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We'll see more shortages of diagnostic tests if the FDA has its way

By Brian H. Shirts

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A Co-Diagnostics lab technician prepares components for Covid-19 testing kits in Salt Lake City.

February was a frustrating month for my laboratory. We wanted to make tests to detect the virus that causes Covid-19. My virology colleagues had great ideas and solid testing platforms. The Food and Drug Administration told us to stop[2].

Why? Because of a quirk in FDA regulations. Diagnostic tests are currently regulated in one of two ways, and there's no clear rule to determine which one applies to coronavirus tests. This uncertainty is a big part of why test shortages have caused a national crisis.

The VALID Act[3], introduced in Congress in early March, aims to address the confusion about who regulates diagnostic testing, but it would make the situation worse. If the VALID Act passes, we would see shortages in diagnostic tests for even more diseases than Covid-19, including cancers.

Under one system of regulation, laboratory directors are licensed by their states to develop tests through a set of rules called the Clinical Laboratory Improvement Amendments[4] (CLIA). When a CLIA-licensed lab creates a test and documents that it works, doctors can order that test.

Diagnostic testing, and interpreting those tests, is considered the practice of medicine. The FDA is not allowed to regulate the practice of medicine. Yet it is responsible for regulating medical devices. Diagnostic tests use machines, sample tubes, and other tools that are clearly medical devices.

Here's where the second system comes in: The FDA approves devices — not the lab that produces it — on a case-by-case basis. So which diagnostic tests are devices regulated by the FDA and which are laboratory-developed tests regulated through CLIA?

The FDA gets to choose.

In early February, the FDA issued an Emergency Use Authorization[6] and by doing so declared that coronavirus tests are medical devices. It assumed authority and chose to work exclusively with the Centers for Disease Control and Prevention to authorize Covid-19 testing. My laboratory, like many other CLIA-licensed labs, had already started developing coronavirus tests. But once the FDA took control, we could not offer those tests to doctors. If we did, the FDA could shut down our hospital labs.

The FDA chose to give the CDC sole responsibility for developing a test. There were glitches at first, but any new technology improves through development and troubleshooting. The real problem was the arbitrary

monopoly. By preventing CLIA-licensed labs from refining tests, the FDA slowed innovation at a time when rapid innovation was critically important.

The VALID Act will give the FDA power to create more monopolies on diagnostic tests. CLIA-licensed labs will be shut out of producing new tests that perform as well as FDA-approved versions — or better than them. The result will be higher costs and periodic shortages, just like we see with prescription drugs[7].

If anyone today needs to have a lab test that must be interpreted by a doctor, it's probably a laboratory-developed test. One advantage of these tests is that they can be quickly updated as medical knowledge and technology improve. Updated tests are used safely every day. Under the VALID Act, existing tests will be grandfathered into the law, but those tests will be frozen in time. Any changes to them will be considered unsafe until proven otherwise through expensive FDA vetting. If a lab can't hire lawyers to shepherd a test through the extensive FDA process, that test won't be available to the public.

This isn't an issue for diseases so rare that fewer than five people per year are tested — the VALID Act has a provision for those cases. The new legislation would affect tests for common diseases like cancer and inflammatory bowel disease. Many Americans need these tests at some point in their lives. If the VALID Act passes, diagnostic test shortages will be a regular feature of life even after the coronavirus pandemic passes.

The VALID Act was created because large pharmaceutical companies wanted to have monopolies on cancer tests.

When the FDA approves a new cancer drug, it always approves a companion diagnostic test. This is because modern drugs target cancers associated with a specific gene mutation. Companion tests looks for those mutations. But during the approval process, the FDA doesn't determine which test is the best. That's not its job. It also can't consider the cost to patients. Instead, it processes

documentation that shows that what it calls a testing device works and meets safety requirements.

When vemurafenib, a drug developed to treat melanoma, was approved with its companion test in 2011, the developers seemed to get a good deal. They'd sell two products: a drug and a test that doctors would order before prescribing it. But the story didn't happen that way. Vemurafenib was a success but its companion test wasn't. Doctors ordered laboratory-developed tests instead. Over time, the companion test became less useful because it couldn't be improved, while laboratory-developed tests were able to take advantage of new technology and medical discoveries. That's how the coronavirus test development got stuck: The government had to approve all test changes.

When I decide which lab my hospital will send patients' tests to, I don't care if a test is FDA-approved. I care if it is the best for our patients. I care if I trust the laboratory. I might choose a test with higher sensitivity, or one that's faster, or one that is a lot less expensive. But if I can choose only FDA-approved tests, I'll have fewer options.

In promoting the VALID Act, pharmaceutical companies and the FDA have pointed to bad and harmful tests that came though the CLIA system. These cases are not unique to CLIA — after all, the FDA approved a Theranos test[10] before the company was exposed as a fraud[11].

It takes time to find and stop bad actors in both the FDA and CLIA frameworks. Supporters of the VALID Act claim the legislation regulates tests that currently[12] avoid oversight. That's not true. CLIA already regulates those tests. CLIA also has an extra layer of protection: it allows a healthy marketplace where multiple competing diagnostic tests are available, so doctors can protect patients from obsolete, harmful, or costly tests simply by choosing a different product.

My virology colleagues and the staff in my laboratory are working nonstop to make up for lost time. We are doing what we can to alleviate the shortage of Covid-19 diagnostics. Let's not pass legislation that will make diagnostic shortages a regular part of medical care.

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