October 22, 2004

The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman: Henry.

Thank you for your letter earlier today. I agree with you that the shortage of flu vaccine is a public health crisis. I do not agree, however, with your characterization of the Administration's actions in response to the Committee's request for documents.

I am forwarding you a copy of a letter sent to me by Dr. Lester Crawford, the Acting Commissioner of the Food and Drug Administration (FDA), which fully explains the agency's reasons for seeking an extension. I find their request both appropriate and understandable. I remain utterly determined to make sure such a vaccine shortage does not happen again, but the priority for both the FDA and Centers for Disease Control and Prevention during this critical period must be to identify, test, and distribute additional doses of the influenza vaccine to keep people healthy during the upcoming flu season. We, as Members of Congress, need to assist those efforts in any way we can.

That is why when I received a call from Dr. Crawford on Thursday, October 21, 2004, requesting an extension of time to respond to our document request, I did not hesitate to grant it. As Dr. Crawford explained to me over the phone and again in his letter, the staff assigned to gather documents to our request is the same staff who are also working on locating additional doses of the vaccine, as well as an ample supply of antiviral medicines to better protect the public.

As you may be aware, FDA is negotiating with Canadian flu vaccine manufacturer, ID Biomedical, to secure 2 million doses of its flu vaccine. FDA will ensure the vaccine meets FDA safety and manufacturing standards. FDA is also negotiating with the French government and others to procure additional flu vaccine. GlaxoSmithKline has a flu vaccine that is approved in Europe, and FDA has entered discussions with the company for possible approval for use in the United States. FDA

is also working with pharmaceutical companies to increase production of antiviral medications for the prevention and treatment of influenza. FDA estimates that approximately 40 million antiviral treatment courses will be available for the 2004-2005 flu season.

I was pleased to learn from Dr. Crawford that significant progress was being made on this front. Dr. Crawford assured me that they would continue to work on collecting documents and we would receive a response to our request as soon as it was completed. Given the current circumstances, a brief extension is warranted and your request for a subpoena is premature.

Frankly, I am concerned that your push to subpoena the FDA is more about politics than fulfilling our oversight responsibility. It is important that we learn what actions or inactions FDA took in preparing for this year's vaccine and to prevent a similar shortage from taking place next year. Providing FDA additional time to fully comply with our request will not impede our ability to investigate the matter. However, requiring them to abandon efforts to locate additional doses of vaccine would be irresponsible of us. It is critical that we put politics aside and focus on protecting the public's health.

Sincerely,

Tom Davis

Tom Davis
Chairman