

SACGHS OVERSIGHT SESSION

**Andrea Ferreira-Gonzalez, Ph.D.
Chair, SACGHS Oversight Task Force
November 20, 2007**

Purpose of Oversight Session

- **Learn about an international analysis of regulatory gaps in the oversight of genetic testing and models to address those gaps**
- **Listen to public perspectives regarding oversight:**
 - **Sharon Terry: stakeholders attending GA summit**
 - **David Mongillo: laboratorians**
 - **Patricia Goldberg: nurses in genetics**

Secretary's Charge

- SACGHS charged in March 2007 to develop a comprehensive map of the steps needed for evidence development and oversight of genetic testing
- Charge included 8 questions about key measures of validity and quality of genetic tests and processes to assure their safety and effectiveness
- Request to consider public and private solutions
- Advised to focus on the future

SACGHS Oversight Task Force

(n=33)

SACGHS Members -- Andrea Ferreira-Gonzalez (Chair), Sylvia Au, Kevin FitzGerald, Steve Teutsch, Marc Williams, Paul Steven Miller

Private Sector and Federal Experts-- Michael Amos, Joe Boone, Linda Bradley, Amy Brower, Marie Earley, Barbara Evans, Phyllis Frosst, Scott Grosse, Steve Gutman, Mark Hoffman, Kathy Hudson, Lisa Kalman, Muin Khoury, Ira Lubin, Marie Mann, Elizabeth Mansfield, Joanne Mei, Richard Naples, Tim O'Leary, Glenn Palomaki, Vicky Pratt, Gurvaneet Randhawa, Carolyn Sue Richards, Jim Robb, Gail Vance, Ann Willey, and Judy Yost

SACGHS Draft Oversight Report

- Broad conceptualization of oversight to include:
 - Federal and State governments and regulatory agencies
 - standard-setting organizations
 - knowledge-generation agencies
 - public and private sector healthcare payers
professional societies
 - health providers
 - patients, and consumers
- 7 chapters, 192 pages
- 16 recommendations

Current Status

- Draft report released for public comment
November 5 until December 21
- Outreach mechanisms
 - Federal Register
 - SACGHS website
 - Dear Colleague via SACGHS Listserv ~2,000
 - Colleagues asked to redistribute request

Secretary's Advisory Committee on Genetics, Health, and Society

Meetings and
Conferences

REQUEST FOR PUBLIC COMMENTS BY DECEMBER 21, 2007

Links

**U.S. System of Oversight of Genetic Testing:
SACGHS' Draft Response to the Charge of the Secretary of HHS**

Contact SACGHS

[DOWNLOAD DRAFT REPORT](#)

OBA Home

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is seeking public comment on a draft report to the Secretary of Health and Human Services (HHS) on the oversight of genetic testing.

In 2004, SACGHS recognized that oversight of genetic testing was a high priority issue that required ongoing monitoring. In 2006, SACGHS began an in-depth fact-finding process on the oversight roles of Federal, State, and private sector entities. In March of 2007, the Office of the Secretary of HHS outlined a specific charge to SACGHS to focus the Committee's inquiry. The charge reads as follows:

Undertake the development of a comprehensive map of the steps needed for evidence development and oversight for genetic and genomic tests, with improvement of health quality as the primary goal. Consider and address the following questions:

- What evidence of harm exists regarding genetic tests? Is that harm attributable to analytic validity, clinical validity, or clinical utility of the tests? If evidence does not exist, what threats are not currently being addressed? What public health benefits are not accruing as quickly as they might?

Current Status

- Targeted outreach:
 - consumer groups, health professionals, professional societies, providers, payers, industry, DTC companies, laboratory groups, 21st Century Coalition, Personalized Medicine Coalition
 - CLIAC, ACHDGDNC, AHIC PHC, IOM Genomics Roundtable, state public health departments, SACGHS *Ex Officio* Agencies
 - Prior commenters on PGx, LPS, C&R, SACGT Oversight

Post-Comment Work Plan

- **Analysis of public comments**
- **Preparation of summary**
- **Chapter leads consider comments, revise chapters, call on chapter team members as needed for expert input**
- **Weekly conference calls of steering group in January to assess progress**
- **Jan. 23 call with entire task force to discuss revised recommendations**

Next Steps

- **Jan. 30: Conference call for steering committee to brief full committee and *ex officios* on revisions to recommendations**
- **Feb. 12-13: SACGHS discusses revisions to report**
- **Feb. 18-Feb 28: Edits to reflect Committee's input**
- **Feb. 29: Final recommendations submitted to the Office of the Secretary (OS)**
- **April 30: Final report formally submitted to OS**

SACGHS Draft Report on the U.S. System of Oversight of Genetic Testing

[http://www4.od.nih.gov/oba/SACGHS/
public_comments.htm](http://www4.od.nih.gov/oba/SACGHS/public_comments.htm)