From: Bick, David [mailto:dbick@mcw.edu]
Sent: Saturday, June 05, 2010 10:54 PM
To: Genetic Testing Registry (NIH/OD/OSP)
Subject: Comment on the NIH Plan to Develop the Genetic Testing Registry - Notice Number: NOT-OD-10-101

Dear Sirs:

I am writing to voice my concerns with the development of the "Genetic Testing Registry (GTR): a centralized public resource that will provide information about the availability, scientific basis, and usefulness of genetic tests."

In the "Request for Information (RFI) on the NIH Plan to Develop the Genetic Testing Registry," the background states: "Although more than 2,000 genetic tests are available, there is no single public resource that provides information about the validity and usefulness of these tests." This presumes agreement on a test's validity and utility and, presumably, a test not meeting "the standard" would not be listed. Therefore, the committee that sets "the standard" can potentially exclude any test method, manufacturer, or laboratory they choose. In the rapidly evolving field of genetic testing, standards will of necessity be arbitrary and subject to personal bias. In turn, these arbitrary standards could have much larger economic ramifications.

While the stated goal of the GTR is laudable, the process and implementation of "the standard" will impede innovation and the rapid introduction of new tests. For example, within the next year many physicians will use whole-genome sequencing in clinical practice. The GTR could simply declare that whole-genome sequencing has not been proven to be clinically valid or useful, and that would, in turn, significantly delay the introduction of this test, potentially disadvantaging large numbers of patients who would otherwise benefit from the information provided by whole-genome sequencing.

Further, policy makers and insurance companies might very well use the GTR’s pronouncement about whole-genome sequencing as an excuse not to cover the test, either as a non-reimbursable expense or by making Medicare/Medicaid recipients ineligible to receive it.

This RFI for the GTR ignores an incredibly valuable, centralized resource called GeneTests (http://www.ncbi.nlm.nih.gov/sites/GeneTests/?db=GeneTests). This site lists more than 2000 tests run by approximately 600 laboratories around the world. There are more than 500 review articles to help physicians and patients understand genetic diseases and how genetic tests can be used as diagnostic tools. If the GTR replaces or interferes with funding for GeneTests, this will significantly damage genetics health care in the United States. Physicians, genetic counselors and patients rely on this site for accurate information about genetic diseases and as a starting point for indentifying laboratories equipped to carry out specific genetic tests. Losing this site will severely impact health care providers, forcing them to waste countless hours seeking out information which would otherwise be available with the click of a button.

If GTR goes forward, I would strongly recommend that it be placed within the GeneTests website with additional funding/personnel under the direction of the current GeneTests leadership. In this way, physicians, counselors and

the public will continue to have access to a resource they have come to trust. The information contained in GTR would represent additional information that physicians, counselors, patients, policy makers, insurance companies and others can consider when making decisions about genetic testing.

As noted in the RFI, the NIH is seeking input on fourteen complex, detailed items. The committee charged with resolving the issues raised by those items will first review this input and then make hundreds of arbitrary decisions. Some, if not many, will advantage some manufacturers and laboratories over others. It is not obvious that this process will create a registry that will improve patient care.

Sincerely,

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