FRANK PALLONE, JR., NEW JERSEY
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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
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January 2, 2020

Dr. Nancy Messonnier
Director
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Messonnier:

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

Nancy Messonnier, M.D. (CAPT, USPHS, RET), Director
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

The Honorable Jan Schakowsky (D-IL)

1. Though a bout of the flu can be miserable for any person affected, in older adults the consequences can be far more severe and long lasting. Frail adults in nursing homes suffering from vaccine preventable illness often experience permanent loss of mobility, reduced independence or ability to engage in activities of daily living, and increased mortality.

   Please elaborate on the specific impact of seasonal influenza in long-term care settings. What can health care providers in long-term care settings or public health officials do to protect this particularly vulnerable population from the flu?

The Honorable Brett Guthrie (R-KY)

1. According to a November 14, 2019, USA Today article, doctors are recommending the Fluzone High-Dose flu vaccine or FLUAD, a regular flu vaccine with an adjuvant, an immune stimulant, over the standard-dose flu vaccine for the demographic most vulnerable to seasonal flu: people 65 and older. In addition, in an October 28, 2019, article, the Boston Globe reported that seniors are requesting the high-dose flu shot, and that roughly two-thirds of older adults who get flu shots now get high-dose vaccines.

   The CDC's Advisory Committee on Immunization Practices (ACIP) has not made a preferential recommendation for Fluzone or FLUAD over the standard-dose flu vaccine, however, even though the high-dose vaccine was approved by the FDA in 2009 and has been on the market for a decade.

   Given the widespread support in the medical community for the high-dose vaccine or adjuvanted flu vaccine over the standard dose vaccine, is there a risk that the Centers for Disease Control and Prevention's (CDC) ACIP is being too cautious by not issuing a preferential recommendation for certain flu vaccines for seniors, and thus conveying the impression that the standard dose vaccine efficacy data is equivalent to the efficacy data of the alternatives?

2. Individuals with the flu have an increased risk of bacterial infections, such as pneumonia. According to a new report published by CDC last month about antibiotic resistance threats, each year in the United States, more than 2.8 million people get antibiotic-resistance infections, and more than 35,000 people die as a result. Given CDC's concerns and the devastating impact that antimicrobial resistance can have on individuals with the flu, what is CDC doing to address antimicrobial resistance?

The Honorable Susan Brooks (R-IN)

1. 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 CDC 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?