Senate Questions Pharmacy Boards after Outbreak

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WASHINGTON (AP) — A Senate committee investigating the deadly outbreak of meningitis wants to know how regulators in all 50 states oversee specialty pharmacies like the one that triggered the illness.

The Senate Committee on Health, Education, Labor and Pensions sent letters Monday to all 50 state boards of pharmacy, seeking details about their oversight of compounding pharmacies.

Contaminated injections from the New England Compounding Center have been blamed for an outbreak of fungal meningitis that has killed 34 people and sickened 490.

Compounding pharmacies, which mix customized medications based on doctors' instructions, are traditionally overseen by state pharmacy boards. But larger compounders like the NECC have emerged in the last two decades, mass-producing thousands of vials of drugs that are often shipped nationwide. That trend has prompted calls for more federal oversight by the Food and Drug Administration.

The NECC shipped more than 17,600 doses of a pain injection to 23 states. Public health officials later identified fungal contamination in two of the lots.

An investigative report issued by the Senate last week concluded that both state and federal regulators missed multiple opportunities to shut down NECC over more than a decade of problematic operations.

"Bureaucratic inertia appears to be what allowed a bad actor to repeatedly risk public health," the report states.

The committee's letter asks state pharmacy boards key questions that might help spot companies like the NECC:

— Are pharmacies required to identify if they produce large quantities of compounded drugs?

— Are pharmacies required to have a patient-specific prescription before producing a compounded drug?

— Are pharmacies required to meet federal guidelines for sterile compounding?

The meningitis outbreak has reignited long-standing questions about who should be responsible for overseeing large compounding pharmacies.

All pharmacies, including compounding pharmacies, have long been regulated by state pharmacy boards, many of which date back to the 19th century. The 1938 law which created the FDA excluded compounding pharmacies and gave the agency power to regulate drug manufacturers.

But in the 1990s, FDA regulators began to more closely scrutinize compounding pharmacies, as some grew into large businesses that resembled manufacturers. However, efforts by FDA to regulate pharmacies have been repeatedly challenged in court.

At congressional hearings last week, the head of the FDA asked lawmakers to draft new laws that would give the agency direct authority over large compounders.