

United States Senate  
COMMITTEE ON FINANCE  
WASHINGTON, DC 20510-6200

May 3, 2010

**Via Electronic Transmission**

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Sebelius:

I would like to thank you for your February 2, 2010 response to the questions I posed regarding the 2009 H1N1 influenza virus vaccines. I would also like to reiterate my appreciation for the Department of Health and Human Services' (HHS or Department) efforts to secure the health of the American public against H1N1 flu in such a short time period.

I am writing today to follow up on the status of the H1N1 influenza virus vaccines procured by HHS and the Department's efforts to protect this country from the ongoing and future threat of H1N1 flu. You stated in your response that HHS ordered 229 million doses of bulk vaccine with 25 million doses for international donation, but does not plan to fill and finish all 229 million bulk doses in vials, syringes, and sprayers. According to the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* issued on April 2, 2010, approximately 81-91 million doses of 2009 H1N1 vaccine were administered to 72-81 million people as of February. News reports earlier this month state that about 162 million doses were produced and distributed, which means about half of the doses—more than 70 million—would need to be administered before they expire.

Depending on the vaccine manufacturer, the shelf life of the H1N1 vaccines range from 18 weeks to 18 months, with some due to expire on June 30, 2010. In addition, CDC states that vaccines that are within one month of expiration will not be distributed for use. I understand that it is not uncommon for some seasonal flu vaccines to be discarded each year, but the H1N1 vaccines were paid for with taxpayer dollars. And we may be discarding millions of doses of that vaccine in light of the large number of vaccines still sitting in inventory and what appears to be waning demand for H1N1 vaccination. In that regard, I would appreciate your responses to the following questions. Please respond by repeating the enumerated question and follow with the appropriate answer and supporting documentation:

- 1) How many doses of vaccine are due to expire on June 30, 2010?

- 2) What are the other expiration dates for the remaining inventory and what are the Department's plans for dispensing of these vaccines to limit the number of doses that will be discarded?
- 3) As of the date of this letter, how many doses of 2009 H1N1 vaccines were filled and finished in vials, syringes, and sprayers? Are there plans to fill and finish any more of the bulk vaccine?
- 4) It is my understanding that there is one distribution depot for the entire nation, Memphis, TN. What are the contingency plans should this depot become unserviceable?
- 5) According to the Flu.gov website, protection against the H1N1 flu virus will be included in the seasonal flu vaccine for the 2010-2011 flu season.<sup>1</sup> What effect will this have on the current 2009 H1N1 vaccine inventory?
- 6) The 2009 H1N1 vaccines were purchased entirely by HHS and distributed to the states. Given that the seasonal flu vaccine will include protection against the H1N1 flu strain for the 2010-2011 flu season, does the Department plan to increase its purchase of the number of seasonal flu vaccines for the 2010-2011 flu season? If so, does that mean HHS will also be extending the Public Readiness and Emergency Preparedness Act declaration for pandemic vaccines to include the seasonal flu vaccine?
- 7) According to your response, over 70 percent of the Department's orders of 2009 H1N1 vaccine had been completed, with about \$1.2 billion invoiced as of the date of your response. According to press reports in September 2009, the Obama Administration earmarked \$1.8 billion in July for H1N1 flu and another \$2.7 billion in September for new vaccines, antiviral drugs and a vaccination campaign. To date, how much of the appropriated dollars from Congress has been obligated and expended? Please provide a breakdown of the spending by HHS and its agencies.

Thank you for your cooperation and attention to this important matter. Please respond to the questions set forth in this letter no later than May 17, 2010. If you have any questions, please do not hesitate to contact Angelia Choy or Thomas Guastini at (202) 224-4515. All formal correspondence should be sent electronically in PDF format to [Brian\\_Downey@finance-rep.senate.gov](mailto:Brian_Downey@finance-rep.senate.gov) or via facsimile to (202) 228-2131

Sincerely,



Charles E. Grassley  
Ranking Member

---

<sup>1</sup> <http://www.flu.gov/individualfamily/vaccination/index.html>.