FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115

Majority (202) 225–2927
Minority (202) 225–3641

February 23, 2011

The Honorable Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Hamburg:

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the unsolved case of who contaminated the U.S. supply of heparin (a blood-thinning drug administered to approximately 12 million individuals in the U.S. annually), and the adequacy of FDA's handling of this matter. It has been almost three years since the FDA linked deaths and serious allergic-type reactions of patients in the United States to supplies of heparin that came from the People's Republic of China which was adulterated with overly sulfated chondroitin sulfate (OSCS). FDA officials believe this was an instance of economically motivated adulteration. However, neither the Chinese government nor the FDA has identified those responsible for the contamination or described how the heparin actually came to be contaminated.

We believe there is a substantial public interest in solving this case. More than 80 percent of the U.S. unfractionated heparin supply is sourced from China and more than 16 percent of U.S. pharmaceutical ingredients are imported from China. There is reason to believe all or some of the individuals responsible for the adulteration are still actively engaged in the Chinese pharmaceutical supply chain and pose a continuing threat to pharmaceutical products imported to the U.S. How the heparin came to be contaminated and the exact nature of the contaminant remain unknown. It is important to determine how the adulteration happened so that industry and government can take more effective proactive measures to reduce the risk of such adulteration in the future.

To assist our investigation, please provide the following within two weeks of the date this letter. The relevant time period for the following requests is January 1, 2008 to the present.

1. All documents relating to heparin-related inspections conducted by the FDA in China, including all attachments and exhibits to such documents, and the FDA Center for Drug Evaluation and Research Office of Compliance reports for each of these inspections.

2. All documents relating to the possible source(s) and/or method(s) of the adulteration of the U.S. heparin supply or the adulteration of heparin supplies in countries other than the U.S.

3. All documents relating to testing result information on heparin lots submitted by heparin firms to the FDA for the purpose of screening for contaminants.

An attachment to this letter provides additional information on how to respond to the Committee's request. The term "FDA" refers to the Food and Drug Administration and any of its offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on behalf or under the control or direction of the FDA. If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Cliff Stearns
Chairman
Subcommittee on Oversight and Investigations

Michael C. Burgess
Member

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations

RESPONDING TO COMMITTEE DOCUMENT REQUESTS

In responding to the document request, please apply the instructions and definitions set forth below:

INSTRUCTIONS

1. In complying with this request, you should produce all responsive documents that are in your possession, custody, or control or otherwise available to you, regardless of whether the documents are possessed directly by you.

2. Documents responsive to the request should not be destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual named in the request has been, or is currently, known by any other name, the request should be read also to include such other names under that alternative identification.

4. Each document should be produced in a form that may be copied by standard copying machines.

5. When you produce documents, you should identify the paragraph(s) and/or clause(s) in the Committee's request to which the document responds.

6. Documents produced pursuant to this request should be produced in the order in which they appear in your files and should not be rearranged. Any documents that are stapled, clipped, or otherwise fastened together should not be separated. Documents produced in response to this request should be produced together with copies of file labels, dividers, or identifying markers with which they were associated when this request was issued. Indicate the office or division and person from whose files each document was produced.

7. Each folder and box should be numbered, and a description of the contents of each folder and box, including the paragraph(s) and/or clause(s) of the request to which the documents are responsive, should be provided in an accompanying index.

8. Responsive documents must be produced regardless of whether any other person or entity possesses non-identical or identical copies of the same document.

9. The Committee requests electronic documents in addition to paper productions. If any of the requested information is available in machine-readable or electronic form (such as on a computer server, hard drive, CD, DVD, back up tape, or removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), you should immediately consult with Committee staff to determine the appropriate format in which to produce the information. Documents produced in electronic format should be organized, identified, and indexed electronically in a manner comparable to the organizational structure called for in (6) and (7) above.

10. If any document responsive to this request was, but no longer is, in your possession, custody, or control, or has been placed into the possession, custody, or control of any third party and cannot be provided in response to this request, you should identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control, or was placed in the possession, custody, or control of a third party.

11. If any document responsive to this request was, but no longer is, in your possession, custody or control, state:

a. how the document was disposed of;
b. the name, current address, and telephone number of the person who currently has possession, custody or control over the document;
c. the date of disposition;
d. the name, current address, and telephone number of each person who authorized said disposition or who had or has knowledge of said disposition.

12. If any document responsive to this request cannot be located, describe with particularity the efforts made to locate the document and the specific reason for its disappearance, destruction or unavailability.

13. If a date or other descriptive detail set forth in this request referring to a document, communication, meeting, or other event is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you should produce all documents which would be responsive as if the date or other descriptive detail were correct.

14. The request is continuing in nature and applies to any newly discovered document, regardless of the date of its creation. Any document not produced because it has not been located or discovered by the return date should be produced immediately upon location or discovery subsequent thereto.

15. All documents should be bates-stamped sequentially and produced sequentially. In a cover letter to accompany your response, you should include a total page count for the entire production, including both hard copy and electronic documents.

16. Two sets of the documents should be delivered to the Committee, one set to the majority staff in Room 316 of the Ford House Office Building and one set to the minority staff in Room 564 of the Ford House Office Building. You should consult with Committee majority staff regarding the method of delivery prior to sending any materials.

17. In the event that a responsive document is withheld on any basis, including a claim of privilege, you should provide the following information concerning any such document: (a) the reason the document is not being produced; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; (e) the relationship of the author and addressee to each

other; and (f) any other description necessary to identify the document and to explain the basis for not producing the document. If a claimed privilege applies to only a portion of any document, that portion only should be withheld and the remainder of the document should be produced. As used herein, "claim of privilege" includes, but is not limited to, any claim that a document either may or must be withheld from production pursuant to any statute, rule, or regulation.

18. If the request cannot be complied with in full, it should be complied with to the extent possible, which should include an explanation of why full compliance is not possible.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; (2) documents responsive to the request have not been destroyed, modified, removed, transferred, or otherwise made inaccessible to the Committee since the date of receiving the Committee's request or in anticipation of receiving the Committee's request, and (3) all documents identified during the search that are responsive have been produced to the Committee, identified in a privilege log provided to the Committee, as described in (17) above, or identified as provided in (10), (11) or (12) above.

DEFINITIONS

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, interoffice and intra-office communications, electronic mail ("e-mail"), instant messages, calendars, contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, power point presentations, spreadsheets, and work sheets. The term "document" includes all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments to the foregoing, as well as any attachments or appendices thereto. The term "document" also means any graphic or oral records or representations of any kind (including, without limitation, photographs, charts, graphs, voice mails, microfiche, microfilm, videotapes, recordings, and motion pictures), electronic and mechanical records or representations of any kind (including, without limitation, tapes, cassettes, disks, computer server files, computer hard drive files, CDs, DVDs, back up tape, memory sticks, recordings, and removable computer media such as thumb drives, flash drives, memory cards, and external hard drives), and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, electronic format, disk, videotape or otherwise. A document bearing any notation not part of the original text is considered to be a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "documents in your possession, custody or control" means (a) documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, or representatives acting on your behalf; (b) documents that you have a legal right to obtain, that you have a right to copy, or to which you have access; and (c) documents that have been placed in the possession, custody, or control of any third party.

3. The term "communication" means each manner or means of disclosure, transmission, or exchange of information, in the form of facts, ideas, opinions, inquiries, or otherwise, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, e-mail, instant message, discussion, release, personal delivery, or otherwise.

4. The terms "and" and "or" should be construed broadly and either conjunctively or disjunctively as necessary to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes the plural number, and vice versa. The masculine includes the feminine and neuter genders.

5. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, limited liability corporations and companies, limited liability partnerships, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, other legal, business or government entities, or any other organization or group of persons, and all subsidiaries, affiliates, divisions, departments, branches, and other units thereof.

6. The terms "referring" or "relating," with respect to any given subject, mean anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is in any manner whatsoever pertinent to that subject.

7. The terms “you” or “your” mean and refers to

For government recipients:

“You” or “your” means and refers to you as a natural person and the United States and any of its agencies, offices, subdivisions, entities, officials, administrators, employees, attorneys, agents, advisors, consultants, staff, or any other persons acting on your behalf or under your control or direction; and includes any other person(s) defined in the document request letter.