**Testimony of Joanne Armstrong, M.D., M.P.H.**

Next we're going to hear from Joanne Armstrong.

DR. ARMSTRONG: Thank you for inviting me to testify regarding this important issue. My name is Joanne Armstrong. I'm a senior medical director for Aetna, and I am testifying today on behalf of America's Health Insurance Plans and its nearly 1,300 member companies.

America's Health Insurance Plans, or AHIP, is a national trade association representing the private sector in health care. AHIP's member companies provide services for over 200 million Americans. Aetna serves approximately 14 million health care members through a national network of about 500,000 service providers, including laboratories, including over 300,000 primary care physicians and specialist physicians, and over 3,000 hospitals in its national network.

Genetic medicine is not new. DNA and non-DNA-based genetic testing has been in wide clinical use for many decades. Examples range from carrier type testing in reproductive health and pediatrics through serum testing for abnormal forms of hemoglobin and others. A promising new area of genetics utilizes genetic test results to guide the choice or the duration of pharmacogenetic therapies. These so-called selected or targeted therapies hold out the promise of directing medications to individuals who may benefit from them, while avoiding side effects and costs in others.

Examples are found in breast cancer and colon cancer treatment already in terms of duration of therapy. We know that pharmacogenetic principles are applied in hepatitis C management.

While genetic testing itself is not new, the rate of new genetic discoveries entering clinical practice is increasing at a dizzying rate. The speed of these new discoveries is challenging our health care system's ability to effectively integrate them into clinical practice and to optimize their benefits to prevent and to possibly cure disease.

Because of the complexity of genetic information, the optimal use of genetic technologies requires informed providers, informed members, and coordination of services across this complex array of delivery systems. Unfortunately, I think we know that much work needs to be done in all of these areas to get it right. For example, we know that 72 percent of physicians are not completely prepared; 72 percent of non-genetics physicians rate their knowledge of genetics as fair to poor, and we've heard some testimony about that. Patients are also not adequately prepared to navigate these waters. Fully 82 percent of consumers cannot correctly answer most genetic medicine knowledge questions in national surveys.

So as with the adoption of other medical services and technologies, health plans are and will continue to be instrumental in the coordination of this care. This process in genetics has already started, and some of the benefits have already accrued. For example, health plans have demonstrated success in improving patient compliance in a number of pharmacogenetic areas, including hepatitis C management.

As the science of genetics advances, concerns over protecting genetic information from inappropriate uses have escalated. There is growing public awareness about the health benefits that can be derived from genetic information and concerns about the potential misuse of this information. We must, however, engage in responsible policymaking on these issues and not unnecessarily restrict the use of genetic information needed to promote appropriate health care

decisionmaking and assist in the coordination of this care, which is already quite fractured.

I'd like to address my remarks today largely to the current use of genetic information by health insurance plans to give the panel an understanding of how it's used today, and also to briefly address some of the issues regarding the laws to protect this information.

So the first question is how do health plans currently use genetic information? Genetic information is just one of many types of medical information that is currently used by plans in all sorts of activities, including the promotion of risk assessment for its members, preventive screening efforts, disease management, pharmacy compliance management programs, quality assurance management programs, and the larger umbrella of just the coordination of these cares across this very complex array of delivery systems.

A key component of health care delivery is to make sure that patients and health care providers have the information they need to make informed decisions, and health plans are facilitating this exchange of information in genetics to encourage appropriate counseling and testing and decisionmaking that follows that. For example, health plans have had for a long time a very active role in promoting genetic counseling in the reproductive health arena to ensure the highest quality of information is provided to members to make the best decisions for themselves. We know that when genetic counseling is provided by formally trained genetic counselors, the amount of actionable and higher quality information that comes out of it is much higher than when it's delivered by non-genetics-trained clinicians. We know when this takes place, patients and members get better results.

As an early adopter of coverage for BRCA breast and ovarian cancer genetic susceptibility testing, Aetna incorporated genetic counseling services into the testing process to ensure that medical appropriateness of testing took place and to ensure that at-risk individuals receive accurate information to support their subsequent decisionmaking. Health plans also use genetic information to help enhance preventive screening and health promotion efforts for individuals who have a disease. Genetic data is used by plans to create deviations in standard coverage benefit packages to enhance the types of services that members get compared to what is available for the general population.

For example, screening tests that are available for hereditary non-polyposis colon cancer for affected individuals, they require earlier and increased frequency of screening. Access to this genetic information allows health plans to create deviations in their coverage processes to provide those services to these members. So obviously, this is an added value.

Similarly, for patients who are BRCA positive, these women need increased, more frequent screening at an earlier time and through different technologies than that which is recommended for the population at large. In order to administer these benefits to make it happen and deliver it across this complex system, this type of data sharing takes place.

Already discussed, obviously, in this meeting, genetic data is multigenerational and in some instances requires new testing paradigms from a health plan perspective to assess risk and deliver the most appropriate services to patients in the best possible way. The most efficient BRCA screening scenario for at-risk individuals may in fact involve the testing of an affected family member who is herself not a covered member. Aetna has led the industry in extending, on a voluntary basis, coverage benefits to non-covered members of the plan if those test results actually help the member of our plan. Again, to administer these types of benefits, data sharing is necessary.

Then on a very practical level, physicians and members call health plans on a daily basis, dozens and hundreds of times a day, with very specific questions about where can I get this genetic test done, what is my contract allow, how do I coordinate these services. So these are very basic operational issues where genetic information is shared on a daily basis.

I should also add that when claims are submitted, these claims come in with specific genetic markers that are on them, and that is a necessary part of getting these services paid for across a very complex health care system.

Finally, as scientists acquire a greater understanding of the role genes play in all disease states, especially chronic diseases, genetic information will be incorporated into disease management programs and pharmacy management programs. It sort of speaks to the comment that was made earlier that genetic information will be part of standard medical practice as we understand its contributions to chronic hypertension and other disease states.

There is every reason to believe that this will lead to improvements in health outcomes beyond that which have already been demonstrated and disease management and pharmacy management programs that take place within health plans today. Again, data sharing will be important to the success of these efforts.

Lastly, I would just like to briefly discuss some of the issues related to the inappropriate use of genetic information. AHIP believes that the importance of protecting genetic information from illegal and inappropriate use if critical. One of the unfortunate myths about genetic information is that health plans use this information to deny insurance at a global level or to disclose genetic information inappropriately. In fact, health plan companies have many years, decades now, of experience in sharing and using genetic information for their members with little empirical evidence that it is being misused.

As a matter of practice, health insurance plans do not use or disclose personal health information for purposes outside their necessary insurance coverage activity, and federal and state laws currently in place do provide some protection. As early as 2002, Aetna recognized the heightened sensitivity of genetic information and incorporated confidentiality protections into the everyday use of genetic information within our plan.

So protecting the confidentiality of all health information, including genetic information, is critical to preserving the open and honest communication between physicians, clinicians, and their patients. We also believe that consumers should be able to both benefit from coordinated and integrated health care delivery systems while being protected against unlawful disclosures of genetic information.

So in conclusion, AHIP and its member companies believe that genetic information can help providers and their patients make informed health care decisions. Health insurance plans have an important role to play in promoting the appropriate use of genetic tests by encouraging evidence-based counseling and testing and supporting consumer education and patient awareness, and using genetic test results to enhance preventive screening and disease management. For many decades, health insurance companies have demonstrated responsible use and management of their insureds genetic data.

Health insurance plans strongly support protecting all patient identifiable health information, including genetic information, from unauthorized disclosures and other illegal uses, and as the

science of genetics advances, we are committed to facilitating access to genetic services and guarding against misuse of this data.

Thank you.

MS. MASNY: Thank you, Dr. Armstrong.