FDA will begin to regulate thousands of lab tests

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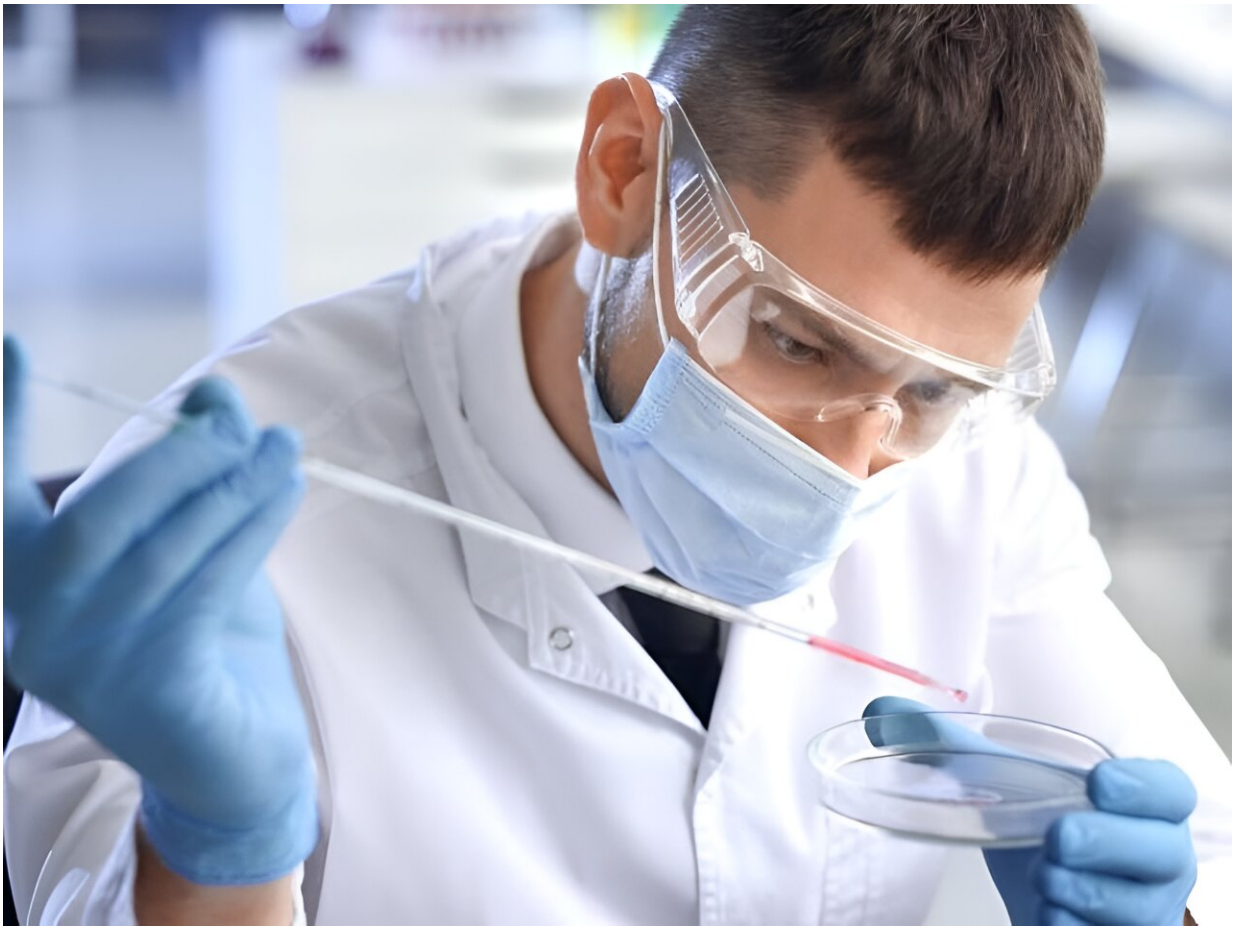

Faced with growing reports of inaccurate clinical lab tests, the U.S. Food

and Drug Administration on Friday announced that it will for the first time regulate these vital diagnostic tools.

"A growing number of clinical diagnostic tests are being offered as laboratory developed tests without assurance that they work. The stakes are getting higher as these tests are increasingly being used to drive treatment decisions," FDA Commissioner Robert Califf, M.D., explained in an agency news release.

Some more common tests—such as those used in hospitals, pharmacies, or doctors' offices to spot strep throat, COVID-19, and other conditions—are already subject to premarketing FDA review. But thousands of so-called "laboratory developed tests" (LDTs), analyzed at many high-tech labs, face no FDA oversight. These tests are often highly sophisticated and are used to identify cancers, sexually transmitted infections, and a host of other conditions.

"In the 1970s and 1980s, many LDTs were lower risk, small volume, and used for specialized needs of a local patient population," the FDA explained.

"Since then, due to changes in business practices and increasing ability to ship patient specimens across the country quickly, many LDTs are now used more widely, for a larger and more diverse population, with large laboratories accepting specimens from across the country. LDTs are also increasingly relying on high-tech instrumentation and software, being performed in large volumes and being used more frequently to help guide critical health care decisions."

Beyond that, some companies are now pitching their tests directly to consumers, the FDA noted. At the same time, reports of problematic tests have increased. Inaccurate test results can lead to devastating consequences for patients. "The FDA is concerned patients could initiate

unnecessary treatment, or delay or forgo proper treatment altogether, based on inaccurate test results, which could result in harm, including worsening illness or death," the agency warned.

The FDA says the new oversight will be phased in gradually over the next few years to avoid "undue disruption to the testing market." The agency claims that the new regulations will be a net cost benefit due to "a reduction in health care costs associated with unsafe or ineffective tests, including tests promoted with false or misleading claims and from therapeutic decisions based on the results of those tests."

The FDA is taking comments on the new proposals over the next 60 days.

More information: More Information

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