

Overview of SACGHS Session on Pharmacogenomics

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Chair, SACGHS Pharmacogenomics Task Force

October 20, 2005

Task Force Members

- Emily Winn-Deen, Chair
- Jim Evans
- Kevin Fitzgerald
- Debra Leonard
- Julio Licinio
- Hunt Willard
- Francis Chesley (AHRQ)
- Gurvaneet Randhawa (AHRQ)
- Muin Khoury (CDC)
- Steve Gutman (FDA)
- Allen Rudman (FDA)
- Sandra Howard (HHS)
- Theresa Lawrence (HHS)
- Suzanne Feetham (HRSA)
- Richard Anderson (NIH)
- Alan Guttmacher (NIH)
- Tim Leshan (NIH)
- Rochelle Long (NIH)

Today's Session Goals

- Continue fact finding on some of the issues identified in June
- Initiate our work plan to develop recommendations

SACGHS Session in June 2005

- Key issues identified through presentations and discussion
- Areas for further SACGHS fact finding efforts identified

Key Issues

➤ RESEARCH AND DEVELOPMENT

- Drug-diagnostic co-development
- Novel research teams
- Collecting evidence on effectiveness
- Funding sources
- Orphan diseases/genotypes

Key Issues

➤ INFRASTRUCTURE

- Data standards
- Regulation
- Surveillance

Key Issues

- INTEGRATION INTO CLINICAL PRACTICE
 - Access
 - Education
 - Need for evidence and guidelines
 - Liability

Key Issues

➤ ELSI

- Allocation of resources
- Health disparities
- Informed consent
- Privacy/confidentiality
- Discrimination
- Race
- Psychosocial harms/unintended consequences
- Intellectual property
- Genetic exceptionalism

SACGHS Task Force Conference Call July 21, 2005

- Guided the planning efforts for today's session
- Asked staff to identify ongoing federal efforts related to pharmacogenomics
- Discussed the development of a framework for Committee recommendations

Focus of Today's Fact Finding

- Update from the FDA
- Economic/Financial Issues
 - Focus on drug development
 - Focus on clinical practice
- Ethical, legal, and social issues
 - Focus on implications of different drug responses among racial/ethnic groups

Federal Efforts in Pharmacogenomics

- The task force requested a review of federal efforts in pharmacogenomics.
- The review will inform an analysis of gaps and overlap in federal efforts and help focus the development of recommendations.

SACGHS Report to the Secretary

- An outline of a comprehensive report to the Secretary was developed to provide a framework for our recommendations.