

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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September 17, 2015

The Honorable Barack Obama  
President  
The White House  
1600 Pennsylvania Avenue, N.W.  
Washington, D.C. 20500

Dear Mr. President:

As you prepare for the visit of Chinese President Xi Jinping to the United States this September, we would urge you to include justice for the Americans harmed in 2007-2008 by heparin contaminated in China as part of your agenda for discussion. This case of intentional adulteration of Chinese crude heparin, a critical drug that helps to prevent blood clots, resulted in deaths and severe reactions in American patients remains unsolved after seven years.

In late 2007 and the first months of 2008, dozens of patients throughout the United States experienced allergic-type reactions from heparin sold by Baxter International. Several patients died, and numerous patients suffered severe allergic-type reactions. Baxter heparin was soon recalled and then came off the market. The surge in the number of adverse reaction reports subsided.

Scientific evidence obtained by the U.S. Food and Drug Administration (FDA), other authorities, researchers, and industry showed that the reactions were linked to a contaminant (overly sulfated chondroitin sulfate or OSCS) that was intentionally introduced in China during the crude heparin manufacturing process. The contaminant was man-made, and not a natural impurity. Once the contaminant was identified, the FDA and other drug-standard authorities, including U.S. Pharmacopeia, established testing methods for detecting the contaminant in heparin. The drug industry, including companies in China, has adopted these testing methods to protect their heparin from this type of intentional adulteration.

The contamination was a crime under U.S. law, but shortly after the crisis ended in 2008 the investigation into the source stopped. The FDA said the case could not be solved because of the lack of evidence to trace back the contaminant to a source in China, and the limited ability to obtain evidence in China. The FDA sought assistance from the Chinese government in June

2008, but the Chinese government declined because of lack of jurisdiction. This reason was based on the official Chinese Government position that OSCS did not cause the adverse events. However, outside the Chinese government, the evidence is indisputable in the scientific and public health communities and the industry, that OSCS can induce allergic-type and life-threatening reactions depending on the amount of contamination and the dosing of the heparin. In 2010, FDA Commissioner Margaret Hamburg tried to re-open this issue with the Chinese government, but the head of the Chinese FDA refused to discuss it.

On April 29, 2008, the Subcommittee on Oversight and Investigations held a hearing, featuring testimony from victim families. More than seven years later, there has been no justice or accountability to provide to these families. Although the primary criminal investigation was closed by the FDA on January 20, 2010, the FDA in July 2015 reported to the committee that there is an open and ongoing related investigation into contaminated heparin.

Our committee has had an ongoing investigation into contaminated heparin since February 2011. It is our hope that this investigation may help reveal at least some of those responsible, and help deter such despicable adulteration in the future.

It is time for the highest level of the U.S. government to convey to the Chinese government the importance to America of the safety of the U.S. drug supply and improving global public-health cooperation, including investigation of the contamination of heparin. Mr. President, we believe you share our concerns, and look forward to your assistance in raising these issues as part of your meetings with President Xi.

Sincerely,



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Fred Upton  
Chairman



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Joe Barton  
Chairman Emeritus



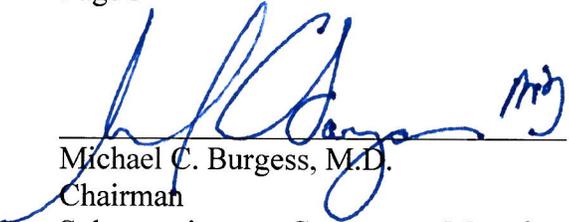
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Joseph R. Pitts  
Chairman  
Subcommittee on Health



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Tim Murphy  
Chairman  
Subcommittee on Oversight  
and Investigations



Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Commerce, Manufacturing,  
and Trade

cc: The Honorable John Kerry, Secretary of State

The Honorable Loretta Lynch, Attorney General

The Honorable Sylvia Burwell, Secretary of Health and Human Services

The Honorable Jeh Johnson, Secretary of Homeland Security

Acting Commissioner of Food and Drugs Stephen Ostroff, M.D.

The Honorable Sarah R. Saldana, Director of Immigration and Customs Enforcement

The Honorable Frank Pallone, Jr., Ranking Member

The Honorable Gene Green, Ranking Member  
Subcommittee on Health

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

The Honorable Jan Schakowsky, Ranking Member  
Subcommittee on Commerce, Manufacturing, and Trade