American Society for Clinical Pathology

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Submitted via e-mail to GTR@od.nih.gov

Dear Dr. Fomous,

The American Society for Clinical Pathology (ASCP) commends the National Institutes of Health (NIH) for convening a public meeting to scrutinize the issues surrounding the development of a Genetic Test Registry (GTR).

While ASCP supports the concept of the GTR, we believe that the NIH needs to coordinate with other government entities in establishing a reliable framework for oversight of the registry. We are concerned that the segregation among federal agencies, all of which have varying agendas regarding the regulation of genetic tests, would compromise the value and credibility of the GTR. The NIH, in partnership with the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Agency for Healthcare Research and Quality (AHRQ) should maintain the authority to remove the genetic test information in the registry if they have a reasonable concern that it provides insufficient clinical validity. There must be assurances that all genetic tests in the registry are clinically valid. This is necessary to ensure that patients gain access to quality advanced diagnostics which can be integrated into the practice of medicine. The ASCP Board of Directors recently approved a public policy statement (attached) with regards to laboratory developed tests (LDTs). While this policy statement examines the regulation of LDTs, ASCP believes that it shares a common goal with the NIH by asserting that diagnostic genetic tests should be of highest quality, reliability, and safety, and that each test should provide valid and useful information for clinical decision making.

In recent years, genetic tests have assumed a more pivotal role in medical decision-making. Therefore, the GTR could prove to be a necessary resource for doctors, industry, researchers and the public but only if it is a reliable source of information. However, ASCP is concerned that the increased utilization of genetic tests, their use outside of the physician-patient context, and their development by larger corporations without proper validation for intended use may put patients at risk for incorrect diagnosis and inappropriate treatment. The voluntary submission of data in the GTR with minimal or no regulation could encourage certain genetic test manufacturers to use the registry as a means to promote their services, whether or not the information they submitted is scientifically accurate. There must be assurances that genetic tests are clinically valid, performed correctly by competent laboratories, and the results communicated to patients by clinicians adequately trained to interpret these tests. ASCP supports strengthened oversight to ensure that genetic tests remain one of the key tools clinicians can use to answer increasingly complex questions regarding patient care.

ASCP believes that comparative effectiveness research (CER) is the best way to demonstrate the value of genetic tests for improving clinical outcomes. Unfortunately, many of the genetic tests being manufactured and utilized today are not associated with enhanced clinical outcomes. Often times, the issue becomes not which test is best, but how many tests can be performed within any given disease profile, despite their lack of clinical utility. As a result, treatment for patients is often inconsistent and based on professional experience rather than data-driven evidence. As a strong proponent of CER, we encourage the NIH to require genetic tests providers who submit their information in the GTR to provide peer-reviewed literature associated with their test.

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. These tests are enabling improved prevention, treatment, and disease management for an array of common chronic conditions as well as rare genetic disorders. They have become indispensable tools in the practice of medicine. However, ASCP strongly believes that only high-quality, clinically and analytically valid genetic tests should be offered to patients. Therefore, we urge NIH to consider featuring a review process 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.

The ASCP is a professional organization with over 130,000 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, tel. 202-347-4450 ext. 30.

Sincerely,

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