DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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December 8, 2004

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

As you know, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) was established to explore and provide advice about the broad range of human health and societal issues raised by the development and use, as well as potential misuse, of genetic technologies. We take this charge and its responsibility related to the public health very seriously. One of the issues we are currently exploring is the public health impact of direct-to-consumer marketing of genetic tests, which refers to both advertising of genetic tests and access to testing without the involvement of a health professional. Although our exploration of this issue is in an early stage, I am writing to you at this time to convey our preliminary thoughts and initial concerns about this issue and to request that you consider taking three important actions.

SACGHS believes the successful integration of genetics and genomics into health care and public health practice and the realization of the benefits of new genetic and genomic discoveries depends to a great degree on how well-informed healthcare professionals and the public are about the validity, risks and benefits of genetic testing. The Committee recognizes the value of consumer access to information about genetic testing and appreciates that direct-to-consumer advertisements, if done appropriately, can play an important role in consumer education and awareness. However, based on our fact-finding and deliberations to date, the Committee is concerned that direct-to-consumer advertising of genetic tests and direct access to tests have the potential to harm consumers, adversely affect public health, and bring about an erosion of trust in genetics and genomics. For example, the Committee has been made aware of advertising claims asserting that an individual's exact nutritional needs can be determined by a genetic test and that genetic tests are able to determine or predict a child's propensity for addictive behaviors. These tests are being advertised through the Internet and other mechanisms and are being offered directly to consumers without the involvement of a health professional even though the clinical validity of the tests is not well-understood and the advisability of providing them without a prescription is not always clear.

We are also concerned about the possibility that consumers can be harmed by such genetic tests if they forgo necessary medical treatments or undergo unnecessary or risky medical treatments in response to invalid test results. Interpretation of genetic tests can be quite complex. Harm may also result if consumers act on misinterpreted results even when the test is valid. Furthermore, social and economic

harm may occur if limited healthcare resources are expended on unnecessary health care treatments or if consumers misunderstand the meaning or significance of the genetic tests and take ill-advised actions as a result.

It is our understanding that the regulation of advertisements for genetic tests is within the purview of the Federal Trade Commission (FTC) and in some instances the Food and Drug Administration (FDA). *Ex Officio* representatives from the FTC and FDA serve on SACGHS, and they have helped inform our deliberations. We have learned that, in the normal conduct of their activities, the FTC and FDA collaborate and exchange information on many issues. We also have learned that FTC could benefit from the scientific and clinical knowledge and expertise about genetic tests that resides in the Department of Health and Human Services. As such, and given the potential health impact of direct-to-consumer advertising of genetic tests, we urge the FDA, working with other relevant HHS agencies, to make the issue a high priority in its collaborative activities with the FTC.

With regard to FDA's purview over advertisements for genetic tests, we have learned that FDA's role in monitoring the advertising of genetic tests offered as laboratory services is not entirely clear, especially with respect to so-called "homebrew" tests. As such, it is important that FDA's role in monitoring the advertisement of genetic tests be clarified.

Finally, given concerns about direct access to genetic tests without the participation of a physician or other health professional, we have learned that additional information is needed to assess the impact of direct-to-consumer marketing on consumers' ability to make appropriate health care decisions. Therefore, we urge you to encourage the relevant HHS agencies to collect the necessary data and conduct an analysis of the public health impact of direct-to-consumer advertising and access to genetic tests without the involvement of an appropriate health professional.

In summary, these three steps—enhanced collaboration between the FTC and FDA and other appropriate HHS agencies on advertising for genetic tests, clarification of FDA's role in monitoring the advertising of laboratory developed genetic tests, and an analysis of the public health impact of direct-to-consumer advertising and direct access to genetic tests-- will enhance the Federal government's ability to protect the public from potential harms of inappropriate direct advertising and access to genetic tests. They will also serve to help maintain public confidence in genetic tests that have been established as valid and beneficial.

Thank you for your attention to this important matter.

Sincerely,

Reed V. Tuckson, M.D.
SACGHS Chair