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

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Gene Patents and Licensing Practices
November 13, 2006

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
- Emily Winn-Deen

Ex Officio Members

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

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

Goal of Today's Session

To discuss and reach consensus on the scope and work plan for a study on the impact of gene patents and licensing practices on patient access

Proposed Scope Statement

While recognizing the benefits and importance of patenting in innovation and technology development, SACGHS will explore whether current gene patenting and licensing practices are having adverse effects on patient access to genetic technologies, and ultimately, on the public's health.

“Patient Access” v “Clinical Access”

Patient access rests on many “upstream” activities. By using the phrase “clinical access,” we intend to encompass factors such as:

- Development and integration of genetic technologies;
- Reimbursement; and
- Cost issues.

Study Questions: Overarching Question

Overall effects of patenting on clinical access

What is the quantitative and qualitative evidence for positive or negative effects of gene patents and licensing practices on clinical access?

Study Questions

Loci of possible problems

Where within the healthcare system are barriers, if any, present (e.g. development, procurement, reimbursement)?

Study Questions

Impact of Licensing Practices

Are licensing practices affecting the ability of industry and academia to develop accessible genetic technologies? What role do technology transfer programs play in influencing clinical access to genetic technologies? Do licensing practices have downstream effects on clinical access to genetic tests?

Study Questions

Effects on cost

Is there quantitative and qualitative evidence of adverse effects of gene patents and licensing practices on the cost and pricing of genetic tests? Are there economic data or studies that analyze the contribution of gene patents to the cost of genetic tests, and ultimately, to patient access?

Study Questions

Effects on development of tests

Do gene patents and/or licensing practices create barriers to the development and implementation of clinical tests?

Study Questions

Effects on quality of testing

Is the quality of genetic testing affected by gene patents and licensing practices? Are current patent and licensing practices having an adverse effect on the independent verification of test results?

Study Questions

Study Approaches

What quantitative and qualitative approaches can be employed to assess the direct effect of gene patents and licensing practices on patient access to genetic technologies?

Study Questions

Alternative Models

Are there feasible alternative models and innovations that could be applied to the patent and licensing system to preserve its inherent incentives?

Discussion Questions on the Proposed Scope and Study Questions

Is the proposed scope appropriate and understandable?

While recognizing the benefits and importance of patenting in innovation and technology development, SACGHS will explore whether current gene patenting and licensing practices are having adverse effects on patient access to genetic technologies, and ultimately on the public's health.

Discussion Questions

Are the study questions appropriate?

Study Question Topics:

- Overall effects of patenting on clinical access
- Effects on development of tests
- Location of possible problems
- Impact of licensing practices
- Effects on cost
- Effects on quality of testing
- Further Study
- Alternative Models

Proposed Study Plan: Four Components

1. In-Depth Research Study
2. Public Consultation Process
3. Consultation on International Perspectives
4. Development of a Comprehensive Report to the Secretary

In-Depth Research

- Refine study topics for literature review. (December 2006)
- Start contract process for literature review.

  (Late 2006/early 2007)
- Commission literature review.

  (Early 2007)
- Analyze literature review and Identify gaps; select experts for roundtable.

  (Late spring 2007)

In-Depth Research

- Conduct roundtable with experts. (Summer 2007).
- Commission studies to address gaps. (Fall 2007).
- Present resulting research findings. (Meeting in 2008).

In-Depth Research
Commissioned Studies

A note on commissioning studies to address gaps

- Make a contribution to the literature
- Ability to specifically look at our issue of interest

Public Consultation Process

- Identify relevant stakeholders.
  (December 2006)
- Develop a request for public consultation. (December 2006)
- Solicit public comments over a 2-month period on the effects of gene patents and licensing practices on patient access to genetic technologies.
  (Early 2007)

Public Consultation Process

- Invite key stakeholders to a SACGHS meeting.

  (June 2007)
- Develop a final product documenting public comments.

  (Fall 2007)

Consultations on International Perspectives

- Identify and invite international experts. (Spring 2007)
- Develop questions for international roundtable session.

  (Summer 2007)
- Convene roundtable session.

  (November 2007)

Development of a Comprehensive Report to the Secretary

- Develop a first draft based on the three prior components.

  (Late spring 2007 and ongoing)
- Draft a notice to solicit comments on the draft report.

  (Summer 2007)
- Solicit public comments on the report.

  (Late Summer 2007)

Development of a Comprehensive Report to the Secretary

- Revise report based on public comments. (Fall 2007)
- Committee reviews revised report.

  (June 2008)
- Complete draft and submit to the Secretary.

  (Mid-2008)

Discussion Questions on Proposed Study Plan

- Will the components of the proposed approach achieve the study goal?
- Is the timetable reasonable?
- What methods should be used to solicit perspectives from the public and other interested stakeholders? What organizations should be targeted? How can patients and consumers who have been affected by gene patent issues be identified?
- Is a 2-month public comment period appropriate?

Next Steps?

- Staff will revise the scope and study proposal based on Committee conversation today
- We will move forward with the work plan after incorporating modifications discussed today.

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Further study

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