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Statement for the Record

Submitted by

Premier Inc.

"Stopping the Spread of Monkeypox: Examining the Federal Response"

Senate Health, Education, Labor and Pensions Committee

September 14, 2022

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Health, Education, Labor and Pensions Committee hearing titled "Stopping the Spread of Monkeypox: Examining the Federal Response" on September 14, 2022. We applaud Chair Murray, Ranking Member Burr and members of the Committee for holding this hearing to evaluate the federal government's response to the Monkeypox outbreak.

At its onset, COVID-19 was novel, with no known treatments, vaccines or prevention protocols in place, enabling a rapid spread that quickly overran the U.S. population and exposed many weaknesses inherent in our public health system. By contrast, today, the nation's latest public health emergency (PHE) concerns Monkeypox, a virus that is well known, with existing treatments and vaccines.

Premier has spent significant time reflecting on the experience of the healthcare industry during COVID-19 response efforts to determine elements that worked well as well as areas for improvement for the future. By examining the weaknesses exposed by COVID-19 and whether we are better prepared to manage these realities for Monkeypox, we have insight into what steps Congress, the Administration and stakeholders need to take now to ensure the nation can respond agilely to Monkeypox and other future emergencies.

Syndromic Surveillance to Predict Community Outbreaks

In the early days of the pandemic, Premier leveraged clinical decision support, powered by machine-learning, artificial intelligence and natural language processing, to effectively predict surges and regional flare ups well before patients started showing up at the hospital for treatment. Armed with positive results, Premier advocated for federal agencies to adopt a national system for syndromic surveillance to better track and predict outbreaks – and quicken response times.

Like for COVID-19, symptoms are the earliest and most reliable indicator of the emergence of Monkeypox. Identifying suspected cases early is the best signal of the need to take action. However, a recent Government Accountability Office (GAO) report notes how a lack of federal action to modernize the public health data infrastructure seriously undercut efforts to combat the COVID-19 virus. This is a situation that is unfortunately being replayed with the Monkeypox PHE. The Centers for Disease Control and Prevention (CDC) reported that in late July it only had current data on half of the nation's reported Monkeypox cases. Even today, the CDC only has data on those with a Monkeypox diagnosis, and no data on early warning symptoms.

America needs an automated, near real-time means to collect symptoms and confirmed case information consistently and comprehensively so that it can be shared between and among multiple public and private stakeholders, including federal, state, local, Territorial and tribal public health authorities as well as on-the-ground providers. Such a system can pull in information on symptoms, comorbidities and other

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vital information, allowing for targeted tracing and interventions to proactively prevent outbreaks. Earlier recognition of new hot spots speeds quarantining of potentially infected persons, reduces the spread of the virus and saves the nation money on contact tracing and testing. This reality is possible today.

Transparency Around Supply Availability and Allocation Methods

A major barrier to the COVID-19 response was the lack of information on the exact quantities and locations of medical supplies and drugs on U.S. soil at any given time. Our nation's limited information on the supply chain led to excessive purchasing of products, the emergence of unscrupulous and fraudulent vendors, shortages and an escalation of supply costs, which we are still seeing today.

We continue to lack information on supplies needed to provide COVID-19 and Monkeypox treatment, all with the 2022 flu season on the horizon and persistent supply chain bottlenecks. Congress should pass the bipartisan Medical and Health Stockpile Accountability Act (H.R. 6520) to enable – for the first time – real-time data on the entire supply chain for critical medical supplies needed to treat patients during emergencies. This legislation will stand up a national automated data collection infrastructure that can track critical product availability across the entire supply chain in near real-time during emergencies. The system would be automated and behind the scenes, ready to be activated during emergencies. It would provide visibility of supplies in hospital inventories with detailed information that would enable accurate and intelligent decisions about supply allocation and needs at the local, state, regional and national levels.

This information will allow healthcare providers, manufacturers, distributors and the government to pinpoint the intersection of supply and demand, more effectively secure needed products, and better identify areas of vulnerability to prevent supply shortfalls.

Automated Tracking and Reporting the Spread of Disease

During COVID-19, virtually all reporting was done using paper-based forms that were then faxed back to the state and local public health departments for recording and follow up. Reporting was limited to hospitals providing treatment for the most severe cases and labs that encountered a positive COVID-19 test. This meant public health agencies received no information from milder cases diagnosed in a physician office, or from patients self-diagnosed via at-home tests.

Fast forward to Monkeypox and some improvements in reporting can be found. Any labs performing a Monkeypox test are now required to report all results directly to public health departments and are strongly encouraged to submit this data electronically, as opposed to via paper forms.

However, electronic reporting is still not a requirement and public health case investigation forms used to track the source of transmission are still paper based – and more than six pages long. The federal government should require and prioritize efforts for automated, streamlined nationwide public health data collection, exchange and sharing using data and interoperability standards.

A Robust Testing Strategy

Early COVID-19 testing was plagued by a lack of testing locations, a shortage of specimen collection swabs, inadequate lab capacity to process tests and sporadic genomic sequencing to monitor for variants. With Monkeypox, efforts to speed access to testing have been far swifter, with the CDC effectively onboarding commercial labs to expand testing for Monkeypox within one month.

While an improvement, that one month delay has had consequences. With only about 70 labs authorized to conduct testing in the spring, bottlenecks were widespread. This is why from mid-May to the end of June, the U.S. had run tests on just 2,500 samples, despite evidence suggesting a large-scale outbreak. Limited capacity has also meant that screening for potential variants has also been lacking, which could open the door to future, more severe threats.

Moreover, the only test the Food and Drug Administration (FDA) has approved requires swabbing the lesions associated with Monkeypox – a later-stage symptom. The declaration of the PHE has helped, as it enabled the FDA to leverage emergency use authorizations to approve other tests that may help with earlier diagnosis, but it did take several months for that authority to be invoked.

In addition, testing takes entirely too long. Currently, labs can only test for orthopoxvirus, the family of viruses that include Monkeypox. Any positive samples are then sent to the CDC for more refined testing. This two-step process means that many are waiting up to four days for results, time when infected individuals can continue to get sicker and spread the virus to more individuals. As we learned during COVID-19, delays of even a day can have dire effects on limiting transmission.

Instead, the government should broaden and better organize the lab network to include hospitals, academic medical centers, and regional testing laboratories that have the ability and capacity to perform these tests in their communities. Broadening the lab network will help ensure that regionally based testing can produce more timely results, empowering immediate and effective public health action. It is also critical for the nation to develop a genomic sequencing strategy for Monkeypox to stay ahead of potential variants.

An Effective Mass Vaccination Strategy

Controlling the growing Monkeypox outbreak not only relies on an effective testing approach, but also the availability of millions of vaccine doses. The U.S. Monkeypox vaccination campaign has faced major hurdles as demand for shots exceeded supply – leading to long lines at clinics and even protests in some cities. The problem rests with the fact that many of the doses in the Strategic National Stockpile (SNS) consisted of the older ACAM2000® vaccine, which can carry significant risk, especially for those with compromised immune systems. The alternative vaccine – Jynneos™ – carries fewer risks, but the SNS only held 2,400 doses at the outbreak's onset.

Since then, officials have been scrambling to secure doses and prioritize Monkeypox vaccination. With lower stock and limited capacity to quickly produce more products, public health officials have now introduced a dose-sparing strategy to stretch limited supply, which some infectious disease experts are calling into question given unknowns around risk to vaccine effectiveness. Preliminary data on Monkeypox vaccination will be forthcoming, and it is vital that our public health vaccination approach is grounded in science – not based on a lack of planning or preparedness.

Limited supplies also restrict access, with vaccines only being distributed to designated health centers and clinics – not to primary care providers or local pharmacies that have the broadest reach into the community.

The good news is Monkeypox vaccine availability will increase in the months ahead. Given concerns around transmissibility, disease spread and the potential for new variants, the Administration should consider invoking the Defense Production Act to help increase supply and enable quicker access to Monkeypox vaccines. As supply improves, equally important is vaccine education to help overcome hesitancy and improve Monkeypox vaccination rates.

Infrastructure Surrounding the Strategic National Stockpile (SNS)

A Premier member survey from October 2020 found that many health systems considered stockpiles to be an important preparation strategy. As demonstrated by COVID-19 and now Monkeypox, a fragmented approach to securing supplies creates confusion and competition that can contribute to shortages**.**

Today, there is greater transparency into the quantities of products and supplies available through the SNS, including available doses of the Monkeypox vaccine. However, the U.S. still lacks a cohesive national stockpiling strategy, and providers remain bogged down with a cumbersome, paper-based process to request SNS supplies.

The Administration and Congress can strengthen the SNS by:

Establishing a Public-Private Advisory Council. This should include a broad range of representatives from the private and public sector to ensure the appropriate expertise is represented for specific SNS product categories. This data-driven approach will remain unbiased and vendor agnostic, support a collaborative decision-making process, identify innovative products, and continuously refine the vision of the SNS. "A SNS built by providers for providers."

Identifying A List of Critical Supplies Necessary to Manage a Surge. The Public-Private Advisory Council should be tasked with: 1) Identifying the list of critical medical supplies, drugs, foods, and other supplies needed to treat a public health threat, including determining the most cost-effective product; 2) Annually, at minimum, refining the list to account for product discontinuations, emerging technologies, changes in clinical guidelines, and identification of best practices.

Creating Transparent & Diverse Sourcing for Critical Medical Supplies & Drugs. A diverse, and reliable supply chain with upstream and downstream visibility into the source of raw materials is essential for ensuring the U.S. is prepared to respond to future public health threats. This is critical information to understand vulnerabilities, foreign reliance on manufacturing, and impact of geopolitical issues such as export bans and manufacturing shutdowns.

Developing a Network of Stockpiles Throughout the Country. Stockpiles should be designed to create coordination, rather than competition, and meet specific needs. A hub-and-spoke model with the SNS acting as an anchor would offer a full array of services that is complemented by state and local stockpiles. Leveraging health system and alternate site provider warehouses in major metropolitan or rural areas would further optimize supply. All stockpiles should meet national standards.

Rotating Inventory. The SNS should rotate out soon-to-expire product. This can be accomplished by 1) contracting with manufacturers to rotate inventory; or 2) selling short-dated products to health systems and alternate site providers at a discounted rate. The SNS could also recoup some expenses associated with managing the SNS and reinvest those dollars while also assisting healthcare providers with decreasing their acquisition costs. Rotation of inventory should also occur as products are discontinued or removed.

Creating an Efficient & Dynamic Fulfillment Process. The current process for accessing the SNS is cumbersome and state specific. The SNS should: 1) Create a single, streamlined electronic process for making requests of the SNS and a standardized process for responding to requests; 2) Develop a dynamic distribution methodology that leverages a data-driven approach; 3) Institute a nimble and flexible distribution method to move supplies among health systems from areas with excess product/declining need to hot spots.

Testing the Functionality, Readiness & Reliability of the SNS. To ensure the next generation SNS can deliver during future public health threats, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide a specified quantity of product. An annual test ensures all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.

Analyzing & Reporting. Transparency regarding the efficiency and utilization of the SNS is critical to understanding its purpose and continued need. The SNS should be transparent regarding distribution of supplies and drugs from the SNS and therefore should provide, at minimum, a detailed monthly report of what supplies were requested versus distributed to where and in what quantities.

Bolstering Domestic Manufacturing for Critical Medical Supplies

COVID-19 was the wakeup call that rang the alarm bell on issues with the globalization, overseas overreliance and fragility of our supply chains. Fortunately, many U.S. lawmakers and private sector actors did hear the alarm, taking steps to bring greater diversity to the market. This includes hundreds of Premier member health systems that have stepped up to incent U.S. manufacturers to domestically produce PPE and critical pharmaceuticals.

While these actions represent meaningful progress, scaling domestic and diverse manufacturing will require a continued and massive effort on behalf of the U.S. manufacturing industry and the federal government to truly compete in the cost-competitive global marketplace.

Premier recommends a two-part approach that leverages tax credits as a mechanism for achieving these goals:

Part I:

- A 30 percent tax incentive for investments to support the domestic manufacturing of critical medical supplies and drugs, including their raw materials. Examples of how the tax incentive could be applied (not intended to be all inclusive – examples only):
    - Investments in advanced manufacturing equipment or machinery
    - Investments to repurpose existing abandoned facilities
    - Investments to build new facilities
    - Investments to expand existing facilities
    - Investments to relocate foreign facilities back to the U.S.
    - Investments to upgrade facilities to meet EPA requirements
    - Regulatory filing fees for new domestic entrants to the market (e.g. FDA, NIOSH, etc.)
- The tax incentive should be reevaluated in five years to determine its ongoing necessity and whether the incentive level can be lowered or eliminated.

Part II:

- A 10 percent tax credit on the income generated from the sale of domestically manufactured goods. This would also help lower the cost of goods manufactured domestically and make them price competitive with globally sourced products.
- To be prudent, companies found to be price gouging or selling counterfeit products by the Department of Justice, Federal Trade Commission, or other agency should not be eligible for the tax credit. Guardrails would help ensure companies aren't artificially increasing their prices to take advantage of the tax credit from higher sales prices and support the integrity of the supply chain.

To truly create a long-term domestic manufacturing infrastructure that is sustainable, incentives for onshoring manufacturing must be coupled to committed purchasing volumes so new entrants to the market have a guaranteed sales channel. To accomplish this goal while cultivating global diversity, Premier recommends that government purchasers be required to contract for critical medical supplies and pharmaceuticals from a mixture of onshore, near-shore (such as Central and South American countries) and off-shore countries. Purchase thresholds based upon a geographical region can help prioritize domestic manufacturers while ensuring global diversity and sustainability of the supply chain.

Finally, Premier supports the Centers for Medicare & Medicaid Services' proposal to adopt a payment adjustment to inpatient and outpatient Medicare payments for domestically produced N95s. This will help to create committed purchasing volume for domestic suppliers and offset higher acquisition costs. We continue to urge CMS to expand this adjustment to other critical medical supplies and pharmaceuticals. Premier also calls on Congress to revise statute to allow for this policy to be implemented in a non-budget neutral manner under the Medicare Outpatient Prospective Payment System (OPPS).

Coordination Among the Various Government Agencies Leading the Response Efforts

With the national response to COVID-19, the array of responding federal and state agencies had little insight into what their counterparts were doing, leading to overlaps, conflicts and duplication. With Monkeypox, the Administration for Strategic Preparedness and Response (ASPR) has been named as national coordinator of the response effort, and the Administration moved swiftly to declare a PHE needed for regulatory flexibility. Premier urges these and other agencies to closely coordinate and quickly solidify oversight and management structures to ensure a cohesive federal response.

Meanwhile, state public health agencies on the frontlines continue to struggle with access to tests, treatments, vaccines and – most important – funding. Congress and the Administration should consider bolstering funding for the Monkeypox response.

Collaboration Between the Public and Private Sectors

From the early days of COVID-19 and through today, the public and private sectors have come together in unprecedented ways to tackle these "once in a century," pandemic-driven challenges, which has entailed:

- Developing and distributing life-saving vaccines and treatments in record time;
- Driving research and the practice of medicine forward; and
- Creating the Private Sector Supply Chain Coalition and the Administration's Healthcare and Public Health (HPH) Sector Joint Supply Chain Resilience Working Group comprised of group purchasing organizations, distributors, manufacturers and others that share invaluable information on the current state of the supply chain and strategies to increase available supplies.

Continued information-sharing and collaboration will help ensure a path to a more agile and robust response to PHEs jointly established by the federal government and industry partners – for Monkeypox and beyond.

Conclusion

In closing, Premier looks forward to continuing to work with Congress and other stakeholders to develop a cohesive and holistic national strategy for addressing public health emergencies.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, PharmD, JD, Senior Vice President of Government Affairs, at soumi_saha@premierinc.com.