



House Committee on Energy & Commerce, Subcommittee on Health

Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain

Wednesday, February 3, 2021

11:00am, Virtual Hearing via Cisco WebEx

Purpose

The purpose of this hearing is to discuss the country's current vaccine, testing, and medical supply chain strength and weaknesses and to address solutions for the future.

Members Present

Chairman Eshoo, Ranking Member Guthrie, Representatives Pallone, McMorris Rodgers, Butterfield, Upton, Matsui, Burgess, Castor, Griffith, Welch, Bilirakis, Schrader, Bucshon, Cardenas, Hudson, Ruiz, Dunn, Dingell, Curtis, Kuster, Joyce, Barragan, Carter, Blunt Rochester, Craig, Schrier, Trahan, Fletcher, Kelly, Sarbanes, and O'Halleran

Witnesses

Luciana Borio, M.D., Vice President, In-Q-Tel; former National Security Council Director for Medical & Biodefense Preparedness; former Food and Drug Administration Acting Chief Scientist

Greg Burel, former Director of the United States Strategic National Stockpile

Michael O. Leavitt, Founder, Leavitt Partners; former Governor of Utah; former Secretary of Health and Human Services for George W. Bush

Julie Morita, M.D., Executive Vice President, Robert Wood Johnson Foundation; former Commissioner of Chicago Public Health Department

Michael Osterholm, Ph.D., M.P.H., Director, Center for Infectious Disease Research and Policy, University of Minnesota.

Opening Statements

Chairman Eshoo said that the coronavirus (COVID-19) pandemic has greatly hurt the country while also having a negative impact of communities of color. She stated that such devastations call for immediate action. The new Administration has a detailed plan on how to address the issues of the pandemic, including vaccinating 300 million Americans by the end of this summer, increasing investments in treatments and the healthcare workforce, and focusing on ensuring strong manufacturing of personal protective equipment (PPE). The previous Administration's team has published a report that stated when more funding is given to vaccinations, it can result in upwards of \$10 billion back into the economy.

Ranking Member Guthrie said that the pandemic has taken more lives than World War II, which furthers the need for the country to react swiftly. In order to do so, leaders need to stop focusing on political ideologies and begin honest negotiation. One of the strongest actions the country has taken to fight COVID-19 has been the speed of the creation of the vaccine through Operation Warp Speed, and no safety measures were skipped in the process. Additionally, it is important to recognize the increased volume of daily testing, which is what hindered the country in the beginning of the pandemic. However, much more work is needed. Moving forward, there needs to be more oversight in order to ensure a smooth transition out of the pandemic.

Rep. Pallone said there is no issue more important than that of the pandemic. It is the responsibility of Congress to ensure that the new Administration has everything it needs to tackle COVID-19 head on. One of the first steps needs to be increased focus on vaccine distribution and the communication between the federal government and states. If vaccine creation and distribution are going to continue, more resources need to be allocated. In this same vein, in order to strengthen contact tracing and testing the nation needs to prioritize funding and planning for communities across the country. The pandemic has also showed the vulnerabilities of the medical supply chain, where miscommunication has caused missed vaccines, loss of supplies, and confusion. Since President Biden has drafted a framework for COVID-19 relief legislation, it is up to Congress to ensure it supports the efforts as appropriate.

Rep. McMorris Rodgers said that the pandemic has wreaked havoc on the country from the economy, to school children, to mental health. Previously, Congress has been able to work together to pass five separate relief packages to respond to COVID-19 and with Operation Warp Speed, the nation can know there is light at the end of the tunnel. In order to move forward, states need more individual support in order to meet their specific needs and structural differences. Issues that have been identified in lieu of the pandemic have been both the vulnerability of the nation's medical supply chain and its dependency on other countries, for example the country's purchase of Personal Protective Equipment from China. Last year was one of the most difficult in the nation's history, so Congress must acknowledge that the problems that are alive today are larger than any political party and requires partnership to solve them.

Testimony

Dr. Borio said that the pandemic situation is dire and may get worse with the three new variants of the coronavirus. There are seven priorities that should be focused on. First, the Centers for Disease Control and Prevention (CDC) must immediately expand its genomic surveillance system. Second, the new Administration should take steps to clarify the vaccine distribution process. Third, the threat of the new variants will not be solved exclusively through travel bans, so it is up to the new Administration to share guidance on wearing masks and changing behavior. Fourth, the supply chain network in the country is extremely fragile so there is an urgent need to expand the industrial base for supplies manufacturing. Fifth, the country needs better therapies while patient care needs to be driven by science not by hope. Sixth, the CDC needs to distribute guidance for testing. Seventh, the US lacks an interoperable structure for public health, so one needs to be created that integrates the private sector and is prepared for future emergencies.

Dr. Morita said that the pandemic illiterates the critical nature of the country's response. First, equity needs to be prioritized since communities of color are disproportionately affected by COVID-19. Communities of color need to be prioritized for vaccines since they have a higher rate of exposure. States should be encouraged and supported to start collecting all data on race and ethnicity, occupation, and neighborhood groups and Covid-19 cases. Second, continued effort needs to be allocated towards vaccines since they are only effective if people can access them. Barriers that have arisen in recent months include lack of internet connection to make an appointment online and reliable transportation to get to appointments. Additionally, the country needs to address vaccine hesitancy through utilizing community stakeholders to work together and to encourage individuals to believe in the safety of the vaccine. Lastly, there needs to be

greater modes of coordination, which illustrates the unique role of the government. By the CDC distributing clear guidance, technical assistance, open lines of communication, increased transparency, and ramping up public health workforce, states can be better equipped to respond to the virus. Congress can provide additional support for all of these categories, including the encouragement of masking up, washing hands, and staying safe.

Mr. Leavitt said this hearing is about looking ahead. While vaccines can strengthen the nation and provide individuals with an opportunity to be protected from the virus, they are voluntary and many individuals are still hesitant. However, in order to open the economy and to return to a version of normal, there needs to be a structure where a vaccine card is a point of entry. However, such a structure does not exist. This does not necessarily mean a mandatory vaccine process, but there needs to be a way for individuals to access their medical records through an online structure. Every state should be participating in the CDC IZ Gateway program, which allows states to share vaccination information. Unfortunately, only half of states are participating. In order for the program to work to its full potential, all states need to. This could be solved by requiring all states that receive vaccines from the federal government to participate.

Mr. Burel said COVID-19 has brought forward the fragility of the country's supply chain network, where one of the most blaring issues was that of the lack of PPE. This must never happen again. In order to address this issue, there needs to be more support for domestic manufacturing of these items. A successful government response needs to address the entire healthcare industry, especially that of the commercial market. Some actions that could address the country's infrastructure issue include: (1) engaging all healthcare stakeholders; (2) appropriating more federal funding to the National Stockpile, and; (3) focusing on strengthening domestic investment in both the supply chain and pharmaceutical manufacturing, including creating additional incentives to build within the country.

Questions and Answers

Chairman Eshoo asked how the new mutant viruses affect the timeline for the vaccine rollout. **Dr. Borio** said in the short term nothing changes. In the long term, more tests need to be done in order to decide whether the public needs to be re-vaccinated. She stated that vaccines need to be more like the one for the influenza, to be repeated every year. **Chairman Eshoo** asked how the increased resources of the new Administration help bring the vaccine to underserved communities. **Dr. Morita** said that sites where vaccinations are occurring need to be in the communities themselves and the appointment process needs to be simplified. **Chairman Eshoo** asked if country of origin is weighed versus cost for the national stockpile. **Mr. Burel** said that there is a priority to buy domestic but normally PPE is found overseas.

Ranking Member Guthrie asked if states would improve their distribution process now that they have more funding for vaccine distribution. **Dr. Morita** said the challenges with the distribution was caused from the lack of resources for the complex structure to vaccinate appropriately, such as a sufficient workforce. **Ranking Member Guthrie** said there is a high rate of competitiveness for funding for both Medicaid and public health spending in general. **Mr. Leavitt** said public health funding has been weakening for a long time.

Rep. Pallone asked to what extent a lack of resources has had an impact on the nation's COVID-19 response. **Dr. Morita** said that if proper resources were provided, supplies would be arriving appropriately, there would be more appropriate guidance, and there would be more stable partnerships. **Rep. Pallone** asked how important it was for the federal government to provide clear testing guidance. **Dr. Borio** said that federal guidance is always important, especially for comprehensive testing, which requires federal coordination.

Rep. McMorris Rodgers asked what the appropriate role of the government is when it comes to vaccines and what flexibilities need to be given to states. **Mr. Leavitt** said both of the vaccines are based on new technologies that were developed in 2006 and if the federal government promoted this information, there may be more public trust for the vaccine. **Rep. McMorris Rodgers** asked if there are immediate actions now to ensure a stable supply chain. **Dr. Borio** said next steps are to expand the manufacturing base.

Rep. Butterfield asked how COVID-19 vaccine data could be improved. **Dr. Morita** said there needs to be additional resources to support the whole distribution plan but especially that of manpower. **Rep. Butterfield** asked how Congress can support retail community pharmacies to administer the vaccine. **Dr. Morita** said that there needs to be more focus on retail pharmacies and community health centers to be prepared by providing them both adequate support and resources.

Rep. Upton asked where the country is short on PPE. **Mr. Burel** said the country is short in every field of PPE. In order to solve this, on shoring or near shoring could be supported through investments and encouragement even in the aftermath of COVID-19. **Rep. Upton** asked how to negate states canceling second dose vaccines due to there being a small supply. **Mr. Leavitt** said there needs to be coordination and collaboration on states' supply bandwidth at all levels of government.

Rep. Matsui asked what the challenges are of a one-size-fits-all process and what needs to be done for the vaccine process to be more efficient. **Dr. Borio** said there will always be challenges for such a large issue but that there isn't such a thing as one-size-fits-all and there needs to be further communication on the local level. **Rep. Matsui** said long term care staff are not taking vaccine or are extremely hesitant. **Dr. Morita** said vaccine hesitancy needs to be addressed across the board and on an individual level.

Rep. Burgess asked what the strengths of the government have been during this emergency. **Mr. Leavitt** said partnerships are essential in an emergency such as COVID-19, the federal government accepted a lot of risk, and there were many seeds that were planted knowing that many would not be successful.

Rep. Castor said most states don't collect data based on race, which is important to better respond to the virus. **Dr. Morita** said that resources need to be provided to underserved communities to support data systems, workforce systems, and supplies. **Rep. Castor** asked why the country is absent of a true diagnostic testing process in the country. **Dr. Borio** said there needs to be a standardization of plans for schools, universities, hospitals, and the workforce. Having an ad hoc process only leads to confusion.

Rep. Griffith asked what percentage of preventative manufacturing supplies needs to be created domestically so the country does not end up in the situation it was in the beginning of the pandemic. **Mr. Burel** said he is unsure of the percentage but there needs to be encouragement of those in the market and those not yet in the market to manufacturer supplies domestically. Additionally, it cannot be restricted to one area such as Puerto Rico; as the country saw during hurricane season, its manufacturing capabilities were hindered. However, since PPE is physically large, it is difficult to keep in storage so the country should consider participating in Bridge Stocks in the future.

Rep. Welch asked how the coordination between the federal government and states and the distribution of vaccines could be improved. **Mr. Burel** said every single stakeholder in the healthcare industry needs to be engaged. **Dr. Morita** said that if health directors were provided with predictable and reliable knowledge of how many vaccines they are projected to get, it would help Directors plan accordingly and would prevent from having to cancel future appointments.

Rep. Bilirakis asked if states were properly set up to receive shipments from the national stockpile. **Mr. Burel** said the stockpile needs to have direct communication access to states. **Rep. Bilirakis** asked what the availability of additional therapeutics are that can help with COVID-19, such as antibody agents. **Mr. Leavitt** said the country has failed to create enough therapeutics and in order to negate this issue in the future, there has to be more tools and more collaboration across governments and healthcare stakeholders. **Rep. Bilirakis** asked how efficiency can be valued by supply chains for the future. **Mr. Burel** said the country should build stock at both the state and the federal level. **Rep. Bilirakis** asked which metrics show improvement, cases, deaths, or vaccines. **Mr. Leavitt** said everyone uses different metrics but there needs to be further focus on reliable and comprehensive data streams.

Rep. Schrader asked what Congress can do to ensure individuals are getting reliable information on vaccines. **Dr. Borio** said the country needs to establish a national infrastructure that can manufacture products quickly in a scientifically valid matter.

Rep. Bucshon asked if there is data to support the claim that vaccines are deliberately not being distributed to communities of color, or if communities of color are facing the same problem as rural communities, which is accessing the vaccines that have been distributed. **Dr. Morita** said it is a problem of access, and it exists in inner cities and rural America alike. **Rep. Bucshon** said that increasing testing capacity is something he's been working on since the beginning of the pandemic, when he heard from constituents that they were having trouble accessing tests. While testing has come leaps and bounds since March, we are still not where we need to be. In rural areas, testing turnaround times are still too long, and nearly 20% of counties lack even a single testing site for COVID-19. As of last fall, nearly 40% of public health labs still lacked access to a single high-throughput testing platform. If we cannot increase our capacity for rapid test results, it will continue to make it difficult to limit the spread. That is why he and Rep. Diana DeGette have reintroduced the Access for Tests Act, which would aid public health labs in acquiring high-throughput platforms, and help hospitals, doctors and pharmacies also acquire these tests. He asked Dr. Borio to speak to the need the country still has for greater testing capacity and more rapid results, and how arming public health labs with high-throughput platforms and

supplying doctors and hospitals with more point of care tests might achieve that goal and better prepare us for the days ahead. **Dr. Borio** said that testing is absolutely critical. If patients cannot access testing or face a delay in their results, they may not be able to access therapeutics that are most effective early in the disease progression.

Rep. Cardenas asked if the country should invest as much money as scientists are suggesting. **Dr. Morita** said that since this is the largest public health emergency the world has ever seen, yes, the funding that is needed is voluminous. **Rep. Cardenas** asked if funding should be targeted. **Dr. Borio** said there is a need to provide more technical assistance due to the chronic underfunding of public health over the decades.

Rep. Hudson asked how coordination can be increased between the federal government and states. **Mr. Leavitt** said collaboration has to be prioritized on all levels, including local health departments, local communities, state legislatures, and the federal government.

Rep. Ruiz asked if Federally Qualified Health Centers (FQHCs) are a point of access for hard to reach communities. **Dr. Morita** said FQHCs can play an incredibly important role in trying to address an equitable approach. The only barriers for FQHC's success is a lack a resources.

Rep. Dunn asked if new and existing therapeutics can fight against the new variants. **Dr. Borio** said there is hope. **Rep. Dunn** asked how the increased funding provided by the new Administration should be spent. **Mr. Leavitt** said the funding should be spent on new technologies, strengthening supply chain managements, and continuation of strong partnerships. **Rep. Dunn** asked how Congress can encourage community partners to utilize already existing therapies to strengthen the immune system. **Mr. Leavitt** said vaccines were able to be distributed and supported because of the resources thrown behind it. As such, if more resources would be placed behind other health measures, public health leaders would be better able to support other treatments.

Rep. Dingell asked what additional steps states could take to address racial disparities. **Dr. Morita** said that access to the vaccines is dependent upon a strong supply, which is not the country's current situation. As the supply increases, vaccination centers need to be developed strategically to best serve diverse communities and states' individual needs.

Rep. Curtis asked how the vaccine distribution efforts can target rural communities. **Dr. Morita** said mobile clinics may be best equipped to meet the needs of rural communities. **Rep. Curtis** asked what the difference is between the roles of states and the federal government. **Mr. Leavitt** said both the states and the federal government play an interdependent role and rely on one another's strength in order to address issues appropriately.

Rep. Kuster asked what a comprehensive 21st century data system looks like. **Dr. Borio** said it would be an integrated interoperable accessible data system. **Rep. Kuster** asked how information systems could be strengthened. **Dr. Morita** said because there is no one system where all stakeholders, hospitals and providers, can share information, the country should focus on creating an interoperable system that is simple and stable. **Rep. Kuster** asked how the public can be ensured that their health care data will stay private. **Dr. Morita** said that because the data

is protected by HIPAA, the information is shared in aggregate so it is absent of identifiable information.

Rep. Joyce asked, given the emergence of new COVID-19 new variants, how Congress can best prepare to face these issues. **Mr. Leavitt** said that this process will be much longer than just the two step vaccination. As the virus mutates, public health leaders need to anticipate future vaccines including new booster shots. **Rep. Joyce** asked how Congress can support the Biomedical Advanced Research and Development Authority for future issues. **Mr. Leavitt** said that the department needs to be funded and needs access to reliable partnerships. **Rep. Joyce** asked how the federal vaccine manufacturing can be strengthened. **Dr. Borio** said the country needs to expand the industrial base to manufacturer the vaccine.

Rep. Barragan asked how Congress can ensure community health centers are getting the support they need. **Dr. Morita** said that the Biden Administration's plan to increase funding for community health centers is the first step in supporting them. Additionally, underlying issues such as lack of health insurance and social determinants of health need to be addressed.

Rep. Carter asked if all pharmacists should be able to administer the vaccine regardless of state rules. **Mr. Leavitt** said pharmacists are very important during this vaccine distribution process and they should be provided with comprehensive support.

Rep. Blunt Rochester asked why the country should continue to invest in the development of treatments for COVID-19. **Dr. Borio** said the vaccines that are available right now are very restrictive. The country needs accessible vaccines, especially because coronavirus is going to be endemic. **Rep. Blunt Rochester** asked how Congress should address vaccinating individuals with long term health issues. **Mr. Leavitt** said the country needs more data on the vaccines effect and on payment systems. **Rep. Blunt Rochester** asked how Congress can address an equitable response for those with have long term health issues. **Dr. Morita** said that future clinical trials need to focus on including people of color. **Rep. Blunt Rochester** asked how using the Defense Production Act will help the country for future supplies. **Dr. Borio** said that although the Defense Production Act is a strong program, it should not be the final solution.

Rep. Craig asked what impact the federal data collection has on states. **Dr. Morita** said that comprehensive data is necessary to understand the breadth of coronavirus's impact. The federal government has the resources to create a standardized data system to then provide guidance and resources to states to participate in the system. **Rep. Craig** asked what the Federal Emergency Management Agency's (FEMA) contributions had on medical supplies. **Mr. Burel** said FEMA has a deep understanding of supply chain management systems across the nation, which can help distribute medical supplies in a more accurate fashion.

Rep. Schrier asked if there has been an effort to establish an independent comparison program for antigen tests. **Dr. Borio** said she is aware of the new Administration creating a comparison board. **Rep. Schrier** asked how involved the previous Administration was in this process. **Dr. Borio** said that the previous Administration was involved on a high level, which caused confusion between departments. The Food and Drug Administration now has more control over scientific boards now.

Rep. Trahan asked how a clinical trial network could be established. **Dr. Borio** said the country needs to be able to leverage technology to be able to capture patients where they are. **Rep. Trahan** asked what lessons could be learned from the country's previous vaccine manufacturing process. **Dr. Borio** said adequate data on safety and effectiveness on vaccines needs to be further prioritized in the future.

Rep. Fletcher asked how the country can efficiently get supplies to public laboratories. **Dr. Borio** said the country needs a clear and definitive strategy to provide supplies to laboratories that need it the most. **Rep. Fletcher** asked what can be done to ensure the proper resources are allocated to the health care workforce. **Dr. Morita** said that funding needs to be provided immediately to hire staff in states while also providing support to be able to sustain the higher workforce volume.

Rep. Kelly asked what the vaccine process has looked like within the disabled communities. **Dr. Morita** said that the vaccine distribution system has to be created on an individual level to make it accessible for all communities. **Rep. Kelly** asked how the panelist feel about schools opening earlier rather than later. **Mr. Leavitt** said that decisions that affect opening schools is not best decided in state or federal legislatures but needs to happen on the community level. **Dr. Morita** said that there needs to be a standardized plan on social distancing, PPE, and constant testing in order for schools to open safely.

Rep. Sarbanes asked what strategies can be deployed for additional health care workers who would be qualified to deliver the vaccine. **Dr. Borio** said there are efforts underway to create more flexibilities between states to hire more and/or retired health officials to be involved. **Mr. Leavitt** said Congress needs to focus on providing these newly integrated health care workers to not only be able to administer the vaccine, but to also have access to patient's medical records.

Rep. O'Halleran asked how an expanded genome project could help the country respond to the coronavirus and for future issues. **Dr. Borio** said that the scientists knew that the virus would mutate but they did not have the ability to measure its genome. **Rep. O'Halleran** asked how long the genome system has been needed. **Dr. Borio** said the need proceeds the pandemic.