Washington Examiner PRESENTS RESTORING AMERICA

The CDC royally messed up COVID testing and is now botching monkeypox testing

By Sen. Rand Paul

August 2, 2022

When the pandemic hit the United States, the Food and Drug Administration decided to approve only one kind of COVID-19 test, one that didn't even work.
The government monopoly on COVID-19 testing meant that when the FDA's test, which had been developed by the Centers for Disease Control and Prevention, failed and had to be recalled in February 2020 , for a while no COVID-19 tests were allowed in America.

This wasn't because the tests weren't available. Laboratory medical professionals across the country were ready, willing, and able to step in and assist the U.S. public health response. But strict adherence to a rigid regulatory regime stifled any attempt to help alleviate the spread of COVID-19.

A scientist named Alex Greninger at the University of Washington, for example, developed an accurate COVID-19 test within days of the first reported U.S. cases. He emailed an application for an emergency use authorization to the FDA on Feb. 18, 2020.

The FDA responded and told him the electronic application wasn't good enough. He had to mail in a paper application, along with a copy burned on a CD or saved on a thumb drive — like it was the year 2000 again.

He complied and sent the hard copies by overnight mail. Four days passed before the FDA finally got back to him. When they did, it wasn't to expedite his application — it was to inform him that he needed to run his test against other diseases, such as SARS.

So, he called the CDC to get some material from a SARS sample.

But the CDC told him he couldn't have it — because, as you might guess, they don't give out the SARS virus to anybody who calls.

By the time Greninger could finally get a sample of the material he needed, the U.S. had its first confirmed COVID-19 death — in his own state of Washington.

And wouldn't you know it — that very same day, the FDA decided to step aside and start letting individual labs test for COVID-19. We lost almost a month of valuable time that could've been used to ramp up testing efforts.

You would think government bureaucrats would learn from past mistakes.

But now, more than two years later, we are facing an outbreak of monkeypox, and the government's response is the same all over again. The CDC continues to control all testing, while medical lab professionals across the U.S. are standing by to help.

That's why now, with confirmed monkeypox cases in all but six states in the U.S ., I am once again encouraging Congress to pass my commonsense Verified Innovative Testing in American Laboratories Act.

The VITAL Act clarifies that thousands of universities and private labs are free to develop tests, including those used to detect monkeypox and COVID-19, without explicit regulator permission from the FDA.

This isn't revolutionary. For decades, university labs have not required permission from the FDA and CDC to develop tests.

If the VITAL Act had been the law in 2020, laboratory professionals could have deployed COVID-19 testing within days of the first case, and test results could have been made available with less than 24-hour turnaround times. Widespread early testing would have cleared up much of the confusion the public was experiencing at the time and ensured that government policies were based on data, not suspicions and fear.

I am not the only one sounding the alarm about the need to rid ourselves of a regulatory apparatus that poses a threat to public health. Dr. Jeffrey Singer of the Cato Institute and a surgeon of 35 years said it best, "As in the early days of the COVID pandemic, tests were initially only done at the CDC and some of its 67 designated federal laboratories in 48 states. … Several days can go by before confirming a patient has monkeypox. … Hopefully the FDA will not repeat the mistakes of March 2020 by throwing regulatory sand in the gears of academic and commercial laboratories that are responding to the demand for rapid monkeypox tests."

Recently, the Stanford University School of Medicine announced its Clinical Virology Laboratory developed an in-house PCR test for monkeypox that bypasses the CDC confirmation system and provides a result in 24 to 48 hours. But because of FDA rules, the lab has to wait for an emergency use authorization before it can assist in the effort to roll out mass testing.

This is the kind of red tape Congress should keep in mind when deciding how lab tests should be regulated and how disease outbreaks should be handled.

After watching the CDC fumble the COVID-19 outbreak, one would think both sides of the aisle would join hands and return the freedom to develop diagnostic testing to the universities instead. Yet the Senate Health, Education, Labor, and Pensions Committee recently passed a bill that takes the freedom of university labs to innovate and places them under the thumb of the FDA.

Our regulatory regime is holding back American innovation and making public health crises worse. The CDC royally messed up COVID-19 testing and is now botching monkeypox testing. It doesn't have to be this way, and Congress has the chance to make it right. I say, give freedom a chance — free our university scientists to do what they do best.