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
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

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

July 28, 2020

Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hahn:

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

Stephen M. Hahn, M.D., Commissioner, U.S. Food and Drug Administration

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

1. 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.

   Clinical trials, and the people who volunteer to participate in them, are essential to help develop vaccines or therapeutics. In order to ensure researchers and Federal agencies have a full picture of the benefits or risks of a medical product, the participants in clinical trials should reflect the makeup of our country and the populations that will be using these products.

   Unfortunately, the Food and Drug Administration's (FDA) 2019 Drug Trials Snapshots report, which highlights the clinical trial diversity for participants in recently approved novel drugs, shows that clinical trial participation of Black Americans was below the percentage of the group's overall representation in our country's population. I recognize the agency is making progress, but there is more work to be done

   a. Seeing that Native, Black, and Hispanic/Latino Americans are disproportionately affected by coronavirus, what specific actions is the FDA and the Administration taking to ensure diverse clinical trials so that we can be sure COVID-19 treatments that are just as safe and effective for these communities?

2. In responding to the COVID-19 public health emergency, FDA has issued a number of emergency use authorizations (EUAs). At an earlier hearing in front of the Health Subcommittee, former BARDA Director Rick Bright said that he faced political pressure from his superiors to request an EUA for hydroxychloroquine and chloroquine, the drugs the President recommended the American people consider taking, without any scientific evidence of their efficacy or potential dangers. FDA granted that EUA request, only to revoke it last week, after finding that the drugs are not effective, may cause dangerous side effects, and may limit the effectiveness of authorized antiviral treatments.

   a. Can you describe why FDA ultimately decided to revoke the EUA for chloroquine and hydroxychloroquine? Please include references to any published literature or studies that FDA relied on when making this determination.

   b. As you know, the Federal Food, Drug, and Cosmetic Act requires FDA to periodically review the circumstances and appropriateness of an EUA. Can you

describe the process FDA is undergoing to review the appropriateness of the EUAs it has issued in response to COVID-19, whether those EUAs are for diagnostic tests, medical devices, or drugs? What criteria will the agency use in deciding to revoke an EUA going forward?

The Honorable Anna G. Eshoo (D-CA)

1. Do you plan on using an Emergency Use Authorization (EUA) for a COVID-19 vaccine and if so, will it still require full safety and efficacy data?

2. What is the timeline for the FDA returning to its drug and API facility inspections in China?

3. How many drugs currently listed on FDA's Drug Shortages Database are in shortage as a result of the COVID-19 pandemic?

4. What has FDA done since the pandemic began in February to track where critical drugs, their active ingredients, and medical products are manufactured, with specific focus on pandemic hot spots?

5. What has FDA done to shore up the U.S. medical product supply chain to avoid disruptions during future waves of the COVID-19 pandemic?

The Honorable Diana DeGette (D-CO)

1. Out of the 20,000 medications FDA regulates, only one requires in-person dispensing and not-in-person administration: mifepristone. As you know, mifepristone is used for medication abortion and early pregnancy loss. Of the 17 drugs that require in-person dispensing, FDA has waived that requirement for two without any publication or justification. However, FDA is still requiring women to travel to get, not necessarily take, mifepristone. What is the health benefit behind continuing to require in-person dispensing of mifepristone, potentially exposing patients and providers to the risk of contracting and spreading Covid-19?

The Honorable Scott Peters (D-CA)

1. We thank FDA for the recent July 2020 release of the Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated:

    a. The agency reported that it has identified 500 Cannabidiol (CBD) products for testing but only had results for 147 of those products. When does the agency expect to complete this testing?

b. Does the agency have a plan for enforcement action against the products its testing revealed are mislabeled? If so, does the agency have sufficient resources to take those actions?

c. The Report stated that the agency identified products based upon, among other things, whether the products' manufacturers had previously received warning letters. What measures are the agency putting in place to make sure that companies that previously received warning letters for marketing illegal CBD products comply with the law?

2. The Committee is particularly concerned that companies illegally marketing CBD for COVID-19 claims cease doing so. What does FDA intend to do to make sure that firms that received warning letters do not continue to market these illegal products?

3. On July 23rd, the Office of Management and Budget (OMB) published that it has received for review from FDA Cannabidiol Enforcement Policy; Draft Guidance for Industry. We strongly support the promulgation of this Guidance. Does the agency have sufficient resources to promptly review the many comments it is likely to receive and swiftly issue a final guidance?

The Honorable Greg Walden (R-OR)

1. Given the recent growth in the cannabidiol (CBD) market, I am supportive of FDA's efforts to bring enforcement actions against those that are illegally marketing CBD products to prevent or cure COVID-19. While the agency's actions are appreciated, the continued uncertainty surrounding the regulation of CBD products remains a concern and unscrupulous actors are taking advantage of consumer confusion during this public health crisis. As such, I ask that you please provide an update on:

    a. FDA's progress toward issuing additional guidance to stakeholders on CBD;

    b. The status of market surveillance and testing of CBD products, and;

    c. Responses that have been provided to the CBD- related citizen petitions that ask the agency to create a regulatory pathway for CBD in dietary supplements and foods, and how many, if any, petitions are still pending a response.

The Honorable Fred Upton (R-MI)

1. Given the amount of enforcement discretion and temporary policy considerations provided during the current public health emergency, how is FDA planning to transition and return to the previous regulatory position?

2. With respect to compounding policy flexibilities, some are suggesting temporary measures, like the ability to compound from bulk substances, be made permanent. Is there a process FDA is following to evaluate this and other temporary measures?

The Honorable Brett Guthrie (R-KY)

1. Commissioner Hahn, I introduced H.R. 5663, the Safeguarding Therapeutics Act, before Coronavirus was on the radar but how can H.R. 5663 help FDA stop counterfeit COVID medical devices and test from being used in the United States?

    a. How many counterfeit COVID tests has the FDA been able to stop thus far?

The Honorable Gus M. Bilirakis (R-FL)

1. COVID-19 threatens to undue the progress we've made in combatting opioid abuse. Many chronic pain patients haven't been able to go in for elective procedures or attend physical therapy to alleviate their pain through non-opioid alternatives. Additionally, those who suffer from opioid use disorder may not have been able to seek mental health or support services during this time. These circumstances may increase the likelihood that patients will revert to prescription opioid use and as such, the COVID-19 pandemic is highlighting how critical it is that we continue to advance non-opioid pain medications?

    a. To that end, can you briefly touch on the ongoing work FDA is doing to provide patients with non-opioid alternatives?

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

3. As our Nation begins to reopen, I've heard reports of supply shortages and "adulterated products" with hand sanitizer. Given the recent rise in positive COVID-19 cases in Florida, I want to ensure as schools and businesses in the state continue to advance toward full reopening that there is enough "FDA approved" hand sanitizer that consumers may need.

    a. Given the U.S. maintains a 25% section 301 tariff on hand sanitizer from China, does FDA anticipate issues regarding the availability of FDA-approved hand sanitizer as the Nation continues to reopen

    b. Does FDA believe the Office of the U.S. Trade Representative (USTR) "temporary waivers" on FDA-approved hand sanitizer from China may be necessary to address potential shortages associated with reopening or is FDA confident in our capacity to address potential shortages domestically?

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?