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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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WASHINGTON, DC 20515-6115

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July 28, 2020

ADM Brett P. Giroir, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear ADM Giroir:

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

ADM Brett P. Giroir M.D., Assistant Secretary for Health
U.S. Department of Health and Human Services

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

1. The COVID-19 public health emergency has triggered distress for many Americans, such as experiencing the loss of family or community members, loss of employment, insurance, or other supports.

   It was reported early on that the Disaster Distress Helpline, which is supported by the Substance Abuse and Mental Health Services Administration (SAMHSA), saw an 891 percent increase in call volume in March 2020 compared to March 2019. Close to half of Americans say that their mental health has been negatively affected due to worry and stress over the virus

   a. What actions are the Administration taking to address the mental health effects of the coronavirus pandemic? Is there a coordinated response among the agencies? If so, who is leading interagency efforts?

   b. The Heroes Act included $3 billion for SAMHSA to increase mental health services, substance use disorder treatment, and outreach to communities during this challenging time. What additional resources do you believe are necessary to help with the Administration's response efforts for individuals experiencing mental health impacts of this pandemic?

   c. Another area of concern and interest has been the mental health impact of this pandemic on our frontline health workers. What does the Administration know now about the short- and long-term effects of the coronavirus pandemic on our Nation's frontline health workers and would the Administration support further research in this area?

The Honorable Tony Cárdenas (D-CA)

1. According to the opinion of experts at the Centers for Disease Control and Prevention/U.S. Department of Health and Human Services (CDC/HHS) and CDC/HHS data, as of June 23, 2020, what diagnostic testing capacity is required for federal, state, and local public health agencies for the detection of COVID-19 in Americans?

2. On what date did the CDC/HHS get notified that COVID-19 was anticipated to affect American citizens in the United States?

    a. What was the first estimated quantity of tests and test kits that the United States would need for the detection of COVID-19? What was the first estimated quantity of Personal Protective Equipment (PPE) – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – that the United States would need?

    b. Subsequent to the initial estimates of tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – needed, when was the next adjustment to that estimate? How often did the CDC/HHS update these estimates and projected needs? What were the estimates per week from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

    c. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – did the CDC/HHS have available per day from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

    d. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – did the CDC/HHS distribute to each state, territory, and tribe per day from the first anticipated date of COVID-19 cases affecting American citizens in the United States through June 23, 2020?

    e. How many tests, test kits, and PPE – specifically ventilators, N95 respirators, surgical masks, face shields, gloves, and gowns – were requested by each state, territory, and tribe per day from the first anticipated date of COVID-19 affecting American citizens in the United States through June 23, 2020?

The Honorable Cathy McMorris Rodgers (R-WA)

1. I read news reports last week about dexamethasone, a low-dose steroid treatment that showed some promising results in helping critically ill COVID-19 patients on ventilators. The UK has added 200K courses to its stockpile. In addition, I have seen studies regarding Giapreza, a Food and Drug Administration (FDA) approved treatment for septic shock. My understanding is about 50% of severe COVID-19 cases develop septic shock and this treatment showed almost a 30% benefit for patients on mechanical ventilation.

    a. Does HHS plan to incorporate potential treatments like these into the Strategic National Stockpile?

    b. And if not, how is the agency ensuring hospitals have all the tools necessary to fight this epidemic?

The Honorable Adam Kinzinger (R-IL)

1. Many on this committee are deeply concerned about – and have pushed for – stronger World Health Organization (WHO) accountability: not only accountability for what the WHO knew and when about the COVID-response, but also accountability to broader U.S. interests, concerns and priorities related to public health. While the WHO can play a critical role in an effective, global pandemic response, the organization – and its leadership – clearly must take steps to rebuild trust through significant reform. The United States has long played a critical role at the WHO pushing for these reforms, speaking up for U.S. interests, and pushing back on harmful initiatives that would undermine U.S. health and economic leadership. The Administration's July 7 letter to U.N. Secretary-General Antonio Guterres giving one year's notice for withdrawal from the WHO sends a clear signal that the United States will not stand for an organization that is unwilling to reform, and provides important leverage to push for both answers about how the WHO has handled the pandemic and how it will change to address current criticisms. Yet the follow-up steps are not quite clear – and many have questions about how the U.S. will use the one-year window to press for the reforms that we all agree are needed. I am concerned that these necessary reforms will not happen without the United States leading the charge for change, while leaning in and working with other likeminded countries that share these concerns.

    a. What reforms does the United States need to the WHO to make to address global criticisms and rebuild trust?

    b. How has the United States presented its priorities to the WHO leadership, and how have they responded?

    c. What is the Administration's plan during the withdrawal period to press for those reforms? How can it work with like-minded countries?

The Honorable Gus M. Bilirakis (R-FL)

1. As we continue to progress, we know there will come a time for the public health emergency declaration associated with COVID-19 to end and with it the waiver authorities associated with response.

    a. Can you describe what metrics will factor into HHS's decision to end the emergency declaration?

    b. With concerns around a potential 2nd wave co-occurring in the fall with the flu season, does the Agency envision making this decision prior to entering the upcoming flu season?

    c. Does HHS envision these waiver authorities expiring immediately or taking more of a glide path?

    d. Are there any specific waivers HHS currently envisions keeping?

e. Will HHS be engaging provider stakeholders on this and, if so, how and when does the Agency envision that occurring?

2. Today's lean manufacturing supply chains often operate "just in time" instead of "just in case" to reduce costs and maximize efficiency; however, this is a duel edge that can present challenges in the midst of a pandemic response – as we saw with personal protective equipment. How can we balance resiliency with value?

3. Did COVID-19 illuminate barriers to care? If so, what are those barriers? Does the Agency have the necessary authority to address these barriers and, if not, what can Congress do to address?

4. Were states and localities properly set up to order and receive shipments from the Strategic National Stockpile – if not, how did that impact the effectiveness of their response?

5. Moving forward, how can essential workers and industries (groceries, meat processing, delivery, etc.) be better reflected disaster planning? Are there best practices states and their localities should be aware of?

6. Under the Inpatient Prospective Payment system, the diagnosis related group (or DRG) is based on the average resources used to treat an inpatient patient from admission to discharge. However, given the novel nature of COVID-19, I'm aware of reports from providers that it's hard to understand the full scope of costs associated with treating these patients and the DRG has the potential to create a cost conflict for hospitals to provide certain treatments for patients – especially impactful to small, rural areas. Is HHS aware of this issue and (if so) what is the Agency considering – has the Agency considered excluding COVID-19 treatments from the DRG bundle?

7. After a COVID-19 vaccine is developed, the conversation shifts to coverage. Are these conversations already occurring – if not, when would you expect those payer conversations to occur?

8. 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?

The Honorable Jeff Duncan (R-SC)

1. Regarding PPE shortages, I'd like to note how amazing it's been to see several local companies just in my district coming forward offering to alter their manufacturing operations to provide PPE to businesses and individuals in need during COVID-19.

    a. Does HHS know if the U.S. manufacturing base for PPE is usually enough to meet the needs of our country, outside of a pandemic situation?

    b. If it's not, are there steps that could be taken by the Administration or Congress to encourage additional domestic production of PPE?

2. Following the release of the Administration's testing blueprint, I know several private companies and universities, including Clemson University in my district, came forward with new widespread diagnostic testing proposals. It's really been a whole-of-America approach here. Can you speak to the overall progress our Nation has made on COVID-19 testing, including the many widespread diagnostic testing proposals that private industry folks have released?