HOUSE COMMITTEE ON ENERGY AND COMMERCE: OVERSIGHT OF THE TRUMP ADMINISTRATION'S RESPONSE TO THE COVID-19 PANDEMIC

EXECUTIVE SUMMARY

vnne

Health Group

The House Committee on Energy and Commerce <u>convened</u> a hearing to discuss the federal government's response to the COVID-19 pandemic. Trump Administration officials from the National Institutes of Health (NIH), the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) testified about their agency's efforts to support COVID-19 response through guidance and guidelines, the development and distribution of diagnostic tests, therapeutics, and vaccines, and the procurement of personal protective equipment (PPE). Members of the Committee focused their questions on the recent spike in cases across the country and the need to continue diagnostic tests. Others questioned the vaccine availability timeline and the use of serology tests. Considerations for reopening schools, and PPE availability were also discussed.

OPENING STATEMENTS

In his <u>opening statement</u>, **Chairman Frank Pallone (D-NJ)** stated that had it not been for a "sluggish" response from the Administration, the country may have had a better outcome in combatting the COVID-19 pandemic. Chairman Pallone highlighted the disproportionate impact the virus has had on older Americans and communities of color and the failure to meet the necessary testing benchmarks to safely reopen the economy. He also emphasized the need to put science over politics to ensure that when a vaccine is available, it is safe, effective, and widely accessible. Chairman Pallone referenced the house-passed Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, which provided additional funding for contact tracing, and vaccine and treatment development, and strengthens the Strategic National Stockpile (SNS). Chairman Pallone urged his colleagues to use this hearing to assess what has gone, what is improving, and how the country better prepare for future pandemic.

Ranking Member Greg Walden (R-OR) asserted that the Administration has quickly adapted to the evolving challenges of the COVID-19 pandemic, during his opening remarks. Ranking Member Walden detailed that with little understanding of the virus and lack of data, the federal government has been able to deploy PPE, diagnostic tests, and therapeutics to areas of need through the Defense Production Act (DPA). He also referenced the collaborative public-private partnerships to increase the accessible of medical supplies. Ranking Member Walden concluded that America works best when it works together, and the government's response must adjust as we move forward.

WITNESS TESTIMONY

In his <u>testimony</u>, **CDC Director Dr. Robert Redfield** noted that as cases begin to rise again, the country's most powerful weapons are social distancing, facial coverings, and hand washing and he urged Americans to remain vigilant in protecting those who are most vulnerable. Director Redfield stated that the CDC is prioritizing racial disparities through the collection of data and the deployment personnel and rapid response teams. Additionally, Dr. Redfield detailed that \$12 billion has been distributed to state, local, and tribal governments, but sustained investment is necessary to modernize the public health infrastructure. He concluded that the CDC is looking ahead to flu season in the fall and is encouraging all Americans to embrace the flu vaccine.

Dr. Anthony Fauci, Director of the National Institute for Allergy and Infectious Diseases at the NIH, outlined the agency's four-prong approach to infectious diseases and COVID-19, in his <u>testimony</u>. Dr. Fauci detailed that the first prong is fundamental research about the virus, which is used help developed diagnostics and therapeutics. The second prong is diagnostics, which Dr. Fauci explained must be available at the point of care, simple, precise, sensitive, specific, in order to capture accurate diagnoses. He continued that the third prong is therapeutics, and he referenced the success of remdesivir in accelerating recovery from COVID-19. Finally, Dr. Fauci stated that the fourth prong, vaccines, is the most important aspect in combatting the virus. He detailed that a favorable vaccine candidate is entering phase three clinical trial in July and while development is happening rapidly, safety and efficacy are not being compromised. He concluded that he is "cautiously optimistic" that a vaccine will be available be the end of 2020 or beginning of 2021.

Admiral Brett Giroir, Assistant Secretary for Health at HHS, <u>testified</u> about the agency's efforts to expand testing capacity. Admiral Giroir detailed that the country is currently conducting 500,000 diagnostic tests per day and will have the capacity to perform 40 to 50 million test per day by the fall. He stated that the Department has established 41 drive through testing sites that have served as prototypes for states to follow and have leverage 611 pharmacies as community testing sites. Additionally, 93 percent of federal qualified health center (FQHCs) currently offer COVID-19 testing, according to Admiral Giroir. He also detailed that the Office of Minority Health awarded Morehouse School of Medicine \$40 million for the National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities.

In his <u>testimony</u>, FDA Commissioner Dr. Stephen Hahn detailed how the agency leveraged regulatory flexibility to increase access to diagnostics, therapeutics, medical devices, and other critical medical supplies. He detailed that the FDA has issued over 100 Emergency Use Authorizations (EUAs) for diagnostics and 50 guidance documents to ensure continuity of health care. Dr. Hahn emphasized the importance of prioritizing the safety of these products and how lessons learned have informed the FDA's actions as the pandemic progresses. He also referenced the importance of real-world data to inform real-time decisions and strategic priorities for the future.



MEMBER DISCUSSION

Diagnostic Tests

Chairman Pallone and **Rep. Diana DeGette (D-CO)** referenced President Trump's recent comments to slow to down testing so that the number of COVID-19 cases does not increase. Each asked the panel if they have been asked to slow down the testing. Dr. Fauci responded that the White House Task Force has not been asked to slow down testing and Dr. Redfield and Admiral Giroir added that their main priority is to increase testing capacity and contact tracing as reopening continues. Rep. DeGette then asked why cases are going up while deaths are going down. Dr. Fauci replied that deaths typically lag behind positive cases.

Rep. Ben Ray Luján (D-NM) referred to the lack of testing as the direct cause of economic suffering and asked how will testing capacity increase to 50 million per day by the fall. Admiral Giroir disagreed with the Congressman's sentiment by detailing the steady increase in testing capacity over time. He also asserted that testing capacity will reach 50 million by the fall because he has direct knowledge of the supply levels necessary to achieve that and believes they are on pace to achieve that.

When examining the FDA's role in authorizing diagnostic tests, **Rep. Scott Peters (D-CA)** referenced in the inaccuracy of some tests. Commissioner Hahn explained that test developers were granted the flexibility to validate their own tests to accelerate entry to the market, however, the agency has also reviewed and removed inaccurate tests. **Rep. Cathy McMorris Rodgers (R-WA)** asked if the regulatory flexibility to develop diagnostics would be made permanent. Dr. Hahn replied that while he hopes that this type of need for diagnostics is not needed in the future, he was supportive of the permanent flexibility provided to state laboratories.

Reopening the Economy

Many members referenced the recent spikes in cases in states like Florida and Texas. **Rep. Pete Olson** (**R-TX**) noted that many of these cases are occurring in the 20 to 39 year old demographic, due to their perceived invincibility to the virus and asked how to change the narrative around COVID-19 for this demographic. Dr. Fauci replied that he has never seen a virus with such a range of responses, from no symptoms to severe hospitalization, which has contributed to conflicting views of the pandemic. He continued that this has created confusion among younger people, but they need to know they have a dual responsibility to protect themselves from infection and protect others by not spreading the infection.

Rep. Kathy Castor (D-FL) expressed similar concern over the younger population and asked how should the states address the spike in cases. Dr. Fauci recommended that states adhere to the reopening guidelines and urged Americans to avoid large gatherings, and when large gatherings cannot be avoided to wear masks.

Rep. G.K. Butterfield (D-NC) and **Rep. Michael Burgess (R-TX)** asked what the Administration was doing to slow the spread in these states. Dr. Fauci noted that the increased cases are not just due to the increase in testing and states need to execute contact tracing to prevent the spread.



Vaccines

Rep. Fred Upton (R-MI) referenced recent estimates that nearly 100 million doses of a vaccine could be available by the end of the year and 1 billion doses by the end of next year, and asked Dr. Fauci how achievable these numbers were. Dr. Fauci stated that those estimates are accurate, and he wanted to emphasize the safety and efficacy are not being risk during the rapid development of this vaccine. He continued that the only thing at risk is financial, with vaccine manufacturing being invested in prior to complete safety and accuracy. He further explained that an unproven vaccine will not be distributed and that is why Operation Warp Speed is pursuing multiple vaccine candidates. Dr. Hahn also added that vaccine candidates not included in Operation Warp Speed will also be considered.

Rep. Rob Latta (R-OH) asked how will the vaccine be distributed. Dr. Redfield responded that the CDC is currently working on its distribution plan and it is dependent upon which vaccine is ultimately approved. Rep. Susan Brooks (R-IN) asked how will the Administration instill vaccine confidence for the American people. Dr. Fauci replied that messaging will focus on the safety and efficacy of the vaccine. Dr. Redfield added that the agency will deploy community outreach mechanisms and the CDC is working on developing a communication strategy.

COVID-19 Antibodies and Serology Tests

Rep. Latta asked the panel to further explain the role of COVID-19 antibodies and serology tests. Dr. Fauci explained that using an FDA approved serology test, COVID-19 antibodies can be detected in recovered individuals. However, he noted that the Administration is still in the process in understanding the type of antibody the infection creates, the duration of the antibodies, and to what extent, if any, antibodies provide protection for reinfection.

Rep. Adam Kinzinger (**R-IL**) asked how the Administration is currently using serology tests. Dr. Redfield responded that due to the unknowns around antibodies, the tests are being used as a surveillance measure. **Rep. Richard Hudson** (**R-NC**) referenced how many serology tests have been inaccurate and asked how do we ensure only high performing tests make it to the market. Commissioner Hahn detailed that the FDA has partnered with the NIH to independently validate serology tests, and inaccurate tests have been removed.

Personal Protective Equipment

Rep. Michael Doyle (D-PA) and **Rep. David Loebsack (D-IA)** asked if there is enough PPE currently available for health care professionals and frontline workers. Admiral Giroir stated that there is no current shortage of PPE and the Administration is currently working on a SNS 2.0, which would store enough PPE for a 60 to 90 supply for a potential fall outbreak. Rep. Doyle then asked how ineffective PPE in the market was addressed. Dr. Hahn noted that companies were provided regulatory flexibility to produce PPE, but the FDA partnered with the CDC to test and verify PPE efficacy. He concluded that ineffective PPE from China was removed from the market for these reasons.



Reopening Schools

Rep. Brett Guthrie (R-KY) and **Rep. Morgan Griffith (R-VA)** asked how would children be able to return to school in the fall. Dr. Redfield stated that the CDC will issue guidelines in the coming weeks on how to safely reopen schools. Dr. Fauci added that reopening primary schools should be a decision made at the jurisdiction level due to the different regional impacts of the virus. **Rep. Tim Walberg (R-MI)** asked what considerations should institutions of higher education make when reopening. Dr. Fauci again reiterated that the school should consider the virus impact on the state before reopening. He also suggested that students wear masks at all times and allow vulnerable faculty the option to teach online.

