

Committee Panel to Hold Hearings on Heparin Failures

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NEWS RELEASE

Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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Contact:

Jodi Seth or Alex Haurek, Energy and Commerce Majority, 202-225-5735

Lisa Miller, Energy and Commerce Minority, 202-225-3641

Committee Panel to Hold Hearings on Heparin Failures Committee Leaders Write to FDA About Inspections of Chinese Plants

Washington, DC — The Committee on Energy and Commerce's Subcommittee on Oversight and Investigations has tentatively scheduled an April 15, 2008, hearing to examine the events leading up to the distribution of a contaminated batch of heparin, a blood-thinning drug that was imported from China. The drug has been associated with at least 19 deaths and hundreds of serious illnesses. A committee investigation found that the Chinese facility where the drug was made had never been inspected by the Food and Drug Administration (FDA), despite the agency's long-held preapproval inspection policy.

Today, as part of this investigation, committee staff is being sent to the Scientific Protein Laboratories (SPL) in Waunakee, Wisconsin, to continue interviews with company officials on this matter. Committee leaders are also sending

a letter to the FDA seeking information about Chinese pharmaceutical plant inspections. During recent testimony before the Committee, the Government Accountability Office (GAO) said there are more than 700 plants that appear to be producing drug products for the U.S. market, yet FDA is only able to inspect about 10 to 20 percent of them annually. The Committee is seeking additional information about these plants (see the letter below).

“According to press reports, it appears that the tainted heparin may have been contaminated in an effort to increase the yield, though we continue to investigate this issue,” said Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce. “This latest development underscores our concerns that FDA does not have a robust enough presence overseas in conducting inspections in plants that make drugs for the U.S. market. Ongoing surveillance inspections are critical if FDA is to find shortcomings.”

“FDA’s recent finding on the heparin-like contaminant only heightens my suspicions about deliberate illegal conduct and reinforces my concerns about the need for closely examining Chinese manufacturers that ship FDA-regulated products to the United States,” said Rep. Joe Barton (R-TX), Ranking Member of the Committee on Energy and Commerce.

“Contaminated Heparin is the second instance in the past year of what appears to be intentional adulteration of food and drugs coming into this country from China,” said Rep. Bart Stupak (D-MI), Chairman of the Subcommittee. “We need better processes for inspecting all foreign-made food and drugs, but at a minimum we must address the China issue now. The FDA should establish a schedule by which all Chinese firms exporting to the United States that have not been inspected in the past three years are inspected in the next three. Commissioner von Eschenbach should be prepared to submit such a plan to Congress to assure the American public that steps are being taken to ensure the safety of food and drug imports. The sad reality is that FDA’s inability to inspect foreign facilities has put American lives at risk. Our hearings will evaluate what went wrong leading up to the Heparin recall and the role increased overseas inspections by FDA could play in preventing future incidents.”

The Subcommittee is also planning a second hearing on April 22, 2008, to ask FDA Commissioner Andrew von Eschenbach to explain how to address the many concerns raised by the Committee regarding FDA’s efforts to inspect foreign drug plants making products for the U.S. market.

In February, the Committee broadened its investigation into FDA’s foreign drug inspection program by opening an inquiry into the contamination of heparin. The Committee requested documents from von Eschenbach, Department of Health and Human Services (HHS) Secretary Michael Leavitt and Robert Parkinson, the Chairman and CEO of Baxter International. To date, the drug, used primarily in open-heart surgery and kidney dialysis, has been associated with at least 19 deaths and 900 serious reactions.

As a result of the failures surrounding the heparin incident, Dingell and Stupak have questioned whether it is necessary to codify FDA preapproval policies.

In addition, Dingell, Stupak and Rep. Frank Pallone, Chairman of the Subcommittee on Health, introduced legislation, H.R. 3610, the “Food and Drug Import Safety Act of 2007,” which would improve our country’s system for ensuring the safety of our imported food and drugs. Dingell plans to move the legislation as soon as possible this year.

Read the letter »

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2125 Rayburn House Office Building, Washington, DC 20515