Highlights of the Fourth Meeting of the Secretary's Advisory Committee on Genetic Testing February 24-25, 2000 Washington, D.C.

The Secretary's Advisory Committee on Genetic Testing (SACGT) met February 24-25, 2000 in Washington, DC to review public comments and develop recommendations on the adequacy of oversight of genetic testing. In June 1999, SACGT was asked by Dr. David Satcher, Assistant Secretary for Health and Surgeon General, to assess the adequacy of oversight in consultation with the public and to report back by March 15, 2000. Dr. Satcher asked the Committee to organize its report around five major issues.

- What criteria should be used to assess the benefits and risks of genetic tests?
- How can the criteria for assessing the benefits and risks of genetic tests be used to differentiate categories of tests? What are the categories and what kind of mechanism could be used to assign tests to the different categories?
- What process should be used to collect, evaluate, and disseminate data on single tests or groups of tests in each category?
- What are the options for oversight of genetic tests and the advantages and disadvantages of each option?
- What is an appropriate level of oversight for each category of genetic test?

On the first day of the meeting, SACGT carefully reviewed a substantial amount of public input that had been received in response to SACGT's 60-day multifaceted public consultation process. The process involved a *Federal Register* notice, a targeted mailing to 2500 individuals and organizations, a website consultation, a public meeting on January 27, 2000, and an analysis of scholarly literature on oversight.

Many of the public comments expressed concern about the potential for genetic test results to be used to discriminate against people. The public comments also highlighted the importance of ensuring the quality of, and access to, genetic tests.

After considering the public comments, SACGT developed preliminary draft recommendations. Among the key draft recommendations were the following:

- The public is best served by ensuring both appropriate oversight of genetic tests and the continued development of genetic tests.

- Additional oversight is warranted for all genetic tests.

- The Food and Drug Administration (FDA) should be involved in the review of all new genetic tests but the review should be appropriate to the level of complexity of the information generated by the test. FDA should develop flexible mechanisms for review of new genetic tests that minimize both the time and cost of review. These mechanisms should, for example, include the use of deemed reviewers and standards developed in concert with professional organizations.

- The FDA should give particular attention to the review of genetic tests for predictive

purposes in diseases and conditions for which a safe and effective intervention has not been established.

- The Clinical Laboratory Improvement Amendments (CLIA) regulations should be augmented to provide more specific provisions for ensuring the quality of laboratories conducting genetic tests.

- Increased knowledge of the clinical validity and utility of genetic tests depends on the collection and analysis of additional data on the correlation between genotype (genetic mutation) and phenotype (disease or condition). Data sharing and analysis is critical, and relevant agencies of the Department of Health and Human Services (DHHS) should work collaboratively with researchers and test developers to advance data collection and dissemination efforts. Initial exploratory data collection efforts among DHHS agencies, which have been coordinated by the Centers for Disease Control and Prevention (CDC), have been of value and should continue. Protecting the confidentiality of the data is essential to the progress of data collection efforts.

- DHHS agencies should be provided with enhanced resources in order to carry out expanded oversight of genetic tests.

- The public, through involvement of advocacy groups and as individuals, needs to be involved in an ongoing manner in consideration of issues about genetic testing. This will be particularly important to allay fears of minority populations and diverse communities regarding the purposes and uses of genetic testing.

- Efforts to ensure the education of the public and health providers about genetics are critical to the appropriate use, interpretation, and understanding of genetic test results.

- To address one of the public's major concerns about genetic testing, Federal legislation should be enacted to prohibit discrimination in employment and health insurance based on genetic information. Federal legislation is also needed to protect the privacy of medical records. The public commentary noted that without these protections, individuals will be reluctant to participate in research on, or the application of, genetic testing.

SACGT, which includes non-voting liaison members from the Agency for Healthcare Research and Quality, CDC, FDA, Health Care Financing Administration, Health Resources and Services Administration, and National Institutes of Health, made a commitment to monitor DHHS' progress in implementing enhanced oversight and to provide ongoing advice about the oversight issues as necessary.

SACGT will forward its preliminary draft recommendations to Dr. Satcher shortly. The Committee will then invite public comment on the preliminary draft conclusions and recommendations and, at its next meeting June 5-7, 2000, SACGT will review comments received and develop a final report to the Secretary. With the completion of this assignment, SACGT will move on to the consideration of a number of other high priority issues, including focused discussions of genetics education for the public and health professionals and the impact of gene patenting on the cost, quality, and accessibility of genetic testing.