THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 16 2006

Reed Tuckson, M.D.
Chair
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Dr. Tuckson:

Thank you for your letter on direct-to-consumer marketing of genetic tests. Like you, I am concerned that the use of genetic tests based on insufficient, unsubstantiated or misleading evidence and marketed directly to consumers without the involvement of a health provider could be detrimental to consumers' health. Your recommendation that the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) issue a joint statement on over-the-counter genetic tests is a constructive suggestion.

I am pleased to report that in response to your recommendation, FDA, FTC and the Centers for Disease Control and Prevention (CDC) are in the process of developing a consumer alert that encourages consumers to talk to their health provider before using direct-to-consumer genetic tests and to question claims made by companies offering such tests. This consumer alert will help to raise public awareness about the importance of careful assessment of genetic test advertisements. The joint backing of FDA, FTC, and CDC will add tremendous weight to this important message.

I thank SACGHS for its continued attention to this issue and look forward to receiving more suggestions on how the Federal departments and agencies can work together to address this and other complex issues raised by new genetic technologies.

Sincerely,

Michael O. Leavitt