The ELSI Research Program and Genetic Nondiscrimination Legislation: A Study in Science and Public Policy

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(ABSTRACT)

The Human Genome Project, a multi-national initiative to map and sequence the entire human genome, is expected to reach completion in the year 2003. One of the more immediate and direct results of this remarkable scientific effort is an increase in both the number and range of genetic tests available. Although there is enormous value in the knowledge gained from information that predicts present or future disease, there are also some risks. This thesis, based on the content analysis of genetic nondiscrimination legislation and evidence obtained from individuals involved in the policy formation process, reveals how the Ethical, Legal, and Social Implications (ELSI) Program of the U.S. Human Genome Project is dealing with the possibility that insurers and employers will misuse genetic information. The findings from both the content analysis and the lived experience survey demonstrate that the ELSI program has made a substantial impact on forming this legislation.

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Table of Contents

List of Tables and Figures

List of Acronyms

ADA	Americans with Disabilities Act
BEAC	Biomedical Ethics Advisory Committee
BERAC	Biological and Environmental Research Advisory Committee
DOE	Department of Energy
EEOC	Equal Employment Opportunity Commission
ELSI	Ethical, Legal, and Social Implications Program
ERISA	Employee Retirement Income Security Act of 1974.
ERPEG	ELSI Research Planning and Evaluation Group
HGI	Human Genome Initiative
HGP	US Human Genome Project
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
NACHGR	National Advisory Council for Human Genome Research
NAPBC	National Action Plan for Breast Cancer
NAS	National Academy of Sciences
NCGR	National Center for Genome Resources
NCHGR	National Center for Human Genome Research
NHGRI	National Human Genome Research Institute
NIH	National Institutes of Health
OBER	Office of Biological and Environmental Research

OHER	Office of Health and Environmental Research
OTA	Office of Technology Assessment
RAC	Recombinant DNA Advisory Committee
SACGT	Secretary's Advisory Committee for Genetic Testing
STS	Science and Technology Studies

Chapter 1: Introduction

Until recently, genetic information useful in predicting the likelihood of disease was limited to an individual's family medical history or the occasional test for an underlying genetic condition, such as the sweat test for cystic fibrosis. Recent advances in human genetics research are accelerating the pace of development and increasing the number of tests that will provide health-related genetic information (NIH/DOE, 1993). Tests are now available for approximately 700 genes, most of which are associated with relatively rare disorders. This research is also uncovering hereditary factors in heart disease, diabetes, Parkinson's disease, cancer, and other more common disorders (Collins, July 2000). With continued effort, these discoveries may lead to the identification of individual susceptibilities to future illnesses and, in some cases, create opportunities for the prevention of certain diseases. Despite such promise, legislators, individuals with genetic disorders, and the general public are beginning to question what effects this new information will have if it is misused. Of particular concern is the loss of a job or health insurance should an employer or insurer obtain an individual's, or their family member's, genetic profile (Juengst, 1994; Collins, 1997).

To address this concern, the National Institutes of Health-Department of Energy Working Group on Ethical, Legal, and Social Implications (ELSI) of the U.S. Human Genome Project and the National Action Plan on Breast Cancer (NAPBC) have jointly developed a series of recommendations for state and federal policy-makers. The ELSI Working Group was originally established in 1989 to explore and propose options for the development of the ethical, legal, and social component of the Human Genome Project. From 1989 to 1997, the Working Group provided overall guidance to the NIH and DOE ELSI programs, facilitated a number of early policy discussions, and participated in the development of a number of policy options and recommendations related to these issues. On July 11, 1995 the ELSI Working Group cosponsored with NAPBC a workshop on genetic discrimination in health insurance. In October of the following year, ELSI and NAPBC held a second workshop on genetic discrimination and the workplace. NAPBC, established in 1993, is a public-private partnership coordinated by the Public Health

Service Office on Women's Health in the Department of Health and Human Services. NAPBC is committed to identifying and addressing priorities in the fight against breast cancer and to developing a national strategy supporting advancement toward that goal.

In this study, I examine whether the ELSI/NAPBC recommendations are dealing productively with the possibility that insurers and employers will misuse genetic information. The question is posed against a backdrop of criticism aimed at ELSI itself. There are claims that ELSI is principally designed to support academic research, that its studies rarely end with policy recommendations, and that it lacks a clear mechanism to ensure its study results make their way into the policy process (Hanna, 1995; Juengst, 1996; Lehrman, 2000). In April 1996, the NIH and DOE advisory councils appointed a committee to evaluate the Working Group's role in the overall ELSI programs at the NIH and DOE. As a result of the evaluation committee's findings, the Working Group was dissolved and its responsibilities were delegated to three newly established committees at various levels within the government.

In answering the question "Is ELSI helping…?" I first describe the existing and proposed federal policies with provisions designed to prevent discrimination based on a genetic condition. I then explore whether and to what extent the recommendations from the ELSI/NAPBC workshops are directing the development of these policies. More specifically, I attempt to determine if there is a direct quantifiable link between the ELSI/NAPBC policy recommendations and the actual genetics nondiscrimination legislation introduced in the 106th Congress. My purpose is twofold. First, I intend to assess how, or if, the ELSI program is influencing federal genetic nondiscrimination policy. Such an understanding can be used to better inform science policy analysts and government officials interested in shaping future ethical, legal, and social implications studies. Second, I intend to provide to the general public information on the issues surrounding genetic privacy and on the current status of federal protections against the misuse of genetic information by insurers and employers. Although this is a scholarly work and its reach limited, this information can be used to develop other works geared toward engaging the public interest in the policy process.

Background Information

The Human Genome Initiative (HGI), a multi-national project to characterize in detail the complete set of genetic instructions in the human genome, is expected to reach completion as early as the year 2003. The goal of the project is to provide biomedical scientists with gene-finding and DNA analysis tools to unravel and better understand human diseases. In June 2000, scientists announced they had mapped (placed large fragments of DNA in the proper order to cover all of the human chromosomes) 97 percent of the human genome (Collins, July 2000; Slaughter, 2000). According to the announcement, 85 percent of the DNA sequence (the linear order of the 3 billion base pairs, or chemical letters that make up a DNA fragments) is known and the goal is to finish the sequencing over the course of the next two to three years.

In the past year, genes responsible for diseases from deafness to kidney disease to cancer have been identified using the knowledge generated from this resource (Collins, July 2000). Given time, it is expected that this knowledge can be instrumental in developing targeted therapies for managing these disorders. More immediately this remarkable scientific effort is increasing the number and range of genetic tests available. These tests examine a person's genes for abnormalities, including carrier status, that link to physical or mental disorders or impairments, or that indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or that demonstrate genetic or chromosomal damage due to environmental factors (Hodge, 1998). While there is enormous value in the information gained from genetic tests that predict possible future disease for oneself or one's children, there are also some risks. Recognizing that advances in human genetics would have important implications for individuals and society, the planners of the Human Genome Project (HGP) established the Ethical, Legal, and Social Implications (ELSI) Research Program. The ELSI program was developed to promote constructive use of genetic information, to minimize its potential harmful consequences, and to develop policy options addressing both.

Table 1.1 Some Currently Available DNA-Based Gene Tests

- **Alpha-1-antitrypsin deficiency** (AAT; emphysema and liver disease)
- **Amyotrophic lateral sclerosis** (ALS; Lou Gehrig's Disease; progressive motor function loss leading to paralysis and death)
- **Alzheimer's disease*** (APOE; late-onset variety of senile dementia)
- **Ataxia telangiectasia** (AT; progressive brain disorder resulting in loss of muscle control and cancers)
- **Gaucher disease** (GD; enlarged liver and spleen, bone degeneration)
- **Inherited breast and ovarian cancer*** (BRCA 1 and 2; early-onset tumors of breasts and ovaries)
- **Hereditary nonpolyposis colon cancer*** (CA; early-onset tumors of colon and sometimes other organs)
- **Charcot-Marie-Tooth** (CMT; loss of feeling in ends of limbs)
- **Congenital adrenal hyperplasia** (CAH; hormone deficiency; ambiguous genitalia and male pseudohermaphroditism)
- **Cystic fibrosis** (CF; disease of lung and pancreas resulting in thick mucous accumulations and chronic infections)
- **Duchenne muscular dystrophy/Becker muscular dystrophy** (DMD; severe to mild muscle wasting, deterioration, weakness)
- **Dystonia** (DYT; muscle rigidity, repetitive twisting movements)
- **Fanconi anemia, group C** (FA; anemia, leukemia, skeletal deformities)
- **Factor V-Leiden** (FVL; blood-clotting disorder)
- **Fragile X syndrome** (FRAX; leading cause of inherited mental retardation)
- **Hemophilia A and B** (HEMA and HEMB; bleeding disorders)
- **Huntington's disease** (HD; usually midlife onset; progressive, lethal, degenerative neurological disease)
- **Myotonic dystrophy** (MD; progressive muscle weakness; most common form of adult muscular dystrophy)
- **Neurofibromatosis type 1** (NF1; multiple benign nervous system tumors that can be disfiguring; cancers)
- **Phenylketonuria** (PKU; progressive mental retardation due to missing enzyme; correctable by diet)
- **Adult Polycystic Kidney Disease** (APKD; kidney failure and liver disease)
- **Prader Willi/Angelman syndromes** (PW/A; decreased motor skills, cognitive impairment, early death)
- **Sickle cell disease** (SS; blood cell disorder; chronic pain and infections)
- **Spinocerebellar ataxia, type 1** (SCA1; involuntary muscle movements, reflex disorders, explosive speech)
- **Spinal muscular atrophy** (SMA; severe, usually lethal progressive muscle-wasting disorder in children)
- **Thalassemias** (THAL; anemias - reduced red blood cell levels)
- **Tay-Sachs Disease** (TS; fatal neurological disease of early childhood; seizures, paralysis)

Test names and a description of the diseases or symptoms appear in parentheses. Susceptibility tests, noted by an asterisk, provide only an estimated risk for developing the disorder.

Already with a limited number of genetic tests in common use, studies report individuals have lost jobs, insurance, or both due to the non-medical use of genetic information. For example, Billings, Kohn, and de Cuevas (Billings et al, 1992) tell of an individual who underwent a genetic test and learned he was a carrier of a gene for Gaucher's disease[1]. When he revealed this information while applying for a job, he was denied the job because of his carrier status even though it had no bearing on his present or future ability to do the job. In the 29 cases evaluated in the Billings study, there were 41 reported incidents of possible discrimination. Several cases involved multiple incidents. Of those 41 incidents reported, all but two involved either insurance or employment. Thirty-two of the incidents involved applications for -or changes in- coverage for health, life, disability, mortgage, and auto insurance. Seven involved the hiring, termination, promotion, and/or transfer of employment.

In a similar study completed in 1996, Geller and colleagues (Geller et al, 1996) reported that 455 participants of 917 individuals who were at-risk to develop a genetic condition or were parents of children with genetic conditions had experienced some form of discriminatory treatment. In this study the majority of the cases of discrimination involved insurance companies. In the cases involving employment, the subjects stated they believed they were not hired or that they were fired because they were at risk for a genetic condition. In one case, a 24 year old woman was fired from her job shortly after her employer learned that she was at-risk to develop Huntington disease despite the fact that in the eighteen-month period prior to her termination she received three promotions and several outstanding performance reviews.

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[1]Gaucher Disease is a lipid-storage disorder and is the most common genetic disease affecting Jewish people of Eastern European ancestry. It results from a specific enzyme deficiency in the body, caused by a genetic mutation received from both parents. The disease course is variable, ranging from no outward symptoms to severe disability. Testing is available to identify carriers and to diagnose those who have the disease (National Gaucher Foundation, 2002).

An additional study, also performed in 1996, involved a survey by Virginia Lapham (Lapham et al, 1996) soliciting information from members of genetic support groups with one or more persons in the family with a genetic disorder. Lapham and associates found that, as a result of a genetic disorder 25 percent of 332 respondents or their affected family members believed they were refused life insurance, 22 percent believed they were refused health insurance, and 13 percent believed they were denied or let go from a job. Fear of genetic discrimination resulted in 9 percent refusing to be tested for genetic conditions or carrier status, 18 percent not revealing genetic information to insurers, and 17 percent not revealing information to employers.

While these early studies do not provide evidence of widespread genetic discrimination, they do describe the variety of circumstances and contexts in which an individual at risk to develop a genetic disorder may experience harm. In a market-based economy where most insurance companies are for-profit corporations, it is not unreasonable to expect that individuals at low risk for genetic disease may pay less for health insurance and individuals at high risk may pay more or, in many cases, find insurance completely unavailable (Greely, 1992). In the United States, the majority of the population receives health benefits from self-funded employer plans. Therefore it is not unreasonable to expect that a consequence of genetic testing may include both the loss of insurance and employment (OTA, 1992).

In this context, it is also reasonable to assume that adverse consequences may reach beyond obtaining and/or retaining health insurance for those identified at risk. For example, insured individuals may choose to deny themselves available health care services in order to avoid a financial penalty, such as a reduction in covered benefits or an increase in premium rates. Furthermore, these concerns may not be confined to how genetic information will be available and applied but may also extend to whether individuals are willing to participate in human genetics research. As a result, the future human genetics research may also be hampered (Zallen, 1997; Collins, July 2000; Slaughter, 2000; Rothenberg, 2001).

According to a number of recent surveys, the non-affected or not-at-risk public is equally sensitive to the predicted increase and current use of genetic tests. In 1998, the National Center for Genome Resources (NCGR) surveyed 1000 American adults to gauge the public's attitude toward genetic issues (National Center for Genome Resources, March 1998). The NCGR survey found that 69 percent of those polled stated that health insurers should be prohibited from obtaining an individual's genetic information and 85 percent stated employers should be so prohibited. In this same survey, a majority of the respondents (63 percent) said they probably (36 percent) or definitely (27 percent) would *not* take a genetic test if insurers or employers could obtain the results.

A similar public-attitude survey (Hart and Teeter, CNN/Time), also conducted in 1998, found that 94 percent of the respondents believed insurers should be prohibited from obtaining an individual's genetic information and 95 percent felt that employers should not have access to an individual's genetic information without explicit permission. Two more recent polls, conducted in 2000, confirm that concern remains high. An NBC News/Wall Street Journal poll (Yankelovich Partners, 2000) found that 56 percent of the respondents stated they were concerned that their health problems could and would be used against them. A Gallup poll commissioned by the Institute for Health Freedom revealed that 86 percent of U.S. adults 18 years of age or older believe that physicians should obtain permission before doing any genetic testing (Gallup Organization for the Institute of Health Freedom, 2000).

Clearly, access to predictive genetic information and to insurance coverage raises a significant set of concerns. The likelihood that market forces will create incentives to use genetic information to determine insurability has led to calls for comprehensive federal legislative action. The social challenge in terms of policy implications is whether and under what circumstances insurers and employers should have access to or release genetically derived information that reveals an individual's or a family member's prospect for future disease or disability.

Genetic Discrimination

Genetic discrimination is defined in this study as the denial of rights, privileges, or opportunities based on actual or perceived differences in the genetic constitution of an individual or members of that individual's family (Gostin, 1991). The definition excludes discrimination against an individual who at the time of the discriminatory act displays symptoms of the genetic disease (Billings et al, 1992; Natowicz et al, 1992). Under this definition, genetic discrimination occurs when an individual is treated differently, not based on having a disability, but based on having a gene that may or may not cause that person to manifest symptoms of a disability *sometime in the future*. For example, the denial of employment to person without physical symptoms but who has the gene for hemochromatosis[2] constitutes genetic discrimination, whereas the denial of employment to a person suffering liver disease caused by hemochromatosis does not. Likewise, the denial of insurance coverage to an individual whose noninherited cancer has long been cured would not constitute genetic discrimination, while the denial of insurance to that individual's relative because of the erroneous belief that that type of cancer is heritable would (Natowicz et al, 1992).

Given the anecdotal evidence of genetic discrimination (cited above), healthy appearing individuals who test positive as carriers and/or persons who are determined to be at risk for disease may now need the same protection offered those diagnosed and known to be suffering a genetic condition. Many of our American institutions, such as business corporations, insurance companies, schools and the courts, seek strategies that

[2] Hemochromatosis is a hereditary condition involving a recessive gene with a variable expression. It is characterized by excessive lifelong absorption of iron from the diet, with iron accumulating in body organs, eventually causing inflammation and damage. Serious and sometimes fatal health effects can result, including cirrhosis of the liver, liver cancer, heart abnormalities, diabetes, impotence, and arthritis. Approximately one in every 200 to 400 persons are affected and one in 10 is a carrier making it one of the most common of the known genetic disorders in the United States. In most cases persons with hemochromatosis can be treated before symptoms occur or can be effectively managed so that the disease is not disabling (CDC, 2001).

will increase economic efficiency, lower costs, and reduce or minimize future risks. Knowledge that predicts current and future risk for disease may well serve these organizational needs (Natowicz et al, 1992; Nelkin, 1992). Due to the economic pressures that encourage an interest in predictive information, customers or potential applicants with a genetic predisposition to a costly disease may be denied coverage or expected to pay inordinate rates (Greely, 1992; Nelkin and Lindee, 1995). Basing employment and/or insurance decisions on predictive genetic information invites unfounded generalizations about an individual's health status and performance that may or may not increase health care costs (Kelves and Hood, 1992). While insurers and employers may insist access to genetic information is necessary given the nature of their corporate and financial responsibilities, their insistence, at this point in time, is debatable and under public scrutiny.

The Ethical, Legal, and Social Implications Program

The multi-national effort to map and sequence the human genome is remarkable in a number of respects. There are, however, two specific features important to the purposes of this investigation. The first is the early recognition by the U.S. Congress that the genetic information generated through this initiative would have profound implications for individuals, families, and society. The second is the unprecedented dedication of federal funds to study and address these issues prior to the commercial application of the knowledge gained. The U.S. government's participation in the Human Genome Initiative (HGI) is a joint responsibility of the National Institutes of Health (NIH) and the Department of Energy (DOE). The Ethical, Legal, and Social Implications component of the U.S. Human Genome Project (HGP) was established in 1990 at the National Human Genome Research Institute (NHGRI) in the NIH and in the Office of Biological and Environmental Research (OBER) at the DOE. The work of the ELSI programs was structured by two goals in the initial plan: to develop programs addressed at understanding the ethical, legal, and social implications of the human genome project,

to identify and define the major issues, and develop initial policy options to address them. The methods for achieving the goals were:

- to adapt existing NIH review and funding mechanisms to create extramural grant support for research, education, and public participation on these issues;
- to collaborate with other institutions and agencies on initiatives of mutual interest;
- to encourage international collaboration in this area, and
- to work closely with those in the field to refine the research agenda, solicit public discussion, and communicate results of the work to policymakers and society.

Since its inception the ELSI program has generated more than 285 research and education projects plus numerous policy conferences and workshops (NHGRI, 1996; ERPEG, 2000). The ELSI Program currently is the largest federal supporter of bioethics research, with an annual budget of over $12 million. Supported projects range from relatively small historical, philosophical, and theoretical research activities and legal analyses to large clinical studies designed to examine the application of particular genetic or educational interventions. By the conclusion of FY 1999, the total expenditure for research activities funded through the ELSI program totaled more than $76 million.

These unique features make the ELSI Research Program of historical importance for, if successful, the science policy positions advocated by the ELSI program of U.S. Human Genome Project (HGP) could potentially set a standard for future federally funded scientific research on controversial science and social policy issues. On the other hand, if unsuccessful, this effort may create the impression that proactive collaborative efforts are undervalued and that the interests of science and society are to proceed in a reactive, after the fact, manner (Annas and Elias, 1992; Collins, February 2000). For example, in 1983 the President's Commission on Bioethics predicted that the cystic fibrosis gene was likely to be identified within the coming decade. Accordingly, the Commission recommended that the development of social and legal policies would help determine who should be screened, what individuals should be told, how the information would be kept confidential, and what the role of insurers and employers should be. The

gene was identified and screening tests were made available in late 1989. However, the contextual perspective of those who might choose to take advantage of such technologies was not considered prior to the 1989 implementation. As a result, social policy on cystic fibrosis screening was identified as a priority, to be dealt within retrospectively, by the ELSI program. Whether or not ELSI proves successful, the U.S. HGP and will remain the first major scientific research project to include from its inception a commitment to the anticipatory exploration of the ethical, legal, and social issues raised by the science itself.

The ELSI-funded activities central to the objectives of this study are confined to two key program areas: (1) the privacy and confidentiality of genetic information; and (2) the potential for employment and insurance discrimination based on the misinterpretation or misuse of genetic information. Of specific interest is the extensive work with the U.S. Equal Employment Opportunity Commission (EEOC) and more recently with the National Action Plan for Breast Cancer (NAPBC). Efforts in these two specific areas of interest resulted in the following widely disseminated works:

- the 1995 EEOC publication clarifying the nature of protection under the Americans With Disabilities Act (ADA);
- the 1993 NIH/DOE ELSI Report of the Task on the Genetic Information and Health Insurance; and
- the 1995 and 1997 ELSI/NAPBC publications providing policy recommendations to protect against the misuse of genetic information by insurers and employers.

Legal Foundations

One of the legal challenges arising from the Human Genome Project is to reduce the potential for genetic discrimination. Genetic-based discrimination could arise in a variety of ways, some of which have already been described. The existing as well as the proposed federal measures and the nature of the protection provided are discussed below.

The Americans with Disabilities Act of 1990

The Americans with Disabilities Act, signed into law on July 26, 1990, prohibits discrimination on the basis of a disability and mandates equal access to private employment, public services (including public transportation), public accommodations (such hotels, stores, and restaurants) and telecommunications (for those with hearing and speech impediments). The purpose of the ADA legislation is to: "(1) provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities; (2) provide clear, strong, consistent, enforceable standards addressing discrimination against individuals with disabilities; (3) ensure that the Federal Government plays a central role in enforcing the standards established in the Act on behalf of individuals with disabilities; and (4) invoke the sweep of congressional authority…in order to address the major areas of discrimination faced day-to-day by people with disabilities" (ADA, 1990, 42 USC § 12102(2) ; Natowicz et al, 1992, p. 470).

Disability is defined to mean (1) "a physical or mental impairment that substantially limits one or more of the major life activities…(2) a record of such impairment, or (3) being regarded as having such impairment" (ADA, 1990, 42 USC § 12102(2); Gostin, 1991, p. 121). Title I of the ADA (the section that states protections for individuals seeking work or employed in the private sector) does not specifically mention genetics. Nonetheless, under the act, persons currently disabled by a genetic condition are clearly covered to the same extent as persons with impairments without a genetic component. The disputable question is whether the ADA also covers *unexpressed* genetic predispositions and/or recessive traits (Gostin, 1991; Yesley, 1997).

In April 1991 the ELSI program issued to the EEOC, which administers the employment provisions of the ADA, a statement concerning the lack of explicit protection for individuals with a genetic predisposition to disease (NIH-DOE Joint Working Group on Ethical, Legal, and Social Implications of Human Genome Research, 1991). After three years of negotiations, the EEOC agreed in 1995 to issue policy guidance on the definition of the term "disability" under the ADA. The 1995 guidance states that protection under the ADA extends to individuals subjected to genetic

discrimination in the workplace if an employer *regards* that individual as having an impairment on the "basis of genetic information relating to illness, disease, or other disorders." This EEOC guidance specifically cites as an example an individual found to have a gene that raises the risk for colon cancer would be subject to protection under the ADA if the employer *regards* the individual as having a disability and has discriminated against the individual because of this perception (EEOC, 1995, 902-45). It remains unclear, however, if this coverage will extend to unaffected individuals who are carriers of recessive genetic mutations (Rothenberg et al, 1997; Miller, 2000).

While the EEOC has issued its position that the ADA protects individuals from genetic discrimination in employment, policy guidance as such does not have the same power of enforcement as does a federal statue or regulation. Whether or not the ADA actually covers unexpressed genetic predispositions is subject to review by the courts. Recent decisions rendered by the US Supreme Court on the interpretation of "*disability*" under the ADA poses legitimate reason to question its applicability (Miller, 2000; Slaughter, 2000). On June 22, 1999, the Court ruled in three separate cases that the ADA does not protect individuals with disabilities that can be corrected by medical treatment. The questions put before the Supreme Court were: (1) whether the determination that a person has a disability under the definitions set forth by 42 USC 12102 (2) (A) of the ADA must be considered without regard to mitigating measures and (2) whether an employer who terminates an employee, because the employer believes the employee does not satisfy physical criteria, could be found to have terminated the employee because the employee was "regarded as having" a disability within the meaning of 42 USC 12102 (2) (C). Although none of the decisions rendered in the three cases actually concern the issue of a genetic predisposition to disease, these cases do restrict the definition of who is an individual with a disability and, therefore, may ultimately have an impact on the issue. The cases and court decisions are reviewed below.

In the case, <u>*Sutton v. United Airlines*</u> (US Department of Justice No. 97-1943), nearsighted twins seeking jobs as pilots for United Airlines were rejected because they did not meet the airline's uncorrected vision standard of 20/100. Both sisters are legally

blind in one eye, but their vision was correctable with lenses to 20/20. The U.S. Court of Appeals for the Tenth Circuit ruled that they were not individuals with disabilities because they were not substantially limited in the major life activity of seeing. The second case, *Murphy v. United Parcel Service* (US Department of Justice No. 97-1992) involved a mechanic who was terminated from his job because of his high blood pressure. United Parcel Service (UPS) requires its mechanics to road test the vehicles they fix and on rare occasions when a delivery truck breaks down to drive a replacement to the stranded driver. According to company policy, the mechanic's blood pressure exceeded the limit set by UPS. The Tenth Circuit held that, when adequately treated with medication, the mechanic had moderate hypertension (160/102) and therefore was not an individual with a disability (Lavelle, 1999; Shapiro, 1999; U.S. Department of Justice, 1999).

In upholding the Tenth Circuit decisions in both cases, the Supreme Court rejected the Department of Justice's argument that mitigating measures should be taken into account. The Supreme Court also rejected the Department's view that, even if with mitigating measures, the individuals would still be protected because they were "regarded as" being substantially limited in the ability to perform a class of jobs and, therefore, restricted in performing the major life activity of working. In *Sutton*, the Supreme Court rejected the argument that the plaintiff's were substantially limited in performing the major life activity of working, because other piloting jobs were available to them despite their impairment. In *Murphy*, the Court ruled that the employer only regarded the employee as unemployable in a mechanic's job requiring a commercial driver's license but did not regard him as unemployable generally as a mechanic (U.S. Department of Justice, 1999, pp. 2-3).

In a third case, *Albertsons v. Kirkingburg* (US Department of Justice No. 98-591), the Supreme Court ruled Albertsons, Inc. was justified in firing a commercial truck driver with monocular vision based on a vision standard established by the U.S. Department of Transportation (DOT). The Supreme Court upheld the firing even though the truck driver had qualified and obtained a DOT waiver based on his safe driving record, because the

Court concluded that the waiver program was experimental and did not represent a change in the basic standard. In overruling the U.S. Court of Appeals for the Ninth Circuit, the Supreme Court rejected the Department's argument that the employee had to justify using the more rigorous DOT vision standard instead of the relaxed standard of the DOT waiver program. The Court also disagreed with the Department's position that the adaptations in the driver's vision patterns to compensate for the lack of vision in one eye should be taken into account. The Court stated there was no reason to distinguish between the adaptation and other mitigating measures, such as eyeglasses and medications (U.S. Department of Justice, 1999, p. 3).

The Health Insurance Portability and Accountability Act of 1996

Since 1995 a number of bills seeking to regulate the use of genetic information have been introduced in Congress (Reilly, 1999). So far, only the Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes a provision that explicitly covers genetic information. HIPAA is designed to allow workers to maintain coverage if they change or leave their jobs. The provisions pertain to both employers who provide insurance through insurance companies as well as employers who provide coverage through self-funded insurance plans. By imposing requirements that the states were not permitted to impose on their own, HIPAA not only increases the number of persons who now have access to health insurance but also the number who maintain health insurance (Nichols and Blumberg, 1998). The states have traditionally regulated insurance except when the federal government explicitly preempts a particular area, as occurred in the Employee Retirement Income Security Act (ERISA). States cannot mandate benefits in self-funded plans nor can states enforce antidiscrimination measures against such plans. In effect, prior to HIPAA, this federal preemption resulted in no regulation of employer self-funded plans (Yesley, 1997).

The HIPAA law specifically prohibits a group health plan from using "genetic information" to establish rules for eligibility or continued eligibility. It also provides that genetic information shall not be treated as a "preexisting condition unless the genetic information results in a medical diagnosis of an actual condition needing medical care or

treatment" (HIPAA, 1996, STAT 1936; Rothenberg, 1997; Colby, 1998). The Act, as so stated, prohibits genetic discrimination against asymptomatic persons, presymptomatic persons with a genetic predisposition, and unaffected carriers. The HIPAA legislation, however, leaves several substantial gaps in federally regulated protection. For example, HIPAA does not provide protection to individuals seeking health insurance in the individual market. Nor does it prevent health plans from charging higher rates for insurance from those persons seeking individual coverage or from requesting that those individuals take a genetic test as a prerequisite to coverage. As a result, individuals seeking coverage outside of the group market may still be denied access to health insurance or may be charged an inordinately high premium. Further, individuals within a group may potentially be charged a higher premium based on the genetic information of one or more members of the group (Collins, 1997).

The Executive Order To Prohibit Genetic Discrimination in Federal Employment

On October 4, 1996, ELSI and the National Action Plan on Breast Cancer cosponsored a workshop on genetic discrimination and the workplace. The workshop's purpose was to consider the EEOC guidance and offer recommendations to assist state and federal policy makers in protecting workers from genetic discrimination and to promote privacy in the workplace. The findings and results of the workshop were published in *Science* magazine in March 1997 (see Rothenberg et al, 1997 and Appendix B). Subsequent to the ELSI/NAPBC publication President Clinton directed the Department of Labor in July 1997 to develop a report on genetic information and the workplace. Representatives from the Department of Health and Human Services, NHGRI, EEOC, and the Department of Justice were invited to work with the Department of Labor in developing this report. On January 20, 1998, Vice-President Gore announced the Administration's support for federal genetics nondiscrimination legislation and released the Department of Labor report summarizing the report's recommendations.

Based on the content of this report, President Clinton signed an Executive Order on February 8, 2000 that prohibited every federal department and agency from using genetic information in employment decisions (White House, 2000). This Executive

Order (Exec. Order No. 13145, 2000) explicitly prohibits genetic discrimination in all aspects of federal employment and limits federal employers' access to, and use of, genetic information. The Order specifically states it is inappropriate to make employment decisions based on a predisposition that has no bearing on that individual's present ability to do the job. It also prohibits federal employers from requiring or requesting genetic tests as a condition of being hired, or from using such information as grounds for denying promotions or evaluating an employee's ability to perform his or her job.

Under the Executive Order, the disclosure of protected genetic information is prohibited and such information must be kept confidential and separate from personnel files (Miller, 2000). The Executive Order assigns the responsibility for coordinating federal policy prohibiting employment discrimination against individuals on the basis of protected genetic information to the EEOC (Exec. Order No. 13145, section 1-103). In signing the order, the President extended protections to 2.8 million federal employees and placed the federal government in a leadership role. In his press release, President Clinton stated "…my goal is to set an example and pose a challenge for every employer in America, because I believe no employer should ever review your genetic records along with your resume" (NHGRI, February, 2000c). At the point of signing the Executive Order, President Clinton also called upon Congress to endorse Senate bill 1322 and House bill 2457.

Genetics Nondiscrimination Legislation

The public policy challenge in preventing genetic discrimination is to address the use of genetic information in the context of (1) a complex market-based economy, (2) the uncertain future scope and impact of genetic testing, and (3) the political realities of a pluralistic society. Despite the number of bills introduced, Congress has thus far failed to pass any genetic nondiscrimination legislation. S. 1322 and H.R. 2457 propose to extend the protections included in the President's executive order to the private sector. Both bills include language that ensures that genetic information used to help predict, prevent, and treat diseases would not also be used to discriminate against Americans seeking

employment (Collins, 2000). Both bills propose to enhance the protections against genetic discrimination as specified in HIPAA. Specifically, S. 1322 and H.R. 2457 proposed to:

- improve the limitations cited in HIPAA on the collection and use of genetic information in the group market and extend these provisions to the individual market;
- amend HIPAA to limit the disclosure of genetic information by health insurers to specific entities (i.e., other insurers, employers and medical information bureaus);
- establish meaningful remedies in HIPAA for violations of the genetics nondiscrimination provisions; and
- enact limits on the collection, use, and disclosure of genetic information in the workplace (Collins, 2000).

The most significant genetics nondiscrimination activity of the 106th Congress (1999-2000) occurred in the Senate. On two separate occasions the Senate passed provisions that either supported or extended attention to genetics nondiscrimination in health insurance. However, it also rejected the provisions that would explicitly offer protections in the workplace (NHGRI, September 2000). The first supporting action, which occurred during the summer of 1999, was the Yea-Nay Vote (53-47) on Title III of S. 1344. This bill, known as the Republican-passed Patient Bill of Rights legislation, concerned health care reforms in Health Maintenance Organizations (HMO) and proposed to amend the Public Health Services Act, the Employment Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 (NHGRI, September 2000). The second extending action was the passage of the language proposed by Senator Jeffords as an amendment to the Labor, Health and Human Services and Education Appropriations bill (H.R. 2990) for fiscal year 2001. This action was taken in lieu of the defeat of an amendment offered to the same bill by Senator Daschle (S. 1322).

The Daschle amendment to H.R. 2990 was defeated for three reasons. First, it was decided that the Americans with Disabilities Act already bans employment discrimination

making this provision unnecessary. Second, the definition of predictive genetic information it contains was found to be overly broad and therefore potentially difficult to implement. Third, unlike other antidiscrimination laws, the provisions permitted complaints to go straight to the courts bypassing the EEOC. The appropriations amendment that was adopted included provisions similar to those in the Daschle amendment regarding restrictions on health insurance providers and group plans but failed to make any mention of employment issues or the enforceable right to sue. If enacted, the Daschle amendment would have prohibited employers from hiring, promoting or basing salaries on genetic information.

Although it was defeated, the Daschle bill (S. 1322) stimulated a vigorous debate and yielded a commitment from Senator Jeffords, Chair of the Health, Education, Labor and Pensions Committee to hold a hearing on genetic discrimination in the workplace (see Collins, July 2000 and Miller, 2000). The hearing focused on (1) whether genetic discrimination in employment exists, (2) whether the ADA sufficiently covers individuals who are at risk for developing genetic conditions and (3) whether additional legislation along the lines of S. 1322 and H.R. 2457 is needed. Testimony was presented by Paul Miller (Commissioner of the EEOC), Francis Collins (Director of NHGRI), Senator Daschle (Sponsor of S. 1322), Hal Coxin (Chamber of Commerce), Sue Messenger (Society of Human Resources Management), and Susannah Baruch (National Partnership for Women and Families, Coalition for Genetic Fairness).

Altogether a total of nine bills with the principal focus of genetics nondiscrimination in health insurance and/or employment were introduced in the 106th Congress (see Appendix C for a complete description of the bills identified). All include various provisions designed to prevent discrimination against individuals with identifiable genetic risk factors. In addition to H.R. 2457 and S. 1322 described in the above paragraphs, it is worth noting that H.R. 2555 contains provisions that address genetic discrimination in health insurance and also incorporates protections that address genetic discrimination in the workplace. H.R. 2555 was introduced to establish limitations on the disclosure and the use of genetic information in both group health and

individual plans. It also includes provisions for (1) consistent standards applicable in hospital care and medical services under title 38 of the United States Code and (2) means to prohibit employment discrimination based on genetic information and genetic testing. Of the nine bills introduced, only a few were actually heard in Congress (Rothenberg, 2001). None of the nine were read in the House. As a result, both Senator Daschle and Representative Slaughter have re-introduced genetics nondiscrimination bills in the 107th Congress.

Thesis Overview

The research objectives are to (1) examine the genetics nondiscrimination content in ELSI/NAPBC insurance and workplace recommendations; (2) identify the congressional bills introduced into the 106th Congress where the principal focus is genetics nondiscrimination; (3) compare the content of the ELSI/NAPBC recommendations against the content of the identified genetics nondiscrimination bills; (4) draw inferences about whether and to what extent the genetics nondiscrimination legislation includes the ELSI/NAPBC policy recommendations; (5) validate the inferences drawn from the content analysis through the lived experience of those involved in the policy formation process; and, (6) provide observations regarding the value of ELSI in directing federal genetics nondiscrimination policy.

The remaining chapters in this thesis are organized as follows. I review the literature contributing to the theoretical framework in Chapter Two. The literature emphasizes the role of public participation in policy-relevant research and decision-making. It also addresses the complexities of constructing measures to protect consumers and the successes and failures of the ELSI program. In Chapter Three, I identify the research design, the different variables investigated, the documents examined, and the population surveyed. The sources and methods of accomplishing this research include comparing the content of genetics nondiscrimination legislation to the content of the ELSI/NAPBC recommendations and validating the degree of correspondence against the responses volunteered by individuals directly involved in the policy formation process. I

discuss the results of my research including the findings from both the survey and the content analysis in Chapter Four.

I found several direct links in the content of the legislation introduced in the 106th Congress and the ELSI/NAPBC recommendations. The lived experience responses of key participants involved in the policy formation process supported my findings. The lived experienced data collected further indicates that the genetics nondiscrimination legislation to be introduced and/or continued in the 107th Congress will also include content from the ELSI/NAPBC recommendations. My conclusions and suggestions for future research are presented in Chapter Five.

Chapter 2: Review of the Literature

Introduction

One of the consequences of human genetic research will be a vast increase in the kind and amount of genetic information available for and about individuals. Genetic information that aids in predicting a person's risk of disease could be very useful to that individual, who might take measures to prevent the disease or to lessen or anticipate its course. At the same time, this predictive information can also result in new forms of discrimination. The likelihood that insurers and employers will increasingly use genetic information to deny or limit health insurance coverage in the future has led to calls for federal legislative action.

Public discussions on the social impact of human genetic research actually date back to the mid-1970s. These discussions, over a period of approximately two decades, were instrumental in establishing a number of federal efforts to determine the nature and scope of the risks posed and to consider corrective policy options. These efforts included not only a number of commissioned papers (see, for example, the National Academy of Sciences, 1975 and the President's Commission, 1982, 1983) but also executive and congressional mandates to the Recombinant DNA Advisory Committee (RAC) and the Biomedical Ethics Advisory Committee (BEAC).[3]

Because the social consequences of human genetic research had already established national concern, it was likely no surprise when during the congressional hearings on the feasibility of the Human Genome Project (HGP) questions were raised about methods to manage the consequences of such an initiative. Both the major HGP feasibility studies, conducted by the National Academy of Sciences (National Research

[3] The RAC proceeded to draft "Points to Consider in the Design and Submission of Human Somatic Cell Gene Therapy Protocols," which was adopted in 1986 as the key document in public oversight of the new gene therapy research. The BEAC, on the other hand, was disbanded before issuing any analyses or reports due to irresolvable conflicts over abortion rights, a charge put before the Committee by the Biomedical Ethics Board, its parent organization.

Council, 1988) and the Congressional Office of Technology Assessment (U.S. Congress, OTA, 1988), recommended attention to these issues.

Like the other national efforts that preceded it, the goals of the Ethical, Legal, and Social Implications (ELSI) Program of the U.S. Human Genome Project are to develop well-informed policy options and convey these recommendations to the public in an effective manner. ELSI, however, has approached its policy-development in a decidedly unusual way: it has turned to the clinical professions, to the social sciences and humanities, and to the public for the insights and inquiry that its agenda requires. Unlike its predecessor commissions and boards on bioethical issues, the ELSI Program's resources are devoted primarily to supporting extramural efforts at achieving its goals, through grants and fellowships.

The program assumes that the dialogue it seeks to further its goal should be pursued by scholars, educators, and policymakers in the field interacting with the scientists involved in genetic research and with the families that may some day use its results. The agenda and content of the program are therefore dependent on the energy of communities that do not ordinarily see themselves as part of the research and development phase of planning science and technology. The value of this structure is the diversity of perspective it encourages and the flexibility it gives to the inquiry. The disadvantage is to have it produce concrete policy options with the speed and authority that other more centrally directed policy mechanisms (such as expert study commissions referenced in the opening paragraphs) have sometimes realized (Juengst, 1994).

Over the last decade the science studies literature has given increased attention to both the theoretical and practical aspects of public participation in policy-relevant research and decisionmaking, such as that suggested by the ELSI structure. Although public participation has a long tradition (for example, see Nelkin (1995) on science controversies, political protests and grass root movements), I have, in developing a theoretical framework for this study, concentrated on more recent accounts addressing a pragmatic anticipatory approach. I found several initiatives of particular interest in this

area. Simon Joss (1999), Senior Researcher at Center for the Study of Democracy at the University of Westminster offers two specific examples.

The first takes place in the Netherlands. There, according to Joss, the goal has been to bring the technology developers and the technology users together for the sole purpose of integrating the contextual perspectives of the users. Public participants act as consultants to guide and improve technology research and development. In Denmark, his second example, participants who may be members of the general public, interest groups, or community representatives (alongside scientists, technical experts and decision-makers) act not only to inform but also to co-determine science and technology public policy. Joss finds that other similar models, such as consensus conferences, scenario workshops, and citizen juries, have been used since the early 1990s by a number of countries, including Europe, North America, and Southeast Asia.

Frank Fischer (1999), Professor of Political Science at Rutgers University discusses formal steps to integrate this approach into science and technology public policy process. Fischer proposes systematically extending the consultation processes (example 1 above) to the co-determining models of public inquiry (example 2 above). He suggests financial assistance and expert resources can be offered by public authorities to further such practice. Fischer recommends continued and ongoing research on participatory technology assessment to determine what types of problems lend themselves to such inquiry and to learn about the capabilities of the general public themselves. He also claims the expert, as facilitator, has to become a specialist in how individuals learn, clarify, and decide important issues. He finds in order to promote meaningful participation there is a need to develop and understand the kinds of intellectual and material conditions that support the general public in formulating their ideas.

Leonhard Hennen (1999), a member of the Office of Technology Assessment of the German Parliament and a lecturer in sociology of technology at the University of Aaschen, approaches the concept of public participation by examining the risks of which traditional policy analysis fail to offer effective solutions. Hennen asks three questions:

What are the reasons given for using participation in technology assessment processes? Which features of modern science have prompted the increasing demands for participation in science and technology policy? And, What role can participation be expected to play in modern society? Hennen suggests that participatory technology assessment, as a response to science and technology controversies, should be understood as an opportunity to deal with the uncertainty of scientific knowledge.

John Durant (1999), Assistant Director and Head of Science Communication at the Science Museum (London), discusses participatory technology assessment in relation to the public understanding of science, a movement over the past 10-15 years concerned with the more widely perceived crisis of public confidence in science and scientists. Durant proposes that developing a participatory agenda can be the key to overcoming the belief that scientists are knowledgeable experts and the public uninformed lay people. (See, for example, Wynne 1995). He calls for a deeper more structured analysis of the public understanding of science than that of scientists merely educating the public. According to Durant, the task must not be to isolate science from the public, but rather to open it up to new forms of public engagement and scrutiny.

The literature reviewed above argues for a better understanding the role of the non-scientist in science and technology public policy decisions. My objective in discussing this literature is to locate the discussion of ELSI's effectiveness as a policy mechanism within a framework of theoretical and empirical scholarship dealing directly with participatory inquiry. Since ELSI is a novel federal policy entity, which involves the public as well as scholars, educators, and policymakers in the field, it is important to understand its issues and methods. The remainder of this chapter therefore focuses on the complexities of constructing genetic nondiscrimination measures and the perceived successes and failures of the ELSI program.

The first part of the two sections below concentrates on the arguments for and against regulating the use of genetic information by the issuers of insurance from 1990 through 1998. The works selected highlight both the impediments encountered in enforcing relevant legislation as well as those encountered in creating new forms of

protection. The specific issues discussed include (1) the difficulty in defining what genetic information is, (2) the conflicts created by restricting access and (3) the potential for violating constitutional rights to privacy.

The second section addresses the policy activities of the ELSI program. While the literature cited appears to support that the attention given the ethical, legal, and social issues by ELSI has been early and intensive, there is considerable disagreement on whether those activities have been productive in directing federal policy. The literature in this last section describes not only the various views of ELSI's track record on policy issues but also the controversy surrounding its contributions and its political authority.

Arguments For and Against Legislated Protection

The arguments reviewed in this section focus on the law as a means to regulate the use of genetic testing results. The content covers the numerous complexities associated with defining a responsible strategy for controlling the social consequences of the applications of genetic research. Although the purpose of this review is to provide a foundation for evaluating the federal genetics nondiscrimination initiatives introduced in the 106th Congress, the evolution of legislated protections in a general sense is important to understanding the complexity in constructing measures of protection. The intent in summarizing these arguments is to support the critical discourse in the final chapter.

In one of the earliest works Capron (1990), Professor of Law and Medicine at University of Southern California and past Executive Director of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, emphasizes the need to reevaluate our understanding of the social consequences posed by genetic research. He argues that although our historical experience has focused on genetic engineering of microbes, recent developments in human genetic research suggest attention should be given the more practical issues of genetic testing and how it relates to insurance and employment. Capron recommends not only regulatory measures restricting the use of genetic information but also a reconsideration of the social attitudes governing normality and abnormality.

Gostin (1991) reiterates the views of Capron in that he also acknowledges genetic testing could encourage genetic discrimination in insurance and employment. He states while there is no reason (in 1991) to believe employers or insurers currently use genetic information in risk-based calculations, rising employee benefit costs and market forces could create powerful incentives to do so. According to Gostin, it is wise to question "whether genetic-specific legislation is necessary or desirable." He argues that policy makers should first identify the gaps in existing legislation, then add amendments to ensure protection and, as a final measure, develop a set of legislative guidelines that clearly outlines issues related to confidentiality and discrimination (Gostin, 1991, p. 143).

Natowicz et al (1992) claim the ADA, the Rehabilitation Act, and various state laws already cover genetic discrimination in employment. These authors, although citing a number of limitations in the provisions of these laws, clearly state that advocating immediate amendment would be premature. They, on the other hand, also admit the use of genetic information by insurers and employers raises significant issues involving the right to privacy and confidentiality. Here, the authors argue "because employers and insurers will claim a right to know the results of any genetic tests…new legislation will be needed to resolve conflicts between the right of privacy and the right to know" (Natowicz et al, 1992, p. 473).

Epstein (1994) in a paper prepared for the Distinguished Lecture Series at Boston University School of Law (September 22, 1993) finds "genetic discrimination raises problems no different from those associated with any other sort of misfortune, and [as such] calls for no different response." In defending his position, Epstein states the "greater knowledge that comes from [genetic] testing [only] increases the informational asymmetries" that are already common in the insurance markets (Epstein, 1994, p. 13). This author implies the imminent dangers inherent in the use of medical and genetic testing are the strategic behaviors that result from either obtaining or withholding such information. Because full disclosure of health related information is an indispensable part of the insurance system Epstein recommends that we should allow market forces to

resolve issues of differential treatment rather than institute government mandated interventions.

Gevers (1995) like Gostin, maintains legislator should be cautious in advocating genetic-specific legislation designed specifically to regulate the use of genetic information in employment and insurance. Legislating protection in this area is exceptionally difficult he contends due to (1) the rapid pace of development in genetic testing technologies, (2) the precarious nature of anticipating social consequences, and (3) the difficulty in determining the similarity or difference between genetic information and conventional medical information. Gevers argues governments could do many things in addition to or instead of making laws such as educating the public, promoting open discussions, establishing advisory or supervisory mechanisms, and financing consumer organizations.

Rothstein (1997), in commenting on genetic discrimination in the workplace, assumes a rights-based position on protections. This author states that the essence of medical privacy is the right to decide whom, if anyone, should have access to medical information, including genetic information. Rothstein suggests that given the recent advancements in genomic information legislators would do well to should shift the focus of legislated protections from controlling use to that of controlling access. According to Rothstein "this right has never been afforded adequate protection by the law" and in the new era of human genetics, "this right must be recognized" (Rothstein, 1997, p. 296).

Powers (1997) finds our policy options for controlling the consequences posed by the new capacities in genetic testing include (1) legislating protections that restrict access by employers and insurers and/or (2) making modifications in the system of health insurance such that the need for health related information is eliminated. However, he also notes that if the financial solvency of insurance plans depends on having access to medical and/or genetic risk information then restrictions on access could potentially jeopardize the solvency and continuity of health insurance. Powers given his analysis of competing interests concludes the "complexity of the patterns in which [the interests of

individuals and the interests of institutions] intersect make uniformly applicable solutions impossible" (Powers, 1997, p. 366)

Alper and Beckwith (1998) claim that immediate calls for genetic-specific protection are unwise in light of the inability to accurately define genetic discrimination or clearly distinguish between genetic and nongenetic information. These authors find that barring the use by insurance companies of a genetic test but not a nongenetic medical test (conceivably for the same multifactorial disease) raises issues of fairness in health insurance. Alper and Beckwith suggest that genetic discrimination should not be addressed by narrowly focused genetic legislation but, rather, should be more broadly approached by demanding protections that include all types of medical testing and which address needed reform in the entire health care system.

Cook-Deegan (1998) like Alper and Beckwith implies although the specific nature of an immediate policy solution is unclear, it is becoming increasingly more clear that genetic legislation is not the solution. Cook-Deegan finds that genetics has to a large extent served to make unfair medical and social practices in general more apparent. He claims regulating genetic tests will only marginally reduce that injustice. According to this author, focusing on genetic technologies is not the way to tackle privacy and discrimination issues. The problem, says Cook-Deegan, cannot be solved by a new genetics law, but only by augmenting several different existing bodies of law.

Takala and Gylling (1998) approach the debate on access by focusing their analysis entirely on the question: who should know and why? Through an analysis of reasonable moral and legal grounds for acquiring the information Takala and Gylling conclude that, at least on the levels of law and social policy, practically nobody is either duty-bound to receive or entitled to have that knowledge. According to these authors, "as long as people whose genes deviate from those of the average individual are likely to face suspicion and discrimination, societies cannot legitimately force people to know [or volunteer information] about their hereditary composition" (Takala and Gylling, 1998, 174).

Hodge (1998) in examining relevant legislation argues these laws do not properly attend to the intricate relationship between the law and the science of human genetics. Hodge suggests that current legislation addressing genetic information is not only limited in scope but also is an ill suited, if not a completely inappropriate, response to needs for privacy and antidiscrimination protections. Hodge states that informed guidance in the drafting and enactment of genetics laws is necessary not only to support the advancement of the law on such matters but also to reinforce the value and integrity of social policy in general.

Colby (1998), like others, claims the popular arguments for legislated protections center on (1) the questionable value of predictive genetic information in determining future risk and (2) the right to authorize the release of sensitive and/or confidential information. Colby, however, adds to the list a less frequently cited argument: the potential for psychological harms resulting from the abuse or misuse of genetic information. According to Colby, this last argument violates not only an individual's personal sense of autonomy but also that individual's "right not to know," for whatever reason, his/her genomic composition (Colby, 1998, pp. 458-459). Colby finds the arguments against legislated protections are primarily concerns associated with maintaining the financial solvency of insurers. This author claims while changing the incentives driving the use of predictive genetic information in actuarial assessments is reasonable, the scientific discoveries made by the advancements in human genetic research should also, at least in the interim, be accompanied by federal legislation that limits the use of this information.

The above references from the literature are not meant to be an exhaustive list of the arguments for and against legislated protections but rather a summary of the major issues debated prior to the 1999-2000 session of Congress. The balance of the opinions cited suggests constructing corrective actions to protect the use of genetic information will be challenging. While there appears to be a general consensus that genetic privacy should be vigorously pursued, there also seems to be a discrepancy about whether federal legislative mandates are the appropriate measures. A dominant theme in this discrepancy

centers on the difficulty in classifying health information as wholly genetic or non-genetic. According to many of the authors, policies intended to protect genetic privacy will need to address the privacy of health related information in general. It is clear that many of these issues identified are highly complex and controversial. Whether or not ELSI has done what its proponents hoped is discussed below.

The ELSI Controversy

Why did the Human Genome Project invest resources in the exploration of the social implications of its research agenda? The opinions regarding the value of funding the ELSI program to direct policy are just as diverse as those contemplating the need for federal intervention discussed above. For instance, writing as early as 1992 Thomas Murray, a member of the ELSI Working Group itself, asks "Are the existing, uncoordinated set of institutions sufficiently adequate to identify and deal with the issues likely to be raised by the Genome Project? Should new institutions, tailored to the need, be established? And, What should scholars and close observers of the project, do?" (Murray, 1992, p.246).

Several years later building on the internal concerns suggested by Murray, Hanna (1995) a science and health policy consultant based in Washington DC writes "the basic problem with the ELSI program and its Working Group rests with the lack of authority to affect policy." According to Hanna, many internal participants as well as external observers viewed the diversion of funds to the study of the ethical, legal, and social implications of Human Genome Project as an "unavoidable political tax" Watson was willing to pay to accomplish scientific goals (Hanna, 1995, p. 434). She argues the value of the program remains to been seen especially if the concerns that generated it are seen by scientists and medical professionals as politically necessary but basically irrelevant to the real work of the Genome Project. Hanna claims the ELSI program has "no clear route for communicating the information it gathers to the policy arena" (Hanna, 1995, p. 442). She finds that ELSI's reliance on an extramural research program to identify and address policy issues "is too elitist and far too slow." She further contends that because it has yet to be tested, "the ability of the ELSI Working Group to clear any

recommendations through the executive branch is purely speculative" (Hanna, 1995, p. 447).

Whether due to dissention among member of the ELSI Working Group (Murray's comments) or due to the alleged ineffectiveness (Hanna's criticisms), the NIH and DOE advisory councils appointed in April 1996 a committee to evaluate the Working Group's role in the overall ELSI programs of the NIH and the DOE. The Committee's final report released December 12, 1996 states:

> The charge of the ELSI Working Group is so broad and complex as to be confusing to various participants and observers. This confusion has led to uncertainty about its primary functions and reporting relationships… Furthermore, serious concerns have been raised about the Working Group's lack of resources and independence, as well as conflicts with the intramural policy-making activities at NCHGR and the inadequate sharing of essential information by staff at NCHGR.
>
> The Working Group is not positioned within the governmental scientific structure so as to fulfill the breadth of its charge. There is a fundamental discordance between a narrowly defined scientific research program and a much broader effort to formulate and implement policy regarding the social consequences of all genetic developments, both research and clinical (Rothstein et al, 1997, p. S: 11).

The evaluation committee recommended dividing the Working Group's responsibilities among three different committees and at various levels within the government. Specifically, it recommended the formation of ELSI committees: an ELSI Research Advisory Committee to provide expert advice and oversight for the ELSI Research Program at NIH and DOE, a trans-NIH body to coordinate ELSI activities at other NIH institutes conducting genetics research, and a genetics and public policy advisory committee in the Secretary of Health and Human Services Office. (Rothstein et al, 1997, pp. S: 7-8).

At its February 1997 meeting, the National Advisory Council for Human Genome Research endorsed all three recommendations and directed the ELSI staff to prepare a plan for implementing the first recommendation. This plan presented to and endorsed by the council in May 1997 established the ELSI Research, Planning and Evaluation Group

(ERPEG). This group is responsible for providing expert advice to DOE and NIH ELSI grant programs and for assisting in the development of a strategic plan for future ELSI Research Program activities.

The second and third recommendations were forwarded to the Director of NIH and the Secretary of Health and Human Services for further consideration, and in July 1997, the NIH Director established the Trans-NIH Ethical, Legal, and Social Implications Coordinating Committee. This committee is charged with providing NIH-wide coordination of information and activities related to bioethical issues, not only issues related to genetics, but also emerging and continuing issues such as research involving the cognitively impaired. The Secretary of Health and Human Services chartered the Secretary's Advisory Committee on Genetic Testing in June 1998. The committee will advise the government on all aspects of the development and use of genetic tests, including the complex medical, ethical, legal, and social issues raised by genetic testing.

In the same year that the ELSI Evaluation Committee released its report, Eric Juengst, chief of the NIH's ELSI program from 1990-1994, wrote a "self-critical essay" addressing from personal experience many of the issues exposed in the ELSI Evaluation report. His essay specifically targeted three ELSI criticisms. Regarding the first two- that program amounts to either "alarmist hype" because there are no special issues or public relations- because it "cannot bite the hand that feeds it" he states both are wrong and will continue to be wrong as long as the program's original concept as an independent source of research is preserved. On the third- that the program is not an effective agent of change he claims the program has a track record of practical accomplishments that makes such complaint unreasonable (Juengst, 1996, p. 64).

Juengst finds that by re-casting the ELSI program as a more traditional commission (referring to the changes addressed immediately above) the "HGP plays into the hands of the critics" and neglects the strengths and protections the program's original concept supplied. According to Juengst, "those who have criticized the ELSI program for lacking policy mechanisms have done so in pursuit of another agenda: building the case for the creation of some new federal body intended to develop policy on ethical,

legal, and social issues in biomedicine" (Juengst, 1997, p. 93). While he refers to this as "friendly fire," he clearly indicates that the agenda must first demonstrate ELSI isn't performing.

The ERPEG report issued in February 2000 describes several ELSI studies that are beginning to demonstrate a measurable influence on public policy and clinical practice (ERPEG, 2000). For example, the report finds one particular project funded by DOE that has had a strong impact is the development of the draft "Genetic Privacy Act." According to the report, while this document has not led to the enactment of federal genetic privacy legislation, it has "provoked substantial dialogue and has helped stimulate legislative activity at the state level" (ERPEG, 2000, pp. *i,* 6). Also cited in the report is the NIH-funded research on cancer genetics. Here the report claims that without NIH's involvement the development of gene testing protocols and the guidance statements on the follow-up care of those with identifiable genetic risk factors for cancer "would almost certainly not have occurred" (ERPEG, 2000, pp. *i*, 8). Finally, the report states that the "fundamental shift" in the genetic research community's view on the ethical and legal status of stored tissue samples can be directly attributed to the collaborative work of NIH and DOE (ERPEG, 2000, pp. *ii,* 11). Although the report lists other ELSI activities resulting in policy recommendations, it also claims that due to the "conceptual nature" of these efforts it is difficult to "show a direct correlation" between the research performed and the actual impact on health or public policies (ERPEG, 2000, p. 5).

ERPEG's report may have been the case of too little, too late. Sally Lehrman in the opening remarks of an August 2000 column in *The GeneLetter* recycles the criticism. She writes "In the triumphant unveiling of the rough draft of the human genome, one component of the massive international effort has received little attention: results from the project's commitment to examine ethical, legal, and social issues alongside the science." Lehrman implies the reason may be that this unprecedented plan to study the social implications of the scientific advances in human genomics has to a large extent "missed its mark." According to the author, while ELSI has generated a great deal of information, observers still question whether the program has or ever will "serve as a

foundation for informed social policy." Some, she says, "complain that ELSI's policy-making efforts have been too fractured and uncoordinated." Others, she reports, say "ELSI has never quite involved the right people or asked the right questions" (Lehrman, 2000). Lehrman draws the conclusion that because ELSI's policymaking efforts are housed within the very agencies that fund its research, it is impossible to believe the programs can speak candidly about its findings before congressional committees.

In November 2000, Ellen Wright Clayton and several ERPEG members published a response to the Lehrman article (Clayton et al, 2000). Clayton and associates argue that Lehrman is for the most part misinformed and that ELSI's principal role is to fund extramural research which in turn has "sharpened and informed" the policy process. According to these authors, "Congress could have chosen to create a think tank to assist it in addressing the implications of genetics, as it had in the Office of Technology Assessment before its demise, but it chose not to do that." They claim much has been learned from ELSI's research and a great deal of effort has been invested in disseminating the results of this research.

The items quoted in this section are those that (1) speak to ELSI' role in directing policy and (2) appeared in the press from near 1995 (the first printing of the ELSI/NAPBC recommendations) and 2000 (the end of the 106th session of Congress). There are other criticisms that do not pertain to the objectives in this research and therefore are not included here. The theoretical concepts discussed earlier in this chapter and the specific arguments outlined in this section are re-visited in the final chapter of this thesis. Because these references are important to the observations I make in Chapter Five I have summarized the structural changes and the perceptions of ELSI's role in directing federal policy for easy reference in the table below.

Table 2.1 Literature on ELSI's Role in Directing Policy 1995-2000

October 1990	The Ethical, Legal, and Social Implications Program is established.
1992	Murray, member of the ELSI Working Group, questions whether the ELSI program can fulfill its mission.
1995	Hanna, a science and health policy consultant based in Washington, D.C., publishes a critical review of the Ethical, Legal, and Social Implications Program in *Society's Choices: Social and Ethical Decision Making.* Hanna calls for a federally chartered commission.
December 1996	Rothstein and members of the ELSI Evaluation Committee publish their final report in *BioLaw: A Legal and Ethical Reporter on Medicine, Health Care, and Bioengineering.* The Committee makes recommendations for restructuring the ELSI program.
Summer 1996	Eric Juengst, Chief of the NIH's ELSI program from 1990-1994, writes a self-critical essay and publishes his work in the journal of *Social Philosophy and Policy.* Juengst defends ELSI's original structure and function and questions the value of creating a federally chartered commission.
May 1997	The National Advisory Council for Human Genome Research establishes the ELSI Research Planning and Evaluation Group
July 1997	The NIH Director establishes the Trans-NIH Ethical, Legal, and Social Implications Coordinating Committee
June 1998	The Secretary of Health and Human Services charters the Secretary's Advisory Committee on Genetic Testing
February 2000	The ELSI Research Planning and Evaluation Group release their final report. The report outlines the strengths and weaknesses of ELSI's extramural grants program.
August 2000	Sally Lehrman, an independent journalist covering health policy, health care and medical technology, writes a featured article in the on-line publication, *GeneLetter.* Lehrman claims ELSI has missed its mark.
November 2000	Ellen Wright Clayton and four other members of the ELSI Research Planning and Evaluation Group publish a guest column response to the Lehrman article in *GeneLetter*. Clayton and associates clarify ELSI's current role and defend its accomplishments.

Chapter 3: Research Methodology

Research Design

This study focuses on two general issues. First, the study looks for relationships between the ELSI recommendations (offered in 1995-1996) and the genetics nondiscrimination legislation of the 106th Congress (introduced in 1999-2000) by measuring and comparing the degree of consistency in content. Second, the study attempts to validate the inferences drawn from the comparative analysis by establishing the actual use of the recommendations through the reported experiences of those involved in the policy process. The methods employed to meet the study objectives are described below.

Data Collection-Documents

The ELSI/NAPBC insurance and workplace recommendations and supporting documents for the background information, the arguments for and against federal legislation on regulating the use of genetic information, and the ELSI policy activities in general were identified through systematic library searches and were obtained from their published sources. The sources consulted included primary source documents, periodicals, texts, public opinion polls, and subject-related Internet websites. Information from the National Human Genome Research Institute (NHGRI) website (http://www.nhgri.gov) was used as a guide for gathering data on federal genetics nondiscrimination legislation.

The NHGRI website identified nine bills introduced in the 106th Congress in which the principal focus is genetics nondiscrimination in health insurance and/or employment. The text for all nine bills identified was downloaded in an electronic format from the THOMAS website at http://thomas.loc.gov/. (See Appendix C for a complete description of the bills identified). An additional search for relevant genetics nondiscrimination bills performed through the Thomas website returned the same nine documents. Upon review of the summary text, three of the nine bills, S. 300, S.326, and

S. 1344 were omitted from this study because their principal focus was health care reform rather than genetics nondiscrimination. The remaining six bills all feature genetic nondiscrimination as their central focus. Three of the six bills, H.R. 2457, H.R. 2555, and S. 1322, were discussed in Chapter One. The other three, H.R. 293, H.R. 306, and S. 543 were included because their intent and primary purpose is to prohibit insurance companies and group health plans from:

- adjusting premiums on the basis of predictive genetic information;
- requesting predictive genetic testing as a condition of enrollment; and
- requiring that an individual disclose or authorize the collection of predictive genetic information for diagnosis, treatment, or payment purposes.

Information from the NHGRI website was also used as a guide for gathering data on the ELSI-supported research that addressed genetic discrimination in health insurance and employment. The NHGRI website identified three ELSI-funded activities wherein the efforts invested produced policy recommendations. The information for all three activities was obtained through their published sources. Upon review of the original publications, the 1993 Report of the Task Force on Genetic Information and Insurance was omitted because the recommendations focused more globally on reforming the health care system rather than offering guidance on how to negotiate adequate protections in the existing and proposed legislation. The other two activities, the 1995 ELSI/NAPBC publication on insurance discrimination and the 1997 ELSI/NAPBC publication on workplace discrimination, were discussed in Chapter One and are included in the analysis discussed below.

Data Analysis-Documents

I used a computer-assisted content analysis program to summarize the content in the genetic nondiscrimination bills. According to Robert Philip Weber (1990), the use of computer-assisted programs allows for (1) rigorous and objective handling of data, (2) flexibility in statistical manipulations, and (3) the ability to handle large amounts of data

in a potentially error-free manner. I not only found all three features valuable to conducting research in general but also considered them particularly important to achieving the objectives set forth in this study.

In selecting the TextAnalyst program (Megaputer Intelligence, 1995-2000), I reviewed the evaluations of several content analysis programs (Weber, 1990; Miles and Huberman, 1994; Alexa, 1997; Roberts, 1997; Riffe et al, 1998). The evaluations I reviewed clearly stated that the scope of the research and the nature of the analysis should determine which program is most appropriate for a given project. Therefore, my decision to use the TextAnalyst program was based on the following.

1. The documents are lengthy and contain a large volume of textual information.
2. The text for analysis belongs to the single domain of legislation making it relatively restricted semantically.
3. The analysis includes all documents available on the subject and all cases under study pertain to the entire document. Therefore, no sampling is required.
4. The scope of the research is to support the absence or presence of a confirmed relationship to the policy recommendations.
5. The content variables are not identified external to the data but are generated through the intercorrelations or associations among the words contained in the documents.
6. The analysis makes no attempt to interpret, critique, or otherwise evaluate the value of the content. Therefore, no human coding intervention or interpretive mode of analysis is required.

The first step in the document analysis was to systematically order the content of the six congressional bills into a format summarizing the most important sentences in the text. To facilitate the ordering of the content, I used the TextAnalyst software to determine what words or word combinations were most important in genetics nondiscrimination legislation. In the TextAnalyst program importance is first determined by frequency of occurrence. The obvious assumption behind this mode of analysis is that

the words appearing most frequently reflect the greatest concerns addressed in the document (Wilson, 1982; Weber, 1990). The advantage of the TextAnalyst program, compared to other computer-assisted programs, is that once the program determines the most frequently occurring words and word combinations it then weights the strength of the relationship of those words to other words contained in the document. The resulting information generated is a statistically weighed summary of the most important sentences in the text and, therefore, the items of most concern. TextAnalyst summaries were generated for each of the six genetics nondiscrimination bills.

A known limitation in the data reduction process of content analytic procedures is the potential loss of information important to the generalizations required by the research (Krippendorff, 1980; Weber, 1990). As a final check against the loss of important information, I selected and added key search terms from the content in the ELSI/NAPBC documents (see Table 3.1) to the TextAnalyst software to guarantee that certain words were detected irrespective of their high or low frequency of occurrence. The terms identified were then viewed in their original text and added to the content summaries.

The second step in the document analysis was to describe and explain the nature of correspondence, if any, in the TextAnalyst summaries and the ELSI/NAPBC policy recommendations. To facilitate the progression from systematically ordering the data in the genetics nondiscrimination legislation to measuring correspondence, the content summaries generated by TextAnalyst were compared to variables in the ELSI/NAPBC recommendations. The variables in the ELSI/NAPBC recommendations were defined based on (1) the dominant subject matter in each recommendation and (2) classification schemes borrowed from two earlier studies on genetics and insurance legislation.

The first study, conducted by Davis and Mitrius (1996), describes key features of federal and state legislation regulating the use of genetic information by insurance companies prior to 1996. According to these authors the laws studied typically prohibited a variety of conduct by insurers. These common features and those used in their analysis included the following.

1. using genetic information in the underwriting process

2. structuring broker fees or commissions to discourage selling policies to persons with genetic defects,
3. disclosing genetic test results, and
4. requiring or requesting an individual to submit to genetic tests or to provide genetic information (Davis and Mitrius, 1996, pp. 70, 78-82).

The second study conducted by Colby (1998) describes, in a similar but more general fashion, the type of protections proposed in the genetics nondiscrimination bills introduced in the 105th Congress. This author ordered and analyzed the fifteen different bills studied according to whether the provisions applied to the following.

1. group and individual plans,
2. health insurance plans,
3. restrictions on employers,
4. privacy,
5. a right of enforcement, and
6. autonomy (Colby, 1998, p. 478).

I adapted the methodologies used in the Davis/Mitrius and Colby studies in the following manner. First, all six genetics nondiscrimination bills of the 106th Congress were evaluated using a modified version of the Colby classification. I ordered the six bills in my study according to whether the bill applied to (1) group health plans, (2) individual health plans, or (3) restrictions on employers. To the data dictionary in the TextAnalyst program, I added three key search terms for recovery of lost information during the content summarization. The terms added were "group," "individual," and the word stem "employ." Second, the ELSI/NAPBC recommendations were cross-mapped to the Davis and Mitrius prohibited act definitions and each bill was then evaluated based on whether the content contained the prohibited acts. Finally, all six bills were reviewed for the inclusion of an enforceable penalty, a feature identified in the workplace recommendation and common to both the Davis/Mitrius and the Colby studies. The results of the cross mapping between the Davis/Mitrius prohibited acts and the ELSI/NAPBC recommendations are outlined in the table below.

Table 3.1 ELSI/NAPBC Recommendations and the Davis/Mitrius Prohibited Acts

Recommendation*	***Prohibited Act***	***ELSI/NAPBC Content and Key Search Terms***
I1, W1	Using genetic information in the underwriting process	Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements. Employment organizations should be prohibited from using genetic information to affect the hiring, firing, or termination of employment unless the employment organization can prove this information is job related and consistent with business activity. ***Key search terms***: deny, limit, coverage, benefit
I2	Structuring rates or premium payments to discourage selling or renewing policies to persons with genetic defects	Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services. ***Key search terms***: rate, premium
I4, W3, W4	Disclosing genetic test results	Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

Recommendation*	***Prohibited Act***	***ELSI/NAPBC Content and Key Search Terms***
		Employment organizations should be restricted from access to genetic information in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs, and other sources. Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made. ***Key search terms***: disclose, authorization, consent
I3, W2	Requiring or requesting an individual to submit to genetic tests or to provide genetic information	Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information. Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all circumstances, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law.

Recommendation*	***Prohibited Act***	***ELSI/NAPBC Content and Key Search Terms***
		Written and informed consent should be required for each request, collection, or disclosure. ***Key search terms***: require, request, collection
W5	Stating penalty or the right to enforcement	Violators of these provisions should be subject to strong enforcement mechanisms, including private right of action. ***Key search terms***: penalty, violate, right

**Key: I1-4: ELSI/NAPBC Insurance recommendation. W1-5: ELSI/NAPBC Workplace recommendation. See Appendices A and B.*

Although the TextAnalyst program systematically selects the predominant word combinations and therefore summarizes the concepts of most importance in the body of the content analyzed, it is unable to determine if the content in the summaries is in any way related to the nature of the study's investigation. Adding the adapted version of Davis/Mitrius and Colby classification schemes to the research design allows for a comparative analysis based on methodologies already tried and accepted within the research community. The combination of the two approaches provides both a robust and a legitimate means to meet the study's objective of measuring the degree of correspondence between the legislation and the recommendations. Based on the above assumptions, the TextAnalyst procedures were used to produce summaries from the legislative document data. The TextAnalyst summaries were then compared to and plotted against the ELSI/NAPBC prohibited acts. The unit of analysis in measuring the degree of correspondence was the presence or absence of an ELSI/NAPBC prohibited act.

A match, based on the definition of the prohibited act variables in the above table, was taken as evidence that the content in the bill (the within-case correspondence) was

linked to the ELSI/NAPBC recommendations. The degree of correspondence between the legislation and the recommendations was evaluated based on the notion that the more legislative content devoted to the ELSI recommendations, the more salient the ELSI recommendations were in the policy formation process (the cross-case correspondence). To demonstrate the extent of both the within-case and the cross-case correspondence, I organized the findings as a matrix (Miles and Huberman, 1994). The matrix contains information on how the different legislative proposals (the rows of the matrix) incorporated the pre-defined prohibited act variables in the ELSI/NAPBC recommendations (the columns of the matrix). According to Miles and Huberman (1994), a matrix is an abbreviated and graphically arranged data display that not only organizes for the reader information that supports the research question but it also presents results wherein the researcher can readily justify inferences and conclusions.

Data Collection-Surveys

The "lived experience" survey questions were designed to obtain first-hand information about (1) whether the ELSI/NAPBC recommendations were used in the policy-formation process and (2) if so, how they were used. All contacts were professionals experienced in their line of work. No attempt was made to protect anonymity. Respondents were selected for the "lived experience" survey based on their membership in organizations or groups involved in some aspects of the ELSI/NAPBC recommendations and/or the legislative process. The names, phone numbers, and email addresses were obtained from the professional literature, a Health Directory Supplement of the Congressional Yellow Pages, and various Internet websites. All individuals who could be identified as formulating the ELSI/NAPBC recommendations, evaluating the ELSI program, and/or drafting the genetics nondiscrimination legislation were included in the survey. Using the membership criterion, three major groups were identified. The first major group identified was the ELSI/NAPBC workshop participants directly involved in assembling the insurance and workplace policy recommendations. A total of 14 individuals were identified; two of the fourteen could not be located. Key individuals identified within this group included:

1. Francis Collins, Director of the National Human Genome Research Institute;
2. Lori Andrews, Chair of the DOE ELSI Working Group;
3. Kathy Hudson, Director for Policy Coordination at the National Human Genome Research Institute and lead author of the 1995 *Science* article; and,
4. Karen Rothenberg, Chair of the Employment Discrimination Workshop Planning Committee and lead author of the 1997 *Science* article on the legislative approaches and policy challenges of genetic information and the workplace.

The second group identified was composed of those elected officials sponsoring genetics nondiscrimination bills introduced in the 106th Congress. The members of Congress who sponsored genetics nondiscrimination legislation in the 106th Congress were:

1. Representative Cliff Stearns (FL),
2. Representative John Sweeney (NY),
3. Representative Louise Slaughter (NY),
4. Senator Thomas Daschle (SD), and
5. Senator Olympia Snowe (ME).

Information provided by Representative Matthew F. McHugh (1979) in *Science, Politics, and Public Policy: A Legislator's Perspective* led to several additional contacts for inclusion in this group. According to Representative McHugh, legislators are often compelled by circumstances to depend on the judgments of knowledgeable support staff regarding the content and import of certain legislation. Additionally, McHugh indicated that the political process by which Congress operates is through a committee system and it is here, in committee, that a Member of Congress has the most influence on public policy (McHugh, 1979). Based on insights gained from McHugh's article, three legislative directors and five legislative assistants and six Committee Chairs were added

to the list of contacts. The Chairs of the Committees charged with review of the genetics nondiscrimination legislation included:

1. Representative Dan Burton (IN)
   Chair, House Commerce Committee
2. Representative Bob Stump (AZ),
   Chair, House Veterans' Affairs Committee
3. Representative William Goodling (PA)
   Chair, House Education and the Workforce Committee
4. Representative Thomas Bliley, Jr. (VA)
   Chair, House Commerce Committee
5. Representative Bill Archer (TX)
   Chair, House Ways and Means Committee
6. Senator Jim Jeffords (VT)
   Chair, Senate Health, Education, Labor and Pensions Committee.

The third category of contacts identified was the members involved in two ELSI evaluation committees: the 1996 ELSI Evaluation Committee and the 1997 ELSI Research and Planning Evaluation Group (ERPEG). Although these members did not participate directly in formulating the insurance and workplace recommendations, they were recognized as having expertise, experience, and/or accomplishments in areas relevant to the ELSI Research Program. It seemed reasonable to consider that these individuals may have been instrumental in advising the policy formation process and therefore were appropriate contacts for information. Twenty-four members were identified from a combined listing of the two committees. One individual could not be located and was removed from the list of potential candidates. Key contacts identified within this group included:

1. LeRoy B. Walters
   Director of the Kennedy Institute of Ethics at Georgetown University;
2. Ellen Wright Clayton

Associate Professor of Pediatrics and Law at Vanderbilt University;

3. Daniel Drell
   ELSI Manager for DOE
4. Mark A. Rothstein
   Co-Chair of the ELSI Evaluation Committee and Director of the Health Law and Policy Institute at the University of Houston's Law Center
5. James Childress
   Professor of Religion and Medical Education at the University of Virginia
6. Charles J. Epstein
   Professor of Pediatrics and Chief of the Division on Medical Ethics at the University of California.

The final list of contacts included a total of forty-six[4] potential respondents. For a complete listing of all contacts see Appendix D. The questions were written in a "yes" "no" "explain" format and used a branching logic. Each participant based on the nature of their response could answer anywhere from one to all six questions. For a copy of the survey questions, see Appendix E. The purpose of the study, the research design, procedures, potential risks, benefits, and all measures to be completed were formally reviewed and approved by Virginia Tech's Institutional Review Board.

Roughly one half of the individuals were initially contacted through electronic mail, which explained the intent of the research and included the six-question survey. Subjects were informed in the email that a phone interview would follow to document their responses. However, these subjects were however also informed that they could, if preferred, respond to the questions via email or return a copy of the email with their responses through the US postal mail service. The early responses returned by email were used to test the clarity, meaningfulness, and relevance of the instrument. Minor

[4] Although a total of fifty-four surveys were mailed, the members of Congress and their legislative assistants/directors were included in the tally as a single potential response.

adjustments were made to the terms "you" and "your" in questions 1 and 2 by tagging the terms with the appropriate referent group. Open response opportunities were also added to questions 4 and 5. All remaining subjects received the survey questionnaire by U.S. postal mail with a cover letter that stated a phone interview would follow to document their responses. The letter also stated they could, if they so desired, return their responses through the mail. A self-addressed stamped envelope was provided should the respondent choose to return the survey through the mail. Non-respondents received a second mailing. All but one contact returned their responses through the mail. The one exception agreed to and was interviewed by phone.

Data Analysis-Surveys

The third and final step in the analysis was to describe the first-hand or the lived experience of those involved in the policy formation process. In all, twenty-six responses were received. Seven of the mailed surveys were returned as "return to sender, attempted not known" leaving a final response rate of 19 out of a possible 39 or forty-nine percent of the individuals surveyed. While this sample of respondents is small, lived experience information provided by participants no matter how few, is extremely valuable (Yin, 1994). The analysis of survey responses included (1) the overall rate of response and (2) a comparison of responses by respondent category. The responses were first calculated in the aggregate (across all respondents) and then summarized by type of respondent (elected officials and/or designee, ELSI conference participants, ELSI evaluation member). Additional information reported included the number of respondents versus non-respondents, those responding but who were disqualified by a screening question, and a per question tabulation of response. The summary of survey results was reported based on the overarching inquiry: were the ELSI/NAPBC recommendations used and, if used, were they all used or were just a select few considered. Responses were hand counted and loaded into spreadsheet software program for graphic display.

Chapter 4: Findings

Introduction

The loss of and inability to obtain health insurance or employment due to a genetic predisposition to a health problem is a major concern in the general public of the United States. In response to this concern, several genetics nondiscrimination bills have been introduced into Congress over the past six years. So far, at the federal level, only the Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes provisions that explicitly cover genetic information (Reilly, 1999). HIPAA, however, has many gaps and is not considered comprehensive protection against the concerns raised (see Chapter One for details).

In 1995 and 1997, the National Action Plan on Breast Cancer (NAPBC) and the NIH-DOE Working Group on Ethical, Legal and Social Implications (ELSI) of the Human Genome Project published a series of joint recommendations to assist policy makers in formulating protections against insurance and workplace genetic discrimination. The goal of this thesis is to examine whether the ELSI recommendations have influenced federal genetics nondiscrimination policy. In order to satisfy the study's objectives, I first analyzed the genetics nondiscrimination legislation introduced in the 106th Congress against the ELSI/NAPBC policy recommendations themselves. Because the results from such a comparative analysis on the correspondence between the legislation and policy recommendations can only infer input, this study also attempted to validate such inferences by eliciting a "lived experience" confirmation. Accordingly, the data have been collected to determine if there is a direct correspondence between the content of the legislative proposals and the ELSI recommendations and, if so, does the "lived experience" data from the policy makers confirm the results obtained from the content analysis.

Content Analysis

In the analysis I first addressed whether the content in the legislation applies to group health plans, individual health plans, and/or specific restriction on employment practices. Then I explored the extent to which the legislation covers the prohibited acts as stated in the ELSI/NAPBC recommendations (see Table 4.1 below). The ELSI/NAPBC prohibited acts (Chapter Three, Table 3.1) include denying or limiting coverage, establishing rates or premium payments, disclosing genetic test results without prior written authorization, requiring or requesting an individual to provide genetic information, and violating the provisions as set forth in the legislative act. The findings are displayed as percentage across all bills (across cross comparison) where the numerator is the number of bills meeting the condition and the denominator is the total number of bills. Each bill is also evaluated individually (within case comparison) where the numerator is the number of prohibited acts included in the bill and the denominator is the total number of prohibited acts. Note the "Applies to" category is not included in the within case comparison.

Application

In determining the extent to which the legislation applied to group plans, individual plans, and/or employers all six bills (100%) included provisions that addressed the use of genetic information by (1) group health plans and (2) individual health plans. On the other hand, only three of the six (50%) included restrictions on employers. The three bills addressing restrictions on employers, HR 2457 (Representative Slaughter, D-NY), HR 2555 (Representative Stearns, R-FL), and S 1322 (Senator Daschle, D-SD) included the employer under the definition of "controlled group." Of these three bills, only HR 2555 clearly states that it is unlawful employment practice for an employer to attempt to acquire or to use the genetic information of an employee or applicant. Under the provisions stated in HR 2555, actions related to "use" include distinguishing among, discriminating against, or restricting any right or benefit otherwise due or available including terms and condition of employment and termination (HR 2555, SEC. 3 (a)(1), SEC. 3 (a)(2), and SEC. 3 (b)). Nonetheless, based on the presence of the term

"employer" in the definition of controlled group, bills HR 2457 and S 1322 were counted as having provisions the applied to employers. The remaining three bills, HR 293 (Representative Sweaney, R-NY), HR 306 (Representative Slaughter, D-NY), and S 543 (Senator Snowe, R-ME) made no specific reference to restrictions on employers.

Prohibited Acts

In determining the extent to which the legislation reflected the prohibited acts in the ELSI/NAPBC recommendations, all six bills (100%) contained limitations on (1) disclosure of genetic test results without consent and (2) the collection of predictive genetic information by issuers of insurance. The prohibited act with the weakest correspondence (50%) in the cross-case analysis (across all six bills) was the statement of an enforceable penalty given a violation of any of the provisions contained in the bill. The remaining two acts, denying or limiting coverage and adjusting premiums, both met an overall correspondence of eighty-three percent (see the bottom row in Table 4.1).

In the within-case analysis (each bill individually), only bill HR 293 displayed a correspondence of less than fifty percent. All other bills fell within the range of 80 to 100 percent correspondence (see the far right column of Table 4.1). HR 293, the bill with the least correspondence, failed to include explicit statements on (1) denying or limiting coverage, (2) establishing rates or premiums, and (3) identifying mechanisms for the enforcement of rights. HR 306 and S 543 (at 80% correspondence) failed only in providing provisions that specified a mechanism for enforcement. Bills HR 2457, HR 2555, and S 1322 contained language addressing all five (100%) of the prohibited acts.

In general, the content analysis revealed a direct relationship between the genetic nondiscrimination legislation in the 106th Congress and the ELSI/NAPBC recommendations. With the exception of HR 293, the measure of consistency between the bills and the prohibited acts in the recommendations was high returning at least an 80 percent correspondence. Overall the weakest correspondence discovered was: (1) in the area of application, establishing restrictions on employers and (2) in the prohibited acts, stating an enforceable penalty for the violation of the provisions set forth. Although HR 2457, HR 2555, and S 1322 contained provisions that applied to all three categories of

insurers and included all of the prohibited acts, HR 2555 appeared to be the most comprehensive (see earlier statements on HR 2555 in the Content Analysis: Application).

Table 4.1 Characteristics of the 106th Genetic Nondiscrimination Legislation

	Applies To			*Prohibited Act*					
	Group Plans	***Individual Plans***	***Restrictions on Employers***	***Deny or limit coverage***	***Adjust rates, premiums***	***Disclose w/o consent***	***Request, require collection***	***Enforceable penalty***	***Within Case***
HR 293	**X**	**X**				**X**	**X**		**40%**
HR 306	**X**	**X**		**X**	**X**	**X**	**X**		**80%**
HR 2457	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**100%**
HR 2555	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**100%**
S 543	**X**	**X**		**X**	**X**	**X**	**X**		**80%**
S 1322	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**100%**
Across Case	**100%**	**100%**	**50%**	**83%**	**83%**	**100%**	**100%**	**50%**	

Survey Results

As explained in Chapter Three, respondents were selected for the survey based on their membership in organizations or groups involved in some aspects of the ELSI/NAPBC recommendations and/or the legislative process. The survey was initially mailed in March 2001. Results were returned from March through the end of May. The survey questions were designed to obtain and describe the first-hand or lived experience on (1) whether the ELSI/NAPBC recommendations were used in the policy-formation process of the 106th genetic nondiscrimination legislation and (2) if indicated, how they were used, inclusively or in part. A total of nineteen responses (49%) were received out

of a possible[5] thirty-nine. The respondents (see Figure 1 below) included three of eight members of Congress (38%), seven of eleven ELSI workshop participants (64%), and nine of twenty ELSI evaluation members (45%). Surveys were completed and returned by the following individuals (see Appendix D for a complete listing of contacts).

Representative Louise Slaughter,
Senator Olympia Snowe,
Representative Dan Burton,
Lori B. Andrews,
Kathy Hudson,
Karen Rothenberg,
Mark Rothstein,
Ellen Wright Clayton,
Daniel Drell,
Rev. William E. Nebo,
Susan L. Rose,
Bailus Walker Jr.,
Sue Levi-Perl,[6]
Francis S. Collins,
Caryn Lerman,
Susan Saylor,
Elizabeth Thompson,
Kenneth Shine, and
Joy Boyer.

Fifty-eight percent (11 of the 19 respondents) indicated they had either participated in formulating the 106th genetic nondiscrimination legislation or the ELSI/NAPBC policy recommendations (Question 1, Figure 2). Eight individuals, one member of Congress and 7 ELSI Evaluation Committee members, returned a survey stating that they had neither participated in the drafting of the legislation nor did they participate in the formulation of the ELSI/NAPBC recommendations. They were subsequently removed from the tabulation on questions relating to use. Their response, however, was considered important (and therefore included in the response tabulation) in

[5] Seven of the mailed surveys were returned as "return to sender, attempted not known."
[6] This individual was contacted by phone all others returned their responses through the mail.

that by the act of returning the survey the respondent appeared to communicate a familiarity with and/or special regard for the subject matter.

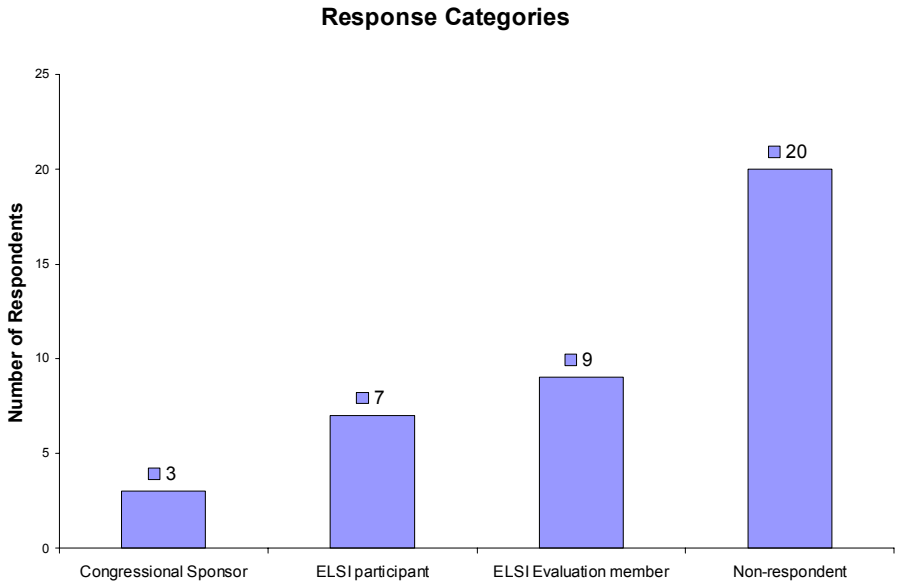

Figure 1. Number of respondents by category polled. The non-response category includes those who chose not to participate.

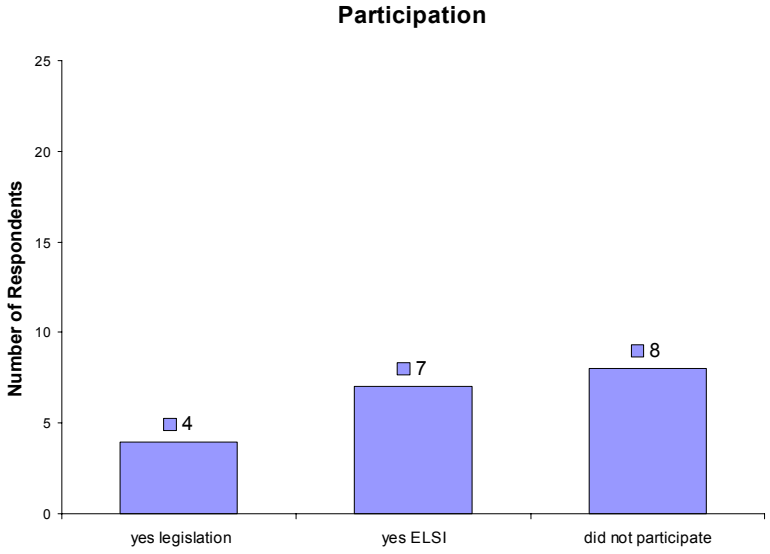

Figure 2. Question 1. Did you (ELSI participant, ELSI evaluation member, or elected official) participate in the drafting or review of any genetics nondiscrimination legislation introduced in either the House or Senate of the 106th Congress? If not, did you participate in the ELSI workshops on insurance or workplace discrimination?

Of those who stated they had participated in either activity, four respondents indicated their participation involved the obtaining or providing of content from the ELSI/NAPBC recommendations (Question 3, see Appendix E for a copy of the survey). Three of the four respondents, Representative Slaughter, ELSI/NAPBC member Kathy Hudson, and ELSI Insurance Task Force member Sue Levi-Perl, claimed they exchanged information in person. Two participants, Kathy Hudson and ELSI/NAPBC member Karen Rothenberg stated they did so through published document.

Sixty-four percent (7 of the 11 claiming a lived experience) stated that to the best of their knowledge the genetics nondiscrimination legislation included the ELSI/NAPBC policy recommendations (Question 4, Figure 3). The one "NO" response came from a ELSI Evaluation Committee member. The anecdotal comments justifying this respondent's negative affirmation stated: "too vague, much legislation on the table, none passed." One respondent admitted that he did not know but added he was aware that "ELSI [had] certainly affected some state laws." Two respondents did not answer the question.

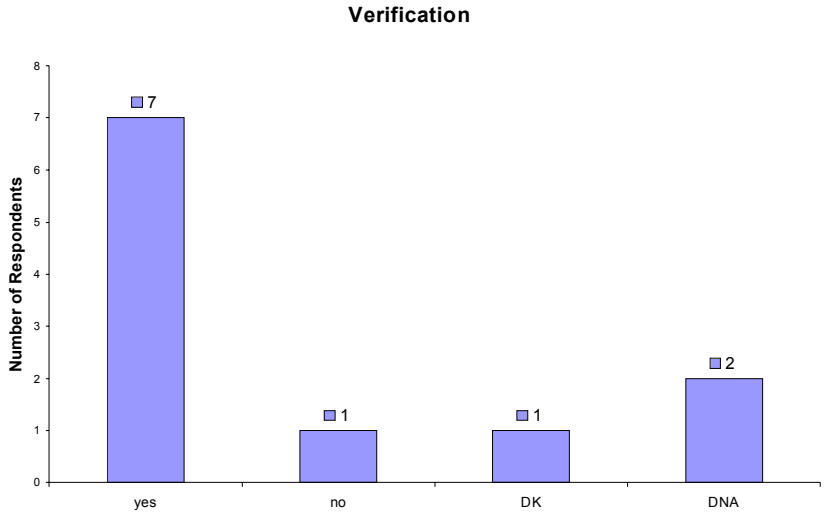

Figure 3. Question 4. To the best of your knowledge, did the final draft of the legislation include the ELSI recommendations? (DK=Don't Know, DNA=Did Not Answer).

The respondents for the most part appeared unsure as to whether the recommendations were wholly or partially incorporated in the legislation (Question 5, Figure 4). Two stated the recommendations were wholly incorporated, three stated partially, two claimed they did not know, and four did not answer the question. The respondents claiming the recommendations were incorporated in their entirety were Representative Slaughter and ELSI Evaluation Committee member Bailus Walker, Jr. The respondents stating partial incorporation were all ELSI/NAPBC workshop participants.

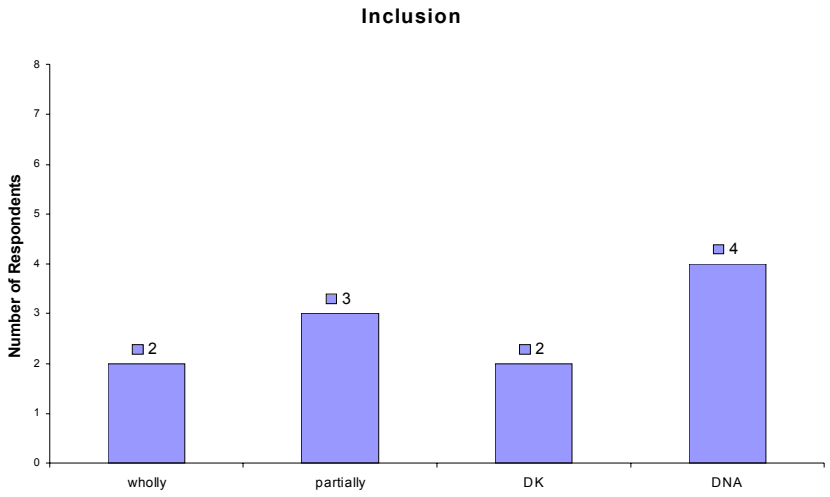

Figure 4. Question 5. Were the ELSI policy recommendations wholly or partially incorporated in the genetics nondiscrimination legislation?

In general, nearly 50% of the individuals polled returned a response. More than half of the respondents returning a survey stated they had participated in the policy-formation process. While only a little more than a third of respondents actually confirmed the active exchange of information, sixty-four percent (7 of 11 respondents) believed to the best of their knowledge the genetic nondiscrimination legislation included the ELSI/NAPBC recommendations. Three respondents indicated they were involved with legislation that will be introduced or continued in the 107th Congress and stated this

legislation also includes the ELSI policy recommendations. Two of the three are ELSI/NAPBC workshop participants and one is a member of Congress.

Summary

In summary, most of the genetics nondiscrimination legislation investigated in this study was similar in nature. The content in some of the bills is very detailed (e.g., HR 2555), while others are less specific. A positive finding on the relationship between the legislation and the ELSI/NAPBC was based on the fact that all six bills contained language that applied to the issuers of insurance and all six bills offered provisions for protection against at least two of the five prohibited acts. HR 293, the first of the six bills introduced in the 106th Congress returned the weakest correspondence. When omitting HR 293 from the analysis, the remaining five bills met 100% correspondence on four of the five prohibited acts investigated.

The data from the survey appeared to confirm the results from the content analysis in that the majority of the respondents who identified themselves as active participants in the policy-formation process stated they believed the legislation included the ELSI/NAPBC recommendations. Among those respondents who indicated active participation, the most frequent category of respondent was the ELSI/NAPBC member. Respondents Kathy Hudson, Representative Slaughter, and Sue Levi-Perl indicated that the legislation in the 107th Congress would also include the ELSI/NAPBC recommendations. While there was a considerable lack of consensus on whether the recommendations were wholly or partially included in the legislation, this may have been due to the narrow scope of the question asked (see Question 5, Appendix E).

Chapter 5: Conclusions

Introduction

In this thesis, I have examined whether the policy recommendations jointly developed by the Ethical, Legal, and Social Implications (ELSI) Program of the U.S. Human Genome Project and the National Action Plan for Breast Cancer (NAPBC) are dealing productively with the possibility that insurers and employers will misuse genetic information. In the current American health care system, information about an individual's risk for disease not only determines the financial burden incurred by those seeking health care services but it can also determine who is eligible for coverage. The link between the likelihood of needing health care services and the ability to obtain insurance coverage has, in and of itself, been a central theme in recent health care reform initiatives. Advances in genetic testing technologies will add a new sense of urgency to resolving current and future access issues.

Until recently the ability to predict the likelihood of disease has been confined to medical histories either elicited at the point of application through questions targeting personal health characteristics or by examining past use of the health care system. Improved prediction through genetic research, on the other hand, can identify individuals who will have some relatively uncommon diseases or who will have a higher than average risk for various diseases not otherwise predicted through these conventional methods. Such turn of events has caused great public concern. In fact, recent studies report individuals have lost jobs, insurance, or both due to the non-therapeutic use of genetic information. According to these studies, many individuals have also refused to be tested for genetic conditions or to participate in human genetics research for fear of adverse consequences.

Basing insurance or employment decisions on predictive information genetic information invites at best speculations about an individual's health status that may or may not increase health care expenditures. In a litigious, rights-based society it is no

surprise that such speculations have led to calls for mandated protection. Over the past seven years many bills with provisions addressing the use of genetic information have been introduced into Congress, none of which have been enacted.

At the federal level, only the Health Insurance Portability and Accountability Act (HIPAA) includes a provision that explicitly covers genetic information. HIPAA, however, leaves many individuals unprotected. For example, the protections under HIPAA do not extend to the individual health insurance market. Therefore, individuals seeking health insurance outside the group market may still be denied access to coverage and/or may be charged higher premiums. Furthermore, while HIPAA prohibits insurers from treating individuals within a group differently from one another, it leaves open the option that all individuals within a group could be charged a higher premium based on the genetic information of one or more members of the group.

At the present time, no federal legislation prohibits an insurer from demanding access to genetic information contained in medical records or family history or requiring that an individual submit to a genetic test. In fact, an insurer can demand that an individual undergo genetic testing as a condition of coverage. Additionally, there are no current restrictions on an insurer's release of genetic information to others. The ELSI/NAPBC policy recommendations cover all such omissions. While my intent was to determine if the ELSI/NAPBC recommendations are directing the current development of genetic nondiscrimination legislation, it is important to recognize that the correlation discovered between the two does not necessarily indicate the one influenced the other. The survey data volunteered by those involved in the policy formation process provide personal experience evidence that help bridge that gap.

Findings

All six genetic nondiscrimination bills reviewed in this study contained provisions that applied to the issuers of insurance, only three of the six specifically addressed employers, and all six offered protection against at least two of the five prohibited acts in the ELSI/NAPBC recommendations. The five prohibited acts in the ELSI/NAPBC recommendations were defined as: (1) using genetic information in the underwriting

process; (2) structuring broker fees or commissions to discourage selling policies to persons with genetic defects; (3) disclosing genetic test results; (4) requiring or requesting an individual to submit to genetic tests or to provide genetic information; and, (5) violating any of the acts so stated. House Bill 293 sponsored by Representative Sweeney, the first bill introduced in the 106th Congress on January 6, 1999, returned the weakest overall correspondence. When omitting HR 293 from the analysis, the remaining five bills met 100% correspondence on four of the five prohibited acts investigated.

The measures of least correspondence in the content analysis were "establishing restrictions on employers" and "stating an enforceable penalty." Information on why these two measures are not well represented in the legislation is limited. On the first point "establishing restrictions on employers" the literature did provide comment from Representative Slaughter. In a testimony before the Committee on Health, Education, Labor and Pensions (July 2000) she stated that the lack of attention was likely due to the fact that many members of Congress erroneously believe the Americans with Disability Act already protects workers against genetic discrimination. On the second point "stating enforceable penalties," I found little information in my research beyond noting that the Daschle amendment to H.R. 2990 was defeated because, unlike other antidiscrimination laws, the enforceable rights provision permits complaints to go straight to the courts bypassing the EEOC. The appropriations amendment that was adopted included provisions similar to those in the Daschle amendment but failed to make any mention of employer restrictions or the enforceable right to sue.

Question 5 in the lived experience survey, if structured a bit differently, might have offered valuable information on these two issues. While the survey asked whether the recommendations were totally or partially incorporated in the legislation, it did not ask, if answered "partially," what was omitted? It did, however, ask the respondent indicating partial inclusion to explain why. Two respondents indicated in their explanation that the recommendations were written as "general policy recommendations" and not as "legislative language," a third commented "politics is local," and a fourth

stated "it depends on the bill." None of these responses provided sufficient information to address why these two measures may have been neglected. Question Five was also the only question in the survey that did not result in a conclusive outcome.

The survey questions were designed to elicit a direct insight on whether the ELSI/NAPBC recommendations were used in the policy formation process and if used, how they were used. All individuals who could be identified as formulating the ELSI/NAPBC recommendations, evaluating the ELSI program, and/or drafting the genetics nondiscrimination legislation introduced in the 106th Congress were included in the survey. Fifty-eight percent (11 of 19 respondents) indicated that they had either participated in formulating the legislation or the ELSI/NAPBC recommendations. Sixty-four percent (7 of 11 respondents) stated that to the best of their knowledge the genetics nondiscrimination legislation included the ELSI/NAPBC policy recommendations.

The data from the survey confirmed the results from the content analysis in that the majority of the respondents who identified themselves as active participants in the policy-formation process also stated the legislation included the ELSI/NAPBC recommendations. The respondents not only confirmed use of the recommendations in forming the legislation investigated but also indicated the genetic nondiscrimination legislation in the 107th Congress would include content from the ELSI/NAPBC recommendations. In fact, two genetic nondiscrimination bills have been introduced since the time the respondents completed the survey. Senate Bill 318 was introduced by Senator Tom Daschle and is, as of May 2001, co-sponsored by 18 senators. A similar bill, House Bill 602, proposed by Representative Louise Slaughter is co-sponsored by approximately 225 of the 435 members of the House of Representatives. HR 602 has also been endorsed by more than 100 organizations, including the National Foundation/March of Dimes, the American Society of Human Genetics, the National Breast Cancer Coalition and the American Civil Liberties Union. Bills S 318 and HR 602 target genetic discrimination in health insurance and employment.

Although the findings from both the content analysis and the lived experience survey demonstrate that the ELSI/NAPBC effort has made a substantial impact on the

genetic nondiscrimination legislation, this study addressed the results from a single ELSI-funded project. As such, inferences about the overall effectiveness of the ELSI program, my second objective, are somewhat restricted to implications based on that outcome. Nonetheless, I believe my research permits some important observations in this area.

Observations

The balance of opinion in the arguments for and against legislation suggests that constructing measures to protect consumers against the misuse of genetic information is and will continue to be a challenge. Protection in this area is exceptionally difficult due to (1) the rapid pace of development in genetic testing technologies, (2) the precarious nature of anticipating social consequences, and (3) the inability to determine the similarities and/or differences between genetic and conventional medical information. Some of the policy issues are of such a magnitude that, if addressed directly, they may require substantial changes in both the health care and health insurance industries. According to the literature cited in Chapter Two, policy options for controlling the consequences posed by the new capacities in genetic testing include: legislating protections that restrict access to and/or making modifications in the system of health insurance such that the need for health-related information is eliminated.

The ELSI Research Program has explored and formulated recommendations addressing both. On discrimination by employers, the ELSI Working Group turned to the American with Disabilities Act and to the Equal Employment Opportunity Commission (EEOC) for assistance in determining the law's prospect for preventing exclusionary use of predictive genetic test results by employers. After several years of active negotiation between the EEOC, ELSI grantees, the Senate Committee on Disability Policy, and the Department of Justice, the EEOC published formal policy guidance that states all forms of pre-employment genetic testing fall under the law's protection. This position has yet to be tested in the courts.

On the issues concerning the use of genetic risk information in insurance underwriting, the ELSI Working Group formed a task force composed of representatives from the insurance industry, consumer and public-interest groups, and state government

officials who are charged with regulating insurance practices. The resulting report argued that the only secure way to prevent discrimination in this context was to institute major reform in the health care and health insurance systems. The argument in the report became part of President Clinton's public case for health care reform and its recommendations were incorporated in the administration's health reform bill, the Health Care Security Act of 1993. This act failed in Congress. Using the same participatory approach, the ELSI Working Group pulled together the ELSI/NAPBC workshops in 1995 and 1996 to develop policy recommendations that would provide a foundation for and assist policy makers in forming legislated protections. The results from this study indicate that not only did six bills in the 106th Congress adopt these recommendations but two in the 107th have also done so.

Like the national efforts that preceded it, ELSI's goal has been to develop well-informed policy options and to convey these recommendations to the public in an effective manner. What makes ELSI unique is that it has approached this task by cultivating a community of committed individuals, professional and lay, to generate a contextual body of science and technology knowledge. Despite such accomplishment, this study has shown there are considerable differences of opinion regarding the value of the ELSI program. The discrepancy can be roughly divided into two categories. The first is whether there is, or ever was, an agreement on the program's original charter. One view suggests that the ELSI program was invented solely as a public relations maneuver to secure approval from Congress for the Human Genome Project. Consistent with this view is the charge that ELSI was never meant to develop concrete recommendations that might jeopardize the future of the project but rather to identify only the urgent issues and to set a policymaking agenda. The counter view claims this criticism is and will continue to be wrong as long as the program's original concept as a source of independent research is preserved.

The second area of discrepancy has deeper implications for the future of participatory inquiry in general. Here, critics claim the ELSI's reliance on extramural research as a policy mechanism has been too slow and too academic. Proponents of this

view argue that a centrally directed panel of experts is not only more capable of identifying pertinent issues in a timely manner but also has the political authority to make their recommendations readily available to decision makers. It also contends these experts are experienced and, therefore can write recommendations better suited to the purposes of forming policy. Those supporting the counter view submit that while cultivating a community of scholars, educators and members of the general public may be more time-consuming, this approach is likely to produce policies that are directly responsive to social needs and expectations. The research supporting this study has made it clear that many of the ethical, legal, and social issues identified are highly complex and controversial. Reaching a consensus about such issues will not be easy.

Structural changes made within the ELSI program itself suggest considerable attention was given both categories of criticism. The decision to restructure the responsibilities of the ELSI Working Group came in 1997, and as a result the Working Group was dismantled into three different ELSI committees at various levels in the government. All aspects concerning the development and use of genetic tests, including the medical, ethical, legal, and social issues raised by genetic testing, have been transferred to the Secretary of Health and Human Services Office. The Secretary's Advisory Committee on Genetic Testing (SACGT) has overlapping membership with the Clinical Laboratory Improvement Advisory Committee and the Medical Devices Advisory Committee. The Committee's recommendations are submitted to the Secretary through the Assistant Secretary for Health, who also is responsible for coordinating common agenda issues among the three advisory committees.

Implications

The findings in this study indicate that ELSI/NAPBC recommendations found their way into the policy process and have exerted a substantial influence on the content in various genetic nondiscrimination bills over an extended period of time. Whether ELSI's efforts actually result in enacted legislation will depend to a large extent on what values are emphasized, that is, whether community, individual, or market based interests dominate the hearings. For instance, from a utilitarian perspective the litmus test will be

in determining whether the proposed genetic nondiscrimination provisions serve the common good. In other words, will such protection collectively and communally help and do they improve us as a society in general? This is at direct odds with an egalitarian stance which will first ask whether the provisions adequately protect the individual from harm? If there are communal concerns, such interest will be placed secondary to that of the individual's welfare. Should the proposed genetic nondiscrimination legislation fail to find a reasonable consensus, the utilitarian might instead argue for a solution that targets changes in insurance industry itself. These members are likely to advocate a return to the community rated system of insurance where risk-calculations are set according to the entire pool of consumers rather than within separate categories of risk-specific groups.

Both perspectives, the greatest good for the greatest number or that which best supports the autonomy of the individual, will meet questions concerning how the enacting the proposed legislation will impact our American system of free market capitalism. The modern business of private health insurance is an economic device designed to protect individuals against unexpected financial loss y transferring the risk of loss to the insurance company. Individuals typically seek insurance when they recognize the cost of care is such that they are either unwilling or unable to bear. Private insurance firms are willing to supply insurance if they perceive that a profit can be made on the transaction (Ostrer et al, 1993). In the system described, there is ultimately some maximum price above which the individual will not purchase insurance. Similarly, there is also a minimum premium that the insurer must receive in order to be willing to supply insurance. As long as the prices overlap, there is in theory a market for health insurance.

As the number of genetic tests increase and their use becomes more widespread, insurers are concerned that individuals who test positive will alter previous relied upon buying practices (Pokorski, 1997). For example, individuals may choose to buy insurance when they would not have done so absent a positive test, and, more importantly, may fail to inform the insurance company of the results at the time of application (a phenomenon in the insurance industry known as adverse selection). Under

such circumstances, the proposed legislative restrictions on insurer access to risk information could potentially result in market dissolution (Pokorski, 1992; Ostrer et al, 1993). Insurers argue that the premium increases, necessitated by unexpected losses resulting from widespread adverse selection, would ultimately exceed the rates that standard policyholders are likely willing to pay. The assessment of higher premiums would, as a result, encourage low-risk applicants to buy from another insurer or to leave the insurance market completely. The exit of lower-risk persons from the risk pool would subsequently increase the proportion of high risks remaining in the pool of insureds. The increasing proportion of higher risks in the pool of insureds could create a spiraling cycle of further increases in premiums, the continued exit of low-risk persons, and eventually the exit of companies from the market due to the lack of the potential for profit.

As issues related to genetic testing and discrimination in the private health insurance industry become more pressing, complex questions will surface regarding whether society should hold private insurance companies socially responsible for the consequences genetic exclusions will pose (Jecker, 1993). For instance, one might expect questions such as: Is a commercial insurance company to be blamed when individuals denied private coverage can no longer cover their medical expenses? Alternatively, one might also expect questions regarding the government's duty to guarantee equal access to health care services. If commercial insurers are determined to have some degree of social responsibility, one might expect questions about the appropriate content and scope of such responsibility. And, as suggested earlier, there is the question of how such responsibility can be reasonably financed.

Achieving consensus on the social and economic issues raised by the recent advances in human genetic research is inevitably contingent upon of our nations political priorities. Legislative solutions to genetic discrimination will most likely suffer delay as Congress turns to issues related to homeland security. Nonetheless, during the next decade there will be continued debate over the acquisition, dissemination, storage, and ownership of genetic information. The debate will likely unfold with repeated efforts to

provide the individuals who will use and/or be affected by the results with some degree of control over this process.

The manner in which that process unfolds will continue to be a major concern for not only the biomedical research community but also academe and industry. It will force a re-thinking of allocating scientific and technical decisionmaking between experts and the lay public, among competing political interest groups, and between citizens and the state. The ELSI program can serve as a rich and useful source of theoretical inspiration albeit a practical example of how to shape some of this re-thinking. While the responsibilities of ELSI program have been subjugated to an authority chartered under the agency of the SACGT, the advisory committees of SACGT appear to have adopted the same participatory approach to advocating social policy as did the extramural programs of the ELSI Working Group.

Definition of Terms

Allele. One of several alternative forms of a gene occupying a given position on the chromosome. A single allele for each position is inherited separately from each parent, so every individual has two alleles for each gene.

Asymptomatic. Without symptoms (Taber's, 1973).

Carrier. An individual with one disease form of a gene and one normal form of the gene (Kelves and Hood, 1992). The presence of the flawed gene is masked by the dominant functional gene (Zallen, 1997).

Chromosome. A rod-like structure composed of proteins and the cellular DNA that bears in its nucleotide sequence the linear array of genes.

DNA. (deoxyribonucleic acid) The molecule that encodes genetic information.

Etiology. The study of the causes of disease (Taber's, 1973).

Gene. A small section of DNA that contains information for the formation a single-protein molecule.

Gene mapping. Assigning the ordered relationships and distances between different genes or DNA segments on a chromosome (Annas and Elias, 1992).

Genetic discrimination. Discrimination based solely on an apparent or perceived difference in the genetic constitution of an individual or members of that individual's family (Gostin 1991; Bilings et al, 1992; Natowicz, 1992).

Genetic information. Information about genes, gene products, or inherited characteristics of an individual or a member of that individual's family (Hudson et al, 1995).

Genetic mapping. Determination of the relative position of genes on a DNA molecule and of the distance, in linkage units, between them.

Genetic predisposition. A genetic propensity for impending illness (Gostin, 1991).

Genetic test. DNA tests or procedures that provide information about the nature of the genes present in the individual tested.

Genome. The total genetic makeup of an organism.

Genomics. A generic term for mapping and sequencing DNA (Annas and Elias, 1992).

Human Genome Initiative. The collective name given to various projects directed toward (1) mapping and sequencing the human genome and genomes of other species, (2) developing of new computational methods for analyzing the genome, (3) development of new instruments and techniques for analyzing DNA (Annas and Elias, 1992).

Human Genome Project. The U.S. federally funded initiative to map and sequence the entire human genome.

Insurance provider. An insurance company, employer, or any other entity providing a plan of health insurance or health benefits including group and individual health plans whether fully or self-funded (Hudson et al, 1995).

Metabolism. The sum of all physical and chemical changes that take place within an organism; all energy and material transformations that occur within living cells (Taber's, 1973).

Metabolite. Any product of metabolism (Taber's, 1973).

Mutation. A permanent change in the number, arrangement, or molecular sequence in DNA that can be inherited.

Predisposition. A tendency to develop a certain disease, either acquired or hereditary (Taber's, 1973).

Recessive trait. A mutation whose effect is revealed only when it occurs in both genes of a gene pair.

Science policy strategy. Propositions used by actors and agents engaged in making science and technology policy (Averch, 1985).

Sequence. The linear order of the bases in the DNA molecule or of amino acids in a protein molecule.

Symptomatic. Of the nature of or concerning a symptom (Taber's,1973).

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Appendix A: ELSI/NAPBC: Insurance Recommendations

1. Insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility, continuation, enrollment, or contribution requirements.

2. Insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services.

3. Insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information.

4. Insurance providers and other holders of genetic information should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made.

Source: Hudson et al (1995)

Appendix B: ELSI/NAPBC Workplace Recommendations

1. Employment organizations should be prohibited from using genetic information to affect the hiring, or termination of employment unless the employment organization can prove this information is job related and consistent with business activity.

2. Employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information prior to a conditional offer of employment, and under all circumstances, employment organizations should be prohibited from requesting or requiring collection or disclosure of genetic information unless the employment organization can prove this information is job related and consistent with business necessity, or otherwise mandated by law. Written and informed consent should be required for each request, collection, or disclosure.

3. Employment organizations should be restricted from access to genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement of health care costs, and other sources.

4. Employment organizations should be prohibited from releasing genetic information without prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure will be made.

5. Violators of these provisions should be subject to strong enforcement mechanisms, including private right of action.

Source: Rothenberg et al (1997)

Appendix C: Genetic Nondiscrimination Legislation

H.R. 293 Genetic Information Health Insurance Nondiscrimination Act of 1999
SPONSOR: Representative Sweeney, R-NY (introduced 01/06/99).
To amend the Public Health Service Act and the Employment Retirement Income Security Act of 1974 to prohibit issuers and group health plans from discriminating against individuals on the basis of genetic information.
Latest Action: 4/12/1999 Referred to House subcommittee
Committees: House Education and the Workforce; House Commerce; House Ways and Means

H.R. 306 Genetic Information Nondiscrimination in Health Insurance Act of 1999
SPONSOR: Representative Slaughter, D-NY (introduced 01/06/99).
To prohibit discrimination against individuals and their family members on the basis of genetic information or a request for genetic services.
Latest Action: 1/22/1999 Referred to House subcommittee
Committees: House Education and the Workforce; House Commerce; House Ways and Means

H.R. 2457 Genetic Nondiscrimination in Health Insurance and Employment Act of 1999
SPONSOR: Representative Slaughter, D-NY (introduced 07/01/1999; companion to S. 1322).
To prohibit health insurance and employment discrimination against individuals and their family members on the basis of predictive genetic information or genetic services. Latest Action: 8/6/1999 Referred to House subcommittee
Committees: House Education and the Workforce; House Commerce; House Ways and Means

H.R. 2555 Genetic Privacy and Nondiscrimination Act of 1999
SPONSOR: Representative Stearns, R-FL (introduced 07/19/1999).
To establish limitations with respect to the disclosure and use of genetic information in connection with group health plans and health insurance coverage, to provide for consistent standards applicable in connection with hospital care and medical services provided under title 38 of the United States Code, to prohibit employment discrimination on the basis of genetic information and genetic testing, and for other purposes. Latest Action: 10/8/1999 Referred to House subcommittee
Committees: House Education and the Workforce; House Government Reform; House Commerce; House Veterans' Affairs

S. 300 Genetic Information Nondiscrimination in Health Insurance Act of 1999
SPONSOR: Senator Lott, R-MS (Title II of S. 300, Patients' Bill of Rights Act introduced 01/22/99).
To improve access and choice of patients to quality, affordable health care.
Latest Action: 1/22/1999 Referred to Senate committee
Committees: Senate Finance

S. 326 Genetic Information Nondiscrimination in Health Insurance Act of 1999
SPONSOR: Senator Jeffords, R-VT (Title II of S. 326 introduced 01/28/99).
To improve the access and choice of patients to quality, affordable health care.
Latest Action: 6/17/1999 Placed on Senate Legislative Calendar under General Orders. Calendar No. 160. (On July 15, 1999, the Senate incorporated the text of S. 326, as reported by the Committee on HELP, into S. Amendment 1232 to S. 1344.) Committees: Health, Education, Labor, and Pensions (HELP)

S. 543 Genetic Information Nondiscrimination in Health Insurance Act of 1999
SPONSOR: Senator Snowe, R-ME (introduced 03/04/1999)
To prohibit discrimination on the basis of genetic information with respect to health insurance.
Latest Action: 3/4/1999 Referred to Senate committee Committees: Health, Education, Labor, and Pensions

S. 1322 Genetic Nondiscrimination in Health Insurance and Employment Act of 1999
SPONSOR: Senator Daschle, D-SD (introduced 07/01/1999).
To prohibit health insurance and employment discrimination against individuals and their family members on the basis of predictive genetic information or genetic services. Latest Action: 7/1/1999 Referred to Senate committee
Committees: Health, Education, Labor, and Pensions

S. 1344 Genetic Nondiscrimination in Health Insurance Act of 1999 (Title III of S. 1344, Patients' Bill of Rights Act, passed Senate 7/15/99).
To amend the Public Health Service Act, the Employment Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage.
Latest Action: 10/14/1999 Senate incorporated this measure in H.R. 2990 as an amendment.

Appendix D: Genetic Nondiscrimination Legislation Survey Contacts

Contact	*Response Category*
ANDREWS, Lori B.	ELSI/NAPBC Participant Chair, ELSI Working Group (1995)
ARCHER, Bill (R-TX)	Chair, House Ways and Means
BLILEY, Thomas Jr. (R-VA)	Chair, House Commerce
BOYER, Joy T.	ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
BUFFLER, Patricia A.	Member of the Joint NIH-DOE Committee to Evaluate ELSI
BURTON, Dan (R-IN)	Chair, House Committee on Government Reform
CALDERWOOD, Jane	Congressional Staff Member SNOWE, Senator (R-ME)
CHILDRESS, James F.	Member of the Joint NIH-DOE Committee to Evaluate ELSI
CLAYTON, Ellen Wright	ELSI Research Planning and Evaluation Group
COLLINS, Francis S.	ELSI/NAPBC Participant Co-Chair, NAPBC Hereditary Susceptibility Working Group Director, National Human Genome Research Institute
CROWE, Veronica	Congressional Staff Member SWEENEY, Representative (R-NY)
DASCHLE, Senator (D-SD)	Congressional Sponsor S 1322
DRELL, Daniel	ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
DUSTER, Troy	ELSI/NAPBC Participant

Contact	*Response Category*
EPSTEIN, Charles J.	Member of the Joint NIH-DOE Committee to Evaluate ELSI
FINE, Beth	ELSI/NAPBC Participant
FULLER, Barbara	ELSI/NAPBC Participant
GOODLING, William (R-PA)	Chair, House Education & the Workforce
GRIFFETH, Jennifer	Congressional Staff Member SNOWE, Senator (R-ME)
HILGARTNER, Stephen	Member of the Joint NIH-DOE Committee to Evaluate ELSI
HUDSON, Kathy	ELSI/NAPBC Participant
JEFFORDS, Jim M. (R-VT)	Chair, Senate Health, Education, Labor and Pensions Committee
KING, Mary-Claire	ELSI/NAPBC Participant
KNOPPERS, Barbara Maria	Member of the Joint NIH-DOE Committee to Evaluate ELSI
LERMAN, Caryn E.	ELSI Research Planning and Evaluation Group
LEVI-PERL, Sue	Insurance Task Force Member
LOEWENSEN, Jane	Congressional Staff Member DASCHLE, Senator (D-SD)
MACKTA, Jayne	Member of the Joint NIH-DOE Committee to Evaluate ELSI
MCEWEN, Jean E.	ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
MCINERNEY, Joseph D.	ELSI Research Planning and Evaluation Group
MURPHY, Patricia	ELSI/NAPBC Participant
NEBO, Rev. William E.	ELSI Research Planning and Evaluation Group
OLSON, Maynard V.	Member of the Joint NIH-DOE Committee to Evaluate ELSI

Contact	*Response Category*
PELLEGRINI, Cindy	Congressional Staff Member SLAUGHTER, Representative (D-NY)
POWER, Michael	Congressional Staff Member SWEENEY, Representative (R-NY)
PRESS, Nancy	ELSI Research Planning and Evaluation Group
ROSE, Susan L.	ELSI/NAPBC Participant ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
ROTHENBERG, Karen	ELSI/NAPBC Participant
ROTHSTEIN, Mark	ELSI/NAPBC Participant Co-Chair of the Joint NIH-DOE Committee to Evaluate ELSI
SAYLOR, Susan	ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
SHINE, Kenneth I.	Member of the Joint NIH-DOE Committee to Evaluate ELSI
SLAUGHTER, Representative (D-NY)	Congressional Sponsor HR 306; HR 2457
SNOWE, Senator (R-ME)	Congressional Sponsor S 543
SPENCE, M. Anne	Co-Chair of the Joint NIH-DOE Committee to Evaluate ELSI
STEARNS, Representative (R-FL)	Congressional Sponsor HR 2555
STUMP, Bob (R-AZ)	Chair, House Veterans' Affairs
SWEENEY, Representative (R-NY)	Congressional Sponsor HR 293
SWERGOLD, Gary	ELSI/NAPBC Participant

Contact	*Response Category*
THOMPSON, Beth	Congressional Staff Member SWEENEY, Representative (R-NY)
THOMPSON, Elizabeth J.	ELSI Research Planning and Evaluation Group NHGRI/DOE Staff
VALLE, David	ELSI Research Planning and Evaluation Group
WALKER, Bailus Jr.	Member of the Joint NIH-DOE Committee to Evaluate ELSI
WALTERS, LeRoy B.	Chair, ELSI Research Planning and Evaluation Group
WASHBURN, Eric	Congressional Staff Member DASCHLE, Senator (D-SD)

Appendix E: Survey Questions

1. Did you (ELSI participant, ELSI evaluation member, or elected official) participate in the drafting or review of any genetics nondiscrimination legislation introduced in either the House or Senate of the 106th Congress?

   _Yes

   _No

   If answered no, did you participate in the ELSI workshops on insurance or workplace discrimination?

   _Yes

   _No, **terminate survey/interview.**

   If answered yes, skip to Question 4.

2. **If answered yes to Question 1**, did your participation involve obtaining (elected official) or providing (ELSI conference or evaluation member) the insurance or workplace policy recommendations generated by the NIH-DOE ELSI research programs?

   _Yes

   _No

   If answered no, explain:

   _Not familiar with the ELSI recommendations

   _Felt the recommendations were flawed in some way

   _Other: (comment required)

   Terminate survey/interview.

3. **If answered yes to Question 2**, how was this information obtained or provided?
   _Published research documents

   _In person, by phone, or personal letter correspondence

   Identify the correspondent: (name/title)

4. To the best of your knowledge, did the final draft of the legislation include the ELSI recommendations?

   _Yes

   _No

   _Don't Know

   If answered No or Don't Know, explain:

   Skip to Question 6.

5. **If answered yes to Question 4**, were the recommendations wholly or partially incorporated?

   _Wholly

   _Partially

   _Don't Know

5a. **If answered partially**, are you aware of why partial versus all information was desired/required?

   _Yes

   _No

   5b. **If answered yes,** explain:

6. Are you currently involved with legislation that you believe will or does include the NIH-DOE ELSI policy recommendations and will be introduced or continued in the 107th Congress?

   _Yes

   _No

Vita

PAMELA J. DEWEESE

PROFESSIONAL HIGHLIGHTS

As a Registered Nurse, I have held responsible positions in the health care industry, managed care industry, and academic community. Throughout my career I have consistently demonstrated strong communication and problem solving skills. The employment history that follows details leadership in both corporate middle management and clinical practice.

EMPLOYMENT HISTORY

ValueOptions, Falls Church, VA 1990-present
Director, Special Projects
Coordinates provider performance activities for the Health Plans Division and Corporate Quality Management's Outcomes and Evaluation Department. Assists corporate utilization efforts by establishing research strategies for improved trends and better outcomes. Works with service center clinical, quality, and data management staff in developing and implementing provider performance and member functional assessment programs. Assists internal Information Technology department in researching, evaluating and integrating applicable software products from external vendors.

Trainer, Corporate Provider Relations
Conducted performance assessments on all direct line staff. Implemented educational programs on change in industry standards and in-house policies and procedures. Trained new staff and provided remedial learning opportunities for improvement.

Case Management Coordinator
Supervised outpatient mental health review activities. Trained and completed performance assessments for all new outpatient care management employees. Developed performance standards and conducted Quality Assurance audits. Acted as liaison for internal account executives, external benefit managers, and the third party payers.

Case Manager
Performed inpatient, outpatient, and catastrophic utilization review. Volunteered as relief staffing for the Clinical Assessment and Referral Department.

Blue Cross Blue Shield, Northeast Ohio 1988-1990
Review Analyst

Performed utilization review and disability evaluations for the Psychiatric Division of the Medical Review Department. Maintained a clinical database for reporting utilization of mental health and substance abuse services. Served as a liaison between the Claims Administration, Provider Relations, and Legal Departments.

Health Care Review Systems, Cleveland, OH 1987-1988
Review Coordinator
Performed prospective, concurrent, retrospective medical record audits to assist client companies in controlling health benefit costs. Co-developed the mental health and substance abuse utilization review protocol.

Cuyahoga Falls General Hospital, Cuyahoga Falls, OH 1979-1986
Health Education Coordinator
Coordinated hospital-sponsored education for patients, their families, and the community at large.

Staff Development Coordinator
Oriented all new employees to the health care facility. Provided training on institutional policies and advanced technologies.

Charge Nurse-Adult and Adolescent Psychiatric Unit

University of Akron, Akron, OH 1978-1979
Faculty-College of Nursing, Department of Psychiatric Nursing

Fallsview State Psychiatric Hospital 1976-1978
Charge Nurse and Shift Supervisor

HONORARIA

Sigma Theta Tau, Delta Xi, Charter member 1975-present

EDUCATION

Case Western Reserve, 1983-1985-College of Nursing.
Kent State University, 1972-1976-College of Nursing