Is The FDA Failing To Regulate Puerto Rico?

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SAN JUAN, Puerto Rico (AP) — Congressional investigators announced Monday they will probe whether the U.S. Food and Drug Administration's office in Puerto Rico has failed to adequately oversee pharmaceutical plants that dot the U.S. island.

House Oversight and Government Reform Committee Chairman Edolphus Towns, a New York Democrat, and Darrell Issa, a California Republican who is in line to head the panel, questioned whether FDA staff are up to the regulatory job on an island with one of the world's highest concentrations of drug makers.

"It appears that FDA's Puerto Rico district office may be having difficulty exercising oversight on the numerous pharmaceutical manufacturing facilities on the island," the lawmakers wrote in a letter to FDA Commissioner Margaret Hamburg.

They asked the FDA chief for a list of current and past employees in Puerto Rico, inspection records and warning letters issued in the last decade "to better understand whether FDA Puerto Rico is fulfilling its regulatory responsibility."

A spokeswoman for the FDA in Puerto Rico did not immediately respond to an e-mail seeking comment.

Critics have accused the FDA's local office of poor quality control. FDA officials have said problems are proportionate to the large number of pharmaceutical plants and generally no worse than those on the U.S. mainland. Consumer advocates say the problems demonstrate that the regulatory agency does not sufficiently monitor the industry in either place.

In their letter, Towns and Issa noted that "additional questions" about Puerto Rico operations were raised after British pharmaceutical company GlaxoSmithKline PLC announced in late October that it would pay $750 million to settle allegations related to faulty manufacturing processes at a plant in Cidra. Last month, GlaxoSmithKline said in a statement that it regrets operating the island plant in a manner that violated good manufacturing practices.

The lawmakers also requested an update on a "phantom recall" of Motrin made by a Johnson & Johnson unit in Puerto Rico. In September, Johnson & Johnson executives and the FDA both shouldered the blame for the secret recall in which hired contractors quietly bought up defective painkillers to clear them from store shelves.

Puerto Rico has long had one of the world's highest concentrations of drug makers, but in recent years companies have shed thousands of jobs and closed several plants for a variety of reasons, including the loss of federal tax breaks and cost-cutting.

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