Coronavirus testing delays caused by red tape, bureaucracy and scorn for private companies

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Chaos, disorganization and cluelessness describe the current state of COVID-19 testing in the United States. Doctors, hospitals and state labs give patients needing tests the runaround, each pointing to the other as the place to get tested. Some people self-quarantine for days awaiting their results, only to be told the lab misplaced or bungled the test. As of March 11, the U.S. trailed most of the developed world in tests administered, with per capita numbers virtually the same as Vietnam's.

A rigid federal regulatory regime that fails to make use of the innovation, flexibility and speed of the private sector is largely to blame.

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Testing is essential to managing an epidemic. It allows public health officials to determine who is infected and needs isolation from others and which of their contacts need isolation, as well. Such information allows for more precise targeting of public health responses, making it possible to avoid quarantining the entire population and shutting down large swaths of the economy, as we have had to do.

The Food and Drug Administration requires an onerous approval process to bring any test to market. Once the FDA granted "emergency use authorization" to the Centers for Disease Control and Prevention to distribute and conduct the coronavirus test that it had developed, the CDC took control of distributing and administering tests while the private sector and foreign-developed tests were kept out of the process during the crucial weeks between when the virus was first identified in December and when it started rapidly spreading among the American public. The obstacles to private-sector action are only now being lifted.

"Emergency use authorization" is a scaled-down approval process that requires fewer criteria to be met to speed a test or treatment to market when time is of the essence. But even a more

streamlined process didn't allow tests developed abroad and distributed by the World Health Organization to make the grade. According to White House officials, the WHO test was meant for research purposes and didn't meet American quality control standards amid concern about incorrect results. Yet other countries have been using the test, suggesting our federal government let the prefect be the enemy of the good.

As a result of the CDC's being the sole organization to make and distribute the authorized test kits, the agency needed to strictly ration distribution. Because of the tight supply, the CDC initially set very restrictive criteria on testing individuals. To make matters significantly worse, by mid-February, the CDC had learned that many of its tests, for all the supposed focus on quality control, were inconclusive because of a flaw in one of its components and needed to be fixed. Meanwhile, no competing manufacturers were ready to meet the increasing demand.

The FDA should have sought to ameliorate the domestic shortage of test kits by granting authorization for tests already in use in other countries. However, the FDA doesn't simply grant reciprocal approval of drugs or tests approved in other countries — they must go through an FDA approval process.

In this country, many public health labs, private-sector organizations and universities grew anxious to develop their own tests. Yet the CDC warned them not to do their own testing without first getting the emergency use authorization from the FDA, a cumbersome process that discouraged many from acting.

Dr. Helen Chu, an infectious disease expert in Seattle working with the Seattle Flu Study, began performing COVID-19 tests on patients without FDA authorization. The FDA and the CDC warned her to stop. A defiant Chu and her colleagues found several cases in the Seattle area.

Finally, on Feb. 29, the FDA announced it would fast-track the emergency use authorization for public- and private-sector labs by reducing several regulatory hurdles, such as shortening the length of clinical trials needed for approval.

Now private-sector labs are rising to the occasion. On Friday, the FDA approved a test by Roche labs that can yield results in just a few hours on machines already in more than 100 labs across the country, which are able to process thousands of tests every 24 hours. In many states, university medical centers also now have fast-tracked testing authorization. In Ohio, for example, the Cleveland Clinic and the University of Cincinnati are operating "drive-thru" testing.

Still, the U.S. is playing a major game of catch-up that it might lose. And we only need to take a look at South Korea to see how we could have been in a better position if we'd let private industry play a larger role in testing. Whereas the U.S. has run 26 tests per million members of the population thus far, South Korea has run more than 4,000 tests per million. There, new cases have been declining as public health authorities have been able to do a better job of early detection and isolation. They report a fatality rate of 0.7 percent.

South Korea's testing capabilities are the result of years of working closely with the private sector to harness its advantages. Seoul enacted a reform after a health crisis triggered by the Middle East Respiratory Syndrome in 2015, which allowed the government to give almost immediate approval to testing systems developed in the private sector in an emergency.

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It's a sad irony that a country that prides itself on a tradition of free enterprise and "rugged individualism" has downplayed the value of private initiative and adopted a top-down government-run posture toward managing emergencies.

Meanwhile, in bottom-up fashion, private "social distancing" initiatives — from the cancellation of events to self-quarantining to companies' having their employees work remotely — fueled a rapid response by the general public to an unprecedented public health crisis.

When the crisis ends, among its lessons should be a renewed respect for the power and beneficence of private institutions.

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