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**Before The House Energy and Commerce Committee
Subcommittee on Health**

on

H.R. 493, The Genetic Nondiscrimination Act

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My name is Kathy Hudson and I am the Director of the Genetics and Public Policy Center at Johns Hopkins University, where I am also Associate Professor in the Berman Institute of Bioethics and in the Institute of Genetic Medicine. Established with a grant from The Pew Charitable Trusts, the Genetics and Public Policy Center works to help policy makers and the public better understand and respond to the challenges and opportunities arising from rapid advances in human genetics and its application to healthcare. Since our founding in 2002, the Genetics and Public Policy Center has conducted in-depth policy analysis and social science research on genetic testing and genetic technologies. This week the Center completed a survey of Americans' attitudes about genetic testing and I am delighted to share our new results with you today¹.

I have been involved in genetics research and genetics policy for many years and have had the pleasure of providing technical assistance and advice to many members and their staff during the crafting of genetic non-discrimination legislation over the last decade. I am delighted to see momentum growing for passage of legislation to prevent genetic discrimination and I appreciate the opportunity to testify today.

The Human Genome Project (HGP) was an historic international effort to decipher, letter by letter, the genetic instruction book for our species. The Human Genome Project was more than a technological tour de force, and the results do more than satisfy biological curiosity. Researchers now have powerful tools to dissect the genetic, environmental, and lifestyle factors that contribute to health and disease, and our nation's robust biotechnology industry is translating those findings into new diagnostics and medicines to preserve health and prevent disease.

¹ This survey was administered online by the Genetics and Public Policy Center to a randomly selected, representative sample of American adults 18 years of age or older. The survey was fielded between February 27 and March 4, 2007 to 1,832 adults. Of these 1,199 responded, for a completion rate of 65%. The margin of error is +/- 2.7 percent. To correct for small sampling errors, the reported results were weighted with respect to U.S. benchmarks for age, gender, race/ethnicity, region, and education.

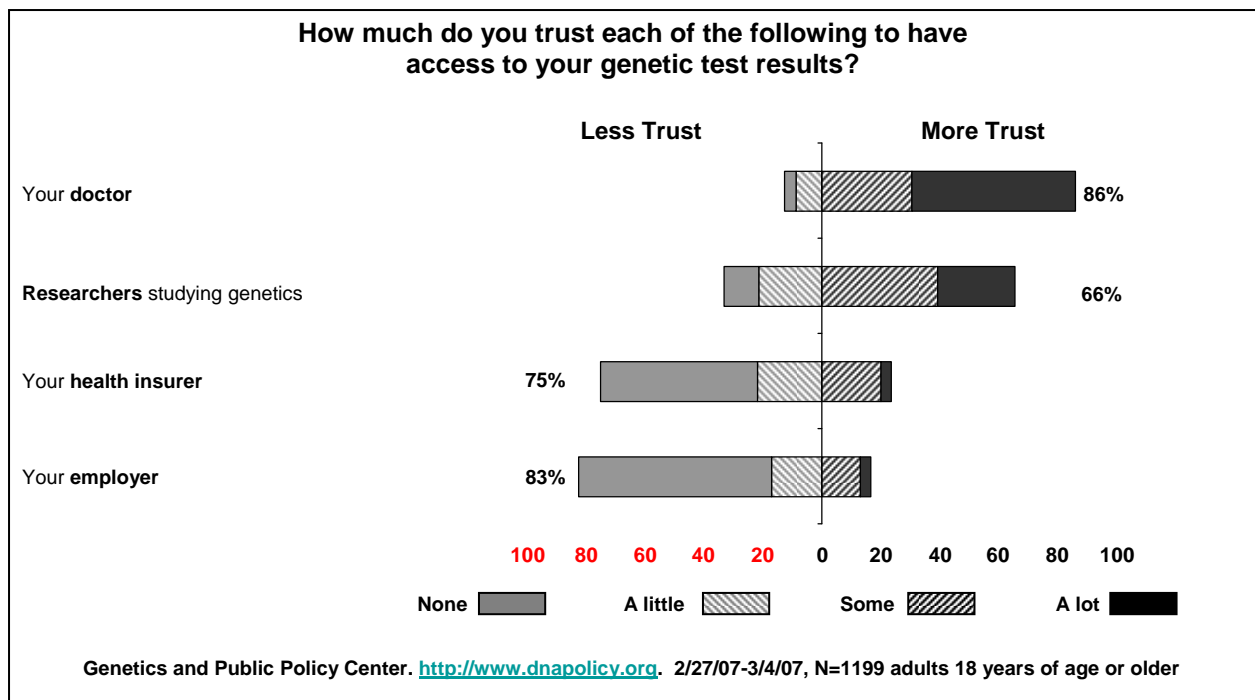
Today there are more than 1000 genetic tests available or in development. Tests are being developed for a wide variety of conditions but they have one thing in common: they provide information. Increasingly, this information can be used to inform personalized health care decisions. Within a decade, it may become common medical practice to test each one of us for our individual susceptibilities to common illnesses or our risk of adverse reactions to commonly prescribed medications. This knowledge will allow the use of individualized preventive care to maintain wellness and save countless dollars spent on trial-and-error prescribing of expensive or ineffective medicines.

Today, the American public is very enthusiastic about the promise of genetic medicine and supports the use of genetic testing in healthcare to learn about future risk of disease. Americans clearly understand the value of genetic testing to improve health care. In our survey, completed this week, we found that more than 90 percent of Americans support the use of genetic testing by doctors to identify a person's risk for future disease when there are treatments or medicines available, or to determine the risk of having a bad reaction to a particular medicine. A large majority of Americans (79 percent) also support the use of genetic testing by doctors to identify a person's risk for future disease even when there currently are no treatments or medicines available for that disease.

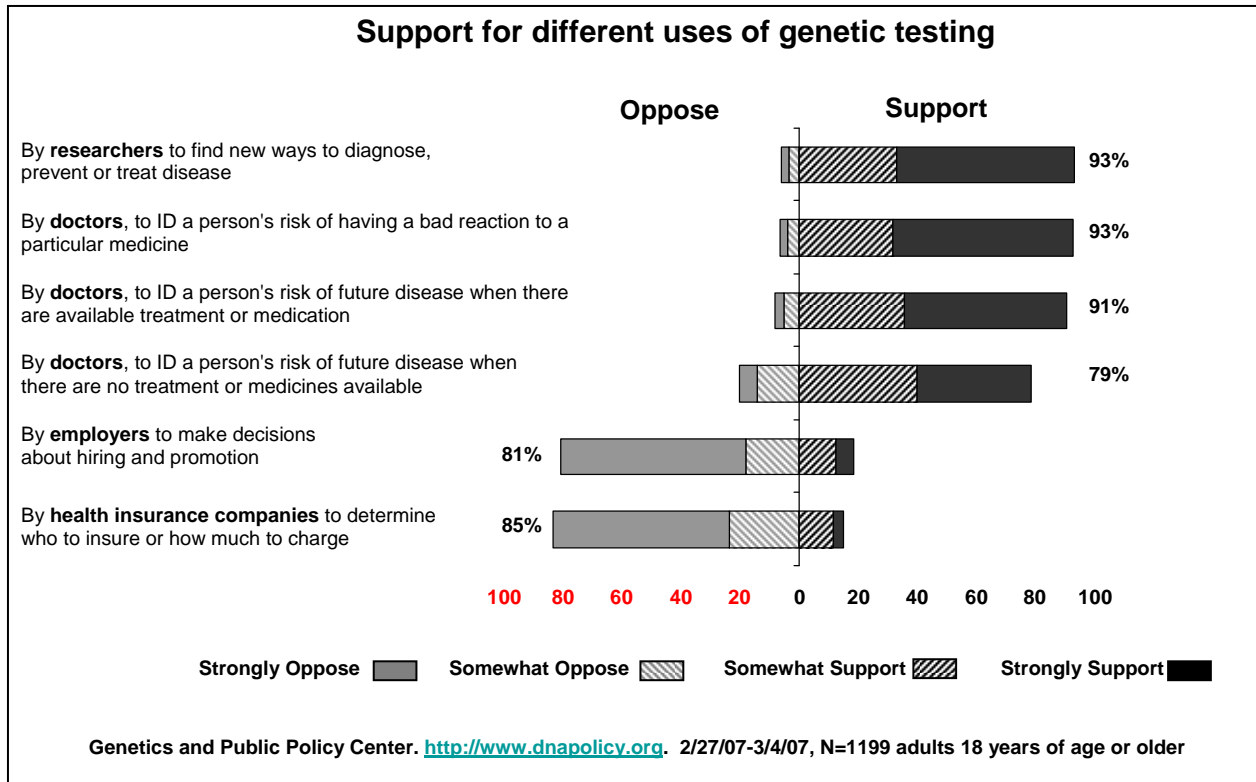
The public also is very supportive of biomedical research to find the genetic contributors to common complex diseases and develop safer and more effective medicines. In our survey, more than 90 percent support the use of genetic testing by researchers to find new ways to diagnose, prevent or treat diseases; two-thirds of Americans trust researchers studying genetics to have access to their genetic test results.

But growing uncertainty and fear threaten the future of genetic medicine. Citizens are increasingly concerned that genetic test results will be used against them in ways that undermine our fundamental values of fairness. Today, more than 90 percent of Americans are concerned that results from a genetic test that can tell patients whether they are at increased risk for a disease like cancer could be used in ways that would be harmful to them; nearly half of all Americans say they are *very* concerned.

There is ample evidence that many patients fear having their genetic information used to deny them health insurance or a job. As a result, patients may pass up genetic testing that could benefit their health, or they could go to great lengths to obtain genetic tests outside the usual health care channels to keep the information from their provider and insurer – paying out of pocket for genetic tests or attempting to keep genetic test results out of their medical records in ways that may jeopardize their care by withholding relevant information. While the public trusts their doctors and genetic researchers, they simply do not trust health insurers or employers to have access to their genetic information.



In our survey, we asked about support for or opposition to various uses of genetic testing, and heard clearly that Americans oppose the use of genetic testing by employers and insurance companies. Four out of five Americans oppose the use of genetic testing by employers to make decisions about hiring and promotion; even more (85 percent) oppose the use of genetic testing by health insurance companies to determine whom to insure and how much to charge. (Figure 2)



When asked specific questions directly relevant to this legislation, nearly all Americans (93 percent) believe that health insurers should not be able to use a person’s genetic test results about increased risk of future disease to deny or limit insurance or charge higher prices. Similarly, 93 percent feel that employers should not be able to use this type of genetic test result to make decisions about hiring and promotion.

These fears about genetic discrimination are a significant factor in research. Just this week I was in Philadelphia conducting focus groups to learn how ordinary citizens would view a proposed large population study to understand the genetic, environmental, and lifestyle factors that contribute to health and disease. By and large, we heard substantial enthusiasm about the study and hopes that such a study could help others at some point down the line. But their enthusiasm and altruism was deeply eroded by concerns about the privacy of genetic information and its possible misuse.

Researchers in a range of genetic studies have reported that potential research participants share this fear of what might happen to their genetic information. The inability of researchers to provide solid evidence of protections against genetic discrimination discourages research participation and endangers genetic research. When citizens give of themselves to help others and to advance biomedical research, don't we at least owe them a solid guarantee that their genetic information will be not be misused?

These issues were anticipated early on in the Human Genome Project and a number of steps already have 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 determining eligibility for benefits and in setting premiums. Congress specifically recognized and listed genetic information as 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. But there are gaps in patient protections both in the group market and more notably in the individual market.

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.

HR 493 goes a long way toward filling the gaps in current law and calming a wary public by making clear that genetic information that is revealed through testing cannot be used to deny insurance to or otherwise prevent an unaffected individual from obtaining the insurance they need. Nor can an employer use such information to discriminate on the job.

I would like to focus my remaining comments on the impact of HR 493 on the provision of healthcare and the conduct of research.

How Does HR 493 Affect Provision of Healthcare?

Some opponents of HR 493 have suggested that the bill would impede the ability of healthcare providers to collect family history information, to request or recommend genetic testing, and to use this information to provide the best possible care to their patients. This is not the case.

HR 493 very clearly and very specifically safeguards the ability of healthcare providers to use the latest genetic tests and genetic medicines to take care of their patients. Indeed, section 101 (c) (2) and section 102 (c) (2) state explicitly that the language of the bill “shall not be construed to limit the authority of a health care professional who is providing health care services with respect to an individual to request that such individual or a family member of such individual undergo a genetic test.”

Let me add that this protects all healthcare professionals, irrespective of their employer or association with a particular plan. Section 202 (b) (2) explicitly exempts health or genetic services offered by an employer from the prohibition on requesting genetic information. This exemption is echoed for health or genetic services offered by employment agencies, labor organizations, and training programs in sections 203, 204, and 205.

Thus, by restricting the discriminatory use of genetic information and expressly protecting the ability of healthcare providers to collect and use genetic information in the provision of patient care, HR 493 protects and nurtures the integration of genetics into medicine to benefit patients.

How Does HR 493 Affect Research?

A substantial impetus for HR 493 was the documented fear of genetic discrimination and its effect on research. It is critical that the bill protect the research enterprise and those that volunteer to participate in research studies. I am convinced that HR 493 protects both research and the research participants who are so vital to finding the tests and treatments of tomorrow.

HR 493 has solid and well-reasoned protections for research. First, by providing strong protections against the misuse of genetic information, HR 493 allows researchers to explain clearly to potential research participants that it is simply against the law for health insurers or employers to use genetic information to alter health insurance coverage or affect employment. The impact of this legal change will be substantial. Second, Section 209 (a) (4) of HR 493 includes language making explicit that nothing in the bill limits the ability of a Federal department or agency to conduct or sponsor occupational or other health research that is in

compliance with Federal human subjects research protections (45 CFR 46). And third, in the employment context, there are specific provisions addressing genetic monitoring to assess chromosomal or DNA damage caused by toxic exposures in the workplace.

In addition to preventing the misuse of genetic information collected as part of a research study, HR 493 offers further protection for research participants. Some are concerned that the mere fact of participation in a genetics research study might be construed by insurers or employers as indicating a heightened genetic risk and might therefore be used to the detriment of the research participant. HR 493 includes restrictions on health insurer and employer use of information about an individual's "request for or receipt of genetic services." Genetic services are defined as (A) a genetic test; (B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or (C) genetic education. Therefore, participation in a genetic research study would be receipt of genetic services and the fact of a person's participation in a genetic research study could not be used to discriminate against them. I believe this language provides strong protections for research participants while preserving the ability of researchers to conduct their studies.

Conclusion

HR 493 prevents the misuse of genetic information while protecting the ability of health care providers to collect family history information, perform genetic tests, and use genetic information to provide the best possible care to their patients. HR 493 also protects individuals who volunteer to participate in research from having their genetic information, or even the fact of their participation in a genetic research study, used in harmful ways by health insurers or employers.

More than three-quarters of Americans believe there should be a law that prevents employers from using genetic test results about risk of future disease to make decisions about hiring and promotion; three-quarters also believe there should be a law to prevent health insurers from using genetic test results about risk of future disease to deny or limit insurance or charge higher prices. The message is clear.

A strong U.S. research and development enterprise is necessary but not sufficient for us to realize the future of personalized genetic medicine. We must also put in place public policies that keep pace with the science and ensure that genetic information is used for benefit and not for harm. We will scare Americans away from these life-saving technologies if they are not confident in the confidentiality of their genetic information.

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, she has many important issues to consider, including what the results will mean for her medically and emotionally. How will the test results affect her treatment? What will the test results 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 will be able to tell their patients that while there is much to consider when deciding to have a genetic test, the threat that genetic test results could be used to deny health insurance or a job is not one of them.

The need for Congress to act grows with every new test developed and with every patient who decides to forego or delay genetic testing because of discrimination concerns. Thank you for taking up consideration of HR 493.