The Partnership for SAFEMEDICINES®

Unsafe Compounded Drugs Harm Patients

Compounded medicine can serve an important role in the U.S. healthcare system, but compounding pharmacies are not regulated like pharmaceutical manufacturing facilities. That heightens risks for patients and has become a particular concern as the demand and popularity of diabetes and obesity drugs skyrockets.

The Food and Drug Administration (FDA) does not oversee most compounded medicines and has issued several public warnings about poorly compounded and counterfeit versions of diabetes and obesity drugs. This follows a long trend of FDA investigations into compounding that have revealed:

- Medicine contaminated with dangerous bacteria in non-sterile working conditions.
- Unapproved ingredients not safety-tested for human use.
- Cheaper, research-grade ingredients not pure enough for human pharmaceuticals.

Case study: New England Compounding Center (2012)

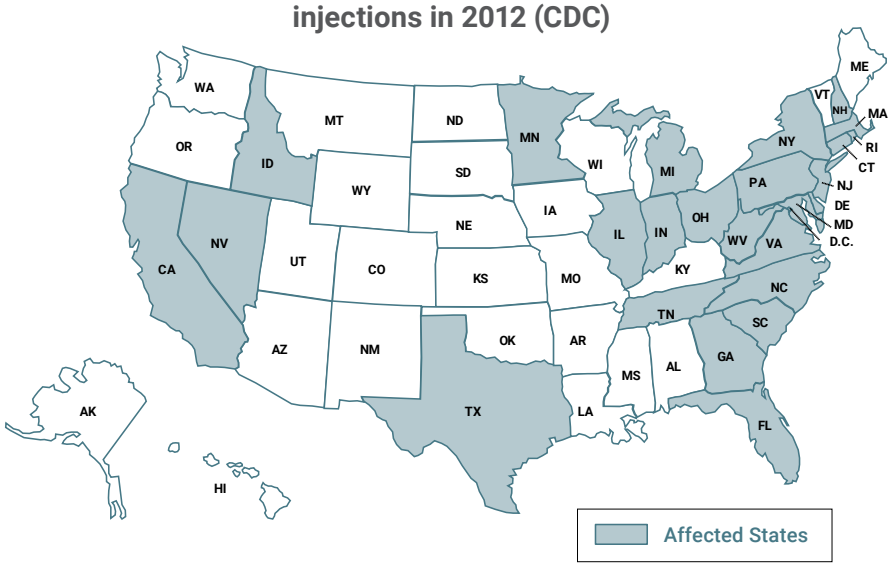
In September 2012, the CDC, FDA, and local health departments investigated a multi-state outbreak of fungal meningitis and other infections among patients who received contaminated steroid injections from the New England Compounding Center (NECC).

The CDC traced the outbreak to three lots of methylprednisolone that NECC **produced beyond its compounding pharmacy license**.

NECC had distributed the product to **75 medical facilities** in **23 states**, starting one of the largest public health crises from a contaminated drug in U.S. history.

In total: **753 people** across **20 states** were diagnosed with fungal meningitis from the contaminated injections and **100** people died. Regulators contacted over **13,500 people** about their potential exposure.

States that received NECC's contaminated injections in 2012 (CDC)



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Concerns with Compounded Diabetes & Obesity Drugs

Experts at the FDA and manufacturers worry compounded diabetes and obesity drugs could be the next cause of widespread patient harms. Some recent developments underscore why:

- FDA issued an alert about dosing errors associated with compounded semaglutide. The agency received reports of adverse events including overdoses that required hospitalization.
- Bacteria and high levels of impurities were found in compounded versions sold in medical spas, weight loss clinics, and compounding pharmacies.
- Customers of various medical spas, wellness clinics and pharmacies were allowed to buy versions without prescriptions that were misleading on safety and effectiveness.
- Patients suffered anaphylaxis and "serious and life-threatening reactions."

The FDA has issued multiple warnings for patients to never use a compounded medicine if an FDA-approved one is available.

Other Examples of Dangerous Compounding Errors

The present and increasing problems with compounded diabetes and obesity drugs follow a long-standing pattern of public health complications from poorly compounded medicines. The total individual fallout often takes years to fully identify and evaluate. Past examples of harrowing compounding consequences include:

- **46 patients** suffered from **eye inflammation, eye infections, high eye pressure, and floaters** after receiving non-sterile eye injections made by an outsourcing facility in Florida in 2019.
- **41 patients** developed **septic arthritis after joint injections** for osteoarthritic knee pain. An investigation found multiple breaches of infection prevention practices during the preparation and administration of compounded products in an outpatient facility in New Jersey in 2017.
- **17 oncology patients** contracted **fungal bloodstream infections** and **two died** after receiving tainted compounded IV medications administered at an oncology clinic in New York in 2016. Patients tested positive for Exophiala dermatitidis, Rhodotorula mucilaginosa, or both fungi.
- **26 patients** suffered from **bacterial** and **fungal infections** in the skin and soft tissue after receiving contaminated steroid injections made by a compounding pharmacy in Tennessee in 2013.
- **12 oncology patients** suffered Pantoea agglomerans **bloodstream infections** because of compounded medication prepared near a contaminated pharmacy sink in Illinois from 2012-13.
- **A dozen people** in South Florida developed streptococcus endophthalmitis after receiving Avastin eye injections prepared by a compounding pharmacy in Florida in 2011. **Three patients required the removal of their eyes.**
- **19 patients** in **six hospitals** in central Alabama contracted Serratia marcescens bacteremia from intravenous feeding solutions in 2011. **Nine patients died.** An investigation revealed a compounding pharmacy failed to adhere to proper sterilization procedures.