J&J, FDA leaders take heat for 'phantom' recall

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Johnson & Johnson Chairman and CEO William Weldon, left, testifies on Capitol Hill in Washington, Thursday, Sept. 30, 2010, before the House Oversight and Government Reform Committee hearing to examine the circumstances surrounding the recall of medicines produced by Johnson & Johnson/McNeil Consumer Healthcare. Johnson & Johnson Consumer Group Chair Colleen Goggins is at right. (AP Photo/Kevin Wolf)

(AP) -- Johnson & Johnson executives and the Food and Drug Administration both shouldered the blame Thursday for a secret recall in which hired contractors quietly bought up defective painkillers to clear them from store shelves.

J&J Chief Executive William Weldon told House lawmakers the company "made a mistake" in conducting the so-called "phantom recall," which is one of a string of problems that have drawn congressional

scrutiny

In the same committee hearing, the FDA's deputy commissioner, Dr. Joshua Sharfstein, said his agency should have acted sooner to halt J&J's plan. At the same time, though, he stressed that regulators were not aware of the deceptive nature of the recall.

Sharfstein and Weldon testified before the House Committee on Oversight and Government Reform, which held its second hearing on J&J's unprecedented spate of recalls. The largest, involving more than 135 million bottles of infants' and children's Tylenol and other medicines, triggered the committee's investigation.

"We recognize that we need to do better, and we will work hard to restore the public's trust and faith in Johnson & Johnson," Weldon told lawmakers.

Democrats and Republicans pressed Weldon on its "phantom" recall involving 88,000 packets of Motrin, which Weldon acknowledged as "not one of our finer moments."

But lawmakers also pressed the FDA on when and what it knew about the activity. New Brunswick, N.J.-based J&J has repeatedly claimed it alerted the agency's officials in Puerto Rico, where the defective Motrin was originally manufactured.

Sharfstein said J&J informed the FDA of its plan to repurchase the pills - which did not dissolve correctly - in April 2009.

"From this point, it took until July for the FDA to tell the company that a recall should be conducted," Sharfstein said in his testimony. "In my opinion that message should have been given sooner."

But Sharfstein stressed that the FDA did not know J&J had instructed contractors to pose as regular customers while buying the product and to not alert store employees to their activity.

"Based on the documents I reviewed, I don't see any indication that the FDA was aware of the surreptitious, lying nature of the recall," he said.

Republican lawmakers criticized a "too cozy" relationship between FDA and J&J employees, citing months-long e-mail exchanges between the two before regulators took action. But Sharfstein said ultimate blame lies with J&J, pointing out that the FDA does not have the authority to order when and how companies conduct recalls.

"I think fundamentally the responsibility is with the company to handle their quality problems in a much different way," Sharfstein said.

Companies are advised to work with the FDA on recalls, although that isn't a legal requirement.

Committee Chairman Edolphus Towns, D-N.Y., has introduced a bill that would give the agency the power to order recalls.

The maker of trusted brands like Tylenol and Benadryl, J&J has announced nine recalls of drugs for children and adults since last September with problems ranging from too much active ingredient to tiny shards of metal.

In May, J&J closed its Fort Washington, Pa., facility, the largest manufacturing site for children's medications. J&J announced Thursday it would begin shipping its grape-flavored Children's Tylenol next week, the first of its children's formulas to return to the market.

Weldon said the company plans to invest $100 million across the

company to improve facilities, equipment and operations around the world.

Weldon, who has been CEO since 2002, missed the committee's last hearing because of back surgery.

Testifying beside him Thursday was J&J executive Colleen Goggins, who oversaw the consumer division of the company's McNeil Healthcare unit during the recalls.

At the May hearing, Goggins told lawmakers she had no knowledge of instructions to contractors involved in the phantom recall to not tell store employees what they were doing. In her testimony Thursday, Goggins acknowledged that the company wrote those instructions.

"Based on what I have learned since May, I believe that McNeil should have handled things differently," Goggins said.

Goggins will retire in March, Johnson & Johnson announced this month.