SACGHS Session on Patents and Access: Overview

Debra Leonard, M.D., Ph.D.
Chair, SACGHS Patents and Access Task Force

June 27, 2006

SACGHS Task Force Charge

- Review the NAS report and assess whether issues and questions raised by SACGHS in March 2003 were addressed
  - ✓ Focus of March session
- Determine whether there are areas that warrant further exploration and/or attention by SACGHS
  - Focus of today's session

Outcomes of March Session

- The Committee agreed that the first 12 NAS recommendations address research issues and focus on ensuring that the public investment in genomics and proteomics is optimally benefiting society

Outcomes of March Session

- The Committee agreed that the clinical practice and economic issues were, for the most part, not addressed by the NAS recommendations and that the one NAS recommendation relating to diagnostic testing (urging the establishment of procedures to enable results from patented tests to be independently verified) was of questionable feasibility

Outcomes of March Session

- No consensus was reached on whether SACGHS should move forward on this issue;
- The Committee asked for further background briefings

Overview of Today's Session

- Informational presentations
  - Fundamentals of Gene Patents and Licensing and the Nature of the Access Problem (Leonard)
  - Data and Analysis of the Impact of DNA-based Patents on Access to Genetic Technologies and Services (Cho)
  - Role and Economic Impact of Gene Patents in Drug and Diagnostics Development (McCamish)
- Roundtable discussion
- Committee discussion to determine whether there are areas that warrant further exploration and/or attention by SACGHS

Goal for Today's Discussion

- Reach consensus on whether SACGHS should do further work on the issue of gene patents and access
  - If yes, determine the appropriate method and mechanism for moving forward

Questions to Consider

- What unique issues does the patenting of genetic information and technology pose for clinical care?
- Can these issues be adequately addressed through existing patent and licensing systems or are new strategies needed?
- Can sufficient evidence be gathered to support the development of recommendations on this topic?

Questions to Consider

- What jurisdiction or authority does HHS have in this area?
- If the development of recommendations seems feasible and warranted, to whom would they be directed?
- Are there areas here that warrant SACGHS's attention?
- In light of all the information received today, what is the appropriate role for SACGHS?

Options for Moving Forward

- Conduct an in-depth study
  - Explore the areas in clinical practice identified by the NAS report through a panel discussion with those who reported to NAS
- Gather public perspectives
- Collect additional information
  - Explore the experiences and patent policies in other countries (e.g., Canada, EU)
- Continue to monitor the issue
  - Follow developments at NIH to address the NAS recommendations
  - Monitor outcome of Supreme Court patent case (Metabolite v. LabCorp)