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

Ninth Meeting March 27-28, 2006 Bethesda, MD

FINAL AGENDA

Monday, March 27, 2006

9:00 a.m. - 9:15 a.m.

Opening Remarks

Reed V. Tuckson, M.D.

SACGHS Chair

Large Population Studies Session (9:15 a.m.-12:30 p.m.)

9:15 a.m. - 10:00 a.m.

Overview of Large Population Studies Policy Issues and Possible

Approaches

Huntington F. Willard, Ph.D.

Chair, SACGHS Task Force on Large Population Studies

10:00 a.m. - 10:45 a.m.

Full Committee Discussion

Facilitator: Dr. Willard

10:45 a.m. - 11:00 a.m.

BREAK

11:00 a.m. – 12:15 p.m.

Full Committee Discussion (continued)

Facilitator: Dr. Willard

12:15 p.m. - 12:30 p.m.

Next Steps

Facilitators: Dr. Willard and Dr. Tuckson

12:30 p.m. – 1:30 p.m.

LUNCH

Pharmacogenomics Session (1:30 p.m. – 3:15 p.m.)

1:30 p.m. - 2:00 p.m.

Update from the Pharmacogenomics Task Force

Emily Winn-Deen, Ph.D.

Chair, SACGHS Task Force on Pharmacogenomics

2:00 p.m. – 2:15 p.m. FDA Draft Guidance for Industry and FDA Staff on Pharmacogenetic

Tests and Genetic Tests for Heritable Markers

Steve Gutman, M.D., MBA

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

FDA

2:15 p.m. – 3:15 p.m. Full Committee Discussion

Facilitator: Dr. Winn-Deen

3:15 p.m. – 3:30 p.m. BREAK

Public Comments

3:30 p.m. – 4:00 p.m. *Public Comments*

Pharmacogenomics Session (continued) (4:00 p.m.-5:00 p.m.)

4:00 p.m. – 4:45 p.m. *Development of Recommendations*

Facilitator: Dr. Winn-Deen

4:45 p.m. – 5:00 p.m. *Next Steps*

Facilitators: Dr. Winn-Deen and Dr. Tuckson

Tuesday, March 28, 2006

9:00 a.m. – 9:10 a.m. *Opening Remarks*

Dr. Tuckson

Genetic Discrimination Session (9:10 a.m.-10:10 a.m.)

9:10 a.m. – 9:25 a.m. Update on the Status of the Genetic Information Nondiscrimination Act

of 2005 (S. 306/H.R. 1227)

Sharon F. Terry, M.A.

Chair

Coalition for Genetic Fairness

9:25 a.m. – 9:35 a.m. *Q&A*

9:35 a.m. – 9:55 a.m. Survey on Public Attitudes toward Genetic Technologies and Genetic

Discrimination
Ms. Christy White
Cogent Research

9:55 a.m. – 10:10 a.m. Q&A and Committee Discussion

Facilitator: Agnes Masny

Public Comments

10:10 a.m. – 10:30 a.m. *Public Comments*

10:30 a.m. – 10:45 a.m. BREAK

Patents and Licensing Session (10:45 a.m.-3:15 p.m.)

10:45 a.m. – 11:00 a.m. Session Overview and Framing the Topic

Debra Leonard, M.D., Ph.D.

Chair, SACGHS Task Force on Patents and Access

11:00 a.m. – 11:45 a.m. Briefing on the Report of the National Academy of Sciences Committee

on Intellectual Property Rights in Genomics and Protein Research and

Innovation

David Korn, M.D.

Member, NAS Committee on Intellectual Property Rights in Genomics

and Protein Research and Innovation

11:45 a.m. - 12:00 p.m. Q & A

12:00 p.m. – 12:30 p.m. Perspectives of the Task Force on the NAS Report and Proposed

Recommendations

Dr. Leonard

12:30 p.m. – 1:30 p.m. LUNCH

1:30 p.m. – 3:00 p.m. Full Committee Discussion

Facilitator: Dr. Leonard

3:00 p.m. – 3:15 p.m. *Next Steps*

Facilitators: Dr. Leonard and Dr. Tuckson

3:15 p.m. – 3:30 p.m. Planning for June 2006 SACGHS Meeting and Concluding Remarks

Dr. Tuckson

ADJOURN