Public Comment to the Secretary's Advisory Committee on Genetic Testing

August 4, 2000

Thank you for the opportunity to provide public comment relative to SACGT discussions.

Genome science is moving incredibly fast. With completion of the draft sequencing of the human genome last month, we are rapidly entering an entirely new stage in genomics research and technology development. Tests are currently available for approximately 700 genes, most of which are associated with relatively rare conditions. That number will soon grow to the thousands with identification of genetic links to more common health problems. Soon we will have the technology to process multiple genetic tests on one assay chip alone.

With this explosion in the ability to diagnose, predict and identify predisposition and susceptibility for a broad range of health problems - from common complex to rare, the Genetic Alliance welcomes the efforts of the Secretary’s Advisory Committee on Genetic Testing in developing appropriate levels of testing oversight for different categories of tests.

As an international coalition of 300 patient advocacy and health professional organizations, the Genetic Alliance is dedicated to supporting people who live with genetic conditions, educating the public and health professionals, and advocating for beneficent and consumer-informed public policies. The Genetic Alliance suggests that several core principles guide the committee’s deliberations, as SACGT makes these necessary and difficult recommendations about oversight and test scrutiny categories.

- The issue of affordable access to quality services must remain central to policy decision-making.

The public deserves genetic tests and technologies of the highest quality possible. There is a delicate and dynamic balance between quality improvements, through increased oversight, and affordable access, that is impacted by added costs and industry disincentives. With respect to rare disease tests, disease advocacy organizations will serve as essential partners in deliberating options, making
recommendations, monitoring impact on affordable access and suggesting adjustments to initial recommendations.

• To sharpen understanding of the clinical validity and utility of each test, central data collection is an absolute imperative.

The Genetic Alliance supports the establishment of central data repositories and will work to raise public awareness of the benefits of these next research steps. As affected individuals and family members, we recognize that improved health outcomes require our active participation in this information gathering process.

The Genetic Alliance stands solidly behind the SACGT with respect to recommendations for increased quality assurances and central data collection. However, until Federal genetic nondiscrimination protections in health insurance and employment are in place, our ability to participate in and contribute fully to the success of SACGT's recommendations is significantly compromised.

• To ensure the promise of genomics to improve individual and public health, protections against the misuse of information must be approved.

Because of the significance of genetics nondiscrimination to the core mission of the Genetic Alliance, we are currently conducting a pilot study to identify and document cases of health insurance and employment discrimination. This pilot study will result in a better understanding about the impact of discrimination, enrich public dialogue about misuse of personal genetic information and bring accurate and relevant data to public policy decision-making. As the study progresses, results will be made available to keep public policy discussions informed and on target.

In preliminary findings, survey respondents indicate that they have experienced discrimination in relation to health insurance, long-term disability insurance, life insurance, and admission to the military. They also report that fear of discrimination has affected a whole range of life decisions. Some choose not to have the genetic testing which is essential for medical treatment. Some report paying for genetic testing out of pocket to ensure that the information would not go on their medical records. Others, fearing discrimination, decide not to participate in the very research that could benefit their own health.

• The Genetic Alliance calls for swift action to safeguard personal genetic information through nondiscrimination protections.

Federal protections will ensure our hopes for improving public health through new genetics knowledge and technologies. Federal protections will facilitate the collaboration of consumer organizations and the general public in the large scale data gathering essential to assuring quality genetic tests. With these assurances that personal information cannot be used in health and employment decision-making, we can move
swiftly to enact the farsighted and thoughtful recommendations of the Secretary's Advisory Committee on Genetic Testing.

Thank you for considering our perspectives.