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

Eleventh Meeting November 13 & 14, 2006 Adelphi, MD

FINAL AGENDA

Monday, November 13, 2006

8:30 a.m. – 8:50 a.m. *Opening Remarks*

Reed V. Tuckson, M.D.

SACGHS Chair

Session on Pharmacogenomics

8:50 a.m. – 9:20 a.m. Update on Efforts of the SACGHS Pharmacogenomics Task Force and

Review of Draft Report

Kevin T. FitzGerald, S.J., Ph.D., Ph.D.

Chair, SACGHS Task Force on Pharmacogenomics

9:20 a.m. – 10:45 a.m. Committee Discussion of Draft Report and Recommendations

10:45 a.m. – 11:00 a.m. BREAK

11:00 a.m. – 1:00 p.m. Committee Discussion of Draft Report and Recommendations

(continued)

1:00 p.m. – 1:45 p.m. LUNCH

Session on Gene Patents and Licensing Practices

1:45 p.m. – 2:15 p.m. Report from the SACGHS Task Force on Gene Patents and Licensing

Practices

James P. Evans, M.D., Ph.D.

Chair, SACGHS Task Force on Gene Patents and Licensing Practices

2:15 p.m. – 3:45 p.m. Committee Discussion of Proposed Study Scope and Work Plan

Public Comments

3:45 p.m. – 4:15 p.m. Public Comments

Session on Oversight of Genetic Technologies and Genetic Testing Laboratories

4:15 p.m. – 4:25 p.m. Session and Issue Overview

Dr. Tuckson Chair, SACGHS

4:25 p.m. – 4:40 p.m. *Developments at CMS*

Thomas E. Hamilton

Director, Survey and Certification Group Centers for Medicare & Medicaid Services

Judith A. Yost, M.A., M.T.

Director, Division of Laboratories and Acute Care

Centers for Medicare & Medicaid Services

4:40 p.m. – 4:50 p.m. Q & A

4:50 p.m. - 5:05 p.m. Developments at FDA

Steve Gutman, M.D., M.B.A.

Director, Office of In Vitro Diagnostic Device Evaluation and Safety,

Food and Drug Administration

5:05 p.m. – 5:15 p.m. Q & A

5:15 p.m. – 6:15 p.m. Full Committee Discussion

Tuesday, November 14, 2006

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

Dr. Tuckson

Session on Large Population Studies

8:40 a.m. – 9:10 a.m. Presentation of Public Comments and Proposed Modifications to Draft

Report on the Policy Issues Associated with Undertaking a Large U.S.

Population Cohort Project on Genes, Environment and Disease

Huntington F. Willard, Ph.D.

Chair, SACGHS Task Force on Large Population Studies

9:10 a.m. – 11:00 a.m. Committee Discussion of Public Comments and Revised Report

11:00 a.m. – 11:15 a.m. BREAK

11:15 a.m. – 12:30 p.m. Committee Discussion of Public Comments and Revised Report

(continued)

12:30 p.m. – 1:15 p.m. LUNCH

1:15 p.m. – 2:25 p.m. Committee Discussion of Public Comments and Revised Report

(continued)

Public Comments

2:25 p.m. – 2:55 p.m. Public Comments

2:55 p.m. – 3:10 p.m. BREAK

Federal Developments and Updates

3:10 p.m. – 3:30 p.m. NIH Proposed Policy on Genome Wide Association Studies (GWAS)

Susan Shurin, M.D.

Deputy Director, National Heart, Lung and Blood Institute

National Institutes of Health

3:30 p.m. – 3:50 p.m. Update on Evaluation of Genomic Applications in Practice and

Prevention (EGAPP) Activities

Linda Bradley, Ph.D.

Geneticist, National Office of Public Health Genomics

Centers for Disease Control and Prevention

3:50 p.m. – 4:10 p.m. Update on Collaboration, Education and Test Translation (CETT)

Program

Steven C. Groft, Pharm. D. Director, Office of Rare Diseases National Institutes of Health

Session on Genetic Discrimination

4:10 p.m. – 4:35 p.m. Update on the Genetic Information Nondiscrimination Act

Sharon F. Terry

President and CEO, Genetic Alliance Chair, Coalition for Genetic Fairness

4:35 p.m. – 5:00 p.m. *Next Steps and Concluding Remarks*

Dr. Tuckson