

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

February 12, 2013

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic 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 titled “Influenza: Perspective on Current Season and Update on Preparedness.” The majority has indicated that the hearing will focus on this season’s flu outbreak, new vaccine technologies, and federal planning and preparedness.

I. 2012-2013 FLU SEASON

Influenza, or the flu, is “a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and lungs.”¹ While typical symptoms include fever, cough, or sore throat, complications from the flu can lead to severe illnesses like bacterial pneumonia or even cause death.² Children younger than age five, adults sixty-five years of age and older, pregnant women, and others with medical conditions (e.g., weakened immune systems or heart disease) are at a higher risk for developing flu-related complications. Flu vaccines protect individuals against the flu by causing protective antibodies to develop in the body.³ Seasonal flu vaccines protect against three influenza viruses that scientists believe will circulate in a given year.⁴ The Centers for Disease Control and Prevention (CDC) recommends that everyone six months of age and older should receive a flu vaccine each year.

¹ Centers for Disease Control and Prevention, *Key Facts About Influenza (Flu) and Flu Vaccine* (Mar. 28, 2012) (online at www.cdc.gov/flu/keyfacts.htm).

² *Id.*

³ Centers for Disease Control and Prevention, *Key Facts About Seasonal Flu Vaccine* (Jan. 16, 2013) (online at www.cdc.gov/flu/protect/keyfacts.htm).

⁴ *Id.*

The timing and duration of flu seasons vary but can begin in October and last as late as May. Peak activity generally occurs in January and February. The severity of flu seasons are extremely unpredictable: “between 1976 and 2007, estimates of flu-associated deaths in the United States [ranged] from a low of about 3,000 to a high of about 49,000 people.”⁵

The 2012-2013 flu season began a month earlier than usual, based on a number of indicators, including patient visits to health care providers and hospitalizations, and has been worse than average.⁶ The latest data from CDC for the week of January 27 – February 2, 2013, show that influenza activity remained elevated but decreased from peak heights in most areas of the country.⁷ Thirty-eight states reported widespread geographic influenza activity,⁸ and 9% of all deaths reported this season were attributable to pneumonia and influenza. Between October 1, 2012, and February 2, 2013, there have been 8,293 confirmed flu-associated hospitalizations. This flu season has also seen 59 pediatric deaths.⁹

By early- to mid-November of the current flu season, 36.5% of people six months of age and older were vaccinated. At the same time during last season, 36.3% of people six months of age and older were vaccinated. Nearly 40% (39.9%) of children were vaccinated in November, compared to 36.7% last season. Flu vaccination coverage was similar across all racial and ethnic groups except for adult Hispanics, who had a lower rate of coverage.¹⁰

Each year, CDC estimates vaccine effectiveness by determining how likely it is that a flu vaccine will keep one from visiting a doctor’s office. For the current flu season, the overall vaccine effectiveness rate is 62%, which means that “if you got vaccinated you’re about 60 percent less likely to get the flu that requires you to go to your doctor.”¹¹ This season’s vaccine effectiveness rate is in line with recent years.

This flu season, the Food and Drug Administration (FDA) licensed seven manufacturers to produce influenza vaccines. In January, during the peak of the season, FDA reported that there were sporadic spot shortages of flu vaccine and the antiviral drug, Tamiflu (which reduces the severity of the flu when taken soon after symptoms appear), in certain parts of the country.

⁵ *Id.*

⁶ *Tough Flu Season in U.S., Especially for the Elderly*, New York Times (Jan. 18, 2013) (online at www.nytimes.com/2013/01/19/health/flu-season-worse-than-average-officials-say.html); Centers for Disease Control and Prevention, *Press Briefing Transcript, CDC Update: Flu Season and Vaccine Effectiveness* (Jan. 14, 2013) (online at www.cdc.gov/media/releases/2013/t0111_flu_season.html).

⁷ Centers for Disease Control and Prevention, *2012-2013 Influenza Season Week 5 ending February 2, 2013* (Feb. 8, 2013) (online at www.cdc.gov/flu/weekly/).

⁸ *Id.*

⁹ *Id.*

¹⁰ Centers for Disease Control and Prevention, *National Early Season Flu Vaccination Coverage* (Dec. 3, 2012) (online www.cdc.gov/flu/fluview/nifs-estimates-nov2012.htm).

¹¹ Centers for Disease Control and Prevention, *Press Briefing Transcript, CDC Update: Flu Season and Vaccine Effectiveness* (Jan. 14, 2013) (online at www.cdc.gov/media/releases/2013/t0111_flu_season.html).

As noted in the Majority's memo, the spot shortages reflected uneven distribution rather than a lack of supply. FDA worked with Tamiflu's manufacturer, Genentech, to ensure adequate supply and issued guidance to pharmacies on how to compound a liquid form of Tamiflu in the event of oral suspension dose shortages.

II. VACCINE IDENTIFICATION AND DISTRIBUTION

Because different strains of the flu can predominate in any given year, the flu vaccine must be modified annually. Throughout the year, the World Health Organization (WHO) monitors worldwide influenza disease. At the beginning of each calendar year, FDA and WHO review data to recommend the composition of influenza virus vaccines for the next winter. In February, FDA convenes its Vaccine and Related Biological Products Advisory Committee and recommends the three different strains of influenza virus that will be included in vaccine produced for the U.S. flu season. The viruses are then adapted for use in manufacturing the seasonal vaccine, which begins shipping at the end of the summer.

III. AGENCY RESPONSIBILITIES

FDA is "responsible for the licensure and regulation of influenza vaccine — including the approval of facilities in which influenza vaccine is produced — for the U.S. market."¹² FDA issues guidance, consults with manufacturers, and regulates the vaccine's production and use. FDA also reviews and approves the composition of the seasonal vaccine annually.¹³

CDC operates the U.S. seasonal flu surveillance systems, which track trends in the rate of illness and hospitalization.¹⁴ CDC also monitors the types and subtypes of circulating flu viruses, the emergence of new strains, and the geographic spread of the flu virus.¹⁵ Additionally, CDC administers two programs that provide vaccines to uninsured and underinsured children, adolescents, and adults and invests in the infrastructure necessary to reach these populations (the Vaccines for Children and Section 317 programs).¹⁶ Finally, CDC maintains the Strategic National Stockpile (SNS), the nation's repository of flu vaccines and other critical pharmaceutical products and medical supplies for use during a public health emergency.

The Biomedical Advanced Research and Development Authority (BARDA), located within the Department of Health and Human Services (HHS), contracts with vaccine

¹² Government Accountability Office, *Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure* (June 2011) (GAO-11-435).

¹³ Centers for Disease Control and Prevention, *Press Briefing Transcript, CDC Update: Flu Season and Vaccine Effectiveness* (Jan. 14, 2013) (online at www.cdc.gov/media/releases/2013/t0111_flu_season.html).

¹⁴ Congressional Research Service, *The 2009 Influenza Pandemic: An Overview* (Nov. 16, 2009) (online at www.crs.gov/pages/Reports.aspx?PRODCODE=R40554&Source=search).

¹⁵ *Id.*

¹⁶ Centers for Disease Control and Prevention, *Justification of Estimates for Appropriations Committees* (Fiscal Year 2013) (online at www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2013_CD_C_CJ_Final.pdf).

manufacturers for advanced research and development for vaccine technologies to respond to public health emergencies. The National Institutes of Health (NIH) conducts basic and clinical research, which supports the development of alternative vaccine technologies.

IV. VACCINE DEVELOPMENT: ALTERNATIVE TECHNOLOGIES

Traditional vaccine development uses egg-based technology, which involves a lengthy manufacturing process. In egg-based manufacturing, each virus strain is injected into eggs, which are then incubated. Once the viruses multiply, the fluid from the eggs is harvested, purified, and tested for potency and safety.¹⁷

There are a number of recently-approved alternative vaccine technologies that will increase vaccine availability and effectiveness, and speed up the production process. These include cell-based technology, recombinant technology, quadrivalent vaccines, and adjuvants. When demand is high, these alternative vaccine technologies will reduce the likelihood of shortages. Cell-based technology uses cells infected with the influenza virus instead of fertilized eggs.¹⁸ Recombinant technology uses a similar technique, but uses specific proteins or genes from the virus instead of the entire virus, as the antigen. Adjuvants are an “antigen-sparing technology” which is added to a vaccine to enhance immune response, allowing smaller doses of vaccines to be used. Adjuvants can be added to vaccines made with different production methods, including egg-based, cell-based, or recombinant technology. Quadrivalent vaccines protect against four strains of influenza virus, as opposed to traditional trivalent vaccines, increasing vaccine effectiveness.

From 2005 through March 2011, the HHS and the Department of Defense “awarded approximately \$2.1 billion in contracts and technology investment agreements for the research and development” of alternative flu vaccine development technologies.¹⁹ In the 2005 *Pandemic Influenza Plan*, HHS set new goals to ensure sufficient domestic capacity of influenza vaccine in the event of a pandemic. As part of the plan, HHS committed to supporting the development of new alternative vaccine development technologies. Following the release of the *Pandemic Influenza Plan*, the agency received new appropriations to contract with manufacturers to develop vaccines using cell-based technology, recombinant technology, and adjuvants. In August 2010, after the H1N1 pandemic ended, HHS used remaining funds obligated for the pandemic, as well as annual appropriations, to further invest in the development of alternative technologies.

The first flu vaccine to use cell-based technology, Novartis’s Flucelvax, was approved by FDA in November 2012 for those aged 18 and older. Flublok, a vaccine manufactured by Protein Sciences using recombinant technology, was approved by FDA in January 2013. In February 2012, FDA approved MedImmune’s FluMist, which is the first approved quadrivalent

¹⁷ Food and Drug Administration, *The Evolution, and Revolution, of Flu Vaccines* (Jan. 18, 2013) (online at www.fda.gov/ForConsumers/ConsumerUpdates/ucm336267.htm).

¹⁸ *Id.*

¹⁹ Government Accountability Office, *Influenza Vaccine: Federal Investments in Alternative Technologies and Challenges to Development and Licensure* (June 2011) (GAO-11-435).

vaccine. GlaxoSmithKline's Fluarix quadrivalent vaccine was also approved by FDA in December 2012. All of these vaccines will be available for use next flu season.

V. THE AFFORDABLE CARE ACT EXPANDS FLU VACCINE ACCESS

The Affordable Care Act (ACA) expands access to preventive services, including flu vaccines, by requiring new health plans to eliminate cost-sharing for certain, recommended services. An estimated fifty-four million additional Americans received preventive services, including flu vaccines, free of cost-sharing in 2011.²⁰ In addition, prior to 2011, those covered under Medicare had to pay for many preventive services like flu shots. Also as a result of the legislation, 19 million Medicare enrollees "received at least one preventive service at no cost to them" during the first eight months of 2012.²¹

Beginning in January 2014, 14 million Americans who would otherwise have no health insurance coverage will now receive insurance under the ACA – providing them with access to health providers and health benefits like flu vaccines.²² By 2017, 27 million Americans who would otherwise be without health insurance will be covered under the ACA.²³

VI. BUDGET SEQUESTRATION COULD ADVERSELY IMPACT FDA AND CDC INFLUENZA EFFORTS

Unless Congress acts to forestall the budget sequestration process, the agencies that manage flu surveillance and ensure the vaccine's efficacy and safety will see large budget cuts beginning on March 1, 2013. FDA and CDC could face cuts of 5.2%.²⁴ If these cuts go into effect, the agencies could be forced to significantly cut resources to ensure vaccine availability and protect against the threat of a pandemic.

Adding to the threat posed by the sequester are the discretionary spending reductions enacted since 2010 that have impacted preparedness for public health emergencies. For example, appropriations for the Strategic National Stockpile "have been cut by 15 percent, from \$596 million to \$504 million."²⁵

²⁰ Department of Health and Human Services, *Fifty-Four Million Additional Americans Are Receiving Preventive Services Coverage Without Cost-Sharing Under The Affordable Care Act* (Feb. 2012) (online at aspe.hhs.gov/health/reports/2012/PreventiveServices/ib.shtml).

²¹ Department of Health and Human Services, *Through the Affordable Care Act, Americans with Medicare will save \$5,000 through 2022* (Sept. 21, 2012) (online at www.hhs.gov/news/press/2012pres/09/20120921a.html).

²² Congressional Budget Office, *CBO's February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage* (Feb. 2013) (online at www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf).

²³ *Id.*

²⁴ *How Big Are the Automatic "Sequestration" Cuts Scheduled for March 1?*, Center on Budget and Policy Priorities (Feb. 11, 2013) (online at www.offthechartsblog.org/how-big-are-the-automatic-sequestration-cuts-scheduled-for-march-1/).

²⁵ House Committee on Appropriations, Minority Staff, *Discretionary Appropriations Will Reach Historic Lows Under Existing Law* (Feb. 2013) (online at

VII. WITNESSES

The following witnesses have been invited to testify:

Dr. Jesse L. Goodman

Food and Drug Administration
Chief Scientist
Office of the Chief Scientist

Dr. Tom Frieden

Centers for Disease Control and Prevention
Director

Marcia Crosse

Government Accountability Office
Director, Health Care