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December 22, 2011

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

Dear GTR Staff,

The National Society of Genetic Counselors (NSGC) is responding to the National Institutes of Health's (NIH) November 23, 2011 request for comments on the practical utility of the proposed collection of information for the Genetic Testing Registry (GTR).

NSGC supports efforts to enhance access to information regarding the availability, validity, and utility of genetic tests. Additionally, NSGC appreciates the previous work that NIH has conducted on accessibility and we encourage NIH to continue to seek out genetic counselors and NSGC for expertise in fine-tuning the GTR. Further, we respectfully request that NIH consider the following comments and recommendations of NSGC.

General recommendations:

- NSGC requests that NIH safeguard against false or inaccurate GTR data by implementing a structured peer-review process.

While the GTR seeks to increase transparency by establishing a general clearinghouse for genetic data, more information is not always better. The volunteer-based submission criteria make the GTR vulnerable to erroneous and false data that can be misconstrued as valid and accurate information. If the GTR links to marketing materials on a company or laboratory's website, there should be disclosure that the viewer is being directed to an external website.

Further, NSGC is concerned that tests that have little or no clinical validity will gain credibility simply by being listed on the GTR. The increased transparency and information available should be weighed against the quality of the data submitted through a peer-review process. If formal peer-review is not feasible, then NSGC recommends that NIH enable providers and other laboratories to submit external comments to all publicized data within the GTR. In the absence of oversight of the information presented, there should be notice that NIH, or any other government entity, does not endorse the information presented on the GTR.

- NSGC recommends that the GTR provide adequate information on all tests.

The GTR should also include Clinical Laboratory Improvement Advisory Committee certifications, as well as the common and commercial name for each test. Issues such as unique product identifiers would help to identify and compare tests, though no current regulations exist that mandate such standards. An example of useful information that should be included is population or demographic data to ensure that tests are appropriately applied to those populations.

- NSGC recommends that the GTR focus on the audience that will benefit most from the GTR.

It is not possible to create a resource that is equally valuable to all audiences. While consumers, researchers, providers, payers, and policy makers may have some overlapping needs, many are distinct. For example, clinicians may value and correctly interpret accuracy and analytical sensitivity/specificity, but consumers may misinterpret these data elements as clinical validity. Even genetics professionals and non-genetics professionals have substantially different needs. Genetics providers will likely use this service as they used GeneTests – a resource for genetic test availability and application. Non-genetics providers and the public may use the GTR to infer validity.

Payers could find the GTR helpful if it addresses clinical validity in addition to analytical validity, as they seek guidance on covering certain genetic tests. However, the GTR, in its current form, will not be sufficient for payers' purposes because it cannot assess the circumstances under which testing should be offered and covered on a case-by-case basis.

NSGC appreciates the opportunity to provide comments. We look forward to collaborating with NIH to ensure that the GTR is a valuable tool for genetics professionals.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Dent', with a long horizontal flourish extending to the right.

Karin M. Dent, MS, LCGC
President