Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing on
"Pathway to Protection: Expanding Availability of COVID-19 Vaccines"
February 23, 2021

John Young, Group President, Chief Business Officer, Pfizer

The Honorable Anne McLane Kuster (D-NH)

1. **Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?**

   Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. Pfizer relies on both domestic and foreign sources for its vaccine manufacturing supplies, and we are continuing to qualify multiple sources for all key raw materials. Pfizer has manufacturing sites across the U.S., and we are leveraging three of them for the COVID-19 U.S. commercial vaccine program including: Saint Louis, MO for raw material manufacturing; Andover, MA for drug substance; and Kalamazoo, MI for formulation, fill and finish. Pfizer's Puurs, Belgium, site is being used for primarily European supply but will also serve as a backup supply to Kalamazoo for the U.S. market.

2. **Considering the federal government's actions to date, what gaps or restrictions still exist across the domestic manufacturing supply chain and the export/import landscape that influence your decision to use foreign over domestic sources?**

   Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

3. **What changes should be made for you to prioritize using domestic sources?**

   Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

4. **Can you speak to what constraints, including with respect to specific products within the supply chain (e.g., APIs, bioreactors, glass vials, stoppers, fills/finishers, etc.), are currently preventing the production of more vaccines?**

   Response: Pfizer has leveraged strategic relationships to help build a robust U.S. supply chain. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we continue manufacturing additional doses.

5. **Can you speak to how making the investments called for in the American Rescue Plan, like the investment in new factories, may optimize vaccine fill lines to ensure maximum efficiency to meet future demands?**

   Response: We appreciate the commitment of Congress to bring an end to this pandemic, including the recent passage of the American Rescue Plan. We remain confident in our close collaboration with the U.S. Government as we work to help deliver the vaccine to Americans as quickly as possible.

   Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. Pfizer's COVID-19 vaccine development costs have been entirely self-funded. We have already invested more than one billion dollars at risk and continue bearing the costs of all development, in an effort to help find a solution to this pandemic. We decided to self-fund our efforts so we could move as fast as possible.

   Because of the urgent need to vaccinate more people, we have ramped up production of doses. We have increased projected 2021 global production from 1.3 billion doses, to at least 2.5 billion doses globally. This is based on continuous improvements and expansion at our current facilities, the updated 6-dose label, and adding more suppliers as well as contract manufacturers.

The Honorable Lori Trahan (D-MA)

1. **T cells and antibodies are two arms of the immune system that provide insights into disease activity and an individual's personal immunity. Serology is more commonly used to measure immune responses to infections. Since antibody responses wane within 2 – 3 months of COVID-19 infection, serology alone is not enough to assess personal immunity or "herd immunity" against SARS-CoV-2. We have seen that other countries have approached vaccine approval differently than the U.S. For example, the United Kingdom established a "vaccine task force" to objectively compare the T-Cell and antibody immune response of each vaccine approved for usage in the country. Based on published reports, the UK government felt this was important to enable objective comparison across vaccine modalities. Did any of your company study T-Cell responses during the development of your vaccines?**

   Response: Yes. On July 20, 2020, Pfizer and BioNTech announced that initial data from an ongoing German Phase 1/2 non-randomized dose-escalation trial demonstrated a concurrent

induction of T cell responses against SARS-CoV-2. On December 14, 2020, Pfizer and BioNTech announced that additional data on neutralizing antibody and T cell responses from the Phase 1/2 trial with BNT162b2 conducted in Germany was available. The data analysis showed a broad immune response with SARS-CoV-2-specific neutralizing antibodies, TH1 type CD4+ T cells, and strong expansion of CD8+ T cells of the early effector memory phenotype.

2. **When thinking about expanding the availability of vaccines, one thing that is extremely important is that vaccine distribution is done in an equitable manner. Many state leaders, including those in my state of Massachusetts, tried to approach plans for vaccine distribution early on in an equitable way—they consulted with public health leaders to develop a tiered plan to equitably prioritize distribution. Due to the limited supply of vaccines and slow distribution to the state, the implementation has heavily relied upon mass vaccination sites. While mass vaccination sites may work well for some patients, others will be best served by their own physicians, in their own communities. Physicians are a trusted source of medical information, and they can proactively reach out to their patients who need the vaccines most, including the elderly, the sick, and specifically communities of color who have been disproportionately affected by this pandemic. Mass vaccination sites, while getting the vaccine out quickly, prioritize those with access to transportation to get to the site, as well as resources to navigate the process to register for a vaccine. What role can manufacturers play in helping states get vaccines distributed to physician practices—whether by allowing smaller shipment sizes tailored to physician offices (that may only need ~50-100 vaccine doses) or creative solutions to aid in vaccine storage?**

   Response: Pfizer is committed to ensuring everyone has the opportunity to have access to our vaccine. There are several options for effective vaccine storage for our vaccine, and over the past several months, we have worked closely with state and local officials, as well as health care providers, to provide guidance on our storage requirements to help ensure our vaccine can reach people in rural and other harder to reach communities across the U.S. Recently, we received approval for an update to our label from the U.S. Food and Drug Administration to permit 2 weeks of storage at standard pharmaceutical freezer temperature. This will help improve the ability to distribute our vaccine in rural and harder to reach communities.

   The U.S. government and Pfizer are continuing to explore optimized packaging that meets the needs of our customers for vaccine planning, distribution, and administration. Through this exploration, we understand that smaller packaging is needed. Based on revised requirements to support the U.S. government, we need to design a new solution versus what was proposed. Packaging, however, is only one lever to optimize the distribution process. To this end, Pfizer has ongoing stability studies that may open up more flexible distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

   In addition, to date, we have trained over 25,000 health care providers and state, local, and tribal nation immunization leaders on our vaccine shipping, storage, and administration requirements. We continue to make these trainings regularly available, which allows us to provide up-to-date information on our vaccine and respond directly to questions about managing our vaccine in different circumstances.

a. What assistance would you need from the government for this, in terms of ramping up production/manufacturing and packaging shipments in a manner tailored to physician offices?

Response: The U.S. government and Pfizer are continuing to explore optimized packaging that meets the needs of our customers for vaccine planning, distribution and administration. Pfizer and representatives at various agencies within the U.S. government meet on a regular basis regarding manufacturing and distribution of the vaccine. We are confident in the ability of the U.S. government to remove any obstacle that may present itself as we work on manufacturing and distribution.

The Honorable Morgan Griffith (R-VA)

1. What types of process improvements and innovation can lead to boosting vaccine production?

Response: Because of the urgent need to vaccinate more people, we have explored innovative plans to increase the number of doses we are able to produce globally by the end of 2021. We're making any improvements and enhancements that can accelerate or increase the number of doses we are able to produce. This includes:

- Making process improvements to our existing production lines – in essence more doses from the current lines;
- Expanding the supply of raw material from existing suppliers and bringing on new suppliers;
- Doubling our batch sizes in order to minimize time between batches;
- Increasing the yield per batch;
- Reducing cycle times at every step; and
- Deploying faster laboratory test methods to reduce release times.

2. Given the variants that are circulating across the world and that we may need a booster or annual shot similar to the influenza vaccine, how quickly can your vaccine manufacturing platform be adapted to scale up and manufacture a new or altered vaccine formula?

Response: As we have said in the past, we selected the mRNA platform because it is flexible enough to enable boosting doses if needed and also allows for a more rapid response in addressing changes that might be needed in the vaccine if a variant were to significantly reduce protection from the current vaccine. Pfizer and BioNTech have been working to understand whether emerging variants of concern of SARS-CoV-2 could impact our vaccine's ability to protect against COVID-19. We are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any variant of concern that significantly reduces the protection afforded by our current vaccine.

3. Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?

Response: Pfizer partnered with BioNTech to jointly develop their COVID-19 vaccine. This collaboration announced on March 17, 2020 aimed to rapidly advance multiple COVID-19

vaccine candidates into human clinical testing based on BioNTech's proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine if approved and while leveraging Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network.

Pfizer is investing significant resources to develop and manufacture the novel technology to provide a safe and effective vaccine. Where appropriate, we will work with our contract manufacturers, but we do not plan to provide drug product or drug substance to third parties.

a. Is your company looking to develop additional partnerships?

Response: Pfizer is continuing to explore all viable options and mechanisms to expand capacity internally and externally as needed to ensure that any potential treatment or vaccine to address the coronavirus pandemic is accessible for those who need it.

4. Is your company utilizing, or has explored utilizing, the Department of Health and Human Services' (HHS) Centers for Innovation in Advanced Development and Manufacturing (CIADM) program to expand existing manufacturing capacity? Why or why not?

Response: Pfizer's COVID-19 vaccine development costs have been entirely self-funded. We have already invested more than one billion dollars at risk and are prepared to continue bearing the costs of all development in an effort to help find a solution to this pandemic. We decided to self-fund our efforts so we could move as fast as possible.

5. As time passes, the virus continues to mutate causing new variants to emerge. Can you explain the level of difficulty involved in creating a booster shot to provide protection against these new variants, specifically in an mRNA vaccine?

Response: Pfizer and BioNTech have been working to understand whether emerging variants of SARS-CoV-2 could impact our vaccine's ability to protect against COVID-19.

- Our in vitro study provided data that demonstrated that sera from individuals immunized with the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) neutralized SARS-CoV-2 with spike protein mutations found in the Brazil, U.K. and South African virus variants.

- On February 25, Pfizer and BioNTech announced an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine to understand the effect of a booster of the current vaccine on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the Phase 1 study in the United States who will be offered the opportunity to receive a 30 μg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose against evolving variants.

- On March 11, Pfizer and BioNTech announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with the Pfizer-BioNTech COVID-19 Vaccine, underscoring the observed substantial

public health impact of Israel's nationwide immunization program. The latest analysis from the Israeli Ministry of Health shows that two weeks after the second vaccine dose protection is even stronger in this population – vaccine effectiveness was at least 97% in preventing symptomatic disease, severe/critical disease and death. Findings from the analysis were derived from de-identified aggregate Israel MoH surveillance data collected between January 17 and March 6, 2021, when the Pfizer-BioNTech COVID-19 Vaccine was the only vaccine available in the country and when the more transmissible B.1.1.7 variant of SARS-CoV-2 (formerly referred to as the U.K. variant) was the dominant strain.

As we've said in the past, we selected the mRNA platform because it is flexible enough to enable boosting doses if needed and also allows for a more rapid response in addressing changes that might be needed in the vaccine if a variant were to significantly reduce protection from the current vaccine.

While we continue to examine emerging data, we are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any strain that significantly reduces the protection afforded by our vaccine.

6. **As you clinically evaluate the dosage for a booster shot to provide protection against new variants, do you have any projections for the necessary dose in these booster shots? How will this estimated dosage affect production capacity?**

Response: On February 25, Pfizer and BioNTech announced an evaluation of the safety and immunogenicity of a third dose of the Pfizer-BioNTech COVID-19 vaccine to understand the effect of a booster on immunity against COVID-19 caused by the circulating and potential newly emerging SARS-CoV-2 variants. The study will draw upon participants from the Phase 1 study in the United States who will be offered the opportunity to receive a 30 μg booster of the current vaccine 6 to 12 months after receiving their initial two-dose regimen. The study is part of the Companies' clinical development strategy to determine the effectiveness of a third dose against evolving variants.

While we continue to examine emerging data, we are taking the necessary steps, making the right investments and engaging in the appropriate conversations with regulators to position us to develop and seek emergency authorization for an updated mRNA vaccine or booster soon after identifying any strain that significantly reduces the protection afforded by our vaccine.

The Honorable Michael C. Burgess, M.D. (R-TX)

1. **One of the greatest inhibitors of distributing the COVID-19 vaccine to rural areas is the lack of cold-chain technologies to store the RNA vaccine. Additionally, as we consider logistics in distributing the vaccine abroad to third-world countries where power may not be available, the Moderna or Pfizer vaccine may not be an option. Are Moderna or Pfizer conducting any research on ways to incorporate new technologies to make the RNA vaccines stable to store at room temperature to allow for broader distribution?**

Response: In February, we submitted new data to the U.S. Food and Drug Administration demonstrating the stability of our COVID-19 vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. The FDA authorized this update which allows for vaccine vials to be stored at these temperatures for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

Pfizer has ongoing stability studies that may open up new distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

2. **Pfizer has agreed to supply the United States with 300 million doses of the COVID-19 vaccine. During last summer, the U.S. purchased 100 million doses while the vaccine was still undergoing trials, and 100 million additional doses were purchased by the U.S. in December. In February, the United States announced it would be exercising its option to purchase 100 million additional doses of the Pfizer COVID-19 vaccine. Can you explain the structure of the contracts between the United States and Pfizer, and clarify the basis on which the options to exercise the decision to purchase additional vaccinations were formed?**

   Response: Pfizer has entered into two contracts with the U.S. government for a total of 300 million doses. On July 22, 2020, we announced an agreement with the U.S. government for 100 million doses to be provided after successful manufacture and approval or authorization from FDA. On December 23, 2020, we announced a second agreement, in the form of a supply contract for an additional 100 million doses, bringing the total contracted number of doses to 200 million. The December 23, 2020 agreement also provided the government an option to acquire up to an additional 400 million doses of our vaccine. On February 12, 2021, we announced the U.S. government has exercised its option for an additional 100 million doses of our vaccine.

3. **Did the Previous Administration's invocation of the Defense Production Act impact the production of Pfizer's Covid-19 vaccine? If so, was it important, and how did it help?**

   Response: Pfizer worked with the previous Administration and is working with the current Administration to help the U.S. Government deliver the vaccine to Americans as quickly as possible. Pfizer and representatives at various agencies within the U.S. Government meet on a regular basis regarding manufacturing and distribution of the vaccine.

The Honorable Billy Long (R-MO)

1. **What are you doing to evaluate and incorporate technology to make vaccines stable at room temperature so they can be more widely distributed, especially if we are faced with annual vaccination efforts against COVID-19 as suggested by some experts? Additionally, are you aware the Infectious Disease Research Institute, located in Washington State, has pioneered technology that allows RNA vaccines to be freeze-dried and stored nearly a year at room temperature or 2 years under simple refrigeration. It's my understanding that this technology, once approved, could be applied to the Pfizer and Moderna vaccines to ensure long-term stability. Is this a technology your company would consider exploring?**

Response: Last month, we submitted new data to the U.S. Food and Drug Administration demonstrating the stability of our COVID-19 vaccine when stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. The FDA authorized this update which allows for vaccine vials to be stored at these temperatures for a total of two weeks as an alternative or complement to storage in an ultra-low temperature freezer.

Pfizer has ongoing stability studies that may open up new distribution options in Q2 2021. Both Pfizer and the U.S. government are excited about these future product options. We look forward to continuing to provide updates as these discussions and decisions unfold.

Pfizer will consider all viable options and mechanisms as needed to ensure that any potential treatment or vaccine to address the coronavirus pandemic is accessible for those who need it.