

Dr. Schuchat Questions for the Record
"Examining the U.S. Public Health Response to Seasonal Influenza"
House Energy and Commerce Subcommittee on Oversight and Investigations
February 3, 2015

The Honorable Marsha Blackburn

- 1. You testified that first drifted viruses were detected on March 8, 2014. You also testified that over the summer of 2014, drifted viruses were detected in greater proportions. By September 2014, the decision was made by CDC and WHO to include one of these drifted H3N2 viruses in the Southern hemisphere vaccine. So it would seem, you would have had some idea at that point that this year's Northern hemisphere vaccine would not be as effective as in previous years.**

About the same time that CDC was looking closely at the drifted flu virus, a Vanderbilt-led study was published. The study shows that a high-dose flu vaccine is 24% more effective in the elderly when compared to the standard dose vaccine. The researchers also concluded that the high dose vaccine is safe.

When it became apparent that this year's vaccine would not protect well against the dominant strain of influenza, did CDC make any recommendations regarding the increase use of high-dose vaccine in the elderly?

- a. If yes, when was that recommendation made?**
- b. If no, can you explain why you wouldn't recommend a safe vaccine that is felt to be 24% better than baseline?**

Answer: The Advisory Committee on Immunization Practices (ACIP) has recommended high-dose inactivated vaccine (Fluzone HD, Sanofi Pasteur) since its licensure by the Food and Drug Administration (FDA) in 2009, and included the vaccine in the 2010-2011 recommendations for use in persons ≥ 65 years old. Adopting ACIP's recommendation, the Centers for Disease Control and Prevention (CDC) has included Fluzone HD, along with other flu vaccines, in the U.S. influenza-vaccine recommendations each season since its approval.

While this vaccine is recommended by the CDC, there is no stated preference for this vaccine over other recommended vaccines for this age group. CDC did not recommend a new national vaccine policy that stated a preference for this vaccine (or any other) once we detected that the drifted H3N2 strain was predominant because: (1) vaccination programs were well underway and many or most vaccination had already been completed by this time; (2) production of all vaccine products, including Fluzone HD, had been completed, meaning that no further doses could be made during this flu season to satisfy an increased demand created by a preferential immunization policy; and (3) the relative effectiveness of the high-dose vaccine against the specific strains circulating this season are unknown – despite one industry-supported study which found a better efficacy compared with standard dose vaccine in a previous year before the drifted strains emerged.¹

¹ For more information, see http://www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm.

2. Moving forward, will CDC make a recommendation for a more widespread use of the high-dose flu vaccine for the elderly?

Answer: While Fluzone HD vaccine is already recommended as an option for persons ≥ 65 years old, ACIP will review the data on efficacy and safety of this vaccine, and determine if amended language in the U.S. vaccine policy is warranted. Note that ACIP recommendations already state that Fluzone HD has been found to be more effective than standard dose vaccine in one study.

The Honorable Morgan Griffith

1. Please provide all of the approximate mismatch percentages for each month from February 2014- January 2015.

Answer:

Month	% Mismatch	% Mismatch combined*
Oct-13 Jan-14	0%	
Feb-14	1%	
Mar-14	4%	17%
Apr-14	11%	
May-14	31%	
Jun-14	6%	36%
Jul-14	34%	
Aug-14	52%	
Sep-14	30%	
Oct-14	30%	
Nov-14	61%	
Dec-14	76%	
Jan-15	69%	

*Combined mismatch is to illustrate the association with what was said during the oral testimony

The Honorable Markwayne Mullin

1. Please provide the language and criteria that is required to declare a public health emergency.

Answer: Under section 319 of the Public Health Service Act, 42 U.S.C. 247d, the Secretary of the Department of Health and Human Services may declare a public health emergency when she determines, after consulting with such public health officials as may be necessary, that: (1) a disease or disorder presents a public health emergency; or (2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists.²

² For more information about the Secretary’s authority to declare a public health emergency, please see <http://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx>.