SENATE HELP COMMITTEE: HOW THE U.S. IS RESPONDING TO THE NOVEL CORONAVIRUS

EXECUTIVE SUMMARY

The Senate Committee on Health, Education, Labor and Pensions (HELP) convened a hearing titled, "An Emerging Disease Threat: How the U.S. is Responding to COVID-19, the Novel Coronavirus." Top administrative officials from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), and the Department of Health and Human Services Assistant Secretary for Preparedness and Response appeared and testified to the government response.

OPENING STATEMENTS

In his opening statement, **Committee Chairman Lamar Alexander (R-TN)** said his one goal for the hearing is accurate information – accurate information to help the American people and Congress decide what they should be doing about the coronavirus. He recounted the status of the spread of the disease in the U.S., noting that there are about 100 confirmed cases and have been six deaths so far. Chairman Alexander also reviewed the funding mechanisms that Congress has at its disposal to address the outbreak, and the steps taken by the government so far, including travel advisories and quarantine requirements and the development of a diagnostic tests and vaccines.

Ranking Member Patty Murray (D-WA) noted in her opening remarks that the six deaths that have occurred in the U.S. so far are in her home state of Washington, where diagnostic testing has not been scaled up quickly enough and frustration has been expressed with the Trump Administration's response. Sen. Murray said she will stay focused on ensuring that the response is based on evidence and public health expertise and is free from political consideration. She urged the Senate to quickly pass the supplemental funding package for coronavirus response as soon as the House does, and stressed the importance of protecting health care workers and the supply of drugs and medical devices. She added that Congress needs to confront the ways in which the undermining of the Affordable Care Act (ACA) will impact the spread of the disease, as the uninsured rate is on the rise and "junk plans" cover fewer benefits.

WITNESS TESTIMONY

CDC Principal Deputy Director, Dr. Anne Schuchat, testified to the CDC's role in the government response. She said the agency's number one goal has been to slow the spread of the virus through "a multilayered aggressive containment and mitigation effort." This has included early case recognition, isolation, contact tracing, travel advisories, and the funneling of flights from Hubei province and other areas

to certain U.S. airports where CDC has supported the quarantine of repatriated American citizens. Dr. Schuchat said that the immediate risk to general public remains low, but that CDC officials are on the ground in certain regions of the country where community spread has begun, including Washington and California. She also noted the importance of CDC's role in informing the public, and encouraged publiuc use of the information on their website.

Dr. Anthony Fauci is the Director of the NIH's National Institute of Allergy and Infectious Diseases (NIAID). He has held his position as Chief of Infectious Diseases at the NIH since the Reagan Administration. Dr. Fauci said that the NIH's role in the all-government response to the emerging outbreak is in the realm of interventions – namely, therapy and treatment of people who are infected; and vaccines or prevention for those who are not infected. In regards to therapy, Dr. Fauci noted that up to 80 percent of infected persons will not need any interventions or treatment. But between 15 and 20 percent may require supportive care including oxygen, intensive care, intubation, or "more dramatic interventions." He said NIH-sponsored randomized control trials are underway now to test a therapy developed by Gilead, and they will know within a matter of months whether it is effective. Implementation of the drug if it is effective would be almost immediate, he said. However, on the vaccine side, Dr. Fauci warned that the process to deploy an effective vaccine could take more like a year because of the more complex phases of trials and ethical considerations for preventive vaccines. This is despite the record-breaking speed with which current vaccine candidates have been brought forward for testing. For both types of interventions, he stressed that there are no guarantees.

Dr. Robert Kadlec is the Assistant Secretary for Preparedness and Response (ASPR). Chairman Alexander noted that he has previous experience assisting the Federal Bureau of Investigations (FBI) and the U.S. Air Force on biological threats. Dr. Kadlec testified on how ASPR is supporting the response with a four-pronged approach: (1) incident management; (2) direct support to states and other entities; (3) supporting the health care system; and (4) medical countermeasure development. Regarding medical countermeasures, he said the agency is working closely with the NIH to focus on point of care diagnostics, as well as promising vaccine candidates from Sanofi S.A. and Janssen Pharmaceutica. He said ASPR is looking at ways to leverage the Hospital Preparedness Program to support the health care system, and added that incident management is coordinated with FEMA. Direct support to states has included with assistance with the repatriation of American travelers, and has included deployments of protective equipment from the Strategic National Stockpile as well as staff to Washington State.

FDA Commissioner Dr. Stephen Hahn testified regarding the FDA's activities to monitor the drug supply chain to resolve any shortages resulting from impacted manufacturing capacities in China. Dr. Hahn shared a recent announcement from India that they have restricted the export of 26 active pharmaceutical ingredients in response to the outbreak, and that the FDA is working to assess the impact and will be as transparent as possible with the public. He noted that the FDA does not have the authority to request supply chain information from device companies, but has been in touch with 63 companies who, like drug manufacturers, have been open and forthcoming in response. They are not aware of any device shortages, but acknowledge pressure on the supply of face masks and gowns. Regarding diagnostic tests, the FDA has quickly facilitated the approval and use of diagnostic tests across the country, including those under development in academic labs.

MEMBER DISCUSSION

Basic Information for the Public

Chairman Alexander began the discussion with a series of questions for Dr. Fauci regarding what people should look for in terms of symptoms and what measures they should take. Among the information he conveyed, he shared that COVID-19 is typically characterized by a lower respiratory infection in the lungs rather than the upper respiratory symptoms (sore throat, congested sinuses) seen at the outset of the common flu. He confirmed that the general public should not be concerned with wearing masks in public right now, as they are ineffective and unnecessary; however, health care workers working with known cases of infection should. He said the mean age of known cases is 50 years old, with those over 80 at highest risk, and confirmed very few children have been impacted. Dr. Fauci said the most effective thing the public can do to protect themselves is washing their hands, staying away from sick people, and staying home themselves if they are symptomatic. If they experience severe symptoms, they should contact their health care provider because it may be the common flu which can be helped with approved treatments. Dr. Schuchat also clarified the meaning of "community spread" to mean that a person has been identified as infected but the source is unknown – in other words, they did not travel to an infection region, nor can they be linked to a specific infected person from whom they contracted the virus "person-to-person."

Diagnostic Testing

Sen. Doug Jones (D-AL) asked what capacity the government has to test for COVID-19 right now and how it will be scaled up. Dr. Schuchat acknowledged that the initial tests provided to state public health labs by the CDC were ineffective, but confirmed that by the end of this week those labs should be equipped with new CDC tests. She noted however that state public health labs play a tiny role in flu testing each year, and pointed to the much larger role played by clinical labs. Getting those testing at full capacity, is more of an FDA and Biomedical Advanced Research and Development Authority (BARDA) issue, she said. Dr. Hahn said that by the end of the week, kits should be available to public health labs to perform about one million tests.

Sen. Richard Burr (R-NC) asked how testing could have been so delayed in Washington state when almost six weeks had passed since the beginnings of the virus in China. Dr. Schuchat defended the speed with which CDC developed a new PCR test for a brand new virus and disseminated it to states. She stated again that the responsibility to equip clinical labs lies with BARDA. **Ranking Member Murray** requested further clarification on how the delays occurred at the Department, and asked how they can be sure that they can truly provide up to one million tests per week. Dr. Hahn clarified that the private companies they are working with have the capacity to develop 2500 test kits by the end of this week, each containing 500 tests, equaling 1.25 million in total.

Paid Sick Leave and Access to Care

Ranking Member Murray expressed deep concern for the ability of low wage workers and people without paid sick leave to follow CDC guidance and stay home from work if they are sick. She asked whether Congress should act to provide a short-term solution allowing for such accommodations for workers – Dr. Schuchat agreed that will be a necessary intervention.

Sen. Bill Cassidy (R-LA) raised concern about the potentially high cost for antiviral drugs under development, particularly how those might be paid for in capitated Medicare Advantage plans, and asked whether Congress needs to enact a carveout. Dr. Hahn said that it is leveraging its authority to assist in the development of such drugs, but defers payment matters to CMS. Sen. Cassidy, **Sen. Jacky Rosen (D-NV)** and Dr. Kadlec each separately endorsed the idea that telehealth capabilities, use authority, and reimbursement need to be bolstered in response to the virus, particularly in rural areas.

Safety for Public Health Staff and Health Care Workers

Ranking Member Murray also raised alarm at reports that HHS did not properly train or protect public health staff deployed to work with repatriated Americans, and were themselves not quarantined or tested and were allowed to return to work, in some cases taking commercial airline flights. Dr. Kadlec acknowledged that what she described was a breech of protocol in regard to that particular mission. **Sen. Bob Casey (D-PA)** asked the witnesses specifically to address safety for workers and the elderly in long-term care settings, like the facility in Washington state where most of the deaths have occurred. Dr. Schuchat shared that the CDC has issued guidance documents and has been doing outreach to clinicians and health systems. She noted that Seema Verma and CMS have been integral in reaching this community. Dr. Kadlec added that it is not just long-term care and nursing facilities that they need to worry about, but potential dialysis clinics, cancer clinics and other areas where people are immunologically at risk.

Pharmaceutical and Equipment Supply Chain

Sen. Cassidy asked whether any of the 26 ingredients that India will restrict are necessary for the coronavirus vaccines or therapies under development. Dr. Hahn said the agency is still evaluating the list. Sen. Cassidy then referenced a recommendation from a drug shortage report release last year that would establish a quality supply chain rating system. He asked Dr. Hahn whether Congress should move to enact this recommendation quickly in light of the potential for critical drugs or ingredients to be delayed or interdicted because of the outbreak. Similarly, **Sen. Chris Murphy (D-CT)** asked whether the FDA would benefit from a new requirement that manufacturers alert the FDA ahead of time when they see a shortage coming, rather than the FDA needing to request it. Dr. Hahn confirmed that the FDA included several proposals to this effect in the FY 2021 Budget Request. Chairman Alexander suggested that the National Academies of Medicine should produce a report on the extent to which the U.S. relies on other countries and sole sources of supply for critical drugs.

Sen. Mitt Romney (R-UT) asked for clarification regarding what percent of supplies like masks and gowns that would be needed in a more severe outbreak are currently available in the Strategic National Stockpile. Dr. Kadlec shared that this figure is only 10 percent, specifically in regards to N95 respirators (masks). Sen. Romney added that this is a failure of appropriations by Congress and not the Administration.

Vaccine Development

Sen. Romney asked how long the mass *production* of a vaccine will take if and when they clear the necessary trial phases, and who would be responsible for this. Dr. Fauci confirmed that the U.S. government alone could not accomplish it and will need a public-private partnership with a manufacturer. Sen Romney underscored that Congress should consider making an investment in this area.