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National Institute of Health
Office of Biotechnology Activities
6705 Rockledge Drive
Suite 750
Bethesda, MD 20892

Attn: Dr. Patterson, FR Doc. 2011-18970

Dear Dr. Patterson:

Genetic Alliance appreciates this opportunity to provide comments on the need and use of information to be collected in the Genetic Testing Registry. As explained below, we believe that the proposed collection of information is necessary for the proper performance of the Genetic Testing Registry and will have enormous practical utility for a number of stakeholders, including consumers, health care providers, and researchers. Although we have some reservations about the accuracy of the agency's estimate of the burden of the proposed collection of information we are pleased to see the steps the agency has taken to minimize the burden of collecting information and offer a few suggestions on further reducing this burden.

Founded in 1986 as the Alliance for Genetic Support Groups, Genetic Alliance has become the world's leading nonprofit health advocacy organization committed to transforming health through genetics. Our open network includes over 1,000 disease-specific advocacy organizations as well as thousands of universities, private companies, government agencies, and public policy organizations. Our mission is to transform health through genetics. As part of this mission, Genetic Alliance is committed to enabling informed decision-making and actively works for programs and policies that improve access to information.

In keeping with our mission, we support and applaud the efforts of the NIH to build and launch a genetic testing registry. We believe that a genetic testing registry will enhance transparency and provide an invaluable resource to a number of stakeholder groups, including consumers, health care providers, third-party payers, and researchers. We appreciate the NIH's effort to build and launch the Genetic Testing Registry (GTR) and offer the following comments and suggestions:

❖ *Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility.*

We believe the proposed collection is a significant improvement compared to the information currently collected in GeneTests. The proposed information, particularly the information on the FDA review status, analytical validity, clinical validity, and clinical utility, has significant practical utility. Including this information within the registry will add new layer of

transparency and enable health care providers and consumers to make better-informed decisions. Likewise, the information included on the testing technique and target will help enable research. Lastly, with a number of both public and private initiatives underway to build databases for warehousing information on clinical grade data on human genetic variation, we feel that the addition of fields on the policy and interpretation of variants of unknown significance has tremendous practical utility.

❖ *Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumption used.*

We have a few concerns with regards to the agency's estimate of the burden of the proposed collection of information, particularly regarding some of the assumptions used in the calculations. Few concerns to be noted here are:

➤ Unlike GeneTests, the GTR would require separate entries for tests that have multiple test codes associated with them. As a result, the number of entries in the GTR will be significantly higher than the estimate provided based on the number of genetic tests listed in GeneTests. We believe the agency should revise its estimation of the frequency of response in a manner that takes into account the fact the tests with more than one test code will require multiple entries.

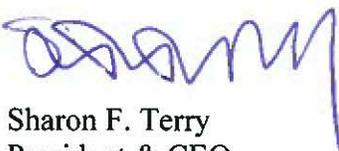
➤ The wrong mean hourly wage has been used to calculate the estimated annual cost per respondent. In the current estimate of annual cost to respondents, the agency has used the mean hourly wage of medical and laboratory technician. However, due to the complicated and technical nature of the fields in the GTR, it is probable that a laboratory technician would not be able to enter the required information. A more knowledgeable member of the staff, such as a genetic counselor or a laboratory director would be required to enter the necessary information into the GTR. We recommend that the agency base its estimate of annual costs on the mean hourly wage of a genetic counselor or laboratory director.

❖ *Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.*

We appreciate the measures that the agency has proposed to minimize the burden on respondents and feel that both the bulk upload feature and the ability to pull content through from GeneTests to the GTR will significantly reduce the burden on many test provider. In addition to these efforts, we suggest that the agency provide a mechanism for allowing test providers to pull content from their existing tests that are already entered in the registry. This will reduce the burden on test providers when a test is offered as part of a panel or in instances where there are multiple test codes for a single test.

Thank you again for this opportunity to submit our comments on the information to be collected in the GTR. We applaud the agency's effort to create what we believe will be an invaluable resource for the entire stakeholder community. We would be happy to provide additional information if that would be useful to the Agency.

Best regards,



Sharon F. Terry
President & CEO