

SACGHS 2004 Strategic Plan Priority Issues/Study Topics

Access + Public Awareness + Genetic Exceptionalism

- ✓ Vision Statement
- ✓ Genetic Discrimination
- ✓ Education & Training
- ✓ Coverage & Reimbursement
- ✓ DTC Marketing
- ✓ Large Population Studies
- Pharmacogenomics
- Gene Patenting
- Oversight

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Coverage and Reimbursement of Genetic Tests and Services

Report of the
Secretary's Advisory Committee on Genetics, Health, and Society

February 2006

http://www4.od.nih.gov/oba/sacghs/reports/CR_report.pdf

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FTC FACTS for Consumers

At-Home Genetic Tests:

A Healthy Dose of Skepticism May Be the Best Prescription

Could a simple medical test tell you if you are likely to get a particular disease? Could it evaluate your health risks and even suggest a specific treatment? Could you take this test in the privacy of your home, without a doctor's prescription or guidance?

Some companies say genetic testing can do all this and more. They claim that at-home genetic testing can screen for diseases and provide a basis for choosing a particular diet, dietary supplement, lifestyle change, or medication. They sell their tests in supermarkets and drugstores, and they advertise their services in print, on television, and online.

The Federal Trade Commission (FTC) wants you to know the facts about the direct-to-consumers marketing of genetic tests. According to the Food and Drug Administration (FDA), which regulates the manufacturers of genetic tests; and the Centers for Disease Control and Prevention (CDC), which promotes health and quality of life, some of these tests lack scientific validity, and others provide medical results that are meaningful only in the context of a full medical evaluation. The FDA and CDC say that because of the complexities involved in both the testing and the interpretation of the results, genetic tests should be performed in a specialized laboratory, and the results should be interpreted by a doctor or trained counselor who understands the value of genetic testing for a particular situation.

Print copies = 11,400

FTC web hits = 6,461

Media coverage:

Wall Street Journal
New York Times
National Public Radio
US News and World
Report
Contra Costa Times
American Health Line
FDA News
Medical Device Week

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**Policy Issues Associated with Undertaking a
New Large U.S. Population Cohort Study of
Genes, Environment, and Disease**

Report of the
Secretary's Advisory Committee on Genetics, Health, and Society

March 2007

**Report Released:
March 23, 2007**

http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_LPS_report.pdf

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Realizing the Promise of Pharmacogenomics: Opportunities and Challenges

*Draft Report of the
Secretary's Advisory Committee on
Genetics, Health, and Society*

Available for Public Comment
March 23 - June 1, 2007

**Public Comment Period:
March 23 – June 1, 2007**

http://www4.od.nih.gov/oba/SACGHS/public_comments.htm

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SACGHS Study on 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

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Proposed New Study Topics

- Economic Consequences of Genomic Innovations (Steve Teutsch)
- Evaluation of Real-World Outcomes of Gene-based Applications (AHRQ-CDC)