Update from the SACGHS Pharmacogenomics Task Force

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SACGHS Task Force Members

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

Background

- First PGX Session, June 2005
  - Key issues identified through presentations and discussion
  - Areas for further SACGHS fact finding efforts identified

Background

- Second PGX Session, October 2005
  - Presentations on financial issues and on the implications of pharmacogenomics for racial and ethnic groups
  - Report Outline approved
  - Discussion of possible approaches

Goals of Today's Session

- Consider and further develop approaches for addressing challenges in pharmacogenomics
- Be briefed on:
  - *FDA Draft Guidance for Industry and FDA Staff on Pharmacogenetic Tests and Genetic Tests for Heritable Disorders*

Proposed Approaches to the Challenges in Pharmacogenomics

- Sources of inspiration
  - SACGHS Discussions
  - Presentations
  - Recent reports
  - Survey of Federal Efforts

Recent Reports

- Consortium on Pharmacogenetics (Spring 2002)
- Nuffield Council on Bioethics (UK - September 2003)
- *Pharmacogenomics Social, Ethical, and Clinical Dimensions* by M. Rothstein (ed.) (2003)
- CIOMS (WHO - January 2005)
- Royal Society (UK - September 2005)

Survey of Federal Efforts in Pharmacogenomics

- Organized by major issue/need areas identified by SACGHS
- Efforts compiled by SACGHS staff from agency presentations in June 2005 and web-based information gathering
- Agencies reviewed, revised, augmented

Federal Efforts: Research and Development

- Needs
  - Novel research teams
  - Incentives to study post-market and generic drugs
  - Evidence on effectiveness
  - Pharmaco-economic models
  - Coordination between drug and test developers

Federal Efforts: Research and Development

- NIH and the VA support investigator initiated research on both new and post-market therapeutics

- FDA has facilitated the development of PGX by engaging pharmaceutical and diagnostics industries through workshops and by developing guidance documents on the use of PGX evidence in the drug approval process

Federal Efforts: Research and Development

- CDC's Evaluation of Genomic Applications in Practice and Prevention (EGAPP) program
- AHRQ' DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) Network
- AHRQ' Research Initiative in Clinical Economics

Federal Efforts: Clinical Practice

- Barriers to integrations
  - Lack of evidence relevant to clinical practice
  - The cultures in medical specialties
  - Lack of awareness of both providers and the public
  - Lack of coverage and reimbursement

Federal Efforts: Clinical Practice

- AHRQ’ Evidence-based Practice Centers
- HRSA’s Maternal Child Health Bureau grant for study of cost effectiveness of aminoglycoside-induced deafness

Federal Efforts: Infrastructure

- Needs
  - Electronic medical records
  - Data standards

Federal Efforts: Infrastructure

- Office of the National Coordinator for Health Information Technology (ONCHIT)
- Veterans' Health Information System and Technology Architecture (VISTA)
- HRSA-funded American Academy of Pediatrics for the Partnership for Policy Implementation Project (PPI)

Federal Efforts: Oversight

- Needs
  - Guidance on the use of PGX in the FDA review process
  - Improved coordination between regulators and industry
  - Guidance needed on labeling changes

Federal Efforts: Oversight

- FDA – ensures safety and efficacy of drugs and medical devices marketed in the U.S.
- CDC – developing Genetic Testing Quality Control Materials Program
- Joint agency effort – MicroArray Quality Control (MAQC) project (FDA, NIH, EPA, and NIST)

Federal Efforts: Education

- Do patients have the information they need to make educated treatment decisions based on PGX testing?
- Are providers prepared to use PGX information in clinical practice?

Federal Efforts: Education

- NIH has produced brochures to inform the public about pharmacogenomics
- NIH and HRSA provide funding for NCHPEG's efforts
- AHRQ' Centers for Education and Research on Therapeutics (CERTs)

Federal Efforts: Surveillance

- Needs
  - Public Health Impact
  - Adverse events
  - Effectiveness
  - Unintended consequences
  - Utilization patterns

Federal Efforts: Surveillance

- CDC's mission is to protect the health and safety of all Americans
- FDA's Adverse Events Reporting System (AERS)
- AHRQ Integrated Delivery System Research Network (IDSRN)
- AHRQ Healthcare Cost and Utilization Project (HCUP)

Federal Efforts: Coordination

- Needs
  - Coordination, attention and/or awareness of pharmacogenomics within federal agencies
  - Mechanisms to promote and facilitate pharmacogenomic data sharing

Federal Efforts: Coordination

- Personalized medicine is part of the Secretary's 500 Day Plan and FDA's Critical Path Initiative
- NIH funded PharmGKB database
- AHRQ, CDC, HRSA and NIH have organized meetings to facilitate sharing of information
- CDC Human Genome Epidemiology Network (HuGENet™)

Federal Efforts: ELSI

- Topics for consideration:
  - Allocation of resources
  - Health disparities
  - Informed consent and human research protections
  - Privacy/confidentiality
  - Discrimination
  - Role of race in pharmacogenomics
  - Psychosocial harms and other unintended consequences
  - Impact of gene patents
  - Genetic exceptionalism as it applies to pharmacogenomics

Federal Efforts: ELSI

- NIH and DOE ELSI programs
- NIH/NIGMS EELSI initiative
- HRSA focuses on improving access to culturally competent, quality health care
- Office of Minority Health focuses on improving and protecting the health of racial and ethnic minority populations

Plan for Today's Session

- Identify the broad areas for the focus or our recommendations
- Use the 16 "Proposed Approaches" as starting point for our discussion