



MEMORANDUM

November 26, 2019

To: Subcommittee on Oversight and Investigations Members and Staff

Fr: Committee on Energy and Commerce Staff

Re: Hearing on “Flu Season: U.S. Public Health Preparedness and Response”

On **Wednesday December 4, 2019, at 10:30 a.m. in the John D. Dingell Room, 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “**Flu Season: U.S. Public Health Preparedness and Response**.” The hearing will examine the Federal Government’s efforts and forecast for the 2019–2020 influenza season and ongoing influenza-related research and innovation.

I. BACKGROUND

Influenza (flu) is a contagious respiratory illness caused by influenza viruses that can infect the nose, throat, and lungs.¹ Typical flu symptoms include fever, cough, and sore throat.² Complications from the flu can lead to serious illness that are life-threatening or potentially even result in death.³ Children younger than age five, adults ages 65 and older, those who are pregnant, and people with other medical conditions are at a higher risk for developing flu-related complications.⁴ Timing and duration of flu seasons vary, but increased flu activity often begins in October and can last as late as May, with peak activity generally occurring between December and February.⁵

Recent flu seasons have been unique in their duration and severity. The 2018–2019 flu season was the longest flu season in a decade, marked by two separate waves of the influenza

¹ Centers for Disease Control and Prevention, *Key Facts About Influenza (Flu)* (www.cdc.gov/flu/about/keyfacts.htm) (accessed Nov. 18, 2019).

² *Id.*

³ *Id.*

⁴ Centers for Disease Control and Prevention, *People at High Risk for Flu Complications* (www.cdc.gov/flu/highrisk/index.htm) (accessed Nov. 18, 2019).

⁵ Centers for Disease Control and Prevention, *The Flu Season* (www.cdc.gov/flu/about/season/flu-season.htm) (accessed Nov. 18, 2019).

type-A virus, beginning with the strain known as H1N1 and ending with the H3N2 strain.⁶ Based on preliminary Centers for Disease Control and Prevention (CDC) estimates, there were 37–43 million flu illnesses, up to 20 million medical visits, as many as 647,000 hospitalizations, and up to 61,200 possible deaths due to flu last season.⁷ The 2017–2018 flu season was shorter, though more severe: nearly 80,000 people died and more than 900,000 people were hospitalized due to the flu, overwhelming hospitals to the point that some pitched tents in parking lots to address the surge of patients.⁸

Thus far this 2019–2020 flu season, the majority of the United States has experienced minimal or low influenza-like activity, with increasing activity in parts of the country.⁹ High influenza-like activity levels have been reported in seven states and Puerto Rico. As of November 16, 2019, four influenza-associated pediatric deaths have been reported to CDC this season.¹⁰ Health officials often look to the severity of the flu season in Australia—which was early and severe this year—as a possible indicator of the upcoming flu season in the United States.¹¹ CDC states, however, that Australia’s flu season is not necessarily a predictor of the flu season to come in the United States because the virus can change within a season as it moves from country to country.¹²

II. FLU VACCINE RATES AND EFFECTIVENESS

CDC recommends that every person over six months of age get a flu vaccine every season “as the first and most important step in protecting against flu viruses.”¹³ Despite this long-standing recommendation, annual flu vaccination coverage for the 2018–2019 flu season remained lower than national target rates, which range from 70–90 percent depending on the population.¹⁴ The vaccination rate among children ages six months through 17 years for the

⁶ Centers for Disease Control and Prevention, *Update: Influenza Activity in the United States During the 2018–19 Season and Composition of the 2019–20 Influenza Vaccine*, Morbidity and Mortality Weekly Report (MMWR) (June 21, 2019).

⁷ Centers for Disease Control and Prevention, *2018–2019 U.S. Flu Season: Preliminary Burden Estimates* (www.cdc.gov/flu/about/burden/preliminary-in-season-estimates.htm) (accessed Nov. 18, 2019).

⁸ *Flu Broke New Records for Deaths, Illnesses in 2017-2018, New CDC Numbers Show*, Washington Post (Sept. 27, 2018).

⁹ Centers for Disease Control and Prevention, *Weekly U.S. Influenza Surveillance Report* (www.cdc.gov/flu/weekly/index.htm) (accessed Nov. 15, 2019).

¹⁰ *Id.*

¹¹ *Health Officials Predict Severe Flu Season*, U.S. News (Sept. 18, 2019).

¹² *Flu Season is Here and Now is the Time to Get a Flu Shot*, CNN (Oct. 7, 2019).

¹³ Centers for Disease Control and Prevention, *CDC Says “Take 3” Actions to Fight Flu* (www.cdc.gov/flu/prevent/preventing.htm) (accessed Nov. 18, 2019).

¹⁴ U.S. Department of Health and Human Services, *Healthy People 2020* (www.healthypeople.gov) (accessed Nov. 18, 2019).

2018–2019 flu season was 63 percent, while the adult vaccination rate for the same season was just 45 percent.¹⁵ The vaccine typically reduces an individual’s risk of becoming infected with the flu by 40 to 60 percent.¹⁶ Even during years of reduced vaccine effectiveness, the flu vaccine is associated with less severe symptoms for those who do become infected and can be life-saving, particularly for children.¹⁷

III. FLU VACCINE ADVANCEMENTS

Influenza viruses mutate rapidly from year to year and throughout the season. While the World Health Organization monitors and recommends compositions of the flu vaccine prior to the following season, each country makes their own determination as to which viruses to include in their flu vaccine. In the United States, the Food and Drug Administration (FDA) makes this final decision.¹⁸

The flu vaccine is manufactured using live viruses, traditionally grown in hen eggs before being inactivated.¹⁹ Newer technology, referred to as a “cell-based flu vaccine,” uses cultured mammalian cells to grow the virus instead of hen eggs. Cell-culture technology presents more flexibility than traditional technology, and has the potential to offer better protection than egg-based vaccines.²⁰ Cell-culture technology may also permit faster start-up of the vaccine manufacturing process in the event of a flu pandemic.²¹

In February 2018, the National Institute of Allergies and Infectious Diseases (NIAID), within the National Institutes of Health (NIH), announced a new initiative to develop a universal vaccine to target influenza type-A virus strains and offer broader protective immunity.²² In April 2019, NIAID announced the start of the first in-human clinical trial of the universal influenza vaccine.²³ On September 19, 2019, President Trump issued an Executive

¹⁵ Centers for Disease Control and Prevention, *Flu Vaccination Coverage, United States, 2018–19 Influenza Season* (Sept. 26, 2019).

¹⁶ Centers for Disease Control and Prevention, *Vaccine Effectiveness: How Well Does the Flu Vaccine Work?* (www.cdc.gov/flu/vaccines-work/vaccineeffect.htm) (accessed Nov. 18, 2019).

¹⁷ *Id.*

¹⁸ Centers for Disease Control and Prevention, *Selecting Viruses for the Seasonal Influenza Vaccine* (www.cdc.gov/flu/prevent/vaccine-selection.htm) (accessed Nov. 18, 2019).

¹⁹ Centers for Disease Control and Prevention, *Cell-Based Flu Vaccines* (www.cdc.gov/flu/prevent/cell-based.htm) (accessed Nov. 18, 2019).

²⁰ *Id.*

²¹ *Id.*

²² National Institutes of Health, *Universal Influenza Vaccine Research* (www.niaid.nih.gov/diseases-conditions/universal-influenza-vaccine-research) (accessed Nov. 18, 2019).

²³ National Institutes of Health, *NIH Begins First-in-human Trial of a universal Influenza Vaccine Candidate* (press release) (Apr. 3, 2019).

Order establishing a National Influenza Vaccine Task Force and other initiatives intended to modernize flu vaccine manufacturing and accelerate universal flu vaccine development.²⁴

IV. FEDERAL AGENCY RESPONSIBILITIES

CDC is responsible for collecting, compiling, and analyzing information on seasonal flu activity year-round in the United States, including tracking trends in the rates of illness, hospitalizations, and death.²⁵ Through its surveillance system, CDC monitors the types and subtypes of circulating flu viruses, the emergence of new strains, and the geographic spread of the flu virus.²⁶ CDC also conducts studies to measure the benefits of seasonal vaccination each flu season to help determine how well vaccines are working.²⁷ Additionally, CDC administers two vaccine programs, the Public Health Services Act Section 317 Immunization Program and the Vaccines for Children program, which provide vaccines to uninsured and underinsured children, adolescents, and adults. CDC also supports local, state, and national public health and emergency preparedness infrastructure.²⁸

NIH, through NIAID, conducts and supports research to generate the essential knowledge for developing safe and effective vaccines, including for influenza and the development of a universal flu vaccine.²⁹ NIAID also conducts and supports research to find new and improved influenza treatments and diagnostics.³⁰ This research includes clinical trials related to influenza vaccines, treatments, and diagnostics.³¹

The Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS) leads Federal public health and medical preparedness, response, and recovery to disasters and public health emergencies, including

²⁴ Exec. Order No. 13887, 84 Fed. Reg. 49935 (Sept. 19, 2019). See White House, *Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health* (Sept. 19, 2019).

²⁵ Centers for Disease Control and Prevention, *U.S. Influenza Surveillance System: Purpose and Methods* (www.cdc.gov/flu/weekly/overview.htm) (accessed Nov. 18, 2019).

²⁶ *Id.*

²⁷ Centers for Disease Control and Prevention, *CDC Seasonal Flu Vaccine Effectiveness Studies* (www.cdc.gov/flu/vaccines-work/effectiveness-studies.htm) (accessed Nov. 18, 2019).

²⁸ Centers for Disease Control and Prevention, *State and Local Readiness* (www.cdc.gov/cpr/readiness/index.htm) (accessed Nov. 18, 2019).

²⁹ National Institutes of Health, *Vaccines* (www.niaid.nih.gov/research/vaccines) (accessed Nov. 18, 2019).

³⁰ National Institutes of Health, *Influenza* (www.niaid.nih.gov/diseases-conditions/influenza) (accessed Nov. 18, 2019).

³¹ *Id.*

pandemic influenza.³² ASPR's Biomedical Advanced Research Authority (BARDA) contracts with vaccine manufacturers for advanced research and development for vaccine technologies to respond to public health emergencies.³³ Effective October 1, 2018, ASPR is also responsible for the oversight and operation of the Strategic National Stockpile (SNS)—previously maintained by CDC—the Nation's repository of flu vaccines and other critical pharmaceutical products and medical supplies for use during a public health emergency.³⁴

FDA is responsible for ensuring the safety, effectiveness, and supply of flu vaccines and flu antiviral drugs through the issuance of guidance, consultation with manufacturers, and regulation of the vaccine's production and use.³⁵ FDA annually reviews and approves the composition of the seasonal vaccine as the flu viruses evolve.³⁶

V. WITNESSES

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³² U.S. Department of Health and Human Services, *HHS Office of the Assistant Secretary for Preparedness and Response* (www.phe.gov/about/aspr/Pages/default.aspx) (accessed Nov. 18, 2019).

³³ U.S. Department of Health and Human Services, *Biomedical Advanced Research and Development Authority* (www.phe.gov/about/bar-da/Pages/default.aspx) (accessed Nov. 18, 2019).

³⁴ U.S. Department of Health and Human Services, *Strategic National Stockpile* (<https://chemm.nlm.nih.gov/sns.htm>) (accessed Nov. 18, 2019).

³⁵ Food and Drug Administration, *FDA's Critical Role in Ensuring Supply of Influenza Vaccine* (Mar. 1, 2019).

³⁶ *Id.*