Report from the 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
- Chira Chen
- Joseph Telfair

Ad Hoc Members

- Mara Aspinall, Genzyme Genetics
- Debra Leonard, Cornell Medical School
- Emily Winn-Deen, Cepheid
- Cynthia Berry, Powell Goldstein LLP

Agency Experts

- Scott Bowen, CDC
- Martin Dannenfelser, ACF
- Denise Geolot, HRSA
- M.K. Holohan, NIH
- Brian Stanton, NIH/OTT
- Bruce Goldstein, NIH/OTT
- John LeGuyader, PTO
- Claire Driscoll, NIH/NHGRI

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 regarding access to genetic tests sought

SACGHS Activities to Date

- June 2006 – Held informational session
  - Decided to move forward with an in-depth study, focused on how gene patents and licensing practices affect patient access to genetic tests
  - 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
  - Outlined potential approaches for study

SACGHS Activities to Date

- November 2006 – SACGHS Meeting
  - Presented study scope and work plan to full Committee
  - Scope and work plan approved
- December 2006 – Second Task Force meeting
  - Refined proposed scope for study
  - Finalized 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

SACGHS Activities to Date

- March 27, 2007 – SACGHS Meeting
  - Primer session on gene patents and licensing practices in the U.S.
  - Update from Duke University collaborators on status of literature review and case study analysis
- May 2007 – Task Force Meeting
  - Discussion of next steps
  - Developed speaker list for International Roundtable

SACGHS Activities to Date

- June 2007 – Task Force Meeting
  - Finalized Discussion Guide for International Roundtable presenters

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

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

Analysis and synthesis of literature review, data collected, input from Roundtable experts, international approaches, and public perspectives and development of recommendations

Draft Report Released for Public Comment

Final Report to Secretary of Health and Human Services

Purpose of Today's Session

1) Gather background information on the gene patenting and licensing practices of other countries

2) Compare and contrast enforcement of intellectual property rights for patented genes in the U.S. and countries with government health systems

3) Learn about the processes utilized by international groups in developing reports and recommendations on issues relating to gene patents and licensing strategies

Discussion Questions

- How should pending U.S. patent reform initiatives be addressed when developing recommendations for the Secretary?
  - Should we have an update on the status of pending legislation during the November SACGHS meeting?

Discussion Questions

- Are there approaches utilized by other countries or international advisory groups that could be adapted for the U.S. system?
  - Which approaches should be used as models?
  - Which do not apply to the U.S. system?

Discussion Questions

- Did the International Roundtable session provide sufficient information about the approaches of other countries and international organizations with regards to gene patents and licensing practices and patient access to genetic technologies?
  - What other information might be critical for the Committee's information gathering process?

Next Steps

- August 2007 – Final literature review from Duke collaborators due to SACGHS staff
- November / December 2007 – Literature review and case study report to be reviewed and revised by Patents Task Force

Next Steps

- February 2008 – Task Force presents draft report to full Committee for public comment solicitation
- March 2008 – Draft report released for 60-day public comment period
- July 2008 – Roundtable with members of the public

Next Steps

- August 2008 – Draft report revised to incorporate public perspectives
- November 2008 – Draft report presented to SACGHS for final approval