Insight

The Drug Compounding Policy Standoff

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Executive Summary

- The regulation of drug compounding has reemerged as a prominent policy issue due to the dramatic increase in popularity of GLP-1 drugs.
- Traditionally, compounding serves a defined clinical purpose: preparing a medication tailored to a patient's needs when a Food and Drug Administration-approved product cannot be used as labeled – for example, when a patient needs an alternative dosage form, a different concentration, or the removal of an inactive ingredient that triggers intolerance.
- The rapid acceleration of compound drug usage creates real compliance issues with existing laws and highlights the need for targeted reform focused on protecting access to appropriate drugs while reinforcing necessary guardrails.

Introduction

Drug compounding – the preparation of a medication outside the standard Food and Drug Administration (FDA) approval pathway to meet a particular clinical need – has long occupied a narrow, pragmatic role in U.S. health care. Under the Federal Food, Drug, and Cosmetic Act's (FD&C Act) compounding provisions – enacted through 1997 and 2013 amendments to the law – pharmacies and registered outsourcing facilities may, in defined circumstances, produce customized therapies (or limited categories of non-patient-specific supply) that are exempt from certain requirements that apply to commercially manufactured drugs. The premise is circumscribed flexibility: Compounding exists to address individualized clinical gaps and, at times, temporary supply disruptions – not to create an enduring, parallel market for widely demanded brand-name therapies.

The skyrocketing popularity of GLP-1 medications is stressing those constraints and has revealed how quickly "temporary relief" from the initial FDA-designated shortages can evolve into a parallel consumer market when coverage is uneven and affordability gaps are wide. Extended shortages of high-demand injectable products created both the practical and legal predicate for large-scale production of "copy" compounded versions. FDA later issued formal determinations concluding that shortages of tirzepatide and semaglutide (GLP-1 active ingredients) injection products were resolved, actions that materially narrowed the circumstances in which copy compounding could be justified.

As shortages receded, the dispute shifted from access-driven improvisation to high-stakes litigation and enforcement. Novo Nordisk has pursued legal action tied to compounded "copies" of its GLP-1 products and has targeted intermediary distribution models; Hims & Hers Health has publicly curtailed at least one compounded GLP-1 offering following FDA warnings of a crackdown; and Eli Lilly and Company has amplified safety and legality concerns in parallel. Federal oversight agencies, including the Department of Health and Human Services and the Department of Justice, have been drawn into the enforcement narrative.

These developments underscore a clear need for reform. The existing statutory framework was not designed for a world in which shortage-driven compounding could scale into a national, consumer-facing supply chain and then persist through contested shortage determinations, enforcement discretion periods, and serial lawsuits. The result is a recurring standoff – between patient access on one side, and the integrity of FDA's approval and quality structures on the other – that will continue unless Congress and regulators clarify the rules of the road for modern, high-volume compounding.

Understanding Drug Compounding and Its Current Legal Framework

At its core, compounding is the customized preparation of a medication to meet a specific clinical need – for example, changing a dosage form, removing an allergen, or preparing a formulation that is not commercially available for a particular patient. Properly done, compounding fills a legitimate gap: FDA-approved products are standardized, while clinical reality can be complex. The modern federal framework largely relies on two sections of the FD&C Act, both shaped by lessons from past safety failures and by Congress' attempt to draw a line between traditional pharmacy practice and manufacturing by another name.

Section 503A: Patient-specific Compounding

Section 503A of the FD&C Act, added by the Food and Drug Administration Modernization Act of 1997, describes the conditions under which compounded drugs can be exempt from

three of the law's major requirements: (1) FDA premarket approval, (2) current good manufacturing practice (cGMP), and (3) certain labeling rules – but only if the compounder meets strict conditions, including compounding based on valid patient-specific prescriptions.

A key limiter is that 503A generally restricts compounding drugs that are "essentially copies" of commercially available products, and it also limits compounding "regularly or in inordinate amounts." The policy logic is straightforward: The exemption exists for tailored care, not for running a parallel, unapproved production line.

Section 503B: Outsourcing Facilities

After major safety incidents tied to large-scale compounding, Congress added Section 503B to the FD&C Act through the Drug Quality and Security Act of 2013. 503B allows certain compounders – called "outsourcing facilities" – to register with FDA and compound (often sterile) products without patient-specific prescriptions, typically to supply clinics and health systems. In exchange for this broader distribution privilege, 503B facilities are subject to cGMP requirements and additional oversight expectations compared with 503A pharmacies.

FDA maintains a public list of registered outsourcing facilities, underscoring that 503B is meant to be an identifiable, inspectable category – not an informal extension of retail pharmacy compounding.

The Shortage "Release Valve"

The legal architecture becomes most controversial when a drug is in shortage. FDA explains that when a drug is on its shortage list, it is generally not considered "commercially available" for purposes of the "essentially copies" restrictions, meaning the usual constraints on compounding copies may not apply in the same way.

This is the release valve policymakers intended: Shortages are a public-health problem, and compounding can sometimes be a temporary pressure-relief mechanism. But the framework was not built for a world where a chronic shortage of a blockbuster drug could support a nationwide, direct-to-consumer alternative supply chain for months (or years).

FDA had previously designated semaglutide injection products in shortage since 2022 due to increased demand, and later determined the shortage was resolved as of February 21, 2025. For tirzepatide injections, FDA removed the products from the shortage list in October 2024 and reaffirmed the shortage resolution in a December 19, 2024, declaratory order after reevaluating the decision (following litigation pressure). FDA also paired those "shortage over" determinations with time-limited enforcement discretion periods to allow

transitions – effectively signaling that compounding of "copycat" versions should wind down on a defined schedule.

What "Mass Compounding" Looks Like in Practice

Once shortages persisted, a national ecosystem formed: Some patients couldn't obtain the branded drug reliably, many couldn't afford it even if they could obtain it, and new telehealth distribution channels made access nearly frictionless. The result was a scale that looks much closer to consumer product distribution than individualized compounding.

Indicators of that scale have been put on the record:

- In late 2024, an industry group told FDA that more than 200,000 prescriptions per month for copies of Wegovy were being filled for U.S. patients.
- By early 2026, Novo Nordisk's CEO publicly cited about 1.5 million U.S. patients using compounded GLP-1 drugs.
- Public company disclosures and reporting highlight how meaningful compounded GLP-1 revenue became for telehealth platforms; for example, Hims & Hers Health projected hundreds of millions in 2025 weight-loss revenue tied to GLP-1-related offerings, illustrating that this wasn't a niche sideline.

At this point, the conflict was baked in. Brand manufacturers argue that widespread, non-patient-specific "copy" production undermines the FDA approval system and their intellectual property; compounders and some clinicians argue they are filling access gaps created by shortages, coverage limits, and affordability barriers.

Generics Are Fundamentally Different From Compounded Drugs

Although both generics and compounded drugs have been discussed as "alternatives" to a brand-name product, they are not interchangeable – either legally or scientifically. Generics are regulated, approved equivalents; compounded drugs are individualized, exempted preparations. Treating them as the same category obscures both the legal structure and the scientific safeguards that underpin generic substitution.

Legally, a generic drug is an FDA-approved product that enters the market through a defined statutory pathway. A generic must match a reference drug in key attributes (active ingredient, strength, dosage form, route of administration) and must meet FDA requirements demonstrating bioequivalence. In other words, it must be scientifically determined that the drug delivers the active ingredient to the body at a similar rate and extent as the brand product. Generic manufacturers are also held to cGMP requirements

and are subject to FDA inspection and enforcement. In other words, generic medicines are a regulated substitute that are affirmatively reviewed and authorized for broad commercial distribution by the FDA. This is why substitution at the pharmacy counter is generally permissible under state laws: The product is expected to behave predictably at population scale.

Compounded drugs operate under a different premise. They are prepared under 503A and 503B compounding authorities intended for patient-specific clinical needs, often when an FDA-approved product is unavailable or unsuitable for a particular patient. Compounded preparations are *not* FDA-approved and typically do not undergo review for safety, effectiveness, or bioequivalence. Because compounding is inherently more customized – and because oversight, testing, and manufacturing controls can vary – compounded products may differ in their inactive ingredients, concentration, sterility assurance, stability, and ultimately clinical performance.

Compounding Should Not Be Used to Address Affordability

Compounding is best understood as a clinical accommodation – not a durable affordability strategy – and policy should treat it that way. Pharmacy compounding plays a legitimate role when an individual patient cannot use an FDA-approved product as labeled: a needed dosage form doesn't exist, an excipient triggers an allergy, a prescriber needs a specific concentration, or a temporary shortage requires an alternative preparation. Those are narrow use cases – accommodations where specific circumstances effectively require patients to accept the risk associated with non-approved drugs that are nevertheless considered safe. Expanding compounding into a broad substitute for high-priced, commercially marketed drugs turns an exception into a parallel supply channel, with predictable tradeoffs in quality assurance, scalability, and oversight.

The central limitation is structural. Compounded drugs generally do not undergo the same premarket review for safety and effectiveness as FDA-approved products, and they are not produced under the same manufacturing and validation regime designed to ensure consistent potency, sterility, labeling, and batch-to-batch reliability. Oversight exists, but it is not identical to the approval-and-inspection framework that governs mass-market drugs. Using compounding to meet widespread demand can therefore raise the risk of variability and quality lapses because the system is operating outside standardized pathways built for population-level distribution.

Compounding also fails a basic test of affordability policy: It does not address the mechanisms that make drugs unaffordable in the first place. High out-of-pocket costs are typically driven by coverage design, list-versus-net price dynamics, formulary incentives,

and uneven competitive pressure – not by an absence of alternative "versions" that can be mixed locally. When compounding becomes the default answer, it can reduce urgency for reforms that target the underlying economics including aligning patient cost-sharing with net prices and value, reducing perverse incentives in the supply chain, and accelerating legitimate generic and biosimilar competition.

None of this suggests eliminating compounding. It suggests maintaining boundaries. Compounding should remain targeted to patient-specific clinical needs and bona fide shortages – not positioned as a generalized affordability valve for widely used therapies. A serious affordability agenda focuses on competition, coverage, and pricing architecture within the approved system. FDA and Congress can reinforce that distinction: Protect access to appropriate compounding while pursuing reforms that make FDA-approved medicines genuinely affordable at scale.

Options to Resolve Current Policy Shortcomings

There is no single "fix" because the standoff between the FDA and dueling members of the pharmaceutical industry is really three problems overlapping: (a) how to treat compounding when shortages end, (b) how to reduce incentives for parallel unapproved supply chains, and (c) how to protect patient safety without abruptly cutting off access.

There are some plausible resolution paths that can be considered to deescalate the current policy standoff and reform the law for future clarity.

1. A clearer, faster shortage off-ramp with credible enforcement: FDA can reduce ambiguity by tightening how it operationalizes the transition from "shortage" to "not shortage," including consistent timelines for enforcement discretion and a sharper definition of when compounding crosses into "regularly or inordinate amounts." FDA already frames the shortage list as pivotal to whether "commercially available" restrictions apply; clearer, predictable off-ramps would reduce the incentive to litigate each delisting and would signal that "temporary relief" cannot become a durable substitute market.
2. A targeted safety floor for high-volume compounding: The reality is that demand shocks will recur (not only for GLP-1s), and policymakers can require more baseline transparency and pharmacovigilance where compounding is effectively at scale. This is consistent with the logic of 503B that broader distribution privilege should come with stronger quality systems. Options include:
    - stronger adverse-event reporting expectations,

- clearer ingredient-sourcing standards,
- standardized labeling on compounded GLP-1-type products, and
- more frequent inspection prioritization for facilities shipping sterile injectables nationwide.

3. A legislative update to fit modern distribution realities: Congress could revisit compounding provisions with the GLP-1 episode as a case study. The aim would be to preserve legitimate patient-specific compounding while reducing the legal room for nationwide "shadow manufacturing" during extended shortages. Potential directions (without picking winners) include:

    - codifying what "inordinate amounts" means in measurable terms,
    - clarifying the role of telehealth "platform" intermediaries in the compounding chain, and
    - modernizing how shortage status interacts with the "essentially copies" concept.

4. A negotiated transition rather than a cliff: Finally, there is the pragmatic option of structured wind-downs when shortages resolve, paired with a near-term access bridge for stable patients (e.g., longer transition windows, prioritized manufacturing allocations, or more explicit guidance for clinicians managing switches). FDA has already used time-limited discretion periods to smooth transitions; making that approach more systematic could reduce both patient harm and political blowback.