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GENETIC NON-DISCRIMINATION: EXAMINING THE IMPLICATIONS FOR WORKERS AND EMPLOYERS

HEARING

BEFORE THE

SUBCOMMITTEE ON EMPLOYER-EMPLOYEE RELATIONS

OF THE

COMMITTEE ON EDUCATION AND THE WORKFORCE
U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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C O N T E N T S

	Page
Hearing held on July 22, 2004	1
Statement of Members:	
Andrews, Robert E., Ranking Member, Subcommittee on Employer-Employee Relations, Committee on Education and the Workforce	3
Johnson, Hon. Sam, Chairman, Subcommittee on Employer-Employee Relations, Committee on Education and the Workforce	1
Prepared statement of	2
Statement of Witnesses:	
Hudson, Dr. Kathy, Director, The Genetics and Public Policy Center, Johns Hopkins University, Washington, DC	5
Prepared statement of	8
Licata, Dr. Jane Massey, Partner, Licata & Tyrell P.C., Marlton, NJ	34
Prepared statement of	35
Lorber, Lawrence, Esq., Partner, Proskauer Rose LLP, Washington, DC, on behalf of the U.S. Chamber of Commerce	37
Prepared statement of	40
Letter answering follow-up questions	85
Wildsmith, Tom, Chairman, Genetic Testing Taskforce, American Academy of Actuaries, Washington, DC	11
Prepared statement of	14
Additional materials supplied:	
Alpha–1 Association and Alpha–1 Foundation, statement submitted for the record	67
American Academy of Family Physicians, statement submitted for the record	69
American Academy of Pediatrics, statement submitted for the record	65
American Association for the Advancement of Science, letter submitted for the record	68
American Cancer Society, statement submitted for the record	84
American Osteopathic Association, statement submitted for the record	83
American Psychiatric Association, statement submitted for the record	83
American Society of Human Genetics, statement submitted for the record	82
Association of Women's Health, Obstetric and Neonatal Nurses, statement submitted for the record	81
Catholic Health Association, statement submitted for the record	94
CARES Foundation, Inc., letter submitted for the record	64
Coalition for Genetic Fairness, statement submitted for the record	96
Digestive Disease National Coalition, statement submitted for the record	65
FORCE, statement submitted for the record	81
Genetic Alliance, statement submitted for the record	69
Gingrich, Hon. Newt, Former Speaker, U.S. House of Representatives, statement submitted for the record	86
Gregg, Hon. Judd, a U.S. Senator from the State of New Hampshire, statement submitted for the record	61
Huntington's Disease Society of America, statement submitted for the record	94
National Breast Cancer Coalition, statement submitted for the record	72
National Council on Disability, statement submitted for the record	73
National Marfan Foundation, letter submitted for the record	68
National Workrights Institute, statement submitted for the record	71
Ovarian Cancer National Alliance, statement submitted for the record	93

Page

Additional materials supplied—Continued
Slaughter, Hon. Louise McIntosh, a Representative in Congress from the State of New York, statement submitted for the record 87
Society for Women's Health Research, letter submitted for the record 62
The Arc of the United States, statement submitted for the record 66
UJA–Federation of New York, Women's Public Policy Task Force, statement submitted for the record 62
United Cerebral Palsy, statement submitted for the record 64
United Spinal Association, statement submitted for the record 95

GENETIC NON-DISCRIMINATION: EXAMINING THE IMPLICATIONS FOR WORKERS AND EMPLOYERS

Thursday, July 22, 2004
U.S. House of Representatives
Subcommittee on Employer-Employee Relations
Committee on Education and the Workforce
Washington, DC

The Subcommittee met, pursuant to notice, at 10:30 a.m., in room 2181, Rayburn House Office Building, Hon. Sam Johnson [Chairman of the Subcommittee] presiding.

Present: Representatives Johnson, Wilson, Kline, Carter, Andrews, Payne, McCarthy, Kildee, Holt, and Grijalva.

Staff present: Kevin Frank, Professional Staff Member; Aron Griffin, Professional Staff Member; Richard Hoar, Staff Assistant; Donald McIntosh, Staff Assistant; Jim Paretti, Workforce Policy Counsel; Deborah L. Samantar, Committee Clerk/Intern Coordinator; Jo-Marie St. Martin, General Counsel; Jody Calemine, Minority Counsel, Employer-Employee Relations; Margo Hennigan, Minority Legislative Assistant/Labor; and Peter Rutledge, Minority Senior Legislative Associate/Labor.

Chairman JOHNSON. Good morning. A quorum being present, the Subcommittee on Employer and Employee Relations of the Committee on Education and the Workforce will come to order. We are holding this hearing today to hear testimony on Genetic Non-Discrimination: Examining the Implications for Workers and Employers. Under Committee Rule 12(b), opening statements are limited to the Chairman and the Ranking Minority Member of the Subcommittee. Therefore, if other members have statements, they will be included in the hearing record.

With that, I ask unanimous consent for the hearing record to remain open for 14 days to allow members' statements and other extraneous material referenced during the hearing to be submitted in the official hearing record. Without objection, so ordered.

STATEMENT OF HON. SAM JOHNSON, CHAIRMAN, SUBCOMMITTEE ON EMPLOYER-EMPLOYEE RELATIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Good morning. I want to welcome you all, and especially Mr. Andrews, our Ranking Member, and my other colleagues. When the NIH and Department of Energy announced they had completed a

rough map of the human genome in 2000, it opened the door to a new era of research. The dream of detecting diseases early on, accurately treating them with minimal side effects, if not preventing them entirely, seemed within reach. And indeed, we move closer to that reality every day.

With this unprecedented potential for discovery, however, comes an equally weighty challenge for public policymakers. The possibility of unjust use of genetic information about individuals and their families must be addressed.

Discrimination against a potential employee because they may get cancer someday is not acceptable. Employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of factors, genetic or otherwise, that have no bearing on job performance.

On the flip side, if in an effort to prevent that sort of discrimination we define genetic information too broadly, it could greatly upset some insurance markets, resulting in an adverse selection.

The government has taken some measures to tackle this issue by expanding the Americans with Disabilities Act to include those that are subject to discrimination on the basis of genetic information in relation to illness, disease or other disorders. Additionally, the Health Insurance Portability and Accountability Act, lovingly referred to as HIPPA, prohibited group health plans from using genetic information to establish rules for eligibility.

In addition, more than half of the states have enacted their own laws that further restrict the use of genetic information in health insurance underwriting and employment decisions. As this Congress continues to consider further legislation, it's vital that we move only after careful deliberation. We need to know and understand the effects of current law before we attempt to take further steps, so as not to be surprised by any unintended consequences of our work to provide the right balance of privacy for Americans.

In short, these are tough issues that have no easy answers, and we appreciate you all being here today to give us a more detailed backdrop for -discussion, your latest research and to answer any questions if you can.

I now yield to the distinguished Ranking Minority Member of the Subcommittee, Mr. Rob Andrews, for whatever opening statement you wish to make, sir.

[The prepared statement of Chairman Johnson follows:]

Statement of Hon. Sam Johnson, Chairman, Subcommittee on Employer–Employee Relations, Committee on Education and the Workforce

Good morning. Let me extend a warm welcome to all of you, to the ranking member, Mr. Andrews, and to my other colleagues.

When the NIH and Department of Energy announced that they had completed a rough "map" of the human genome in 2000, it opened the door to a new era of research. The dream of detecting diseases early on, accurately treating them with minimal side-effects if not preventing them entirely seemed within reach, and indeed we move closer to that reality every day.

With this unprecedented potential for discovery, however, comes an equality weighty challenge for public policy makers. The possibility of unjust use of genetic information about individuals and their families must be addressed. Discrimination against a potential employee because they MAY get cancer some day is not acceptable. Employment decisions should be based on an individual's qualifications and ability to perform a job, not on the basis of factors, genetic or otherwise, that have no bearing on job performance.

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As this Congress continues to consider further legislation, it is vital that we move only after careful deliberation. We need to know and understand the affects of current law before we attempt to take further steps, so as not to be surprised by any unintended consequences of our work to provide the right balance of privacy and for Americans.

In short, these are tough issues that have no easy answers. We appreciate you being here today to give us a more detailed backdrop for discussion, your latest research and to answer any questions you can.

STATEMENT OF HON. ROBERT E. ANDREWS, RANKING MEMBER, SUBCOMMITTEE ON EMPLOYER-EMPLOYEE RELATIONS, COMMITTEE ON EDUCATION AND THE WORKFORCE

Mr. ANDREWS. Good morning. Good morning, Mr. Chairman. Thank you for your courtesies, and welcome, ladies and gentlemen. We look forward to hearing from you this morning.

We're interested in this subject, and we're here this morning because of people like a young woman named Kim who was a social worker at a human services agency. One day she went to a workshop for her staff about caring for people with chronic illnesses. She mentioned at the workshop that she had been the primary caretaker for her mother, who had died of Huntington's Disease. It appears that because of her family history, this young woman, Kim, had a 50 percent chance of developing the disease herself.

Kim had always received outstanding performance reviews as a great employee of her agency. One week later, after disclosing casually in the workshop that she had a family history of Huntington's Disease, Kim was fired.

At best under present law—at best—it is ambiguous as to whether Kim is protected by the employment discrimination laws of our country. She should be. And if in fact the reason for her dismissal was her genetic predisposition for a disease, she should be protected by the laws of this country.

The purpose of this hearing today is to figure out exactly how to do that. This is one of the rare issues in the field of employment law where there is, at least on the surface, very broad agreement. One voice in this debate said this: "Genetic discrimination is unfair to workers and their families. It is unjustified. Among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. To deny employment or insurance to a healthy person based only on a predisposition violates our country's belief in equal treatment and individual merit."

I could not have said it better myself. These words were not spoken by me. They were spoken by President George W. Bush.

This is an issue on which we should reach prompt agreement. There are many ways that we can approach this problem, and I would hope that the hearing this morning will explore the assets and liabilities of those various ways. But our goal needs to be to move as the Senate has moved very expeditiously in a nearly unanimous vote toward legislation—in fact, it was a unanimous vote of those present—toward legislation that will prohibit discrimination in hiring, promotion, employment status, legislation that will protect the rights of people to be free from invasive testing with respect to their genetic status. This is what we need to do.

If a person walks into a hiring office this morning and the human resources director says we're not going to hire you because we're not hiring dark-skinned people or women or Catholics, if an H.R. director says that this morning, they've violated the law. And I think the law should be no less profound if a person walks in and their medical history shows that they have a predisposition toward leukemia or heart disease. It's an immutable characteristic.

The point of employment discrimination law for decades in this country, really longer than that if one looks at the constitutional law, is that people should not be judged on their immutable personal characteristics. They should be viewed, as the President stated, they should be viewed on the merit of their performance in the job. We should be judged by who we are, not by what our genetic makeup does to the color of our skin or our gender or our health care status.

I think it's very important that we move quickly toward a legislative resolution of this problem. I thank the Chairman for holding the hearing, and I look forward to working with him and his good offices to achieve a level of consensus as the Senate did to get this on the President's desk and outlaw this practice.

Thank you very much.

Chairman JOHNSON. Thank you, Mr. Andrews. We've got a very distinguished panel of witnesses before us today, and I want to thank you all for coming. Dr. Kathy Hudson is the Director and founder of The Genetics and Public Policy Center and an associate professor in the Berman Bioethics Institute and Institute of Genetic Medicine, Department of Pediatrics, at Johns Hopkins University.

Before founding the Genetics and Public Policy Center, Dr. Hudson was the assistant director of the National Human Genome Research Institute. That's an acronym I haven't seen. How do you pronounce it?

Dr. HUDSON. It's not possible.

Chairman JOHNSON. NHGRI. Responsible for communications, legislation, planning and education activities.

Mr. Tom Wildsmith is currently a consultant in the Hayes Group's Arlington, Virginia office. Mr. Wildsmith has 21 years of experience dealing with all aspects of health insurance policy and financing, including 12 years operational experience with a commercial carrier, 9 years advocacy experience with a major health insurance trade organization.

Dr. Jane Massey Licata, a biotechnology patent lawyer representing universities, biotechnology companies, and major pharmaceutical companies, Dr. Licata has been involved in the filing of

numerous patent applications concerning diagnostics and therapeutics which rely upon genetic information and human genes, and you've been here before. We welcome you back.

Mr. Lawrence Lorber, a partner in the Washington, D.C. office of Proskauer Rose, is an employment law practitioner who counsels and represents employers in connection with all aspects of labor and employment law. Mr. Lorber was formerly the Deputy Assistant Secretary of Labor and director in the Office of Federal Contract Compliance Programs during the Ford Administration.

Before the witnesses begin their testimony, I want to remind members we will be asking questions after the entire panel has testified. In addition, the Committee Rule 2 imposes a 5-minute limit on all questions, and you've got lights down there which were used for he and I, and if you see the yellow light come on, we'd like you to try to tie it up and close it out.

And I'll now recognize Dr. Hudson as the first witness, and you may begin your testimony.

STATEMENT OF KATHY HUDSON, DIRECTOR, THE GENETICS AND PUBLIC POLICY CENTER, JOHNS HOPKINS UNIVERSITY, WASHINGTON, DC

Dr. HUDSON. Thank you, Mr. Chairman, Members of the Committee. Thank you for inviting me to appear before you, and thank you for your consideration of this important issue.

My name is Kathy Hudson. I'm the director of the Genetics and Public Policy Center at Johns Hopkins University. The Center was created in 2002 by a grant from the Pew Charitable Trusts, and our mission is to provide information and analysis on genetic technologies and genetic policies for the public, the media and policymakers.

In my current position, and in my former position at the Human Genome Project, I've had the pleasure of working with both Republican and Democratic staff to help craft genetic discrimination legislation. I'd ask that my written testimony be made a part of the record, and I'll proceed to make three points about the promise of genetic medicine.

Chairman JOHNSON. We'll do that for all of you.

Dr. HUDSON. Thank you.

Chairman JOHNSON. If you want to submit them for the record.

Dr. HUDSON. The threats to realizing that promise, and the need for public policy protections. Last year marked the completion of the Human Genome Project, a historic international effort to decipher letter by DNA letter the entire sequence of all human genes. Genes are simply instructions, instructions for the human body to develop and function normally, but a misspelling in those instructions can cause disease or increase the risk of disease.

With the human genome sequence in hand, scientists can identify quickly DNA misspellings associated with disease, and it's relatively straightforward then to develop a genetic test.

Genetic tests provide information, information that can provide a diagnosis and guide treatment decisions, prognostic information about the future course of a disease, and probabalistic information about the future risk of developing a disease.

Today there are over a thousand different genetic tests available, and that number is increasing steeply. They range from tests for fatal and untreatable diseases such as Huntington's to tests for mutations that detect a risk for future disease such as breast cancer.

And not only is the number of tests increasing, but the technology for testing is getting ever more powerful. It used to be that a genetic test looked for one DNA misspelling at a time. With new gene chip technology, we can look at hundreds, even thousands of DNA misspellings in a single test.

As we move ahead to integrate genetics into mainstream medicine, we need to make sure that public policy keeps pace. Protections must be in place to assure people that the results of their genetic tests will not be used against them. There have been cases of genetic discrimination and breaches of genetic privacy. Workers at Burlington Northern Santa Fe Railroad were subjected to surreptitious genetic testing to determine if they had a supposed genetic basis for work-related carpal tunnel syndrome.

More recently, Heidi Williams has shared the story of how her two young children were denied health insurance even though they were only carriers of a recessive genetic disease and would not themselves become ill.

Should a person's job be dependent on whether they may or may not develop a disease at some point in the future, or should the ability to land a keep a job be based on whether the person can do the job today?

A number of steps, as the Chairman mentioned, have been taken to put limited protections in place. HIPPA includes some restrictions on the use of health-related information and explicitly includes genetic information. The privacy regulations afford the same privacy protection for genetic information as other health-related information, and the EEOC has issued guidance that genetic information should be protected under the Americans with Disabilities Act, though the extent of those protections remains largely untested and unclear.

As the Chairman noted, a key challenge in drafting genetic discrimination legislation is getting the definitions right. The key definitions are genetic tests and genetic information. Definitions that are inexact will undermine an otherwise well-intentioned effort. In crafting a definition that is neither too broad nor too narrow, it's also important to ensure that the definition is not rooted in genetic testing technologies of the present time that will rapidly become obsolete. So the definitions need to be able to accommodate new innovations in genetics and genetic testing.

Finally, I want to share with you results from new research conducted by the Genetics and Public Policy Center to look at what the public knows, thinks, and feels about genetic testing. We completed a very large survey in April and found that Americans are generally very optimistic about the future of genetic testing and its potential for improving human health, but they are also very concerned about who is going to have access to these test results. An overwhelming majority, 92 percent, oppose employers having access to genetic information. Similarly, 80 percent oppose health insur-

ance companies having access to that information. Opposition is growing since we asked an identical question in 2002.

In conclusion, the need for protections against genetic discrimination grows with every new test developed and with every new patient who decides to forego or delay genetic testing because of their concerns about genetic discrimination.

I am confident that as you chart a path forward, you will be able to meet the needs of scientists, health care providers, insurers, employers, and most importantly, of patients.

Thank you.

[The prepared statement of Dr. Hudson follows:]

Statement of Dr. Kathy Hudson, Director, The Genetics and Public Policy Center, Johns Hopkins University, Washington, DC

Mr. Chairman and members of the subcommittee, thank you for inviting me to be with you today to discuss the medical possibilities and policy challenges arising from the dazzling scientific and technical achievements in genetic research.

My name is Kathy Hudson and I am the Director of the Genetics and Public Policy Center and Associate Professor in the Berman Bioethics Institute and in the Institute of Genetic Medicine at Johns Hopkins University. Established with a grant from The Pew Charitable Trusts, the mission of the Genetics and Public Policy Center is to be an independent and objective source of credible information on genetic technologies and genetic policies for the public, media and policymakers and to create the environment and tools needed by key decision makers in both the private and public sectors to carefully consider and respond to the challenges and opportunities that arise from scientific advances in human genetics.

I have been involved in genetics research and genetics policy for over a decade and had the privilege of serving as the assistant director of the National Human Genome Research Institute from 1995 to 2002.

Last year marked the completion of the human genome project, an historic international project to decipher, letter by DNA letter, the sequence of all the human genes. I believe that the mapping and sequencing of the human genome is the "moonlanding" of the current generation. It is an accomplishment that is stunning in its own right. It also serves as the centerpiece of a wide array of breathtaking breakthroughs in genetics research that have provided new insight into human health and disease. Now these advances are beginning to change the practice of medicine in ways that are at once exciting and challenging.

Today, I am pleased to discuss the rapid advances in genetic testing and the importance of public policies that will keep pace with the science and will ensure that genetic information is used for benefit and not for harm.

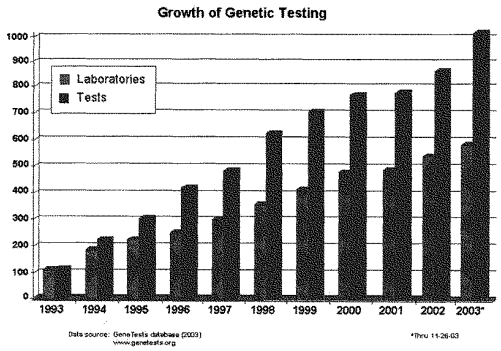
The Human Genome Project

The Human Genome Project was more than a technological tour de force. The genome project and genetic research are providing brilliant new insights into the role of genes in health and disease. Genes are instructions, instructions for building cell structures and proteins needed for the human body to develop and function properly. With the genome sequence in hand and with new tools for genetic research, scientists can quickly identify DNA misspelling in the genetic instructions that can cause disease or increase the risk of disease. Once a gene is identified that, when misspelled, causes or contributes to disease, it is relatively straightforward to develop a genetic test that can detect that misspelling.

There are some genes that if misspelled will always cause disease—if you have the disease-causing mutation for Huntington disease, for example, you will, at some stage, develop the disease. But many diseases are not that simple. Many common diseases such as heart disease and diabetes are the result of many genes and many complex environmental factors. For example, scientists have recently discovered variants in a gene that appear to increase the risk of type 2 diabetes by about 30 percent. An individual found to have this increased genetic risk could potentially start an active program of prevention including losing weight and regular exercise. Yet, when this test becomes available, some may be afraid to get tested for fear their employer may gain access to the information and use it against the employee out of the belief that the employee will be too costly to employ and insure.

Fueled by progress in genome science, genetic tests can detect a growing number of diseases with increasing precision. Today there are over 1000 genetic tests available or in development. They range from tests for fatal and untreatable diseases such as Tay Sachs disease to tests for gene mutations that increase the risk of developing a disease at some point in the future, such as the BRCA1 and BRCA2 mutations that are associated with an increased risk of breast and ovarian cancer.

Not only are the number of tests increasing but the technology for genetic testing has become ever more powerful. It used to be that a genetic test involved looking for one DNA misspelling at a time. Now, hundreds, even thousands, of possible DNA misspellings can be looked at simultaneously with new "gene chip" technology, exponentially increasing the power and scope of genetic testing.



Genetic tests provide information. Information that can provide a diagnosis and guide treatment decisions, prognostic information that can help tell the course of a disease, or probabilistic predictive information about the future risk of disease.

Within a dozen years, it may be common medical practice to test each one of us for our individual susceptibilities to common illnesses. This knowledge will allow the use of individualized preventive medicine to maintain wellness, rather than spending society's health care resources on expensive and ineffective treatments for advanced disease. Genetic tests can also reveal how an individual will respond to a drug therapy and who will experience serious side effects. The future holds the possibility of pharmaceuticals that can target illnesses at the molecular level, truly revolutionizing drug therapy for diseases.

The information to be gained from genetic testing is incredibly powerful and can lead to life altering decisions that improve health and the quality of life. But it is important to remember that our ability to detect gene misspellings precedes, sometimes by decades, the development of effective prevention and treatment. For example, we have had a genetic test for Huntington disease for over a decade but still have no effective intervention.

The Importance of Protecting Genetic Information

As we move ahead to integrate genetics into mainstream medicine, we need to make sure that public policy keeps pace. The same genetic test that can guide treatment decisions and improve human health can also be used in ways that are fundamentally at odds with our most basic, shared American values. The promise of genetic medicine will only be realized if protections are in place to assure people that the results of genetic testing will not be used against them.

There have been cases of genetic discrimination in the past few years. For example, beginning in March 2000, workers at Burlington Northern Sante Fe Railroad were subjected to surreptitious genetic testing to determine if they had a supposed genetic basis for work related carpal tunnel syndrome. Many observers believe that the company was interested in using this information to limit workers' compensation claims by these employees. More recently, at a press conference held on Capitol Hill earlier this year, Heidi Williams told how her two young children were denied health insurance even though they were only carriers of a recessive genetic disease and would not themselves become ill.

Finding principles to guide the fair use of genetic information and prevent test results from being misused is critical to all of us. Each of us has a number of misspellings in our DNA that can forecast our future health risks. But, like the weather forecast, this information is often probabilistic. There is a greater or lesser chance that it will rain, there is a greater or lesser chance that an individual will develop any number of diseases or conditions.

Should a person's job be dependent on predictions whether they might or might not develop a disease at some point in the future? Or, should the ability to land and keep a job be based on whether the person can do the job today?

These are issues that were anticipated early on in the Human Genome Project and a number of steps have already been taken to put limited protections in place. With the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, Congress put in place some restrictions on group health insurers' use of health related information in making coverage decisions and in setting premiums. Congress specifically recognized and listed genetic information as among the protected health information. Subsequently, in promulgating privacy regulations called for by HIPAA, the Department of Health and Human Services made clear that access to and disclosure of genetic information is protected.

In the workplace setting, the EEOC has interpreted the Americans with Disabilities Act to provide some protections from the use of genetic information by employers, but the extent of those protections is largely untested and unclear.

Both President Clinton and President Bush have recognized the need to protect workers from genetic discrimination. On February 8, 2000, President Clinton issued an Executive Order that prohibits Executive departments and agencies from using protected genetic information as a basis for employment decisions. The Executive Order provided important protections to millions of federal workers and placed the federal government in the laudatory position of leading by example.

In a June 22, 2001 Radio Address, President Bush said "I look forward to working with members of Congress to pass a law that is fair, reasonable, and consistent with existing discrimination statutes. We will all gain much from the continuing advances in genetic science. But those advances should never come at the cost of basic fairness and equality under law."

The challenge is to nurture scientific exploration, encourage the translation of these new discoveries into life saving medicines, and to put in place public policies that reflect our core American values that prevent the unjust, unfair, and discriminatory use of genetic information.

Definitions

As part of my work at the National Human Genome Research Institute I had the distinct pleasure of working with scientists, health care providers, legal scholars and ethicists to craft principals that we felt should be embodied in public policy to protect patients from unjust uses of genetic tests. Since that time, I have been asked and had the privilege to provide technical assistance and advice to Republican and Democratic Senate staff members as they sought to craft definitions that are both pragmatic and scientifically sound.

The key terms in genetic discrimination legislation are "genetic test" and "genetic information." Definitions that are inexact can undermine a well-intentioned effort. In crafting a definition that is neither too broad nor too narrow, it is also important to ensure that the definition is not rooted in genetic testing methods that will become rapidly obsolete. The technology for genetic testing is changing and a statutory definition must be able to accommodate these innovations.

Public Opinion

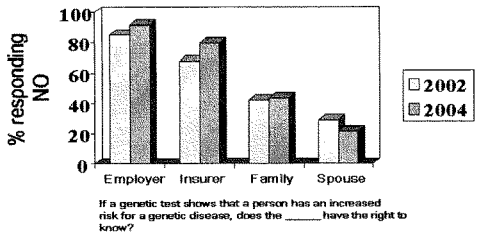
Finally, I want to share with you some research conducted by The Genetics and Public Policy Center, to find out what the public knows, thinks and feels about new genetic testing. Members of the public have shared with us their hopes for healthy children, for reducing the burden of disease and disability, and for reducing health care costs. They have also shared with us their fears and concerns.

We know from genetics researchers that all too often, those offered genetic tests decline, citing their concerns about the privacy and use of their test results. These concerns are widespread and, interestingly, are growing in America.

Our recently completed survey of 4,834 Americans shows that Americans generally approve of genetic testing procedures to benefit health but are concerned about who will have access to genetic test results.

This survey, unprecedented in its scope, shows that an overwhelming majority of Americans oppose employers and health insurance companies having access to genetic information. When asked the question "if a genetic test shows that a person has an increased risk for disease, does the employer have the right to know," 92% said "no". Similarly, 80% opposed health insurance companies having access to this information. In contrast, most respondents are comfortable with their spouse or partner knowing their genetic test results.

Opposition to employer and health insurer access to genetic test results has grown since a similar survey was conducted by the Genetics and Public Policy Center in 2002. The opposition to employer and health insurer access does not vary based on age, sex, or political affiliation. However, attitudes do vary by educational level of the respondents with more than 97% of respondents with a college education opposing employer access.



	Employer	Insurer	Family	Spouse
2002 [a]	85	68	42	29
2004 [b]	92	80	43	21

[a] 2002 Genetics & Public Policy Center survey
"Public awareness and attitudes about genetic technologies" (n = 1211).

[b] 2004 Genetics & Public Policy Center survey
"Public awareness and attitudes about genetic technologies" (n = 4834).

To explore public opinion about genetic technologies in more detail, the Genetics and Public Policy Center is facilitating public discussion of the issues surrounding reproductive genetic testing in cities across America this summer. The Center is inviting citizens in six U.S. cities to participate in "Genetic Town Halls: Making Every Voice Count". In the Town Halls, the public is invited to learn about genetic testing through presentations and interactive discussion, discuss and debate the issues with their fellow citizens, and register their attitudes and opinions.

At the three Genetics Town Halls held this month – in Sacramento, CA, Seattle, WA, and Kalamazoo, MI – participants voiced a broad range of opinions. Participants' opinions about the types of genetic technologies that are acceptable ranged widely, and their opinions about who should decide which genetic tests are available were even more diverse. Still, participants in all three town halls have spontaneously expressed deep concern about how information from genetic testing will be used. As a participant in Sacramento asked, "Will you have trouble getting a job because you have this gene that may cause cancer, whether or not you have cancer?"

Conclusion

As a scientist, I am eager to bring genetic research out of the lab and to the patient's bedside. As someone who believes in the public policy process, I want to make sure that we have policies in place to make genetic testing as safe and beneficial for as many as possible.

When a woman goes to her doctor to discuss the possibility of having a genetic test to learn whether she has an increased genetic risk for a disease, there are many important issues to consider to understand what the results will mean for her medically and emotionally. How the test result will affect her treatment, what it will mean for her reproductive decisions, what it will mean for her family, and what it will mean for her, personally, to have this information about her own genome. It is my hope that soon, very soon, doctors can confidently tell their patients that while there is much to consider when deciding to have a genetic test, the threat that those genetic test results might be used to deny her a job is not one of them.

The need for such protections grows with every new test developed and with every new patient who decides to forego or delay genetic testing because of discrimination concerns. I am confident that as you chart a path forward you will be able to meet the needs of scientists, health care providers, and patients alike in creating the appropriate protections.

Chairman JOHNSON. Thank you, Dr. Hudson.

Mr. Wildsmith, you may begin.

STATEMENT OF THOMAS F. WILDSMITH, CHAIRMAN, GENETIC TESTING TASK FORCE, AMERICAN ACADEMY OF ACTUARIES, WASHINGTON, DC

Mr. WILDSMITH. Chairman Johnson, Ranking Member Andrews, and distinguished Members of the Committee, I thank you for this opportunity to testify on behalf of the American Academy of Actuaries. My name is Tom Wildsmith, and I currently serve as the vice chairperson of the Academy's Federal Health Issues Committee.

I've also served as the chairperson of the Academy's Task Force on Genetic Testing in Health Insurance. The Academy is a nonpartisan public health policy organization for actuaries of all specialties.

Scientific understanding of human genetics is advancing rapidly, and the technology continues to evolve. It's difficult to predict the impact this technology will ultimately have on the health insurance system. There are several key factors to consider in the public policy debate over the proper regulation of genetic information, especially with respect to health insurance.

First, basing premiums and eligibility for coverage on a specific person's own health is a characteristic of the voluntary individual health insurance market, not the employer-sponsored group insurance market. Thus, while possible future use of genetic information for medical underwriting is a potentially significant issue in the individual medical expense insurance market, it's not a significant concern in the group insurance market.

Second, medical expense coverage is unique, because beyond the questions related to the use of genetic information, it involves the

question of whether the direct cost of genetic testing and treatment will be covered.

Third, innovative disease management and prevention programs depend on the ability to identify patients and high risk individuals for appropriate interventions. It's important that rules governing the use of genetic information not hamper the ability of such programs to improve care.

Finally, all personal health information is, as it should be, protected. Applying special rules to genetic information would increase the complexity of an already quite complicated health care system. I'd like to discuss each of these in turn.

Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored health insurance coverage, which covers nine out of ten privately insured Americans. Private group and individual health insurers do not currently require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions.

Of course, the debate is really over the future. The impact of genetic information on the health insurance system will change over time as the technology develops and may often be overshadowed by broader societal concerns about the meaning and significance of the information.

Employers will have to decide whether or not to pay for new genetic tests and treatments. It's unclear whether genetic technology will increase or decrease overall lifetime spending on medical care, and what the timing of those changes may be. We expect genetic tests that aid in the diagnosis of disease and genetic treatments for disease to be gradually recognized and covered by medical expense plans. Unless these new tests and treatments produce an offsetting reduction in other medical expenses, they may produce an overall increase medical care cost. As the use of genetic technology becomes routine, the question of how to pay for it will become more important.

Employers are increasingly turning to a variety of targeted programs to prevent the development of disease in high risk individuals and to manage its progression in those who are already ill. To be successful, all of these programs depend on information. As we attempt to ensure that personal health information is not used against employees, it is important that we not inadvertently preclude its beneficial use on their behalf.

There is broad agreement that patients' privacy must be protected and the confidentiality of sensitive health information must be secured. Underwriting and pricing for group insurance has historically focused on the overall makeup of the eligible group, rather than on the health of any particular individual. And HIPPA prohibits employers from using health status to deny coverage to an employee or to make an employee pay more than a coworker.

Genetic information is subject to the same confidentiality rules as other forms of health information. Separate rules governing genetic information could increase complexity in a system that's already quite complicated.

I would also note that the definitions in the first genetic information legislation to be enacted would likely set an important prece-

dent for the future. As genetic science advances, additional legislation will be needed to address future issues that we can't predict in advance. Legislation in this area should be drafted carefully and try and capture what is unique about the newly emerging genetic technologies.

Again, I thank you for the opportunity to testify on behalf of the Academy.

[The prepared statement of Mr. Wildsmith follows:]

Statement of Thomas F. Wildsmith, Chairman, Genetic Testing Taskforce, American Academy of Actuaries, Washington, DC

Chairman Johnson, Ranking Member Andrews, and distinguished committee members, I thank you for the opportunity to comment on an increasingly important issue that could have a significant impact on the health insurance market – the use of genetic information. My name is Tom Wildsmith, and I currently serve as the vice chairperson of the American Academy of Actuaries' Federal Health Issues Committee. I have also served as chairperson of the Academy's Task Force on Genetic Testing in Health Insurance. The Academy is the non-partisan public policy organization for actuaries of all specialties in the United States. I would like to submit for the written record the Academy monograph *Genetic Information and Medical Expense Insurance,* which expands on some of the key points that I will address today regarding genetic information and health insurance.

Legislation is pending before the House and has passed the Senate that would regulate the use of genetic information, particularly with respect to health insurance and employment. Scientific understanding of human genetics is advancing rapidly, but the technology continues to evolve. It is difficult to predict the impact this technology will ultimately have on the health insurance system. There are several key factors to consider in the public policy debate over the proper regulation of genetic information especially with respect to health insurance:

- Basing premiums and eligibility for coverage on a specific person's own health is a characteristic of the voluntary individual health insurance market – not the employer-sponsored group insurance market. Thus, while possible future use of genetic information for underwriting medical expense insurance is a potentially significant issue in the individual market, it is not a significant concern in the group market.
- Medical expense coverage is unique because, beyond the questions related to the use of genetic information, it involves the issue of whether the direct costs of genetic testing and treatment will be covered.
- Innovative disease management and prevention programs depend on the ability to identify patients and high-risk individuals for appropriate interventions. It is important that rules governing the use of genetic information not hamper the ability of such programs to improve care.
- All personal health information is, as it should be, protected – applying special rules to genetic information would increase the complexity of an already complicated health care system.

Policymakers must balance these and other competing social and economic concerns in considering legislation on this issue.

Group vs. Individual Medical Expense Insurance

Americans currently receive health care coverage through a variety of public and private systems. While some issues raised by genetic technology are common among most or all of these systems, others are specific to particular types of health care coverage. Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored health coverage – which covers nine out of 10 privately insured Americans.

Voluntary, individually purchased coverage in particular presents unique issues. A ban on the use of genetic information that would prohibit insurers from asking for genetic tests may remove applicants' fears of genetically based denial of coverage. However, barring insurers from obtaining test results already known to the applicant could result in adverse selection, which would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

Any attempt to regulate the use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated. If a ban on information obtained from "genetic tests" defines such tests broadly to include medical history or routine physical exams, it would severely hamper

Private group and individual health insurers do not currently require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions. Of course, the current debate is really over the future. The various impact of genetic information on the health insurance system will change over time as the technology develops, and may often be overshadowed by broader societal concerns about the meaning and significance of genetic information. When balancing social and economic concerns, a clear understanding of the economic impact of alternative policies is vital.

Costs of Covering Genetic Testing and Treatment

The employer-sponsored medical expense insurance market will be faced with the question of whether the direct costs of various genetic technologies will be covered. It is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans. Unless these new tests and treatments produce an offsetting reduction in other medical expenses they may produce an overall increase in medical care costs.

Disease Management and Prevention

Employers are increasingly turning to a variety of targeted programs to prevent the development of disease in high-risk individuals, and to manage its progression in those who are already ill. To be successful, all of these programs depend on information. As we attempt to ensure that personal health information is not used against employees, it is important that we not inadvertently preclude its beneficial use on their behalf.

Confidentiality of Health Information

There is broad agreement that patients' privacy must be protected and the confidentiality of sensitive health information must be secured. The possibility of testing for abnormal genes has, in particular, raised fears about access to health coverage. However, underwriting and pricing for group insurance has historically focused on the overall makeup of the eligible group rather than the health of any particular individual – and HIPAA prohibits employers from using health status to deny coverage to an employee or to make them pay more than a coworker. (Of course, for small groups, a single high-cost individual can significantly affect the average cost of an entire group.) In addition, genetic information is subject to the same confidentiality rules as other forms of health information. While there may be particular sensitivities in the case of genetic information, this is part of the broader issue of health information confidentiality. Separate rules governing genetic information could increase complexity in an already complicated health care system.

Conclusion

For the employment-based health insurance system, the use of genetic information in individual underwriting is not a significant issue. As the technology advances and becomes a routine part of medical care, the question of how to pay for it will likely take on increasing significance. Personal health information is already subject to a variety of protections. Any additional protections placed on genetic information should allow for the use of such information in the development of new disease management and prevention programs, which could improve care and reduce costs. Rules governing genetic information should be balanced against the need to better manage an already complex health care system, and the need to use genetic information for legitimate, beneficial purposes. I would also note that the definitions in the first genetic information legislation to be enacted would likely set a precedent for the future. As genetic science advances, it is inevitable that additional legislation will be needed to address future issues we cannot predict in advance. It is important that legislation in this area be drafted carefully, and reflect what is unique about the newly emerging genetic technologies.

Thank you for this opportunity to testify on behalf of the American Academy of Actuaries.

Public Policy Monograph

June 2000

Genetic Information and Medical Expense Insurance

AMERICAN ACADEMY of ACTUARIES

AMERICAN ACADEMY *of* ACTUARIES

The American Academy of Actuaries is the public policy organization for actuaries practicing in all specialties within the United States. A major purpose of the Academy is to act as the public information organization for the profession. The Academy is non-partisan and assists the public policy process through the presentation of clear and objective actuarial analysis. The Academy regularly prepares testimony for Congress, provides information to federal elected officials, comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification, and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

This monograph was prepared by the Academy Task Force on Genetic Testing in Health Insurance, which educates legislators and regulators about actuarial aspects of genetic testing, its use by health insurers, and related actuarial issues important to an understanding of the potential impact of genetic technology on the private health insurance system. The monograph's sole purpose is to assist the public policy process through the presentation of clear, objective analysis.

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18

Genetic Information and Medical Expense Insurance

Executive Summary

Scientific understanding of human genetics is advancing rapidly, but the technology is not yet mature. It is difficult to predict the impact this technology ultimately will have on the insurance system. Key concerns that have been raised include access to health care, the cost of health care and health insurance,and the privacy of genetic information. Policy-makers must balance these and other competing social and economic concerns.

Key Issues

Americans currently receive health care coverage through a variety of public and private systems. Some issues raised by genetic technology are common among most or all of these systems; others are specific to particular types of health care coverage.

- The impact of genetic testing on the cost and delivery of health care likely will have an effect on all forms of health care financing.
- Genetic information is subject to the same confidentiality rules as are other forms of health information. While there may be particular sensitivities in the case of genetic information, this is a part of the broader issue of health information confidentiality.
- The possible future use of genetic information in risk selection and risk classification is a potentially significant issue only for the voluntary individual market.
- While most Americans are guaranteed access to some form of medical expense insurance, the cost of coverage varies significantly, and there are still some gaps. Filling those gaps could help reduce the potentially adverse impact of genetic testing on an individual's future ability to purchase medical expense insurance.

Costs of Covering Genetic Testing and Treatment

Any program of medical expense coverage will have to face the question of whether the direct costs of various genetic technologies will be covered. It is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans as they are demonstrated to be more effective than other, more traditional approaches. Unless these new tests and treatments produce an offsetting reduction in other medical expenses, they may produce an overall increase in medical care costs.

Current Use of Genetic Technology

Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored medical expense programs — which cover nine out of ten privately insured Americans. Private health insurers do not currently require applicants for insurance to undergo genetic testing or use genetic testing to limit coverage for preexisting conditions. Insurers in the voluntary, individual medical expense market do ask applicants about their health and some may inquire about the results of any prior tests. Currently insurers rarely encounter any such information. Once a medical expense insurance policy has been issued, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits cancellation based on the health of the policyholder.

Legislative Proposals and the Voluntary Individual Market

State and federal legislators have developed proposals to regulate the use of genetic information. While actuaries support many of these initiatives, proposals that ban the use of any genetic information may be overly broad, and conflict with the principles that underlie the financial soundness of voluntary, individually purchased medical expense insurance.

The process of risk classification is fundamental to a voluntary, individually purchased medical expense insurance market. Voluntary markets operate most efficiently where there is a rough equality of information between buyers and sellers. But individuals who know, or suspect, that they have genetic disorders fear that this information could be used to deny or terminate insurance coverage. When balancing social and economic concerns,a clear understanding of the economic impact of alternative policies is vital.

Some believe that banning the use of information gained from genetic testing in risk classification would help to alleviate problems in recruiting research subjects, would encourage individuals to seek out test results, and would reduce insurance fears. Unfortunately, such proposals often contain three elements that concern many actuaries:

- the scope of any definition of "genetic tests"
- any limitations placed on insurers' knowledge of applicants' health status that would result in asymmetric information
- the effect of new genetic testing technologies on the concept of preexisting conditions.

Definition of "genetic tests": Any attempt to regulate the use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated. If a ban on information obtained from "genetic tests" defines such tests to include medical history, routine physical examinations, and other routine laboratory testing, it would severely hamper individual medical expense insurance underwriting. Since some individuals' health risks would be unknown, the pool of insurance purchasers might soon include a disproportionate number of people with higher-than-average anticipated medical expenses. This biased selection would cause premium rates to rise, making individual medical expense insurance even less affordable than it is now.

Asymmetric information: Would a ban on the use of genetic information merely prohibit insurers from asking for genetic tests, or would they also be barred from obtaining test results already known to the applicant? While a more encompassing ban may remove applicants' fears of genetically based denial of coverage, the imbalance of information would leave insurers at a disadvantage. A ban on genetic information about minor conditions probably would not have a serious impact on insurers. In the case of more serious conditions, however, an information imbalance might allow one applicant to benefit financially over others by choosing the timing, type, and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

Preexisting Conditions: Preexisting conditions typically are covered on the same basis as any other condition, but only after an individual has been covered under a health plan for a specified period of time (typically six to 12 months). However, state and federal laws increasingly limit the extent to which group and individual health plans may exclude coverage for preexisting conditions. Does a positive test result on a genetic test constitute a preexisting condition? Currently, for employer-sponsored health plans,HIPAA specifies that if genetic information is used to screen for a genetic predisposition to disease, and is not related to a diagnosis, it may not be treated as a preexisting condition. A similar approach might be appropriate for individually purchased medical expense insurance.

Guaranteeing all Americans access to medical expense insurance, while preserving the viability of a voluntary system of individually purchased insurance, is a difficult but important challenge that policy-makers have struggled with for a number of years. Some believe that banning the use of information gained from genetic testing in risk classification would alleviate problems in recruiting research subjects, would encourage individuals to seek out test results, and would reduce insurance fears. The impact of a ban on the use of genetic tests would depend on the ban's duration, the scope of the definition of "genetic testing" used, and the cost and predictive power of the tests covered by the ban. A moratorium on some types of tests would cause minimal disruption at first. However, such a ban could have more severe consequences over time, as genetic technology advances. A long-term ban on genetic testing has the potential to disrupt the voluntary individual medical expense insurance system, ultimately hurting the American people by making individual insurance more expensive and more difficult to obtain. On the other hand, mechanisms are needed to ensure that everyone has access to needed medical care.

Conclusion

The Academy believes that further research should be undertaken on the issues raised by genetic testing. Potential test recipients, physicians, plan sponsors, and insurers are all concerned by, and need information about, the implications of genetic test results for future health and health care expenses. Research focusing not only on survival rates and the probability of future disease, but on future health care needs and the availability, effectiveness, and potential cost savings of early intervention,is of great potential benefit. Not only would patients better understand their prognoses, but physicians could improve treatment modalities, and plan sponsors and insurers could better evaluate the appropriateness of covering specific tests, their likely impact on insurance costs, and their potential implications for risk classification in the individual market.

Some of the key questions that remain are:

- How accurately will genetic tests predict future health care needs?
- Will meaningful interventions be available for genetic disease?
- Will genetically based treatments become available?
- What impact will genetic technology have on overall medical care expenditures?

Policy-makers need a clear understanding of these issues so that proposals regulating the use of genetic testing information can find the best balance between the concerns of the public, the predictive ability of genetic test results, and the affordability of health insurance.

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[1] Medicare Payment Advisory Commission, Report to the Congress-Selected Medicare Issues, June 1999

Introduction

Recent scientific advances in the understanding of human genetics, particularly those achieved by the Human Genome Project, hold the hope of significant progress in the prevention, diagnosis and treatment of disease. This in turn will affect the various public and private systems for financing medical care. It is difficult to predict what impact advances in genetic technology will have on the insurance system, because this technology is not yet mature[1]. Interested groups are looking into a future that promises rapid and significant changes. Each group has unique concerns, and many are seeking legislative solutions to the problems they foresee. Key concerns include access to health care, the cost of health care and health insurance, and the privacy of genetic information. Policymakers must balance these and other competing social and economic concerns.

Americans currently receive health care coverage through a variety of public and private systems. While some issues raised by genetic technology are common among most or all of these systems, others are specific to particular types of health care coverage. Voluntary, individually purchased medical expense coverage in particular presents unique issues. Almost all elderly Americans are covered through the Medicare program. Most also have private coverage to supplement the benefits available through Medicare[2]. Among the non-elderly, six out of ten are covered through employer-sponsored programs, and more than one out of ten are covered though public programs. While fewer than one out of ten are covered through individually purchased policies[3], this market is an important residual source of coverage for those who do not have access to an employer-sponsored or government-sponsored program[4].

The impact of genetic testing on the cost and delivery of health care will likely have an effect on all forms of health care financing. It is impossible to predict with confidence the future cost of covering genetic testing and genetic treatments, but that cost could potentially be significant. The possible future use of genetic information in risk selection and risk classification is, however, a potentially significant issue only for the voluntary individual market[5]. The various impacts of genetic technology on the medical expense insurance system will change over time as the technology develops,and may often be overshadowed by broader societal concerns about the meaning and significance of genetic information.

The American Academy of Actuaries is committed to assisting the political process by providing independent, non-partisan actuarial information on current public policy issues. This monograph on genetic information and medical expense insurance is provided for the information of elected officials, regulators, and the general public. It is based on the current state of genetic technology, and our understanding of potential future developments.Genetic technology is evolving rapidly, and its future course is difficult to predict with any certainty. Answers given today to questions raised by genetic technologies may no longer be valid tomorrow, and even the questions themselves may change over time.

Unless otherwise stated, the terms "genetic test" and "genetic testing" will be used to refer to tests whose immediate object is to determine the presence or absence of particular variations in a person's genetic code, in contrast to tests whose immediate object is to examine the physical structure or functioning of a person's body. Medical expense insurance is a form of health insurance. Other forms of health insurance include disability income insurance and long-term care insurance. This monograph focuses on medical expense insurance. The term "medical expense coverage" will be used on occasion to include self-insured employee benefit plans. The term "health insurance" will be used only when discussing concepts that apply to all forms of health insurance[6].

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[1]Several alternative scenarios are outlined in the appendix. These are intended to illustrate a number of key factors that the work group believes will affect the future impact of genetic technology, and should not be interpreted as forecasts or predictions.

[2]EBRI Databook on Employee Benefits, Fourth Edition, Table 36.1, page 302, Employee Benefit Research Institute,1997.

[3]Paul Fronstin, Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the 1997 Current Population Survey, EBRI Issue Brief Number 192, Employee Benefit Research Institute, December 1997

[4]Medicaid also serves as a residual source of coverage, serving "categorically eligible" low-income individuals.

[5]Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999. The market for very small employer groups is in many respects similar to the individual market,and similar considerations may apply.

[6]The term "health care coverage" is used by many as a synonym for medical expense coverage. This usage will be avoided in this brief to prevent confusion with the more general term "health insurance."

Genes and Medical Expense Insurance

Background

The discovery of DNA has produced an explosion of research into the genetic structures fundamental to life and heredity. Since 1990, the Human Genome Project, a $3 billion, 15-year joint effort of the National Institutes of Health and the U.S. Department of Energy, has been mapping the human genome. A complete map of the human genome could allow geneticists, researchers, and the medical profession to better understand and deal with human characteristics, including those that may lead to disease. Many have recognized that as we map the human genome and gain the ability to test individuals for gene abnormalities, we confront a host of ethical, legal, and social issues. A unique aspect of the Human Genome Project is that 3 percent to 5 percent of the annual budget for the project is allocated to studying the ethical, legal, and social issues surrounding availability of genetic information, making it the world's largest bioethics program.

For a number of years, newborns and their parents have been tested for several genetic birth defects, such as Tay-Sachs disease and Phenylketonurea. Fetuses are also routinely tested in utero to detect diseases such as Down's Syndrome. There are roughly two dozen genetic tests that can at this time be considered practical for adults (several dozen less practical ones are also available). While many more tests are expected to be developed during the next few years, currently only a few are clinically useful. Newer tests are generally being used to study specific populations and for experimental purposes. This is likely to be the case with any test until it can be incorporated into medical practice in a way that leads to meaningful medical decisions and advice to patients. Even so, advancing technology appears to be on the verge of creating genetic microchips that can screen for hundreds of genetic abnormalities at once[7].

While there is a general perception that an individual who tests positive for a gene linked to a specific disease will contract that disease, in most cases a positive genetic test result indicates only an increased probability of developing such a disease. Only a few genetic abnormalities are known to lead directly and certainly to disease. The vast majority of genetic conditions require a combination of genetic and environmental factors in order to result in disease. Almost all of us are born with genetic risk factors, but it is not possible to determine when, or even if, individuals who are predisposed to a disease will actually contract it. Nonetheless, these genetic factors may provide an important indication of the relative health risks different individuals face.

Medicare, a social insurance program designed to cover medical expenses for Americans over age 65, does not consider an individual's health in determining eligibility or for establishing the premium paid by a beneficiary[8]. Because virtually all eligible individuals are covered, there is no concern that biased selection might increase overall program costs[9]. Private health insurers do not currently require insurance applicants to undergo genetic testing, nor do they use genetic testing to limit coverage for preexisting conditions. Insurers in the voluntary, individual medical expense market do, however, ask applicants about their health and some may inquire about the results of any prior tests. Currently, insurers rarely encounter any such information[10].

Fears About Insurability and Confidentiality

The possibility of testing for abnormal genes has, in particular, raised fears about access to medical expense coverage. Insured individuals who learn they carry genes linked to medical conditions worry their coverage may be canceled or their premium raised. Potential applicants for insurance fear they may be forced to take genetic tests, perhaps receive unwanted information about their health status, and perhaps be denied access to coverage now and in the future. Individuals are also concerned about the privacy of genetic information and the implications such information may have for their families and for their prospects for employment and career advancement. Researchers worry that fears about the use of genetic information will deter volunteers from participating in research projects. And finally, there is concern that insurers will use genetic tests to select only low-risk individuals, excluding many other individuals from coverage. These concerns lead some to believe that insurers should not be permitted to consider genetic test results in determining the cost and availability of insurance products.

Questions about Coverage and the Cost of Medical Care

The potential impact of genetic technologies on medical expense insurance goes beyond its effect on other forms of insurance. In addition to questions of access and privacy, any program of medical expense coverage must face the question of whether the direct costs of various genetic technologies will be covered. In addition, it is unclear whether genetic technology will increase or decrease overall lifetime expenditures on medical care, and what the timing of those changes may be. These are questions that will need to be continually reevaluated as genetic technology advances. In particular, since basic technical advances often have multiple applications and because advances in diagnosing or treating one disease often facilitate advances in dealing with other diseases, the number of genetic tests and treatments accepted into standard medical practice may grow quite rapidly once a critical level of base technology is achieved.

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[7] Charles S. Jones, Jr. M.D., The Current State of Genetic Testing An Insurance Industry Perspective on the Rush to Legislate, Thomas P. Bowles Symposium on Genetic Technology and Underwriting, March 26-27, 1998, Georgia State University, Atlanta, Georgia.

[8] The tendency for late enrollees to have higher than average medical costs, due to biased selection, is reflected in an increased Part B premium. Indicators of future claim levels (i.e., age, sex, institutional status and Medicaid eligibility) are used in establishing the capitation paid by the Medicare program to private Medicare+Choice plans for Medicare enrollees. A more accurate method of establishing Medicare+Choice plan payments is being developed.

[9] There have been suggestions, however, that biased selection by Medicare beneficiaries choosing between traditional fee-for-service benefits and HMO coverage may affect the overall cost of the Medicare program.

[10] Mark A. Hall and Stephen S. Rich, "Laws Restricting Insurers' Use of Genetic Information: Impact on Genetic Discrimination," American Journal of Human Genetics, January 2000.
Paul R. Lenz, M.D., F.A.C.P.E., The Current State of Genetic Testing in Health Insurance, Symposium Proceedings, Genetic Testing: Implications for insurance, Sponsored by the MetLife Medical Department, the University of Pennsylvania Health System Center for Bioethics and The Actuarial Foundation, June 1997.
William J. Warfel, Ph.D., CLU, CPCU, Peter Mikolaj, Ph.D., Alex Hamwi, Ph.D., Genetic Information and Risk Classification in Individual Life and Health Insurance, Journal of the American Society of CLU & ChFC, September 1998.
This Academy Task Force is not aware of any health insurer that requires applicants to take a genetic test.

Considerations Common to Both Employer-Sponsored Programs and Individually Purchased Insurance

Common Coverage Considerations

Genetic technology has a number of potential uses. One way of understanding these uses is by grouping specific genetic technologies into the following general categories: tests used for general population screening; tests used to screen populations at high risk for a particular disease; tests used in the diagnosis of disease; and treatments for disease[11]. Each of these categories has implications for medical expense coverage.

Medical expense insurance has historically focused on covering the cost of medical care necessary for the diagnosis and treatment of an injury or an illness. This approach is consistent with the need to protect insured individuals from catastrophic medical costs, while avoiding coverage of expenses that are largely non-random or discretionary, because insurance is not generally an efficient way to fund such expenses. Over time, government-sponsored and employer-sponsored medical expense programs gradually began covering some preventive care and screening tests. This is at least partly because program subsidies, in the form of both sponsor contributions and tax preferences, have outweighed the economic inefficiency of using insurance to fund expenses that could otherwise be handled through routine budgeting. In addition, some forms of preventive care have been found by program sponsors to be cost-effective in reducing medical expenses that would otherwise be covered,and some programs of network-based managed care have been developed with a philosophical orientation toward coordinating all forms of "primary care."[12] Coverage of screening tests and preventive care is less prevalent in the voluntary, individual medical expense market, where program subsidies are generally limited or unavailable, and where the process of individual purchase decisions makes biased selection against the insurance system[13] a more significant problem.

We expect genetic tests that aid in the diagnosis of disease, and genetic treatments for disease, to be gradually recognized and covered by medical expense plans as they are demonstrated to be more effective than other, more traditional approaches. From the standpoint of an insurance program, they are no different from any other new approach to diagnosis or treatment. Many new genetic tests have, at least initially, very high per-unit costs. The likely cost of future genetic treatments is not yet clear, but they may also have very high per-unit costs. Unless new tests and treatments produce an offsetting reduction in other medical expenses, or unit costs drop significantly, they may produce an overall increase in medical care costs.

Genetic screening tests for high-risk populations present a more complex question. If a high-risk population is relatively small and well defined, if a positive test result indicates a high likelihood of developing the disease, and if effective early interventions are available, then screening of that population may be cost effective[14]. If positive results do not strongly correlate with future disease, or if no effective intervention is available, then the result of the screening test may have no direct impact on clinical care,and testing may not be medically appropriate. Of course, even if an effective intervention is available,high unit costs for either the test or the intervention itself may raise overall medical spending if not offset by other cost reductions. In addition, even if lifetime medical expenses are reduced, short-term medical expenses may increase. This could happen, for example, if screening and intervention early in life becomes practical for diseases of old age such as Alzheimer's disease. Costs would then rise for the programs providing medical expense coverage to non-elderly Americans, even though lifetime costs might ultimately fall, with Medicare benefiting from the reduction in the medical costs of old age. In the absence of legislative requirements, private medical expense plans are likely to decide whether to cover screening tests for high risk populations on the basis of their effectiveness relative to existing methods of screening and diagnosis, the cost effectiveness of early identification and intervention in reducing overall claim costs, and on consumer demand.

The use of genetic screening for large segments of the general population also requires tests that are highly predictive of future disease and have effective interventions, but in addition requires very low unit testing costs to be practical. Typically, most of the direct cost of a broadly based population-screening program will be for individuals who receive negative test results. In addition, if a test for a rare condition is used to screen the general population, a significant number of false positive results may be obtained, even if the test is highly accurate[15]. False negative results may be an even more serious concern because of their potential for providing a false sense of security, possibly leading to delays in treatment. Again, private plan sponsors are likely to make coverage decisions based on comparisons to existing medical practice, the cost effectiveness of screening in reducing future covered medical expenses, and on consumer demand.

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[11]Others distinguish between diagnostic tests and predictive tests. We are characterizing predictive tests as screening tests, and distinguishing between those applied to the general population and those applied to specific high-risk populations because slightly different considerations may apply in the two cases.

[12]Non-specialist, basic medical care - typically, the care provided by a general practitioner or family physician, gynecologist or pediatrician, including routine physical examinations.

[13]Biased selection against an insurance program,also known as antiselection or adverse selection, occurs when applicants can expect to gain financially by making purchase decisions based on risk characteristics known or suspected by them but unknown to, or not considered by, the insurer or administrator of the program. The opportunity for biased selection arises from an imbalance in the information available to the consumer and the insurer.

[14]Because much genetic research has focused on specific ethnic and racial groups, genetic diseases for which tests have been developed are often closely associated with such groups. Because of this, even if well defined populations at risk can be defined, there may be social policy reasons for avoiding their use. This creates a difficult problem. If extended to the general population, a particular test may no longer be affordable. But,if it is limited to an ethnically or racially defined risk group, it may serve to reinforce negative stereotypes.

[15]Even a very low error rate for a test, when applied to a large number of healthy individuals,may produce a large number of incorrect positive test results. If the condition involved is sufficiently rare,the number of false positive results may exceed the number of individuals correctly identified as having the condition. For a more complete discussion, please see Patrick L. Brockett, Richard MacMinn and Maureen Carter, Genetic Testing, Insurance Economics and Societal Responsibility, Thomas P. Bowles Symposium on Genetic Technology and Underwriting, March 26-27,1998, Georgia State University, Atlanta, Georgia.

Regardless of the populations involved, many screening tests will present plan sponsors with difficult ethical questions. For instance, by covering testing for BRCA mutations (which are correlated with an increased incidence of breast cancer), would a plan sponsor be encouraging women to take a test whose implications are not yet fully understood, and which may cause women to have radical, possibly unnecessary surgery? On the other hand, if a plan sponsor does not cover BRCA testing, is it failing to encourage the use of a procedure that has the potential to prevent breast cancer?[16]

Because prenatal screening tests pose particularly difficult ethical issues, it is difficult to predict the extent to which they will be covered. Tests for such diseases as Down's Syndrome are already being used to help parents decide whether to terminate a pregnancy. While many Americans have religious and moral objections to abortion, others are beginning to see this testing almost as a moral duty because of its potential impact on future generations. The availability of more tests is unlikely to reduce the controversy[17].

Prenatal testing is likely to be viewed as particularly objectionable if it begins to deal with factors that might be considered eugenic, such as blindness, deafness, mild mental retardation, or susceptibility to heart disease or cancer. Some private-plan sponsors may have moral objections to paying for such tests, and there may be political objections to paying for them through publicly sponsored programs. Of course, the availability of appropriate and effective treatments would change the situation dramatically, but unfortunately testing technology appears to be advancing much more rapidly than treatment. Depending on its unit cost, prenatal treatment for serious genetic disorders might reduce the overall health care costs for pregnancies that are brought to term, while potentially raising them for pregnancies that would otherwise be terminated.

Tests that deal with susceptibility to disease, rather than the diagnosis of an illness that has already manifested itself, challenge our conventional ideas of what constitutes a medical condition or "disease," and when illness begins. The ability to test for genetic abnormalities that have not yet produced any symptoms will require plan sponsors to address how existing benefit provisions, such as pre-existing conditions clauses, should be applied to the new technologies.

Common Confidentiality Considerations

Genetic information presents serious confidentiality concerns, because of its very personal nature, public fears and uncertainty about its implications, and because an individual's genetic information may have potentially serious implications for family members. In addition to concerns about future access to health insurance, individuals contemplating undergoing genetic testing are often concerned that a positive test result could lead to social stigmatization or employment discrimination. While there may be particular sensitivities in the case of genetic information, this is a part of the broader issue of health information confidentiality.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a process for setting national standards for confidentiality of personal health information. In the event Congress did not enact national confidentiality standards by August of 1999, the Secretary of Health and Human Services was instructed to issue regulations establishing standards no later than August of 2000[18]. HIPPA also stipulates criminal penalties for wrongful disclosure of individually identifiable health information in violation of those standards. In September 1998, the National Association of Insurance Commissioners (NAIC) adopted a Health Information Privacy Model Act with a recommendation that it be enacted by state legislatures. If states enact this model, then it has the potential to strengthen and standardize the privacy protections already provided by state insurance law[19]. It is, however, unclear whether the federal standards, when ultimately established, will preempt existing state standards.

Some policy-makers and consumers are particularly concerned that health insurers will not maintain the confidentiality of genetic test results revealed on applications for insurance. However, disclosure of personal health information is not required for enrollment in employer sponsored medical expense programs[20]. Even in the case of voluntary, individually purchased medical expense insurance, state law requires insurers to keep all underwriting information confidential. Currently, an applicant's consent is required before an insurer is permitted access to personal medical records. The confidentiality of this information is protected by law, and its use by insurers is tightly restricted. In the 1980s and early '90s, many states reviewed and strengthened their confidentiality laws in response to the AIDS epidemic, and the continuing regulatory trend is to toughen such safeguards.

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[16]Current evidence indicates that prophylactic mastectomy may result in significant gains in life expectance. Prophylactic oophorectomy (surgical removal of the ovaries) appears significantly less effective. For a discussion of the effectiveness of prophylactic surgery, see Deborah Schrag, MD, MPH, Cancer Prevention for Individuals with Inherited Mutations, Risk in Perspective, Harvard Center for Risk Analysis, Volume 6, Issue 5, May 1998 and Lynn C. Hartmann, MD, et al., Efficacy of Bilateral Prophylactic Mastectomy in Women with a Family History of Breast Cancer, New England Journal of Medicine Volume 340, Number 2, January 14,1999.

[17]Work is currently being done on in vitro fertilization, followed by pre-implantation genetic testing. It is unclear to what extent this might reduce ethical concerns about prenatal testing. This approach is also quite expensive.

[18]As of early May 2000, no such legislation has yet been enacted, although several proposals are before Congress. Preliminary regulations have been exposed for comment,and the comment period has expired, but final regulations have not yet been issued.

[19]There are two relevant NAIC model acts. The first,the Insurance Information and Privacy Protection Model Act: 1) establishes standards for the collection,use and disclosure of information gathered in connection with insurance transactions by insurers and insurance related entities; 2) allows individuals the opportunity to access and verify the accuracy of information maintained about them by these entities; and 3) enables applicants for insurance to obtain the reasons for any adverse underwriting decision. This model act has been adopted by seventeen states (AZ,CA,CT, GA, HI, IL,KS, ME,MA,MN, MT, NV, NJ, NC, OH,OR, & VA).
The second is the more recent Health Information Privacy Model Act, which imposes much more detailed and prescriptive mandates on health plan operations and procedures. No states have adopted this model to date.
While not all states have adopted one of the NAIC models on this issue, almost every state has one or more laws that directly or indirectly relate to how insurers must protect the confidentiality of personally identifiable health or insurance information.

[20]HIPAA prohibits employer-sponsored group health plans from basing enrollment eligibility on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability or disability. No plan participant may be required, on the basis of any health status related factor, to pay a higher premium or contribution than that of a similarly situated participant. ERISA Title I, Subtitle B, Part 7, Section 706 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101. State insurance law governs the premiums that a health plan charges an employer for insured coverage.

Employer-sponsored Medical Expense Programs

Access and Renewability

Employer-sponsored medical expense plans are generally structured with a significant subsidy from the employer, ensuring that participation is attractive to the healthy as well as to those who anticipate significant medical expenses. Because of this, these group plans are less likely to experience a disproportionate enrollment of relatively unhealthy individuals than are individually purchased medical expense insurance policies. Historically, underwriting and pricing for group insurance has focused on the overall makeup of the eligible group rather than the health of any particular individual[21]. HIPAA now prohibits "group health plans"[22] from basing eligibility on the health of an individual[23]. Genetic information is explicitly included in this prohibition. Any insurer offering medical expense insurance in a state is required to accept any small employer from that state who applies for coverage[25]. According to the U.S. General Accounting Office "[v]irtually all medium and large employers have access to group health insurance, and about 90 percent actually offer health coverage to their employees."[26] HIPAA also requires guaranteed renewability of coverage for both small and large employers.[27]

Enrollee Self-Selection and Costs

In most cases, employer-sponsored plans should not be seriously affected by a disproportionate number of high-cost individuals enrolling as a result of genetic information. Among the very smallest employer groups, those with an owner or key employee with poor health or high anticipated medical costs may be somewhat more likely to seek coverage. If covered genetic therapies have very high unit costs, they may significantly impact the cost of smaller plans that happen to have an individual needing treatment. This would be similar to the way in which a transplant case or premature infant can significantly raise a small plan's costs for a given year. It is also possible that the widespread availability of genetic testing or treatment will raise the overall level of claim expenditures and, in turn, premiums for employer-sponsored programs. Because employer-sponsored plans are tax-subsidized fringe benefits as well as insurance programs, they are probably more likely to cover screening tests and preventive care than are individually purchased policies.

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[21]Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999.

[22]Defined as employee welfare benefit plans,as defined by the Employee Retirement Income Security Act of 1974 (ERISA),that directly, through insurance, or otherwise provide benefits or reimbursement for medical care. Accident and disability insurance,liability insurance or coverage supplemental to liability insurance, worker's compensation insurance, automobile medical payment insurance,credit insurance, coverage for on-site medical clinics,and other similar secondary or incidental benefits as specified by regulation are excluded. Limited scope dental or vision benefits, long-term care, nursing home, or home-health care, and other similar, limited scope benefits are excluded if offered separately. Specified disease and hospital or other fixed indemnity coverages are also excluded if offered as independent,noncoordinated benefits. Medicare supplement benefits are also excluded if offered as a separate insurance policy. ERISA Title I, Subtitle B, Part 7, Section 706 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

[23]ERISA Title I, Subtitle B, Part 7, Section 702 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

[24]Small employers are defined as those with at least two, but no more than 50, employees. Public Health Service Act, Title XXVII, Part C, Section 2791(e)(4) as amended by HIPAA Title I, Subtitle A, Part 1, Section 102.

[25]Public Health Service Act, Title XXVII, Part A, Subpart 2, Section 2711 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102. Provision is made for limitations in managed care network service areas, the capacity of networks to provide medical services, and the reserve capacity of insurers.

[26]Larger firms are more likely to offer coverage than are smaller ones, and full-time employees are more likely to be eligible to participate than are part-time or temporary employees. Employment Based Health Insurance: Medium and Large Employers Can Purchase Coverage, but Some Workers Are Not Eligible, United States General Accounting Office, GAO/HEHS-98-184, July 1998

[27]Exceptions are made for nonpayment of premiums, fraud, violation of participation or contribution rules, movement outside of a plan's service area, or in the case of coverage offered through a bona-fide association the termination of association membership. Provision is also made for insurers to update their products on a uniform basis,and to withdraw from the market in a particular state. Public Health Service Act, Title XXVII, Part A, Subpart 2, Section 2712 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102.

Individually Purchased Medical Expense Insurance

Access

Many states give insurers flexibility in establishing initial premiums for individual medical expense insurance, and most states give insurers a great deal of flexibility in accepting or rejecting each application for coverage. Because most consumers only keep their policies in force for a few years, the underwriting of medical expense policies focuses on medical care costs likely during the first few years after a policy is sold[28]. Family history is rarely, if ever, used in evaluating applicants for individual medical expense insurance because it has not proven to be a good predictor of short-term medical costs. It seems likely that most genetic screening tests will identify the same types of hereditary susceptibilities to disease that might otherwise be revealed by family history. Because of this, we do not anticipate that most individual medical expense insurers will, in the foreseeable future, routinely require predictive genetic screening tests of applicants, even if allowed to do so. On the other hand, individuals who have undergone genetic testing for other reasons and thus have personal knowledge of a specific genetic susceptibility or disorder may be more likely to purchase coverage. Because of the adverse impact that this self-selection could have on their expected costs, individual market insurers do ask for the results of any prior genetic testing[29].

Where genetic information is available, it will not have a uniform effect on availability of voluntary, individual medical expense insurance. Some people could benefit from greater access to coverage; others with specific genetic conditions could see reduced access to coverage or higher premium costs. In some cases genetic information will lead to early treatment or rule out a particular predisposition to disease. In other cases it may confirm the likelihood of future illness. Depending on the predictive power of the test, the seriousness of the disease, the likely timing of its manifestation, and the cost of treatment, this information may or may not prevent the individual from being able to purchase individual medical expense insurance at a standard premium.

If information about a disease were to prevent an individual from participating in the voluntary, individual medical expense insurance market, other sources of coverage might currently be available. Most recent efforts to restructure or reform the individual medical expense insurance market have focused on guaranteeing access to coverage for those who would otherwise be considered medically uninsurable[30]. COBRA continuation coverage provides significant short-term protection to individuals leaving employers with 20 or more employees. HIPAA guarantees access to coverage to certain individuals who lose group medical expense coverage[31], but at a cost that varies significantly from state to state[32]. Currently, 13 states have a guaranteed-issue requirement in the individual medical expense insurance market, requiring insurers to issue some form of coverage to all applicants regardless of health status (specifics, such as the type of policy that must be issued, vary by state), and 20 states limit the extent to which insurers can vary premium rates between individuals or the risk characteristics they may consider[33]. High-risk health insurance pools have been created in 27 states to ensure access to individuals who would otherwise be medically uninsurable[34]. In other states, Blue Cross and Blue Shield plans guarantee access during annual open enrollment periods[35]. Six states[36] have no mechanism in place to guarantee access to uninsurable individuals who are not eligible for HIPAA-mandated coverage[37].

Renewability

Contract provisions and state insurance law restrict a health insurer's ability to raise an individual's premium once the policy is in force, and have historically restricted an insurer's ability to cancel a policy. Typically, the insurer can only raise premiums if the increase is applied uniformly to a "class" of policyholders, usually defined as all policies of a particular type sold in a given state. Most states reserve the right to review and disapprove rate increases. HIPAA prohibits the cancellation of a medical expense policy based on the health of the policyholder.

Costs and Coverage

Depending on unit costs, and the offsetting savings from more traditional services that would otherwise be required, the widespread availability of genetic diagnostic testing or treatment has the potential to raise the overall level of claim expenditures, and, in turn, premiums, for individually purchased medical expense insurance policies. Even though these policies are more likely to be affected by beneficiary self-selection than are employer-sponsored programs, individually purchased policies are probably less likely to face increased expenses due to the direct cost of screening tests. Because individuals purchase these policies directly and face the full cost of the premiums with limited, if any, tax subsidy, they typically select less expansive coverage than is provided by employer-sponsored plans. As a result, individually purchased medical expense policies are probably less likely to cover screening tests and preventive care than are employer-sponsored plans.

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[28] Disability income and long-term care policies, in contrast, are typically viewed by buyers as permanent insurance. As a result, the underwriting of those products considers the long-term health of applicants.

[29] For a more complete discussion of the use of medical underwriting in the individual medical expense insurance market, please see the Academy issue paper Risk Classification in Individually Purchased Voluntary Medical Expense Insurance, American Academy of Actuaries, January 1999.

[30] For a more complete discussion of the actuarial issues surrounding guaranteed access please see the Academy monograph Providing Universal Access in a Voluntary Market, American Academy of Actuaries, February 1996.

[31] Public Health Service Act, Title XXVII, Part B, Section 2741 as amended by HIPAA Title I, Subtitle B, Section 111. Their most recent prior coverage must have been with a group health plan, governmental plan or church plan; they must be ineligible for group medical expense coverage, Medicare Parts A or B, Medicaid, and without any other medical expense coverage; they must not have been terminated from their most recent prior coverage for nonpayment of premiums or fraud; they must have exhausted any COBRA coverage available to them; and they must have had at least 18 months of "prior creditable coverage." Most forms of medical expense coverage count as creditable coverage, as long as it has not been interrupted by a break in coverage of more than 63 days. (COBRA coverage also counts toward the 18-month requirement). The mechanism used to provide access varies by state.

[32] Concerns have been expressed that some HIPAA-eligible individuals may encounter access barriers and high premiums in the 13 states that have implemented the default "federal fallback" rules. These default rules require the guaranteed issue of individual health insurance policies to HIPAA-eligible individuals, but do not limit the premiums that may be charged. It appears that most states implementing an alternative mechanism are including a requirement for risk spreading, some form of premium regulation, or an explicit subsidy. Letter from William J. Scanlon, Director, Health Financing and Systems Issues, U.S. General Accounting Office, to the Honorable Nancy L. Johnson, Chairman, Subcommittee on Oversight, Committee on Ways and Means, House of Representatives, "Alternative Mechanisms" Under HIPAA, GAO/HEHS-98-161R, May 20, 1998.

[33] Private Health Insurance: Declining Employer Coverage May Affect Access for 55- to 64-Year-Olds, GAO/HEHS-98-133, U.S. General Accounting Office, June 1998, page 80.

[34] Ibid., page 81.

[35] Ibid., page 81.

[36] Alabama, Arizona, Delaware, Georgia, Hawaii and Nevada. Hawaii mandates employer-sponsored health insurance. As a result, relatively few Hawaiians must rely on the individual health insurance market for coverage.

[37] Private Health Insurance: Declining Employer Coverage May Affect Access for 55- to 64-Year-Olds, GAO/HEHS-98-133, U.S. General Accounting Office, June 1998, page 82.

[38] Exceptions are made for nonpayment of premiums, fraud, movement outside a plan's service area or, in the case of coverage offered through a bona-fide association, the termination of association membership. Provision is also made for insurers to update their products on a uniform basis and to withdraw from the market in a particular state. Public Health Service Act, Title XXVII, Part B, Section 2742 as amended by HIPAA Title I, Subtitle B, Section 111.

26

Key Questions

How accurately will genetic tests predict future health care needs?

Some believe that genetic technology will eventually be able to chart accurately an individual's medical future, and are concerned about the ways in which that ability might be used. While tests for some single-gene disorders may prove almost certain predictors of disease, in most cases illness is likely to arise from a complex interplay of many genetic, environmental, and lifestyle factors, and testing will reveal predisposition rather than fate. For instance, an individual with a genetic predisposition for diabetes may, through a program of weight control, reduce the probability of developing the disease. While the predictive value of genetic testing will likely improve over time, currently it is limited.

Will meaningful interventions be available for genetic disease?

Some are available now. For example, individuals who suffer from hemochromatosis, or iron-rich blood, face serious medical consequences if their condition is left undetected and untreated. However, if a test reveals genetic predisposition for the condition, early treatment, which usually is low in cost, can prevent complications and avoid early death due to the condition. There is evidence that prophylactic surgery may be an effective intervention for women with the BRCA1 and BRCA2 genes. If, as genetic technology advances, we are able to identify predispositions for conditions such as obesity, diabetes, or coronary artery disease, lifestyle interventions may prove useful. For other conditions there may be no useful intervention. The availability of effective treatment, along with the predictive power of a test, will largely determine its practical value. If the results of a test do not lead to a change in clinical treatment, the test will most likely not be considered medically necessary and as a result not be covered by most medical expense programs.

Will genetically based treatments become available?

Genetic treatment appears to be developing more slowly than genetic testing. However, once a genetic mutation has been identified, it seems natural to ask whether it can be repaired, or if the product of the affected gene can be artificially replaced. Such treatment would hold the potential to significantly improve the health of affected individuals. Depending on the unit cost of treatment, whether it was a one-time repair or an on-going maintenance program, and on the cost of other care that would be avoided, it could either reduce lifetime health care costs or significantly raise them.

Genetic technology also may allow the growing of replacement tissues and organs tailored for specific individuals. The use of transplant technology is currently limited by the availability of donor organs, and by the need to deal with donor/recipient compatibility and tissue rejection. If genetically engineered replacement tissues and organs become available, the frequency of transplantation may increase dramatically. Two other factors affecting the impact of genetic technology on lifetime health care costs will be the expense of genetically engineered tissues and organs relative to the expense of donor tissues and organs, and the extent to which a reduced risk of tissue rejection reduces the need for follow-up care and repeat transplants.

What impact will genetic technology have on overall medical care expenditures?

The impact of genetic technologies on overall medical care expenditures will depend on the unit costs of the technologies, how often their use is required, and what offset savings are created by reductions in the use of other more traditional services that may no longer be needed. It is impossible to predict the impact that developing technologies will have. Historically, however, most advances in medical technology have increased total expenditures, rather than reduced them. While genetic technology holds the promise of improved health, that improvement may come at an economic price.

Current Concerns

Access to Medical Expense Insurance

Genetic disease, like any other health factor, may not be used to restrict eligibility for participation in employer-sponsored health plans.[39] Insurers in the individual medical expense market do not require genetic testing of applicants, but in most states are allowed to inquire about the results of any previous tests. Most individuals in most states have guaranteed access to medical expense insurance, though the nature of the program and its costs may vary significantly.[40] The exceptions are non-HIPAA eligible individuals in the six states that have not implemented any mechanism for guaranteed access to medical expense insurance for those individuals. Once a person has purchased medical expense insurance there are a limited number of reasons for which it may be canceled, none of which has anything to do with the person's health.

Potential Difficulties in Recruiting Participants for Genetic Research Studies

Researchers are currently reporting some difficulty in recruiting research study participants. This is a result of the informed-consent process and fears about the use of information and resulting discrimination. A primary fear is that future access to medical expense coverage may be compromised.

As described above, access to employer-sponsored medical expense programs cannot be denied based on genetic information, or indeed on any other health factor. Both group and individual medical expense coverage already in force cannot be canceled due to genetic information or health status, nor can an individual be singled out for a rate increase. Individuals may, of course, lose their eligibility for employer-sponsored coverage due to a change in employment, or for other reasons. Federal law, under COBRA and HIPAA, guarantees continuing access to coverage for those losing employment-based coverage.[41] Particular concerns have been expressed about access and affordability in the 13 states that have not implemented an "alternative mechanism" for providing HIPAA-mandated access, but have instead relied upon the default "federal fallback" rules.[42] Implementation of a high-risk pool or other mechanism to subsidize coverage for HIPAA-eligible individuals in those states could help address those concerns.

Some people may not have access to an employer-sponsored program. In most states some form of guaranteed access to coverage is provided, even for individuals who do not qualify for guaranteed access under HIPAA. Of course, the details of the program and the costs involved vary significantly by state, and there are currently six states that do not have any form of guaranteed access for individuals who are not qualified under HIPAA. Providing guaranteed access to health insurance to all individuals in those states through high-risk pools or other mechanisms could help reduce the need for concern. In any event, participation in a blind study that does not inform participants about their test results would have no effect on insurability.

Potential research participants also fear social stigmatization and employment discrimination if a positive test result becomes known. They often fear that, in order to avoid potentially high benefit costs and the costs of recruiting and training replacement workers, employers may be less likely to hire or retain individuals with a genetic predisposition to disease. The Americans with Disabilities Act (ADA), state disability discrimination laws, existing state privacy laws and the model act on health information privacy recently adopted by the NAIC and recommended to the states for enactment, are intended to address these concerns for all types of health conditions, and not just genetically based conditions.

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[39] As noted above, HIPAA prohibits employer-sponsored plans from using health status, including genetic information, as a basis for eligibility.

[40] As discussed earlier, thirteen states have enacted individual market guaranteed-issue requirements, twenty-seven states have established high-risk health insurance pools, and in others guaranteed access is provided to Blue Cross and Blue Shield plans during annual open enrollment periods.

[41] Premiums for COBRA continuation coverage are limited to 102 percent of the average cost to the employer-sponsored plan for active employees and their dependents. The mechanism through which HIPAA coverage is provided, and the cost to purchasers, vary significantly by state.

[42] Health Insurance Standards: New Federal Law Creates Challenges for Consumers, Insurers, Regulators, U.S. General Accounting Office, GAO/HEHS-98-67, February 1998

Legislative and Regulatory Issues

In response to growing public concern, legislators at both the state and federal levels have developed proposals to regulate the use of genetic information. Many of these initiatives reinforce well-established industry practices concerning confidentiality and disclosure of sensitive information. Actuaries fully support many of these initiatives. However, some legislative initiatives would go so far as to ban use of any genetic information. Such limitations conflict with the principles that actuaries believe underlie the financial soundness of voluntary, individually purchased medical expense insurance and consequently have raised concerns among many actuaries. Voluntary markets operate most efficiently where there is a rough equality of information among buyers and sellers. When balancing social and economic concerns,a clear understanding of the economic impact of alternative policies is vital.

It has been suggested that banning the use of information gained from genetic testing in risk classification would alleviate problems in recruiting research subjects, encourage individuals to seek out test results, and reduce insurance fears. Unfortunately, such proposals often contain two elements that are of serious concern to many actuaries: the definition of "genetic test" and limitations on insurer knowledge of applicants' health status that would result in "asymmetric information." A related issue is how the new genetic testing technologies affect the concept of "preexisting conditions."

Definition of "genetic tests."

Most people assume that the term "genetic testing" is reasonably well defined. Actually, the range of procedures that are sometimes considered genetic tests is broader than is commonly assumed.

DNA-based tests that tie specific conditions to specific genes are becoming more common as research advances through the work of the Human Genome Project. These tests are commonly cited in the debate about genetic privacy in underwriting. However, genetic information also is revealed through tests that insurers have used for many years. For example, blood and urine tests reveal evidence of conditions that may have a genetic basis, and which insurers take into account in their risk classification procedures as a matter of course. Should such analyses be considered tests for genetic information similar to DNA-based tests? Any attempt to regulate use of genetic tests and the information derived from them should provide a clear definition of the tests being regulated.

In the event of regulatory restrictions, the scope of such a definition of genetic testing would have a serious impact on insurers and consumers. A total ban or moratorium on information obtained from genetic tests – if broadly defined to include medical history, routine physical examinations, or routine laboratory testing of the structure and function of the body – would severely hamper individual medical expense insurance underwriting.

An analogy might be to fire insurance. Imagine that there were good reasons to prohibit fire insurers from going to the building department and pulling the blueprints on structures that they were considering insuring. This might not be a serious impediment if they were still allowed to send in building inspectors to examine the physical structures involved. However, fire insurance might well become impractical if insurers were required to cover buildings sight unseen. In a sense, genetic technology is giving us, for the first time, access to human "blueprints." Not being able to directly access the blueprints (i.e., require applicants to undergo genetic testing) may not adversely affect the individual medical expense market as long as insurers are still able to examine physical structure and functioning (i.e., through medical history, routine examinations and laboratory tests). Of course, if the applicant has voluntarily undergone genetic testing in the past,that information may be relevant also.

Under a broad ban that includes information from routine physical examinations, some individuals' health risk would be unknown and hence the pool of insurance purchasers might soon include a disproportionate number of individuals with higher-than-average anticipated medical expenses. This biased selection would cause premium rates to rise, making individual medical expense insurance even less affordable than it is now.

Asymmetric information.

Would a ban on the use of genetic information in individual medical expense insurance underwriting merely prohibit insurers from asking for tests to be performed or would they also be barred from obtaining test results the applicant already knows? Clearly, a more encompassing ban would more completely remove applicant fears of genetic-based denial of coverage. However, from an insurer's point of view, there is a world of difference between the two prohibitions.

When purchasing insurance, consumers weigh the price they must pay against the value they expect to receive. Individuals generally will not pay significantly more in premiums than they expect to receive back in benefits. Most healthy individuals are willing to pay a premium somewhat higher than the benefits they would receive given their usual health care expenditures, in order to have the peace of mind provided by protection against unanticipated injury or illness. However, there is a limit to the additional premium any given consumer is willing to pay in order to obtain this peace of mind. If premiums for a health insurance policy rise above this threshold, then healthy individuals will not purchase the coverage. If no insurer offers coverage at a premium below this threshold, healthy individuals will drop out of the insurance marketplace.

Whenever an applicant knows critical information but the insurer does not, the asymmetry of information may lead to biased selection, depending on the value of the information for predicting future health care needs and thus the potential impact on premium costs. This could result in insurance becoming less affordable. As prices rise, consumer buying patterns may change. With healthier individuals becoming less likely to purchase coverage, average claims costs would increase, and prices would rise yet again to keep the system in balance. These increasing prices would not only affect affordability, but over the long term could also cause insurers to withdraw from the market or restrict coverage.

Some have suggested that individuals would be more likely to use helpful genetic information if individual medical expense insurers were prohibited from using genetic information already known to applicants. Certainly, putting information about minor conditions that do not indicate a significant increase in future health care needs "off limits" would not have a serious impact on the insurer. However, in the case of a medical condition with more serious consequences, an information imbalance might allow the applicant to financially benefit, relative to other purchasers, by choosing the timing of purchase,and the type and level of benefits purchased. This biased selection would have a direct impact on premium rates, ultimately raising the cost of insurance to everyone.

The impact of a ban on insurance company use of genetic tests would depend on the ban's duration and the scope of the definition used.A moratorium on some types of tests would cause minimal disruption at first, but could have more severe consequences over time. This is primarily because the new genetic tests of DNA are currently very expensive and provide little additional information about the probable health care needs of an individual. When tests become more accurate, less expensive,and better able to detect a wide range of conditions, this is likely to change.

Preexisting Conditions.

Historically, medical expense policies have either excluded or limited coverage for expenses incurred as a result of medical conditions that existed or became obvious to the covered individual before becoming insured. This is intended to prevent individuals from seeking coverage only when they need medical care, and discontinuing coverage during periods of good health.

Employer-sponsored programs typically exclude or limit benefits for an injury or illness that occurred during a specified period, such as three or six months, prior to the effective date of coverage. Preexisting conditions are typically covered on the same basis as any other condition after an individual has been covered under the plan for a specified period of time (typically six to 12 months). Individual medical expense policies generally exclude coverage for preexisting conditions for a specified period of time, typically either one or two years.[43] However, state and federal laws are increasingly limiting the extent to which group and individual health plans may exclude coverage for preexisting conditions.[44]

As genetic tests become increasingly available, the question of whether or not a positive test result constitutes a preexisting condition will arise. An important consideration may be whether a given test is used to screen for a genetic predisposition to disease, or is used diagnostically to identify or confirm the existence of a particular condition. For employer-sponsored health plans, HIPAA uses this distinction to specify how genetic information may be used for purposes of applying preexisting condition limitations, explicitly stating that if genetic information is not related to a diagnosis, it may not be treated as a preexisting condition.[45] A similar approach might be appropriate for individually purchased medical expense insurance.

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[43] Preexisting condition limitations apply to medical conditions that already exist at the time application is made for coverage, even if the insurer is not aware of them. Contract riders may be used to limit or exclude coverage for conditions that become evident through the application or underwriting process.

[44] Many states restrict the applicability of preexisting conditions limitations for both small group and individual coverage, by limiting the period of time during which coverage for preexisting conditions may be excluded or by requiring carriers to credit prior health coverage against the preexisting conditions exclusion period. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) has a number of provisions to minimize the impact of preexisting conditions limitations on insured individuals. With group health plan coverage an exclusion of up to 12 months can be imposed only once, the "look-back" period cannot exceed six months,and when insured individuals change plans the new plan must give credit for previous coverage toward any new preexisting condition limitation. Qualified individuals losing group health plan coverage must be provided access to individually purchased coverage,although the mechanism used varies from state to state, and must be given credit for prior coverage against any new preexisting condition limitation. ERISA Title I, Subtitle B, Part 7, Section 701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101; Public Health Service Act, Title XXVII, Part A, Subpart 1, Section 2701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 102; Public Health Service Act, Title XXVII, Part B, Section 2741 as amended by HIPAA Title I, Subtitle B, Section 111.

[45] ERISA Title I, Subtitle B, Part 7, Section 701 as amended by HIPAA Title I, Subtitle A, Part 1, Section 101.

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Coverage Options

In evaluating the concerns raised by genetic information, it is important to understand the sources of coverage already in place. There are a number of alternative sources of health insurance coverage currently available. Six out of 10 Americans are covered through employment-based plans,and one out of four are covered through government-sponsored plans.[46] Most individuals already have guaranteed access to health insurance,although for some individuals who are not eligible for employment-based coverage the cost may be high. The coverage needs of participants in genetic research projects may require special consideration.

Options Currently Available

- Coverage through employer-sponsored programs.
- Individually purchased voluntary medical expense insurance for those who qualify.
- Guaranteed-issue COBRA or HIPAA coverage for those who qualify.
- Guaranteed-issue coverage through high-risk pools or other state programs for the medically uninsurable.
- For some, individually purchased coverage with an extra premium reflecting the added risk.
- For specific population segments, government programs such as Medicare and Medicaid.

Potential Options for Research Participants

- Increased use of blind studies to avoid any impact on future insurability.
- Requirement of existing coverage for study participation.
- Purchase of catastrophic coverage on a group basis for all study participants.
- Purchase of specified disease coverage, where applicable, prior to study participation.
- Creation of a trust fund to subsidize participants' future excess costs of purchasing coverage through risk pools or other guaranteed-issue programs.

Potential Public Policy Options

These are intended to illustrate the range of possible policy options available to address the potential impact of genetic information on the availability of medical expense coverage. Inclusion in this list should not be interpreted as an endorsement by the American Academy of Actuaries.

- Establish high-risk pools, or other similar safety net programs in all states, open to all who are medically uninsurable, including those with significant genetic risks.
- Establish high-risk pools, or other similar safety net programs in all states, open to all those with significant genetic risks.
- Mandate purchase of coverage (to avoid self-selection), then require guaranteed issue and modified community rating in the individual market.47
- Encourage the development of insurance for "genetic risks" (to be purchased before testing).
  - ▲ Guaranteed insurability coverage for individuals.
  - ▲ "Excess premium" insurance to cover the additional cost of guaranteed-issue coverage for those developing genetic illnesses.
  - ▲ Specified disease coverage for genetic diseases.

[46] Jennifer A. Campbell, Health Insurance Coverage: 1998, Current Population Reports, U.S. Census Bureau, Economics and Statistics Administration, U.S. Department of Commerce,October 1999. Some individuals have coverage from more than one source.

Need for Research

Potential test recipients, physicians, plan sponsors, and insurers are all concerned with, and need information about, the implications of genetic test results for future health and health care expenses. Research focusing not only on survival rates and the probability of future disease, but future health care needs and the availability, effectiveness, and potential cost savings of early intervention,is of great potential benefit. Not only would patients better understand their prognosis, but physicians could improve treatment modalities, and plan sponsors and insurers could better evaluate the appropriateness of covering specific tests, their likely impact on insurance costs, and their potential implications for risk classification in the individual market.

Summary

Information on the health status of individual program participants is not used to determine eligibility for participation in employer-sponsored medical expense plans. However, the process of risk classification is fundamental to a voluntary, individually purchased medical expense insurance market. Risk classification places applicants into groups with roughly equivalent levels of risk, thereby ensuring their premium cost is commensurate with their risk level. Individuals who know, or suspect, they have genetic disorders fear this information could be used to deny or terminate insurance coverage. As a result, some individuals may avoid taking genetic tests that provide potentially beneficial information about their condition, even if that information might help prevention or treatment.

Various programs have been developed to guarantee access to medical expense insurance to those who would otherwise be uninsurable. While most Americans are guaranteed access to some form of medical expense insurance, the cost of coverage varies significantly, and there are still some gaps. Filling those gaps could help reduce the potentially adverse impact of genetic testing on an individual's future ability to purchase medical expense insurance.

While only a minority of Americans receive coverage through the voluntary, individual medical expense market, it plays an important role as a residual market for those who do not have access to coverage through an employer-sponsored or government-sponsored program. In addition, many policymakers have suggested that there might be significant advantages to moving away from an employment-based system of health insurance. As a result, the individual market may have a greater significance than its size might otherwise indicate.

Guaranteeing all Americans access to medical expense insurance, while preserving the viability of a voluntary system of individually purchased insurance, is a difficult but important challenge that policymakers have struggled with for a number of years. Banning the use of genetic tests by health insurers is one policy option often suggested. The impact of a ban on the use of genetic tests would depend on the ban's duration, the scope of the definition of "genetic testing" used,and the cost and predictive power of the tests covered by the ban.A moratorium on some types of tests would cause minimal disruption at first, because relatively few genetic tests are currently available and their predictive power is generally limited. However, a ban on the use of genetic testing could have more severe consequences over time, as genetic technology advances. As tests become more accurate, less expensive, and better able to detect a wide range of conditions, the potential impact of a ban would increase.

A long-term ban on genetic testing has the potential to disrupt the voluntary individual medical expense insurance system, ultimately hurting the American people by making individual insurance more expensive and more difficult to obtain. On the other hand, mechanisms are needed to ensure that everyone has access to needed medical care. For these reasons, the Academy believes that further research should be undertaken on the issues raised by genetic testing. As the public debate continues on how best to face the multiple challenges posed by developing genetic technologies, the actuarial profession, through the American Academy of Actuaries, will continue to assist public understanding of actuarial aspects of this complex issue.

Appendix

Hypothetical Future Scenarios

These scenarios are entirely speculative, and are not intended as projections or predictions of future developments. Rather, they illustrate the significance of several key factors and the wide range of possibilities the future holds. Among the key factors considered are the number of genetic tests available, their unit costs and predictive power, and the availability and cost of treatments for the conditions identified. Also considered are the availability of genetic treatments and the unit cost of those treatments. Roughly speaking, the scenarios progress from one that assumes genetic technology will have only a modest impact on the health care system to one that assumes much more significant changes in our ability to identify and treat disease. We attempt to qualitatively describe the likely impact of each scenario on health plan costs and premiums.

Scenario One

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only 1 percent or 2 percent of the general population. Roughly half are treatable; for the rest, only palliative care is available. Unit costs of testing are initially quite high, but drop steadily over time.

Roughly 100 tests are developed that show, to varying degrees, predisposition to diabetes, heart disease, and several of the more common forms of cancer. In general, they have roughly the same predictive power as moderately elevated cholesterol levels for heart disease, or mild obesity for diabetes.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Tests for diseases that cannot be treated are typically not covered except on a diagnostic basis, to confirm the existence of disease once it has been manifested. The medical community generally avoids use of those tests. The cost to health plans (and the consequent impact on premiums) of covering testing for single-gene disorders is mild, due to the relative infrequency of use. Most individuals are covered through employer-sponsored programs. Individual market insurers do not require applicants to undergo genetic testing. However, those who have an identified single-gene disorder generally do not qualify for newly purchased private-market individual medical expense insurance, and must rely on subsidized high-risk coverage. Specialty insurers develop specified disease coverage that pays a lump sum, or monthly indemnity, on first manifestation of one of the "untreatable" single-gene disorders. This coverage must be purchased before any testing.

Screening tests that show a predisposition to disease are gradually accepted as covered expenses when used to further evaluate individuals with other risk factors, such as family history or excess weight. The impact of covering these tests on health plan costs and premiums is somewhat higher, due to broader use of the tests. Private individual market insurers do not require applicants to take these screening tests either. The impact of an identified predisposition depends on the presence of other risk factors,and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, or employer-sponsored coverage, rely on subsidized,guaranteed-issue coverage.

Scenario Two

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only 1 percent or 2 percent of the general population. Direct genetic therapy is developed for all of them, generally within a few years of their identification. Unit costs of testing are initially quite high, but drop precipitously over time. While genetic therapy resulting in a complete cure is available, unit costs for treatment are extremely high.

Roughly 100 tests are developed that show, to varying degrees, predisposition to diabetes, heart disease, and several of the more common forms of cancer. In general, they have roughly the same predictive power as moderately elevated cholesterol levels for heart disease, or mild obesity for diabetes.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is initially covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. The impact of testing for single-gene disorders on health plan costs and premiums is mild, due to the low unit costs. Covering treatment has a significant impact on health plan costs and premiums, however, due to very high unit costs. Most individuals are covered through employer sponsored programs. Due to the combination of low unit costs for testing, broad medical acceptance, and high predictive power, individual market insurers gradually begin requiring applicants to undergo testing for the most prevalent single-gene disorders. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

Screening tests that show a predisposition to disease are gradually accepted as covered expenses when used to further evaluate individuals with other risk factors, such as family history or excess weight. The cost impact is somewhat higher, due to broader use of the tests. Private individual market insurers do not require applicants to take these screening tests. The impact of an identified predisposition depends on the presence of other risk factors, and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, or employer-sponsored coverage, rely on subsidized, guaranteed-issue coverage.

Scenario Three

Several dozen tests are developed that identify single-gene abnormalities that lead almost inexorably to serious illness. Taken together, these single-gene abnormalities affect only one or two percent of the general population. Direct genetic therapy is developed for all of them, generally within a few years of their identification. Unit costs of testing are initially quite high, but drop precipitously over time. While genetic therapy resulting in a complete cure is available, unit costs for treatment are extremely high.

The combination of genetic microchips and sophisticated computer models allows the automatic, low-cost screening of tens of thousands of genetic variations and their interactions. They are able to identify predisposition to a wide array of illnesses. In general, they have roughly the same predictive power as do moderately elevated cholesterol levels for heart disease, or does mild obesity for diabetes. Unit costs are relatively low. The tests identify one or more predispositions in most people tested.

Medical expense programs begin covering tests for those single-gene disorders that are treatable as effective interventions are identified. Testing is initially covered on a medical necessity basis as determined by family history and other risk factors, or early warning signs of disease. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. The cost to health plans of testing for single-gene disorders is mild, due to the low unit costs. The cost impact of treatment is significant, however, due to very high unit costs. Most individuals are covered through employer-sponsored programs. Due to the combination of low unit testing costs, broad medical acceptance, and high predictive power, individual market insurers gradually begin requiring applicants to undergo testing for the most prevalent single-gene disorders. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

Individualized screening tests to identify a predisposition to disease are gradually accepted as covered expenses,driven largely by consumer demand. The cost of covering these tests is somewhat higher than that of covering screening for single-gene disorders, due to broader use of the tests and somewhat higher unit costs. Unlike tests for single-gene disorders, private individual market insurers do not require applicants to take these screening tests. The impact of an identified predisposition depends on the presence of other risk factors, and may result in an increased premium or an inability to qualify for coverage. Most individuals show a susceptibility to one or more diseases, and it is common for many with identified potentials for future disease to be accepted as standard risks. Those who do not qualify for private coverage, and do not have employer sponsored coverage, rely on subsidized, guaranteed issue coverage.

Scenario Four

The combination of genetic microchips and sophisticated computer models allows the automatic, low-cost screening of hundreds of thousands of genetic variations and their interactions. They are able to predict with a high degree of accuracy the future likelihood of most non-infectious disease other than poisoning. In general, they have very high predictive accuracy. Unit costs are moderate.

Roughly 2 percent to 3 percent of the general population are identified as having single gene abnormalities, for which direct genetic therapy is developed. Genetic treatment of single gene abnormalities is moderately expensive. Direct genetic therapy for conditions arising from the interaction of more than a handful of gene abnormalities is impractical. Where genetic therapy is available, the result is a complete cure.

As consumers realize the predictive power of individualized assessments, they begin demanding access to them. When not covered by medical expense programs,individuals seek them on their own. Pressure from the medical community and the general public leads to mandated coverage of the tests on a broad population screening basis. Treatment is covered. Covering testing has a significant impact on health plan costs and premiums, due to the combination of moderate unit costs and almost universal usage. The cost impact of genetic treatment is moderate, due to high unit costs. Most individuals are covered through employer sponsored programs. Due to the predictive power of these individualized assessments, individual market insurers gradually begin requiring applicants to undergo testing. However, this becomes a largely moot issue, as most individuals have already sought testing for other reasons. Those who have an identified single-gene disorder generally do not qualify for newly purchased private market individual medical expense insurance until they have been successfully treated, and must rely on subsidized high-risk coverage. Once treatment is complete, affected individuals are considered cured and the condition has no further effect on insurability.

The impact of an identified multi-gene disease on the expected cost of traditional treatment varies, and may result in an increased premium or an inability to qualify for coverage. Those who do not qualify for private coverage, and do not have employer-sponsored coverage, rely on subsidized, guaranteed-issue coverage. Those individuals who have no identifiable genetic disease begin seeking very low cost coverage, and are often unwilling to pay for anything other than catastrophic coverage for injury or infectious illness. In this case the ultimate character of the market depends on the relative number of these "genetically blessed" individuals. If there are relatively few, then the impact may be relatively small. If they are relatively many, their unwillingness to pay for anything other than minimal coverage may undermine the stability of the market for broad coverage,leading to a voluntary market that only provides catastrophic coverage and the need for a mandatory mechanism to provide for genetically based illnesses.

Chairman JOHNSON. Thank you, Mr. Wildsmith. We appreciate your comments.

Dr. Licata, you may proceed.

STATEMENT OF DR. JANE MASSEY LICATA, PARTNER, LICATA & TYRRELL P.C., MARLTON, NJ

Dr. LICATA. Good morning. When the Federal Government first began really trying to address the issue of genetic privacy and nondiscrimination it was around 1995, and at that time, I was pregnant with my youngest child. In September of 2001, I came before this Committee on his very first day of kindergarten, and was slightly late, and thank you for your indulgence. And at that time, we were beginning to really take a serious attack on the issue, figuring out how to create a balance that fairly allocated the risks and obligations between all the players in this very complex situation.

And here we are today, a few years later. He's getting ready to start the third grade in a few weeks, and some things have changed, and we've progressed, and we actually have a much more complex proposal before us, but it actually is very well crafted and very well balanced. So I would just very quickly like to talk about what the risks and obligations that we need to address are, and how the—some of the suggestions that are currently before us that have been very well stated in the Senate proposal, could be considered by this Committee and hopefully the House.

We've talked about HIPPA and all the wonderful things that HIPPA does. It's a very important legislation. The Act has done a lot for Americans, but it does not prevent insurers from collecting genetic information or limit the disclosure of genetic information about individuals to insurers, and it does not prevent insurers from requiring applicants to undergo genetic testing.

We have the ADA. And although the law is a very important law and we have guidance, it does not explicitly address genetic information in all cases or deal with unaffected carriers of a disease who may never get the disease themselves, individuals with late onset genetic disorders who may be identified through genetic testing as being at risk of developing a disease, or others identified through family history as being at risk for developing the disease. It does not protect workers from requirements or requests to provide genetic information to their employers.

And we also have Title VII of the Civil Rights Act, which could—and I'm a law professor, so I'm always looking for good arguments—provide a basis that genetic discrimination based on racially or ethnically linked genetic disorders constitutes unlawful race or ethnicity discrimination. But there's only really a few markers where that would be relevant. The two that have actually been addressed in most stages of legislation are Tay-Sachs and sickle cell anemia.

Forty-one states have actually enacted some sort of legislation on genetic discrimination in health insurance, and 31 have enacted legislation on genetic discrimination in the workplace. So we've come a long way. there's been good progress. There's been a great public debate.

But we're at a critical point now where we need to create a basis for all the players in the market. When I speak of all the players, I'm talking about the individuals who clearly have a privacy interest to protect themselves and their families; the researchers, who want to continue this important research who need to recruit subjects and be able to have as much information as possible to really

get the right answer as to the relevance of the marker and the correlation to a particular disease or condition.

We need to talk about business, and not just the people that are insuring through self-insurance and providing this as a benefit to their employees, but the companies that need to get investors, particularly in the biotechnology and medical industries where people are very concerned about this as an issue because it creates unpredictability and risk.

We're talking about unpredictability in a genetic marker and how you interpret it; it's even worse if you're a biotechnology company and you're trying to raise money, and the thought of whether if you even could come up with a good genetic diagnostic or a good genetic therapy, how that would play out in the marketplace, given people's fears that they're afraid of what is going to happen to the information once it's created, because you're opening literally a Pandora's box.

And we're also looking at the broader economy. OK, we're looking at the issue of the cost to the employer and the cost in the workplace of protecting this information. But there's a greater cost in the overall economy for not taking the opportunities for the best medical care, for not allowing people to get the information and use the information to preserve their health and to be able to actually maybe even reduce health care costs overall, and also basically to be able to compete in a worldwide economy where we are the leaders right now in genetic research.

So asking to create a basis where we really have a fair apportionment of risk and also responsibility is what the bill that we're currently considering is all about. We're looking at what is the job of the employer and what is the rights of the individual. And the perspective on the individual is terrific, because we are giving the autonomy to the individual to give the consent as to how their information is used, and we're putting the responsibility on the company to protect that information and preserve the public trust. Thank you.

[The prepared statement of Dr. Licata follows:]

Statement of Dr. Jane Massey Licata, Partner, Licata & Tyrell P.C., Marlton, NJ

With the completion of the first map of the human genome, we now have a basis for determining our unique genetic makeup and probable medical future and to permit personal diagnostics and therapeutics to be created for us. This is no longer the stuff of science fiction. Everyday new genetic markers are identified and correlated with human biology and disease. The future of medicine lies in genomics. Worldwide, university and pharmaceutical company researchers alike are mining databases of genetic information and rapidly identifying new drug targets, diagnostic markers and creating a basis for novel therapies. Tests designed to determine the presence or version of genes that cause diseases or conditions carry with them the most intimate details of our biological past and future as well as a devastating potential for discrimination. Analysis of our genetic material also provides information about our parents, siblings and children which impacts not only on ourselves but on family privacy. The potential for misunderstanding or misuse of this information is so great, however, that it is essential that we establish a national policy for the protection of an individual's privacy interest in their genetic information.

The Genetic Information Non-discrimination Act is an important and timely legislative initiative to prohibit health insurance and employment discrimination against individuals and their family members on the basis of predictive genetic information or genetic services. Predictive genetic information is information about an individual's genetic tests (i.e., the analysis of human DNA, RNA, chromosomes, proteins,

and certain metabolites in order to detect genotypes, mutations, or chromosomal changes); information about genetic tests of family members; or information about the occurrence of a disease or disorder in family members. Information about the sex or age of the individual, information about chemical, blood, or urine analysis of the individual, unless these analysis are genetic tests, and information about physical exams and other information relevant to determining the current health status of the individual are specifically excluded from the definition of predictive genetic information. Genetic services are health services, including genetic tests, provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

An insurer may not deny eligibility or adjust premium or contribution rates for a group on the basis of predictive genetic information or information about a request for or receipt of genetic services. An insurer may also not request or require genetic testing. Further, the insurer may not request, require, collect or purchase such predictive genetic information. The insurer may also not disclose predictive genetic information or a request for genetic services; disclosures to the Medical Information Bureau and the individuals's employer or plan sponsor are specifically prohibited. However, with respect to payments for genetic services, the insurer may request evidence that such services were performed (but not the results) and if the evidence is not provided, may deny payment. An insurer may also request that an individual provide predictive genetic information so long as such information is used solely for the payment of a claim and limited to information that is directly related to and necessary for the payment of the claim (i.e. the claim would otherwise be denied). Disclosure is limited to individuals within the plan who need access to the information for payment of the claim.

Prior, knowing, voluntary, written authorization for the collection or disclosure of predictive genetic information is provided for. Disclosures between health care providers for the purpose of providing treatment are exempted.

Civil actions for legal and equitable relief including civil attorney fees and the costs of expert witnesses are provided for. Civil penalties, payable to the United States Treasury, are also provided for. Further, it is provided that these provisions shall not be construed to supersede any State law provision that more completely protects confidentiality or privacy or protects against discrimination with respect to such information.

Further, employers, employment agencies and labor organizations are prohibited to fail or refuse to hire, discharge or otherwise discriminate on the basis of predictive genetic information. Employees may also not be classified on the basis of predictive genetic information or a request for genetic services. Employers may not request, require, collect or purchase predictive genetic information about employees for genetic monitoring without prior, knowing, voluntary and written authorization by the employee and without informing the employee of the monitoring results. Genetic monitoring is the periodic examination of employees to evaluate changes in their genetic material (e.g. chromosomal damage or evidence of increased occurrence of mutations) that may have developed during the course of employment due to exposure to toxic substances in the workplace in order to deal with adverse environmental exposures in the workplace. Any monitoring must conform to OSHA or FMSHA requirements. Further, the results of the monitoring may not disclose the identity of an employee. Any predictive information about an employee must be treated or maintained as part of the employee's confidential medical records. A Federal or State court may award any appropriate legal or equitable remedy which may include payment of attorney's fees and costs, including the costs of experts. The EEOC may also enforce.

This bill is a well considered proposal. It addresses some of the most significant privacy and nondiscrimination issues in a thoughtful and balanced manner.

Many genetic marker are not conclusively diagnostic but rather may indicate a predisposition to a disease or condition or may presently be believed to have a correlation with a disease or condition. In such cases it would be especially troublesome if the information were relied upon to make employment or insurance decisions. However, there are well established genetic markers which can be diagnostic. It is therefore important that the definitions of genetic information and information relevant to determining the current health status of an individual not allow for inadvertent access to some genetic information or test results. There is also an exception concerning sharing of information between health care providers for treatment. Again, I would suggest that health care providers are accustomed to dealing with sensitive, confidential information, for example HIV status, and accordingly a blanket exception is not required. The individual's prior written consent to make the information available between health care providers should not be an undue burden and helps identify the information as sensitive and confidential. Further, there is

an exception for information for payment of a claim. This provision places individuals in the position of paying for the genetic test themselves or risking the disclosure. While there are provisions that restrict the scope of the disclosure and to whom the information would be disclosed, I would suggest that the results never be disclosed an insurer or employer. I would also suggest that there be clarification as to what would be sufficient evidence that the services were performed, i.e. a receipt from a licensed laboratory or health care professional that a genetic test was performed should be sufficient.

Unfortunately it is those seeking individual health insurance protection who may be at the greatest risk for discrimination. While there are provisions that cover individual policies in some instances, individuals require the same protections as group participants. Also, while there are provisions for civil suits and administrative actions, I would suggest that there should be significant penalties for any knowing violation by an insurer or employer. Under the current scheme, the employee or insured, who may not have reasonable access to legal representation, may not be able to effectively protect their privacy interests. I would therefore suggest the Government take a proactive role and that there be substantial civil penalties provided for in the event there is any violation. Clearly, this is provided for to some extent under the proposed legislation, however, strengthening the role for government enforcement could be helpful.

While some states, like my state, New Jersey, have enacted genetic privacy acts, I believe it is essential to establish a consistent, national policy to protect against genetic discrimination in employment and insurance and to protect the privacy of this most sensitive and personal information. These issues cross state boundaries and affect all of our citizens. New Jersey's Genetic Privacy Act which was enacted in 1996 declared that genetic information is personal information that should not be collected, retained or disclosed without the individual's authorization. The Act prohibits discrimination by employers against employees carrying genetic markers of diseases or behavioral traits. It is unlawful for an employer to refuse to hire or employ, or to discharge or require to retire, an employee because of the employee's genetic information, or atypical hereditary cellular or blood trait, or because the employee refused to submit to a genetic test or make available the results of a genetic test to the employer. It also prohibits the use of genetic information in the fixing of rates or withholding of life insurance and bans the use of genetic information to establish the amount of insurance premiums, policy fees, or rates charged for a health insurance contract. The penalties for violation of the provisions of the Act include fines and prison terms. Actual damages, including economic, bodily or emotional harm proximately caused, may also be recovered for wanton disclosure of genetic information. The New Jersey Act is an important first step in controlling the flow of genetic information, however, Federal legislation is still needed.

The time is now for the Genetic Information Nondiscrimination Act. This legislation addresses some of the most urgent needs in protecting an individual's privacy and in assuring access to genetic testing and services. Until recently, access to this type of testing was limited to those who could afford to pay for it privately. By paying it for it themselves, they could also have greater assurance of confidentiality concerning the testing and the results. While wider acceptance of the need and validity of genetic testing has made insurers more comfortable with reimbursement for this type of service, there is a huge risk to the insured or employee that very sensitive information, which could easily be subject to misinterpretation may be widely distributed as a part of the insurance information system. I would suggest erring on the side of making such information as inaccessible as possible to third parties since the risk of misunderstanding or misuse is so great.

Chairman JOHNSON. Thank you, ma'am. Appreciate your testimony, too, and thank you for coming back.

Mr. Lorber, you may begin your testimony now.

STATEMENT OF LAWRENCE Z. LORBER, ESQ., PARTNER, PROSKAUER ROSE LLP, WASHINGTON, DC, ON BEHALF OF THE U.S. CHAMBER OF COMMERCE

Mr. LORBER. Thank you, Mr. Chairman and Members of the Committee. My name is Lawrence Lorber. I am a partner in the Washington office of the Proskauer Rose law firm and have practiced labor law in government and private practice for over 30

years. I am here testifying on behalf of the United States Chamber of Commerce. We are honored to be invited to this extremely important hearing.

At the Chamber, I am chairman of the Equal Employment Opportunity Subcommittee of the Chamber's Labor Relations Committee. The Chamber also serves as co-chair of the Genetics Information Nondiscrimination in Employment Coalition, the GINE coalition, which is a group of trade associations and professional organizations formed to address concerns about workplace discrimination based on employees' genetic information.

I have served as a technical adviser to the coalition with respect to the various genetics bills introduced in the House and Senate. And briefly, as the Chairman noted, in my prior government experience, I was the Director of the Office of Federal Contract Compliance Programs at the Department of Labor and issued the first regulations under Section 503 of the Rehabilitation Act, which prohibited discrimination and required affirmative action with respect to then called handicapped or disability discrimination. Those regulations established the principle of job relatedness in the area of disability discrimination, and they also set the standards for pre- and post-offer employment medical inquiries of employees.

And I was honored to be appointed to the first board of directors of the Office of Compliance, the congressional office which interprets and enforces the Congressional Accountability Act, which, as you know, applies 11 labor and employment laws, including the ADA, to the Congress and congressional instrumentalities.

The issue before the Congress is whether a new Federal law regulating employer collection and use of information about an individual's genetic predisposition to disease or disorders is necessary at this time, and if so, what form should the law take. However, the Congress and certainly this Committee must be aware of a very salient fact. It must be acknowledged today that the workplace is already subject to extensive and complex statutory and regulatory oversight by Federal, state and local government. This has created a confusing matrix of overlapping laws and regulations and imposes a significant cost on our economy. And while in many cases providing important protections, also opens the door to abusive, frivolous and costly litigation.

Therefore, as a matter of sound pubic policy, there ought to be a reluctance to add to this mass of regulation and a requirement that any law address a real issue which is not dealt with by the existing body of employment law. Therefore, I believe it is critical to make one salient point. There is simply little or no evidence of employer collection or misuse of genetic information in today's workplace. This is despite continued predictions that in the absence of new law, the fear of increased insurance costs, absenteeism and low productivity will inevitably drive vast numbers of employers to genetic testing of the workforce and employment discrimination or exclusion based upon genetic makeup.

Well, whether it's due to the threat of liability under the extensive existing protections, fear of public backlash, moral concerns or simply a lack of interest, employer collection and misuse of genetic information remains largely confined to the pages of science fiction. As my testimony makes abundantly clear, the current body of Fed-

eral law, including the ADA, Title VII of the Civil Rights Act, HIPPA and other Federal laws are more than ample to deal with any misuse of genetic information.

And even if there were some lapse in Federal law, 32 states have laws specifically prohibiting employment discrimination based upon management makeup. Twenty-six have laws specifically regulating employer acquisition and disclosure of genetic information, and 25 states have laws regulating the privacy of genetic information. Forty-nine states have laws similar to the ADA.

I would like to discuss the development of the reported cases in these states except for one problem—there isn't any. In states such as California, which has, as we all well know, an extensive employment litigation docket, there are no reported cases. In New Jersey, which also has a vigorous state employment litigation practice, there are no cases under the genetic privacy law.

Employment plaintiff lawyers are not the proverbial potted plants, nor are they shy about attempting to extend the parameters of the law. Yet there are no reported cases. If the states are deemed to be the laboratories for the Federal Government in this area, the Petri dishes have grown no cultures.

Perhaps it is because there is no problem, or perhaps it is because there are sufficient causes of action under existing law to temper the enthusiasm of any employer which for whatever reason may wish to exclude someone because of their genetic makeup.

We would also note that the EEOC, the Federal Government's primary agency dealing with issues of employment discrimination, has already taken the position that discrimination on the basis of genetic information violates the ADA, and in the one reported case, the EEO swiftly and effectively dealt with the issue, enjoined the practice and secured a multi-million-dollar settlement for the alleged victims.

In conclusion, as the representative of employers and as a leader in the effort to increase health insurance coverage, the Chamber of Commerce is excited about the potential of genetic science leading to more effective treatments and early interventions. However, we just as strongly believe that an additional broad workplace regulatory scheme is unnecessary at this time. Science is not assisted by overregulation and frivolous litigation.

We appreciate the opportunity to highlight the extensive existing protections against genetic discrimination as well as the complete lack of evidence that employers are engaged in the collection and misuse of genetic information.

Thank you.

[The prepared statement of Mr. Lorber follows:]

Statement of Lawrence Z. Lorber, Esq., Partner, Proskauer Rose LLP, Washington, DC, on behalf of the U.S. Chamber of Commerce

Chairman Johnson and Members of the Subcommittee, I am pleased and honored to be here today on behalf of the U.S. Chamber of Commerce to testify about predictive genetic information and the workplace. I am a member of the Chamber's Labor Relations Committee and Chair of its Equal Employment Opportunity Subcommittee. Thank you for your kind invitation.

By way of introduction, I am a partner with the law firm of Proskauer Rose LLP and have been practicing labor and employment law for almost thirty years both in the government and in private practice. Early in my career, I served in the Office of Solicitor, U.S. Department of Labor, including serving as Executive Assistant to the Solicitor. I was appointed as Deputy Assistant Secretary of Labor and Director of the Office of Federal Contract Compliance Programs (OFCCP), the agency within the Department of Labor that administers the government's affirmative action and non-discrimination requirements for federal contractors, including the requirements under Section 503 of the Rehabilitation Act of 1973. During my tenure the initial regulations under the 503 program were issued which established the basis for the enforcement of the non-discrimination and affirmative action requirements in employment for individuals with handicaps. Those regulations established the principle of job relatedness under the Rehabilitation Act. They also established the principle that there could be no pre-offer inquiry regarding physical conditions. I left that position in 1977 and since then have been in private practice, where I primarily represent employers.

Over the course of my career, I have taken an interest and remained involved in workforce policy issues. This has included, among other things, frequently testifying before Congress and serving as counsel to The Business Roundtable with respect to the 1991 Civil Rights Act. In addition, I was honored to be appointed as one of the original five members of the Board of Directors of the Office of Compliance, the congressional agency established by the Congressional Accountability Act to administer eleven employment statutes, including the Americans with Disabilities Act (ADA), with respect to the Congress and congressional instrumentalities. I remained on the Board until my term was completed in 1998.

Of particular relevance to this hearing, I also act as a technical advisor on the genetics bills introduced in the House and Senate for the U.S. Chamber of Commerce and the Genetics Information Nondiscrimination in Employment (GINE) coalition. The coalition, which is co-chaired by the Chamber, is a group of trade associations and professional organizations formed to address concerns about workplace discrimination based on employees' genetic information as well as the confidentiality of that information.

The issue before us today is whether a new federal law regulating employer collection and use of information about an individual's genetic predispositions to diseases or disorders is necessary at this time, and if so, what form that law should take.

As I will discuss in more detail, these are complex issues and it is certainly appropriate for Congress to review them carefully. A rush to enact broad legislation at this time, however, would be a major mistake.

In this regard, it is extremely important to note that the workplace is already subject to extensive and complex statutory and regulatory oversight by federal, state and local government. This has created a confusing matrix of overlapping requirements administered by a multitude of different agencies. Each one of these laws and regulations imposes a cost on our economy and, while in many cases providing important protections, also opens the door to abusive, frivolous, and costly litigation. Therefore, as a matter of sound policy there ought to be a reluctance to add to this mass of regulation.

If, however, it is determined that Congressional action is warranted, any response should be narrowly targeted and consistent with the substantial body of law already governing employer collection and use of genetic and other health information. It also must be designed to minimize unnecessary and overly complex regulation, frivolous litigation, and unforeseen consequences.

Unfortunately, the bills currently before Congress completely fail to meet these criteria. In order to understand why this is the case, some background is necessary.

I. Protections Under Existing Law

Existing federal laws already provide substantial protections against employer acquisition, disclosure, and misuse of genetic information. States have also enacted a variety of laws, some of which specifically regulate the collection and use of genetics information in the workplace, others of which deal more generally with the issue of the confidentiality of medical information.

A. The Americans with Disabilities Act

Among other things, the ADA created a comprehensive scheme regulating employer collection and disclosure of medical information and providing protections for the disabled against employment discrimination.

The Equal Employment Opportunity Commission (EEOC), which is the federal agency charged with enforcing ADA provisions on employment, has made it clear to employers that, in its opinion, the ADA provides protections against collection and disclosure of genetic information as well as employment discrimination based on an individual's genetic makeup.[1] The agency also has made it clear that it has no compunction about bringing an enforcement action under the ADA against an employer engaged in such behavior. Specifically, it has said "the Commission will continue to respond aggressively to any evidence that employers are asking for or using genetic tests in a manner that violates the ADA . . . . Employers must understand that basing employment decisions on genetic testing is barred under the [ADA and, m]oreover, genetic testing, as conducted in this case, also violates the ADA as an unlawful medical exam."[2] The EEOC's position that the ADA provides these protections certainly belies the argument that there a gap which must be filled by federal legislation.

ADA & Discrimination

There are two theories under which the ADA can be interpreted to bar discrimination based on genetic makeup.

The first, which has been advocated by the EEOC, is based on the ADA's "regarded as" prong. To be protected from employment discrimination under the ADA, an individual must have one of the following: an actual disability, a record of such a disability, or be regarded as having a disability. The EEOC has taken the position that discrimination based on

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[1] *See EEOC's Memorandum in Support of Petition for Preliminary Injunction, EEOC v. Burlington Northern Santa Fe Railroad,* (N.D. IA, settled April 18 2001); *EEOC Compliance Manual, section 902: Definition of the Term Disability,* Sec. 902.8(a); *EEOC Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act,* available at http://www.eeoc.gov/policy/docs/guidance-inquiries.html.

[2] *EEOC Settles ADA Suit Against BNSF For Genetic Bias,* EEOC Press Release (April 18, 2001), available at http://www.eeoc.gov/press/4-18-01.html.

genetics is tantamount to discrimination against an individual because he or she is regarded as having a disability.[3] The agency's position, which is clearly articulated in its compliance manual, is based in part on explicit statements in the ADA's legislative history.[4]

While some have hypothesized that the EEOC's theory may not hold up to judicial scrutiny,[5] it was the foundation for the Commission's suit and favorable settlement in the only recorded case where a private employer was accused of genetic discrimination.[6] In the settlement, the employer agreed to pay $2.2 million to 36 workers, not engage in any further genetic testing of employees or applicants, provide enhanced ADA training to its medical and claims personnel, and have senior management review all significant medical policies and practices.[7] Given the end result of the case and the public relations damage associated with an EEOC suit, we do not believe that it is reasonable to expect that there are any employers that are anxious to "test" the "regarded as" theory in court.

Several commentators have advanced a second theory under which the ADA may bar genetics discrimination. Under this theory, the mere possession of a genetic marker for a disease could constitute an actual (opposed to being "regarded as" having a) disability under the ADA, even though the individual has not manifested symptoms of the underlying disease.[8] The theory is based on the 1998 the Supreme Court case *Bragdon v. Abbott*.

In *Bragdon*, the Court found that asymptomatic HIV (i.e., the disease had not progressed to the symptomatic stage) is a disability under the ADA.[9] It reasoned that even though symptoms of the disease had not yet manifested, the danger of passing HIV on to one's partner or children substantially limited the major life activity of reproduction.[10] With respect to offspring, the same could be said about certain genetic disorders.[11]

Of course, whether or not the genetic marker substantially limits reproduction will depend on likelihood of passing it to one's children. In the *Bragdon* case, the Court found an 8% risk of passing on the disease significant enough to substantially limit reproduction.[12]

The ADA & Collection & Disclosure of Information

There are also provisions in the ADA governing employer acquisition and disclosure of genetic information. The section of the statute regulating acquisition provides distinct rules for different stages of the employment relationship. Courts have found that these restrictions apply regardless of whether the applicant or employee is disabled.[13]

Applicants are provided the greatest protections. The ADA specifically prohibits medical examinations or any disability-related inquiries of job applicants. According to EEOC guidance, this means employers may not ask applicants any questions "likely to elicit information about a disability, [including those] about an employee's genetic information" and may not require applicants undergo medical examinations, including genetic tests.[14]

After an applicant receives an offer but before he or she begins employment, however, an employer may ask disability-related questions, including those concerning genetic-related information, and require that the employee undergo medical examinations, including genetic tests. The provision allows employers to obtain important information regarding the employee's ability to perform the job in a safe manner—information that may be unbeknownst to an employee until the medical examination or inquiry.

The examinations and inquiries are only permitted, however, if the employer makes the same inquiries and requires the same tests of every person with an offer in that job category. This ensures that individuals, or classes of individuals, are not singled out for inquiries or examinations.

Once a person begins employment, the ADA only permits employers to make medical inquiries or require medical exams that are job related and consistent with business necessity. This allows employers to acquire specific targeted information that may be necessary to ensure a safe workplace or to provide benefits under employer policies or federal or state laws, or to provide an employee with a reasonable accommodation as required by the ADA and similar state laws.

The ADA requires, however, that employers keep any health information they acquire from post-offer applicants or employees in confidential separate files only to be revealed to:

1. first aid and safety personnel, if emergency treatment may be needed;
2. supervisors, as it pertains to the individual's work restrictions; or

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[3] *See EEOC's Memorandum in Support of Petition for Preliminary Injunction, EEOC v. Burlington Northern Santa Fe Railroad,* (N.D. IA, settled April 18, 2001); *EEOC Compliance Manual, section 902: Definition of the Term Disability,* Sec. 902.8(a) ("Covered entities that discriminate against individuals on the basis of genetic information are regarding the individuals as having impairments that substantially limit a major life activity."); Testimony of EEOC Commissioner Paul Steven Miller Before the Senate Committee on Health, Education, Labor and Pensions (July 20, 2000).

[4] *EEOC Compliance Manual, section 902: Definition of the Term Disability,* Sec. 902.8(a) (citing 136 Cong. Rec. H4623 (daily ed. July 12, 1990) (statement of Rep. Owens), at H4624-25 (statement of Rep. Edwards), and at H4627 (statement of Rep. Waxman)).

[5] *See, e.g.*, Testimony of Andrew J. Imparato Before the Senate Committee on Health, Education, Labor and Pensions (February 13, 2002); *see also* Testimony of EEOC Commissioner Paul Steven Miller Before the Senate Committee on Health, Education, Labor and Pensions (July 20, 2000) (expressing concerns over language in the dissent in *Bragdon v. Abbott,* 524 U.S. 624 (1998)).

[6] *See EEOC's Memorandum in Support of Petition for Preliminary Injunction, EEOC v. Burlington Northern Santa Fe Railroad,* (N.D. IA, settled April 18, 2001).

[7] *EEOC Settles ADA Suit Against BNSF For Genetic Bias,* EEOC Press Release (April 18, 2001), available at http://www.eeoc.gov/press/4-18-01.html; *EEOC's First Genetic Testing Challenge Settled for $2.2 Million, Parties Announce,* BNA The Daily Labor Report (May 9, 2002).

[8] *See, e.g.*, Testimony of Andrew J. Imparato Before the Senate Committee on Health, Education, Labor and Pensions (February 13, 2002).

[9] *Bragdon v. Abbott,* 524 U.S. 624 (1998).

[10] *Id.* at 640-41.

[11] The ADA defines an actual disability as an impairment that substantially limits a major life activity. While a marker for a genetic disorder certainly might substantially limit reproduction in the same manner as HIV, it is not completely settled whether a court would find that a genetic predisposition to a disease constitutes an impairment. Under the ADA, an impairment is a condition which affects one of the body's key systems. The Court in *Bragdon* concluded that "[i]n light of the immediacy with which the virus begins to damage the infected person's white blood cells and the severity of the disease, we hold [that HIV] is an impairment from the moment of infection." 524 U.S. at 638. A court may or may not come to the same conclusion with regard to any given genetic marker.

[12] 524 U.S. at 641.

[13] *See, e.g., Cossette v. Minnesota Power and Light,* 188 F.3d 964 (8th Cir. 1999); *Fredenburg v. Contra Costa County Dep't of Health Servs.*, 172 F.3d 1176, 1182 (9th Cir. 1999); *Roe v. Cheyenne Mountain Conference Resort, Inc.*, 124 F.3d 1221, 1229 (10th Cir. 1997).

[14] *EEOC Enforcement Guidance: Disability-Related Inquiries and Medical Examinations of Employees Under the Americans with Disabilities Act*, available at http://www.eeoc.gov/policy/docs/guidance-inquiries.html. The guidance defines genetic information as information about an individual's genetic tests, genetic tests of his or her family members, or the occurrence of a disease, medical condition, or disorder in his or her family members.

3. government officials.

Also, the information may not be used to discriminate in violation of the ADA or any other federal or state statute for that matter. Thus, even if an employer collected genetic information, it could not base an employment decision on the information without the threat of liability under ADA, or other federal or state laws.

B. The Health Insurance Portability and Accountability Act

In addition to the protections afforded by the ADA, the Health Insurance Portability and Accountability Act (HIPAA) regulations restrict employer collection, use and disclosure of genetic information acquired through administration of employer sponsored group health plans. Although the HIPAA regime does not directly govern the employment relationship, HIPAA prohibits group health plans and insurers from providing employers with employees' and beneficiaries' health information, including genetic information, unless certain requirements are met. More specifically, in order to receive health information, the employer/plan sponsor essentially must amend the plan to include assurances that it will only use the information for plan administration with specific guarantees that it will not use the information for employment decisions. The regulations also require that employers who provide group health plans create a firewall to separate plan administration from human resource functions. Violations can result in severe criminal penalties.[15]

C. Title VII of the Civil Rights Act of 1964

Title VII of the Civil Rights Act of 1964 (Title VII), in certain circumstances, also prohibits genetic testing/inquiries and discrimination based on genetic makeup. Title VII bars employers from discriminating based on race, color, religion, sex, or national origin. Although on its face the statute may not appear to protect against genetic discrimination, it does prohibit employers from singling out a certain group for testing or inquiries.

This was exactly the situation in a case against Lawrence Berkley Laboratory, a research institution jointly operated by state and federal agencies. As part of its occupational medical program, the laboratory required prospective employees (those who had been given a conditional offer), to undergo medical examinations, including testing of African American candidates for the sickle cell anemia trait. Sickle cell anemia is the most common inherited blood disorder in the United States, affecting about 72,000 Americans or 1 in 500 African Americans.[16] Several employees sued and the United States Court of Appeals for the Ninth Circuit ruled that by singling out African Americans for the test, the laboratory violated Title VII.[17]

Likewise, Title VII would prevent employers from singling out women for tests for BRCA 1 and BRCA 2 genes, which can reveal a predisposition for breast and ovarian cancer. [18]

Title VII also bars discrimination based on genetic traits, if the discrimination has a disproportionate adverse effect on individuals of a certain race, sex, color, or national origin. For example, the genetic mutation associated with Tay-Sachs Disease is found most commonly in persons with an Eastern European Jewish ethnic background.[19] As was aptly pointed out by the Senate Committee on Health, Education, Labor and Pensions in its Committee Report on S. 1053, "if an employer were to selectively refuse to hire carriers of the Tay-Sachs mutation, this action would have a disproportionate effect on people with a specific national or ethnic origin . . ." and thus may constitute a violation of Title VII.[20] This would hold true for many genetic mutations, including BRCA 1 and BRCA 2 (more prevalent among those with Ashkenazi (Eastern European) Jewish ancestry),[21] Hemophilia (a genetic blood clotting disorder primarily affecting males)[22] or Fragile X-associated Tremor/Ataxia Syndrome (a genetically neurological disorder which only affects men).[23]

Nor could an employer specifically discriminate against a subgroup of individuals with the gene, if that subgroup is a class protected by Title VII. For example, it would be unlawful sex discrimination to refuse to hire women with BRCA 1 and BRCA 2 genes, unless the employer also refused to hire men with the genes.

D. State laws

There are 32 states that have laws specifically prohibiting employment discrimination based on genetic makeup, 26 have laws specifically regulating employer acquisition and disclosure of genetic information, and more than 25 states have laws regulating the privacy of genetic information.[24] Forty-nine states have laws protecting against disability discrimination similar to the ADA, which also may provide protections.[25] All states have laws with some restriction on access and disclosure of medical information.[26]

II. Case for Congressional Consideration of Additional Regulation

A. Given the Lack of Appreciable Evidence of Genetic Discrimination or Misuse of Genetic Information and Existing Laws Regulating Genetics in the Workplace, Further Regulation Aimed at Creating Additional Deterrents Appears Unnecessary at This Time

There is little to no evidence of employer collection or misuse of genetic information in today's workplace. This is despite continued predictions that, in the absence of a bill, the fear of increased insurance costs, absenteeism, and low productivity would inevitably drive vast numbers of employers to genetic testing of the workforce and employment discrimination based on genetic makeup.[27] Whether it is due to the threat of liability under existing protections, fear of

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[15] $250,000 and 10 years in prison, *see* 42 U.S.C. sec. 1320d-6.

[16] Information provided by the National Institutes of Health, available at http://www.ncbi.nlm.nih.gov/books/bv.fcgi?call=bv.View..ShowSection&rid=gnd.section.98.

[17] *Norman-Bloodsaw v. Lawrence Berkeley Laboratory,* 135 F.3d 1260, 1272 (9th Cir. 1998).

[18] *See Genetic Testing for BRCA 1and BRCA 2: It's Your Choice, Cancer Facts,* National Cancer Institute, available at http://cis.nci.nih.gov/fact/3_62.htm.

[19] *See The National Tay-Sachs and Allied Diseases Association web site,* available at http://www.ntsad.org/pages/t-sachs.htm.

[20] Senate Committee on Health, Education, Labor and Pensions in its Committee Report on S. 1053, 108th Congress, at 11.

[21] *See Genetic Testing for BRCA 1and BRCA 2: It's Your Choice, Cancer Facts,* National Cancer Institute, available at http://cis.nci.nih.gov/fact/3_62.htm.

[22] *See* http://www.hemophiliagalaxy.com/patients/about/index.html.

[23] *See Fragile X-associated Tremor/Ataxia Syndrome,* Paul J. Hagerman, M.D., Ph.d and Randi J. Hagerman, M.D., available at http://fragilex.org/FXTAS.pdf.

[24] National Conference of State Legislatures, available at http://www.ncsl.org/programs/health/genetics/charts.htm.

[25] *Id.*, available at http://www.ncsl.org/programs/employ/empdisc.htm.

[26] *Id.*, available at http://www.ncsl.org/programs/health/genetics/charts.htm.

[27] *See, e.g.,* Melinda Kauffman, *Genetics Discrimination in the Workplace: an Overview of Existing Protections,* 30 Loy. U. Chi. L.J. 393, 395 (1999); Testimony of Andrew J. Imparato Before the Senate Committee on Health, Education, Labor and Pensions (February 13, 2002); Testimony of the National Partnership for Women and Families Before the House Subcommittee on Employer-Employee Relations (July 24, 2001).

public backlash, moral concerns or simply a lack of interest, employer collection and misuse of genetic information remains largely confined to the pages of science fiction.

Indeed, there is but one recorded case alleging inappropriate collection and misuse of employee genetic information by a private employer. As I said before, the EEOC prosecuted that company under the ADA and, through settlement, recovered over $2 million for the affected employees in addition to injunctive relief.

Despite this lack of evidence, proponents of broad genetic legislation continue to claim that a new law imposing significant compliance costs is necessary in order to deter employers from collecting and misusing genetic information. Yet, if anything, the lack of litigation under available avenues of redress, such as the ADA, Title VII and the multitude of state laws, indicates that existing legal protections are a more than adequate deterrent against employer collection and misuse of genetic information.

Let me speak plainly. Even assuming for the purposes of argument that some number of employers were disposed to engage in genetic discrimination, the threat of allegations of discrimination from both a liability and public relations perspective is enough to prevent these employers from ever contemplating acquiring any genetic information. The simple fact is if they never have the information, they cannot be accused of using it to discriminate.

Many of the proponents of broad legislation have attempted to prop up their weak case by alleging—without factual support—that employer misuse of genetic information is prevalent. For example, the Council for Responsible Genetics contends that there have been hundreds of instances of genetic discrimination by employers and insurers.[28] Yet, the group produces no hard statistical data supporting its claim. Given the existing protections under federal and state law and the aggressiveness of the trial bar with respect to employment litigation, it is highly unlikely that none of these people would have sought legal redress.[29]

There have also been attempts to misleadingly characterize the available research to suggest that employers are routinely performing genetic tests on their employees. For example, some proponents cite research conducted in 1989 for the now defunct Office of Technology Assessment (OTA).[30] The OTA reported that, in a survey of fortune 500 companies, 12 employers reported conducting genetic tests. However, as it turns out these tests were not for nefarious purposes at all, but rather performed as part of a voluntary wellness program, or other tests performed at the employee's request, and tests performed as part of diagnosing an employee's medical condition.[31] The OTA study most certainly did not demonstrate that employers were systematically using genetic information to make adverse personnel decisions. In fact, of the universe samples, only a single employer reported making an adverse employment decision based on genetic information.[32]

Likewise, proponents have cited survey research performed by the American Management Association (AMA) of 2,133 companies in which three employers (in 1999) and seven employers (in 2000) reportedly utilized genetic tests of some of their employees. What proponents leave out is that the AMA also noted that "unanimously, the companies that did genetic tests told us they performed them for no other reason than concerns over workplace safety and health."[33] Likewise proponents misleadingly fail to report that for the last survey year that data are available for, 2001, only two employers reported performing any such tests. As the AMA concluded, "if genetic testing is being done to any appreciable degree among AMA membership and client base that together employ about one-fourth of the American work force, we haven't been able to find it."[34]

B. Is Fear of Discrimination Discouraging Testing and Participation in Research?

Some also claim that legislation is necessary to promote genetic testing and research. More specifically, they allege that some individuals are failing to seek out genetic testing and avoiding participating in genetic research because they are afraid that results of the test will be used to deny them or their family members employment opportunities.[35] These claims are based on several surveys that have been conducted in the last decade.

The Chamber believes that public policy should not allow fear of genetic discrimination to discourage individuals from seeking health information that will assist in the diagnosis and treatment of possible illnesses or participating in research that contribute to the evolution of genetic science. Rather it believes that sound public policy should make it clear that such fears are unfounded under the laws and protections in effect today.

III. Devising an Appropriate Response to Possible Problems

The surveys on genetic testing and fear of discrimination should be the starting place for further Congressional investigations into the matter. If it is determined that such fear does exist and is discouraging genetic testing and/or research, Congress should weigh the various possible solutions, including increasing education about existing legal protections to employees,[36] or if necessary, enacting targeted legislation that protects against discrimination based on the results of genetic tests. If drafted correctly, such a bill could get to the root of the problem (if there is indeed one) without imposing undue transactional compliance and litigation costs.

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[28] The Council for Responsible Genetics: Genetic Testing, Discrimination and Privacy, available at http://www.gene-watch.org/programs/privacy.html.

[29] Employees may not be aware of existing protections until they face genetic testing or discrimination in the workplace, and, as I discuss later, this lack of information could discourage people from seeking genetic tests. Once an employee is faced with genetic testing or genetic discrimination in the workplace, however, such protections are quickly revealed by a simple search on the internet or trip to the local trial attorney.

[30] OTA, which operated from 1972 to 1995, was designed to assist Congress with the complex and technical issues that impacted society.

[31] *Genetic Monitoring and Screening in the Workplace,* Office of Technology Assessment, at 171-93 (1990).

[32] *Id.* at 182.

[33] *See* Testimony of Eric Greenberg Before the House Subcommittee on Employer-Employee Relations (July 24, 2001).

[34] *Id.* (emphasis added)

[35] Of course, the ongoing drumbeat by proponents of legislation that existing laws provide insufficient protections against genetics discrimination, coupled with their accusations that employers are engaged in widespread discrimination, are likely to have exacerbated any misplaced fears that exists regarding employer misuse of genetic information.

[36] For example, nowhere in the EEOC's posters that employers must post at the workplace does it mention that it is the agency's position that the ADA prohibits discrimination based on genetic discrimination and regulates the collection and disclosure of genetic information. Nor is there any information contained in it about the possible protections offered under Title VII. Thus, while many employers may be aware of the EEOC's position, employees may not be as well informed.

Congress should not, however, rush to pass broad sweeping legislation where there is no evidence that greater protections are needed to prevent against inappropriate collection and use of genetic information in the workplace—above all at a time when over regulation is already choking our economy.[37]

It is extremely important to again note that the workplace is subject to an already extensive and complex statutory and regulatory scheme and, that as a matter of sound policy, Congress should be reluctant to add to this mass of regulation, particularly where there has been no evidence that existing protections are somehow inadequate, or, indeed, that there is even a compelling problem that needs to be addressed by sweeping federal legislation.

Furthermore, even if Congress was presented with evidence that existing laws somehow are failing to provide the necessary protections, the bills currently before it, namely S. 1053 and H.R. 1910, would not be appropriate responses. There are numerous reasons for why this is the case, most of which are laid out in the attached letter from the GINE Coalition to the Senate. There are, however, two additional points worth making.

First, neither bill is consistent with the existing law. Both create new regulatory schemes governing how employers handle genetic information—schemes which differ substantially from those under the ADA.

For example, under the ADA, an employer may request medical information of an employee if doing so is job related and consistent with business necessity and may only disclose that information to medical personal, supervisors (if the information is relevant to work restrictions), and the government. Rather than using these same criteria, S. 1053 and H.R. 1910 create a broad prohibition against acquisition and disclosure of genetic information and a laundry list of exemptions for specific situations.

Thus, employers would face one set of rules for how they handle genetic information and an altogether different one for how they handle all other health information. This is despite the fact that as genetic science progresses it will be difficult for trained technicians, let alone human resources professionals, to separate the two.[38] Furthermore, from a practical perspective, employers would be required to keep health information and genetic information in two separate files, leading not only to administrative and compliance burdens, but vastly increasing the chance that information important to the health and safety of the employee or others in the workforce is overlooked in a crucial moment.

Both bills also suffer from drafting problems. For instance, both would allow plaintiffs to use existing legal theories under Title VII to sue employers for failing to provide health coverage for specific genetic-related conditions. According to the EEOC, sex and pregnancy discrimination provisions of Title VII require that employers who provide comprehensive health insurance also offer coverage for gender specific drugs, such as oral contraceptives.[39] The only court to address the issue has agreed with the EEOC's interpretation.[40] S. 1053 and H.R. 1910 borrow language from the relevant provisions in Title VII; thus, if these bills were to become law, the theory could be applied in the context of genetics.

Permitting lawsuits for yet another health care mandate would be troubling. This was clear to the Clinton Administration, which specifically stated in its executive order barring genetic discrimination against federal employees that "[n]othing in this order shall be construed to . . . require specific benefits for an employee or dependent under the Federal Employees Health Benefits Program or similar program."[41]

These types of drafting problems are particularly troublesome when the legislation is regulating such an important and rapidly developing area. As was noted before this Subcommittee in 2001, legislating on such a dynamically developing subject matter can be fraught with potential missteps and "several states already have updated laws enacted years before and many lawmakers foresee the need to regularly review state genetics policies to account for new developments and guard against unforeseen consequences."[42] As EEOC Chair Cari Dominguez said in testimony before the Senate Committee on Health, Education, Labor and Pensions "we need to be careful that we do not create overly inflexible restrictions that inhibit beneficial uses of this information."[43]

Both the inconsistency with existing law and drafting problems also invite unnecessary and abusive litigation and costly regulation. This is particularly true with respect to laws governing the workplace, where employers already face vast amounts of costly litigation, which, unfortunately is often unwarranted. In 2003, for example, the EEOC only found cause in 5.7% of the over 87,000 charges that it resolved and found absolutely no cause for discrimination in 63.1% of the charges (amounting to over 55,000 "no cause" findings).[44] With respect to S. 1053 and H.R. 1910, this would certainly be exacerbated by the fact that both bills call for recovery of punitive and compensatory damages and jury trials. H.R. 1910 is particularly objectionable in that it allows unlimited damages and it would permit a plaintiff to bypass the administrative and dispute resolution functions of the EEOC.

IV. Conclusion

As a representative of employers and as a leader in trying to increase health insurance coverage, the Chamber is excited about the potential of genetic science leading to more effective treatments and early interventions.

However, we just as strongly believe that an additional broad workplace regulatory regime is unnecessary at this time. Science is not assisted by over regulation and frivolous litigation, and we appreciate this opportunity to highlight the extensive existing protections against genetics discrimination, as well as the complete lack of evidence that employers are engaged in the collection and misuse of genetic information.

To the extent that greater education about existing law or targeted legislation is needed to allay fears, however misplaced, we are ready to work with the Congress to address this issue.

Thank you. That concludes my prepared remarks.

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[37] *See, e.g.*, W. Crain, T. Hopkins, *The Impact of Regulatory Costs on Small Firms*, Report RFP No. SBAHQ-00-R-0027, The Office of Advocacy, U.S. Small Business Administration (July 2001) (estimating the cost federal regulations at about $843 billion).
[38] *See, e.g.*, *Mutated Gene Can Help Drug Combat Cancer*, Wall Street Journal, April 30, 2004.
[39] *Commission Decision on Coverage of Contraceptives*, available at http://www.eeoc.gov/policy/guidance.html; *Question and Answers: Commission Decision on Coverage of Contraceptives*, available at http://www.eeoc.gov/policy/guidance.html.
[40] *Erickson v. The Bartell Drug Company*, 141 F. Supp.2d (W.D. Wash. 2001).
[41] Executive Order 13145, 1-402(b).
[42] Testimony of Cheye Calvo Before the House Before the House Subcommittee on Employer-Employee Relations (July 24, 2001).
[43] Testimony of Cari Dominguez Before the Senate Committee on Health, Education, Labor and Pensions (February 13, 2002).
[44] EEOC enforcement statistics, available at http://www.eeoc.gov/stats/all.html.

Genetic Information NonDiscrimination in Employment Coalition

June 12, 2003

[Address]

RE: S. 1053, the Genetic Information Nondiscrimination Act of 2003

Dear Senator [ ]:

We write on behalf of the Genetic Information Nondiscrimination in Employment (GINE) Coalition to express our concerns with S. 1053.

The GINE Coalition is a group of employers, national trade associations, and professional organizations formed to address concerns about workplace discrimination based on employees' genetic information as well as the confidentiality of that information. The Coalition firmly supports a policy of nondiscrimination and confidentiality, and believes that employment decisions should be based on an individual's qualifications and ability to perform a job, not on characteristics that have no bearing on job performance. We also believe, however, that any legislation on this issue must be carefully designed to minimize uncertainties, unintended consequences, and unwarranted litigation. To this end, the Coalition, while at times questioning the need for legislation, has worked diligently with Congress over the past several years, consistently advocating that any legislation be fair, reasonable, and narrowly drafted.

On May 21, 2003, the Senate Health, Education, Labor, and Pensions Committee approved S. 1053 – Title II of which is the most recent incarnation of workplace genetics legislation.[1] While the bill is a vast improvement over S. 16 – introduced earlier this year by Minority Leader Daschle – aspects of S. 1053, nonetheless, remain extremely troubling. More specifically, certain overly broad provisions in the bill conflict with other laws, and may invite unwarranted litigation and unnecessary regulation.

General Concerns with S. 1053's Breadth

The driving force for this legislation is not an ongoing practice of discrimination or mishandling of genetic information. Indeed, there is no appreciable evidence of possession or usage of genetic information by employers. Rather, the bill's supporters argue that legislation is needed to prevent *possible* future misconduct and, more importantly, to ensure that individuals do not hesitate to avail themselves of genetic tests out of fear of employer discrimination.

Legislating based on theoretical discrimination and predictions of future behavior, however, is fraught with opportunities for unintended consequences, unnecessary regulation, and unwarranted litigation. It also sets a new precedent, as Congress has never created a new cause of action against employers based on potential or theoretical discrimination, only on some appreciable history of actual discrimination. For these reasons, any bill you enact must be *clearly* and

[1] Title I of S. 1053 addresses issues related to genetics and insurance coverage. Although certain individual Coalition members may have views on Title I, the Coalition's comments are limited to Title II of the bill.

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Genetic Information NonDiscrimination in Employment Coalition

narrowly drafted and *only* address the problem that has fueled its creation – in this case – that the fear of possible discrimination may deter employees from availing themselves of genetic tests.

This is particularly important given that the Americans with Disabilities Act (ADA) and the regulations under the Health Insurance Portability and Accountability Act already provide significant protections against collection, disclosure, and discrimination based on medical information, including any medical information containing genetic information. Obviously, further legislation in this area should be consistent with these existing laws.

Legislators should also keep in mind the vast and costly amount of litigation employers face under current discrimination laws, and, unfortunately, that much of this litigation is unwarranted. In 2002, for example, the Equal Employment Opportunity Commission only found reasonable cause in 7.2% of the nearly 85,000 charges of discrimination that it received – and found absolutely no cause for discrimination in almost 60% of the charges (amounting to 55,000 "no cause" charges). A study of previous years' statistics yields similar results.

Our concerns over frivolous litigation are heightened by the fact that S. 1053 provides for jury trials and recovery of compensatory and punitive damages. We strongly question the need for such remedies. The availability of non-economic damages and jury trials arguably may be justified based on a record of discrimination, as was the case with the 1991 Civil Rights Act, but is hard to justify in the case of genetic discrimination, where equitable relief (which could include agency enforcement and lost wages and attorney fees) should be sufficient to ensure that employers do not begin discriminating based on genetic information.

In short, it is important that new discrimination legislation be narrowly tailored to achieve the stated goal of its proponents, which brings us to our specific concerns about S. 1053. Attached is a list of these concerns. We hope that we can work with you to address some of these issues as the bill moves through the legislative process.

Please contact us if you would like to discuss these matters further.

Very Truly Yours,

The GINE Coalition Steering Committee:

U.S. Chamber of Commerce
Society for Human Resource Management
National Association of Manufacturers
LPA, The HR Policy Association
College and University Professional Association for Human Resources

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S. 1053

Limit the Scope of S. 1053 to Genetic Tests

The driving force for this legislation is not an ongoing practice of discrimination or mishandling of genetic information, but, rather that the fear of possible discrimination may deter employees from availing themselves of genetic tests. Accordingly, S. 1053 *only* should prohibit employers from discriminating based on genetic tests, not family history that could be – and most times is – completely unrelated to tests. This would greatly minimize the opportunity for unintended consequences and unnecessary litigation under the bill, while also thoroughly addressing the issue which fueled the bill's creation. It would also greatly reduce the probability that the bill will conflict or complicate compliance with other laws, such as the Americans with Disabilities Act (ADA).

Narrow the Definition of Family Member

If there must be a cause of action based on family history, then it should be of reasonable scope. S. 1053 defines family members as *any* individual related by blood or *any* individual related by blood to a child placed for adoption with the employee no matter how remote the relation. This is merely an opportunity for plaintiffs' attorneys to exploit, and an invitation for frivolous litigation. The bill only should cover situations where the information is scientifically proven to reveal patterns of inheritance of genetic conditions and is useful for medical diagnosis in the employee and his or her immediate family.

An Independent Commission

S. 1053 would require the creation of a commission six years after the bill's enactment to "review the developing science of genetics and to make recommendations to Congress regarding whether to provide a disparate impact cause of action under this act." The Commission, to be known as the Genetic Nondiscrimination Study Commission, is to be housed and funded by the Equal Employment Opportunity Commission (EEOC).

While the Coalition has no objection to the Genetic Commission, we do object to tying both its housing and funding to the EEOC. No one would ever suggest that the business trade association or law firm that regularly defended claims made under S. 1053 would be an appropriate source of funding or housing for the Commission. So too, it should be with the EEOC – the agency tasked with ***prosecuting*** violations of the bill. Clearly, the EEOC will have its own views on what changes should be made to genetics legislation, and it is unlikely those views would be objective. By tying the Commission's housing and funding to the EEOC, it is inevitable that the Commission will be largely staffed with former or current EEOC employees – some of whom will have been responsible for prosecuting claims under S. 1053. To prevent this undue influence, the Commission should be funded and housed independent of the EEOC.

Expanded Commission & Sunset

Any genetic nondiscrimination legislative proposal should contain a mechanism to ensure that public policy keeps pace with future scientific advances. Given the rapid evolution in the field, legislation drafted now is unlikely to anticipate developments in genetic science that could occur even in the *near* future. As demonstrated by state experience – where several states were compelled to revisit their original legislation - unintended consequences can sometimes force the legislature to rewrite legislation within just a few years. Thus, the Genetic Nondiscrimination Study Commission should study and report on all aspects of the bill – as it name implies – not just disparate impact. The bill should also provide for a sunset date, at which time Congress may consider new issues related to genetic discrimination raised by the Commission and adjust

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the legislation accordingly. Such a model creates a powerful incentive for Congress to revisit the law and make appropriate modifications.

Direct Threat - Protecting Employees and the Public

The ADA, Title VII of the Civil Rights of 1964, and other discrimination laws recognize that there can be rare cases where an employer has a legitimate reason to make employment decisions based on information that would otherwise be protected. Courts have interpreted these exceptions extremely narrowly but have recognized that employers can have valid reasons for such policies. For example, under the ADA, a health condition likely to cause uncontrollable seizures could properly be considered a "direct threat" to safety if the employee were a bus driver, thus justifying an employment decision that would otherwise be unlawful. A similar narrow exception should exist for genetic discrimination. If science progresses to the point where it is possible to determine that an individual is virtually certain to have a health condition which poses "a direct threat" – such as an uncontrollable seizure when driving a bus – then employers should be able to make employment decisions based on this information in order to protect employees, customers and the public. Thus, we propose adding the following language, which mirrors that of the ADA: "Nothing in this bill shall be construed to prohibit an employer from requiring that an individual not pose a direct threat to the health and safety of other individuals in the workplace."

Safe Harbor

Any legislation should recognize the problems faced by employers as they try to comply with the numerous genetic discrimination laws already in existence. More than 30 states have enacted laws prohibiting discrimination based on genetic information. However, these laws vary widely from state to state. If Congress enacts legislation barring employment discrimination based on genetic information then it should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination.

Choice of Remedies

In the only recorded case where an employer was accused of engaging in genetic testing and genetic discrimination, the individual plaintiffs filed claims against their employer with the EEOC, which, in turn, sued the employer under the ADA. The agency successfully settled the case for $2.2 million. Thus, if S. 1053 is enacted, individuals and the EEOC will be empowered to bring suit against an employer on the same facts under both S. 1053 and the ADA.

Last year, the original sponsors of S. 1053 introduced similar legislation (S. 1995) that included an "election of remedies," under which a plaintiff could sue under the genetics bill or the ADA, but not both. That provision is not in S. 1053. It should be re-inserted in the bill in order to prevent multiple lawsuits, double recovery and unnecessarily complex litigation.

Damages

Given the lack of genetic discrimination and availability of significant protections under other laws, administrative enforcement and equitably based remedies (including loss of wages) should be sufficient to allay fear of possible discrimination while mitigating the risk of a dramatic increase in baseless and inherently expensive litigation. The inclusion punitive and compensatory damages will necessarily invite additional litigation, as was the case when such damages were made available under other discrimination laws. The courts already are inundated with employment litigation and certainly do not need the additional workload.

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Chairman JOHNSON. Thank you, sir. You know, in your written testimony, I think you mention two concerns that have not been mentioned in the past. Would you detail those a little bit further?

Mr. LORBER. Well, there have been some concerns, and as pointed out by another member of this panel, that there may be a lapse in the ADA. There may be a gap in the ADA's coverage with respect to testing. And we don't believe that's the case the EEOC has taken that position, and I think that nevertheless, if there is such a gap, if it's identified, we believe the EEOC in the first instance could deal with it, and second, to the extent to which even after that experience is examined, perhaps there might be some need for limited targeted legislation.

But beyond that, as I indicate in a broad discussion in the testimony, there are a plethora of laws to deal with it, and indeed, Congressman Andrews, in your instance, I believe that individual would have a cause of action under Section 504 of the Rehabilitation Act as well as the ADA if she were a public employee. So that I don't believe there simply is a gap that necessitates this very expansive legislation.

Chairman JOHNSON. Could you maybe give me a hypothetical example about how an employer without trying to discriminate might inadvertently run afoul of the proposed law this coming out?

Mr. LORBER. Oh sure. Well, the proposed laws, we must understand, don't only deal with genetic testing, and that's an issue that's front and center. The genome studies are indeed studying and mapping genetic information. The proposed laws deal with genetic history, and indeed the proposed laws have no limit on the length, the extent to which genetic history or family history could be found.

Indeed, it's been stated that if there were a descendant of the Plantagenets working in the United States today and somebody read one of their histories, an employer could be found guilty because it knew that someplace in the far distant past there might be a condition which might be indicative of a genetic marker.

So there is no limit in the proposed legislation with respect to what the scope of it is. We're not talking about genetic testing. We're talking about family history. If an employer sends flowers to somebody because a parent died of a condition which might be indicative of a genetic marker, that employer could be deemed to have genetic information.

So I think that we're looking at laws that are so broadly framed that there is no exclusion. And indeed, the legislation before the House, I might add, is the unique situation of having no limits on damages, no requirement to go to an administrative agency. This problem, which is a problem perhaps in the future, is dealt with more severely than the problems of racial discrimination, disability discrimination and gender discrimination in which the laws have been carefully tailored to strike a balance between the remedy and the harm.

Chairman JOHNSON. I might add that anytime you all have a comment to make, we would let you do that. That's one of the benefits of running a Committee. Dr. Hudson, we hear the terms "predictive" and "protected" genetic information used. Can you tell us about the significance of those two terms?

Dr. HUDSON. Predictive and protected. Predictive genetic information generally refers to when a genetic test result gives information that provides a probability that the individual will develop a disease at some point in the future. That information is usually based on a person will have a 50 percent increased likelihood of developing a certain disease by age 60, for example. So it's imprecise information, but it's valuable in the health context because an individual and their doctor can put in place preventive measures to decrease that risk.

Protected genetic information is not used in the medical context, but is used in the legal context and has been variably defined. And in fact, how that term is defined is really the crux of good genetic discrimination legislation. If that definition is too narrow, then the bill will be meaningless, and in fact that's the case in many states that do have genetic discrimination legislation. The definition is so narrow as to make it virtually meaningless. And in other cases, the definition is so broad that it includes virtually anything.

For example, the definition of genetic information in the HIPAA regulations starts out with a fine definition of genetic information—results of genetic tests, analysis of DNA. And then it goes on to say it's information from medical examinations. Well, of course, that brings in almost the entire universe. So somewhere in between is a nice, precise definition that will work legislatively.

Chairman JOHNSON. Thank you very much. Mr. Andrews, do you care to question?

Mr. ANDREWS. I want to thank each of the witnesses for their efforts, outstanding testimony. I especially want to welcome Dr. Licata back. And I think that your remarks about balance are correct. I appreciate the contribution that you and your colleagues and the many groups that support this legislation made in trying to strike that balance.

Mr. Lorber, I want to ask you some questions. I understand that part of your position is that existing law would deal with any problem that might manifest itself. Is that a fair statement?

Mr. LORBER. That's correct.

Mr. ANDREWS. I want to walk through the existing law as I understand it. The EEOC has given an interpretation or issued a guideline I suppose it is, that says that a genetic predisposition if used in a discriminatory way, violates the ADA, correct?

Mr. LORBER. That's correct.

Mr. ANDREWS. But the EEOC's position is not binding on the courts, is it?

Mr. LORBER. Well, it's an agency interpretation. As you well know, in the Burlington Northern case, it acted upon and enforced that interpretation.

Mr. ANDREWS. But the court was not compelled to accept that interpretation, correct?

Mr. LORBER. It's an interpretation that was issued—I would think it would fall within the Chevron protections of agency interpretations, but then again, Mr. Congressman, the courts sometimes don't accept—

Mr. ANDREWS. But under ADA, it doesn't flow from a rulemaking or from an adjudicatory proceeding, so it's not due any specific

legal deference, other than what the courts in their discretion want to give it, right?

Mr. LORBER. The EEOC guidelines have, and I would add that the impact of the guidelines obviously affects a charge filed with the EEOC. And if the charge raises those issues, the EEOC district office will act upon that guidelines and issue probable cause determination. The individual then could be represented by the EEOC.

Mr. ANDREWS. But you don't take the position that those guidelines bind a court, do you?

Mr. LORBER. Courts could—obviously, courts interpret regulations and guidelines as they see fit, as we well know.

Mr. ANDREWS. Is that a no?

Mr. LORBER. And they interpret statutes, as well.

Mr. ANDREWS. We'll take that as a no. With respect to Title VII, you point to a couple of cases where there is a disproportionate racial or gender impact which gives rise to a Title VII claim. What about cases where the condition or disease does not give rise to such an impact? For example, my understanding of dementia, of Alzheimers, is that it cuts across racial and gender lines rather equally. So if someone was denied employment because they had a genetic predisposition toward dementia, are they protected under Title VII?

Mr. LORBER. Well, I think they'd be protected under the ADA, because remember, the ADA—

Mr. ANDREWS. I understand your position on ADA.

Mr. LORBER. Well, but let me—

Mr. ANDREWS. What about Title VII?

Mr. LORBER. Let me talk about Title VII cases, and indeed Mr. Wildsmith must be aware of the Manhart and the Norris cases involving sex-based actuarial tables. And the Supreme Court said, regardless of what the actuarial tables may show, the reliance upon them to the detriment of somebody who we certainly don't know when they will die, violated Title VII. That same analogy, because the ADA brings into its ambit job-relatedness, would apply to the ADA. So you cannot parse these laws.

Mr. ANDREWS. I asked you about Title VII, and I asked you about a case where someone has a predisposition toward dementia, where there is to my knowledge no evidence of any disparate racial impact. Does that lay out a claim of violation in Title VII?

Mr. LORBER. Well, it may not. But again, we're talking about the Congress knows a plethora of employment laws, and you can't parse one and not the other.

Mr. ANDREWS. I didn't ask about the plethora. I asked about Title VII.

Mr. LORBER. Well, lawyers deal with the plethora, and that's their problem.

Mr. ANDREWS. I know that. But does this lay out a claim—is it your position that it doesn't lay out a claim under Title VII?

Mr. LORBER. It depends how the employer and what the underlying data would show. To the extent to which, for example—

Mr. ANDREWS. If the underlying data say that there is no disparate racial impact for dementia does it lay out a claim under Title VII?

Mr. LORBER. If hypothetically it doesn't and there's no gender impact, then perhaps not. But as I said—

Mr. ANDREWS. The list of state privacy protections that you cited, that you went through, aren't these privacy protections preempted by ERISA? So if someone is in an ERISA plan—

Mr. LORBER. That's not been litigated. I don't know that they are, and—

Mr. ANDREWS. Is it your position that it is or it isn't?

Mr. LORBER. Well, I would suggest that it may be helpful to have one body of employment law and not have employers subject to 32 state laws and a Federal law. So if you're talking about preemption, if you're talking about this law preempting all of these state laws, and if this law is carefully tailored, and if we don't find employers whipsawed, then maybe there are areas of discussion.

Mr. ANDREWS. I would never want to prejudge the position of any group, least of all the Chamber, but the Chamber pretty consistently has argued for a broad ERISA preemption, and I'd be surprised if the Chamber didn't argue for a rather broad ERISA preemption here. If it touches the concerns—

Mr. LORBER. But would this Committee recognize preemption of the legislation before it with respect to all of these state laws?

Mr. ANDREWS. I think the state laws are valid. But for those who favor a broad ERISA preemption, it seems to me that you have to draw the conclusion that state laws don't protect the millions of people who are in ERISA plans, do they?

Mr. LORBER. Well, I don't believe that's—and again, that's an area of legislation we know about the Delta Airlines case, which goes one way—

Mr. ANDREWS. So can we count on the Chamber to argue in favor of upholding these state privacy laws against an ERISA preemption claim?

Mr. LORBER. If and when those are litigated, we'll have to see what the matter is before the court.

Mr. ANDREWS. We eagerly await your position. Thank you very much.

Dr. LICATA. Could I interject a data point?

Chairman JOHNSON. You may.

Dr. LICATA. Just in case you're interested in knowing, is that I've actually looked at most of these state laws, and if you're trying to sort of get a feel for where perhaps the House version and the Senate compromise version sort of would place you, is that there's only basically—less than the number of state laws I could count on one hand. I'm not sure whether it's four or five. I could double check for you—that would actually have more stringent requirements. The position that the Federal legislation is considering is very well balanced and has taken a lot of these issues into consideration, so that—most states in fact are much narrower and have a lot of gaps in them, so that if your concern is what would be the impact of preemption, is that right now, the Federal Government is extremely on target in addressing a broad base of concerns.

Chairman JOHNSON. Thank you. Mr. Carter, you are recognized for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman. Mr. Wildsmith, on page 2 of your testimony, you claim that basing premiums and eligibility

coverage on specific person's own health is not a characteristic of the employer-sponsored group insurance market. Why is that?

Mr. WILDSMITH. If you think about an IBM, for instance, they have tens of thousands of employees. They have millions of dollars in medical expense each year. It's very easy to predict what their costs will do from year to year. Whether any particular employee gets sick or not is not going to move the number appreciably at all.

With group insurance with any employer of any size, you're dealing with the aggregate cost for all of the employees and all of the dependents. So you look at the age, the gender makeup. You look at the claims from last year, and that gives you the information you need to predict what next year's costs are going to be. It's simply not cost effective to ask every member of the group to undergo medical testing or to pull medical records on them, because it's the aggregate costs that count.

Mr. CARTER. But you will—I used to be in county government, and we were self-insured.

Mr. WILDSMITH. Yes.

Mr. CARTER. And we would hear the argument as our costs went up, they could individually say it was the money that was spent by that sick person and by that sick person and by that sick person, and, you know, we've got these many people that seem to be headed for being chronically ill and this, that and the other. And, therefore, the price of poker is going up. But it's still not—they still don't look at it that it—they're making the argument to us as county employees, they certainly made that argument on an individual health basis.

Mr. WILDSMITH. If you look at the projections, what's generally going on is you have X million dollars in claims in fiscal year 2003. You're projecting them forward to 2004. If you have a truly catastrophic claim, a really nasty trauma case or a really nasty neonatal case, that will cause a blip in your experience, and many employers buy stop loss insurance to protect against that.

But it's not generally good practice to base your pricing on an act of God in 1 year, because you purely don't know whether that's going to reoccur in the next year.

Mr. CARTER. You mentioned in your testimony that HIPPA already prohibits discrimination against the individual members of a health insurance plan on the basis of current health status or on the basis of some future predisposition to a particular disease.

Mr. WILDSMITH. Yes.

Mr. CARTER. How do these protections work?

Mr. WILDSMITH. The easiest way to think of them is to think about yourself as a new employee with the company and what the employer can or cannot do. If you meet the requirements, you're a full time employee, whatever it is to qualify for the medical benefits, when the open enrollment comes around, the employer cannot say, eh, you can't come in because you've got cancer or because your wife had cancer or because you have a genetic predisposition.

The employer also can't say, well, the contribution is 40 bucks a month for everybody else, but for you, it's 60 because you're getting a little older, you're a little sicker. We think you're going to have bad things happen. At core, those are what the HIPPA protections do.

Mr. CARTER. How do the HIPPA privacy regulations address the de-identification of medical information?

Mr. WILDSMITH. I can talk to you about how the information is used in pricing. I'm not an attorney, so the details of the privacy rules, I need to step away from.

Mr. CARTER. That's fair enough. Thank you, Mr. Chairman. I yield back my time.

Chairman JOHNSON. Thank you, Mr. Carter. Mrs. McCarthy, do you care to question? You are recognized for 5 minutes.

Mrs. MCCARTHY. Thank you, Mr. Chairman, and I thank the Committee for bringing this subject to this debate. I think it's extremely important.

First, I'd like to say that I believe decisions about generic testing and what to do with the results should be made by patients and their health care providers without fear of negative consequences, such as an employer choosing not to hire them because they carry a gene for a disease. Whether or not this discrimination is actually happening already, I do believe that it is happening. But whether you believe it's happening or not, the fact is that people fear that it's happening or it can happen to them, and I think that's the part we have to really start to address there, and therefore will opt out not to get the testing done unless we in Congress take a definite stance against this type of discrimination.

There's a family that I've be working with on Long Island who came to me because they lost their son to a disease called Long QT, which is a genetic disorder. After this boy's death, each one of the immediate family members was genetically tested for the disease, and it was found that some were carriers of the gene that caused the disease, and one child is actually having the disease. The child with the disease is now being monitored and treated, so the genetic testing in this case has prevented the family from possibly losing another child.

In New York, we already have some legislative protections against genetic discrimination, health insurance and in the workplace. And yet this family still experienced concerns about whether they or their kids would be discriminated against once people knew they had these genes, and they aren't the only ones.

Since I introduced my bill to help screen people with genetic cardiac disease, I have gotten calls from people from all over the country with this disorder, but also expressing to me their concerns about genetic discrimination. In January when I reintroduce this bill, because my bill is not going to go anywhere this year—we've just run out of time—I plan to add a clause with regards to the discrimination.

About 40 other states besides New York have taken action to protect, but as you have mentioned, it's a web, and it is a web. We've looked at that.

I guess my question to all of you would be, in the Senate version, which has already passed overwhelmingly, the genetic discrimination bill, when a health care plan or an employer misuses an individual's genetic information, what can a person do? Can you compare for me what rights the individual has in the same circumstances under the House version which Louise Slaughter has been trying to get passed for I believe over 5 years? I'm not sure

if you're even familiar with it. It's H.R. 1910, which is a lot more in detail. And I think, Dr. Hudson, more to the point of where it's not too wide and it's not too narrow from everything that I know, and I believe she's been working with a lot of the groups that do the genome research and everything, and I have a place on Long Island, Cold Spring Harbor, that's doing genome research, and I'm very involved with them on that issue, too.

Our world is changing tremendously because of the medical technology that's out there. But I have to say with that, we are going to have to start looking at things because, you know, when you do the genetic testing or if you—I'm working with Dr. Watson, who is doing—looking into cancer, so we can have the markers. And so it's going to be a new world probably within 5 years even more advanced than what we have out there today.

So I appreciate any insight any of you have on that.

Dr. HUDSON. Well, you're exactly right that the fear of the misuse of this information is very widespread. We've been doing town halls around the country this summer and talking to citizens in cities across the United States. And recurrently, the biggest concern that they share with us is their fear if they have this test results, it may be misused.

Mr. Lorber raised the issue of, well, there's not really a whole lot of genetic discrimination cases being brought. But in those that have been brought, it has not been a normal American. It has been extraordinary individuals who have learned about this discrimination and pursued it.

Because in these cases, the employers aren't saying, oh, and by the way, we're doing these genetic tests. This was secretive genetic testing, and the fact that it was uncovered at all is a fairly remarkable testament to the individuals who were involved in that case.

So it is not widespread cases, but the cases that have been brought should reflect to us that it's not unheard of that these cases are happening. So I agree with you there.

The other point I'd like to make is that even without widespread discrimination, the fear that citizens have is going with them into their doctor's office and influencing their decisions of whether or not to have a genetic test and whether or not to participate in genetic research. We know this is happening. It's damage now, it's damage today, it's damage that we can do something to prevent.

Mrs. MCCARTHY. And just to follow up, I'd like to go backwards, because I always like to go back in history, especially medical history. It wasn't that long ago, 30 years ago, when we started discovering more and more women were getting breast cancer, and no one in the family would even talk about cancer, mainly because they felt they would be discriminated against.

We got over that. We did pass laws to make sure that someone couldn't be discriminated against, and this is what we're dealing with now, because we're into a different world of medicine.

Dr. LICATA. If you'd like the answer to the question about the individual's remedies, there's actually in terms of this concept I'm trying to promote about if people understand, everybody understands the rules that we're playing under and what's important to each stakeholder, that you can come up with good solutions, is that the currently pending House version took a more traditional litiga-

tion mindset. So if you were wronged, what could you do as the employee? Well, you could go to court, and the court could award appropriate legal or equitable relief and attorney's fees, including the cost of expert witnesses, which you would definitely need in a case like this. In cases where your plan sponsor or your insurer violated any of the provisions. It was a very broad, general type term you see in Federal legislation.

And there was provision also for civil penalties that were fairly modest, $50,000 for a first violation, $100,000 for subsequent violations, and it was paid to the government, and there was provisions for private right of action. So basically, if something happened that the law was violated, you had—you basically would have to be one of these extraordinary individuals to basically be able to go through all of this litigation.

What I particularly think is a great provision is what are people afraid of? I'm going to lose my health insurance.

Mrs. MCCARTHY. Right.

Dr. LICATA. Right? Isn't that the issue?

Mrs. MCCARTHY. Yes.

Dr. LICATA. All right. What does the compromise bill do? It establishes additional enforcement for violations by allowing the participant or the beneficiary the right to benefits that they do under the plan without exhausting administrative remedies if doing so would cause irreparable harm to their health.

OK. Right when you have the risk, when they need their doctor's counsel, when they need the health services to possibly even mitigate downstream health issues, they would be able to keep their insurance or get it back fairly quickly. Great remedy.

In addition, the court can reinstate the coverage retroactive to the date of violation. OK. There might be a period where the family can suffer, but they might not be forced into bankruptcy over these issues. It allows the Department of Labor—and this is great from my standpoint too—is I think the best way to get people to comply with the law is to let them know what the rules are and then say it's a compliance issue. Build it into your cost of doing business.

But frankly, it's cheaper to do this than to contemplate litigation. What happens? You're in violation. A hundred dollar a day fine. What's your cap? Half a million dollars. OK, a business can deal with that. They can factor that in, and it would be stupid for them not to make a relevant plan of doing business that takes into consideration protection of this information. They do it for HIV. They do it for other very sensitive information. It's something businesses know how to do.

So here you have a rational proposal that allows the business to make good decisions, allows investors to make good investments in the health care industry going forward for the next decade, gives autonomy and protection to the individual. I mean, what a perfect balance.

Mrs. MCCARTHY. Thank you.

Chairman JOHNSON. The gentlelady's time has expired. Mr. Payne, you're recognized for 5 minutes.

Mr. PAYNE. Thank you very much. This is a very interesting topic. I'm sorry I missed the testimony, and I might ask a question that may have been covered in the testimony. But I'd like to ask

Ms. Hudson, Dr. Hudson, the principles of any generic nondiscrimination bill.

Could you just briefly articulate the principles that any generic nondiscrimination legislation should encompass? And this business about core definitions. I didn't get a chance to go through it, but I know that you highlighted the important of core definitions for any generic discrimination bill, and I wonder if you could comment on the existing definition, how many fall short in your opinion.

Dr. HUDSON. So the definition in my view of a genetic test should incorporate analysis of DNA, of RNA, of proteins, of chromosomes, and also include beyond that the genetic test of information from family members. And the broad definition of genetic information really needs to include the family medical history information.

So in talking about how that information can be used, I think we would all agree that it would be unjust if an individual's employment was conditioned on the health of some blood relative. I think we would agree that it would be unjust if their employment were conditioned on whether or not they carried a genetic mutation that predisposed them to some genetic disease in the future.

This does not restrict an employer's ability to use information about a person's current health that interferes with their ability to currently perform the essential functions of that job. So we're not altering the ability of employers to make sure that their workforce is able to do the job.

Mr. PAYNE. Thank you. Yes?

Mr. LORBER. Well, I would just point out that Dr. Hudson talked about blood relative. H.R. 1910 is not restricted to blood relatives. It is absolutely not restricted to blood relatives. And indeed, I think 1053 has the same infirmity. So that the extent to which we're looking at genetic information which is genetically passed down through blood relatives, the bills don't go beyond that, and that's one of the problems. The bills are expanded beyond what science seems to think is appropriate.

Mr. PAYNE. Dr. Licata, and then we could hear from Dr. Hudson again.

Dr. LICATA. I think it's a really important issue, because my initial position when I first started thinking about this issue, was as a scientist. And when I looked at it as a scientist, I said, why would you ever consider outside of someone that has a genetic link? Because that's the relevant information.

And it was pointed out to me something very important which completely altered my understanding of why the bill is crafted as it is, which is that we're in the employment context, OK, we're in the health care context for a family. If this information is available that someone in the family has a particular genetic marker, the record does not necessarily and probably would not reflect if that family member was adopted.

So that what's happening is the whole family, without a complex explanation or actually even—revealing even more private information, that a child was adopted or something, you know, there was some relationship in a family that was not as it might have appeared to be.

They're still going to have this issue of discrimination in the workplace, the health care issue, without explanation. What hap-

pens to them during that gap period? So I think that it makes a lot of sense to put the burden not on the individual but the burden on the employer, and then you can balance it out. But the information, it can still be explained, but the immediate reaction is it covers everybody without asking all of those underlying questions.

Chairman JOHNSON. Mr. Lorber, do you care to follow up?

Mr. LORBER. Yeah. The burden we're talking about is the burden of litigation. And I simply want to point that out. And second, to the extent to which we're talking about symptomatic conditions, they are covered by the ADA. To the extent we're talking about asymptomatic conditions, the Supreme Court in the Bragden case talked about an 8 percent correlation between carrying an HIV gene and being HIV positive. Yet they found that sufficient to find coverage under the ADA.

The point we're trying to make is not that this is an issue which should be ignored. The point we're simply trying to make is that this is an issue which we believe is susceptible to the vast body of law today, and the extent to which we're dealing with a real problem, I don't know that it's sound public policy to pass yet another law to have another 18-month period before the law takes effect, which once the new law is passed, it will presumption that the old laws don't cover this situation, have yet a new body of regulations.

This doesn't make any sense when we believe and we've stated in our testimony, and I think we've taken an expansive view, as Congressman Andrews noted, an expansive view, of what the ADA covers. We believe that this is the situation which should be protected against, but we believe that this is a situation which is protected against. And that's the problem we're dealing with.

Do you really want yet another law on top of all the other laws and have some court, with all due respect, whether they'll adopt one regulation or another regulation. Then we're going to have the courts parsing or triaging among all these laws to determine what little niche this problem fits in. It doesn't make any sense. And for the employers, the problems that Dr. Licata are talking about are problems of litigation, and they are very expensive. They are a disincentive to hiring, and they are a disincentive to providing the basic level of benefits that we want employers to provide.

Mr. PAYNE. Let me just—I guess reclaiming my time, I guess I might have about 2 minutes left since you preempted my time—I assume you'll give me my time back. Thank you. I'm not a lawyer. I didn't know the rules now.

[Laughter.]

Mr. PAYNE. Let me ask Dr. Licata if you would like to just comment briefly on that, and then I'd like to hear from Dr. Hudson and then one last short question.

Dr. LICATA. And I guess the point is, is that I'm really concerned and what I think is the importance of this legislation is it is a way of managing information. It's information that is very precious, and it's information where we have to set forth a national public policy about how we're going to do business with this type of information, and how we're going to respect this information that belongs and can have such a huge impact on a personal interest.

So what I suggest, and if you look at the problem, it's how to properly manage the information in a business context. We know

how to do that. And it's by creating a scheme that has a basis of good regulations built on a good, rational law that allow people to know what the ground rules are. Once they know that, they will comply with the law so the rare case that's going to be litigated is not what you should be afraid of. We should be worried about the huge cost of doing business and the huge cost to our medical economy, our health care economy, if we don't step in and make some rational decisions now.

Mr. PAYNE. Thank you very much. And Dr. Hudson? Thanks, Dr. Licata.

Dr. HUDSON. Thank you. I'd like to respond to Mr. Lorber's argument that it should be crystal clear to all of us that the ADA covers genetic discrimination based on predictive genetic information. He uses in support of that argument a Supreme Court case, Bragden v. Abbott. That was an HIV case. There is no HIV gene. There are a number of interesting correlations between the rationale that was used in that case. It was not a genetics case, and we have not tested whether or not the ADA does or does not cover genetic information.

There are cases that are being brought under the ADA where people who have cancer are not being considered disabled under the ADA. The notion that somebody who is at risk of developing cancer would be covered under the ADA I think leaves a lot of uncertainty and thus the concern among the American public.

Mr. PAYNE. Thank you. My time is probably—Mr. Lorber, I just want to ask a simple question. You could probably give another little response, so it's giving you an opportunity. Let me just ask you, does the Chamber support the predisposition, that genetic disposition should be a disability under the ADA?

Mr. LORBER. We believe it is. We believe the agency has stated that it is.

Mr. PAYNE. And therefore the Chamber would support that?

Mr. LORBER. The agency has taken that position. And we've endorsed that position in the testimony.

Mr. PAYNE. And they agree with the ADA?

Mr. LORBER. That the ADA covers this issue, yes.

Mr. PAYNE. OK. Thank you.

Chairman JOHNSON. Thank you, Mr. Payne. If you all have additional comments, we would accept them in writing. Mr. Lorber, let me just ask you one quick question. Do you know of any employer that is considering—that asks people that question about genetic history before they hire them?

Mr. LORBER. Mr. Chairman, absolutely not. As I said, I'm Chairman of the Chamber's EEO committee. We asked the Chamber members, we surveyed the Chamber members, does any employer—and there are a lot of employers who are members of the Chamber—conduct genetic testing, as for genetic information, want to have genetic information—let me go beyond the Chairman's question. And the response was no, they don't want it. They don't need it. They don't know what to do with it, and they're afraid if they have it, they're going to be sued under all the laws we've talked about.

Chairman JOHNSON. Thank you.

Mr. ANDREWS. Mr. Chairman, if I may, I have three unanimous consent requests—two unanimous consent requests.

Chairman JOHNSON. Go ahead.

Mr. ANDREWS. One is I'd like to enter into the record a list of 23 national health care and advocacy organizations that are in support of genetic non-discrimination legislation. The second is, I have statements from our colleague, Congresswoman Slaughter, who has introduced an excellent bill, and from Senator Gregg, who championed the bill in the Senate. I'd ask that those be entered into the record.

The final, if I could make one more—

Chairman JOHNSON. Without objection, so ordered.

Mr. ANDREWS. Thank you. Let's be careful when we talk about employers asking for information to also understand that health insurers may ask for information, which is where the rubber really meets the road.

Mrs. MCCARTHY. Mr. Chairman, may I ask one question that I'm confused on? I know you want to leave.

Chairman JOHNSON. Go ahead, Mrs. McCarthy.

Mrs. MCCARTHY. I'll go down there and talk to—

Chairman JOHNSON. I might add, you've had 4 minutes already. We'll give you one more.

Mrs. MCCARTHY. Well, there's only a few of us here.

Chairman JOHNSON. One for the road.

Mrs. MCCARTHY. Let me understand something. Let's just say I go to the dentist and obviously they basically ask me for my medical history, has anything changed, and I say no, whatever. But supposing I did tell them, all right, I've just discovered I have this. Now when I go outside, each and every one of us nowadays has to sign a form that says that we are—the Privacy Act—that we are doing this. I'm not so concerned about my doctor having all the information in the world. But I also know if I'm going to a new insurance company, they are going to research my past history of health care, wherever I have been in the last two, three, 5 years. Now if I come up, just say, with something genetic and I'm going to tell my doctor that because I wanted him to know, you know, what I'm dealing with, then eventually, if I change insurance companies and another insurance company gets the information from my doctor, how do we protect our patients?

Mr. WILDSMITH. Actually, in the group market, if you get your coverage through an employer, they are not going to go back and pull your medical history.

Mrs. MCCARTHY. That's actually the part I wanted to know. I never was clear on that issue.

Chairman JOHNSON. We'll call you "ten minute McCarthy." Thank you, ma'am.

Listen, I want to thank the witnesses for their valuable time and your testimony and both the witnesses and members for their participation and let you know that if you have something to hand us in writing, we'll take it.

If there's no further business, the Committee stands adjourned.

[Whereupon, at 11:41 a.m., the Subcommittee was adjourned.]

[Additional material submitted for the record follows:]

Statement of Hon. Judd Gregg, a U.S. Senator from the State of New Hampshire, Submitted for the Record

The rapid advances in the science of genetics are creating opportunities for all of society that must not be hindered. At the same time, these same advances, and the prospects for legislating in this area, rightly raise serious challenges and concerns that must be fully understood and addressed. I commend Chairmen Boehner and Johnson for holding this hearing to review the important implications of genetic non-discrimination for workers and employers.

Last year we celebrated the 50-year anniversary of the now fabled discovery by Watson and Crick of the double helix. Also last year, the Scientists at the NIH Human Genome Project completed the sequencing of human DNA. These are major historical developments that will permanently change the course of biological science.

As the science has progressed, so too have reservations with what we will do with this new information we are uncovering. This new understanding of the genetic basis of disease holds dangers as well as opportunities. Although we have yet to see proof of widespread discrimination, it is difficult to ignore the few, albeit egregious, cases that have been publicly documented.

Further, we know that individuals are afraid to get genetic tests or seek genetic counseling out of fear that they will lose their health insurance or face discrimination in their employment. The medical progress made possible by genetic research is dependent on the willingness of study volunteers and patients to undergo genetic testing. However, such consent can be difficult to obtain today. Fears about the possible misuse or unauthorized disclosure of genetic information appear to adversely impact the desire of individuals to participate in genetic research. Such fears also extend to clinical practice, discouraging both patients and providers from taking full advantage of genetic tests and technologies. For instance, a national telephone survey of more than 1,000 people found that 63 percent of respondents said they would not take genetic tests if health insurers or employers could get access to the results.

Because our public policies lag behind the science, the promise of the Human Genome Project is going unfulfilled. Fear of discrimination, or even potential discrimination, threatens society's ability to use new genetic technologies to improve human health and the scientific community's ability to conduct research needed to understand, treat, and prevent disease.

After six years of dialogue, numerous hearings, and hours of deliberation, I am pleased that the Senate adopted important legislation in this field which was unanimously reported out the Health, Education, Labor, and Pensions Committee. I am also pleased that the first civil rights legislation adopted under my Chairmanship deals with an issue of true 21st Century concerns. This is the first civil rights act of the 21st Century.

Summary of S.1053, the Genetic Information Nondiscrimination Act

The Genetic Information Nondiscrimination Act, which passed the Senate on October 14, 2003 by a vote of 95 to 0, establishes in federal law basic legal protections that prohibit discrimination in health insurance or employment based on genetic information. It is our belief that establishing these protections will allay concerns about the potential for discrimination and encourage individuals to participate in genetic research and to take advantage of genetic testing, new technologies, and new therapies.

I want to acknowledge that in drafting this legislation we encountered many challenges. There are numerous, and sometimes conflicting, statutes in both the health and employment fields that had to be reconciled. Likewise, we devoted considerable attention to crafting definitions that matched the developing science of genetics, as well as fit with the realities of the workplace and benefits practices.

The legislation provides substantive protections to those individuals who may suffer from actual genetic discrimination now and in the future. Further, it establishes clear, common sense rules that will prevent confusion, litigation, and, most importantly, discrimination.

- A key component of the legislation is its privacy provisions. Although current law already contains medical privacy rules covering genetic information, this legislation addresses some additional concerns and closes loopholes that are unique to genetics. For instance, it protects the privacy of genetic information at work and prohibits the use of genetic information in health insurance underwriting.
- This bill prohibits an employer from making employment decisions (hiring, firing, etc.) based on genetic information, or even the fact that an individual or family member requested or received genetic services.

- This bill prohibits health insurance plans from denying eligibility or enrollment in the health plan based on genetic information. And it prohibits health insurance plans from charging higher premiums based on an individual's—or his or her family member's—genetic information.
- Most importantly, the legislation recognizes that all individuals, whether they are healthy or sick, and ALL medical information, whether genetic or otherwise, should be afforded the same protections under law.

While genetic discrimination may not be widespread at this point in time, this legislation ensures that discriminatory practices will never become common practice. From the past we have learned that employees, employers, insurers and others all work best together when the rules are clear and opportunities for personal achievement and health are available. This legislation tells everyone what is expected of them and avoids the trip wires and uncertainty of some of our existing laws.

Unlocking our genetic code unleashes new power. And power produces new responsibilities in protecting the privacy of our genetic information and protecting it from misuse. It is my sincere belief that any concerns about new regulations on employers or health plans are far outweighed by the benefits of scientific advances that will further revolutionize the medical field. With no silver bullet solution in sight to cure what ails our expensive and troubled health care system, I believe all stakeholders—employees, insurers, health providers, as well as the employers that provide the health care benefits—will welcome reasonable legislation that fosters medical advances that can lead to the prevention and cure of disease.

Statement of the Society for Women's Health Research, Submitted for the Record

The Society for Women's Health Research supports a ban on discrimination by health insurers and employers on the basis of predictive genetic information. For several years the Society has endorsed genetic nondiscrimination legislation. Today we urge the House Education and the Workforce committee to consider and pass S. 1053, the Genetic Information Nondiscrimination Act. S. 1053 passed the Senate unanimously and is supported by the Administration.

Over the past several years, remarkable advances have been made in the field of human genetics that hold extraordinary promise for improving the health and quality of life for millions of Americans. Scientists can use predictive genetic testing to determine an individual's susceptibility to illnesses such as breast and ovarian cancer, colon cancer, amyotrophic lateral sclerosis (ALS), and Alzheimer's disease. The availability of this information can help people make informed decisions about prevention and treatment options, and allow them to live longer and healthier lives,

However, the ability to determine genetic predisposition to disease can also have negative repercussions. Many people who might be helped by genetic testing are afraid to take advantage of this medical technology because of tears that their genetic information will be used against them. Health insurers may deny coverage to individuals who carry genetic mutations that may cause theta to develop serious or debilitating diseases later in their lives. As a result, many individuals choose not to undergo genetic testing or to take part in medical research.

The Society is particularly concerned about the impact of genetic discrimination on the participation of women in clinical trials. For over a decade, the Society has worked to secure the inclusion of women in medical studies, and to encourage them to take part in this research. However, women will be reluctant to enroll in clinical trials if they fear that their medical information will be used against them by health insurers and employers. Without a guarantee of protection from genetic discrimination, all of the progress which has been made in ensuring that women have access to clinical trials will be of little value, and both women and research will suffer.

The Society encourages the passage of S. 1053, the Genetic Information Nondiscrimination Act, which will allow Americans to utilize the enormous potential of genetic testing and further medical research.

Statement of the UJA–Federation of New York, Women's Public Policy Task Force, Submitted for the Record

The UJA–Federation of New York Women's Public Policy Task Force submits this testimony to with regards to The Genetic Information Nondiscrimination Act of 2003 (S. 1053). This historic act will prohibit discrimination as a result of genetic information with regard to health insurance and employment.

UJA–Federation of New York is an umbrella organization that raises funds through an annual campaign of more 77,000 donors and distributes the funds to a

network of more than 100 member agencies serving the greater metropolitan area of New York. The Women's Public Policy Task Force of UJA–Federation of New York is an advocacy group comprised of volunteers and professionals seeking to work with state and federal legislative bodies in an effort to improve the lives of women and thus strengthen all communities.

The issue of genetic testing has become increasingly relevant as the mapping of the Human Genome has been completed and as new advances in science and technology are continuously being discovered. Many potentially life-saving genetic tests have been developed, allowing people to identify their personal risk profile for developing certain diseases in the future. While the findings of most tests do not guarantee the development of a disease, the knowledge that a genetic predisposition exists gives a person the opportunity to take steps that may prolong or enhance the quality of life.

The genetic testing issue has specific relevance to the Jewish community. Specific mutations of two genes, commonly known as BRCA1 and BRCA2, have been proven to indicate a greater risk of developing breast cancer (it is strongly suspected by the medical community that both of these mutated genes could also cause prostate/colon cancer). These genes are prevalent among Ashkenazi Jewish women. As early detection leads to the highest breast cancer survival rates, it is beneficial for a woman to find out whether she is at increased risk; having that knowledge would allow her to be vigilant and ensure early detection. Women should be free to use this genetic technology without fear of discriminatory ramifications.

Despite the potential benefits of this genetic test, studies have shown that women are not likely to undergo a genetic test, regardless of whether the test would be for their own health reasons or as part of a scientific research project. The reason why people are shying away from genetic testing is a pervasive fear of discrimination. Many people genuinely believe that their eligibility for health insurance or employment opportunities may be compromised based on their genetic information.

Underlying the fear of discrimination is the issue of privacy and the fact that people feel that their private genetic information is not protected and can be disclosed to any employer or insurer. While protections relating to health insurance, employment and privacy do exist to some extent, they are clearly not sufficient to allow people to be tested with confidence that there will be no negative repercussions. Discovering an increased risk of disease is traumatic enough without having to worry about losing employment or insurance coverage. Existing protections must be improved and better communicated to the public. It is unacceptable to allow important research to falter and to let life saving genetic advances go to waste.

The bipartisan Genetic Information Nondiscrimination Act of 2003 (S. 1053) addresses these legitimate fears. This legislation will establish strong protections against discrimination based on genetic information both in health insurance and employment. Support for the bill has come from a wide range of organizations representing patients, medical professionals, families and employees. We should give all Americans the comprehensive protections against genetic discrimination in health insurance and employment they deserve by enacting this important legislation.

With regard to health insurance discrimination, the Act will:

- Prohibit enrollment restriction and premium adjustment on the basis of genetic information or genetic services.
- Prevent health plans and insurers from requesting or requiring that an individual take a genetic test.
- Prevent health plans and insurers from pursuing or being provided information on predictive genetic information or genetic services prior to enrollment—the time when this information is most likely to be used in making enrollment decisions.
- Cover all health insurance programs, including those regulated by the federal government under ERISA, state-regulated plans, Medigap, and the individual market.

With regard to employment discrimination, the Act will:

- Prohibit discrimination in hiring, compensation, and other personnel processes.
- Prohibit the collection of genetic information.
- Require genetic information possessed by employers to be confidentially maintained and disclosed only to the employee or under other tightly controlled circumstances.
- Cover employers, employment agencies, labor organizations, and training programs.

We are happy to support The Genetic Information Nondiscrimination Act of 2003 (S.1053), legislation that will protect people from the threat that their genetic information can be used against them in any way. We hope that Members of the House will join Members of the Senate in passing this historic legislation.

Letter from CARES Foundation, Inc., Submitted for the Record

July 20, 2004

The Honorable Sam Johnson
Committee on Education and the Workforce
Subcommittee on Employer–Employee Relations
House of Representatives
Washington, DC 20515

RE: Statement for the Record–Hearing on Genetic Nondiscrimination Policies

On behalf of the CARES (Congenital Adrenal Hyperplasia Education and Support) Foundation, Inc., I thank you for holding this hearing on genetic nondiscrimination policies. This is an issue of great importance to people with Congenital Adrenal Hyperplasia (CAH) and their parents.

CAH is a genetic condition which results in the body's failure to produce either or both of two critical hormones, cortisol and aldosterone. With diagnosis and proper treatment, people with CAH can lead normal and healthy lives. In its classical form, it affects 1 in 12–15,000. In its non-classical form, it affects 1 in 100. It is one of the most common genetic diseases identified to date.

As you know, genetic testing holds enormous promise to prevent health problems and help people cope more effectively with conditions that are unavoidable. In the case of CAH, genetic testing can determine whether parents are carriers of the gene variants that cause CAH. In addition, genetic testing of a fetus can help begin treatment for this condition even before birth.

Unfortunately, the same technologies that predict disease through genetic testing and family history can be used to open the door to discrimination. Currently there is no federal standard in place to prevent to use of genetic information to deny people with CAH jobs or insurance coverage.

This is of personal concern, as my six-year-old son has classical CAH. Not that anyone could tell; he is a healthy, active, and intelligent child. But because of his genetic condition, he is at risk of facing discrimination from employers and insurers; as parents, we already worry about our family insurance coverage.

As Senate Majority Leader Frist stated on the Senate floor about genetics nondiscrimination legislation: "As we greet the future, as we look at new technology, this is just one example of this body acting proactively, acting preemptively, so that such potential use in a discriminatory fashion of medical advances is kept from hurting the American people. We must take care to protect our body politic, and this legislation does just that."

Thank you again for holding this hearing, and the CARES Foundation, Inc. urges you to support the enactment of genetics nondiscrimination legislation in order to protect our children.

Sincerely,

Mark Engman
Member of the Board of Trustees
CARES Foundation, Inc.
(Congenital Adrenal Hyperplasia Research, Education and Support)

Statement of United Cerebral Palsy, Submitted for the Record

United Cerebral Palsy (UCP) thanks you, Mr. Chair, for conducting this hearing on the crucial issue of discrimination based on genetic information, and urges you to give the issue further serious consideration for meaningful action by the House before this Session of Congress ends.

For 50 years, UCP has been committed to change and progress for persons with disabilities. The national organization and its nationwide network of 105 affiliates in 37 states strive to ensure the inclusion of persons with disabilities in every facet of society—from the Web to the workplace, from the classroom to the community. As one of the largest health charities in America, UCP's mission is to advance the independence, productivity and full citizenship of people with cerebral palsy and other disabilities, through our commitment to the principles of independence, inclusion and self-determination. An integral, and often overriding, part of our mission

is to ensure that people who experience disability are free from discrimination in all facets of American society, most especially in the workplace and in the health care and health insurance arenas.

Clearly, at the dawn of the 21st Century, medical and scientific advancements, including genetic testing, can improve our lives. Genetic testing can provide information on how we can prevent future health problems and cope more effectively with unavoidable conditions. As advocates for people who daily face discrimination on many fronts simply because they have a disability, however, we are concerned that the ability to predict disease and disability through genetic testing and family history, as valuable as it is, opens the door for yet another form of discrimination in those extremely sensitive areas of employment and health care. Employers, for instance, finding that there is a genetic marker for disease or disability (e.g. breast cancer, diabetes, some forms of dwarfism, certain learning disabilities, might refuse to hire a person, assuming there may be an impact on the business, and the "bottom line," if the person actually contracts the disease or disability in the future. Insurance companies might refuse to cover people with genetic markers for "high-cost" conditions, or impose restrictions on coverage.

We were extremely gratified and encouraged when the Senate worked hard, achieved a compromise and passed the Genetic Information Non–Discrimination Act, S. 1053, in October of 2003. We have also been happy to see that President Bush has expressed strong support for the legislation and promised to sign a bill that mirrors the Senate's provisions. We are further encouraged that this Subcommittee is holding a hearing on the issue.

Now it is up to the House of Representatives to pass S. 1053, or similar legislation, in order to protect American citizens from the vulnerability experienced by those who are discriminated against for characteristics, in this case literally imperceptible genetic characteristics, over which they have no control.

We ask you, as a follow-up to this hearing, to support a vote on S. 1053, or to move similar legislation through the House as soon as possible.

Statement of the Digestive Disease National Coalition, Submitted for the Record

The Digestive Disease National Coalition (DDNC) applauds Chairman John Boehner (R–OH) and the members of the House Committee on Education and the Workforce for initiating this important hearing on Genetic Discrimination.

Established in 1978, the Digestive Disease National Coalition (DDNC) is a national non-profit advocacy organization comprised of the major gastrointestinal voluntary patient organizations and professional societies. Currently there are 26 member organizations that belong to the DDNC. The mission of the Digestive Disease National Coalition (DDNC) is to work cooperatively to improve access to and the quality of digestive disease health care in order to promote the best possible medical outcome and quality of life for current and future patients with digestive diseases. The DDNC has supported and advocated for genetic non-discrimination legislation for many years

The Digestive Disease National Coalition enthusiastically endorses the passage of H.R. 1910, The Genetic Nondiscrimination in Health Insurance and Employment Act as well as S. 1053, the Genetic Information Nondiscrimination Act of 2003. The DDNC urges the committee to pass these bills quickly so that Congress can finally address an issue that has dangerous repercussions for millions of Americans families. H.R. 1910, is bipartisan legislation introduced by Congresswoman Louise Slaughter (D–NY) with currently 241 cosponsors including 27 members of the Education and the Workforce committee. S. 1053 was introduced by Senator Olympia Snowe (R–ME) and passed the Senate unanimously in October 2003.

This legislation has the potential to assist families, with inherited chronic and catastrophic disorders, to be able to live without fear of losing their health insurance coverage or their jobs. Without safeguards in place employers and health insurance providers could subvert science to meet their financial bottom line.

The DDNC calls on Chairman Boehner and members of the committee to pass H.R. 1910, The Genetic Nondiscrimination in Health Insurance and Employment Act and S. 1053, The Genetic Information Nondiscrimination Act of 2003 as quickly as possible.

Letter from the American Academy of Pediatrics, Submitted for the Record

July 20, 2004

The Honorable Sam Johnson, Chairman
Employer–Employee Relations Subcommittee
Committee on Education and the Workforce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Johnson:

The American Academy of Pediatrics urges prompt passage of federal legislation that would prevent genetic discrimination, thereby allowing continued progress in prevention efforts through genetic screening and ensuring that all children have access to health insurance coverage. The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health and well being of all infants, children, adolescents, and young adults.

The American Academy of Pediatrics strongly supports efforts to enhance, improve and expand the ability to provide newborn screening, counseling and health care services. Advances in genetic research promise great strides in the diagnosis and treatment of many childhood diseases, detected as early as the newborn period or later in childhood. With early identification and timely intervention, we have the ability to significantly reduce morbidity, mortality and associated disabilities in infants and children affected with certain genetic, metabolic and infectious conditions.

With these opportunities, however, we also have a responsibility to ensure that careful consideration is given to the testing and screening of children so that emerging technologies are used in ways that promote the best interest of patients and their families. Potential benefits of genetic screening and testing are limited by the risks of harm that may be done by gaining certain genetic information, including potential for discrimination by insurers and employers. For this reason the American Academy of Pediatrics supports passage of legislation that protects children and families from genetic discrimination.

Furthermore, the American Academy of Pediatrics is concerned that genetic discrimination is a barrier for families to access health insurance for their children. More than 9 million children are currently uninsured in this country, and millions more are underinsured. We will never achieve our goal of ensuring that every child has health insurance coverage if genetic discrimination is permitted. The American Academy of Pediatrics therefore urges Congress to pass legislation that protects American families from genetic discrimination.

Sincerely,

Carden Johnston, M.D., FAAP
President
American Academy of Pediatrics

Statement of The Arc of the United States, Submitted for the Record

The Arc of the United States thanks the House Committee on Education and the Workforce Subcommittee on Employer–Employee Relations for holding this important hearing on the crucial issue of discrimination based on genetic information. We urge you to give the issue serious consideration for action by the House before the close of the 108th Congress.

The Arc of the United States (The Arc) is the national organization of and for people with mental retardation and related developmental disabilities and their families. Through its approximately 900 state and local chapters, The Arc is devoted to promoting and improving supports and services for people with mental retardation and their families. The association also fosters research and education regarding the prevention of mental retardation in infants and young children. An integral part of our mission is to ensure that people who experience mental retardation or related disabilities are free from discrimination in all facets of society, including in the workplace and in the health care and health insurance arenas.

As you know, genetic testing can improve our lives by providing information on how we can prevent future health problems and cope more effectively with unavoidable conditions. As advocates for people with mental retardation who daily face discrimination, however, we are concerned that the ability to predict disease and disability through genetic testing and family history, as valuable as it is, opens the door for yet another form of discrimination in the extremely sensitive areas of employment and health care coverage.

We are very concerned about the possible misuse of genetic information for families where mental retardation or related disabilities are present or predicted. With evidence of genetic markers for impairments (such as Down Syndrome, Fragile X

Syndrome, and others) in individuals or their children, insurance companies might refuse to cover people with potential for "high-cost" conditions, or impose restrictions on coverage for "pre-existing conditions". In addition, employers, finding that there is a genetic marker for a disability, might refuse to hire a person, assuming there may be an impact on the company's health insurance premiums, absenteeism, or other costs of doing business, if the employee should give birth to a child with the disability in the future.

Last fall, the Senate, achieved a compromise and passed the Genetic Information Non–Discrimination Act, S. 1053. President Bush has expressed strong support for the legislation and promised to sign a bill that mirrors the Senate's provisions. We are encouraged that the Subcommittee on Employer–Employee Relations is holding this hearing on the issue.

We urge the Subcommittee and the full House of Representatives to pass S. 1053, or similar legislation, in order to protect American citizens from the vulnerability experienced by those who are discriminated against for genetic characteristics. We would be happy to assist the Subcommittee regarding the issues that could affect people with disabilities and their families.

Statement of the Alpha–1 Association and the Alpha–1 Foundation, Submitted for the Record

Last fall the Senate passed the Genetic Information Nondiscrimination Act of 2003 by a vote of 95 to 0 giving us great hope that federal protections against the misuse of genetic information would finally be put into place. The Alpha–1 Association and Alpha–1 Foundation support S. 1053 and H.R. 1910 believing there is a great need to protect all Americans from genetic discrimination.

We need to live without fear of retribution in the form of genetic discrimination. In the absence of federal legislation, states have implemented a patchwork of laws that shield individuals from employment and insurance discrimination. We need national policy to ensure that all Americans have the same protections. Genetic testing allows individuals to exercise preventative health measures, seek appropriate therapies, and engage in essential life planning. Unfortunately, this same information may be used to discriminate against individuals who have no control over their inherited condition. S. 1053 and H.R. 1910 protect individuals who fear that genetic information could be misused to ruin job opportunities, forcing them to choose between the benefit of testing and the risk of losing employment or insurance.

Why are S. 1053 and H.R. 1910 important to individuals with Alpha–1?

- As a genetic condition, those with Alpha–1 or seeking Alpha–1 testing may face health and employment insurance discrimination. Fear of genetic discrimination may also significantly impact individual and family decision making.
- The Alpha–1 Foundation's Ethical Legal and Social Implications (ELSI) Working Group, has continued to discourage general population screening in absence of protective legislation.
- Those concerned about the ethics of genetic testing have recommended Targeted detection for Alpha–1 for those currently suffering from defined lung disease such as COPD or a family history of Alpha–1.
- The Alpha–1 Coded Testing Trial[1] has offered individuals an opportunity to receive confidential test results since September of 2001; to date over 2,400 test kits have been requested. Of those returning the test kits and responding to the survey questionnaire:
  - Over 30% report fear of losing insurance as the reason for seeking confidential testing;
  - 34% report concern about facing higher health care costs if results were public;
  - 85% seek testing for the Genetic Knowledge. In fact, this was the most popular response to the perceived benefits of seeking testing.

Alpha–1 Antitrypsin Deficiency is an inherited genetic disorder that can result in devastating and fatal lung disease that is often misdiagnosed as asthma or Chronic Obstructive Pulmonary Disease. Alpha–1 afflicts an estimated 100,000 individuals in

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[1] The ACT Trial is funded by the Alpha–1 Foundation and conducted at the Medical University of South Carolina under the direction of Dr. Charlie Strange, Program Director. The ACT Trial offers a free and confidential finger-stick test that can be completed at home with results mailed directly to the participants. The test is administered through a research study which evaluates perceived risks and benefits of genetic testing. For more information or a test kit please email the Registry Coordinator at alphaone@musc.edu, or call toll free at 1–(877)–886–2383.

the US with fewer than 6,000 accurately diagnosed. Alpha–1 is a major cause for lung transplantation in adults and the second leading cause of pediatric liver transplants.

Letter from the National Marfan Foundation, Submitted for the Record

July 21, 2004
The Honorable Sam Johnson, Chair
House Education and Workforce Committee, Subcommittee on Employer–Employee Relations
2181 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Robert E. Andrews, Ranking Member
House Education and Workforce Committee, Subcommittee on Employer–Employee Relations
2181 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Chairman Johnson and Ranking Member Andrews:

On behalf of the National Marfan Foundation, I would like to submit this statement on Genetic Non–Discrimination. The National Marfan Foundation represents approximately 20,000 members throughout the United States. Marfan syndrome is a life threatening genetic disorder that results in weakening of the aorta, the main artery that carries blood away from the heart. With time, progressive enlargement of the aorta causes leakage of the aortic valve or tears in the aorta wall, which in some instances can cause death within a few minutes.

In 1991, researchers discovered the gene responsible for Marfan syndrome, fibrillin–1. This was a dramatic step to help understand the underlying causes of the syndrome and the hope to finding treatments that may cure this disorder. Individuals with Marfan syndrome now face the fear of being labeled as having a genetic disorder, a label which employers and health insurers may use to deny their access to employment and healthcare. This discrimination causes under utilization of genetic tests that may be used to help diagnose other members of the family and ultimately save their lives.

The National Marfan Foundation urges you to consider federal legislation that contains strong genetic discrimination protections as described by the Coalition of Genetic Fairness. Passage of legislation this year would greatly benefit the millions of people affected with a genetic disorder.

Sincerely,

Josephine Grima, Ph.D.
Director of Research and Legislative Affairs
National Marfan Foundation

Letter from the American Association for the Advancement of Science, Submitted for the Record

July 20, 2004
The Honorable Sam Johnson
U.S. House of Representatives
1211 Longworth House Office Building
Washington, DC 20515

Dear Representative Johnson:

On behalf of the American Association for the Advancement of Science (AAAS), I am writing to bring to your attention the conclusions of a AAAS working group concerning the need to protect against genetic discrimination.

The completion of the human genome sequence has raised hopes of a medical revolution, but to take full advantage of this momentous achievement, we must ensure the highest levels of public confidence that genetic information will be used appropriately to improve health and not to discriminate unfairly against people. The Senate has taken a great stride toward this goal by passing S. 1053, the Genetic Information Nondiscrimination Act, which is consistent with the conclusions of our working group. AAAS encourages the House to consider similar action as it deliberates on H.R. 1910.

The working group released a statement in 1999 which included the following conclusions:

- Individuals should be able to gain information about their genetic makeup, but should be able to protect themselves against discrimination by controlling access to such information.
- Genetic information should be used only to enhance, not undermine, an individual's quality of life. Society, therefore, in pursuit of the common good, has a responsibility to protect citizens against the misuse of genetic information.
- Policies should be adopted to ensure opportunities for people to participate in research studies and clinical trials without fear that their genetic information could adversely affect their health insurance status.

Founded in 1848, AAAS is the world's largest general scientific society and publisher of the journal, Science. The Association serves some 262 affiliated organizations in more than 130 countries, serving some 10 million individuals. The non-profit AAAS is open to all and fulfills its mission to "advance science and serve society" though initiatives in science policy and more.

The complete genetic discrimination working group statement is available on the AAAS website at http://www.aaas.org/spp/dser/bioethics/resources/gdiscrim.shtml. For further information, please do not hesitate to contact Joanne Padron Carney of the AAAS Center for Science, Technology, and Congress at 202/326–6798, or you may call my office.

Sincerely,

Alan I. Leshner

Statement of the Genetic Alliance, Submitted for the Record

The Genetic Alliance is an alliance of genetic disease advocacy groups, which represent millions of individuals. We understand the promise of advanced medical research and are appalled that many families and individuals have experienced genetic discrimination.

We urge the House of Representatives to consider and pass the Genetic Information Nondiscrimination Act [S. 1053], to prohibit discrimination on the basis of genetic information with respect to health insurance and employment. We believe that all genetic information, including family history, deserves strong and enforceable protections against misuse in health insurance and employment. Such safeguards will protect the rights, privacy and confidentiality of the individual and their family.

This is an exciting and hopeful time for medicine. It is imperative, however, that we, the public, be able to take full advantage of new medical advances that could help prevent disease before it develops. Genetic nondiscrimination legislation will reduce the likelihood of genetic information being misused in health insurance or employment decision-making. Genetic information is merely predictive information. Simply having a positive genetic test does not mean one will develop a disease—thus this information should not be used to make decisions about insurance coverage or employment.

As biomedical research advances, genetic testing will become a critical tool in the provision of healthcare. As a result, many more people will know about their own genetic makeup, putting them at risk of genetic discrimination. People who would like to avail themselves of genetic testing already have enough to worry about. They should not have the additional burden of genetic discrimination.

And so, on behalf of thousands of consumers and patient groups, we urge Speaker Hastert to move S. 1053 off the desk and bring it to a vote. President Bush has said he'll sign it. Public policy must keep pace with scientific advances, and provide those advances with a climate conducive to their translation into health benefits for all Americans.

Statement of the American Academy of Family Physicians, Submitted for the Record

The 93,700 member American Academy of Family Physicians submits this statement for the record in support of HR 1910/S 1053, the Genetic Information Nondiscrimination Act of 2003, which would prohibit genetic discrimination in health insurance and employment. The AAFP strongly supports effectively translating genetic advances to the practices of primary care physicians, who provide most of the health care the majority of Americans receive. Primary care physicians will need to receive appropriate education and training, and research translation needs to include the development of primary care tools for delivering the fruits of genetic ad-

vances to all Americans. Nevertheless, Americans must be legally protected from discrimination based on their genetic make up, which is the goal of this legislation.

Background

Completion of the sequencing of the human genome of April 2003, inaugurated an era in which genetic information will become an increasingly indispensable part of quality health care. Researchers predict the advent of individualized treatment, ranging from preventive strategies to "designer drugs," specifically formulated for a patient's genetic makeup.

With these potential benefits, however, comes potential for the abuse of personal information in non-healthcare settings such as insurance and in the workplace, abuses that the above measures have been designed to address. For example, HR 1910/S 1053 would forbid insurance companies from restricting enrollment or changing premiums based on an individual's genetic makeup. The bill also would ban discrimination based on genetic information in the workplace. Underpinning these issues are patients' concerns about the privacy of their genetic information and informed consent. In short, with the proliferation of new genetic information, lawmakers must determine how to protect this sensitive health data.

Relationship to Primary Care

In addition to concerns about discrimination, family physicians are keenly interested in the impact that genetic information will have on their individual practices. Specifically, family physicians want genetic research translated into information that can be used to help their patients. Family physicians do address patients' illnesses, but more importantly, they help patients integrate information about all of their health conditions with their particular life goals. This important family practice function will need new tools to deal with genetic information, including the ability to perform diagnostic genetic tests in the physician's office.

Currently, family physicians conduct almost 200 million office visits each year, which is 73 million more visits than any other medical specialty. In addition, according to "The Ecology of Medical Care Revisited," (New England Journal of Medicine, 2001, 344:2021–25) more than 12 times as many people are seen in the offices of primary care physicians as in hospitals. The sheer number of visits to family physicians, as well as to other primary care doctors, means that most Americans will approach them first about questions on genetic information. We wish to be able to counsel our patients about these issues without fear that this information could somehow be used against them in insurance or employment.

Education and Training

Education and training of primary care physicians in genetic information, testing diagnosis and counseling is also critical. Long the province of subspecialists, the Genetics in Primary Care Initiative (GPC), supported by three federal agencies (Health Resources and Services Administration; National Human Genome Research Institute and the Agency for Healthcare Research and Quality) was established to "plan, implement, and evaluate outcomes of training programs in genetics."

As W. Burke, et al., point out, ("Genetics in Primary Care," Community Genetics, 2002; 5:138–146) "Genetic tests have become increasingly accurate in diagnosing both chromosomal and single gene disorders and predictive tests have begun to emerge—" Primary care physicians need to be trained to administer and interpret these tests so that they can provide appropriate counseling and referrals.

In addition, the Advisory Committee on Training in Primary Care Medicine and Dentistry, which Congress established to review primary care training programs that support family medicine, general internal medicine and pediatrics, general dentistry and physician assistants, also recognized the emerging field of genetic training. Its November 2001 report states, "Primary care training programs are ideally positioned to react quickly to meet ever-changing health care needs and issues, whether they are related to HIV/AIDS, growing numbers of elderly with chronic illnesses, implications of the modern genetics revolution, the threat of bioterrorism, or other issues that will continue to emerge and demand rapid educational intervention."

Conclusion

While genetics is still a relatively young field, now is the time for developing the plan to deliver genetic testing and treatment discoveries to all Americans. There is no better mechanism for applying these discoveries than the primary care workforce, but this workforce will need new and special preparation and tools. The lag between discovery and delivery in healthcare is typically 17 years, and the primary care workforce-training pipeline is 7 or more years. The federal government will

need to be proactive in its planning and support if Americans are to realize the fruits of genetic discoveries in the next decade.

Statement of the National Workrights Institute, Submitted for the Record

THE NEED FOR GENETIC NONDISCRIMINATION LEGISLATION

During the past several decades, our understanding of genetics has multiplied as procedures for identifying, analyzing and manipulating DNA have advanced. Among the many benefits of these efforts are the ways they may influence preventive health, reproductive planning and eventually therapies to cure illnesses with a genetic component. No one can deny that this knowledge may be a blessing in finding cures to diseases with genetic origins, including Alzheimer's, Huntington's and many forms of cancer. Nevertheless, the ability to identify individuals based on genetic characteristics necessarily predates the ability to use this information in the treatment of the corresponding diseases and therefore the immediate consequences of such advances have and will continue to lead to a number of forms of individual discrimination.

Genetic Discrimination in the Workplace:

Employers are beginning to acquire and use genetic information. In a 2001 survey of U.S. firms almost 2% were currently conducting genetic tests for Sickle Cell and Huntington's Disease, 14% were acquiring genetic information during workplace susceptibility testing and 20% reported requesting family medical histories containing information on the likelihood of disease.[1]

As the acquisition of genetic information by employers increases there have been numerous examples of discrimination. Consider:

* In a 1996 Georgetown University study of 332 families belonging to genetic disease support groups, 22% of the respondents stated that they that they had knowingly been refused health insurance and 13% stated that they had knowingly been terminated from their jobs because of the perceived risks attributed to their genetic status.
* Lawrence Berkeley Laboratories conducted testing of their employees for sickle cell trait throughout the 1990's without their knowledge and consent for decision-making purposes.
* In 1999 Terri Sargent, despite excellent past performance reviews was fired from her job for having the genetic predisposition to Alpha–1 disease though she remained asymptomatic.
* In 2001 Burlington Northern Railroad conducted genetic testing of their employees for carpal tunnel syndrome for purposes of refuting workers compensation claims.

Public Concern:

There has been continuing widespread concern in this country about the potential for misuse of genetic information. Consider:

* A Harris Poll taken in 1995 of the general public finds 86% of those surveyed indicated they were very concerned or somewhat concerned that employers and insurers might have access to and use genetic information.[2]
* A 1996 study finds 87% of respondents would not want their employers to know that they were tested and found to be at a high risk of a genetic disorder.[3]
* In 1997 a survey finds that 63% of participants reported they would not take genetic tests for disease if employers and health insurers could access the results.[4]
* In a 2000 CNN/Time Magazine Poll 80% of those surveyed did not believe employers or insurers should have access to genetic information.
* A 2003 poll found 69% of respondent surveyed were very worried or somewhat worried that employers and insurers would discriminate using genetic information.[5]

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[1] American Management Association. "Summary of key findings." 2001 AMA Survey on Workplace Testing: Medical Testing

[2] Harris poll, 1995, 34

[3] E. Virginia Lapham. Et al. "Genetic Discrimination: Perspectives of Consumers." Science, October 25, 1996, p.622

[4] National Center for Genome Resources unpublished survey, 1997. Cited in Department of Labor "Genetic Information and the Workplace", January 20, 1998.

[5] Genetic Engineering News (GEN) Website poll (www.genengnews.com).

Restrictions must be placed on the accumulation and use of genetic information by employers before discrimination becomes rampant. There is a pressing need for Congress to pass genetic nondiscrimination legislation to address this issue. The overwhelming demand by the American public for such legislation is clear. Without meaningful privacy safeguards and protections against discrimination, the benefits of genetic testing will ultimately be lost as individuals avoid tests in the fear of adverse consequences. Indeed, if one really doubts this growing trend of genetic discrimination consider asking an employer the following question: "If an inexpensive and accurate test existed that would indicate that an individual had a predisposition to a particular illness that would cost thousands of dollars to treat and limit their ability to perform would you be interested conducting and using such testing?"

Statement of the National Breast Cancer Coalition, Submitted for the Record

I am Fran Visco, a breast cancer survivor, a wife and mother, a lawyer, and President of the National Breast Cancer Coalition (NBCC). On behalf of NBCC, and the more than 3 million women living with breast cancer, I would like to thank you for the opportunity to provide this testimony.

The National Breast Cancer Coalition is a grassroots advocacy organization made up of more than 600 organizations and tens of thousands of individuals and has been working since l99l toward the eradication of breast cancer through advocacy and action. NBCC supports increased funding for breast cancer research, increased access to quality health care for all women, and increased influence of breast cancer activists at every table where decisions regarding breast cancer are made.

With the knowledge of the human genome expanding exponentially, the National Breast Cancer Coalition (NBCC) believes strongly that legislative and regulatory strategies must be established to address the protection of individuals from the misuse of their genetic information at the national, state and local levels of government. Genetic information is uniquely private information that should not be disclosed without authorization by the individual. Improper disclosure can lead to significant harm, including discrimination in the areas of employment, education, health care and insurance.

In 1996, the Health Insurance Portability and Accountability Act (HIPAA, P.L.104–191), also known as HIPAA, was the first federal law that took some significant steps toward extending protection with regard to genetic discrimination in the health insurance arena. HIPAA mandated the Department of Health and Human Services (HHS) to create privacy standards to prevent unwarranted disclosures of medical information if Congress did not enact privacy legislation by August 1999. After this deadline passed, HHS established the standards for privacy of individually identifiable health information (known as the "privacy regulation"). While the privacy regulation establishes some guidelines for the methods of disclosure and access to medical information by health plans and providers, it does not specifically address the issue of genetic discrimination. Moreover, even within the health care arena, the privacy regulation does not extend to all group plans.

The time is now to extend protections against genetic discrimination to everyone. The release of the working draft of the human genome sequence in June 2000 and the development of new genetic tests necessitate legislative and regulatory strategies to address the issue of how to protect individuals from the misuse of their genetic information.

Furthermore, the fear of potential discrimination threatens both a woman's decision to use new genetic technologies and to seek the best medical care from her physician, and the ability to conduct the research necessary to understand the cause and find a cure for breast cancer. Fear of discrimination can also prevent individuals from enrolling in clinical trials and forgoing possible life-saving treatment.

NBCC strongly supports the enactment of legislation that would protect millions of individuals against discrimination not only in health insurance but also in the workplace, and that would provide strong enforcement mechanisms that include a private right of action. For these reasons, NBCC supports H.R. 1910 (Slaughter) the Genetic Nondiscrimination in Health Insurance and Employment Act. This legislation prohibits health plans from:

- Requesting, requiring, collecting or disclosing genetic information without prior specific written authorization of the individual;
- Using genetic information, or an individual's request for genetic services, to deny or limit any coverage for established eligibility, continuation, enrollment or contribution requirements;

- Establishing differential rates or premium payments based on genetic information, or an individual's request for genetic services.

This legislation also prohibits employers from:

- Using genetic information to affect the hiring of an individual or to affect the terms, conditions, privileges, benefits or termination of employment, unless the employment organization can prove this information is job related and consistent with business necessity;
- Requesting, requiring, collecting or disclosing genetic information prior to a conditional offer of employment; or under all other circumstances, 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;
- Accessing genetic information contained in medical records released by individuals as a condition of employment, in claims filed for reimbursement for health care costs, and other services;
- Releasing genetic information without specific prior written authorization of the individual.

Most importantly, H.R. 1910 contains strong enforcement language and provides individuals with a private right of action to go to court for legal and equitable relief if they are a victim of genetic discrimination, whether they are subject to discrimination by their health plan or their employer.

NBCC does not support the Genetic Nondiscrimination in Health Insurance and Employment Act (S.1053) passed by the Senate on October 14, 2003 because it does not contain sufficient enforcement provisions. Unlike H.R. 1910, S. 1053 does not provide individuals with a private right of action should they become a victim of genetic discrimination in the individual insurance market.

NBCC's number one legislative priority if guaranteed access to quality health care. However, the only way to guarantee patients have access to the care they deserve is to provide strong enforcement. If health care providers, employers, and insurance companies comply with the law, then those enforcement mechanisms will never have to be used. But as patients, we need to know that they are in place for our protection.

NBCC believes that a right with no enforcement is really no right at all. It is for that reason that no matter how carefully a bill is worded, no matter how much effort is put into including "protections" that breast cancer patients need—if that bill does not have a strong enforcement mechanism, then NBCC simply will not support it.

I urge you to consider and pass legislation that will protect individual's privacy and guarantee them access to quality health care by passing legislation to prevent genetic discrimination that includes meaningful enforcement provisions, such as H.R. 1910. Thank you for the opportunity to share the views of the National Breast Cancer Coalition.

Statement of the National Council on Disability, Submitted for the Record

PRINCIPLES FOR GENETIC DISCRIMINATION LEGISLATION

Protections for Individuals with Actual Health Conditions: The same interpretations that make the ADA difficult to enforce by individuals with genetic markers make it difficult to enforce by individuals with a range of health conditions. When Congress considers protections for individuals who experience discrimination based on genetic information, it should also ensure that if these individuals are eventually diagnosed with medical conditions, they will be protected against discrimination.

Workplace Discrimination: Employers must not be permitted to use predictive genetic information as a basis for taking any employment actions or as a term or condition of employment. Nor should employers be permitted to use this information to limit, segregate or classify employees or job applicants.

Employers' Collection of Information: Employers should be permitted to request predictive genetic information only: (1) to monitor effects of toxic substances in the workplace upon an employees' written consent to such monitoring, with the employer receiving only aggregate results and not results for particular employees, or (2) to provide genetic services to employees upon the employees' written consent. In either case, results should be provided only to the employee.

Employers' Disclosure of Information: Genetic information must be kept strictly confidential and maintained separately from personnel files and other employee information. It should be disclosed only to the employee, officials enforcing this legislation, or as required by other federal laws.

Insurance Discrimination: Insurers must not be permitted to make decisions about enrollment in health, life, disability, or other types of insurance based on genetic information. They must also be prohibited from using genetic information in determining premium or contribution rates, or other terms or conditions of coverage. They must be barred from requesting or requiring genetic tests.

Collection of Information by Insurers: Insurers must not be permitted to request, require, collect or buy genetic information except for the limited purpose of paying for claims for genetic testing or other genetic services. Strict protections must ensure that when such information is requested, it is not used to affect an individual's enrollment, premiums, or terms or benefits of coverage.

Disclosure of Information by Insurers: Insurers must be prohibited from disclosing genetic information to employers, entities that collect or disseminate insurance information, or health plans or health insurance issuers except in the limited circumstance of payment for claims.

Health Care Discrimination: Legislation must bar health care providers from refusing treatment to individuals, or treating them differently, based on genetic information.

Collection of Information by Health Care Providers: Legislation must prohibit health care providers from requiring, requesting, or collecting genetic information about individuals who are seeking treatment. Providers may only collect this information for the purpose of providing genetic testing or other genetic services.

Disclosure of Information by Health Care Providers: Health care providers must not be permitted to disclose genetic information except to the patient, to insurers only for the limited purpose of seeking payment for genetic testing or genetic services rendered, to officials enforcing this legislation, or as required by other federal laws.

Education and Technical Assistance: Funding should be provided for education and technical assistance in order to ensure that individuals affected by the legislation are aware of its requirements.

Effective Enforcement: A private right of action to enforce genetic discrimination legislation must be included. The EEOC should have authority to investigate and resolve complaints relating to employment. The full range of remedies, including attorney's fees, must be available.

Relationship to Other Laws: Legislation must not preempt existing state or federal laws to the extent that they provide greater protections for individuals who experience genetic discrimination.

POSITION PAPER ON GENETIC DISCRIMINATION LEGISLATION

Introduction

The National Council on Disability (NCD) is an independent federal agency that advises the President and Congress on issues affecting 54 million Americans with physical and mental disabilities. NCD's fundamental purpose is to promote policies, programs, practices, and procedures that guarantee equal opportunity for all individuals with disabilities, regardless of the nature or severity of the disability; and to empower individuals with disabilities to achieve economic self-sufficiency, independent living, inclusion, and integration into all aspects of society.

For a number of years, NCD has recognized the harmful effects of discrimination based on individuals' genetic information and supported the need for federal legislation prohibiting genetic discrimination as well as the enforcement of existing legislation that may prohibit certain types of genetic discrimination. It has addressed the issue of genetic discrimination in several reports, including the following:

- Achieving Independence: The Challenge for the 21st Century. July 26, 1996 (expressing serious concern about the quandaries and implications of obtaining and using genetic information; calling for further examination of the interface of genetic testing practices with antidiscrimination law and access to health insurance for people with disabilities).
- National Disability Policy: A Progress Report. July 26, 1996 Oct. 31, 1997 (noting the potential for discrimination based on genetic information in employment, health care and other areas, and urging the President to work with Congress to enact legislation outlawing genetic discrimination and restricting access to genetic information by employers, insurance carriers and others).
- National Disability Policy: A Progress Report. Nov. 1999 Nov. 2000 (applauding the Clinton Administration for issuing an executive order prohibiting certain types of genetic discrimination by federal employers, and urging the prompt reintroduction of legislation prohibiting genetic discrimination by employers and health insurers).

- Promises to Keep: A Decade of Federal Enforcement of the Americans with Disabilities Act. June 27, 2000 (supporting the U.S. Equal Employment Opportunity Commission's (EEOC) position on genetic discrimination in its guidance on the definition of disability, which considered an individual discriminated against based on a genetic predisposition to disease or disability to be a person with a disability protected by the Americans with Disabilities Act (ADA) by virtue of being "regarded as" substantially limited in a major life activity; calling for technical assistance from federal agencies in emerging areas of ADA policy and enforcement such as genetic discrimination).

NCD's interest in genetic discrimination legislation stems partly from the fact that the need for this legislation arises due to narrow judicial interpretations of ADA, and these same interpretations also create the need for legislation to restore protections for individuals who have actually developed health conditions. NCD believes that the concerns of individuals with actual health conditions have not been fully addressed in the dialogue about legislative proposals to address genetic discrimination.

The Need for Federal Legislation Prohibiting Genetic Discrimination

Recent Advances in Genetic Research Have Brought Increasing Potential for Genetic Discrimination

Recent years have brought dramatic scientific advances in the study of human genetics. Scientists have mapped out DNA sequences in the human body and have identified many genes that cause disease. Consequently, they have been able to use genetic testing to identify individuals who may be susceptible to many diseases that are genetically linked.[1] Tests now exist that are able to detect genetic predispositions for many diseases and illnesses, such as Huntington's Disease, breast cancer, cystic fibrosis, Alzheimer's disease, colon cancer, and Parkinson's disease.[2] The number of conditions that may be detected by genetic tests is rapidly growing.[3] While these genetic advances hold tremendous potential for early identification, prevention and treatment of disease, they also create opportunities for discrimination against individuals based on their genetic information, even where individuals have no symptoms of disease.

In recent testimony before Congress, Dr. Francis Collins, Director of the National Human Genome Research Institute at the National Institutes of Health, observed:

> while genetic information and genetic technology hold great promise for improving human health, they can also be used in ways that are fundamentally unjust. Genetic information can be used as the basis for insidious discrimination. . . . The misuse of genetic information has the potential to be a very serious problem, both in terms of people's access to employment and health insurance and the continued ability to undertake important genetic research.[4]

Genetic Discrimination is a Historical and Current Reality

Discrimination based on genetic information is not a new phenomenon. During the early 1970s, employers used genetic screening to identify and exclude African Americans carrying a gene mutation for sickle cell anemia.[5] These individuals were denied jobs despite the fact that many of them were healthy and never developed the disease.[6] During the same time period, individuals who were carriers of sickle cell anemia were also discriminated against by several insurance companies despite the fact that they were asymptomatic.[7]

Genetic discrimination by employers and insurers has continued to be a systemic problem. According to a 1989 survey conducted by Northwestern National Life Insurance Company, 15 percent of the companies surveyed indicated that by the year

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[1] Deborah Gridley, Note, Genetic Testing Under ADA: A Case for Protection from Employment Discrimination, 89 Georgetown Law Journal 973, 976 (2001).

[2] Id. at 975; Testimony of Mary Davidson, Executive Director of Genetic Alliance, before U.S. House of Representatives Subcommittee on Commerce, Trade and Consumer Protection of the Committee on Energy and Commerce (July 11, 2001).

[3] Testimony of Mary Davidson, supra note 2.

[4] Congressional Research Service, Genetic Information: Legal Issues Relating to Discrimination and Privacy, Report No. RL30006 (July 19, 2001) (hereafter "Congressional Research Service Report"), at 2.

[5] Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, Department of Justice, Genetic Information and the Workplace (Jan. 20, 1998) (hereafter "Joint Government Report"), at 3.

[6] Id.

[7] E. Virginia Lapham et al., Genetic Discrimination: Perspectives of Consumers, 274 Science 621 (1996).

2000, they planned to check the genetic status of prospective employees and their dependents before making employment offers.[8]

A 1996 survey of individuals at risk of developing a genetic condition and parents of children with specific genetic conditions indicated more than 200 instances of genetic discrimination reported by the 917 respondents. The discrimination was practiced by employers, insurers, and other organizations.[9] Another survey of genetic counselors, primary care physicians, and patients identified 550 individuals who were denied employment or insurance based on genetic information.[10] A study on genetic discrimination, published in 1996, found that health and life insurance companies, health care providers, blood banks, adoption agencies, the military, and schools engaged in genetic discrimination against asymptomatic individuals.[11]

Science magazine reported that in a study of 332 individuals with one or more family members with a genetic disorder who are affiliated with genetic support groups, 40 percent of the respondents recalled being specifically asked about genetic diseases or disabilities on their applications for health insurance.[12] Twenty-two percent of the respondents said they or a family member were refused health insurance as a result of the genetic condition in the family.[13] Fifteen percent of the respondents reported that they or affected family members had been asked questions about genetic diseases or disabilities on employment applications.[14] Thirteen percent reported that they or a family member had been denied a job or fired from a job because of a genetic condition in the family, and 21 percent reported being denied a job or fired due to their own genetic disorder.[15]

In addition to these and other studies, numerous anecdotal examples of genetic discrimination by employers and insurers have been detailed in testimony before Congress in hearings about genetic discrimination.

Genetic Discrimination Undermines the Purposes of Genetic Research and Testing

The misuse of genetic information not only excludes qualified individuals from employment and denies insurance coverage to individuals without justification, but also undercuts the fundamental purposes of genetic research. Such research has been undertaken with the goals of early identification, prevention and effective treatment of disease. These goals will be undermined if fear of discrimination deters people from genetic diagnosis and prognosis, makes them fearful of confiding in physicians and genetic counselors, and makes them more concerned with loss of a job or insurance than with care and treatment.[16]

The fears engendered by genetic discrimination fears of disclosure of genetic information to physicians and of participation in genetic testing and research have been well documented in numerous studies. In one study, 83 percent of the participants indicated that they would not want their insurers to know if they were tested and found to be at high risk for a genetic disorder.[17] In a 1997 survey of more than 1,000 individuals, 63 percent of the participants reported that they would not take genetic tests for diseases if health insurers or employers could get access to the results.[18] Additionally, researchers conducting a Pennsylvania study to determine how to keep women with breast cancer gene mutations healthy reported that nearly one third of the women invited to participate in the study declined out of fear of discrimination or loss of privacy.[19] The results of a national survey released by the California HealthCare Foundation in 1999 indicate that 15 percent of adults surveyed took steps to keep genetic information private, such as paying for testing out of pocket rather than using their insurance coverage, constantly switching doctors to avoid the compilation of a comprehensive medical history, refusing to seek needed medical care, and/or providing false or incomplete information to physicians.[20] Another study showed that 57 percent of surveyed individuals at risk for breast or ovarian cancer had chosen not to take a needed genetic test, and 84 percent of those

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[8] Larry Gostin, Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers, 17 American Journal of Law & Medicine 109, 116 (1991).

[9] Joint Government Report, supra note 5, at 2.

[10] Id.

[11] Congressional Research Service Report, supra note 4, at 3.

[12] Lapham et al., supra note 7, at 622.

[13] Id. at 624.

[14] Id. at 626.

[15] Id.

[16] Gostin, supra note 8, at 113.

[17] Lapham et al., supra note 7, at 622.

[18] Joint Government Report, supra note 5, at 2.

[19] Id.

[20] Genetic Alliance, The Insured, the Underinsured, and the Uninsurable: the Role of Genetics in Health Care Coverage (Oct. 2001) (unpublished), at 2–3.

individuals who had decided to forego the test cited fear of genetic discrimination as a major reason for their decision.[21]

These fears eliminate people's opportunities to learn that they are not at increased risk for the genetic disorder in the family or to make lifestyle changes to reduce risks.[22] They may also affect the number of people willing to participate in scientific research.[23]

Genetic Test Information Has Little Value for Purposes of Making Employment Decisions and Insurance Decisions

There is no consensus on the scientific validity of genetic tests or their usefulness for predicting an individual's susceptibility to exposure.[24] The results of genetic-based diagnosis and prognosis are uncertain for many reasons. First, the sensitivity of genetic testing is limited by the known mutations in a target population. Many individuals with a genetic predisposition for a particular disease will not be identified because these markers are not among the known genetic mutations.[25] Secondly, many individuals are falsely labeled "at risk" due to the genetic screening of family members.[26] Thirdly, genetic markers are generally not valid predictors of the nature, severity and course of disease. For most genetic disease, the onset date, severity of symptoms, and efficacy of treatment and management are highly variable, with some people identified by screening remaining symptom-free and others progressing to disabling illness.[27] Genetic tests alone cannot predict with certainty whether an individual with a particular genetic error will actually develop a disease.[28] These tests evaluate people according to stereotypes of future ability to function and the probability that disease will occur, rather than evidence of actual disease and ability.[29]

Existing Laws Are Insufficient to Protect Individuals from Genetic Discrimination

There are existing laws that may prohibit genetic discrimination in some contexts. However, these laws do not reach much of the discrimination that occurs and, in some cases, may be interpreted not to apply to genetic discrimination at all.

The Americans with Disabilities Act[30]

The Americans with Disabilities Act (ADA), an anti-discrimination law, protects individuals who have an impairment that substantially limits them in a major life activity, who have a record of such an impairment, or who are regarded as having such an impairment.[31] Congress intended ADA to cover individuals with a broad range of diseases, and some members of Congress explained at the time of ADA's passage that it would protect people who experience discrimination on the basis of predictive genetic information where those individuals were regarded as having a disability.[32] ADA has also been interpreted by EEOC to prohibit some forms of genetic discrimination. In 1995, the EEOC issued enforcement guidance advising that an employer who takes adverse action against an individual on the basis of genetic information may regard the individual as having a disability and, therefore, may be violating ADA.[33] EEOC recently settled its first court action challenging an employ-

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[21] Caryn Lerman et al., BRCA1 testing in families with hereditary breast-ovarian cancer. A prospective study of patient decision making and outcomes, 275 Journal of American Medical Ass'n 1885 (1996). In another study, concern about health insurability was the leading reason for individuals' decisions to decline cancer genetic counseling services. Katherine P. Geer et al., Factors Influencing Patients' Decisions to Decline Cancer Genetic Counseling Services, 10 Journal of Genetic Counseling 25 (2001).

[22] Lapham et al., supra note 7, at 622.

[23] Id.

[24] Joint Government Report, supra note 5, at 3.

[25] Gostin, supra note 8, at 113.

[26] Id. at 114.

[27] Id.

[28] Joint Government Report, supra note 5, at 1; Elaine Draper, The Screening of America: The Social and Legal Framework of Employers' Use of Genetic Information, 20 Berkeley Journal of Employment & Labor Law 286, 290–91 (1999).

[29] Draper, supra note 28, at 290.

[30] The analysis of ADA's application to genetic discrimination in employment also applies to Section 504 of the Rehabilitation Act, which applies to federal employers and entities receiving federal funds. Section 504 has the same definition of disability as that contained in ADA.

[31] 42 U.S.C. § 12102(2).

[32] 136 Cong. Rec. H4627 (statement of Rep. Waxman).

[33] Joint Government Report, supra note 5, at 6; EEOC Compliance Manual § 902, Order 915.002, 902–45 (1995).

er's use of genetic testing[34] and also issued a finding of cause in an administrative complaint filed by a woman who was terminated based on a genetic test result.[35]

Nonetheless, ADA is a highly problematic vehicle for fully addressing genetic discrimination. At recent Senate hearings, EEOC Commissioner Paul Steven Miller testified that while ADA could be interpreted to prohibit employment discrimination based on genetic information, it "does not explicitly address the issue and its protections are limited and uncertain."[36]

ADA could be interpreted to protect individuals with genetic markers for disease in two ways. First, as described above, such individuals may be protected if they are regarded as substantially limited in a major life activity B for example, if they are regarded as substantially limited in working due to their genetic predisposition. However, recent Supreme Court cases discussing what it means to be regarded as substantially limited in working suggest that such claims are extremely unlikely to succeed. In Sutton v. United Airlines, Inc.[37] and Murphy v. United Parcel Service, Inc.,[38] the Court stated that a job requirement excluding individuals based on their impairments does not necessarily establish that the employer regards individuals excluded by this requirement as substantially limited in working. To be covered under the "regarded as" prong, the plaintiffs would have to prove that they were regarded as substantially limited in performing a broad class of jobs, not merely their own jobs. It may prove extremely difficult for plaintiffs with genetic markers who are denied employment due to an employer's concern about health insurance premiums or productivity losses to show that the employer regarded them as substantially limited in performing not only the job in question but a broad class of other jobs as well.

Individuals who experience genetic discrimination may also be covered under ADA if they are regarded as substantially limited in other major life activities besides working. It is unlikely that most plaintiffs will be able to establish the requisite proof to prevail on such claims. Most courts have interpreted "substantially limited" so restrictively that an individual must be extremely debilitated.[39] Moreover, the courts have interpreted ADA to require consideration of any measures that an individual takes to control the effects of her limitations.[40] Thus, it is unlikely that an individual with a genetic predisposition for a disease, but who has not actually developed the disease, will be able to show that he was regarded as substantially limited in any major life activity.

An individual who experiences genetic discrimination may also be covered by ADA under the first prong of the definition of disability—that is, by showing that she has an actual impairment that substantially limits her in a major life activity. In Bragdon v. Abbott,[41] the Supreme Court held that an individual with asymptomatic HIV was covered under the first prong because she was substantially limited in reproduction due to the risk of transmitting HIV to a fetus. The Court found that the asymptomatic HIV was a physical impairment based on the physiological effects of the infection. It is unclear, however, whether courts would find a genetic marker to constitute an actual impairment.

Even assuming ADA did apply, in many situations it might not prevent employers from accessing genetic information. While ADA does bar medical inquiries before a conditional offer of employment is made, it would permit employers to request genetic information if they could establish that the information was job-related and consistent with business necessity.[42]

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[34] EEOC v. Burlington Northern Santa Fe Railroad, Civ. No. 01–4013 MWB (N.D. Iowa Apr. 23, 2001) (Agreed Order). The Railroad, which had tested for carpal tunnel syndrome propensity, agreed to stop requiring genetic tests, using genetic information relating to its employees, and disclosing such information to the public.

[35] Congressional Research Service Report, supra note 4, at 9 (describing complaint filed by Terri Sergeant alleging a violation of ADA based on her termination after being diagnosed with Alpha 1 Antitrypson Deficiency).

[36] Id.

[37] 527 U.S. 471, 473–74 (1999).

[38] 527 U.S. 516, 516–17 (1999).

[39] For a discussion of how the courts have interpreted ADA far more restrictively than Congress intended, see Chai Feldblum, Definition of Disability Under Federal Anti–Discrimination Law: What Happened? Why? And What Can We Do About It?, 21 Berkeley Journal of Labor & Employment 91 (2000).

[40] Sutton v. United Airlines, Inc., 527 U.S. at 481–88; Murphy v. United Parcel Service, 527 U.S. at 521.

[41] 524 U.S. 624 (1998).

[42] 42 U.S.C. § 12112(c); Congressional Research Service Report, supra note 4, at 13.

The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) prohibits genetic discrimination by insurers in very limited circumstances. It prohibits group health plans from using any health status-related factor, including genetic information, as a basis for denying or limiting coverage or for charging an individual more for coverage.[43] However, a plan may still establish limitations on the amount, level, extent or nature of benefits or coverage provided to similarly situated individuals.[44] Thus, plans may still provide substantially fewer services even though they may not charge more for coverage. In addition, privacy regulations issued pursuant to HIPAA require patient consent for most sharing of personal health information by health insurers, providers, and health care clearinghouses. Companies that sponsor health plans are prohibited from accessing personal health information for employment purposes unless the patient consents. These provisions do little to prevent genetic discrimination in the workplace and, while they do prohibit some forms of genetic discrimination by insurers, that protection is extremely limited.

Title VII

Race and gender discrimination laws may apply to certain forms of genetic discrimination as well.[45] For example, Title VII of the Civil Rights Act of 1964, which prohibits employment discrimination based on race or gender, may prohibit employers from denying employment based on genetic markers linked to race, such as that for sickle cell anemia, or linked to gender, such as those for breast or ovarian cancer. Some courts have said in dicta that employment classifications based on sickle cell anemia would create a disparate impact on African Americans, but no lawsuit has successfully been brought challenging such classifications under Title VII.[46] At least one court has rejected such a claim.[47]

State Laws

A number of states have passed state laws that prohibit certain forms of genetic discrimination. These laws, however, vary widely in the scope of their protection.[48] Many are narrowly targeted to particular genetic conditions, some prohibit only certain types of screening but do not prohibit adverse employment actions based on genetic information, and some only address genetic counseling and confidentiality.[49] These laws have been described as "a patchwork of provisions which are incomplete, even inconsistent, and which fail to follow a coherent vision for genetic screening, counseling, treatment and prevention of discrimination."[50]

In light of the inadequacies of federal and state law to address genetic discrimination issues, comprehensive federal legislation that specifically addresses these issues is necessary.

Principles for Genetic Discrimination Legislation

NCD believes that it is crucial for any proposed legislation addressing genetic discrimination to reflect the following principles:

Workplace Discrimination:

Any proposed legislation must provide effective prohibitions against discrimination by employers based on genetic information. Employers must not be permitted to use predictive genetic information as a basis for hiring, firing, or taking any other employment action, or as a term or condition of employment. Nor should an employer be permitted to use this information, or be permitted to limit, segregate or classify employees or job applicants. This information should not be permitted to play a role in an employment agency's referral of individuals for employment; in decisions by a labor organization about admission to its membership; or in admission to or employment by a training program.

Collection and Disclosure of Genetic Information by Employers:

Any proposed legislation must contain strict limits on the collection and disclosure of genetic information by employers so as to prevent that information from being used for discriminatory purposes. Employers must not be permitted to collect ge-

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[43] 29 U.S.C. § 1182(a)(1), 1182(b)(1).
[44] Id. § 1182(a)(2)(B).
[45] See Gostin, supra note 8, at 109; Congressional Research Service Report, supra note 4, at 30 n.8.
[46] Gostin, supra note 8, at 138.
[47] Id. at 138–39.
[48] Joint Government Report, supra note 5, at 8.
[49] Gridley, supra note 1, at 980–81.
[50] Gostin, supra note 8, at 142.

netic information except under very limited circumstances that will be used only to benefit employees and only on a voluntary basis.

Specifically, employers should be permitted to request predictive genetic information only: (1) for the purpose of monitoring effects of toxic substances in the workplace, and only if an employee has provided written consent to such monitoring, the employee is informed of the results, the monitoring conforms to national standards, and the employer does not receive results for particular individuals but rather receives only aggregate results for all individuals monitored; and (2) for the purpose of providing genetic services to employees, but only if such services are provided with the employee's written consent and only the employee receives the results.

Additionally, employers must maintain strict confidentiality of genetic information of applicants or employees that is in the employers' possession. Genetic information should be kept confidential and maintained separately from personnel files and other non-confidential information. It should be disclosed only to the employee, to officials enforcing this legislation, or as required by other federal laws.

Insurance Discrimination:

Any proposed legislation should contain comprehensive protection against genetic discrimination by providers of health, life, disability, and other types of insurance. Legislation must bar insurers from making decisions about enrollment based on genetic information. It must also prohibit insurers from using genetic information in determining premium or contribution rates, or other terms or conditions of coverage. Finally, it must bar insurers from requesting or requiring an individual to undergo genetic testing.

Collection and Disclosure of Genetic Information by Insurers:

Any proposed legislation must prohibit insurers from requiring, requesting, collecting, or buying genetic information about individuals who are covered or seeking coverage.

Insurers should be permitted, however, to obtain this information only for the limited purpose of paying for claims for genetic testing or other genetic services. Strict protections must be in place to ensure that when such information is requested, it is not used to affect an individual's enrollment, premiums, or terms or benefits of coverage.

Insurers must also be prohibited from disclosing genetic information to health plans or issuers of health insurance (except in the limited circumstances described above where the information is used for purposes of payment of claims), employers, and entities that collect and disseminate insurance information.

Health Care Provider Discrimination:

Any proposed legislation should protect against genetic discrimination by health care providers. Health care providers must not be permitted to refuse treatment to individuals, or treat them differently, based on genetic information. For example, "futile care" policies, under which medically indicated treatments may be denied based on determinations that such treatments would be "futile" in light of an individual's expected quality of life, should be prohibited to the extent that they result in denials of treatment based on genetic information.

Collection and Disclosure of Genetic Information by Health Care Providers:

Any proposed legislation must prohibit health care providers from requiring, requesting, or collecting genetic information about individuals who are seeking treatment. Providers may only collect this information for the purpose of providing genetic testing or other genetic services.

Health care providers must not be permitted to disclose genetic information except to the patient, to insurers only for the limited purpose of seeking payment for genetic testing or genetic services rendered, to officials enforcing this legislation, or as required by other federal laws.

Education and Technical Assistance:

Any proposed legislation should include funding to permit education and technical assistance to be provided by appropriate organizations in order to ensure that individuals affected by the legislation are aware of its requirements. Such assistance is important to ensure effective enforcement of the legislation.

Effective Enforcement Mechanisms:

Any proposed legislation must contain a private right of action for individuals to enforce its provisions. Additionally, EEOC should have the authority to investigate and resolve complaints of violations of the employment provisions of the law. In

order to be effective, the legislation must provide for the full panoply of legal remedies, including attorney's fees.

Relationship to Other Laws:

Any proposed legislation must serve as a set of minimum standards that do not preempt more stringent standards that may exist in other laws. Thus, the legislation must not preempt stronger state laws. Similarly, it must not preempt other federal laws that may be applicable where those laws provide stronger protection against genetic discrimination.

Addressing Protections for Individuals with Actual Health Conditions:

As discussed above, courts have interpreted ADA in a number of ways that severely restrict the number of people protected.[51] They have interpreted ADA to protect only individuals who are so limited in major life activities that they are extremely debilitated, and to exclude protection for many individuals who take mitigating measures to control the effects of their impairments. They have made it extraordinarily difficult for individuals to establish that an employer regards them as substantially limited in working. These interpretations of ADA have resulted in far more limited protection than Congress envisioned when it passed ADA.

The same interpretations that make ADA difficult to enforce by individuals with genetic markers make it difficult to enforce by individuals with a range of health conditions. When Congress considers protections for individuals who experience discrimination based on genetic information, it should also ensure that if these individuals are eventually diagnosed with medical conditions, they will be protected against discrimination.

Statement of FORCE, Submitted for the Record

FORCE: Facing Our Risk of Cancer Empowered is a national organization representing the concerns of the estimated 500,000 Americans with hereditary predisposition to breast and ovarian cancer. Our organization urges the House to vote on S.1053, the Genetic Information Nondiscrimination Act. Our members are concerned citizens who have been impacted by hereditary cancer. They favor passage of this comprehensive bill to protect individuals from insurance and employment discrimination on the basis of predictive genetic test results.

Current laws such as HIPAA do not go far enough to protect citizen's rights. The general population still feels vulnerable to the possibility of discrimination. By passing this bill, Congress will be making a strong statement that discrimination based on genetic information is unacceptable. As genetic research progresses and more disease-predisposing genes are identified, it is important that genetic discrimination is outlawed. Individuals who have already had gene testing and those who might choose to be tested in the future must be protected from possible discrimination.

Genetic testing is improving the lives of thousands of Americans, providing information on how to prevent future health problems, and cope more effectively with unavoidable conditions. Nevertheless, under current law, many people are afraid to be tested or to participate in research that will lead to better prevention and treatment of diseases. They fear that their genetic information will be misused by employers and health insurers.

Our organization strongly endorses the passage of a comprehensive federal legislation to prohibit genetic discrimination in health insurance and employment. We urge the House of Representatives to call a house vote on S1053. Passage of a nondiscrimination bill will save lives by removing a significant barrier to patients availing themselves to genetic testing.

Thank you in advance for your consideration of this matter. We hope that you will keep the best interests of your constituents in mind and take immediate action to pass this bill.

Statement of the Association of Women's Health, Obstetric and Neonatal Nurses, Submitted for the Record

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to comment on the issue of Genetic Discrimination. AWHONN is a membership organization of 22,000 nurses whose mission is to promote the health of women and newborns.

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[51] See Feldblum, supra note at 39.

AWHONN members are registered nurses, nurse practitioners, certified nurse-midwives, and clinical nurse specialists who work in hospitals, physicians' offices, universities and community clinics across North America as well as in the Armed Forces around the world.

Last October the United States Senate took historic action when it passed S.1053, the "Genetic Information Nondiscrimination Act" by a margin of 95–0. The bill's passage was the result of years of hard work and bi-partisan compromise. The legislation establishes strong protections against discrimination based on genetic information both in health insurance and employment.

The bill prohibits health insurance enrollment restriction and premium adjustment on the basis of genetic information and prevents health plans and insurers from requesting or requiring than an individual take a genetic test. The bill also prohibits discrimination in hiring, compensation and other personnel processes, prohibits the collection of genetic information and covers employers, employment agencies, labor organizations and training programs.

The benefits of genetic testing are enormous and science is revealing genetic markers for many different ailments at an increasing rate. Research has already identified genetic markers for conditions including cancer, diabetes, Alzheimer's disease, Huntington's Disease and cystic fibrosis.[1] Unfortunately, the same science that can help reveal an individual's predisposition to certain health problems may also open the door to discrimination. No individual should have to choose between the benefits of genetic testing and keeping a job or health insurance.

The House needs to take immediate steps to act on this legislation—the fear of genetic discrimination has prompted many Americans to avoid genetic tests that could literally save their lives. By providing patients with this type of health information, we empower them to seek appropriate treatment options and/or lifestyle changes that can prevent disease onset. As a nursing organization whose mission is advancing women and newborn health, AWHONN recognizes the need for comprehensive federal legislation that protects individuals from genetic discrimination and believes that the "Genetic Information Nondiscrimination Act" passed by the Senate will provide strong protection against access to and misuse of genetic information.

The House must act now and take action on the Senate version of the "Genetic Information Nondiscrimination Act" to help secure the health and well-being of all Americans.

Thank you for the opportunity to submit testimony on this crucial legislation.

Statement of the American Society of Human Genetics, Submitted for the Record

The American Society of Human Genetics (ASHG) has endorsed the passage of federal legislation to prohibit discrimination in health insurance and employment on the basis of genetic information. ASHG commends the bipartisan enthusiastic passage of S. 1053 last year in the Senate, and urges similar House action.

ASHG is the primary professional organization for human genetics in the Americas, representing nearly 8000 researchers, physicians, laboratory practice professionals, genetic counselors, nurses, and trainees actively engaged in genetics discovery, teaching and the development of health care applications and services derived from research findings.

Our members are keenly aware of the challenges faced by individuals and families involved in genetic evaluation and diagnostic procedures at the rapidly evolving interface between biomedical research and health care. Many of us have personally experienced cases in which testing or its outcome led to adverse effects on insurance or employment. While the number of publicly documented cases of discrimination based on genotype may be considered small at this time, the rapid advances being made in genetics will provide more opportunities for persons to be adversely affected by test results. The potential misuse of genetic information by insurance companies and employers has also been an impediment in recruiting subjects for some research studies.

From the geneticist's point of view, the absence of a federal standard that prohibits employment and health insurance discrimination based on genetic information results in:

1. difficulty in recruiting subjects into genetic research studies
2. patient avoidance of genetic services

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[1] Mary Davidson testimony—cancers, Alzheimers. For CF, see i.e http://odp.od.nih.gov/consensus/cons/106/106statement.htm.

3. underutilization of genetic testing
4. difficulty in obtaining insurance coverage when attempted
5. several cases recognized that have not resulted in legal action
6. significantly increased time and effort in genetic evaluation and counseling sessions resulting in increased service costs

Many states have enacted some form of genetic non-discrimination legislation, but the laws are quite varied in their focus and scope. Federal legislation would assure individuals and families in our mobile society that neither health care coverage nor employment status would be jeopardized by their participation in genetic testing. Such protection will eliminate some of the concerns (real or perceived) that have deterred participating in genetic research studies or seeking genetic testing. This protection will speed the progress in understanding genetic disease and how we can prevent or treat these disorders.

We appreciate the opportunity to comment on this important issue, and will work with you and your staff on any details necessary to accomplish the task.

Statement of the American Osteopathic Association, Submitted for the Record

The American Osteopathic Association (AOA) represents the nation's 54,000 osteopathic physicians. The AOA is pleased that the Subcommittee on Employer–Employee Relations of the House Committee on Education and the Workforce is holding a hearing on genetic nondiscrimination. It is an issue that will increasingly affect patients and physicians as further advances are made in the field of genetic testing.

In 1997, the AOA House of Delegates adopted a policy prohibiting discrimination in employment, insurance, coverage, and access to care based on genetic information. The policy was reaffirmed in 2002.

The completion of the Human Genome Project and genetic testing are contributing to advances in medical knowledge that hold great promise for the future in diagnosis, management, and treatment of the human condition. However, such knowledge can also provide the basis for unethical and discriminatory behavior in employment and insurance coverage.

It is the position of the AOA that access to health care should not be restricted on the basis of genetic testing and that discrimination in employment on the basis of genetic testing should be prohibited. Furthermore, health care plans should be prohibited from restricting or denying coverage or raising premiums on the basis of genetic testing.

We believe that patients must be able to discuss genetic testing options with their osteopathic physicians without fear of discrimination from employers, potential employers, or health care plans for having undergone such genetic testing or participating in clinical trials to test new therapies. We are concerned that there is no law on the books to prevent such discrimination.

For the past several years, the AOA sent letters in support of genetic nondiscrimination legislation. Most recently, letters were sent to Senator Snowe (R–ME) in support of S.1053 that passed the Senate last year and Representative Slaughter (D–NY) in support of H.R.1910.

As physicians, we understand the value of genetic research, testing, and therapy in the diagnosis and treatment of certain diseases. Our patients should not forego genetic testing or promising therapy out of fear of discrimination. We urge the House of Representatives to pass genetic nondiscrimination legislation. President Bush stated publicly that he supports S.1053 and is committed to enacting legislation to prohibit genetic discrimination in health insurance and employment.

The President and the Senate have acted. It is now time for the House to act.

Statement of The American Psychiatric Association, Submitted for the Record

The American Psychiatric Association (APA), the national medical specialty society, founded in 1844, whose over 35,000 psychiatric physician members specialize in the diagnosis and treatment of mental and emotional illnesses and substance use disorders, appreciates the opportunity to provide a statement on genetic non-discrimination. We thank the Committee for allowing us to provide this statement.

Genetic testing offers tremendous promise in identifying current and potential future health risks. At the same time, we have significant concerns that Americans' genetic information could be misused. Our concerns are shared by a strong majority of Americans: a U.S. Department of Labor survey showed that 63 percent of re-

spondents would refuse to take a genetic test if insurers or employers could access their private results.

We believe Congress can help by passing the strongest possible enforceable genetic non-discrimination legislation. Employers and insurers should not be permitted to discriminate on the basis of a person's genetic profile and family history.

Our concerns extend beyond patients' reluctance to take a genetic test. Such reluctance means that people are disinclined to participate in clinical studies that require genetic testing, hurting our efforts to identify causes and new treatments for diseases, including mental illnesses. Worse, some patients' reluctance could keep them from getting a proper diagnosis today, as well as potentially life-saving treatment. Perhaps the most pernicious potential consequence of not enacting a ban on genetic discrimination is that Americans could lose their jobs or their health insurance, based simply on their family history.

Protecting patients' genetic information is essential to providing the highest quality medical care. We believe a patient's genetic information should only be used or disclosed by a health care plan, provider, or clearinghouse with the informed, voluntary, and non-coerced consent of the patient. As our knowledge of genetics grows, especially through the Human Genome project, the possible misuses of genetic information will expand unless enforceable safeguards are enacted.

The U.S. Senate voted 95–0 to pass the "Genetic Information Non-discrimination Act of 2003" (S. 1053), with the support of President Bush. Similar but stronger legislation (H.R. 1910) is now cosponsored by 241 members of the House. Both bills would ban employers and insurers from discriminating on the basis of a person's genetic profile and family history. APA urges Congress to pass and the President to sign the strongest possible enforceable genetic non-discrimination legislation into law.

Thank you for this opportunity to deliver this statement. Please call on the APA as a resource, as we would be happy to assist the Committee on the vital issue of genetic non-discrimination in any way.

Statement of the American Cancer Society, Submitted for the Record

Genetic research is one of the most exciting areas of scientific advancement today. As our knowledge about the genetic basis of common disorders grows, however, so does the potential for discrimination in health insurance and employment. This possibility can have a dramatic and chilling impact on patient care and research. For example, a genetic test exists for inherited breast cancer that allows healthy, high-risk women to find out whether they carry the altered gene so they can determine with their doctor whether to pursue available medical options. Unfortunately, many of these women may choose not to be tested for fear that the information could be used to deny them the health insurance coverage they need to fight disease or to deny them future employment.

We need legislation that allows medical research to advance, while at the same time protects the rights and needs of patients and their family members. The American Cancer Society endorses the "Genetic Nondiscrimination in Health Insurance and Employment Act" now pending in the House (H.R. 1910) and its companion "Genetic Information Nondiscrimination Act" (S. 1053) in the Senate. These bills support the goal of allowing people to benefit from advances in genetic testing without fear of losing their heath insurance or job opportunities.

Specifically, the legislation prohibits health insurance companies from denying or canceling health coverage on the basis of genetic information, using genetic information to determine insurance rates, and requesting or requiring genetic information or genetic tests. Decisions about genetic testing and results from genetic testing should be made by patients and their health care providers, without fear of negative consequences. The bills also provide important workplace protections, prohibiting employers and employment organizations from using genetic information as a means to deny or limit employment for individuals who they suspect may have an inherited predisposition to disease.

The Senate has already taken a strong stand on the need for this type of legislation, passing S. 1053 overwhelmingly by 95–0 vote in October 2003. The American Cancer Society urges the House to take prompt action on this important legislation to ensure that critical patient protections are enacted before the end of this Congress.

Letter from Lawrence Lorber Answering Follow-Up Questions, Submitted for the Record

August 4, 2004

Mr. Sam Johnson, Chair
House Subcommittee on Employer-Employee Relations
2181 Rayburn House Office Building
Washington, DC 20515

Mr. Rob Andrews, Ranking Member
House Subcommittee on Employer-Employee Relations
2181 Rayburn House Office Building
Washington, DC 20515

RE: **Genetic Non-Discrimination: Examining the Implications for Workers and Employers**

Dear Chairman Johnson and Ranking Member Andrews:

Thank you for inviting me to testify at last week's hearing on "Genetic Non-Discrimination: Examining the Implications for Workers and Employers." I hope my testimony will assist Congress in its deliberations over this important issue.

I want to follow up on two questions asked of me during the hearing.

First, Mr. Andrews asked if the U.S. Chamber of Commerce took the position that the Employee Retirement Income Security Act preempts state statutes regulating the privacy of genetic information. ERISA governs employee benefit plans and preempts state laws that relate to an employee benefit plan. In circumstances where ERISA preempts, however, employees would be entitled to protections offered by the Health Insurance Portability and Accountability Act (HIPAA) regulations, as HIPAA is part of ERISA. Outside of the employee benefits context, state laws would not be preempted by ERISA, and thus, to the extent they are otherwise lawful, state genetic privacy laws would continue to regulate collection and use of genetic information in the employment relationship.

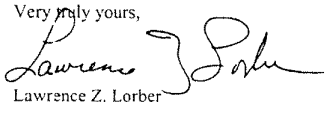
It is worth noting again, as I testified during the hearing, that we do believe any law Congress might choose to enact governing genetic privacy in the employment context should preempt these laws with regard to their applicability to the employer-employee relationship in order to simplify the handling of genetic information and avoid redundant but differing requirements. The plethora of laws impacting the workplace in this area will not serve the purposes of any legislation and will only serve to confuse compliance and increase unnecessary and wasteful litigation.

Second, Mr. Payne asked whether the Chamber supports the Equal Employment Opportunity Commission's guidance on genetics and the workplace. While we have no current objections to the EEOC's guidance, to a great extent the Chamber's position will depend on the agency's future interpretations and enforcement positions. Since employers are not engaged in collection or misuse of genetic information, nor have any apparent intention to do so, there has been little opportunity for the EEOC to enforce its guidance, so it remains to be seen how the agency will apply the Americans with Disabilities Act with respect to genetics and as to how the statute is interpreted in the broader context. The Chamber respects EEOC's role as an agency tasked with interpreting and enforcing the employment provisions of the ADA and looks forward to working with it as it shapes its enforcement position on this important issue.

I request this letter be submitted for the hearing record.

Again, thank you for inviting me to testify on this important issue.

Very truly yours,



Lawrence Z. Lorber

/vh

Statement of Hon. Newt Gingrich, Former Speaker, U.S. House of Representatives, Submitted for the Record

Fifteen years ago, Congress launched and sustained the Human Genome Project for which it deserves enormous credit. Despite the skepticisms of many in the scientific community, Congress supported this ambitious scientific quest because it believed that it was not only doable but held enormous potential to transform healthcare. Indeed, the successful sequencing of the human genome represents a breathtaking leap forward in our understanding of biology. This landmark accomplishment in the history of bioscience was completed last year not only ahead of schedule but also under budget. Yet, it is only the beginning and many are still fearful of the potential consequences of this advancement.

Because of Congress' leadership, we now stand poised on the threshold of a new era in science and medicine - the genomic era. Already, over 1,000 genetic tests are now available that have the potential to save lives by helping shape an individual's healthcare decisions. For example, individuals with a strong family history of colon cancer can be tested to assess their personal risk. If an elevated risk is confirmed, screening for precancerous polyps can be initiated at a much earlier age than usually recommended. Critical dietary changes can also be made to lower the risk of cancer. Recently, it was reported that women who carry mutations in the genes known as BRCA1 and BRCA2 face an increased risk for breast cancer. Again, genetic testing can reveal these mutations and lead to earlier detection and intervention and thus increase the likelihood of a better health outcome.

Genomics research has also already shed light on the causes of other common conditions, such as Alzheimer's disease, Parkinson's disease, schizophrenia, heart disease, diabetes, and obesity. This is but a hint of the medical benefits to come. It is clear that the current trajectory of U.S. medical costs, based on the model of treating disease once it has fully developed, is on a collision course with fiscal realities. Genomic medicine offers one of the best hopes for not only saving lives but also saving money. Understanding how our genes predispose us to develop various illnesses will lead to effective individualized prevention strategies, more accurate diagnostics, accurate prediction of drug efficacy or toxicity, and innovative treatments with better outcomes.

The dawn of the genomics era is not all rosy, however. Many surveys have documented that the American people reasonably fear discrimination based on their individual genetic makeup and the denial of either health insurance or employment. Many Americans simply will not take advantage of the tools of genomics for fear their medical privacy might be compromised, thus putting their own health and lives at risk. In order to realize the full life saving potential of the Human Genome Project, Congress should put this fear to rest.

After nearly six years of bipartisan effort to protect Americans from discrimination based on genetic information, in October of this year, the Senate unanimously (95-0) passed the Genetic Information Non-Discrimination Act of 2003 (S.1053), legislation that offers the American people appropriate protection against misuse of their genetic information. The President has endorsed this legislation banning genetic discrimination, but the House of Representatives has yet to pass this bill.

While there are already examples of genetic discrimination in health insurance and in the workplace, fortunately they are, thus far, few. Unless the House acts now, however, such examples will inexorably grow more and more numerous. It is time for the House to reap the full benefits of what they sowed over a decade ago by passing this legislation. Doing so will allow the American people to realize the promise of the project in their own lives, and the lives of their families.

Congress did not support the Human Genome Project just so that we could know the sequence of the human genome. It did so in the expectation that this knowledge would in turn lead to new discoveries and applications that could dramatically improve human health. Now that the Human Genome Project is completed, the American people have a right to expect that their investment in it will lead to better health--as soon as the House acts, it will.

Statement of Hon. Louise McIntosh Slaughter, a Representative in Congress from the State of New York

Mr. Chairman, I appreciate this opportunity to submit testimony for this hearing, "Genetic Non-Discrimination: Examining the Implications for Workers and Employers." I hope very much that this hearing will lead to speedy and decisive passage of strong genetic nondiscrimination legislation.

Ten years have now passed since the world was electrified by the discovery of the first genetic mutation linked to breast cancer in 1994. In that short decade, scores more genetic links to disease have been identified, dozens of genetic tests have become commercially available, and genetic technology has become firmly embedded in the practice of medicine.

As technology has raced ahead, ethical, legal, and social challenges have presented themselves. We are now faced with critical questions about how we, as a nation, will allow genetic information to be handled and used. Genetic issues are insinuating themselves into not only health care decisions, but into many other facets of Americans' lives. Witness the following:

- Under a program called Dor Yeshorim, Hasidic youth take a battery of genetic tests to determine whether they are carriers for any of ten serious genetic disorders. Young men and women who are both carriers for a given disorder are discouraged from courting each other, based on the fact that there would be a 25% chance that their children would be born with a genetic disorder.
- Advertisements for genetic tests for paternity can be seen in newspapers and roadside billboards.
- Certain fertility programs are permitting parents to select the gender of implanted embryos under some circumstances.

Congress must be at the forefront this national debate, deliberating and crafting policies that will allow science and health care to realize the full potential of genetic research while prohibiting the abuse of genetic information. Unfortunately, the House of Representatives has failed to fulfill this duty. In fact, the House has all but abdicated its central role in this debate, largely failing even to hold hearings into these controversial matters, much less pass legislation.

Almost nine years ago, I introduced the first legislation in Congress to ban genetic discrimination in health insurance. I considered the bill to be a simple, straightforward, noncontroversial proposal that would pass easily. I could hardly have imagined that six years would pass before the House held the first hearing on the issue, and far more than that without any meaningful action at all. At this point, it looks all but certain that the 108th Congress will also adjourn without acting on genetic discrimination.

Genetics – A Primer

No human being has a perfect set of genes. In fact, every one of us is estimated to be genetically predisposed to between 5 and 50 serious disorders. Every person is therefore a potential victim of genetic discrimination.

Simply carrying a given genetic mutation almost never guarantees that one will fall ill, however. A genetic flaw simply confers a level of risk upon the carrier. Today, with our knowledge of genetics still in its infancy, scientists have only a rudimentary understanding of how much additional risk a genetic mutation may carry. We have virtually no understanding of how environmental factors – such as diet, smoking, and exposure to chemicals or radiation – interact with genetics to cause disease.

Given that scientists cannot accurately predict when or whether a carrier will develop a genetic disorder, it seems ludicrous to allow this information to be used by health insurers or employers to discriminate. An insurance bureaucrat or human resources professional would be as accurate with a dartboard as with a genetic test result in predicting who will get sick.

Genetic Discrimination – Cases and Fears

Some have called the legislation in Congress "a solution in search of a problem" because they state that genetic discrimination is rare, if it happens at all. Unfortunately, genetic discrimination is occurring:

- In 2000, the Burlington Northern Santa Fe Railroad performed genetic tests on employees without their knowledge or consent. The workers involved had applied for workers compensation, and the tests were being done in hopes of undermining their claims.

- A Kentucky family was denied health insurance for their children because they were known to be carriers for a genetic disorder – even though they did not have the two copies of the mutation required to become ill.
- A North Carolina woman was fired after a genetic test revealed her risk for a lung disorder and she began the treatments that would keep her healthy.
- In the early 1990s, Lawrence Livermore Laboratories in Berkeley was found to have been performing genetic tests on employees without their knowledge or consent for years.
- In the 1970s, many African Americans were denied jobs and insurance based on their carrier status for sickle cell anemia – again, despite the fact that a carrier lacks the two copies of a mutation necessary to get sick.

It is imperative that Congress stop this practice before it becomes widespread. Moreover, the fear of genetic discrimination is playing a major role in many patients' decisions about whether to take a genetic test or participate in genetic research. A survey of 159 genetic counselors found that 108, or 68%, would not seek insurance reimbursement for a genetic test for breast or colon cancer due to the fear of discrimination. Sixty percent would not share the information with their colleagues due to the fear of discrimination in the workplace. Several other studies have shown that the fear of discrimination plays a significant role in decisions about whether to take a genetic test, whether to do it under one's own name, paying out of pocket versus seeking insurance reimbursement, and with whom the information would be shared, including health care providers, coworkers, and family members.

House Legislation, H.R. 1910

I am proud to be the author of H.R. 1910, the Genetic Information Nondiscrimination in Health Insurance and Employment Act. This legislation currently has the support of 242 bipartisan Members of Congress and has been endorsed by over 300 organizations that care about health issues. Despite this broad support and an aggressive grassroots campaign, the House has taken no action on H.R. 1910. In April, an article in *Congress Daily AM* described the lack of action on this legislation as "a textbook case of obstruction by inertia." The article also identified the U.S. Chamber of Commerce as the primary interest group lobbying Congress not to take up this bill.

Senate Action

Throughout the first half of the 108th Congress, a group of committed Senators came together to negotiate a compromise genetic nondiscrimination bill. Under the leadership of Democratic Leader Tom Daschle, Majority Leader Bill Frist, Health Committee Chairman Judd Gregg, Health Committee Ranking Member Edward Kennedy, Senators Olympia Snowe and Tom Harkin, among others, the Senate produced a mutually agreed-upon version of the legislation. In October 2003, the Senate passed S. 1053, the Genetic Information Nondiscrimination Act, by a unanimous 95-0 vote. The White House issued a Statement of Administration Policy expressing its support for this legislation.

Here in the House, S. 1053 has not even been referred to committee. Instead, it has been held at the desk for the past nine months at the direction of the House leadership. Even if this committee were interested in taking up S. 1053, it would be unable to do so because the bill is not actually in the committee's possession.

Myths About Genetic Discrimination Legislation

Those opposing S. 1053 and H.R. 1910 have made a number of arguments in opposition. I have reviewed these concerns at some length and would like to share my conclusions.

1. There is no evidence that employers or insurers are, in fact, engaging in discrimination based on genetic makeup.

Several cases have emerged where employers did indeed engage in genetic discrimination or attempted to do so.

Congress should not wait to act until hundreds or thousands of people have experienced genetic discrimination. Today, the opportunities for genetic discrimination are limited precisely because *people are not taking genetic tests for fear that this information will be used against them.* By doing so, however, they are denying themselves valuable information that they could use to make important health care decisions.

*2. **Genetic information can be useful in making some employment decisions.** For example, a health condition likely to cause seizures could properly be considered a threat to others if the employee were a bus driver or an airline pilot.*

Scientists and geneticists have been unable to identify any existing genetic test that would guarantee that a person would develop a condition that would pose a significant danger to others. A genetic mutation only confers a higher risk of developing a disorder; it is not a guarantee. Moreover, few such conditions develop in adulthood suddenly or without warning. Should such a genetic test exist in the future, however, the legislation passed by the Senate would permit employers to test workers and make decisions in accordance with any guidelines produced by OSHA.

Expecting a human resources professional to interpret a genetic test accurately is about as realistic as asking them to predict the weather for May 2009. The vast majority of genetic tests have no bearing whatsoever on an individual's ability to perform the duties of his or her job today. Employers should not be permitted to deny job opportunities to entire categories of workers on the theory that a person *might* get sick *someday.*

*3. **It's too difficult for employers to comply with 50 different state laws.** If Congress enacts legislation barring employment discrimination based on genetic information then it should include a safe harbor providing that employers in compliance with the federal standards cannot be liable under state or local laws banning such discrimination.*

A federal law can provide valuable uniformity, but it does not have to trample states' rights in the process. At present, over 30 states have passed laws dealing with some aspect of genetic discrimination, but they are a patchwork of different definitions, standards, and remedies. A federal "floor" would provide a coherent national statement of policy while allowing states to pass additional protections for their residents if they so chose. This is the same model followed by civil rights laws, the Health Insurance Portability and Accountability Act (HIPAA), and numerous others.

Congress has a long history of avoiding state pre-emption whenever possible in deference to states' rights. If a given state wishes to be more explicit or extensive in banning genetic discrimination, it should have the right to do so.

*4. **It makes sense to allow a genetic nondiscrimination law to expire.** Any federal legislation should include a sunset date at which time Congress can decide how effectively the law has worked and whether it should be reauthorized.*

Congress routinely uses its committee oversight and hearing processes to examine whether existing laws need to be updated or changed. A sunset could only create a dangerous situation where the law would lapse and genetic discrimination would become legal after a period of being banned.

No major law protecting Americans' rights has ever contained a sunset – including the Americans with Disabilities Act, the Civil Rights Act of 1964, or the Health Insurance Portability and Accountability Act. There is no reason why genetic discrimination should be banned only temporarily.

*5. **A genetic nondiscrimination law can be effective if it only protects the genetic information of immediate relatives.** Genetic discrimination should only be illegal if the employer has direct knowledge of the history of an immediate family member related by blood, not more distant relatives.*

If an employer engages in genetic discrimination, it should not matter how close or distant the blood relationship is. The legislation before Congress does not penalize employers from coming into possession of family medical history or other genetic information inadvertently. It does, however, prohibit the employer from using that information to discriminate. If all genetic information is not protected, Congress could create a perverse loophole that would allow employers to discriminate based on the genetic mutations of distant relatives, but not close ones.

The Senate-passed bill would not outlaw a casual workplace conversation where someone mentions that an uncle or cousin died of cancer. But it would bar employers from using that information in decisions about hiring, firing, promotions, and other job-related benefits.

*6. **Only actual genetic tests should be protected.** A bill should focus on employment discrimination based on genetic tests, not family history.*

There is no reason to allow employers to discriminate based on an individual's family medical history. A healthy worker should not be denied jobs or opportunities based on a relative's health status. The fact that a person's parent, cousin, or great-uncle died of cancer or Alzheimer's should be irrelevant to an employer.

As stated above, the bills before Congress would not outlaw a casual workplace conversation about a relative's illness. But employers would be prohibited from using that information in determining the terms and conditions of employment.

Conclusion

Mr. Chairman, Congressional action on genetic discrimination is long overdue. This body is doing a tragic disservice to the people we are sworn to serve by allowing this practice to continue. I appreciate your effort to bring attention to this issue by holding today's hearing; however, that effort will be wasted if it is not followed by rapid action to pass a strong genetic nondiscrimination law like S. 1053 or H.R. 1910.

The American people desperately want these protections in federal law. The Genetics & Public Policy Center at Johns Hopkins University recently released a set of surveys on the public's views about the privacy of genetic information. In 2002, 85% of those surveyed did not want employers to have access to their genetic information. By 2004, that number had risen to 92%. In 2002, 68% of those surveyed said their genetic information should be kept private from health insurers; by 2004, it had increased to 80%. Clearly, overwhelming majorities wish to keep this information out of the hands of insurers and employers, who may use it to undermine rather than advance an individual's best interests.

The arguments against this legislation are no more than delaying tactics. I call upon the House leadership to recognize them for the red herring they are, and to move ahead aggressively on this issue. Surely we will not make the American people wait another year before they can take a genetic test with full peace of mind. Surely we will not force people to deny themselves valuable health information because of their fear of discrimination!

I look forward to working with the members of this subcommittee and all other interested parties of good will to enact S. 1053 to protect all Americans against genetic discrimination in health insurance and employment. Again, Mr. Chairman, thank you for this opportunity to add my voice to the millions of others calling for action on genetic discrimination.

U.S. Senator Judd Gregg, Chairman

Senate Committee on Health, Education, Labor and Pensions

July 21, 2004 **CONTACT:** Gayle Osterberg/202-228-4729

GREGG PUSHES PATIENT PROTECTIONS FROM GENETIC DISCRIMINATION

WASHINGTON – Sen. Judd Gregg, Chairman of the Senate Committee on Health, Education, Labor and Pensions, today urged Congress to move forward on legislation prohibiting genetic discrimination, and applauded the House Education and Workforce Committee for holding a hearing the subject.

"Fear of discrimination threatens society's ability to use new genetic technologies to improve human health and the scientific community's ability to conduct research needed to understand, treat and prevent disease," Gregg said. "Legislation passed by the Senate last year provides substantive protections to individuals who may suffer from genetic discrimination now and in the future and establishes clear, common sense rules that will prevent confusion, litigation and, most importantly, discrimination.

"It is truly the first civil rights act of the 21st Century."

The Senate passed Gregg's Genetic Information Nondiscrimination Act 95-0 in October of 2003. Gregg will submit a statement for the record at a hearing to be held July 22 by the House Subcommittee on Employer-Employee Relations.

The Gregg bill would:

- Establish privacy protections governing genetic information in the workplace and in health insurance underwriting.

- Prohibit employers from hiring and firing based on genetic information.

- Prohibit health insurance plans from denying eligibility or enrollment based on genetic information, and prohibit plans from charging higher premiums based on the genetic information of individuals or their families.

U.S. Rep. Louise M. Slaughter
28th Congressional District of New York

PRESS RELEASE

2469 Rayburn House Office Building, Washington D.C. 20515 http://www.louise.house.gov

FOR IMMEDIATE RELEASE:
July 21, 2004

CONTACT: Megan Thompson
202-225-3615

REP. SLAUGHTER: REAL ACTION STILL NEEDED ON GENETICS LEGISLATION

Washington, DC – U.S. Rep. Louise M. Slaughter (D-NY28) today acknowledged that the House Committee on Education and the Workforce Subcommittee on Employer-Employee Relations hearing on genetic non-discrimination will help continue to call attention to this important issue, but expressed disappointment that more is not being done. As the lead sponsor of the Genetic Information Nondiscrimination in Health Insurance and Employment Act, Rep. Slaughter warned that real action on the bill is still needed.

"I hope that this hearing leads to serious action, but I am not optimistic," said Rep. Slaughter. "We have had the better part of a year since Senate passage to vote on this bill and make it law. Instead, all we will have done is hold one hour hearing at the eleventh hour. I am disappointed that it appears that nothing more will be done on this vitally important bill before the end of this session.

"Passing this bill should be neither controversial nor partisan. The bill, which passed the Senate unanimously last October, is supported by a majority of Members of Congress, over 200 advocacy groups and President Bush. It is unbelievable to me that the leadership in the House is ignoring the clear will of Congress and the people by refusing to take up and pass this bill. We cannot squander the chance to prevent this insidious form of discrimination. Everyday we hear of more medical breakthroughs that will improve and save lives. But they are meaningless if Americans cannot fully take advantage of them for fear of reprisal."

Rep. Slaughter, a microbiologist with a Master's Degree in Public Health, has led the fight in the House to pass legislation to ban genetic discrimination since 1995. Her bill, H.R. 1910, has 242 bipartisan co-sponsors and is supported by over 300 organizations. The Genetic Information Nondiscrimination in Health Insurance and Employment Act would prevent health insurers and employers from discriminating against patients and employees based on genetic information. The bill would prohibit health insurance companies from denying coverage or adjusting premiums based on genetic information and would ban them from requiring genetic testing or genetic information. The bill would also prevent employers from making hiring and compensation decisions based on genetic information and would allow genetic testing only for the purpose of monitoring hazardous workplace exposure.

In anticipation of the hearing, the National Partnership for Women and Families issued a report, "Faces of Genetic Discrimination: How Genetic Discrimination Affects Real People," which contains testimony from medical professionals, patients and others about the need for protections against genetic discrimination. "This document clearly shows that our bill is not a solution searching for a problem," said Rep. Slaughter. "Genetic discrimination is already happening, and the fear of discrimination is playing a key role in people's health care decisions. I call on the leadership of the House to take up this bill and pass it immediately. We cannot continue to jeopardize the quality of our health care and American lives."

Statement of the Ovarian Cancer National Alliance, Submitted for the Record

On behalf of the Ovarian Cancer National Alliance, I am submitting these remarks to the Education and the Workforce Subcommittee on Employer-Employee Relations to indicate our support of moving federal genetic nondiscrimination legislation forward now so that no one will have to forgo the potential benefits of genetic testing for fear of losing their job or health insurance.

As you may know, ovarian cancer is the deadliest of gynecologic cancers, because the vast majority of cases are not detected until advanced stage, when survival is only about 25 percent. However, when detected early, ovarian cancer survival improves to 90 percent. This toll is harsh on the 25,580 women and their families who each year receive a diagnosis of ovarian cancer. Without an early detection screening tool for ovarian cancer, there are very few options that healthy women have to learn whether or not they have or will potentially get ovarian cancer. Genetic testing is one of these few options.

For women with a family history of breast or ovarian cancer, getting a genetic test to find out if they are BRCA1 or BRCA2 positive can give them valuable information about their potential risk. Once equipped with this genetic information, women can make more informed decisions about their healthcare.

Even with these known benefits, many women opt not to get genetic testing in the first place due to the out-of-pocket costs and the fear that employers and insurers could potentially use their genetic information in ways that could harm their ability to get work and health coverage. If the decision has been made to actually get the test, women must then face an additional series of difficult choices, depending on the outcome of the test. Prophylactic surgery is not an easy choice for women who have no definitive way of knowing whether or not they will ever get ovarian or breast cancer. Placing family members in a position where they will have to make similar choices about testing, does not help make the decision to get tested initially any easier for women. The concern that genetic information could be accessed and used by an employer or health insurer to deny coverage or influence hiring practices - because there are no federal protections preventing them from doing so - should not be an additional factor for women who already have such difficult decisions to make.

The Senate took a historical step forward in helping patients take advantage of America's advancing medical technologies when they passed the Genetic Information Nondiscrimination Act of 2003 (S.1053). This measure is a significant advance that will move us toward the day when citizens do not have to fear that private genetic information will be used to deny them jobs or insurance coverage. Currently, 36 states have patchwork genetic protection laws, in addition to federal employees – many of these laws are ineffective and weak on protections. Federal protections are needed in order to effectively mandate protections for patients' genetic information.

With overwhelming support for genetic non-discrimination legislation demonstrated in both Houses of Congress, the Alliance urges key Leadership in Congress and the Administration to pass a comprehensive bill before the session ends.

The Ovarian Cancer National Alliance, formed in 1997, is the creation of leaders from the growing number of ovarian cancer groups across the country. These groups united to establish an umbrella group, the Alliance, because we believed that it was essential to have a coordinated, professionally managed effort to put ovarian cancer policy, education and research issues squarely on the agenda of national policy makers and leaders in women's health. Today, our network of survivor and advocacy partners across the country represent tens of thousands of women in scores of communities across the country. Together we are working to raise awareness by educating women, health care providers and policy makers about ovarian cancer and most importantly, we are united in our efforts to bring more attention to the need for more research funding, in order to find an early detection tool, more effective treatments and ultimately a cure for this deadliest of gynecologic cancers.

Statement of the Catholic Health Association, Submitted for the Record

The Catholic Health Association (CHA), the national leadership organization of more than 2,000 Catholic health care sponsors, systems, facilities, and related organizations, would like to commend the House Education and Workforce Subcommittee on Employer–Employee Relations, and its chairman, Representative Sam Johnson, for holding a hearing on the problem of genetic nondiscrimination.

As the Subcommittee is no doubt aware, last year the United States Senate overwhelmingly passed the Genetic Information Nondiscrimination Act of 2003 (S 1053). CHA strongly supports this legislation, which we believe would serve as an important compliment to other federal and state laws that recognize the need to protect an individual's genetic information from being used in a discriminatory manner in the health insurance and employment markets.

Specifically, the bill would:

- Prohibit health insurers from restricting enrollment or adjusting fees on the basis of predictive genetic information
- Bar health insurers and employers from requiring genetic testing and from obtaining predictive genetic information
- Prevent employers from discriminating based on genetic information in all areas of employment, including hiring and compensation

Genetic science has seen marvelous growth over the past several years, and Catholic social teaching validates its use when respect for personal dignity, the defense of human life, and support of the common good is its goal. CHA believes that S 1053 reflects this principle. It is our hope that today's hearing will be the first step toward passage of the legislation by the House of Representatives before the end of the 108thCongress.

Statement of the Huntington's Disease Society of America, Submitted for the Record

As staunch supporters of legislation banning genetic discrimination in the workplace and by health insurers, the Huntington's Disease Society of America (HDSA) urges Congress to schedule immediate House action on the "Genetic Information Nondiscrimination Act" (S.1053), which was unanimously passed by the Senate in November 2003.

HDSA believes Genetic Nondiscrimination legislation must include strong and enforceable protections against wrongful discrimination in health insurance and employment so that individuals may utilize genetic testing in order to make critical life decisions as well as to be able to participate in clinical research without fear of consequence for themselves or their families. Individuals at risk for Huntington's Disease (HD) often elect to pay for testing out of pocket for fear of genetic discrimination.

The Huntington's Disease Society of America urges Congress to pass comprehensive federal legislation prohibiting genetic discrimination. Genetic testing can improve our lives by providing information on how we can prevent future health problems, and cope more effectively with unavoidable conditions. But the ability to predict disease through genetic testing and family history opens the door for genetic discrimination, particularly in employment and health insurance.

Sincerely,

Huntington's Disease Society of America

Statement of the United Spinal Association, Submitted for the Record

July 21, 2004

The Honorable Louise McIntosh Slaughter
U.S. House of Representatives
Washington, DC 20515

VIA FAX: 202-225-7822

Dear Representative Slaughter:

United Spinal Association strongly supports S. 1053, the Genetic Information Nondiscrimination Act. This important legislation passed the Senate by a unanimous vote in October of 2003. It is time for the House of Representatives to act.

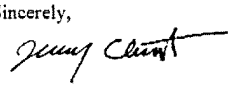
Modern technology has paved the way for incredible medical breakthroughs, including the diagnosis and treatment of a wide array of diseases. However, the same technology that allows for medical advances sometimes also can be used in harmful ways. Specifically, genetic testing has the potential to be both extremely beneficial and extremely injurious.

Through genetic tests, doctors can now predict whether individuals are *predisposed* to developing an array of diseases, including diabetes, several varieties of cancer and multiple sclerosis, but *not* whether an individual will definitely get that disease. Discovering genetic predispositions can allow people to make lifestyle changes and take other measures to prevent disease. Ultimately, this could lead to lower over-all health costs across the country.

Unfortunately, because there are no laws restricting the use of genetic information, the results of an individual's genetic tests can now be used against him or her. Employers can refuse to hire an otherwise qualified person because he or she is more likely than others to develop a certain disease. Health insurers can deny coverage to, raise premiums for or impose coverage restrictions on individuals who have a genetic predisposition to a disease. The Genetic Information Nondiscrimination Act (S. 1053) would prohibit discrimination by employers and health insurance companies based on genetic information. Backing in the Senate for S. 1053 was unanimous. President Bush has expressed support for it. The final hurdle is passage by the House of Representatives.

Tomorrow, on Thursday, July 22, the Committee on Education and the Workforce Subcommittee on Employer-Employee Relations will hold a hearing on genetic discrimination. United Spinal urges you to attend the hearing and asks for your active support of S. 1053. Thank you for your attention to this commonsense, long overdue legislation.

Sincerely,



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Statement of the Coalition for Genetic Fairness, Submitted for the Record

July 20, 2004

The Honorable Sam Johnson, Chair
House Education and Workforce Committee, Subcommittee on Employer-Employee Relations
2181 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

The Honorable Robert E. Andrews, Ranking Member
House Education and Workforce Committee, Subcommittee on Employer-Employee Relations
2181 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Chairman Johnson and Ranking Member Andrews:

I write to you on behalf of the Coalition for Genetic Fairness to submit testimony for the July 22, 2004 hearing, "Genetic Non-Discrimination: Examining the Implications for Workers and Employers." The Coalition for Genetic Fairness is an alliance of civil rights, patients' and health care organizations created to urge Congress to pass comprehensive federal legislation outlawing genetic discrimination. The Coalition was founded by several national organizations, representing thousands of Americans, of which the National Partnership for Women & Families is a founding and leading member. We applaud your initiative in holding this critically important hearing on the problem of genetic discrimination and its impact on Americans today, and offer our new report, "Faces of Genetic Discrimination," to inform your consideration of this issue.

One of the most significant scientific accomplishments in history has been cracking the human genetic code – a breakthrough that is already transforming the battle against a broad range of medical conditions. As a result, scientists have identified genetic markers for such health conditions as cancer, diabetes and Alzheimer's disease, increasing the potential for early treatment and prevention. However, the enormous promise of genetic research and technology is not being realized, due to individual's fears that employers and health insurers will use genetic information to deny access to health insurance or employment.

The attached report, "Faces of Genetic Discrimination," presents a snapshot of how Americans are affected by genetic discrimination today. Current federal and state laws do not prevent employers and insurers from denying health coverage or job opportunities on the basis of genetic information. And, as the report outlines, both actual discrimination and the fear of discrimination bear significant costs for individual Americans, their families, and society as a whole. Without strong federal protections against genetic discrimination, these costs will accrue unchecked.

On October 14, 2003, the Senate took an historic step in establishing strong federal genetic discrimination protections by passing S. 1053, the "Genetic Information Nondiscrimination Act," by a unanimous vote of 95-0. S. 1053 represents an important compromise in providing strong federal protection for Americans in both the health insurance and employment arenas. Importantly, S. 1053 meets the Coalition's core principles for strong genetic discrimination protections. Unfortunately, although S. 1053 is supported by President George W. Bush and has been cited by Senate Majority Leader Bill Frist as one of three health legislative priorities that could be enacted on a bipartisan basis this year, the bill has languished in the House of Representatives since its passage last year.

We urge you to take action to ensure the prompt consideration of federal legislation that meets the Coalition's core principles. Passage of genetic nondiscrimination legislation in the House of Representatives this year would represent a major victory for the American people. The House now has a vital opportunity to provide protections against genetic discrimination after a decade of debate. We look forward to working with you to ensure that Americans can reap the full benefits of genetic research and technology without fear of losing health insurance or their jobs.

Sincerely,

Debra L. Ness
President
National Partnership for Women & Families

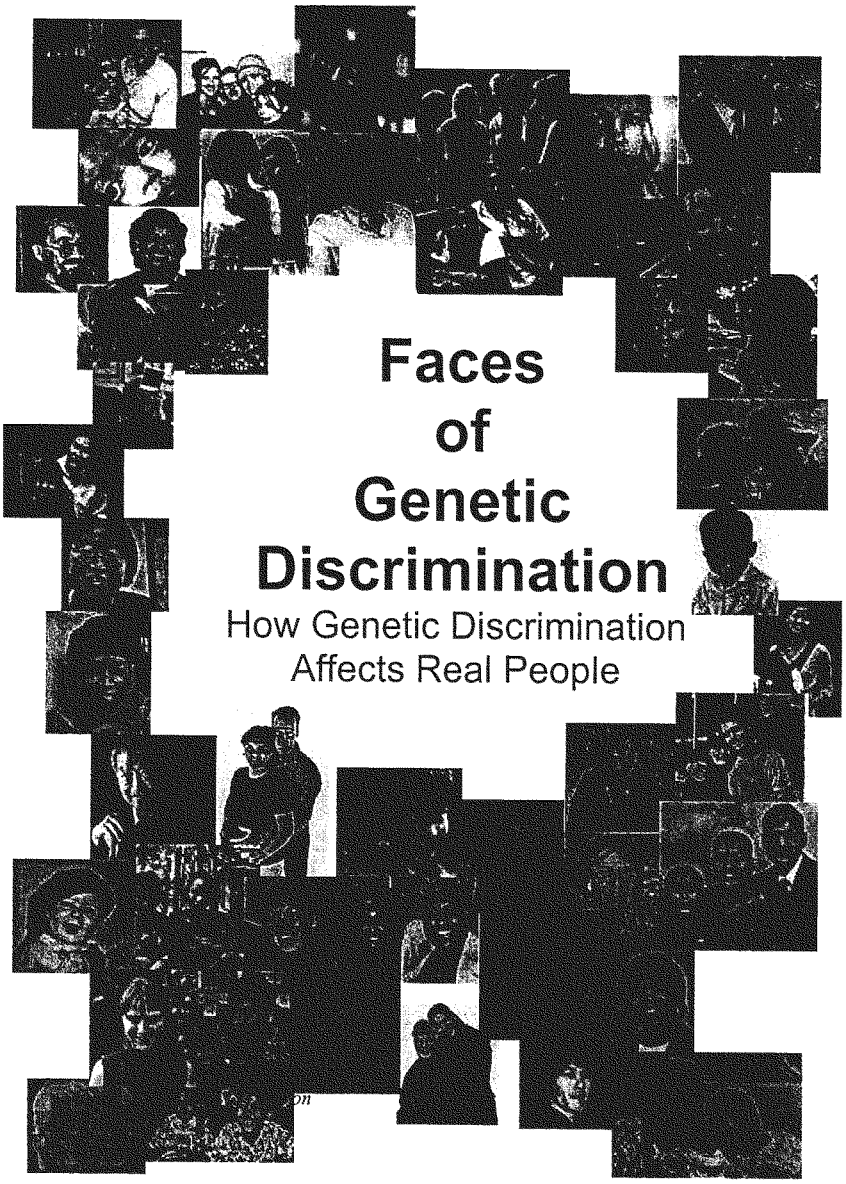

Faces
of
Genetic
Discrimination
How Genetic Discrimination
Affects Real People

TABLE OF CONTENTS

Introduction .....

Health Insurance Discrimination .....

Employment Discrimination .....

Fear of Discrimination .....

Costs to Individuals .....

Costs to Families .....

Impact on Public Health .....

Racial and Ethnic Discrimination .....

Impact on Scientific Advancement .....

Strong Federal Law on Genetic Discrimination is Needed .....

Conclusion .....

Appendix:
More Faces of Support For Genetic Nondiscrimination Legislation .....

Endnotes .....

ACKNOWLEDGMENTS

This report, ***Faces of Genetic Discrimination: How Genetic Discrimination Affects Real People***, could not have been completed without the hard work and assistance of many individuals. Staff at the National Partnership for Women & Families devoted countless hours and much energy to conceptualizing, researching, writing, editing, and producing this report. The principal authors were Debra L. Ness, Alice M. Weiss, Myra Clark-Siegel, and law clerk Courtney Rogers. Additional critical contributions of collecting, organizing, and reviewing submissions for this report were made by Vanessa Lopes, Ali Cherry, and our consultant Andrea Maresca of DDB Bass & Howes. In addition, Debbie Wilkes, Kamilah Woods, and our communications intern Trista Kendall provided invaluable assistance in formatting and editing the document. We are also deeply indebted to the dedicated commitment and hard work of our consultants Joanne Howes of DDB Bass & Howes and Lisa Lederer of PR Solutions for their excellent input and clear thinking which helped to shape and strengthen the final report.

This report would not have been possible without the valuable and informative contributions made by members of the Coalition for Genetic Fairness and others, and their contributions are acknowledged specifically in this report. In addition to these contributions, a number of organizations and individuals provided invaluable data, reports, research, and advice that improved the document significantly. In that regard, the National Partnership would like to thank staff at the National Institutes of Health National Human Genome Research Institute, and Kathy Hudson, Susannah Baruch, and Daryl Pritchard at the Johns' Hopkins University Genetics and Public Policy Center.

Introduction

> *No individual should have to choose between the benefits of genetic testing and keeping a job or health insurance. In some cases, fear of genetic discrimination can be as destructive as traditional discrimination. Unless Congress acts quickly and decisively, people's fears may prevent them from getting the health care they need. And the more individuals fear discrimination, the less willing they will be to participate in clinical trials and studies that may require genetic testing – the very kind of research that could help all of us live longer, healthier lives.*[1]
>
> - ***Debra L. Ness, President***
> ***National Partnership for Women & Families***

In an era filled with technological and scientific marvels, one of the most significant scientific accomplishments has been cracking the human genetic code – a breakthrough that is already transforming the battle against a broad range of medical conditions. After a nearly $3 billion investment,[2] society is finally beginning to reap the benefits of this new technology.

Scientists have already identified genetic markers for various diseases and health conditions, including cancer, diabetes, Alzheimer's disease, Huntington's disease, cystic fibrosis, and potentially thousands of others.[3] Genetic tests are currently available to identify predispositions to specific conditions,[4] and more are expected as science advances.[5] Although none of these tests predict with full certainty that a condition will develop, they provide a new opportunity for individuals to know more about the potential risk of disease for themselves and their families. Once informed about their genetic status, individuals can take proactive steps to protect their health, enhance their well-being, and lower health care costs for themselves and society as a whole.

However, the enormous promise of genetic research and technology is not being realized. Along with the increasing prevalence of genetic testing comes a growing fear that employers and health insurance companies will use genetic information to deny access to employment or health insurance coverage. Numerous respected surveys report that the vast majority of Americans want to keep their genetic information private. The more individuals know about genetic technology and their own risk for a genetically linked condition, the more likely they are to report concerns that employers or insurers will misuse their information. Discrimination based on genetic information is especially pernicious because genetic markers nearly always only indicate an increased chance, but no certainty, that a manifested condition will develop.

Although some state and federal laws now protect against genetic discrimination in health insurance and employment, these laws are limited and incomplete, leaving individuals vulnerable once their genetic information is known. People who fear they will lose their job or health insurance because of their genetic makeup avoid getting tested, never realizing the potential benefits of early detection and prevention. They also shy away from participating in medical research, hindering scientific progress and the ability to fully enter this new era of medical promise. As a result, individuals and our society as a whole cannot enjoy the full benefits and savings that could be reaped from genetic science.

Public concern about genetic discrimination will only increase as genetic science advances and becomes a greater part of our medical care. A few policymakers confronted with these concerns allege that discrimination is not prevalent and therefore is unworthy of attention. But genetic discrimination and the fears about its effects are real and are already having a major impact on our health care system. There is a human cost to genetic discrimination that is too often hidden from public view. This report reveals the faces of those affected by genetic discrimination in America today.

> *Genetic discrimination is unfair to workers and their families. It is unjustified – among other reasons, because it involves little more than medical speculation. A genetic predisposition toward cancer or heart disease does not mean the condition will develop. To deny employment or insurance to a healthy person based only on a predisposition violates our country's belief in equal treatment and individual merit.*[6]
>
> - ***President George W. Bush***

The potential for medical advances made possible from our knowledge of the human genome are dramatic. Research involving the human genome may open doors to new methods of medical diagnoses and treatment - to a new practice of medicine involving drugs designed for specific genes, genetically engineered organs for use in transplants, or even the ability for preventive care based in large part on genetic testing. At the same time, we must ensure that this information is not used to harm people. We must protect consumers from the threat that their genetic information may be used to deny them access to health insurance coverage or to the benefits of employment. This is a moral responsibility and a practical necessity. [The Senate genetic nondiscrimination] legislation takes that necessary step by protecting individuals with genetic predisposition toward certain diseases from the threat of discrimination.[7]

- ***Senator Bill Frist, M.D., Majority Leader U.S. Senate***

Almost two centuries ago, Thomas Jefferson, one of this country's foremost scientists and original thinkers, wrote that 'laws and institutions must go hand in hand with the progress of the human mind. As...new discoveries are made [and] new truths disclosed...institutions must advance also, and keep pace with the times.' In this age of genetic breakthroughs, it is essential that our laws catch up with the science. We can't afford to take one step forward in science but two steps backward in civil rights. Our laws must specify, clearly and unambiguously, how genetic information may be used and how it may not be used.[8]

- ***Senator Thomas A. Daschle, Minority Leader U.S. Senate***

Faces of Discrimination

Sometimes, the human face of issues can get lost in Congress amid the general debate. The reality behind this issue is that without prompt legislative action, people will suffer. Average Americans are already being subject to genetic discrimination, and their ranks will grow. Some people will be denied treatment altogether and go without if they cannot afford it. Others will receive treatment but not be able to pay, thereby contributing to the skyrocketing cost of health care in our nation and the growing burden of medical costs on our federal, state, and local governments. Still others will manage to scrape together enough to purchase treatment, but will suffer terrible financial hardship in the process. This is a tragedy we can prevent. This is a tragedy we must prevent.[9]

- Congresswoman Louise McIntosh Slaughter

U.S. House of Representatives

Genetic discrimination is occurring today in two primary areas: health insurance and employment. Several well-documented cases of health insurers' and employers' attempts to use an individual's genetic information against them have already been reported. Some health insurers have denied coverage to healthy individuals based on their genetic profile. Insurers have also used genetic information in the medical underwriting process, either to increase the price of coverage or to limit coverage for related benefits.

Employers have used genetic information to deny employment, fire current employees, or deny workers compensation benefits. A 2001 American Management Association survey of U.S. firms found a number of employers already accessing genetic information in a number of ways – one percent was conducting genetic tests for Sickle Cell Anemia, 0.4 percent was testing for Huntington's disease, 14 percent were conducting workplace susceptibility testing which surveyors acknowledged might include genetic testing, and 20 percent were requesting family medical histories.[10] Employers' increasing access to genetic information poses new threats of employers misusing this information in their employment decisions, fueling Americans' fears that they may be at risk.

It is impossible to say how many thousands of Americans are affected by this problem today. Many who experience discrimination may be afraid, uncomfortable, or unable to come forward with their story. Others steer clear of discrimination by avoiding genetic services altogether. Those who fight discriminatory practices and win often have to invest significant time, money and effort to assert their rights. Unfortunately, not every victim will have the savvy and resources available to mount such a defense. Most are simply without meaningful protections against discrimination. Many will find themselves uninsured or unemployed at considerable personal and financial risk because of their genetic makeup. Here are some of the faces of those already affected by discrimination in health insurance and employment.[11]

Health Insurance Discrimination

Having a gene associated with Alzheimer's disease does not mean a person has the disease. The presence of a gene is not a basis for underwriting insurance premiums for health care...nor should it be used to infringe on any individual's access to care and services.[12]

- ***Alzheimer's Association***

Jacob

Jacob, a boy who carries a gene for a disorder called Long QT Syndrome (LQTS), was denied coverage under his father's health insurance policy because of his "pre-existing condition." LQTS is a rare and little-known genetic disorder that sometimes triggers sudden cardiac death. Those who carry the gene may be healthy until they suffer an attack without warning, but carriers can control their risk of cardiac arrest with preventive beta-blocker therapy. Jacob's father wanted Jacob to be insured, but even after their state enacted a law prohibiting genetic discrimination, Jacob's insurance company still refused to cover him. After fighting the insurance company for a year and a half, Jacob's family finally won and got Jacob the health insurance he needed.[13]

Heidi

Heidi was denied health insurance for her children, who were carriers of Alpha-1-Antitrypsin Deficiency, a genetic condition that destroys lung tissue and exposes those with the disease to emphysema and difficulty breathing. Even though medical professionals knew that Heidi's children would never develop the disease themselves, the insurance company nonetheless denied them coverage because they carried the Alpha-1 genetic marker. Heidi appealed the decision a number of times, but her appeals were denied. Her insurance company only finally reversed its decision after a reporter contacted the insurer indicating that Heidi's story was to be profiled in a national newspaper.[14]

Anonymous

A 28-year-old woman who tested positive for BRCA-1, one of the genes that indicates a predisposition to breast cancer, was denied health insurance coverage because of her genetic status. Although she was not asked for genetic information when she applied for insurance, when the woman reported on her application that she had undergone prophylactic mastectomies and a hysterectomy, the insurance company requested her medical records, which included her genetic information. Her application for coverage was rejected and she was later able to determine that the denial was due to her positive BRCA-1 test result. Only after involving a lawyer, and after much time and effort, was she ultimately able to secure insurance coverage.[15]

Employment Discrimination

Workers fear that employers will use genetic information to lower their insurance and sick leave costs by weeding out individuals who have traits linked to inherited medical conditions. There is both hard and anecdotal information indicating that employees' fears are not baseless, and that the problem will only get worse as technology develops.[16]

- ***Commissioner Paul Miller***
  U.S. Equal Employment Opportunity Commission

What happened to me should not happen to anyone especially in the United States. It is a direct infringement on our fundamental right to be who we are. No one can help how they are put together, only God knows that – your employer, insurance companies or anyone else has no business of that knowledge. That information.... should not be used against you and your family for hiring and firing practices, or acceptance and/or denial into insurance programs.[17]

- Gary Avary, Worker Burlington Northern Santa Fe Railroad

Gary Avary

Gary Avary's employer, Burlington Northern Santa Fe Railroad, tried to fire him after he refused to undergo mandatory genetic tests. Gary was diagnosed with Carpal Tunnel Syndrome (CTS) in 2000 and took leave from work to have surgery and recover. When he returned to work, Gary was told that he would have to undergo a mandatory medical examination. Gary was told that if he refused to submit to the examination he would be fired. He later learned that his employer was administering secret genetic tests to workers without their consent to identify a possible genetic predisposition to CTS as a defense to workers' compensation claims. Gary refused to take the exam and his employer began disciplinary proceedings to fire him. After seeking help from his union and the Equal Employment Opportunity Commission (EEOC), who filed and settled a suit against Burlington Northern on Gary's behalf, Gary was finally reinstated.

Kim

Kim was a social worker with a human services agency until she was fired because of her employer's fears about her family history of Huntington's disease. During a staff workshop on caring for people with chronic illnesses, Kim mentioned that she had been the primary caretaker for her mother, who died of Huntington's disease. Because of her family history, Kim had a 50 percent chance of developing the disease herself. One week later, despite outstanding performance reviews, Kim was fired from her job.[18]

Berkeley Labs

Between 1968 and 1993, Lawrence-Berkeley Laboratories, a state and federal research institution, gave its employees pre-placement and annual medical examinations that included tests for syphilis, sickle cell genetic markers and pregnancy that were given without the employees' knowledge or consent. This testing was revealed and condemned in a major lawsuit decided in 1998, in which the court held that the employers' actions constituted the "most basic violation possible" of the employees' rights to privacy guaranteed under the Constitution.

One can think of few subject areas more personal and more likely to implicate privacy interests than that of one's health or genetic make-up.... [T]he conditions tested for were aspects of one's health in which one enjoys the highest expectations of privacy.[19]

- Judge Stephen Reinhardt
U.S. Court of Appeals, Ninth Circuit

As the cost of testing declines and the number of conditions with identified genetic links increases, genetic testing and the use of genetic information may become as common in the American workplace as drug testing is today. In the absence of meaningful legal protection, we may well be on the road to a future in which thousands, or even millions, of people face lifelong job discrimination –and worse – because of something over which they have no control and which has no bearing on their ability to perform their jobs. This is not only a massive injustice, it denies society the benefit of the contributions they could have made in their productive years.[20]

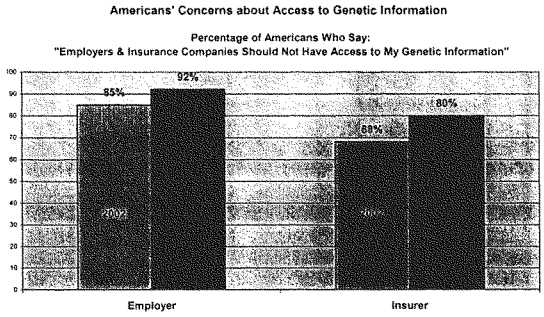
- Jeremy Gruber, Legal Director, National Workrights Institute

Fear of Discrimination

> *We are on the verge of a true revolution in medicine. But there is a chance it will not happen as we hope. It will not be a failure of the science. There is increasing evidence people fear their genetic information will be used to deny them health insurance or a job. This fear is keeping them from seeking medical help. If people believe that a new system of individualized medicine will lead to denial of health insurance or other benefits, they will not take advantage of what the new system could offer. The revolution at hand may not be realized because people are afraid to take part in it.*[21]
>
> – ***Dr. J. Craig Venter, President and Chief Scientific Officer Celera Genomics***

The fear that health insurers and employers will misuse genetic information is real and exacts a human cost. Numerous respected studies indicate that a strong majority of Americans do not want insurers or employers to have their genetic information, and that they are increasingly concerned about the risk of genetic discrimination.

- A 2004 survey by the Genetics and Public Policy Center at Johns Hopkins University found that an overwhelming majority of Americans do not want their employers or health insurers to have access to their genetic information. Over 9 out of 10 individuals (92%) oppose allowing employers access to their genetic information, and 8 out of 10 (80%) oppose allowing health insurers access. Among college-educated respondents, nearly all (97%) oppose both employer and insurer access.[22]



Source: 2004 Genetics & Public Policy Center Survey, "Public Awareness and Attitude about Genetic Technologies"

- In a 2001 academic survey, more than seven in ten Americans (84%) expressed concerns that health insurance companies would deny coverage based on genetic information. Nearly seven out of ten (69%) believed that employers would deny jobs because of genetic testing results.[23]

- A 1998 study by the National Center for Genome Resources found that more than eight out of ten individuals (85%) surveyed did not want employers to have access to information regarding employees' genetic conditions, risks, or predispositions.[24]

- Americans' concern about misuse of genetic information is longstanding – nearly a decade ago, a 1995 Harris Poll reported that most Americans were worried that their genetic information could fall into the wrong hands – among the general public, 86 percent of those surveyed were concerned that employers and insurers might have access to, and use, genetic information.[25]

Research also shows that the fear of discrimination can prevent individuals at risk from getting tested or participating in clinical research that could save their lives.

- In a 2003 study of 470 people with a family history of colorectal cancer who enrolled in the Hereditary Colorectal Cancer Registry at The Johns Hopkins Hospital, nearly half rated their level of concern about genetic discrimination as high. Those individuals with high levels of concern indicated that they would be significantly less likely to consider meeting with a health care professional to discuss genetic testing, or to undergo testing. If they were to pursue testing, the individuals who had a higher level of concern reported they would be significantly more likely to pay out-of-pocket, use an alias, or ask for results to be excluded from their medical record.[26]

- A 2000 survey of 296 cancer genetics specialists' views about what they would do if they were personally at 50 percent or greater risk for carrying a BRCA mutation, found that nearly seven out of ten of the specialists (68%) said they would not bill their insurance companies for genetic testing because of fear of genetic discrimination.[27]

- In a 1997 survey by the National Center for Genome Resources, 63 percent of participants reported that they would not take genetic tests for disease if employers and health insurers could access the results.[28]

The real stories of individuals struggling with the choice of whether or not to get tested illustrate the considerable impact that fear of genetic discrimination is currently having on Americans' health care decisions and attitudes.

Mary

Mary had a family history of breast cancer – both her mother and an aunt had been diagnosed with the disease. Concerned about her own future, Mary considered being tested for BRCA-1, hoping to take prophylactic measures to reduce her risk if the result was positive. Ultimately, she decided not to take the test because she feared a positive result would jeopardize her chances for promotion at her law firm.[29]

> *It was extremely important to me to know that I could be tested and not dropped from my insurance or job if I were found out to have a BRCA1 or BRCA2 mutation.... The fear of possibly having a disease and either losing insurance or a job when I would need it most, would be frightening beyond words. How sad if people like myself, who are most at risk, would not test and therefore possibly die an early and preventable death.* [30]
>
> *- Anonymous*

Anonymous

A patient advocate working at an oncology clinic had a telling encounter with a young woman whose mother and sister died of breast cancer. The young woman visited the clinic, but refused to sign in. The advocate explained that registration was required, and that the woman's genetic information would be kept entirely confidential. The woman became extremely emotional, saying that she believed she would expose herself and her children to the risk of discrimination if her visit were in any way documented. The advocate tried to encourage the woman to stay, but she left the office without testing or counseling, and without scheduling a screening.[31]

> *Despite the availability of insurance reimbursement for genetic testing, many patients still choose to pay cash in advance of genetic testing and only submit to their insurance company if their test is negative. Such a course of action is not available to individuals who are not able to afford this option. A major reason for patient cancellation in our clinic is advice from a physician or friend not to be tested because of fear of discrimination.... Such a fear stands as a barrier to improved and targeted preventive care and screening.* [32]
>
> *- American Society of Clinical Oncology*

Costs to Individuals

The risk of genetic discrimination takes a toll on individual health and financial well-being. Perhaps the most critical benefit genetic testing offers is its potential to improve personal health by enabling individuals to better predict risk and possibly to prevent or delay the onset of serious health conditions. A predictive test for diabetes risk, for example, could influence an individual to make dietary and lifestyle changes that might significantly improve his health prognosis, lessening, delaying or even preventing the onset of disease altogether.[33] If a woman has a BRCA-1 genetic mutation, a bilateral prophylactic mastectomy can reduce her risk of developing breast cancer by a striking 90 percent.[35] As more tests are developed, increasing numbers of people will be able to reap dramatic health benefits from genetic tests. Conversely, foregoing genetic tests due to a fear of discrimination means a loss of opportunity to improve one's health.

> *Unfortunately, many individuals do not seek genetic services because they fear genetic discrimination. This fear hampers the medical care of individuals and their families, either because it prevents them from obtaining beneficial medical information or because individuals who undergo genetic testing decide not to share these results with their health care providers.*[36]
>
> - ***National Society of Genetic Counselors***

Individuals' fear of discrimination often leads them to shield their genetic information, even from their health care providers, but this can actually pose new health risks. When people refuse to be tested, or are tested using an alias or other device which keeps the results out of their medical records, they lose the benefit of more complete medical histories which could have enabled their health providers to better diagnose, treat, or prevent the onset of illness. Doctors are not fully informed, which can hinder patients' ability to get the best care possible and ultimately jeopardize their health.

Gail

Gail, a physician with a family history of breast and ovarian cancers, faced potentially disastrous consequences because of her incomplete medical records. Gail decided to take a genetic test to determine her risk for cancer. In order to avoid losing health insurance coverage, she took the test under an assumed name and kept her family history information out of her medical record. Before she received her results, Gail's gynecologist noticed a possible abnormality on her ultrasound during a routine visit. As Gail's risk factors for cancer and her genetic test were not noted on her medical chart, her doctor was unaware of a possible hereditary risk, and recommended neither follow-up testing nor a course of treatment. Thankfully, as a physician Gail understood the significance of her exam results and knew what she needed to do to protect herself. For most other patients, however, this story could have had a different ending, with the lost opportunity for follow-up resulting in a missed detection of a life-threatening disease.[37]

Fear of genetic discrimination can also have an adverse financial impact. The early detection and prevention that genetic tests can offer could lessen the financial costs caused by untreated or undetected illnesses, but those who fear discrimination will avoid these tests and consequently may face thousands of dollars in additional health care costs. Individuals treated at a later stage of illness often face the double whammy of health problems compounded by financial crisis – significant cost-sharing and out-of-pocket medical bills that can threaten mounting medical debt. Medical debt is a leading source of personal financial bankruptcy in our nation, and can lead to home foreclosures and financial ruin for an entire family. The burden of lost income during extended illness can also be crippling. Individuals who can access and use their genetic information without fear will be at lesser risk for these financial losses.

Individuals who fear future discrimination may face an additional financial strain if they choose to pay for their genetic tests out-of-pocket to keep the information out of their medical record. For those who can afford this option, there are significant costs – genetic testing and counseling can cost thousands of dollars for a single diagnosis.[38] Unfortunately, many cannot afford the expense of testing, and their fear of genetic discrimination ultimately prevents them from reaping the health and financial benefits of knowing their own genetic information.

Janet

Janet is a cancer survivor with a family history of breast and ovarian cancer and a sister who tested positive for BRCA-1. Janet wanted to be tested for the BRCA-1 gene in order to help her son and his future children make informed health care decisions. She was prepared to pay the $325 required for the test, an amount she was told the test would cost based on the availability of her sister's results. But when the lab lost her sister's results, the cost of Janet's genetic test jumped to $3,000. She was covered under her husband's health insurance, but wanted to pay for the test out-of-pocket to avoid discrimination. Since she could not afford the $3,000, she chose not to be tested. She now fears she will never know her genetic risk.[39]

Costs to Families

Genetic discrimination puts entire families at risk. Unlike most other medical tests and diagnoses, an adverse genetic test can have a substantial impact not just for the individual who is tested, but also for their entire family tree. Even if one family member is willing to take the risk of discrimination to get tested, she cannot escape the impact that a positive result could have on her family. In the genetic age, medical information and decision-making have ripple effects for all blood relations – when a patient gets a genetic test, her results could impact access to insurance or employment for her mother, her son, her sister, her grandson. And, because many individuals are covered under family health insurance policies, even non-blood family members are affected by insurers' decisions to deny coverage or limit benefits based on genetic information.

[Taking a genetic test] would help me make some personal choices in my life like whether or not I should have more children. Since my sister died my life has been on hold. I can't go forward unless I know whether or not I carry this gene. If I can, I hope to avoid what happened to my sister from happening to my loved ones or me. The current laws just don't offer enough protection. I can't risk losing my job, paying higher health premiums, or being denied future coverage. Neither can my family.[40]

- Julie, Patient

Julie

Julie has a long history of breast and other cancers in her family. Tragically, her sister discovered that she was sick with breast cancer while pregnant with her third child and died only a little over a month after giving birth. After a string of similar tragedies, Julie consulted a genetic counselor, and learned that there was a strong chance that a gene was responsible for these family deaths. But Julie and many members of her family remain afraid to undergo testing.

Kathy

Kathy is a breast cancer survivor with a strong family history of the disease. Her daughter initially encouraged Kathy to get tested for the BRCA-1 gene. After the testing, however, her daughter changed her position completely, based upon her own fear of genetic discrimination. Kathy's daughter now refuses to be tested herself or to participate in any genetic research.[41]

Becky and Kate

Becky is a breast cancer survivor whose 20-year-old daughter, Kate, has tested positive for the BRCA-1 gene. Kate, still in college and yet to embark on her career, already faces tough choices about her future health insurance and employment. Kate needs to keep group health insurance coverage so she is protected against being rejected or charged more based on her genetic information. If she loses coverage, she puts herself at risk for having to shop for coverage in the individual market, where insurers can reject her outright or charge her exorbitant rates because of her genetic status. Kate also knows that carrying the BRCA-1 gene means she needs access to quality, affordable health coverage more than most young women her age to ensure she can afford preventive screenings and treatment if she develops breast cancer. Becky is also concerned that Kate could be asked to take a genetic test as a condition of employment. She devotes her energy to this issue out of concern for her children.[42]

Impact on Public Health

Unfortunately, while there are over 1 million Americans that carry genetic mutations which dramatically increase their risk of developing cancer, fewer than one percent know it.... Ultimately, this reduces quality of care and wastes healthcare dollars in the treatment of otherwise preventable or, at least, manageable conditions.[43]

- ***Gregory C. Critchfield, President***
  Myriad Genetic Laboratories

Genetic discrimination also has an impact on public health. Millions of people could benefit individually from knowing their genetic profile, adding up to fewer seriously ill patients overall, which could ease the stress on our already overburdened health care system. However, the risk of discrimination has kept millions of Americans from taking advantage of these preventive services that could deter illness, improve health outcomes, and reduce costs system-wide. Delayed preventive and therapeutic treatment can lead to higher health care costs in the form of higher out-of-pocket costs and health insurance premiums for the insured, and a greater need for uncompensated care for the uninsured or underinsured.[44] This increases the financial and physical burden on health care providers,[45] drives up health care costs for employers, and strains public health resources.[46] Insurers' ability to limit or deny coverage based on genetic information also leads to greater numbers of uninsured and underinsured individuals, which reduces access to needed health care services and increases costs for the entire health care system.

Individual choices to forego genetic tests because of fear also rob our nation of the potential public health benefit of increased awareness of rare genetic disorders. If people with rare genetic markers are afraid to come forward, their stories cannot be heard. But by sharing what they have experienced and learned, they can raise awareness, campaign for funding and research, and help others to understand confusing symptoms and diagnoses, thereby improving public health outcomes.

> *[My family] decided that what we had learned from [our experience with Long QT Syndrome] needed to be shared beyond the confines of our family. If this could happen to us, we wondered, how many others had lost a child under similar circumstances and did not have a clue as to the cause?*[47]
>
> - ***Doris Toran Goldman, Co-Founder and Director Cardiac Arrhythmias Research & Education Foundation (CARE)***

Racial and Ethnic Discrimination

Scientists have found several genetic markers that seem to be more prevalent in certain races and ethnicities. For example, women of Ashkenazi Jewish descent are more likely to have the BRCA-1 mutation that indicates a predisposition toward breast cancer.[48] African Americans are more likely to carry the gene for sickle cell disease.[49] For certain minority groups, public perceptions about genetic status could compound existing societal racial and ethnic discrimination.

A dramatic and telling example of the ways in which genetic discrimination could compound existing racism occurred in the early 1970s with a scientific mandate to use genetic tests to screen for sickle cell anemia and its impact on the African American community. At that time, scientists had raised concerns that individuals with sickle cell anemia carried a heightened risk from some workplace toxins. Screening programs were developed to identify both healthy carriers and carriers with a manifested condition. Although African Americans were not the only ethnic group at risk for being genetic carriers for sickle cell anemia, states that instituted mandatory genetic screening targeted only this community. They did not mandate screening for other groups, despite the fact that other ethnicities, such as individuals of Mediterranean descent, might also be at risk to carry the disease.[50] Results were not kept confidential, and individuals identified as carriers were stigmatized and discriminated against in employment and health insurance.

Fortunately, Congress passed the National Sickle Cell Anemia Control Act in 1972, barring states from receiving federal funds unless their sickle cell screening programs are voluntary. However, for African Americans, the history of genetic discrimination and its reinforcement of institutional racism resonate more intensely. And their experience provides a telling lesson for all of us about the potential for invidious discrimination that could arise from new discoveries in genetic technology.

Genetic information may be linked to certain ethnic and racial groups, many of whom have suffered from discrimination and eugenic policies that historically were "justified" by genetic findings. For example, restrictive immigration laws against Eastern Europeans in the 1920s, sterilization policies, Nazi atrocities, and insurance and employment discrimination against carriers of the sickle cell trait were justified by the power of genetic information. Even the discovery in the mid-90s of specific gene mutations that may be associated with higher rates of breast and ovarian cancer in the Ashkenazi Jewish community has raised concerns about how this information may be used to discriminate against them. The African American and Indian communities are also very concerned about behavioral genetic studies on violence and alcoholism.[51]

– ***Karen H. Rothenberg, Dean***
Marjorie Cook Professor of Law, and
Founding Director of Law and Health Care Program,
University of Maryland School of Law

Imprecise press accounts and other forms of misinformation have raised the specter that Jewish women have a unique and greatly heightened predisposition to breast cancer, with implications for potential discrimination in employment and insurance.[52]

– ***Hadassah, The Women's Zionist Organization of America***

Impact on Scientific Advancement

Fear of genetic discrimination has also kept many individuals from participating in medical research studies, stunting scientific advancement and undermining the tremendous investment in new technologies that the federal government and private industry have already made. Genetic research holds tremendous promise to unlock new diagnoses and new treatments, and even to assist in the tailoring of pharmaceutical therapies for an individual's genetic makeup. However, scientific research and development cannot progress without clinical trials, and these trials can only move forward if individuals who could benefit are willing to participate. Fear that information will be made public, or will become available to health insurers or employers, has chilled participation in many studies of genetic conditions. Low participation rates in already developed genetic tests may also chill further private investment in developing new tests. Because of the fear of discrimination, science cannot fully realize the advances and benefits that await on the horizon.

[Genetic discrimination] can slow the pace of scientific discovery that will yield crucial medical advances... Without protections in place, individuals who do participate will represent a self-selected group that could skew research results, producing a negative impact on all of us who look to genetics to help find better ways of diagnosing, treating and preventing disease...The longer this problem remains unresolved, the greater the damage that will be done to U.S. science and medicine.[53]

- ***James D. Watson, President***
Cold Spring Harbor Laboratory, and
Dr. Francis S. Collins, Director
National Human Genome Research Institute
National Institutes of Health

Understanding the function of genes in key biological processes will also become an even bigger part of drug discovery and development. This information could, for example, tell us how and why certain diseases afflict certain people and why certain medications are safe and effective for some people, but not others with the same diagnosis. Thus, genomic information could speed the development of cures and treatments for illnesses that afflict millions of Americans and their families. However, public fear and anxiety are obstacles to achieving this goal... People must have confidence they can take advantage of technological developments without fear that the information gained from this technology will be used against them.[54]

- ***Carl B. Feldbaum, President***
Biotechnology Industry Organization (BIO)

[Federal] legislation will provide protection to those generous individuals considering participating in clinical studies and clinical trials. I am afraid that without it, it will be extremely difficult or impossible to carry out the large clinical studies needed in many important disease areas.[55]

- ***Janet A. Warrington, PhD, Vice President for Clinical and Applied Genomic Research & Development***
  Affymetrix, Inc.

Strong Federal Law on Genetic Discrimination is Needed

This is an exciting and hopeful time for genetic medicine. It is imperative, however, that we, the public, can take full advantage of new medical advances that could help prevent disease before it develops. Genetic nondiscrimination legislation will reduce the likelihood of genetic information being misused in health insurance or employment decision-making.[56]

- ***Sharon F. Terry, President/CEO***
  Genetic Alliance

Current state and federal laws provide a limited patchwork of protection against genetic discrimination whose gaps leave Americans vulnerable. A majority of states have enacted protections against genetic discrimination in health insurance or employment or both, but these laws are inconsistent and limited in what and who they cover. These state laws fail to ensure a uniform floor of protections in employment and health insurance on which American families can rely. And in the health insurance context, they fail to ensure coverage for a sizable number of those covered by private health insurance coverage. Because of a federal law known as the Employee Retirement Income Security Act of 1974 (ERISA), many of these state laws may not apply to as many as 131 million American workers and families covered under private, job-based health plans.

State laws certainly have had a limited impact. Almost no one knows they exist, they are not enforced and, to my knowledge, no cases have been tried using them. But the hundreds of individuals who have self-reported experiences of genetic discrimination still require relief.[57]

- ***Paul Billings, PhD., Board Member***
  Working Group on Genetic Discrimination & Privacy
  Council for Responsible Genetics

Federal law provides some protections, but they are also limited and incomplete. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established some protections for individuals in group health plans, namely that they cannot be rejected for coverage or charged more than others in the group based on their genetic information. However, HIPAA still allows insurers to charge an entire employer group more for coverage because of one individual's genetic information, which can deter employers from hiring or keeping individuals they suspect may have a genetic predisposition to disease. HIPAA also offers no nondiscrimination protections to individuals purchasing coverage in the individual market, and few states extend these protections to individuals. The federal HIPAA privacy rules also create some protections to ensure the privacy of genetic information, as with all medical information, but they are not strong enough to provide security against insurers either collecting or disclosing private genetic information.

In the employment context, civil rights protections under the Americans with Disabilities Act (ADA) purport to protect individuals against genetic discrimination by employers who perceive genetic predisposition to disease as a form of disability. However, these protections are untested and uncertain. Although the Equal Employment Opportunity Commission (EEOC) has brought at least one suit to enforce these rights in the Burlington Northern case discussed above, that case was settled and it is unclear how a court would rule on the EEOC's interpretation of the law. Proving employer bias under the ADA has also been a difficult burden for employees to meet, and recent decisions by the Supreme Court that limit the reach of the ADA and narrow its protections indicate that it is not likely to provide a wellspring of support for employees seeking to enforce new rights.

For Americans at risk for genetic discrimination, these gaps in the law pose a serious barrier to their security. Without strong, meaningful federal protections, genetic discrimination will continue to be a serious problem that has a real and human cost for Americans, as individuals and as a nation.

It's a very important point to state that it will be much easier to nip this in the bud before it has become widespread than to wait until there is already a sort of standard practice in the insurance industry or the human resources office to find out information about people's genetics. That's one of the reasons I think it's very shortsighted to say: 'We don't have strong evidence of a lot of trouble now, so let's just wait.' The longer you wait, the harder it will be to fix this problem.[58]

- ***Dr. Francis S. Collins, Director***
  National Human Genome Research Institute
  National Institutes of Health

Conclusion

Our nation is at a crossroads. We can realize the enormous promise of genetic research by ensuring that Americans do not lose their health insurance or their jobs because of their genetic test results. Or we can allow a patchwork of inadequate and incomplete protections to continue, forcing millions of people to choose between their economic security and the genetic tests that can improve their health and possibly prolong their lives.

One thing is clear. Lawmakers have a critical decision to make. Without strong, meaningful federal protections, genetic discrimination will continue to be a serious problem that has a real cost for Americans – and there will be many more faces of genetic discrimination in the months and years ahead. The well-being of our country is at stake.

Appendix: More Faces of Support for Genetic Nondiscrimination Legislation

A broad and diverse array of organizations is joining in support of federal genetic nondiscrimination legislation. Here are a few examples of these organizations and their rationale as to why this remains a critical national priority.

American Civil Liberties Union:
Individuals need clear and comprehensive protections against genetic discrimination in the workplace and in the provision of health insurance. The current patchwork of state and federal law does not provide needed basic protection against genetic discrimination.
Congress must protect employees from employers or insurance companies who have the opportunity to discriminate based on genetic characteristics. The House should pick up the baton handed to it by the Senate by passing genetic privacy legislation to protect the health and livelihood of all Americans.[59]

Alpha-1 Foundation and Alpha-1 Association:
As a genetic condition, those with Alpha-1 or seeking Alpha-1 testing may face health, employment, or insurance discrimination, [the fear of] which may significantly impact individual and family decision-making... [E]arly diagnosis and treatment improves health outcomes and allows the individual to make lifestyle and therapeutic changes that can slow the progression of this devastating lung disease and delay the need for transplantation. The Alpha-1 Coded Testing Trial has offered individuals an opportunity to receive confidential test results since September of 2001; since 2001 2,400 test kits have been requested. [Of t]hose returning the test kits and responding to [a] survey questionnaire, [o]ver 30% report fear of losing insurance as the reason for seeking confidential testing [and] 34% report concern about facing higher health care costs if results were public...

American Academy of Pediatrics:
[T]he American Academy of Pediatrics is concerned that genetic discrimination is a barrier for families to access health insurance for their children. More than 9 million children are currently uninsured in this country, and millions more are underinsured. We will never achieve our goal of ensuring that every child has health insurance coverage if genetic discrimination is permitted. The American Academy of Pediatrics therefore urges Congress to pass legislation that protects American families from genetic discrimination.[60]

American Cancer Society:
Genetic research is one of the most exciting areas of scientific advancement today. As our knowledge about the genetic basis of common disorders grows, however, so does the potential for discrimination in health insurance and employment. This possibility can have a dramatic and chilling impact on patient care and research. The American Cancer Society urges the House to enact genetic information nondiscrimination legislation by taking prompt action on S. 1053, which represents a major step forward in ensuring that people do not face discrimination as a result of their medical or family history, while at the same time allowing medical research to advance.[61]

American Medical Association:
The AMA has a long-standing policy against genetic discrimination. This legislation would enable and encourage patients to take advantage of genetic screening, counseling, testing and new therapies resulting from the scientific advances in the field of genetics without worrying that such information could be used against them by their health insurers or employers.[62]

American Osteopathic Association:
It is the position of the American Osteopathic Association that access to healthcare should not be restricted on the basis of genetic testing and that discrimination in employment on the basis of genetic testing should be prohibited. Patients must be able to discuss genetic testing with their osteopathic physicians without fear of discrimination from employers, potential employers, or healthcare plans for having undergone such testing or participating in clinical trials to test new therapies.[63]

American Psychiatric Association:
As biomedical research advances, especially through the Human Genome Project, the possible abusive uses of genetic information will expand unless enforceable safeguards are enacted. A person's genetic information should only be used with his or her informed, voluntary, and non-coerced consent. Protecting patients' genetic information is critical to providing the highest quality medical care.[64]

American Society for Human Genetics:
From the geneticist's point of view, the absence of a federal standard that prohibits employment and health insurance discrimination based on genetic information results in:

1. *difficulty in recruiting subjects into genetic research studies;*
2. *patient avoidance of genetic services;*
3. *underutilization of genetic testing;*
4. *difficulty in obtaining insurance coverage when attempted;*
5. *several cases recognized that have not resulted in legal action; and*
6. *significantly increased time and effort in genetic evaluation and counseling sessions resulting in increased service costs*[65]

***Biotechnology Industry Organization (BIO)*:**
BIO has long supported national policies to ensure that individuals' personal medical information, including genetic information, is safeguarded against misuse. It is essential to assure the public that the great promise of biotechnology research will not be tarnished by abuses of this technology.[66]

***B'nai B'rith International*:**
[S]ome people, including many of the Ashkenazi Jewish women who have heard and read that they may be at risk for breast cancer because of their genes, are afraid that testing might expose them to discrimination by their insurers and even their employers...Having a genetic mutation linked to a disease is not a death sentence – many people with mutations ***will never even develop*** *the associated disease. The decision whether to test for these mutations should be one made by individuals and families in consultation with their doctors and genetic counselors. This information can allow people to make better choices about everything from scheduling their first diagnostic screening to diet and exercise. We should all be free to take advantage of these new information opportunities without fear of discrimination. When people are afraid of being branded by information, they don't get genetic counseling, and they don't get testing. They are even reluctant to participate in important scientific research studies that advance our ability to prevent, diagnose and treat any number of diseases.*[67]

***Juvenile Diabetes Research Foundation*:**
As our understanding of human genetics moves forward, genetic testing will become increasingly used in health evaluation and prevention. It is important in this context to protect Americans from misuse of genetic information that would lead to discrimination in insurance coverage or employment...Although the folly of discrimination based on genes would probably become clear to all at some point, it is preferable that laws be enacted to prevent such discrimination from ever occurring. In fact, categorizing people on a genetic basis in any context, whether it involves health care or any other aspect of social policy, violates the basic principles on which the United States was founded—that each individual is born equal and deserves equal treatment under law.[68]

National Breast Cancer Coalition:
[C]omplex questions about insurance coverage and discrimination are raised by the availability of a genetic test for breast cancer. The National Action Plan and the Human Genome Project has held a two day Genetic Discrimination and Health Insurance Workshop at which women with the breast cancer gene would only agree to tell their stories under the strictest confidentiality agreement. Quite simply, they were afraid of the discrimination they would face with their employers and insurance companies if anyone knew they had this gene...At present, there is no federal legislation that prevents insurance companies from denying coverage based on genetic status. While a few states have enacted laws, all of those provisions contain loopholes which, to varying degrees, undermine the intent of the legislation. Therefore, it is our position that any health care or insurance reform must include protections against discrimination in the provision of coverage based on genetic information, or predisposition to disease.[69]

National Organizations of Rare Disorders:
Genetic information that is revealed to...insurance companies, employers and other family members may pose a risk to individuals – leading them to refuse genetic tests. Since there are no current government protections, nor prohibitions against genetic discrimination, individuals could be subject to severe psychological, emotional and financial risks...Congress must act to ensure that the highest levels of protection are afforded to personally identifiable genetic information so that it can never be used against a person, nor accessed without a person's permission. Failure to guarantee protection of genetic information may lead to underutilization of genetic test, and discrimination against people with certain traits, which impacts Americans alive today, as well as future generations.[70]

National Workrights Institute:
During the past several decades, our understanding of genetics has multiplied as procedures for identifying, analyzing, and manipulating DNA have advanced. Among the many benefits of these efforts are the ways they may influence preventive health, reproductive planning and eventually therapies to cure illnesses with a genetic component. No one can deny that this knowledge may be a blessing in finding cures to diseases with genetic origins, including Alzheimer's, Huntington's and many forms of cancer. Nevertheless, the ability to identify individuals based on genetic characteristics necessarily predates the ability to use this information in the treatment of the corresponding diseases and therefore the immediate consequences of such advances have and will continue to lead to a number of forms of individual discrimination.[71]

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