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

Twenty-first Meeting
February 4-5, 2010
Washington, D.C.

DRAFT AGENDA

Thursday, February 4, 2010

8:30 a.m. – 8:45 a.m. Opening Remarks
Steven Teutsch, M.D., M.P.H.
SACGHS Chair

Preliminary Planning for Session on the Affordable Genome

8:45 a.m. – 9:15 a.m. Discussion of June 2010 SACGHS Session on the Implications of Affordable Whole-Genome Sequencing
Dr. Teutsch
SACGHS Chair

Clinical Utility and Comparative Effectiveness

9:15 a.m. – 9:45 a.m. Update on the Clinical Utility and Comparative Effectiveness Task Force
Marc Williams, M.D.
SACGHS Member

9:45 a.m. – 10:00 a.m. BREAK

Genetics Education and Training

10:00 a.m. – 11:45 a.m. Public Consultation Draft Report on Genetics Education and Training and Draft Recommendations

10:00 a.m. – 10:05 a.m. Introductory Remarks
Barbara Burns McGrath, R.N., Ph.D.
SACGHS Member

10:05 a.m. – 10:20 a.m. Briefing on the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) Education Subcommittee
Jana Monaco
Co-Chair, Education and Training Subcommittee, ACHDNC

10:20 a.m. – 10:45 a.m. Overview of Draft Report and Draft Recommendations
Dr. McGrath

10:45 a.m. – 11:45 a.m. Committee Discussion

Public Comment Session

11:45 a.m. – 12:15 p.m. Public Comments

12:15 p.m. – 1:15 p.m. LUNCH

Genomic Data Sharing

1:15 p.m. – 5:30 p.m. Genomic Data Sharing—Objectives, Mechanisms, and Policies

1:15 p.m. – 1:20 p.m. Introduction
Charmaine Royal, Ph.D.
SACGHS Member

1:20 p.m. – 1:40 p.m. Review of Federal Activities Related to Genomic Data Sharing
Laura Lyman Rodriguez, Ph.D.
Acting Director, Office of Policy, Communications, and Education
National Human Genome Research Institute

1:40 p.m. – 1:55 p.m. Committee Discussion

1:55 p.m. – 2:10 p.m. Future Directions in Health Information Technology
Joyce Mitchell, Ph.D.
Professor and Chair, Department of Biomedical Informatics
University of Utah School of Medicine

2:10 p.m. – 2:25 p.m. Committee Discussion

2:25 p.m. – 2:40 p.m. BREAK

2:40 p.m. – 4:50 p.m. Genomic Data Sharing Models

2:40 p.m. – 3:00 p.m. *Health Care Systems Model*
Catherine Schaefer, Ph.D.
Executive Director, Research Program
Kaiser Permanente

3:00 p.m. – 3:20 p.m. *Academic Model*
Daniel Masys, M.D.
Professor and Chair, Biomedical Informatics
Vanderbilt University

3:20 p.m. – 3:40 p.m. *Government Model*
Laura Lyman Rodriguez, Ph.D.
Acting Director, Office of Policy, Communications, and Education
National Human Genome Research Institute

3:40 p.m. – 4:00 p.m. *Commercial Model*

Mark Hoffman, Ph.D.
Director, Translational Medicine
Cerner Corporation

4:00 p.m. – 4:20 p.m. *Consumer-Controlled Model*
Robert H. Shelton, M.B.A.
Co-Founder, Chairman, Chief Executive Officer
Private Access, Inc.

4:20 p.m. – 4:50 p.m. Committee Discussion

4:50 p.m. – 5:20 p.m. Committee Discussion of Next Steps

5:20 p.m. – 5:30 p.m. Summation of Session
Dr. Royal

Updates from Federal Agencies

5:30 p.m. – 6:30 p.m. Update of Federal Activities

5:30 p.m. – 5:50 p.m. Development of Genomics Objectives for Healthy People 2020
Muin Khoury, M.D., Ph.D.
National Office of Public Health Genomics
Centers for Disease Control and Prevention

5:50 p.m. – 6:10 p.m. AHRQ Evidence-Based Reports Relevant to Genetic Testing
Gurvaneet Randhawa, M.D., M.P.H.
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

6:10 p.m. – 6:30 p.m. MEDCAC Meeting on Pharmacogenomic Testing for Anticancer Therapies
Jeffrey Roche, M.D., M.P.H.
Coverage & Analysis Group, Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services

6:30 p.m. – 6:35 p.m. Closing Remarks – Dr. Teutsch

Friday, February 5, 2010

7:30 a.m. – 7:35 a.m. Opening Remarks
Dr. Teutsch
SACGHS Chair

Gene Patents and Licensing Practices

7:35 a.m. – 8:35 a.m. Overview of Revised SACGHS Report *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* and Discussion and Coming to Closure
Dr. Teutsch
SACGHS Chair

Public Comment Session

8:35 a.m. – 8:45 a.m. Public Comments

Updates from Federal Agencies

8:45 a.m. – 9:45 a.m. Update of Federal Activities

8:45 a.m. – 9:05 a.m. ACHDNC Efforts to Develop National Policy Recommendations for the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening and Proposal for a Joint Task Force on Carrier Screening
R. Rodney Howell, M.D.
Chair, ACHDNC

9:05 a.m. – 9:25 a.m. Development of an FDA Adverse Event Reporting Mechanism for Laboratory Developed Tests
Alberto Gutierrez, Ph.D.
Office of In Vitro Diagnostic Device Evaluation and Safety
Food and Drug Administration

9:25 p.m. – 9:45 p.m. Interim Final Regulations for Standards for the Meaningful Use of Electronic Health Records
David Hunt, M.D.
Office of Health Information Technology Adoption
Office of the National Coordinator for Health Information Technology

9:45 a.m. -- 9:50 a.m. Concluding Remarks – Dr. Teutsch

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