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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

October 26, 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 the contamination of the U.S. supply of heparin (a blood-thinning drug administered to approximately 12 million individuals in the U.S. annually). We have very serious public health concerns arising from our investigation that we want to bring to your personal attention.

Documents provided by FDA show that over the last few years the Food and Drug Administration (FDA) has had credible evidence that at least two Chinese firms in the supply chain of Baxter and Scientific Protein Laboratories (SPL), the active pharmaceutical ingredient manufacturer for Baxter, supplied lots of heparin contaminated with oversulfated chondroitin sulfate used to make lots of Baxter heparin. This contaminated heparin has been linked to deaths of American patients. These two Chinese companies are also implicated in supplying contaminated heparin to other heparin companies besides Baxter and SPL. We also have reason to believe that these two Chinese firms are still supplying crude heparin that is being imported into the United States. Based on available information, we have seen no indication that the FDA has issued warning letters and/or import alerts to these firms even though FDA has issued warning letters and import alerts to other Chinese heparin firms. Moreover, FDA inspections and correspondence with Chinese heparin firms that possessed/controlled contaminated heparin show that in some cases the Chinese firms identified to FDA the particular workshop that provided the tainted heparin and the workshop was then disqualified. However, we have seen no indication that FDA took any further action to alert heparin companies to avoid these disqualified workshops or to investigate the findings.

We are trying to understand FDA's enforcement policy regarding Chinese firms implicated by industry sources as suppliers of contaminated heparin. To assist our inquiry, please respond by November 9, 2011, to the following:

1. Has the FDA made a determination that any firms (including workshops) that were in the supply chain of the contaminated heparin lots provided to Baxter/SPL were not responsible for the contamination? If so, what was the basis for this conclusion? If not, why did FDA fail to issue a warning letter or import alert for these firms? Has the FDA confirmed that none of the firms (including workshops) in the supply chain of contaminated Baxter/SPL heparin lots are currently supplying heparin that is imported into the United States?

2. Does the FDA lack the authority to notify the industry about Chinese heparin firms that have been disqualified because they were believed to be the source of contaminated heparin? If so, please explain. If not, why did FDA fail to take further action?

If you have any questions regarding this request, please contact Alan Slobodin with the Committee staff at (202) 225-2927.

Sincerely,

Fred Upton
Chairman

Joe Barton
Chairman Emeritus

Cliff Stearns
Chairman
Subcommittee on Oversight and
and Investigations

Joseph R. Pitts
Chairman
Subcommittee on Health

Michael C. Burgess, M.D.
Vice Chairman
Subcommittee on Health

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable John D. Dingell, Chairman Emeritus

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

The Honorable Frank Pallone, Jr., Ranking Member
Subcommittee on Health