

**ADVISORY COMMITTEE ON HERITABLE
DISORDERS AND
GENETIC DISEASES IN NEWBORNS AND
CHILDREN**

**FIRST LIAISON REPORT OF THE SECRETARY'S
ADVISORY COMMITTEE ON GENETICS
HEALTH AND SOCIETY**

Presented by

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SACGHS Mandate

- **To explore, analyze and deliberate on the broad range of human health and societal issues raised by the development and use, as well as potential misuse, of genetic technologies**
- **To make recommendations to the Secretary of HHS and other Departments upon request**

SACGHS SACGHS Scope

- **Integration of genetic technologies into health care and public health**
- **Clinical, ethical, legal, and societal implications of new medical applications**
- **Research and data collection**
- **Misuse of genetics in bioterrorism**
- **Patent policy and licensing practices**
- **Broader social applications of genetics (forensics, education, etc.)**
- **Emerging applications and issues**

SACGHS Current Priorities

(as of May 2006)

- **Genetic discrimination**
- **Coverage & reimbursement**
- **Pharmacogenomics**
- **Large population studies**
- **DTC marketing**
- **Patents and licensing**
- **Oversight**
- **Genetics education and training**
- **Access**
- **Public awareness**
- **Genetic exceptionalism**
- **Vision statement**

SACGHS Work Products to Date (1)

- **Reports**
 - *A Roadmap for the Integration of Genetics and Genomics in Society: Report on the Study Priorities of SACGHS*
 - **Coverage and Reimbursement for Genetic Tests and Services**
 - *Draft Report on Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease*
 - **Resolution on genetics education and training of health professionals**

SACGHS Work Products to Date (2)

- **Letters**
 - **Three letters on genetic discrimination and**
 - **Compilation of public comments**
 - **DVD highlights of public testimony**
 - **Legal analysis of existing federal laws**
 - **Two letters on DTC marketing of genetic tests**
 - **Letter on national health information infrastructure**
 - **Letter on family history**

**Meeting of the Secretary's
Advisory Committee on Genetics,
Health, and Society**
Highlights

March 27-28, 2006

Meeting Highlights (1)

- The *ninth* meeting of the Secretary's Advisory Committee on Genetics, Health, and Society, March 27-28, 2006, focused on:
 - Reviewing policy issues concerning large population studies

Meeting Highlights (2)

- **A briefing on the Food and Drug Administration's (FDA) draft guidance for industry and FDA staff regarding pharmacogenetic tests and genetic tests for heritable markers, and developing policy approaches concerning issues surrounding pharmacogenomics**

Meeting Highlights (3)

- **Receiving an update on the status of pending genetic non-discrimination legislation and hearing new data about public perceptions of genetic technologies and genetic discrimination**

Meeting Highlights (4)

- **Being briefed on the National Academy of Sciences' recent report on intellectual property rights in genomic and protein research and innovation, and determining how to proceed on the topic.**
- **The Committee's deliberations resulted in the following decisions in each of the listed areas.**

Large Population Studies

- **The Large Population Studies Task Force will be revising and augmenting a draft report on a large population cohort project of genetic variation, the environment, and common disease as well as the associated policy issues and options for addressing them**
- **The Committee plans to solicit public comment on the draft report and recommendations before they are finalized**

Pharmacogenomics

- **The Pharmacogenomics Task Force will continue developing a draft report and will refine recommendations, based on the Committee's discussion, for consideration by the full Committee at the June 2006 meeting**

Genetic Discrimination

- **The SACGHS Task Force on Genetic Discrimination will organize a meeting with the Coalition for Genetic Fairness, the Chamber of Commerce, and the National Association of Manufacturers to discuss unresolved concerns regarding H.R. 1227**

Genetic Discrimination

- **The Committee will be writing another letter to the Secretary discussing the impact of public fear of genetic discrimination on research, research investment, and access to beneficial health information and reiterating the importance of Federal non-discrimination legislation in allaying such fears.**
- **The letter will urge the Secretary to take specific actions to advance the passage of Federal genetic nondiscrimination legislation.**

Patents and Access

- **After reviewing the National Academy of Sciences' recommendations on intellectual property rights in genomic and protein research and innovation, the Committee asked for additional information to inform its decision on next steps on this topic.**
- **Thus, the Patents and Access Task Force will plan an informational session for the June 2006 meeting**

**For more information about SACGHS,
please visit:**

<http://www4.od.nih.gov/oba/SACGHS.HTM>

**For a copy of SACGHS Work Products,
please visit:**

<http://www4.od.nih.gov/oba/sacghs/reports/reports.html>

**Draft SACGHS Report on
*Policy Issues Associated with
Undertaking a Large U.S. Population
Cohort Project on
Genes, Environment, and Disease*
May 2006**

**Draft Report available for public comment at:
[http://www4.od.nih.gov/oba/sacghs/public_com
ments.htm](http://www4.od.nih.gov/oba/sacghs/public_comments.htm)**

Comments due July 31, 2006