Direct-to-Consumer Genetic Testing

Discussion of Final Draft Paper

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Secretary's Advisory Committee on Genetics, Health, and Society
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DTC Genetic Testing Task Force

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- Penny Meyers, CMS
- Jeff Roche, CMS

Ad Hoc Members
- Colleen McBride
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SACGHS Staff
- Cathy Fomous

Session Goals

- Come to consensus on
  - Key areas for the Secretary's attention
  - Prior SACGHS recommendations and action steps that address these areas
  - Remaining concerns that may require additional action
- Approve the paper for transmission to the Secretary of Health and Human Services

Background

- March 2009: short-term task force established to draft a paper on direct-to-consumer (DTC) genetic testing
- Objectives of the paper
  - Outline benefits and concerns related to DTC genetic testing
  - Highlight prior SACGHS recommendations that address concerns
  - Identify issues not adequately addressed by prior SACGHS recommendations
- June 2009: Committee discussion and suggestions to include an executive summary and specific actions steps based on prior SACGHS recommendations

Other Relevant Information

FTC letters to Sciona, Inc and Genelex Corp

- FTC concerned about the companies' representations that the MyCellf™ Program enables consumers to achieve long-term or permanent weight loss
- Companies have discontinued marketing activities for the MyCellf™ Program; Sciona has ceased operations
- Letters available at
  - http://www.ftc.gov/os/closings/090814genelexclosingletter.pdf
  - http://www.ftc.gov/os/closings/090814scionaclosingletter.pdf

Intent of the DTC Paper

The paper:

- Recognizes that some concerns are not unique to DTC testing or genetic testing but may apply broadly to provider-based laboratory tests
- Identifies issues that may be unique to DTC genetic testing if a consumer's personal health provider is not involved in health decisions or government regulations do not apply to entities providing DTC services

Executive Summary

- An executive summary was added to the paper, as recommended by the Committee

- It highlights three key areas for the Secretary's attention and five specific actions steps

Key Areas for Attention

Gaps in the federal oversight of DTC genetic testing, particularly the absence of review of DTC genetic testing promotional materials and claims by the Food and Drug Administration (FDA) due to limitations under current regulatory practices, and lack of evidence of clinical validity and utility for most health-related DTC tests

Key Areas for Attention (continued)

Gaps in privacy and research protections for consumers utilizing DTC genetic services because federal regulations may not apply to companies offering DTC testing and state-level protections may be inadequate

Key Areas for Attention (continued)

Insufficient knowledge about genetics among many consumers and health care providers, and limited involvement of consumers' personal health care providers to assist consumers in selecting genetic tests and in making health decisions based on DTC test results

Prior SACGHS Recommendations

9 prior SACGHS recommendations, if implemented, would address concerns related to

- Oversight gaps
- Marketing claims
- Promotional materials
- Analytical validity
- Clinical validity
- Clinical utility
- Standardization
- Privacy
- Consumer and provider education

Action Steps

Based on its prior recommendations, SACGHS proposes the following specific actions that the Secretary of Health and Human Services (HHS) can take to address gaps and inconsistencies in federal regulations and to accelerate the coordination of programs that facilitate comprehensive and consistent consumer and health provider genetics education:

Action Steps (continued)

- Direct the FDA Commissioner and CMS Administrator to solicit broad stakeholder input through a series of public hearings, then convene jointly to draft and publish an Advance Notice of Proposed Rulemaking that (1) analyzes gaps, inconsistencies, and duplications in regulations related to DTC genetic testing and (2) identifies specific proposals to address them within relevant statutory authority
- Include laboratories that provide DTC genetic testing and services, if HHS establishes a laboratory registry

Action Steps (continued)

- Convene a joint HHS-FTC task force—with industry, consumer, academic, and government stakeholders—to propose specific guidelines for DTC genetic test advertising, promotion, and claims consistent with existing statutory authority. The task force should also identify gaps in that authority relevant to this emergent industry. These guidelines, which will form the basis of more targeted federal enforcement of claims that are misleading and/or not truthful, should be grounded in evolving evidence standards—which are accepted by experts in relevant fields—for identifying and evaluating competent and reliable scientific evidence of DTC genetic test performance consistent with the claims made by DTC companies related to these tests.

Action Steps (continued)

- Direct the HHS Office for Civil Rights, with support from the Office for Human Research Protections and other relevant HHS agencies, to identify specific gaps in state and federal privacy protections for personal health information that may be generated through DTC genetic testing and propose to the Secretary specific strategies the federal government can undertake consistent with its existing authority to address these gaps and inform consumers of potential risks to privacy.

Action Steps (continued)

- Develop an initiative within the Office of the Assistant Secretary for Planning and Evaluation (ASPE) focused on genetics education, including information specific to DTC genetic testing and links to HHS educational resources for consumers and health practitioners. ASPE should also follow up its March 2009 report, *Consumer Use of Computerized Applications to Address Health and Health Care Needs*, by conducting research and evaluating studies specific to DTC genetic testing, developing policy analyses, and estimating the cost and benefits of policy alternatives and potential regulations under consideration by HHS.

Concerns Not Adequately Addressed by Prior SACGHS Recommendations

The following concerns may benefit from further evaluation by SACGHS and/or appropriate federal agencies

- Nonconsensual testing
- Limited data on psychosocial impact of DTC genetic testing
- Impact of DTC genetic testing in children
- Potential exacerbation of health disparities
- Inadequate protection for research use of specimens and data derived from specimens
- Impact of DTC testing on the health care system

Finalizing the DTC Paper

- Are there any significant issues or actions steps that are missing from the paper?
- Is the paper approved for transmission to the Secretary?
- What, if any, additional actions are warranted for issues not adequately addressed by prior SACGHS recommendations?

Final Steps

Submit edits

- by October 19
- to Cathy Fomous