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Comments to the Secretary's Advisory Committee on Genetics, Health, and Society

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by Sharon Terry

The Genetic Alliance Board of Directors appreciates the opportunity to address the Committee regarding the *Coverage and Reimbursement of Genetic Tests and Services* draft report. We would like to applaud the Committee for tackling this complicated and controversial topic, and commend it on a job well done.

An international coalition comprised of more than 600 advocacy, research, and health care organizations that represent over 14 million individuals with genetic conditions and their interests, Genetic Alliance is guided by the conviction that access to health care, education, and employment is essential to all individuals, regardless of genetic inheritance. As such, the issues surrounding the coverage and reimbursement of genetic tests and services are of significant interest to our organization and its members.

While we appreciate the thoughtful recommendations outlined by the Committee's report, we must first acknowledge that the effectiveness and impact of all proposals is dependent on the passage and enactment of Genetic Information Nondiscrimination Legislation. Furthermore, adequate education, for both health care professionals and consumers, on the subjects of genetics and genetic testing is essential to ensure appropriate coverage and reimbursement for genetic tests and services.

After examining the recommendations made in the *Coverage and Reimbursement of Genetic Tests and Services* draft report, Genetic Alliance recommends the following additions and clarifications:

- **Allowing qualified health care providers to bill directly for genetic counseling services.**
- **The Secretary should expeditiously identify an appropriate mechanism for validating the credentials of approved providers and for determining the credentials non-physician health care providers must present to be deemed qualified.**
- **Adding "informational utility" to the criteria—which now includes analytical and clinical validity—used to determine the value and importance of genetic tests.**
- **Ensuring that the use of cost-effectiveness data does not eliminate coverage for services related to rare diseases.**

- **Reducing private insurer's reliance on Medicare and Medicaid decisions related to coverage and reimbursement of genetic tests and services.**
- **Creating an environment in which preventative care is more likely to be covered by insurers.**

Qualified health care providers should be allowed to bill directly for genetic counseling services.

Referring specifically to the potential recommendation on page 52 of the Committee's report that addresses qualified providers of genetic counseling services, Genetic Alliance recommends that the language be revised to read:

"Qualified health providers—including board certified genetic counselors and advanced practice nurses with the APNG credential provided by the GNCC - should be allowed to bill directly for genetic counseling services. The Secretary should expeditiously identify an appropriate mechanism for validating the credentials of approved providers and determining the credentials and criteria necessary to classify non-physician providers as qualified to provide, and eligible to bill directly for genetic counseling services."

Until genetic specialists are fully integrated into the health care system, medical genetics will not achieve its incredible potential.

Genetic tests and services that have not demonstrated analytical and/or clinical validity must be, at the very least, considered for coverage.

As the Committee's report correctly indicates, genetic tests and services often do not qualify as either analytically or clinically valid. However, these tests should continue to be considered necessary research tests. Furthermore, this report acknowledges the importance of the utility of a test—usually determined by the potential medical interventions—to the coverage decision-making process. However, genetic tests may demonstrate utility that extends beyond the bounds of the traditional medical model. Through discussions with our members, we have become acutely aware that information is critical. Sometimes all a family has is information, knowledge that then becomes a fundamental component in all of their planning processes. In addition, particularly in the case of rare diseases, affected individuals and families who learn about a condition can participate in registries and research, allowing for an improved characterization of that disease and the possible development of medical, psychosocial, and educational interventions.

Cost-effectiveness data, while necessary, must not be overemphasized in the coverage decision-making process.

Though Genetic Alliance recognizes the reality of cost-effectiveness as a criterion for determining coverage, we urge the Committee to stress the importance of providing services to individuals with rare diseases despite the cost. Individuals with rare conditions represent a community that faces a seemingly infinite stream of challenges; the lack of insurance coverage

for testing services is one of the many barriers impeding the maintenance of an individual's health and well-being. Additionally, in order for research to advance, registries and cohorts must be built with accurate data from test results. We know that the study of rare diseases can lead to extraordinary progress in the diagnosis and treatment of common diseases that share a pathway, but this will happen only if we make a concerted effort to encourage research in this area.

Coverage decisions should not be made based on the Medicare program's coverage alone.

While Medicare is the largest health insurance provider in the United States, by definition it excludes a number of segments of the population. That fact notwithstanding, private insurers use coverage decisions made for the Medicare program as guidelines for their own policies. Unfortunately, as the Committee has acknowledged, the result of this behavior is a system that limits coverage of certain tests and services for everyone simply because those tests do not necessarily have significant value for the Medicare population—people age 65 and older, people with certain disabilities, and people with end-stage renal disease. To address this problem, Genetic Alliance recommends creating a mechanism that would assist insurers through the evaluation and subsequent coverage decision-making process, thus improving consumer access to appropriate care across all populations. With the decoding of the human genome and the subsequent move toward personalized medicine, has come a demand for health insurance that recognizes and values individual needs in all populations. As such, technology assessment must be revamped to engage in accurate assessment of new tests and their impact on individuals in addition to larger populations.

We must embrace preventive care as an absolutely essential component of any health care system.

As it stands, coverage for preventive care in public health insurance programs requires Congressional authorization, a fact that significantly limits access to predictive and predispositional genetic tests and services. Furthermore, while private insurers are free to cover these services, too often they follow the lead taken by public programs and exclude the preventive procedures. We at Genetic Alliance recognize the significant value and very often cost-effective nature of preventive care, and we support the Committee's recommendation to "add a benefit category for preventive services." In doing so, the Committee would help establish an environment in which preventive care is appropriately valued.

However, Genetic Alliance also urges the Committee to re-examine the evidence standards used to determine whether or not a procedure—in this case, a preventive procedure—should be covered. As was previously discussed, predictive and predispositional genetic tests and services are often dramatically different from traditional tests and services. Therefore, these procedures do not necessarily meet the evidence standards outline by the Centers for Medicare & Medicaid Services (CMS). However, genetic tests provide valuable information about an individual's future health risks and can influence health care and lifestyle decisions, much like mammography and newborn screening programs. As such, we should encourage coverage for these services to ensure broad access for all consumers.

Once again, I thank you for the opportunity to address this Committee. Should you desire it, I am happy to provide documentation to support these suggestions. Please, feel free to contact me.

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