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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Meeting: Secretary's Advisory Committee on Genetic Testing

Pursuant to Public Law 92-463, notice is hereby given of the ninth meeting of the Secretary's Advisory Committee on Genetic Testing (SACGT), U.S. Public Health Service. The meeting will be held from 9:00 a.m. to 5:00 p.m. on May 2, 2001 and 8:30 a.m. to 3:00 p.m. on May 3, 2001 at the National Institutes of Health, Building 31, C Wing, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892. The meeting will be open to the public with attendance limited to space available.

The Committee will discuss a number of topics, including continuing FDA activities to develop a review template for genetic tests and FDA's labeling authorities as they pertain to genetic tests, as well as interagency progress on the development of coordinated genetic testing information systems. The Committee will begin exploring best practices in the development of clinical guidelines for genetic testing and hear progress reports from the Committee's work groups. There will be time provided for public comment and interested individuals should notify the contact person listed below. The Committee is particularly interested in hearing from members of the public about FDA's draft review template for genetic tests. Copies of the draft template can be obtained from SACGT staff listed below.

Under authority of 42 U.S.C. 217(a), Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGT to advise and make recommendations to the Secretary through the Assistant Secretary for Health on all aspects of the development and use of genetic tests.

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The SACGT is directed to (1) recommend policies and procedures for the safe and effective incorporation of genetic technologies into health care; (2) assess the effectiveness of existing and future measures for oversight of genetic tests; and (3) identify research needs related to

the Committee's purview.

The draft meeting agenda and other information about SACGT will be available at the following web site: <http://www4.od.nih.gov/ba/sacgt.htm>. Individuals who wish to provide public comments or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGT Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or E-mail at sc112c@nih.gov. The SACGT office is located at 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892.

Dated: April 4, 2001.

Sarah Carr,

Executive Secretary, SACGT.

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