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

Tenth Meeting
June 26-27, 2006
Bethesda, MD

A G E N D A

Monday, June 26, 2006

9:00 a.m. – 9:15 a.m. *Opening Remarks*
Reed V. Tuckson, M.D.
SACGHS Chair

Oversight Session

9:15 a.m. – 9:30 a.m. *Update on the Notice of Proposed Rule Making on a Genetic Specialty
for the CLIA Program*
Judith A. Yost, M.A., M.T.
Director
Division of Laboratories and Acute Care
Centers for Medicare & Medicaid Services

9:30 a.m. – 9:40 a.m. *Q&A*

Pharmacogenomics Session

9:40 a.m. – 9:55 a.m. *Overview of Pharmacogenomics Session and Update on Efforts of the
SACGHS Pharmacogenomics Task Force*
Emily Winn-Deen, Ph.D.
Chair
SACGHS Task Force on Pharmacogenomics

9:55 a.m. – 10:25 a.m. *Critical Path Initiative and FDA's Vision for Personalized Medicine*
Janet Woodcock, M.D.
Deputy Commissioner for Operations
FDA

10:25 a.m. – 10:35 a.m. *Q &A*
Facilitator: Dr. Winn-Deen

10:35 a.m. – 10:45 a.m. BREAK

10:45 a.m. – 12:45 p.m. *Full Committee Discussion*
Facilitator: Dr. Winn-Deen

12:45 p.m. – 1:30 p.m. LUNCH

Public Comments

1:30 p.m. – 2:00 p.m. *Public Comments*

Pharmacogenomics Session (continued)

2:00 p.m. – 4:00 p.m. *Full Committee Discussion (continued)*
Facilitator: Dr. Winn-Deen

4:00 p.m. – 4:10 p.m. BREAK

Large Population Studies Session

4:10 p.m. – 4:20 p.m. *Update on SACGHS's Draft Report on the Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment and Disease*
Dr. Tuckson

4:20 p.m. – 4:40 p.m. *Environmental Components of Gene-Environment Studies*
David A. Schwartz, M.D., M.P.H.
Director
National Institute of Environmental Health Sciences

4:40 p.m. – 5:00 p.m. *Social and Behavioral Components of Environment in Gene-Environment Studies*
John K. Hewitt, Ph.D.
Director
Institute for Behavioral Genetics
University of Colorado

5:00 p.m. – 5:30 p.m. *Q&A*
Facilitator: Dr. Licinio

Tuesday, June 27, 2006

8:30 a.m. – 8:40 a.m. *Opening Remarks*
Dr. Tuckson

Patents and Access Session

8:40 a.m. – 9:20 a.m. *Patenting and Licensing Fundamentals and the Nature of the Access Problem*
Debra Leonard, M.D., Ph.D.
Chair, SACGHS Task Force on Patents and Access

9:20 a.m. – 10:00 a.m. *Data and Analysis of the Impact of DNA-based Patents on Access to Genetic Technologies and Services*
Mildred K. Cho, Ph.D.
Associate Director, Stanford University Center for Biomedical Ethics
Associate Professor of Pediatrics (Genetics)
Stanford University School of Medicine

10:00 a.m. – 10:40 a.m. *The Role and Economic Impact of Gene Patents in Drug and Diagnostics Development*
Mark McCamish, M.D., Ph.D.
Chief Medical Officer
Perlegen Sciences

10:40 a.m. – 10:50 a.m. BREAK

10:50 a.m. – 11:30 a.m. *Full Panel Roundtable Discussion*
Facilitator: Dr. Leonard

11:30 a.m. – 12:10 p.m. *Full Committee Discussion and Next Steps*
Facilitator: Dr. Leonard

Public Comments

12:10 p.m. – 12:40 p.m. *Public Comments*

12:40 p.m. – 1:25 p.m. LUNCH

1:25 p.m. – 1:40 p.m. *Updates from Working Groups on Direct-to-Consumer Marketing of Genetic Tests and Services*

FDA – FTC Collaboration – Dr. Hackett & Mr. Daynard

Data Collection on the Public Health Impact – Mr. Bowen

Genetic Discrimination

1:40 p.m. – 2:10 p.m.

Update from Key Stakeholders on the Status of the Federal Genetic Information Nondiscrimination Legislation

Michael J. Eastman

Director, Labor Law Policy, U.S. Chamber of Commerce

Co-Chair, GINE Coalition

Sharon F. Terry

President and CEO, Genetic Alliance

Chair, Coalition for Genetic Fairness

2:10 p.m. – 2:25 p.m.

Presentation of Certificates

2:25 p.m. – 3:00 p.m.

Next Steps and Concluding Remarks

Dr. Tuckson

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