## Opening Statement of Ranking Member Morgan Griffith Subcommittee on Oversight & Investigations Virtual Hearing "Pathway to Protection: Expanding Availability of COVID-19 Vaccines" February 23, 2021

## As Prepared for Delivery

Thank you, Chair DeGette, for holding this important hearing on the availability of COVID-19 vaccines.

I also want to thank the witnesses for taking the time to join us today. Two of the companies before us—Pfizer and Moderna—have COVID-19 vaccines that have been granted emergency use authorizations (EUAs) by the FDA; one company—Johnson & Johnson has filed an EUA application; and two companies—AstraZeneca and Novavax—have ongoing Phase 3 clinical trials.

Thanks to the last administration's great partnership with private industry, Pfizer and Moderna started shipping vaccines across the United States within 24 hours of receiving their EUAs. They have committed to supply 600 million doses to the United States government by the end of July—that will mean we will have enough supply to vaccinate 300 million people. In addition, more COVID-19 vaccine doses will be available should more companies receive authorization or approval from the FDA.

This timeline is unprecedented, especially since the path from clinical trial production to commercial scale manufacturing is highly complex. For example, according to a U.S. Government Accountability Office (GAO) report, the

traditional vaccine timeline from the exploratory stage all the way to the large-scale manufacturing and FDA review and licensure takes approximately ten years, or longer. But in just 11 months since our first reported case of COVID-19 two companies received EUAs from the FDA for their vaccines. As of February 18, over 73.3 million doses of COVID-19 vaccine have been delivered across the U.S. This is a remarkable achievement—we should applaud these efforts that have been undertaken by manufacturers to help crush the virus.

However, as we heard at a Subcommittee hearing a few weeks ago with representatives from a handful of states – vaccine supply remains the number one hurdle to vaccinating Americans at a faster pace.

The challenge is that the vaccine manufacturing process takes time. The immediate availability of vaccine doses was made possible because of the efforts of the private sector, as well as their partnerships with the federal government.

Because manufacturing was being done at-risk and in parallel with the clinical trial process, we were able to move fast.

In addition to at-risk manufacturing, the vaccine manufacturers have looked for ways to increase and expand their manufacturing capacity. Some efforts undertaken by manufactures include rearranging existing capacity, acquiring additional facilities, partnering with other companies to increase their production capacity, or hiring and training additional personnel to work in the manufacturing

facilities. Some companies have even looked to increase the number of doses included in their vials, which conserves resources and supplies. Other companies have been able to increase efficiencies in their processes by incorporating lessons learned. All of these efforts not only allow vaccines to reach Americans faster, but it also highlights private sector innovation.

But to be clear—expanding capacity takes time. This is a complex process that includes the availability of every piece of equipment and material needed, making sure that the equipment is approved, and ensuring all of the processes and people in the facility are validated.

There have also been disruptions to manufacturing supply chains and processes throughout the pandemic. With the demand for medical supplies at an all-time high across the world and disruptions in the workforce, we have faced challenges in securing materials for vaccine production. The federal government, including Operation Warp Speed and the use of the Defense Production Act (DPA), have helped to boost and secure essential supplies that are needed to manufacture COVID-19 vaccines. While the DPA has been a useful tool thus far, we must be judicious in how we utilize it as it can lead to major disruptions in our health care supply chain.

Finally, COVID-19 continues to mutate, causing new variants to emerge that seem to spread more easily and quickly. Thankfully, vaccine manufacturers are already looking at ways to stay ahead of theses variants.

I look forward to our discussion today to learn more about your manufacturing processes, actions you have taken to expand your manufacturing capacity, and whether you feel more capacity or resources are needed to meet the demands for COVID-19 vaccines. I also look forward to hearing about any challenges manufacturers are facing and how we might address them. We are all in this fight together, and I want to thank you all for the important work you've already done.

Thank you, Madam Chair, I yield back.