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STOPPING THE SPREAD OF MONKEYPOX: EXAMINING THE FEDERAL RESPONSE

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING STOPPING THE SPREAD OF MONKEYPOX, FOCUSING ON THE FEDERAL RESPONSE

SEPTEMBER 14, 2022

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C O N T E N T S

STATEMENTS

WEDNESDAY, SEPTEMBER 14, 2022

STOPPING THE SPREAD OF MONKEYPOX: EXAMINING THE FEDERAL RESPONSE

Wednesday, September 14, 2022

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m., in room 216, Hart Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Casey, Baldwin, Murphy, Kaine, Hassan, Smith, Rosen, Hickenlooper, Burr, Paul, Collins, Cassidy, Braun, Marshall, Romney, and Tuberville.

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. The Senate Health, Education, Labor, and Pensions Committee will please come to order. Today we are having a hearing on the Federal response to the monkeypox outbreaks, as we work to stop the spread of this virus.

I will have an opening statement followed by Senator Burr, and then we will introduce our witnesses. Before we start, I do—I want to take a moment to congratulate one of our witnesses, Dr. Fauci, on announcing his upcoming retirement.

Dr. Fauci, you have served through multiple decades and Presidents and public health threats, and worked to save countless lives, and I hope you know that you have the thanks of a grateful nation for your incredible service to this country. So, thank you and thank you for being here today.

After the witnesses give their testimony, Senators will each have 5 minutes for a round of questions. And while we are unable, again, to have this hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at *help.senate.gov*. If anyone is in need of accommodations including closed captioning, please reach out to the Committee or the Office of Congressional Accessibility Services.

According to the Centers for Disease Control and Prevention, the U.S. now has over 21,000 confirmed cases of monkeypox, more than anyone else in the world, and my home State of Washington has over 500 cases. I have heard from families who are rightly concerned about how bad this has gotten.

Public health officials, including back in Washington State, who are frustrated to see the response, run into issues we should be prepared for by now. That is why I have continued to push the

Biden administration about my concerns with the monkeypox response and urge quick action on testing, on treatments, on vaccines, and on clear guidance to the public, to their health care providers, and state public health officials.

It is reassuring to see that we are making progress on testing, capacity has increased 1,000 percent, and FDA just approved a faster track for additional tests. On vaccines, BARDA is helping to stand up a new vaccine fill and finish site in Michigan. HHS is working to expand the number of distribution sites and states, and the Administration's advice for splitting doses has greatly stretched our vaccine supply.

On outreach, the Administration has started working with states to make vaccines available at events with many people from the LGBTQ community in attendance. And perhaps most importantly, the rate of new cases is going down. Now, that is all encouraging news, but let me be clear, we must remain vigilant in our response.

These promising improvements do not excuse the issues I have been hearing about from communities, from state health officials, and advocates from the very start of this outbreak. Patients have spoken out about how hard it is to get tested. Some even waited days despite having clear symptoms. Providers have had to jump through hoops to get their patients treatments.

I am constantly talking to public health officials in my state who have told me how communications with states could have been far clearer and faster, and how the challenges in accessing tests and vaccines have delayed the response. I know states have especially struggled with the Federal Government's decision to forgo the system we typically use to distribute vaccines, the one we are already using for COVID vaccines.

When it comes to vaccine distribution, some shipments have been sent to the wrong state and even spoiled after storage at the wrong temperature. There have been issues with vaccine supply as well, like when thousands of vaccine doses were delayed because FDA had yet to inspect the new plants they were coming from, or when the Biden administration missed an opportunity to procure more vaccines at a crucial point in this outbreak.

Again, we are seeing inequities worse in this outbreak for some communities. Advocates in the LBGTQ community, who face the vast majority of cases, have also made clear they feel they are being overlooked or in some instances, stigmatized.

We need to keep focusing and improving on outreach, and on getting information and resources like vaccines to those who are most in need and most at risk. And that must include communities of color who we know do not have equitable access to vaccines. This is especially important, as early data suggests that Black and Latino communities are disproportionately burdened by this outbreak.

We have to do better. We need to be applying what we learned from the COVID response and providing the resources communities have made clear they need. Of course, there is an enormous difference between this and the COVID pandemic, which is thanks to

decades of investment in smallpox research, we already had tests and treatments and vaccines ready to go before this crisis began.

That should serve as a reminder to all of us about the immense value of investing in public health preparedness. But it is also why the stumbles in getting these tools deployed were especially frustrating and inexcusable. To learn from this, we need to be clear eyed about what went wrong, not just on the challenges we faced in the last several months, but that we have faced for decades.

Challenges that, to be frank, has spanned many Administrations, not just this one. For example, we had over 20 million vials of smallpox vaccine in our national stockpile, but they were not replaced as they expired over the course of a decade. I know I join my Ranking Member and Members of this Committee when I say we have got to do better, not just on COVID, not just on monkeypox, but on public health threats, period, because we know there will be more.

Just last week, New York declared an emergency due to polio, yet another public health risk we need to watch closely. I want to hear from our witnesses today about not just what they are doing right now to improve our response to the monkeypox outbreak and fast, but also how we can fix this in the long term and make sure the stumbles of the past couple of months never happen again.

I want to know what you and the Administration are doing to make sure we have enough tests and treatments and vaccines for this outbreak and get them where they need to go, while also maintaining an adequate stock of supplies for any smallpox threats.

What you are doing to improve outreach to the LGBTQ community, address disproportionate harm to Black and Latino communities, fight stigma and misinformation, and right the inequities we have seen in our response so far?

How are we making the most of new research to develop promising vaccines and therapeutics, and then make them more quickly available, while continuing to uphold the gold standard of safety and effectiveness? And are we getting schools and colleges everything they need to stay open and keep students and schools, communities safe?

I am glad CDC has provided guidance for K–12 schools. And fortunately, the science tells us elementary and secondary school kids are not at high risk. And CDC has also released resources for colleges, which is critical with students returning to campus this fall. We need to make sure that colleges and universities are equipped to prevent potential outbreaks as students move into dorms and live in close quarters with each other.

I realize you have got your work cut out for you in all of this, especially with COVID still raging, but there is no reason for us to fall behind. I am going to keep pushing you here because families back in Washington State and across the country are counting on all of you to get it right. That is also why I am going to keep pushing my colleagues here in Congress about the need for funding to support all of this work.

I know I am not the only one here with concerns about the monkeypox response, but we can't just say this isn't working with-

out providing the funding to end this outbreak and build the public health system Americans deserve. I will continue to work with colleagues on both sides of the aisle and push to deliver the resources that will help get families the testing, treatments, and vaccines they need.

I am interested in hearing from the witnesses on what the needs are when it comes to investing in our monkeypox response. It is also important to me we continue to keep our eyes on the horizon when it comes to future outbreaks and pandemics and build a stronger public health system for whatever threat comes next.

As the saying goes, an ounce of prevention is worth a pound of cure, and that starts with building a world class public health system rather than one that lags behind our peers. Our communities deserve to be as safe as anyone in the world, which is why Senator Burr, and I are continuing to work to pass our Prevent Pandemics Act.

Our bipartisan legislation implements the lessons from our COVID response and improves our policies and processes on issues like strengthening supply chains, improving management of our national stockpile, modernizing data systems, and other items which would address many of the challenges we faced with monkeypox.

But a strong public health system also requires strong investments, because our public health system was underfunded before COVID struck, and it has been overwhelmed ever since. We have to end the cycle of crisis and complacency by making sustained investments that allow us to build and maintain robust public health infrastructure at all levels.

I will keep pushing for all of these steps because we should all know by now just how much is at stake. I can tell you that families in Seattle know, parents in Spokane know, nurses in Yakima know, workers in Olympia know, people across Washington State and across the country know.

COVID was never going to be the last public health crisis we face, and neither is monkeypox. The question is not whether there will be a new threat, it is when it will strike and whether we will be ready. The truth is, the monkeypox response so far has not been encouraging.

But there are some clear signs of progress, and there are clear steps that we can and should take to improve. I don't want to just hear today about the steps we will be taking, I do want to see action, and I will be watching closely.

I hope we can work together to build on the progress and end this crisis and make the kind of improvements we need to put our public health security on solid footing once and for all. Thank you very much, and I will turn it over to Senator Burr for his opening remarks.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chair.

Good morning. I am glad that we are finally here having a hearing on monkeypox outbreak, and it is—as it hits our Nation.

Well, monkeypox is now a public health emergency. It didn't have to become one. I think the one promising thing that can be said this morning is the infection rate has slowed. That may be the only thing.

Since May, when the first transmission was reported in the UK, in Europe, I have been pressing the Administration for strategy and a plan. After almost 3 years of the COVID pandemic, you would think that the public health agencies responsible for our preparedness and response would be prepared for anything, particularly a threat like monkeypox, which we have known about for decades, and for which we have vaccines and treatments.

Dr. Fauci has talked to this Committee before about monkeypox. It is almost definition—It is almost a definitional case of what CDC and ASPR, and their sister agencies, should be prepared to tackle, a virus that spreads through physical contact, a virus that spreads when one—when an infected person has an obvious sign of infection.

This is not like COVID, which was a newly emerged virus that spreads asymptomatic infection. But by any measure, in fact by every measure, the response from the Biden administration on monkeypox crisis has been a catastrophic failure.

You repeated each of the mistakes from the early days of COVID response, and the cultural arrogance from public health officials, who were supposed to be at the forefront of our response, let this country down again. Since the COVID pandemic started, this Committee has held 13 hearings on the response during both the Trump and the Biden administrations. I think you were sick of being called to the carpet and us having to hold you accountable for systematic failures.

But it seems that nothing has changed. You can't blame the last Administration on this failure. The first confirmed monkeypox case in 2022 was May 7th in the United Kingdom. The first case of monkeypox in this outbreak was reported in the U.S. on May 18th. We had warning. We had warning that this was coming. We should have been prepared to manage what came when it arrived.

Let's review. We failed testing. Although you eventually made testing available through laboratory response networks, these tests were too hard to access. It took weeks before doctors were able to get their patients tested without having to first consult public health officials.

There was also a significant delay in engaging the private sector on testing at the beginning of the outbreak. We waited until June 22d to announce that engagement with the private sector. Still, after that, companies interested in developing additional diagnostic tests, that could help address some of the slow turnaround times and improve access, had been left waiting months for samples needed to develop those test.

Without delay—upon delay, you failed on vaccines. An enhanced strategy to offer vaccines to at risk individuals known—in known contact was announced June 28. But this was already after some local jurisdictions had already taken upon themselves to use the vaccine in this manner, and a full month after the UK Joint Com-

mittee on Vaccines and Immunizations met to discuss a similar strategy for their citizens.

Why do we continue to be behind? Meanwhile, decisions about vaccine administration in the U.S. have made—seem to have been made seemingly on the fly. Even when FDA issued an emergency use authorization last month, allowing vaccines to be administered intradermal injections, there were no public meetings of FDA, CDC, outside experts to discuss relevant questions on the minds of impacted Americans and inform these decisions.

Health professionals were confused about the initial decision and patients were scared that they were being experimented on. To make matters worse, states had no time to prepare for this change in vaccine administration. Right after the FDA made its decision, ASPR reduced state vaccine allocations under the assumption that every vial would yield five doses.

Yet you know that this has not been the case in every state, resulting in some vaccine—some vaccinating fewer, not more at risk people. You failed at having a plan. Monkeypox outbreaks have been occurring in Nigeria and other places with increasing frequency. It was identified a threat under our threat matrix, and a threat for which we had countermeasures in our stockpile.

I might also add that our earliest purchase of the Bavarian Nordic vaccine in bulk was in 2017. But it seems there was no real plan on how to respond and what information and research we needed to understand this outbreak. Only after both I and the Chair sent separate letters asking for a plan, that the Office of Science Technology Policy blogged about their research priorities.

But the priorities were vague. It is not clear what research activities HHS has actually undertaking in response. These failures have allowed the disease spread. 31 cases in May quickly turn into 650 cases in June, more than 6,000 cases in July and more than 12,000 cases in August, and near 22,000 so far in September.

It should have been obvious to all of us that the timing of these early cases, coupled with evidence that the cases were not linked, would create a perfect storm for a large outbreak. Monkeypox is a virus that largely transmits through skin to skin contact, most easily and frequently transmitted between sexual partners.

Monkeypox arrived just before the Pride celebrations across the country, and after 2 years of lockdown and social distancing, your agency should have been screaming from the rooftops about what you knew or suspected about how monkeypox was spread. Instead, we remain silent. People got sick because of that silence.

This isn't rocket science. But consenting adults need to be told what behavioral changes they should consider to avoid getting a preventable disease like monkeypox. You failed at a time when the communities most at risk needed you. Disease control and prevention and preparedness and response is literally in the name of two of your agencies.

Yet you did none of that. It was no surprise to me that the Administration, after months of floundering, appointed a new czar at the White House to coordinate the response. It shows why this Committee passed the PREVENT Act to create a mission control.

Secretary of HHS has been totally absent, and when he has been involved, it only seems it makes matters worse.

But new ad-hoc groups within Government are exactly the problem. We need a consistent, coherent, Government wide response to be effective, and that can only be led by the White House. I hope that in the coming weeks we will be able to get that legislation over the finish line, and I will commit to spending my remaining weeks in the U.S. Senate doing everything I can to help the White House set up the new office with a lasting mission and clear agenda.

If I were not retiring, I would spend the next several years conducting a thorough examination of each of your agencies, highlighting each and every one of the systematic and bureaucratic failures that we have seen now and seen in response after response and demand accountability for the American people. This isn't a question of authority. You have the authority. It is a question of—it isn't a question of money.

You have been given astonishing amounts of money. It is a question of leadership. It is a question of focus. It is a question of squashing the typical bureaucratic roadblocks, arrogance and ineptitude. You need to do better.

We learned in Operation Warp Speed that when you press outside the box, when you focus on public-private partnerships, when you get bureaucracy tamed so that it serves the American people and doesn't try to control them, we can actually make Government work.

I would ask you for your plan, but you don't have one. I would ask you for what you changed, but your agency seem to think that they are doing everything right. I would ask you who you are going to hold accountable, but failures at each of your agencies show that you don't believe in that type of accountability.

Instead, I will express my outrage and hope that eventually we will get people in your agencies who will do the job to protect the American people instead of protecting their bureaucracies. Madam Chair, before I close, I want to address a serious issue. The last time we were here, there was a coordinated assault pretending that somehow Republicans were at fault for there not being additional money for the pandemic.

Let's revisit some of the facts, if we can. The Senate on a bipartisan basis actually passed extra funding for COVID, $15.6 billion, in March in the omnibus for testing, treatment, vaccines, and global aid. But the Speaker of the House either couldn't pass that legislation or didn't think pandemic money was a priority so she stripped it out.

I have worked with her for a long time, and I am pretty sure she is a Democrat. Then Democrats—then Senator Romney and Blunt and myself engaged in deep negotiations with the Majority Leader and the Chair of the Committee, and we reached a deal for $10 million in domestic funding for COVID.

But the Majority Leader didn't want to take a vote against lifting a COVID restriction on the Southern border, probably because he knew it would pass so the deal was killed. I am pretty sure Chuck

is a Democrat. So then at our last meeting, the Chair and each of you got together and pretended that somehow Republicans were at fault.

The Republicans tried twice to provide additional funding for COVID, but Democrats couldn't take yes for an answer. Then last month, Democrats conducted a partisan spending exercise where Republicans weren't even in the room. They dramatically raised taxes by hundreds of billions of dollars, provided funding for 87,000 IRS agents to audit the middle class, and spent hundreds of billions of dollars on green new deals that will mostly impact billionaires and millionaires.

Those same Democrats who complain about no COVID spending didn't spend a dime of those new taxes on pandemic expenses. I often hear my colleagues say that your budget shows your priorities. But Democrats have the power to spend money on pandemic and chose not to. I guess making energy more expensive was more important.

I think all of you know, I have had in my jacket pocket a card with four simple requests from this Administration and told them all they needed to do for me to get my Senate colleagues, my Republican colleagues to support additional funding was to provide answers to those four things.

Give us a detailed plan for COVID. Detailed accounting of where the money has been spent. Offsets to match new spending for pandemics. And a simple vote on a COVID restriction at the border. I first started that in April. Today, none of those four things have been presented. So to date, the Administration has failed to deliver.

Maybe they don't want to actually have transparency on what they have spent. Or maybe they don't want to come clean to the American people what their plan is until after the election. Not sure what it is. I am tired of being the one that is blamed. I have got just as much as invested as anybody on this Committee in making sure that your agencies are successful for the American people. I will continue to do that, whether I am in Congress or not.

Tony, I can't thank you enough for your years of service. It has been incredibly beneficial to the American people and to the health care of this country. I hate to see you go, but I also look forward to that day in January where we both are on the other side of this mountain, and I can actually not have to plan to fly on a Monday and I can spend some time with my wife and grandchildren.

Having said that, Madam Chair, let's have a reset this morning. Let's quit blaming everybody and let's start showing some leadership. If the Administration needs money, then send us a budget requests money. There is no increased spending for COVID in next year's request.

They believe that this is all going to happen by an emergency, that the American people shouldn't be held accountable. That's wrong. Get the Administration to request the money. Let's work through the normal appropriations process. My hope is that there is a plan and someday they will share it with us. I yield back.

The CHAIR. Thank you, Senator Burr. I will now introduce today's witnesses. Dr. Rochelle Walensky is the Director of the Centers for Disease Control and Prevention and the Administrator of the Agency for Toxic Substances and Disease Registry. Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases and the Chief Medical Adviser on President Biden's COVID–19 response team.

Dr. Robert Califf is the Commissioner of the Food and Drug Administration. Don O'Connell is the Assistant Secretary for Preparedness and Response. Dr. Walensky, Dr. Fauci, Commissioner Califf, and Assistant Secretary O'Connell, thank you all for being here today. We all look forward to your testimony.

With that, we will begin with Dr. Walensky.

STATEMENT OF ROCHELLE WALENSKY, M.D., M.P.H., DIRECTOR, UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. WALENSKY. Chair Murray, Ranking Member Burr, and Members of the Committee, I appreciate the opportunity to discuss monkeypox and CDC's response to this global outbreak. To date, there have been over 59,000 cases of monkeypox reported globally, including over 22,000 cases and one confirmed death in the United States.

In the current outbreak, the first cases were diagnosed in the United Kingdom on May 14th, and within days, additional countries began identifying case clusters. On May 17th, a case was reported in Massachusetts and was confirmed by CDC the following day.

CDC immediately began its work searching for additional cases, educating clinicians and the public about this disease, and supporting our state and local public health partners in their response. In less than 1 week, CDC reached out to commercial labs to increase testing capacity and began to scale up an incident response.

Over the last several weeks, we have been pleased to see a decline in the growth of new cases here and abroad, though there are areas in the United States where the rate of rise in new cases is still increasing. We approach this news with cautious optimism, recognizing that we must continue to aggressively respond to our—use with our entire toolkit, including vaccination, testing, and education about risk to inform behavior change.

This outbreak has been notable for transmission primarily, but not exclusively, through sexual contact. It has disproportionately affected gay, bisexual, and other men who have sex with men, with a large majority of cases in this population. CDC has been studying monkeypox for decades and has contributed to the creation of the test, experimental therapeutics, and vaccines that are available today.

But as a relatively rare disease, almost no providers in the U.S. have seen or even heard of monkeypox. Provider education has been a key component, indeed a remarkable challenge, but critical to our response.

CDC has issued four health advisories, each reaching over a million people, and host clinician outreach calls joined by tens of thousands of clinicians. We have also shared monkeypox information for congregate living and K-12 schools to prevent monkeypox spread in these settings.

Initially, our public health laboratory response network labs across the country were able to collectively test up to 6,000 clinical specimens each week using a diagnostic test developed to detect orthopox viruses, including monkeypox.

CDC worked with our public health partners to quickly expand testing capacity and engage commercial laboratories to increase capacity to 80,000 tests per week. While weekly testing volume is currently 14 percent of total testing capacity, we are working with academic medical centers, commercial and public health laboratories to make testing even more accessible to all who need it.

From the beginning of this response, CDC has worked closely with ASPR to make JYNNEOS vaccine available to jurisdictions based on their case numbers and underlying population at increased risk. Based on data from 39 jurisdictions reporting to CDC, a total of over 540,000 JYNNEOS vaccine doses have been administered.

Collaboration with communities most affected by the outbreak, including the LGBTQ+ community, is critical to our response. We rely on our partners across public health and LGBTQ+ advocates and community based organizations to contribute to their expertise to our response, to challenge us to continue to do better, and to amplify our public health messages.

In recent weeks, CDC has provided technical assistance and support for vaccination efforts and other monkeypox response activities at large events serving LGBTQ+ audiences like Charlotte Pride and Atlanta Black Gay Pride weekend. These efforts and others have facilitated delivery of vaccines to those who may face unique barriers to access, including racial, ethnic, and geographically diverse populations.

The robust response required for public health threats like monkeypox underscores the importance of sustained investments in the core capabilities that should constitute the foundation of a 21st century public health system. In addition, CDC needs additional policy levers to enable the timely reporting of data necessary to take the informed action the public expects of us.

Despite having a vaccine distribution strategy since June 28th, it took until early September to complete all 61 data use agreements needed to receive vaccine administration data. While we work to control this outbreak in the United States, we anticipate that monkeypox will continue to be a global threat.

Once this outbreak is controlled, we will need to maintain vigilance, education, and vaccination efforts so that another outbreak does not emerge. That is why now it is important for Congress to act upon the supplemental request.

CDC will use the additional resources to support testing and laboratory capacity expansion, vaccination efforts, surveillance, epidemiologic investigations, outreach, education, and global efforts.

Together, we can meet the fast evolving threat of monkeypox, successfully end the current outbreak, and prepare for any future outbreaks. Thank you. I look forward to your questions.

[The prepared statement of Dr. Walensky follows:]

PREPARED STATEMENT OF ROCHELLE WALENSKY

Chair Murray, Ranking Member Burr, and distinguished Members of this Committee, it is my honor to appear before you today to discuss the Centers for Disease Control and Prevention's (CDC) response to the global outbreak of monkeypox. The world is experiencing an unprecedented outbreak of monkeypox, with tens of thousands of cases reported worldwide, predominantly in countries where this disease is not endemic. We are still learning more about this outbreak every day but are relying on the tools we have—diagnostics, vaccines, therapeutics, and community education and outreach—to continue our public health response efforts.

State of the Outbreak

On May 17, 2022, the Massachusetts Department of Public Health contacted CDC about a case of suspected monkeypox in the United States. CDC's Laboratory Response Network (LRN) testing confirmed orthopoxvirus infection and, the next day, testing at CDC confirmed the patient was infected with monkeypox virus. The case was identified as Clade II (formerly known as the West African strain), which is associated with less severe disease than Clade I (formerly known as Congo Basin strain). This case, and many of the first cases identified in the United States in this outbreak, were among persons with a history of international travel to Europe or Canada, countries that were also reporting clusters of cases. From detection of the first case, CDC immediately began enhancing surveillance and testing to identify additional cases; supporting jurisdictions in post-exposure prophylactic vaccination of close contacts; educating clinicians, public health partners, and the public; conducting outreach to LGBTQ+ organizations, and advocates to share information and amplify messaging; and preparing for community spread of monkeypox within the United States. On June 28, 2022, CDC elevated its response to monkeypox by activating its agency-wide Emergency Operations Center. On July 23, 2022, the World Health Organization declared the current outbreak and Public Health Emergency of International Concern, and Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a U.S. Public Health Emergency on August 4. In the United States, as of September 12, there have been 21,985 reported monkeypox cases, one confirmed death, and two additional deaths currently under investigation. Globally, there have been 57,016 cases reported with 19 deaths.

Monkeypox can be transmitted through close, personal contact. This is often skin-to-skin-contact, including hugging and intimate activity, but also through respiratory secretions during prolonged face-to-face contact and skin contact with fabrics and surfaces used by persons with monkeypox—although respiratory droplet and indirect transmission do not appear to be significant drivers of the current outbreak. While anyone who comes into close contact with an infected person or contaminated items like bedding or clothing could contract monkeypox, the current outbreak is disproportionately affecting gay, bisexual, and other men who have sex with men. The characteristic rash of monkeypox can initially look like pimples or blisters and can appear on the hands, feet, chest, face, mouth, or anogenital region, and may sometimes occur with other flu-like symptoms. Monkeypox is transmissible from the time symptoms begin until the rash has healed, all scabs have fallen off, and a fresh layer of skin has formed. Infection typically lasts for two-to 4-weeks. CDC recommends people with monkeypox isolate at home, keep rashes covered until they have fully healed, and notify close contacts, including sexual partners. The clinical presentation in this outbreak is atypical. The characteristic rash is still common, but lesions associated with this outbreak have often occurred in the anogenital region or in the mouth, and rash may be confined to only a few lesions or even a single lesion. In addition, prior to and after the rash, other symptoms may be mild or non-existent.

Similar to COVID–19 and many other public health challenges before it, the burden of monkeypox is not distributed equitably. In this outbreak, and based on available data, over 90 percent of U.S. cases have occurred among gay, bisexual, and other men who have sex with men. Although case data for race and ethnicity are incomplete, Hispanic/Latinx and Black men have represented more than 50 percent of cases in recent weeks among those case reports for which we have data on race and ethnicity. Where the data is clear, we know that we must act to address the

monkeypox outbreak in communities that are disproportionately impacted. And where a lack of complete data constrains our ability to understand the full extent of these disparities, we are working to better understand these impacts.

The monkeypox response is impacted by one of the fundamental constraints CDC faces in its response to public health threats—we are often limited in our ability to quickly and reliably access the data we need to maximize the impact of our public health response. We need to bring the Nation's public health data infrastructure into the 21st century so that CDC and state, Tribal, local and territorial health agencies may review, analyze, and report data in real time. The public health workforce is stretched thin, and sustained investment in the workforce is needed to provide Americans with a data-fluent, pandemic-ready public health system. Our nation's public health laboratories are essential to early detection, and equipping these labs with the best available resources enables a faster response. Committing to rebuilding public health infrastructure through a revitalized public health workforce, modern data pathways, and strong laboratories supports the foundation for an immediate and robust response to public health emergencies like monkeypox.

Diagnostic Testing

Since 2003, CDC's LRN has provided state and local health departments with a way to test and identify orthopoxvirus cases, including monkeypox. CDC has a Food and Drug Administration-cleared test capable of detecting non-variola orthopoxviruses like monkeypox pre-positioned within the LRN due to previous work in smallpox public health preparedness supported by investments from Congress. These nearly 70 laboratories that are part of the LRN could test about 6,000 specimens per week at the start of the outbreak, a capacity which CDC worked quickly to expand to about 10,000 tests per week. A positive orthopoxvirus test result is enough for clinicians and patients to act to prevent additional spread. States may also send samples to CDC for further viral characterization and genomic sequencing.

Even while testing capacity through LRN labs greatly exceeded demand, CDC and FDA began working with five U.S. commercial laboratory companies to improve the accessibility of orthopoxvirus testing to the Nation's providers. In June 2022, CDC began shipping orthopoxvirus tests to these five commercial laboratories. By July, testing capacity in the United States increased to 80,000 tests per week. As of September 7, orthopoxvirus testing throughput is at about 14 percent of total capacity. This Administration is preparing for potential increased demand for testing in the future and is exploring all available avenues to make testing more accessible.

Vaccines and Therapeutics

Through Federal investments in public health preparedness, the U.S. supported the development of vaccines and therapeutics for orthopoxviruses, like monkeypox, before detection of the first U.S. case associated with the 2022 outbreak. The FDA-cleared non-variola orthopoxvirus test, antiviral tecovirimat (also known as TPOXX), and ACAM2000 and JYNNEOS vaccines were all developed as part of the Smallpox Research Agenda. Under this ongoing U.S. smallpox preparedness work, CDC has collaborated with other U.S. public health officials to work to ensure medical countermeasure tools are available in the event of a smallpox outbreak. Unlike COVID–19, the monkeypox virus is not a novel pathogen, and our response benefited from our ability to mobilize existing countermeasures and move swiftly to acquire more.

From the beginning of the outbreak, CDC has worked closely with the Administration for Strategic Preparedness and Response and its Strategic National Stockpile to make vaccines available quickly, efficiently, and equitably. CDC's role in the monkeypox response vaccine strategy is to prioritize the allocation of our limited supply of the JYNNEOS vaccine to maximize public health impact. Allocations to jurisdictions are based on two factors: recent population-adjusted case incidence and the number of people who have the highest risk for disease in the current outbreak, as estimated by the number of gay, bisexual, and other men who have sex with men who are living with HIV or are eligible for HIV pre-exposure prophylaxis within a jurisdiction.

In light of FDA's August 9, 2022 Emergency Use Authorization for the JYNNEOS vaccine allowing for intradermal administration for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection, CDC released interim clinical considerations with relevant information on how to administer the JYNNEOS vaccine intradermally. This approach provides a level of immune response comparable to that achieved by subcutaneous administration without com-

promising safety and can extend the vaccine supply by administering 0.1mL doses, allowing multiple doses to be administered from one 0.5mL vial.

Equitable allocation of vaccines and therapeutics for those at greatest risk of monkeypox is not possible without robust data. Vaccine and therapeutic administration data are important to verify that vaccines and therapeutics are going to the populations most affected by this outbreak. Other data, such as race and ethnicity data or HIV status, are also important to contextualize the distribution and administration. For example, we know that in the current monkeypox outbreak, more than one third of U.S. cases are occurring in people living with HIV. CDC has published Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV and, with additional data, will continue to share treatment and prophylaxis considerations with clinicians. CDC is building on the approach and infrastructure established for COVID–19 to receive monkeypox vaccine administration data, including race and ethnicity, and has a data use agreement in place with every state to receive these data. On August 15, 2022, we began receiving vaccine administration data from high-burden jurisdictions and currently, a total of 35 jurisdictions are reporting these data to CDC.

CDC also is committed to increasing access to therapeutics for monkeypox patients. We acted quickly on reports from our state, local, and territorial health partners to reduce the burden of administering the FDA-approved smallpox treatment, tecovirimat or TPOXX, through the Expanded Access Investigational New Drug protocol. We did this because TPOXX has shown promising efficacy in preventing serious illness from monkeypox based on animal studies. To balance the need for safety and efficacy information with the need for timely administration, we worked closely with FDA to revise the protocol to allow for telemedicine check-ups, make laboratory sample collection optional, and streamline regulatory reporting.

Community Outreach and Public Awareness

While anyone—irrespective of age, gender identity, or sexual orientation—can contract monkeypox if they are exposed, engaging with populations currently disproportionately affected by the monkeypox outbreak is a cornerstone of the government-wide response. CDC is committed to collaborating and sharing timely knowledge with members of the LGBTQ+ community, especially gay and bisexual men. We know that successful public health efforts depend on authentic collaboration where the community is at the table, leading discussions, informing and grounding decisions based in the reality of those affected, and otherwise making vital contributions to our public health response. We are working closely with partner organizations and offices like AIDS United, UnidosUS, the Ryan White HIV/AIDS Program, Southern AIDS Coalition, and event organizers who bring LGBTQ+ people together across the country. Trusted community leaders are providing a voice to amplify messages for prevention, testing, and treatment. We are also working with our core public health partners at the local and state level to provide technical assistance on engaging local community partners to support prevention, vaccination, and testing. HHS launched pilot programs to provide additional vaccine allocations to state and local health departments in jurisdictions that are hosting large events that attract gay, bisexual, and other men who have sex with men and to ensure more vaccines reach populations that face additional barriers to access through support for equity interventions. CDC will continue to provide technical assistance and support to jurisdictions for these large events and equity interventions, such as helping to develop testing and vaccine strategies, providing messaging and communication resources, and developing tools for information-gathering from event participants.

Stigmatization of diseases and groups of people hinders public health efforts and contributes to poorer health outcomes. CDC is drawing on what we have learned through decades of work in sexually transmitted infections (STIs) and HIV to ensure that CDC messaging does not contribute to the stigmatization of gay, bisexual, and other men who have sex with men. CDC is conducting community listening sessions and working closely with LGBTQ+, sexual health, and HIV advocacy organizations to take our fight against stigma to the next level by creating messaging that is sex-positive and LGBTQ-affirming. We will work with healthcare providers, organizations of all kinds, and public health partners to support better approaches that reach affected communities.

CDC uses a variety of mechanisms including the Morbidity and Mortality Weekly Report to disseminate information to public health partners and healthcare providers about outbreaks of rare pathogens like monkeypox. Our monkeypox clinical considerations have received hundreds of thousands of page views. On May 20, 2022, CDC released the first Health Alert Network Health Advisory on the

monkeypox outbreak, and we have issued three subsequent advisories, each reaching over 1 million people. CDC regularly hosts Clinician Outreach and Communication Activity calls where subject matter experts provide the latest information and considerations for tens of thousands of clinicians. The agency continues to work closely with clinical and core public health partners to amplify messaging to their members, including the American Medical Association, Infectious Disease Society of America, American Academy of Pediatrics, American Academy of HIV Medicine, Council of State and Territorial Epidemiologists, Association of State and Territorial Health Officials, National Association of County and City Health Officials, Association of Public Health Laboratories, National Coalition of STD Directors, Big Cities Health Coalition, and National Indian Health Board.

CDC is also providing information to a wider U.S. audience about the symptoms of monkeypox and how to mitigate the spread of the disease. Because of how monkeypox is transmitted, CDC recognizes that individuals may be concerned about the spread of monkeypox in group settings. CDC has developed recommendations for reducing infection risk in group settings and will continue to adapt and refine these recommendations based on what we learn about virus transmission. A priority of our response to monkeypox is to support early identification of monkeypox spread in congregate living settings, like dormitories, correctional facilities, shelters, and others. Informational resources for populations that could be at increased risk continue to be developed. CDC has also posted responses to frequently asked questions from facilities serving children to provide administrators, parents, and caregivers with information as their students return to school.

Looking Ahead

There is much more research to be done to better understand this unique monkeypox outbreak and other diseases with pandemic potential. Flexible, disease-agnostic investments are critical to inform our efforts to respond to emerging public health threats. Additionally, sustained support for core capabilities—such as modernized data systems, public health infrastructure, and a diverse public health workforce—are critical for an effective and equitable disease response at the national, state, Tribal, local, and territorial levels. Epidemiologic studies on the characteristics of monkeypox and spread in this outbreak can provide better understanding to improve the efficacy of prevention and intervention efforts.

Access to timely and actionable data has been a challenge during the initial stages of the monkeypox outbreak given our Nation's fragmented streams of data collection and reporting. The COVID–19 pandemic demonstrated and the monkeypox outbreak has reaffirmed that nothing about public health data in the United States is easy—it is a complex, de-centralized landscape with many points of friction that can keep data from getting from its source to where it is needed to inform public health action. CDC's new Center for Forecasting and Outbreak Analytics is already enabling timelier, more effective decision-making in responding to monkeypox, but its work in modeling and analytics hinges on our ability to collect and integrate high-quality data.

CDC has deep collaborative partnerships with state and local jurisdictions to help navigate these challenges, but the fact remains that ongoing modernization and support from Congress is needed to provide CDC additional policy levers to enable timely reporting of actionable data before the next threat arrives. In particular, COVID–19 and monkeypox have showed the importance of timely and comprehensive data to support decision-making at Federal, state, and local levels. This data is most effective when collected before and during an outbreak to mount a fully effective response. To achieve this goal, CDC will need support from Congress for an updated authority to set a common framework for how data is reported to support Federal, state, and local decision-making. In the absence of this authority, CDC must spend precious time negotiating bespoke data use agreements with many dozens of jurisdictions and rely on voluntary data reporting—a process that took months for both the COVID–19 and monkeypox responses for key data elements.

As COVID–19 demonstrated, and as we see again now with monkeypox, the American public health system is fragile due to years of underinvestment in national preparedness and in state, Tribal, local, and territorial public health agencies. And yet, our Nation's security depends on the strength of its public health system. It is for this reason that long-term, foundational investments must be made to ensure we are prepared to respond rapidly and effectively to future pandemics and other public health threats. Moving from reliance on unpredictable supplemental resources to reliable multi-year funding will enable us to transition the infrastructure built for the COVID–19 response to a sustained core infrastructure—including data,

workforce, and laboratories—capable of addressing current and future public health challenges. Investment in laboratory capacity and standards across the country, regardless of the diseases they are used for, ensures that laboratories can process tests quickly and effectively when a health threat arrives. Workforce funding gives health departments the personnel they need to pivot and respond to new threats, untethered to a specific funding line or program activity. The fiscal year 2023 President's Budget included a 5-year request for $88 billion for pandemic preparedness, including $28 billion for CDC to transform our public health capacities nationwide, which is urgently needed to ensure we are prepared for any infectious disease threat that comes our way.

Conclusion

As CDC continues to contribute to a robust whole-of-government response to this outbreak, we are working with governmental and non-governmental partners to ensure easy, safe, and equitable access to diagnostic tests, vaccines, and therapeutics. We will continue to educate healthcare providers and the American public on monkeypox, with a particular emphasis on the disproportionately impacted community of gay, bisexual, and other men who have sex with men. We are working to share scientific findings and data faster; to translate science into practical, easy-to-understand policy; and to optimize public communications. The current outbreak demonstrates that the work of public health is never done and that we must continue to make investments and structural changes now to address the long-standing vulnerabilities in our public health system. We must stay vigilant in global disease surveillance and efforts to modernize the public health data landscape. Resources to support public health preparedness and infrastructure, including at the state, Tribal, local, and territorial levels, remain as necessary as they have been during and prior to the COVID–19 pandemic. I am committed to working with Congress to advance these efforts and build a more resilient public health system that contributes to a healthier, safer, and more secure future for all Americans.

Thank you, and I look forward to your questions.

The CHAIR. Thank you.

Dr. Fauci.

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. FAUCI. Madam Chair, Ranking Member Burr, Members of the Committee, thank you for giving me the opportunity to discuss with you the role of the National Institute of Allergy and Infectious Diseases in conducting and supporting research to address the ongoing monkeypox public health emergency.

I will outline how long standing NIAID supported research efforts have enhanced our preparedness for, response to the emergence of monkeypox virus. First, I want to provide some historical context that relates to past, current, and future NIAID research efforts. It is worth noting that the emerging epidemiological pattern of monkeypox cases bears a striking resemblance to the early cases of HIV/AIDS.

In the United States and other non-endemic countries, monkeypox is disproportionately affecting men who have sex with men. However, anyone exposed to the circulating virus can get infected with monkeypox regardless of their age, gender identity, or sexual orientation.

Thus, we would be wise to heed an observation I made 40 years ago in an article I published in the Annals of Internal Medicine in 1982 during the first year of the HIV/AIDS pandemic when I re-

ferred to what we would soon call AIDS, a disease that did not even have a name at that time.

I quote from that publication, "any assumption that it would remain restricted to a particular segment of our society is truly an assumption without a scientific basis." And so although we must focus our efforts on the group that is most predominantly afflicted and at risk, there is still much we must learn about this disease.

Additional epidemiological and observational cohort studies, surveys, ongoing surveillance for new cases are of critical importance. In addition, much work needs to be done in virology, immunology, transmission, and animal reservoirs, as well as diagnostics, therapeutics, and vaccine, which I will address in a moment.

There are certainly some sharp differences between the early years of AIDS and our current situation with monkeypox. Unlike the situation at the start of the AIDS outbreak, the etiologic agent of monkeypox has been known for decades and medical countermeasures have been developed, namely a vaccine, JYNNEOS, and an antiviral, tecovirimat or TPOXX.

This is the result of decades of NIAID supported research on monkeypox virus and other orthopox viruses, including the variola virus that causes smallpox. NIAID supported research was essential to the development of the JYNNEOS vaccine.

We funded a number of studies of JYNNEOS from the pre-clinical stage through phase two clinical trials to evaluate safety, immunogenicity, duration of protection, and route of administration. We then transitioned the vaccine to BARDA, which supported advanced clinical evaluation, and we have recently launched a clinical trial further evaluating alternative routes of administration.

In the area of therapeutics, NIAID funded the discovery of tecovirimat and the preclinical studies to determine the mechanisms of action and its safety and efficacy in animals. Again, together with BARDA, we also funded phase one and phase two clinical trials of tecovirimat.

Clinical trials to evaluate this drug in humans with monkeypox are needed to gather additional data about the safety and efficacy of the drug in the context of the current outbreak. NIAID supported investigators have recently launched a phase three clinical trial of tecovirimat, focused on outpatient setting in the United States through the AIDS clinical trials group.

A separate NIAID clinical study of tecovirimat in collaboration with researchers in the Democratic Republic of the Congo will begin imminently. It is worth noting that the study in the DRC was planned prior to the current global outbreak as part of our preparedness efforts to study high consequence pathogens in key international locations where they are endemic.

Lessons learned during the response to AIDS and COVID–19, such as avoiding stigma and ensuring the medical countermeasures get to where they are needed most, should help us in our efforts to respond to the ongoing monkeypox emergency.

In addition, the U.S. response to monkeypox should in turn help to inform our response to the inevitable next emerging or re-emerging infectious disease of pandemic potential. Thank you for

your attention. I would be happy to answer your questions following the presentation of my colleagues.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY FAUCI

Madam Chair, Ranking Member Burr, and Members of the Committee:

Thank you for the opportunity to discuss the role of the National Institute of Allergy and Infectious Diseases (NIAID) in the research response to the ongoing monkeypox public health emergency. Within the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), NIAID is responsible for conducting and supporting basic and clinical research on emerging and re-emerging infectious diseases, including monkeypox. As the Director of NIAID and the Chief Medical Advisor to the President, I am pleased to discuss NIAID research addressing the U.S. monkeypox outbreak. NIAID is committed to accelerating efforts to answer critical monkeypox research questions in alignment with the U.S. Monkeypox Research Priorities identified by the White House Office of Science and Technology Policy.

Pandemic Preparedness and Prototype Pathogen Approaches for Medical Countermeasures

The monkeypox virus is part of the Orthopoxvirus genus, which includes the variola virus that causes smallpox. Available medical countermeasures against monkeypox were made possible by decades of NIAID-supported research on orthopoxviruses. Our orthopoxvirus research is an example of the NIAID prototype pathogen approach to pandemic preparedness, in which basic research and countermeasures for a prototype pathogen within a given family of viruses can be used to help treat and prevent diseases caused by closely related pathogens within that family.

As part of its longstanding investment in biodefense research, NIAID supported early stage development of the second-generation smallpox vaccine ACAM2000. NIAID further identified the need for a vaccine to overcome the limitations of ACAM2000, which cannot be used by individuals with weakened immune systems. In close collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and the U.S. Food and Drug Administration (FDA), NIAID played a key role in developing a third-generation vaccine against smallpox and monkeypox now known as JYNNEOS (Imvamune or Imvanex).

NIAID-supported research also facilitated the development of an antiviral for smallpox called tecovirimat (TPOXX). This drug is now being used to treat patients with monkeypox under an expanded-access investigational new drug protocol. NIAID is supporting new clinical trials of tecovirimat to gather additional safety and efficacy data to inform clinical and regulatory decision-making on the use of tecovirimat for the treatment of monkeypox. In addition, NIAID-supported scientists continue to conduct basic research to better understand monkeypox virus transmission and disease, and to identify additional antiviral candidates. NIAID researchers at the Vaccine Research Center (VRC) are isolating antibodies for evaluating vaccine-induced immune responses as well as the development of immune assays, diagnostic reagents, and therapeutics in the form of monoclonal antibodies.

Vaccines to Prevent Monkeypox Disease

As noted, NIAID-supported research was essential to the development of the JYNNEOS vaccine made by Bavarian Nordic A/S and approved in the United States and other countries for the prevention of monkeypox (and smallpox). JYNNEOS features a weakened form of live vaccinia virus (modified vaccinia Ankara-Bavarian Nordic [MVA-BN]) that does not replicate or cause disease. MVA is an orthopoxvirus related to the viruses that cause monkeypox and smallpox. NIAID provided significant support for the research and development of JYNNEOS as an alternative to the ACAM2000 smallpox vaccine, which contains replication-competent vaccinia virus and can cause severe adverse events in people with weakened immune systems and individuals with eczema. NIAID has funded studies of JYNNEOS from the preclinical stage through Phase 2 clinical trials to evaluate safety, immunogenicity, duration of protection, and route of administration. NIAID then transitioned the vaccine to BARDA, which supported advanced clinical evaluation.

In 2019, FDA approved JYNNEOS for individuals at high risk for smallpox or monkeypox virus infection. On August 9, 2022, FDA issued an emergency use au-

thorization (EUA) for JYNNEOS to allow healthcare providers to administer the vaccine by intradermal injection, an alternative to the standard subcutaneous route of administration. The FDA EUA will increase the total number of available JYNNEOS vaccine doses by up to five-fold. The EUA decision was informed by an NIAID-supported clinical study of the vaccine published in 2015 demonstrating that the intradermal route of administration—using just one fifth of the vaccine volume—produced a similar immune response to subcutaneous administration.

NIAID recently launched a clinical study of the JYNNEOS vaccine via different routes of inoculation, including intradermal administration, in adults 18 years of age and older at high risk for monkeypox virus infection. This study may be expanded to provide data to support use of the vaccine against monkeypox for individuals who are pregnant or under the age of 18 years, or to inform potential Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations for a lower dose vaccination regimen.

NIAID VRC scientists are developing mRNA-based monkeypox vaccines in collaboration with Moderna, Inc., and will conduct efficacy studies in animal models to select lead vaccine candidates. Blood samples from these and other VRC studies will be used to isolate monoclonal antibodies for vaccine antigen design and for evaluation as potential monkeypox therapeutics and diagnostic reagents.

Therapeutics to Treat Monkeypox Disease

Currently, no specific treatment is approved by the FDA for monkeypox virus infection. However, the antiviral tecovirimat (TPOXX), developed to treat smallpox, is being used to treat patients with monkeypox under an expanded-access investigational new drug protocol. NIAID funded the discovery of tecovirimat as well as preclinical studies to determine its mechanism of action and its safety and efficacy in animals. NIAID and BARDA also have funded Phase 1 and Phase 2 clinical trials to test the safety and pharmacokinetics of an oral formulation of tecovirimat. The FDA approved the oral formulation of tecovirimat in 2018 for treating smallpox in adults and children and this formulation is part of the U.S. Strategic National Stockpile. An intravenous formulation of tecovirimat subsequently received FDA approval. Although this antiviral was approved for the treatment of smallpox, the drug's FDA approval was based on studies in animals infected with monkeypox virus. Clinical trials to evaluate tecovirimat in humans with monkeypox are needed to gather additional data about the safety and efficacy of the drug in the context of the current outbreak to aid clinical and regulatory decision-making.

In this regard, NIAID-supported investigators have launched a Phase 3, randomized, placebo-controlled, double-blind trial of tecovirimat for the treatment of monkeypox in outpatient settings in the United States through the AIDS Clinical Trials Group (ACTG). Using this established and successful HIV clinical trials infrastructure will facilitate community engagement and help researchers ensure that vital community input is reflected in the conduct of the study. The study also has an open-label component to ensure that certain high-risk populations (e.g., pregnant or breastfeeding individuals, those who are heavily symptomatic, and those with severe immune deficiencies) are not randomized to placebo, while also providing a means to collect important data on the safety and pharmacokinetics of tecovirimat in these populations.

NIAID, in collaboration with Institut National de Recherche Biomèdicale of the Democratic Republic of Congo (DRC), also is planning a double-blind, randomized controlled trial of the safety and efficacy of tecovirimat for treating adult and pediatric patients diagnosed with monkeypox. The study in the DRC was planned prior to the current global outbreak as part of NIAID preparedness efforts to study high-consequence pathogens in key international locations where they are endemic.

NIAID also supports early stage research to help identify additional candidate antivirals for monkeypox. It is possible that monkeypox virus will develop resistance to tecovirimat. This is one of the reasons NIAID-supported scientists are screening novel compounds to help find new antiviral candidates to treat monkeypox.

Understanding Monkeypox Transmission and Reservoirs

Monkeypox is disproportionately affecting men who have sex with men in non-endemic countries. However, anyone exposed to the circulating virus can get monkeypox regardless of their age, gender identity, or sexual orientation. Of note, the previous outbreak of monkeypox in the United States in 2003 was driven by animal-to-person spread and involved domesticated prairie dogs that were infected by small mammals imported from West Africa. NIAID scientists are conducting animal

studies to understand the human-animal interface with monkeypox virus and its suspected reservoir hosts, such as Gambian pouched rats, rope squirrels, and dormice. NIAID also is supporting the development of animal models to evaluate vaccine-induced immune responses to monkeypox virus.

In addition, NIAID-supported scientists are performing genomic sequencing to better understand the monkeypox virus and its various strains. Investigators with the NIAID-funded Centers for Research in Emerging Infectious Diseases (CREID) are supporting clinical surveillance in the DRC, Nigeria, and Sierra Leone. CREID investigators also are providing validated molecular primers and probes to help strengthen diagnostic capacity in Kenya, Tanzania, Panama, and Brazil. In addition, the NIAID International Centers for Excellence in Research (ICER) program has helped enhance diagnostic capacity in Mali, Ghana, Republic of the Congo, and Cambodia.

NIAID scientists also are developing a high-throughput serologic assay that can distinguish between individuals infected with monkeypox virus and people who may have received a vaccinia-based vaccine, such as JYNNEOS or ACAM2000. In collaboration with the CDC and other U.S. and international researchers, NIAID will use this assay to conduct retrospective and prospective serological studies to better understand the extent of monkeypox virus circulating in the United States and worldwide. In addition, NIAID is making viral isolates available, free-of-charge, for distribution to the global research and surveillance community via the NIAID-funded BEI Resources repository. Distribution of these resources will facilitate additional priority research throughout the broader scientific community, particularly in the areas of diagnosis and surveillance.

Conclusion

NIAID continues to expand research on the biology, pathogenesis, and clinical manifestations of monkeypox virus infection as well as studies of existing and potential interventions to diagnose, treat, and prevent monkeypox. NIAID also is committed to working in partnership with those populations, including men who have sex with men, that currently are most at-risk of monkeypox to help identify and address key monkeypox research questions. These efforts will improve our response to the ongoing public health emergency.

The CHAIR. Thank you.

Dr. Califf.

STATEMENT OF ROBERT CALIFF, M.D., COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

[Technical problems.]

The CHAIR. Turn on your mic.

Dr. CALIFF. There we go. Chair Murray, Ranking Member Burr, Members of the Committee, thanks for the opportunity to provide information on FDA's ongoing work related to the monkeypox virus public health emergency. FDA has been actively working with our Government and private sector collaborators to respond to the continuing public health threat since the first monkeypox case came to the U.S.

We have been working diligently to help ensure access and proper information regarding vaccines, diagnostics, and treatments for those who need the most. There is currently one FDA licensed vaccine, JYNNEOS, available for the prevention of monkeypox. We originally approved this Modified Vaccinia Ankara vaccine for the prevention of smallpox.

Following reports of monkey pox in May, FDA recognized that production for this vaccine would need to be accelerated. FDA and BARDA worked together to expedite the submission of a manufac-

turing supplement that would allow more doses to be used in the United States.

FDA approved that supplement in July, following an inspection of the manufacturing facility in Europe. In August, we granted an emergency use authorization for intradermal Administration of the vaccine, which has helped to increase the supply of vaccine available to Americans up to five fold.

The authorization allowed additional review of a 2015 clinical study that evaluated a two dose series of JYNNEOS, given intradermal versus subcutaneously in individuals aged 18 years or older.

Consistent with previous studies, and extensive experience with a similar vaccine in Germany, data indicated that intradermal administration produced a similar immune response to subcutaneous administration with a modestly different reaction profile at the injection site.

The combination of vaccination and preventive measures to reduce the risk of contact with the virus remains the best way to prevent the spread of monkeypox. The vaccine is available via intradermal administration for individuals 18 years of age and older, determined to be at high risk for monkeypox infection, and available via subcutaneous administration to those under the age of 18 determined to be at high risk for monkeypox infection.

It is important to recognize that we do not have clinical data on safety and efficacy, so FDA continues to monitor safety data we are receiving following the administration of JYNNEOS nationwide. Additionally, as you have heard from Dr. Fauci, NIH has initiated a clinical trial to obtain further data. FDA has also worked closely with CDC, manufacturers, and laboratories to support diagnostic test development.

Currently, CDC has an FDA cleared test that can detect non-variola orthopox viruses, including monkeypox, by a swab from the lesion. This test is available through 67 CDC laboratory response network labs, as well as through five large commercial labs. On September 7th, following an emergency declaration from HHS, FDA issued an EUA for an additional test from a commercial developer.

We also issued guidance on the development of diagnostic tests and hope it will increase the diversity and availability of tests for monkeypox. Currently, there are no FDA approved treatments for monkeypox. TPOXX or tecovirimat is an FDA approved treatment for smallpox currently made available to monkeypox patients under a CDC expanded access investigational new drug protocol.

TPOXX was originally approved for smallpox using FDA's animal rule. The animal rule is an approval pathway that relies on animal studies and can be used only when human trials are not ethical or feasible.

Because monkeypox remains endemic in countries around the world, and we now have a large outbreak in the U.S., human clinical trials are both ethical and feasible in a way that they were not feasible for smallpox, and smallpox has been eradicated and has a 30 to 50 percent mortality rate.

Without human trials, we don't know if TPOXX is beneficial for patients with monkeypox. Drugs that show efficacy in animals are not always effective in humans. Therefore, clinical trials, one of which is now underway, as Dr. Fauci has mentioned, through the NIH, will be necessary for FDA to determine if TPOXX is safe and effective to treat monkeypox.

In the meantime, because there is a significant risk of the development of our resistance to TPOXX, judicious use of TPOXX and careful monitoring for the development of resistance are a paramount importance for stewardship of this potentially beneficial drug while we study it in clinical trials.

FDA has dedicated staff continue to work to ensure an appropriate and robust response to the monkeypox outbreak. Thanks for the opportunity to testify today and I look forward to answering your questions.

[The prepared statement of Dr. Califf follows:]

PREPARED STATEMENT OF ROBERT CALIFF

Chair Murray, Ranking Member Burr, distinguished Members of the Committee, thank you for this opportunity to testify before you today to describe the Food and Drug Administration's (FDA's or the Agency's) monkeypox disease response efforts. All of our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the Federal Government, to help ensure the development, authorization, licensure, approval, and availability of critical, safe, and effective medical products to address the monkeypox virus public health emergency.

We are closely monitoring the situation and responding aggressively, while also preparing for potential changes and shifts as the public health emergency continues. The Agency is using lessons learned from the coronavirus disease 2019 (COVID–19) response effort to inform our decision-making going forward and aid in our response to monkeypox disease. For eligible Americans, getting vaccinated and following Centers for Disease Control and Prevention (CDC) guidance remain the best way to protect themselves and their families.

Presently, JYNNEOS is the only FDA-licensed vaccine in the United States that is approved for the prevention of monkeypox disease. JYNNEOS, the Modified Vaccinia Ankara (MVA) vaccine, is approved for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. JYNNEOS was approved in 2019. The recent Emergency Use Authorization (EUA) allowing for intradermal administration of JYNNEOS for individuals 18 years of age and older determined to be at high risk of monkeypox infection will increase the supply of available doses by up to five-fold.

In addition, the CDC has an FDA-cleared test that can detect non-variola orthopoxviruses, including monkeypox. FDA also recently granted the first EUA for a monkeypox test, and we have issued policy guidance to support development of additional validated monkeypox tests and expand access to tests. [1]

While there is no FDA-approved treatment for monkeypox, through the use of existing FDA authorities, tecovirimat (TPOXX), an antiviral medication, is available to patients under an Expanded Access Investigational New Drug protocol (EA-IND).

Since the first positive case of monkeypox disease in the United States, FDA has taken an active role in responding to the ongoing public health threat posed by the spread of monkeypox. This testimony is only a snapshot of the continued work the Agency is doing to address the monkeypox outbreak.

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[1] U.S. Food and Drug Administration, "Monkeypox Update: FDA Takes Significant Action to Help Expand Access to Testing," September 7, 2022, available at *https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-takes-significant-action-help-expand-access-testing*.

Supporting Timely Access to Monkeypox Vaccines

FDA's Center for Biologics Evaluation and Research (CBER) continues to use every tool available to help facilitate the development of biological products to aid in the Agency's larger effort to respond to the monkeypox public health emergency.

JYNNEOS is the only vaccine that is FDA-approved for the prevention of monkeypox disease. JYNNEOS is a live virus vaccine that contains MVA-Bavarian Nordic, a weakened, non-replicating orthopoxvirus, and was developed for use in certain populations (e.g., immunocompromised individuals) as an alternative to ACAM2000, a licensed vaccine, in the event of a smallpox bioterrorist attack. This virus strain has been safely administered to thousands of individuals intradermally in the past, both as a smallpox vaccine and in investigational studies for other zoonotic orthopoxviruses and variola viruses.[2] Further, JYNNEOS may be safely used in significantly immunocompromised individuals, including individuals with Human Immunodeficiency Virus (HIV), for whom it may not be advisable to receive certain live vaccines.

ACAM2000 is an FDA-licensed live replicating vaccinia virus vaccine approved for the prevention of smallpox disease. It is associated with a higher risk of certain serious adverse reactions compared to JYNNEOS, including myocarditis and pericarditis, which are inflammation and swelling of the heart and surrounding tissues, respectively. The risk of accidental infection by someone who just received ACAM2000 can also present serious health complications in certain populations, including those who are pregnant. The ACAM2000 vaccine also causes a blister to develop at the vaccination site. Exposure to the blister and its contents may lead to accidental infection. This risk of accidental infection following vaccination does not occur with JYNNEOS, as the vaccination does not cause a blister to form at the injection site.

In late May 2022, following reports of monkeypox in the United States, FDA worked with the Biomedical Advanced Research and Development Authority (BARDA) to expedite the submission of a manufacturing supplement to FDA to facilitate JYNNEOS production at an additional site that was originally planned for fall 2022. After receiving the supplemental application for the additional facility, FDA immediately expedited our evaluation of the application and corresponding inspection of the facility. FDA evaluated the information required to validate product quality and determined that the vaccine meets our quality standards. The evaluation and inspection were necessary to help ensure the quality and safety of the vaccine.

On July 26, 2022, FDA approved a supplemental biologics license application for JYNNEOS, which allowed for additional doses manufactured at a facility in Europe to be further distributed and administered in the United States to help address the monkeypox outbreak.

Given the emerging public health need, FDA facilitated advance shipments of manufactured doses to the United States for prepositioning so that they would be onshore and ready to be distributed once we completed our inspection and approved the manufacturing changes.

On August 9, 2022, FDA issued an EUA for JYNNEOS to allow healthcare providers to administer the vaccine intradermally (between the layers of the skin) for individuals 18 years of age and older determined to be at high risk for monkeypox infection. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk for monkeypox infection; in these individuals, JYNNEOS is administered by subcutaneous injection. For all age groups, JYNNEOS is given as a two-dose series, 4 weeks apart. In issuing this EUA, FDA determined that the known and potential benefits of JYNNEOS outweigh the known and potential risks for the authorized uses.

A 2015 clinical study[3] evaluated a two-dose series of JYNNEOS given intradermally compared to subcutaneously in individuals 18 years of age and older. Individuals who received the vaccine intradermally received a lower volume (one-fifth) of the vaccine than individuals who received the vaccine subcutaneously. The results of this study demonstrated that intradermal administration produced a similar immune response to subcutaneous administration. Administration by the

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[2] For detailed information on the study, please visit Sharon E. Fry et al., "Comparison of lyophilized versus liquid modified vaccinia Ankara (MVA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-na—ve subjects," Vaccine, 33:39, September 22, 2015, pp. 5225–34, available at *https://www.sciencedirect.com/science/article/pii/S0264410X15008762—via percent3Dihub*.

[3] Ibid.

intradermal route resulted in more redness, firmness, itchiness, and swelling at the injection site, but less pain.

The JYNNEOS EUA will increase the total number of doses available for use by up to five-fold.

To support FDA's authorization of two doses of JYNNEOS administered by the subcutaneous route of administration in individuals younger than 18 years of age, FDA considered the available JYNNEOS safety and immune response data in adults as well as the historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.

Following the EUA, the Agency has participated in calls with healthcare providers to discuss the newly authorized administration method and provide the most up-to-date information to those administering the vaccine.[4] It is important to recognize that we do not have clinical data on safety and efficacy of JYNNEOS, so FDA will continue to monitor the safety data received from jurisdictions as administration of JYNNEOS increases across the United States. Additionally, NIH has initiated a prospective clinical trial to obtain these data.

Supporting Monkeypox Test Development and Timely Test Access

Since the first case of monkeypox was detected in the United States, FDA's Center for Devices and Radiological Health (CDRH) has been working closely with CDC, laboratories, and commercial manufacturers to support test development and help make monkeypox tests more readily available to consumers who need them. CDC has an FDA-cleared test that can detect non-variola orthopoxviruses, including monkeypox, by a swab from a lesion (rash or growth). The Agency engaged early with CDC and other agencies to support 67 CDC Laboratory Response Network laboratories' use of the FDA-cleared test. FDA and Federal authorities subsequently worked with industry to help make this test available through five large commercial laboratories (LabCorp, Mayo, Aegis, Sonic, and Quest). Presently, more testing capacity for monkeypox exists than is being used.[5] However, FDA knows the value of assuring patients have test options and timely access to test results—and we have continued working toward expansion of testing capacity nationwide in an effort to stem the spread of the virus.

FDA has been working proactively with commercial manufacturers on the development and validation of both laboratory-based molecular diagnostic tests and rapid molecular or antigen tests for use at the point-of-care (such as clinics) or at home.

As part of this close work with CDC and the private sector, FDA has undertaken additional efforts that are critical to support test developers, laboratories, and patients as the Nation responds to the monkeypox virus outbreak. To increase the availability, accessibility, and throughput of the CDC test, FDA has updated the test's clearance and provided temporary enforcement discretion as needed regarding the test's use with additional instruments, extraction reagents, and automated extractions. FDA has also been monitoring the availability of test components and testing supplies and provided temporary enforcement discretion regarding the use of substitute components to help address shortage issues. Subsequently, these laboratories have had additional options and flexibility, which helps to improve timely patient access to monkeypox tests throughout the country. FDA also has provided temporary enforcement discretion regarding laboratories' reporting of test results from the CDC test, allowing results reported as "detected," and "positive," rather than "presumed positive," so that samples do not need to be sent to CDC for confirmation prior to initiating treatment.

In addition, FDA has reached out to commercial control manufacturers to encourage them to produce orthopoxvirus and monkeypox control material that can be used for test development and test validation as well as batch testing once clinical testing has been launched. Control material is now available from at least two sources—the National Institute of Standards and Technology and a commercial provider. This control material is another important resource for laboratories that are working to develop additional tests for monkeypox.

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[4] The most up-to-date information can be found on FDA's monkeypox homepage: U.S. Food and Drug Administration, "FDA Monkeypox Response," updated continuously, available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fda-monkeypox-response*.

[5] For the latest data on testing capacity and positivity rates please visit CDC's website: Centers for Disease Control and Prevention, "Monkeypox Signs and Symptoms," available at *https://www.cdc.gov/poxvirus/monkeypox/index.html*.

On September 8, 2022, Secretary Xavier Becerra signed a declaration under section 564 of the Federal Food, Drug, and Cosmetic Act to allow the FDA Commissioner to issue emergency use authorizations for in vitro diagnostics to expand the availability of tests for monkeypox. On the same day, FDA issued the first EUA for a monkeypox in vitro diagnostic—the Quest Diagnostics Monkeypox Virus Qualitative Real-Time PCR[6] intended to detect monkeypox and other non-variola orthopoxvirus DNA using lesion swab specimens.

As part of the guidance, FDA has provided voluntary templates that test developers may use when validating a test or when submitting an EUA request. These templates include recommendations—not requirements—for how a developer could validate a test to help ensure it is appropriately accurate and reliable. FDA intends to update its recommendations, as needed, in response to the developing emergency.

FDA will also continue its partnership with the National Institutes of Health's (NIH) Independent Test Assessment Program (ITAP),[7] which helped streamline validation and authorization of COVID tests. ITAP showed the great value of an independent validation program for tests and, based on this experience, we will partner with NIH/ITAP to help streamline validation and authorization of point-of-care and home monkeypox virus tests. On September 7, 2022, ITAP announced it is accepting proposals.[8]

FDA continues actively working with private and public entities on monkeypox test development and availability. This includes meeting regularly with the CDC, academic, commercial, and public health laboratories and addressing monkeypox during FDA's monthly virtual town hall series for test developers.[9] FDA is also fully engaged with CDC and key stakeholders in the laboratory community under a memorandum of understanding to collaborate on enhancing diagnostic surge testing capacity during public health emergencies.[10] This has helped facilitate communications between FDA, our Federal partners, and laboratory professional associations and large commercial laboratories, including, for example, helping gain an understanding of willingness to participate in developing increased testing capacity, any barriers to such participation, and suggestions on next steps.

FDA will continue working with our U.S. Government partners, laboratories, and commercial manufacturers to support access to the CDC test and the development of additional tests. FDA's efforts are critical to help ensure patients can depend on their test results and receive care as needed, and to avoid or mitigate further spread of monkeypox.

Supporting Timely Access to and Careful Evaluation of Monkeypox Therapeutics

Currently there are no FDA-approved products for the treatment of monkeypox. Tecoviramat, or TPOXX, was approved for the treatment of smallpox in adults and children in 2018 under FDA's "Animal Rule" and is being made available for the treatment of monkeypox under an EA-IND through FDA's Expanded Access program.

The Animal Rule[11] allows efficacy to be established based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans for the disease of interest and when conducting clinical trials in humans is not feasible or ethical. Smallpox is caused by the variola virus. Animal studies using variola virus are not

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[6] 1A U.S. Food and Drug Administration, letter (EUA) to Quest Diagnostics Incorporated, September 7, 2022, available at *https://www.fda.gov/media/161454/download*.

[7] U.S. Department of Health and Human Services, "New HHS Actions Add to Biden administration Efforts to Increase Access to Easy-to-Use Over-the-Counter COVID–19 Tests," October 25, 2021, available at *https://www.hhs.gov/about/news/2021/10/25/new-hhs-actions-add-biden-administration-efforts-increase-access-easy-use-over-counter-covid–19-tests.html*.

[8] National Institute of Biomedical Imaging and Bioengineering, "Independent Test Assessment Program (ITAP): Announcement: See New Opportunity for Monkeypox Virus Diagnostics Below," available at *https://www.nibib.nih.gov/covid—19/radx-tech-program/ITAP*.

[9] U.S. Food and Drug Administration, "Virtual Town Hall Series—Coronavirus (COVID–19) Test Development and Validation," August 24, 2022, available at *https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-coronavirus-covid–19-test-development-and-validation–07272022*.

[10] MOU 225–22–020, "Memorandum of Understanding for Diagnostic Surge Capacity for Public Health Emergencies," effective May 6, 2022, available at *https://www.cdc.gov/csels/dls/documents/2022-revised-mou-for-surge-capacity—final—signed.pdf*.

[11] For more information on the Animal Rule, please visit U.S. Food and Drug Administration, "Animal Rule Approvals," June 2, 2022, available at *https://www.fda.gov/drugs/nda-and-bla-approvals/animal-rule-approvals*.

consistently reproducible and do not mimic human disease. They are extremely challenging to conduct as research is restricted to two maximum-containment laboratories located in the United States and Russia. TPOXX's efficacy for the treatment of smallpox was established, and the drug approved, based on studies in animal models using orthopoxviruses related to the smallpox virus—specifically, nonhuman primates infected with monkeypox virus and rabbits infected with rabbitpox virus. Safety data was obtained in healthy human volunteers without monkeypox virus infection.

The Animal Rule can be used only when it is not feasible or ethical to conduct human clinical trials, as was the case with smallpox. Human studies of TPOXX's efficacy against smallpox disease were not ethical or feasible as smallpox has been eradicated. The Animal Rule was not a viable regulatory pathway to approve tecovirimat for the treatment of monkeypox as the disease was endemic in West and Central Africa, and it was both feasible and ethical to conduct clinical trials in humans.

It is important to note that drugs that show efficacy in animal studies are not always effective in humans. Currently there are no human data demonstrating the efficacy of TPOXX for the treatment of monkeypox or its safety and pharmacokinetic profile in patients with monkeypox; therefore we do not know if TPOXX will be beneficial in treating patients with monkeypox.

Thus, conducting randomized, controlled trials to assess tecovirimat's safety and efficacy in humans is essential.

In parallel with planning for a randomized controlled trial, access to TPOXX for the treatment of monkeypox has been made available through an EA-IND held by CDC under FDA's Expanded Access program. FDA has worked closely with CDC to streamline the protocol based on input from stakeholders to reduce data collection and reporting requirements.

We understand, however, that challenges remain with the current EA-IND mechanism, and we continue to consider all potential regulatory options to best address this situation. Regardless of the regulatory mechanism used to facilitate access to TPOXX, it is important that access does not compromise the ability to conduct randomized, controlled trials that can establish whether TPOXX helps patients with monkeypox. Such clinical trials will be key to any potential consideration of approval of TPOXX.

It is also critical to note that viral resistance to tecovirimat is a concern. TPOXX works by inhibiting a protein called VP37 that all orthopoxviruses share. Even a small change to the VP37 protein can have a large impact on the antiviral activity of tecovirimat. Therefore, judicious use of TPOXX and careful monitoring for the development of viral resistance are of paramount importance for stewardship of this potentially beneficial drug while we study it in clinical trials.

Conclusion

FDA continues to advance its mission to protect and promote public health by helping to ensure the safety of human and animal food, and the safety and effectiveness of medical products. We take our public health mandate very seriously and will continue to work each day to help end the monkeypox public health emergency. FDA and our HHS partners are working tirelessly to ensure a robust and comprehensive response to monkeypox that considers the ever-changing nature of the outbreak. We continue to communicate with the American public and make regulatory decisions based on data and sound science. The Agency looks forward to working with sponsors to increase vaccine supply, increase testing options and capacity, and increasing the number of available treatments, while ensuring that the products meet applicable standards for safety and effectiveness. I hope to continue working with the Committee on these efforts. Thank you again for the opportunity to testify today.

The CHAIR. Thank you.

Assistant Secretary O'Connell.

STATEMENT OF DAWN O'CONNELL, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE, WASHINGTON, DC

Ms. O'CONNELL. Chair Murray, Ranking Member Burr, and distinguished Members of the Committee, it is an honor to testify before you today on ASPR's work and the ongoing monkeypox response. Let me start by sharing the work ASPR has done to procure and distribute vaccines. The Strategic National Stockpile stores vaccines that can be used in a smallpox outbreak.

Among the vaccines it stores is a small stockpile of JYNNEOS, a relatively new vaccine for those that are immunocompromised and unable to tolerate the live replicating virus and the other smallpox vaccines. And since JYNNEOS is also licensed for monkeypox, we have deployed these vaccines for the current response.

When the first case of monkeypox in the U.S. was identified, the SNS had 2,400 vials of JYNNEOS in its on hand inventory, and immediately deployed vaccine to support the first cases. And when there were still only two known cases in the U.S., ASPR requested 36,000 JYNNEOS vaccine vials be shipped to the SNS from our U.S. Government owned reserve stored by Bavarian Nordic. When there were only 13 known cases, ASPR ordered an additional 36,000 vials from its reserve. And when there were only 35 known cases, ASPR ordered an additional 300,000 vials from its reserve. All of this was done to stay ahead of the virus.

Though case counts were very low in the United States, we were watching the quick spread of cases in Europe, which was about 2 to 3 weeks ahead of us, and we moved out quickly, anticipating similar spread in the U.S. in the weeks to come.

ASPR has made over 1.1 million vials of JYNNEOS available to states and jurisdictions for use against the current outbreak, and we have purchased 5.5 million more to arrive over the next months. Bringing JYNNEOS manufacturing capability onshore has been another focus of mine at ASPR.

This summer when we purchased the second 2.5 million doses from BN to be filled and finished, our contract required that those doses be filled and finished in the U.S., and we have been pleased to support BN's arrangement with GRAM to do that fill finish in Michigan. We have provided GRAM with $11 million to secure the equipment and staff it needs to ramp up quickly.

I visited GRAM 2 weeks ago as they are bringing on this new line and was pleased with the progress that I saw, and to hear that they will be adding over 70 new jobs in Michigan to support this work. Vaccines are not the only medical countermeasure ASPR has made available in this outbreak. We have also made available the therapeutic TPOXX.

Prior to the start of the outbreak, the SNS held more than 1.7 million courses of TPOXX. To date, over 37,000 courses have been distributed. I have been pleased to make both of these medical countermeasures available for the current monkeypox outbreak. It is the right thing to do. But I have not lost sight of the fact that

both JYNNEOS and TPOXX were developed and stockpiled for use in a smallpox outbreak.

I have consulted with the PHEMCE, the inter-agency body responsible for advising HHS on medical countermeasures, development, and procurement, and they have agreed with the approach we have taken. It is important, however, that as we move forward with our response, we consider ways to preserve our smallpox capability.

We have also applied several lessons learned from the COVID–19 response to our work in monkeypox. As we digitized the SNS countermeasure ordering system, we opted to use a program that allows states to order both vaccines and therapeutics from the same system, rather than using separate non-interoperable systems for each as they have had to do in the COVID–19 response.

Using this multi-platform ordering system is a step toward modernizing our public health infrastructure for the current response and for future responses. We have also expanded the number of sites to which the SNS delivers. At the start of the outbreak, the SNS only delivered to five sites in each jurisdiction.

This was more than enough for the high consequence, large scale events the SNS has been deploying to, such as hurricanes and tornadoes. However, after seeing the advantage of multiple distribution sites and the COVID–19 vaccine and therapeutics effort, the SNS contracted to create a similar distribution network for its countermeasures.

These are just two of the examples of the lessons we have taken from the ongoing COVID–19 response and applied to the current monkeypox response. Responses cannot be static. They must continue to evolve and calibrate to the current set of circumstances and regularly account for new information and evolving scientific understanding.

This has been true of the monkeypox response thus far and will be true as it continues. Thank you again for inviting me to testify before you on efforts within ASPR to support the ongoing monkeypox response. I look forward to answering your questions.

[The prepared statement of Ms. O'Connell follows:]

PREPARED STATEMENT OF DAWN O'CONNELL

Chair Murray, Ranking Member Burr, and distinguished Members of the Committee, it is an honor to testify before you today on the efforts within the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) to support the ongoing response to the monkeypox outbreak. I am grateful for this opportunity to address this Committee and appreciate your continued support for the ongoing response efforts.

ASPR's core mission is to ensure that we are prepared and able to respond to public health and medical emergencies. In ASPR's 16-year history, ASPR has invested in a range of efforts to prepare for threats identified by the Department of Homeland Security (DHS). One of the key identified threats—by DHS, ASPR, and Congress—is smallpox. ASPR and other Federal partners have invested in preparing for the threat of smallpox for over a decade. We have a number of countermeasures within the Strategic National Stockpile (SNS) to aid in a response, should this country experience any sort of smallpox attack. Certain medical countermeasures we procured and stockpiled for smallpox also protect against and treat the symptoms of monkeypox. We are grateful to be in a position where our existing smallpox medical countermeasure portfolio can be leveraged against monkeypox. In doing so we must not lose sight of the need to maintain a strong smallpox preparedness posture

and replace those countermeasures intended for smallpox that we have distributed in response to the current monkeypox outbreak.

Since becoming the ASPR in the summer of 2021, one of my priorities has been to ensure that programs within the organization are appropriately resourced. The SNS has played a large role in the current response. One of the biggest challenges ASPR faces is fully funding the SNS. Despite growing responsibilities, the SNS has had a relatively flat budget for a number of years. The Administration requested $975 million in the fiscal year 2023 President's Budget to ensure SNS could better carry out its mission. As this Committee knows well, ASPR's authorizing structure is such that the Biomedical Advanced Research and Development Authority (BARDA) advances the development of medical countermeasures, the Public Health and Emergency Medical Countermeasures Enterprise—or PHEMCE—makes a recommendation regarding their usefulness in our stockpile, and then SNS is supposed to be able to purchase the products PHEMCE determines to be needed within available resources.

While BARDA has been successful in supporting the advanced development of a number of medical countermeasures to aid our preparedness and response portfolio, the SNS's flat budget has made it challenging to fully meet PHEMCE-identified goals for these countermeasures. We are fortunate to have products in the SNS to combat the ongoing monkeypox outbreak, but there will be lasting impacts on overall preparedness against other threats, such as smallpox, because of the realignment of medical countermeasures for this outbreak.

The Administration's continuing resolution proposal requests $3.9 billion for HHS to aid in the continued monkeypox response and ensure stockpile preparedness is restored. I look forward to continuing to brief Congress on preparedness levels and the impact that the current response is having on our overall future preparedness efforts.

For the current response to the monkeypox outbreak, ASPR is partnering with many sister agencies within HHS and across the Federal Government, industry representatives, as well as state, tribal, and other jurisdictional health leaders to accelerate progress on vaccines and treatments—and strengthen our response. I will now highlight ASPR's efforts to support development, procurement, and distribution of vaccines and therapeutics and how we are disseminating information relevant to these efforts.

National Vaccine Strategy

Since the first reported case of monkeypox in the United States on May 18, 2022, ASPR has worked tirelessly to accelerate the acquisition and delivery of vaccines and therapeutics to jurisdictions.

This important work first started with an examination of our holdings within the SNS. As reported publicly, the SNS contains both ACAM2000—our first line of defense to vaccinate Americans in the event of accidental or intentional release of smallpox—and JYNNEOS, for which we keep a small stockpile to routinely vaccinate laboratory workers at risk of exposure to smallpox and other orthopoxviruses such as monkeypox. In addition to the 2,400 doses the SNS kept on-hand for rapid deployment, ASPR kept an additional 1.4 million vials of JYNNEOS in –50 degree storage at Bavarian Nordic (BN) to be available if needed for response to a larger outbreak. Those doses are now being deployed for use in the current outbreak. ASPR also had an additional 16.5 million vial equivalents in bulk drug substance to be lyophilized (or "freeze dried") in the coming years for easier storage and longer shelf-life. 5.5 million vial equivalents of that bulk drug substance are being filled and finished now and in the coming months to respond to the current outbreak.

ACAM2000, which is not approved or authorized by the U.S. Food and Drug Administration (FDA) for emergency use to prevent monkeypox disease, contains live, replicating virus and may not be advisable for those who are immune compromised. Given the potential of monkeypox cases in persons who may also have HIV or other immune compromising conditions, ASPR worked with other HHS agencies and offices to determine the JYNNEOS vaccine was our best line of defense against this monkeypox outbreak.

On Wednesday, May 18, the first case was identified in the United States. By Friday, May 20, there were two known cases of monkeypox in the United States, and CDC recommended those known to be exposed to the virus get vaccinated. On Sunday, May 22, the SNS deployed the first vials of JYNNEOS vaccines to Massachusetts to be used as post-exposure prophylaxis for those first exposures.

At this time, while there were still only two known cases of monkeypox in the US, ASPR requested 36,000 JYNNEOS vaccine vials be shipped to the SNS from our U.S. government-owned reserve stored by BN in Denmark. When there were only 13 known cases, ASPR ordered an additional 36,000 vials from its reserve. And when there were only 35 known cases, ASPR ordered an additional 300,000 vials from its reserve. All of this was done to stay ahead of the virus. Though case counts were very low in the United States, we were watching the quick spread of cases in Europe, which was about 2–3 weeks ahead of us, and moved out quickly anticipating similar rapid transmission in the weeks to come.

Ultimately, of the additional 5.5 million vials we have ordered filled and finished, we anticipate that deliveries will begin arriving at the SNS in the next few weeks and will continue through early 2023. To support this effort, 3 million vials will be manufactured at BN's line in Denmark and 2.5 million will be manufactured here in the United States at Grand River Aseptic Manufacturing (GRAM) in Grand Rapids, Michigan. The GRAM facility is the first fill and finish line for the JYNNEOS vaccine in the U.S. and not only supports our current response to monkeypox but enhances preparedness for smallpox as well. Within ASPR, we helped spur this agreement and the technology transfer that was necessary for this production at GRAM and have invested $11 million in securing supplies and staff to ensure the line is up and running as quickly as possible. The transfer is on track to start manufacturing later this year. I was pleased to visit GRAM on August 29, where I met with the CEO and leadership team, and observed the hard work being done to bring the line up as quickly as possible.

ASPR has made over 1.1 million vials of JYNNEOS available to states and jurisdictions for use against the current outbreak—the largest JYNNEOS monkeypox vaccine program in the world. Moving fast and distributing the product ensures equity and access for those who require the product. To support the allocation and distribution of vaccine, in late June 2022, HHS announced an enhanced National Vaccine Strategy (Strategy) to mitigate the spread of monkeypox. This Strategy outlines efforts to ensure that those at higher risk of monkeypox disease receive vaccine, vaccines are prioritized for areas with the highest numbers of cases, and that guidance is provided to state, territorial, tribal, and local health officials to aide their planning and response efforts. Using this strategy we have made vaccine available in phases throughout the summer. Phase 4 of the Strategy that focuses on distribution and allocation efforts is well underway. Currently, allocation amounts are based on a combination of case counts and population (population is based on the estimated size of the underlying population in the jurisdiction that might benefit from expanded vaccination at this point in the outbreak). Jurisdictions are eligible to draw down doses against their allocations once they have attested to adequate utilization of their currently allocated vials. Requiring jurisdictions to inform HHS of their administration data plays an important role in informing the response and ensuring monkeypox doses make it into the arms of those most at risk, rather than sitting on shelves. Once jurisdictions receive vaccine, they are responsible for distributing vaccine within the jurisdiction and setting their eligibility criteria for vaccination. Jurisdictions may choose to expand eligibility in the future depending on the state of the outbreak and the available supply of the JYNNEOS vaccine as it continues to increase.

Currently, doses are held in a small stockpile within the SNS and, as such, distribution of the product has been managed by the SNS. The SNS' traditional distribution framework is based on getting material into jurisdictions quickly to respond to high-consequence events such as hurricanes and other large-scale disasters. Having access to five distribution points in any given jurisdiction has been satisfactory under these traditional circumstances to move the necessary medical units and countermeasures into place. As the SNS is now being asked to distribute vaccines nationwide from its stockpile, something it has not traditionally done, it is in the process of making arrangements with a large distributor to increase distribution to more sites. This is not a static response effort. At each point that I receive feedback from jurisdictions on ways to make the response easier for them to manage, I have worked with the programs here to adjust and incorporate the feedback just as we are doing now with SNS distribution efforts. You have my commitment that I will continue to do that throughout this and future responses.

We are also providing a portion of vaccine for distribution through existing Federal channels (the Departments of Veterans Affairs and State, and agencies within HHS including the Health Resources and Services Administration, the Indian Health Service, and the National Institutes of Health). ASPR is working closely with HRSA to ensure they are able to vaccinate individuals via their Ryan White networks; IHS is able to vaccinate tribal members, often in rural and remote areas of

the country; VA is able to vaccinate our Nation's veterans; NIH is receiving doses to conduct research; and DoS is able to ensure at-risk personnel serving overseas are protected.

Treatment to Combat Symptoms of Monkeypox

Tecovirimat (TPOXX), a therapeutic drug licensed for smallpox treatment, was developed with BARDA support and can be used to treat individuals with monkeypox with an appropriate regulatory mechanism. CDC currently holds, through FDA's Expanded Access program, an Expanded Access Investigational New Drug (IND) protocol that allows its use for monkeypox.

Prior to the start of the outbreak, the SNS held more than 1.7 million courses of TPOXX, or tecovirimat, in its immediate holdings. In addition to deploying bottles directly to those who qualify under CDC's IND protocol, on August 18, ASPR made available 50,000 patient courses of TPOXX for pre-positioning throughout the country. Jurisdictions have been allocated courses of TPOXX using a formula based 75 percent on the number of cases in their jurisdiction and 25 percent on the number of individuals who are at the highest risk of contracting the virus, including individuals who are living with HIV or who could benefit from HIV pre-exposure prophylaxis. This allocation is in addition to the over 20,000 courses ASPR deployed to jurisdictions from the SNS prior to August 18.

Engaging Those at Highest Risk for Severe Disease

HHS has launched two pilot programs to provide additional vaccine allocations to state and local health departments. The first provides doses to jurisdictions that are hosting large events that attract gay, bisexual, and other men who have sex with men in the coming weeks and months and the second provides doses to smaller more targeted outreach efforts. The larger pilot program is setting aside 10,000 vials of vaccine from the SNS that jurisdictions can request to order on top of their existing vaccine allocations and supply. The number of additional doses made available to a jurisdiction will be based on the size and nature of the event, and the ability to reach attendees at highest risk for monkeypox. The smaller pilot program is setting aside 10,000 vials of vaccine from the SNS that jurisdictions can also request on top of their existing vaccine. Working with CDC, ASPR is pleased to provide these additional doses for targeted equity interventions.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the ongoing monkeypox response. I look forward to answering your questions and working with my team at ASPR and our colleagues across HHS to mitigate the impact of this virus.

The CHAIR. Thank you. Thank you very much to all of our witnesses for your testimony and for being here today. We will now begin a round of 5 minute questions of our witnesses, and I ask my colleagues to keep track of your time. As always, hopefully you can stay within those 5 minutes.

I know each of your agencies have worked relentlessly to respond first to COVID and now monkeypox, but I have to say, frankly, too many missteps were made early on in the response and a couple hundred cases turned into 21,000. It is unacceptable to communities who already experience barriers to accessing health care, like the LGBTQ+ and the Black and Latino communities that are hardest hit by this outbreak.

Access to testing was an early challenge in the monkeypox response, with many people reporting significant delays in both accessing the tests and learning their results. To continue to have these challenges around testing is just simply unacceptable.

Dr. Walensky, let me start with you. How is the CDC working to make sure tests are more accessible and results are available earlier?

Dr. WALENSKY. Thank you, Senator, for that question. One of the big challenges that we had in terms of access to testing was both patients understanding what they—that they were presenting with a new infection, and providers understanding that this was a new infection that they had to test for.

Indeed, another important clinical consideration was that people were coming in requesting a test when they had no symptoms, and they had no rash. As Dr. Califf noted, the test for this infection is a swab of the rash.

In fact, there is no other FDA approved test. We need to have a rash in order to conduct those tests. So much of what we have done—and I should mention that we have always had more capacity than we have had tests coming in. To date where we have used about 14 to 20 percent of our capacity.

But to address these access issues, we had to work with clinicians, we had to work with patients. We had to do an extraordinary amount of outreach so that providers would understand how to test patients, would understand when to come in for a test, and our public health partners would know not to gatekeeping those tests.

That was the work that we did early on as we were scaling up testing, knowing that we may need more testing coming forward. So through the laboratory response network, we increased our capacity to test through expanding the manual extraction to automated extraction.

Then we worked, as you heard, through our commercial labs to expand testing across the country, and simultaneously working with outreach and education to providers, clinicians, patients, and public health. Thank you.

The CHAIR. Thank you. Dr. Califf, Secretary Becerra recently declared that FDA can use the emergency use authorization pathway for monkeypox tests. How will that improve the availability of new tests, and what steps are you taking to improve on the progress that you have made?

Dr. CALIFF. First of all, let me concur with Dr. Walensky. There has never been a shortage of tests but there has been a shortage of access to tests because of inefficiencies in the system. So the EUA authority has enabled us—we have given one EUA already, but we also have five commercial labs which are offering the tests at this point.

We issued a guidance just the other day which makes it clear that individual institutions that are developing laboratory developed tests should proceed ahead. And we have given people clear guidance and templates for developing their test and figuring out if they work.

I would say on all fronts, the gates are open under a watchful eye because we also must keep in mind that one of the lessons from COVID was that when the gates were open, a lot of tests turned out not to be so good, got out there, and we had to rein them back in.

The CHAIR. Well, look, I am encouraged by the decline in cases, but it really is imperative that we remain vigilant. And despite efforts by HHS to increase access to vaccines, some people in my home State of Washington still go to great lengths to get one, including crossing the border into Canada.

Now people, understandably, want to be vaccinated before they get exposed, but that needs we need more vaccines. Ms. O'Connell, some serious stumbles were made this year when it came to our vaccine supply. What have you done to make sure that never happens again, and what are you doing to increase the supply and distribution of vaccines right now?

Ms. O'CONNELL. Chair Murray, thank you so much for that question. What is most important to us is that those that need access to this vaccine get it. So if you continue to hear from constituents that are unable to access a vaccine or having to cross the border, please let us know.

We are in the business right now of knocking down those hurdles and making sure the vaccine can be accessed. We did take a very small stockpile that was intended for smallpox, that was eventually intended to be lyophilized, freeze dried for smallpox, and converted it to this active monkeypox response.

That required a couple of challenging problems to solve. We moved the first 372,000 vials, as I mentioned in my opening statement, immediately. We needed FDA to approve, and they were terrific partners moving quickly, to approve that second manufacturing line that began—drew the 800,000 vials we were waiting for.

That is what it manufactured on. We needed that approval to happen before we could deploy those. FDA worked quickly and we got those out in July. We have also ordered an additional 5.5 million vials of the bulk drug substance that was intended to be lyophilized for smallpox.

We have ordered that to be filled and finished and shipped to the United States. 2.5 million of those will be manufactured in the United States. By adding a second line in GRAM, one that is onshore, domestic manufacturing, we will be able to access these vaccines much quicker in the future.

It is a critical step forward in our preparedness, both for this monkeypox response and for future smallpox programs.

The CHAIR. Senator Burr.

Senator BURR. Thank you, Chair. Tony, last time you spoke on monkeypox here, you made it very clear that monkeypox is a result of animal to human transmission, and that happened abroad. Here is my question.

If we allow monkeypox to circulate in our population indefinitely in the United States, what are the chances and has it been studied whether there can be a transmission from human to animal in the United States where we could have a threat that is—animal to human transmission then that is domestic?

Dr. FAUCI. It is certainly possible, Senator Burr. Whenever you have a situation where you have an animal reservoir, and the virus has already shown you from the standpoint of transmission that it can infect animal species and you actually have an individual who

is infected, there is no real reason why that not could go the other way. I don't believe that we have seen that. But I would not be surprised if we do see a essentially going back and forth. That is possible.

Senator BURR. That would present a real problem.

Dr. FAUCI. Well, that would present a problem of the propagation. I mean, when you want to eliminate an infection—I mean, there is eradication, there is elimination, and there is control. The best way to eradicate or eliminate it is if you keep it out of the realm of an animal reservoir which continues to re-feed into the human population.

Senator BURR. Great. Thank you. Dawn, news outlets recently reported the Administration is evaluating whether some doses of JYNNEOS should be held back in the stockpile to meet our requirements for smallpox rather than distributed to support the current monkeypox response.

This seems to conflict with FDA's recent decision to implement dose sparing strategies, which indicates that we need to maximize the number of available doses. Can you square this up for me?

Ms. O'CONNELL. Thank you, Ranking Member, for that question. So we continue to maintain our smallpox preparedness. That is critical. Our front frontline vaccines continue to be available and have not been impacted by our monkeypox response.

But we have added the capability to be able to provide the JYNNEOS vaccine to those that are immunocompromised in the case of a smallpox outbreak. And we are evaluating with each dose that we make available to the monkeypox outbreak what it means for that preparedness and smallpox.

I have met with the PHEMCE. I have consulted with them to understand whether we need a separate monkeypox stockpile so we can pull those vaccines off the shelf and not worry about the preparedness for the immunocompromised in a smallpox outbreak.

Senator BURR. Have you ever thought about the message you send to the at risk population when you suggest to them that though they are in the midst of an infection problem, that we are going to—we are discussing holding back in case we have an outbreak of smallpox.

Let me just explain. We know that we have 13 to 15 million gay men in this country, in the United States. Tony, we have about 1.9 million HIV/AIDS positive gay men. There is your immunocompromised population, 1.9 million. Your risk pool of sexual for sexually transmitted monkeypox, about 13 to 15 million. And somehow we are cheering the fact that we put out 700,000 vaccines.

If I am in that community, and then on top of that we have the subdermal decision, I am going to cut the amount that you get, and there is not sufficient public transparent information about that, you have got a population that is a little bit questioning whether you are doing everything to help them.

That may be a reason that we have only had 461,000 people vaccinated out of a pool, a defined pool, of up to 15 million people, of which 1.9 million are immunocompromised because they are HIV

positive. Dr. Califf, currently the FDA—I switched gears just real quick.

Currently, the FDA authorizes COVID–19 vaccines and antiviral treatments to be purchased only by the Federal Government, prohibiting anyone else that is not Government from purchasing these vaccines.

I believe we all agree on the crucial role vaccines and treatments play in stopping and reducing the spread of the virus. So why must every dose pass through the bureaucracy of Washington before it reaches a patient, and why are we still restricting access like that?

Dr. CALIFF. Well, thank you, Senator Burr. It is—by the way, I am glad you are fully functional after your recent surgery, and you are definitely spry. You are showing good evidence of that.

Let me just say that we have the vaccine. It is available. It is everywhere. You can just make your appointment and get it. And we expect that this will transition, as there has been much discussion, over the next period of time. But for right now, those are the rules under which we operate.

Senator BURR. That is why a plan is somewhat important. Ms. Chairman, just one last question for Dr. Fauci, if I can. Tony, the pediatric immunization schedule recommends four doses of polio vaccine before one reaches the age of 6 years old.

With new cases of polio being detected in New York State, I am wondering, do we know how long immunity for the vaccine lasts? To what extent is someone protected if they were completely polio vaccinated as a child?

Dr. FAUCI. It is not necessarily life long, but it is measured in decades and decades. So the—if a person has the full series of vaccinations, you could expect that they would be fully protected.

The situation that we are concerned about are those who have either had no vaccination, like we saw with the case in Rockland County in New York, or individuals who have incomplete or did not complete their full course.

But if you have a full course—however, since it isn't necessarily life long, when a person goes into a zone where there is a lot of polio, you would recommend that they would get a boost. But I would refer to perhaps that Dr. Walensky has something further to add to that.

Dr. WALENSKY. I have nothing to add. That is exactly right.

Senator BURR. I thank the Chair. Thank you.

Senator CASEY. Thank you, Senator Burr. I wanted to start by thanking the witnesses, and obviously thank you for their public service. I will start with Dr. Walensky. Part of the success of the COVID–19 vaccination campaign was the gradual shift from large vaccination sites to hyperlocal sites where people could find vaccines in their own neighborhood, for example, like at a local pharmacy.

We have seen the way in which convenient and local access to vaccines can help with uptake, whether they are—whether we are talking about a vaccine for a new treatment like COVID–19—or a

new threat, I should say, like COVID–19, or for routine vaccines like influenza and childhood vaccines.

Obviously people know and trust their own doctor and their providers, and they respond to community based and community member led efforts that meet them where they are.

Doctor, how are you working with state and local partners to make sure we reach everyone who is at risk for infection, to make sure that they have the opportunity to get vaccinated if they so choose?

Dr. WALENSKY. Thank you, Senator. A really important question in terms of outreach. So early on as vaccines were being distributed, we were doing it in places where people were seeking care. Many of that—many of those places were in sexual health clinics or state run clinics where people were receiving care. It is the case that not all members of this community have told their own clinicians about their sexual activity.

It is very important that we do this in a sensitive and non-stigmatizing, affirming manner. So we were doing it in places initially where people were receiving care, but then many of the lessons again learned from COVID, as we have rolled out these vaccines and delivered over a half a million to members of these community, is that we need to do more and more outreach.

We learned that we need trusted messengers, we need community based organizations. I am pleased to say that over the last several weeks, we have sponsored vaccine activities in several large scale distribution sites like Atlanta Black Gay Pride, like Charlotte Pride, like Boise Pride, and like Southern Decadence. When we have done so, we have had really successful campaigns.

In the Atlanta Gay Pride, we vaccinated over 4,200 people. Similarly with Southern Decadence, around 4,000—3,000 people. What we need to do now is do those in smaller scale, and we are actively doing that scale up in smaller scale.

Rather than these big events, we need to meet people where they are with community based organizations, trusted messengers, exactly as you say. Thank you.

Senator CASEY. Thanks, doctor. Next question will be for both you and Assistant Secretary O'Connell.

We know that in the aftermath of the pandemic and now with the emergence of monkeypox as a public health threat, the need for ongoing, dedicated investment in our Nation's public health infrastructure, similar to what Chair Murray has called for and her Public Health Infrastructure Save Lives Act—our state and local health departments have been struggling for years after two and a half years of the COVID–19 pandemic and now with monkeypox in addition to that.

They simply don't have the resources they need for routine public health work. So when an emergency comes up, they have to move funds around and sacrifice from their core programing.

Other programing, like the ongoing opioid epidemic, lead screenings, anti-tobacco efforts, cancer screenings, routine vaccinations, on and on. So how would additional sustained funding for local public health infrastructure help us be better prepared for

new threats like a new viral outbreak? Maybe I will start with you, Assistant Secretary O'Connell.

Ms. O'CONNELL. Thank you so much, Chair, for this question. We continue to see states, jurisdictions, or public health departments worn out, tired, exhausted.

We know they have been working for two and a half years around the clock, and we have been relying on them to distribute vaccines and therapeutics, both in the COVID–19 outbreak, as well as this new monkeypox outbreak. So one of the most critical investments we can make would be in additional staffing and not just throwing supplemental funds out that hire people but don't sustain them.

It is important that we have multiyear funding that supports our public health departments. It is also critical that they can build these systems. I talked about the HPOP system that we put in place for the SNS digitized ordering, which is interoperable.

That we are no longer having them trained on something called VTrckS that CDC sets up, and then HPOP that H-CORE sets up, but we have it on one system that talks to each other. They can order their vaccines and their therapeutics.

By introducing that in this outbreak, we knew that the states were tired, and we worked very carefully with them on making sure they understood why we made this decision. And while it was hard, it does push us forward in a supportive way as we face this current outbreak and future ones.

Dr. Walensky, I know that you might want to say more.

Dr. WALENSKY. Thank you. If I could just briefly add that the core public health infrastructure is key. This needs to be disease agnostic and long term sustainable rather than from crisis to complacency. I will just give you the example that our public health partners in the states and local jurisdictions do not have a line item for monkeypox resources.

They have had to respond, trying to be flexible with other resources that sometimes are not legally allowed. So as you know, the key core public health infrastructure are the workforce, diverse as the communities they serve, laboratory infrastructure so we can scale up new labs swiftly, and then data infrastructure, so we have interoperable data, just as the ASPR noted. Thank you.

Senator CASEY. Thanks very much.

Senator Paul.

[C-SPAN video clip playing].

> News Anchor. *"—But she has had the flu for 14 days. Should she get a flu shot?"*
>
> Dr. Fauci. *"Well, no. If she got the flu for 14 days, she is as protected as anybody can be because the best vaccination is to get infected yourself."*
>
> News Anchor. *"And—"*.
>
> Dr. Fauci. *"If she really has the flu—if she really has the flu, she definitely doesn't need a flu vaccine—if she really has the flu."*
>
> News Anchor. *"She should not get it again?"*

Dr. Fauci. *"She doesn't need it because it is the best—it is the most potent vaccination is getting infected yourself."*

[End of video clip.]

Senator PAUL. This is an ongoing question. And we have had ever evolving opinions from you, Dr. Fauci. Currently, antibody surveys show that 80 percent of children, approximately 80 percent of children have had COVID.

Yet there are no guidelines coming from you or anybody in the Government to take into account their naturally acquired immunity. You seem quite certain of yourself in 2004, but in 2022 there is a lot less certainty. One of the things that we also know after looking at this for 2 to 3 years, is that the mortality from COVID is very similar, if not less than influenza.

When we look at this, we wonder why you seem to really embrace basic immunology back in 2004, and how you or why you seem to reject it now.

Dr. FAUCI. Well, I don't reject basic immunology, Senator, and I have never denied that there is importance of the protection following infection.

However, as we have said many times and as has been validated by the authorization of the—by the FDA through their committee and the recommendation by the CDC through their committee, that a vaccination following infection gives an added extra boost, and that film that you showed is really taken out of context.

I believe that was when someone called in who had a reaction to a vaccine and asked me through a telephone in the interview if they should get vaccinated again. So it was in the context of someone who had a reaction.

As a matter of fact, Reuters fact check looked at that and said, Fauci's 2004 comments do not contradict his pandemic claim.

Senator PAUL. Actually, words don't lie. If you look at the words behind me, we can go over them a little bit at a time. "She doesn't need it because the most potent vaccination is getting infected yourself."

Dr. FAUCI. It is true. It is true, Senator. It is a very potent way to protect.

Senator PAUL. When you are trying to tell us that kids need a third or a fourth vaccine, are you including the variability or the variable of previous infection in the studies? No, you are not. Because when you have approved vaccines in recent times, in the committees that have approved it for children, don't report anything on hospitalization or death or transmission.

They only report that if you give them the jab, they will make antibodies. And you can give kids hundreds of jabs and they will make antibodies every time, but that does not prove efficacy. So what you are doing is denying the very fundamental premise of immunology that previous infection does provide some sort of immunity. It is not in any of your studies.

Almost none of your studies from the CDC or from the Government have the variable of whether or not you have been previously

infected. So let's look at adults. I have had three infections. Should I get a fourth one?

If you are going to measure whether you get a fourth one, you need a category that has a fourth one in it and you need one that has nothing in it, no vaccine or the fourth vaccine. But you also need to know whether they have been infected. If you ignore whether they have been infected, you are ignoring a vaccine basically, so you are ignoring a variable.

What you are giving us is this—you decry, and people decry vaccine hesitancy. It is coming from the gobbledy-gook that you give us. You are not paying attention to the science. The very basic science is that previous infection provides a level of immunity.

If you ignore that in your studies, if you don't present that in your committees, you are not being truthful or honest with us.

Dr. FAUCI. Senator, if I might respond, I have never, ever denied fundamental immunology. In fact, I wrote the chapter in the textbook of medicine on fundamental immunology. You know——

Senator PAUL. Is it—any of the guidelines for vaccines—any of the guidelines for vaccines from the Government include previous infection as something to base your decision-making on with vaccines? Do any of the guidelines involve previous infection?

That is why you are ignoring previous infection, because it doesn't involve any of the guidelines. And furthermore, we have been asking you and you refuse to answer whether anybody on the vaccine committees gets royalties from the pharmaceutical companies.

I asked you last time and what was your response? We don't have to tell you. We have demanded them through Freedom of Information Act, and what have you said? We are not going to tell you.

But I tell you this, when we get in charge, we are going to change the rules and you will have to divulge where you get your royalties from, from what companies, and if anybody in the Committee has a conflict of interest. We are going to learn about it, I promise you that.

Dr. FAUCI. Mr. Chair, can I respond to that, please?

Senator CASEY. You may.

Dr. FAUCI. Okay. There are two aspects for what you said. You keep saying, you approve, you do this, you do that. The committees that give the approval are FDA through their advisory committee.

The committees that recommend are CDC through their advisory committee. And you keep saying I'm the one that's approving a vaccine based on certain data. I don't really understand, with all due respect, Senator——

Senator PAUL. You are the one that said you would not reveal—you would not reveal what company gave you royalties or what company gave the other scientists royalties——

Senator CASEY. We have got to move on.

Senator PAUL. That is what you told the Committee.

Senator CASEY. Senator Paul——

Dr. FAUCI. Sir, could I please answer that?

Senator CASEY. Briefly, yes.

Dr. FAUCI. You keep asking committees—they are not my committee. They are the VRBPAC committee for the FDA and the ACIP for the CDC. I don't have any idea what goes on——

Senator PAUL. They won't reveal, as well as you, won't reveal what companies——

Senator CASEY. We are going to move on. We are over time.

Senator PAUL [continuing]. royalties from.

Senator CASEY. Senator Paul, you are over. Everyone is over a little bit. I just want to make sure we keep on time here. For the record, I know Chair Murray and previous Chairs of this Committee of both parties, both parties have found videos to be out of order, and I will note for the record, the video is out of order.

We will move to Senator Smith.

Senator SMITH. Thank you, Mr. Chair.

Mr. Chair, I ask unanimous consent to submit a letter from AIDS United, the AIDS Institute, the National Alliance of State and Territorial AIDS Directors, the National Coalition of STD Directors, and the National Minority AIDS Council outlining recommendations for a comprehensive approach to the monkeypox response...Mr. Chair, can I have unanimous consent for that, please?

Senator CASEY. Yes. So ordered.

[The following information can be found on page 60 in Additional Material:]

Senator SMITH. Thank you very much. Thank you to our witnesses. I want to add my gratitude to Dr. Fauci for your service to our Country during some of our Country's most challenging times.

Thank you so much. I want to also start by associating myself with Senator Murray's remarks about the importance of Congress coming together to make sure the Administration has the resources that it needs to respond to the monkeypox public health emergency.

I also agree on the need to sharpen our response and to work effectively with public health departments, including in Minnesota. Assistant Secretary O'Connell, we had a good discussion last week about distribution of the monkeypox vaccine, and I want to follow-up on that.

We talked about some of the challenges that the Minnesota Department of Health has experienced. The issue is that ASPR has opted to use the HPOP system, the health partner order portal, as I understand it, to distribute vaccines rather than the VTrckS system, which is how COVID vaccines were distributed and what the Department is used to.

As I understand it from ASPR's perspective, the HPOP system works better for distributing both monkeypox vaccines and treatments directly from the Strategic National Stockpile. There are also some challenges with interoperability, as I understand it, with the VTrckS system.

But of course, the issue, as we discussed, is that by using two different systems, one for COVID vaccines and one for monkeypox

vaccines, this is a real challenge for the Minnesota Department of Health, and I suspect that this is a challenge for other agencies as well.

Of course, this is happening at a time when these challenges are falling on public health departments and staff that are exhausted and burned out after the last two and a half years of responding to COVID–19 and learning a new system in the midst of all of this is really a challenge.

It is sort of exacerbated, I think, by the Department having trouble tracking shipments of vaccines through VTrckS and sometimes monkeypox doses just showing up unexpectedly. So could you just address for me—I appreciate you talked about this in your written testimony.

Could you address what steps you are taking to work with state health departments that are in similar situations to Minnesota's to help improve how this distribution process is working?

Ms. O'CONNELL. Senator Smith, thank you and thank you for the good conversation we had last week, and an opportunity to talk about some of these challenges. So most important to us is that those that need vaccines can get them.

If anyone continues to find this to be a difficult system, please reach out and let me know. We want to knock down these hurdles to ensure that folks have access. We now have enough vaccine supply to meet demand, so it is important that people are able to access it.

We have a similar challenge that Dr. Walensky mentioned it with the states. The states aren't able to use their COVID funding for the monkeypox response. We haven't been able to use our COVID funding for the monkeypox response either. So when it came to digitizing the SNS process, we were going to have to put new money into either the VTrckS system or the HPOP system.

The HPOP system is currently being used in COVID–19 to order therapeutics, so states do have familiarity with HPOP, VTrckS was being used for the vaccines. Only HPOP could do both. And we were faced with putting annual budget funding into one of these systems in order to digitize the SNS ordering.

We chose to put it into the system that could actually do both. We believe that was an important step in moving forward. But we do acknowledge, Senator Smith, that our public health department colleagues are worn out and tired.

We have had countless office hours with them to make sure they understand the system. If they are running into any problems, we are available to answer them. And as hard as this changed management is in the middle of two responses, it was the right thing to do to move forward to an interoperable system.

We also have added additional distribution sites. That is one of the things we did with the SNS. We could not just piggyback on the COVID–19 distribution network. That was funded with COVID dollars. We had to go with the SNS, do an entirely new contract with a different distributor with annual funds, and set that up.

That was one of the reasons why there was a delay. We have needed to overcome this, and we will look forward to working with Congress on making response dollars more fungible in the future.

Senator SMITH. I know that would be helpful, and I appreciate your continuing to work the Department. And you know, obviously getting the distribution right is everything when it comes to getting vaccines and making sure that people have access to vaccines.

Mr. Chair, I am out of time, but I will submit a question for the record about the importance of tribal consultation to our witnesses and look forward to your response.

Senator CASEY. Thank you, Senator Smith.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Secretary O'Connell, I want to follow-up on the statement you just made. I don't recall any requests from the Administration to use leftover COVID money for monkeypox.

Moreover, it is not at all clear to me that you could not submit a reprograming request to the Senate Appropriations and House Appropriations committees for those—that purpose.

What exactly are you implying when you say that you haven't been able to transfer funds? You have taken funds for other purposes, including sending it to the border.

Ms. O'CONNELL. Senator Collins, thank you so much for your question and for the conversations we have had recently about issues. We have been advised by our legal counsel and by our appropriations team, our budget and finance team, that the money that is currently in the contract for McKesson, which is our distribution network that each H-CORE is managing, could not be—we could not piggyback on that same contract to set up a monkeypox distribution network.

The way those funds work, we were restricted to supporting COVID response efforts and not additional response efforts. But I would be more than happy to meet with you and your team again and see if it is possible to do a reprograming.

But that was what we were advised, and so we took additional funds, different funds, non-COVID funds, and set up a different contract with AmerisourceBergen for the SNS to set up a distribution network.

Senator COLLINS. Let me turn to another issue that we have discussed several times, and I do appreciate the fact that you have made yourself available. We have statements from Dr. Jha from OMB back in March that laments the decline of domestic manufacturing for COVID tests.

It talks—OMB in its March supplemental request talks about the volatility, which makes it difficult to preserve manufacturing, domestic manufacturing of tests. Dr. Jha says the U.S. Government put a lot of efforts and resources into building up domestic manufacturing.

What we are seeing day by day, week by week, is that is beginning to go away. I would suggest that it is the Administration's contracting policies that have weakened our domestic manufac-

turing of COVID tests. As you and I have discussed before, the majority of the at home tests the Administration purchased for COVID were manufactured outside the United States.

For example, the Administration awarded a Chinese company, iHealth, a $1.3 billion contract. That is roughly four times the size of the contract that was awarded to an American company, AVID, which has a considerable presence in my state.

How is it that the Administration is working with domestic testing manufacturing when you are at the same time awarding contracts to Chinese companies? That does not help to preserve domestic manufacturing.

Ms. O'CONNELL. Senator Collins, thank you. Domestic manufacturing of tests is a critical mission of ours in ASPR, making sure it is supported and an enduring part of the COVID–19 response. When it moves from an acute response to a steady state, we will always want to know whether we have had COVID, whether someone we have interacted with had COVID.

Testing is critical and domestic manufacturing of tests are also critical. And regarding the iHealth contract, you will recall when the President made the announcement that he was going to make 1 billion tests available through the U.S. Postal Service distribution system, the *covidtest.gov*.

He also vowed at the time that he would not interrupt the commercial market, that he would not take tests that were currently going to the pharmacies and into other stores, he would not take them out of the market and put them into the *covidtest.gov program*

In order not to disrupt that, the domestic manufacturers at the time were seeding the local pharmacies, we pulled in tests internationally so as not to interfere with what was available at the pharmacies.

As soon as that leveled out, we made a commitment in the spring to only support domestic tests moving forward, but that initial decision was to not interrupt the domestic tests that were currently feeding the schools, the pharmacies, and the other pieces of the response. We wanted those to remain available.

Senator COLLINS. Dr. Fauci, I just want to wish you well in your retirement. And a very quick question for you. And it is based on what you have written recently about the lessons of the AIDS pandemic.

Though monkeypox cases are overwhelmingly related to sexual transmission and men who have sex with other men, should we be doing more to look at community spread and cases in the broader community, such as, for example, testing anyone with an atypical case of herpes or shingles regardless of their sexual history?

Dr. FAUCI. Thank you for that question, Senator. The answer is yes, we are doing now sero surveys and surveillance that go beyond the well-established high level of infection in certain demographic groups.

That was part of the five pillars that I mentioned in my statement about virology, immunology, transmission, reservoirs, and

serosurveillance. We are doing that in some of our studies, but the CDC is also doing that.

We are actually doing it in collaboration with them, using some of our cohorts in collaboration with the CDC's capability to do that. Perhaps you want to comment.

Dr. WALENSKY. Yes, maybe I will add, and thank you Dr. Fauci, that among our health advisory networks that we send to clinicians and our outreach, for example, to the American Academy of Pediatrics, we make recommendations just like that say, if there is an atypical rash, please consider monkeypox and test for it on your differential diagnosis. We make those recommendations. Thank you.

Senator COLLINS. Thank you.

Senator CASEY. Thank you, Senator Collins.

We will turn next to Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chair.

First, I would like to ask unanimous consent to enter into the record an April 11th, 2022, article from Reuters entitled, Fact Check of Fauci's 2004 Comments Do not Contradict His Pandemic Stance.

Senator CASEY. Without objection.

[The following information can be found on page 63 in Additional Material:]

Senator BALDWIN. Thank you. I want to join my colleagues, Dr. Fauci, in wishing you very well in your retirement and thank you so much for your service to this country. I want to start with you for a question on basic research.

I think we are falling short when it comes to providing sustained investments in preparedness. That is why I led the Disease X Act to provide sustained funding for BARDA to focus on medical countermeasure development for viral families of concern.

We can't just keep on responding to the threat in front of us. Dr. Fauci, can you explain how investments in smallpox research have made us better prepared for this outbreak had we—than had we not made those investments?

Dr. FAUCI. Thank you very much for that very important question, because it relates not only to smallpox and the extrapolation of knowledge to monkeypox, but it relates to virtually all elements of fundamental basic research, that ultimately when you get to a problem that is a public health problem, it can be applied.

As I mentioned in my written and in my oral statement, the original work that had been done on orthopox viruses dating back to 2001 and 2002 following the anthrax attacks, when we put a lot of work into developing the countermeasures that Assistant Secretary O'Connell mentioned regarding smallpox, allowed us by getting another type of vaccine that is less reactogenic and has less adverse events, which led to JYNNEOS, which is now the primary vaccine for monkeypox.

The relationship between the smallpox research that had been done for decades on orthopox viruses and the acceleration of that research when we had the bioterror threat in 2001 and 2002, al-

lowed us to respond rapidly with already developed countermeasures in the form of TPOXX and JYNNEOS.

Senator BALDWIN. Thank you. Dr. Walensky, for me, as we had a chance to speak earlier, monkeypox is all too reminiscent of our initial response to HIV/AIDS. I actually started my career in 1986 on the Dane County Board of Supervisors. In that year, the first cases of HIV/AIDS were reported in Wisconsin.

There was a tremendous amount of fear and paranoia and sorrow in our community. We had to fight both the disease, and the fear and the stigma and the discrimination that was present in the community.

Dr. Walensky, can you describe CDC's efforts to work with the LGBTQ+ community to combat misinformation, to reduce stigma, and to ensure that folks have access to care?

Dr. WALENSKY. Thank you, Senator, for that question. Their involvement and integration into our response has been critical.

One of the first thing that we did when we heard about the case on May 17th was outreach between our smallpox branch and our HIV branch, because we knew that it was—both those communities, both those scientists that were going to need to come together to make our—to make a robust response. We have had extraordinary outreach with the LGBTQ community.

We have met several times with the Human Rights Campaign, the LGBTQ serving FQHCs, inter-pride and pride organizers. We have facilitated best practice exchanges with tourism hubs. We have palm cards for Provincetown, Fire Island, Palm Springs. And then we have supported these large events like Black Gay Pride, and Boise Pride, Charlotte Pride.

Importantly, one of the things that we did early on, and this was one of the lessons learned from HIV decades ago, was that on May 27th, we first published an iteration of sexual health information on monkeypox for the LGBTQ community, so they would understand what practices would decrease their risk of monkeypox.

All of this engaging a very robust, very active, and very helpful and informed LGBT community that have been essential in not only working with us, but in educating their own community. Thank you.

Senator BALDWIN. Thank you. I will enter my last question into the record for Secretary O'Connell on what ASPR is doing to ensure this delay in vaccine availability is not a problem in the future, and anything you need from Congress to help address this.

Thank you, Mr. Chairman.

Senator CASEY. Thank you, Senator Baldwin.

I will be turning the gavel over to Senator Baldwin, and our next Senator, Senator Cassidy.

Senator CASSIDY. Thank you, Mr. Chair. I was a medical resident in 1983 to 1986 during the HIV epidemic when HIV just exploded, so I am very aware of the need to have a robust research and public health response to infectious diseases.

Now, Dr. Walensky, part of this has got to be predicated upon trust between the American people and the agencies, that the agen-

cies are functioning as best as they can. I feel like that trust is frankly been dissipated. I am sorry to say that because I respect you as a clinician, as a person.

But I have asked you on multiple occasions as to what percent of the CDC workforce is actually showing up. Frankly, you have always blocked that. You have never given a straight answer. I would like to enter for the record an article from the Epoch Times in which they did a FOIA request to find out how many folks at CDC were actually working, showing up, so to speak.

Roughly 2,772 out of roughly 13,000 employees are showing up every day, but 78 percent are working completely remotely or come in maybe only twice every 2 months. Now, why is that important? First, that was a knowable fact, but it was not shared with Congress, we the representatives of the American people. I think the American people would like to know that if CDC is not functioning well, how many of the people are actually showing up?

Now, I mentioned CDC is not functioning well because I now reference an article which I will enter for the record from New York Times on August 17th, in which you frankly, to your credit point out, CDC has not been working well and that there is need for wholesale change.

At the end of the article, they quote an acting director of—under President Obama, Dr. Besser, who says that it is hard—first pointing out that you are still working remotely, you, yourself are working remotely, at least of August 17th, and then he says, but it is hard to see how Dr. Walensky could execute wholesale changes when she only sees most of her staff at a distance."

I don't know how you motivate and inspire culture change when people aren't together." Now CDC is requesting billions of dollars for public health initiatives in an agency which, by your assessment, is not functioning well, in which only about 22 percent of the people are showing up every day, and in which previous Obama officials are doubtful that you are going to affect change because you don't show up every day.

I say that kind of painfully because I want the CDC to work. And yet—and one example, and I am sure there is a reason for it, but there has been a lot of talk about the need for local agencies to have to modernize.

But the CDC was given $200 million under the CARES Act for data modernization to be awarded to 64 different state, territorial, local jurisdictions. And maybe this is HHS, maybe it is not CDC, but most of it has not yet been spent or allocated.

This is according to the CRS. So it is incredibly frustrating that a deliberate decision was made to not be transparent with the American people as regards the amount of people who actually shown up for work. It takes a FOIA request from a newspaper and now you are asking for billions more, why should we trust?

Dr. WALENSKY. Thank you, Senator, for that comment. I will say that we are an agency of 13,000 people. The people who need to be at CDC are at CDC, of course, our laboratory workers. We have many people in the field. We have people in 60 different countries.

Senator CASSIDY. Yes, but the article points out that there are many—that it is just wide open. That there is nobody showing up. That the offices are empty. So to suggest that all these people are field workers, I think, again, is another example of being opaque.

Dr. WALENSKY. I don't imply that they are all field workers. I am saying that many of them are field workers. Many of them are working at CDC and then deployed in responses, and many of them are on the road. I myself was in Atlanta last week for a day, but I was in New Mexico with tribal visits and doing a Secretaries tribal advisory committee meeting. So many of us are on the road. I am here today, and I am working——

Senator CASSIDY. I am sorry, what percent of CDC employees before the pandemic actually showed up for work every day as opposed to the only 22 percent now?

Dr. WALENSKY. I don't have those numbers for you.

Senator CASSIDY. Yes, that is—I just feel like, how should—and let me go back to, why should we trust CDC with billions when it is very difficult to get, I would say, a straight answer on what is the workforce in-person effort, and particularly when by your own assessment, the agency is working so poorly?

Dr. WALENSKY. The review that we did on August 17th was to demonstrate the lessons learned from the COVID–19 response. That people of the CDC are working well, they are working hard, and they don't necessarily need to be onsite in Atlanta. In fact, oftentimes they are more productive offsite, in the field, doing the work of public health.

Senator CASSIDY. I would just—we are out of time but let me just say that the former Acting Director of CDC from President Obama, when he said in the last paragraph of The New York Times article, he did not see how you were going to be able to, speaking of you in particular, affect change when you only see people every now and then.

He was both suggesting that it was not a work completed, but it was something that had to happen now, and that when people not working together made that more difficult to execute.

I don't think anybody in here or anybody watching really thinks that only 22 percent of the CDC employees showed up for work at the building every day before the pandemic. They think it was probably 78 percent and now the number is reversed.

It is going to be hard for me to support more appropriations until we have a better relationship, a more trusting relationship, a more transparent relationship between the agency and Congress, which you are asking to fund your activities. With that, I yield.

Senator BALDWIN. Next, Senator Hickenlooper.

Senator HICKENLOOPER. Great. Thank you, Madam Chair. And thank all of you for your service through obviously one of the great challenges this country has ever faced in its public health history, the pandemic.

Then coming out of the pandemic, now we see other challenges. Let me talk a little bit about COVID–19 and the lessons learned. And we learned what to do and also what not to do. Again, we are back here with another public health emergency.

I guess I would ask you, Dr. Fauci, and I would want to echo also my gratitude and salutations for—I know that you won't really retire because I don't think you are capable of not contributing to the public good, but I know you will try.

But the pathogen research at NIAID was critical to the development of orthodox vaccines and treatments, obviously a big help with monkeypox. But we may not have stockpiled vaccines for the next pandemic similar to COVID.

I am just asking, in terms of the next public health emergency, how concerned are you that this next one, the next public health emergency will be one that we don't have vaccines or therapeutics for?

Dr. FAUCI. Thank you for that question, Senator. We always are concerned when you get a brand new infection that you have had no experience with, that you are not going to have countermeasures, particularly vaccines, that are ready in a timely fashion. So there are two approaches to that.

We have described in detail in several publications and in some of our white papers what is called the prototype pandemic and prototype pathogen response. In other words, to look at multiple families, and there are about seven or eight high priority families.

By families we mean alphaviruses, arenaviruses, filoviruses, flaviviruses, and to do fundamental core research, for example, to get commonalities among the pathogens within a family, and to start to develop vaccines, put them in phase one, and have them ready to go. With the new mRNA technologies, it is very simple to switch one epitope or one antigen in and out of the vaccine.

That is the core of our approach right now, and I think you will probably be hearing more about it, because that is the thing that we are putting forth as the NIH's contribution to the Government wide pandemic preparedness, is the prototype pathogen approach.

Senator HICKENLOOPER. I support that approach. I think that is the right direction to go and to be make sure that we are as prepared as one can be for what is unknowable and respect the challenges of that preparation but also the urgency.

We can agree and argue about—I think that the Government agencies across the board are going through the issues of how many people are going to work and how many of people are working remotely. Every large corporation is dealing with this right now and we are going to have to process through that.

But in the meantime, we have got to make sure that we have the funding for pandemic preparedness because that is essential to the long term future of this country in almost every way. Let me switch to this outbreak of monkeypox. When it broke out, we had almost 800,000 vials sitting at the manufacturers facility in Denmark. But the shipment of these critically needed vaccines to the U.S. was held up pending.

There was an FDA inspection of the facility even though European regulators had approved it. Dr. Califf, I would ask you, how do—how can we help the FDA better balance safety protocols with the urgency and the need to respond quickly to these emergencies?

Dr. CALIFF. Thanks, Senator. You know, the issue that occurred in this case was there was a new plan that the BN had switched to. It had not been inspected by the FDA. I probably don't need to remind you that we had more than one incidence in COVID times of a manufacturing facility not being up to par, which created a lot of difficulty and trouble. So we felt it was essential to get there.

In fact, we got there very quickly after the application came in from the company to do it and the outbreak occurred. But I think the balance here is the risk of a vaccine which is not up to par with the time it takes to make sure that the vaccine coming out actually will do the job that is intended.

I would also just add, Europe doesn't have a central inspections team for vaccine facilities. Each country does its own, and we have had some discordance historically between findings in some of those facilities and what we found in our inspection. So we really felt we had to get this right, even if it took a bit more time.

Senator HICKENLOOPER. Okay, fair point, great.

I yield back to the Chair.

Senator MURPHY. Senator Marshall.

Senator MARSHALL. Thank you, Mr. Chair.

To my panelists, as I read your testimony, listen to your testimony, what you described to me as an academic response to a problem. As opposed to being proactive, we are being reactive.

I would challenge you all to change your culture so that we are more proactive, a more of a military response to a problem like this. When I look back through the history of this virus, July 2021, there was a case in Texas from Nigeria, November 2021, a case in Maryland from Nigeria.

In May 2022 of those cases in multiple countries, all linked to Nigeria. And there was a moment in time before the horse was out of the barn that we could have stopped this. And now I fear that this virus is being transmitted from human to animal. Once it is in the animal kingdom, we will never be able to get ahead of this.

My question for Secretary O'Connell is, did you ever consider a travel ban or requiring vaccinations from people that have traveled from Africa before they get back in this country?

Then you made a statement on June the 3d of 2022 that you said, I want to say we have enough on hand to manage this current outbreak. Do you still think that was the case then? And if so, why is it still exploding?

Ms. O'CONNELL. Thank you. Senator Marshall, I would like to take the second one first, and then invite Dr. Walensky, who has——

Senator MARSHALL. We don't have much time but go ahead.

Ms. O'CONNELL. Okay. At the time that I made that statement, we were using the ring vaccination strategy, which is a strategy that has been effective in monkeypox outbreaks, including the ones that you just mentioned previously. It requires vaccine being administered to the person that has the virus and their close contacts.

As the spread of the current outbreak began to indicate that anonymized partners would make it difficult for contact tracing to happen, we pivoted to those that were likely to be exposed and we expand——

Senator MARSHALL. There is plenty of vaccines, and the problem was the execution and getting the vaccines to where they were needed?

Ms. O'CONNELL. The strategy that we were using to vaccinate the at risk population changed as we were seeing the transmission change.

Senator MARSHALL. Okay. Dr. Walensky, just briefly, yes or no, did you all consider some type of a travel ban or requiring people to have a vaccine before they came to this country?

Dr. WALENSKY. Maybe if I could just clarify. The two cases in 2021, one in Texas, one in Maryland we were aware of, there were no contacts that ultimately had monkeypox. Those were isolated cases and——

Senator MARSHALL. But they traveled to Nigeria—from Nigeria.

Dr. WALENSKY. Yes. And we have known that monkeypox is endemic in Nigeria as well as DRC. And intermittently over years, including two last year, we have intermittent travel cases that have led to no further cases. That happened in 2021.

This is a different outbreak. This is May 17th was our first case, when we had our first case. I spoke to the clinician who made the diagnosis. We called Public Health Canada as that patient had traveled from Canada and we immediately started outreach with our colleagues in UK as well.

Senator MARSHALL. I think it is a no. But there was multiple cases across Europe already with most of them connected to Nigeria. I want to turn to fentanyl poisoning just a second, Dr. Walensky.

Probably two people, one or two people have died with monkeypox in the United States that I am aware of, but everyday hundreds of Americans die from fentanyl poisoning. Why have you not declared this a public health emergency? Why have you not asked the Administration to shut down the border where 90 percent of this fentanyl comes from?

Dr. WALENSKY. The declaration of a public health emergency is under the Secretary, so I would have to defer that comment. I will say that——

Senator MARSHALL. But you could recommend to him that would be done.

Dr. WALENSKY. We have those conversations. But what I will say is that our ability to shut down the border at the CDC level is related to communicable diseases. And while the fentanyl challenge——

Senator MARSHALL. You are turning your back on the fentanyl——

Dr. WALENSKY. Not at all. I just said I don't have the authority——

Senator MARSHALL. More people have died of the poisoning—more Americans have died from fentanyl poisoning than we lost in Vietnam. This is what is killing Americans every day, is fentanyl. Do you not have a heart for these people, for these moms and dads and these kids?

Dr. WALENSKY. I absolutely do. And in fact, through my career, I have cared for many of them. And it is tragic. And we are doing a lot at CDC——

Senator MARSHALL. What are we doing?

Dr. WALENSKY. But we do not at CDC have the authority to shut down the border on anything except a communicable disease.

Senator MARSHALL. What are we doing?

Dr. WALENSKY. We are doing outreach. We are doing mental health. We are doing community violence. We are doing surveillance. We are doing——

Senator MARSHALL. But tons of fentanyl continue across the border. Really quickly, in 2017, there had been no cases in Nigeria for 40 years. Suddenly there was an outbreak, I guess 218 cases since then.

The CDC, Echo Health, UC Davis, funded by USAID were all doing research in Nigeria at the time. I think it is for Dr. Walensky as well as Dr. Fauci. Were you aware of this research? What was the purpose of the research? Was it just collecting or were we doing more than collecting? Were we concerned about lab outbreaks?

I have got a list of questions related to that research, but Dr. Fauci, were you aware of that research in 2017?

Dr. FAUCI. No, I am not. But I could get that information to you, if—I will have to check with the staff. I was not aware of it myself personally.

Senator MARSHALL. Dr. Walensky were you aware——

Dr. WALENSKY. We have been conducting monkeypox research in Nigeria for years, and I would be happy to get you the details.

Senator MARSHALL. You know what the purpose of that research is?

Dr. WALENSKY. I would be happy to get you the details.

Dr. FAUCI. As I mentioned in my remarks, we are conducting, will be imminently conducting a clinical trial of JYNNEOS—of TPOXX, excuse me, in the Democratic Republic of the Congo. That is not fundamental basic research, that is a clinical trial in the Democratic Republic of the Congo.

Senator MARSHALL. Thank you, and we look forward to your answers. I yield back.

Senator MURPHY. Senator Hassan.

Senator HASSAN. I want to thank the Chair and Ranking Member for this hearing, and all of our witnesses for your work. Ms. O'Connell, I want to start with a question for you to really just give you an opportunity to build on earlier testimony.

The Department of Health and Human Services has been responding to COVID–19 now for over 2 years. You address this to some extent in your testimony, but could you just explain further

how the Department's experience with COVID–19 is informing its monkeypox response?

Ms. O'CONNELL. Thank you so much, Senator, for that opportunity. So we are continuing to actively respond to COVID–19 but are continuing to pick up lessons as we go.

One of the critical lessons is making sure that we have systems, when countermeasures are ordered, where states can order both the therapies and the vaccines on a same interoperable system.

We have done that now as we have digitized the SNS's ordering process. It was also important that the SNS have multiple distribution sites across jurisdictions and states. Jurisdictions and states got used to that in our COVID–19 response.

The SNS up until this point has really only been able to do five distribution points in any state, consistent with the large scale high consequence incidents it has been responding to, like hurricanes, tornadoes. But now that we move to this national vaccine strategy, where we are trying to get vaccine out quickly to the high risk populations, having those additional distribution sites is critical.

We have, the SNS has entered into a contract now with AmerisourceBergen, which will allow it to distribute to multiple places, 500 ambient, 500 frozen distributions a day for 5 days a week. So up to 5,000 distribution points. Another thing that we have done is we have created a framework to ensure that the vaccines aren't going to the wrong place.

One of the things we saw when we seeded the country in COVID and made sure we were giving it out on a prorata basis, that sometimes it would end up in the wrong place and was not being administered.

We have asked states to self-attest to 85 percent usage. Is it going to the right places? That has not been a barrier. We are continuing to work with states to ensure that their second courses don't count against their 85 percent, and that those that are in the field don't count against their 85 percent.

But it has been a good framework for us to make sure shots are getting in arms, most important thing right now, and not sitting on shelves.

Senator HASSAN. Thank you very much. I am going to switch to a different topic with Dr. Califf. I want to build, Dr. Califf, on conversations we have had before to discuss another public health emergency, which is the opioid crisis. During your confirmation hearing, we discussed how the FDA helped fuel this crisis by approving and labeling opioids for long term use, despite a lack of strong evidence supporting those labels.

I was encouraged when you told this Committee that under your leadership, the FDA would aggressively look at relabeling. But in the 6-months into your confirmation, the FDA has yet to change any labels.

The opioid epidemic continues to ravage communities in New Hampshire and all across the country, as we have all acknowledged this morning, and your agency needs to move swiftly to correct its previous mistakes.

You, yourself have repeatedly said that the FDA needs high quality evidence to support the long term use of opioids. The agency has the authority to remove labels from drugs now, given the absence of this evidence. So why is the process taking so long?

Dr. CALIFF. I want to express appreciation for your question. And to mirror what has already been said here today, we are currently losing more people from opioids than we are from COVID. So this is a national issue that we need to all take seriously.

I have taken the first 6 months to get an assay of everything that is going on inside the FDA and all of Government response, and also in the face of the fentanyl mail order issues that are going on with high dose fentanyl.

None of that obviates the need to get back to the basics of the prescription of opioids. We published our framework last week. You will see changes over the next few months within the context of that framework.

Senator HASSAN. Are you telling me that you are considering that the framework calls for relabeling opioids?

Dr. CALIFF. It is under active consideration and discussion within the FDA, yes.

Senator HASSAN. Because look, I just was at a recovery rally in my state with people who have engaged in peer to peer recovery. People who are helping pregnant women with their recovery, people, parents who have lost two children to fentanyl and to opioids.

The FDA first approved and labeled opioids for long term use more than 25 years ago. That means that they have been on the market for more than 25 years without substantial evidence that they are effective for that purpose and with plenty of evidence about the harm that these drugs can cause.

I appreciate that there is a framework out there, but what people are looking for right now is action. I will continue working with my colleagues on both sides of the aisle to ensure that it happens. And again, I thank you for your service and your attention to this.

Dr. CALIFF. I appreciate that.

Senator MURPHY. Senator Rosen.

Senator ROSEN. Thank you, Chair Murphy, and for holding this important hearing. Thank you for everyone being here, doing all that you do in these trying times, that is for sure. I want to talk a little bit, though, however, about clinical guidance for all our practitioners, of course, their support staff, to prevent and treat monkeypox.

Because I would say many clinicians, maybe a majority of clinicians, have not directly treated monkeypox and may have not seen a wide range of cases, so it is critical for clear guidance to be widely available to all medical professionals, and I would also say their support staff who don't—do answer the phones, take the questions in the room when they are doing their own histories and physicals. It is important for treatment and prevention.

Regarding monkeypox prevention, I have concerns about the, not just the slow rollout of vaccines to vulnerable populations—and I

appreciate that you have been doing significant work to make the vaccines more available.

But with all these vaccines rolling out, there is a new COVID vaccine, the flu vaccine, there is a pneumonia, there is a shingles, of course, then there is other things that people might get, tetanus, this or that—for adults. I am talking about adult population. So a lot of confusion about boosters. Can I combine vaccines?

I am really, really concerned that the CDC, Dr. Walensky, what are you doing to mount this public information campaign on the wide variety of vaccines, important ones available—we don't want someone and maybe not get a shingles.

My parents both had it. It is very painful. How are we going to do that at pharmacies and public spaces, even besides our doctors—people may not be going to a doctor or a clinic, but maybe they are going into their local drugstore or grocery store every week, right?

Dr. WALENSKY. Yes. So thank you, Senator, for that important question. I think one of the things you raise is one of the challenges that we have seen first with COVID, now with monkeypox, and one of the places I would really welcome Congress's help. We don't have a mechanism in this country by which we inform our clinicians of a new outbreak or a new disease.

This has been through a lot of public education. We have had a massive amount of outreach. We have health advisory networks that we reach out to. When we put out a health advisory, and we have done four for monkeypox, they reach about a million clinicians.

We have done what we call clinician outreach webinars and calls, COCA calls. They reach about 6,000 clinicians. We put them online, they are reaching about another 10,000 each one that we do. We have done several of those. I personally have sent a letter to all board of clinicians through the AAMC.

I am working with each state to try and send letters out to inform people of a disease that they may have never heard of and may have never seen but tomorrow might walk into their clinic.

What do they need to know, what are the protections that they need to take, and how would they diagnose, treat, and care for a patient with this infection. So that has been a lot of the work that we have had to do during this outbreak. I will say from a health worker safety standpoint, at least as far as monkeypox is concerned, we have seen very little outbreak in health care workers.

We have had one diagnosed health care worker after a needle stick injury, but we have seen very little health care worker outbreak due to our personal protective equipment and the outreach that we have done in telling healthcare workers how to protect themselves.

Senator ROSEN. What about the broader idea of that we have this fall so many vaccines that are available, we will just say to the adult population, preventative vaccines for—that we normally have, flu, shingles, pneumonia for a few of those, now a COVID booster, now potentially a monkeypox shot. How are you going to just get this out to patients and consumers, people in general?

Dr. WALENSKY. We do a lot of provider calls for that as well. Our advisory committee——

Senator ROSEN. What if you are not going to a provider, how are you going to get it to the average person?

Dr. WALENSKY. Well, so we have been doing public—we have been doing press conferences, we have been doing advisories as we have rolled out both the BIVALENT booster. We have a massive flu campaign that we roll out in early October, which we will again do this year.

One important thing I want to just highlight, though, is that we at CDC and we in this country do not have a mechanism like we do with children. You listed adult vaccines. I believe there are 13 of them that are advised. Adult vaccines, we do not have a mechanism in this country to finance adult vaccines the way we do it at Vaccines for Children's Program.

When we look at the equity of getting vaccines to rural populations, to other populations, we do not have a mechanism by which to do that in an equitable fashion the way we do for children, and that is a big constraint that we have right now.

Senator ROSEN. Thank you. I know I only have 20 seconds left, but Dr. Fauci, I just want to ask you quickly, we have monkeypox, so medication to treat the infection, but their symptom management.

We hear a lot of talk about opioids. I know it is very painful, monkeypox. I don't know what the treatment might be, but what kind of guidance are you giving the medical community about effective pain management as it relates to the neuropathy, I would imagine, that monkeypox causes.

Dr. FAUCI. There are medications for the neuropathy, but importantly, particularly when it is on the mucosal surface, be it the anal, rectal, mucosal, or the urethral mucosal, they can be extraordinarily painful. We recommend, and the hospitals do this anyway, I think that is pretty common knowledge—it is an acute not a chronic pain.

It is the kind of thing that you would not hold back on any type of pain medication just because you are concerned about addiction. The discussion that we have been having about fentanyl and the opioids is not using it for chronic pain.

This is not chronic pain. This is very acute pain that usually resolves itself within a period of a couple of weeks, but you certainly don't want your patient to suffer inordinately by holding back pain medications.

Senator ROSEN. Similar to that pain of shingles in that same way. Thank you. My time has expired. Thank you very much.

Senator MURPHY. Thanks, Senator Rosen. I will recognize myself for questions. I have two. One for you, Dr. Walensky, and one for Dr. Fauci. Dr. Walensky, one of the things I panic about is your access to data. And you have talked to this Committee about it. We have talked personally about it.

But outside of emergency authorities, you are stuck in a position today in which you have to negotiate 50 different data sharing agreements with states all over the country. And we expect a lot

of the CDC, but it is hard to expect too much of the CDC when you don't have the authorities, as I understand it, to get the data you need absent an emergency.

When we look at what is happening today with monkeypox, you are getting data, but it is patchy. For instance, you are not getting full demographic data. So there is a lot of states that aren't reporting to you, for instance, breakdowns of cases on race or ethnicity. And that really hurts our ability to target who gets the vaccine, right, who gets resources.

It is certainly in the context of monkeypox, but maybe more broadly, what position does it leave you in when you don't have the authorities to be able to compel states in a uniform way to get you good data?

Dr. WALENSKY. Thank you, Senator, and thank you for the question and for your leadership in working with Senator Kaine and Senator Baldwin in trying to get us the authority so that we can provide these data to you.

We have been working closely, tirelessly with state and local public health staff who have been doing the same to extract data on this outbreak specifically. We have actually negotiated now 61 data use agreements. We have navigated bureaucratic approvals for data to get flowing. We have set up voluntary arrangements directly with large commercial labs to send their data.

But it has been hard, and it should not be this hard. And if we can't make informed decisions based on the best possible data coming into us, we are not making the best decisions for the American people. The existing patchwork of data systems is not working. It is not working to the best ability of the American people.

For monkeypox specifically, I can tell you that I don't know the total number of people hospitalized with monkeypox, the data on laboratory testing in the United states, complete demographic data, as you noted. Which people with monkeypox have been vaccinated? We can't then link the monkeypox vaccine data to the laboratory data.

Demographic data, as you noted, we get 27 percent of our demographic data on testing. We have received 47 percent of our demographic data on cases. 91 percent of our demographic data, because of these data use agreements, on vaccination.

Senator MURPHY. I would just much rather have you be in the business of fighting the public threats presented to the country than in constant negotiation over data sharing agreements. It seems like an essential function of the Federal Government to set up a uniform way in which you get data, rather than putting you in the position of negotiating over and over and over again these data use agreements.

My hope is that soon we will be able to find a consensus on that here. Scary that you don't know how many people are hospitalized with monkeypox today because of your inability to get that data.

Dr. Fauci, in the minute and a half remaining, I just want to talk a little bit about what we learned, what you learned over the course of the information distribution campaign for the COVID vaccine, and how that relates to what we are communicating about

JYNNEOS. Because there has been some amount of information regarding questions about the level of protection, the duration of the immunity when it comes to the monkeypox vaccine.

I don't know that this was necessarily your fault, but in the euphoria of the sort of early news of the COVID vaccine, we probably got out a little bit ahead of ourselves in terms of what level of protection it could provide.

What did we learn about how to talk about a vaccine in its early distributions stages, and how does that inform how we should talk about the monkeypox vaccine?

Dr. FAUCI. Well, first of all, they are two entirely different pathogens. And the response and the durability of response to each is really quite different. It was a rather unique situation with COVID vaccine, where there was no doubt that the initial protection against symptomatic disease as well as severe disease, was well into the 90's.

That was the really good news. The sobering news was the durability of protection, particularly against infection and symptomatic disease. Fortunately, the durability against severe disease lasted.

But if you look at coronaviruses in general, which is usually a good parameter of what the response to a vaccine is, even with a coronavirus infection, the durability of protection against reinfection long before COVID came along, just the typical common coronaviruses, did not last very long.

We see instances of reinfection with the same coronavirus. That poses a very different situation, which leads to the need for and the importance of updating vaccines and giving the boosters that are part of the regimen in addition to the primary regimen. When you are dealing with a pox virus, inherently pox viruses have a much greater durability of protection.

We know that because smallpox itself, once you get infected, you are essentially protected for life, against reinfection. Once you get vaccinated with the standard smallpox vaccination, you can be sure that the durability is measured at least in decades and maybe lifetime.

What we are dealing with now with JYNNEOS is that it likely is going to have a durability of protection if you get the two doses, not just one. We want to make sure people get their two doses. The durability very likely is going to be much greater than that shorten durability of the COVID because they are really fundamentally two different viruses.

Senator MURPHY. Thank you very much, Dr. Fauci.

Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. I have two questions. First for Dr. Walensky and then for Dr. Fauci. Over the last two decades, HHS has issued only four public health emergency declarations, H1N1, Zika, opioid crisis, and COVID–19. On August 2d, declared monkeypox a nationwide public health emergency.

Of the over 20,000 people diagnosed with monkeypox, since May 2022 there has been one fatality. I am concerned that the public health emergency declarations will not be taking seriously if it is

a litany for every new challenge that comes along, the way we are going to get the public to buy into it.

I guess I would like to ask, what are the criteria used for determining whether a disease or a disorder constitutes a public health emergency?

Dr. WALENSKY. Thank you for that question, Senator. What we were seeing in late May, early June, was a doubling time of this, of new cases of about every 8 days. So increased number of new cases.

Among the things that is important, I think, is we understand when a public health emergency—and in fact, I will invite the Secretary, Assistant Secretary O'Connell to maybe chime in here as well, is what are the things that public health emergency unlocks for us to be able to do, whether it be in flexibility of funding in resources, whether it be in emergency use authorizations, whether it be in other flexibilities, so that we have the capacity as an agency to deliver as much health as possible.

I don't know if Dr. Califf or Secretary O'Connell want to chime in there.

Ms. O'CONNELL. Just to concur with what Dr. Walensky said. The public health emergency created an atmosphere in which FDA was willing to use its emergency use authorization authority, on which it was easier for states to give us the data that Senator Murphy and Dr. Walensky just talked about.

It makes it easier for local public health departments to shuffle employees around in order to put them toward the current response. So it created some flexibility. That was also an important signal to the community that we were paying attention, that this is an emergency in our view, and that we want to provide as much countermeasures and response mechanisms as possible.

It also aligned with what WHO did. It declared a public health emergency of international concern. We have the most cases in the world. So it was consistent with what their determination was. Ultimately, it is the Secretary's decision, and he made that decision in August, as you said.

Dr. CALIFF. Senator Braun, I would just chime in quickly. I agree on all the things that were unlocked. And the point is, we need to keep looking at our emergency capacity and our planning for it. I think we all agree we need to keep looking at this as a continuum because with climate change and everything else, there are going to be a lot more of these that come along.

Senator BRAUN. I basically agree with that conscientiousness, that kind of a being ready for it. But you do have to keep in mind that if it does enter some kind of a sequence where it gets dismissed because it is being declared too often, to me it looks like you would want to develop some criteria that I know it is difficult to get everything into a subset, but I worry about how people will view it if it is a litany of public health crises.

When we went through the COVID–19 journey, I learned so much about it along the way. And of course, it was the last time, I think, Dr. Fauci, you and I spoke. We were talking about shutting

down the economy. And you said that we did that out of uncertainty.

We probably never would want to do that again. And that cost trillions and trillions of dollars along the way. So we surely have learned a lot with that experience that we might use on others. Dr. Fauci, a lot of Americans are worried about the power of social media. And it was back over a year ago or—yes, in July that we talked about, had there been any contact with your office?

I know that here recently a Federal judge in Louisiana ruled that the Biden administration, including yourself, must turn over external communications with social media companies. So we will see what happens there.

You said there had not been a contact up to that point. Had any social media company contacted you since July when we spoke last? I know it has been a decent amount of time, so I was just curious.

Dr. FAUCI. I don't believe that I said there was no contact. I have had over a period of time, and I would have to check the date, Senator—honestly, I would have to get the correct dates. That Mark Zuckerberg of Facebook had contacted me to make some Facebook live discussions about encouraging people to get vaccinated and how we can make sure that people understand the importance of vaccination.

There has been, and that is public record. I think anybody who has access to the public face of that Facebook would see, I think there were three conversations that I had back and forth with him about promoting the use of vaccinations as a public health intervention.

Senator BRAUN. I think on that particular public health advice about the benefits of a vaccine, it is probably not where that contention arises. I want to narrow in on this, and it would be the original discussion of where it came from, the leak. And then they used from a lab or from a wet market. And was there ever discussion on that? And to me, that is a different kind of issue to——

Dr. FAUCI. To my knowledge, there was not. I mean, I would want to make sure I get correct your question. If the question is, do we influencing social media in any way, the answer is a categorically no at that. And any communications that are made in that regard, as far as I am concerned, are an open book and available.

The lawsuit that you mentioned, I think it is Missouri and Louisiana versus Biden and HHS and CDC and FDA and the entire Government, because it involves the President is under the Department of Justice right now.

I have handed, and my staff have handed over every document that the Department of Justice has asked for, and it is up to them to make it available. But I have held nothing back from anything that I was asked to provide.

Senator BRAUN. Thank you——

Senator MURPHY. Senator Braun, we have got a vote pending, so I want to turn it over to Senator Burr.

Senator BRAUN. Thank you.

Senator MURPHY. Thank you.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman. Let me conclude, if I can. I want to thank all of you and more importantly, thank your workforces for the work they have done over the last 3 years. Tony. I wish you well in the transition. I want to state this, and I want to be perfectly clear, we don't act or react fast enough. I will say it again. We don't act or react fast enough.

We have been focused on monkeypox. Let me do a recap real quick. May 17th, infection in the United States. 2 weeks prior, 10 days prior, or 11 days prior we see this in the UK. We already owned a big bulk storage of vaccines sitting at BN in Denmark.

BN apparently speeds up their fill finish line that wasn't supposed to go online until sometime in the fall. They apply. FDA on June 30 inspects. It is July 27th before the approval is made. Here is the concerning part. It is April 18th when we signed a deal for domestic fill finish somewhere else.

Let me say that again. We start with May. We know we have got domestic infection. We are concerned with our ability to deal with this. And there is a big period that we don't look for domestic fill finish. I am not asking for a response, I am just making a point. That if we have a pandemic response plan, things like this get resolved.

I don't know what the limitations that have been placed on any of you about sharing the specific plan, whether it was on COVID or whether it was on monkeypox. I don't really care today.

What I do care about is that if you are in the role of leadership in your agency, or if somebody else is in the role of leadership in the future, the first thing they ought to be saying is, let's sit down as a group and let's put together a plan. Let's know what everybody is going to do. This BS of working independently, the turf wars that exist, we own testing, we own this, we own that, to hell with it.

These are—when you declare a national emergency, this is no time to protect territorial turf. And every response to us is about money. Dawn, if you need something changed to reprogram, for God's sakes, ask us. Don't use it as an excuse as to why you couldn't do something. Rochelle, we have reached out many times, and the only thing I hear, data, data, data, money, money, money.

Listen, take it to heart what the doctor said to you, when 78 percent of the employees aren't coming in the office, you don't get much sympathy from us. Rob, it may be the wrong time to do a demonstration project about working remotely. You know, the biggest trouble we have got is putting people back in the office.

Congress did it. The Government is not capable of doing it. Private sector is struggling with it. Post-COVID is very different, but the responsibilities that you have as the emergency response components haven't changed. You have got to look at your workforce. You have got to look at the challenges.

You have got to look at the procedures that you have got in place and say, have we really learned from the last one? Now, I am not

going to be here to see you probably again. I am not sure Patty will hold another hearing before now and the end of the year.

But I want you to know, I look forward to working with you and I will continue to be a resource to any of you because I only have one goal, and that is that I know for the next one, we have got to respond a hell of a lot faster than we did for COVID, and we have got to do much better than we did on monkeypox.

Because on the other side of this potentially is one that gets out of control with massive amounts of loss of life. Mr. Chairman, I thank you for your indulgence. I probably missed the vote, but that is okay, because I think this is more important. I yield back.

Senator MURPHY. Thank you very much, Senator Burr. Thanks all the Members of the Committee for participating. To all of our witnesses, Dr. Walensky, Dr. Fauci, Dr. Califf, Ms. O'Connell, thanks for this really important and thoughtful discussion about the response to the monkeypox outbreak.

For any Senators who wish to submit additional questions, the record will be open for 10 business days. The HELP Committee is pretty generous. 10 business days. So you got until September 28 at 5.00 p.m. for additional questions for the record.

With that, this Committee stands adjourned.

ADDITIONAL MATERIAL

AIDS UNITED
September 13, 2022

Senator PATTY MURRAY, Chair
Senator RICHARD BURR, Ranking Member
U.S. Senate Committee on Health, Education, Labor, and Pensions,
217 Russell Senate Office Building,
Washington, DC 20510.

DEAR CHAIR MURRAY AND RANKING MEMBER BURR:

As the Administration and Congress respond to the ongoing monkeypox (MPV) outbreak in the United States, the Partnership to End HIV, STDs, and Hepatitis is concerned that opportunities to take a syndemic and comprehensive approach are not being utilized due to the urgency of the situation. Since the first days of the outbreak, we have heard of "lessons learned from HIV and COVID–19"; yet many of those lessons remain unimplemented—to the detriment of public health in the United States.

Some of the lessons from the COVID–19 pandemic are positive ones. The creation and mass-distribution of easy-to-use diagnostics and vaccinations via partnerships with local trusted leaders and community providers proved very effective in ensuring testing and vaccinations were widely available. We hope the Department of Health and Human Services (HHS) will move quickly to replicate that approach as much as possible, and we applaud Secretary Becerra's decision to declare MPV a public health emergency. Yet, the early days of the pandemic also laid bare our Country's continued struggle with health inequities, ill-equipped health care infrastructure, and conflicting and poorly disseminated communications. We must learn from these mistakes, lest we repeat them.

Based on its current presentation, MPV is most similar to the HIV and STD epidemics in this country. Our collective experience with these epidemics gives our organizations a unique perspective and expertise, and we would like to take this opportunity to offer these recommendations for creating a more thoughtful and comprehensive response to MPV.

Resources should follow the disease.

Right now, the vast majority of MPV cases is within the gay, bisexual, and other men-who-have-sex-with-men (GBM) community, with Black and Latino men experi-

encing the brunt of the outbreak. We ask that you continue to dedicate resources, education, vaccines, treatment, etc. within the GBM community, with specific attention to mitigating racial inequities.

However, limited data collection on testing and treatment inhibits the government's ability to know where resources are most needed. Therefore, we also ask that you take swift and necessary action to use the recent declaration of a public health emergency to instruct the Centers for Disease Control and Prevention (CDC) to expand the collection of national demographic and geographic information beyond case counts, and vaccinations, to include testing and treatment information. We are specifically concerned, as evidenced in CDC data, that Black, Brown, and younger GBM are being disproportionately impacted. Whereas only 21 percent of first doses of the vaccine have at this point been administered to Black individuals, the same population makes up nearly 40 percent of cases.[1] We ask that the Administration operate based on existing data showing that racial health inequities are present and work diligently to counter them. As with COVID–19, communities of color are going to be hardest hit, and the Administration must correct for that in the response.

Take a syndemic approach.

The National Coalition of STD Directors (NCSD) conducted a survey of sexual health clinics early in the outbreak and found that 60 percent of people presenting for monkeypox testing had an STD that was not MPV.[2] This number has more recently been confirmed by the CDC, which found that 61 percent of MPV patients had either HIV or an STI. This is unfortunately not surprising. HIV and STD testing dropped dramatically during COVID–19, with testing for HIV dropping by nearly 50 percent in 2020,[3] which allows infections to move through the American population undetected and leads to rising rates. STD rates, for example, are at an all-time high for the sixth year in a row.

There is an opportunity, as individuals seek out testing and vaccination for MPV, to also educate on HAV, HBV, and meningitis vaccinations and conduct testing and treatment for HIV, hepatitis, and STDs, especially since—at this time—the communities being targeted for testing and treatment also ought to be offered HIV and STD testing. We ask HHS to create protocols and dedicate resources to incentivize providers to offer HIV, hepatitis, and STD testing alongside MPV testing and vaccination.

Additionally, the very population currently being targeted for vaccination and education on MPV is the same population targeted for pre-exposure prophylaxis (PrEP). Right now, GBM across the country are seeking out care providers for vaccinations, testing, and information about the disease. This is a significant opportunity to simultaneously screen and educate for PrEP and increase uptake. And we ask that HHS create protocols and dedicate resources to incentivize providers to offer PrEP counseling and linkage to PrEP services at vaccination and testing appointments whenever feasible.

Engage in accurate, honest, and culturally competent communication.

Since the first days of the MPV outbreak, the public health field has worked scrupulously to mitigate stigma against GBM and monkeypox. However, in service of this work, national communications efforts to the GBM population have been muddled, leaving the most affected population without the information they need to make informed choices about their health. We ask the Administration to prioritize streamlining and improving culturally competent communication—in multiple languages—related to MPV for those most at risk.

Properly equip the people doing the work.

As you know, for decades, the United States has asked our public health infrastructure to do more with less. Currently, we are hearing from sexual health clinics around the country that they have essentially become MPV clinics. One provider shared that they spent an entire 10-hour shift enrolling four patients in TPOXX due to the still time-intensive administrative requirements. This is unacceptable.

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[1] *https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html* accessed September 12, 2022

[2] *https://www.ncsddc.org/wp-content/uploads/2022/06/Clinic-Monkeypox-Capacity-Survey-Handout.pdf*

[3] *https://www.cdc.gov/mmwr/volumes/71/wr/mm7125a2.htm's—cid—mm7125a2—w*

We ask that you immediately support the frontline public health employees and health care providers by expediting the creation and dissemination of provider trainings and education; funding public health departments and clinics' increased staffing and supplies needs; protecting health care providers with sufficient PPE and prioritizing those that work with MPV patients for vaccination; and lifting administrative burdens, such as the time-intensive protocols for TPOXX.

These recommendations are intended to build upon other recommendations that have been made in response to the MPV outbreak, including greater access to vaccinations and testing, reduced administrative burdens, and increased funding.

We are in an emergency situation, but it is also an opportunity to demonstrate the Administration's ability to respond agilely—and ultimately build on the lessons learned from HIV, STDs, and COVID–19 to create a stronger public health system. The partnership stands ready to help the Administration do so. If you have any questions or would like to discuss our recommendations, please reach out to the National Coalition of STD Directors' director of Federal policy, Rachel Deitch, via email at *rdeitch@ncsddc.org* or by phone at 847–804–6672, or Rachel Klein, Deputy Executive Director of The AIDS Institute by email at *rklein@taimail.org* or by phone at 202–815–2973.

Sincerely,

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REUTERS FACT CHECK

APRIL 11, 2022 / 7:27 AM / UPDATED 5 MONTHS AGO

Fact Check- Fauci's 2004 comments do not contradict his pandemic stance

By Reuters Fact Check

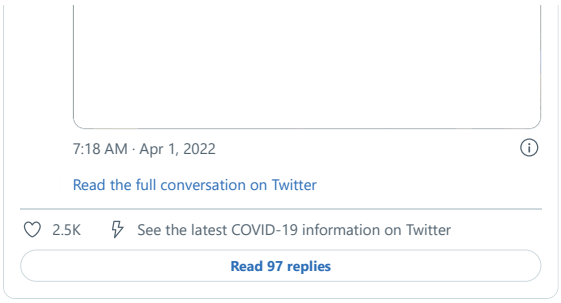
Social media users are sharing a comment top U.S. infectious disease expert Dr. Anthony Fauci made in 2004 about influenza and using it to discredit his response to the COVID-19 pandemic.

Examples can be seen (here) and (here).

Tom Elliott
@tomselliott · **Follow**

Fauci, in 2004: "If she got the flu for 14 days, she's as protected as anybody can be, because the best vaccination is getting infected yourself. If she really has the flu, she definitely doesn't need a flu vaccine ... the most potent vaccination is getting infected yourself"

Watch on Twitter



The text in one post reads: "Fauci, in 2004: 'If she got the flu for 14 days, she's as protected as anybody can be, because the best vaccination is getting infected yourself. If she really has the flu, she definitely doesn't need a flu vaccine ... the most potent vaccination is getting infected yourself.'" The video shows Fauci saying this during an interview.

The posts show a short clip of Fauci from an Oct. 11, 2004, interview with the Washington Journal, visible on C-SPAN (here). The exchange begins at around the 30-minute mark when Fauci speaks to a caller who describes having a reaction to an influenza vaccine.

When asked if the caller should receive a flu shot if she's had the flu for 14 days, Fauci responds with the quote seen in the clip.

Fauci is giving advice for a specific situation pertaining to this caller. Natural immunity from infection does not mean flu vaccinations do not help curb community spread and protect vulnerable people.

The Centers for Disease Control and Prevention (CDC) recommends receiving the influenza vaccine (here) and says getting vaccinated is a safer choice than risking illness to get immune protection (here).

A flu vaccine is recommended each year as the influenza virus changes and the vaccine is adjusted accordingly, according to the CDC (here).

The Food and Drug Administration (FDA) advises on its website (bit.ly/3Js43yP) that receiving a flu vaccine after recovering from flu is important as it helps prevent illness from different strains of influenza.

Furthermore, COVID-19 is a different virus from influenza and receiving a vaccine is safer than risking severe illness with the virus, according to the CDC.(bit.ly/3vc95u8).

Although people who recover from COVID-19 usually gain some immune defenses against reinfection, they get additional protection from vaccines, especially against severe disease, according to two studies published on March 31 in The Lancet Infectious Diseases journal (see here).

Reuters has previously debunked claims comparing the influenza virus and the COVID-19 virus (here , here , here and here).

VERDICT

Missing context. Top infectious disease Dr. Anthony Fauci's comments made in 2004 were regarding a specific case of influenza.

This article was produced by the Reuters Fact Check team. Read more about our fact-checking work here .

Our Standards: The Thomson Reuters Trust Principles.

[Whereupon, at 12:21 p.m., the hearing was adjourned.]

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