



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Secretary's Advisory Committee on
Genetics, Health, and Society
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April 27, 2007

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

Dear Secretary Leavitt:

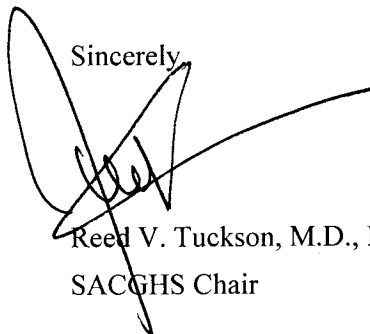
On behalf of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), I am writing to commend you for your leadership in addressing the critical issues associated with appropriate oversight for the safety of genetic and genomic diagnostic tests. As you know, this has been a high priority for our Committee since its inception. We appreciate your efforts to assess the adequacy of Federal agency oversight, to identify gaps in that oversight, and to involve the private sector as participants in advancing appropriate solutions.

At our meeting last month, we were particularly impressed with Ms. Sheila Walcoff's presentation of activities underway at HHS and are hopeful that they will result in more coordinated efforts among the appropriate Federal agencies. As a part of that effort, we willingly accepted your challenge to us, as delivered by Ms. Walcoff, to explore a set of specific and relevant questions about processes for evidence development and oversight. We are confident that our contribution, when combined with other initiatives, will serve to clarify the regulatory system for genetic tests, improve its transparency, identify the scientific information and oversight needed to assure that tests are being developed and properly used, and preserve innovation and patient access to safe genetic tests.

On a related matter, we are aware of the introduction of two Senate bills—the Laboratory Test Improvement Act (S. 736) and the Genomics and Personalized Medicine Act (S. 976)—that also address the oversight of genetic tests. We hope that the bill sponsors and other interested Members of Congress are cognizant of your leadership in this area and that they will carefully weigh Departmental perspectives on the impact of these proposals.

Clearly, all of these initiatives are inspired by the same goal of enhancing public health and safety. We trust that the efforts you have initiated within HHS, the fact-finding and deliberations of our Committee, and appropriate legislative actions will work synergistically to bring that goal to fruition. We look forward to doing our part on this important issue and appreciate the opportunity to be of service to you and the Department.

Sincerely,

A handwritten signature in black ink, appearing to read 'Reed V. Tuckson', with a long horizontal flourish extending to the right.

Reed V. Tuckson, M.D., FACP
SACGHS Chair