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THREATS & OPPORTUNITIES:

A PHARMACY COMPOUNDING POLICY UPDATE

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Tenille Davis is speaking in her personal capacity and not as a member of the Arizona Board of Pharmacy.

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APC is the voice for pharmacy compounding, representing more than 600 compounding small businesses – including 5,300+ compounding pharmacists and technicians in both 503A and 503B settings – as well as prescribers, educators, researchers, and suppliers.

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Tenille Davis, faculty for this activity, has no relevant financial relationship(s) with ineligible companies to disclose.

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

01

COMPOUNDING 101

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What is compounding?

- For centuries, pharmacy = compounding
  - Before the advent of FDA-approved drugs, pharmacists prepared medications from raw ingredients for a specific patient.
  - Compounding has been an essential part of the American healthcare system for generations
- In traditional compounding, a medication is custom made for an individual patient by a pharmacist in a state-licensed pharmacy
- Compounded drugs are not “knock-offs,” “dupes,” or “counterfeits.” They are legitimate and often essential therapies created in regulated labs from pure pharmaceutical ingredients.

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What is compounding?

- Authorized in Food, Drug & Cosmetic Act:
  - **Appropriateness:** *Prescriber* judges an FDA-approved drug is not suited
  - **Accessibility:** Appropriate FDA-approved drug is "currently in shortage"
- **Patient-specific:** Nothing happens in a compounding pharmacy without a prescription.

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What is compounding?

- Compounded meds are **not FDA-approved**. FDA-approved drugs *should always be first choice* … when *available* and *appropriate*.
- Compounded medications are **not intended to compete** with FDA-approved drugs.
- Compounded meds are **not inherently unsafe**.
  (Nor is FDA approval an ironclad safety guarantee.)
- Compounding's **compliance/safety framework is robust**.
  - State boards of pharmacy
  - FD&C Act and FDA guidance
  - USP standards

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What is compounding?

- Preparing **acetaminophen suspension for a child** when that FDA-approved drug was in shortage
- Compounding a **mouthwash for cancer patients** for mouth sores resulting from chemotherapy
- Preparing a **hydroxyurea suspension for pediatric sickle cell patients** who can't swallow the FDA-approved pill
- Compounding **post-op eye drops for cataract patients**, combining multiple meds into a single dosage
- Preparing **creams used in aesthetic procedures** (laser hair removal or tattoo removal, for instance)
- Creating **compounded hormone therapies** when there's no FDA-approved drug suited for a particular patient
- **Animal compounding**: Because so few FDA-approved drugs exist for the range of animal species, sizes, needs

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What can be compounded?

- Under federal law, **to be eligible for use in a compounded product**, an API must meet **one** of the following criteria:
  - Be a **component of an FDA-approved drug** product
  - Have a **USP or NF monograph**
  - **Appear on the 503A Bulks List** published by the FDA (or the interim bulks list)
- FDA guidance prohibits traditional pharmacies from compounding a drug that is "essentially a copy" of an FDA-approved drug –
  - **EXCEPT:** When a drug appears as "currently in shortage" on FDA's drug shortage list

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What is a copy?

- FDA defines copies in its "Essentially a Copy" GFI.
- It's a copy of a commercially available drug product if:
  - The compounded drug product has **same API** as the FDA-approved drug
  - The API(s) have the **same, similar, or an easily substitutable dosage strength**
  - The FDA-approved drug can be used by the **same route of administration** as prescribed for the compounded drug
- Unless prescriber determines that there is **a change that produces, for a patient, a significant difference from the FDA-approved drug**

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What is a copy?

- **Essentially** a copy …
  - *"The limitations in section 503A(b)(1)(D) apply to the compounding of drug products that are **essentially copies** of a commercially available drug product – **not only to drugs that are exact copies or even to drugs that are nearly identical**. This is to ensure that compounders do not evade the limits in this section by making relatively small changes to a compounded drug product and then offering the drug to the general public without regard to whether a prescribing practitioner has determined that the change produces for the patient a significant difference."*

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What is a copy?

- **Essentially** a copy:
  - *Still a copy = Combining two commercially available drugs*

- **FDA will not question prescriber's judgment:**

It is not possible to offer exhaustive guidance about when a difference will be "significant" to an identified individual patient. At this time, FDA generally does not intend to question prescriber determinations that are documented in a prescription or notation. However, we do intend to consider whether a prescription or notation relied upon by a compounder to establish that a drug is not essentially a copy documents that the determination was made.

  - (Page 9)

  - Doesn't mean BOPs will take same approach.
  - Doesn't mean drugmakers won't sue you for patent infringement.

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503A vs. 503B

- **503A:** A traditional pharmacy
  - Patient-specific: Dispenses compounded medications pursuant to a prescription
  - Regulated and inspected by state boards of pharmacy
  - 503As *dispense*

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503A vs. 503B

- **503B** outsourcing facility
  - Created 2013 in the wake of NECC tragedy
  - Regulated by FDA
  - Must follow cGMP
  - May compound in bulk for office use, without a patient specific prescription
  - Only 87 of them nationwide
  - 503Bs *distribute*
  - May only compound:
    - Copies of FDA-approved drugs in shortage
    - API listed on the 503B Bulks List
    - (Semaglutide and tirzepatide are not on that list.)

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Threading the regulatory needle

Keep patients safe via rules and standards that are:

- Rooted in scientific evidence demonstrating that the regulation enhances safety and quality of the compounded drug
- Understandable by regulants
- Implementable by regulants
- Objectively and consistently enforceable by regulators

Regulation simply because more of it just *seems* better.

- Not rooted in scientific evidence
- Arbitrary or subjective enforcement
- Impedes patient access by having the effect of so raising costs that:
  - Compounders can't afford compliance; and/or
  - Patients can't afford the resulting drug
- More regulation in lieu of enforcement of current regs

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The primary lens through which any proposed compounding regulation should be assessed:

"How does this make patients safer?"

(and is the evidence of it apparent and replicable?)

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02

COMPOUNDING IN THE NEWS

2024

THE WALL STREET JOURNAL. Bloomberg HealthCentral teenVOGUE
RollingStone WebMD Forbes Los Angeles Times WIRED
STAT SCIENTIFIC AMERICAN The Washington Post USA TODAY CNN HEALTH WATCH AXIOS
The New York Times THE NEW YORKER NEW YORK BARRON'S GOOD MORNING AMERICA CBS NEWS
FORTUNE REUTERS VANITY FAIR abc NEWS
EVERYDAY HEALTH Medscape KFF Health News The Atlantic yahoo! news THE HILL
npr NIGHTLY NEWS WITH LESTER HOLT NATIONAL GEOGRAPHIC InsideHealthPolicy FT FINANCIAL TIMES

2024

QUALITATIVE METRICS

Proactively sent **2 targeted, customized pitches per day**, on average

Conducted **18 media interviews per month**, on average

Conducted 200+ interviews January-December

Over **40 outlets** covered APC in **multiple stories**

+%

Secured **200 media placements – a 174% increase** over 2023

Garnered **UVM reach of 3,384,853,558**

2024

QUALITATIVE METRICS

Hosted 11 journalists for pharmacy compounding site tours, including CNN, Bloomberg, MedPage Today, The Washington Post + STAT

Hosted Media Roundtables on GLP-1 Best Practices in Pharmacy Compounding + Tirzepatide. **Attended by 20 + 32 reporters**, respectively, including WIRED, POLITICO, The Hill, Inside Health Policy, New York Times, Kaiser Family Foundation News + Reuters

2025

MEDIA SUCCESSES ... SO FAR

Secured **58 unique stories** in outlets like USA Today + The Washington Post

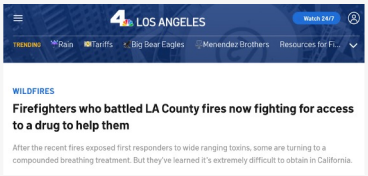
Fielded **40+ incoming media requests**

2025

MEDIA SUCCESSES ... SO FAR

We continue to **advance APC's thought leadership** + improve accuracy in reporting about compounding with a **high volume of steady top-tier national coverage with strong message pull-through**

"However, it doesn't follow that compounded drugs are unsafe, Scott Brunner, chief executive officer of the Alliance for Pharmacy Compounding (ACP), which advocates for compounding pharmacies, said in an interview. "I think you can say that there is a higher degree of risk if the drug is not FDA-approved, but compounding does have a rigorous enforcement framework," Brunner said. Brunner and Gaunt agree that commercially available drugs should always be the first choice. They advise patients to verify a compounding facility's licensing and other credentials before filling out a script."



"Glutathione is currently under review by the FDA with other compounded substances, like vitamin B12. "The FDA says until it has finalized what it's going to do on those two substances, compounding pharmacies across the country can continue to compound with these substances," said Scott Brunner, who represents pharmacists nationwide as the CEO of the Alliance for Pharmacy Compounding. Brunner said California's Board of Pharmacy is the only one in the country that has heavily restricted access to glutathione by requiring cost-prohibitive testing by small compounding pharmacies.

03

THE GLP1 FRENZY

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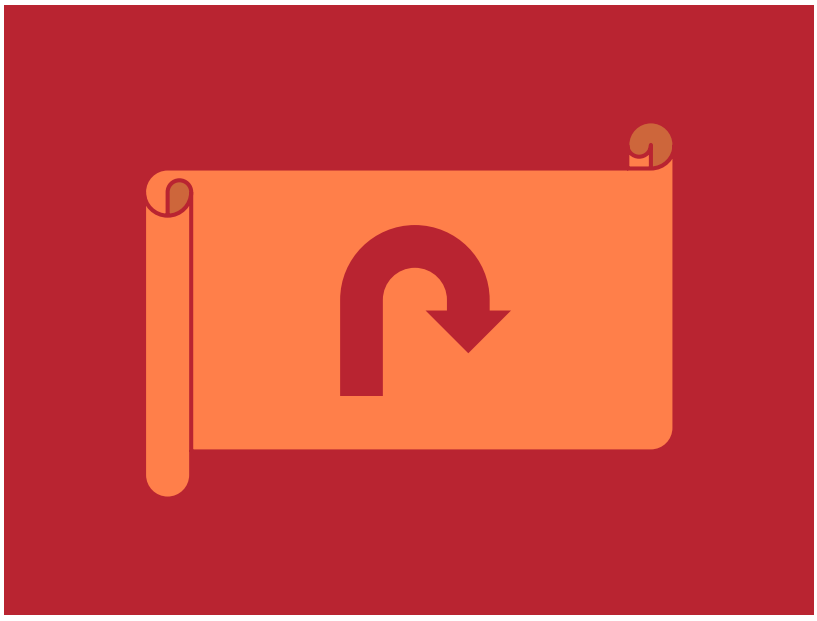
A.

DRUGMAKER LAWSUITS AGAINST COMPOUNDERS

B.

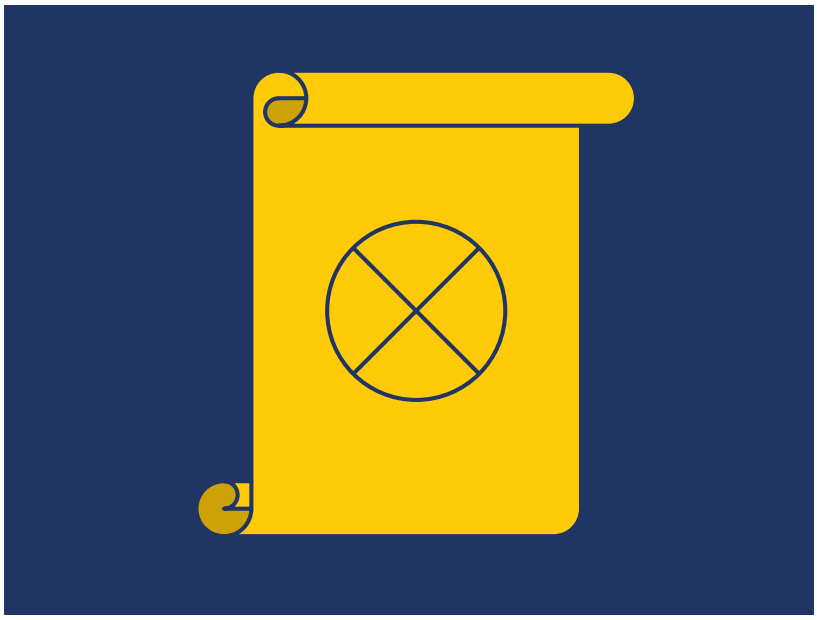
OFA LAWSUITS AGAINST FDA



C.

DDC LIST

(Demonstrably Difficult to Compound)



D.

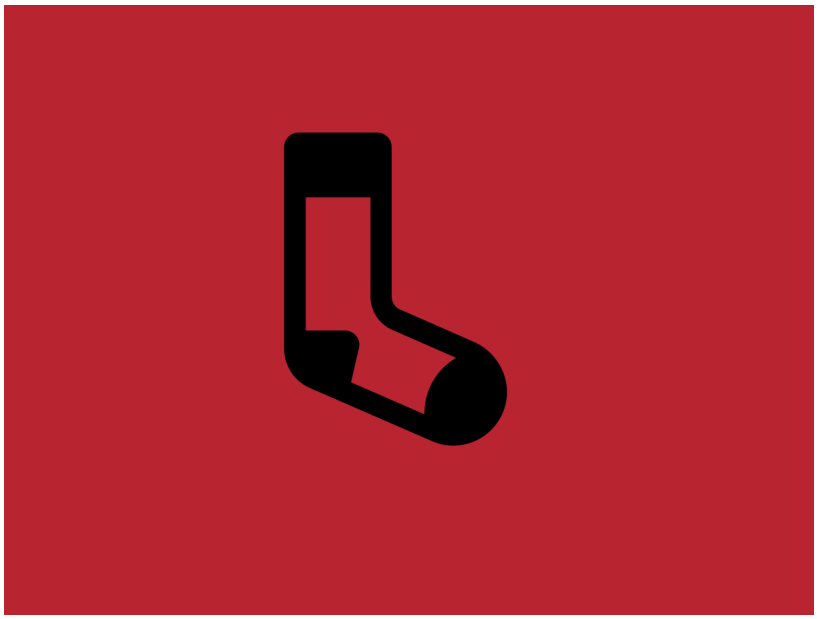
DRUGMAKER FOCUS ON STATE BOPs ...

E.

CEASE-AND-DESIST LETTERS

F.

THE SOCK-PUPPET GROUPS THAT SPREAD DRUGMAKER MISINFOR-MATION

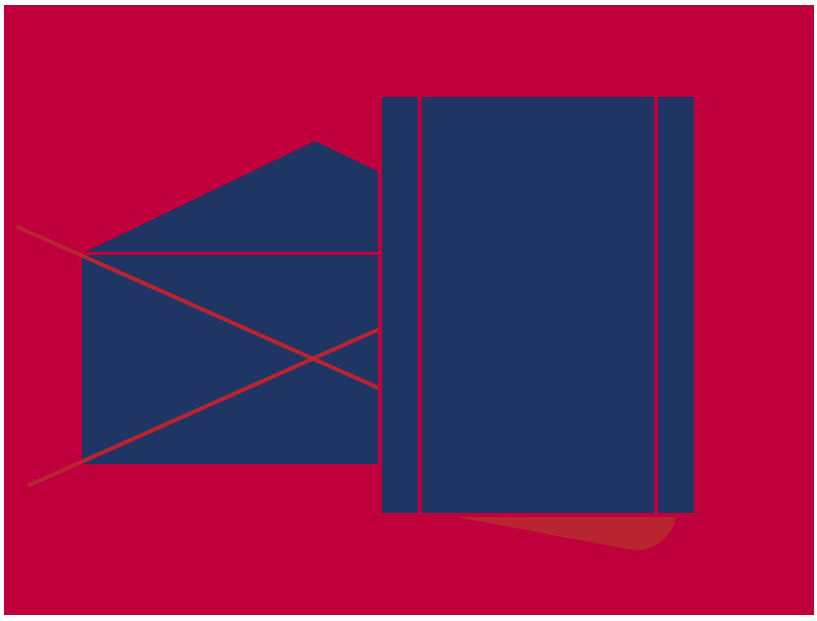


EXAMPLE 1.

“REPORT” ON SHIPMENTS OF COUNTERFEIT DRUGS

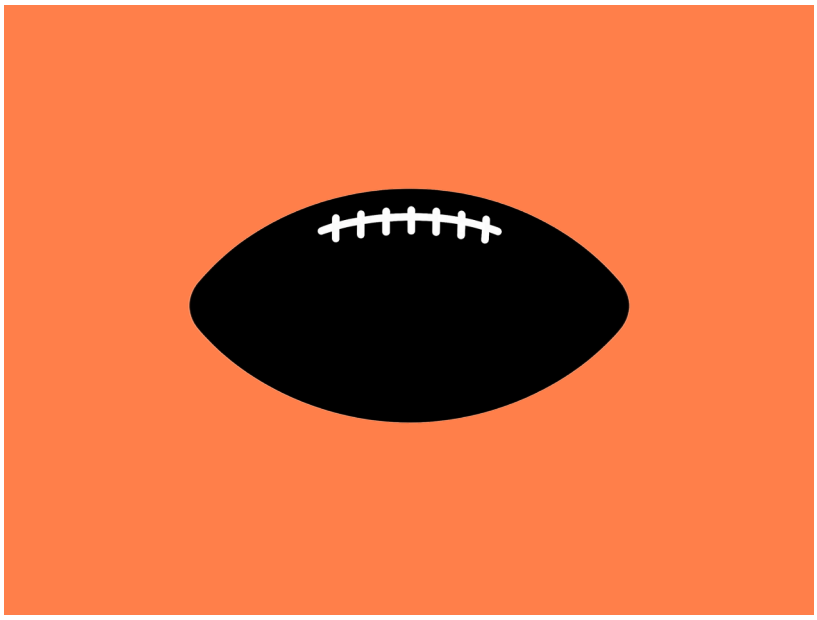
EXAMPLE 2.

STATE AG ASSOCIATION LETTER TO FDA ... AND AN FBI WARNING



G.

THAT SUPER BOWL AD...



H.

PRICE-BASED MARKETING & OPPORTUNISM

04

SHORTAGE DRUG LEGISLATION

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Compounding for shortage and urgent use

- Lidocaine. Amoxicillin suspension. Acetaminophen. Ibuprofen. *All recently or currently in shortage.*
- Compounding pharmacies and outsourcing facilities can help alleviate drug shortages, if allowed to do so in law.
- 2020: FDA temporary guidance allowed 503As to source 13 COVID drugs to hospitals until 503Bs could ramp-up production.

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Compounding for shortage and urgent use

- The End Drug Shortages Act was introduced in both the House and Senate in 2024 – a bipartisan bill that would improve the FDA's drug shortage list

What will the *End Drug Shortages Act* do?

Every American deserves access to life-saving medicines. The *End Drug Shortages Act* aims to prevent drug shortages from occurring and minimize the impact of shortages when they do occur. Specifically, the bill would:

- Improve communication between drug manufacturers, the FDA, and the pharmacies that support hospitals and health systems by -
  - Requiring drug manufacturers to notify the FDA when there is a surge in demand of a drug that is likely to lead to a disruption in the supply of the drug;
  - Establishing a definition of the term "surge"; and
  - Ensuring that FDA considers information reported by patients, health care professionals, and manufacturers when designating a drug shortage.
- Instruct FDA to finalize October 2021 guidance for hospital and health system pharmacies and ensure that such guidance is consistent with the most current research and best clinical practices.

Supporting Organizations: American Hospital Association, American Society of Health System Pharmacists, Angels for Change, Association of American Medical Colleges, Alliance for Pharmacy Compounding, Children's Hospital Association, Federation of American Hospitals, Inova, Kaiser Permanente, National Community Pharmacists Association, UVA Health, Virginia Commonwealth University, Vizient

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New legislation on the horizon – stay tuned

05

MOU & 503A ADVERSE EVENTS REPORTING

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The MOU

- In 1997, Congress directed FDA to create a Memorandum of Understanding with states to track compounding and distribution by traditional compounding pharmacies of non-patient-specific medications intended for in-clinic administration.
- Multiple iterations over 25 years, each of which exceeded what Congress authorized FDA to do
- Finalized in 2020, and seven compounding pharmacies immediately filed a lawsuit against FDA
- February 2022: FDA concedes in federal court that it did not follow the law and says it will start over

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The MOU

- But why? After 25 years, the MOU is out-of-date and unnecessary.
- Compounding and distribution by traditional compounding pharmacies of non-patient specific medications intended for in-clinic administration was prohibited by Congress when it passed the 2013 DQSA
- Why not eliminate the MOU?
- Eliminates having to cajole states to sign a document they can't or won't sign and eliminates an unnecessary 5% penalty cap on out-of-state shipping in states that can't/won't sign

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06

FDA'S PCAC PROCESS

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07

DEA

- **Anticipatory compounding**
- **Constructive transfer**

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DEA and Compounding

- Proposed changes do away with constructive transfer rules
- Would allow pharmacies to dispense controlled substance prescriptions directly to a physician's office if the physician and patient sign a POA
- State-by-state POA challenges exist
- Will greatly affect intrathecal compounders and also those that dispense compounded ketamine to be used under supervision of a prescriber
- Other issue – anticipatory compounding vs manufacturing

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08

503B SSOURCING TO 503A

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09

THE BLUEPRINT

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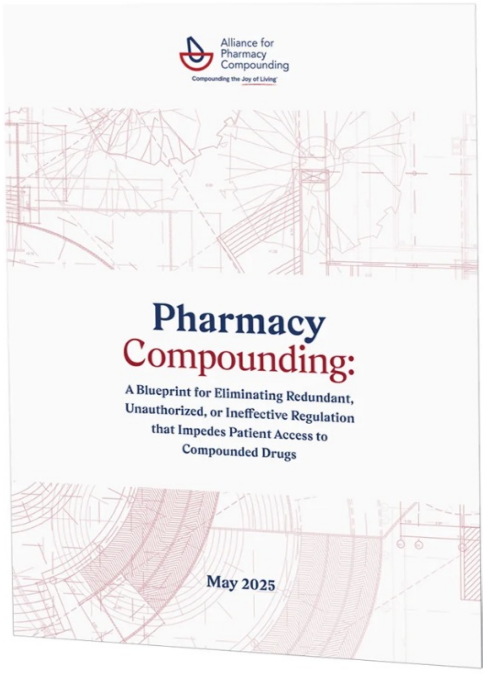

Key Priorities for Removal or Reform:

- **Eliminate** the 1997 MOU requirement.
- **Correct** overreach in FDA's draft DDC rules.
- **Mandate** that both drug and dietary supplement USP monographs "applicable" in law and regulation.
- **Demand** balance and evidence in FDA communication.
- **Reject** drugmaker asks to add GLP-1 APIs to the DDC list.
- **Reject** restricting access to CBHT.
- **Support** legislation to require FDA to rely on a broader range of data in determining drug shortages.
- **Overhaul** the FDA PCAC.
- **Rescind** FDA's GFI 256 regarding animal drug compounding.
- **Instruct** DEA to clarify "constructive transfer" policies.
- **Amend** FDA's "Insanitary Conditions" Guidance to include bright-line standards for compliance.
- **Instruct** FDA to finalize a robust 503B bulks list.

10

COMPOUNDING IS A DATA-POOR INDUSTRY.

WE NEED TO WORK ON THAT.

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11

ZYLA v. WELLS PHARMA

12

USP UPDATES

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BUD and Batch Sizes

- The U.S. Pharmacopeia: The standards-setting body for compounding, biologics, pharmaceutical manufacturing, and other fields.
  - Highly regarded, traditionally very science based
- Three USP chapters specific to compounding, and most states adopt some of all of those USP chapters into state law or regulation.
- In 2019, USP announced changes to the compounding chapters that would impose restrictions on:
  - The beyond-use-dates compounders can assign compounded sterile medications
  - The sterile batch sizes compounderers can produce: reduced to no more than 250 units

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BUD and Batch Sizes

- Both restrictions may profoundly increase costs to patients
  - Shorter BUDs mean more frequent refills, and payments
  - Smaller batch sizes increase production costs (time and resources) and those will be passed along to the patient
  - Smaller batch sizes also increase risk of contamination because they require more frequent entry into the cleanroom
- How does this make patients safer?
  - USP applied what is correct for the more unstable drugs to all drugs
- An aside – USP 800

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13

JULY 17 HORMONE PANEL AND DOCKET

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14 DESICCATED PORCINE THYROID

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Post Test Questions

What is the primary lens through which any proposed compounding-related regulation be assessed?

a. Is this regulation enforceable?
b. Is this regulation rooted in science?
c. How does this make patients safer?
d. How will this regulation affect the price of medications?
e. Is enforcement arbitrary or subjective?

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Post Test Questions

What is the largest batch size of a compounded sterile product that a pharmacy may produce at one time?

a. 100 units
b. 50 units
c. 500 units
d. 250 units
e. 1000 units

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Lecture Panda Code: