



1



COMPOUNDERS
POLITICAL ACTION COMMITTEE



**CompPAC investment
required to attend**
\$1,000 for Pharmacists/Pharmacy Owners
\$250 for technicians



Rep. Jake Auchincloss (MA)
5:30pm on September 15
Separate Ticketed Event
A donation to Rep. Auchincloss'
campaign is strongly encouraged

2

Only 20 seats available

Minimum contribution of \$1,000 required

Rep. Morgan Griffith (VA)

Chair of the House Energy & Commerce
Committee's Subcommittee on Health

7:00pm TONIGHT

Bobby Van's Steakhouse

3

**Thank you to PCCA for sponsoring
tonight's welcome reception.**

4



5



6



International Filter Products

Revolutionary systems for your Industry

**Thank you to International Filter
for sponsoring breakfast.**



7

FDA Perspective on Compounding

Gail Bormel, JD, RPh



8

Compounders on Capitol Hill

SEPTEMBER 15, 2026

*Gail Bormel, Principal and Co-Founder
Compounding Strategy Advisors*



COMPOUNDING
STRATEGY
ADVISORS

9

COMPOUNDERS ON CAPITOL HILL · SEPTEMBER 15, 2026

Overview

01



State of compounding

Past, present and future

02



What to watch

03



What's next

© Compounding Strategy Advisors 2026 All rights reserved.

10

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Past

**Highlights of Certain Policies*

2015	Request for Nominations For Bulk Drug Substances for use in Compounding under Section 503A	2020	COVID Guidances
2015	Pharmacy Compounding Under Section 503A	2020	Final Standard Memorandum of Understanding
2016	Prescription Requirement under section 503A	2021	Hospital and Health Systems Compounding
2018	Mixing, Diluting or Repackaging Biological Products	2022	Extension on the Statutory 5% Limit on Interstate Distribution
2018	Final Guidance Compounded Drug Products that are Essentially Copies of Commercially Available Drug Products	2023	Prohibition on Wholesaling under Section 503B
2018	Final Rule List of Drugs Products that Have Been Withdrawn or Removed for Safety or Effectiveness	2024	Proposed Rule on Demonstrably Difficult to Compound
2019	Final Rule on 503A Bulks List	2025	Final Interim Policies on Compounding under section 503A and 503B of the FDCA
2019	Oxtripitan Guidance		

© Compounding Strategy Advisors 2026 All rights reserved.

3 / 12

11

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Past: 2020- Temporary Policies related to Compounding during the COVID-19 Public Health Emergency

- Compounding of certain drugs for hospitalized patients by outsourcing facilities
- Compounding of certain drugs for hospitalized patients by pharmacy compounders not registered as outsourcing facilities
- Compounding of certain alcohol-based hand sanitizer products
- Repackaging or combining propofol drug products
- Non-standard PPE for sterile compounding by pharmacy compounders not registered as outsourcing facilities

© Compounding Strategy Advisors 2026 All rights reserved.

3 / 12

12

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Past

 **Building Policy**

Lawsuits related to Section 503A compounding-MOU - Shortages:

2020

Wellness Pharmacy and other compounding pharmacies sued FDA over the finalized MOU

2024

Evexias Life Sciences filed suit regarding bulk drug substance placement in Category 2

2025

Outsourcing Facilities Association and FarmaKeio files suit challenging the FDA's decision to remove semaglutide and tirzepatide from the FDA Drug Shortage list

© Compounding Strategy Advisors 2026 All rights reserved. 4 / 12

13

STATE OF COMPOUNDING

PAST · **PRESENT** · FUTURE

The Present


503A Bulks List

- Rulemaking process continues


Pharmacy Compounding Advisory Committee Meeting

July 2026

February 2027


Biologics


Peptides


Safe Drugs Act

© Compounding Strategy Advisors 2026 All rights reserved. 5 / 12

14

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Present

**Partial 503A Bulks List**

- Rulemaking process continues

**Pharmacy Compounding Advisory Committee Meeting**

July 2026

February 2027

**Biologics**

**Peptides**

**Safe Drugs Act**

© Compounding Strategy Advisors 2026 All rights reserved.

5 / 12

15

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Present

**Partial 503A Bulks List**

- Rulemaking process continues

**Pharmacy Compounding Advisory Committee Meeting**

July 2026

February 2027

**Biologics**

**Peptides**

**Safe Drugs Act**

© Compounding Strategy Advisors 2026 All rights reserved.

5 / 12

16

8

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Present


Partial 503A Bulks List

- Rulemaking process continues


Pharmacy Compounding Advisory Committee Meeting

July 2026

February 2027


Biologics


Peptides


Safe Drugs Act

© Compounding Strategy Advisors 2026 All rights reserved. 5 / 12

17

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Future


Peptide—What will happen with compounding peptides that are removed from Category 2 and recommended by the PCAC for the bulks list?


Evolving business practices

New entities, practices


Oversight of 503A compounding

FDA /State

© Compounding Strategy Advisors 2026 All rights reserved. 7 / 12

18

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Future (continued)

Peptides—possible next steps



Notice and comment rulemaking



Enforcement discretion



Silence



Enforcement



Does this represent a shift in the 503A Bulks List process?

© Compounding Strategy Advisors 2026 All rights reserved.

8 / 12

19

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Future (continued)



Essentially a Copy

- Addressing mass compounding of copies
- How to define a change that makes a significant difference
- State and federal policies
 -
 -



Memorandum of Understanding

What about the MOU--29 years and counting?

- Status

© Compounding Strategy Advisors 2026 All rights reserved.

9 / 12

20

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

The Future (continued)



State issues

- Evolving practice of compounding—
- Mass compounding copies of commercially available drugs
- Relatively new entities forming (MedSpas, telehealth)
 - How to track and regulate
- AE reporting
- Information coordination



Wholesaling-relationship between 503B and 503A compounders

- What will the revised draft guidance address?
- States interpretation of wholesaling
- How to address different interpretations

© Compounding Strategy Advisors 2026 All rights reserved.

10 / 12

21

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

What to Watch



Peptides



Biologics



PCAC



Safe Drugs Act



State activities



Rulemaking, Guidances, FR Notices

© Compounding Strategy Advisors 2026 All rights reserved.

6 / 12

22

11

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

What's Next



Enforcement



Supply chain issues



Shortages



MOU



Essentially a Copy



Wholesaling draft guidance

© Compounding Strategy Advisors 2026 All rights reserved. 6 / 12

23

STATE OF COMPOUNDING

PAST · PRESENT · FUTURE

How to Prepare



- Keep up with federal laws, regulations and policies
- Know laws in the state you are located and those you ship into
- Establish and implement SOPs the practices and procedures
- Ensure compliance

 Document compliance

 Know what is reviewed on inspection

 If certain practices are likely to be questioned, document reasoning

 Seek advice

© Compounding Strategy Advisors 2026 All rights reserved. 11 / 12

24

Questions?

25



26



Peptides: PCAC Update

Karla Palmer



27

Peptides: PCAC Meetings and Where *ARE* We Going?

Karla L. Palmer, Esq.
Hyman, Phelps & McNamara, PC
Washington, DC
kpalmer@hpm.com



28

REGULATORY UPDATE – COMPOUNDED PEPTIDES

FDA / COMPOUNDING

PCAC’s review of unapproved peptides

Seven bulk peptide substances nominated for the 503A Bulks List. What the committee recommended, what actually changes, and when?

FDA MEETING
July 23–24, 2026

LOCATION
FDA White Oak, Bldg. 31, Silver Spring, MD

DOCKET
FDA-2025-N-6895 (closed July 22, 2026)

01 · THE MEETING

PCAC / JULY 2026

Seven peptides on the agenda over two days at White Oak.

DATES
July 23–24, 2026

VENUE
FDA White Oak Campus, Bldg. 31 Great Room, Silver Spring, MD

SCOPE
Nominations to the 503A Bulks List

DOCKET
FDA-2025-N-6895 · closed July 22, 2026

DAY 1 · JULY 23

Four peptides — free base and acetate forms

- **BPC-157** — ulcerative colitis
- **KPV** — wound healing / inflammatory conditions
- **TB-500** — wound healing
- **MOTS-c** — obesity and osteoporosis

DAY 2 · JULY 24

Three peptides — free base and acetate forms

- **Emideltide / DSIP** — opioid withdrawal, chronic insomnia, narcolepsy
- **Semax** — cerebral ischemia, migraine, trigeminal neuralgia
- **Epitalon** — insomnia

PCAC PEPTIDES · JULY 2026

30

15

02 · THE OUTCOME

VOTE · JULY 23–24

RECOMMENDED FOR LISTING

6 of 7

PCAC recommendations ran **contrary** to FDA’s **scientific reviewers**, who (in the pre-meeting briefing documents and during the meeting) concluded the record was insufficient to evaluate the safety and effectiveness of the peptides for use in humans.

PCAC vote by substance

PEPTIDE	PCAC VOTE
BPC-157	Recommended
KPV	Recommended
TB-500	Recommended
MOTS-c	Recommended
Semax	Recommended
Epitalon	Recommended
Emideltide / DSIP	Not recommended

03 / 10

PCAC PEPTIDES · JULY 2026

03 · WHAT ACTUALLY CHANGES — AND WHEN

NON-BINDING RECOMMENDATION

A (PCAC) committee recommendation, not a rule change.

PCAC recommendations are advisory. FDA generally follows them, but it is not required to — and the legal status of these peptides -- at this point — has not really changed.

01

Nothing is lawful yet

As of today, none of the seven peptides can be lawfully compounded. FDA can continue enforcement against compounders that produce them.

02

Only path right now is rulemaking

Adding a substance to the 503A Bulks List requires notice-and-comment rulemaking — or an act of Congress amending the FDCA.

OR

Can HHS/FDA return to a period of enforcement discretion and permit use with certain guardrails in place?

03

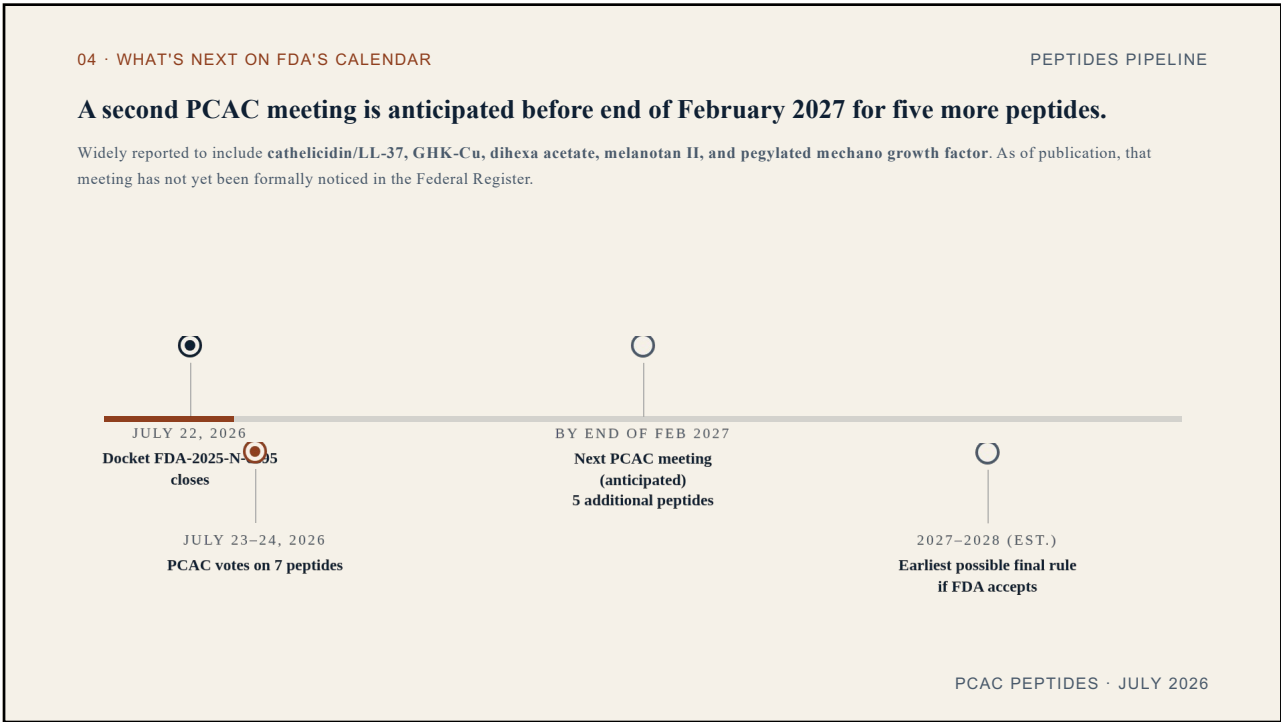
Realistically 12–24 months

Rulemaking on listing decisions of this kind typically takes 12–24 months, putting any binding change most likely in **2027 or 2028**, and only if FDA accepts the recommendation.

Note currently FDA has completed rulemaking on only a handful of substances... since 2014.

04 /

PCAC PEPTIDES · JULY 2026



33

05 · BOTTOM LINE ON TIMING		WHERE THINGS STAND
GLP-1 mass compounding	CLOSED	Effectively closed under the "essentially a copy" and shortage-list analyses. The April 30, 2026 proposed 503B exclusion , locked the door – semaglutide and tirzepatide are not on the 503B list.
“Novel” peptides BPC-157, KPV, TB-500, MOTS-c, Semax, Epitalon	PENDING RULEMAKING	PCAC recommended listing, but no legal status change yet . None until FDA issues a final rule through notice-and-comment — realistically 2027–2028 at the earliest. Compounding these today still carries enforcement risk.
Emideltide / DSIP	EXCLUDED	PCAC recommended against listing. Assume continued exclusion from the 503A Bulks List
Next PCAC meeting	WATCH	Targeted for before end of February 2027 to consider five more peptides (cathelicidin/LL-37, GHK-Cu, dihexa acetate, melanotan II, pegylated MGF).
06 / 10		PCAC PEPTIDES · JULY 2026

34

06 · FDA WARNING LETTERS

TWO ENFORCEMENT THEMES

Seven FDA warning letters on peptides — Two distinct theories

Six letters target U.S.-based peptide sellers under an “unapproved new drug” theory (FD&C Act §§ 301(d), 505(a)). A seventh targets a Chinese API manufacturer for CGMP violations. All letters require a written response within 15 working days; failure to correct may lead to seizure or injunction.

“Unapproved New Drug” — Six U.S. Peptide Sellers

FDA reviewed each firm’s website and concluded the peptides and companion “bacteriostatic water” are **unapproved new drugs** whose distribution violates §§ 301(d) and 505(a) of the FD&C Act.

Even though labeled “research use only,” website claims about **weight loss, appetite suppression, glucose control, and sexual function** establish intended drug use under 21 U.S.C. § 321(g)(1).

Bacteriostatic water treated as a drug because it is sold alongside injectable peptides to reconstitute them for injection.

FDA flags injectable products as **especially concerning** because they bypass the body’s normal defenses against toxins and microorganisms.

CGMP — Chinese API Manufacturer

Harbin Jixianglong Biotech (MARCS-CMS 723330; May 1, 2026). FDA inspected a peptide-API facility in China and cited significant **CGMP deviations** rendering APIs adulterated under § 501(a)(2)(B).

Key issue: Harbin **purchased semaglutide API from unapproved suppliers**, repackaged/relabelled it as its own, and shipped to the U.S. — apparently circumventing Import Alert 66-80 (GLP-1 Green List).

FDA placed Harbin on Import Alert 66-40 and removed it from the Green List (Feb 27, 2026). Harbin voluntarily recalled two batches on Feb 19, 2026.

Also cited: process/cleaning validation failures, analytical method deficiencies, water system deficiencies, drug-listing violations, and misbranding.

07 / 10

PCAC PEPTIDES · JULY 2026

06 · FDA WARNING LETTERS

SIX U.S. PEPTIDE-SELLER LETTERS

All six letters follow an identical “unapproved new drug” theory (§§ 301(d), 505(a)).

FIRM	MARCS-CMS	DATE	KEY PRODUCTS CITED
Gram Peptides grampeptides.com	721806	March 31, 2026	Retatrutide, Tirzepatide, BAC Water. Claims: appetite suppression, insulin sensitivity, weight reduction.
Pink Pony Peptides pinkponypeptides.com	721088	March 31, 2026	Tirzepatide, Retatrutide, BAC Water. Claims: reduces appetite, fat loss, insulin sensitivity.
NuScience Peptides LLC nusciencepeptides.com	733652	August 24, 2026	Tirzepatide, Semaglutide, Retatrutide, Survodutide, Mazdutide, PT-141, Tesamorelin + blend. Broadest roster.
Peak Performance Peptides pppepz.com	735127	August 24, 2026	Retatrutide, Semaglutide, SS-31, PT-141, Tesamorelin. Claims: mitochondrial/neuroprotection, sexual arousal.
Royal Peptides LLC royal-peptides.com	734884	August 24, 2026	Tirzepatide, Semaglutide, Retatrutide, SS-31, PT-141, Tesamorelin, BIMORELIN. Quantified: up to 22.5%/24.2% weight loss.
Tex Peptides (TXP Innovations) texpeptide.com	735067	August 24, 2026	Semaglutide, Tirzepatide, Retatrutide, SS-31, Tesamorelin, PT-141, BAC Water. Claims: blood-sugar, weight/lipid metabolism, CNS arousal.

Common thread: Products labeled “research use only” but marketed with therapeutic claims. FDA treats bacteriostatic water as a drug when sold alongside injectable peptides. All six warn failure to correct may lead to seizure or injunction; response required within 15 working days.

08 / 10

PCAC PEPTIDES · JULY 2026

Harbin Jixianglong Biotech Co., Ltd.

MARCS-CMS 723330 · May 1, 2026 · Peptide-API manufacturing facility, China · Inspected Nov 3–7, 2025

CRITICAL Relabeling and Import Alert Circumvention

Purchased semaglutide API from unapproved suppliers, repackaged/re-labeled two batches as its own manufacture, and shipped to the U.S. — **apparently circumventing Import Alert 66-80** (GLP-1 Green List). FDA placed Harbin on IA 66-40 and removed it from the Green List (Feb 27, 2026). Voluntary recall of two batches (Feb 19, 2026).

Stability and Validation Failures

Distributed tirzepatide API **before stability was established**. Two semaglutide batches released without process validation. Cleaning validation lacked maximum carryover limits, swab-location justification, and swab test results.

Analytical Method Deficiencies

Tirzepatide API lots shipped 2024–2025 **without completed analytical method validation** (HPLC assay/related substances, SEC aggregates, amino acid ratio, bacterial endotoxin). FDA rejected the “R&D use only” defense — shipment volumes were inconsistent with R&D quantities.

Water System, Drug Listing, and Misbranding

Water used for non-sterile APIs (intended for sterile injectables) not monitored for objectionable organisms or endotoxins. Drug-listing failures under § 510(j). Misbranding under §§ 502(a), 502(b)(1), and 502(o). FDA strongly recommended engaging a qualified CGMP consultant.

Bottom line: A very different letter from the six U.S. seller letters. Harbin’s CGMP failures — especially the apparent circumvention of the Import Alert Green List — raise supply-chain integrity concerns for anyone sourcing peptide APIs from China. Response required within 15 working days; failure to correct may lead to further regulatory action.

37

QUESTIONS?**THANK YOU!**

Karla L. Palmer, Esq.
Hyman, Phelps & McNamara, PC
 Washington, DC
kpalm@hpm.com

VISIT OUR BLOG:

<https://www.thefdalawblog.com/>



38



39



40

Compounding & GLP-1s: Regulatory and Litigation Update

Rachael G. Pontikes, Esq.
Blank Rome LLP

Karla L. Palmer, Esq.
Hyman, Phelps & McNamara, PC



41

Compounding: Litigation Update

What law applies to these cases? Is there federal preemption? What about state laws vs. FDC Act? State law claims vs. Federal claims?

- *Nexus Pharmaceuticals v. CAPS, et al.* (9th Cir. 2022) — Court denied preliminary injunction and matter dismissed.
 - Lower court: *Nexus Pharmaceuticals, Inc. v. Central Admixture Pharmacy Services, Inc.*, 2020 WL 6555052 (C.D. Cal. Oct. 29, 2020). Court denied preliminary injunction and dismissed the case. Also dismissed SCA, QuVa, and Leiters matters that Nexus filed.
- *Hope Medical v. Fagron* (9th Cir. 2022) — After the 9th Circuit decided preemption issue in the CAPs matter, the 9th Circuit similarly ruled in favor of Fagron, finding Hope Medical's claims preempted.
- *Azurity v. Edge* (1st Cir.) — No preemption.
- *Zyla v. Wells* (5th Cir.) — No preemption; Supreme Court writ of certiorari denied.
- *Pacira v. Nephron* — No Preemption. Motion for summary judgment denied in part, August 2026.



42

Lilly Escalates Fight Against Retatrutide Sales

Six New Lawsuits Filed

- Filed six new lawsuits against U.S. entities selling black-market retatrutide products, including compounding pharmacies, medical spas, and online sellers falsely claiming “research-use only.”

200+ Referrals to Authorities

- Referred more than 200 individuals and entities to the FDA, U.S. Department of Justice, state attorneys general, law enforcement, and professional licensing boards.

14,000+ Listings Reported Globally

- Reported more than 14,000 websites, ads, social media posts, and product listings unlawfully marketing retatrutide across more than 100 countries.



43

Six New Lawsuits

- *Eli Lilly & Co. v. Aesthetic Envy Cosmetic Centers LLC, d/b/a Aesthetic Envy* (N.D. Cal.)
- *Eli Lilly & Co. v. Astra LLC, d/b/a Astra Peptides* (W.D. Tex.)
- *Eli Lilly & Co. v. Legendary Peptides, LLC* (E.D. Tex.)
- *Eli Lilly & Co. v. Striker Pharmacy, LLC* (S.D. Tex.)
- *Eli Lilly & Co. v. Texas Peptides Inc.* (W.D. Tex.)
- *Eli Lilly & Co. v. Lone Star Peptide Co.* (S.D. Tex.)

Defendants include compounding pharmacies, medical spas, and online sellers allegedly falsely claiming “research-use only.”



44

Lilly's Actions Concerning Retatrutide

- **Regulators, Customs, and Law Enforcement**

Treat unapproved retratrutide sales and an "urgent public health crisis" and coordinate enforcement across borders

- **Social Media and E-Commerce Platforms**

Stop enabling the illegal marketing of these products; blocking conduct and content before it reaches consumers

- **Credit Card Companies, Payment Processors and Shipping /Logistics Carriers**

Cut off infrastructure that enables trade



45

Strive Specialties Antitrust Lawsuit

- Antitrust lawsuit against Eli Lilly and Novo Nordisk; dismissed with prejudice by the U.S. District Court for the Western District of Texas on August 5, 2026.

Claims

- Claims asserted: Violation of Section 1 of the Sherman Act (exclusive dealing arrangements with telehealth providers); Violation of Section 3 of the Clayton Act; Monopolization under Section 2 of the Sherman Act (against Eli Lilly only).

Court's Ruling

- Judge dismissed all claims with prejudice on two independent grounds:
 - Relevant market definition: Strive's compounded GLP-1 medications are not reasonably interchangeable with defendants' branded drugs, placing the plaintiff's products outside the relevant antitrust market.
 - Antitrust injury: The court also found that the plaintiff failed to adequately allege an antitrust injury.

Strive Specialties Inc. v. Eli Lilly & Co., et al., No. 5:26-CV-00155-MA (W.D. Tex. Aug. 5, 2026).



46

GLP-1 Litigation Overview

GLP-1 Litigation Throughout the United States

- Multiple cases pending across federal and state courts.
- Some dismissals winnowing cases; most are proceeding to discovery.

Key Themes

- **General claims:** Trademark infringement, unfair competition (Lanham Act), consumer protection, and FDA regulatory enforcement actions involving compounded GLP-1 products.
- **Compounder wins:** Some favorable outcomes for compounders, particularly on Lanham Act, personal jurisdiction.
- **Compounder struggles:** Dismissals on standing, market definition, and failure to allege injury).



47

GLP-1 Litigation Overview

• Conduct-Based Cases:

- *Eli Lilly & Co. v. Revive RX, LLC*, No. 4:23-cv-03521 (S.D. Tex. Sept. 19, 2023)
- *Eli Lilly & Co. v. Empower Clinic Servs., LLC*, No. 3:25-cv-03464 (S.D. Tex. July 25, 2025)
- *Novo Nordisk Inc. v. Link Pharmacy LLC*, No. 3:25-cv-02061 (N.D. Tex. Aug. 4, 2025)

• Marketing-Based Cases:

- *Eli Lilly & Co. v. Willow Health Servs., Inc.*, No. 2:25-cv-03570 (C.D. Cal. Apr. 23, 2025), *appeal docketed*, No. 26-1317 (9th Cir. Mar. 5, 2026)
- *Eli Lilly & Co. v. Adonis Health, Inc.*, No. 4:25-cv-03536 (N.D. Cal. Apr. 23, 2025) (“Henry Meds”)
- *Eli Lilly & Co. v. Mochi Health Corp.*, No. 3:25-cv-03534 (N.D. Cal. Apr. 23, 2025)
- *Novo Nordisk A/S v. Amble Health, Inc.*, No. 4:25-cv-01048 (N.D. Ohio May 21, 2025)
- *Novo Nordisk A/S v. Mochi Health Corp.*, No. 5:25-cv-06563 (N.D. Cal. Aug. 4, 2025)



48

QUESTIONS?

THANK YOU!

Rachael G. Pontikes
Rachael.pontikes@blankrome.com

Karla L. Palmer
kpalmer@hpm.com



49



50

10-Minute Break

Program resumes at 10:15 AM



51



The Future of Precision Dispensing

Dara SX-50 SpeedFill®

Tabletop Peristaltic Pump Delivering <0.5% Dispensing Accuracy



52



A Legacy Solution Facing Today's Demands

- Nearly 20 Years in Service
- 50+ Weeks / Uncertain Lead Time
- Refurbished / Secondary Market — High Risk
- Operates at 5%-10% Dispensing Deviation
- Requires multiple calibrations per batch

Nearly Every Pharmacy We Know Is Growing — Expanding Operations or Building New Facilities.



53

SX-50: The Upgrade for Optimal Sterile Compounding

- <0.5% Dispensing Deviation
- Up to 6.4 L/min
- One Prime. One Calibration. Entire Batch.
- 0.1–1,050 mL Dosing Range
- Touchscreen + Admin Control
- 200 Recipe Storage
- Dispense Time + Vial Tracking



54

SX-50: The Upgrade for Optimal Sterile Compounding

Precision That Pays

- 250 x 2 mL Vials = 500 mL Batch | \$100/mL Medication

5% Deviation

- 525 mL Required (500 mL x 1.05)
- **\$2,500** Excess / Batch (25 mL x \$100)

<0.5% Deviation

- 502.5 mL Required (500 mL x 1.005)
- **\$250** Excess / Batch (2.5 mL x \$100)

\$2,250 POTENTIAL SAVINGS / BATCH



- Greater savings with larger dispense volumes (5 mL or 10 mL)
- Significant savings when calculated annually.

+ Faster Flow • One Prime • One Calibration / Batch



55

Why Purchase Your SX-50 from IFP?

A Complete Solution — Before, During & After Purchase

Ready When You Are
In-stock pumps + sterile tubing sets & bag assemblies with CoC/Sterility documentation

Supported from Day One
Authorized distribution + warranty + setup, training & technical support

Built for Long-Term Success
IFP R&D expertise + ongoing application/consumables support + optional IQ/OQ



56



Onyx Ahmad

VP of Business Development
International Filter Products

Phone: 818-504-8115 ext 105
Email: onyx@internationalfilterproducts.com
Website: internationalfilterproducts.com



Meet Us at the
Booth for a Live SX-
50 Demo




57






58

Your Biggest Legal Risks

Jay McEniry & Stephen Snow



59

Your Biggest Legal Risks Right Now: A Pharmacy Owner's Legal Checkup

Stephen Snow
Bendin Sumrall & Ladner, LLC
ssnow@bsllaw.net

Jay McEniry
Fagron North America
jay.mceniry@fagron.com



60

TELEHEALTH COMPANIES AND MEDICAL SPAS

- Marketing materials
- Clinical Oversight
- Essentially a Copy – Statements of Significant Difference
- Prescriber Licensure
- Controlled Substances
- Atypical Prescribing Patterns



61

CONTRACTS AND DUE DILIGENCE

- Supply Agreements
 - Qualification
 - Representations and Warranties
 - Indemnity Protections
 - Ongoing Qualification and Inspection Rights
 - Quality Agreement
 - Does This Agreement Work With Your SOPs?



62

CONTRACTS AND DUE DILIGENCE

- Professional Service Agreements
 - Reps and Warranties / Compliance with Law
 - Essentially a Copy
 - Patient's Rights
 - Patient Billing
 - Term of Agreement
 - Indemnity Protections



63



64

Thank You

*And Remember ... ALWAYS Scrutinize and Verify AI Results
Or, Better Yet, Call Karla, Mark, Rachael and Stephen*



65



66

50 States, 50 Rules

Mark Boesen, Jay McEniry & Rachael Pontikes



67

50 States That Don't Love You

...And a District and Five Territories. All With Rules of Their Own.

...And Paul Simon Doesn't Have a Song to Teach You How to Leave Them.

50 States, 50 Sets of Rules: Where State Regulators Are Headed

Rachael Pontikes | Jay McEniry | Mark Boesen

10:50 a.m. to 11:20 a.m.

BLANKROME

Fagron
personalizing
medicine

BSL BOESEN
& SNOW LAW



68

One Supply Chain, Fifty Rulebooks

Legislation

- New bills are redefining what compounding is, who may prescribe, and what may be dispensed.

Board of Pharmacy Rules

- USP adoption, sterile standards, and nonresident licensure conditions keep shifting.

Enforcement

- Complaint driven inspections, records demands, and discipline are the practical front line.



69

Why Divergence Is Accelerating

Three forces are pulling the states apart. A fourth is quieter but just as costly: boards now share information faster than ever, so one complaint can become several investigations.

Federal Gaps

When federal policy pauses, the states legislate.

GLP-1 Demand

High volume therapies draw high volume scrutiny.

Telehealth Reach

Platform prescribing tests every nonresident rule.



70

Bill Themes to Watch in 2026

01. Scope and Definitions

Compounding versus manufacturing, and what counts as patient specific.

02. Product Specific Bills

Peptides, GLP-1s, and state bulk drug substance lists.

03. Channel Rules

Office use authority, telehealth platforms, and prescriber relationships.

04. Transparency Mandates

Volume reporting, fees, and disclosure duties.



71

Boards of Pharmacy: Rulemaking Watch

01. USP 795, 797, and 800

Adoption timing and state specific amendments.

02. Sterile Facility Standards

Beyond use dating, testing, and environmental controls.

03. Nonresident Licensure

Inspection requirements, reciprocity, and conditions of licensure.

04. Reporting Duties

Recalls, adverse events, and self reporting obligations.



72

What Boards Are Actually Doing

Enforcement is where divergence gets expensive. Watch one trend in particular: AI assisted and anonymous complaints are reaching boards faster than boards can vet them.

Inspections

Complaint driven, and competitors file too.

Records Demands

Broad requests with short deadlines.

Discipline

Consent orders, fines, and cross state referrals.



73

The Flashpoints Driving State Attention

GLP-1s After the Shortage

- Copies, dosing, and marketing are all under review.

Peptides, Bulk Substances, and Essentially a Copy Interpretations

- State lists are diverging from federal categories.

Hormones, Med Spas, and Platforms

- Claims, consents, and who is really practicing, and where.



74

Where States Agree, and Where They Do Not

Converging

- USP based quality standards, nonresident licensure, sterile compounding scrutiny, and recordkeeping expectations.

Diverging

- Essentially a Copy, peptide and bulk substance lists, telehealth prescribing limits/modalities, and enforcement appetite.

The Compliance Takeaway

- Build to the strictest state you serve, then document the state specific deltas.



75

What to Watch Next

01. Now

Legislative sessions and bill drafts.

02. Mid 2026

Board rule packages and comment periods.

03. Into 2027

Enforcement follows the new rules.

04. Practical Move

Track the bills, comment early, and build to the strictest state you serve.



76

Three Things to Take Home

Fifty jurisdictions means fifty answers. The work is knowing which answer applies where, and getting in front of the rule before it is final.

Assume Divergence

Map the rules for every state you touch.

Engage Early

Comment periods are the cheapest place to influence outcomes.

Be Ready

A written response protocol keeps a board inquiry manageable.



77

Thank You

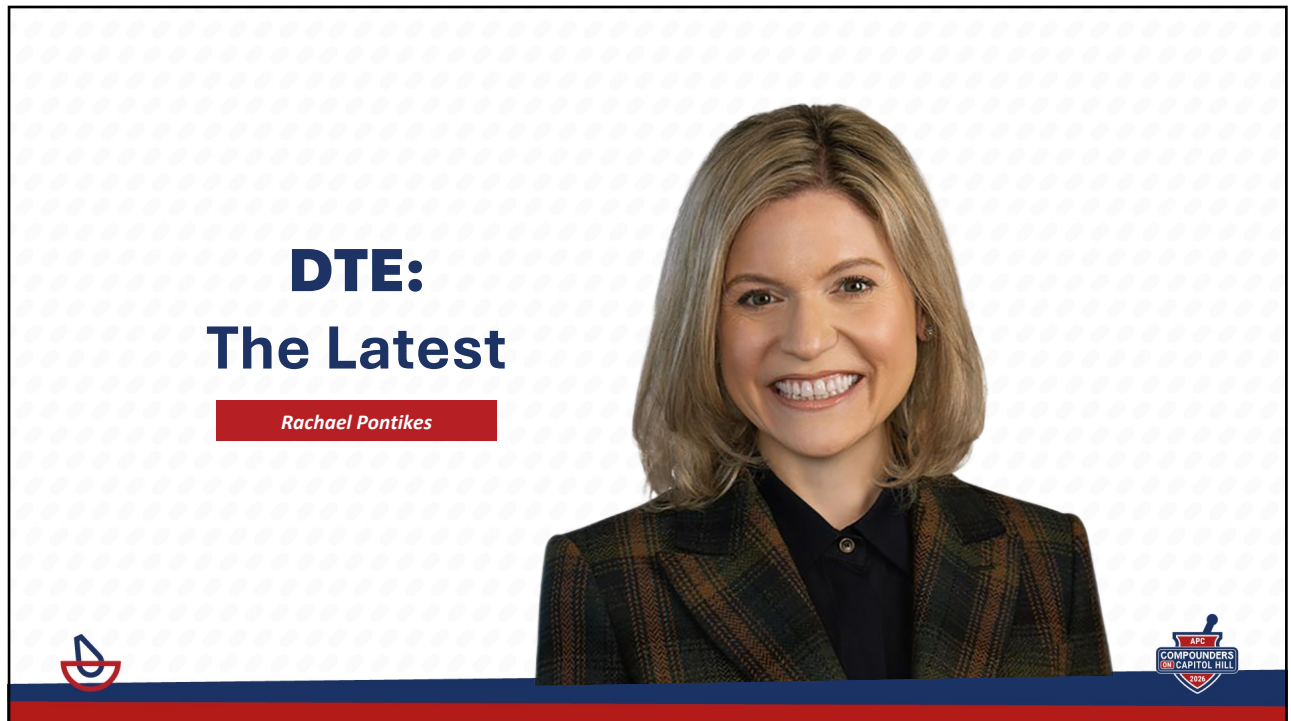
Rachael Pontikes | Jay McEniry | Mark Boesen
Questions and discussion



78



79



80

DTE: The Latest

Lawmakers are invited to sign a congressional letter to FDA expressing shared concerns with issues raised in the Citizen Petition and requesting swift consideration and response from the Agency. Efforts are led by Representative Mike Rulli (R-OH) and joined by Diana Harshbarger (R-TN).

Interested parties can contact Mr. Rulli's staff to learn more:
Geo Marcial Geornalier.Marcial@mail.house.gov



Scan here to access the **Citizen Petition**
and submit a comment

Docket ID FDA-2026-P-10231



81

Quality in Compounded Peptides

*What every healthcare professional should know
about the pharmaceutical supply chain*

A closer look at what quality really means in compounded peptides, from where ingredients come from to how they're tested and verified. This presentation explores what healthcare professionals should be looking for behind the scenes to make more informed, confident decisions.



82



Built Around Pharmaceutical Quality

For more than 35 years, Medisca has supported pharmaceutical compounding through quality ingredients, scientific expertise, rigorous quality principles, and education.

Our role helps strengthen quality, traceability, and supply chain integrity.

35+ YEARS EXPERTISE
Advancing personalized medicine through quality, science, and education

500+ QUALIFIED MANUFACTURERS
Global sourcing with rigorous due diligence and GMP oversight

INDEPENDENT QUALITY VERIFICATION
Analytical testing, stability assessment, and complete lot traceability

7+ FDA-REGISTERED FACILITIES
Controlled repackaging, validated systems and rigorous quality operations



83



Quality Begins Before Compounding

Patient confidence starts long before a prescription is written.

Every compounded therapy depends on the quality of the pharmaceutical ingredient and the systems used to source, verify, and protect it before it reaches the compounding pharmacy.

- Selecting qualified manufacturers
- Demonstrating GMP compliance
- Independent analytical verification
- Stability-supported shelf-life data
- Complete traceability




84



What every healthcare professional should look for

A trusted pharmaceutical supply chain is built on rigorous quality principles.

- Manufacturer qualification and due diligence
- FDA registration ≠ FDA inspection
- Independent analytical testing
- Stability programs and CoA verification
- Complete lot traceability and transparency



85



What every healthcare professional should look for

How quality is tested:

- Identity testing
- USP compendial verification
- Elemental impurity testing
- Residual solvent testing
- Stability studies
- Independent testing by FDA-registered laboratories



86

Going Further at the Source

MQ™ is Medisca's approach to going further upstream. Strengthening how pharmaceutical ingredients are sourced, qualified, tested and continuously monitored.

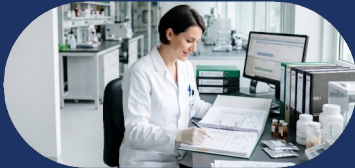


01. Qualify the source

Rigorous manufacturer qualification, due diligence and quality-system oversight.

02. Verify the evidence

Independent testing and deeper analytical review to confirm identity, purity and quality.



03. Maintain oversight

Ongoing supplier monitoring, traceability and action when quality expectations are not met.



Thank You

*Going further at the source
Because quality isn't a checkpoint.
It's a continuous commitment.*



Anna Di Nezza

Director of Quality & Compliance

Medisca

Phone: +1-514-809-3813

Email: adinezza@medisca.com

Website: www.medisca.com






89

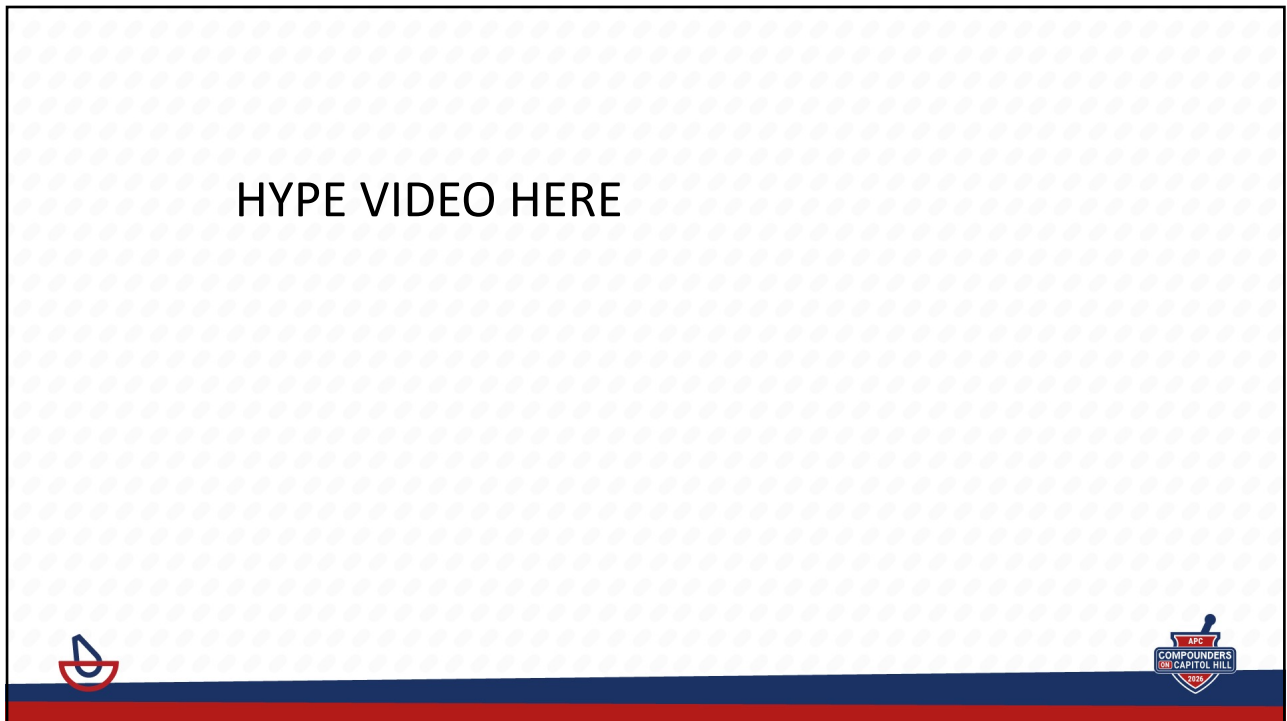





90



91



92



94



95



**Thank you to Medisca
for sponsoring lunch.**



96



International Filter Products

Revolutionary systems for your Industry

**Thank you to International Filter
for sponsoring breakfast.**



97



98



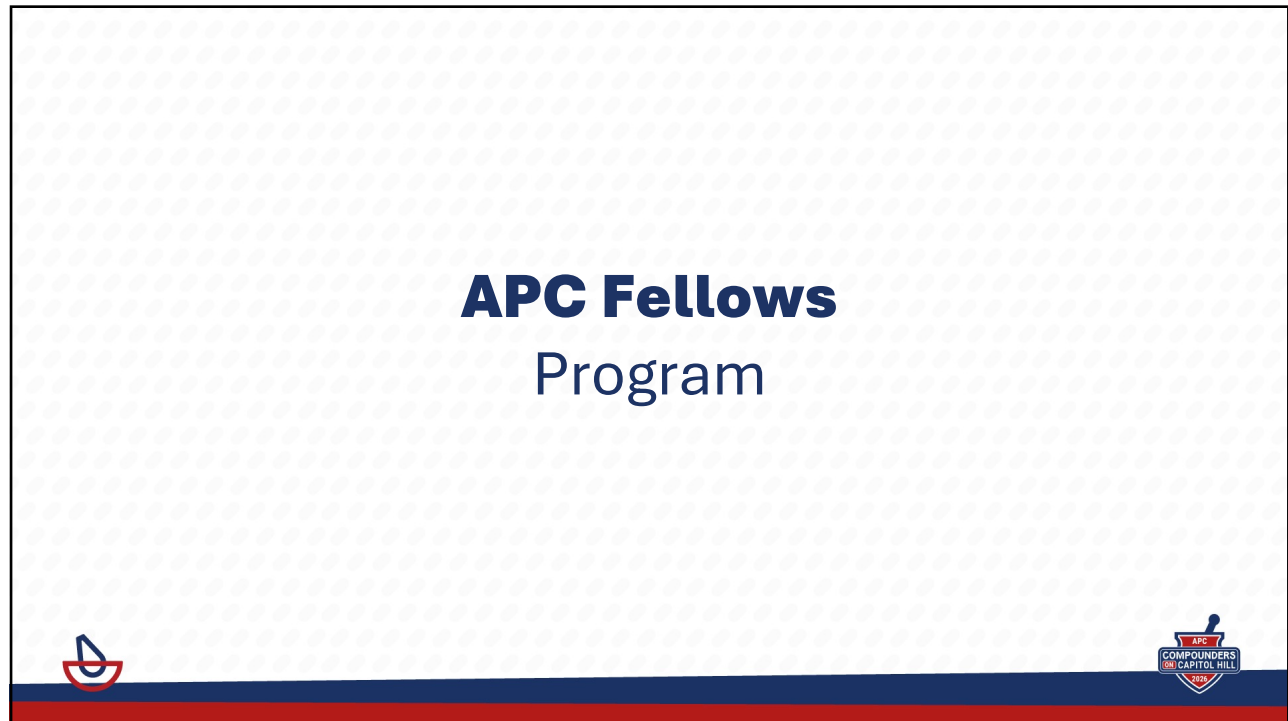
99



100



101



102



103



Ashley Barton
CPhT

Peoples Pharmacy
Austin, TX



104



L. Rad Dillon
RPh

**Coalition for
Compounding Excellence**
Loveland, CO



105



Natalie Gustafson
PharmD, FAPC

**Lloyd Central
Compounding Pharmacy**

Portland, OR



106



Robert Nickell
RPh

**Nickell Professional
Pharmaceutical Services**

Torrance, CA



107



Adrianna Rodriguez
CPhT

Stone Oak Pharmacy
San Antonio, TX



108



Sara Whitt
PharmD

**Strive Compounding
Pharmacy**
Sandy, UT



109



The Pharmacy Compounding Professional's Code of Ethics

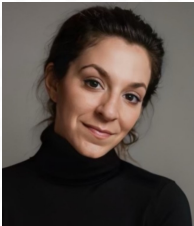
Responsibilities to One's Patients, Self, Colleagues, and Profession

As a pharmacy compounding professional, I will:

1. Uphold the triad relationship — patient, prescriber and pharmacist — as the foundation of pharmacy practice, acting in patients' best interest by collaborating with patients, their caregivers, and other healthcare professionals to manage a patient's treatment.
2. Comply with all applicable state and federal laws and regulations.
3. Practice the art and science of pharmacy compounding with competence and integrity, assuring patient safety and the quality of compounds, maintaining accurate records, and utilizing the proper compounding facilities, equipment, and materials in compounding for the benefit of patients.
4. Recognize the limits of my own expertise, practice only if I am fit and competent to do so and refer to colleagues on issues beyond my knowledge and skill.
5. Continually improve the quality of my work by keeping my knowledge and skills up to date via continuing education that enhances my practice.
6. Assist my healthcare colleagues, sharing information and ideas both to serve the best



110





CLASS OF 2026



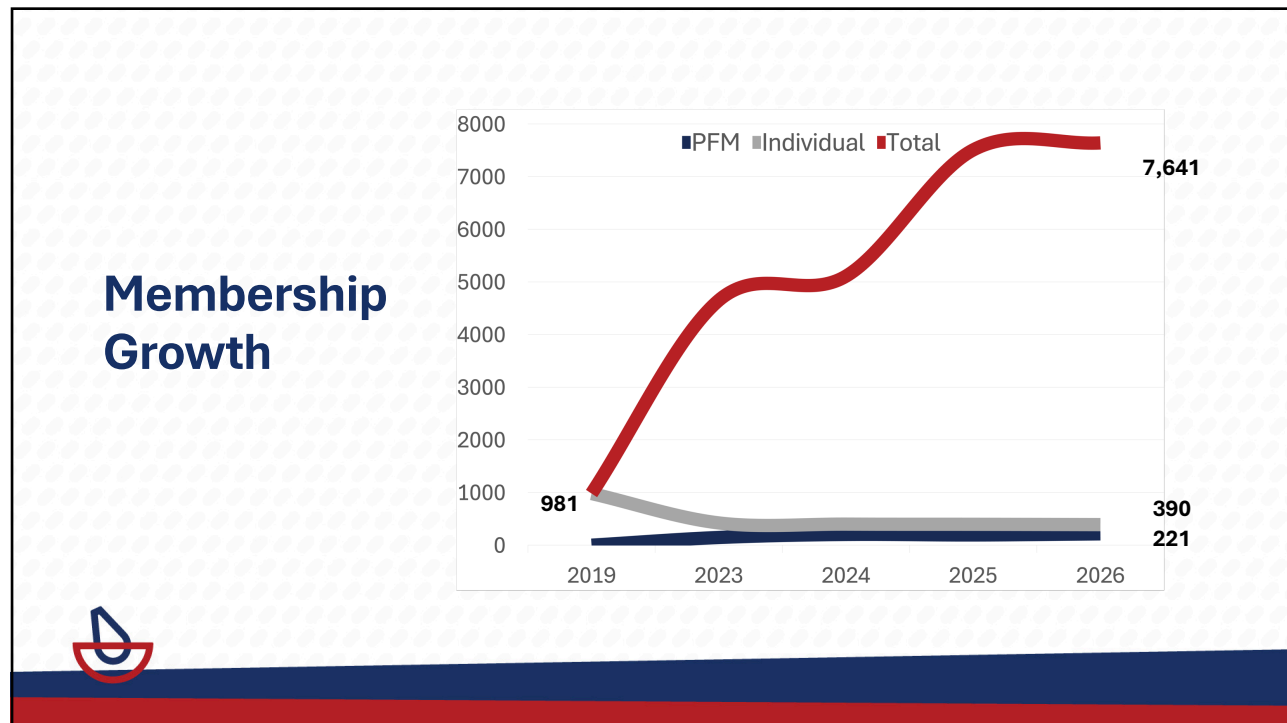
111



112



113



114

24 New PFMs in 2026 ... so far

AccuMix Pharmacy	Millers of Wyckoff
AGErte Pharmacy & Wellness Center	Northwest Compounding
Align Pharmacy LLC	Parkside Pharmacy
Allen Family Drug	Perfection Rx
Carolina Compounding Pharmacy & Health Center	The Compounder
Colonia Pharmacy	The Druggist Pharmacy
Custom Med Apothecary	The Woodlands Compounding Pharmacy
GoGoMeds	Top Notch Family Pharmacy
Greenhill Specialty Pharmacy	VITALRX Pharmacy LLC
Healing Dose Compounding Pharmacy	Wellspring Custom Pharmacy & Health Source
Meds for Vets	West Cocoa Pharmacy & Compounding
Meta Pharmacy Services	Yost Pharmacy Inc.

115

Lapsed PFM's 2026

GreenLeaf Apothecary	1/31/2026
Pure Path Pharmacy	1/31/2026
Xact Rx	1/31/2026
MSP	2/28/2026
Pinellas Compounding Pharmacy	2/28/2026
Archway Apothecary LLC	5/31/2026
Drug Crafters Compounding Pharmacy	5/31/2026
Dakota Precision Rx Labs	7/31/2026
University Compounding Pharmacy (CA)	7/31/2026
Wellness Compounding Pharmacy	7/31/2026
GreenLeaf Apothecary	1/31/2026
Pure Path Pharmacy	1/31/2026
Xact Rx	1/31/2026



116

Financials

2026 Budgeted **Revenue**: \$2,817,663

2026 YTD **Revenue**: \$2,464,160

2026 portion of total revenue received thus far: 87.45%

2026 Budgeted **Expense**: \$2,815,955

2026 YTD **Expense**: \$1,651,031

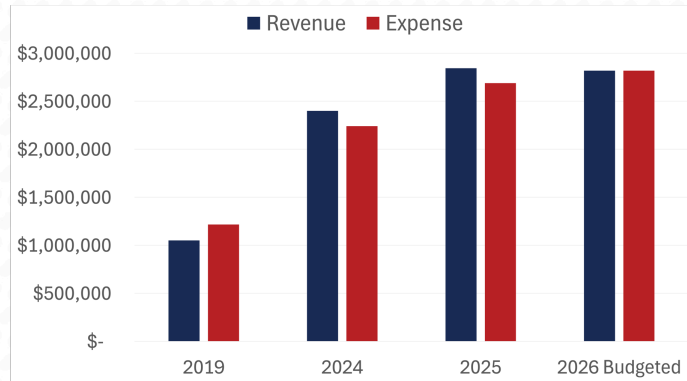
2026 portion of total budgeted expense thus far: 58.63%



117

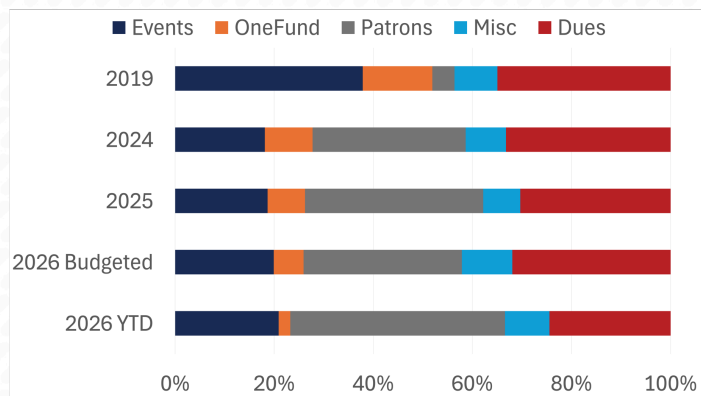
Financials: Budget

- **2019: Deficit**
 - Revenue: \$1,050,242
 - Expense: \$1,216,277
- **2024: Surplus**
 - Revenue: \$2,398,874
 - Expense: \$ 2,240,108
- **2025: Surplus**
 - Revenue: \$2,843,071
 - Expense: \$2,700,383
- **2026 Budgeted: Surplus?**
 - Revenue: \$2,817,663
 - Expense: \$2,815,955

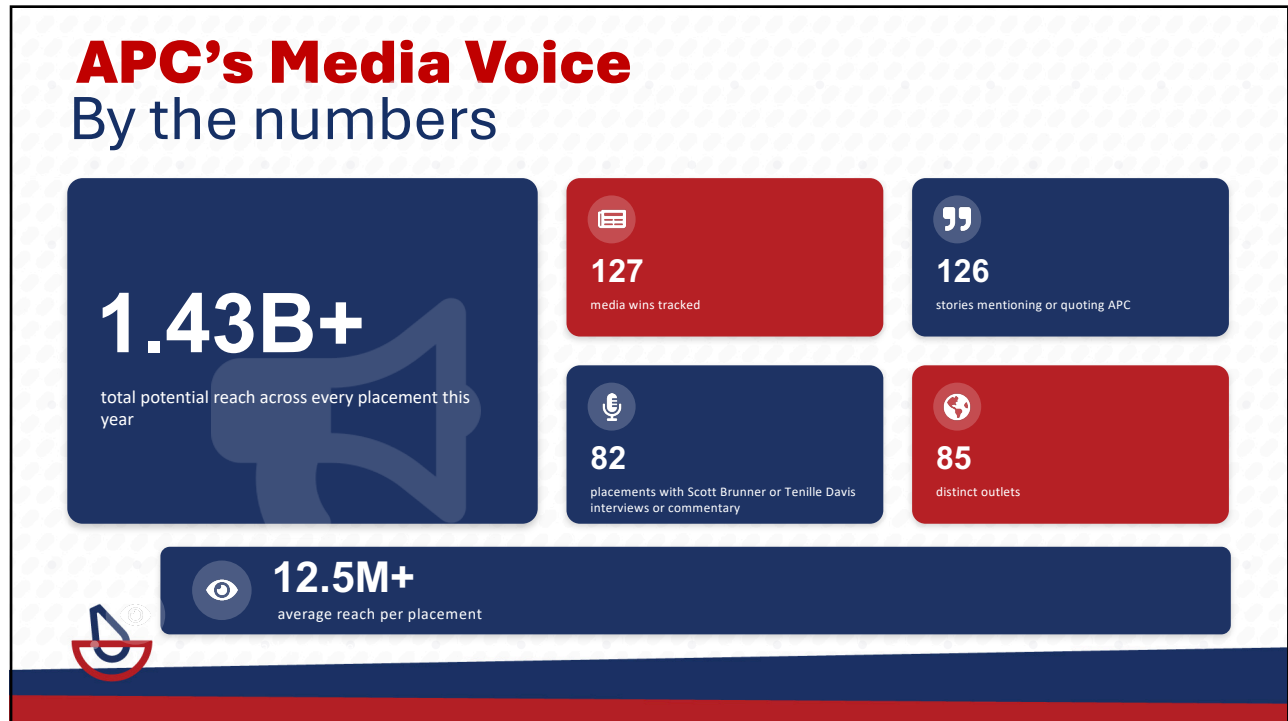


118

Finances: Sources of Revenue



119



120



121



122

2026 Successes

- **Defeated ten bills and mitigated one major threat** through advocacy efforts
- **Held 19 state briefings** to hear from members and prepare them for 2027 legislation
- Achieved **7,500+ followers** on LinkedIn, an increase of 20% compared to 2025
- **Increased staff count**, adding a State Regulatory Affairs Director manager and Events & Engagement Manager manager

123

2026 Successes

- Event attendance continues to grow with **more than 300 attendees registered for Compounding on Capitol Hill**
- Record attendance at Owner Summit with **204 paid attendees in 2026**, a 30% increase year over year
- Sent **40** letters to state boards of pharmacy, legislatures, nursing boards, the FDA, DEA **to provide input on compounding policy in those states**
- **Provided input to NABP** to improve the Model State Pharmacy Act and Model Rules



124

2026 Successes

- APC's podcast, ESSENTIAL, **has been downloaded more than 12,000 times since launch**
- **Created Real Solutions for Real Concerns** – Five proposals that can be used as a roadmap for legislators
- Advocacy efforts led to more than **2,000 messages delivered to state lawmakers** asking them to vote against anti-compounding legislation
- Media relations continues to be highly effective with **126 mentions or quotes in news stories so far in 2026**



125

2026 Successes

- Hosted our **largest Owner Summit ever** and exceeded budget for exhibits and sponsorships
- **Hired lobbyists in 10 states** to successfully fight anti-compounding legislation
- CEO Scott Brunner, CAE, represented APC twice at **FDA's PCAC meeting on peptides** offering recommendations for peptide stewardship
- Launched **new ScriptSafe member benefit** to save members time and money on payment and ad certification for their pharmacies



126

APC's Dispensing Data Project

Tenille Davis



131

Data is power – and credibility.

The purpose of our data project, in partnership with researchers at Emory University, is to build a clearer picture of pharmacy compounding across the United States, so APC can answer policy questions with evidence, not just anecdote. APC is the curator of the data, and the APC Board determines analysis to release.



132

What is the APC Data Project?

Participating pharmacies contribute de-identified dispensing data so researchers can build a clearer picture of pharmacy compounding across the United States.

COLLECT

Build a large, consistent dataset from participating pharmacies.

COMPARE

Understand how the sample differs from the broader U.S. compounding market.

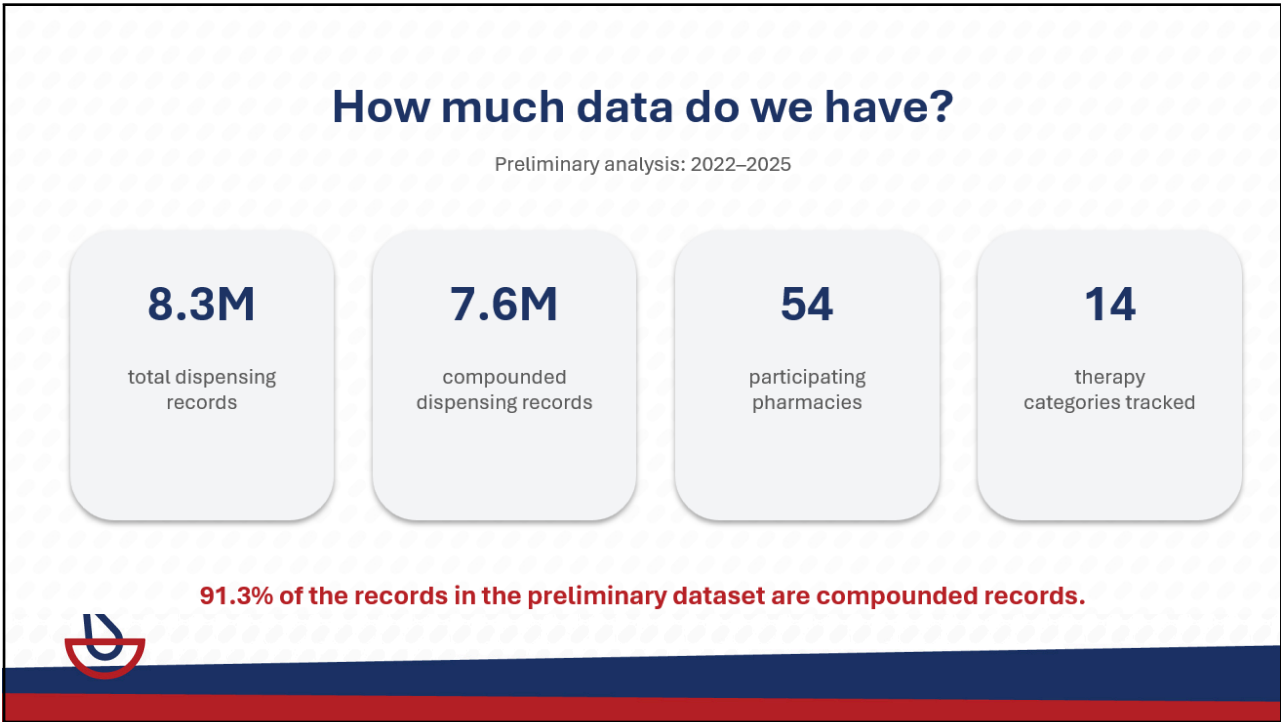
ESTIMATE

Develop credible national estimates of compounding activity.

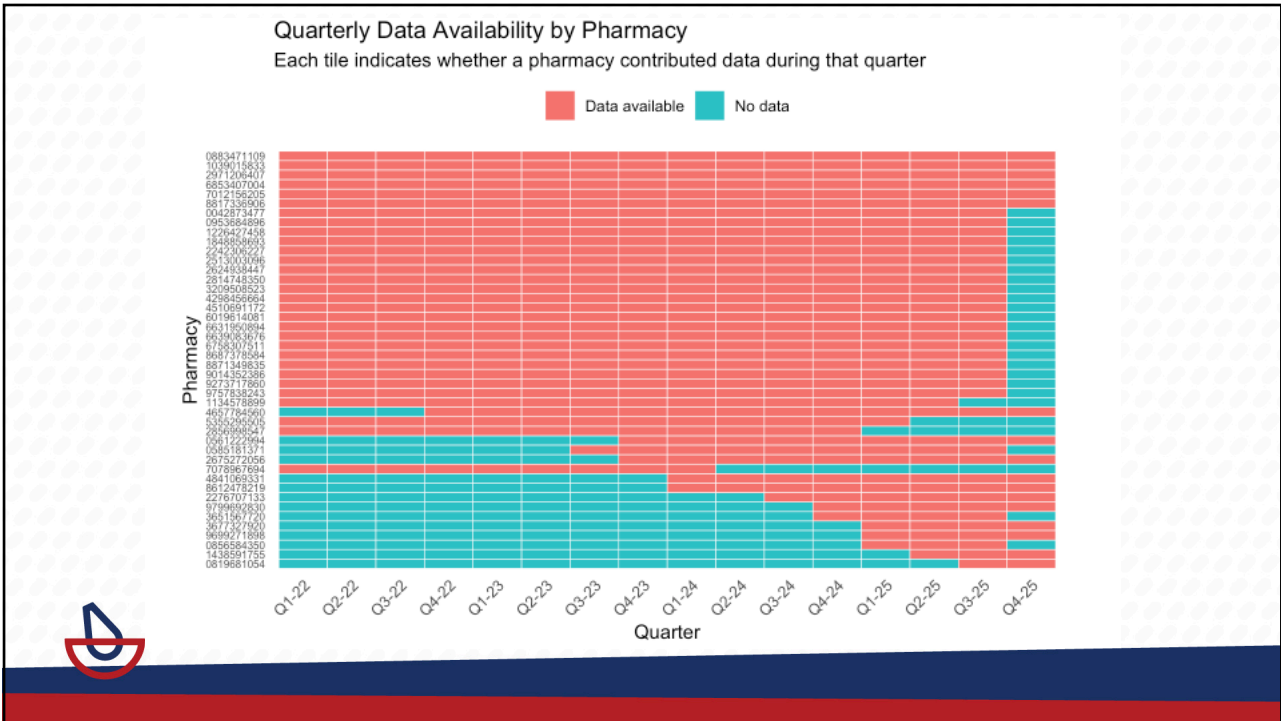
This is how we move from anecdotes to evidence.



133



134



135

We can demonstrate trends we've never been able to show before

01. Data beginning to show

- Hormones for women consistently represent a large share of compounded activity
- GLP-1 compounding increased substantially from Q1 2024 to Q3 2025

02. Pharmacy Size

Participating pharmacies vary enormously in size. For example, in Q3 2025, pharmacy-level quarterly volume ranged from 43 to more than 1.5 million prescriptions

03. "Other" is a high-volume category

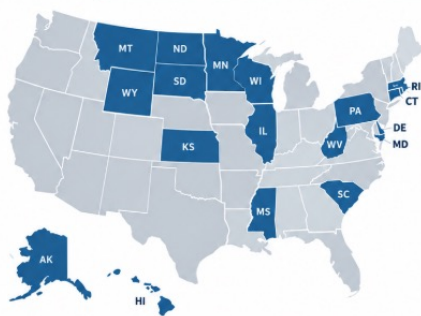
The "Other" category is one of the highest median volume categories, meaning that pharmacies are making many different types of compounds



136

19 States with No Participating Pharmacies in the APC Data Project

OPPORTUNITIES TO EXPAND REPRESENTATION



These 19 states have no pharmacies currently submitting data.

We see a significant opportunity to expand participation and improve national representation in the APC Data Project.

A more complete data set strengthens our advocacy, our profession, and patient access to compounded medications.

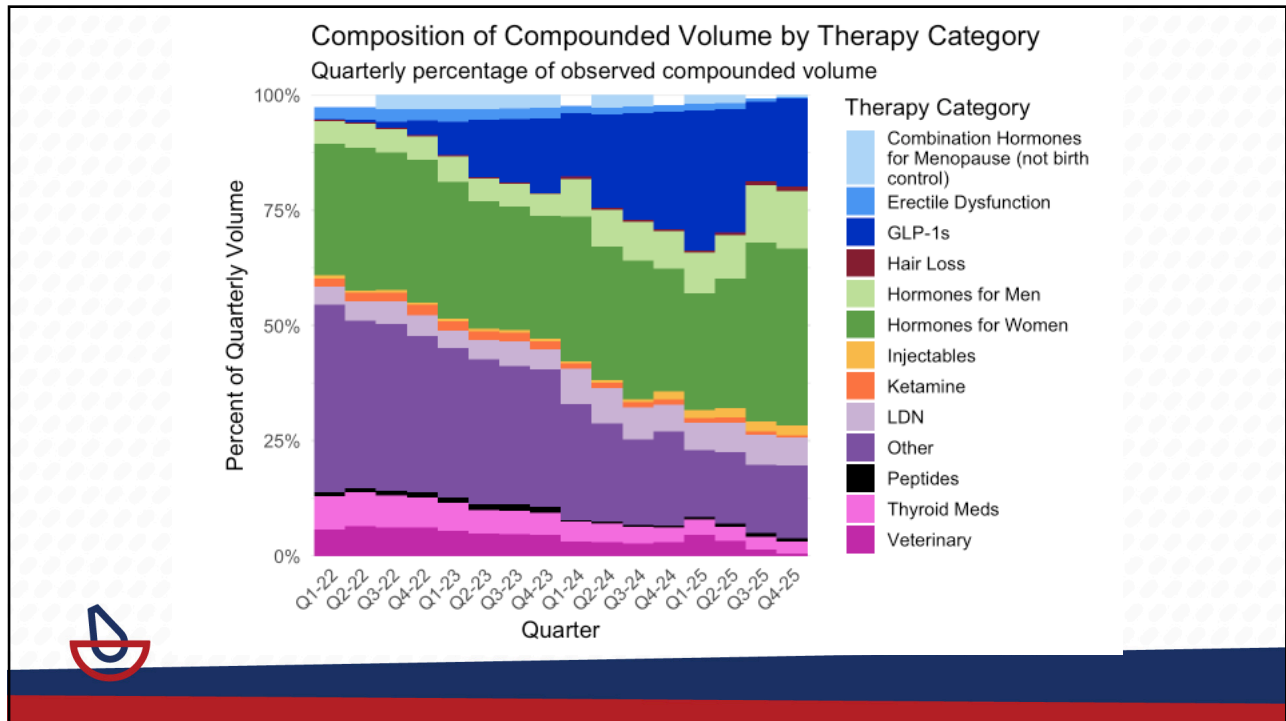
State	Vetted Compounding Pharmacy Listings
Illinois	102
Pennsylvania	131
Wisconsin	108
South Carolina	103
Maryland	78
Mississippi	41
Kansas	38
Minnesota	30
Maine	27
West Virginia	26
Hawaii	25
Montana	22
Connecticut	22
North Dakota	20
South Dakota	15
Wyoming	10
Rhode Island	8
Alaska	7
Delaware	6
Total	19 states

Is your state on this list?

If so, please consider joining APC's Data Project



137



138



139

apcpayments.com + ScriptSafe

Aaron Van Stone



140

This member benefit could be paying your APC dues

APC has negotiated two paths to the lowest credit card processing rates in the industry.

Choose your path to lower credit card processing costs

Option 01:  Tabz [™] Formerly known as HealNow	Option 02: worldpay
• Pharmacy Commerce Platform • Rates of 2.8% + \$0.30 and lower • Collect payment before dispensing • Integrates with PioneerRx, Liberty, SiCompounding, and more	• Group Processing Program • Now 9.5 bps, and still dropping • Effective rate as low as 2.5% to 2.8% • No switching your software, POS, or equipment



141

Know your savings in 60 seconds

Upload your latest processing statement. Every fee itemized, every junk fee flagged, and your estimate on the APC member rates ... before your coffee cools.



apcpayments.com



142

apcpayments.com

Demo



143

Introducing: Script Safe, Payment and Ads Certification for Pharmacies

A brand new APC member benefit

- A certification specifically built for pharmacies
- **Saves money**
 - Typically half the cost of similar services
- **Fast service**
 - The goal is to get you an answer in ten days



144

Addressing the needs of pharmacy owners

The top certification complaints:

- Only two vendors to choose from
- Cost: three thousand dollars or more
- Time: stories of 3, 6, 9 months before a decision
- No timeline
- There is even an industry of consultants just to push your application through



145

ScriptSafe speeds up the process by leaning into licenses you already have

- You already have the licenses you need:
 - Your State Board of Pharmacy license
 - DEA registration and NPI
- You upload what you already hold, and our system runs a 152-point verification against your state board (we have access to all 50 states), the DEA, and federal databases
- Internal scoring system to help determine the approval process



146

A process pharmacies can actually afford

Discounted APC member pricing

- Standard ScriptSafe certification is \$1,685
 - APC members get **twenty percent** off
 - That's only \$1,348
 - No application fee stacked on top



147

How to get started with SafeScript

Contact us

- Stop by the SafeScript table here and talk to Jason or Aaron
- Email Aaron at avanstone@processingbrokerage.com or call 646-875-5516
- Scan the QR code



148

APC Package Deals

 ADVOCATE • Flat annual investment of \$2,500 • Supports: • Legal Action – \$300 • Media Campaign – \$950 • OneFund – \$950 • Pharmacy Compounding Foundation – \$300	 GUARDIAN • Flat annual investment of \$5,000 • Supports: • Legal Action – \$750 • Media Campaign – \$1,750 • OneFund – \$1,750 • Pharmacy Compounding Foundation – \$750	 DEFENDER • Flat annual investment of \$10,000 • Supports: • Legal Action – \$1,500 • Media Campaign – \$3,500 • OneFund – \$3,500 • Pharmacy Compounding Foundation – \$1,500	 CHAMPION • Flat annual investment of \$15,000 • Supports: • Legal Action – \$2,500 • Media Campaign – \$5,000 • OneFund – \$5,000 • Pharmacy Compounding Foundation – \$2,500
---	---	--	--



a4pc.org/packagedeals

149

2027 Leadership Installation

Past Board Chair Gina Besteman, RPh, FAPC



150

2027 APC Leadership Team



Board Chair
Alexander Pytlarz, PharmD
St. Petersburg, FL



Chair-Elect
Peter Koshland, PharmD, FAPC
Berkeley, CA



Immediate Past Chair
Philip Smyth, CPhT, FAPC
Lebanon, OH



Vice President
Matt Johnson
Denver, CO



Treasurer
Chad Thompson, PharmD
Cincinnati, OH



Chief Executive Officer
Scott Brunner, CAE
Washington, DC



151



152



153

2027 George & Lucy Malmberg
Compounding Advocacy Champion

**Joseph
Navarra**

PharmD, FAPC

Woodbury, New York



154



155



156



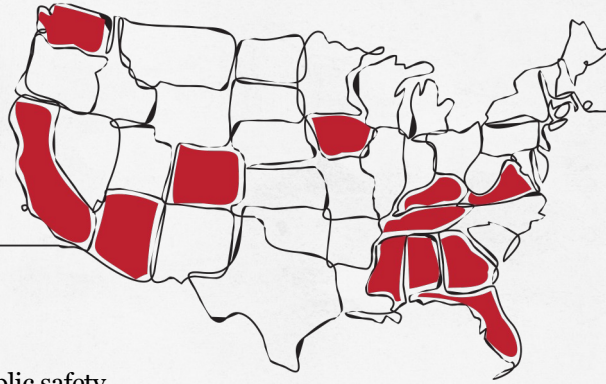
Alliance for
Pharmacy
Compounding
Compounding the Joy of Living®

We won the fights – but more are on the way.

The Compounding Defense Initiative: An Update

157

A pattern across the states

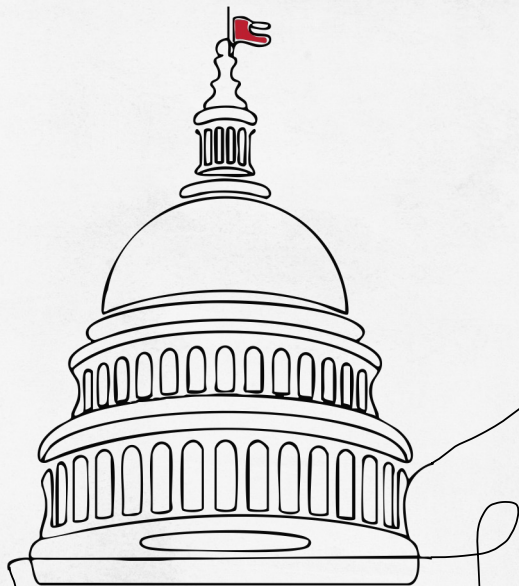


- * 10 states, 10 bills killed, one mitigated
- * Each drugmaker-backed, pitched as public safety, “anti-counterfeiting” measures – *but that’s not what the bills targeted*
- * Each written to make it harder for compounding pharmacies to serve patients who depend on compounded medications
- * APC raised \$1.5m to engage lobbying and comms support and built in-state coalitions to confront the threat

158

2027 bills are already being drafted

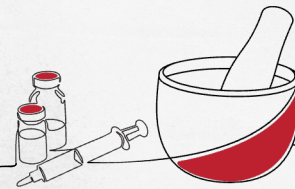
- * Similar bills are being shopped in multiple states right now: **as many as 30**
- * Drugmakers have studied what didn’t work in 2026 and likely will **adjust their approach** in 2027
- * Waiting until a bill is introduced **is too late to take action** —
- * our work must be funded first
- * That \$1.5m we raised? It’s allocated. **It’s spent.**
- *



159

What the Compounding Defense Initiative funds

- * State-level lobbying and coalition building
- * Communications support: message development, op-eds, digital advertising
- * Grassroots rapid-response capacity the moment a bill is introduced
- * **For 2027, we need \$2.5 million by December 31**



162

Invest today

at a4pc.org/invest



163

The Menu

2026

A tool for supporting influential legislators in key states



The Menu

ALLIANCE FOR PHARMACY COMPOUNDING

A tool for supporting influential legislators in key states

2026 WAS ONLY THE FIRST WAVE

This year, drugmakers aggressively supported restrictive compounding legislation in **10 states**. The bills were sold as "anti-counterfeiting" measures, when in fact, they would have placed onerous requirements on legitimate state-licensed pharmacies.

The good news: we won those fights in all 10 states – and we raised \$1.3 million to do it. Huge success, no doubt about it.

The bad news is that drugmakers have indicated they'll be back in 2027 – with legislation in as many as **25 or 30 states**. That means we have to get ready.

GETTING READY FOR 2027

Getting ready means building the relationships we'll need with influential state legislators when bills are introduced. Building relationships means meeting members of your state's House and Senate health committees, as well as your House and Senate leadership. It means inviting them for a compounding pharmacy tour so they can see compliance in action.

And – YTS – it means contributing to their campaigns.

WHY YOU SHOULD PAY ATTENTION

If your pharmacy is based in or licensed in a state where restrictive legislation is introduced, you have a lot to lose. Think about the slippery slope: if drugmakers can pass a bill this year restricting GLP-1 compounding, what's to say they won't be back next year with a bill to restrict compounded

THE ASK

APC has identified **five priority legislators** in each targeted state who are likely to be important voices on any legislation affecting compounding. Now is the time to begin building and strengthening those relationships.

SET ASIDE \$5,000
Before year-end 2026, budget this amount for political giving.

CONTRIBUTE \$100 EACH
Make 50 contributions to priority legislators in states where you are licensed.

Political giving is one way to demonstrate engagement and help establish a foundation for continued outreach.

WE CALL IT THE MENU

We've made it easy for you. Just click on the link for each legislator and contribute online. **\$100 to each**. And be sure to state that you are a compounding pharmacist or pharmacy.

164

Build the relationships we'll need in 2027



Curated legislator list

This is not a full legislative roster. It is a select list of priority legislators in each state, chosen because of their potential influence on pharmacy compounding policy.

Click a state below to view its list.

- Review the Donation Limitations column to confirm whether each candidate may accept personal funds, corporate funds or both.
- When writing a check, make it payable to the candidate's campaign committee, not the individual. For example, write "James Barnes for Senate," not "James Barnes."
- Many states require contributors above certain thresholds to list their occupation and employer. Please list "Compounding Pharmacist" as your occupation.
- If you are contributing corporate funds, the check must come from the business's account. A personal check cannot be designated as a corporate contribution.
- Contribution limits can change from year to year. Confirm your state's current limits before giving, particularly for larger contributions.
- Contributions are not deductible for federal or state income tax purposes. Contributions from foreign nationals may be prohibited.
- If APC has a direct campaign contribution link**, click the legislator's name below to contribute online. If no link is available, mail your contribution to the address listed.

Please send contributions directly to the legislator's campaign committee. APC does not collect or forward state political contributions on members' behalf.

Use the buttons below to filter by legislator type and select one or more states, then browse or search the resulting list for contact and donation details.

Priority Legislators
Leadership
All Health Committee Members

All States
Alabama
Arizona
Colorado
Connecticut
Florida
Georgia
Illinois
Indiana
Kentucky
Louisiana
Massachusetts
Mississippi
New Jersey
North Carolina
Oregon
Pennsylvania
Tennessee
Texas
Virginia
Washington

Select a state above to view its legislators.

165

Live demo

166



167

Program resumes at 3:35 PM

A portrait of Louie Gohmert, a Republican member of the U.S. House of Representatives. He is a white man with short brown hair, wearing a dark suit, white shirt, and a patterned tie. He is standing in front of an American flag.

A donation to Rep. Auchincloss' campaign is strongly encouraged







Only 20 seats available

Minimum contribution of \$1,000 required

Rep. Morgan Griffith (VA)

Chair of the House Energy & Commerce
Committee's Subcommittee on Health

7:00pm TONIGHT

Bobby Van's Steakhouse




170






171



173

Build the relationships we'll need in 2027



Curated legislator list

This is not a full legislative roster. It is a select list of priority legislators in each state, chosen because of their potential influence on pharmacy compounding policy.

Click a state below to view its list.

1. Review the Donation Limitations column to confirm whether each candidate may accept personal funds, corporate funds or both.
2. When writing a check, make it payable to the candidate's campaign committee, not the individual. For example, write "James Barnes for Senate," not "James Barnes."
3. Many states require contributors above certain thresholds to list their occupation and employer. Please list "Compounding Pharmacist" as your occupation.
4. If you are contributing corporate funds, the check must come from the business's account. A personal check cannot be designated as a corporate contribution.
5. Contribution limits can change from year to year. Confirm your state's current limits before giving, particularly for larger contributions.
6. Contributions are not deductible for federal or state income tax purposes. Contributions from foreign nationals may be prohibited.
7. **If APC has a direct campaign contribution link**, click the legislator's name below to contribute online. If no link is available, mail your contribution to the address listed.

Please send contributions directly to the legislator's campaign committee. APC does not collect or forward state political contributions on members' behalf.

Use the buttons below to filter by legislator type and select one or more states, then browse or search the resulting list for contact and donation details.

Priority Legislators	Leadership	All Health Committee Members
All States	Alabama	Arizona
Colorado	Connecticut	Florida
Georgia	Illinois	Indiana
Kentucky	Louisiana	Massachusetts
Mississippi	New Jersey	North Carolina
Oregon	Pennsylvania	Tennessee
Texas	Virginia	Washington

Select a state above to view its legislators.

174



175



176



OKPAREKE
FOR CONGRESS

FROM COMPOUNDING TO
CONGRESS

Max: \$3500/person

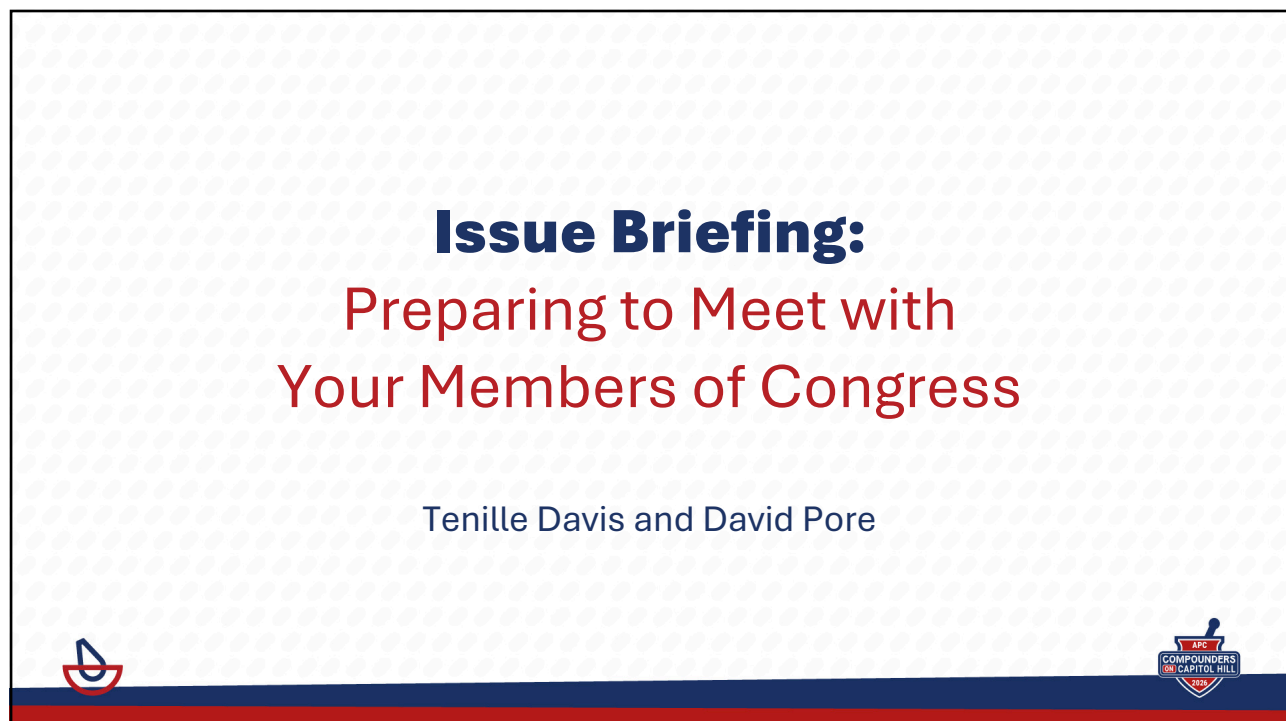
Didforcongress.com

177

Issue Briefing:

Preparing to Meet with Your Members of Congress

Tenille Davis and David Pore



178

Learning Objectives

1. Explain the key federal policy issues impacting pharmacy compounding.
2. Understand the components of a successful legislative meeting.
3. Explain how to be a successful advocate for the compounding pharmacy industry to Congress.
4. Describe common pitfalls of a Capitol Hill meeting



179

Preparing for a Hill Visit

Know your message

- Be clear about the purpose of your visit, know your key points and specific “ask”
- Practice your message so you can deliver it succinctly and effectively

Do your homework

- Research the member of Congress or Senator to see where they may stand on the issue you’re discussing
- Understand the basics of the legislative process and where your issue currently stands

Dress appropriately, business attire is expected. Look professional



180

Preparing for a Hill Visit

- Meetings will be set in groups, see meeting schedule in Advocacy Associates app
- One folder of leave-behind materials will be provided per Member of Congress...only have one member of the group pick up a folder
 - A team lead will be indicated in the Advocacy Associates app. Please see Tenille or Missy if you are set to be a team lead and want to opt out.



181

Meetings

Meetings are often with staffers

- Don't underestimate the importance of staffers, they are often the ones that brief the Members of Congress and can be key influencers on decisions
- Staffers are often from your home state or city, which means they have a vested interest in understanding and addressing the concerns of constituents

Be respectful, professional, and concise when meeting with staffers. They appreciate a well-organized presentation.

Be on time

- Plan to arrive at least 15 minutes early if possible, you will have to go through security at each building
- We are hearing that there are longer than usual security lines this year



182

Meetings

Deliver your message clearly

- Start by introducing yourself and your organization
- Clearly state your purpose and what you are asking the Member of Congress to do (support a bill, oppose legislation, etc.)

Leave behind short materials summarizing your points, which staffers can reference later

Be ready for questions

- Recognize a “leader” of your group to organize and assign questions

Send a thank-you message through app or via email

- Reiterate your key points and offer to be a resource on the issue



183

Meetings

This is not a chance to push your personal agenda

Stay as nonpartisan as possible

APC members all advocating for the same issues will have the most impact—don't go *"off script"* on another issue

Do take this chance to invite your Member of Congress or their staffer to your pharmacy for a tour



184

Navigating Capitol Hill

Understanding the layout

- The House and Senate Buildings are on opposite sides of the Capitol

Three House buildings on the south side

- Cannon, Longworth, and Rayburn

Three Senate office buildings on the north side

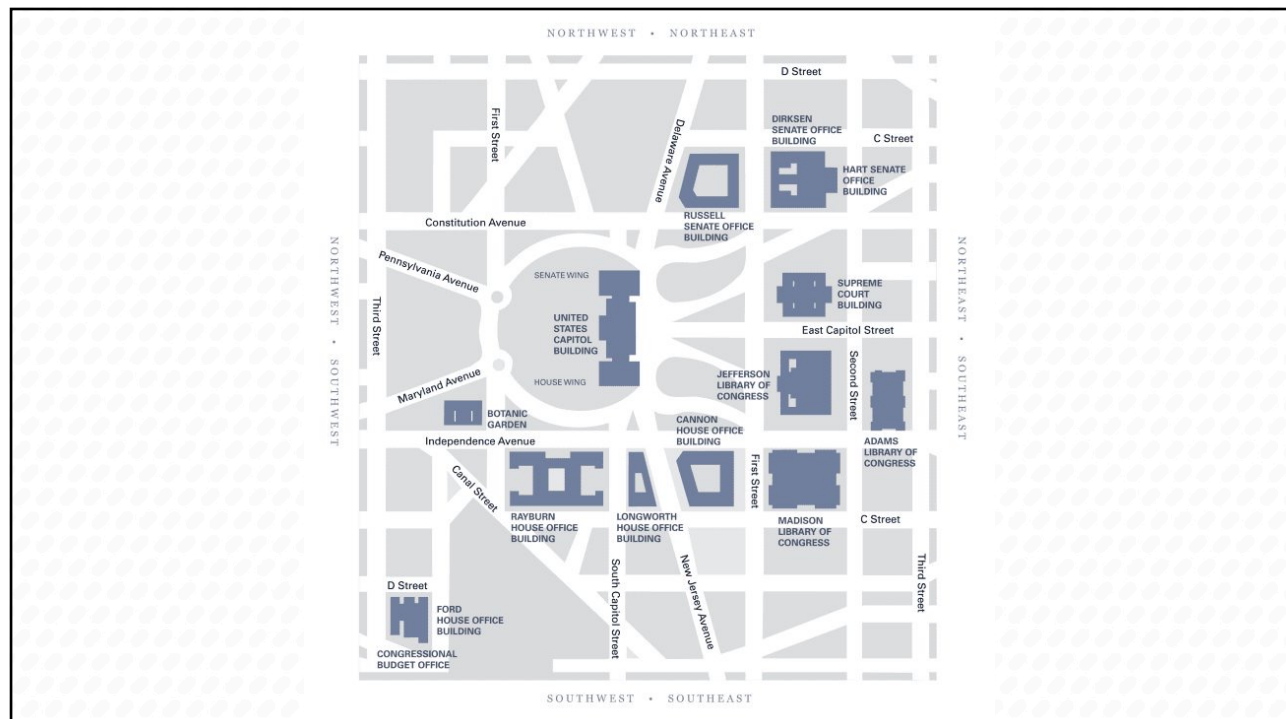
- Russell, Dirksen, and Hart

Getting between buildings

- Walking – Capitol is large, wear sensible shoes and expect 10-15 minutes between House and Senate buildings
- Underground tunnels – can be quicker than walking outside, accessible to visitors with a staff escort



185



186

TIPS:

Remember who you're talking to...and summarize.

- Except for Buddy Carter and Diana Harshbarger, members of Congress and their staffers are laymen. They don't know all the stuff you know – and they don't need to!
- So...don't talk down to them, but don't talk like pharmacology professors either. Simplify, but don't mislead.

Tell stories that illustrate the issues

- Cover the bases but emphasize the impact on you and your patients.
- Get quickly to the ask, don't get bogged down. Your time is short.



187

Go ahead and assume the first thing they will ask you is about peptides

Patient and prescriber interest in peptides has grown dramatically,
as well as within the administration

That demand has fueled a large online market for products labeled
"research-use only" for "not for human use"

**Demand already exists. The policy question is whether patients access these
therapies through licensed pharmacies or an unregulated gray market**



188

You May Get Asked About: **Peptides**

Preserve a legitimate pathway for peptide compounding. APC is asking policymakers to support a regulatory framework that provides access with guardrails:

1. Qualified API sources – API manufacturer must be on "green list"
2. Controlled supply chain – pharmacies could purchase API only through an FDA-registered repackager, relabeler, or reseller



189

You May Get Asked About: **Peptides**

3. Patient-specific prescriptions
4. Enhanced patient disclosure – patients would be told clearly that their medication is compounded, not FDA-approved, and that evidence concerning the active ingredient may be limited
5. Safety + Traceability – pharmacies would report serious adverse events
6. Real-World Utilization Data – participating pharmacies would submit a small, de-identified dataset for analysis to a third-party



190

You May Get Asked About: **Peptides**

Ask FDA to:

- Honor the PCAC process
- Create an extended interim pathway
- Condition access on meaningful safeguards
- Enforce against the illicit market

“We’re not asking Congress to approve peptides or tell FDA they’re safe. We’re asking Congress to encourage FDA to take the middle path: allow the six substances recommended by its own advisory committee to be compounded under strict guardrails while FDA gathers safety and utilization data, and crack down on the illicit research-grade market.”



191

Your Three Priorities

- The So-Called SAFE Drugs Act
- APC's Real Solutions Package
- Desiccated Thyroid Extract



192

The So-Called “SAFE Drugs Act”

December 9, 2025: Rep. Rudy Yakym (R-IN) introduced **H.R. 6509** with Rep. André Carson (D-IN)

February 5, 2026: Sens. Jim Banks (R-IN) and Martin Heinrich (D-NM) introduced the senate companion, **S. 3794**.



193

The So-Called “SAFE Drugs Act”

As introduced, the bill would have:

- Capped 503A pharmacies at 20 compounded prescription per drug per month for drugs considered "essentially a copy"
- Applied that restriction even when the FDA-approved drug was on the shortage list
- Rewritten the federal definition of "essentially a copy" in a way that conflicts with FDA's existing guidance
- Imposed new interstate reporting requirements on 503A pharmacies



194

Major Changes in Senate HELP

After advocacy by APC and other stakeholders, the Senate HELP committee adopted a manager's amendment and advanced the bill 17-5

The amendment removed the 20-prescription cap and the new "essentially a copy" language



195

Major Changes in Senate HELP

What remains the amended bill:

- Mandatory reporting of serious adverse events for certain interstate 503A compounding
- Annual reporting when more than 5% of compounded products are sent out of state
- New compounded-drug labeling, including: *"This medication has been compounded for dispensing to an individual patient and has not been approved the FDA."*

APC continues to have concerns about the interstate reporting provision and is working to improve the bill as it moves forward



196

The So-Called “SAFE Drugs Act”

- H.R. 6509 and S. 3794 now require two different conversations

OPPOSE

HOUSE – H.R. 6509

Still contains the original shortage-compounding restrictions, including limits on how many copies of a commercially available drug a 503A pharmacy could prepare even when the drug is on the FDA's shortage list.



PRESERVE

SENATE – S. 3794

HELP removed the original shortage restrictions and narrowed the bill to areas such as serious adverse-event reporting, patient disclosure and interstate reporting. It is substantially improved, but the MOU conflict still needs to be fixed



197

Why does the SAFE Drugs Act Matter?

Section 503A is the federal law that governs traditional pharmacy compounding. The SAFE Drugs Act **proposes to change Section 503A itself**, meaning its impact would extend beyond any single drug.

If Congress is going to create a new interstate-reporting framework for 503A pharmacies, it should finish the job: repeal the old MOU provisions and make the new reporting system the single, clear federal standard.



198

What to say about shortage drug compounding

The strongest point is simple: **a shortage policy should help patients during a shortage.**

"When the manufactured drug is unavailable, compounding is a bridge. Arbitrarily limiting how many patients a pharmacy can serve defeats the reason shortage compounding is permitted."



199

The Asks

HOUSE ASK – Oppose H.R. 6509 in its current form

POSITIVE ALTERNATIVE – Support H.R. 5316, the Drug Shortage Compounding Patient Access Act

SENATE FIX – Repeal obsolete Section 503A MOU provisions so the new interstate-reporting framework does not conflict with existing law.

**Smart oversight should protect patients,
not take needed medication away from them.**



200



ALLIANCE FOR
Pharmacy
Compounding
Compounding the Joy of Living®

REAL SOLUTIONS FOR REAL CONCERNS

Targeted policy proposals for patient
safety and pharmacy compounding

APC's Real Solutions Package

- Model Legislation
- Targeted policy proposals that address specific risks without restricting lawful pharmacy compounding or patient access




201

2026 wake-up call

- Compounding became a state legislative target in 2026
- GLP-1 related compounding bills were introduced in almost a dozen states
- Many were promoted as "patient-safety" legislation
- This was not a one-state problem, it's a coordinated policy trend that is likely to continue in 2027




202

How compounding is being framed

Policymakers are hearing about legitimate pharmacy compounding, but also:

- Research-use-only peptides being sold for human use
- Unlicensed or questionable online sellers
- Counterfeit or fraudulently labeled GLP-1 products
- Aggressive telehealth and DTC marketing
- Medical spas with unclear clinical oversight
- Products represented as equivalent to FDA-approved drugs

When all of those actors are described as "compounders," licensed compounding pharmacies end up carrying the regulatory consequences for conduct they may have nothing to do with



203

The wrong problem leads to the wrong solution

Much of the conduct alarming policymakers is already illegal or occurs outside of traditional pharmacy

Yet many of the legislative responses we saw in 2026 focused on imposing new restrictions on licensed pharmacies, rather than targeting

- Unlicensed entities selling prescription drugs
- RUO products marketed for human use
- Misleading DTC advertising
- Medical spas operating



204

Real Solutions Package

We can acknowledge real problems without accepting bad policy

- APC is bringing policymakers solutions, not just objections
- Most can work federally or at the state level, medical spa oversight is principally a state issue

The ask: Use APC's targeted proposals as a roadmap instead of broad new restrictions on compounding



REAL SOLUTIONS FOR REAL CONCERNS

Targeted policy proposals for patient safety and pharmacy compounding



205

Five Targeted Reforms

1. **Clear disclosure:** Tell patients the medication is compounded and not FDA-approved
2. **Serious AE reporting:** Require 503A pharmacies to report serious adverse events through MedWatch
3. **Stop illicit DTC promotion:** Prohibit consumer marketing of substances that cannot lawfully be compounded for human use
4. **Close med-spa gaps:** Require appropriate licensure/registration, practitioner accountability, and product-source documentation
5. **Protect lawful pharmacies:** prevent knowing or material misrepresentations of law used to intimidate pharmacies into stopping lawful compounding



206

Desiccated Thyroid Extract



DTE is not new: it has been used for more than a century

For decades, DTE was treated as a drug

- In August 2025, FDA declares animal-derived thyroid a biologic
- Nothing about the patients or the therapy suddenly changed



207

Desiccated Thyroid Extract

- This reclassification would force DTE into the biologics approval pathway – **more expensive and restrictive than the drug approval pathway**
- Medications classified as “biologics” are not eligible for compounding for patients that need custom strengths or dosage forms **OR** during drug shortages
- The push came from a petition by drugmaker AbbVie, who is working towards a Biologics License and would become the exclusive manufacturer, **effectively giving it a monopoly**



208

Desiccated Thyroid Extract

- APC filed a Citizen Petition with FDA in February 2026, **a recent additional petition was filed by a coalition of pharmacies**
- Rep. Michael Rulli (R-OH) has introduced legislation that would amend the Public Health Service Act to **prohibit treating a product as a biologic** based solely on the presence of a protein that is an inactive component
- FDA has communicated that they intend to **issue draft guidance on DTE**



209

Desiccated Thyroid Extract

The most recent Citizen Petition argues thyroglobulin is a carrier, not the active ingredient.

T3 and T4 are small-molecule hormones providing the pharmacological effect.

Please contact Geornalier Marcial at Geornalier.Marcial@mail.house.gov for lawmakers to sign the letter, or if you have further questions.

September xx, 2026

The Honorable Kyle Diamantas JD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Diamantas,

We write to express deep concern regarding the Food and Drug Administration's ("FDA") recent statements on animal-derived thyroid ("ADT") medication. We ask that you give full and fair consideration to the substantial legal and scientific concerns raised in the August 28, 2026 citizen petition requesting that FDA revoke its determination that ADT products are biological products (Docket Number FDA-2026-P-10231).

Approximately 1.5 million Americans depend on ADT to treat hypothyroidism. This includes patients who have had their thyroid removed, destroyed by Hashimoto's disease, or irradiated during cancer treatment, and they suffer from debilitating symptoms that are not adequately treated by FDA-approved synthetic alternatives. Moreover, many of these patients rely specifically on compounded ADT formulations dosed to their individual needs. For all of these patients, ADT is often the difference between severe illness and a functional, thriving life.

The Ask: Congress and FDA can preserve product quality and patient access by restoring a durable drug pathway for DTE.



210

Three concrete DTE Requests

1. **Co-sponsor H.R. 8630:** Protecting Equal Access to Thyroid Act of 2026. It clarifies that a protein's presence alone does not make a product a biologic when that protein is not responsible for the therapeutic effect
2. **Press FDA on the Citizen Petitions:** Urge FDA to respond promptly to the August 2026 petition and reconsider its classification of DTE products as biologics
3. **Preserve compounded access:** Ask FDA to maintain patient access to compounded DTE while establishing a durable regulatory pathway for animal-derived thyroid products.

Key Distinction: this is not an argument against FDA oversight. It is an argument for the correct regulatory pathway.



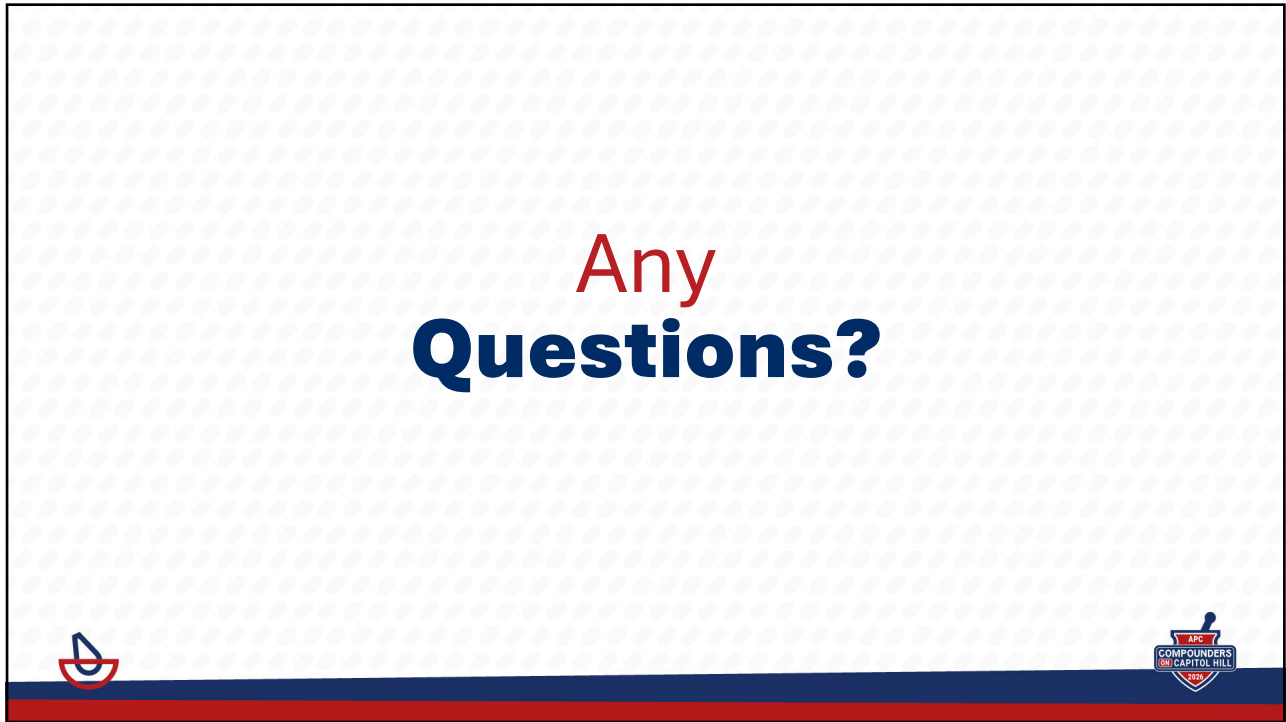
211

Our Three Main Asks

- **The So-Called SAFE Drugs Act:**
 - HOUSE: Oppose H.R. 6509 as written
 - SENATE: preserve the HELP Committee improvements to S. 3794
- **Real Solutions:** Work with APC on practical legislative and regulatory language that focuses on the conduct creating risk
- **DTE**
 - Co-sponsor H.R. 8630
 - Press the FDA on the Citizen Petitions
 - Preserve compounded access to DTE products



212



213



215



218



219



Sabina Hemmi

CEO and Founder
GLP Winner

- Worked in video games
- Started GLP Winner in 2024
- Started becoming a “GLP-1 influencer” in 2025
- sabina@glpwinner.com
- [@lawliepop](#) on social media





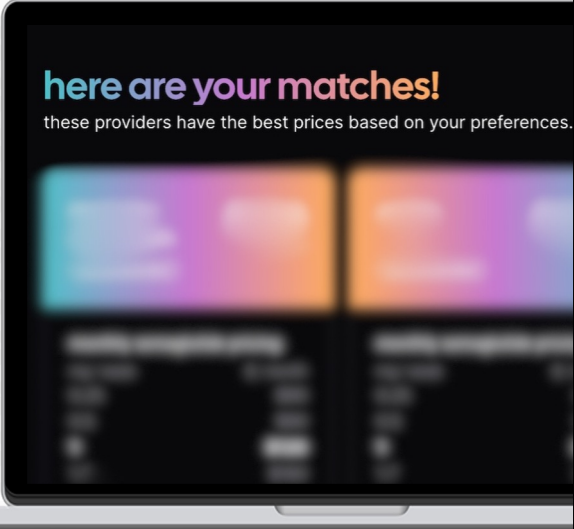
220

GLP Winner

Kayak for GLP-1s

Patients compare telehealth options with transparent prices, sourcing and reviews

Comprehensive compounding pharmacy listing with reviews, licensing and information





221

Usage of Brand-Name GLP-1s Significantly Outpaces Compounded or Custom-Mixed Versions

Which of the following best describes the weight loss medication you currently use?



Based on current users of GLP-1 medicine for weight loss purposes

May 28-June 5, 2026

GALLUP



222

About One-Third of Current Compounded or Custom-Mixed GLP-1 Users Have Switched From Brand-Name Version

	Current brand-name GLP-1 users	Current compounded or custom-mixed GLP-1 users
% Have only used current type	86	64
% Have switched from other type	10	35
% Don't know/Unsure	4	1

Based on current users of GLP-1 medicine for weight loss purposes

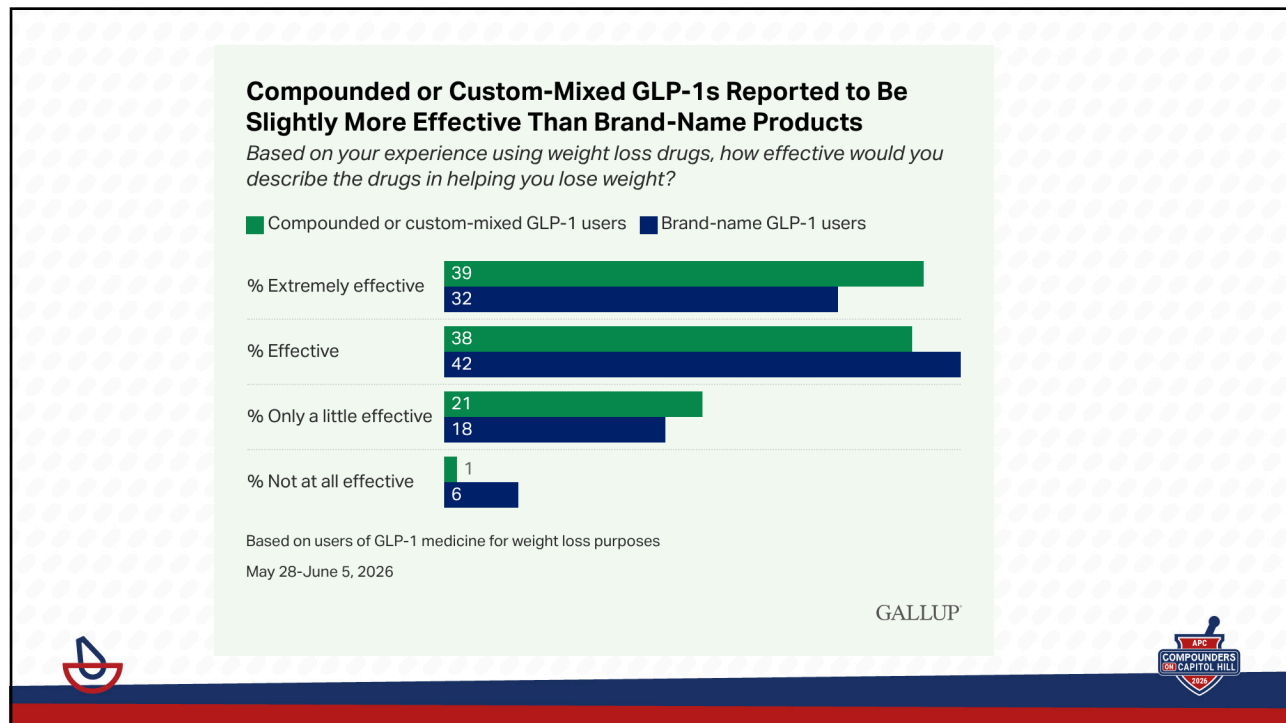
► [Click to see the full question wording.](#)

May 28-June 5, 2026

GALLUP



223



224

Do Patients Know What Compounding Pharmacies are?

Somewhat...

- They know enough to think they know things
- Engaged consumers are influential within their immediate circle of friends/family

Perspective depends on exposure to compounding

- Physician/News told them not to trust compounding
- Best friend tried compounded medication and had a bad experience (unlikely the fault of the pharmacy)

Or good experiences

- Multiple people in their life have used compounded medication, social media introduction, or a Dr recommended it

225

Disinformation on Compounding

Conflation of compounding and ANY other non-FDA approved medication

- “RUO/Grey market is the same thing”
- “Doctors who prescribe compounded medication are bad”

Influential organizations that may impact information

- Charities funded by pharma such as American Diabetes Association, Obesity Action Coalition
- Academic organizations with proximity to research such as The Obesity Society, Obesity Medicine Association, universities

SAFE Drugs ACT (Federal Bill)

- Patients are confused by bill wording
- Don’t understand why it harms access to medication
- Solutions? Press coverage, industry experts, SEO/AEO/LLM optimization



226

Patient Expectations

Shipping Speed

- They want an Amazon Prime shipping experience
- >24 hours before shipping means something might be wrong

Unboxing Experience

- Cold chain medication must be cold – the logic doesn’t make sense if medication needs to be refrigerated
- Injectables: needles in packaging (either a sealed package or individually wrapped)
- Includes education, side effects, etc.

Medication

- BUD dates longer than the prescription duration
- 28 day puncture rule



227

Medication from Central Fill Pharmacies Confuses Patients

A central fill pharmacy ships for another pharmacy who makes the medication

- Patients get confused with multiple branding
- Patients are confused on if this is compliant (but not all patients care about compliance)
- Who do they call if there are issues?
- Who do they blame if their medication is warm or ineffective?



228

Patients are Superstitious

Medication can feel different week to week

- If they recently switched pharmacies, they will blame the medication

"I won't be taking this medication because I don't want something with a dye in it"



229

“Just got this in the mail but just wanted to ask if this is normal? TIRZ is red color?”
– Reddit

Just got this in the mail but just wanted to ask if this is normal? TIRZ is red color?



My last stuff was clear and im just wondering if maybe the colors vary by manufacturer? Thanks



230

Who do Patients Blame?

The Compounding Pharmacy?

OR

The Telehealth Brand/Prescriber?

Scenario 1

Compounding pharmacy not licensed in my state

Scenario 2

Medication did not ship for 5+ days

Scenario 3

Medication arrived warm



231

GLP Winner Analysis of Reviews

286,165 Patient reviews for telehealth brands and compounding pharmacies
4.4 / 5 stars average rating

34,571 Reviews mentioned shipping
30.6% were negative (10,581)

What region of the US is most negative in reviews?



232

Western US - More Negative Reviews Related to Shipping



● Shipping ● Communication (control) — 95% confidence interval

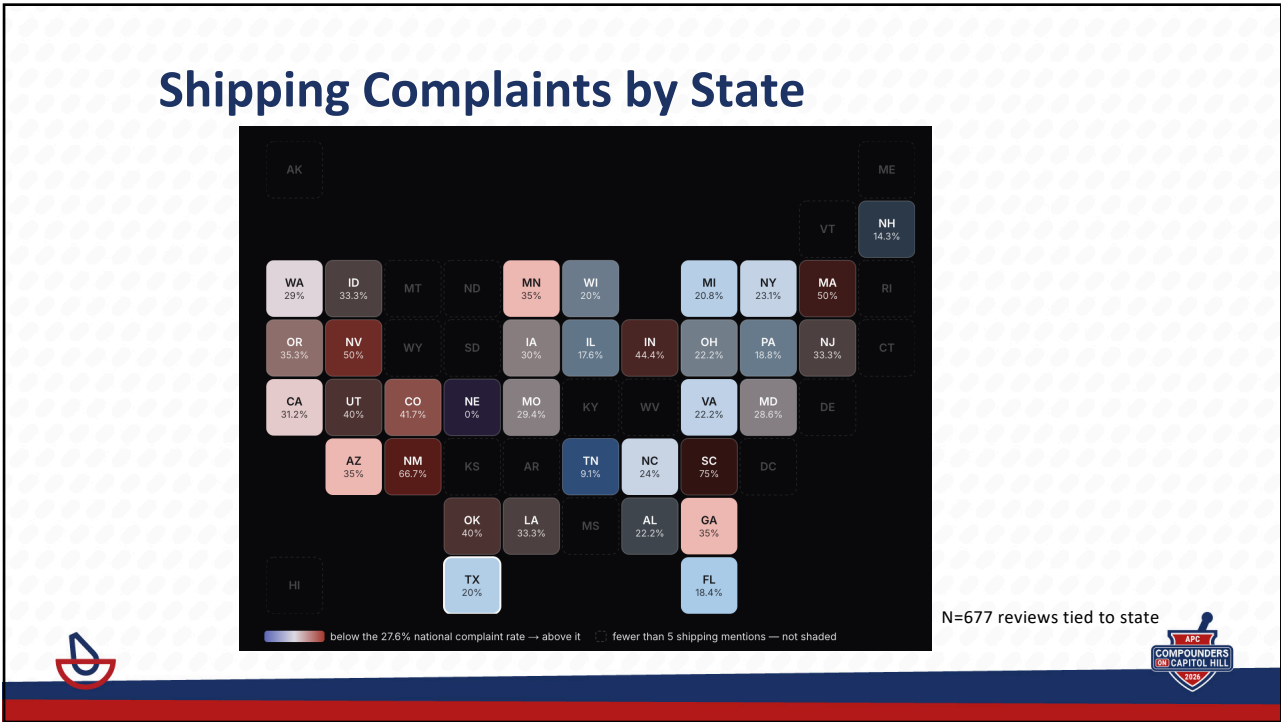
national 27.6%

Region	Shipping (%)	Communication (control) (%)	n
West	~33	~35	196
Midwest	~28	~32	141
Northeast	~28	~32	71
South	~25	~25	298

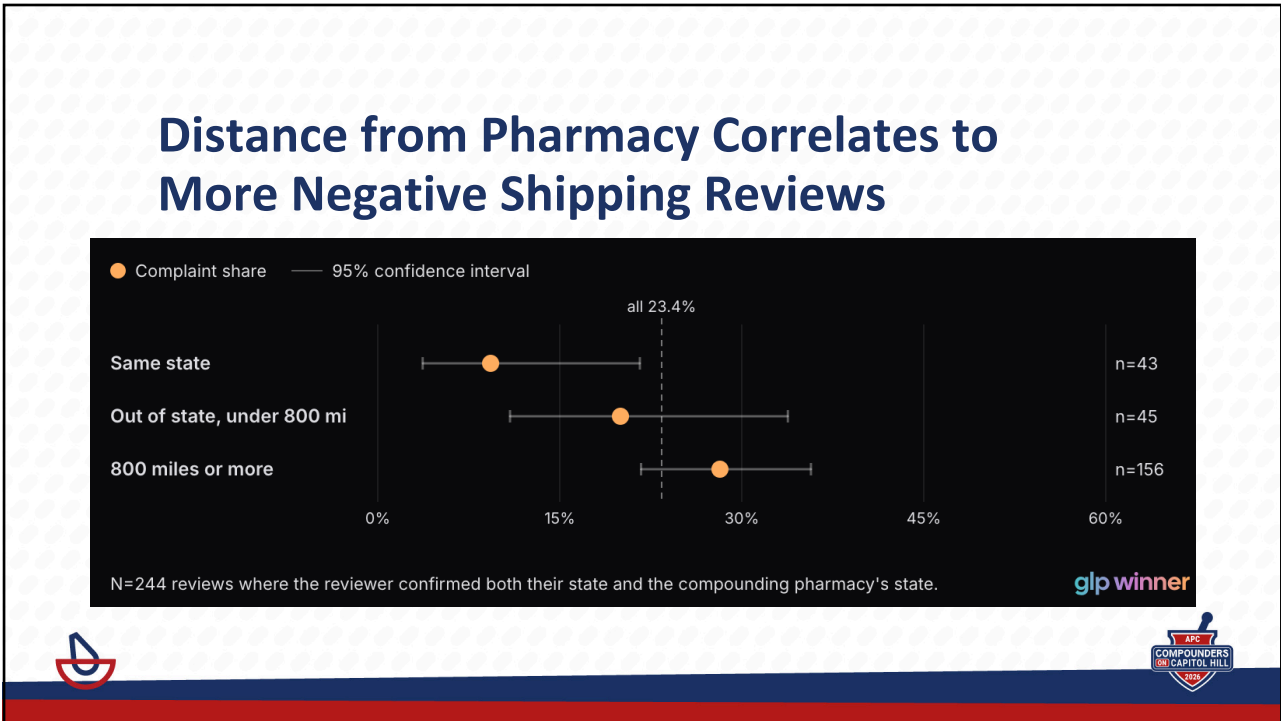
Shipping complaints by region compared to a control of communication complaints by region. 1,287 reviews tied to state.

glp winner

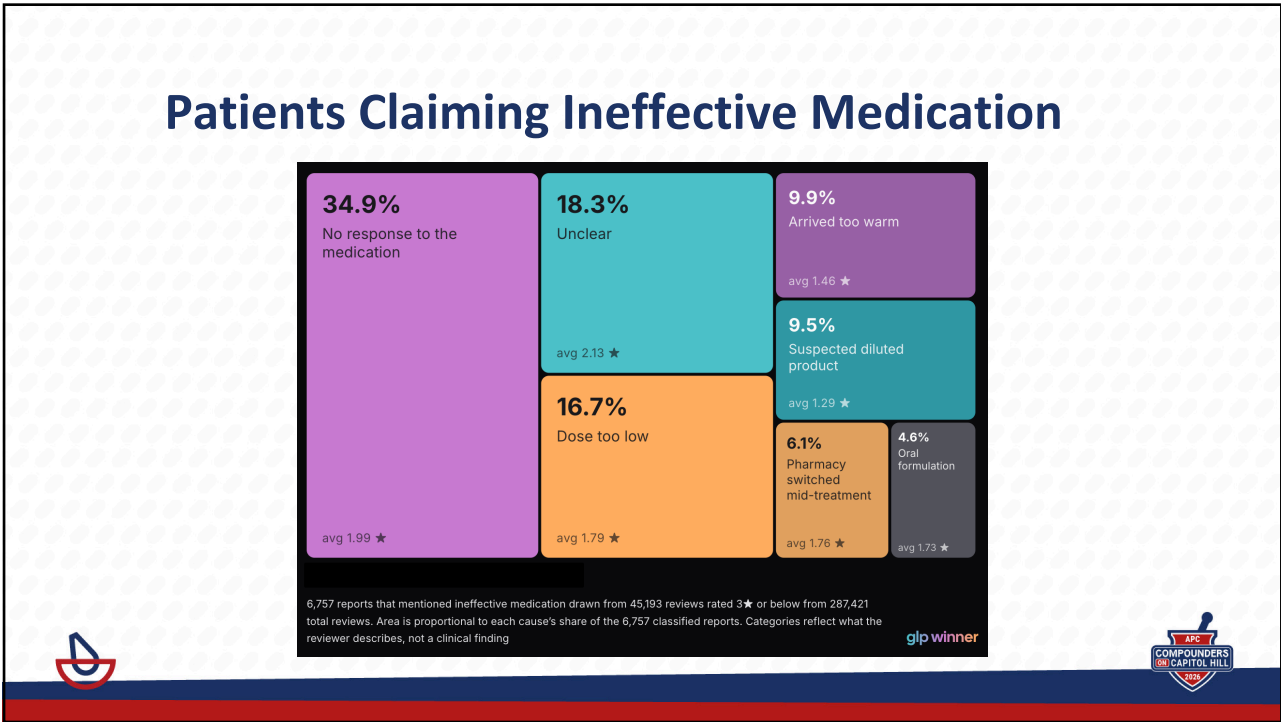
233



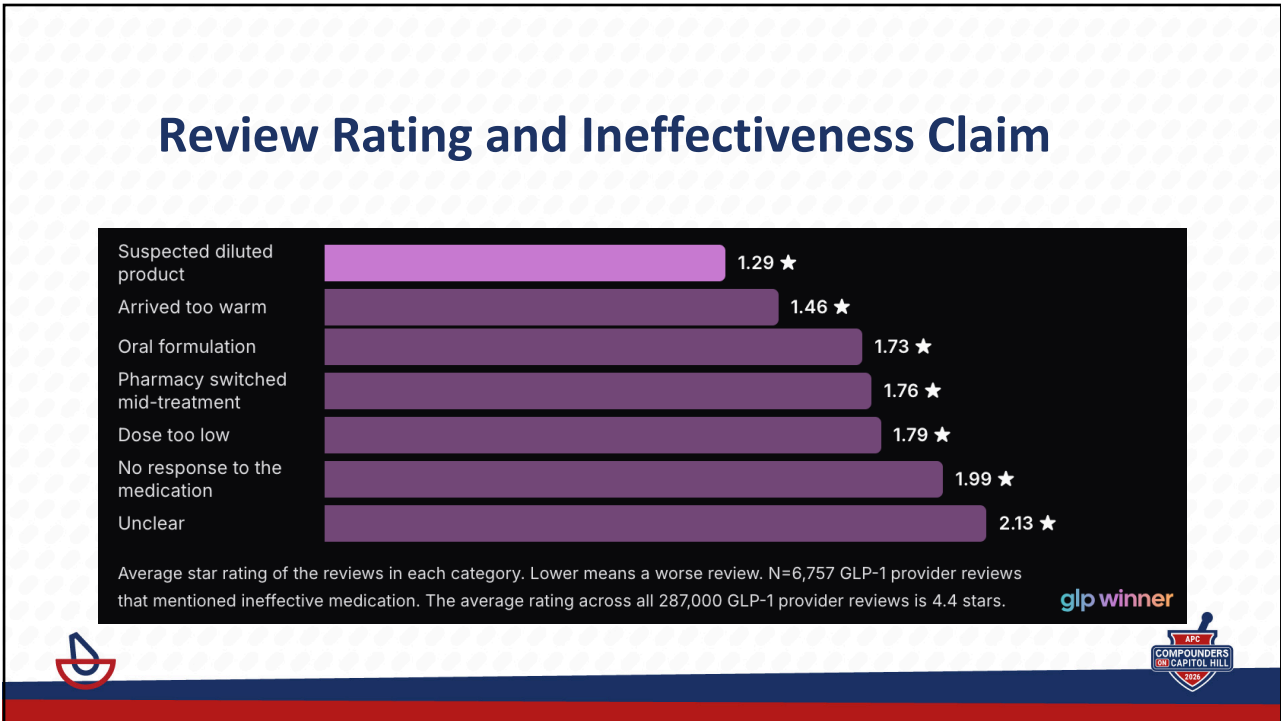
234



235



236



237

Are Patients Loyal to Compounding?

Patients care more about their compounding pharmacy than their telehealth brand

- Unless they are getting exceptional wrap around care
- Unless they have a strong emotional connection to the doctor/brand
- Pharmacy is the second most important buying factor

Most patients care most about price

- For GLP-1s - I think the RUO/Grey market is larger than compounded
- Compounding pharmacies could get priced out with generics and significantly more FDA approved GLP-1 options
- I think the RUO/Grey market for peptides will always be bigger than the compounded market (without significant access changes)



238

Questions?

Sabina Hemmi
@lawliepop
glpwinner.com



239



240



241

ComPAC Chair

Alexander Pytlarz

PharmD

COO SiCompounding



242



2026 Silver Investors

Jay Bhaumik; Plano, TX	Ryan Hayes; Fishers, IN	Alexander Pytlarz; St Petersburg, FL
Marcy Bliss; Swedesboro, NJ	Jonathan Head; Irving, TX	Jim Smith; Richmond, TX
Mark Boesen; Gilbert, AZ	John Herr; North Haledon, NJ	Christian Stella; Merrick, NY
Will Douglas; Sulphur Springs, TX	Jim Hrcir; Irving, TX	T.W. Taylor; Williamsburg, VA
Ernesto Garza Gongora; Helotes, TX	Peter Koshland; San Francisco, CA	John Tran; Torrance, CA
Lorri Gebo-Shaver; Pocatello, ID	Robert Nickell; Torrance, CA	Jesse Vidrine; Lake Charles, LA
Edgar Gonzalez; Houston, TX	Chris Pucillo; Scottsdale, AZ	Warren Ybos; Scott, LA
Adam Gustafson; Vancouver, WA		Ed Zatta; Athens, OH



243



2026 Gold Investors

Carl Allison
Lake City, FL

Arthur Blaire
Point Lookout, NY

Michael Blaire
Scottsdale, AZ

Jason Jerusik
Conshohocken, PA

David Martinez
Sugar Land, TX



244



2026 Platinum Investors

Lisa Everett Andersen
Olathe, KS

Shawn Hodges
Marietta, GA

Joseph Navarra
Woodbury, NY

Dawn Ipsen
Snohomish, WA

Brad McCloskey
Troy, MI

David Sparks
Richmond, TX



245

Support



COMPOUNDERS
POLITICAL ACTION COMMITTEE





246



COMPOUNDERS
POLITICAL ACTION COMMITTEE

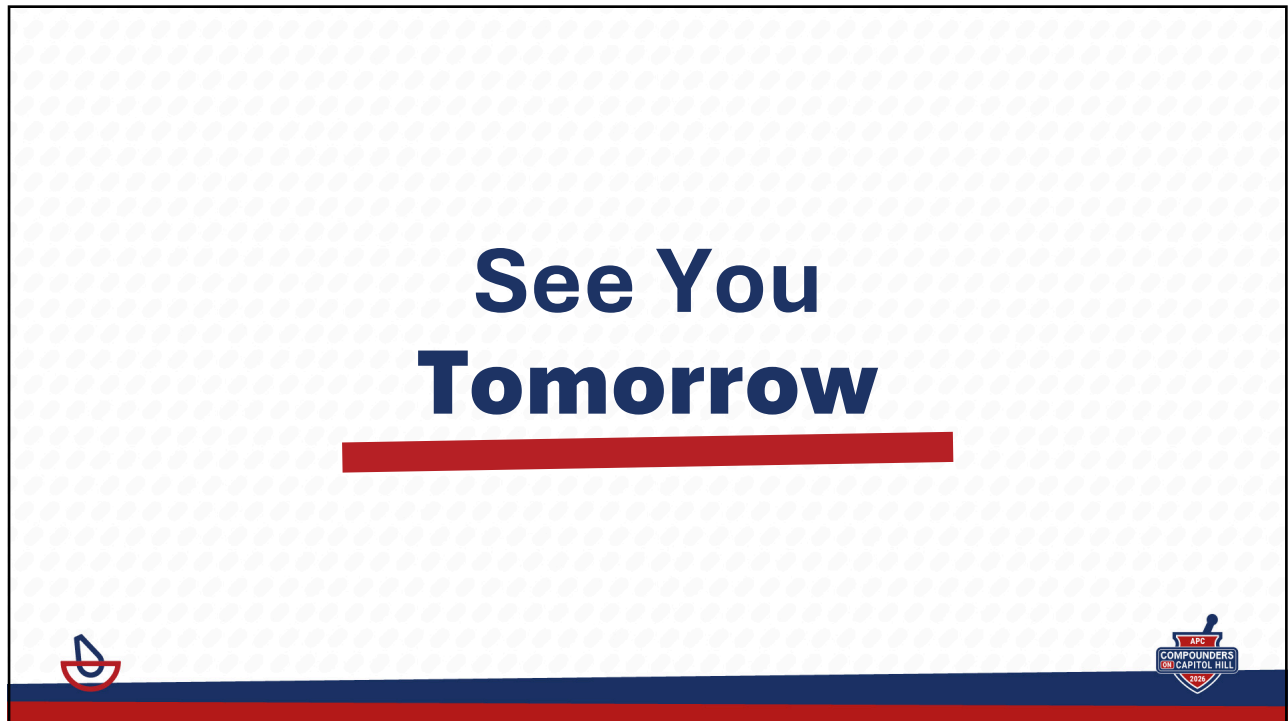


**CompPAC investment
required to attend**
\$1,000 for Pharmacists/Pharmacy Owners
\$250 for technicians



Rep. Jake Auchincloss (MA)
5:30pm on September 15
Separate Ticketed Event
A donation to Rep. Auchincloss' campaign is encouraged

247



248



249