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November 2, 2010  
Genetic Testing Registry Public Meeting

Good morning. My name is Barbara Harrison. I am a certified genetic counselor and am here today as an official representative of the National Society of Genetic Counselors or NSGC. NSGC appreciates the work of the NIH to make information about genetic tests available to the public. We strongly recommend that the NIH include an official representative from the NSGC in ongoing discussions about the development of a genetic test registry. I am sure you agree that genetic counselors are a critical stakeholder in the GTR and we appreciate that the NIH has genetic counselors already working on this project. However, an official NSGC representative would represent the collective interests of genetic counselors without influence by other perspectives such as employers, colleagues in specific practice areas, or allegiance to other institutions.

Before addressing question #4, I want to briefly comment on your question #5. In the NSGC's initial response to the RFI, we recommended a focus on one audience rather than trying to serve multiple audiences. The needs of consumers, researchers, providers, payers and policy makers have some areas of overlap but also some critical differences. For example, clinicians may value and correctly interpret accuracy and analytical sensitivity/specificity, but consumers may misinterpret some of these data elements as clinical validity. Non-genetics professionals may also incorrectly infer validity. Simply providing a definition of these data elements, as suggested by your question #5, is insufficient and will be difficult to develop for an audience with widely varying levels of genetics expertise and knowledge. If the NIH is committed to serving multiple audiences, the NSGC strongly recommends development of different interfaces for different users. In direct response to question #4 regarding safeguards to prevent misunderstanding, misinterpreting or misusing information, the NSGC does not believe that adequate safeguards exist to prevent misinterpretation or misuse of information if the GTR is intended to be used by multiple audiences. However, assuming the project moves forward, we would recommend a prominently displayed disclaimer throughout the site stating that inclusion of a test does not imply any type of regulatory review. Inclusion of a data element about the applicability and status of regulatory oversight would be appropriate for each test. Lastly, peer review by genetics experts would also allow for an avenue for mediation of the most significant risks.

Thank you for the opportunity to provide additional input today and we would like to provide additional comments through another forum.