Twentieth Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) October 8-9, 2009 Meeting Summary

This report provides a brief summary of the 20th meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), which was held October 8-9, 2009 in Washington, D.C. Meeting minutes will be posted at a later date. The archived webcast of the meeting is available at: http://oba.od.nih.gov/SACGHS/sacghs_past_meeting_documents.html#oct2009

Update on the Implementation of the Genetic Information Nondiscrimination Act (GINA)

Genetic discrimination has been a long-standing priority issue for the Committee. The Committee celebrated the enactment of GINA in May 2008 and has been following developments within the Executive Branch to implement the law. Attorneys in the Department of Labor (DOL), the Internal Revenue Service (IRS), the Centers for Medicare & Medicaid Services (CMS), the HHS Office for Civil Rights (OCR), and the Equal Employment Opportunity Commission (EEOC) provided reports on the status of the implementation of GINA. DOL, IRS, and CMS attorneys discussed the interim final rule (with a 60-day comment period) that was published on October 7, 2009 to implement Title I. Title I applies to group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare supplemental, or Medigap, policies, and generally prevents health insurance plans and issuers from collecting genetic information, adjusting premium or contribution amounts for a group or an individual based on genetic information, or using genetic information as a condition of eligibility for insurance coverage. OCR reported on the proposed regulations implementing the privacy provisions of the law. EEOC reviewed the agency's proposed regulations, which were published in March 2009, implementing Title II provisions. Title II prohibits discrimination in employment based on genetic information and limits the acquisition and disclosure of such information by employers and other entities covered by Title II. After the presentations, a question-and-answer session clarified further details, particularly regarding wellness programs, and how employers can best protect the health of their employees. See also:

> Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (http://edocket.access.gpo.gov/2009/E9-22504.htm).
>
> HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information (http://edocket.access.gpo.gov/2009/E9-22492.htm).
>
> Regulations under the Genetic Information Nondiscrimination Act of 2008 http://edocket.access.gpo.gov/2009/pdf/E9-4221.pdf.

Gene Patents and Licensing Practices

During an extensive session, the Chair of the Gene Patents and Licensing Task Force described the wide range of public comments received on the draft report and policy options; the comments were considered in producing the revised draft report and proposed recommendations reviewed at the meeting. SACGHS members discussed, revised, and approved the recommendations with some clarifying language. After further discussion, the Committee voted on each recommendation. While most members voted in favor of the revised recommendations, there were several dissenting votes. The revised recommendations are presented below.

1. ***Supporting the Creation of Exemptions from Infringement Liability*** (13 members supported, 2 opposed, 1 abstained)

The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

> *A. The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes.*
>
> *B. The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research.*

2. Promoting Adherence to Norms Designed to Ensure Access (14 members supported, 1 opposed, 1 abstained)

Using relevant authorities and necessary resources, the Secretary should explore, identify, and implement mechanisms that will promote more than voluntary adherence to current guidelines that promote non-exclusivity in licensing of diagnostic genetic/genomic technologies.

The Secretary should convene stakeholders—for example, industry, academic institutions, researchers, patients—to develop a code of conduct that will further encourage broad access to such technologies.

3. Enhancing Transparency in Licensing (13 members supported, 2 abstained)

Using relevant authorities and necessary resources, the Secretary should explore, identify, and implement mechanisms that will make particular information about patent licenses readily available to the public. The specific licensing terms that should be made available are those that pertain to the type of license, the field of use, and the scope of technologies.

4. Establishing an Advisory Body on the Health Impact of Gene Patenting and Licensing Practices (13 members supported, 1 abstained)

The Secretary should establish an advisory body to provide ongoing advice about the health impact of gene patenting and licensing practices. The advisory body also could provide input on the implementation of any future policy changes, including the other proposed recommendations in this report.

5. Providing Needed Expertise to US Patent and Trademark Office (USPTO)

The Secretary should work with the Secretary of Commerce to ensure that the USPTO is kept apprised of scientific and technological developments related to genetic testing and technology.

6. Ensuring Equal Access to Clinically Useful Genetic Tests

Given that genetic tests will be increasingly incorporated into medical care, the Secretary should ensure that those tests shown to have clinical utility are equitably available and accessible to patients.

Although the Committee approved the recommendations, the members stopped short of approving the entire draft report. They called for particular revisions to the report's background sections, including a more extensive incorporation of public comments received at the meeting and during the prior public consultation process. A subgroup of the Committee will guide the revision process. The revised report will be reviewed again preferably at a special meeting in December (yet to be scheduled) or at its next regularly scheduled meeting in February.

Genomic Data Sharing

During SACGHS' priority-setting process in December 2008, the ethical implications of genomic data sharing emerged as one of seven priority areas. Broad genomic data sharing facilitates important research, but also raises issues about consent and privacy, particularly given the wide range of research questions such data can help address, and the growing concerns about the identifiability of genomic data. The Committee will be assisted in its analysis of the issues by the Lewin Group, which was awarded a contract by the Assistant Secretary for Health to study key policy questions in this area.

During discussion, Committee members reached a consensus on two action steps to take: (1) forming a steering group to organize a session at the February 2010 meeting to explore models of genomic data sharing and usage, and (2) providing input to the Lewin Group as appropriate. Members suggested that the steering group should also look at sharing of data collected by companies providing direct-to-consumer tests, how research participants feel about their data being shared, systems for data sharing, what other agencies are doing, and consideration of the entire range of social and clinical implications of genomic data sharing.

Genetics Education and Training

The Chair of the Genetics Education and Training Task Force reviewed the Task Force's findings from surveys, interviews, and literature searches and presented draft recommendations for the Committee's consideration. In its data-gathering efforts, the Task Force found that genetics education for health professionals lacks integration across learning environments, and competing priorities are one of several barriers to optimizing genetics education and training. The Task Force also learned that the diverse roles and education paths of the public health workforce present a challenge for implementing genetics education. Consumers and patients primarily rely on media and health care providers for information.

The 13 draft recommendations are summarized as follows: (1) integrate genetics and genomic content into all levels of health professional education; (2) stimulate creative, innovative, collaborative care delivery through creation of genetic education advisory panels; (3) support genetic knowledge sharing by facilitating interdisciplinary collaborations; (4) assess the genetics public health workforce to plan for future needs; (5) develop core competencies for the public health workforce; (6) promote collaborative training among medical and public health professionals; (7) improve genetic literacy for consumers; (8) expand development of educational resources for the public; (9) promote the importance of family history; (10) increase public understanding of genetic research; (11) fund strategic planning for education and training in genetics; (12) increase training for academic health professionals; and (13) develop effective translation methods. The Task Force also identified several applicable recommendations from prior SACGHS reports.

Points made during the discussion regarding the recommendations included: emphasizing genomic education at the point of care where it will be clinically useful; collaborative relationships among genetic and non-genetic health care professionals to enhance training will require innovative reimbursement incentives; focusing on primary care vs. specialists; focusing public education on family history to improve genetic literacy; defining and promoting successful models of health literacy and engaging other

Federal departments and agencies such as the Department of Education; and establishing an HHS clearinghouse for information on understanding clinical utility as new genetic associations are discovered.

The Task Force will bring back a public consultation draft report to the Committee in February. If the Committee approves the draft, it will be issued for public comment after the meeting. A revised report will be developed based on public comments and reviewed at the Committee's subsequent meeting.

Direct-to-Consumer Genetic Testing

The Chair of the Direct-to-Consumer (DTC) Genetic Testing Task Force presented a revised draft paper that reflects changes recommended by Committee members at the June 2009 SACGHS meeting. The Task Force Chair also brought to the Committee's attention letters to two DTC companies that were investigated by the Federal Trade Commission (FTC). The FTC *ex officio* member explained some of the details of the investigation.

The objectives of the paper are to outline benefits and concerns related to DTC genetic testing, highlight relevant prior SACGHS recommendations, and identify issues not adequately addressed by prior recommendations. Key areas for attention are gaps in the Federal oversight of DTC genetic testing (e.g., no Food and Drug Administration (FDA) review of promotional materials due to limitations under current regulatory practices), gaps in privacy and research protections when Federal regulations do not apply to a company offering DTC testing, and insufficient genetics knowledge about the implications of a genetic test result among consumers and health care providers.

Nine relevant prior SACGHS recommendations relate to oversight gaps, marketing claims, promotional materials, analytical and clinical validity, clinical utility, standardization, privacy, and consumer and provider education. Proposed action steps include soliciting stakeholder input in rulemaking; convening a joint HHS-Federal Trade Commission task force on specific guidelines for DTC genetic test advertising, promotion, and claims; identifying specific gaps in state and Federal privacy protections related to DTC testing through efforts by OCR and other relevant HHS agencies,; and developing an initiative on genetics education that includes information specific to DTC genetic testing.

DTC concerns not adequately addressed in prior SACGHS recommendations include nonconsensual testing, limited data on psychosocial impacts of DTC genetic testing, impact of DTC testing in children, potential exacerbation of health disparities, inadequate protection for research uses of specimens and data derived from specimens, and impact of DTC testing on the health-care system.

SACGHS members voted unanimously to move the report forward. A final draft report that reflects the Committee's discussion will be developed before Thanksgiving 2009, and final comments from SACGHS members will be due in mid-December.

Public Comment Sessions

During the public comment periods of each day's session, the Committee heard from representatives of:

Association for Molecular Pathology
Biotechnology Industry Organization
College of American Pathologists
Athena Diagnostics
Wisconsin Alumni Research Foundation
Personalized Medicine Coalition
Association of University Technology Managers

Facing Our Risk of Cancer Empowered (FORCE)

A postdoctoral fellow from Howard University's National Human Genome Center and a research associate at the Institute of Ethics at Georgetown University also made comments.

Future Activities

Possible agenda items for the February 2010 SACGHS meeting were identified as follows:

- Public consultation draft report on genetics education and training
- Educational session on models of agreement for genomic data sharing and usage
- Progress report from the Clinical Utility and Comparative Effectiveness Task Force
- Plans for a session on the affordable genome
- Update on the implementation of GINA
- Update on health care reform
- Report from the Clinical Laboratory Improvement Advisory Committee on good laboratory practices

SACGHS also decided to organize an educational session on the implications of an affordable genome, possibly during its second meeting of 2010. Also, several members will draft a paper highlighting previous SACGHS recommendations for publication in a medical journal or other suitable forum.