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October 26, 2004

The Honorable Lester Crawford, D.V.M, Ph.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

According to a confidential communication I have received from inside the Food and Drug Administration, your office is withholding documents from Congress, the news media, and the public that address whether the flu vaccine crisis could have been prevented.

The documents at issue describe FDA's oversight of the contaminated Chiron vaccine plant in Liverpool, England, that is the center of the flu vaccine crisis. On October 13, 2004, the Committee on Government Reform requested documents from FDA's June 2003 inspection of the facility, which apparently found severe problems. The Committee also requested copies of FDA's communications with Chiron after bacterial contamination was discovered again this August. Some of these materials — including the Form 483, which summarizes the problems found during the 2003 inspection — are considered public documents under the law. I am aware that several news organizations have requested these documents under the Freedom of Information Act.

So far, FDA has not released a single document related to its oversight of the Chiron facility, either to Congress or, as far as I am aware, to the news media or the public. On Friday, October 22, you wrote me to say that producing documents would interfere with the FDA's work attempting to find additional vaccine to mitigate the flu vaccine crisis.

In fact, I have received a confidential communication from inside your agency that the FDA Center for Biologics sent a set of responsive documents to your office prior to your letter of October 22. According to this communication, you or someone working for you made a decision not to release these documents to Congress until after the election. I was also informed that FDA has decided not to release these or other documents to the media under the Freedom of Information Act prior to the election. According to the communication I received, e-mails within FDA can confirm the transfer of documents to your office.

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These are serious allegations. Public health, not political expediency, should be guiding FDA's actions. Millions of Americans who are at high risk of severe illness from influenza will not be vaccinated this year. They and their elected representatives in Congress have a right to know whether FDA acted responsibly and what can be done to prevent this health crisis from happening again.

If the confidential communication I received is mistaken, I would appreciate a prompt clarification in writing. Otherwise, I urge you to immediately provide the documents in your possession, as well as copies of the e-mails relating to their transmittal to your office.

Sincerely,

A handwritten signature in black ink that reads "Henry A. Waxman". The signature is written in a cursive, flowing style.

Henry A. Waxman
Ranking Minority Member

cc: The Honorable Tom Davis