

**Issues Addressed by the
Secretary's Advisory Committee on
Genetic Testing
(1999 – 2002)**

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SACGT Mandate

To identify policy issues raised by genetic testing and to make policy and procedural recommendations to the Secretary of Health and Human Services on how such issues should be addressed, including:

- The safe and effective incorporation of genetic technologies into health care;
- The effectiveness of existing and future measures for oversight of genetic tests; and
- Research needs related to the Committee's purview.

SACGT Policy Recommendations

- Reports
 - Oversight of genetic tests
 - Methodology for classifying genetic tests into scrutiny levels
- Letters to the Secretary
 - Genetic discrimination in health insurance and employment
 - Gene patenting and licensing
 - “Secondary subjects” in research

Oversight of Genetic Tests

- Oversight issue addressed at the request of the Assistant Secretary for Health
- Involved a comprehensive assessment of the adequacy of oversight of genetic tests, a broad multifaceted, public consultation process, and a consideration of all options
- Resulted in *Enhancing the Oversight of Genetic Tests: Recommendations of the SACGT*
 - Increased Federal involvement is needed in the oversight of new genetic tests through flexible regulation by FDA, augmentation of the Clinical Laboratory Improvement Amendments, and development of collaborative post-market data collection efforts led by CDC.

Oversight of Genetic Tests (cont)

- FDA is presently considering developing a proposed rule classifying ASRs used in high-risk in-house tests, including genetic tests, as Class II (special controls) or Class III (pre-market approval) devices, depending on their intended use and risk profile.
- CDC and CMS are in the process of preparing a Notice of Proposed Rulemaking to develop a genetic testing specialty under CLIA.

Methodology for Classifying Genetic Tests

- SACGT considered several options for classifying genetic tests, but concluded that classifying genetic tests based on a limited set of elements applied in a simple, linear fashion for oversight purposes is infeasible.
- SACGT's decision to defer further work on the methodology was also based on significant progress made by FDA to develop an innovative regulatory process for genetic tests, including a template for facilitating and ensuring appropriate review of relevant data.

Letters to the HHS Secretary

- Genetic Discrimination – Place a high priority on the passage of Federal legislation prohibiting genetic discrimination in health insurance and employment.
- Gene Patenting and Licensing – Conduct a study to determine whether certain licensing practices are adversely affecting access to beneficial genetic tests.
- Secondary Subjects – Develop guidance to help define situations in which secondary subjects (e.g., family members of primary research subjects) become human research subjects whose consent must be obtained or waived.

SACGT Reports in Development

- DHHS Efforts to Advance Knowledge of Genetic Tests
Genetics Education of Health Professionals
- Public Understanding of Genetic Testing
- Informed Consent in Clinical and Public Health Practice
- Reimbursement of Genetic Education and Counseling Services
- Development, Translation, Oversight, Availability and Accessibility of Genetic Tests for Rare Diseases

DHHS Efforts to Advance Knowledge of Genetic Tests

- Assessment of DHHS efforts to advance knowledge of the clinical validity and utility of genetic tests in both pre-market and post-market phases
 - Analyzed projects supported by relevant DHHS agencies in primary research, secondary analyses, summary information development, and summary information dissemination
 - Developed case studies illustrating on the development of three genetic tests to learn more about how the agencies work together and with the private sector to advance the validation and integration of genetic tests

Genetics Education of Health Professionals

- Exploration of the educational challenges posed by the expansion of genetic testing and the adequacy of efforts to prepare health professionals to use these new technologies appropriately
- Held a policy conference in May 2002 that identified need for:
 - Teaching/faculty development
 - Training of geneticists/collaborative teams
 - Funding for translational research, outcomes research (evidence-based medicine), development of pedigree tools, and data on the application of lab guidelines and reimbursement patterns and codes

Access to Genetic Testing Services

- Exploration of issues in access to genetic testing services, including:
 - Coverage, billing and reimbursement of genetic testing services
 - Disparities in access to genetic testing services
- Held town meeting on the accessibility of genetic testing services and to hear perspectives on how the problem should be addressed

Additional Topics Under Study

- Importance of public understanding and need for information materials on specific tests and categories of tests to reach disparate communities; a generic information brochure targeted to general public was to developed as a model
- Conceptual framework correlating test characteristics and approaches to informed consent in order to improve decision making and the consent process in clinical and public health practice
- Assessment of the development, translation, oversight, availability and accessibility of genetic tests for rare diseases