Chairman Lamar Alexander – Opening Statement
COVID-19: An Update on the Federal Response
U.S. Senate HELP Committee – Wednesday, September 23, 2020

Introduction

This is likely the final health hearing during my six years as chairman of this committee.

Last week at our hearing I thanked Senator Murray for her friendship, diligence and cooperation, without which our Committee would not have accomplished so much during those years.

This week I would like also to thank the most senior Republican member, Sen. Enzi, and the 20 other senators on the committee, both Democrats and Republicans.

Senator Ted Kennedy used to say that our Committee had the broadest jurisdiction of any committee.

You only have to look around the room to see that we also have the broadest range of views of any Senate committee as well as some of the ablest advocates of those views. But thanks to the Committee members, as well as Senator Murray, most of our hearings have been bipartisan, in that we were able to agree to hear witnesses from a variety of views.

And while the questioning and statements of senators have been probing, there has always been a high level of courtesy demonstrated to our witnesses and to each other.

I believe that this ability to work well together during a rancorous time has been a major reason we have accomplished so much.

The work of the members of this Committee has reflected my view that it's hard to get here, hard to stay here and while you're here you might as well try to accomplish something good for the country—which we have on numerous occasions.

Opening Statement

The Trump Administration's program to develop and deploy a vaccine that will protect against COVID-19 is on track to be an unprecedented sprint to success. The program, called Operation Warp Speed, will save lives without cutting corners on safety and efficacy.

The COVID-19 vaccine development process is likely to produce its first tens of millions of doses within one year. The United States has never developed a vaccine this fast before.

When I was a child, I saw classmates in iron lungs while we waited 10 years for a polio vaccine. Many existing vaccines for other diseases like measles and chickenpox, typically took about 10 years to develop.

The secret to this success is that the government – in partnership with private industry – is for the first time developing and manufacturing a vaccine in parallel.

In other words, the Operation Warp Speed plan is to manufacture tens of millions of doses of the six vaccine candidates at the same time the clinical trials are ongoing and the Food and Drug Administration (FDA) works to determine whether they are safe and effective.

If the FDA does not approve the vaccine, it will not be distributed. So the risk is taxpayer money, not the safety and efficacy of the vaccines.

The administration has set a stretch goal that once seemed impossible but now seems likely. The administration hopes to have as many as 300 million doses of vaccines available to be deployed by mid-2021, according to an August 26 article by the "Operation Warp Speed" program's principal adviser, Dr. Moncef Slaoui, and vaccine expert Dr. Matthew Hepburn, in the New England Journal of Medicine.

"No scientific enterprise could guarantee success by January 2021," the article's authors wrote, "but the strategic decisions and choices we've made, the support the government has provided, and the accomplishments to date make us optimistic that we will succeed in this unprecedented endeavor."

Mr. Paul Mango, with the Department of Health and Human Services, recently said in a meeting that, if all goes well, it is possible that up to 700 million doses will have been manufactured by April of 2021.

The Department of Health and Human Services, Department of Defense, private sector, and public health and medical professionals are already working together to lay the groundwork for deciding who gets the first doses – such as health care workers, and certain high-risk populations– and how to get those doses to those individuals.

The Centers for Disease Control and Prevention (CDC) has asked states to submit their plans by the middle of October this year to be ready to begin distribution.

Vaccines: There has been much back and forth about on exactly which date the first vaccine doses—which, remember, are already being manufactured and made ready for distribution—will be available.

The answer of course is that the only people who know when a vaccine will be ready are the scientists at FDA who will review the science and clinical trial data and determine whether the vaccine is safe and that it works.

Even Dr. Stephen Hahn, the FDA Commissioner, who is testifying today, does not now know when that date will be because FDA will not approve a vaccine until three things happen:

1. Independent experts overseeing clinical trials determine there is enough data available for FDA to review

2. After demonstrating safety and efficacy based on clinical trials, the vaccine manufacturer submits an application to FDA
3. FDA experts conduct their review and make the final determination that it is safe and that it works.

Treatments: The second unprecedented story of the United States' response to COVID-19 is the development of treatments. There are five products authorized for emergency use today to help treat and manage COVID-19 symptoms, including remdesivir, certain steroids, a blood thinner, and convalescent plasma.

Operation Warp Speed officials are optimistic that more treatments will also be identified or developed and in clinics this fall, with potential for approval or authorization by the end of the year. The most promising appear to be monoclonal antibody cocktails, which have also been used to prevent and treat other diseases, like Ebola. Three companies are in clinical trials of antibody cocktails.

Knowing that there is some medicine that will help treat COVID-19 should greatly relieve the anxiety Americans feel about going back to school, college, work, and out to eat.

Tests: A third success story is the explosion of fast, cheap, reliable diagnostic tests. After initial missteps, our country lost several crucial weeks in distributing the diagnostic tests that would help to identify and isolate those who contracted the virus.

But since then, an unprecedented effort of public and private research has created capacity this month for administering more than 90 million tests, about half of them rapid tests, according to Admiral Giroir, one of our witnesses today.

Abbott Laboratories says that it is on track to produce 50 million of its new tests a month by October, which can produce a result in 15 minutes and costs $5 per test. The government has purchased 150 million of Abbott's tests to help expand testing in places like schools and nursing homes.

Congress funded the so-called "shark tank", or Rapid Acceleration of Diagnostics (RADx) initiative at NIH, with the objective of developing and deploying tens of millions of new, reliable, inexpensive rapid tests.

Dr. Francis Collins, Director of the NIH, has reported that combined, these new technologies have the potential to add to the country's testing capacity by at least 60 million tests a month by December. Dr. Collins has told me: "this is not the end of the story—there are lots of additional technologies coming through the pipeline, many of which are rapid, inexpensive, point-of-care and home-based tests."

Until vaccines and treatments are widely distributed, the explosion of many cheap, reliable, rapid diagnostic tests is our best weapon to build confidence among the American people that it is safe to go back to school, college, back to child care, and back to work.

There should be plenty of tests—in fact, there are now—to do surveillance testing of those without symptoms in certain settings, like colleges and child care centers.

It is important to give credit to this Congress and President Trump for funding an unprecedented effort to develop and manufacture vaccines before they are approved, knowing full well that one or all of them might fail with a considerable loss of money.

Since March, Congress has appropriated more than $47 billion for tests, treatments, and vaccines, a large amount that pales in size to the $3 trillion spent to try to ease the pain caused when the government closed businesses, schools, and the economy to try to contain the virus.

And it is important to give credit to the previous presidents and previous Congresses for the bipartisan work they have done over the last 20 years to make possible these remarkable successes in developing and manufacturing vaccines, treatments, and diagnostic tests.

Dr. Slaoui told me that the government could not be manufacturing four of the vaccines that are currently being developed if Congress had not provided HHS with funding to make awards in 2012 to build three manufacturing plants that would be on standby for the next epidemic. The decision to look ahead then to the next pandemic he said was "visionary."

Good Preparation

On March 1, the *New York Times* said, "the United States is among the countries best prepared to prevent or manage such an epidemic."

Why did the *New York Times* say that?

NIH: For five consecutive years Congress has significantly increased investment in research at the National Institutes of Health and in training emerging infectious disease researchers.

NIH's Infectious Diseases Clinical Research Consortium, which was established in 2019, was able rapidly to shift ongoing clinical trials and quickly enroll volunteers for COVID-19 vaccine and treatment clinical trials.

FDA: Congress provided FDA with specific authorities beginning in 2004 to review and issue emergency use authorizations for tests, treatments, and vaccines to respond to a public health emergency.

FDA has used its emergency use authority to authorize 250 tests and 5 treatments as quickly as possible, and also to remove tests or treatments when additional evidence showed they did not work as well as they should.

BARDA: Congress established the Biomedical Advanced Research and Development Authority in 2006 to help companies work with FDA to get safe and effective tests, treatments, and vaccines to people during emergencies.

BARDA was able to announce awards for potential COVID-19 treatment and vaccine candidates just over one month after the virus was first reported in China.

Four of the six vaccines currently being manufactured are being made at manufacturing facilities built in 2012 for this purpose – for a future pandemic.

Federal support for state, local, and hospital preparedness: HHS spent $21 billion between 2002 and 2017 to help state and local health departments and hospitals prepare for and respond to public health emergencies.

CDC has used existing programs to help states maintain a trained workforce, expand laboratory capacity, and improve surveillance systems.

CDC also used planning for a flu pandemic, and lessons learned from the H1N1 response, to inform the COVID-19 response.

Supercomputing: Congress has increased funding for the Department of Energy Office of Science, which funds our 17 national laboratories, by 38% and increased funding for supercomputing by 60% over the last 5 years. Supercomputers at 7 national laboratories are being used to help develop treatments and vaccines, and 3-D printing is being used to make medical supplies.

All of this is what the last several congresses and presidents have done to help be prepared for this pandemic.

Conclusion

I would like for this Congress to be visionary as well and, while we are in the midst of this pandemic, do what we need to do to prepare for the next one.

Former Senator Frist testified before this committee that the next pandemic is not a question of if, but when.

Jared Diamond, the author of *Guns, Germs, and Steel*, says that it's the jet plane that makes COVID-19 unique because it can spread so rapidly.

Congress should take stock now, while our attention is on the current crisis, of what we've learned during COVID-19 and address some of the problems we know we can solve.

Many of the witnesses that have appeared before the Committee have agreed that we should do three things:

1. Sustain on-shore manufacturing of tests, treatments and vaccines

2. Create and sustain state stockpiles of supplies we know we will need in a public health emergency, such as personal protective equipment and medical supplies

3. Strengthen the Strategic National Stockpile

We've seen time and time again that attention spans are short.

We must act now to stop the cycle of "Panic. Neglect. Panic."

I look forward to hearing from all of our witnesses today about:

- how the federal government is continuing to respond and help states respond
- how soon we can expect more treatments and a vaccine for COVID-19
- what steps we can take now to prepare for the next pandemic