

White House blocks FDA's power to regulate lab tests

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(HealthDay)—The Trump administration has blocked the U.S. Food and



Drug Administration from regulating a wide swath of laboratory tests, including ones for the coronavirus.

The <u>new policy</u>, which was posted Wednesday and is strongly opposed by the FDA itself, stunned health experts and laboratories because of its timing, the *Washington Post* reported.

The change could result in unreliable coronavirus tests getting on the market, potentially worsening the testing crisis in the United States, experts told the newspaper. The one thing the change won't do is solve testing shortages, because those are due mostly to a lack of the swabs and chemical reagents needed to perform COVID-19 tests, the *Post* reported.

However, supporters claimed it could help get innovative tests to market more quickly. They said that the FDA review process sharply slowed testing at the beginning of the pandemic, and that the new policy could guard against future bottlenecks, the *Post* reported.

Administration officials told the *Post* that the decision was made for legal reasons. But FDA Commissioner Stephen Hahn staunchly opposed the change, arguing that such authority is critical during a public health emergency like the pandemic, the newspaper reported.

The tests affected by the change are those developed by and used at laboratories regulated under the federal government's Clinical Laboratory Improvement Amendments program, the newspaper said. Such labs are in big academic medical centers, smaller commercial laboratories and big testing companies such as Quest and LabCorp, the *Post* reported.

The history of the FDA's power to regulate lab-developed tests has long been murky. For years, the FDA has asserted authority over the tests but



has typically only acted on it in the midst of health crises, the *Post* reported.

During the Obama administration, the FDA proposed tighter regulation during normal times, a move that drew intense opposition from labs and never happened. But during public health emergencies, the FDA has required test developers to seek an emergency use authorization that allows regulators to review the tests for accuracy, the newspaper said.

Thousands of child abuse cases missed during pandemic?

Child abuse reports have plunged during the coronavirus pandemic, a troubling sign that the constraints of social distancing may mean thousands of cases are being missed, a new survey suggests.

The survey, conducted by the Children's National Alliance, found that children's advocacy centers across the country reported serving 40,000 fewer children nationwide during the first six months of this year than the same period last year, the *Post* reported.

In 2019, more than 192,000 children were served by the centers while just over 152,000 were helped in 2020, a 21 percent drop, the survey showed.

But in no way can the decline be viewed as good news, said Teresa Huizar, executive director of the alliance.

"We have absolutely no reason to believe the actual incidence rate has declined," she said. "What we really believe is that there are 40,000 fewer kids that haven't been saved from abuse."



"What we were dreading did in fact happen," Huizar told the *Post*.

And the damage may be even more widespread, since the numbers from the centers, which receive referrals from child protective services departments and law enforcement, do not take into account all child abuse reports nationwide. A full third of U.S. counties don't even have access to a children's advocacy center, the *Post* reported.

More than two-thirds of child abuse cases are reported by teachers and other community professionals, the newspaper reported. Educators alone were responsible for 21 percent of the 4.3 million referrals made to child protective services in 2018, according to federal data. But with many schools, daycare centers and summer camps closed, vulnerable children have fewer contacts with adults who might spot signs of abuse or neglect, the *Post* reported.

Parents overwhelmed as school year starts

To make matters worse, another new survey shows most parents are feeling overwhelmed and abandoned as the school year starts.

Just 1 in 7 parents said their children would be returning to school full time this fall, and most children need help with remote schooling, *The New York Times* survey released Wednesday found. Yet, 4 in 5 parents said they would have no help in that endeavor, whether from relatives, neighbors, nannies or tutors. As well, more than half of parents said they will be taking on this burden while still holding down paid jobs.

Of course, when both parents are wage earners who need to work outside the home, they cannot be in two places at once. But three-fourths of these parents said they will be overseeing their children's education, and nearly half plan to handle child care, according to the survey of more than 1,000 parents polled between Aug. 4 and Aug. 8.



Of the parents who are both working remotely during the pandemic, 80 percent will also handle child care and education, the survey showed. One in five are considering hiring a private teacher or tutor to help with remote learning.

"All the choices stink," Kate Averett, a sociologist at the University at Albany in New York who has been interviewing parents since the spring, told the *Times*. "There is a lot of stress, a lot of anxiety. Parents tell me about not being able to sleep because they're so anxious, or tell me they've been crying a lot. There's been a lot of actual crying during interviews."

By Friday, the U.S. coronavirus case count neared 5.6 million as the death toll eclipsed 174,000, according to a *Times* tally.

According to the same tally, the top five states in coronavirus cases as of Friday were: California with over 653,000; Florida with more than 588,000; Texas with over 587,000; New York with over 432,000; and Georgia with over 230,000.

Nations grapple with pandemic

Elsewhere in the world, the situation remains challenging.

India has passed Britain to have the fourth-highest death toll in the world from the coronavirus, after the United States, Brazil and Mexico, the *Post* reported.

By Friday, India had more than 2.9 million confirmed cases of the infection and nearly 55,000 deaths, a John Hopkins tally shows. Britain remains the worst-hit country in Europe, the *Post* reported.

Brazil is also a hotspot in the coronavirus pandemic, with over 3.5



million confirmed infections by Friday, according to the Hopkins tally. It has the second-highest number of cases, behind only the United States.

Cases are also spiking in Russia: As of Friday, that country reported the world's fourth-highest number of COVID-19 cases, at nearly 944,600, the Hopkins tally showed.

Even New Zealand, a country that hadn't seen a new coronavirus case is 100 days, hasn't been spared.

This week, New Zealand Prime Minister Jacinda Ardern said the country's general election, scheduled for Sept. 19, would be pushed back a month, the *Post* reported. The move comes as New Zealand grapples with a new wave of COVID-19 infections that have prompted a return to lockdown restrictions in parts of the country.

Worldwide, the number of reported infections passed 22.7 million on Friday, with over 794,000 deaths, according to the Hopkins tally.

More information: The U.S. Centers for Disease Control and Prevention has more on the <u>new coronavirus</u>.

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