ONE HUNDRED EIGHTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT REFORM

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October 22, 2004

The Honorable Tom Davis
Chairman
Committee on Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington DC 20515

Dear Mr. Chairman:

I am writing to urge you to subpoena important documents that should reveal whether the Food and Drug Administration could have prevented the flu vaccine crisis. At issue is the agency's oversight of the Chiron manufacturing facility in Liverpool, England, which British regulators shut down on October 5 after finding bacterial contamination of the flu vaccine. Despite our joint request for information from FDA, the agency failed to provide any documents or to make any knowledgeable officials available for interviews by the deadline we set. FDA is now asking for an indefinite extension of time for its response to Congress.

What is happening is obvious. The Administration is trying to delay the release of the vaccine documents until after the election. At the same time, senior Administration officials, including the Secretary of Health and Human Services and the FDA Commissioner, are holding press conferences at which they are asserting that FDA did everything correctly. We should not condone this attempt to conceal relevant information and manipulate public opinion.

The shortage of flu vaccine is a public health crisis unfolding across the nation. Public concerns are high, and the shortage is being discussed by both candidates in the presidential campaign. Yet members of Congress and the public do not have access to the basic facts about what FDA knew and how the agency responded to early warning signs of problems at the Chiron facility. As the oversight committee in Congress, we have a clear obligation to ensure that these facts are promptly disclosed.

Withholding Documents from Congress

On October 8, under your leadership, our Committee held the first and so far the only hearing on the flu vaccine crisis. Senior Administration officials participated and promised to supply documentation to the Committee. For example, Rep. John Mica asked acting FDA

Commissioner Dr. Lester Crawford whether he would provide the Committee with a record of FDA's last visit to the Chiron facility. Dr. Crawford responded, "Absolutely."[1]

On October 13, you and I wrote to Dr. Crawford and asked for this record.[2] We also requested a range of other documents about FDA's response to several warning signs at the Chiron facility. For example, we requested the inspection report prepared by FDA officials after FDA's June 2003 inspection of the Chiron facility, including the Form 483 that lists the safety deficiencies found during the inspection. According to the *Wall Street Journal*, the June 2003 inspection found "systemic quality-control issues" that "led inspectors to conclude that Chiron wouldn't necessarily be able to discover problems, identify the root cause and take steps to prevent similar issues from arising again."[3]

We also requested documents that would explain what FDA did after it learned in August 2004 that several million doses of Chiron flu vaccine were contaminated with bacteria, as well as documents that would disclose what information was exchanged between FDA and the British regulators. Further, we asked for interviews with "those FDA employees who were responsible for inspections of Chiron's Fluvirin facility and communications with the company from June 2003 to the present."[4]

Our request fell squarely within our Committee's jurisdiction, which is to oversee the actions of federal agencies. The documents we requested are not excessive. In fact, some of the documents, such as the Form 483, are supposed to be accessible to the public under the Freedom of Information Act.

Nonetheless, the Administration has withheld the documents we requested. Given the urgency of the situation, our letter set a deadline of October 20. From October 13 to October 20, FDA did not contact anyone on my staff about the document request. Late in the afternoon on October 20, my staff called FDA and learned that no documents would be provided by our deadline. While FDA staff said that the agency was working on responding, a request for a specific date by which documents would be provided was referred to FDA's Assistant Commissioner of Legislation. My staff called this political appointee, but the call was never returned.

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[1] Testimony of Dr. Lester Crawford before the House Committee on Government Reform (Oct. 8, 2004).

[2] Letter from Reps. Tom Davis and Henry A. Waxman to acting FDA Commissioner Dr. Lester Crawford (Oct. 13, 2004).

[3] *U.S. Uncovered Problems at Chiron Plant in 2003: 'Quality Control Issues' Were Similar to Concerns,* Wall Street Journal (Oct. 11, 2004).

[4] Letter from Reps. Tom Davis and Henry A. Waxman, *supra* note 2.

FDA has also failed to arrange a single interview with an FDA official. The only such interview scheduled — with Dr. Jesse Goodman of FDA's Center for Biologics — was planned for 3:00 p.m. on Friday, October 17. The Administration canceled the interview just hours beforehand.

Yesterday, I learned that Dr. Crawford has asked you for an indefinite extension of time to obtain all of the responsive documents. His reason for delay appears to be that FDA personnel who are needed to provide documents are out seeking vaccine from other countries.

There is no excuse for FDA's refusal to cooperate. FDA routinely provides timely responses on active issues to this Committee. When there are problems obtaining all responsive documents, FDA can provide a subset of documents quickly. For example, on October 5, 2004, you wrote to FDA seeking documents about the withdrawal of Vioxx from the market.[5] FDA provided a partial response, with documents, on October 7.[6] That is exactly what should happen in this case.

Misleading the American People

At the same time that FDA officials are refusing to provide relevant documents to the Committee, senior Administration officials are making false or misleading assertions about what FDA actually did. During the presidential debates, President Bush told the American people that the Administration officials "took the right action and didn't allow contaminated medicine into our country."[7] In fact, it was British regulators — not FDA officials — who shut down the plant and prohibited the facility from exporting vaccine to the United States. FDA's only "action" was to learn over the telephone about what the British had done.

At a White House news conference, Health and Human Services Secretary Tommy Thompson also erroneously asserted that FDA officials prohibited the distribution of the contaminated Chiron vaccine. He said:

> We understand yours and the public's concern about the loss of the Chiron flu vaccine supply. Removing this vaccine was a necessary step, however, that helped to be able to

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[5] Letter from Rep. Tom Davis to Acting FDA Commissioner Lester Crawford (Oct. 5, 2004).

[6] Letter from Patrick Ronan, FDA Assistant Commissioner for Legislation, to Rep. Tom Davis (Oct. 7, 2004).

[7] *President George W. Bush and Senator John F. Kerry Participate in the Third Presidential Candidates' Debate*, FDCH Political Transcripts (Oct. 13, 2004).

keep contaminated vaccine out of the arms of Americans. And this of course is the responsibility of this department, and specifically FDA, and they did it well.[8]

During our Committee hearing on October 8, Dr. Crawford was asked to compare the visits to the Chiron facility made by British and U.S. regulators after the August contamination was discovered. He said that the two countries did "about the same thing."[9] In fact, I subsequently learned that while British regulators conducted a thorough inspection over three days, FDA officials visited only once, at the company's request, to hear about Chiron's plans for response. Rather than conduct its own investigation on behalf of the American public, FDA relied upon weekly conference calls with Chiron — until, on October 5, British regulators shut the facility down.

Conclusion

The American people are depending upon Congress to fulfill its oversight responsibility and get real answers about what has led to the flu vaccine crisis. Given the Administration's refusal to cooperate voluntarily, we have only one option: you should use the Committee's subpoena power to ensure that the documents we have jointly sought are turned over as quickly as possible.

Sincerely,

Henry A. Waxman
Ranking Minority Member

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[8] *White House Briefing: News Conference with Secretary of Health and Human Services Tommy Thompson*, Federal News Service (Oct. 19, 2004)

[9] Testimony of Dr. Lester Crawford, *supra* note 1.