FRANK PALLONE, JR., NEW JERSEY
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RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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Minority (202) 225-3641

July 28, 2020

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, MD 20852

Dear Dr. Fauci:

Thank you for appearing before the Committee on Energy and Commerce on Tuesday, June 23, 2020, at the hearing entitled "Oversight of the Trump Administration's Response to the COVID-19 Pandemic." We appreciate the time and effort you gave as a witness before the full Committee.

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, August 14, 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

Committee on Energy and Commerce

Hearing on
"Oversight of the Trump Administration's Response to the COVID-19 Pandemic"

June 23, 2020

Anthony S. Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

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

1. It is perplexing that the Trump Administration decided to cancel a research grant that was specifically focused on coronavirus emergence while we are in the midst of a coronavirus pandemic.

   Over 70 Nobel-prize winning American scientists raised alarm about this move, saying it "sets a dangerous precedent by interfering in the conduct of science" and "deprives the nation and the world of highly regarded science that could help control one of the greatest health crises in modern history and those that may arise in the future." More than 30 different scientific societies expressed concern with this decision as well.

   The reported reason for this grant's cancellation was because the Administration "does not believe the current project outcome aligns with the program goals and agency priorities."

   a. What does the science around the coronavirus show regarding the virus's origins? Does the science show that the coronavirus was initially created in a lab or does it show that it was transmitted from an animal to a human?

   b. How would research such as the EcoHealth Alliance grant titled, "Understanding the Risk of Bat Coronavirus Emergence" (funded under grant R01 AI110964 and terminated on April 24, 2020), be relevant to the coronavirus pandemic we are experiencing today?

2. The ongoing inequities in health and health care access among communities of color are concerning, and one critical way to help address these gaps is to ensure diverse participation in the development of medical treatments.

   a. What actions is Operation Warp Speed or the ACTIV partnership taking to address inequities in our research and development of vaccines or treatments for COVID-19?

   Participation aside, we must also make sure approved treatments are effective for all communities. In the case of coronavirus treatment candidates, for example, while results from the Remdesivir clinical trial were positive, the recovery rate ratio reported for Black, Hispanic/Latino, and Asian participants was less than that of White participants. No such reporting line for American Indians or Alaska Natives existed.

Additionally, while news has emerged about another possible breakthrough treatment from the University of Oxford, there is some evidence that some minority populations may respond differently to this type of drug compared to White patients

b. What have the studies shown regarding why Remdesivir may be less effective for Black, Hispanic/Latino, and Asian patient populations? How will the Department of Health and Human Services (HHS) ensure that clinical trials for medical treatments for COVID-19 move forward that benefits or risks for certain populations are adequately communicated?

The Honorable Anna G. Eshoo (D-CA)

1. When does the National Institutes of Health (NIH) anticipate beginning human clinical trials on candidates you are supporting?

2. How many people will need to enroll in these clinical trials to get adequate data?

3. How quickly will you be able to assess a vaccine candidate's safety and effectiveness, the standards for the Food and Drug Administration (FDA) approval, after the trials begin?

4. Would early clinical trial data showing that a patient develops high levels of antibodies without severe side effects be enough to demonstrate safety and effectiveness of a vaccine?

5. What additional data is necessary to prove that a vaccine is safe and effective?

The Honorable Diana DeGette (D-CO)

1. We have seen the importance of medical research that relies on fetal tissue for developing vaccines including polio, rubella, measles, chickenpox, adenovirus, rabies, as well as treatments for debilitating diseases such as rheumatoid arthritis, cystic fibrosis, and hemophilia. Hundreds of millions of lives have been saved worldwide because of these advancements. What ways can research using fetal tissue be used to help scientists find a treatment, cure, or vaccine for COVID-19?

The Honorable Jerry McNerney (D-CA)

1. Do you think that the President's words, actions, or lack of actions, much of which either have ignored or acted against expert medical or epidemiological advice, has enabled the virus to spread beyond what it should have, causing unnecessary illness and death?

The Honorable Gus M. Bilirakis (R-FL)

1. What have you learned about the management of chronic care conditions (like diabetes, hypertension, asthma, etc.) with regard to complications and poor outcomes associated with COVID-19?

    a. Are there differences between patients who manage their condition well versus those who don't?

    b. Can certain treatments make these patients even more susceptible to adverse COVID-19 outcomes – how is this data captured and communicated to patients and their providers expeditiously?

2. As policy makers consult the data to direct response efforts, where do you suggest the goal posts be erected – in other words, where should the bulk of our attention and resources be directed as states reopen?

    a. Is it about total confirmed cases, hospitalizations, or deaths?

    b. Does a response addressing mortality have different considerations than one that prioritizes transmissibility?

3. As we learn more about how COVID has unfolded in our country, we are seeing that it has had a disproportionate impact on certain populations, especially those in nursing homes, frontline healthcare workers, and Native Americans. The underlying challenges that caused these populations to be hard hit in the first place will still be around when we get to the resurgence of COVID in the fall. For example, nursing home patients will continue to have major underlying health conditions; healthcare workers will continue to have the highest exposure risks, even as the demands placed on them increase; and Native Americans will continue to have challenges receiving primary and secondary care services.

    a. Recognizing the challenges for each of these populations, can you describe what special considerations should be made for testing and treatment needs of these populations above and beyond what a response plan might be for the general population?

    b. Can you describe the role of the Federal government to ensure that it is able to provide sufficient testing and treatment needs of these populations?

4. Are there any underreported successes in the Administration's COVID-19 response that you would like to discuss?

The Honorable Earl L. "Buddy" Carter (R-GA)

1. My understanding is that there are a number of drugs currently in shortage or at-risk of being in shortage. In some cases, the ingredients that go into making these drugs are manufactured exclusively overseas which presents national security concerns. I also read that some of the products in the national stockpile needed to be discarded because they had passed their expiration date.

    a. What do you think about using the existing commercial distribution network here in the U.S. to manage and replenish a supply of pharmaceutical products identified by the government as being at high risk of market disruption?

    b. Wouldn't a government-private sector arrangement to ensure we have a stockpile of needed medicines available enable us to address the ongoing shortage concerns and more urgently, ensure we are prepared for future unforeseen health care outbreaks?

    c. How can we develop a longer-term solution to this problem so we are ready for the evolution of the current crisis and for critical patient needs for these products in the future?

2. All of the vaccines being developed appear to be focused on the spike protein which can and does mutate. Should we be looking at the non-mutating part of the virus?

    a. In particular, what about consideration of other targets for immune-therapy?

3. I understand that the National Institute of Allergy and Infectious Diseases (NIAID) has worked in the past with an immunotherapy company that tested ligand epitope antigen presentation system (LEAPS) technology as a new immune-based treatment for influenza virus infection in a mouse model. The study demonstrated a reduction in virus replication in the lungs, enhance survival, and modulate the protective immune responses that eliminate the virus while preventing excessive cytokines that could injure the host. In other words, it reduced mortality and morbidity. And that further work in collaboration with the University of Georgia Vaccine Center is prepared to move forward with further research in this direction.

    a. Do you think this approach (based on previous studies at NIAID) holds some promise as an adjunct to antiviral treatment of COVID-19?