CMPI
Center for Medicine in the Public Interest

Myth *or* Fact: Mass Compounding

A temporary shortage of FDA-approved GLP-1 drugs opened the door to a flood of unapproved knock-offs from compounding pharmacies looking to cash in. The shortage has ended, but some compounders continue to mass-produce the drugs. Below are some myths mass compounders continue to use to justify their illegal actions —and corresponding facts that policymakers, providers, and the public should know to keep patients safe.

MYTH #1: Compounded medications are prepared under rigorous oversight.

FACT: Unlike FDA-approved drugs manufactured under strict standards, compounded drugs are not subject to FDA approval and are never reviewed by FDA for safety, efficacy, or quality. Compounding pharmacies are not required to meet the same manufacturing standards as manufacturers of FDA-approved drugs. FDA-approved manufacturing sites must be inspected before they begin making products for human use; many compounders have never been inspected.

MYTH #2: Warnings about the dangers of compounded medications are alarmist.

FACT: The FDA has already received reports of more than 1,100 adverse events tied to compounded GLP-1s, and they are more than twice as likely to result in hospitalization. Because there are minimal requirements on compounders to report adverse events, these reports are likely just the tip of the iceberg. Lax standards by mass compounders are threatening another tragedy like the fungal meningitis outbreak that killed more than a hundred patients and sickened hundreds more.

MYTH #3: GLP-1 formulations are safely compounded.

FACT: Compounded GLP-1s are untested, unproven, and subject to minimal (if any) oversight. FDA inspections of compounding facilities, though infrequent, often reveal serious safety issues, such as failures to sterilize products that put patients at risk of "serious and potentially life-threatening adverse health consequences, including infections and sepsis."

MYTH #4: Unnecessary regulation poses a threat to access and is a burden.

FACT: Patients deserve access to medicines that are safe and effective—that's why the FDA approval system exists. Compounding was intended as a narrow exception to the FDA approval system for patients whose unique medical needs can't be met by approved drugs. It was never supposed to be a backdoor for unregulated mass-production of untested drugs. Compounders are mass-producing so-called "personalized" knock-offs to sidestep the law, not to meet special patient needs.

MYTH #5: Compounded GLP-1s provide patients with personalized products tailored to their needs.

FACT: Phony "personalization" schemes ignore the text and purpose of the Federal Food Drug and Cosmetic Act. Compounders are simply making the same change—typically just adding one untested ingredient, sometimes in amounts they know are not therapeutic—across the board for all patients with no "personalization." This allows them to incorrectly claim they're not illegally copying FDA-approved drugs.

To learn more, visit cmpi.org or read CMPI's report,
***FDA Regulatory Failures in Enforcing Limits on GLP-1 Compounding Puts Patients at Risk*, here.**