MedicalXpress

FDA to start regulating lab-developed tests

July 31 2014, by Matthew Perrone

(AP)—The Food and Drug Administration announced Thursday it will begin regulating laboratory-developed tests, a growing class of medical diagnostics that have never before been subject to federal oversight.

The agency says its proposal is designed to make sure that the tests used to diagnose cancer, heart disease and thousands of other conditions are safe, accurate and reliable.

"Inaccurate test results could cause patients to seek unnecessary treatment or delay and sometimes forgo treatment altogether," said FDA Commissioner Dr. Margaret Hamburg, on a call with reporters. "These devices need to be accurate and reliable."

In recent years scientists have documented laboratory-based tests that provided incorrect results for diagnosing conditions like autism, Lyme disease and antibiotic resistance.

Hamburg said the agency will introduce a proposal to regulate these tests within the next 60 days.

Regulation of laboratory-developed tests has been a subject of debate since at least the 1990s. Several federal advisory committees, including the Institute of Medicine, have recommended that the FDA exercise more authority over such testing. That's also been the position of diagnostic test manufacturers, who have long been subject to rigorous FDA reviews before they can launch new products. The industry has complained to Congress and the FDA that their products must compete

with cheaper laboratory-developed tests that have not undergone federal testing.

FDA regulators estimate that about 2,000 laboratories in the U.S. market more than 11,000 medical tests. But the agency's proposal would not apply to routine laboratory tests or tests for rare diseases where there is no FDA-approved option. Instead regulators are focusing on those that pose a higher risk for patients. The agency wants to require premarket review of accuracy and reliability for tests that:

- compete with FDA-approved, manufactured tests
- perform the same function as high-risk medical devices
- are used in screening blood

After the FDA introduces a draft proposal later this year, regulators will take comments and feedback from interested parties. The agency will then prepare final, binding regulations. Medical laboratories will not have to begin submitting their tests for review until one year after the final regulations have been in place, according to the agency.

The American Clinical Laboratory Association said in a statement it is urging the FDA to "exercise caution, and expressed concern that another layer of regulation could stifle diagnostic innovation."