WSJ NEWS EXCLUSIVE | REGULATORY

FDA Proposal Casts Cloud Over Startups in Lab-Testing Market

The agency has concerns about the efficacy of lab-developed tests and plans to regulate them

By Brian Gormley

Oct. 5, 2023 6 00 am ET | WSJ PRO

The Food and Drug Administration has left lab companies with less certainty about future regulation, complicating investment and product-development decisions, some observers say. PHOTO: JACQUELYN MARTIN/ASSOCIATED PRESS

A proposed regulatory shift has injected uncertainty into the laboratory-testing market just as startups are advancing an array of tests to detect diseases sooner and personalize treatments.

Startups seizing advances in fields such as genomics and artificial intelligence are designing laboratory-developed tests to spot cancer and other illnesses before symptoms arise and to identify optimal therapies.

Lab-developed tests are created and carried out in a single lab. Labs perform these tests on blood or other specimens shipped to them. Most genetic tests, for example, are lab-developed tests.

The Food and Drug Administration says it historically has exercised its discretion not to regulate such tests. This has allowed startups to introduce them quickly and at relatively low cost.

That would change under a proposal the FDA issued Friday. The agency, citing concerns about the efficacy of lab-developed tests, said it plans to regulate these diagnostics. As a result, many lab-developed tests would require review by the FDA before they can be sold.

The proposal initiated a rule-making process that will take industry comments into account. They could lead to changes to the proposal, and it is possible the proposal will never take effect. The FDA has sought to regulate lab-developed tests before but pulled back after facing resistance.

But the agency's latest salvo leaves lab companies with less certainty about future regulation, complicating investment and product-development decisions, some observers said.

"If the path to market becomes longer, less predictable and more expensive, that will affect our ability to invest and will affect the number of new diagnostics that come to market," said Greg Yap, a partner with venture firm Menlo Ventures.

For a startup, performing all tests in its lab appeals because that can simplify quality control, especially for new and complex diagnostics.

In the 1970s and 1980s, the FDA said, many lab-developed tests were lower-risk and used for specialized needs of local populations. Today, they are applied much more widely, and modern lab tests pose more risks, according to the agency. It noted it is aware of lab-developed tests that led to over- or under-treatment for heart disease, patients being exposed to inappropriate therapies or not getting effective therapies, and incorrect diagnoses of diseases including Alzheimer's.

"Some of these tests perform poorly or don't work at all," Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, said on a call with reporters.

Entrepreneurs said regulators must protect patients from faulty tests without impeding development of innovative, potentially lifesaving diagnostics.

CellMax Life introduced lab-developed tests, including for hereditary cancer, last decade. But by the end of 2019, CellMax discontinued the tests, co-founder and Chief Executive Atul Sharan said, because it faced competition from a flood of other lab-developed tests.

CellMax, which has raised $52 million in venture capital, instead focused on data regarding colorectal cancer. The company is now seeking $100 million for clinical trials that could lead to FDA approval of its colorectal cancer test, which will initially be run in its lab, Sharan said.

"It has become a system where anybody can market any test," Sharan said. "It's overdue to be fixed."
The FDA proposes to regulate lab-based tests as medical devices. Medical devices include products such as coronary stents, pacemakers and surgical instruments.

The agency and Congress have sought to increase oversight of lab-developed tests for years. Last year, lawmakers considered a bill, the Valid Act, that proposed a framework, tailored to diagnostics, for regulation of lab-developed tests. The bill wasn't approved. As a result, the FDA is taking another swing at lab-test regulation.

Susan Van Meter, president of the American Clinical Laboratory Association, said there needs to be a diagnostic-specific regulatory framework that keeps pace with innovation in the industry.

The FDA proposes to phase out its current approach of exercising enforcement discretion of lab-developed tests over four years. That would give the industry time to adjust, said Kyle Mikson, an analyst with investment bank and financial services firm Canaccord Genuity.

However, Mikson said, costs to introduce lab tests would likely rise and insurance reimbursements may not offset the increased expenses.

Lisa Dwyer, a partner in the FDA and life-sciences practice of law firm King & Spalding, said she suspects the FDA's proposal aims to spur the industry to try again to seek legislation on a satisfactory regulatory framework.

If the FDA proceeds with its rule, industry groups would likely try to delay its implementation with lawsuits, she said, adding the FDA would risk losing court challenges.

Write to Brian Gormley at brian.gormley@wsj.com