THE COMMITTEE ON ENERGY AND COMMERCE

February 11, 2013

Majority Memorandum

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on "Influenza: Perspective on Current Season and Update on Preparedness"

On Wednesday, February 13, 2013, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Influenza: Perspective on Current Season and Update on Preparedness."

The Department of Health and Human Services (HHS) and its agencies play key roles in combating seasonal influenza. This hearing will provide perspective on this year's flu season and address ongoing efforts at the Federal level to prepare for and respond to future influenza outbreaks.

I. WITNESSES

One panel of witnesses will testify at the hearing:

Thomas Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
Department of Health and Human Services

Jesse L. Goodman, MD, MPH
Chief Scientist
Food and Drug Administration
Department of Health and Human Services

Marcia Crosse, PhD
Director, Health Care
Government Accountability Office

II. BACKGROUND

Influenza is a contagious respiratory illness caused by varying virus strains and can range in severity from mild to lethal. The timing and severity of flu season is unpredictable and can vary year to year. The current season began relatively early compared to recent seasons and by mid-January, influenza activity was high across most of the country. While declining overall nationally, as of February 2, 38 States reported widespread activity.

According to Centers for Disease Control and Prevention (CDC) estimates, seasonal influenza has been associated with as few as 3,000 and up to almost 50,000 deaths each year in the U.S. since 1976.[1] On average each year, more than 36,000 individuals die and more than 200,000 are hospitalized from influenza and related complications. In general, CDC estimates that about 90 percent of influenza-related deaths are people 65 and older. While seasonal influenza always impacts seniors at a higher rate, this year's predominant strain—H3N2—has resulted in an increase in cases. Since States are not required to report individual cases or influenza-related deaths of people older than 18, CDC's estimates will not be available until after the season ends. However, CDC has confirmed that hospitalization rates and deaths associated with laboratory-confirmed cases of influenza in individuals 65 and older has increased sharply this season.

Unfortunately, on the other side of the age spectrum, 59 pediatric deaths have been reported through February 2. As CDC Director Thomas Frieden stated on January 18 (when the number of pediatric deaths was 29), "That's well below the 153 [pediatric] deaths reported in the 2003-2004 season[,] which was another H3N2 season, but as I say we're only in the middle of our season and even a single death in a child is one too many." He continued, "[W]hat we generally find is that more than half of the children who die from flu haven't been vaccinated. And we do find that usually a large proportion of the children who die from flu have other health problems as well."[2]

The primary method for preventing influenza is annual vaccination. CDC recommends annual vaccinations for all persons aged 6 months and older. Because circulating influenza virus strains change, a new vaccine is produced and administered each year to protect against the strains expected to be most prevalent that year. This is a collaborative effort between vaccine manufacturers and several government agencies.

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[1] Seasonal-influenza related deaths are deaths that occur in people for whom seasonal influenza infection was likely a contributor to the cause of death, but not necessarily the primary cause of death. CDC does not know exactly how many people die from seasonal flu each year since: (1) States are not required to report individual seasonal flu cases or deaths of people older than 18 years of age to CDC; (2) seasonal influenza is infrequently listed on death certificates of people who die from flu-related complications; and (3) many seasonal flu-related deaths occur one or two weeks after a person's initial infection. *See* Estimating Seasonal Influenza-Associated Deaths in the United States: CDC Study Confirms Variability of Flu, *available at* http://www.cdc.gov/flu/about/disease/us_flu-related_deaths.htm.

[2] Ctrs. For Disease Control & Prevention, Telebriefing on Flu Season and Vaccine Effectiveness (Jan. 18, 2013) (transcript available at http://www.cdc.gov/media/releases/2013/t0118_flu_season.html).

Currently, in late winter each year, the Food and Drug Administration (FDA), using surveillance information from the World Health Organization (WHO) and CDC, selects three virus strains that manufacturers must include in the influenza vaccine for the following flu season—two strains of influenza A and one of influenza B.[3] FDA and the manufacturers subsequently test the virus strains to determine the purity and yield of the virus and to ensure that the potency is adequate for immunization. Once the potency of each strain is determined to be adequate, manufacturers combine the strains to create the vaccine for that season. FDA may conduct additional testing before officially releasing the vaccine for distribution. Vaccine is ultimately shipped to customers, which can include distributors, physicians, hospitals, and State and local health departments.[4]

There have been reports of spot shortages this season, but ultimately flu vaccine supply will have exceeded demand. As of January 25, 2013, approximately 134.2 million doses of seasonal influenza vaccine had been distributed in the U.S., as reported to CDC by the manufacturers, and it was projected that 145 million doses of flu vaccine will ultimately be produced.[5] There have also been reports of shortages of antiviral products in the market. As CDC has described them, antiviral products are "the second line of defense against influenza" and can reduce the severity of illness, particularly when taken promptly after the onset of symptoms. Some locations did experience intermittent, temporary shortages of certain antiviral formulations. FDA worked with the company and providers to address this issue.[6]

There has also been discussion about the effectiveness of this season's influenza vaccine. Vaccine viruses are chosen to maximize the likelihood that the influenza vaccine will protect against the viruses most likely to spread and cause illness among people during the upcoming flu season. Throughout the season, CDC conducts studies to determine how well the vaccine protects against illness. Findings from early data suggest that this season's vaccine is reducing the risk of having to go to the doctor for influenza by about 62 percent for vaccinated people. CDC asserts that these estimates are within the range of what is expected during seasons when most of the circulating influenza viruses are similar to the viruses included in the vaccine. Vaccination, even with effectiveness of about 62 percent, has been shown to also reduce flu-related illness, antibiotic use, time lost from work, hospitalizations, and deaths.[7]

While 62 percent is within the expected range, recent developments in production technologies and product approvals may lead to more effective vaccines reaching patients. For instance, within the past year, FDA has approved two quadrivalent vaccines. These vaccines contain four strains of the influenza virus. The addition of a fourth strain increases the likelihood

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[3] FDA has recently approved quadrivalent vaccines that protect against four strains of influenza by adding a second B strain.

[4] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-27, INFLUENZA VACCINE: ISSUES RELATED TO PRODUCTION, DISTRIBUTION, AND PUBLIC HEALTH MESSAGES, at 11 (October 2007), *available at* http://www.gao.gov/new.items/d0827.pdf.

[5] *See id.* at note 2.

[6] *Id.*

[7] *See* What You Should Know for the 2012-2013 Influenza Season, *available at* http://www.cdc.gov/flu /about/season/flu-season-2012-2013.htm.

of adequate protection. In addition, FDA has recently approved both recombinant and cell-based vaccines, which may offer more robust and reliable protection against influenza.

III. ISSUES

The following issues may be examined at the hearing:

- What are the most up-to-date facts and figures relating to this flu season?
- How does this season compare to previous seasons, particularly with regard to the impact on seniors?
- What steps can the public take to prepare for every flu season?
- Can the annual process for developing seasonal influenza vaccine be improved?
- Are the various agencies within HHS responsible for coordinating preparedness and response measures adequately communicating with vaccine and antiviral manufacturers?
- What else can be done to ensure adequate preparation and response to future influenza outbreaks, both seasonal and pandemic?
- Can vaccine effectiveness be improved?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Karen Christian, Sean Hayes, or John Stone with the Committee staff at (202) 225-2927.