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*Submitted via email to [GTR@od.nih.gov](mailto:GTR@od.nih.gov)*

Dear Dr. Patterson,

The American Society for Clinical Pathology (ASCP) commends the National Institutes of Health (NIH) for its continued effort in addressing the issues surrounding the development of the Genetic Testing Registry (GTR) and for requesting comments on the practical utility of the proposed collection of information for the GTR.

In recent years, genetic tests have assumed a more pivotal role in medical decision-making. Therefore, the GTR could prove to be an essential resource for doctors, researchers, industry and the public. While ASCP supports the concept of the GTR, we believe that diagnostic tests submitted in the registry should be of highest quality, reliability, and safety, and that each test should provide valid and useful information for clinical decision making.

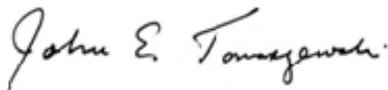
ASCP is concerned that the voluntary submission of data in the GTR with minimal or no regulatory oversight could encourage certain genetic test manufacturers to use the registry as a marketing tool to promote their services, whether or not the information they submitted is scientifically accurate. Furthermore, with the GTR submission not being limited to U.S. respondents, the registry may function as an international, centralized, online resource for detailed information about genetic tests. As such, ASCP continues to urge NIH to consider featuring a thorough review process and oversight for every submission to the registry. In doing so, health care providers and patients can avoid being misled by the idea that each genetic test entered in the database is clinically valid just because it is an NIH mandated database.

Genetic tests are increasingly being integrated into standard practice for diagnosing and managing disease, predicting the risk of developing disease, and informing decisions about lifestyle and behavior. ASCP is concerned that some of the respondents in the registry may lack enough data to support the validity of their test. Newly formed genetic tests submitted in the registry may not be associated with enhanced clinical outcomes and therefore may lead to treatments not based on data-driven evidence. Therefore, we encourage the NIH to require genetic test providers to provide peer-reviewed literature associated with their test. Moreover, ASCP believes that, at a minimum, entities submitting tests to the registry should be required to certify under penalty of perjury that the information and literature submitted in support of the test provides an accurate and reliable representation of the testing device.

Development of the GTR is necessary to increase awareness in the science community as well as among clinicians so that patients can gain access to quality treatments. Genetic tests are becoming indispensable tools in the practice of medicine. They are enabling improved prevention, treatment, and disease management for an array of common chronic conditions as well as rare genetic disorders. ASCP will continue to support the NIH in its efforts to provide a way for government entities and public/private institutions to collaborate in order to improve the function of GTR.

The ASCP is a professional organization with 100,000 members working as pathologists, residents, and other physicians, pathologists' assistants, laboratory professionals, medical students and laboratory students. As a patient-centric organization, ASCP's mission is to protect patient safety while promoting advances in medicine. As the largest specialty society representing the field of pathology and laboratory medicine, ASCP appreciates the opportunity to comment on the development of genetic testing registry. Please do not hesitate to contact me or Edna Garcia, MPH, ASCP Research Assistant, for questions or comments, [edna.garcia@ascp.org](mailto:edna.garcia@ascp.org), tel. 202-347-4450 ext. 2903.

Sincerely,



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