FDA urged to provide oversight of high risk laboratory developed tests

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The American Association for Cancer Research (AACR) issued a policy statement Tuesday, Sept. 9, that underscores the importance of safe, accurate, and effective diagnostic tests by recommending that the U.S. Food and Drug Administration (FDA) begin to actively exert its authority to regulate high-risk laboratory developed tests (LDTs) that are being utilized by physicians to make treatment decisions, including the tailoring of an individual's cancer treatment regimen.

"FDA's policy of enforcement discretion over LDTs was acceptable when these tests were mostly routine laboratory procedures; however, as LDTs have evolved in complexity, the risk posed to patients has also increased," said Charles L. Sawyers, MD, immediate past president of the AACR, chair of the Human Oncology and Pathogenesis Program at the Memorial Sloan Kettering Cancer Center in New York, and co-author of the policy statement. "It is therefore vital that all diagnostic tests used to make high-risk treatment decisions be FDA-approved, so patients and physicians can be assured of the test's safety and accuracy," he said.

"Diagnostic tests play a central role in the success of personalized medicine by helping oncologists identify the right treatment for the right patient," said Margaret Foti, PhD, MD (hc) chief executive officer of the AACR. "Therefore, we strongly support the FDA exerting its authority to regulate LDTs that pose a high risk to cancer patients."

The AACR believes that a robust, predictable, and reliable evidence-based regulatory framework will ensure that future treatments and cures will reach patients in an efficient and expeditious manner. Implementation of a risk-based framework by the FDA that would provide for evaluation of all high-risk molecular diagnostic tests would balance the need for encouraging innovative medical product development with the need for ensuring patient safety.

"Having a single approval standard for all tests regardless of origin would also create a more predictable regulatory and investment climate for both the diagnostics and the pharmaceutical industries," said Laura van 't Veer, PhD, director of applied genomics at UCSF Helen Diller Family Comprehensive Cancer Center and co-author of the policy statement.

"As an oncologist, I rely on these complex diagnostic test results to make treatment decisions," said Carlos L. Arteaga, MD, AACR president and professor of medicine and cancer biology, and associate director for clinical research at the Vanderbilt-Ingram Cancer Center of Vanderbilt University, Nashville, Tennessee. "I need to be confident in the test results that form the basis of high-risk treatment decisions for my patients, whether these tests are developed as LDTs or as kits approved by the FDA."

Provided by American Association for Cancer Research