Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine"

July 21, 2020

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The Honorable Frank Pallone, Jr. (D-NJ):

1. The clinical trial work for Johnson & Johnson's vaccine candidate is on a different timetable than the other manufacturers we heard from at the hearing. As you even noted in your testimony, Johnson & Johnson will likely begin its Phase III trials after other companies have already begun large trials in the United States.

    a. What steps is Johnson & Johnson taking to ensure the company is able to recruit the tens of thousands of healthy participants needed for a Phase III clinical trial?

    Our pivotal Phase III clinical trial will be initiated once adequate safety and immunogenicity data are obtained in the current Phase I/IIa first-in-human trial, subject to all appropriate regulatory and health authority consultations. We are working to ensure that we have adequate numbers of sites for our Phase III clinical trial in areas where the incidence of COVID-19 is predicted to be high, both within the U.S. and in several other countries around the world. We are assessing a site's capacity to enroll participants as part of site selection, and we expect to have more sites selected and ready than will be utilized in the study, given that site activation will be guided by current and predicted epidemiology. The company is conducting outreach efforts to raise awareness of our Phase III clinical trial in local communities, particularly in diverse populations that are disproportionately affected by COVID-19. The overall timing of recruitment for our Phase III clinical trial will depend on the timing of approvals related to the Phase III clinical trial from the FDA and other health authorities and endorsement of the Phase I/IIa first-in-human trial data that support its start.

    b. How many participants do you anticipate recruiting?

    We anticipate that our Phase III clinical trial will include up to 60,000 people. The final number will be based on predictions of epidemiology and endorsement by the U.S. government.

The Honorable Brett Guthrie (R-KY):

1. Through Operation Warp Speed and the efforts of your companies and many more, we are seeing an unprecedented effort to quickly develop a safe and effective vaccine. What lessons or changes from this process should we consider making permanent in an effort to fundamentally change the traditional, years-long process for vaccine development going forward?

   Efforts to develop safe, effective, high-quality COVID-19 vaccines have accelerated clinical trial recruitment, and public dialogue around these trials has significantly raised awareness of clinical research within the general population. This acceleration is further enhanced by the investments we are making in several specific community engagement initiatives to build trust and raise interest in study participation, particularly in Black and Hispanic/Latinx communities that are disproportionally affected by the COVID-19 pandemic. In addition, Janssen has established partnerships that facilitate connection with potential trial candidates within specific high-risk populations who already have expressed their interest in participation to a COVID-19 vaccine trial. Finally, our partnership with the U.S. government has opened up opportunities for conducting clinical research in broader geographic locations outside of the traditional large cities. These include the deployment of mobile clinical research capabilities, partnerships with local community organizations, and connections with companies that employ large numbers of individuals at high risk of COVID-19. This geographic expansion enables us to respond to the changing disease incidence in a more rapid and patient-focused way. We believe these learnings will enable us to shorten time needed to identify and recruit volunteers for future clinical research programs.

2. How did investments into platform technology help speed up the vaccine development process?

   Platform technologies and modalities, like our proprietary AdVac® platform, allow for the development and application of experience and deep scientific and technical insights across different products. Janssen Vaccines has invested in developing the AdVac® platform and applying it to develop vaccine candidates for diseases like Zika, HIV, respiratory syncytial virus, and Ebola (the Ebola vaccine was recently licensed in Europe).

   When Johnson & Johnson joined the global fight against the COVID-19 pandemic in early January, we applied the understanding of our platform and the knowledge of the genome of SARS-CoV-2 to design our COVID-19 vaccine candidate. Utilizing our knowledge of the platform enabled us to move quickly by leveraging our prior investment and knowledge, while maintaining rigorous scientific standards.

3. Do any of your companies have recommendations about how to further innovate clinical trials?

   First, we recommend exploring direct-to-participant trial models. We are building the internal infrastructure necessary to launch a direct-to-participant trial model that brings clinical trials into people's everyday lives. We continue to invest in remote clinical trial

capabilities and expand innovative approaches to clinical trial conduct and research by exploring initiatives such as home healthcare nurse visits, telemedicine, direct medication shipment and bringing trial participation into community locations like pharmacies.

Second, we recommend developments in data science and digital health. Janssen seeks to improve participation and retention of clinical trial participants through use of technology for increased engagement and improved clinical trial access. Examples of our digital efforts include wearable devices and voice/chat-enabled software platforms that are designed to expand participants' ability to provide feedback in an alternative and more convenient platform.

4. COVID-19 has been with us for about seven months. There is still much we don't know about the antibody response and how long it lasts. Is there anything from the last seven months that has been learned that provides any insights into immune responses, and why it might suggest that our vaccine enterprise is on the right track?

   Preclinical studies with vaccine candidates from different developers have shown that animals can be protected against a SARS-CoV-2 challenge, supporting the idea that vaccines can induce the type of responses that prevent infection or prevent disease. Neutralizing antibodies have been shown to correlate with protection in animals, and several of the vaccine candidates already in the clinic have been shown to induce such neutralizing antibodies.

5. Do you have plans to have human challenge studies where you will take healthy individuals, immunize them with your vaccine candidate, and then challenge them with an infectious dose of COVID-19?

   We have not yet made a decision about whether to conduct human challenge studies.

   a. If yes, how is this ethical, and will your human challenge studies include participants over 55 years of age?

   b. If nobody under 55 will be enrolled, will there be a gap in our knowledge about vaccine effectiveness in the 55 years and older age group?

   The design of any study (or studies) would be subject to health authority consultations and approvals and would take into account the age of the study population.

6. Could your vaccine candidate(s) be used with an adjuvant? If so, how many additional doses could be generated from the use of an adjuvant.

   a. If not, are there other ways your vaccine could be boosted to strengthen the immune response in patients?

   Adenoviral vectors have an adjuvant activity on their own. As such, our vaccine candidate will not be used in combination with an adjuvant. We are evaluating multiple

dose levels and schedules to be able to determine the optimal and minimum effective dose of our vaccine candidate.

The Honorable David B. McKinley (R-WV):

1. When H.R. 3, the Lowering Drug Costs Now Act, was being considered in the House, members of this Committee raised concerns about what such legislation could do to innovation and drug development in the U.S., and Dr. Gerberding mentioned in her testimony how a robust biopharmaceutical research network has contributed to the accelerated development of a vaccine. H.R. 3 would undermine the important role of private-sector R&D in the U.S., as countries with price controls have suffered a decline in pharmaceutical R&D.

   Do you all have concerns about impacts on your research and development efforts, should such legislation become law in the U.S.? Why or why not?

   We believe that H.R. 3 would have a significant negative impact on drug development. This view aligns with analyses from Vital Transformations (http://vitaltransformation.com/wp-content/uploads/2020/01/Vital-Trans-HR3-Exec-Summ-11-22-2019-30JAN20.pdf), the Congressional Budget Office (https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf) and the Council of Economic Advisors (https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients/).

2. Most of you have accepted awards from the U.S. Department of Health and Human Services (HHS) to assist with the development and manufacturing of a COVID-19 vaccine?

   a. Are each of you on schedule and on budget?

      Janssen is on schedule.

   b. If you are behind schedule, do you plan to invest your own capital if the government grant runs out before you are finished with development?

      N/A.

   c. If you are ahead of schedule and you have grant money left over, what are your plans for those funds?

      N/A.