



OCT 19 2009

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

Danielle Brian
Executive Director
Project On Government Oversight
1100 G Street, NW
Washington, DC 20005

Dear Ms. Brian:

Secretary Sebelius has asked me to thank you for your letter regarding greater transparency of the production of the 2009 H1N1 influenza vaccine and to respond to you directly. We agree that transparency is essential to our H1N1 response and we work continuously to maximize transparency to the greatest extent practicable.

The Department is committed to a common sense approach to maximize transparency of H1N1 preparedness efforts, including vaccine production. This approach includes safeguards for procurement sensitive and proprietary information, such as performance evaluations and source selection information according the Federal Acquisition Regulation. Such safeguards are critical to our preparedness since public disclosure of sensitive information could discourage our industry partners contracted to manufacture vaccines to protect against 2009 H1N1 and other partners working on the advanced development of newer technologies.

HHS has undertaken a number of measures to foster transparency in the production of vaccine for 2009-H1N1. The Federal government has established the www.flu.gov information portal, a one-stop source for significant and timely information on 2009-H1N1 response planning and implementation, managed by HHS. In addition to extensive guidance for multiple populations on 2009 H1N1, updates are provided regularly on the progress in manufacturing, testing, and the vaccine including the dollar amounts issued to Novartis, GlaxoSmithKline, Sanofi Pasteur, CSL Biotherapies and MedImmune, the five vaccine manufacturers with which we contracted to supply the U.S. with 2009 H1N1 influenza vaccine. HHS has also posted a great deal of information on each of the step leading to the implementation of the 2009 H1N1 vaccination program, for which States began vaccine orders on October 2, 2009.

Each of the vaccine manufacturers listed above are already licensed to produce a seasonal influenza vaccine for the US and this has allowed them to rapidly license a 2009 H1N1 vaccine. Four 2009 H1N1 vaccines have now been licensed by the FDA. Previous pandemic influenza preparedness investments in building the domestic vaccine manufacturing infrastructure have contributed to our ability to meet the goal having sufficient vaccine for all Americans who wish to be vaccinated. Other investments in newer technologies such as cell-based vaccine development have increased the global supply of influenza vaccine, making more total doses available to the world's market.

To support a thorough evaluation and sharing of contractor past-performance before contracts are awarded, 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. Finally, HHS conducts regular and timely updates to Congress on contract status, manufacturing progress, and manufacturing strategies for ensuring the timely availability of vaccine. We share your belief that transparency is essential for the nation's preparedness and will continue to work to ensure that timely and relevant information is easily accessible as appropriate.

Sincerely,

A handwritten signature in black ink, appearing to read "Nicole Lurie". The signature is fluid and cursive, with a large initial "N" and a long, sweeping underline.

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