

**Testimony of Karen H. Rothenberg, JD, MPA**  
**Presented before the House Committee on Education and Labor**  
**Subcommittee on Health, Employment, Labor, and Pensions**  
***“Protecting Workers from Genetic Discrimination”***  
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Good morning, Chairman Andrews and members of the Subcommittee. Thank you for the opportunity to speak with you today. I am Karen H. Rothenberg, Dean, Marjorie Cook Professor of Law, and the founding Director of the Law & Health Care Program at the University of Maryland School of Law. Over the last decade or so, a primary area of my research has been on the ethical, legal, and social implications of genetic information and I have published numerous articles on genetics and public policy. I also chaired the Committee on Genetic Information and the Workplace (a joint project of the NIH-DOE Working Group and National Action Plan on Breast Cancer) that developed the framework for state and federal legislative proposals. Most recently, I co-authored an article in *Science* with my colleague Diane Hoffmann of the University of Maryland School of Law on the use of genetic information in the courtroom.

I would like to begin by putting in context our concerns about genetic discrimination in the workplace. Almost 20 years ago, Congress committed to investing in the Human Genome Project because it shared the vision of a revolution in medicine that would improve the health of all Americans. Their goal was not to provide health insurers and employers new tools to weed out individuals that might someday generate large health

care costs. To date, close to three-and-a-half billion dollars has been appropriated to fund the promise of genomic research for the American people. The return on this investment is substantial and has the potential to transform medicine as we know it. But, unless Congress acts to address the perils associated with unauthorized dissemination of citizen's genetic information, we may never be able to make the transition from the research laboratory into the doctor's office.

Even in the early days of the Human Genome Project, people were concerned about the social risks associated with genetic research and anticipated that strong protections against misuse of genetic information would be established. Yet here we are almost 20 years later, with enormous advances in scientists' ability to sequence and interpret our DNA, and we have yet to achieve a federal law to safeguard genetic information. The tremendous promise of genomics is hamstrung by fear.

How extensive is this fear of genetic discrimination, and why does it matter?

- Fear of genetic discrimination is widespread in the American public. A 2006 survey by Cogent Research showed that 72 percent of respondents agreed the government should establish laws and regulations to protect the privacy of genetic information. Eighty-five percent believed that without a specific law on point, employers will discriminate. Sixty-four percent believed that insurance companies will do everything possible to use genetic information to deny health coverage. Recent polls conducted by the Wall Street Journal Online/Harris

Interactive Healthcare and the Genetics and Public Policy Center showed similar results.

- Fear of genetic discrimination has a negative impact on biomedical research and potentially, healthcare decision making. Genetic research holds tremendous promise to unlock new diagnoses and new treatments, and even to assist in the creation of pharmaceutical therapies tailored to an individual's genetic makeup. However, scientific research and development cannot progress without clinical trials, and these trials can move forward only if individuals who could benefit are willing to participate. Fear that information will become available to and be misused by health insurers or employers has chilled participation in many studies of genetic conditions. For example, in a 2003 NIH study of families at risk for heredity nonpolyposis colorectal cancer (HNPCC), the number one concern expressed by participants regarding genetic testing was concern about losing health insurance should the knowledge of their genetic test result be divulged or fall into the "wrong hands". Thirty-nine percent of participants cited this as the most distressing issue relating to genetic testing. Nearly half of family members at 50 percent risk for inheriting a cancer-inducing mutation were not willing to participate in any aspect of the study because of their fear of discrimination.

Where does this fear of genetic discrimination come from; and is it justified?

Perhaps it would be helpful to place these questions in historical context. In the early 1900's, Congress relied on the use of "genetic science" and the "genetic inferiority" of racial, ethnic, and disadvantaged groups to restrict their immigration into this country. State legislatures promoted sterilization laws based on the same rationale and eugenics was the "scientific justification" for killing millions during the Holocaust. During the early 1970's, African Americans who were carriers for the gene mutation associated with sickle cell disease were denied insurance coverage, charged higher rates, and lost their jobs. More recently, the Burlington Northern Santa Fe Railway Company paid up to \$2.2 million to settle a 2002 lawsuit brought by employees who were secretly tested for a genetic variation purported to be associated with carpal tunnel syndrome.

Nevertheless, because there is currently little evidence of major problems with widespread discrimination, some might argue that there is no need for legislation. It is true that in recent years we have not been able to quantify the incidence of genetic discrimination. Why? First, we do not have widespread utilization of genetic services. Second, individuals often will not know or understand the underlying basis for an insurance or employment decision. Third, without clear legal remedies, healthy individuals with a genetic predisposition for a medical condition may be averse to risking loss of privacy for themselves and their families by going public with a discrimination claim, a greater risk than if the claim were based on race or sex. Finally, there may in fact be discrimination cases settled or resolved at the trial court levels that are never formally reported.

This raises an interesting public policy question: is it prudent to pass preventive federal legislation based on a fear of genetic discrimination? I would argue “yes,” if we are to fully benefit from the promise of genetic research.

Over the last decade, most states have enacted genetic nondiscrimination legislation, although the scope of protection varies widely. Forty-one states have passed laws on discrimination in the individual health insurance market and thirty-four states have passed laws on genetic discrimination in the workplace. There have also been patchwork approaches at the federal level. For example, President Clinton’s Executive Order 13145 protects federal employees from genetic discrimination in the workplace. Federal laws such as HIPAA, the ADA, and Title VII of the Civil Rights Acts may provide some protection, but there remain loopholes and gaps in coverage:

- HIPAA prohibits raising rates for or denying coverage to an individual based on genetic information within the group coverage setting, but HIPAA protections are limited to only the group market. It does not cover individual insurance plans. The Federal Privacy Rule, authorized by HIPAA, protects the use and disclosure of individually identifiable health information, including genetic information. The Rule does not prohibit the use of genetic information in underwriting. If a company determines that the individual is likely to make future claims, they could be charged higher premiums or denied coverage.
- The ADA was designed to protect those individuals who are living with a disability. The ADA defines disability as 1) a physical or mental impairment that substantially limits one or more of the major life activities of an individuals; 2) a

record of such impairment; or 3) being regarded as having such an impairment.

While the ADA provides protections for people who have current disabling genetic illnesses, it is not at all clear whether the law covers individuals who have a genetic mutation that predisposes them to disease. Although guidance issued by the Equal Employment Opportunity Commission (EEOC) suggested a number of years ago that the ADA could apply in situations where an employer treats or regards an employee as impaired based on their genetic makeup, no court has ruled specifically on this issue. To the contrary, recent court cases have established a general trend of narrowing the ADA's scope stretching the ADA's definition of "impairment" to cover genetic predisposition to disease is inconsistent with the current judicial interpretation of the ADA.

- It is not clear whether Title VII of the 1964 Civil Rights Act would provide protection for those claiming genetic discrimination in most circumstances. Protection under this law is available only where an employer engages in discrimination based on a genetic trait that is substantially related to a particular race or ethnic group.

Thus, there is no uniform protection against the use of, misuse of, and access to genetic information in the workplace. As a matter of public policy, we still need to achieve a comprehensive approach that includes the following:

(1) Employers should be prohibited from using genetic information in hiring, firing, and determination of employee benefits.

(2) Employers should be prohibited from requesting or requiring collection or disclosure of genetic information unless they can show that the disclosure is relevant to the job.

This is a very high standard and one that will rarely be met. Written and informed consent should be collected for each request, collection, or disclosure of genetic information.

(3) Employers should be restricted from access to genetic information contained in medical records released as a condition of employment, in claims filed for health care benefits, or any other sources.

(4) Employers should be prohibited from releasing genetic information without prior written authorization of the individual for each and every disclosure.

(5) Employers who violate these provisions should be subject to strong enforcement mechanisms, including a private right of action.

I understand that there might be concern that new federal legislation may place an undue burden on the business community. This is unlikely for two reasons: First, if we are to assume that employers are complying with applicable state laws then a federal law should not represent a significant new burden. Second, employers and those representing the insurance community have long maintained that they are not currently using genetic information to determine eligibility or employment status. If so, a federal prohibition should not burden their business practices. It would simply prevent the misuse of genetic

information and be integrated into their legal compliance efforts. I am not aware of any data that demonstrates increased costs to employers for complying with these state laws.

In conclusion, the era of genomic medicine is here, but fear continues to paralyze its future. In the words of Dr. Francis Collins, Director of the NIH Human Genome Research Institute:

Unless Americans are convinced that their genetic information will not be used against them, the era of personalized medicine may never come to pass. The result would be a continuation of the current one-size-fits-all medicine, ignoring the abundant scientific evidence that the genetic differences among people help explain why some patients benefit from a therapy and, while some do not, and why some patients suffer severe adverse effects from a medication, while others do not.

It is my hope that passage of comprehensive federal legislation will move us forward to honoring our commitment to improving our understanding of genetics and its positive impact on the health of all Americans.

Thank you. I welcome your questions.