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Secretary's Advisory Committee on Genetic Testing Launches Public Consultation on Oversight of Genetic Tests

The Secretary's Advisory Committee on Genetic Testing (SACGT) has launched a major effort to consult the American people on issues of oversight of genetic testing. Public input is being sought through the *Federal Register*, a targeted mailing to 2,000 individuals and organizations, a website consultation, and a major SACGT public meeting on January 27, 2000 in Baltimore, Maryland.

Public consultation is a central element of the assignment Dr. David Satcher, Surgeon General and Assistant Secretary for Health, gave SACGT in June, 1999. Dr. Satcher charged SACGT to "review the current extent of Federal oversight of genetic tests and, in consultation with the public, consider whether further oversight is needed and, if so, what mechanisms should be employed and to what degree." The assessment requires consideration of the potential benefits and risks (including socioeconomic, psychological, and medical) to individuals, families, and society, and, if necessary, the development of a method to categorize genetic tests according to these benefits and risks. Considering the benefits and risks of each genetic test is critical in determining appropriate use of each test in clinical and public health practice.

Dr. Satcher emphasized the need to gather public perspectives on the oversight questions and, today, commended SACGT for undertaking such a comprehensive effort. "Secretary Shalala and I want the Nation to be aware of the issues in genetic testing, and SACGT is helping to foster a national dialogue about them. SACGT needs to confer with the American people before decisions are made about whether additional safeguards, which could have financial implications and possibly slow the clinical application of new genetic discoveries, should be put in place for genetic tests used in clinical and public health practice. SACGT and its public outreach efforts will play a pivotal part in helping the Department of Health and Human Services determine the appropriate level of oversight for genetic tests."

"We are making a major effort," said Dr. Edward McCabe, SACGT Chairman and Professor and Chair, Department of Pediatrics, University of California, Los Angeles and Physician-in-Chief of Mattel Children's Hospital, "using all the tools at our disposal to gather a broad range of public perspectives on oversight of genetic testing. We need to hear from the American people, including members of diverse communities, about genetic testing. We need to know whether they have hopes or concerns about genetic testing and what sort of oversight of the field they expect. We need to hear from the public so that we can appropriately advise Dr. Satcher and Secretary Shalala on whether additional oversight of genetic tests is needed."

SACGT is trying to reach as many people as possible, both professionals as well as the general public, to ensure that their recommendations on oversight of genetic testing take account of public perspectives. The issue of oversight of genetic tests has many levels of complexity that will need to be carefully evaluated before any recommendations can be made. Public involvement in this process will enhance SACGT's analysis of the issues and the advice it provides to

DHHS. A document, A Public Consultation on Genetic Testing, was developed by SACGT to provide background information about genetic testing and current issues related to oversight. The document, along with summaries in English and Spanish, can be obtained from the SACGT Web site or by contacting SACGT at the address below.

Genetic testing is a relatively new approach to diagnosing and predicting diseases and it is expanding into many areas of health care and public health practice. The following are among the many questions on which SACGT is hoping to gather public comments:

What are the benefits/risks of having of a genetic test?

What are the major concerns regarding the different genetic tests that are currently available?

Do some genetic tests raise more ethical, legal, medical, and social concerns than others and should they be in a special category and require some special oversight?

Is making information available to the consumer about a genetic test, such as information about its accuracy, predictive power, and available therapy, a sufficient form of oversight?

Are consumers willing to pay for the cost of additional oversight of genetic tests (in the form of higher prices, health insurance premiums, or taxes)? Are consumers willing to wait for the effectiveness of genetic tests to be demonstrated before having access to a new genetic test?

The January 27, 2000 public meeting will be held at the University of Maryland, School of Nursing, located at 655 W Lombard Street in Baltimore, Maryland, from 8:45 a.m. to 5:00 p.m.

The explosion of knowledge on the structure and function of human genes is expanding the development and use of genetic tests and revolutionizing health care and public health practice. When Secretary Shalala chartered SACGT to provide advice to the Department of Health and Human Services (DHHS) on these issues, she recognized the importance of preparing for change and for the medical, scientific, ethical, legal, and social ramifications. SACGT is composed of thirteen non-governmental experts from diverse backgrounds including genetics, law, industry, and consumer advocacy, and six non-voting liaison members representing DHHS agencies.

SACGT's recommendations are due to the Surgeon General on March 15, 2000.

Further information about the consultation process and the January 27 meeting is available on SACGT's Web site (www4.od.nih.gov/oba/sacgt.htm) or by contacting SACGT at 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, 301-496-9838.

Note: HHS press releases are available on the World Wide Web at <http://www.hhs.gov>.