How GLP-1s Have Changed Compounding

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Compounding the Joy of Living®

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Disclosure Statement

- Scott Brunner, CAE has no relevant financial relationship(s) with ineligible companies to disclose.

and

- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

At the completion of this activity, the participant will be able to:

1. describe the current federal regulatory framework governing GLP-1 compounding;
2. recognize misinformation related to compounded GLP-1s; and
3. explain the emerging legal and legislative challenges facing compounding pharmacies, including cease-and-desist activity, lawsuits, and proposed state-level restrictions on API and compounding practices.

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APC is the voice for pharmacy compounding, representing 600+ licensed compounding small businesses – including 7,500+ compounding pharmacists and technicians in both 503A and 503B settings – as well as educators, researchers, suppliers, regulators, and prescribers.

APC Media Interviews 2024: 200 | 2025: 115

The “reporter whisperer” on compounding

… explaining law, policy and guidance
… interpreting current practice
… correcting misunderstandings
… poking holes in drugmaker misrepresentations

We’ve earned credibility for **telling the truth**

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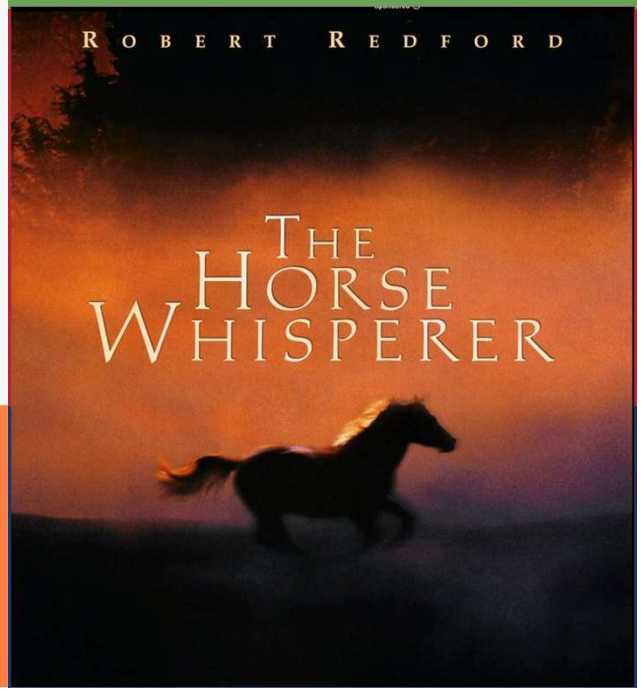
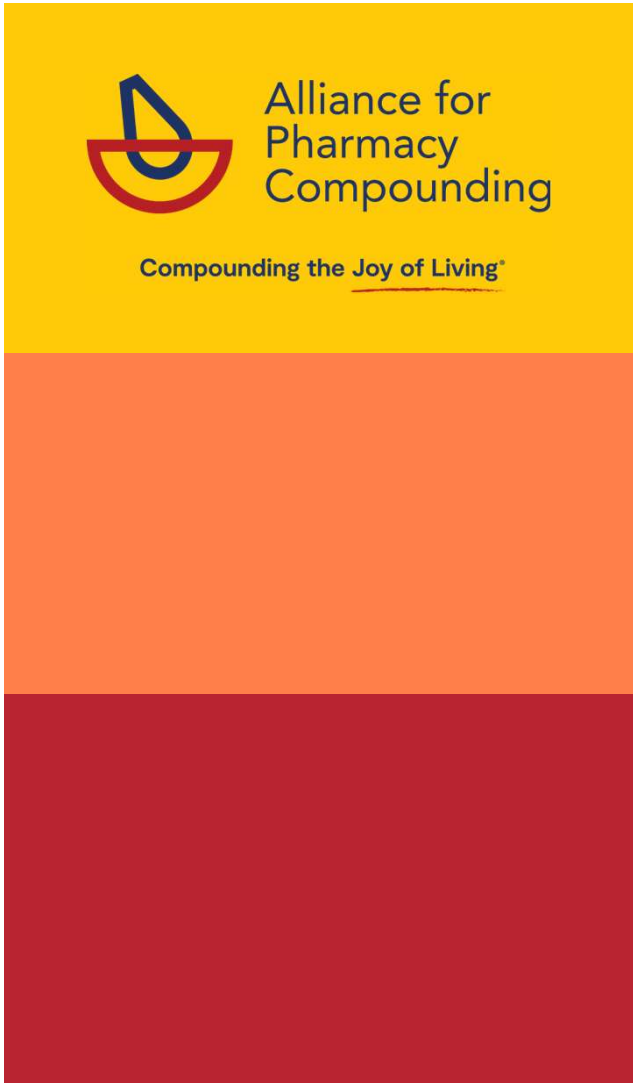


The current situation: The law and FDA

- **Shortages of GLP-1s are resolved**, and FDA has ended "enforcement discretion"
- Compounding of **copies** of FDA-approved GLP1s **no longer allowed**
- 503B outsourcing facilities may **no longer** compound GLP1s **at all**
- **Prescribers continue to exercise judgment** in prescribing custom formulations, per FD&C and FDA guidance, and pharmacies are filling them
- FDA has reiterated that pharmacies must use API from FDA-registered manufacturers, but until Feb 6 **had raised no concerns** about quality of API used or custom formulations
- The **counterfeit and gray markets** are a problem



The events of February 5-6 …

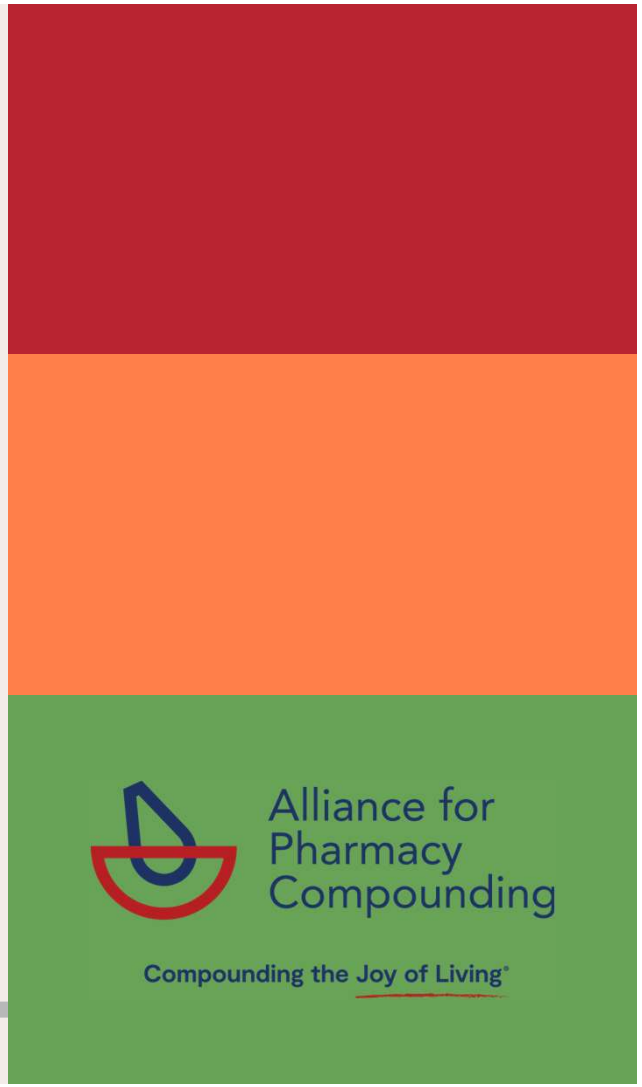
- Unnecessarily provocative marketing play by a major telehealth platform: compounded **oral** semaglutide
- Only a month after FDA-approved oral Wegovy hits market
- FDA Commissioner tweets, issues statement:
  - “mass marketing”
  - “intend to take action to restrict GLP-1 API”
  - Inappropriate marketing claims

Over the past three+ years, compounding pharmacies have:

… given millions of patients access to a wonder drug …
… at a time when drugmakers could not …
… at a (coincidental) price the patient could afford …
… with a track record of reasonable safety.

That compounding generally has adhered to FDA guidance.

Arguable: The scale and marketing of that compounding post-shortage violates the spirit of FDA guidance.



Legitimacy

- General recognition that compounding is authorized to fill gaps FDA-approved drugs don't fill:
  - Continuation of therapy when an FDA-approved drug is in shortage
  - Special circumstances when a prescriber judges a custom formulation makes a "significant difference" for individual patient
- Not "a loophole"
- More than GLP-1s, long before GLP-1s
- It's not 2013 anymore
  - Post-DQSA regulatory framework is robust
  - USP: Appropriate for a drug made for N=1

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Autoimmune cBHT ENT
Veterinary Woundcare
Dental Dermatological
Pain Management Urology
Womens & Mens Health
Ophthalmology

Litigation

- Cease-and-desist letters (pharmacies *and* providers)
- Lawsuits: Med spas, pharmacies, telehealth
  - Deceptive claims (see **a4pc.org/bestpractices**)
  - "Unauthorized drug manufacturing"
  - Mass production of compounded drugs
  - Federal Lanham Act (trademarks, deceptive practices)
  - Corporate practice of medicine
  - Efforts to have their drugs classified as biologics
  - **Feb 9**: first GLP-1 patent infringement lawsuit

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Conflation

- Ongoing misrepresentation by drugmakers and their front groups
  - “Compounded and counterfeit drugs”
  - “Illegally compounded weight loss drugs”
- False assertions that illicit substances are being ordered, imported and prepared by legitimate compounding pharmacies → not a shred of evidence …
- Taking aim at customization and medical judgment

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Manipulation

- Questioning (and distorting) the quality of compounded GLP-1 API → FDA's Green List
- Petitioning FDA: Ban GLP-1 API from compounding because it is "demonstrably difficult" to do
- Letters to state boards of pharmacy
  - Misstatements of law, regulation, and FDA's position
  - Attempts to influence/amend regs
    - Compounding regs in general
    - 503B to 503A sourcing rules
  - Nuisance complaints against pharmacies
- **Legislation implementing restrictions…**

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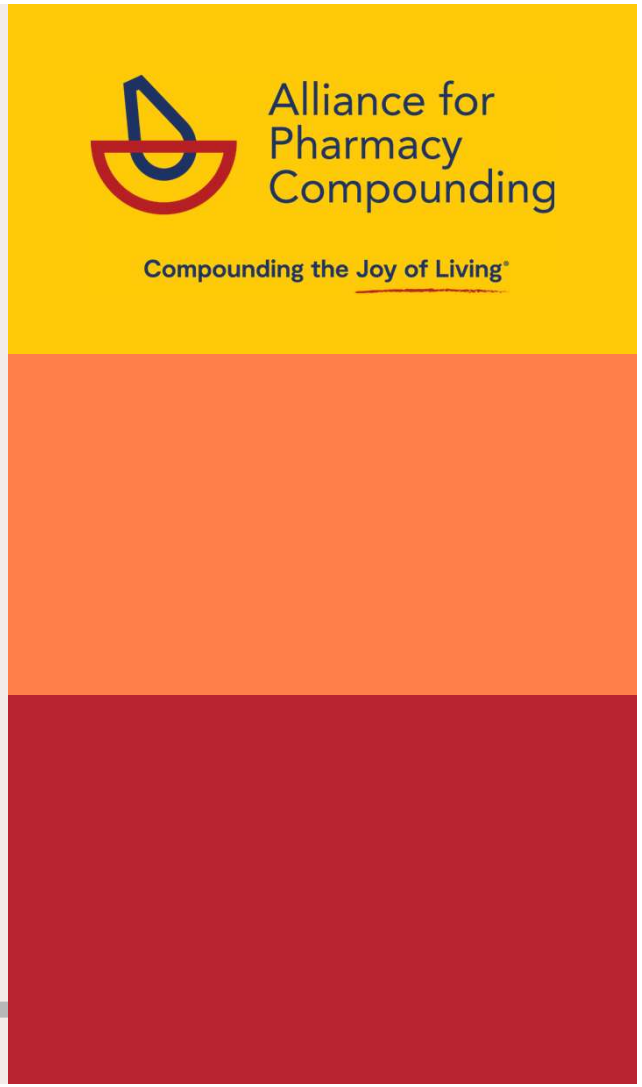
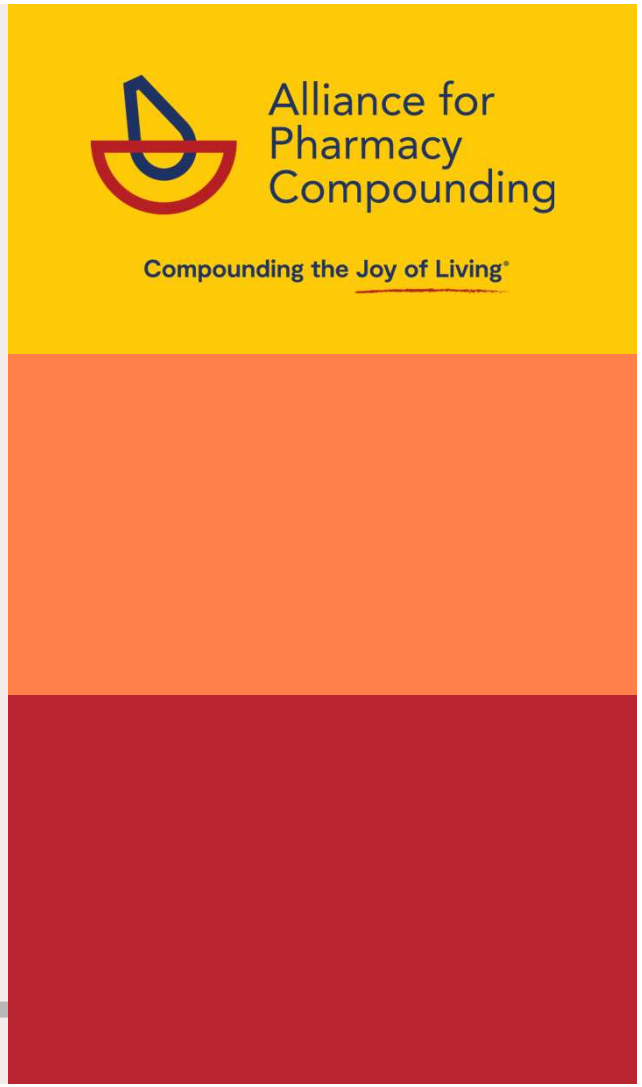
503Bs

- FDA **Draft** “Wholesaling” Guidance drops June 2023, amid the GLP-1 shortage – authorizes 503B sourcing to 503A (for patient-specific dispensing)
- **The earthquake no one noticed**
- 503Bs are FDA-regulated, so most states have no regs on books
- Several 503Bs – < dozen per FDA website – begin sourcing compounded GLP-1s to 503As
- Since then, state boards have awakened to need for regulation/authorization
- *503Bs still restricted in what API they can prepare*



Money

- **Price** – coincidental to the dispensing of a compounded drug – has become cause célèbre
- Infusion of profits → facility improvements
- Entrance of corner-cutters vs quality focused
- The rise of **private equity investment** in compounding → consolidation, fewer mom&pops
- The growth of **telehealth**, cultivated in the pandemic, has flowered in the GLP-1 era
  - No doubt has enhanced patient access
  - Commodification, scale of customization
  - That Super Bowl ad → results in calls for disclosure
  - Now: generics → compounded drugs



High stakes

- Lots of potential profits
- Attacks on FDA's "essentially a copy" guidance
  - Ability to customize therapies to meet needs of individual patients
  - Prescribers' ability to use medical judgment
- Implications well beyond GLP1s
- Patient access to compounded therapies they can't access anywhere else
- And what happens (or doesn't) next may affect everything else …

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Legislation

- Federal:
  - SAFE ACT (House and Senate)
    - Guts shortage drug compounding
      - Changes the definition of when a pharmacy can prepare copy of FDA approved drug
      - Set's arbitrary monthly cap of 20 prescriptions
  - Requires any pharmacy compounding a drug to report 2x/year to FDA

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Legislation

- Drugmaker-authored legislation in several states: Florida, Indiana, Colorado, Georgia, Kentucky, Mississippi, Washington, Arizona, Pennsylvania
  - Pitched as “weight-loss drug safety” and “counterfeit API” bills
  - Actually much broader and more restrictive
  - Some would apply to nearly *all* compounding – some narrower: “weight-loss drugs”
  - 6 bills killed, 5 still in play
  - Some well-meaning lawmakers are buying it

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These bills:

- **Do not address counterfeiting or illicit substances.**
- **Do not elevate patient safety**
- **Impose *conflicting or unachievable regulation* on what is already rigorously regulated.**

ALSO: Generally, boards of pharmacy are not asking for this legislation – and in several states, the board opposes the bill.

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What's next?

- Industry reckoning: Feb 5 has put much at risk
- Blunt instruments:
  - Follow-up to FDA's Feb 6 statement
  - Congress: SAFE Act … and hearings?
  - Drugmaker-drafted state legislation
- APC: Are reforms needed?
  - Require all sellers of API in U.S. to be FDA-registered and inspected?
  - Prescriber judgment: replace "significant difference" standard with "clinically significant difference" … and define it well

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Gearing up

- Raising funds for the fight
- Coordinating with partners
- Determining what potentially is 50 strategies for opposing and defeating

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COMPOUNDING DEFENSE FUND

Prediction:

- Compounding pharmacies can take credit for lowering the price of the FDA approved GLP-1s
- As the price* of the FDA-approved GLP-1s continues to drop, more patients will transition to the FDA-approved drug

*** Price alone is not a legitimate reason to dispense a compounded drug, but it has undeniably been a driver of GLP-1 compounding over the past four years.**

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