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## Secretary's Advisory Committee on Genetics, Health, and Society

Second Meeting  
October 22-23, 2003  
Washington, DC

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### D R A F T A G E N D A

Wednesday, October 22, 2003

#### Opening Remarks

9:00 a.m. - 9:05 a.m. Edward R.B. McCabe, M.D., Ph.D.  
SACGHS Chair

#### Oversight of Genetic Technologies, Marketing, and Laboratories and the Role of Pharmacogenetic Tests in Therapeutics

9:05 a.m. – 9:25 a.m. *Oversight of Genetic Testing Laboratories Through the Clinical Laboratory Improvement Amendments (CLIA)*  
Judith A. Yost, M.A., M.T.  
Director, Division of Laboratories and Acute Care  
Centers for Medicare & Medicaid Services

9:25 a.m. – 9:45 a.m. *Plans for Augmenting CLIA to Specifically Address Genetic Testing Laboratory Issues and Concerns*  
D. Joe Boone, Ph.D.  
Associate Director for Science, Division of Laboratory Systems  
Public Health Practice Program Office  
Centers for Disease Control and Prevention

9:45 a.m. – 10:15 a.m. Roundtable Discussion  
Facilitator: Dr. Winn-Deen

10:15 a.m. – 10:30 a.m. BREAK

- 10:30 a.m. – 10:50 a.m. *Impact of Pharmacogenomics on Prescription Drug Labeling*  
Lawrence J. Lesko, Ph.D.  
Director, Office of Clinical Pharmacology and Biopharmaceutics  
Center for Drug Evaluation and Research  
Food and Drug Administration
- 10:50 a.m. – 11:10 a.m. *FDA's Current Approach to the Review, Labeling and Marketing of Genetic Tests*  
Steven I. Gutman, M.D.  
Director, Office of In Vitro Diagnostics  
Center for Devices and Radiological Health  
Food and Drug Administration
- 11:10 a.m. – 11:30 a.m. *FDA's Future Plans to Enhance Oversight of High Risk Genetic Tests*  
David W. Feigal, Jr., M.D., M.P.H.  
Director, Center for Devices and Radiological Health  
Food and Drug Administration
- 11:30 a.m. – 12:30 p.m. Roundtable Discussion  
Facilitator: Dr. Leonard
- 12:30 p.m. – 1:30 p.m. LUNCH
- 1:30 p.m. – 1:50 p.m. *FTC's Regulation of the Advertising and Promotion of Consumer Products and Its Application to Genetic Technologies*  
Matthew Daynard, J.D.  
Senior Attorney, Advertising Practices Division  
Bureau of Consumer Protection  
Federal Trade Commission
- 1:50 p.m. – 2:45 p.m. Roundtable Discussion Regarding FDA and FTC Regulation of Advertising and Promotion of Genetic Technologies  
Facilitator: Ms. Zellmer

2:45 p.m. – 3:00 p.m. BREAK

**Public Comment Session**

3:00 p.m. – 3:30 p.m. Members of the Public

**Continued Discussion of Oversight and Pharmacogenetics**

3:30 p.m. – 5:00 p.m. Committee Members

## **Genetic Discrimination in Health Insurance and Employment**

5:00 p.m. – 5:30 p.m.                      *Update on the Status of Federal Legislation to Prohibit Genetic Discrimination*

*Report from the U.S. House of Representatives*  
Ms. Kristin Fitzgerald  
Professional Staff Member  
U.S. House Committee on Education and the Workforce

Roundtable Discussion  
Facilitator: Ms. Berry

Thursday, October 23, 2003

## **Other Nations' Approaches to Addressing Issues Involving Genetic Technologies**

8:30 a.m. – 9:00 a.m.                      *Human Genetics Commission, United Kingdom*  
Mr. Philip Webb  
Member, Human Genetics Commission

9:00 a.m. – 9:30 a.m.                      *Australian Law Reform Commission*  
David Weisbrot, J.D.  
President, Australian Law Reform Commission

9:30 a.m. – 10:15 a.m.                      Roundtable Discussion  
Facilitator: Dr. Hook

10:15 a.m. – 10:30 a.m.                      BREAK

## **Genetics Workforce, Education, and Training**

10:30 a.m. – 10:40 a.m.                      *Framing the Issues*  
Joann Boughman, Ph.D.  
Executive Vice President, American Society of Human Genetics  
Chair, Former SACGT Education Work Group

10:40 a.m. – 11:00 a.m.                      *Federal Efforts to Address Genetics Workforce, Education, and Training Issues*  
Sam Shekar, M.D., M.P.H.  
Associate Administrator, Bureau of Primary Health Care  
Health Research and Services Administration

11:00 a.m. – 11:20 a.m.                      *Preliminary Findings of the Genetics Workforce Study*  
Judith A. Cooksey, M.D., M.P.H.  
Adjunct Associate Professor, Department of Epidemiology and Preventive Medicine  
University of Maryland School of Medicine

11:20 a.m. – 12:15 p.m. Roundtable Discussion  
Facilitator: Dr. Willard

12:15 p.m. – 1:00 p.m. LUNCH

**Public Comment Session**

1:00 p.m. – 1:30 p.m. Members of the Public

**Genetics Workforce, Education, and Training (continued)**

1:30 p.m. – 1:50 p.m. *Overview of Efforts by Organizations and Professional Societies to Address Genetics Workforce, Education, and Training Issues*  
Joann A. Boughman, Ph.D.  
Executive Vice President, American Society of Human Genetics  
Chair, Former SACGT Education Work Group

1:50 p.m. – 2:10 p.m. *Educational Programs for Health Professionals: Addressing the Gaps*  
Joseph D. McInerney, M.S.  
Director  
National Coalition for Health Professional Education in Genetics

2:10 p.m. – 2:30 p.m. *Genetic Counselor Training Program Capacities and Needs*  
Robin Bennett, M.S., CGC  
Past President I  
National Society of Genetic Counselors

2:30 p.m. – 3:20 p.m. Roundtable Discussion  
Facilitator: Dr. Tuckson

**SACGHS Discussion of Next Steps and Plans for the March 1-2, 2004 Meeting**

3:20 p.m. – 4:00 p.m. Committee Members

**Closing Remarks**

4:00 p.m. Dr. McCabe

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