

## CHARTER

### SECRETARY'S ADVISORY COMMITTEE ON GENETIC TESTING

#### **Purpose**

Innovations in molecular genetics and genetic testing are bringing about rapid changes in health care. These changes have far-reaching medical, social, ethical, and legal implications and raise many practical challenges for health care providers, clinical laboratories, patients and their families, and regulatory agencies. Genetic testing promises tremendous potential benefits with respect to preventing or treating inherited diseases and disorders. But genetic testing also can result in considerable harm if the tests are flawed or used inappropriately, if test results and their significance are communicated inaccurately or incompletely to health care providers and patients, or if test results are handled without adequate attention to privacy and confidentiality.

The Department of Health and Human Services (DHHS) has a vital role in safeguarding public health while fostering the development of valid genetic tests and facilitating their availability and beneficial use for medical and public health purposes. The several agencies within the Department that help carry out this role must collectively address the broad array of important and complex policy issues raised by genetic testing. To assist in addressing these cross-cutting policy issues, the Secretary's Advisory Committee on Genetic Testing identifies policy issues raised by genetic testing and makes policy and procedural recommendations to the Secretary on how such issues should be addressed.

The establishment of such a Committee was recommended by the Task Force on Genetic Testing of the NIH-DOE Working Group on the Ethical, Legal and Social Implications (ELSI) of the Human Genome Project as well as the Joint NIH-DOE Committee to Evaluate the ELSI Program of the Human Genome Project.

#### **Authority**

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

#### **Function**

The Secretary's Advisory Committee on Genetic Testing shall advise and make recommendations to the Secretary through the Assistant Secretary for Health on all aspects of the development and use of genetic tests. The scope of the Committee's charge includes recommending policies and procedures for the safe and effective incorporation of genetic

technologies into health care; assessing the effectiveness of existing and future measures for oversight of genetic tests; and identifying research needs related to the Committee's purview.

### **Structure**

The Committee shall consist of a core of 13 members, including the Chair, and the following 6 nonvoting, *ex officio* members: the Administrator, Agency for Healthcare Research and Quality; the Director, Centers for Disease Control and Prevention; the Commissioner, Food and Drug Administration; the Administrator, Health Care Financing Administration; the Administrator, Health Resources and Services Administration; and the Director, National Institutes of Health; (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Committee to effectively carry out its function. Members and the Chair shall be selected by the Secretary, or designee, from authorities knowledgeable in fields of genetic testing, medical genetics, genetic counseling, ethics, law, primary health care, public health, clinical laboratory management, diagnostic technology, psychology, social sciences, and other relevant disciplines. Of the appointed members, at least one shall be a current member of the Clinical Laboratory Improvement Advisory Committee, at least one shall be a current member of the Medical Devices Advisory Committee, and at least one member shall be specifically selected for knowledge/expertise as a consumer of health care services.

Members shall be invited to serve for overlapping terms of up to four years; terms of more than two years are contingent upon the renewal of the Committee by appropriate action prior to its termination. Members may serve after the expiration of their term until their successors have taken office.

A quorum for the conduct of business by the full committee shall be six of the appointed members.

As necessary, standing and ad hoc subcommittees composed of members of the parent committee may be established to perform specific functions within the Committee's jurisdiction. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

The Committee shall be able to call upon special consultants, assemble ad hoc working groups, and convene conferences and workshops as necessary to assist in the work of the Committee.

Coordination of agenda development and management and operational services shall be provided for the Committee by the Office of Science Policy, Office of the Director, National Institutes of Health, with direction and guidance from the Assistant Secretary for Health.

### **Meetings**

Meetings shall be held at least two times per year at the call of the Chair with the advance

approval of a Government official, who shall also approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable laws and Departmental regulations.

### **Compensation**

Members shall be paid at a rate not to exceed the daily equivalent of the rate in effect for Executive Level IV of the General Schedule for each day they are engaged in the performance of their duties as members of the Committee. Members shall receive per diem and travel expenses as authorized by Section 5703, Title 5 U.S.C. for persons employed intermittently in the Government service. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee.

### **Annual Cost Estimate**

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support is \$432,763. Estimated annual person-years of staff support required is 4.0 at an estimated annual cost of \$198,399.

### **Reports**

In the event a portion of a meeting is closed to the public, an annual report shall be prepared which shall contain, at a minimum, a list of the members and their business addresses, the Committee's function, dates and places of meetings, and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.


### **Termination Date**

Unless renewed by appropriate action prior to its expiration, the Charter for the Secretary's Advisory Committee on Genetic Testing shall expire on August 10, 2002

### **Approved:**

JUN 10 2002

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Date

  
Secretary