Compounded Drugs:
How They Differ from FDA-Approved Medicines

Traditional drug compounding is generally a practice in which a licensed pharmacist or physician mixes, alters or combines ingredients to create a medication tailored to the needs of an individual patient. While compounding serves a limited role in health care, some companies are exploiting the system by mass-producing compounded drugs under the guise of "personalization" to generate profits. The rapid growth of mass-compounded, unapproved GLP-1 medicines is an example of this trend.

The availability of mass-produced compounded drugs marketed directly to patients raises serious safety and public health concerns. Here are several important facts patients should know about drug compounding and the risk associated with these products:

Compounded drugs are not FDA-approved

- Compounded drugs do **not** undergo FDA review for safety, effectiveness or quality.
- They are not supported by the rigorous research, development and multi-phase clinical trials required for FDA approval.
- By contrast, FDA-approved medicines are carefully evaluated by the FDA to ensure they are safe, effective and manufactured to high quality standards before they reach patients.

Increased risks to patients

The FDA has warned that compounded drugs pose a **higher risk to patients** than FDA-approved medicines because they do not undergo FDA review for safety, quality or effectiveness. Even with significant underreporting of adverse events, there have been numerous reports of compounded drugs that were contaminated, impure or substandard - resulting in serious problems for patients.

Common safety risks associated with compounded drugs include:

- Inaccurate dosing that can lead to overdose or toxic exposure
- Contamination due to poor sterile practices
- Inconsistent potency and quality
- Use of poor-quality active pharmaceutical ingredients, including wrong ingredients or ingredients from unregistered foreign facilities

These risks can all impact patient safety. Patient harm from compounded drugs is not theoretical—it is well documented.

- In 2012, contaminated compounded injections caused a fungal meningitis outbreak that killed more than 60 people and sickened hundreds, becoming one of the deadliest pharmaceutical compounding disasters in U.S. history.
- More recently, the FDA has reported adverse events related to compounded eye drops and dosing errors with compounded injectable GLP-1s.

These incidents highlight how failures in quality control, testing and oversight can have devastating consequences for patients.

Misleading marketing and mass compounding

Some compounders and telemedicine companies aggressively market compounded drugs as "safe," "effective" or equivalent to FDA-approved medicines. These claims are false and misleading and thus violate the law.

Some compounders are also mass compounding drugs under the guise of "personalization." This approach undermines:

- The integrity of the FDA drug approval process
- Patient trust in the safety of the U.S. drug supply
- Incentives for pursuing FDA-approval

When is compounding appropriate?

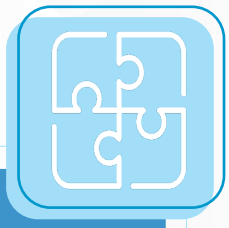
Compounding may be appropriate in the limited circumstances set forth in law, such as:

- When a patient cannot take an FDA-approved medicine due to an allergy or specific medical need
- For outsourcing facilities during shortages of the FDA-approved drug

Outside of the narrow situations, compounding is inappropriate and illegal.

Protecting patients and the drug supply

PhRMA supports strong oversight and enforcement to ensure patient safety and protect the integrity of America's drug development and innovation ecosystem. The FDA has tools within its authority to address illegal compounding, misleading claims and unsafe practices—and continued action is critical to keeping patients safe.



Key Takeaways:

- Compounded drugs are not FDA-approved, have not been approved by the FDA as safe or effective and have been associated with serious harm.
- Deceptive advertisements for mass compounded drugs directly targeting patients are often misleading and include false claims.
- The companies mass compounding drugs under the guise of "personalization" appear to be doing so illegally, purposely undermining the drug approval process and jeopardizing patient safety.