

COMMONWEALTH OF PENNSYLVANIA OFFICE OF THE SECRETARY OF HEALTH

## Senate Health & Human Services Committee and the Senate Aging & Youth Committee Hearing on COVID-19 Vaccine Rollout in Pennsylvania

Testimony of

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Good morning Chairwoman Brooks, Chairwoman Ward, Chairman Haywood, Chairwoman Collett and members of both the Health and Human Services and Aging & Youth Committees. Thank you for the opportunity to appear before the committee today to discuss the challenges presented by one of the biggest public health crises facing this country in the last century, the COVID-19 pandemic. With me today is Interim Acting Physician General Dr. Wendy Braund and Deputy Secretary Cindy Findley. We are happy to join you today to discuss COVID-19 vaccine distribution efforts in Pennsylvania.

The introduction of safe and effective COVID-19 vaccines adds a critical tool, partnered with containment and mitigation strategies, to combat the rampant viral spread in the United States. However, the distribution of the COVID-19 vaccine along with its administration is a herculean effort, one that our nation has never experienced. Currently, there are two vaccines that received an Emergency Use Authorization (EUA) from the US Food and Drug Administration (FDA); and one of which, the Pfizer BioNTech vaccine, requires ultra-cold storage capacity and ships in quantities of 975 doses that cannot be broken down into smaller allotments. The second product is from Moderna. The Moderna COVID-19 vaccine does not have the same logistical constraints as the Pfizer BioNTech vaccine. The Moderna COVID-19 comes in quantities of 100 doses and can be stored and handled much like other vaccines that providers use daily. In addition to the complexities around transportation and storage of both vaccines, each vaccine requires a second dose in a specified timeframe.

It is important to note that there are two immunization programs in Pennsylvania. One is administered by the Department which covers 66 of our 67 counties. The other is administered by the Philadelphia Department of Public Health (PDPH). Philadelphia is one of only a handful of large cities that administer their own immunization program. Functionally, both the Department and PDPH receive separate allocations of vaccine from the federal government, have separate plans for prioritization of the COVID-19 vaccine, have separate enrolled providers, and separate reporting structures for counting doses administered to residents.

Like other states and jurisdictions receiving vaccine, Pennsylvania developed a COVID-19 Interim Vaccine Plan to offer a roadmap for vaccine distribution to protect persons at the highest risk along with those making up the most critical workforce through to the general public. The Department continues to update the plan as the federal government issues new guidance and recommendations. The plan prioritizes Phase 1, with sub-prioritizations of 1A, 1B, and 1C, and Phase 2 populations in efforts to best align with federal recommendations offered by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP). All of the specific information on these Phases can be found on our website.

The process of vaccine transportation, from its arrival in Pennsylvania until it is administered is a complex process. First, Pennsylvania receives notice of an amount of vaccine to be allocated to the Commonwealth from the federal government each week. Our current allocation this week was set at 166,375 first doses. Next week, we anticipate our allocation to be 175,175 first doses. Once we receive the allocation information, the Department allocates vaccine to our two current missions, our long-term care mission carried out by the Federal Pharmacy Partnership, and our community mission, through the Retail Pharmacy Partnership and our hospital, pharmacy, and Federally-Qualified Health Center and County/Municipal Health Department partners. Department staff work to allocate doses to our many providers across the commonwealth. To assist with this allocation, Department sends out a survey to enrolled providers asking how much vaccine product they can handle from both a storage and administration capacity. Because we are in a position where we have more requests for doses than we have available doses, our allocations to providers are not always able to be filled fully. To ensure an equitable distribution statewide, we apply a formula to allocations to providers based on the following four factors: 1.) County Population; 2.) County Population over age 65; 3.) Total COVID-19 cases to date; and 4.) COVID-19 deaths to date. We also review a provider's vaccine stock and throughput to ensure we are incentivizing providers who are pushing vaccine out quickly and efficiently.

Following the application of the formula, the department sends finalized orders of vaccine on behalf of enrolled providers to the federal government. From there, the federal government handles all of the specific scheduling, shipping, and delivery of the vaccine product itself directly to providers. The Department of Health does not physically warehouse vaccine doses under this process. Vaccine is shipped from Monday through Friday, excepting holidays, to vaccine providers. As a commonwealth, we recognize that our local providers know their communities best and are well positioned as trusted partners in the community. We entrust vaccine providers with vaccine product and, once in their hands, providers are responsible to administer the vaccine according to the phased distribution described in the Department's Interim Vaccine Plan. Rounding out the community strategy through an effort to reach a wider range of targeted populations for vaccine administration across the state, the Department has partnered with two retail pharmacy chains, Rite-Aid and TopCo, through the Retail Pharmacy Partnership. Initially there may not be enough vaccine to have product in all locations however the Department is working weekly with allocations and store locations based on an equitable mapping in areas of need with the advice of our Office of Health Equity.

As this mission in the community occurs, a separate mission led by the Federal Pharmacy Partnership - a collaboration between the CDC through Operation Warp Speed, CVS, and Walgreens - is also underway. The Federal Pharmacy Partnership is coordinating all the logistics for this mission from the shipping to the actual vaccine administration and reporting. This effort will work to vaccinate both the staff and residents of licensed skilled nursing facilities, personal care homes, assisted living facilities and other long-term care facilities. This partnership began its work on December 28<sup>th</sup> and Pennsylvania has invested a significant amount of vaccine resources to ensure that CVS and Walgreens can accomplish their mission quickly and efficiently. All nursing homes, totaling about 650 sites, enrolled in the Federal Pharmacy Partnership have completed their first clinics. The remaining second and third clinics are on course to finish by early March. The Federal Pharmacy Partnership mission will continue to vaccinate over 2,200 long-term care facilities. Many of these sites have had clinics scheduled thus far and that work will likely be completed by mid-April.

As we move into later phases of the vaccine distribution, we will hold additional community vaccination clinics in close partnership with PEMA who will coordinate logistics with our local county partners in communities across the Commonwealth to make the vaccine available to all who desire to be immunized. Pennsylvania specifically focused our COVID-19 Interim Vaccine Plan with deliberate intent to reach individuals in rural areas or those in historically marginalized communities These efforts are executed with advisement by our Office of Heath Equity and existing community partners established through our COVID-19 testing initiatives.

At the Pennsylvania Department of Health, our vision is a healthy Pennsylvania for all. Right now, we are laser focused in moving towards that vision by developing avenues to give all people access to the lifesaving COVID-19 vaccinations. Running vaccination programs is foundational to our work in public health. We know many Pennsylvanians are eager to receive this vaccine and we are working diligently, both internally and with our partners to meet the challenge of this historic moment. However, it will take a comprehensive approach to be successful, making coordinated adjustments along the way, to successfully vaccinate millions of Pennsylvanians and help bring an end to the pandemic. An endeavor of this magnitude will not be a short-term operation. We expect this operation will take months to vaccinate all willing Pennsylvanians.

Compounding the enormity of this effort is a baseline level of distrust that could significantly negatively impact vaccine uptake in the Commonwealth. Combatting this vaccine hesitancy and building trust is a cornerstone of the Commonwealth's Interim Vaccine Plan. In addition, the unprecedented speed with which these vaccines have gone from concept to production has caused a level of distrust nationally that must continue to be addressed with accessible, actionable, and coordinated messaging. Further, both vaccines have been shown to have some side-effects which may prompt some people to be more hesitant to receive a second dose.

As noted earlier both currently available vaccines were approved by the FDA through an EUA. Because of the severity of COVID-19, the FDA is working to get vaccine to Americans through the EUA process. An EUA is used by the FDA to approve the use of safe and effective medical products during a public health emergency to diagnose, treat or prevent serious life-threatening diseases or conditions. For an EUA to be issued for a vaccine, the FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine. During the review process, the FDA has a duty to thoroughly analyze the safety and efficacy results of clinical trials. With the advanced technology available today, the FDA can expedite this review. However, no steps have been skipped in these reviews.

All vaccines must undergo the EUA approval process before being fully licensed. After a vaccine is approved and licensed, the FDA continues to oversee its production to ensure continued safety. It is important to remember that monitoring of the vaccine and its production activities continue even when the manufacturer holds a license for the vaccine product. Vaccine manufacturers are all following the same process to make a COVID-19 vaccine available through an EUA.

In public health emergencies, such as a pandemic, the development process may not follow routine timelines. However, it is important to remember that these COVID-19 vaccines have been produced according to rigorous standards set by the FDA and are safe for people to get when available. The COVID-19 vaccine will help to prevent the virus or lessen the severity of the symptoms if someone does get it. According to EUA data, both vaccines are within the 90<sup>th</sup> percentile of efficacy, giving a great deal of confidence in their ability to be a highly effective tool against this virus. While there have been some adverse reactions reported, they have largely been mild to moderate and usually last only a few days.

However—now that the vaccine is available, it is not a simple cure to the coronavirus and will not quickly end the pandemic. This is why it is critical that all Pennsylvanians continue to follow the targeted mitigation orders set in place and do their part to stop the spread of the virus. Mitigation is more important now than ever. We still need to wear a mask and we still need to physically distance. In fact, we will have to continue to take these steps until most people have been vaccinated.

We know there have been challenges thus far and we know more await us in the future. I am proud of the immense amount of public health work that has brought us to this point. I look forward to partnering with all of you as trusted community messengers on the hard work needed to bring this pandemic to an end. Thank you for the opportunity to offer remarks. I am happy to take any questions you may have.