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Responses to Questions for the Record

Subcommittee on Oversight and Investigations, Committee on Energy and Commerce
February 23, 2021

The Honorable Ann McLane Kuster (D-NH)

1. **Can you speak to your reliance, if any, on foreign sources for vaccine manufacturing supplies?**
   Johnson & Johnson's global manufacturing and supply network has enabled us to develop our COVID-19 vaccine at an extraordinary pace since January 2020. In addition to our manufacturing facility in the Netherlands, the partners who are central to our global supply network include: Merck & Co. (US); Emergent BioSolutions (US); Catalent (US, Italy); Grand River Aseptic Manufacturing (US); Sanofi Pasteur (France); IDT Biologika (Germany); Reig Jofre (Spain); Biological E (India); and Aspen Pharmacare (South Africa).

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?**
   In general, we have used the sourcing that is most conducive to developing and producing a safe and effective vaccine at an accelerated pace. We have a substantial manufacturing and supply network located in the United States. In our view, government actions should take into account the need to use a global supply chain to allow manufacturing plants to operate at maximum capacity without disruption or slowdown.

3. **What changes should be made for you to prioritize using domestic sources?**
   As noted above, we have a substantial manufacturing and supply network located in the United States, and we have expanded our network as part of our effort to produce our vaccine at a rate of one billion doses globally by the end of 2021. We do not currently believe changes are needed.

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?**
   We have been working since the beginning of the pandemic to expand our global manufacturing and supply network, including by contracting with established third-party vaccine manufacturers for additional production. Our current manufacturing plans are designed to meet our objective, which we announced last year, to produce our vaccine at a rate of one billion doses globally by the end of 2021. Currently, we are witnessing some disruptions in the global consumables market (components needed for manufacturing), which we are closely monitoring.

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?**
   We support Congress's efforts to strengthen the vaccine supply chain as we work collectively to optimize and accelerate our response to COVID-19 and ensure we are better prepared for emerging epidemic threats in future. We also believe continued investment is needed to ensure that domestically we have the highly specialized and technical competencies required for both current and next-generation manufacturing jobs. The free flow of essential supplies and equipment across borders also needs to be assured to allow facilities to operate at maximum capacity without disruption or slowdown, which could allow for greater quantities of vaccine to reach more people more quickly.

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?**
   Yes, we are studying T-Cell response in our COVID-19 vaccine development program. Our vaccine drew a strong antibody and T-Cell response in humans, as described in the data from our phase 1/2a clinical trial published by Sadoff et al. in the January 13, 2021 New England Journal of Medicine – https://www.nejm.org/doi/full/10.1056/NEJMoa2034201.

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?

The Janssen COVID-19 vaccine is well suited to community deployment, including via physician offices and pharmacies, because it remains stable for two years at -20°C, three months of which can be at temperatures of 2°C to 8°C. During the emergency pandemic period, we are operating under the special circumstances of the federal coordinated response to COVID-19. Our priority is to deliver supplies of the Janssen COVID-19 vaccine to the federal government as part of this response, and the government then coordinates all aspects of vaccine distribution.

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?**

   As noted above, our vaccine is well suited to community deployment, including via physician offices and pharmacies, because it remains stable for two years at -20°C, three months of which can be at temperatures of 2°C to 8°C. The U.S. government's support has been an important contributor to Johnson & Johnson's ability to develop our vaccine on an accelerated pace, and the government's commitment to purchase our vaccine was important for our ability to invest in the increased production capacity necessary to bring millions of vaccine doses to Americans.

<u>The Honorable Morgan Griffith (R-VA)</u>

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

   We have invested in process improvements and innovation, including through the development of technologies such as our AdVac® platform. Additionally, in response to the urgent public health demands of the pandemic, we have worked around the clock to develop and broadly scale our manufacturing capabilities to supply the United States and other countries. Currently, our focus is on working with our partners to scale up the production process. The production of our vaccine is a highly complex process, requiring very particular staff capabilities and experiences.

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?**

   A key advantage with our AdVac® technology platform is its versatility in facilitating vaccine candidates for a range of infectious diseases, as well as viral variants that may emerge over time. The same platform is used for our Ebola vaccine and is being explored in our vaccine candidates for HIV and respiratory syncytial virus.

   We anticipate an accelerated timeline for developing versions of our COVID-19 vaccine tailored to viral variants, if needed. We also welcomed FDA's recent guidance outlining a streamlined approach for clinical studies. It is important to monitor the evolution of the pandemic closely in order to determine whether, and exactly how, vaccines should be updated. For example, it is possible that the variants that we are concerned about now are not the ones that may have the

biggest impact on COVID-19 infection rates in the future.

3. **Has your company developed partnerships with other companies to provide your company with assistance in the vaccine manufacturing process?**
   Yes. Beyond our manufacturing facility in the Netherlands, the partners who are all central to our global manufacturing and supply network include: Merck & Co. (US); Emergent BioSolutions (US); Catalent (US, Italy); Grand River Aseptic Manufacturing (US); Sanofi Pasteur (France); IDT Biologika (Germany); Reig Jofre (Spain); Biological E (India); and Aspen Pharmacare (South Africa).
   a. **Is your company looking to develop additional partnerships?**
      We continue to evaluate opportunities to expand our manufacturing capabilities with additional production sources. Since the time of the hearing, we have announced additional partners. At this time, we believe we have sufficient manufacturing capacity secured to support the production of up to one billion vaccines in 2021.

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?**
   We recognize CIADM as an excellent and worthwhile initiative, and a review of CIADM participants and their respective skill sets informed our manufacturing planning in the early stages. Ultimately the partners that we have engaged in our manufacturing network meet our stringent criteria to ensure that technology transfers could be successfully executed.

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?**
   Our vaccine utilizes our AdVac® technology platform, which allows for updates on an accelerated timeline should newly emerging SARS-CoV-2 variants of concern dictate that need. We welcomed FDA's recent guidance outlining a streamlined approach for clinical studies.

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?**
   We will continue to use the science as our guide as to new variants, and we will continue to utilize our expanded global manufacturing and supply network for our vaccine.

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

1. **It has been brought to my attention that the Johnson and Johnson COVID-19 vaccine uses abortion-derived cell lines in the vaccine production process. Is it possible to improve and move beyond this controversial technology in future vaccine development and production?**
   Our vaccine contains no fetal tissue. Rather, our vaccine is produced using a harmless cold-like virus into which we insert a piece of the coronavirus spike protein.

The technology platform uses cells that were engineered and grown in labs from a single cell more than 30 years ago into a fully engineered cell line. This cell line enables us to manufacture hundreds of millions of single-shot COVID vaccines that can be transferred and stored without the need for deep freezing.

The Honorable Neal P. Dunn, M.D. (R-FL)

1. **In addition to your heroic efforts in vaccine development, are your companies also engaged in research and development of therapeutics? That is to say anti-virals that could potentially have a broader spectrum of activity across the coronavirus variants?**
   Yes. In addition to accelerating the clinical development, manufacturing, and distribution of the Janssen COVID-19 vaccine, we have been working in collaboration with the U.S. government and other research partners to identify potential therapeutic solutions by screening a library of compounds and conducting clinical trials to explore potential therapeutics. For example, we are participating with the NIH in a master protocol study called ACTIV-1 Immune Modulators (IM) which is evaluating REMICADE®, a Janssen-developed Tumor Necrosis Factor (TNF) inhibitor or anti-TNF, as a potential treatment for hospitalized patients with inflammatory complications of COVID-19. From the start of the pandemic, Janssen also has collaborated with BARDA to share research and development costs and mobilize resources to screen a library of compounds (both ours and other companies') for activity against SARS-CoV-2. Currently, none of our medicines have been approved for use in treating COVID-19.