SENATE HELP: COVID-19: AN UPDATE ON THE FEDERAL RESPONSE

EXECUTIVE SUMMARY

The Senate Health, Education, Labor & Pensions (HELP) Committee convened a hearing to examine the Trump Administration's COVID-19 response efforts. Top officials from the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services (HHS), and the Food and Drug Administration (FDA) testified about the separate agencies' efforts to develop medical countermeasures such as diagnostics, therapeutics, and vaccines. Many senators focused their questioning on the vaccine development process, while others emphasized the need to ensure that the scientific process remains free of political interference. Additionally, a few senators expressed concern that if the Affordable Care Act (ACA) was struck down, COVID-19 could become a preexisting condition that would preclude Americans from healthcare coverage.

OPENING STATEMENTS

In his opening statement, **Committee Chairman Lamar Alexander (R-TN)** spoke about the significant process the United States has made in delivering diagnostics, therapeutics, and vaccines to the American people to combat the COVID-19 pandemic. Regarding vaccines, Chairman Alexander commended the speed in which the vaccine development process accomplished due to the ability to manufacturer and determine safety and efficacy in parallel. He emphasized that the only risk being taken is financial, and not the safety and efficacy. Chairman Alexander expressed optimism that 300 million doses of a vaccine could be delivered to the American people by March 2021. He also stressed the importance of the FDA review process in instilling confidence in the American people. Chairman Alexander then spoke about the new therapeutics and diagnostics that have emerged because of the pandemic, including remdesivir and the Abbott BinaxNOW rapid point-of-care test. He concluded by urging Congress to be visionary and prepare for the next pandemic by supporting onshore manufacturing and the Strategic National Stockpile (SNS).

Ranking Member Patty Murray (D-WA) began her opening remarks by recounting the ways in which the Trump Administration has "fumbled" the COVID-19 response, including delays in diagnostics and the spreading of misinformation about seriousness of the virus. She then detailed the ways in which President Trump has imposed political interference upon scientific processes, such as the emergency use authorization (EUA) of hydroxychloroquine and convalescent plasma, and the withholding of CDC guidance from publication. She noted that each witness today plays an important role in upholding the scientific integrity of the COVID-19 response and spoke about her bill, the Science and Transparency Over Politics (STOP) Act, which would increase oversight over HHS decision-making related to the COVID-19 pandemic.

WITNESS TESTIMONY

National Institutes of Allergies and Infectious Diseases (NIAID) Director Dr. Anthony Fauci testified about the role of the NIH in addressing COVID-19 through its four-part strategic plan, which includes understanding the virus and advancing diagnostics, therapeutics, and vaccines. Regarding understanding the virus, Dr. Fauci detailed that there is new evidence about the long-lasting impact the virus may have on heart. He also addressed how the NIH has supported the development of new diagnostics and therapeutics, specifically new technologies for rapid point-of-care testing and therapeutics such as monoclonal antibodies, which is currently conducting clinical trials. Dr. Fauci then provided an update on the vaccine development process and expressed optimism that a safe and effective vaccine could be possibly approved by the end of the year. He felt strongly that if the country moves forward with a combination of public health measures and vaccines that we would be able to turn around the pandemic.

In his testimony, **CDC Director Dr. Robert Redfield** spoke about the agency's role in bring scientific evidence and expertise to the frontline of the pandemic. Dr. Redfield noted that since the peak of the pandemic COVID-19 cases have decreased 50 percent and deaths have decreased 32 percent. He warned that without the American people continuing public health measures such as wearing a mask, or hand washing, this progress could be erased. He also emphasized the importance of individuals receiving the seasonal flu vaccine this year and referenced how the CDC purchased additional doses to support this effort. To support vaccine efforts, Dr. Redfield noted that $200 million has been deployed to assist states in developing distribution plans in accordance with the recently released playbook. The CDC is also working with states on developing flexible plans for distribution that utilize the existing infrastructure.

Assistant Secretary for Health Admiral Brett Giroir detailed recent efforts to increase COVID-19 diagnostic testing capacity in his testimony. Admiral Giroir emphasized how smart testing coupled with smart public health has led to significant decreases in COVID cases, hospitalization, and deaths. He detailed that to-date the United States has conducted 106 million tests, with capacity expected to reach 3 million tests per day, most of which will be rapid of point-of-care. Admiral Giroir also referenced recent efforts to increase testing in nursing homes, which includes the deployment of testing instruments and the accompanying supplies to every nursing home. He concluded that the recent contract with Abbott for 150 million tests will be used to increase testing at sites like schools, nursing homes, assisted living facilities, and to the Indian Health Service.

In his testimony, **FDA Commissioner Dr. Stephen Hahn** emphasized that all decisions made within the agency are driven by science and free from political interference. He then detailed the process in which a COVID-19 vaccine would be authorized or licensed. Dr. Hahn explained that once the vaccine sponsor determines that there is sufficient evidence for safety and efficacy, they will decide whether to pursue EUA or licensure. He noted that prior to application submission data will be reviewed by an independent committee to be determine if the threshold that was predetermined in the FDA guidance was met. After this, career scientists at the FDA will consider all the data and confer with the vaccine advisory committee to come to a final decision. He concluded by emphasizing that a vaccine will not be approved before it meets all standards and all decisions will be made be career scientists who will put the safety of Americans first.

MEMBER DISCUSSION

COVID-19 Vaccine Safety and Efficacy

Chairman Alexander asked Dr. Hahn who at the FDA is responsible for making the decisions related the safety and efficacy of vaccines. Dr. Hahn replied that career scientists are solely responsible for the decision to approve vaccine candidates and he is only briefed on the decision. Chairman Alexander then asked if the Administration was cutting corners on safety and efficacy to which Dr. Hahn responded that the rapidity is only the result of financial risk and not a safety risk. Dr. Hahn also committed to receiving a vaccine once one was available. **Sen. Bob Casey (D-PA)** asked the other members of the panel if they would be willing to receive a COVID-19 vaccine and they all replied that they were willing.

Sen. Richard Burr (R-NC) asked if new approval standards were being applied for the COVID-19 vaccine or would the normal FDA standards be used. Dr. Hahn noted that the FDA approval process is the "gold-standard" for the world and the agency intends on using the same rigorous standard for a COVID-19 vaccine. Sen. Burr also asked whether the COVID-19 clinical trials are among the most expansive trials in history. Dr. Hahn agreed that the COVID-19 vaccine clinical trials represent some of the most diverse and expansive trials and should yield the data necessary to determine safety and efficacy. He also added that the Data Safety Monitoring Board (DSMB) adds an extra layer of oversight to the data review process.

Sen. Mitt Romney (R-UT) asked how long it would take the FDA to review and approve a vaccine candidate. Dr. Hahn detailed that the process could take weeks or months, but typically depends on the amount data. He also acknowledged the urgency of the situation and stated that the agency will not delay its decision.

COVID-19 Vaccine Distribution and Prioritization

Sen. Mike Enzi (R-WY) referenced how some of the vaccine candidates require extremely cold storage and how rural areas do not have the capacity to store the vaccines. He then asked how these supply chain issues would be addressed. Dr. Redfield replied that the CDC is working with states to ensure that each jurisdiction is equipped to distribute the vaccines equitably and fairly. He also noted that the CDC is collaborating with states to identify other gaps and strategies to address the gaps so that states are prepared when a vaccine is approved. Sen. Enzi followed up by asking if the plans being developed now will be sufficient or would modifications be needed once a vaccine is approved. Dr. Redfield was optimistic that the plans currently under development would achieve 95 percent of the needed planning.

Sen. Romney asked how many people will be vaccinated in the two months following FDA approval or authorization of a vaccine. Dr. Fauci detailed that production will be a rolling process and by April the United States will have a total of 700 million doses. He continued to explain that in November and December, vaccines will be distributed to a small portion of the population and likely to targeted groups, such as healthcare workers and vulnerable individuals. **Sen. Lisa Murkowski (R-AK)** similarly asked how distribution and prioritization would be decided for the initial doses of vaccine. Dr. Redfield detailed that Operation Warp Speed (OWS) would decide the distribution, but the Advisory Committee on Immunization Practices (ACIP) would provide recommendations on prioritization for OWS to use. Dr. Redfield also added that the ACIP recommendations would be made after a vaccine candidate is approved and a separate recommendations will be made for each approved candidate.

Sen. Tina Smith (D-MN) referenced Dr. Redfield's recent testimony in which he estimated that vaccines will be distributed by quarter 2 or quarter 3 of 2021 and asked if he still stood by this timeline. He reiterated that 700 million doses should be available by April 2021 and it may take several months to vaccinate the remaining population that was not initially prioritized. Sen. Smith then asked if diagnostics would be important after vaccines were available. Dr. Fauci responded that diagnostics will still be important in identify infected people because not everyone will receive a vaccine.

Agency Independence

Many senators expressed concern that the federal agencies are subject to political interference and sought reassurance from the panel that COVID-19 decisions will be made solely based on science. Ranking Member Murray referenced the recently rescinded CDC guidance that recommends against asymptomatic testing and asked why the guidance was issued if it contradicted scientific opinion. Dr. Redfield emphasized that the guidance was misinterpreted, and more testing would lead to less cases. He further explained that the goal was to link testing to a public health action such as seeing a physician or quarantining.

Sen. Susan Collins (R-ME) stressed the importance of Americans needing confidence that all agencies will abide by scientific integrity and ask how Secretary Azar's recent decision to approve all rules would impact COVID response efforts. Admiral Giroir responded that the decision was to ensure that there is an extra level of oversight for these important decisions. Sen. Collins expressed concern that this decision would result in delays for important COVID-19 medical countermeasures.

Sen. Doug Jones (D-AL) mentioned recent reports of a deep state within the FDA that is attempting to limit access to medical countermeasures and asked Dr. Hahn about the validity of this statement. Dr. Hahn replied that he has the utmost confidence in all FDA employees and emphasized that the agency is doing all it can to provide access to safe and effective therapeutics and vaccines for Americans.

Long-Term Effect of COVID-19

Sen. Chris Murphy (D-CT) referenced recent studies that reveal the long-term effect COVID-19 has on some individuals and asked Dr. Fauci to further explain. Dr. Fauci detailed that two studies, one among athletes and one among mostly asymptomatic individuals, reveal that recovered individuals exhibit some level of heart inflammation despite the severity of the infection. He noted that this condition could eventually lead to arrhythmias or cardiomyopathies. Sens. Murphy, Casey, and Murray all expressed concern that COVID-19 could eventually become a preexisting condition, which could leave individuals without insurance if the ACA was struck down.