Attachment—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain"
February 3, 2021

The Honorable Michael O. Leavitt, Founder and Chair, Leavitt Partners, Former Secretary of Health and Human Services, Former Governor of Utah

The Honorable Frank Pallone, Jr. (D-NJ)

1. Gov. Leavitt, I appreciated in your testimony your suggestion that government at all levels needs to prepare for the next pandemic. As someone who has had to worry about balancing a state budget, can you describe the challenges that states have in funding core public health activities that can help ensure they are prepared?

Governor Leavitt Response

States have faced a number of challenges in sustaining for funding for core public health and pandemic preparedness activities. Yet, with leadership, planning, and partnership at the state and local level, our state leaders are quite capable and able when given the right tools.

Most notably, pandemic preparedness often does not feel like an urgent priority when everything is going well. As you may have heard me say, everything we do before a pandemic will seem alarmist. Everything we do after will seem inadequate.

However, in my verbal testimony, I believe I also mentioned that the growth of the Medicaid program as a large portion of the average state budget also puts pressure on states who want to make investments in public health and pandemic preparedness. One way this Committee could help address that issue is to identify a handful of once well-intended but perhaps now-outdated requirements that CMS still requires states to adhere to in Medicaid. Even small changes to remove outdated federal requirements can help free up limited state dollars and make a notable difference at the state level.

Let's be clear: public health is often a forgotten function of government, working quietly behind the scenes and not drawing attention to the part it plays when things are going well. But the COVID-19 pandemic has thrust public health into the spotlight, and it is now getting the attention it warrants. The public health function of our state and local governments is being tested in many ways through the current public health emergency, and it is in desperate need of modernization.

As I said during the Committee hearing, in my judgement, now is the time not just to note important lessons, but to harvest them. I hope that funding provided by Congress to states is used *wisely* to help states and local agencies make long-term improvements. It is not enough to simply issue a funding notice or hold some listening sessions or publish a report. The hard work of state and local improvements need to be well-designed and carefully thought-out, embedded in relationships, and connected to a strategic vision and operational plan. For example, if state and local public health agencies had steady funding to maintain their capacity to trace contacts for emerging infectious diseases, well-trained personnel, IT infrastructure, and surge capacity, it would not be as great of a strain to respond to a pandemic or any other health emergency.

Finally, one significant opportunity state leaders have at the moment is to help take advantage of the "teachable moment" in their states to show how investment in long-term public health capacity has positive economic impacts on the private sector. Over the past year, the livelihoods of many employers and workers are threatened by the economic impacts of COVID-19. Never before have we seen such a stark economic argument for public health infrastructure that can help mitigate and reduce risks. Seeing this visceral connection between public health and private sector wellbeing should spur employers and leaders in the business community to step up in new ways to partner with and support state and local public health agencies, not only during the COVID-19 pandemic, but on a going-forward basis.

The Honorable Nanette Diaz Barragán (D-CA)

The Port of Los Angeles, which is in my district, is currently experiencing one of the most serious outbreaks of COVID-19 in the nation. Numerous Southern California longshore workers have been unable to work due to contracting the virus, potential exposure, or remaining in their home out of concern of infection because of a pre-existing medical conditions. The total number of positive cases in the last two months of 2021 is greater than all of 2020 combined. The Port of Los Angeles' COVID-19 test positivity is accelerating at an alarming rate, and 12 longshore workers have lost their lives.

1. Given the severity of this situation and the very real risk of terminal shutdowns at one of America's most critical ports, should national vaccination prioritization be considered for frontline logistics workers such as the longshore workforce, truckers, railroad workers, etc.?
2. If not, why not, and what can we do to ensure these workers are vaccinated as quickly as possible?

Governor Leavitt Response

I am genuinely saddened to hear about the hardship of the longshore workers in your district and the increased number of positive COVID-19 cases early this year. I hope the situation has been much improved in recent weeks.

Certainly, we do need to recognize the challenges and hardships faced by the longshore workforce, truckers, railroad workers, and others. While I know it was so hard for many to wait as the early vaccines went to our first responders, physicians, nurses, and the elderly at the greatest risk from COVID-19, I think the last few months generally have shown that the CDC's recommendations were based in science, and also gave states the ability to prioritize limited supplies for the most at-risk individuals and needs of populations in their own states. The prioritization is very challenging and imperfect, but it is necessary.

Thankfully, the last number of months have been a tremendous success with regard to the increased supply of and access to COVID-19 vaccinations. This is due to the tireless efforts of literally thousands of men and women—from scientists and researchers, to manufacturers and distributors, to unprecedented partnerships and collaboration across the private sector and all levels of government. From retail pharmacies to primary care physicians offices, from federally qualified health centers to large health care systems – there has been an unprecedented effort to convert *vaccines* into *vaccinations* by getting shots in arms. We have so many of our fellow Americans to recognize and thank for their service and assistance during this period.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. Technology has become an integral part of our public health response to COVID-19. County health departments in Texas have been standing up their own websites to allow for online vaccine registration. This seems like a prime opportunity for private sector entrepreneurial leaders to help develop products to streamline this process.

   State flexibility to choose what works best for the state is key, but would it be helpful to disseminate a list of best practices or guidelines to states regarding the development and use of technology for testing and vaccine registration?

   Governor Leavitt Response

   The development of a set of best practices for states, counties, and cities regarding the use of technology would be a valuable exercise. Incentives to leverage these best practices that are tied to increased funding opportunities associated with modernizing state public health technology infrastructures would also be helpful.

   Assuming states would like the flexibility to provide their residents with voluntary, digital proof of their vaccination status, here are some thoughts on best practices for how to do that:

   - **Identity Proofing**: Ensure that when an individual is receiving a vaccine their identity is validated and accurate demographic information is included in the initial vaccine administration record that can tie that vaccine administration to the individual. Their legal first and last name, mobile phone number, email address, and date of birth are all identifiers that can assist in helping to identify the individual. If possible, include their vaccine information as part of their electronic health record.

- **Use of open standards**: Each vaccine administration system of record should use open standards (e.g., HL7® FHIR®, W3C, etc.) to transmit data between systems. The health care industry is supporting the SMART Health Cards Framework to transmit data between systems in a secure, privacy-by-design method. Each vaccination system of record should implement the standard to ensure citizens of their state can securely and voluntarily access their vaccination information on an application of their choice for a variety of different use cases.
- **State Immunization Information Systems (IIS):** All states should require that when vaccination information is recorded, that information is automatically sent to the state immunization information system via the use of open standards. Currently, many states don't require all vaccinations to be reported to the state IIS therefore when adults are looking for a digital proof and representation of their vaccination information they can access it similar to how they access the information for their children's vaccination information when they enter the school system.

2. I have heard that some state vaccination and testing sites have been struggling to identify patients who are truly uninsured compared to those who have other insurance available. Either insurance is not captured at scheduling or onsite, and/or is unknown to the patient or the testing/vaccine administrator. What are states doing to ensure program integrity and maximization of insurance coverage for their COVID testing and vaccines?

Governor Leavitt Response

As you are identifying, with the breadth, complexity, and speed of the vaccination efforts that states have been leading in partnership with their local organizations, there will be challenges identified along the way. As you know, there is wide variation amongst states practices and approaches even before the public health emergency, so I don't know that I can characterize current practices with precision. But as a former Governor, I always think the best way to understand the challenges states face is to talk with governors and other state officials leading the relief effort. I do think it helps to keep the challenges in context by realizing that the vast majority of Americans have health coverage, the vaccinations are not only life-saving, but they are essential to helping us advance along the road to recovery and soon find a greater sense of normality.

3. The current vaccine distribution chain only involves one distributor. Have there been capacity issues with distribution that could be solved by involving more private distribution companies? Are there certain areas, for example rural, that are more difficult to reach under the existing distribution channels?

Governor Leavitt Response

The challenge in effective distribution of vaccines is high, and especially when usual methods are disrupted by the very pandemic itself. As is obvious, the pandemic impacts the very workforce and availability of equipment and supplies required for the response. It is an insidious, inherent consequence of a pandemic. While I am not directly familiar with all of the channels used, let alone the challenges experienced, it is evident that more than one channel was available even in the early stages of the pandemic. For example, one of the early vaccine manufacturers deployed its own distribution system for its product, and the other relied on a government-procured system. This diversification has its own risks. But the advantages became apparent during our own pandemic preparations in 2005 despite the complexity and risks of such diversification across systems, and even across public and private actors. Such diversification can in fact lead to a stronger response capacity when it optimizes relative strengths in access to financing and diverse human and other essential resources, nimbleness in response, innovations in technology, capacity to convene and call to action, and even the incentives to excel when measured against others.

The Honorable Brett Guthrie (R-KY)

1. Your testimony mentions the need for open communication with manufacturers and stakeholders to ensure COVID vaccines and therapeutics remain available. Can you elaborate as to why it is important for the government to maintain an open dialogue and why it would be helpful to extend those channels of communication to manufacturers of non-COVID products?

    a. You recommend this communication be collaborative and use innovative, non-compulsory procurement tools, can you provide an example of what this would look like?

    Governor Leavitt Response

    As a nation, our culture and our economy have thrived when grounded in an ethic that balances our instinct for compassion to those in need with a passion for economic excellence and innovation. We have a history of responding best to those who inspire and propose, and not so well to those who impose and compel. We have seen the best of this culture and ethic in the nation's response to this pandemic. Health care providers came to service of the nation, at great peril to their own health. Essential workers continued to produce and deliver essential products and services. The nation's manufacturers of vaccines, diagnostics and tests, therapeutics, and devices stepped up to innovate and to deliver life-saving products that responded to the pandemic, while keeping non-COVID products available to patients. Many of the supplies, supply chains, products, and people

involved in COVID response are also used with non-COVID response. Government plays its role best when it communicates the need, helps organize the field of play, sets basic rules of conduct, and provides the essential financing and resources needed, not just for the immediate response but also for genuine and enduring preparedness for the future. I have some confidence that the example we provided in the run up to the avian flu threats in 2005-2009 may serve as one example for how this might look, using many of the tools that Congress provided in the aftermath of 911 and the anthrax attacks

2. How to best incentivize the development of new antimicrobial drugs has long been an interest of Members on this Committee. As you mention, the pipeline of drugs to fight these infections is thin, making the threat of an antimicrobial-resistant superbug even more dangerous. As you likely know, encouraging this type of research and development, while critical, is challenging given that we are asking companies to invest heavily – both their time and resources – into products we hope to never have to use and for which there is a limited market. What lessons realized from the response to this pandemic should inform our efforts to advance the development of antimicrobial drugs and be best prepared for an antimicrobial-resistant threat?

Governor Leavitt Response

Thank you for that important question. As I have said before, we are immensely fortunate that because of scientific advancements, dedicated leadership, intense collaboration, and private and public sector investments in American innovation before and during the current health emergency, we have multiple very safe and highly-effective vaccines approved to prevent severe COVID-19. This accomplishment is unprecedented and historic, and worth celebrating.

This accomplishment is also worth learning from – and not just learning from, but we should be seeking to replicate the best successes and most effective collaborations from 2020 to prepare for the threat of antimicrobial resistance.

One success from the past year has been the federal government investing in multiple platforms in a portfolio approach. It seems to me that funding should be prioritized in a manner that ensures a diversified approach with a stable time horizon. Clearly one of the lessons for this Committee from COVID-19 is that investment in combatting known threats can save thousands of lives and livelihoods and therefore merits Congress's focus to act now.

Another success has been the unprecedented collaboration of scientists, researchers, clinicians, and regulators across the private and public sector. Another one of the lessons for this Committee is that honest collaboration which prioritizes the common scientific challenges helps avoid knee-jerk institutional reactions and foster trust.

We have to acknowledge that the threat of antimicrobial resistance is not a distant hypothetical; it is a present threat that grows with time. The CDC has reported that more than 2.8 million antimicrobial-resistant infections occur in the U.S. each year, and an estimated 35,000 Americans die as a result.[1] Imagine how much worse the problem would be if we had no new drugs to combat antimicrobial resistance. Unfortunately, such an dire outcome is possible because the pipeline of drugs to fight these infections is tepid. So, if an antimicrobial-resistant superbug were to cause the next pandemic, the U.S. would not have the ability to fight it like we did COVID-19. Antimicrobial resistance is already a challenge –so its danger and deadliness as a threat to American lives grows in direct proportion to our inaction.

3. In your discussion about Immunization Information System, you point out that several states that do not require everyone who administers a vaccine to report that information to a state Immunization Information System. What federal policies could incentivize and encourage the reporting of more complete information to state Immunization Information Systems?

Governor Leavitt Response

Any federal policies that provide additional funding to states to modernize their public health technology infrastructure should include a requirement to ensure the following:

- **Digital reporting by vaccine administrators:** All states should require that when vaccination information is recorded, that information is automatically sent to the state immunization information system via the use of open standards. Currently, many states don't require all vaccinations to be reported to the state IIS therefore when adults are looking for a digital proof and representation of their vaccination information they can access it similar to how they access the information for their children's vaccination information when they enter the school system.
- **Ongoing funding for state public health:** One of the major issues state public health agencies have today is they only receive significant funding when a pandemic or significant public health event occurs. Ongoing incentive-based funding could be provided to states if they commit to implementing a modern, Application Programming Interface (API)-based architecture that would allow individual consumers to access their testing and vaccination information from an application of their choice.
- **CMS Interoperability rules:** Recently, CMS issues an interoperability rule (9115-F) that discussed the need for payers (including state Medicaid agencies) to build a modern, API-based infrastructure that would help to modernize the ability for payers to transmit data in the 21st Century. HHS could develop additional federal regulatory policies incentivizing states to

[1] https://www.cdc.gov/drugresistance/biggest-threats.html#:~:text=According%20to%20the%20report%2C%20more,at%20least%2012%2C800%20people%20died

implement the same modern technology open standards that were discussed in the CMS rule.

4. In many cases, targeted upfront investments in public health modernization at the state and local levels can save the federal government money over time. Can you further explain why increased state and local funding for public health would reduce the strain to respond to a pandemic or any other health emergency?

Governor Leavitt Response

In addition to my reply to the full Committee Chairman on a very similar question, it is worth saying that funding for state and local public health activities does need to be increased, but it must also be sustainable. We all know the familiar story of Congress or a state legislature passing a bill and declaring victory. Such an approach is well intended but overlooks the continued focus over time that is needed to repair and restore public health. Think of a holistic vision of dedicated attention that covers a wealth of services and activities, like training and retaining qualified staff, developing and maintaining 21st century data and surveillance systems, and ensuring the proper expertise and experience of public health professionals is retained. In its best sense, funding can help build public and private sector partnerships, support learning collaboratives, and support pandemic planning and readiness response activities.

5. Federal and state officials have a unique responsibility to prepare for pandemics, but they are not the only leaders who need to be prepared. You recommend that preparedness exercises must be done regularly at the federal, state, and local government levels, as well as by the private sector, communities, and families. Where are these preparedness exercises not standard practice, and how can we make these exercises more widespread, more frequent, and flexible in preparing states and localities for both known and unknown threats?

Governor Leavitt Response

Many state, local, and business leaders periodically conduct readiness assessments and update protocols that focus on continuity of operations in the event of a natural disaster (such as a wildfire, hurricane, or tornado) or a security incident (like an act of terrorism or an active shooter). These exercises are seen as prudent steps that responsible leaders take to anticipate known threats, identify measures that can be put into place to be prepared to respond to known risks, and implement practices to protect the safety and welfare of the individuals for whom they are responsible. In many respects, state and local leaders – as well as business leaders – need to approach pandemic preparedness the same way.

As I have often said, pandemics are a fact of biology and a reality of history. While the world has not witnessed a pandemic as deadly or disruptive as the

COVID-19 public health emergency in many years, they have occurred.[2] in certain regions and locations around the world, there have been some pandemics certainly have been very serious outbreaks. In the years since I began my tenure as Secretary of Health and Human Services through today, the world has witnessed a number of very serious, deadly, infectious diseases, ranging from SARS in 2003, to H1N1 in 2009, from Ebola in 2014, to Zika in 2015.[3] While none of those infectious diseases resulted the widespread disruption that COVID-19 has caused, each posed a serious threat.

We must be clear eyed that with worldwide commerce and travel, biological agents from one corner of the globe can be on our doorstep in a matter of hours. Thus, state, local, and business leaders need to anticipate future pandemics and future scenarios where infectious disease spreads and promote a culture of readiness reviews and continuity of operations planning.

States and businesses need to be prepared for different types of challenges, and need to think categorically about preparedness through the lens of continuity and protection of personnel, access to data and files, physical building security, and other such divisions of operations and service. State and local leaders have a tremendous opportunity to collaborate with the private sector to foster a sense of shared ownership and collaboration for preparing for challenges that we all hope never occur.

6. In your testimony, you discuss "long haulers" or individuals who virologically have recovered from infection, but still suffer from persistent symptoms, such as fatigue, muscle pains, and cognitive abnormalities. How can federal and state health programs such as Medicare, Medicaid and the Children's Health Insurance Program help meet the needs of long haulers?

Governor Leavitt Response

I appreciate your question because it is an important one. As you may know, Nancy-Ann DeParle and I co-convene the COVID Patient Recovery Alliance[4] We just recently publicly announced our efforts (April 2021), but have been organized as a group and working since last fall (2020). We certainly commend you and your colleagues for your recent hearing on long-COVID.[5]

Our multi-sector alliance is a collaboration of leading organizations whose mission is to define, develop, and assist in implementing a national strategy to characterize, diagnose, ensure care for, and sustainably fund the full recovery of individuals with long-COVID. Our Alliance is linking diverse data sources to

[2] https://www.cdc.gov/flu/pandemic-resources/basics/past-pandemics.html
[3] https://www.cdc.gov/globalhealth/infographics/global-health-security/global-disease-detection-timeline.html
[4] https://covid19patientrecovery.org/about-us/
[5] https://tinyurl.com/HouseECletter

inform the development of models of care and assess whether current payment structures are adequate for the care and full recovery of these patients.

The Alliance is building out a comprehensive list of ideas and actions that federal policymakers in Congress and the Administration can take to help respond to the needs of individuals with long-COVID. While the Alliance does not yet have a consensus-based, comprehensive blueprint of actions to share externally with you and your colleagues, we would welcome the chance to be in touch with you and share ideas as we move forward. In broad strokes, we see the need for

(1) Efforts that promote iterative learning and direction insights from data in the nearer-term (rather than wait years for ideal precision in a way that could miss out on informing the health care system's near-term response to current needs);
(2) Collaborative efforts from medical and scientific leaders to better understand long-COVID and develop clinical care pathways for long-COVID;
(3) A focus on the delivery system to ensure models of care that ensures patients can get the appropriate care from the right providers and reaches patients regardless of their source of health care coverage – especially prioritizing individuals who already are underserved, face disparities, or face inequities.
(4) A careful assessment regarding the degree to which our current payment systems and strategies adequately resource and account for the delivery of appropriate care for patients with long-COVID.

More generally, as you think about this issue, here are a few ideas to start:

- Perhaps one of the simplest but most impactful things that Medicare, Medicaid, Marketplace plans, and the Children's Health Insurance Program can do is to recognize that many of the individuals served by these programs (and the plans with whom they contract) will have long-COVID – a range of ongoing symptoms for some period of time. As clinical understandings of long-COVID increase and clinical care pathways emerge, these programs can help amplify efforts that educate providers, inform patients of how to get the care they need, and reduce any potential stigma from long-COVID. Given the scope of those programs and the likely size of patients experiencing long-COVID, there are likely millions of such patients.[6]
- The Committee's hearing on long-COVID was important way to both educate members and draw attention to this evolving issue. The Committee's continued engagement with the health care community – medical leaders, scientific researchers, data analysts, health plans, and others – to closely monitor the evolution of the science, emergence of clinical care pathways, and efforts of the health care community to address this issue.

[6] Based on estimates from CDC and the Institute for Health Metrics and Evaluation, it is thought that roughly 100 million Americans have been infected by the virus causing COVID-19. Published studies indicate 10-30 percent of people diagnosed with COVID-19 may have ongoing symptoms (long-COVID) after acute infection, many of which can impact return to work and life.

- Policymakers could work with researchers to support surveys of patients enrolled in those programs to better understand their needs.
- Given the disproportionate impact that COVID-19 has had on communities of color and underserved populations, it is likely there are more individuals with long-COVID who already faced disparities and inequities. Policy strategies should be responsive to this dynamic. For example, consider the value of targeted resources to Federally Qualified Health Centers to help scale up care pathways for patients with long-COVID.
- Consider what types of grants and funding can help scale up delivery system efforts when clinical care pathways emerge.
- As data and evidence becomes clear, CMMI may have a role to play in supporting the primary care workforce and advancing payment models that support value-based strategies for the care that patients with long-COVID will need.

The Honorable Gus M. Bilirakis (R-FL)

1. As policy makers consult the data to direct response efforts, where should the goal posts be erected – in other words, where should the bulk of our attention and resources be directed as states reopen? Does a response addressing mortality have different considerations than one that prioritizes transmissibility?

   Governor Leavitt Response

   The unprecedented collaboration across the health care community and beyond to make available and promote widespread vaccination against COVID-19 helps reduce both the mortality associated with COVID-19 and the transmissibility of COVID-19. Vaccination is critical to safely returning to a sense of normality and the continued widespread vaccination of individuals against COVID-19 should be a priority for policymakers.

2. One of the issues we hear about is the difficulty states and providers are having at the last mile, actually getting shots into arms. Once phase 1 has been completed, do you agree that we should have an all-hands-on deck approach, using all of America's commercial distribution resources, customer connectivity, expertise and end-to-end logistics across a multitude of provider settings, to ensure the American public has expedited and equitable access to a vaccine once we get to broad distribution?

   Governor Leavitt Response

   The last number of months have been a tremendous success with regard to the increased supply of and access to COVID-19 vaccinations. This is due to the tireless efforts of literally thousands of men and women—from scientists and researchers, to manufacturers and distributors, to unprecedented partnerships and

collaboration across the private sector and all levels of government. From retail pharmacies to primary care physicians offices, from federally qualified health centers to large health care systems – there has been an unprecedented effort to convert *vaccines* into *vaccinations* by getting shots in arms. As we have entered a phase in which there is less demand than supply in some areas, it is critical that vaccines be available in multiple settings to eliminate barriers to vaccination and ensure equitable access to vaccines. We are seeing many success stories in this respect, thanks to the unprecedented collaboration of employers, community leaders, non-profits, educators, state and local leaders, and so many others.