

## 2002 Current Fiscal Year Report: Secretary's Advisory Committee On Genetic Testing

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### 1. Department or Agency

Department of Health and Human  
Services

### 2. Fiscal Year

2002

### 3. Committee or Subcommittee

Secretary's Advisory Committee On  
Genetic Testing

### 3b. GSA

### Committee No.

5237

### 4. Is this New During Fiscal Year?

No

### 5. Current Charter

06/10/2002

### 6. Expected Renewal Date

### 7. Expected Term Date

### 8a. Was Terminated During Fiscal Year?

Yes

### 8b. Specific Termination Authority

### 8c. Actual Term Date

08/10/2002

### 9. Agency Recommendation for Next Fiscal Year

Terminate

### 10a. Legislation Req to Terminate?

### 10b. Legislation Pending?

### 11. Establishment Authority

Authorized by Law

### 12. Specific Establishment Authority

42 U.S.C. 217a

### 13. Effective Date

11/17/1962

### 14. Committee Type

Continuing

### 14c. Presidential?

No

### 15. Description of Committee

National Policy Issue Advisory Board

### 16a. Total Number of Reports

1

### 16b. Report Date

09/30/2002

Annual Report to the Secretary

### Number of Committee Reports Listed:

1

### 17a.

Open

3

17b. Closed

0

17c. Partially Closed

0

Other Activities

0

17d. Total

3

### Meetings and Dates

Purpose

Start

End

Discussion of various topics relating to genetic testing, including how genetics fits into current or future health practice. 11/15/2001 - 11/16/2001

Discussion of a report from HHS agencies on their support of activities that increase the knowledge and utility of genetic tests and exploring issues regarding the collection of data in genetic testing. 02/14/2002 - 02/15/2002

Review outcomes of SACGT Education Conference and presentations by SACGT working groups. 05/14/2002 - 05/15/2002

### Number of Committee Meetings Listed: 3

	Current FY	Next FY
<b>18a(1). Personnel Pmts to Non-Federal Members</b>	\$18,600.00	\$0.00
<b>18a(2). Personnel Pmts to Federal Members</b>	\$0.00	\$0.00
<b>18a(3). Personnel Pmts to Federal Staff</b>	\$258,705.00	\$0.00
<b>18a(4). Personnel Pmts to Non-Member Consultants</b>	\$0.00	\$0.00
<b>18b(1). Travel and Per Diem to Non-Federal Members</b>	\$31,834.00	\$0.00
<b>18b(2). Travel and Per Diem to Federal Members</b>	\$0.00	\$0.00
<b>18b(3). Travel and Per Diem to Federal Staff</b>	\$0.00	\$0.00
<b>18b(4). Travel and Per Diem to Non-member Consultants</b>	\$0.00	\$0.00
<b>18c. Other(rents,user charges, graphics, printing, mail, etc.)</b>	\$361,849.00	\$0.00
<b>18d. Total</b>	\$670,988.00	\$0.00
<b>19. Federal Staff Support Years (FTE)</b>	3.00	0.00

### 20a. How does the Committee accomplish its purpose?

This committee was composed of highly qualified experts in issues related to genetic testing. They provided a breadth and balance of specialized

knowledge necessary to recommend 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.

**20b. How does the Committee balance its membership?**

The committee consisted of 13 members, including the Chair, and 7 non-voting ex-officio members. Members and the Chair were selected by the Secretary, or designee, from authorities knowledgeable in the 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. One member was a member of the Clinical Laboratory Improvement Advisory Committee, one member was a member of the Medical Devices Advisory Committee, and at least one member was specifically selected for knowledge/expertise as a consumer of health care services.

**20c. How frequent and relevant are the Committee Meetings?**

The committee met four times during the reporting period. They continued to address the oversight of genetic tests and remain actively involved in the development and implementation of a pre-market review process for new genetic tests as well as a program for post-market data collection and dissemination efforts. The committee developed, gathered public comment and sought expert advice on a proposed template for genetic test information for use by health professionals and a

proposed classification methodology for determining level of review for genetic tests, which culminated in the preparation of a report to the Secretary on the development of a classification methodology for genetic tests. In addition, the committee made recommendations on gene patents and licensing, genetic non-discrimination legislation, and informed consent of third parties indirectly involved in genetic research. They continued to address issues relating to institutional review boards and informed consent for genetic testing in clinical and public health practice; access to genetic tests and services; health disparities as it relates to genetic testing; genetics education of health professionals; and development, provision, and review of tests for rare genetic diseases.

**20d. Why can't the advice or information this committee provides be obtained elsewhere?**

After a broad review of the functions of its advisory committee, HHS determined that the Committee's functions as set forth in its charter should be broadened. Consequently, a new committee with a mandate encompassing genetic technologies and their health and social implications was chartered on November 6, 2002. The new committee is called the Secretary's Advisory Committee on Genetics, Health, and Society.

**20e. Why is it necessary to close and/or partially closed committee meetings?**

N/A

**21. Remarks**

**Designated Federal Officer**

Sarah Carr Executive Secretary

<b>Committee Members</b>	<b>Start</b>	<b>End</b>	<b>Occupation</b>	<b>Member Designation</b>
Barr, Patricia	04/15/1999	02/28/2002	Lawyer	Special Government Employee (SGE) Member
Baumiller, Robert	03/07/2002	08/10/2002	Professor of Philosophy	Special Government Employee (SGE) Member
Beardsley, Kate	04/12/1999	02/28/2002	Lawyer	Special Government Employee (SGE) Member
Berry, Cynthia	03/10/2002	08/10/2002	General Counsel and Principal	Special Government Employee (SGE) Member
Boldt, Ann	04/13/1999	02/28/2002	Professor	Special Government Employee (SGE) Member
Bonham, Jr., Vence	03/21/2002	08/10/2002	Assistant Professor of Health Policy and Law	Special Government Employee (SGE) Member
Boughman, Joann	04/14/1999	08/10/2002	Vice President and Dean	Special Government Employee (SGE) Member
Burke, Wylie	04/13/1999	08/10/2002	Associate Professor	Special Government Employee (SGE) Member
Charache, Patricia	04/13/1999	08/10/2002	Professor	Special Government Employee (SGE) Member
Davidson, Mary	04/13/1999	08/10/2002	Executive Director	Special Government Employee (SGE) Member
Hillback, Elliott	04/14/1999	08/10/2002	Senior Vice President	Special Government Employee (SGE) Member
Koenig, Barbara	04/13/1999	02/28/2002	Executive Director	Special Government Employee (SGE) Member
Lewis, Judith	04/13/1999	08/10/2002	Associate Professor	Special Government Employee (SGE) Member

McCabe, Edward	04/13/1999	08/10/2002	Professor and Chair	Special Government Employee (SGE) Member
Penchaszadeh, Victor	04/17/1999	08/10/2002	Chief, Division of Medical Genetics	Special Government Employee (SGE) Member
Robinson, Daniel	03/01/2002	08/10/2002	Professor of Psychology	Special Government Employee (SGE) Member
Tuckson, Reed	04/13/1999	08/10/2002	Senior Vice President	Special Government Employee (SGE) Member

**Number of Committee Members Listed: 17**

## Narrative Description

**What are the most significant program outcomes associated with this committee?**

Checked if  
Applies

Improvements to health or safety	<input type="checkbox"/>
Trust in government	<input type="checkbox"/>
Major policy changes	<input type="checkbox"/>
Advance in scientific research	<input type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input type="checkbox"/>
Increased customer satisfaction	<input type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

## Outcome Comments

**What are the cost savings associated with this committee?**

Checked if Applies

None	<input checked="" type="checkbox"/>
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- |                            |                          |
|----------------------------|--------------------------|
| Unable to Determine        | <input type="checkbox"/> |
| Under \$100,000            | <input type="checkbox"/> |
| \$100,000 - \$500,000      | <input type="checkbox"/> |
| \$500,001 - \$1,000,000    | <input type="checkbox"/> |
| \$1,000,001 - \$5,000,000  | <input type="checkbox"/> |
| \$5,000,001 - \$10,000,000 | <input type="checkbox"/> |
| Over \$10,000,000          | <input type="checkbox"/> |
| Cost Savings Other         | <input type="checkbox"/> |

**Cost Savings Comments**

**What is the approximate Number of recommendations produced by this committee for the life of the committee?**

0

**Number of Recommendations Comments**

**What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?**

%

**% of Recommendations Fully Implemented Comments**

**What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?**

%

**% of Recommendations Partially Implemented Comments**

**Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?**

Yes ☐ No ☐ Not Applicable ☒

**Agency Feedback Comments**

**What other actions has the agency taken as a result of the committee's advice or recommendation?**

Checked if Applies

- |                                   |                          |
|-----------------------------------|--------------------------|
| Reorganized Priorities            | <input type="checkbox"/> |
| Reallocated resources             | <input type="checkbox"/> |
| Issued new regulation             | <input type="checkbox"/> |
| Proposed legislation              | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other                             | <input type="checkbox"/> |

**Action Comments**

**Is the Committee engaged in the review of applications for grants?**

No

**Grant Review Comments**

**How is access provided to the information for the Committee's documentation?**

Checked if Applies

- |                           |                          |
|---------------------------|--------------------------|
| Contact DFO               | <input type="checkbox"/> |
| Online Agency Web Site    | <input type="checkbox"/> |
| Online Committee Web Site | <input type="checkbox"/> |
| Online GSA FACA Web Site  | <input type="checkbox"/> |
| Publications              | <input type="checkbox"/> |
| Other                     | <input type="checkbox"/> |

**Access Comments**