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

Seventeenth Meeting
December 1-2, 2008
Washington, D.C.

DRAFT AGENDA

Monday, December 1, 2008

8:00 a.m. – 8:30 a.m.	Opening Remarks Steven Teutsch, M.D., M.P.H. SACGHS Chair

Session on Gene Patents and Licensing Practices

8:30 a.m. – 9:45 a.m.	Review of SACGHS Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests – James P. Evans, M.D., Ph.D., Chair, SACGHS Task Force on Gene Patents and Licensing Practices
9:45 a.m. – 10:30 a.m.	Discussion of Public Consultation Draft Report and Range of Potential Policy Options for Public Consideration
10:30 a.m. – 10:45 a.m.	BREAK
10:45 a.m. – 12:15 p.m.	Continued Discussion of Public Consultation Draft Report and Range of Potential Policy Options for Public Consideration
12:15 p.m. – 1:00 p.m.	LUNCH

Public Comment Session

1:00 p.m. – 1:30 p.m.	Public Comments

Session on Gene Patents and Licensing Practices (continued)

1:30 p.m. – 3:15 p.m.	Continued Discussion and Consensus on Releasing Public Consultation Draft Report for Public Comment
3:15 p.m. – 3:30 p.m.	BREAK

Session on Standards Development Initiatives to Enhance Oversight and Advance Innovation of Genetic Technologies

3:30 p.m. – 3:35 p.m.	Overview of Session – Dr. Teutsch
3:35 p.m. – 3:50 p.m.	Initiatives of the National Institute of Standards and Technology (NIST) in Clinical Diagnostics Standards Development – Willie May, Ph.D., Director, Chemical Science and Technology Laboratory (CSTL), NIST
3:45 – 3:50	Q&A
3:50 p.m. – 4:30 p.m.	Standards Development for New Technologies
3:50 – 4:00	Nucleic Acid Tests – John Butler, Ph.D., Biochemical Science Division, CSTL, NIST
4:00 – 4:10	Proteomic Tests, David Bunk, Ph.D. – Analytical Chemistry Division, CSTL, NIST
4:10 – 4:20	Metabolomic Tests, Karen Phinney, Ph.D. – Analytical Chemistry Division, CSTL, NIST
4:20 – 4:30	Q&A
4:30 p.m. – 5:00 p.m.	Standards Development Challenges Facing Stakeholders
4:30 – 4:40	Regulatory Agency Perspective – Steven Gutman, M.D., M.B.A., Director, Office for In Vitro Diagnostic Device Evaluation and Safety, Food and Drug Administration, SACGHS *Ex Officio*, FDA
4:40 – 4:50	Clinical Perspective – Jeff Cossman, M.D., Chief Scientific Officer, Critical Path Institute
4:50 – 5:00	Q&A
5:00 p.m. – 5:10 p.m.	Future Directions in Clinical Diagnostic Standards Development – Michael Amos, Ph.D., Scientific Advisor, CSTL, NIST, and SACGHS *Ex Officio*, NIST
5:10 – 5:30	Discussion
5:30 p.m. – 5:35 p.m.	Closing Remarks – Dr. Teutsch

Tuesday, December 2, 2008

8:00 a.m. – 8:05 a.m.	Opening Remarks – Dr. Teutsch
8:05 a.m. – 8:15 a.m.	Review of Priority Setting Process and Proposed Priority Issues – Paul Wise, M.D., M.P.H., Chair, SACGHS Task Force on Priority Setting

8:15 a.m. – 10:00 a.m.	Discussion of Proposed Priority Issue Areas – Dr. Wise
	Cluster 1: Coverage and Reimbursement for Genetic Services – Marc Williams, M.D.
	Cluster 2: Ensuring the Clinical Utility of Genetic Information – Dr. Teutsch
	Cluster 3: Genetics Education and Training – Barbara Burns McGrath, R.N., Ph.D.
	Cluster 4: Informed Consent, Privacy, and Discrimination Issues That Relate to Genomic Data Sharing – Kevin FitzGerald, S.J., Ph.D., Ph.D.
	Cluster 5: Implications of Consumer-Initiated Use of Genomic Services – Sylvia Au, M.S.
	Cluster 6: Public Health Applications of Genomics Research – Joseph Telfair, Dr.P.H., M.P.H., M.S.W.
	Cluster 7: Genetics and the Future of the Health Care System – Mara Aspinall, M.B.A.
10:00 a.m. – 10:15 a.m.	BREAK

Public Comment Session

10:15 a.m. – 10:45 a.m.	Public Comments

Session on SACGHS Priority Setting (continued)

10:45 a.m. – 12:30 p.m.	Determination of Priority Issue Areas and Action Plan – Dr. Teutsch
12:30 p.m. – 1:15 p.m.	LUNCH
1:15 p.m. – 3:00 p.m.	Review of Draft Progress Report – Dr. Teutsch and Dr. Wise
3:00 p.m. – 3:15 p.m.	Concluding Remarks – Dr. Teutsch
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