DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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February 8, 2006

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Leavitt:

In prior correspondence dated December 8, 2004, (attached), I wrote about the efforts of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) to explore the public health impact of direct-to-consumer marketing and distribution of genetic tests. That letter noted our appreciation of the role of advertisements in facilitating consumer access to information about genetic tests; but, expressed a strong concern that the promotion of such tests to consumers could be harmful if a health professional is not involved in the process. SACGHS recommended enhanced collaboration between the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) in monitoring direct-to-consumer advertising for genetic tests and encouraged relevant HHS agencies to carry out an analysis of the public health impact of direct-to-consumer marketing of genetic tests.

We were pleased to report that the HHS agencies and the FTC have taken steps to respond to our suggestions. Two inter-agency work groups have been formed to help monitor claims made by companies advertising genetic tests on the Internet and to evaluate the public health impact of DTC marketing of genetic tests. The first work group, composed of staff from the FTC, FDA, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH), is providing a forum for HHS agencies to collaborate with FTC in the assessment of the scientific accuracy of claims made by companies advertising genetic tests on the Internet. The second work group, composed of staff from the FDA, CDC, NIH, and the Health Resources and Services Administration (HRSA), is exploring mechanisms for collecting data on the public health impact of direct-to-consumer marketing of genetic tests. Both efforts will benefit greatly from the collective resources and expertise of the CDC, FDA, HRSA, and NIH.

Given this progress, the Committee urges that the FTC and FDA issue a joint statement about genetic tests marketed directly to consumers. Such a statement should help raise public awareness about the issues associated with genetic testing and the importance of careful assessment of such advertisements. It could also result in the reinforcement of the important role of health providers in the testing decision process and the interpretation of test results, and appropriate use of test results in the management of an individual's health. Finally, such a statement might serve to remind the industry of Federal government agencies' monitoring of marketing behavior in this area.

We commend you and your agencies for enacting these initiatives. Such inter-agency cooperation serves as a model for addressing other complex issues raised by new genetic technologies and developments. Thank you for your leadership.

Sincerely,

Reed V. Tuckson, MD, FACP
SACGHS Chair

Attachments: Tab A – 2004 SACGHS letter

cc: Carolyn M. Clancy, Director, Agency for Healthcare Research and Quality
Julie L. Gerberding, Director, Centers for Disease Control and Prevention
Mark B. McClellan, Administrator, Centers for Medicare & Medicaid Services
Lydia B. Parnes, Director, Bureau of Consumer Protection, Federal Trade Commission
Andrew C. von Eschenbach, Acting Commissioner, Food and Drug Administration
Elizabeth M. Duke, Administrator, Health Resources and Services Administration
Elias A. Zerhouni, Director, National Institutes of Health