that the insurance company only has access to certain limited information, but the tradeoff is it increases the number of individuals with access to the information.

The following can serve as a useful analogy for securing genetic information. Suppose Alice wants to send a package to Bob. This package contains a compact disc (CD) that contains an encrypted form of Bob's genetic information. Alice encloses the disc in a box, places a lock on it and mails it to Bob. Bob, upon

89. *Id.* at 115, 120.

receiving the package, places a second lock of his choosing on the box and mails it back to Alice. Alice removes the lock she originally placed on the box and once again mails it to Bob. Finally, Bob can remove the lock he originally applied to the box and access the CD. The advantage of this scheme is that Alice and Bob can securely exchange information without knowing the combination of each other's locks.

Let us now translate this analogy to our question of securing genetic information. An individual may approach an insurance provider or providers and request a policy customized to his genetic profile. The insurers request that the individual have his genome sequenced so that the information may be used to customize a policy. The individual may approach any one of a number of DNA sequencing service providers and request that his genome be sequenced. He can do this anonymously by purchasing a kit that contains a lancet for obtaining a blood sample, a collection device such as paper card, an envelope to mail the sample, and a "card" that contains a unique identifying number that corresponds to the envelope.

The individual encloses a non-identifying form of payment and sends off the sample. After his genome has been sequenced, the information is encrypted, and mailed to a local post-office. The location of this post-office is specified by the individual but is not written on the card to prevent an unauthorized third-party from intercepting the package. The individual then picks up the information by displaying the appropriate "card."

In this setting, the DNA sequence is obtained anonymously. The sequencing service provider may perform any one of a number of statistical surveys on the data obtained from multiple individuals however they will not be able to directly identify them.⁹⁰ The individual, now in possession of an encrypted, electronic copy of the DNA sequence of his genome returns it to the insurance company. In addition to his entire genome sequence, the individual is provided with a separate disk that contains unencrypted sequence information for those genes known to confer susceptibility to a given disease. This list of genes will be the same as those approved for screening purposes by the FDA.⁹¹

If the individual must renew his policy or switch to another insurer, then he may need to provide additional genetic information. For example, more genes may have been approved for screening purposes by the FDA. Because the individual

90. This last statement is not entirely true in that it may be possible to determine a number of an individual's features based on their DNA sequence information. Traits that could be determined include race, hair and eye color, blood type and possibly facial features.

91. Although having a hard-copy is nice, there is no particular reason why this entire transaction could not be performed electronically to ensure the anonymity of the individual. For example, the individual could access his information by providing a code that was supplied in the blood draw kit and then simply download the information.

has a copy of his entire genome sequence on disc, he need only go to the sequencing company's web page, enter the security code he was supplied with at the time of initial sequencing and click "update." This will un-encrypt those genes that have been added to the list of approved genes since his last update. A second blood draw and DNA sequencing payment are obviated yet the identity of the individual remains confidential.

The insurance company now requests that he provide sequence information pertaining to a collection of genes that are important for determining the specifics of a policy. Only information on those genes that are associated with diseases deemed amenable to prevention and or treatment may be requested. The disc containing sequence information pertaining to the aforementioned subset of genes is provided to the insurance company. This guarantees that the insurance company only accesses the relevant information.

V. CONCLUSION

The technology required to effect rapid, whole genome sequencing will likely become available within the next decade. There are many potential uses of this technology. A model for health insurance in which screening guidelines are customized to an individual policy holder is presented. This model strives to simultaneously deliver better health care to the insured and increase profits for the insurer. The model presented posits that insurers may have practical reasons to refrain from using genetic information in a discriminatory manner.

Even imputing the worst motives to insurance companies, there has been an ongoing debate as to whether a special branch of "exceptionalism" law is needed to address the potential for abuse. Whether there have even been serious instances of actual discrimination is a matter in which reasonable minds have differed. Nonetheless, federal and state responses have been expansive but there remain serious open questions about the adequacy of the responses.

Finally, insurance models that use genetic information will require excellent security to ensure that genetic information remains private. An anonymous system in which DNA sequence information is gathered by a third party will be required in order to safeguard the confidentiality of this genetic information.

Sequencing of the human genome is a technology whose time has "almost" arrived. This model of using sequencing to design a health insurance system has tremendous potential. Scientists and informatics specialists will have to work closely with policymakers to guide this technology through uncharted waters. Former Vice President Al Gore, speaking before the National Academy of Science,

may have captured this idea best when he said, “[s]cience and society must always advance together, for neither can ever truly advance alone”.⁹²

92. Press Release, Office of the Vice President, Vice President Calls for Legislation on Genetic Discrimination (Jan. 20, 1998), *available at* 1998 WL 7378521.