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by
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Introduction

In the waiting room of an obstetrician's office, Lisa and Rick, a couple in their late 30's, anxiously await the results of an amniocentesis test.[1] Lisa is in the 16th week of what may be her last viable pregnancy. She previously postponed having children in favor of establishing a career for herself and developing a healthy relationship with her second husband. The procedure she awaits requires extraction of a small amount of amniotic fluid, a clear liquid teeming with fetal cells that may be analyzed at a lab.[2] Lisa's test results are the fruit of a powerful prenatal diagnostic technique that can, with a high degree of reliability, ascertain the sex of the child and indicate whether the fetus might be afflicted with one of over 80 genetically based metabolic disorders.[3] While their particular amniocentesis results may only test for three or four genetic diseases, Lisa and Rick may choose to seek limited intrauterine treatment or

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1. *See generally American Academy of Pediatrics – Committee on Genetics, Prenatal Diagnosis for Pediatricians*, 84 PEDIATRICS 741 (1989).

2. *Id.* at 742.

3. *Id.* at 741-742.

termination of the pregnancy based on this information. Although this medical technology was developed and first applied less than forty years ago, it is already considered a common element of medical practice.[4]

As the above vignette suggests, the fruits of genetic research have enabled doctors to estimate childrens' chances for developing hundreds of types of diseases, some of them fatal. Other technologies include new identification techniques (witness the use of polymerase chain reaction techniques during the O.J. Simpson trial), medical diagnostics, limited therapies, and even the development of new forms of life through genetic recombination. With these unprecedented and powerful new possibilities, it is clear that the legal dimensions of genetic research and related technologies must be carefully examined.

This note seeks to analyze the social and legal issues that result from the research, development, and deployment of genetic information technologies (hereinafter "GITs") that provide us with increasingly more information about our genetic make-up. In part one of this note, I develop a general treatment of the issues unique to GITs. In part two, I trace policy concerns and outline a paradigm of improved education, discussion, and law that I believe must ultimately contribute towards more democratic lawmaking in genetic research and technology development. As Robert Proctor, a scholar studying the politics of cancer, announces, "ours has been heralded—perhaps with some hyperbole—as the Age of Genes."[5]

I. General Overview of Major Issues

The majority of current genetic research applications consist of diagnostic techniques that can provide detailed information about an individual's genetic makeup. However, because the successful identification of the "gene for" a condition is rarely concurrent with the development of a treatment for that condition, most techniques derived from genetic research are extremely limited in a therapeutic capacity.[6] There are only a dozen or so active gene therapy protocols worldwide, and experts agree that use of such is limited to relatively rare disorders, is very expensive, and requires special expertise.[7]

4. For a discussion of alternative genetic diagnostic tests such as chorionic villi sampling (CVS) and maternal serum alpha-fetoprotein sampling, see David T. Morris, *Cost Containment and Reproductive Autonomy: Prenatal Genetic Screening and the American Health Security Act of 1993*, 20 AM. J. L. & MED. 295, 296-97 (1994).

5. ROBERT V. PROCTOR, CANCER WARS: HOW POLITICS SHAPES WHAT WE KNOW AND DON'T KNOW ABOUT CANCER 217 (1995).

6. *See* Denise K. Casey, *What Can the New Gene Tests Tell Us?*, JUDGES' J., Summer 1997,at 14, 15.

7. Benjamin P. Sachs & Bruce Korf, *The Human Genome Project: Implications for*

Furthermore, the most reliable diagnoses returned by genetic testing often indicate the need for prophylactic coloectomy, ovariectomy, or mastectomy.[8] In some cases, genetic testing can only reveal the likelihood of an incurable condition (e.g., Huntington's disease).[9]

This scarcity of successful genetic treatments is known as the "therapeutic gap."[10] Thus, the primary use of genetic research has been as an information technology. In the near future, it is likely that we will continue to develop a science that will provide more precise indicators of our genetic fate, but do little to enhance our capability to control that trajectory. Even without the ability to directly intervene in the genetic course of human beings, there are still many legal implications to be discussed.

A. Genetic Information and the Specter of Eugenics

The modern collection and organization of genetic information in the United States is based in the National Center for Human Genome Research, established by the National Institutes of Health (NIH) on October 1, 1989.[11] The Human Genome Initiative (HGI) was approved shortly afterward by Congress in 1990.[12] Today, HGI is jointly implemented by the NIH and Department of Education.[13] Its goal is to map and sequence the entire human genome, an undertaking projected to require fifteen years for completion.[14] The ultimate goal of the project is to characterize all of the more than 50,000 human genes for further biological study.[15] James D. Watson, Ph.D., co-discoverer of the DNA double helix and former director of the Human Genome Initiative, believes the HGI contributes to the "public good in the best sense" by helping to "assist biomedical researchers in their assault on disease."[16] Benjamin Sachs, an obstetrician studying the implications of the HGI, predicts that the "Genome Project will have a greater impact on medical practice than any previous contribution to medical research."[17] At the time of this writing, more than 3,000 medical disorders resulting from a single

the Practicing Obstetrician, 81 OBSTETRICS AND GYNECOLOGY 458, 460 (1993).

8. *See generally id.*

9. *See generally* Eric T. Juengst, *The Ethics of Prediction: Genetic Risk and the Physician—Patient Relationship*, 1 GENOME SCI. & TECH. 30 (1995).

10. *See id.*

11. *See* Sachs & Korf, *supra* note 7, at 458.

12. *See id.*

13. *Human Genome Project Information, available at* http://www.ornl.gov/hgmis/ (last modified Aug. 28, 2001).

14. *Id.*

15. *Id.*

16. Richard M. Glass MD, *AAAS Conference Explores Ethical Aspects of Large Pedigree Genetic Research*, 267 JAMA 2158 (1992).

17. Sachs & Korf, *supra* note 7, at 458.

gene disruption have been catalogued, and new genetic disorders are discovered almost monthly.[18]

The stated goals of HGI seem noble and admirable. Many scientists argue that the HGI is essential for solidifying the foundation of modern biology and medicine, as well as for furthering the understanding of human genetics and the development of viable medical applications.[19] The European counterpart to HGI is the Human Genome Organization (HGO), founded in 1988.[20] What goes unspoken, however, is that projects like the HGI and HGO can also serve as government-funded and administered genetic databases of the human genetic formula. The information provided by the HGI and current genetic diagnostic techniques is sensitive and could conceivably be used for a variety of purposes. Who should have access to and control over genetic information? Furthermore, the HGI will create a complete database of human genetic information. This genetic database can be accessed to determine what it means to be a "normal" human being. Who will have the authority to determine what is normal and what is sub-standard? What will form the basis for these judgments?

Thus, concern over privacy rights regarding who shall have access to genetic information and eugenics and who shall determine the genetic choices, have achieved escalating attention as the science of genetics has matured. Today, the focus on genetic information has shifted away from hypothetical moral questions to more practical, legal concerns. The American Association for the Advancement of Science (AAAS) held an interdisciplinary conference in 1992 to discuss the legal implications of the Human Genome Project.[21] They predicted that any arising conflicts would involve three basic issues: "1) a core of self-identity-heightening concerns about privacy and confidentiality; 2) the potential to predict an individual's future; and 3) implications extending beyond the individual to family members and even potential family members."[22]

Increasingly sophisticated and reliable information from genetic diagnostic tests presents a dilemma of information and privacy rights. As researchers continue to make progress in deciphering the human genetic code, more and more genetic information will become available. Who should control the release of such information? Furthermore, who should know the results of the genetic test? What diseases should be disclosed using genetic tests? Questions like these

18. *Id.* at 459.
19. *Id.* at 458.
20. *Id.* at 458-459.
21. Glass, *supra* note16.
22. *Id.*

make it clear that the use and release of genetic information must be carefully studied.

B. Studying the Legal Implications of Genetic Information Technologies

Recent genetic research has reaped the benefits of some federal study. In the United States, the Department of Energy (DOE) and the National Institute of Health (NIH) have collectively designated five million dollars per year to the National Center for Human Genome Research (NCHGR) for "the study of ethical, legal, and social issues raised by the clinical application of new genetic information, an unprecedented public investment."[23] The NCHGR committee sponsored by the DOE and NIH is known as ELSI: the Ethical, Legal, and Social Implications Program, housed within the HGI.[24] Consequently, the official mandate of ELSI is to anticipate problems resulting from continuing advances in genetic technology, educate the public about genetics, and develop policies to guide its use.[25]

The NIH and the DOE allocate, 5% and 3% respectively, of their genome budgets to ELSI, representing the first and largest federally supported program devoted to research of bioethical issues raised by ongoing research.[26] Similar groups include the Ad Hoc Committee on Insurance Issues in Genetic Testing, formed by the American Society of Human Genetics (an academic group) in 1991.[27] The Genetics Research Group of the Hastings Center Institute of Society, Ethics, and the Life Sciences is another "interdisciplinary task force of people with academic training in law, medicine, philosophy, theology, biology, genetics, and the social sciences, [that] has been considering many of these questions for more than twenty years." [28] Similarly, there are numerous universities and organizations around the country sponsoring programs related to bioethics and the Human Genome Initiative; enough for any respectable science and technology. But are such groups effective in safeguarding the proper release and use of genetic information? Recent developments in the

23. Juengst, *supra* note 9, at 30.

24. Eric T. Juengst, *Human Genome Research and the Public Interest: Progress Notes from an American Science Policy Experiment,* 54 THE AM. J. OF HUMAN GENETICS 121, 122 (1994).

25. *Id.*

26. Lisa S. Parker, *Bioethics for Human Geneticists: Models for Reasoning and Methods for Teaching,* 54 THE AM. J. OF HUMAN GENETICS 137, 138 (1994).

27. *Id.*

28. Tabitha M. Powledge & John Fletcher, *Guidelines for the Ethical, Social, and Legal Issues in Prenatal Diagnosis: A Report From the Genetics Research Group of the Hastings Center, Institute of Society, Ethics, and the Life Sciences,* 300 NEW ENG. J. MED. 168, 169 (1979).

deployment of genetic technologies suggest the answer is no.

Current genetic research is advancing rapidly and medical applications are not far behind. "With the development of the first detailed index and reference marker maps of the human genome, the pace of gene localization and subsequent diagnostic and predictive test development is accelerating dramatically."[29] And yet, the nature of genetic information, as it relates to humans, is completely unique and unprecedented in the field of medicine.[30] This innovative data could affect serious scientific, commercial, and social changes.[31] For instance, genetic research on severe mental disorders such as schizophrenia and Huntington's Disease raises several unique legal questions about patient discrimination and fair treatment. Primary concerns include the protection of confidential research data and the establishment of proper research protocols that protect subject health and privacy and reduce risk.[32] Since these mental diseases reduce mental competency and impair decision-making abilities, researchers and clinicians face a different sort of dilemma. They must contend with assessing mental competency and informed consent, as well as evaluating the legal and competent transference of substituted judgment for subjects with compromised mental ability.[33] In addition, there is great potential for discrimination against these patients if their genetic susceptibility is disclosed.[34] Many neurological disorders such as Huntington's disease show a Mendelian pattern of inheritance with high penetrance, meaning that individuals found to be at risk through genetic tests are extremely likely to develop the disorder.[35]

Consider also the recent implication of the *MSH2* gene in colon cancer, which was immediately followed by efforts to develop a diagnostic screening application. About "one in 200 Americans is suspected of harboring the gene, which confers a 70 to 90 percent risk of colon cancer and a number of other malignancies over the lifetime of the carrier."[36] The development of a diagnostic technique would have profound social and health-care policy ramifications. Once identified, what would happen to those diagnosed with the colon cancer gene? Lacking any effective treatment to eradicate colon

29. Juengst, *supra* note 9, at 23 (Quoting Cooper, DN, & Schmidtke, *Molecular genetic approaches to the analysis and diagnosis of human inherited disease: An Overview*, 24 Ann Med 29 (1992)).

30. *Id.*

31. *See id.*

32. *See* David Shore et al., *Legal and Ethical Issues in Psychiatric Genetic Research*, 48 AM. J. OF MED. GENETICS (NEUROPSYCHIATRIC GENETICS), 17, 17 (1993).

33. *Id.*

34. *Id.*

35. *Id.* at 19.

36. PROCTOR, *supra* note 5, at 237.

cancer, would those diagnosed with the gene simply be handed a death sentence? What would insurers and employers think of these people? And what of the children who carry the gene but have not manifested any symptoms? There is no telling how their lives might be affected. Currently, there are no clearly structured policies to judiciously control the release of this kind of information.

Similarly, the development of breast cancer detection techniques is an indicator of future legal quandaries. Recently, the *BRCA1* and *BRCA2* genes were implicated in female breast cancer.[37] Already, a diagnostics firm from Gaithersburg, Maryland, has announced plans to commercialize diagnostic tests that would contribute to a database to provide genetic risk profiles to the health-care community.[38] OncoMed, Inc., plans to use the medical records of the Cancer Family Genetic Database compiled by the Hereditary Cancer Institute of Omaha, Nebraska.[39] This database contains the records of more than 200,000 people from 2,300 cancer families throughout the world.[40] Accessing such a vast, global database for commercial purposes raises serious legal questions. How will privacy be maintained? Is it legal to put the genetic code of a person up for sale? These concerns remain unanswered even as research, development, and use of GITs continue.

Genetic applications have developed so quickly that many clinicians find themselves in the position of having powerful information but no established program or protocol with which to adequately communicate this information to the patient. Further pressure is placed upon the clinician because genetic information can often have a very significant effect on important decisions, such as planning for children.[41] Again, these issues are unique to genetic diseases. The technology to diagnose is less of an issue than the legal framework to deal with the questions raised by the release of genetic information.

The National Advisory Council (NAC) for the Human Genome Research Project tamely responded to possible infringement of privacy rights by commenting that it was "premature to offer DNA testing or screening for cancer predisposition outside a carefully monitored research environment."[42] Unfortunately, while independent groups that examine and discuss social and legal issues do exist, they can do little more than suggest possible guidelines for GIT use, and do not appear to be effective in providing a unified,

37. *Id.* at 239.
38. *Id.*
39. *Id.*
40. *Id.*
41. *See generally* Juengst, *supra* note 9, at 22.
42. PROCTOR, *supra* note 5, at 239.

effective policy for regulating the release of genetic information. Given the sizable profits that may result from such tests and information, commercial development may be difficult to slow. Less than two years after the cloning of *BRCA1*, a legal dispute over who owns the property rights to the gene was filed.[43] Examples of this kind demonstrate how the unique nature of genetic technologies makes it tempting to brush aside legal considerations in the rush to develop profitable medical applications.

C. Genetic Discrimination

The term "genetic discrimination" has been coined by many academics to describe the possibility of social, economic, and political discrimination against individuals who have been diagnosed with genetic disorders.[44] Accordingly, Professor Paul Billings, a geneticist, is wary of how genetic applications can highlight differences in social populations:

> Social, political, and economic changes in the United States have encouraged the notion that the origin of difference is biological or genetic.... By promoting the idea that human traits are genetic and amenable to scientific analysis—ideas and approaches which emphasize difference—the determinative nature of such traits is highlighted, and social or political parties are relieved of responsibility. The outcome.... is unequal treatment of groups justified by their biological variation, and the socio-political absolution of injustice, ignorance, fear or social/political failures as causal.[45]

An example of such treatment occurred in December of 1992, when the Centers for Disease Control and Prevention explained that a high percentage of breast cancer in a certain US urban city was the result of an excessive concentration of Jewish residents there.[46] At the time, people of Jewish descent were believed to have higher rates of breast cancer than other Americans.[47] In this case, genetic data has been used to explain away the presence of cancer clusters by placing

43. *Id.*

44. Genetic discrimination has been defined as "discrimination against an individual or against members of that individual's family solely because of real or perceived differences from the 'normal' genome in the genetic constitution of the individual." George P. Smith II, *Accessing Genomic Information or Safeguarding Genetic Privacy*, 9 J.L. & HEALTH 121, 124 (1994-95) (*quoting* Marvin R. Natowicz et al., *Genetic Discrimination and the Law*, 50 AM. J. HUM. GENETICS 465, 466 (1992)).

45. Paul Billings, *Genetic Discrimination and Behavioural Genetics: The Analysis of Sexual Orientation,* INTRACTABLE NEUROLOGICAL DISORDERS, HUMAN GENOME RESEARCH AND SOCIETY: PROCEEDINGS OF THE THIRD INTERNATIONAL BIOETHICS SEMINAR IN FUKUI 38 (1993).

46. *See* PROCTOR, *supra* note 5, at 241.

47. *Id.*

blame on ethnic predispositions.

The hereditary nature of genetics also means that information from diagnostic tests almost always pertains to family members as well as the individual. If a patient is diagnosed as a carrier, another relative may also have a high chance of being a carrier.[48] The hereditary nature of genetic diseases sometimes means that the individual's parents, siblings, and potential offspring are all at risk. Should parents have the right to test their children for genetic diseases? As discussed earlier, tests can *predict* the chances a child may develop Huntington's Disease, but tests *offer no cure.*[49] Could knowledge of the possibility of manifesting the disease actually detract from the child's quality of life more than the disease itself? Inevitably, difficult issues of patient confidentiality and professional responsibilities arise. Juengst asks, "If the patient decides not to warn relatives about their common risks, does the professional have an obligation to do so? . . . The question is, how far into the gene pool do the geneticist's professional obligations go?"[50]

In his Editor's introduction to Juengst's article, Michael Yesley contends that "genetic information will play a central role in health care, but [it] may destroy individuals' self-esteem and be used to discriminate against them."[51] Genetic information has often been cited to justify discriminatory and sometimes bizarre behavior. For example, research data from the HGI is cited in Germany where sexual variation has been "treated" by psychosurgery and hormone injections.[52] Behavioral genetic research from the United States is used to justify eugenic policies and legislation in Malaysia and Singapore.[53] Similarly, electro-convulsive therapy is used on homosexual men in China, a "treatment" which may have found its inspiration in Western behavioral genetic research.[54] Here in the United States, screening for sickle-cell anemia, a condition of fatigue and weariness due to improperly developed red blood cells, was correlated with employer discrimination.[55] Given these global effects, some scientists recommend "the embargoing of research results and ending scientific collaborations . . . until adverse practices arising

48. *See Technological Advances in Genetic Testing: Implications for the Future, 1996: Hearing Before the Subcomm. on Tech. of the House Comm. on Science*, 104th Cong. 79 (1996) (statement of Karen Rothenberg, Director, Law & Health Care Program, University of Maryland School of Law).

49. *See* Lynn Ludlow, *For Genetic Honesty*, S.F. EXAMINER, Sept. 27, 1994, at A14.

50. Juengst, *supra* note 9, at 26.

51. *Id.* at 21.

52. *See* BILLINGS, *supra* note 45, at 39.

53. *See id.*

54. *See id.*

55. *Id.*

from defining a normal, human trait as a 'biological entity,' a 'disease' or 'illness' ceases."[56] In part two, I discuss whether a general moratorium on genetic research is necessary.

D. Genetic Determinism and the Uncertain Fortune Cookie

The perceived infallibility of genetic information has engendered a sense of fatalism in those families diagnosed with a genetic condition: "If the demon seed of cancer followed an unalterable course from parent to offspring, what were physicians to tell the children of cancer victims?"[57] In truth, many genetic diseases have a genetic component as well as an environmental influence.[58] As with almost all conditions that have a genetic basis, environmental factors and chance are significant, if not equal determinants of susceptibility.[59] This means that environmental factors can speed or slow the onset of a disease or condition that is genetically predicted.[60] An overemphasis on genetics and assignment of blame to the biology of the individual is imprudent. For, "Carcinogens work on predispositions, but this should not overshadow the fact that the majority of cancers are environmentally induced and therefore preventable."[61] Furthermore, even though a disorder may be strongly influenced by a single gene, the outcome will also depend on interactions with other genes and hormones inside the cell.[62] The public must be made acutely aware of the *conditional nature of most genetic information.* Current applications are sometimes inaccurate, reflecting the limitations of genetic science, which deals in statistics and probabilities, and *not* certainties:

> Yet genetic susceptibility testing will introduce a perhaps heretofore unprecedented level of *uncertainty* into medical practice. If, in the pursuit of health, women are exposed to decades of uncertainty during which they anxiously await the fulfillment of some, not yet understood, genetic destiny.... Then the wonder, power, immediacy and seeming clarity of genetic technology may begin to appear more in the guise of Pandora's Box than the Holy Grail.[63]

The conditional nature of information provided by genetic tests

56. *Id.*

57. PROCTOR, *supra* note 5, at 220.

58. *See* Janet Basu, *Genetic Roulette*, STANFORD, Nov./Dec. 1996, at 36, 43.

59. *See* Eric Mills Holmes, *Solving the Insurance/Genetic Fair/Unfair Discrimination Dilemma in Light of the Human Genome Project*, 85 KY. L.J. 503, 522 (1996-97).

60. *See* Basu, *supra* note 58, at 43.

61. PROCTOR, *supra* note 5, at 243.

62. *See* Basu, *supra* note 58, at 43.

63. Nancy Press, *Genetic Testing for Breast Cancer: Women's Knowledge, Medicine's Hope*, GENETICS AND THE HUMAN GENOME PROJECT SYMPOSIUM 12-3 (1995).at 11 (emphasis added).

needs to be underscored, while the perceived infallibility and inevitability of genetic diagnoses needs to be de-emphasized and exposed as untrue. It is unlikely that an absolute diagnosis will ever be possible. As Proctor concludes:

> Even if individuals vary in susceptibility to such agents, it is probably wishful thinking to imagine that physicians may one day be able to assure people, from their genetic profiles alone, that they are or are not at risk for common diseases such as cancer.... It is misleading to suggest that physicians will ever have this power.[64]

E. Legal Fallout Due to the Release of Genetic Information in the Public Domain

This note has focused on how genetic information can be mishandled. The discussion of genetic discrimination and genetic determinism have shown that genetic information is highly sensitive and unlike traditional medical information. An issue that has received a great deal of attention is whether insurance companies and employers should be afforded access to genetic information about clients or employees, current or potential.[65] Clearly, genetic risk assessments could have a dramatic effect on insurance policies and hiring practices. As early as 1934, Du Pont Company refused employment to people that admitted a family history of cancer.[66] This is one of the earliest examples of genetic discrimination in U.S. history.[67] Society will quickly be forced to evaluate the use of these information technologies as more financial institutions, such as health and life insurers, demand greater access to genetic information.

Consider, for example, an episode in February of 1996 involving Dr. Jonathan Evans, Professor David Nutt, and other scientists at the University of Bristol's Department of Mental Health.[68] By analyzing the blood samples of a group of people who have attempted suicide, they were able to identify a common brain enzyme that all patients seemed to be deficient in: 5-HT.[69] In England and Wales,

64. PROCTOR, *supra* note 5, at 243-44.

65. *See* Kathy L. Hudson et al., *Genetic Discrimination and Health Insurance: An Urgent Need to Reform*, 270 SCIENCE 391, 391 (1995) (a father was unable to obtain insurance for his four-year-old son, who was fatally diagnosed with a genetic predisposition); Richard A. Bornstein, *Genetic Discrimination, Insurability and Legislation: A Closing of the Legal Loopholes*, 4 J.L. & POL'Y 551, 564-68 (1996) (studies detailing genetic discrimination by health insurers conclude that millions of Americans are at risk of losing health coverage as a result of carrying genes that give them a predisposition for certain diseases).

66. PROCTOR, *supra* note 5, at 221.

67. *Id.*

68. *See* Robert Matthews, *Scientists Discover that Suicide is in the Blood*, SUNDAY TELEGRAPH, Feb. 4, 1996, at 1.

69. *Id.*

approximately 10 people commit suicide daily, and the local life insurance companies are interested in the Bristol development.[70] Like all other chemicals produced by the human body, production of 5-HT is regulated by a gene, and insurers have encouraged efforts to develop a genetic test that could diagnose suicidal tendencies.[71]

Professor Nutt insists that the gene does not guarantee that those carrying it will take their own lives.[72] He stresses the existence of several influential factors on suicidal propensity, such as alcohol, psychological dysfunction, and life stress.[73] However, the Association of British Insurers (ABI) has already said that it will require any life insurance applicant that has taken a suicide risk test to disclose the result.[74] Although ABI stressed that there are no plans for mandatory screening for their applicants, that guarantee was made before scientists at the University of Illinois developed a simple blood test to identify people at high suicide risk based on 5-HT levels.[75] The researchers claim that a positive result for their test indicates a 55% probability of suicide.[76]

The isolation of a "suicide gene" and reliable tests for this condition represent an example of the kind of detailed information genetic science can provide. Already, some companies are seeking to determine premium rates based on genetically predicted health risks.[77] What is their reasoning for pursuing such policies? Health insurance companies claim that access to this information is vital, and that the current insurance system would collapse if insurers took on too many high-risk individuals and not enough "good" risk clients. Conceivably, access to genetic information might facilitate the efficient spreading of risk.

The Center for Biomedical Ethics at Case Western University has been investigating the potential involvement of insurance carriers with sensitive genetic information. Thomas Murray of the Center has been leading an ELSI sponsored task force charged with studying the ethical dilemmas associated with release of prospective genetic information.[78] Murray concludes that insurance carriers should be denied access to genetic information that might indicate a person is genetically susceptible to illnesses or symptoms.[79] He states, "My task

70. *Id.*
71. *Id.*
72. *Id.*
73. *Id.*
74. *Id.*
75. *Id.*
76. *Id.*
77. *See id.*
78. *Id.*
79. *See id.*

force investigated the ethics, the science and economics. Our conclusion was that the only genuine solution is to do away with all health insurance considerations."[80] Murray was cynical of claims by insurance companies that such information was vital for setting premiums:

> The coming ability to predict who is at genetic risk of disease is undermining the way we do health insurance in the United States. Health insurance in the US is built on a Catch-22. Insurers don't want to cover you for things you're most likely to need.... It shows the sort of the moral craziness, the moral perversity of the current system.[81]

Murray's incisive analysis of the American health care system demonstrates how increasingly advanced GITs will continue to underscore legal weaknesses in a system that is not prepared to deal with genetic information. The tension between ethicists, such as Murray, and insurance companies, such as ABI, demonstrates how differing parties with special interests will disagree on why access to genetic information should or should not be granted, and for what purposes. New policies must be developed which reflect the involvement of science, commercialism, and the law.

II. Negotiating an Improved Policy for the Future: Prudent Science and Proactive Law

As demonstrated in part one, genetic research has generated a number of unique social and legal dilemmas. For example: Who will decide what is defective and what is not? How will parents decide whether to abort a fetus whose genes predict a mentally deficient, moderately painful, or shortened life? Just how far should a society go in trying to prevent people from passing incurable, hereditary diseases on to their children? Genetic information is intimate knowledge, a biography in advance (depending on environmental cues), not just of the individual but also of his or her relatives. The genetic information that can be disclosed must be examined carefully, because we don't yet have the criteria for making these types of decisions judiciously. Should insurers and employers be allowed to use genetic tests to deny coverage and jobs to people with "defective" genes? What of borderline cases where "healthy" can be a very subjective criteria? What of government projects such as the HGI? While pursued in the name of science, one side effect of such an information database is that a definition of what it means to be genetically normal may be established. We see that social and legal issues are inextricably intertwined with scientific endeavors.

80. *Id.*
81. *Id.*

Although issues such as discrimination certainly existed long before the study of genetics, GITs could act to amplify and worsen existing negative social trends without a proper legal framework. Professor Paul Billings has assembled a host of examples that support this hypothesis.[82] He points to the 24 year old woman who was fired from her job after her employer learned of her genetic predisposition for Huntington's Disease, a condition that is latent until after 40; or to the recruits rejected by the Air Force because they were recessive carriers—but with no symptoms—of sickle cell anemia; or to the case where a health insurer threatened to cut off medical coverage to a pregnant woman whose child had been diagnosed with cystic fibrosis unless the woman agreed to an abortion.[83] Billings has documented over 455 cases in which people were denied insurance, health care, employment, schooling, or the right to adopt children, all on the basis of a family history of genetic disease.[84] These are the first members of a new genetic social underclass, one that is being created and shaped with the help of GITs.

These trends should not be encouraged by another vehicle for their expression; society cannot allow itself to be seduced by the immediate benefits of science and technology, and sacrifice long-term social concerns. Legal steps can be taken to curb negative social effects. I argue that the unique nature of genetic science and related technologies has created a *condition of uncertainty*. The social fallout from these technologies is poorly understood and unpredictable, and any experimentation with genetics may cause changes that may only be fully seen generations from now. The condition of uncertainty justifies more prudent development and deployment of GITs, supported by proactive legal measures that take into account the unique nature of genetic information.

A. More Prudent Research, Development, and Deployment of Genetic Information Technologies

How do we go about improving the process of research, development, and implementation? In Philip Sieb's article, it is noted that "If the uses and ethics of genetic research are to be properly evaluated, education about this science *and scientific literacy generally* must be vastly improved. That presents a clear mandate to schools, the news media, the religious community and all others who help shape public knowledge and public opinion."[85] Shared education

82. *See* Basu, *supra* note 58, at 42.

83. *See id.*

84. *See id.*

85. Philip Sieb, *Molecular Genetics May Change Our Lives*, DALLAS MORNING NEWS, May 22, 1995, at 11A (emphasis added).

within and between the scientific and civic community, combined with increased cultural dialogue, will be key to successfully informing the public of the limitations and capabilities of GITs.

This could be achieved if government or medical associations involved in genetic work sponsored public courses on basic genetics. Or, universities similarly involved with such work could be persuaded to open such courses to the public. I do not deny that such a policy implies a responsibility on the part of public and private institutions to educate the public. But if these institutions are going to produce technologies that are such potent agents of social change, I believe that programs for public education must become part of their operational existence. If citizens are better informed about what genetics can and can't tell them, genetic information may not seem so mysterious, and instances of genetic discrimination and premature fatalism may decrease. Furthermore, better civic education should be supplemented by strengthening the role of the genetic counselor in medical decisions. Moreover, a great percentage of the population would be better served by improving the availability and quality of educational programs *prior* to the use of diagnostic techniques. The benefits of increased and improved civic education are clear.

In order to begin the process, there should be improved dialogue between policy makers and scientists. Effective cross-disciplinary programs must be developed to encourage scientists and clinicians to think through the legal implications of their work and to emphasize the linkage between science and policy. Integrating an ethics dialogue into cross-disciplinary education will also bring ethicists in at an earlier stage of research and development, possibly increasing the amount of influence they have on GITs at the research stage.

Although improved public and scientific educational programs, increased dialogue between the general community and the scientific community, and empowered watchdog groups are good proactive steps towards formulating improved future policies on GIT development and deployment, we cannot overlook the fact that GITs are already in use today. There are numerous legal strategies that can be adopted to deal with genetic information in the public domain.

B. Proactive Law: Genetic Information Disclosure in the Public Domain

Insurance companies continue to assert that genetic information able to predict symptoms or susceptibility are imperative to risk assessment.[86] Regardless of whether such disclosure is necessary for the efficient continuation of insurance policies, experience has shown that such information can expose subjects to increased premiums,

86. Shore, *supra* note 32, at 18.

cancellation of policies, loss of employment, and other negative effects.[87] Companies and universities have already developed tests to diagnose dozens of genetic conditions and are poised to put them into widespread operation.[88] In a society where many people are unfamiliar with the particulars of gene theory, this could result in negative and premature judgments. For example, if people do not understand that harboring one copy of a "bad" gene does not mean having a genetic disease, unfounded discrimination and needless anxiety might result. What can genetic scientists, clinicians, and researchers who work with human subjects do to minimize these effects? I advocate using current legal measures as well as promoting legislation to protect patient privacy and discourage discriminatory practices.

Psychiatric genetic researchers have the option of obtaining a "certificate of confidentiality."[89] This certificate prevents insurance companies, government authorities, and other third parties from gaining access to sensitive research data.[90] Investigators cannot be forced through legal processes to reveal this information once the certificate is granted.[91] However, the certificate does not mean that the subject gives up his or her rights of access to information that he or she has provided.[92] Nor does it mean that the investigator cannot report cases of child abuse, and possible suicide or homicide.[93] These communications between the patient and investigator are specified in the informed consent disclosure.[94] The certificate of confidentiality is significant in that it is a readily available legal method to ensure non-disclosure of genetic information. It should be exercised more vigorously within the scientific community when questionable instances of information disclosure arise.

What about the problem of discrimination resulting from the use of genetic information in the public domain? There is substantial evidence that suggests genetic discrimination is not only a likely probability, but a reality. In 1989, the Office of Technology Assessment's "Medical Monitoring and Screening in the Workplace" conducted a survey of Fortune 500 companies.[95] Survey results indicated that only a small number (not even 10%) use genetic testing

87. *Id.*
88. *Id.*
89. *Id.*
90. *Id.*
91. *Id.*
92. *Id.*
93. *Id.*
94. *See id.*
95. Sachs & Korf, *supra* note 7, at 461.

to assess worker health and/or susceptibility to workplace hazards.[96] These figures may seem somewhat encouraging, but are really deceptive. Further research indicated that "36% of surveyed health officers assessed the health insurance risk of job applicants and used this information in their decision to hire an individual."[97]

Legal measures should be vigorously pursued at both the state and federal level to prevent irrational genetic discrimination.[98] By late 1998, genetic discrimination legislation had been passed or drafted in thirty-nine states.[99] For example, in September of 1991, the California state legislature passed Assembly Bill 1888 to amend the California State Civil Rights Act in an attempt to prevent the creation of a genetically determined underclass.[100] The bill added genetic makeup to the list of traits protected from employer discrimination.[101] Health insurers are also prohibited from declining to cover or overcharging clients known to carry disease genes.[102] Life and disability insurance carriers are also prohibited from rejecting applications on the sole basis of a person's genetic disposition.[103] Finally, the bill made it illegal for insurers to mandate genetic testing.[104] This seems to be a well reasoned legislative acknowledgment that genes only comprise a fraction of the medical history of a patient. Although a gene may indicate a person is at risk, he or she may not develop the condition if it is dependent on environmental activating cues.[105]

Although such state legislation is encouraging, it is not sufficient on its own to prevent genetic discrimination. State laws cannot regulate self-insured employers exempted by ERISA.[106] As almost two-thirds of employers in the United States are self-insured, state legislatures are already at a disadvantage in their attempts to curb genetic discrimination.[107] Further, state laws are more focused on genetic diagnostic tests, as opposed to the general dissemination of

96. *Id.*

97. *Id.*

98. *See* Karen Rothenberg, *Miracles of Genetics Can Bear Heavy Cost*, BALT. SUN, July 20, 1997, at 6F.

99. *See* Jeremy A. Colby, *An Analysis of Genetic Discrimination Legislation Proposed by the 105th Congress*, 24 AM. J.L. & MED. 443, 463-464 *(1998)*.

100. Sachs & Korf, *supra* note 7, at 460-61.

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. *Id.*

106. Colby, *supra* note 99, at 465.

107. *See* Theresa E. Morelli, *Genetic Discrimination by Insurers: Legal Protections Needed from Abuse*, HEALTHSPAN, Sept. 1992, at 9.

genetic information.[108] Finally, due to the varying nature of state legislation, state laws are inconsistent and can provide only limited protection.[109] For these reasons, state legislation must be passed in conjunction with federal legislation in order to provide an effective shield against abusive use of genetic information.

The Americans with Disabilities Act of 1990 (ADA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are the primary federal laws that address genetic discrimination.[110] In 1995, the Equal Employment Opportunity Commission included "genetic information relating to illness, disease, or other disorders" in the ADA's definition and protection of disabilities.[111] However, it is still difficult to obtain relief under the ADA because it must be shown that the employer "regarded the individual as having a genetic defect" and "acted on that basis."[112] Also, recall that a common perception is that genetic conditions tend to "run in the family." Therefore, if an employer or insurer sees that a family member is afflicted by a disease with a genetic basis, it may terminate the policy-holder or employee. This situation is not protected by the ADA.[113] Other uniquely "genetic" situations that the ADA does not contemplate are the protection of asymptomatic carriers of recessive genetic mutations, or genetic privacy.[114] Here too, the ADA falls short of accounting for the unique problems raised by genetic information, although there is hope for enlightened interpretation by the courts.

HIPAA, in turn, provides some specific protection against genetic discrimination by insurers.[115] It prohibits insurers from using genetic information to determine eligibility for enrollment or continuation of insurance coverage.[116] This gives some peace of mind to employees with genetic conditions who wish to change jobs without losing health insurance. Unfortunately, HIPAA falls prey to the same shortcoming as state legislation in that it fails to address ERISA-exempted self-insured employers and health maintenance organizations.[117] HIPAA also does not address genetic privacy

108. Colby, *supra* note 99, at 466.

109. *See id.*

110. *See* Pub. L. No. 101-336, 104 Stat. 327 (1990) and Pub. L. No. 104-191, 110 Stat. 1936 (1996).

111. Bornstein, *supra* note 65, at 581.

112. *Id.* at 581-82.

113. *See* Karen Rothenberg et al., *Genetic Information and the Workplace: Legislative Approaches and Policy Challenges*, 275 SCIENCE 1755, 1756 (1997).

114. *See* Colby, *supra* note 99, at 467.

115. *See* Ari Patrinos & Daniel W. Drell, *Introducing the Human Genome Project: Its Relevance, Triumphs and Challenges*, 36 JUDGES' J. 5, 9 (1997).

116. *See* Holmes, *supra* note 59, at 658-59.

117. *See id.* at 659.

concerns resulting from the dissemination of genetic information, does not regulate genetic testing by insurers, does not address those who are self-employed, does not prevent the use of genetic information in risk classification, and does not prohibit employers from genetically discriminating against people seeking health insurance.[118]

Less than 10 years after the Office of Technology Assessment's survey,[119] genetic discrimination in the workplace has made its way to the courts. In *Norman-Bloodsaw v. Lawrence Berkeley Laboratory*, the blood and urine samples of employees obtained during pre-employment medical exams were tested for pregnancy, sickle cell trait, and syphilis without their knowledge or consent.[120] The employees sought relief under Title VII of the Civil Rights Act of 1964 and the ADA.[121] The California district court dismissed the ADA and federal privacy claims, finding that they were time-barred, and, in the alternative, failed on the merits.[122] The district court believed that the employees had sufficient notice of the possibility of these tests because of the highly personal questions unrelated to employment that appeared on the pre-placement exams.[123] Further, they had consented to a comprehensive medical examination that included the taking of blood and urine samples.[124] As a result of this notice and consent, the district court wrote that any "additional incremental intrusion" resulting from the genetic testing was negligible.[125]

Perhaps as a portent of future court decisions on genetic cases, the Court of Appeals for the Ninth Circuit reversed and remanded the case for trial on the merits.[126] The court of appeals found that there was a material factual dispute regarding whether the employees should have had reason to believe their employer would perform the genetic tests without their consent.[127] Further, it was unclear to them whether performing such tests was consistent with sound medical practice.[128] Defendants' motion for summary judgment, which had been granted by the district court, was vacated.[129] Since the female employees had been tested for pregnancy, there was a valid Title VII

118. Colby, *supra* note 99, at 468.
119. *See* Sachs & Korf, *supra* note 7, at 461.
120. 135 F.3d 1260, 1265 (9th Cir. 1998).
121. *Id.* at 1264-66.
122. *Id.* at 1266.
123. *Id.*
124. *Id.*
125. *Id.*
126. *See id.* at 1261.
127. *Id.* at 1267-68.
128. *Id.*
129. *Id.* at 1275.

claim for sex discrimination.[130] The court also found that the black employees, who had been targeted for sickle cell trait testing, had alleged a sufficient cause of action for race discrimination under Title VII.[131] However, the court affirmed the dismissal of the ADA claims because pre-employment medical examinations of unlimited scope are permissible, and need not be job-related.[132] Ultimately, the court concluded that there were valid constitutional claims, even going so far as to state that "one 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."[133]

Legal measures such as the ADA and HIPAA, though imperfect, suggest that it may be worthwhile to continue to try to work within the existing political and legal framework to increase awareness of the issues unique to GITs. However, it is critical that education and awareness about genetic science and technology be improved. This will be the key to successful future policies regarding genetic research and information technologies. Mary Warnock suggests that "Discussion, explanation, education, and dialogue are needed, within the context of which people can see what moral issues are at stake."[134] Absent such discussion, there will be no way of achieving the moral consensus needed to produce judicious legal policies to guide the development and deployment of genetic applications.

Conclusion

I encourage a policy of proactive legislation; that is, predictable issues about genetic science should be dealt with *before* the technology is developed and deployed. This can be accomplished by requiring that scientists and lawmakers have consistent contact and dialogue. Groups like ELSI are certainly a start, but greater efforts should be made to provide the community of scientists, physicians, educators, and lawmakers in the federal and state governments with a competent education in genetic research and information technologies.[135]

Admittedly, the situation at hand does not lend itself to easy solutions. Nevertheless, informing the public about the capabilities and limitations of current genetic science, combined with instilling the

130. *Id.* at 1272.

131. *Id.*

132. *See id.* at 1273-74.

133. *Id.* at 1269.

134. Phyllida Brown, *Geneticists Told to Sing for Their Supper,* 13 NEW SCIENTIST, 8, (Aug. 31, 1991).

135. Kenneth L. Garver et al., *Editorial: New Genetic Technologies: Our Added Responsibilities,* 54 AM. J. OF HUMAN GENETICS 120 (1994).

involved professional parties with an interdisciplinary background, will form the backbone of a competent and intelligent movement to address the new and exciting issues raised by genetic research and applications. Working within the existing legal system to establish a proactive global policy of preventive ethics will facilitate efforts to conscientiously administer development of GITs.

What new wonders and hazards will this science and technology bring us in the future? In the realm of genetic research and increasingly powerful information technologies, it is safe to presume that we will be surprised by possibilities never before considered. If history has taught us any lessons about our technological advances, it is that we are woefully ill-prepared to deal with the fallout from our technologies (for example, ozone depletion, nuclear waste disposal, and poorly understood health effects resulting from chemical manufacture). Charting a judicious course will involve many considerations including the ones I have outlined, but above all, it will involve value judgments. These determinations will be less a questioning of the quality of science involved, but more of a consensus of how we see risks and benefits. Such trade-offs are the kind that can—indeed, must—be democratically mediated. Values require no scientific expertise; any citizen can participate in this discussion.

Walter Gilbert, a Nobel laureate and a prominent figure in the realm of biology and scientific research, referred to the human genome as the "grail of human genetics."[136] By this he meant that the genome was the key to what makes us *Homo sapiens*. Unlocking the secrets of the genome would further our understanding of the limits and possibilities of our own humanity, and help to better human lives through practical application. However, the societal and legal ramifications of genetic science and technology are equally impressive, and some would say that the continuing, unrestricted and unregulated advance of genetics is akin to opening a Pandora's Box. Throughout this note, I have tried to show that GITs can be either a Holy Grail for science, *or* a Pandora's Box for society. The case for continued scientific advancement and discovery is compelling, but upon closer examination, the possible damage to a society unprepared for a fast arriving brave new world warrants caution and justifies a policy of prudent science and proactive legislation. More than likely, genetics will be *both* a Holy Grail and a Pandora's Box in the immediate future, as scientists continue to make incredible new revelations about our humanity, and policy-makers struggle to frame those discoveries within our society and legal system.

136. *See generally* PROCTOR, *supra* note 5.

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