



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

AUG 8 2001

Assistant Secretary for Health  
Office of Public Health and Science  
Washington D.C. 20201

Edward R. B. McCabe, M.D., Ph.D.  
Chair, Secretary's Advisory Committee on Genetic Testing  
6705 Rockledge Drive, Suite 750  
Bethesda, MD 20892

Dear Dr. McCabe:

On behalf of Secretary Thompson, I am responding to your letter of November 17, 2000 expressing concern about the possible effect of certain gene patenting and licensing practices on accessibility to and the cost and quality of genetic tests. The letter recommends that the Department of Health and Human Services initiate further study of the issue by appropriate experts.

We appreciate the effort of the Secretary's Advisory Committee on Genetic Testing (SACGT) to gather diverse perspectives on this issue and the careful and balanced consideration you gave to both the benefits of gene patenting and to public concerns about possible adverse effects of certain licensing practices. Your findings indicate that members of the public are concerned that certain commercialization approaches may be affecting both the cost and accessibility of genetic testing products. In addition, you heard concerns about the effect of certain licensing practices on the availability of genetic tests and on training and quality assurance programs.

We agree that these issues are important and that they require further exploration. In fact, very little data currently exist about the types, terms and conditions of licensing agreements for gene-based discoveries and the advantages and disadvantages of the various types of agreements, particularly as they pertain to National Institutes of Health (NIH) funded research. We also do not know the extent to which exclusive licenses are being used in genetic testing or the overall impact of such licenses. Additional data are needed to determine whether the concerns raised by SACGT are widespread.

The Ethical, Legal, Social Implications program of the National Human Genome Research Institute is in the process of initiating such a study to gather the necessary data. Once we have the data in hand, we will request that the NIH Office of Technology Transfer, which has been delegated the lead for the Department on patenting and licensing matters, work with us to determine whether further steps need to be taken. We will keep you apprised of NIH's progress and let you know when the data become available.

Thank you again for bringing this issue to our attention. The continued development of genetic tests is important. It is also essential that we assure their quality and accessibility.

Sincerely,

A handwritten signature in black ink, appearing to read "Arthur J. Lawrence".

Arthur J. Lawrence, Ph.D.  
Assistant Surgeon General  
Acting Principal Deputy Assistant  
Secretary for Health