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U.S. Regulator Needs New Authority Over Compounding Pharmacies: Report

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By David Morgan

WASHINGTON (Reuters) Oct 29 - The U.S. Food and Drug Administration's power to regulate compounded drugs similar to those linked to a deadly meningitis outbreak is legally nonbinding and lacks the authority of stringent standards imposed on drug manufacturers, according to a congressional report released on Sunday.

The report, compiled by the staff of U.S. Representative Edward Markey, a Massachusetts Democrat, drew an immediate response from FDA Commissioner Margaret Hamburg, who said the agency is committed to working with Congress and others to garner "the authority we need to help prevent tragedies like this from happening again."

"Over the years, there has been substantial debate within Congress about the appropriate amount of FDA oversight and regulation of compounding pharmacies. But unfortunately, there has been a lack of consensus and many challenges from industry," Hamburg said in a statement emailed to Reuters.

"As pointed out in the report from Congressman Markey, FDA's authority over compounding pharmacies is more limited by statute than with drug manufacturers," she added.

The Markey report and Hamburg's comments surfaced as Congress has begun preliminary discussions that could give the FDA new powers to oversee compounding pharmacies like the New England Compounding Center, which is at the heart of a fungal meningitis outbreak that has sickened 337 people, including 25 who have died, in 18 states.

But the public health crisis has also stirred debate about how much authority the FDA actually needs. Last week, the advocacy group Public Citizen called on the Department of Health and Human Services to investigate the agency on grounds that it failed to exercise its existing authority to prevent the meningitis outbreak.

The FDA issued a warning letter to NECC in 2006 describing potential health risks including microbial contamination. But there has been little evidence of a follow-up.

Congressional investigators also say there is evidence that the FDA and state regulators knew of potential problems at NECC in 2002.

Hamburg has had little to say publicly about the regulatory issue. "FDA's primary focus right now is containing the immediate crisis, protecting patients and their families from any further harm and completing our investigation," she said.

Compounding is a traditional pharmacy practice in which a pharmacist alters, mixes or recombines ingredients to make a drug that meets the special needs of a patient with a physician's prescription.

But in recent decades, officials say some compounding operations have grown to resemble full-scale manufacturing without meeting FDA standards.

DOZENS OF WARNING LETTERS

The congressman's report, based partly on documents gathered by investigators in the House of Representatives, says state governments that are now the chief regulators of pharmacy compounding cannot perform the kind of safety oversight necessary to prevent more drug-related outbreaks from occurring.

The FDA has issued dozens of warning letters against compounding pharmacies since 2001. But the report said the agency has based its enforcement actions on relatively weak, nonbinding guidance documents since a 1997 law granting it oversight of "new drugs" was struck down in U.S. courts more than a decade ago in cases brought by compounders.

"Guidance documents do not establish legally enforceable rights or responsibilities and do not legally bind the public or the FDA," said a Congressional Research Services report cited by Markey's staff.

That gives the agency far less power over compounding operations than it has over conventional drug manufacturers, which must submit to stringent safety and efficacy standards.

"Absent clear new authority, FDA's efforts will ultimately be constrained by gaps in regulatory authority and thwarted by an industry that has historically resisted a federal role for the oversight of its activities," said Markey.

An aide to Markey, who is on the House Energy and Commerce Committee which is conducting one of two congressional investigations into the outbreak, said the report was compiled from staff research. The aide acknowledged that some of the documents also form part of the House panel's probe.

Markey has said he will propose legislation to enhance FDA oversight when Congress returns after the November 6 election. The committee is expected to hold hearings by the end of the year.

The report cites FDA documents as saying that compounded drugs may have been responsible for at least 23 deaths and 86 other cases of disease or injury before the current outbreak, related to injectable steroid treatments for back and joint pain first drew public attention last month.

FDA records described by the report also show that 10 of 29 compounded products tested by the FDA in 2003 failed at least one of the regulatory agency's safety or efficacy tests. Three years later, in 2006, one-third of 36 compounded drug samples failed FDA analytical testing.

"The risks of allowing the safety of compounding pharmacies to go largely unregulated have been recognized for years, and the devastating tragedies of this outbreak will be felt well beyond it," Markey said.

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