The Partnership for SAFEMEDICINES®

COMPOUNDING DANGERS: Mass Prescription Drug Compounding Puts Patients at Risk

Compounded medicines can play an important role in our health care system, but the rise in demand for GLP-1 medications and the resulting shortage fueled an unprecedented volume of compounded medication in the U.S. drug supply. Despite the end of the shortages, compounding continues on a large scale. This activity is not only illegal, but it puts Americans at risk because drug compounders do not follow the same rules and regulations as pharmaceutical manufacturers.

The Partnership for Safe Medicines has a number of key questions for compounders:

Tirzepatide and semaglutide products are no longer in shortage, but telehealth companies and compounders continue to produce and dispense these products on a mass scale. How is that legal?
It's not. Telehealth companies and compounders are skirting the law by making knockoff versions of branded products – offering "custom" dosages and "personalized" formulations, often with additives like vitamin B12, which is also commercially available and therefore not necessary to be compounded.

If thousands of patients receive the same "personalized" formulation, is that truly personal?
It's not. Patients shouldn't receive altered doses of their medicines unless there is legitimate medical reason to do so. There is no legal exception that allows compounding for a lack of insurance coverage.

Compounding facilities can ship medications without ever having been inspected by the FDA. How can we be sure compounding facilities are capable of safely making sterile products like weight loss injectables?
We can't. And a number of compounding facilities that have been inspected have received warning letters about unsanitary conditions and unsafe products. Just this year, multiple compounders have recalled weight loss injectables due to lack of assurance of sterility.

Compounded medicines don't require serial numbers. What happens when a compounded product causes an adverse event and we can't trace products from manufacturer to dispenser to patient?
More people get hurt. When a patient receives a substandard product with no serial number, there's no way to trace it back to the source and more people can be exposed to the harmful product.

The FDA's import database shows that active pharmaceutical ingredients from unregistered foreign sellers have repeatedly made their way into the U.S. Can compounders show that they don't get their ingredients for compounded weight loss drugs from sketchy foreign sources?
They won't. Once those fraudulent shipments get past the border, they aren't tracked. Many shipments of foreign ingredients are specifically marked for compounding, but we don't know where it ends up and the compounders have not committed to transparency in their labeling.

Will the FDA's new Green List project address these issues? What else should FDA be doing?
The FDA's new Green List will help streamline the refusal of non-compliant imported GLP-1 ingredients. This is a great first step in a comprehensive response the FDA should undertake:

- ☑ Refusal of shipments GLP-1 ingredients from unregistered foreign manufacturers
- ☐ End illegal prescribing, marketing, and compounding of GLP-1s and aggressive enforcement against illegal online sellers of unapproved and fake GLP-1s
- ☐ Congress grants FDA destruction authority for dangerous imports and cross-designation of FDCA crimes with HSI/CBP.