Report from the SACGHS Task Force on Gene Patents and Licensing Practices

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Chair, SACGHS Task Force on
Gene Patents and Licensing Practices
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SACGHS Task Force on Gene Patents and Licensing Practices

SACGHS Members

- **Jim Evans (Chair)**
- Sylvia Au
- Cynthia Berry
- Chira Chen
- Andrea Ferreira-Gonzalez

Ad Hoc Members

- Mara Aspinall, Genzyme Genetics
- Debra Leonard, Cornell Medical School
- Emily Winn-Deen, Cepheid

Ex Officio Members

- Scott Bowen, CDC
- Martin Dannenfelser, ACF
- Denise Geolot, HRSA
- M.K. Holohan, NIH
- James Rollins, CMS
- Brian Stanton, NIH/OTT
- John Leguyader, PTO

Duke University Collaborators

- **Robert Cook-Deegan, M.D.**
- **Christopher Conover, Ph.D.**
- **Subhashini Chandrasekharan, Ph.D.**
  - Emily Pitlick
  - Patrick Sobczak, Ph.D.
  - Melissa Fiffer
  - Tamara James
  - Chris DeRienzo
  - Julia Carbone, LL.M

SACGHS Activities to Date

- March 2004 – Identified gene patents and licensing as a SACGHS priority issue; deferred further effort given NAS activity
- October 2005 – Formed a small group to review the NAS report
- March 2006 – Conclusions about the NAS report accepted by full Committee; more information sought

SACGHS Activities to Date

- June 2006 – Held information session
  - Decided to move forward with an in-depth study
  - Discussed study scope and work plan
  - Established SACGHS Task Force on Gene Patents and Licensing Practices to guide study
- October 2006 – First Task Force meeting
  - Refined proposed scope for study
  - Developed of approach for study

SACGHS Activities to Date

- November 2006 – SACGHS Meeting
  - Decided to move forward with an in-depth study
  - Discussed study scope and work plan
- December 2006 – Second Task Force meeting
  - Refined proposed scope for study
  - Developed of approach for study

SACGHS Activities to Date

- February 2007 – Third Task Force Meeting
  - Discussion of study scope and work plan
  - Meeting with Robert Cook-Deegan and other members of Duke University Center for Genome Ethics, Law, and Policy (CGE) to develop literature review and relevant case studies
- March 26, 2007 – Special Task Force Meeting
  - Presentations by Duke CGE
  - Discussion of next steps

Scope of SACGHS Study

- **Positive and negative effects of current gene patenting and licensing practices on patient access to genetic technologies**
  - **focusing on gene patents for health-related tests (diagnostic, predictive, or other clinical purposes)**
  - **encompassing both “clinical access” and “patient access”**
  - **considering the effects on translational research**

SACGHS Study of Gene Patents and Licensing Practices

STUDY PLAN

Part 1:
Data Gathering & Analysis

- Literature Review
- Expert Consultations
- Case Studies
- Additional Research?

Part 2:
Gathering
Public Perspectives

- Solicitation
- Compilation and Summary of Comments
- Roundtable / Public Hearing
- Analysis of Public Perspectives

Part 3:
Gathering
International Perspectives

- Data Gathering
- Identification of Experts
- Roundtable
- Analysis of International Perspectives

Final Report to the Secretary of Health and Human Services

Goals of Today's Session

To provide the Committee with a primer on gene patents and licensing practices that will assist in the development of this study.

1) Overview of various forms of intellectual property
2) Use of gene licenses by the Federal and private sectors
3) History and current landscape of gene patent policies