Employer-Employee Relations Subcommittee of House Education and the Workforce Committee hearing on "Genetic Non-Discrimination: Examining the Implications for Workers and Employers."

DATE: Thursday, July 22, 10:30 a.m.

PLACE: 2175 Rayburn Bldg.

WITNESSES SCHEDULED:

Kathy Hudson - director, Genetics and Public Policy Center, Johns Hopkins University – **Testimony Follows**

Tom Wildsmith - chairman, Genetic Testing Task Force, American Academy of Actuaries

Lawrence Lorber - attorney and partner, Proskauer Rose L.L.P., representing U.S. Chamber of Commerce

Jane Massy Licata - Licata and Tyrrell P.C., Marlton, N. J.

Testimony of Kathy Hudson, Ph.D.
Director, Genetics and Public Policy Center
Berman Bioethics Institute & Institute of Genetic Medicine
Johns Hopkins University

Before the Committee on Education and the Workforce
Subcommittee on Employer-Employee Relations
"Genetic Non-Discrimination:
Examining the Implications for Workers and Employers"

US House of Representatives
July 22, 2004

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

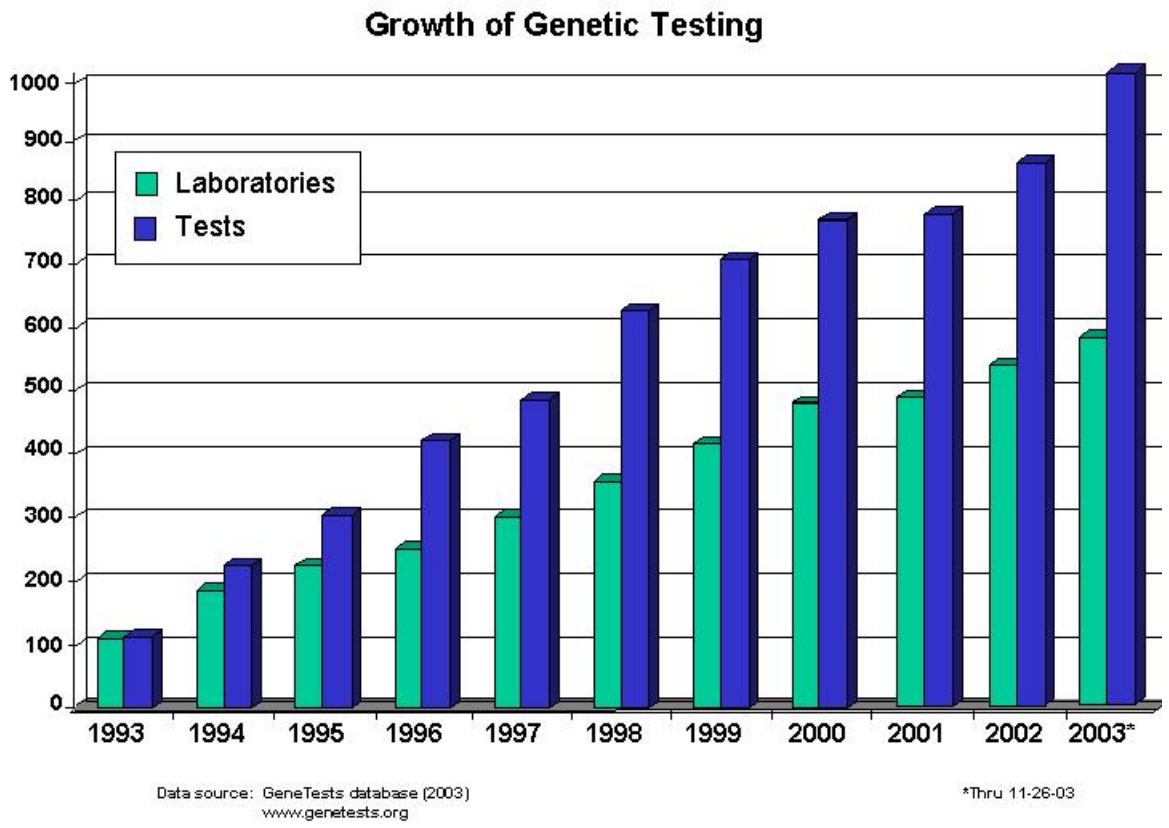
The Human Genome Project was more than a technological tour de force. The genome project and genetic research are providing brilliant new insights into the role of genes in health and disease. Genes are instructions, instructions for building cell structures and proteins needed for the human body to 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

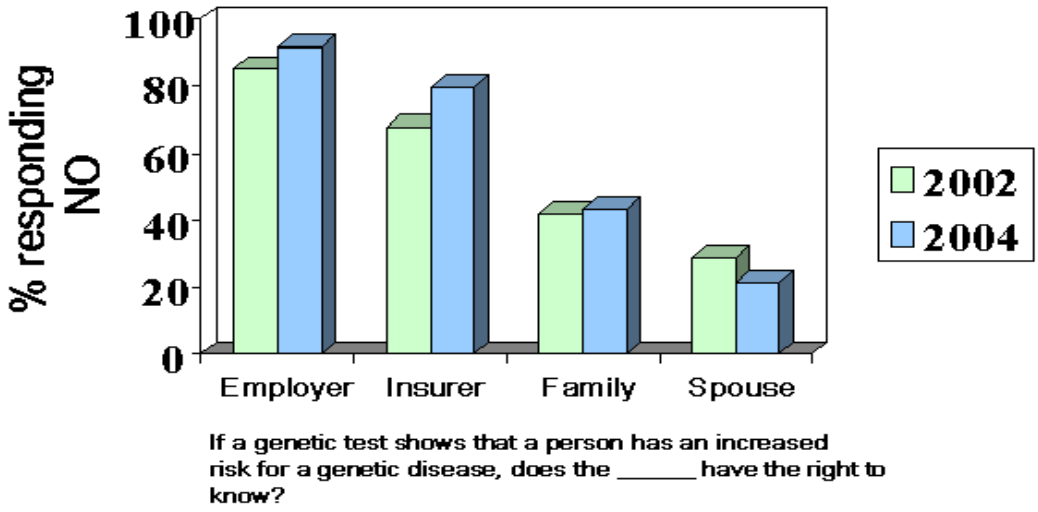
Finally, I want to share with you some research conducted by The Genetics and Public Policy Center, to find out what the public knows, thinks and feels about new genetic testing. Members of the public have shared with us their hopes for healthy children, for reducing the burden of disease and disability,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