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

January 12, 2010

Via Electronic Transmission

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

The Honorable Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333

Dear Secretary Sebelius, Commissioner Hamburg and Director Frieden:

As the senior Senator from Iowa and Ranking Member of the United States Senate Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the Department of Health and Human Services (HHS or Department) and its agencies, and to ensure that taxpayer dollars are appropriately spent on safe and effective drugs and vaccines.

In April 2009, the Centers for Disease Control and Prevention (CDC) identified two children with the H1N1 influenza virus in southern California. Since then, CDC estimates that between 34 million and 67 million cases of 2009 H1N1 have occurred in the United States between April and November 14, 2009.

On September 15, 2009, the Food and Drug Administration announced that it had approved vaccines against the H1N1 influenza virus made by CSL Limited, MedImmune LLC, Novartis Vaccines and Diagnostics Limited, and Sanofi Pasteur, Inc. A fifth vaccine manufactured by ID Biomedical Corporation of Quebec was approved two months later.

The CDC testified before the House Committee on Energy and Commerce on November 18, 2009, that within five months, "CDC, in collaboration with the Food and Drug Administration (FDA), characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, initiated clinical trials, and licensed four 2009 H1N1 influenza vaccines."

I greatly appreciate the efforts of the Department, the CDC and the FDA in making the vaccines available in this country in such a short timeframe. At the same time, there have been questions raised by, among others, patients and some health care providers regarding the safety and efficacy of these new vaccines. In addition, last month, Sanofi Pasteur and MedImmune voluntarily recalled specific lots of their H1N1 vaccines because they found decreases in vaccine potency. Accordingly, I would appreciate your responses to the following questions, and for each question, please respond by first repeating the enumerated question followed by the appropriate answer:

1. What criteria were used to select the five companies that are currently manufacturing the 2009 H1N1 influenza virus vaccines?

    a) How many companies submitted bids?

    b) If more than five companies submitted bids, what were the reasons for rejecting the other bids?

2. How many doses of each vaccine have been purchased by HHS to date?

3. What is the total amount being paid to each of the five companies for their vaccines?

    a) How much has been paid as of the date of this letter?

4. When will the clinical trials on the H1N1 vaccines that were already underway in September be completed?

    a) Are there additional findings to date regarding the adverse event profiles of any of the five vaccines?

5. In light of the two recalls last month, what are HHS, CDC, FDA and the vaccine manufacturers doing to ensure the potency of the vaccines to be delivered in the coming months?

    a) Last week, a press report stated that "truckloads of swine flu vaccines" were being returned in New York State because there was not as much demand for the vaccine as expected. Are there plans to check the potency of the returned vaccines?

    b) What is the expected shelf life of the H1N1 vaccines?

6. How many manufacturing facilities have been approved by the FDA for production of the H1N1 influenza virus vaccines?

    a) How many times have each of these facilities been inspected to ensure good manufacturing practices?

b) On what dates were those inspections conducted and what were the findings of the inspections?

7. On June 25, 2009, HHS extended the Public Readiness and Emergency Preparedness Act declaration for pandemic vaccines to include H1N1 vaccines, which provides immunity from tort liability to individuals and entities involved in the manufacture, distribution and administration of the H1N1 vaccines. What oversight is in place to ensure that the individuals and entities covered by the amended declaration manufacture, distribute and/or administer the vaccines as intended and as legally authorized?

8. A shortage of seasonal flu vaccine was reported in November. I understand that at that time, there were still about 24 million doses yet to be shipped.

   a) What is the status of the 24 million doses?

   b) Did the commitment from five of the seasonal flu vaccine manufacturers to manufacture the H1N1 vaccine contribute to the seasonal flu vaccine shortage?

   c) What steps are being taken to prevent severe seasonal flu vaccine shortages in the future?

Thank you in advance for your assistance. Please provide written responses to the questions set forth in this letter by no later than January 26, 2010. If you have any questions regarding this letter, please do not hesitate to contact Emilia DiSanto or Angela Choy at (202) 224-4515.

Sincerely,

Charles E. Grassley
Ranking Member