Highlights of the First Meeting of the Secretary's Advisory Committee on Genetic Testing

Wednesday, June 30, 1999
Building 31C, Sixth Floor, Conference Room 10
31 Center Drive
Bethesda, Maryland

Overview

The first meeting of the Secretary's Advisory Committee on Genetic Testing (SACGT), chaired by Edward R.B. McCabe, M.D., Ph.D., was held June 30, 1999. The meeting was open to the public. The 13-member committee was chartered last year to help the department formulate policies on the development, validation, and regulation of genetic tests, particularly DNA-based diagnostics.

The meeting began with welcoming remarks and the committee charge by U.S. Surgeon General Dr. David Satcher. It included presentations on a number of topics relevant to the work of SACGT such as the Human Genome Project and its impact on the development and application of genetic tests; an overview of DHHS Clinical Laboratory Improvement Amendments regulations and the Clinical Laboratory Improvement Advisory Committee recommendations on genetic testing; and the status of the Food and Drug Administration's (FDA's) regulatory oversight of genetic tests. In addition, Dr. Neil Holtzman discussed the final report of the NIH/DOE Task Force on Genetic Testing. During the afternoon, committee members participated in working sessions to determine how the committee will proceed in responding to the oversight questions presented in the charge as well as to identify additional topics for SACGT to consider over the next one to two years. The meeting also included a period for public comment.

Highlights

Introductions

In preparation for the afternoon discussion of additional issues in genetic testing to be considered by the committee, each member and *ex officio* member during introductions suggested an issue or topic that he or she believed to be of high priority, unique to genetic testing, or in need of enhanced public understanding.

Final Report of the NIH/DOE Task Force on Genetic Testing

Dr. Holtzman reviewed the most recent task force's recommendations, one of which was to form SACGT, and noted that the FDA will be adding a genetics panel to its advisory panels. He urged members to focus on areas in which the committee could have the greatest impact in its role of advising the Secretary and emphasized the importance of ensuring the clinical validity and the utility of genetic tests as well as the need to look carefully at the need for FDA authority in this area.

Discussion of Oversight of Genetic Tests

Ms. Beardsley led the committee in discussion of its charge from Dr. Satcher to address several specific questions regarding the adequacy of governmental oversight of genetic tests and to gather public perspectives about the questions. She suggested that the committee review the three questions presented to them in the charge and consider whether any clarification is required; determine whether any additional information is needed by the committee; and develop a work plan to gather input from the public and prepare a report for Dr. Satcher by December 1, 1999.

Dr. Francis Collins proposed that the committee consider the following four questions rather than the three presented in the charge:

- Are there genetic tests that require greater scrutiny than the current system offers? If so, how should stringency criteria be defined?
- If yes, what kind of data is needed before such tests become used in clinical, as opposed to research, activities?
- Who should be responsible for collecting the data? Where will the data come from?
- Who will review the data and decide whether they are convincing and therefore that the test is ready for clinical application?

In response to the committee's concerns regarding whether the wording of the oversight questions as charged by Dr. Satcher could be revised, Dr. William Raub (Deputy Assistant Secretary of Science Policy, Office of Planning and Evaluation, Office of the Secretary) informed committee members that they have latitude in how they approach this task and are not limited to addressing the questions as they currently are presented.

Some members proposed policy addenda to the questions. It was agreed that the report should include a preamble that explains the purpose of addressing the questions. Dr. McCabe suggested something along the following lines:

"The Committee is seeking public perspectives on the considerations associated with the regulation of genetic tests to assist in providing advice to the Department of Health and Human Services about whether additional oversight of genetic tests is necessary. The Department is endeavoring to ensure that its regulatory framework in this area is appropriately tailored to meet current and emerging needs and technologies and that it is capable of protecting and benefitting those undergoing testing."

Dr. Holtzman commented that the Task Force on Genetic Testing failed to reach full agreement in only one specific area covered by the suggested questions. He remarked that the committee can best build on the

task force's work by considering carefully its full report and moving forward to address areas in which agreement has not been reached.

Dr. McCabe proposed that the committee hold an additional meeting, possibly in early September. He also proposed that at this time a working group should be formed to move forward in the area of addressing the oversight charge. The Oversight Working Group is to be chaired by Ms. Beardsley and will include the following members: Dr. Boughman, Dr. Burke, Dr. Charache, Mr. Hillback, and Dr. Penchaszadeh. Dr. McCabe will serve as an *ex officio* member. The working group will generate an outline for reaction from the larger group on the oversight charge. This plan of action was accepted by the full committee.

Ms. Beardsley summarized the charge and next steps agreed upon by the committee. The charge to the Oversight Working Group is to review the HHS staff paper on "Oversight of Genetic Tests" and develop a plan for responding to the questions to be addressed. The Working Group will: 1) recast to some degree the original questions presented in the staff paper, possibly using the four questions proposed at the meeting by Dr. Collins; 2) gather relevant background information from the Task Force report and other materials; and 3) develop an outline or framework that includes a concise preamble defining the purpose of the oversight review and summarizes information necessary for a consideration of the questions both by the Committee itself at the next meeting and subsequently by the public. The Working Group will also develop a list of possible mechanisms for soliciting public comment.* Before the next meeting, the Working Group will present a draft report to committee members for feedback.

Discussion and Prioritization of Other Issues

Dr. McCabe led committee members in a discussion aimed at identifying five to ten high priority issues that warrant committee consideration over the next one to two years. The discussion was in part based on members' introductory comments in which they suggested issues that they consider high priority, unique to genetic testing, or in need of enhanced public understanding.

After an extensive discussion of a broad range of issues, the Committee identified the following issues as high priority:

- education, including counseling and comprehensive education of professionals and the public;
- access to testing;
- diversity issues, particularly special concerns raised by the use of genetic tests in ethnic and minority populations;
- stigmatization, including concerns about insurance discrimination and privacy and confidentiality;

- rare disorders, including access to rare disease testing;
- introduction of tests into clinical practice;

- use of evidentiary-based models and outcomes assessment;
- economic issues in genetic testing and oversight; and

- the impact of direct marketing of tests.

Committee members acknowledged the broad scope of these issues, and the role of other entities in addressing some of them. They recognized the need to focus their attention on matters upon which they can make a unique contribution and have the highest impact. The SACGT also made a commitment to evaluate its role, effectiveness and accomplishments at the end of two years of operation.

*After the meeting adjourned, Dr. McCabe decided that the task of considering mechanisms for gathering public perspectives should be shared by a second working group given the importance of this element of the assignment. He tasked Dr. Lewis with chairing the Outreach Working Group, whose members will be Ms. Barr, Ms. Boldt, Ms. Davidson, Dr. Koenig, and Dr. Tuckson. Dr. McCabe will also serve as an *ex officio* member of this working group. The charge to the Outreach Working Group is to develop several options for assessing public perspectives on oversight issues that go beyond the traditional method of soliciting comments through the *Federal Register*. The Outreach Working Group will also develop cost estimates and timelines for each option.