How The COVID Testing Failure At The CDC Mirrored The Cleantech Crash Failure At The Dept of Energy

On a Jan. 15 conference call, a leading scientist at the federal Centers for Disease Control and Prevention assured local and state public health officials from across the nation that there would soon be a test to detect a mysterious virus spreading from China. Stephen Lindstrom told them the threat was remote and they may not need the test his team was developing "unless the scope gets much larger than we anticipate," according to an email summarizing the call.

"We're in good hands," a public health official who participated in the call wrote in the email to colleagues.

Three weeks later, early on Feb. 8, one of the first CDC test kits arrived in a Federal Express package at a public health laboratory on the east side of Manhattan. By then, the virus had reached the United States, and the kits represented the government's best hope for containing it while that was still possible.

For hours, lab technicians struggled to verify that the test worked. Each time, it fell short, producing untrustworthy results.

That night, they called their lab director, Jennifer Rakeman, an assistant commissioner in the New York City health department, to tell her it had failed. "Oh, s---," she replied. "What are we going to do now?"

In the 21 days that followed, as Trump administration officials continued to rely on the flawed CDC test, many lab scientists eager to aid the faltering effort grew increasingly alarmed and exasperated by the federal government's actions, according to previously unreported email messages and other documents reviewed by The Washington Post, as well as exclusive interviews with scientists and officials involved.

In their private communications, scientists at academic, hospital and public health labs - one layer removed from federal agency operations - expressed dismay at the failure to move more quickly and frustration at bureaucratic demands that delayed their attempts to develop alternatives to the CDC test.

"We have the skills and resources as a community but we are collectively paralyzed by a bloated bureaucratic/administrative process," Marc Couturier, medical director at academic laboratory ARUP in Utah, wrote to other microbiologists on Feb. 27 after weeks of mounting frustration.

The administration embraced a new approach behind closed doors that very day, concluding that "a much broader" effort to testing was needed, according to an internal government memo spelling out the plan. Two days later, the administration announced a relaxation of the regulations that scientists said had hindered private laboratories from deploying their own tests.

By then, the virus had spread across the country. In less than a month, it would upend daily life, shuttering the world's largest economy and killing thousands of Americans.

In a statement to The Washington Post, the CDC said an investigation of the initial problems is ongoing. The test is now in use in every state and is "accurate and reliable," the agency said.

Stephen Hahn, the commissioner of the Food and Drug Administration, which regulates testing, told The Post the agency is continuously adapting to an "unprecedented global public health crisis."

"Right now, our efforts are focused on doing everything we can do to fight COVID-19, but we know there will certainly be a time to learn larger lessons from the agency's response," he said in a statement, referring to the disease caused by the novel coronavirus.

In an interview Thursday, Brett Giroir, a Public Health Service admiral who on March 12 was named the top administration official on the testing effort, acknowledged the government should have moved more decisively to detect and contain the virus.

"There was a clear need for a more aggressive posture," said Giroir, an assistant secretary at the Department of Health and Human Services.

Asked who was responsible for the delays in the early stages of the crisis, he paused.

"A problem like this is bigger than any single agency," he said. "Clearly, there needed to be a higher level of leadership and organization."

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The first reports about a strange, possibly unknown virus started leaking out of China in late December. Scientists and researchers in the United States and around the world began paying keen attention to the apparent epicenter of the spread, a sprawling industrial city in central China called Wuhan.

Among those keeping close track were virologists and other specialists at the U.S. Centers for Disease Control and Prevention, the country's flagship public health agency. Founded in 1946 to fight malaria in Southern states, the CDC is at the vanguard in the fight against infectious diseases throughout the nation. It employs some 22,000 epidemiologists, biologists, behavioral scientists and others. Recent successes include rapid responses to contain the Zika, MERS and Ebola viruses.

In early January, the CDC publicly treated the virus from Wuhan as a distant potential threat, issuing an advisory urging that the "usual precautions" be taken when traveling abroad.

The agency also began laying plans to protect the country. Led by Lindstrom, one team began considering the kinds of tests, technically called assays, that could identify the virus.

Lindstrom is a microbiologist with an impressive track record: He had helped develop a testing method critical to detecting the H1N1 virus in 2009. During a Jan. 7 conference call, he told public health officials that the CDC's aim was to "plan for the worst, hope for the best," according to an email exchange among scientists and others. Lindstrom, like several other officials named in this report, did not respond to requests for interviews.

On Jan. 10, CDC scientists received an important break when the Chinese government published the pathogen's genetic

sequence. The sequence, a long string of letters representing the RNA structure of SARS-CoV-2 described a coronavirus never before seen in humans. It also gave scientists a path to create a precise diagnostic test that could detect the virus.

CDC has long led the nation's efforts to create diagnostic tests when a public health threat emerges. The agency usually distributes the tests to a network of state and county public health labs nationwide, using the results to track and contain new pathogens until large-scale commercial tests come online.

But state and local public health labs juggle an immense array of responsibilities, including water and food safety, and government studies dating back two decades have found the public health labs often lack the money and resources to keep pace with the demands.

On the Jan. 15 call, Lindstrom told more than a dozen public health officials that the CDC planned to make its test available to all state and county public health labs. He assured them "there will not be pressure for everyone (at least from CDC) to implement unless the scope gets much larger than we anticipate right now," according to the email summary written by Kelly Wroblewski, director of infectious disease programs at the Association of Public Health Laboratories.

CDC scientists were not the only ones interested in creating a test. Commercial laboratories began to mobilize, and scientists at major hospitals and universities sprang into action to develop tests of their own.

One of them was Alex Greninger, 38, an assistant director of the University of Washington's clinical virology lab. For Greninger,

the chance to create a diagnostic test for a novel coronavirus was a rare opportunity.

Researchers at the University of Nebraska, Stanford University and elsewhere also began taking their first steps toward inventing tests for the virus to use in their own labs. These academic labs didn't have the capacity to process the millions of tests that would be needed in the event of a pandemic, a scale that is achievable only by commercial labs, but their limited testing capabilities might have helped efforts to detect and slow the virus in its early stages.

On Jan. 16, the day Greninger started buying supplies for his test, a 35-year-old man who had recently visited Wuhan became ill with flu-like symptoms after returning to the Seattle area, according to a CDC incident report. The man went to his doctor, who swabbed his nose and sent the sample to the CDC, according to the report.

Four days later, using its newly developed test, the CDC confirmed that the man was the first person in the United States known to be infected with the novel coronavirus.

In a CNBC interview two days after that, President Donald Trump downplayed the threat to Americans.

"We have it totally under control," he said.

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Designing the test took CDC scientists seven days -- a stunningly short period of time for a health-care system built around the principles of medical quality and patient safety, not speed.

The CDC could use the test in its Atlanta labs but could not send it out to public health labs until it won approval from the FDA. On Jan. 28, Lindstrom and others at the CDC assured public health scientists in a conference call that "CDC's goal is to get (FDA approval) as quickly as possible and expects the assay will be ready to deploy within two weeks, possibly sooner," according to an Association of Public Health Laboratories' summary of the call.

Although the CDC test was a priority, the FDA was also fielding inquiries from other test developers. At the end of January, about 20 companies and scientific groups were talking with the FDA about their plans to develop tests, according to two government officials familiar with those inquiries who like many others interviewed for this story spoke on the condition of anonymity to discuss sensitive matters.

At the same time, pressure on the Trump administration to take action was growing. The number of people who had died of the infection worldwide spiked to 200 by Jan. 30, when the World Health Organization declared the virus a public health emergency of international concern.

The next day, Health and Human Services Secretary Alex Azar announced a health emergency in the United States. At the time, Azar was the leader of the White House's newly created coronavirus task force.

The declaration was one of the most significant moments in the unfolding crisis. Such declarations provide the FDA flexibility to speed up approvals for critical medical products, including commercial diagnostic tests. But they also trigger strict limits on

scientists in government-certified clinical labs at universities, research centers and hospitals.

Those labs are typically permitted by the FDA to make and use their own tests without government approval, including to make decisions about patient care, as long as they use them only in their own facilities and do not sell them.

But once Azar announced a public health emergency, tests created in such laboratories had to receive an "emergency use authorization," or EUA, from the FDA. The additional regulation is intended to ensure the efficacy of tests in public health crises in which inaccurate results could be damaging.

The new regulatory hurdle stalled efforts like the one underway by Greninger at the University of Washington. Greninger and other scientists were located in some of the nation's early coronavirus hot spots, where successful tests might have helped reveal the scope of the outbreak. Suddenly, their hands were tied.

Clinical scientists fumed about the new obstacle, according to exchanges in private online chat groups among academics and scientists.

"The EUA process is flawed, broken, and inefficient," Couturier, the medical director and diagnostic specialist at ARUP Laboratories in Utah, wrote later on ClinMicroNet, a private message system for microbiology lab directors across the world.

In a statement this week, the FDA said its regulations "had not hindered or been a roadblock" to the rollout of tests.

"Every action the FDA has taken during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make diagnostic tests available with providing a level of oversight that ensures accurate tests are being deployed," the agency said.

But in his interview, Giroir offered a different analysis.

"If someone says they were a barrier, to me, you have to believe them," he told The Post. "If they thought it was a barrier, it becomes a barrier."

One person familiar with the emergency declaration told The Post that FDA career staff did not raise concerns about the EUA's burdens on clinical labs to Azar or to FDA leaders. Azar oversees the FDA.

Hahn had been confirmed by the Senate as FDA commissioner on Dec. 12 - just seven weeks before Azar's declaration. Before that, Hahn was a radiation oncologist and chief medical executive at the MD Anderson Cancer Center in Houston.

Hahn's agency approved the CDC test on Feb. 4, making it the country's only accepted test for the novel coronavirus. Public health officials in New York City, Nebraska, Colorado, Minnesota, New York state and elsewhere began receiving them four days later.

The test kits contain compact collections of chemicals known as reagents. The chemicals help isolate viral genetic material and then amplify it so that it can be detected by probes that also came with the kit.

Scientists in the local labs quickly recognized something was wrong. The assays often produced results that suggested the virus was present in samples in which scientists knew it was not.

On Feb. 8, when lab technicians for New York City's health department ran the test on samples that contained the virus, they saw on their computer screens a logarithmic curve sloping upward, indicating the virus was present. The problem was, they saw something similar when they ran the test on distilled water that contained no trace of the virus.

When they finally gave up that evening, the technicians called their director, Rakeman. Shortly before midnight, she relayed the bad news in an email to local health authorities. "The issue will need to be investigated and could result in significant impact to testing availability at the CDC and across the country until the issue is resolved," she wrote.

New York state lab officials also passed on the news, according to documents and interviews. "There is a technical problem in one of the reagents which invalidates the assay and will not allow us to perform the assay," the lab director of New York state's Wadsworth Center, Jill Taylor, wrote to state health officials in an email that same night.

"I am sorry to not have better news," she wrote. "It is a bummer."

Word that some labs were having problems with the test quickly made its way back to the CDC.

"Is this something to worry about?" Daniel Jernigan, a leader of the CDC's coronavirus response, wrote to the Association of

Public Health Laboratories the next morning as he prepared to board a plane.

It was, he was told.

Later that day, Scott Becker, chief executive of the association, raised concerns to another CDC official. "The states and their governors are going to come unglued," he wrote, adding later, "If CDC doesn't get ahead of this it will be a disaster."

As they struggled to make the test kit work, many of the public health labs realized they might succeed by eliminating one of its three main chemical components. But under the FDA's emergency rules, they could use the test only as it was approved. The flaw meant they could not use it at all.

"The silence from CDC . . . is deafening," Joanne Bartkus, the Minnesota health department's lab director, wrote to Becker on Feb. 10. "What is going on? We are getting questions from our governor's office and other labs are getting media requests asking when we will be starting."

By Feb. 12, a total of 2,009 tests had been conducted in the United States, according to CDC data.

"We're screwed from a testing standpoint if this thing takes off in the US," Susan Butler-Wu, director of medical microbiology at the Los Angeles County and University of Southern California Medical Center, warned in a Feb. 13 email to fellow scientists.

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The United States was clearly falling behind in the fight against covid-19. Other countries such as Singapore and Taiwan were

ramping up testing quickly. In South Korea, 1,000 people were being tested each day by mid-February, a number that would increase more than tenfold by the end of the month.

The Geneva-based World Health Organization, meanwhile, had already delivered 250,000 diagnostic tests designed and manufactured by a German lab to 70 laboratories around the world.

Academic and hospital researchers including Greninger eagerly experimented with the German lab design early on and found it workable, but U.S. health officials continued on their own path.

"To our knowledge, no discussions occurred between WHO and CDC (or other USG agencies) about WHO providing COVID-19 tests to the U.S.," WHO spokesman Tarik Jasarevic told The Post.

Hahn defended the U.S. government's approach at a news conference weeks later.

"In the U.S., we have policies in place that strike the right balance during public health emergencies of ensuring critical independent review by the scientific and public health experts and timely test availability," he said in a White House press briefing. "What's important here is that we have a test that the American people can trust."

The FDA's confidence in the flawed test was based in part on assurances from the CDC that it could be fixed easily, according to officials familiar with the agency's deliberations.

In its statement to The Post, the CDC said it collaborated closely with the FDA and "encouraged our government partners to work

with the private sector to develop diagnostic tests for commercial use and to remove restrictions for . . . labs in hospitals and universities across the county."

On Feb. 16, officials from the FDA and CDC met to discuss solutions, including the possibility of eliminating the component of the test that was causing problems, officials said. FDA officials said that would be a fast solution that could quickly get the public health labs up and running. But in the following days, the FDA learned that some public labs were reporting continuing problems with the test, the officials said.

As officials struggled to understand the test flaws, leading clinical labs were spending much of their time and energy on the FDA's paperwork and data demands to win approval for their tests.

The Mayo Clinic created its first-ever rapid response team. A third of the 15 members were devoted solely to the FDA's data and paperwork demands. Like others on the team, they worked 15-hour days for three weeks.

"It's unlike anything we've ever done before," said Matt Binnicker, a director of clinical virology at Mayo.

He said they decided to persist because, in a worst-case scenario, the public health labs alone could not test on the scale that would be needed. "The public health infrastructure is really not set up to handle a pandemic," he said.

At the University of Washington, Greninger and his fellow scientists were initially baffled by an FDA process they viewed as baroque. They had always worked under strict guidelines, aimed

at protecting patients and guaranteeing quality. But the EUA was a bureaucratic puzzle they had never encountered.

"The most pernicious effect of the current regulatory environment is that it kneecaps our ability for preparedness should a true emergency emerge," Greninger wrote to colleagues on Feb. 14.

Greninger channeled his energy into the paperwork problem, spending more than 100 hours filling out forms and collecting information needed for the application, he told The Post. But when he finally submitted the material, an FDA official told him the agency could not accept it - because he had emailed it.

"We received your email and attachments regarding the UW 2019-nCoV assay pre-EUA," an FDA official wrote on Feb. 20. "However, we have not received the official submission through DCC."

"What is the DCC?" Greninger wrote back.

"The Document Control Center," came the reply.

"What is the Document Control Center?"

Greninger then learned about another requirement. Under FDA rules, he was supposed to digitally copy the electronic documents he had emailed to the FDA, burn the copies onto a disk and mail the hard disk to an office in suburban District of Columbia.

Greninger shared his exasperation in a Feb. 20 email to a colleague: "repeat after me, emergency."

In a statement, an FDA official said information sent by Greninger on Feb. 19 was promptly reviewed, despite not having been submitted properly, and was found to be insufficient to demonstrate that the test would work. The official said that after that interaction, "we immediately addressed how we receive applications."

"The FDA is improving ways we interact with developers of products to address the pandemic, including those we don't normally interact with," the official said.

By the time Greninger sent his email, the FDA was in discussions with dozens of test developers, a number that was growing quickly. But none had managed to complete a formal application to the FDA, according to officials familiar with the agency's actions. FDA officials interpreted the paucity of applications as a sign of limited ability or interest, the officials said.

Some private labs struggled to obtain samples of the virus necessary to verify their tests and complete their applications, according to government officials and lab representatives. An FDA official said that, at the time, the agency supported efforts to help those labs secure the necessary samples.

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On Feb. 22, an FDA official named Timothy Stenzel flew to Atlanta. The director of a diagnostic office at the FDA, Stenzel was a key figure in the decisions about testing. The purpose of his visit was not clear to CDC officials, but he said he wanted to understand the testing development and help find a way to fix the troubled assay, according to three people familiar with the visit.

Stenzel spent much of the following week attending CDC meetings, touring the facilities and offering suggestions about how to cobble together viable tests from existing materials, the officials said.

At the same time, CDC officials, including Jernigan from the agency's influenza division, urged Stenzel to convince the FDA to approve other tests under development in private laboratories.

Anxiety about the lack of widespread testing, meanwhile, was cresting among scientists and public health officials nationwide. Many felt the country could wait no longer.

On Feb. 24, the Association of Public Health Laboratories formally asked Hahn to loosen the FDA's rules.

"We are now many weeks into the response with still no diagnostic or surveillance test available outside of the CDC for the vast majority of our member laboratories," the association's letter said. "While we understand that the EUA process is open to [public health labs], we believe a more expeditious route is needed at this time."

Two days later, the FDA allowed public health labs to begin using the CDC test, with the troubled component eliminated.

On Feb. 27, Anthony Fauci, the government's top infectious disease expert, added to the pressure to expand testing further. He spoke in person with Brian Harrison, Azar's chief of staff, and underscored the urgent need to accelerate the approval of new tests, according to two people familiar with the call. At noon that day, Harrison convened a teleconference of officials from the FDA, CDC and other agencies.

In strong language, Harrison told the group to come up with a new test approval plan before they left the meeting. The participants scrambled to swap ideas. At the FDA and CDC, Stenzel, Jernigan and others worked on a memo into the evening that outlined a new strategy.

The memo, "A Plan to Increase Covid-19 testing in the U.S.," frankly acknowledged that the original approach had not worked. The spread of the virus was "leading to significant impact on healthcare systems and causing social disruption," it said.

"CDC has worked with FDA to assure that testing is available at Public Health Laboratories to support public health investigations and control efforts; however, a much broader interagency approach is needed to fill the greater need for diagnostics by commercial manufacturers and laboratories capable of developing their own tests."

It recommended giving clinical laboratories, such as the University of Washington, leeway to create and begin using their own tests while seeking FDA approval. The memo was forwarded to top government officials, including Azar, who supported loosening the regulations.

The next day, Greninger and scores of other clinical scientists appealed to Congress in a letter of their own. They complained that "significantly more stringent" FDA rules had nearly frozen the country's fight against the virus.

"Notably, no test manufacturer or clinical laboratory has successfully navigated the EUA process for SARS-CoV-2 to date," the Feb. 28 letter said. "Therefore, the CDC test remains the only

test available with EUA status, and it has not been made available to hospital laboratories."

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On Feb. 29, the FDA finally reversed course, opening the way for clinical labs outside the government to begin testing for coronavirus. Under a revised policy Hahn announced at a White House briefing, the labs would have to notify the FDA when testing began, but they would not have to submit paperwork for 15 days.

"The FDA recognized the urgent need for even faster testing availability," the agency said in a statement this week. "Although laboratories could use the EUA pathway, many were hesitant or didn't know the pathway was available to them."

Giroir told The Post that the FDA was right to reverse itself but could have done so sooner.

"In retrospect, it might have been useful earlier, right?" he said. "I mean, it was the right decision to make."

On March 2, Greninger and his colleagues at the University of Washington went live, testing 30 patients in a single day. Two days later, they tested 202 people. That number soon soared to over 2,800 per day, roughly the equivalent of a quarter of tests done by all state and federal public health labs on the same day.

About two weeks after the FDA loosened its grip on testing, two major manufacturing giants, Roche and Thermo Fisher Scientific, won approval. By then the number of confirmed cases in the United States had grown to more than 2,000.

On March 12, Fauci, who runs the National Institute of Allergy and Infectious Diseases, told lawmakers the problem was not simply the failure of the CDC test. The coronavirus testing debacle had exposed deep structural problems in the nation's public health system, he said.

"Yeah, it is a failure, let's admit it," he said. "The idea of anybody getting it easily the way people in other countries are doing it, we're not set up for that. Do I think we should be? Yes, but we're not."

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The Washington Post's Emily Rauhala, Yasmeen Abutaleb and Josh Dawsey contributed to this report.