

**Testimony on
Genetic Information and Testing**

By

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on behalf of
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Subcommittee on Health**

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I. Introduction

Mr. Chairman, Mr. Deal, and members of the subcommittee, my name is Dr. William Corwin. I am the medical director for clinical policy at Harvard Pilgrim Health Care. Harvard Pilgrim Health Care is a not-for-profit health plan that provides a variety of insurance plan options to more than a million members in Massachusetts, New Hampshire and Maine. Harvard Pilgrim provides innovative approaches to health improvement and disease management, unique online tools that speed and simplify key transactions for employers and providers, and personalized health support.

Harvard Pilgrim was named the #1 health plan in America in three consecutive years according to a joint ranking by *U.S. News & World Report* and the National Committee for Quality Assurance (NCQA). The November 6, 2006 edition of *U.S. News & World Report* ranked the nation's best health plans and determined that Harvard Pilgrim continues to lead the country for member satisfaction and quality of care. Harvard Pilgrim is the only health plan to earn the nation's top rating from NCQA three years in a row. Harvard Pilgrim's HMO and PPO plans have been recognized by J.D. Power and Associates for providing health plan members with an outstanding member experience for a third consecutive year.

Harvard Medical School and Harvard Pilgrim Health Care jointly sponsor The Department of Ambulatory Care and Prevention (DACP). This is the nation's only medical school department that is jointly sponsored by a health plan. The DACP is actively engaged in both research and teaching. The DACP leads in the creation and dissemination of new knowledge and skills essential to maximizing the health of defined populations within available resources. Research conducted by the DACP is routinely vetted through the Harvard Medical School Institutional Review Board process.

I appreciate this opportunity to testify about issues relating to genetic information and testing, including H.R. 493, the "Genetic Information Nondiscrimination Act of 2007" (GINA). I am testifying today on behalf of America's Health Insurance Plans (AHIP), which is the national association representing nearly 1,300 health insurance plans providing coverage to more than

200 million Americans. AHIP's members offer a broad range of products in the commercial marketplace – including health, long-term care, dental, disability, and supplemental coverage – and also have demonstrated a strong commitment to participation in public programs.

Health insurance plans are working on a daily basis to promote the appropriate use of genetic tests to help clinicians and patients make informed health care decisions and improve health outcomes. We agree with the sponsors of H.R. 493 that health care consumers should not face discrimination on the basis of their genetic makeup and that genetic information should be protected from unauthorized disclosure. Our policies and programs reflect this belief.

Our testimony today will focus on three broad areas:

- examples of how health insurance plans are promoting the appropriate use of genetic tests to improve patient care;
- opportunities for improving H.R. 493, the “Genetic Information Nondiscrimination Act of 2007”; and
- our support for strong protections with respect to nondiscrimination and confidentiality of genetic information.

II. Improving Patient Care Through the Appropriate Use of Genetic Tests

Health insurance plans are strongly committed to helping their enrollees receive the highest quality care possible. Through early detection, disease management programs, and other quality improvement initiatives, we are working on a daily basis to identify individuals who can benefit from early intervention to guide patient-centered care and choices while supporting the best evidence-based treatment for specific illnesses and diseases. Genetic information, including the results of genetic tests, is just one more sophisticated source of data that clinicians and health

insurance plans are using to ensure that patients receive appropriate preventive care, coordination of services, and early treatment for their medical conditions.

Health insurance plans encourage appropriate genetic testing for individuals who are at risk of certain genetic conditions for which there are specific interventions for prevention or treatment. Such tests can provide information that may positively affect the course of an individual's treatment. The following are several examples of how genetic tests are being used to improve patient care:

- According to guidelines issued by the National Institutes of Health (NIH), the treatment for hepatitis C patients should be extended – from 24 weeks to 48 weeks of therapy – but only in cases where a viral genotype guide has been identified in an individual. In this situation, a genetic test can determine whether the patient could benefit from an additional 24 weeks of therapy and thereby help the clinician prescribe a more effective course of treatment. The health insurance plan will need to know whether the genetic test was performed in this situation in order to authorize and/or pay for the extended course of therapy for the individual.
- In February 2007, the Food and Drug Administration (FDA) approved a new genetic test, a MammaPrint, which indicates whether a woman is likely to have a breast cancer relapse. This test allows physicians to tailor therapy for individual patients and administer chemotherapy to only those patients who would benefit. At the same time, the test allows physicians to identify patients who would not benefit from chemotherapy and should not be subjected to this risky and costly treatment. This new test will help guide the treatment of roughly 100,000 women each year who are diagnosed with early stage breast cancer.
- Breast cancer patients can benefit from HER-2 genetic tests that indicate whether their tumors would be responsive to herceptin therapy. Significantly, this test also allows physicians to identify patients who would face adverse side effects, including increased risk of heart disease, if they received herceptin therapy that is not appropriate given their genetic makeup.

- Another test, the Cytochrome P450 enzyme, is genetically coded. The identification of the presence or absence of this genomic marker enables a physician to evaluate a patient's ability to process many different medications, adjust dosages intelligently, and avoid potential adverse drug reactions in patients who either metabolize a drug quickly or do not metabolize a drug at all. This test also is used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy. Health insurance plans may request that this test be performed before authorizing a course of therapy or treatment to ensure that appropriate care is being provided to meet the patient's individual needs.
- Genomic signatures can be used to drive gene profiles from cell-lines that predict drug sensitivity for difficult-to-treat malignancies such as lung cancer. Genomic signatures will direct the choice of drug therapy as determined by the tumor's biology and not a "best guess" about what "might" work in an individual's situation.

To help patients understand the appropriate use of these and other genetic tests, health insurance plans are partnering with physicians and other providers to ensure that enrollees have access to informational materials about the impact of genetics on health care. This consumer education is helping to increase patient awareness about the availability of coverage for genetic tests and services as well as treatments and therapies that can be used to combat and treat genetic diseases and conditions. The value of this information can reduce unneeded anxiety about possible gene mutations or genetic diseases and conditions.

Health insurance plans are using genetic test results to promote preventive screening and disease management programs. These programs can help to improve health care for individuals who have tested positive for a genetic disease or who have a family history of a specific disease or condition. For example, individuals who have the gene for the familial form of colorectal cancer can receive coverage for more frequent preventive screenings. As scientists acquire a greater understanding of the role genes play in disease and develop more genetic therapies and possibly even cures, preventive screening and disease management programs can be tailored to improve outcomes for individuals. This ability will become even more important in the future.

Individuals also benefit from research projects that health insurance plans conduct to examine the genetic and environmental factors that influence common diseases such as heart disease, cancer, diabetes, high blood pressure, Alzheimer's disease, and asthma. By combining the genetic, health, and survey information from hundreds of thousands of members into databases, researchers hope to gain a deeper understanding of what combinations of genes and environmental factors influence the risk of complex diseases.

Such research projects meet the highest scientific standards and comply with the legal requirements for privacy and confidentiality, including the requirements applicable to federally-funded research projects under HIPAA (e.g., 45 C.F.R. 164.508, 512(i)) and other applicable legal provisions. One example is a project being conducted by another AHIP member, Kaiser Permanente of Northern California's Division of Research. In that project, individual participation in the research is completely voluntary and individual genetic information will not be used in genetic studies without written consent. The data will be used only for research purposes and ultimately is expected to yield findings that will enable the medical community to be more precise in pinpointing the causes of disease and tailoring treatment for patients.

III. Opportunities to Improve H.R. 493

We appreciate the interest many subcommittee members have shown in passing additional legislation addressing the use and disclosure of genetic information. As you consider such legislation, we urge you to fully evaluate the implications of any additional requirements or prohibitions and ensure that new legislation does not unnecessarily restrict the use of information needed to promote appropriate health care decision-making.

Working through AHIP, our industry association, we have reviewed H.R. 493 and identified several areas where we believe changes are needed to ensure that genetic information can continue to assure appropriate coverage decisions and be available to improve the quality of patient care. We would like to publicly state that we do not oppose the bill and agree with its

intent. However, once enacted, the bill will be interpreted by clinicians, non-clinicians, individuals, lawyers, courts, and other interested persons who can take various interpretations of Congress' intent and how the requirements can apply in various settings. To avoid any confusion, health insurance plans would like to engage subcommittee members in a dialogue about our suggestions for clarifying the statutory language of the bill. We respectfully offer the following issues for your consideration.

- **Medically-indicated testing should be encouraged to promote consumer access to appropriate coverage and treatment.**

As currently drafted, section 101 of the bill could limit consumer access to life-saving treatments because it prohibits health insurance plans from “requesting or requiring” an individual or a family member of an individual to undergo a genetic test. This prohibition can be read as restricting the ability of a health insurance plan to request this information, even when it is needed to determine the appropriate course of treatment and evaluate the patient's eligibility for coverage.

As noted in the previous section, a genetic test is needed to determine whether hepatitis C patients could benefit from an additional 24 weeks of therapy under NIH guidelines. However, by prohibiting plans from requesting or requiring this test, H.R. 493 may cause some individuals to forego coverage for the extended therapy that is needed to effectively treat their particular condition.

Looking to the future, unforeseen advances in medical treatment and technologies may lead to many additional circumstances where health insurance plans will need to request genetic tests to determine whether customized therapies or treatments are warranted. Therefore, we urge the subcommittee to consider changes that would allow proper uses of genetic tests while at the same time meeting the bill's original goal of prohibiting genetic discrimination.

- **Health insurance plans should be allowed to request “genetic tests” to promote preventive screening and disease management.**

Another concern is that this legislation would prevent health insurance plans from continuing to use genetic tests to promote preventive screening and disease management programs.

We are proud of the success health insurance plans have achieved in promoting preventive health care services to keep Americans healthy, detect diseases at an early stage, and avoid preventable illnesses. Plans also have been proactive in developing innovative disease management programs to improve patient care and health outcomes for persons with diabetes, congestive heart failure, and other chronic conditions.

Because of these private sector initiatives, millions of Americans are healthier and enjoying a higher quality of life. Congress should be making every possible effort to support these initiatives. Unfortunately, H.R. 493 could stifle health insurance plans from utilizing genetic tests to identify patients who may benefit from specific types of preventive screening or disease management services.

For example, a person who has the gene for the familial form of colorectal cancer could benefit from earlier or more frequent screenings for the disease. As genetic science advances over the next decade and beyond, health insurance plans will have a legitimate need to use genetic testing to identify these persons and ensure that they receive the necessary screening and early intervention to detect and treat cancers for which they are highly susceptible.

Current law allows health insurance plans to use genetic testing in this manner, but H.R. 493 could prevent plans from taking such proactive measures on behalf of their enrollees. We urge the committee to change the bill to ensure that it does not unintentionally undermine preventive health care services and disease management programs.

- **A clearer, more precise definition of “genetic information” would promote optimal patient care and help avoid unintended consequences for consumers.**

We also are concerned that H.R. 493 includes an excessively broad definition of the term “genetic information.” As currently written, this definition could apply to diseases, tests, and conditions that are completely unrelated to genetics.

Another problem is that the bill’s definitions arguably could apply to certain conditions – such as obesity or high cholesterol – that are not genetic, but may be linked to a person’s family history. Even though there is no connection to a specific gene for these conditions, the bill in its current form could be interpreted to prevent health insurance plans from requesting tests that could help patients avoid or overcome health problems caused by obesity or high cholesterol.

These are serious issues with far-reaching implications for health care consumers. As this bill moves through the legislative process, we urge the subcommittee to define “genetic information” with greater clarity and precision.

- **The threat of litigation can be alleviated by clarifying that Title II of the bill, encompassing employers and unions, does not cover the administration and operation of employer-sponsored group health plans.**

Although the bill includes separate titles addressing health insurance issues (Title I) and employment issues (Title II), the legislative language of Title II could be interpreted to include the terms of an employer-sponsored group health plan as an employer practice that could be the basis for a discrimination complaint. Specifically, section 202 states that it is an unlawful employment practice for an employer to “discriminate against any employee with respect to the compensation, terms, conditions, and privileges of employment.” This language can be interpreted as applying to a health benefits plan or health coverage sponsored or offered by an employer. Some employers may be discouraged from offering employee health benefits to avoid the threat of litigation. It is our understanding that the Title II provisions were not intended to cover health benefits plans and we suggest that the language be clarified to ensure that employer-sponsored group health plans are not covered under the Title II language.

We also would like to bring certain technical issues to the subcommittee's attention. It is our understanding that the sponsors of H.R. 493 do not intend for the bill to cover long-term care products. Also, the bill may be read to effectively create "two classes" of health information, creating barriers to optimal patient care and the advancement of a national health information infrastructure. AHIP is communicating with subcommittee members and staff about these and other significant issues.

IV. Industry Support for Nondiscrimination and Privacy Protections

It is important for the subcommittee to understand that genetic information is not used to deny or cancel coverage or set premiums. At the same time, health insurance plans are accustomed to and understand the importance of protecting the privacy and confidentiality of individually-identifiable health information, including genetic information. Our industry's practices reflect our strong support for provisions of current law that: (1) prohibit discrimination against individuals based on their genetic information; and (2) protect the confidentiality of patient-identifiable genetic information.

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits employers and health insurance plans in the group market from using the results of genetic tests to deny coverage or set different premium rates for individuals who participate in group health plans. HIPAA specifically prohibits group health insurance plans from:

- refusing to cover employees or their family members based on genetic information;
- refusing to renew coverage based on genetic information;
- charging employees and their family members higher premiums based on genetic information; and

- canceling coverage based on genetic information.

In addition to providing these nondiscrimination protections, HIPAA established an effective framework for health insurance plans, health care providers, and health care clearinghouses to protect individuals' health information. In addition, a number of state privacy laws impose similar restrictions on the use and disclosure of health and genetic information by health insurance plans.

The following examples highlight some practical examples of how these privacy protections apply in real-life settings:

- HIPAA prohibits health insurance plans or health care providers from disclosing information about an individual's genetic tests to an employer who sponsors a health insurance plan.
- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for the individual's treatment.
- HIPAA permits health insurance plans and health care providers to use and disclose genetic information when needed for coverage determinations – such as to determine whether coverage for a genetic test or genetic service will be authorized or paid for by a health insurance plan.
- HIPAA permits individuals to authorize a health insurance plan or health care provider to disclose their genetic information to a person who would otherwise not be entitled to receive the information (e.g., to a family member interested in learning about the individual's genetic conditions).

V. Conclusion

Thank you for considering our perspectives on these important issues. Health insurance plans are strongly committed to ensuring that genetic information is used to help clinicians and patients make informed health care decisions and, at the same time, maintaining strong protections in the areas of nondiscrimination and confidentiality. We appreciate this opportunity to testify and we stand ready to work with the subcommittee on this and other health care priorities facing our nation.