Alliance for Pharmacy Compounding
Compounding the Joy of Living®

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Real solutions for patient safety in pharmacy compounding

Patient-safety concerns that have emerged in the GLP-1 era deserve real answers. APC has developed five targeted policy proposals that address identifiable risks without unnecessarily restricting lawful pharmacy compounding, prescriber judgment or patient access.

THE ISSUE

The rapid growth of GLP-1 medications, telehealth, medical and wellness businesses, and online sellers has exposed gaps in the way prescription medications and drug ingredients are marketed, prescribed and provided to patients.

Some concerns involve pharmacy compounding. Many do not.

Too often, policy proposals treat state-licensed pharmacies, 503B outsourcing facilities, medical spas, telehealth platforms, research-chemical sellers and counterfeiters as though they present the same regulatory problem.

They do not.

Pharmacies already operate under federal and state law, state board of pharmacy oversight and applicable USP standards. Outsourcing facilities operate under a separate federal framework that includes FDA registration and cGMP requirements. Problems within those systems should be addressed. But restricting lawful pharmacy compounding does little to stop illicit sellers, improperly sourced ingredients, or medical spas operating outside meaningful pharmacy oversight.

APC's approach is straightforward: **Identify the risk. Target the conduct creating it. Protect patients without unnecessarily restricting lawful pharmacy practice or access.**

THE DETAILS

APC proposes five practical reforms. Except for medical-spa licensure and oversight, which is principally a state responsibility, these solutions can be pursued at either the federal or state level.

Require clear disclosure that compounded medications are not FDA-approved.
Patients should receive a straightforward, factual statement that their medication is compounded and has not been FDA-approved. The disclosure should inform, not stigmatize.

Require 503A pharmacies to report serious adverse events via FDA's MedWatch system.
APC supports reporting deaths, hospitalizations, life-threatening events, significant disability and other medically serious outcomes. That provides regulators meaningful safety signals without flooding reporting systems with minor symptoms and routine complaints.

Prohibit direct-to-consumer promotion of substances that cannot lawfully be compounded for human use.
Products labeled “research use only” or “not for human use” – or ingredients that otherwise do not meet legal sourcing requirements for human drug compounding – should not be marketed directly to consumers. The substances themselves are illegal. Marketing them to consumers should be, too.

Close oversight gaps involving medical spas and similar businesses.
States should require appropriate licensure or registration, practitioner accountability, product-source documentation and enforcement when these businesses handle prescription drugs. Prescription-drug activity should not become less accountable because it occurs outside a pharmacy.

Protect lawful pharmacies from deceptive legal intimidation.
Drug manufacturers have every right to protect intellectual property, pursue legally cognizable claims and report suspected violations to FDA, state boards of pharmacy or other regulators. But they should not knowingly or materially misrepresent the law or their own legal rights in order to pressure a pharmacy or outsourcing facility to stop otherwise lawful compounding. Good-faith legal arguments and legitimate disputes about unsettled law should remain protected.

The principle is straightforward: Lawful compounding should be governed by what federal and state law actually permit – not by a manufacturer’s ability to use a misleading legal threat to obtain a result the law itself does not provide.

THE ASK

- Use APC’s five proposals as a roadmap for addressing legitimate patient-safety and marketplace concerns.
- Pursue them federally or at the state level as appropriate, with medical-spa licensure principally addressed by states.
- Focus new requirements on the conduct creating the risk rather than broadly restricting lawful pharmacy compounding.
- **Contact APC for the detailed proposals and regulatory language.**

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