Overview of SACGHS Session on Pharmacogenomics

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Task Force Members

- Emily Winn-Deen, Chair
- Kevin Fitzgerald
- Chris Hook
- Julio Licinio
- Debra Leonard
- Ed McCabe
- Hunt Willard
- Suzanne Feetham (HRSA)
- Steve Gutman (FDA)
- Alan Guttmacher(NIH)
- Joseph Hackett (FDA)

Planning Framework for Addressing Topic

- State of the field
- Translational efforts
- Ethical, legal, and social issues
- Role of government agencies

Request to HHS Agencies

- What does your agency see as the most important policy issues, concerns, or voids in the field of pharmacogenomics?

- What, from your agency's standpoint, are the specific questions that SACGHS should address on each policy issue?

Issues Identified by Agencies

- Applying pharmacogenomics knowledge in the drug development process
- Assessing analytic validity, clinical validity, and clinical utility
- Integration of pharmacogenomics into clinical and public health practice

Issues Identified by Agencies (cont'd)

- Monitoring the impact of pharmacogenomics on broader public health issues
- Access to pharmacogenomics by low-income and uninsured populations
- Cost of pharmacogenomics

Issues Identified by Other Outreach Efforts

- Barriers
  - No uniform reporting standards
  - Need for appropriate approach for evaluation of the PG tests
  - Lack of robust technology available at a reasonable cost
  - FDA approval will be required for reimbursement and acceptance of pharmacogenomic technology

Issues Identified by Other Outreach Efforts

- Barriers (cont'd)
  - Lack of clear reimbursement strategy
  - Data is overwhelming and not useful to physicians in clinical practice
  - Need for a catalytic event to move pharmacogenomics out of academia into clinical practice
  - Clarification is needed on that what actually drives changes to drug labeling

Issues Identified by Other Outreach Efforts

- Strategies
  - Facilitate broad coordination efforts
    - Pharmacogenomics is a paradigm shift and all key constituencies within the health care system need to understand its role
  - Encourage innovation with financial incentives

Issues Identified by Other Outreach Efforts

- Strategies (cont'd)
  - Bolster and support the current multiple approaches to accessing diagnostics, including laboratory developed tests and test kits
  - Government should demand (as regulator) and pay for (as payer) high efficacy and improved safety

Purpose and Goals of Today's Session

- Provide a common understanding of the fundamentals of pharmacogenomics and the state of the field
- Identify policy issues that will be critical for this field to move forward
- Determine a specific focus for further work on this topic and a process for the development of a report and/or recommendations to the Secretary

Outline of Today's Session on Pharmacogenomics

- Fundamentals--Origins, Definitions and Concepts
- The Public Health Perspective
- In the Practice of Medicine
- Perspectives from Industry
- HHS Efforts and Future Directions
- Ethical, Legal and Social Implications
- Full Committee Discussion and Next Steps