

Senate Committee on Health, Education, Labor, & Pensions

COVID-19: Safely Getting Back to Work and Back to School

May 12, 2020

10:00 am, 106 Dirksen Senate Office Building

Purpose

The purpose of this hearing was to understand the current state of the COVID-19 pandemic and examine how to best prepare to reopen the country.

Members Present

Chairman Alexander, Ranking Member Murray, Senators Enzi, Sanders, Burr, Casey, Paul, Baldwin, Collins, Murphy, Cassidy, Paul, Warren, Roberts, Kaine, Murkowski, Hassan, Scott, Smith, Romney, Jones, Braun, Rosen, and Loeffler

Witnesses

Anthony Fauci, MD., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD

Robert Redfield, MD., Director, United States Centers for Disease Control and Prevention, Atlanta, GA

ADM Brett Giroir, MD., Assistant Secretary for Health, United States Department of Health and Human Services, Washington, DC

Stephen Hahn, MD., Commissioner of Food and Drugs, United States Food and Drug Administration, Silver Spring, MD

Opening Statements

Chairman Alexander said that all roads back to work and back to school run through testing. The nation has made significant progress in regard to increasing testing capacity. However, there is still room for improvement. It remains true that the United States has tested more people than any other country. The federal government has done a remarkable job helping states procure testing equipment and other important supplies. So far, Tennessee has been able to test 4% of the overall population. Currently, there is significant innovation happening which would help to scale up the nation's manufacturing capacity and supplement already available tests. Widespread screening at schools and places of work will ease the transition from quarantine back to normal life. Furthermore, the nation must consider whether to begin producing a vaccine before it has been proven to work. Vaccines are the ultimate solution. However, until then, testing must remain the top priority. Today is a bipartisan hearing to examine how to move safely back to into society. It is time to work together and put partisan differences aside. There also must be a sincere focus on the next pandemic because it is certainly coming.

Ranking Member Murray said that American families are counting on Congress for the truth about COVID-19. Truth is essential so that people can make informed decisions for themselves and their family. Today is an opportunity to understand where things went wrong so that these mistakes can be corrected. Currently, there are significant testing shortages, personal protective equipment (PPE) shortages, and antibody tests with almost no reliability. Furthermore, this is not the first time that this administration has attempted

to silence career professionals who are trying to protect the public's health. It is clear that we are nowhere close to where we need to be in order to safely reopen. It is abundantly clear that the nation needs significantly more tests. It is shameful that there is still not national strategic plan to procure testing supplies and diagnostic materials. However, testing alone is not enough. There need to be fact-based guidelines to support communities as they begin to reopen.

Testimony

Dr. Fauci said that the strategic plan developed by the NIH is four fold. One is to improve the fundamental knowledge of the virus and the disease it causes. Second is to develop new point of care diagnostics. Third is to characterize and test therapeutics. Fourth is to develop safe and effective vaccines. The NIH has developed the rapid acceleration of diagnostic products to support the development of COVID-19 diagnostics. This is a national call for innovative technologies, which would be evaluated in a shark tank like environment. The NIH will begin looking at plasma from individuals who have recovered from COVID-19 and its potential role in prevention. The clinical trials surrounding Remdesivir were significant but modest. The NIH hopes to build on these clinical trials. The NIH has also been heavily involved in developing a vaccine. The NIH has now begun a phase 1 clinical trial with the intention of moving to phase 2 and 3 in the early summer. The NIH has also launched a private public partnership to prioritize and accelerate therapeutic candidates to treat COVID-19.

Dr. Redfield said that the CDC has been working 24/7 to try to combat the COVID-19 pandemic. As local leadership makes decisions to reopen, they will require different levels of federal support. The CDC has conducted a state-by-state analysis of the available testing and diagnostic infrastructure. CDC is currently providing assistance to states through the CARES Act. Rapid, extensive and widely available testing is essential to reopening America. In addition, increasing contact tracing capacity is critical to reducing the spread of COVID-19. The nation's surveillance program is built on a combination of systems in different locations. The CDC is working to integrate these surveillance systems in order to improve early case identification. This includes active surveillance of the most at-risk populations. Now is the time to put this type of system into place in order to better prepare for future outbreaks.

Adm. Giroir said that the United States has increased its testing capacity significantly. Currently, the United States can test more people than any other nation. The federal government has achieved this by collaborating with private community-based testing sites such as CVS and Rite-Aid. Utilizing the Defense Production Act has allowed the federal government to prepare to reopen. Furthermore, new guidelines expand the criteria to receive a COVID-19 test. Now, asymptomatic individuals can get tested for the virus. Leadership continues to hold calls with state lawmakers and other relevant stakeholders. The purpose of these calls is to support states, territories and any other affected entity. Just last week, the FDA approved a new antigen test. It is the hope of the Administration that increasing tests similar to the antigen test will support the nation's ability to return to normal.

Dr. Hahn said that the FDA has worked to develop products to help combat the COVID-19 pandemic. Every decision made by the FDA has been driven by data with the goal of protecting the American people. The FDA has worked to balance the need for new and robust supplies with the need for proper oversight. The return to work and school has to start with testing. For this reason, the FDA is consistently supporting the production of tests. However, during a public health emergency, the accuracy of these tests is crucial. The FDA is working diligently to ensure that all products on the market are reliable and monitor for fraudulent products. Of course, the only way to completely defeat the virus is with a vaccine. The FDA intends to use its regulatory flexibility to ensure the rapid production of a safe and effective vaccine.

Questions and Answers

Chairman Alexander asked what Dr. Fauci would say to the dean of a school. **Dr. Fauci** said that he would be realistic with the dean. It is not likely that there will be a vaccine that creates the conditions to return to school in the fall. There may be a treatment at that point, but that cannot be promised. Students need to know that they are safe. This cannot be guaranteed. **Adm. Giroir** said that the strategy that needs to be employed will be based on the community. It is likely that antibody tests can play a significant role in returning to school. Furthermore, a surveillance strategy may attempt to target the most vulnerable populations and aid the return. **Dr. Redfield** said that it is important to evaluate the role of social distancing on college campuses. Testing will also be vitally important.

Ranking Member Murray asked what the most important message is to send to communities as they attempt to reopen. **Dr. Fauci** said there are several checkpoints needed in order to reopen. Communities need to see a decrease in cases for 14 days straight. If some communities jump over this checkpoint and prematurely open up, there will be spikes in cases that can lead to more outbreaks. **Ranking Member Murray** asked if communities that do not follow these guidelines run the risk of a deadly outcome. **Dr. Fauci** said yes. Communities also need to have the capability to respond to new infections as they appear. **Ranking Member Murray** asked if the Administration's forthcoming strategic plan includes specific numeric targets for testing capacity, supply chain capacity and relevant shortages. **Adm. Giroir** said yes.

Sen. Enzi asked how the evolving nature of the virus affects the development of a vaccine or treatment. **Dr. Hahn** said that the clinical nature of development takes into account the evolving nature of the virus. These evolutions inform the endpoint of clinical trials. **Sen. Enzi** asked what HHS has done to ensure that the nation has sufficient capacity to deliver a vaccine. **Dr. Hahn** said there is currently an all-of-government approach to ensure that the appropriate supplies exist to deliver a vaccine. Currently, the government is looking forward to determine where there may be gaps in the supply chain and create a solution to this problem.

Sen. Sanders asked if Dr. Fauci believes that the actual number of deaths related to COVID-19 are higher than the documented deaths. **Dr. Fauci** said yes. **Sen. Sanders** asked if there is fear that the virus could become worse in the fall or the winter. **Dr. Fauci** said yes, the possibility does exist. However, it is possible that if there is a second wave, the nation will be significantly

more prepared. But the right steps must be taken. **Sen. Sanders** asked if it is fair to assume that the vaccine would be distributed to everyone free of charge. **Dr. Hahn** said the FDA is committed to ensuring that everyone has access to the vaccine. **Sen. Sanders** asked if Dr. Hahn can commit today that the vaccine will be free for everyone who needs it. **Dr. Hahn** said while he wants it to be free, that is not under the FDA's scope. **Sen. Sanders** asked Adm. Giroir if the vaccine should be available to all regardless of income. **Adm. Giroir** said that a vaccine needs to be available to everyone regardless of ability to pay.

Sen. Burr asked if anyone in the Administration has tried to prevent the development of a cure or treatment. **Dr. Fauci** said no. **Sen. Burr** asked why the CDC does not contract with private sector tech companies to use their tools for surveillance. **Dr. Redfield** said the CDC does have contracts with some private sector groups. **Sen. Burr** asked how many employment slots that Congress allotted to be filled for bio surveillance have been filled by CDC. **Dr. Redfield** said they are in the process of trying to fill the positions. **Sen. Burr** asked what the biggest unknowns are related to the virus. **Dr. Fauci** said that there is no guarantee that the vaccine is going to be effective given the way the body responds. The other unknown is whether or not there is an enhancement effect. This means that a vaccine actually enhances the potency of a disease and does not provide any efficacy. **Dr. Hahn** said the regulatory obstacles are being addressed by HHS. The barriers include a common pre-clinical pathway and a common control group and endpoint across trials.

Sen. Casey asked when the public will be able to see data from long-term care facilities and nursing homes. **Dr. Redfield** said that now all nursing homes are required to report cases to the CDC. There is also a guidance that requires nursing homes to inform family members of new COVID-19 cases within the nursing home.

Sen. Paul asked if the scientific record supports the idea that exposure to COVID-19 likely leads to some type of immunity. **Dr. Fauci** said that it is likely that antibodies will result in some form of immunity. However, it is unknown what level of protection would be provided.

Sen. Baldwin asked if the current testing protocols at the White House presents a model for other essential work places. **Dr. Redfield** said that each work place needs to define their own approach. **Sen. Baldwin** asked if the current PPE protocols at the White House presents a model for other essential work places. **Dr. Redfield** said work places should follow the CDC guidelines. **Sen. Baldwin** asked if there is a national testing strategy in place today. **Adm. Giroir** said yes. The strategy could be expanded but it exists. Furthermore, there are vastly different testing needs based on region.

Sen. Collins asked if dentists who institute strict preventative measures, follow guidelines set by the American Dental Association, and see declining cases in their community, can reopen. **Dr. Redfield** said yes. The CDC is also updating guidelines directly for dental practices. **Sen. Collins** asked how Remdesivir can best be allocated going forward. **Dr. Hahn** said the distribution needs to be an evidence based approach. HHS has received guidance on where the most significant outbreaks have occurred.

Sen. Murphy asked if the witnesses are receiving a salary during quarantine. **Dr. Fauci** said yes, but they are not quarantined like most individuals because they are essential workers. **Dr. Hahn** said yes. **Sen. Murphy** asked why the CDC guidelines to reopen America were not released. **Dr. Redfield** said that guidance often undergoes interagency review. This particular guidance has undergone interagency review and will now head to the task force for final review. **Sen. Murphy** asked when the guidance will be released. **Dr. Redfield** said soon.

Sen. Cassidy asked if children are included in the vaccine testing trials. **Dr. Hahn** said when phase 2 and 3 trials are in place, they will include the most vulnerable populations. **Sen. Cassidy** asked if the current phase 2 trials include children. **Dr. Hahn** said the trials are not in phase 2 yet. **Sen. Cassidy** asked if testing will be included in guidelines for schools to reopen. **Dr. Redfield** said the testing strategy will need to be individualized. **Sen. Cassidy** asked if there needs to be a balance between keeping children safe and ensuring they are not losing important educational development years. **Dr. Fauci** said yes, but there is not an easy answer. There will not be a universal or homogenous response.

Sen. Warren asked if the coronavirus is contained. **Dr. Fauci** said it is not completely under control. However, some places have seen a decline in cases and hospitalizations. The dynamics of new cases suggest that we are going in the right direction but not under control. **Sen. Warren** asked if it is possible that there could be 200,000 new cases a day by June. **Dr. Fauci** said he does not think that will happen. **Sen. Warren** asked if the US has enough robust counter measures in place that there is no need to worry about a second spike in cases in the winter. **Dr. Fauci** said the projections suggest the measures will be in place by fall. **Sen. Warren** asked if deaths will increase if the response is not adequate. **Dr. Fauci** said yes.

Sen. Roberts asked if increasing rapid diagnostics in the food chain would be useful. **Adm. Giroir** said yes.

Sen. Kaine asked if the death rate in the United States is unacceptable. **Dr. Fauci** said yes. **Sen. Kaine** asked if the evidence from other countries suggest that this death rate was avoidable. **Dr. Fauci** said he is not sure how avoidable the death rate is. **Sen. Kaine** asked if the United States can do better. **Dr. Fauci** said of course. **Sen. Kaine** asked if it is true that access to healthcare keeps people safer. **Dr. Fauci** said of course.

Sen. Murkowski asked how it is possible to prevent communities from becoming hotspots. **Adm. Giroir** said utilizing mitigation strategies such as testing, contact tracing, wearing PPE and social distancing are effective measures in preventing communities from becoming hotspots. **Sen. Murkowski** asked what more needs to be done to improve contact tracing. **Dr. Redfield** said that increasing contact tracing capabilities is critical. The CDC is positioned to redeploy nearly 500 CDC officials into communities. The CDC is also trying to work with local health departments to create effective response strategies.

Sen. Hassan asked how frequently nursing home patients and staff should be tested. **Dr. Fauci** said in the long term there will have to be infection control capabilities in nursing homes. There needs to be general consistent testing of all staff. **Sen. Hassan** asked if nursing homes should follow the same mask guidelines as the White House. **Dr. Fauci** said perhaps not the exact same

guidelines, but there need to be strict guidelines that are followed by everyone. **Sen. Hasan** asked what steps can be taken to ensure sufficient production of a COVID-19 vaccine. **Dr. Fauci** said that the investment in production capacity is happening before the vaccine is proven to work. This will improve capabilities.

Sen. Scott asked what more can be done to protect the most vulnerable populations. **Dr. Fauci** said the vulnerable populations should be the last populations to have relaxed guidelines. These individuals have a greater likelihood of getting infected and having comorbidities.

Sen. Smith asked how Dr. Fauci is doing. **Dr. Fauci** said fine. **Sen. Smith** asked what guidance should be given to at-risk work places. **Dr. Fauci** said workers need as much protection as possible. Workers also need to be able to leave work and seek the proper care in the event they get sick.

Sen. Romney asked if President Obama or Trump are responsible for the fact that there is no vaccine. **Dr. Fauci** said no. **Sen. Romney** asked how it is possible that the CDC has never established a real-time surveillance system. **Dr. Redfield** said the CDC needs funding for data modernization. In reality, the public surveillance system is archaic. Many different public health entities have old and non-uniform systems. **Sen. Romney** asked if it is likely that there will be a vaccine within a year. **Dr. Fauci** said it is more likely than not.

Sen. Jones asked how testing and contact tracing plans will be developed. **Dr. Redfield** said the CDC is working with state health department leaders in order to understand the capacity needs. The CDC is also working with other government programs such as AmeriCorps to support contact tracing capabilities.

Sen. Braun asked if vaccines and therapeutics will be pushed through in a quicker method than in the past. **Dr. Hahn** said the FDA began working with test developers all the way back in January. This is an opportunity to examine how the process can be done better. Looking forward, every regulatory authority will be used to provide flexibility in bringing new treatments and tests to market.

Sen. Rosen asked what research is happening to identify monoclonal treatment options. **Dr. Fauci** said there is significant research surrounding monoclonal treatment options. This research is happening in tandem with the development of a vaccine. **Sen. Rosen** asked what the next generation of PPE should look like. **Dr. Fauci** said the best PPE for the general public is to maintain social distancing. When physical distancing is not possible, wearing a covering over the face is crucial.

Sen. Loeffler asked about the timing and accuracy of the data that was received from China. **Dr. Redfield** said the US partners with the CDC in China and that has been a very important relationship. China communicated with the CDC as early as January. At the scientific level, the interactions were very positive. **Sen. Loeffler** asked if the witnesses have a tense relationship with the President. **Dr. Fauci** said there is not a confrontational relationship between himself and the President. **Dr. Redfield** echoed what Dr. Fauci said. **Dr. Hahn** agreed with Dr. Fauci. **Adm. Giroir** also agreed with Dr. Fauci.