ONE HUNDRED TENTH CONGRESS

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

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

February 21, 2008

Mr. Robert L. Parkinson, Jr.
Chairman of the Board, Chief Executive Officer and President
Baxter International Inc
One Baxter Parkway
Deerfield, IL 60015-4625

Dear Mr. Parkinson:

A recent disclosure in the Wall Street Journal alleges that a Chinese facility that has not been inspected by the Food and Drug Administration (FDA) produced the active ingredient in Heparin, a widely used blood-thinning drug manufactured by Baxter International, Inc., which has recently been associated with over 350 adverse events, including 4 deaths. While it is not clear from the article whether this plant is the source of the problem that caused the adverse reactions and deaths, we are troubled by the possibility that Baxter has been selling a drug with an active ingredient that has never been approved. We have asked FDA to explain a claim made by its press office that FDA had never inspected the Chinese facility, which made the active ingredients in the Baxter drug, due to "human error and inadequate information technology systems."

The key question that Baxter must answer is this: Was your firm mislead by FDA into believing that the Chinese firm was an approved supplier of an active ingredient for Heparin? If not, then we are concerned that your company was knowingly distributing an unapproved drug.

In order for us to properly evaluate the relative roles of the FDA and Baxter in this tragedy, we request that you supply all records (the terms records and relating to are defined in the attachment to this letter) since January 1, 2002, relating to:

1. Suppliers of active ingredients for the drug Heparin;

2. Inspection documents such as 483s and EIRs for all Baxter manufacturing facilities that produce Heparin or any intermediates used in the production of Heparin;

3. Correspondence with FDA or other regulatory bodies inside or outside the United States relating to Heparin;

4. Promotional or marketing materials relating to Heparin, including but not limited to documents that discuss the pricing policies for this drug;

5. All due diligence performed on Heparin and/or the facilities used to manufacture the drug or its intermediates;

6. Recalls of the drug or requests to recall the drug;

7. All adverse events reports associated with Heparin whether or not such reports were forwarded to FDA or other regulatory bodies.

Please send your response and supply the requested documents within two weeks of the date of this letter. If you have any questions regarding these requests, please contact David Nelson or Chris Knauer with the Committee on Energy and Commerce staff at (202) 226-2424.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations

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," or "relate" 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.