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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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August 25, 2020

Mr. John Young
Chief Business Officer
Pfizer
235 East 42nd Street
New York, NY 10017

Dear Mr. Young:

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

John Young, Chief Business Officer, Pfizer

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

1. During the hearing, you indicated that Pfizer was putting together its clinical trial protocol for its Phase III study and would follow the U.S. Food and Drug Administration's (FDA) guidelines that suggest enrollment of up to 30,000 patients.

    a. What is the minimum number of patients Pfizer will seek to enroll in its Phase III trial, and how did the company arrive at this range?

    b. What makes your company confident this will be a large enough pool of participants to adequately assess the safety and efficacy of any of its vaccine candidates?

2. As we heard at the hearing, there are many companies racing to begin and complete the Phase III clinical trials that will be necessary to support an authorization or approval by FDA. What steps is Pfizer taking to ensure the company is able to recruit the tens of thousands of healthy participants needed for a Phase III clinical trial?

3. Ensuring quality manufacturing of a future vaccine is critical to ensuring rapid access for patients, as well as preventing any potential disruptions that could limit such access. At the hearing you noted that Pfizer's previous manufacturing quality issues associated with sterile injectables were attributable to facilities associated with Hospira that was acquired by the company in 2017. You noted that your remediation for those sites was to be completed by 2020 and that those sites "were on track." While I understand you intend to manufacture a future COVID-19 vaccine candidate in your legacy Pfizer network, what are the lessons learned for Pfizer in the remediation of the sterile injectable facilities you acquired, and what steps is the company taking now to mitigate against any potential quality or compliance issues in your legacy facilities to ensure uninterrupted access to a future vaccine?

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?