

July 16, 2010

NIH GTR RFI Comments
National Institutes of Health
Office of Science Policy
6705 Rockledge Dr., Room 750
Bethesda, MD 20892

Dear GTR Staff,

PGxHealth, LLC enthusiastically supports the goal of improving access to information on available genetic tests in the United States. To further this goal, we offer the following comments on the proposed Genetic Testing Registry (GTR) for your consideration.

First, we propose that the GTR mirror the current genetic testing database known as *GeneTests* in its inclusion of specific, objective information about each laboratory's offerings, such as the scope of each test and the platform employed. In contrast, some of the fields proposed for the GTR would include information that tends to be both subjective and ever-evolving, such as that pertaining to clinical validity and utility. This information more properly belongs in either (or both) expert-written summaries, such as *GeneReviews*, or on the websites of each laboratory; links to these external resources could then be provided from within the GTR. We believe that the current separation of laboratory listings from clinical interpretation is prudent and should be maintained, as presenting subjective data alongside objective data in a government-run registry could be unintentionally misleading. Another important reason to maintain separation of clinical validity and utility assessments from the laboratory entries is that such assessments are not laboratory-specific.

Second, we feel the most important user group for the GTR will be clinicians (as it is with *GeneTests*) and secondarily, patients and family members; researchers, payers, etc. should not be a focus. Moreover, the needs of clinicians and patients are different; this is often reflected in the websites of laboratories, many of which maintain separate physician and patient sections. We recommend the GTR, as well as the expert reviews espoused above, also establish separate interfaces and materials.

We look forward to participating in the GTR program when it is implemented and to continued community involvement as it is developed.

Sincerely,



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