



July 29, 2010

Cathy Fomous, Ph.D.
National Institutes of Health (NIH) Office of Biotechnology Activities
6705 Rockledge Drive, Room 750
Bethesda, MD 20892

Dear Dr. Fomous:

On behalf of the National Business Group on Health, representing 300 large employers providing health coverage to more than 55 million U.S. employees, retirees and their families, I appreciate the opportunity to submit comments on the National Institutes of Health (NIH) plan to develop a Genetic Testing Registry (GTR). Requests for employers to cover genetic testing are growing steadily. Technicians and labs perform more than 40 million genetic tests annually in the U.S. and the number is expected to double by 2012. Employers want to support appropriate access to genetic services and support efforts that improve tools for clinical decision making, improve patient safety and reduce wasteful spending.

We support your plan to catalog genetic tests in a database designed to enhance transparency by publicly sharing information about the availability and utility of tests, providing an information resource for the public, and facilitating genomic data-sharing for research and new scientific discoveries. However, we recommend a mandatory registry due to concerns about the public's, the research community's and the provider community's ability to evaluate the quality and balance of information in a registry populated on a voluntary basis by the makers of genetic tests and the clinical laboratories performing them.

We recommend that the registry permit only Clinical Laboratory Improvement Amendments (CLIA)-certified labs to participate. The registry must have additional safeguards and oversight to assure the accuracy of information. The current plan to give sole responsibility for content and quality of data to entities populating the database is insufficient. In addition to ensuring the quality of information, the registry must have an oversight mechanism to make certain that information is updated when new findings are available as entities that originally submitted information may have no incentive to update the registry.

We know that the NIH and the Food and Drug Administration (FDA) provide scientific advice to each other. Although not directly relevant to your request and more appropriate for the FDA, we are deeply concerned about direct-to-consumer (DTC) selling of genetic tests. We will express our concerns to the appropriate individuals and agencies but wanted you to know that DTC advertising of genetic tests sends the signal that genetic tests by any company are acceptable and equal in value.

NATIONAL BUSINESS GROUP ON HEALTH

Again, we appreciate the opportunity to provide comments on your plan to develop a genetic testing registry. Please contact me or Steve Wojcik, Vice President of Public Policy, at 202.585.1812 if you have questions or would like to discuss this feedback in further detail.

Sincerely,

A handwritten signature in cursive script that reads "Helen Darling".

Helen Darling
President

cc: Raynard S. Kington, M.D., Deputy Director, National Institutes of Health