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ONE HUNDRED EIGHTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOE BARTON, TEXAS
CHAIRMAN

November 18, 2004

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

Dear Dr. Crawford:

As part of its continuing oversight of matters of public health, the Committee is examining issues surrounding the recent loss of nearly half of the flu vaccine needed by the United States this year as a result of contamination at the Liverpool, UK manufacturing facility of Chiron Corporation ("Chiron"). We are deeply troubled by this sudden shortage of U.S. supplies of flu vaccine.

Of particular concern is the question of whether Chiron and/or the U.S. Government had sufficient notice from available evidence to take additional steps to safeguard against this sudden shortage. According to news reports, in late August 2004, Chiron discovered bacterial contamination in its Liverpool UK plant where it makes Fluvirin, the commercial name of the flu vaccine on order from the U.S. The U.S. Food and Drug Administration ("FDA") learned of the situation shortly after its discovery and coincidentally had a team at Chiron at the time on another matter and they were able to begin a review of the issue. This was not the first time, however, that the FDA had encountered problems at this Chiron facility. In June 2003, shortly after Chiron purchased the Liverpool plant, the FDA conducted an inspection of the site and found quality-control problems and contamination at an early stage of the production process, but these issues were reportedly resolved.

Another question of interest is whether Chiron and the U.S. Government should have taken immediate steps when the contamination came to light to ascertain better the precise scope of the problem and to react more effectively to protect the public health. On August 26, 2004, Chiron publicly disclosed its discovery of contamination of some flu vaccine lots and shortly thereafter received inspectors from the UK Medicines and Healthcare products Regulatory Agency ("MHRA") to assess the situation. MHRA

suspended Chiron's license on October 5, 2004, thereby revealing more widespread contamination of the vaccine lots. It is our understanding that the U.S. Government has claimed that it was not aware of the more widespread contamination until about the time the MHRA took action in early October 2004.

We are concerned that the situation presented here may have common roots in problems this Committee has already identified for the FDA. For example in our earlier hearings on Counterfeit Bulk Drugs, this Committee presented instances of flaws in the FDA's ability to track and inspect foreign firms that send drug products to the U.S. We are troubled by the prospect that the many management concerns and resource constraints raised by this Committee already to the FDA may still plague the agency today and affect its ability to oversee this key sector of drug manufacturing.

The safety and availability of the medicines needed for public health in the U.S. are of paramount concern to this Committee and, as such, we request that, pursuant to Rules X and XI of the U.S. House of Representatives, you provide us the information requested below by Wednesday, December 1, 2004:

1. A timeline beginning with Chiron's acquisition of the Liverpool facility to the present, which includes all the following events:

   a. Any and all events related to the safety of and/or any potential, possible or actual contamination of flu vaccines, at any stage of manufacture, at the facility;
   b. All communications with Chiron or any regulatory authority relating to either the safety of or any potential, possible or actual contamination of vaccines, at any stage of manufacture, at the facility;
   c. All inspections of the Chiron facility by the FDA or any other third party;
   d. All public statements or communications made by the FDA relating to Chiron; and
   e. All public statements or communications made by the FDA relating to the adequacy and/or availability of influenza vaccine to the U.S. public for the 2004 – 2005 flu season.

   Please produce any records relating to the information identified in this timeline, unless otherwise produced in response to this letter.

2. All records relating to any potential, possible or actual contamination of flu vaccines, at any stage of manufacture, at Chiron's Liverpool facility.

3. The dates, purpose and findings of all FDA inspections of Chiron's Liverpool facility.

4. All records relating to any inspections by you, or any regulator, of Chiron's Liverpool facility, including, but not limited to:

a. The June 2003 inspection by the FDA including, but not limited to, all records relating to any action contemplated, proposed or undertaken with respect to Chiron as a result;
b. The August 2004 inspection by the FDA;
c. The September 2004 inspection by the MHRA; and
d. The October 2004 inspection by the FDA.

5. What specific issues did the FDA identify at Chiron in the June 2003 inspection and what specific actions did Chiron take in response to each such issue?

6. Did any problems or concerns with the process, practices, techniques, standards, facilities, equipment or personnel associated with the manufacture of vaccine at Chiron's Liverpool plant identified in the FDA's June 2003 inspection contribute, in any way, to the matters leading to the October 2004 scrapping of Chiron's vaccine production?

7. All records relating to communications between the FDA and Chiron, from May 2003 to the present, related to the Liverpool facility.

8. All records relating to communications between the FDA and any other party, including, but not limited to, the MHRA, relating to Chiron, from May 2003 to the present, related to the Liverpool facility.

9. For each foreign country in which there are facilities or firms which the FDA must inspect for current good manufacturing practices, please state the following:

a. A list of all subject facilities within each foreign country and the date of the last FDA inspection of each such facility;
b. The foreign regulatory body (bodies) in each foreign country with relevant jurisdiction over matters of product safety;
c. Describe the manner in which the FDA receives all necessary and relevant information and reports about each such facility;
d. Is there any formal information exchange process with the relevant foreign regulators, such as in the form of a Memorandum of Understanding or other such agreement and, if not, why not; and
e. What procedures must be followed for the FDA to visit and inspect any subject facility?

10. With respect to the FDA's inspections of foreign facilities, as discussed above, please state the following:

a. What is the average cost of each such foreign facility inspection;
b. What is the total amount the FDA has spent on such inspections in the past 5 years;

c. What is the total budget at the FDA for such inspections; and
d. What is the number of inspectors currently available for such inspections?

Please note that, for purposes of responding to this request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. If you have any questions about this matter, please contact either Anthony M. Cooke of the Majority Committee Staff at (202) 226-2424, or Chris Knauer of the Minority Committee Staff at (202) 226-3400.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.