



JAN 15 2010

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

Ned Feder, M.D.
Staff Scientist
Project On Government Oversight
1100 G Street, NW
Washington, DC 20005

Dear Dr. Feder:

Secretary Sebelius has asked me to thank you for your letter regarding the production of H1N1 influenza vaccine and to respond to your questions directly. In your letter dated October 30, 2009, you posed a number of questions, which I will address below.

As of January 11, 2010, over 137 million doses of H1N1 vaccine have been allocated for ordering by Federal Project Areas. Due to the abundance of vaccine, it is being made available to all who wish to be vaccinated. The daily allocation of vaccine by Federal Project Area is available <http://www.flu.gov/individualfamily/vaccination/supply.html>. Additionally, in order to promote transparency and communication, HHS has posted a series of question and answers regarding H1N1 vaccine supply and production: http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm#s_and_d.

In regard to your request that HHS post vaccine manufacturing contracts online, the Federal Acquisition Regulations (FAR) 42.1503(b) does not allow for making the evaluation of proposals available on publicly available websites. By their nature, contracts contain confidential information which would be redacted, rendering the contracts uninformative. In keeping with these regulations, HHS contract officers share contractor past performance with other agencies through the National Institutes of Health Contractor Performance System and the Past Performance Information Retrieval System.

In your letter, you expressed concern regarding the domestic vaccine manufacturing capacity. In keeping with the *National Strategy for Pandemic Influenza*, HHS has made a series of commitments to increase domestic capacity. These efforts have included retrofitting existing manufacturing sites to make influenza vaccines (which were used this year to make H1N1 vaccine) and substantial investments in cell-based manufacturing sites for seasonal and pandemic influenza vaccines, the first of which was inaugurated in November. These investments facilitated availability of sufficient vaccine for H1N1, and are expected to provide a considerable addition to domestic influenza vaccine capacity in the coming two years. About 48 percent of the H1N1 vaccine produced thus far was made domestically. All of these factors lead us to believe that dependence on foreign-produced vaccines should continue to decline as these new domestic facilities are licensed.

Your final concern was regarding alternatives to current vaccines, specifically recombinant vaccines. HHS is prevented from publishing a comprehensive history of recombinant vaccine acquisition process for the program you mention by the provisions of the FAR that safeguard the

confidentiality of technical, commercial and financial information provided to HHS by offerors during the acquisition process. Contract awardees are similarly protected. A high-level timeline for the advanced development of recombinant vaccines can be obtained through <http://www.hhs.gov> and advanced search of <http://www.fbo.gov>.

HHS plans to review the advanced development program for recombinant influenza vaccines with the National Biodefense Science Board, an advisory board to the HHS Secretary, and will present for their consideration the desirability of enlarging the domestic capacity to produce recombinant vaccine.

Thank you for the opportunity to clarify and provide additional information on this important issue. I am sending an identical letter to Danielle Brian.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicole Lurie". The signature is fluid and cursive, with a long, sweeping tail on the final letter.

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response