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NIH GTR RFI Comments  
National Institutes of Health  
Office of Science Policy  
6705 Rockledge Drive, Room 750  
Bethesda, MD 20892  
Via: [GTR@od.nih.gov](mailto:GTR@od.nih.gov)

To Whom It May Concern:

Thank you for the opportunity to advise the National Institutes of Health (NIH) on its efforts to implement the Genetic Testing Registry (GTR). We hope that you find our perspective as a research tools manufacturer and collaborator with diagnostic developers helpful as you consider the structure, function and components of the registry.

Life Technologies is a global biotechnology tools company dedicated to improving the human condition. Our products are used in 110 countries to make life-saving medical research breakthroughs as well as to advance regenerative science and personalized medicine. We are a major supplier of genetic testing equipment, components and IVD tests.

Life Technologies believes that access to high quality information about genetic testing is beneficial to both the public and health professionals as they evaluate testing for clinical indications. The value of any registry or database of information, however, lies in the accuracy, credibility and reliability of the included data. Another genetic test registry, GeneTests, is reviewed by professionals with scientific expertise to ensure the accuracy of the information it contains. We encourage the NIH to develop its own review mechanism to screen GTR entries for accuracy and reliability. The NIH will need to consider the appropriate review strategy taking into account various users. The needs of the lay public will be very different than the needs of a trained health professional and/or a genetics professional. We encourage NIH to ensure that the general public can readily access and understand the information, so that individuals can appropriately incorporate it into their lives and healthcare.

To create a global database of tests that is meaningful to patients and health professionals, the GTR must include analytic and clinical validity data. These terms need to be clearly defined and standards for the data to be included must be developed. This will enable test developers to meaningfully comply and allow patients and health professionals to directly compare one test to another.

In addition to the quality of the information contained in the GTR, the functionality and ease of use of the database and its web interface will be key to its success. Users should be able to readily conduct both specific and aggregate searches of the data.

The GTR could serve as a useful tool for regulators to build their understanding of the genetic testing marketplace, enable them to categorize the range of tests available, and move toward a more risk-based approach to the oversight of laboratory developed tests (LDTs).

At the NIH/FDA Joint Leadership Council on Regulatory Science public meeting held on June 2<sup>nd</sup>, two presenters encouraged the NIH to make the GTR mandatory. Life Technologies believes that to avoid redundancy and burdensome compliance requirements, there should only be one mandatory registry housed within the Department of Health and Human Services. Additionally, if the mandatory registry is intended to move beyond an informational resource and have a regulatory purpose, then it should be managed by the US Food and Drug Administration to supplement their authority and inform their oversight approach to LDTs.

In sum, Life Technologies supports the concept of a voluntary GTR at the NIH that serves as a clearinghouse of reliable information about the availability and validity of genetic tests in the marketplace. Such a tool will help increase the transparency of what tests are currently marketed and serve as an important resource to the public, government and health professionals.

Thank you for the opportunity to respond to the Request for Information. We look forward to future opportunities to inform the development of the registry.

Sincerely,

A handwritten signature in cursive script, appearing to read "Kimberlee Caple".

Kimberlee Caple  
Head of Molecular Diagnostics Product Business