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Congress slams US health officials on tainted drugs

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US lawmakers slammed federal and state health officials Wednesday for failing to properly police a pharmacy whose tainted drugs caused a deadly fungal meningitis outbreak.

"This tragedy could have been avoided," said Congressman Cliff Stearns, who chairs the Energy and Commerce Committee's oversight and investigations panel.

The Florida Republican cited a litany of complaints against the New England Compounding Center and problems found during inspections over the past decade that were insufficiently investigated.

One such incident was when the Food and Drug Administration received reports in 2002 that patients receiving NECC steroid injections had experienced "adverse events," including "meningitis-like" symptoms.

"The product in question was the very same product connected to the current outbreak. In that case, the NECC drug was contaminated with bacteria," Stearns said.

While the FDA inspected NECC's Massachusetts facility in response to the complaints, that did not prevent more patients from getting sick from the same drugs six months later.

At a 2003 meeting with Massachusetts health officials—who hold primary responsibility for regulating pharmacies in their state—Stearns

said the FDA made a "prophetic statement."

"The FDA stated that there was the potential for serious public health consequences if NECC's compounding practices, in particular those relating to sterile products, are not improved," Stearns said.

Some 461 people have been sickened—and 32 of them have died—after receiving injections of NECC's tainted steroids, according to the latest tally by the Centers for Disease Control and Prevention.

The outbreak has led to calls for tighter regulation of the loosely controlled pharmaceutical compounding industry. Federal investigators have launched a criminal probe into the case.

"Even though FDA was clearly aware of the risks posed by NECC's compounding practices, the agency was slow to act," Stearns said.

It took the agency four years to issue a warning letter based on problems it found with NECC's sterility practices in 2002 and two more years for the FDA to respond to the company's claims challenging the report.

"When FDA finally responded in 2008—six years after the agency first inspected the NECC—it directed the company to correct the violations and warned that it would follow-up with future inspections. But FDA never did," Stearns said.

The FDA also failed to follow up after it received notification from the Colorado State Board of Pharmacy in 2011 that NECC was again violating the rules by sending its drugs to out-of-state hospitals without first receiving patient prescriptions.

And the Massachusetts Board of Pharmacy failed to correct problems at NECC despite receiving at least 12 separate complaints.

Critics say drug manufacturers have found a way to sidestep costly and strict oversight by classifying themselves as pharmacies, which are given freer rein to mix drug compounds for patients.

FDA Commissioner Margaret Hamburg told lawmakers that the agency lacked sufficient authority to regulate pharmacies that cross the line into mass production.

"FDA's ability to take action against compounding that exceeds the bounds of traditional pharmacy compounding and poses risks to patients has been hampered by gaps and ambiguities in the law," said Hamburg, who has led the agency since 2009.

These gaps in legal authority "have led to legal challenges to FDA's authority to inspect pharmacies and take appropriate enforcement actions," she told the panel.

NECC president Barry Cadden invoked the constitutional right to refuse to implicate himself as he declined to answer questions from the subcommittee, which did however hear testimony from a widow of one of the victims.

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