

China Never Investigated Tainted Heparin, Says Probe

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WASHINGTON—The Chinese government didn't pursue an investigation into contaminated heparin sent to the U.S. in 2007 and 2008, despite suggestions from U.S. officials that it did, according to a congressional probe.

Two House Republicans said the Food and Drug Administration has recently admitted to them that it has been "severely hampered" by the lack of cooperation from China in finding those responsible. Contamination in the widely used blood-thinner was linked to at least 81 deaths in the U.S.

The probe by Reps. Joe Barton and Michael Burgess, both from Texas, comes as FDA Commissioner Margaret Hamburg prepares for her first trip to China since assuming her post last year.

"It is shocking to find out two years after Chinese-made heparin was killing Americans, the Chinese government still has done no investigating to find out why," said Mr. Barton, the top Republican on the House Energy and Commerce Committee. He called on Dr. Hamburg to raise the issue with Chinese officials.

A spokesman for the Chinese Embassy in Washington, Wang Baodong, disputed contentions that China didn't help the FDA heparin probe. He said China "took a serious attitude toward the situation ... and provided full cooperation to the U.S. side."

Mr. Wang said it wasn't the job of Chinese authorities to get to the bottom of the matter. "The company that produced heparin in China is an American company and the heparin product is completely for exporting to the U.S., so it's up to the relevant U.S. agencies to supervise and regulate," he said.

The FDA declined to comment.

In a June 16 letter to the congressmen, the FDA wrote that it was "denied full access" to manufacturers of crude heparin in China "and not permitted to review records."

Mr. Barton and Mr. Burgess said the FDA told members of Congress that China hasn't had any breakthroughs in the investigation, which they said left the "misleading impression" that "there was some kind of open investigation."

In fact, Chinese security authorities told a U.S. official in Beijing on June 18, 2008, that China wasn't investigating the heparin issue as either a criminal or administrative matter, according to the congressmen.

Chinese officials have disputed the FDA's finding that the contaminant was a substance called oversulfated chondroitin sulfate. FDA officials have said that that product, a synthetic molecule, was deliberately added to heparin crude product in China to make the drug faster-acting, which increases its price. Heparin is used to prevent blood clots, and is crucial to many heart and diabetes patients.

Allan Coukell of the Pew Charitable Trusts, who has studied problems in the U.S. drug supply chain, said: "If we are to rely on overseas drug makers, we need regulators to work together effectively. ... The suggestion that the FDA has not been able to obtain a complete picture is of serious concern."

China's food and drug regulator has had several shakeups. In June, a deputy director was fired in connection with a bribery investigation, while in 2007, its chief was executed after a scandal.

Mr. Barton and Mr. Burgess released a report in April highly critical of the FDA's efforts to track the Chinese heparin supply chain, saying it failed to follow clear leads suggesting Chinese companies that lied about their suppliers.

In June, the FDA wrote the congressmen, "Solving the question of who caused the contamination is an important issue for FDA; however our initial primary focus was containing the risk from contaminated heparin."

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