Documents for the Record 6.7.2023

Energy and Commerce Committee

Subcommittee on Oversight and Investigations

1. Ranking Member Castor - Letter from HHS to E&C Oversight Subcommittee responding to our letter regarding CDC Reorganization.
2. Dr. Burgess – Article from Washington Post regarding Zika Testing
3. Mr. Armstrong – CDC uses report
4. Dr. Ruiz – Letter from Miller Meeks on CDC reform
5. Ranking Member Castor – Fact Check Article from USA Today

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June 6, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Rodgers:

Thank you for your May 5, 2023, letter to Dr. Rochelle Walensky, MD, MPH, regarding the Centers for Disease Control and Prevention's (CDC) Moving Forward Initiative. I am pleased to respond on the Director's behalf.

CDC works 24/7 to protect America from health threats and increase the health security of our nation. To accomplish its mission, CDC conducts critical scientific work and provides health information that protects our nation against dangerous health threats and responds when these threats arise.

As CDC has publicly recognized, the COVID-19 pandemic exacerbated many existing structural and systemic operational challenges across the U.S. public health system. CDC is committed to using lessons learned from the COVID-19 pandemic to ensure the agency is better prepared to lead the country through the next pandemic.

To this end, beginning in spring 2022, the CDC Director launched an extensive review of the agency's organizational structures, systems, and processes to strengthen its ability to deliver on its core mission. There were two components to this review:

1. **Scientific and Programmatic Review**: To identify ways to improve and institutionalize how CDC develops and deploys its science, both in pandemic and non-emergency times. To accomplish the Scientific and Programmatic Review, approximately 120 interviews were conducted from April through June 2022 with CDC leadership, staff, and external partners (e.g., those from academic, jurisdictional public health, and former CDC employees and leaders). A final report was provided to the CDC Director capturing findings and recommendations to identify ways to improve and institutionalize how CDC develops and deploys its science. The full report can be found online.1

2. **Structural Review**: To gather feedback on the agency's current processes, systems, and structure and solicit suggestions for strategic change, with a strong focus on the agency's core capabilities – a diverse public health workforce, data modernization, laboratory capacity, rapid response to disease outbreaks, and preparedness within the United States
1 https://www.cdc.gov/about/organization/cdc-moving-forward-summary-report.html

and around the world. This review included over 50 interviews, including the entire CDC leadership team and others who are intimately familiar with how CDC operates. The final summary of the Director's recommendations from this effort can also be found online.2
In August 2022, based on this review along with substantial internal and external input, the CDC Director launched the Moving Forward initiative,3 which focuses on the following top improvement areas:

- Share scientific findings and data faster
- Translate science into practical, easy to understand policy
- Prioritize public health communications
- Develop a workforce prepared for future emergencies
- Promote results-based partnerships

CDC leadership established working groups to develop concrete implementation steps to address lessons learned from the Scientific and Programmatic Review, and to enable the agency to function more effectively. These working groups – referred to as priority action teams – included over 320 staff and leaders from across CDC. Their charge was to develop internal, implementable actions that would strengthen how CDC delivers science for action. As a result of this work, over 100 recommendations were developed for current and future implementation within CDC. Of note, some recommendations require increased resources, which the agency does not currently have. Implementation of other recommendations are either completed or already well underway.

Following the release of the report related to the Structural Review, which drove specific internal structural recommendations, ten working groups of more than 180 CDC staff – led by members of the agency's leadership team – were formed, each focused on a priority operational area. These priority areas were a direct result of input gathered during the Structural Review and the Director's recommendations regarding where to first focus realignment efforts. The focus of the working groups – referred to as "strike teams" – included areas such as science, policy, laboratory capacity, communications, public health data, and external affairs. Strike team leads presented their recommendations to the senior leadership team over several meetings and gathered thorough input. Ultimately, the CDC Director made the final decision on what aspects would move forward as part of the initial CDC reorganization.

CDC leadership heard both internal and external feedback and swiftly acted upon it. On January 24, 2023, the CDC Director announced a CDC reorganization, one of several foundational steps to achieve progress in the improvement areas outlined above. This reorganization aimed to eliminate bureaucratic reporting layers, break down silos in the agency, promote foundational public health capabilities, and improve accountability with the goal of creating a CDC that swiftly responds to public health challenges facing the nation, while prioritizing clear external communication to ensure everyone in America understands its guidance and decisions.
2 https://www.cdc.gov/about/organization/cdc-moving-forward-summary-report.html
3 https://www.cdc.gov/about/organization/cdc-moving-forward.html

To be clear, this was not a "large-scale reorganization," but rather a first step toward making CDC more action-oriented and accountable. At a high level, the reorganization 1) removed a

reporting layer to increase accountability, enabling direct reporting of core functions into the CDC Immediate Office of the Director, and 2) combined two organizations that were doing similar work. In doing so, CDC aims to improve management, reduce bureaucracy, strengthen its emergency readiness and response, and elevate some of the agency's most important enterprisewidefunctions. These steps are designed to strengthen how CDC operates, orienting it toward timely action and ensuring CDC's science reaches the public in an understandable, accessible, and implementable manner. CDC publicly released this new structure4 and leadership team5 immediately following its establishment.

As is reflected in publicly released materials, no functions or authorities were moved out of any of CDC's National Centers. Your letter incorrectly states that the reorganization "appears to expand greatly the size and power of the Office of the Director at the expense of the agency's national centers." The activities that were shifted as part of the reorganization were primarily between existing offices and what were referred to previously as cross-cutting centers that support work across CDC. One example of such a move is the Community Guide activity, which shifted from the policy to science office. The only example in which a "National Center" was impacted during this reorganization was the moving of CDC's genomics activities from the Office of Science to the National Center for Birth Defects and Developmental Disabilities – a shift that actually moved additional responsibilities to this Center.

As the summary of activities above makes clear, this effort was not executed behind closed doors. CDC leadership communicated directly with staff – the Director held a total of 13 all-staff meetings since her arrival – and provided information on the agency's internal website throughout the process. In addition to the more than 170 interviews conducted during the spring and early summer of 2022, over 420 CDC staff and leaders were involved with taking the findings of these reviews and driving the agency toward concrete actions through the strike teams and priority action teams. The reorganization – along with the changes from the priority action teams – were designed in partnership between the agency's senior leaders and CDC staff. In addition to the extensive internal engagement of CDC staff, allowing them to be part of the solution to improve CDC operations, the agency kept key stakeholders updated along the way. CDC followed all necessary reorganization steps, including Congressional Notification to the House and Senate Appropriations Committees, as well as briefing Congressional Members and their staff on more than 50 occasions and testifying publicly on the findings and recommendations during four congressional hearings. Other examples of external engagements include updates to public health partners who work most closely with CDC, engagement with the agency's Advisory Committee to the Director (which includes a public facing component and opportunity for feedback), and proactively publishing the entire report, organizational chart, and leadership team. CDC also provided updates to the media, including findings, recommendations, and actionable next steps. Throughout this process, CDC has demonstrated its commitment to

4 https://www.cdc.gov/about/pdf/organization/cdc-org-chart.pdf
5 https://www.cdc.gov/about/leadership htm

transparency so, as a country, we are better prepared for the next large-scale infectious disease outbreak.

Despite these efforts, CDC alone cannot make all the necessary changes to be better prepared. New authorities and flexibilities, along with increased public health funding for core capabilities

(e.g., data, laboratory capacity, readiness, etc.), will be required to support the necessary changes within the agency. The request for new authorities was also considered as a part of the reviews and recommendations. For example, CDC has been forced to rely on time-consuming processes within its existing authorities to meet operational and programmatic needs when time is of the utmost essence. The COVID-19 pandemic and other outbreaks have underscored how much these challenges have hampered the agency and continue to do so. Data is the foundation for everything CDC does, particularly in the context of a public health emergency response where critical decisions on where and how to target interventions must be made quickly. Having timely access to high-quality data on where a disease is spreading, the severity of illness, and the populations most impacted is a critical element of operational readiness. It allows state and local public health and other health care professionals, as well as policy makers, to target resources to mitigate an outbreak and predict future spread. The authorities CDC has requested are consistent with the authorities that other Federal agencies already have and exercise when needed. Additionally, CDC has been openly discussing these challenges for years and engaged with Congress on potential solutions, as appropriate.

In closing, CDC has worked to identify challenges and implement solutions to improve CDC's ability to effectively deliver on its mission all while continuing the critical work of responding to COVID-19 and other infectious disease outbreaks (e.g., Ebola and Marburg in Africa). This work has been transparent, and CDC staff have worked tirelessly to rebuild trust in public health and the agency. The need for new authorities and the changes that are underway have been validated by outside independent organizations, and with the help of Congress, these changes can improve the agency's operations and better prepare this nation for the next pandemic.
Thank you again for your interest in this issue. CDC remains committed to leading with science and protecting the American public. If you or your staff have any questions, please feel free to contact the Office of the Assistant Secretary for Legislation at (202) 690-7627.

Sincerely,
Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

cc:
The Honorable Frank Pallone Jr.
Ranking Member
Committee on Energy and Commerce

2) Dr. Burgess – Article entitled, "Lessons unlearned: Four years before the CDC fumbled coronavirus testing, the agency made some of the same mistakes with Zika" from the Washington Post. Published July 4, 2020.

Four years before the federal Centers for Disease Control and Prevention fumbled the nation's chance to begin effective early testing for the novel coronavirus, the agency similarly mishandled its efforts to detect another dreaded pathogen.

Amid a feared outbreak of the newly emerged Zika virus, senior CDC officials in 2016 sidelined an effective test for it — and instead directed public health laboratories nationwide to use a more complicated test that failed about one-third of the time.

The agency's response to Zika now stands as an unheeded prequel for how the CDC stumbled this year as it confronted the coronavirus pandemic, which has claimed more than 125,000 lives nationwide.

Both Zika and the coronavirus originated overseas and became American health emergencies that have challenged the CDC's ability to carry out its fundamental mission to rapidly identify and contain newly arrived pathogens.

In both emergencies, the CDC pressured the public health labs to shelve the effective tests and to use less reliable kits manufactured by the agency that sought to detect multiple pathogens. The agency stood behind the troubled test kits despite internal data indicating they were flawed. Ultimately, the CDC notified the public lab officials that they could switch to more effective tests.

With Zika, the CDC took nearly a year to change course. With the coronavirus, the agency took more than a month, delaying a nationwide rollout of effective testing as the malady it causes, covid-19, erupted into the nation's most deadly infectious disease in a century. Clinicians and public health officials say the delay caused additional deaths, although the total number is uncertain.

The component of the CDC's coronavirus test kits that was designed to detect strains other than SARS-CoV-2 became contaminated during manufacturing at the agency in January, causing false-positive results at 24 of 26 labs that first tried out the kits, The Washington Post revealed in April. The CDC waited until Feb. 28 before dropping the problematic "pan-coronavirus'' segment from the kit — while the public labs were precluded from using other options, such as an effective test made available in mid-January by the World Health Organization.

The parallels in how the CDC responded to the two health crises emerge from a Washington Post examination of federal investigative and regulatory records, congressional testimony, CDC emails and documents, and interviews with scientists and other technical experts.

"It's painful to watch the same challenges again and again,'' said Timothy M. Persons, who has reviewed the efforts to counter Zika and the coronavirus as chief scientist of the U.S. Government Accountability Office. "As I think we saw with Zika, we need to apply lessons learned to definitely try and respond better."

An audit that Persons led three years ago for the government faulted CDC leaders for not being more rigorous in evaluating the troubled test for Zika.

Reliable early testing "is a critical piece of the overall preparedness and response system," Persons said in an interview.

President Trump and his appointees have generally praised the administration's response to the coronavirus. But a review released on June 19 by the Department of Health and Human Services said that CDC officials — despite seeing worrisome "anomalies" — skipped standard quality control checks before distributing the test kits for detecting the nation's earliest cases of the virus. The review also confirmed that the kits were "likely" contaminated during the CDC's manufacturing.

CDC coronavirus test kits were likely contaminated, federal review confirms

Robert S. Lanciotti, a virologist who headed the CDC's diagnostic efforts with Zika until May 2016 — when the agency stripped him of his leadership role after he warned against distributing the deficient test kits — said the decision-making with the coronavirus mirrored what he witnessed.

"This is exactly the same mistake I saw during Zika,'' Lanciotti said in interviews with The Post.

Lanciotti said that by shelving effective tests in favor of less reliable approaches, CDC officials "slowed things down and screwed things up.''

As reported in The Post in 2016, Lanciotti had raised concerns then that the CDC's preferred Zika test missed infections and that the agency withheld information about its deficiencies from local lab officials.

CDC officials did not respond to questions for this article.

On Saturday, an HHS spokeswoman, Caitlin Oakley, said the government at no point blocked the public health labs "from using any other" available test for the coronavirus. Representatives of the labs, however, have complained that then-existing regulations tethered them to the CDC's troubled test.

Former CDC Director Tom Frieden, who led the agency's efforts against Zika in 2016, praised its overall performance with that virus and defended the decisions made with the Zika test.

"Any test can get improved with time," Frieden said. "And any action can be looked back on. . . . In the course of refining the test, you expect it to get better with time."

Not 'taken by surprise'

Researchers discovered the virus that came to be called Zika in 1947 in the blood of a rhesus monkey in Uganda's Zika Forest. Initially, the virus posed little threat to humans: Over the next three decades, fewer than 20 Zika infections would be diagnosed from Africa to Southeast Asia, and the reported symptoms were nonexistent or mild — occasional fever, headache and malaise. No deaths or other severe outcomes emerged.

In June 2007, the CDC first dealt with Zika when the agency's diagnostic lab in Fort Collins, Colo., received blood samples from physicians in Yap state, a cluster of tiny Pacific islands about 500 miles east of the Philippines in the Federated States of Micronesia. The island doctors suspected that an epidemic of rashes, eye redness and joint pain had been touched off by disease-carrying mosquitoes.

At the time, Lanciotti was chief of the lab, which specialized in diseases spread by mosquitoes and ticks.

Using a well-established molecular testing technique called polymerase chain reaction, or PCR, Lanciotti and his colleagues discovered that the epidemic in Yap was caused by the Zika virus. Lanciotti also developed a separate enzyme-based test, which showed whether a person's blood carried Zika antibodies, another sign of infection.

His lab continued to use those tests on Zika samples as small outbreaks emerged in the coming years elsewhere in the Pacific, still thousands of miles from the U.S. mainland.

The CDC's concern rose by late 2015, after Zika infections were detected widely along the northern coast of Brazil. This marked Zika's first confirmed appearance in the Western Hemisphere — and the stakes were made more urgent by mysterious clusters of microcephaly, a birth defect that left newborns with tiny heads.

In December 2015, Lanciotti began distributing instructions for how to conduct the molecular test, which his team was already using, to public health labs in 21 states and the District of Columbia, along with several counties, records show.

A top priority, Lanciotti recalled during recent interviews, was to prevent Zika's spread in the United States by likely hosts — including infected airline passengers returning from the 2016 Summer Olympics in Rio de Janeiro. If an infected person were bitten by a mosquito, Zika might spread to whomever the insect next found. Zika, he knew, could also be transmitted sexually.

"When this hit in 2015, we weren't taken by surprise," Lanciotti recalled. "We had testing in place. . . . We knew there would be travelers returning, potentially infected with Zika."

Lanciotti's approach was informed by his CDC experience with West Nile disease, another mosquito-spread virus: Using molecular and antibody testing, he and his colleagues had been the first to confirm that an outbreak in 1999 of human encephalitis in New York City was caused by West Nile.

Lanciotti said the CDC did not manufacture the Zika test kits but told others how to build them.

The Zika molecular testing protocol that Lanciotti distributed instructed the local labs where to purchase chemical mixtures necessary for the tests and specified the temperatures and durations at which blood samples, along with the mixtures, should be heated, cooled and reheated during testing.

Lanciotti also sent a "proficiency panel," which each lab could use to verify whether it was generating reliable results with the test, called "Singleplex." The panels included small tubes of inactivated Zika virus and a non-viral substance to verify accuracy.

Within two weeks of receiving Lanciotti's testing instructions, public labs in Florida, Texas, California, New York and Maryland were analyzing samples, interviews and CDC records show.

"The approach that my lab took was, we want to develop a very rapid way for state public health partners detecting these viruses," Lanciotti said. "We want to know right away if a traveler has Zika.''

Rapid detection would enable health authorities to isolate an infected person and, if a cluster of cases emerged, the affected neighborhoods could be promptly sprayed with insecticide. If a pregnant woman were diagnosed with Zika, she would be informed immediately.

More elaborate testing

By early 2016, CDC scientists based in Puerto Rico and at agency headquarters in Atlanta saw the emerging Zika crisis as an opportunity to deploy a new — and more elaborate — approach to detecting the virus.

Instead of using the molecular test to look only for Zika, they would also target five additional pathogens: chikungunya virus and four strains of dengue fever. The new test, referred to by scientists as an "assay," was called

“Trioplex” and was intended to provide convenience for labs that wanted to look simultaneously for Zika and the other pathogens.

The portion of the Trioplex test targeting the four strains of dengue fever was known as the “pan-dengue” component. Four years later, the CDC would complicate its SARS-CoV-2 test with the “pan-coronavirus” component, designed to search for additional coronavirus strains.

All of the viral strains targeted in the new test were transmitted by mosquitoes, but only Zika posed an imminent threat to the continental United States. Even if Trioplex detected a case of dengue or chikungunya, no effective medical treatments existed for their often mild symptoms, and neither dengue nor chikungunya was associated with birth defects.

Unlike Lanciotti’s test, the CDC would manufacture and distribute the Trioplex test kits, each with 41 pages of instructions, versus two for Lanciotti’s concise protocol.

The expanded diagnostic approach, however, introduced a challenge: Targeting multiple pathogens typically reduces a test’s sensitivity, according to scientific experts.

“You always are careful about sacrificing sensitivity,” said Richard Meyer, a microbiologist who designed and conducted molecular tests before retiring as chief of the CDC’s rapid response lab for bioterrorism.

Lanciotti said he worried about the change because he knew from his work during the Yap outbreak that, with Zika, only a relatively small amount of the virus could be detected in a person’s blood. Because of Zika’s low viral load, detecting it required a test with great sensitivity.

“A small reduction in analytical sensitivity leads to a big problem because most of the Zika cases had low levels of” virus in the blood, Lanciotti said.

But Lanciotti did not oppose developing Trioplex — as long as it was not distributed until its sensitivity was upgraded, CDC records show.

Lanciotti said he remained confident in the Zika test already in use, Singleplex.

His work with Zika and other viruses drew accolades from the CDC. On Feb. 16, 2016, the agency gave Lanciotti a “Director’s Recognition Award,” noting his “timely development of diagnostic tests that provided the first . . . evidence of a linkage between microcephaly and Zika virus.’’

By early that month, the testing had confirmed 50 cases of Zika infection among returned U.S. travelers, according to CDC documentation provided to the White House. President Barack Obama cited the cases in a letter on Feb. 22, 2016, when he asked Congress for a $1.9 billion emergency appropriation to counter Zika. Nearly half, $828 million, was intended for the CDC’s efforts.

At about the same time, the CDC began manufacturing the new Trioplex test kits in Atlanta.

In a briefing with reporters on March 10, 2016, CDC Director Frieden said the “new PCR test [Trioplex] will be particularly helpful” in combating Zika. The emergency funding, he said, “is crucially important and urgently needed.”

“The sooner we’re able to get a robust program up and running, the more we can reduce the risk to pregnant women,” Frieden said.

On March 17, 2016, the Food and Drug Administration, which regulates some disease tests, granted the CDC an emergency use authorization for Trioplex, signifying it "may be effective." The CDC then directed public health labs to use the test for Zika, records show.

Six days later, Frieden told a House appropriations subcommittee that the agency had already "produced more than half a million" Zika test kits. At least 13 states, he said, were at "high risk" of Zika being spread by the *Aedes aegypti* mosquito. In Puerto Rico alone, "we could see thousands of affected pregnancies," he said.

Missed infections

Health officials had another concern: that Zika could be transmitted through blood transfusions involving an infected donor.

Because of that, in early 2016, the nonprofit Blood Systems Research Institute began to assess the reliability of the Trioplex test. The work was performed under a long-standing contract with the National Institutes of Health.

The blood organization, based in San Francisco, quickly found trouble with Trioplex.

On April 13, 2016, Michael P. Busch, the institute's director, sent an email to a senior CDC official: Testing over the previous two months had generated "disturbing'' results. The data, Busch said, showed that Trioplex had missed 18 of 48, or 37.5 percent, of Zika infections it should have detected.

Trioplex appeared to be "less sensitive than . . . Lanciotti's assays," Busch wrote in the email to Lyle R. Petersen, a division director at the CDC, along with three other officials at both the CDC and the FDA.

Busch's email asked the officials "to support rapid publication" of the test data that his institute had analyzed.

One of the FDA officials, Jay Epstein, its director of blood research, responded to Busch on April 15: "I support publication," and "Re lower sensitivity . . . it seems to me that users need to shift to better assays."

"There was a lot of controversy over the accuracy of that [Trioplex] test and performance," Busch recently told The Post, adding that it reminded him of "the current situation with" the coronavirus.

A senior CDC official who was involved with the Zika response from the outset said the agency did not take "enough time to evaluate" Trioplex before distributing it.

"We made a bad decision with this Trioplex," said the official, who spoke on the condition of anonymity because they were not authorized to comment publicly. "We already knew how to diagnose for Zika virus. We already had the tests, which were developed in Rob Lanciotti's lab."

Lanciotti, meanwhile, was conducting his own studies in early 2016 on the reliability of Trioplex.

In mid-April, Lanciotti sent emails to a handful of senior CDC colleagues, reporting that analyses performed on patient samples in his lab found that "Trio misses 30-39% of the Zika positives."

One of the email recipients, Ronald M. Rosenberg, the CDC's associate director of vector-borne diseases, suggested informing the state labs.

"The simplest solution might be to convey this information to the states and let them decide" which test to use, Rosenberg wrote in an email on April 18 to Lanciotti and four other CDC scientists. "But whatever they decide . . . it might be unwise to abandon the singleplex."

As concerns mounted over the accuracy of Trioplex, its lead designer, Jorge L. Munoz, chief of the CDC's dengue virus lab in Puerto Rico, told colleagues he saw no deficit in sensitivity, records show.

Also on April 18, Frieden touted Trioplex to more than 1,500 health officials invited to a "Zika Action Plan Summit" at the agency's headquarters. Frieden said CDC scientists had "done a phenomenal job" developing Trioplex and the antibody tests. He again called for the emergency funding from Congress.

Two days later, Lanciotti voiced his growing concerns over Trioplex with Petersen, who had been detailed from Fort Collins to Atlanta to manage the CDC's response to Zika. Lanciotti said the state labs "that have validated and are using the singleplex should be encouraged to make no changes until they hear from us about the revised trioplex." Lanciotti also sent the email to 11 other senior CDC scientists.

Petersen did not respond to Lanciotti, according to documents gathered by a subsequent CDC review.

The next afternoon, on April 21, Lanciotti went a step further and emailed officials at 29 state labs that were using or had qualified to use Singleplex: "We want to inform you that in the Fort Collins laboratory we are continuing to use the Zika singleplex due to its greater relative sensitivity (that we have just established/become aware of through comparative analyses in several laboratories)."

Another senior CDC official, virologist Ann Powers, admonished Lanciotti for his email.

"While I certainly appreciate that you are wanting to make sure states are doing top quality testing, this email has created more trouble and confusion than it clarified," Powers wrote on April 25.

Two days later, CDC officials in Atlanta notified more than 100 public health labs that Trioplex was "recommended for use in the current Zika response."

The email made no mention of the Singleplex test or the data reflecting Trioplex's inferior sensitivity.

Some CDC officials had hoped that even if Trioplex failed to detect a Zika infection in pregnant women, those false negatives would be caught through later antibody tests.

But because of Zika's low viral load, that was not a reliable alternative: Antibodies in patients' blood typically are not seen during the first few days of infection and are never present in samples of urine or amniotic fluid. Of 13 patients with Zika that Trioplex had failed to detect, four were also missed by the antibody test, according to analyses done by Lanciotti's lab.

If those samples had not been subjected to the Singleplex test, "4 confirmed cases would have gone undetected,'' Lanciotti wrote in an April 28 email to CDC officials Petersen, Powers and Rosenberg. The scientists were usually based in Fort Collins, and Lanciotti reported to both Powers and her superiors, Rosenberg and Petersen.

In a reply to the group titled, "trioplex sensitivity," Rosenberg wrote: "Shouldn't CDC officially communicate this limitation to users?"

On May 2, Trioplex's sensitivity was discussed during a conference call involving Lanciotti, Powers, Munoz and Julie M. Villanueva, a senior CDC scientist put in charge of the new Zika Emergency Operations Center. Villanueva this year co-developed the CDC's test for the novel coronavirus, according to a scientific journal article she co-wrote.

Two days later, according to the CDC's subsequent review, "potential enhancements to the Trioplex'' were also discussed with Frieden during a "daily update call" that included Munoz. Frieden said he did not remember the call.

Munoz, Petersen, Rosenberg, Powers and Villanueva did not answer written questions from The Post.

“What bothered me the most was, we were telling our state public health lab partners to use a test that we weren’t fully convinced was ready for prime time,” Lanciotti recalled. “There was no question in my mind that we were going to be missing cases.”

Lab chief blows whistle

On May 17, 2016, Rosenberg informed Lanciotti that the agency was stripping him of his duties as lab chief, but Rosenberg relayed no reason for the demotion, according to Lanciotti.

Within days, Lanciotti filed a whistleblower complaint with the U.S. Office of Special Counsel. In his complaint, Lanciotti alleged that the CDC had endangered public health by withholding the data about Trioplex’s sensitivity. He spoke recently about the issue with the Project on Government Oversight.

On July 1, 2016, the special counsel’s office, which protects federal employees who reveal potential wrongdoing, determined there was a “substantial likelihood” that Lanciotti’s allegations were credible.

Special Counsel Carolyn N. Lerner contacted the CDC to recommend Lanciotti’s reinstatement as lab chief, according to people familiar with the matter. The CDC promptly restored Lanciotti’s title — but continued to exclude him from the agency’s response to Zika.

Lerner also referred Lanciotti’s allegations to then-Health and Human Services Secretary Sylvia M. Burwell for further investigation.

That type of referral typically would have been assigned to the HHS Inspector General, experts said. Instead, Burwell sent the matter to Frieden, who assigned it to the CDC’s associate director for laboratory science and safety, Stephan Monroe. His review, released on Sept. 2, concluded that Trioplex had posed no danger and that agency officials acted prudently.

Monroe’s review cited the favorable conclusion about sensitivity reached by Trioplex’s designer, Munoz, and described the available data for comparing the two tests as “inconclusive and contradictory.” His review also said, “It was reasonable to not share this information with external public health laboratories, as it did not provide any meaningful information for laboratories to act upon.”

Lerner, the special counsel whose initial investigation won Lanciotti’s reinstatement, closed her office’s file on the case in a letter to the White House on Sept. 27, concluding that Monroe’s findings “appear reasonable.”

A later Government Accountability Office report in May 2017 would find that Monroe’s review did not conduct “a comprehensive comparison of Trioplex and Singleplex.”

Monroe did not respond to written questions from The Post. Frieden, to whom Monroe had reported directly, said he viewed the report as an independent review. It established to his satisfaction, Frieden said, that the CDC acted correctly with Trioplex, including the decision to withhold the test data from the public health labs and other users.

“I think it’s very important in public health to share more rather than less,” Frieden said in an interview. “But that doesn’t necessarily mean that you share the results of evaluations that have not been done in a systematic way, that may not be accurate.”

President Trump speaks during a tour of the Centers for Disease Control and Prevention in Atlanta on March 6, flanked by Health and Human Services Secretary Alex Azar, left, CDC Director Robert Redfield, second from right, and Stephan Monroe, the CDC's associate director for laboratory science and safety. Monroe reviewed the CDC's handling of a test for the Zika virus and concluded in September 2016 that the agency had acted prudently and that "it was reasonable" not to share data with public health labs that raised questions about the test's accuracy. (Jim Watson/AFP/Getty Images)

At least seven state and local public labs defied the CDC's original directive and continued to use Singleplex, according to scientists familiar with the matter and CDC records. Among them were the central labs for the states of New York, Maryland, Florida, Massachusetts and New Jersey.

Burwell, now the president of American University, declined through a spokeswoman to be interviewed.

The CDC eventually tried to improve Trioplex's sensitivity.

On Sept. 21, 2016, the FDA approved a CDC-requested change to Trioplex, telling lab officials nationwide that they could try to boost its sensitivity by first extracting higher volumes of genetic material from samples of blood or urine. The samples would then be analyzed in the PCR machines.

But few of the labs had the specialized instruments necessary for the larger extractions, according to scientists familiar with the matter, including Busch, who had warned in April about Trioplex's sensitivity.

The CDC's modification of Trioplex, Busch said, "didn't really fix the problem."

Within days of the change to Trioplex, the CDC's request for emergency funding to counter Zika was granted: On Sept. 28, 2016, Congress passed a spending measure that included $1.1 billion of the $1.9 billion that Frieden had for months sought on the Obama administration's behalf. A total of $394 million wound up going to the CDC.

Meanwhile, in a dynamic that would be repeated this year with the coronavirus, many state lab officials privately fumed over the CDC's handling of Trioplex, afraid to speak out because their operations depended on funding from the agency.

But in an extraordinary plea on Oct. 14, 2016, the presidents of three organizations representing government and commercial scientists urged the CDC to release data that would illuminate Trioplex's "performance characteristics." The presidents, PhD scientists Susan E. Sharp, Charles E. Hill and Alexandra Valsamakis, represented the American Society for Microbiology, the Association for Molecular Pathology and the Pan American Society for Clinical Virology, respectively.

Their letter noted that "comparative studies of the Trioplex and Singleplex . . . suggest that Trioplex is significantly less sensitive than the Singleplex assay."

"The lack of access to all data regarding test performance of these assays prevents laboratory professionals from making informed decisions about which test to adopt or recommend. Access to these data would provide transparency and allow for optimal patient care."

On Jan. 12, 2017, 10 months after the rollout of Trioplex, the CDC informed users of the test that they could discard the non-Zika components of Trioplex. This essentially reduced Trioplex to the original Singleplex test.

In the end, Zika did not inflict widespread harm within the United States.

Reported Zika infections — mostly among returned travelers — totaled 5,168 in 2016 before declining to 452 in 2017, 74 in 2018 and just 22 last year, according to CDC records and interviews.

Lanciotti retired in December 2018, after 29 years with the CDC.

This story has been updated to include comment from HHS.

Alice Crites contributed to this report.

3) Mr. Armstrong – CDC uses report

C.6 Potential CDC Use Cases for Data:

1. Implementation and cancellation of community mitigation measures and its impact on case and fatality rates.
2. Impact of state limitations on close person-to-person contacts outside the household: comparing gathering density in 2019 and 2020.
3. The effect of large-scale anti-contagion policies on the COVID-19 pandemic
4. Analysis of bar and restaurant closure dataset compared to COVID-19 incidence and death rates.
5. Examination of volume of mobile phones grouped in proximity each month and compare 2019 to 2020 data to see the impact of these orders. Project how much worse things would have been without the bans.
6. Developing a clearer picture of IHE openings on mobility and COVID-19 case incidence, e.g. comparing areas with and without college campuses before and after re-openings.
7. Follow shifts in school decisions over time and its potential on student mobility and potential illness.
8. Track patterns of those visiting K-12 schools by the school and compare to 2019; compare with epi metrics if possible.
9. Hot spot detection - counties with more mobile residents more likely to be detected as hotspot counties
10. Prediction of hot spot counties due to influx of persons from nearby hot spots
11. Monitoring adherence to state-level policies to quarantine after arrival from another state
12. Examination of the effectiveness of public policy on Navajo nation.
13. Examination of COVID-19 vaccination rates, mobility, and incidence/seroprevalence/% positivity, etc. at the county or sub-county level (this could also be applied to flu and mask use).
14. Examination of the correlation of mobility patterns data and rise in COVID-19 cases:
    a. Schools (K-12) opening/closing/re-opening
    b. Shelter in Place Orders
    c. Social distancing measures (local/regional)
    d. Mass gatherings (Concerts, Games, Places of worship etc.)
    e. Public transit stations
    f. Major destinations (retail, grocery stores, parks etc.) correlated with COVID infection waves (2nd, 3rd, etc.)
    g. National Shelter Data for disasters
    h. Movement restrictions (Border closures, inter-regional and nigh curfews) and patterns
    i. Movement restrictions (Border closures, inter-regional and nigh curfews) to show compliance
15. Examination of mobility data for tracking school closures such as school bus routes and cell phone data around institutes of higher education around events like spring break.
    a. County, weekly number of visits to K to 12 schools as a dataset that could feed into other reports
    b. Compare with previous year as baseline
    c. Could help supplement the situation awareness data for K-12 and IHE
16. Assess movement in and out of counties during periods of natural disasters to assist with planning and distribution of COVID resources to evacuation areas
17. Research points of interest such as visits to pharmacies in a vaccine distribution plan or grocery stores
18. Exposure to place-based environmental exposures, like places with high air pollution and area-level incidence of pollution-related outcomes like asthma
19. Research points of interest for physical activity and chronic disease prevention such as visits to parks, gyms, or weight management businesses
20. Creation of user-defined queries and metrics of population mobility such as inferring mode of transport (e.g. walking, biking)
21. Exposure to certain building types, urban areas, and violence.

C.5 IT Security and Privacy Considerations:

A. Baseline Security Requirements

4) Dr. Ruiz – Letter from Miller Meeks on CDC reform

April 5, 2023

To all Interested Parties,

I write today seeking your insights and perspective to inform Congressional efforts to reform and improve upon the Centers for Disease Control and Prevention (CDC). As our nation's preeminent public health agency, my constituents expected more of CDC during the COVID-19 pandemic and were thoroughly disappointed.

In place of clear, reasonable guidance backed by the best scientific evidence available at the time, my constituents were faced with confusing inconsistencies at best, and clear political bias at worst. Politics aside, there is a near collective recognition that the CDC failed to execute its primary mission of "protect[ing] America from health, safety and security threats" by "conduct[ing] critical science and provid[ing] health information that protects our nation against expensive and dangerous health threats, and respond[ing] when these arise."[1] This included numerous core operational failures, as well as total lapses in reliable communication. The CDC's sprawling bureaucracy of siloed and uncoordinated administrative, academic, and disease, condition, or issue-specific programs was also put on full display. As a result, public trust and faith in our public health agencies and leaders has been decimated. To its credit, the CDC has also recognized the internal and external breakdowns and has started to begin down a path of reform through its own "Moving Forward" initiative.[2] Unfortunately, I am concerned this will be insufficient to remedy the concerns of my constituents and the healthcare community.

I am seeking specific guidance, feedback, and information from stakeholders in the public and private sectors on how best to reform, improve, and authorize the CDC and its programs to rebuild trust and ensure the agency is nimble in addressing public health threats. My goal is to ensure a productive discussion and examination regarding the inadequacies and failures of the CDC's response to the COVID-19 pandemic and to better prevent, prepare for, and respond to future public health threats. My hope is that will serve as an opportunity for robust, honest, and comprehensive reflection, discussion, and action.

I thank you in advance for your time and consideration in sharing your specific thoughts, expertise, and perspective on these issues. Responses are due April 23, 2023. Please submit responses to at CDC.Reform@mail.house.gov.
Most gratefully,

Mariannette Jane Miller-Meeks, M.D.
Member of Congress

5) Ranking Member Castor – Fact Check Article from USA Today

"Fact check: Missing context in claim about emails, Fauci's position on masks"

The claim: An email from Dr. Anthony Fauci proves he knew masks were ineffective at mitigating the spread of COVID-19

More than a month before the World Health Organization labeled the COVID-19 outbreak a global pandemic, Dr. Anthony Fauci received an email asking whether the writer should wear a face mask while traveling.

"Masks are really for infected people to prevent them from spreading infection to people who are not infected rather than protecting uninfected people from acquiring infection," Fauci wrote back in a Feb. 5 message. "The typical mask you buy in the drug store is not really effective in keeping out virus, which is small enough to pass through the material."

The country's leading infectious disease expert went on to say he would not recommend the writer wear a mask during travel to a "very low risk location."

Fauci's response was among thousands of pages of emails released to media outlets under the Freedom of Information Act. Buzzfeed News and The Washington Post used the emails to paint a picture about the early days of the pandemic response, but some of the messages also have spread rapidly as misinformation on social media platforms.

Fact check: False claims about Fauci email 'leak' mischaracterize FIOA requests and release

More: How Dr. Anthony Fauci's private comments in newly released emails stack up with what he said in public

Anthony Fauci Add Topic

For example, Fauci's response about masks has been held up as evidence that he knew early on that masks were ineffective. One commenter on a June 2 Instagram post wrote that Fauci "sat back and watched as we put face diapers on our children."

Different versions of the post have been shared thousands of times, but this line of thinking ignores the evolution of understanding about the effectiveness of masks and guidance about wearing them.

Responding to questions about the Feb. 5 email during a June 3 appearance on CNN, Fauci said his understanding changed as more information became available about asymptomatic transmission of the virus and the effectiveness of masks outside of hospitals.

“If we realized all of those things back then, of course, you’re asking the question would you have done something different if you knew what you know now, of course people would have done that. It’s so obvious,” he said on CNN.

The Instagram user who shared the post on June 2 did not respond to a request for comment.

Evolving guidance

Fauci and public health agencies have updated their guidance on masks and other mitigation measures as scientists learned more about how COVID-19 works and spreads.

Public officials initially discouraged masks over fears of shortages for health care providers.

Fact check: No, email to Fauci doesn't contain origin of a 'coronavirus bioweapon'

Then-U.S. Surgeon General Dr. Jerome Adams tweeted in all caps on Feb. 29, 2020, that people should “STOP BUYING MASKS!” He said in the since-deleted tweet that masks were ineffective and widespread use could lead to shortages.

Fauci said during a March 8 interview on "60 Minutes" that “there’s no reason to be walking around with a mask.”

But on April 3, 2020, the Centers for Disease Control and Prevention began urging people to wear masks in public. That was nearly a month after the WHO labeled the COVID-19 outbreak as a pandemic.

Fauci’s position changed, too. The same day the CDC released its new guidelines, Fauci said during an appearance on “Fox & Friends” people should wear masks when they can’t social

distance.

Since then, Fauci has explained his recommendation on masks changed as more information became available about the way COVID-19 spreads and the effectiveness of masks outside of hospitals.

The WHO changed its mask recommendation in June 2020. In July 2020 the CDC said, “cloth face coverings are a critical tool in the fight against COVID-19 that could reduce the spread of the disease, particularly when used universally within communities.”

Fact check: What's true and what's false about face masks?

In March, the CDC released new guidelines for people vaccinated against COVID-19. Those included guidance that vaccinated people could resume activities without wearing a mask.

Our ruling: Missingcontext

The claim that an email from Fauci proves he knew masks were ineffective at mitigating the spread of COVID-19 is MISSING CONTEXT, based on our research. Fauci sent the email on Feb. 5, 2020, more than a month before the World Health Organization declared COVID-19 a worldwide pandemic. The understanding about the effectiveness of masks and guidance about wearing them evolved during the pandemic, as did Fauci's position on their use.

Our fact-check sources:

The Washington Post, June 1, Anthony Fauci's pandemic emails: 'All is well despite some crazy people in this world'

Buzzfeed News, June 1, Anthony Fauci's Emails Reveal The Pressure That Fell On One Man

The Centers for Disease Control and Prevention, July 14, CDC calls on Americans to wear masks to prevent COVID-19 spread

The World Health Organization, June 5, WHO Director-General's opening remarks at the media briefing on COVID-19 - 5 June 2020

Forbes, Oct. 20, Is Trump Right That Fauci Discouraged Wearing Masks? Yes—But Early On And Not For Long

The New York Times, April 27, How Mask Guidelines Have Evolved

YouTube, March 8, 2020, Dr. Anthony Fauci talks with Dr. Jon LaPook about Covid-19 CNN, June 3, Berman reads Dr. Fauci some of his released emails. Hear his response

USA TODAY, Feb. 17, Fact check: Trump surgeon general initially dismissed mask-wearing, but then endorsed

The New York Times, April 3, 2020, A Debate Over Masks Uncovers Deep White House Divisions

The World Health Organization, March 11, 2020, WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020

Fox News, April 3, 2020, White House coronavirus task force to announce face covering guidance

The Washington Post, July 24, Fauci on how his thinking has evolved on masks, asymptomatic transmission

The Centers for Disease Control and Prevention, accessed June 3, When You've Been Fully Vaccinated How to Protect Yourself and Others

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