U.S. House Energy and Commerce Health Subcommittee Hearing
"Road to Recovery: Ramping Up COVID-19 Vaccines, Testing, and Medical Supply Chain"
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"Scouting the Next Valley: Preparing for the Next Phase of the COVID-19 Pandemic"

Good Morning, Chairwoman Eshoo, Ranking Member Guthrie, and Members of the Health Subcommittee.

Thank you for the invitation to appear before the Health Subcommittee. The topic of this hearing is of great importance to me personally and to the nation.

As I begin, I want to acknowledge the sobering milestones we recently marked: more than a year into our COVID-19 public health emergency and more than 400,000 Americans lost to this novel virus.

- To the families who have lost loved ones, I convey my greatest sympathies to you.
- To my fellow Americans who have suffered loss of income or job, I empathize with you and hope you are able to use your time and talents professionally again soon.
- To all the heroes in the public and private sectors who have helped us respond to this health emergency, combat the virus, and keep essential businesses open to serve our communities, thank you for your work. We are indebted to you.

This pandemic has affected each one of us in profound and different ways. As the pandemic grinds on, we acknowledge the accumulating toll it places on our friends, families, neighbors, and communities.

That is why the committee is holding this hearing today, even as we seek to assess where we are and to plan for the months and years ahead. Already, this committee has shown bipartisan leadership in enacting legislation to provide authorities and resources to address the health and economic challenges faced by our country. But we know more needs to be done. We know the months ahead are full of both promise and peril; they hold both hope and hardship.

As we look at the road ahead and what the future of the pandemic holds, I want to share with the committee a leadership framework I call "scouting the next valley." After explaining this framework, I will provide specific recommendations on how we can apply this framework to the current COVID-19 pandemic.

I. Pandemic Response Requires Strategically "Scouting the Next Valley"

Let me begin by sharing a useful framing concept for how to approach the activities needed for a more adequate pandemic response: the idea is *scouting the next valley*. In exploring new challenging terrain, an essential task for leaders seeking to lead people safely along a journey is to look ahead – not merely to seek the flattest or smoothest terrain, but to assess the potential threats and environmental conditions along the way that can impede progress.

The charge of federal policymakers in pandemic response is to *scout the next valley* – anticipating dangers, developing contingencies, and adopting strategies to mitigate potential threats. While the committee is not tasked with the operational response to the pandemic, you have a critical role to play. Members can help us all learn from past errors or missed opportunities, to understand all the current developments, and to help prepare for the challenges ahead. Members occupy a vitally important role by providing resources and authorities, asking questions, and helping hold accountable the agencies leading the response. Members have the opportunity and the obligation to hear from stakeholders and the private sector as the response is ongoing.

One perspective to emphasize with you is that the road to recovery is a winding one and will likely take much longer than any of us anticipated. From studying the history of pandemics, it is important to say that we should view our response as not just a "this-year" effort but along a multiple-year horizon. Even once we as a country achieve widespread vaccination for COVID-19, we must anticipate that the virus will continue to circulate and evolve. Thus, the pattern of changing course in our response needs to be "par for the course," as we seek to also evolve our response and stay ahead of developments.

To help inform your efforts, I offer you my current assessment of issues I see in the next three to six months or six to nine months that are important for planning. As you would expect, there is more granularity in the near term while the broad outlines of looming challenges further out on the horizon are also included.

II. Scouting the Next Valley for COVID-19 – Issues and Recommendations

A. Developing an Open-Source Vendor-Agnostic Digital Vaccination and Testing Credential

Many workers, contractors, small businesses, and large business have been hit very hard by the economic fallout related to the pandemic. As more Americans get vaccinated and testing becomes a built-in expectation in certain sectors of the economy, one way to foster our recovery is to enable individuals to voluntarily, digitally have secure and trusted access to their testing and vaccination information. Giving consumers an easy means of voluntarily demonstrating their vaccination status could help encourage vaccination at a popular level, especially to the extent business leaders in the future require some verification of vaccination and testing to enable sites like football stadiums and theaters to have larger numbers of in-person patrons once again. To help foster the ability for private sector business and consumer interests to make this attractive, we need to remove the barriers to making digital access to an individual's vaccination information a reality. To advance this idea, we need to prioritize supporting efforts that are open-source and vendor-agnostic. We have all seen the challenges in how proprietary approaches in electronic health records slowed the progress of interoperable medical records. It literally took an act of Congress that originated in this committee to prevent information blocking.

- *All vaccinations should be reported to the state Immunization Information Systems.* Vaccinations are being administered both by traditional health care entities and by non-traditional ones. Currently, there is no national vaccination registry that includes personally identifiable information, nor should there be. Public health is administered at a state and local level and that should continue. The challenge is, depending on the state, not every vaccine administration is necessarily reported to the state's vaccination database, which is called the Immunization Information System or IIS. In fact, there are several states that do not require everyone who administers a vaccine to report that information to a state Immunization Information System. Federal policy can incentivize and encourage a future state where

individuals administering a vaccine report such information through the proper channels to their state IIS so there is a single, statewide trusted source that houses this information for consumers and others who voluntarily need to access it.

- *Consumers should have access to their immunization information from their state Immunization Information System.* Numerous states do not provide digital access to consumers so they can access their vaccination history from a state Immunization Information System. To ensure we can restart the economy and put more people back to work, Congress should encourage states to provide consumers with digital and paper-based access to this information through the state immunization information system. Federal funding associated with modernizing public health could be tied to enhancing state immunization information systems to allow consumers access to their vaccination history.
- *All states should participate in the CDC/APHL IZ Gateway*. Working in conjunction with the CDC and the Association of Public Health Laboratories, HHS developed a technology called an IZ Gateway, which allows cross-state jurisdictions to share vaccination information. This enables individuals and providers to access vaccination information from any jurisdiction in the country. Unfortunately, only about half of the jurisdictions (there are 64 total) are participating in the IZ Gateway today. I believe that to ensure individuals have dependable access to their complete vaccination history, all states and jurisdictions should be participating in the IZ Gateway. Congress can help encourage and incentivize that reality.

B. Strengthening Domestic Capacity to Rapidly Manufacture Vaccines After the Emergence of a Virus

Today, there are two COVID-19 vaccines authorized for emergency use by the FDA, with more promising vaccine candidates in the development pipeline. In addition to recognizing the countless efforts that have brought us this far, we should also recognize how fortunate we are to benefit from the unprecedented efficacy of the two approved vaccines. Reflecting on my time at HHS as the H5N1 avian flu emerged as a serious pandemic threat, I continue to be amazed at what seemed unthinkable just 15 years ago. Today, we have seen the development and manufacture, distribution and administration, and ongoing monitoring of a safe and effective, novel vaccine, all under the close and expert regulatory and scientific review of the federal government. The accomplishment is not without its challenges and imperfections, but it is worth remarking on. However, the ongoing scouting challenge for our country is to ensure that we maintain ample supply of the vaccine through the entire course of what may be a multi-year pandemic. Essential to that scouting will be open communication with manufacturers and stakeholders about their needs, to ensure that COVID vaccines and therapeutics remain available. That open communication must also apply, frankly, to non-COVID products. Each product category uses similar manufacturing, supply chains, and even components (such as caps, high-quality glass for syringes and vials, and drug ingredients). That communication should also be collaborative, looking to innovative and non-compulsory procurement tools, especially as we seek to ensure domestic production where feasible.

Pandemics evolve in part because viruses evolve. We are seeing that now as new strains of the virus appear to be more transmissible and thus more deadly. We urgently need to prioritize the development of resourced capacities at scale to analyze the genome of variants of the virus that causes COVID-19, so we can more quickly understand the ramifications of such variants and work to develop interventions to help mitigate the threat.

C. Anticipating the Potential Needs of Patients with "Long-COVID"

As Dr. Fauci explained last year in testimony before the Senate, "a number of individuals who virologically have recovered from [their COVID-19] infection, [who] in fact have persistence measured in weeks to months of symptomatology that does not appear to be due to persistence of the virus. They're referred to as long haulers." He explained that "they have fatigue, myalgia, fever, and involvement of the neurological system, as well as cognitive abnormalities, such as the inability to concentrate."[i] The CDC said, "persistent symptoms are being reported among COVID-19 survivors, including individuals who initially experience a mild acute illness," and cautioned that "these persistent symptoms pose new challenges to patients, healthcare providers, and public health practitioners."[ii]

A few weeks ago, NIH Director Dr. Francis Collins wrote about these patients with "long-COVID." As Dr. Collins explained, "thousands of [people] who've gotten sick and survived COVID-19 are finding that a full recovery can be surprisingly elusive. Weeks and months after seemingly recovering from even mild cases of COVID-19, many battle a wide range of health problems."[iii] Dr. Collins highlighted one study in which nearly half of respondents with ongoing symptoms from COVID-19 reported they "had to reduce their hours at work due to the severity of their symptoms," and "another 22 percent weren't working at all due to their Long COVID." Dr. Collins concluded, "while the number of people affected isn't yet known, if even a small proportion of the vast numbers of people infected with COVID-19 develop Long COVID syndrome, it represents a significant public health concern."[iv]

Dr. Collins noted that in the appropriations health extenders bill enacted several weeks ago, Congress included funding "for NIH to support continued study of these prolonged health consequences." While research on long-COVID funded by NIH and others is ongoing, the committee should be aware of this growing cohort of patients. With jurisdiction over the ACA Marketplaces, Medicaid, the state Children's Health Insurance Program, and Medicare, the committee has a unique view of understanding to what extent these federal and state programs may be helping meet the needs of patients with "long-COVID."

D. Anticipating and Addressing the Barriers of Social Determinants of Health and Inequity

In a matter of months, we expect a greater supply of vaccine. Yet a crucial step toward recovery is not merely manufacturing vaccines but achieving widespread vaccination of the American people. As part of pandemic response, states and health systems will have a significant amount of work to do to ensure that minority communities, low-income individuals, rural residents, non-native English speakers, and others who face adverse social determinants of health (SDOH) are not left behind in this process.

While there is a long road ahead toward fundamentally tackling SDOH, for pandemic response today we should recognize that there will be people whose circumstances – such as not having a car, poor broadband access, or language barriers – may prevent them from signing up for a vaccine appointment or reaching a health care provider to receive their shot. There also may be people who are hesitant to take a vaccine. State public health officials, health care providers, and the federal government can all be planning now for how to educate, communicate with, and creatively provide access to these harder-to-reach populations to ensure they have the chance to be vaccinated.

While also taking longer to fully address, as part of the pandemic response, we must acknowledge the stubborn persistence of inequities in our health care systems and consider how these can be barriers to receiving care for many of our friends and neighbors. At a state and local level, leaders should look for partnerships and collaboration with community leaders and health care leaders to design and deploy

strategies that seek to overcome inequities. We certainly will not get it right every time, but a recognition of the presence of these challenges is the necessary predicate for working to address them.

E. Resourcing and Sustaining Our Public Health Infrastructure

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 since we are not likely to see full economic recovery until we have public health risks fully mitigated. We should seek this opportunity to invest in public health. In many cases, targeted upfront investments in public health modernization at the state and local levels can save the federal government money over time. 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.

F. Resourcing and Sustaining Medical and Scientific Innovation

We are 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 now have multiple COVID vaccines available. We need to maintain investment in innovation – not only for vaccines against new strains that emerge, but investments in the kind of medical research that will help us better understand the virus that causes COVID-19. Beyond COVID-19, we should consider areas where scientific and medical limitations could metastasize into public health threats. One area in desperate need of fresh investment is antimicrobial resistance. 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.[v] Unfortunately, as antimicrobial resistance accelerates, the problem could grow much worse because the pipeline of drugs to fight these infections is very thin. 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.

G. Strengthening Our Commitment to Mental Health

As the COVID-19 pandemic continues into its second year, the mental health consequences caused by the pandemic have become painfully clear. Unfortunately, as the public health emergency continues, mental health needs will worsen.[vi] There is much the federal government can do directly to help through existing health programs and authorities, as well as indirectly in its role as a collaborator and partner with states, grantees, the medical and mental health community, and the private sector. Clearly, reviewing federal tools and authorities to help to respond to these unprecedented demands in mental health needs is within the purview of the committee, and should be a priority area of focus.

In recent years, this committee has helped develop and enact important legislation to combat the opioid epidemic and ongoing substance abuse.[vii] Given the growing scope of mental health needs this committee may have a key opportunity to reprise its policy leadership role and advance new bipartisan policy that could make targeted improvements in the federal government's response to widespread mental health needs. Some promising policy directions for your consideration might include:

- Improving the oversight of existing mental health parity requirements to ensure that the commitment made to patients under current law occurs in practice. Where workforce limitations

make it challenging to effectuate parity, efforts to improve and strengthen the mental health community workforce could help ensure a sustainable supply for increased demand.
- Leveraging workforce funding such as loan forgiveness and repayment to help increase the availability of behavioral health experts, especially in settings of care for at-risk populations.
- Collecting and disseminating through a learning collaborative a wide array of evidence-based practices that providers, plans, patient advocates, and community-based organizations identify to link patients to care, ensure successful care coordination, leverage telehealth services, and improve access to quality peer supports.

H. Responding to the Challenges that Pandemic Presents to Medicare's Financing

The economic disruption resulting from the COVID-19 pandemic has further eroded Medicare's financing. That is because the pandemic resulted in depressed payroll tax collections compared to previous projections. These payroll tax collections comprise roughly 90 cents of every dollar in the Medicare Hospital Insurance (HI) Trust Fund – and this Fund in turn pays for items and services provided to Medicare beneficiaries in inpatient hospitals. In September, the Congressional Budget Office reported that "[t]he HI trust fund is projected to become exhausted in 2024, two years sooner than CBO estimated this past March. After the date of exhaustion, the Centers for Medicare & Medicaid Services (CMS) could not make payments in excess of the available receipts."[viii] CBO explained that "the projections for deficits were revised upward in part because of the economic disruption stemming from the 2020 coronavirus pandemic, which reduced CBO's estimates of payroll tax revenues."

As we anticipate the challenges beyond the current COVID-19 public health crisis, there is an urgent need to focus on Medicare. Medicare beneficiaries are currently among the country's most vulnerable to the virus due to their age and health conditions. At the same time, thousands of Medicare providers are serving tirelessly on the frontlines of health care delivery, battling the virus in order to save them. Given the committee's jurisdiction over Medicare and your interest in sustainable and strong access for beneficiaries during the pandemic and beyond, I believe this issue merits your thoughtful attention now. I believe remedying them is an important opportunity – not only for keeping our commitment to Medicare beneficiaries, but also for advancing value-based care and the role that value plays in our health care system.[ix]

While 2024 may feel like a long way from now, we must acknowledge that we do not know how long this pandemic will persist, the precise course it will run, and the degree to which Medicare's financial outlook could even worsen. Adopting reasonable policies to address the financing gaps early on is a more prudent path than waiting for a more ideal time.[x] While this task requires collaboration and hard work, it is eminently doable. It was not that many years ago that this same committee achieved what was then thought unachievable by leading the Congressional effort to enact MACRA. I believe bipartisan collaboration and cooperation from this committee can again set the tone and pace for needed improvements.

I. Prioritizing Pandemic Preparedness on An Ongoing Basis

A frequent observation I have shared with many during the past year is that actions taken by federal and state policymakers before a pandemic often appear or sound alarmist, while much they do after a pandemic is already here may feel inadequate. Such is the nature of pandemic planning and response. We must acknowledge that pandemics are a fact of biology and human history. The very goal of preparedness is to recognize this fact and identify potential threats and responses before they happen.

While we cannot take our eye off the pandemic we are in, we must acknowledge the hard reality that additional pandemics will come, whether we are ready, and they will arrive on their own timeframe. Future pandemics could be more contagious or deadly than even this COVID-19 pandemic. Federal and state officials have a unique responsibility to prepare for pandemics, but they are not the only leaders who need to be prepared. Preparedness exercises must be done regularly at the federal, state, and local government levels, as well as by the private sector, communities, and families. In many places, these exercises are a standard practice already, and I think that they should become more widespread, more frequent, and should focus on known and unknown threats.

J. Assisting the Nation's Governors in Strengthening Medicaid's Response to the Pandemic

The collective footprint of the states' Medicaid programs will provide coverage and care to nearly 100 million Americans this year. Yet the economic effects of the pandemic have reduced the ability of states to resource their own programs, even as enrollment has increased due to the pandemic. Several Medicaid policy areas merit thoughtful review by engaging with governors and Medicaid stakeholders.

- *Giving State Medicaid Programs More Tools to Better Integrate Care for Dually Eligible Beneficiaries.* Of the more than 12 million individuals dually eligible for and enrolled in Medicare and Medicaid, many face challenges due to comorbidities, mental health conditions, or the social determinants of health.[xi] The Medicaid and CHIP Payment and Access Commission has reported that "dually eligible beneficiaries are at particular risk during the COVID-19 pandemic due to their age and underlying medical conditions." Data released from CMS shows that dually eligible beneficiaries are at greater risk of hospitalization or mortality due to COVID-19 compared to other patient populations.[xii] Yet, as MACPAC noted, "covering individuals under two programs can result in fragmented care and promote cost shifting instead of ensuring that beneficiaries receive services that best meet their needs." To help, the Committee should advance MACPAC's recommendation that Congress "provide additional federal funds to enhance state capacity to develop expertise in Medicare and to implement integrated care models." Modest federal investments in state Medicaid programs in this moment can help ensure states maintain the expert staff, information technology, and data capacity to enact needed reforms. Beyond this, the committee should consider the benefit of creating a new option for states that lets them leverage Medicare dollars under a shared savings model to offer a single integrated product to dually eligible beneficiaries while maintaining current benefits and protections.
- *Strengthening Home- and Community-Based Services.* There was bipartisan interest in increasing access to HBCS before the pandemic. Now, with a significant portion of fatalities from COVID-19 connected to institutional care settings during the pandemic, this topic feels even more timely. Going forward, exploring opportunities to increase the provision of HCBS by identifying and addressing complex and interconnected dynamics is an area of great potential.

K. Learning Continually by Scouting Valleys Beyond

As we have learned firsthand during the past year, pandemics are unpredictable. The thing about scouting the next valley is that, as the journey continues, there are valleys beyond the next valley. While the more distant future may feel abstract at times, blazing trails through new territory always requires looking ahead. This mean there will always be valleys to scout, so we must scout the next valley not just today, but on an ongoing basis. The lessons we learn now will provide important insights for how to fight both COVID and future pandemics. They will also offer insights on how we can address important health care issues outside of pandemics. One way to elicit these insights is to use the following

framework of categories, which can help as we conduct our analysis now and as the pandemic continues:

- What we have learned during the last year that should inform how we handle the rest of this pandemic.
- What we are learning that should inform future pandemic preparedness.
- What we are learning that should inform how we do non-pandemic things (e.g., we have learned how to develop vaccines faster – consider how could we apply those learnings to antimicrobial resistance or possibly to brain diseases).

Applying this framework will help us capture important insights and employ them appropriately.

III. Conclusion

Scouting the next valley is a responsibility of leaders. As members of Congress and members of this committee, you have both a special opportunity and unique obligation in this moment of our national public health crisis to work together in this effort. I appreciate that this is not an easy task. Not only is the work of scouting usually unglamorous, but it is also often complex and sobering work.
But this work of looking ahead to be prepared is as honorable as it is essential. As you undertake this work, you have my support and appreciation for your service to our country. Thank you for the opportunity to address this committee. I look forward to answering any questions you may have.

Endnotes

[i] https://www.help.senate.gov/hearings/covid-19-an-update-on-the-federal-response
[ii] https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/late-sequelae.html
[iii] https://directorsblog.nih.gov/2021/01/19/trying-to-make-sense-of-long-covid-syndrome/
[iv] https://directorsblog.nih.gov/2021/01/19/trying-to-make-sense-of-long-covid-syndrome/
[v] https://www.cdc.gov/drugresistance/biggest-threats.html#:~:text=According%20to%20the%20report%2C%20more,at%20least%2012%2C800%20people%20died
[vi] We see Americans' mental health needs growing in several ways. First, the public health emergency has disrupted and stressed the care delivery system of patients who, even before COVID-19, had mental health needs or mental illness. Second, as the CDC has noted, "public health actions, such as social distancing, are necessary to reduce the spread of COVID-19, but they can make us feel isolated and lonely and can increase stress and anxiety." Third, many Americans have lost income or job, lost a loved one or friend, lost their sense of security and safety, and they worry for the future.
[vii] https://www.congress.gov/bill/114th-congress/senate-bill/524/text and https://www.congress.gov/bill/115th-congress/house-bill/6
[viii] https://www.cbo.gov/publication/56541
[ix] https://leavittpartners.com/press/leavitt-partners-releases-medicare-drifting-toward-disaster-white-paper/
[x] To get a sense of the growing gap between incoming revenue and projected outlays, consider what the Congressional Budget Office outlined in its report several months ago. In a hypothetical scenario without interventions in which the HI trust fund was allowed to reach insolvency and the fund's outlays were limited to its income, expenditures in 2025 would be 17 percent below the amounts scheduled under current law.
[xi] https://www.macpac.gov/topics/dually-eligible-beneficiaries/
[xii] https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf