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ONE HUNDRED FOURTEENTH 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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July 29, 2015

The Honorable Sylvia Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee on Energy and Commerce is continuing its examination of the U.S. public health response to seasonal influenza. We received HHS's response to our letter dated March 9, 2015, as well as the responses from HHS agencies involved in seasonal influenza preparedness activities (National Institutes of Health, Centers for Disease Control and Prevention, Food and Drug Administration, and Biomedical Advanced Research and Development Authority). The responses are attached for your reference.

The mismatched seasonal influenza vaccine and the high death rate among the elderly and other high-risk populations in the U.S. during the 2014-2015 influenza season highlight the need for an improved response, including making seasonal influenza vaccines more effective and promptly available. We believe understanding the lessons from the 2014-2015 influenza season could improve the U.S. public health response in the future and possibly save thousands of lives. We write to seek further information on HHS's current preparedness efforts for the 2015-2016 influenza season, and to work with you to improve the nation's response to seasonal influenza.

To assist the committee, please provide the following by August 12, 2015:

Unredacted versions of any documents sent to and/or from you or the Office of the Secretary that discuss recommendations or lessons learned from the 2014-2015 influenza season or preparations for the 2015-2016 influenza season, and/or any unredacted versions of documents related to a briefing or briefings for you or the Office of the Secretary in 2015 on seasonal influenza vaccine mismatch issues.

Production of the documents will facilitate our investigation and an accurate understanding of the facts. The committee seeks to work cooperatively with HHS to safeguard any sensitive information to address any concerns in this area.

Please also respond by August 12, 2015 to the following questions:

1. What are the mismatch risks this year? What are the contingency plans for the upcoming 2015-2016 season in the event of a mismatch?

2. CDC has provided a 94 percent expected coverage estimate for the mammalian cell propagated parent of the egg-adapted H3N2 strain, which appears to have undergone significant antigenic change during egg passage. What is the expected coverage by the egg-adapted H3N2 strain in most of the vaccine supply for the 2015-16 influenza season?

3. Seasonal influenza has significant health and economic impacts, and in some cases greater impact than in a pandemic. For example, the 2009 H1N1 pandemic resulted in about 12,000 deaths, but close to 50,000 deaths have resulted from seasonal influenza when the H3N2 strain is dominant such as in the most recent influenza season. According to the World Health Organization (WHO), annual seasonal influenza epidemics result in about 3 million to 5 million cases of severe illness and about 250,000 to 500,000 deaths worldwide, which is likely an underestimation. As noted in a 2012 report by the Center for Infectious Disease Research & Policy, "[T]hese figures indicate that the cumulative health impact of seasonal influenza over the last century rivals the potentially explosive, but time-limited, impact of the four pandemics of the past 100 years."

   Given that the health and economic impacts of severe influenza outbreaks are significant, and arguably on par with other threats such as Ebola, MERS, H5N1 and H1N1 for which public health emergency declarations and Public Readiness and Emergency Preparedness (PREP) Act declarations have been used to support availability of medical counter-measures, should seasonal influenza outbreaks (for example, in the event of a vaccine mismatch) be considered public health emergencies?

4. According to the FDA response, a monovalent rescue vaccine was prepared in response to a possible vaccine mismatch because of a drifted (H1N1) strain for the 1986-1987 season in July 1986, even though there was very little information about the mismatch. In contrast, no action was taken in the early summer of 2014 for emerging evidence of a drifted strain in the 2014-2015 season, even though CDC testified that the mismatch was around 36 percent at the time. The CDC witness testified at the February 3 oversight hearing that by the time a 50 percent mismatch was determined in September 2014, it was too late to pursue a monovalent vaccine. However, CDC's acting influenza division director told committee staff in a briefing by telephone that a mismatch between 20-30 percent would be significant evidence of drift.

   (a) What criteria will trigger action on pursuing a monovalent rescue vaccine in the event of a mismatch?

(b) Under what circumstances would it be appropriate to pursue a monovalent rescue vaccine to respond to a drifted seasonal influenza strain?
(c) Are there any contingency plans for a monovalent rescue vaccine in the event of a seasonal influenza vaccine mismatch?

5. A recent CDC study that examined clinician treatment practices for outpatients with influenza during the 2012-2013 season showed that only 16 percent of patients with laboratory-confirmed influenza were prescribed antiviral drugs, while as many as 30 percent were prescribed one of three common antibiotics. In light of such findings, should there be greater emphasis and timeliness in federal public communications about the use of antiviral medications as a "second line of defense" against seasonal influenza?

6. According to the HHS website, flu.gov, 90 percent of influenza-related deaths and more than half of influenza-related hospitalizations occur in people age 65 and older. Last year's severe influenza season was reportedly the deadliest for seniors in five years. A recent study showed that a new high-dose vaccine was 24.2 percent more effective in preventing influenza in adults 65 years and older relative to a standard-dose vaccine. Another study based on data from more than 2 million Medicare beneficiaries suggests that the high-dose influenza vaccine works better than a standard-dose vaccine for preventing probable influenza illness and influenza-related hospital admissions in elderly people. The study, published by the journal *The Lancet Infectious Diseases*, was funded by the FDA and included authors from that agency as well as from the Center for Medicare and Medicaid Services and the CDC. The CDC says it has not expressed a preference for either the high-dose or standard vaccine, but that the new findings will be considered in the future policy deliberations of the CDC's Advisory Committee on Immunization Practices (ACIP). CDC told committee staff in a briefing that the high-dose vaccine would not be on the CDC's ACIP agenda until February 2016. In light of these studies, is there any way to expedite consideration of these studies to see if CDC should express a preference on high-dose vaccines?

7. The Department's response stated that HHS/CDC purchases and distributes approximately 10 to 15 percent of the total seasonal influenza vaccines available in the United States each year through CDC's Vaccines for Children and Section 317 Immunization Programs. What are the total annual expenditures for seasonal influenza vaccines under these programs? Does HHS/CDC use its purchasing power to require measurement of outcomes for the seasonal influenza vaccines it purchases (i.e., vaccine effectiveness as measured by the degree of match of the vaccine to circulating seasonal strains or reductions in deaths or hospitalizations)? If so, what are the measurements, and what have they shown?

8. Has there ever been an emergency use authorization and/or an expanded use authority to allow use of an unlicensed seasonal influenza vaccine?

An attachment to this letter provides additional information about how to respond to the committee's request. If you have any questions regarding this request, please contact Alan

Slobodin with the majority committee staff at (202) 225-2927 and Una Lee with the minority committee staff at (202) 225-3641.

Sincerely,

Fred Upton
Chairman

Frank Pallone, Jr.
Ranking Member

Tim Murphy
Chairman
Subcommittee on Oversight
and Investigations

Diana DeGette
Ranking Member
Subcommittee on Oversight
and Investigations

Attachments: Instructions on Responding to Committee Document Requests

April 27, 2015 letter from HHS Assistant Secretary for Legislation Jim R. Esquea

April 13, 2015 letter from BARDA Director Robin Robinson

April 9, 2015 letter from CDC Director Thomas R. Frieden

April 8, 2015 letter from FDA Associate Commissioner for Legislation Thomas A. Kraus

April 2, 2015 letter from NIAID Director Anthony S. Fauci

cc: Dr. Thomas Frieden, Director, CDC

Dr. Stephen Ostroff, Acting Commissioner, FDA

Dr. Robin Robinson, Director, BARDA

Dr. Anthony Fauci, Director, National Institute of Allergies and Infectious Diseases.