

SACGHS Session on Patents and Access

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Goals of Today's Session

- Be briefed about the NAS Report on Intellectual Property Rights in Genomic and Protein Research and Innovation
- Review the report and recommendations of the SACGHS Patents and Access Task Force
- Through Committee discussion, reach consensus on next steps

Background

- March 2004 – As part of the priority setting process, SACGHS identified concerns about the effects of DNA-based patents and licenses on access to genetic/genomic tests and services as a high priority issue
- NIH commissioned the NAS to review the patenting and licensing of human genetic material and proteins
- SACGHS deferred consideration of this topic until the NAS work was complete

Background

- November 2005 – NAS report released
- October 2005 – SACGHS organized Task Force to:
 - Review the NAS report and assess whether issues and questions raised by SACGHS were addressed
 - Determine whether there are areas that warrant further exploration and/or attention

Areas of Concern in Prior SACGHS Discussions

- Issues specific to:
 - Patents
 - Licensing practices
- Impacts on:
 - Research
 - Clinical practice
 - Economics

SACGHS Questions: Patent Issues

- Do DNA-based patents blur the distinction between information and products?
- Are DNA-based patents too broad or obvious to a person practiced in the art?
- Have the changes in the PTO's utility guidelines been effective in reducing DNA-based patent submissions whose utility is questionable?

SACGHS Questions: Licensing Practice Issues

- Which licensing terms are creating the majority of problems for genetic/genomic test providers?
 - high royalty fees?
 - the field of use?
 - sublicensing?
 - reach-through rights?
 - exclusivity?
- Do exclusive licenses raise particular concerns for genetic/genomic testing providers and how prevalent are exclusive licenses?

SACGHS Questions: Impacts on Research

- To what extent do gene patents and licensing practices inhibit research progress?
- To what extent do delays in publications due to patent submissions affect the progress of science?
- Does patent stacking inhibit scientific discovery and technology development by making it difficult for a researcher to obtain all of the licenses necessary to carry out research?

SACGHS Questions: Impacts on Research

- In 2000, technology transfer laws were amended to prohibit federally funded researchers from imposing undue restrictions on future research and discovery.
 - Is the impact of this amendment being monitored and analyzed?
 - Has it had an effect?

SACGHS Questions: Impacts on Clinical Practice

- Do patents facilitate or inhibit the translation of scientific information into medical practice?
- Are patent incentives needed for the translation of genetic/genomic discoveries in the area of genetic/ genomic testing?

SACGHS Questions: Impacts on Clinical Practice

- How do patent and licensing policies affect the availability of and equitable access to genetic test services and the practice of medicine?
- Does the current system of patents and licensing genetic technologies affect the training of laboratory clinicians?

SACGHS Questions: Impacts on Clinical Practice

- DNA-based patent holders can license their inventions to a single provider of a genetic test. Is this in the best interest of the public health given the difficulty of sending samples to multiple labs, lack of competition, and absence of independent test validation?
- Do DNA-based patents and licenses reduce access by either increasing costs licensing fees, reduced availability, or other reasons?

SACGHS Questions: Impacts on Clinical Practice

- Is there a mechanism for balancing the protection of an inventor's intellectual property with the broad utilization of gene discoveries for health care?
- Do DNA-based patents require special consideration due to their potential ability to improve public health?

SACGHS Questions: Economic Impacts

- Do patents and licensing policies increase the cost of medical products, including genetic tests and gene-technology based treatments?
- Are current patenting policies and practices critical to the success of the biotechnology and pharmaceutical industries?
- Could any changes in current law undermine innovation, thus doing more harm than good?

Briefing on the NAS Report

*Reaping the Benefits of Genomic and
Proteomic Research –
Intellectual Property Rights, Innovation, and
Public Health*