Written Testimony of
John Young, Chief Business Officer, Pfizer

Hearing on "Pathway to Protection: Expanding Availability of COVID-19 Vaccines"

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Chairwoman DeGette, Ranking Member Griffith and Members of the Subcommittee, thank you for inviting me to testify today. I am honored to be part of this panel. My name is John Young and I am the Chief Business Officer at Pfizer.

When I appeared before this Committee last July, we were in the middle of our journey to develop a potential COVID 19 vaccine. Since that time, our vaccine became the first to be granted emergency use authorization by the FDA.

This EUA was based on data from our Phase 3 study which demonstrated our vaccine met the FDA's stringent safety requirements and indicated vaccine efficacy of 95%. Efficacy was consistent across age, gender, and racial demographics, in a study that recruited participants that reflected the diversity of the United States population.

As of February 17th, we have shipped approximately 40 million doses to points of use as directed by the U.S. government. To date, no serious safety concerns have been identified that have changed the favorable risk-benefit profile of the vaccine.

To get these vaccines to points of use, we provide the U.S. government a rolling forecast of vaccine doses available for shipment each week that enables the U.S. government to provide states with three weeks of data.[1] The U.S. government allocates doses weekly to states, which is their purview. Providers submit orders through CDC's VTrackS system, which are submitted to us. Weekday orders are shipped the day after.

Because of the dire need to vaccinate more people, we have ramped up production of doses. Since July, we have increased projected 2021 global production from 1.3 billion doses, to at least 2 billion doses.

This is possible because Pfizer has made *significant* investments in our U.S. manufacturing sites including Saint Louis, MO; Andover, MA; Kalamazoo, MI; and Pleasant Prairie, WI. In addition, we have added new lines at our site in McPherson, KS, started lipid production at our site in Groton, CT; and added two contract manufacturers. Further improvements have come from FDA's recent

[1] All estimates regarding forecasted shipments reflect the number of doses we expect to make available for shipment to points of use as directed by the U.S. government.

approval of a 6-dose label for each vial, the doubling of our batch sizes, increased yields per batch, and reduced cycle times, as well as deployment of faster laboratory tests to reduce release times.

As a result of these improvements, we expect to increase the number of doses we make available for shipment from approximately 4 to 5 million doses per week at the beginning of February to more than 13 million doses per week by the middle of March.

We are on track to make 120 million doses available for shipment by the end of March and an additional 80 million doses by the end of May. And, we anticipate all 300 million contracted doses will be made available for shipment by the end of July, enabling the vaccination of up to 150 million Americans.

We continue to gather evidence on safety and efficacy to potentially support the use of the vaccine by important subpopulations of patients not indicated under the current EUA.

We are conducting studies in patients between 12-15 years of age and hope to soon begin studies in children under the age of 11. Last week we initiated a study in pregnant women.

We are laser focused on the potential impact emerging variants of SARS-CoV-2 virus could have on the ability of our vaccine to protect against COVID-19.

The mRNA platform of our vaccine affords the opportunity to provide boosting doses if needed, and the ability to rapidly alter the mRNA sequence in the vaccine to address potential changes in the virus if evidence suggests they might reduce protection from the current vaccine.

With 95% protection against the original strain, we have now performed in-vitro studies on immune responses elicited by the vaccine against new variants, such as those from the UK and South Africa. Based on the responses we believe that the vaccine should provide protection from those variants as well. Real world evidence from the UK and Israel appears to confirm this in-vitro data related to the UK strain, and we have seen no real world evidence to date that suggest a significant reduction in protection provided by our current vaccine.

However, we are preparing to respond quickly and initiating a study to investigate the effectiveness of a third-dose booster of our current vaccine in trial participants who have already received 2 doses.

We are also discussing clinical study designs with the FDA to investigate the safety and immunogenicity of an updated vaccine that involves a change to the mRNA construct to target an emerging variant.

We will fight every step of the way until this devastating pandemic is under control.

In closing, I would like to express Pfizer's sincere thanks to the more than 46,000 trial participants, the hundreds of investigators; and the thousands of Pfizer and BioNTech scientists, clinicians and manufacturing professionals, many of whom have worked literally day and night, knowing every moment matters.

Thank you for the opportunity to be with you today.