

Chairman Dingell at the Subcommittee on Oversight and Investigations hearing entitled, "The Heparin Disaster: Chinese Counterfeits and American Failures"

Statement of Congressman John D. Dingell, Chairman
Committee on Energy and Commerce

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS HEARING ENTITLED "THE HEPARIN DISASTER:
CHINESE COUNTERFEITS AND AMERICAN FAILURES"
April 29, 2008

Mr. Chairman, thank you for holding this hearing and leading this investigation into the ability of the Food and Drug Administration (FDA) to assure the safety of prescription medications from foreign sources.

Today we examine the tragedy of contaminated heparin, which killed some 81 of our citizens and made hundreds if not thousands very sick. Heparin is a blood-thinning drug given to people receiving dialysis or undergoing open-heart surgery, people whose health is already compromised and for whom contaminated drugs pose potential fatal consequences.

Doctors, hospitals, and clinics administered millions of doses of this drug believing it was safe and not one so contaminated that it would cause a critical allergic reaction. Baxter Healthcare, which manufactured the drug, supplies many patient care items to hospitals. But there was no label that indicated to doctors, hospitals, or their patients that the active ingredient in heparin was made in China, a country with an unreliable drug or food safety regime, as noted by many experts and confirmed by this Committee.

Baxter knew the heparin ingredients came from China. We will assume, however, that they and the other American firm that owned the Chinese plant had no warning that criminals in China were capable of substituting an inexpensive counterfeit ingredient into the production process that mimicked heparin's properties so closely it was undetectable by the standard tests used to determine purity in drug products.

Certainly the FDA, the Government agency responsible for assuring the safety of Americans' prescription drug products, had no idea that this supply of heparin contained a deadly contaminant, until the reports of adverse events started to soar upwards.

Today, we seek answers to whether these companies or FDA should have been able to prevent this situation. Could they have anticipated the actions that led to these deadly counterfeits?

Our investigations have revealed an FDA woefully lacking in the personnel, effective policies, and the will at the highest level to perform the duties entrusted to it by the Congress and the American people. Our citizens can no longer trust that their food, drugs, or medical devices are safe when FDA says they are.

I was disappointed last week by the FDA Commissioner's unwillingness to provide us with the cost of properly conducting foreign inspections. Make no mistake: FDA has a workforce of dedicated public servants who do their best to keep fingers in the dike, and we commend them for their efforts. One such employee is with us today—Regina Brown, the FDA

investigator who inspected the Changzhou SPL plant last February.

I hope this hearing, as well as the legislation that this Committee is now working on, will not only protect the American people, but also ensure that those dedicated FDA employees who serve on the front line are able to do their jobs more completely and effectively.

Prepared by the Committee on Energy and Commerce
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