

**FOR IMMEDIATE RELEASE**  
March 18, 2008

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**IN LIGHT OF HEPARIN CONTAMINATION, KENNEDY URGES FDA,  
INDUSTRY TO INVESTIGATE FOREIGN-SOURCED DRUG INGREDIENTS**

WASHINGTON, DC— Today, Senator Edward M. Kennedy, Chairman of the Health, Education, Labor and Pensions Committee, sent the following letters to the FDA and four industry groups urging an investigation into the sourcing of ingredients used in drugs.

The text of the letters are below.

March 19, 2008

Andrew von Eschenbach, M.D.  
Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner von Eschenbach:

I commend you and the Food and Drug Administration for your investigation of the Heparin tragedy, and I urge you to take additional steps to protect the safety of the nation's drug supply.

At least 19 people have died recently because of reactions to contaminated Heparin, and hundreds have been seriously injured. The FDA has just announced that it has identified a contaminant in Heparin from China that looks like Heparin in the assay used to test the potency of Heparin. This contaminant, an over-sulfated chondroitin sulfate, does not appear to be a naturally-derived compound. It seems likely that it was added intentionally to protect the sales of Heparin. Pigs are the source of Heparin but are in short supply in China because of rampant disease, which may have led to use of the contaminant.

Eighty percent of the active ingredients in our drugs are derived from overseas sources, and 40 percent come from China and India. The FDA does not have sufficient records and databases to enable it to determine where drug companies obtain their ingredients and what they are doing to ensure that the ingredients are pure and potent. I believe the agency could build such databases if drug companies inform you of these sources, and I have written to the major drug industry trade associations asking them to urge their members to cooperate with the FDA on this issue. I would appreciate a written

report from you by April 9, 2008, on how the agency and industry members are responding to this request.

I also believe those responsible for the Heparin tragedy need to be held accountable, and I urge you to work with the Justice Department as you continue your investigation and pursue enforcement actions related to this tragedy. Thank you very much, and I look forward to your response.

With great respect and appreciation, as always

Sincerely,

Edward M. Kennedy  
Chairman

March 19, 2008

W.J. Tauzin  
PhRMA  
950 F Street, NW  
Washington, DC 20004

Congressman James Greenwood  
Biotechnology Industry Organization  
1201 Maryland Ave., SW, Ste. 900  
Washington, D.C. 20024

Ms. Kathleen Jaeger  
Generic Pharmaceutical Association  
2300 Clarendon Blvd. Suite 400  
Association Arlington, VA 22201  
700

Dr. Linda Suydam  
President  
Consumer Healthcare Products  
900 19th Street, NW, Suite  
Washington, DC 20006

Dear Mr. Tauzin, Mr. Greenwood, Ms. Jaeger, and Ms. Suydam:

I'm writing to ask you to urge your member companies to work expeditiously with the Food and Drug Administration to improve the safety of the nation's drug supply.

At least 19 people have died recently because of reactions to contaminated Heparin, and hundreds have been seriously injured. The FDA has just announced that it has identified a contaminant in Heparin from China that looks like Heparin in the assay used to test the potency of Heparin. This contaminant, an over-sulfated chondroitin

sulfate, does not appear to be a naturally-derived compound. It seems likely that it was added intentionally to protect the sales of Heparin. Pigs are the source of Heparin but are in short supply in China because of rampant disease, which may have led to use of the contaminant.

Eighty percent of the active ingredients in our drugs are derived from overseas sources, and 40 percent come from China and India. The FDA does not have sufficient records and databases to enable it to determine where your members obtain their ingredients and what they are doing to ensure that the ingredients are pure and potent. Today I have written the FDA to assess this situation and move to ensure the safety of our nation's drug supply. I ask you to urge your members to inform the FDA immediately about the source the ingredients and what they are doing to see that the ingredients are pure and potent.

I would appreciate a written report from you by March 28, on how your members plan to respond to this request. Thank you very much for your assistance on this important issue.

With respect and appreciation,

Sincerely,

Edward M. Kennedy  
Chairman

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