



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

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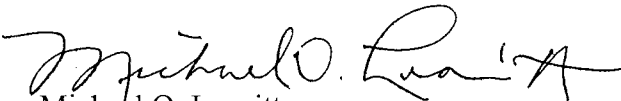
Reed V. Tuckson, M.D.  
Chair  
Secretary's Advisory Committee on Genetics, Health, and Society  
NIH Office of Biotechnology Activities  
6705 Rockledge Drive, Suite 750  
Bethesda, MD 20892

Dear Dr. Tuckson:

I am writing to acknowledge receipt of your letter expressing the concerns of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) about direct-to-consumer marketing of genetic tests. I appreciate the Committee's work on this important issue and will carefully consider the steps that you recommended be taken to gather additional information about the extent to which such marketing may pose a public health risk and to encourage further collaboration between relevant agencies of our Department and the Federal Trade Commission. I also will request that the Food and Drug Administration's *ex officio* representative to SACGHS provide additional information to the Committee to clarify the agency's role in regulating direct-to-consumer advertising of genetic tests offered as laboratory services.

Thank you again for your work on direct-to-consumer marketing of genetic tests. I understand that your analysis of this issue is just beginning, and I look forward to receiving future recommendations from the Committee on this topic.

Sincerely,

  
Michael O. Leavitt