Lawmakers Seek More Regulation of Compounded Drugs

MATTHEW PERRONE, AP Health Writer

WASHINGTON (AP) — Two Democratic lawmakers on Tuesday called for stricter federal oversight of compounding pharmacies in the wake a deadly meningitis outbreak linked to contaminated injections made by a Massachusetts specialty pharmacy.

Representatives Rosa DeLauro and Edward Markey said in separate statements that they will draft legislation to give the Food and Drug Administration more authority to police the safety of custom-mixed medicines, known as compounded drugs.

Compounding pharmacies traditionally supply products that are not available commercially, based on an individual doctor's prescription. But some pharmacies have grown into larger businesses, operating across state lines and supplying drugs to thousands of hospitals, clinics and physicians.

As many as 13,000 people received steroid shots from the New England Compounding Center of Framingham, Mass, according to The Centers for Disease Control and Prevention.

The contaminated shots have now been associated with 119 cases of meningitis, including 11 deaths, the agency said Tuesday. The company has recalled the fungus-contaminated steroid, which was shipped to 23 states.

Meningitis is an inflammation of the lining of the brain and spinal cord. Symptoms include severe headache, nausea, dizziness and fever.

Unlike drugs manufactured by large pharmaceutical companies, compounded drugs have never been reviewed for safety and effectiveness by FDA. Compounding pharmacies have long operated in a legal gray area between state and federal laws. Efforts to more tightly regulate the industry have been knocked down by federal courts, including the Supreme Court.

Despite that history, Markey said Tuesday the FDA should have authority to bar compounding pharmacies from using ingredients that haven't been cleared by the agency. The Massachusetts congressman says his legislation would also require the pharmacies to report all safety issues to the FDA.

"Unfortunately, compounding pharmacies are a 19th century service operating in a 21st century industry, and we need to update and strengthen the rules that govern these operations so that patients can safely benefit from the unique service they offer," said Markey, who sits on the House Energy and Commerce Committee, which oversees the FDA.

Rep. DeLauro of Connecticut sent a letter Tuesday to Department of Health and Human Services Secretary Kathleen Sebelius, asking what additional powers would help the department improve the safety of compounded drugs.

"Because of the current vague patchwork of federal and state oversight and regulation of these pharmacies, consumers are left at risk and often unaware of the differences between these products and others," said DeLauro, who sits on the House committee that sets the FDA's budget.

Compounded drugs are not mentioned in the landmark 1938 law that gave the FDA authority to regulate virtually all drugs sold in the U.S. For more than 50 years, the FDA exercised little oversight over the space.

Compounding pharmacies technically fall under the jurisdiction of state pharmacy boards, which also regulate traditional pharmacies, though experts say these organizations often lack the resources and expertise to inspect the more than 7,500 compounding pharmacies operating in the U.S.

In the 1990s, FDA regulators began to more closely scrutinize the industry, as some compounding pharmacies grew into larger operations that resembled small pharmaceutical companies.

In 1997, Congress passed a law bringing compounded drugs under FDA oversight, requiring that they meet certain standards for production, labeling and advertising. Specifically, the law banned compounding pharmacies from advertising their products.

A 9th Circuit court ruled that this last requirement was unconstitutional, and the Supreme Court upheld the decision in 2002. The court did not rule on the other portions of the law, though the FDA has not actively enforced them.

Since the decision, the FDA has generally only gotten involved in compounding drug cases that involved large numbers of products distributed across state lines.