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ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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January 2, 2020

The Honorable Robert Kadlec
Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Dr. Kadlec:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, December 4, 2019, at the hearing entitled "Flu Season: U.S. Public Health Preparedness and Response." 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 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 Thursday, January 16, 2020. As previously noted, this transmittal letter and your responses, 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 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
"Flu Season: U.S. Public Health Preparedness and Response"

December 4, 2019

The Honorable Robert Kadlec, M.D. M.T.M&H, M.S.
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

The Honorable Brett Guthrie (R-KY)

1. One division within the U.S. Department of Health and Human Services (HHS) that did not testify at the December 4, 2019 hearing was the Centers for Medicare and Medicaid Services (CMS). CMS, however, can impact flu vaccination through its reimbursement policies.

   In order to improve both seasonal and pandemic influenza preparedness, should CMS consider preferential reimbursements—reimbursing certain products at a higher rate—to incentivize a greater domestic manufacturing footprint for different types of flu vaccines, such as the cell-based and recombinant vaccines?

2. What steps is the Administration taking to address the pipeline of antibiotic drugs that are so critical for our pandemic response and national security?

The Honorable Brett Guthrie (R-SC)

1. In your March 14, 2019 testimony to the Senate Appropriations Committee, you stated "I think if you ever had a chance to look at the curves of, not necessarily what happened in 1918, but if we projected what would happen today in terms of the speed of the transmission of a flu-like illness in a population that's vulnerable, it would be explosive. And in some ways, the faster you can get vaccines, literally, saves thousands of lives. And again, the economic benefits are also derived from that." You stated that "One of the challenges we have now quite frankly with our flu vaccine supply is the predominance of that is from eggs."

   a. Given the issues associated with derivation of vaccines from eggs, both in time and efficacy, do you support investment in late-stage non-egg-based technologies?

   b. Do you believe HHS, specifically BARDA, should ensure novel, multi-modal technologies are being supported to better respond to influenza?

   c. Is there a benefit to our population to invest in platform technology that cannot only respond rapidly to influenza, but Ebola and other emerging threats?

The Honorable Susan Brooks (R-IN)

1. Pandemic influenza and emerging infectious diseases are one of the greatest biological threats we are facing – but one thing I am aware of are the significant funding pressures on the entire Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), especially the strategic national stockpile (SNS).

   The PHEMCE Multi-Year Budget outlined $1.2 billion in funds needed for the SNS in FY20. These funds are needed for replenishment of existing countermeasures and procurement of new products. And last year, I believe the FDA approved 28 new medical countermeasures & more were approved this year. The House Labor-HHS bill got as close to the needed number as possible - $920 million.

   a. Could you explain how important adequate funding for the SNS is for ensuring we are prepared for the threats of pandemic influenza, emerging infectious diseases like Zika and Ebola, and intentional biological threats like smallpox or anthrax?

   b. And, could explain what happens if the SNS does not receive funding? My understanding is that inadequate funding places stress on the larger PHEMCE – and especially other priority areas like the Special Reserve Fund, or funding to combat Pandemic Influenza, EIDs like Ebola or Zika, or antimicrobial resistance.

2. As you know, in October the White House issued an Executive Order titled "Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health." The Executive Order looks at four critical areas: (1) the health and economic impact of a flu pandemic; (2) ensuring an "all of government approach" to preparedness; (3) improving existing vaccines and developing new technologies; and (4) manufacturing more effective vaccines faster.

   The EO referenced a recent Council of Economic Advisors (CEA) report which found a severe pandemic could have $3.7 trillion in economic costs and would lead to the hospitalization of 4.3 million people. The EO recommended a range of government actions to improve the 80-year old egg-based technology used in today's vaccines and speed the vaccine manufacturing process.

   We know that HHS lacks sufficient Congressional funding to achieve these goals. Last year, BARDA received just $270 million for pandemic flu preparedness, while the most recent PHEMCE multi-year budget outlined $775 million in funding needed this year alone to achieve basic preparedness.

   Dr. Kadlec, we know that once a pandemic is identified, the U.S. government will immediately need $10-12 billion just to provide vaccines to protect the American people. That doesn't take into account all of the funding now to prepare and implement the Executive Order.

a. Do you agree we need to devote substantially more funding to pandemic preparedness?

b. What are you doing to ensure BARDA, CDC and other HHS agencies have the resources they need to be prepared?

c. Will we see additional funding requests to support the EO in the President's Budget in February?

3. We know that influenza viruses change over time, creating serious challenges for public health. As a New York Times article described earlier this year, flu viruses evolve constantly – they are "ruthless masters of disguise" when it comes to tricking our immune systems.

   The egg-based manufacturing process has been a mainstay of influenza vaccine production for more than 80 years. This process is well established and has made a significant contribution to public health. However, dependence on egg-based technology has significant limitations, including long supply times and the potential for virus mutations during the production process as the virus adapts to grow in the eggs.

   Cell- based vaccine manufacturing can address limitations of the egg-based process. This technology provides the ability to scale flu vaccine manufacturing with greater efficiency and avoids egg-adaptation, thereby providing a better "antigenic" match to circulating strains.

   a. What is ASPR and BARDA doing to optimize the use of cell-based manufacturing processes for flu vaccines?

   b. How can the growth and expansion of cell-based vaccines technologies improve our ability to respond to a flu pandemic and protect the American people?

   c. Does the government have plans to procure additional doses of cell-based vaccines through agencies such as the VA and the Department of Defense to support the growth and usage of these innovative technologies, especially as I understand there is some evidence that these vaccines could provide better protection for vulnerable veterans and the military that stands on the frontline of America's defense.

4. During FDA's vaccine approval process, randomized clinical trials (RCTs) are essential to determining the safety and efficacy of a vaccine. However, after a vaccine becomes licensed, a tremendous amount of real-world evidence (RWE) is generated from the millions of Americans being vaccinated each season.

   Given the changing nature of the influenza virus, this data can show how vaccines behave and protect diverse and critical populations, such as children and the elderly, in "real" and across multiple influenza seasons. It allows researchers to better measure clinical outcomes and could be useful in guiding policies for FDA and CDC and improving vaccine technology in the future.

In practice, RWE provides a living, breathing, pool of data to help the U.S. government and the global influenza community gain a practical perspective on how to predict and prevent the spread of influenza each season, and potentially determine best programs for vaccine implementation. But it appears the government and public health stakeholders are not taking advantage of these benefits and the data collected each year from vaccination programs run by CMS, the VA, and the DOD.

a. What is FDA doing to capture more RWE during each flu season?

b. What public health lessons could be learned from examining RWE every year?

c. Do you believe it would be useful to incorporate RWE into your decision making processes during each flu season?

d. Could RWE be included in the future in FDA product labels?

5. The President's September Executive Order (EO) on flu vaccines directs agencies, including ASPR and BARDA, to 'advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunities.' However, the recent BARDA RFI posted on October 30 only requests information on manufacturing capacity for vaccines and adjuvants. Will there be additional BARDA opportunities that are intended to help with research and development for new, broadly protective vaccine candidates – particularly for technologies that may be in Phase I?