DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 10, 2009

Dear Healthcare Professional,

I am writing first to thank you for your extraordinary efforts during the 2009 H1N1 influenza outbreak.

As this new infectious disease sweeps through communities across the country, you must juggle your usual patient care responsibilities with a special role in influenza response. Delays in vaccine delivery and the persistence of myths about vaccination have not made your job any easier. Thank you for rising to this public health challenge.

I am also writing to provide information that can be helpful as you talk to patients about the 2009 H1N1 influenza vaccines -- the best tools we have to prevent severe illness and death caused by the virus.

As the Commissioner of the U.S. Food and Drug Administration (FDA), I am pleased to have this opportunity to communicate with you directly at this key moment in time.

The Department of Health and Human Services is working with influenza vaccine manufacturers and state and local public health officials to make these vaccines widely available. So far, more than 41 million doses of the 2009 H1N1 vaccine have been allocated to the states for distribution across the country, and more is becoming available every day.

Some of your patients may be asking how the FDA, the manufacturers, and the scientific community can have confidence in vaccines that were available just six months after the 2009 H1N1 virus emerged. Understanding more about the manufacturing and approval process for these vaccines should help you to answer their questions.

Every year, FDA and vaccine manufacturers follow a series of steps to make a new influenza vaccine targeted to the three main circulating strains of influenza. These steps have produced effective and very safe vaccines time and again, adding up to hundreds of millions of doses administered in the United States alone.

We followed this same path for the 2009 H1N1 vaccines.

Making the 2009 H1N1 Vaccine

First, scientists at laboratories in the United States and elsewhere modified the 2009 H1N1 virus into a version suitable to be used as the "seed" for the development of vaccines. The process that

was followed is similar in every respect to that which is employed every year for the preparation of seasonal influenza vaccines, as slightly different strains appear regularly each year. For the 2009 H1N1 virus, modified strains suitable for vaccine manufacturing were created and provided to influenza vaccine manufacturers by late May.

Next, companies began manufacturing the 2009 H1N1 vaccines in the same factories where they are licensed to manufacture seasonal influenza vaccines – using the same equipment and the same testing procedures. FDA inspects these plants at least once a year to assure that quality controls are followed at every step in the production process. FDA's oversight covers both those facilities that make the inactivated vaccines (the "flu shot") and those that make live attenuated viral vaccine (the "nasal spray").

A critical part of influenza vaccine production is the growth of the vaccine strain in specially produced eggs. After inoculation of the eggs, the virus replicates, creating hundreds of thousands of copies of itself. It is the efficiency of this growth that determines how much vaccine can be produced and how quickly. The material harvested from these eggs is then further processed into the vaccines that you administer to your patients.

As recently as a few years ago, egg shortages would have prevented summertime and fall production of a vaccine against a new strain of influenza. Fortunately, this year, manufacturers could tap into a reserve supply of eggs made by additional flocks of chickens. These flocks were available under contracts put in place for just this purpose – to respond to a possible pandemic.

At the end of July, FDA sought public input. We convened a public meeting of FDA's expert vaccine advisory committee to review the agency's approach to approval of the 2009 H1N1 vaccines. This committee includes scientists, physicians, public health officials and a consumer representative. The committee supported making the vaccines according to the same approach used every year for the seasonal influenza vaccines.

The next step was to develop a tool to accurately measure the amount of vaccine antigen that was being produced. Scientists from the United States, United Kingdom, Australia, Japan, and other nations, working together as part of the World Health Organization, developed the reagents needed to assure the proper amount of antigen goes into each dose of vaccine.

On September 15, after reviewing applications from manufacturers similar to those submitted each year for licensed seasonal vaccine, FDA licensed four vaccines against the 2009 H1N1 influenza virus.

The agency found that all of the appropriate documentation had been submitted, and all of the standards had been met. In fact, had this new virus emerged a few months earlier, it could have been included as one of the three strains in the 2009 seasonal vaccine. In this key respect, although the strain of the 2009 H1N1 virus is new, the 2009 H1N1 influenza vaccines are not.

Over the summer, the National Institutes of Health and vaccine manufacturers initiated clinical trials to determine the dose and number of doses needed to induce an optimal immune response. The good news is that just as for seasonal vaccine, one dose of H1N1 vaccine will likely be protective for healthy adults, the elderly, and older children. For children ages nine and younger, two doses of the H1N1 vaccine will likely be optimal, also similar to seasonal vaccine. No serious adverse events attributable to the vaccine have emerged during the clinical trials, which have so far included over 3600 patients at NIH-supported institutions alone.

Monitoring Vaccine Safety

We are now in a position never before experienced in the history of influenza. Just as a new and serious virus is spreading widely around the country, causing hospitalizations and deaths, a vaccine is becoming available to help prevent infection and protect the public. This accomplishment is the result of the efforts of hundreds of scientists across the world in the private and public sectors. Although a gap still remains between the demand for the vaccine and the currently available supply, this is the first time in history that any vaccine has been available at the time that an influenza pandemic has struck.

We are not cutting any corners. Just as for seasonal influenza vaccine, no lot of the 2009 H1N1 vaccine can be used until it has been carefully evaluated and released as sterile and potent by both the manufacturer and by the FDA.

In addition, the FDA and other agencies are looking for any unexpected, rare, serious adverse events and are quickly investigating concerns. We are also collaborating with our global counterparts to share information and experience. Should any safety concerns arise, we will evaluate them thoroughly and bring them to the public's attention quickly.

I encourage you to report any adverse effects that you believe are linked to any vaccine, including the 2009 H1N1 influenza vaccine, to the Vaccine Adverse Event Reporting System (http://vaers.hhs.gov/index). Other resources for 2009 H1N1 influenza, including a detailed description of vaccine safety efforts, are online at www.flu.gov.

It is likely that most families in the United States will be touched by H1N1 influenza this year. Fortunately, many will experience mild illness. Others will endure unspeakable tragedy. The benefits of preventing serious consequences from infection with the 2009 H1N1 influenza virus far outweigh the risks associated with vaccination. All Americans, and especially pregnant women and others at high risk of severe influenza infection, should seriously consider the recommendation for vaccination to help protect themselves and their loved ones.

Thank you for your critical work during this challenging time.

Sincerely,

Margaret A. Hamburg

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs