



Secretary's Advisory Committee on Genetic Testing  
National Institutes of Health  
6000 Executive Boulevard, Suite 302  
Bethesda, Maryland 20892  
<http://www4.od.nih.gov/oba/sacgt.htm>

November 17, 2000

The Honorable Donna E. Shalala  
Secretary of Health and Human Services  
The U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Shalala:

On behalf of the Secretary's Advisory Committee on Genetic Testing (SACGT), I am writing to bring to your attention an issue related to access to genetic tests. SACGT recognizes that gene patents can be critical to the development and commercialization of gene-related products and services. However, through consultations with the public, we have become aware that certain gene patenting and licensing practices may be having adverse effects on accessibility to and the cost and quality of genetic tests. We believe that further study of this issue by appropriate experts within the Department of Health and Human Services may be warranted.

In response to concerns raised during our public consultation process, which was held to assess the adequacy of oversight of genetic tests, SACGT organized a diverse panel of experts in government, industry, academia, law, and clinical, ethical, and patient communities to explore the medical, ethical, legal, and economic issues related to gene patenting and licensing of genetic tests. The wide range of perspectives presented by the panel provided SACGT with an increased level of knowledge about how patents and licenses work, how they enhance the public good, and what concerns are being raised about them. A summary of the panel session is enclosed.

The expert presentations highlighted two key points for us. First, the U.S. patent system provides manufacturers of gene-related products and services with an incentive to invest in the research, development, and commercialization of these products. Gene patents and licenses are essential to the development and commercialization of high-quality diagnostic and therapeutic products. Second, there is a perception that commercialization approaches may affect accessibility to and the cost of a product. SACGT was told that laboratories were being deterred from offering tests beneficial to patients by certain licensing practices. These practices were also said to have raised concerns about the training of specialists who offer genetic testing services and the development of quality assurance programs.

The presentations raised a number of critical questions that the Committee is not equipped to address. These include the effects on access, cost and quality of genetic tests. Genetic testing is based on new technology that holds enormous potential to improve people's health and quality of life. As with any evolving technology, we must carefully evaluate the balance between public and private sector interests.

Given the importance of gene patents and licenses, we believe that current concerns and questions about possible adverse effects on access should be assessed more fully. If you should agree that this area requires further study to address these questions, we respectfully recommend that you initiate further study by appropriate experts. While we wish to see the continued development of genetic tests and gene-related technologies, we would also like to ensure that these tests are of high quality and both accessible and affordable to the public.

Thank you for your consideration and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Ed McCabe". The signature is fluid and cursive, with a long horizontal stroke at the end.

Edward R.B. McCabe, M.D., Ph.D.  
Chair

Enclosure