FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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Majority (202) 225-2927
Minority (202) 225-3641

August 25, 2020

Dr. Julie Gerberding
Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health
Merck
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Gerberding:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 21, 2020, at the remote hearing entitled "Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from me and other members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, September 4, 2020. As previously noted, your responses to the questions in this letter, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by email in the Word document provided with this letter to Benjamin Tabor with the Committee staff (benjamin.tabor@mail.house.gov). A paper copy of your responses is not required. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please have your staff contact Mr. Tabor at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachment

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

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

Dr. Julie Gerberding, Executive Vice President and Chief Patient Officer, Strategic Communications, Global Public Policy and Population Health, Merck

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

1. Completion of Phase III clinical trials will be critical to ensuring the safety and efficacy of any future COVID-19 vaccine. The U.S. Food and Drug Administration's guidance suggests that a Phase III clinical trial must enroll thousands of individuals in order to generate robust data to support an authorization or approval. Historically experts have suggested Phase III trials enroll upwards of 60,000 patients. How many patients does Merck intend to enroll in Phase III trials for a COVID-19 vaccine, and how will the company work to ensure that this goal is achievable given other competing trials?

2. You stated in your testimony that, "Under normal circumstances, manufacturing and distributing a vaccine is exceedingly complex … When we think about what will be needed to address this pandemic, we are talking about orders of magnitude beyond what we as an industry are currently doing."

    a. What challenges remain to be able to drastically ramp up manufacturing capacity for a COVID-19 vaccine?

    b. What steps is Merck taking now to achieve this goal?

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?

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

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

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?

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?

    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?

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?

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?

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?

    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?

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