



APC

COMPOUNDERS
ON CAPITOL HILL

2023



Ashley Berthelot

Professional Arts Pharmacy
Lafayette, Louisiana



Let me tell you a story...



Let me tell you a story...

Pharmacy compounding plays an essential role in our healthcare system and drug supply chain.

Compounders are professionals and problem-solvers, and we can help alleviate some important therapy and supply chain gaps the American healthcare system ... if we're allowed to do so.



Let me tell you a story...

Policymakers must adjust their view of compounded drugs to see – and portray – them as appropriate therapies when a manufactured drug isn't suited or is in shortage – with appropriate focus on risks, yes, but greater focus on rewards and compounding's essential role in the drug supply chain.



CHAPTER ONE

Excellence





Dave Miller

Keystone Pharmacy
Grand Rapids, Michigan



Tenille Davis

Civic Center Compounding
Scottsdale, Arizona





APCTM

FELLOW of the
ALLIANCE OF
PHARMACY COMPOUNDING



Faded version of the text: "FELLOW of the ALLIANCE OF PHARMACY COMPOUNDING"



Edward DeCaria
RPh, FAPC





Patricia Douglas

RPh, FAPC



Lisa Everett Andersen RPh, FAPC



Cheri Garvin

RPh, FAPC





Shawn Hodges

PharmD, FAPC





Jim Hrncir
RPh, FAPC





Masoud Rashidi

PharmD, FAPC





Nicolas Ruiz
CPhT, FAPC





Doug Yoch
PharmD, FAPC





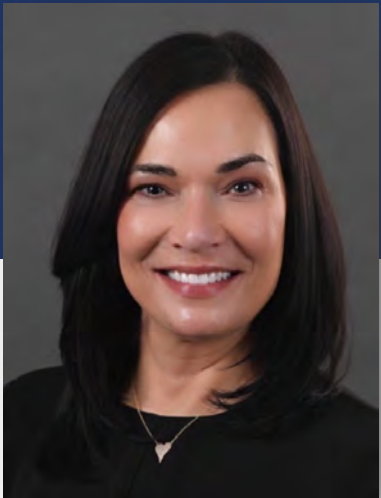
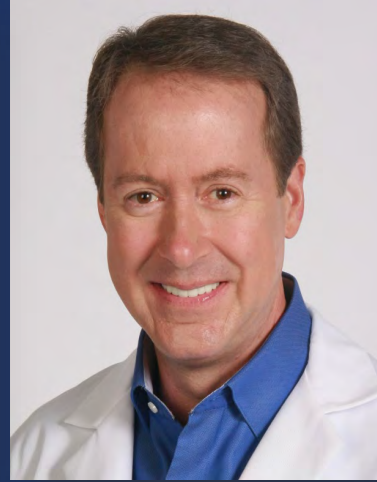
The Pharmacy Compounding Professional's Code of Ethics

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.





Class of 2023



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ON CAPITOL HILL

2023

CHAPTER TWO

Effective Regulation, Fair Enforcement



Threading the Regulatory Needle



Alliance for
Pharmacy
Compounding

Compounding the Joy of Living

CHAPTER TWO

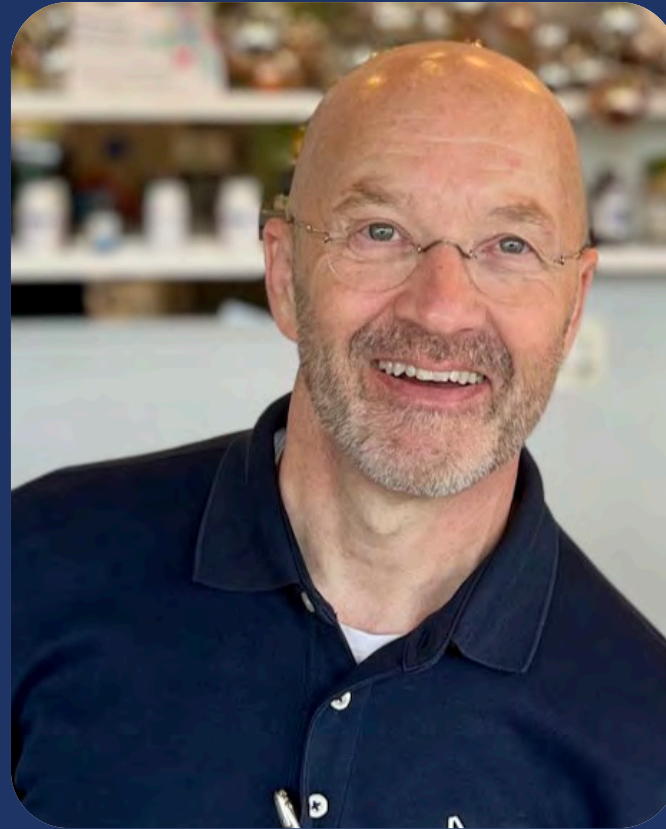
Effective Regulation, Fair Enforcement





Gail Bormel

Director, FDA Office of
Compounding Quality &
Compliance



Scott Brunner

CEO, Alliance for Pharmacy
Compounding



CHAPTER TWO

Effective Regulation, Fair Enforcement





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2023

CHAPTER THREE

We Have a Voice





Tenille Davis

Civic Center Compounding
Scottsdale, Arizona



Alexander
Pytlarz

Infuserve America
St. Petersburg, Florida



Scott Brunner

APC



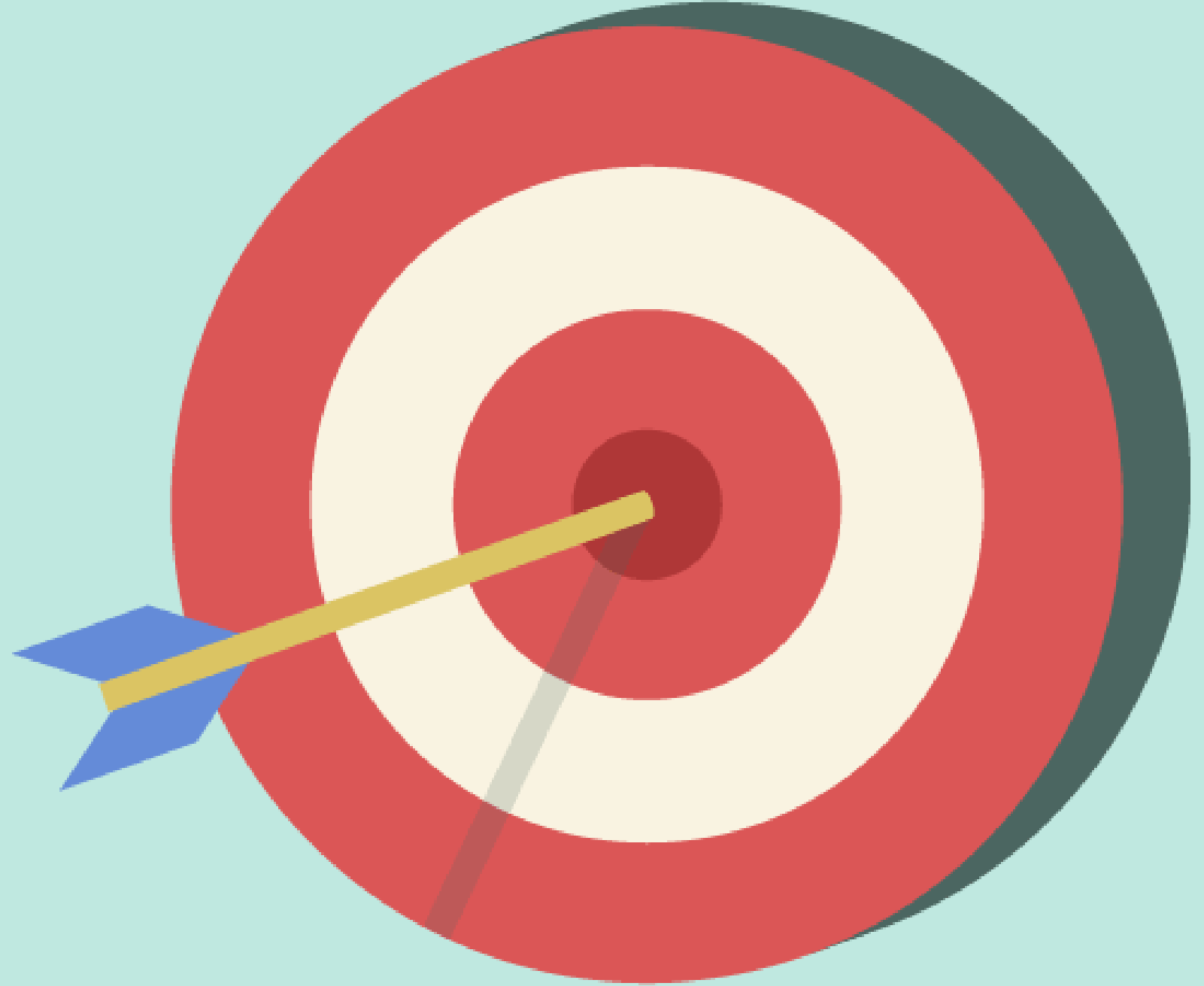


Alliance for Pharmacy Compounding

Compounding the Joy of Living

APC Membership Meeting

The State of the Alliance • September 19, 2023



Financial Snapshot*

Income Sources: Membership 31% • CE & Conferences 18% • CPs 17% • OneFund 15%

Primary Expenses: Staffing 58% • Advocacy 14% • Conferences 8% • Operations 19%

2021 YE

- Total Income:
\$1,305,563
- Total Expense:
\$1,201,665
- YE Surplus:
\$103,898
- **Net Worth:**
\$1,005,398
- Reserve:
\$467,483.28

2022 YE

- Total Income:
\$1,601,897
- Total Expense:
\$1,555,628
- YE Surplus: \$46,269
- **Net Worth:**
\$1,166.014
- Reserve:
\$415,363.07

• 2023 YTD

- *Budgeted* Income: \$1,693,356
- *Budgeted* Expense: \$1,660,212
- *Budgeted* YE Surplus: \$33,144
- 7/31 Income: **79.52%**
- 7/31 Expense: 57.34%
- **7/31 Net Worth: \$1,322,217**
- 7/31 Reserve: \$558,692.76

No media campaign funds are represented here. The media campaign is accounted for separately.

Membership

2021 YE

- Individual Ph: 661
- Individual Tech: 191
- Individual Supporter: 78
- Students: 114
- **Total Members: 1,044**

• 2022 YE

- PFM Members: 3,223
- Individual Ph: 372
- Individual Tech: 35
- Individual Supporter: 34
- Prescribers: 11
- Students: 26
- **Total Members: 3,701**

- **PFM Companies: 100**



• 2023 YTD

- PFM Members: 3,723
- Individual Ph: 341
- Individual Tech: 29
- Individual Supporter: 35
- Prescribers: 9
- Students: 26
- **Total Members: 4,163**

- **PFM Companies: 125**



Thank you,
Fagron!

FOR SPONSORSHIP OF APC-BRANDED
YETI MUGS FOR PHARMACY/FACILITY
MEMBERS



Defending the Profession

Legal:

- APC to file amicus briefs in 4 Novo Nordisk lawsuits against compounders
- Funded by APC's Legal Action Fund (current LAF balance: ~\$67k)
- Attorney: Mark Boesen, Boesen & Snow, Scottsdale, Ariz.
- Our interest: Preserving the ability of pharmacy compounders to prepare copies of FDA-approved drugs when those drugs appear as "currently in shortage" on FDA's shortage list



Defending the Profession

Advocacy:

- California
 - Via APC's Legal Action Fund, a group of California compounders is seeking to influence the CA General Assembly's upcoming reauthorization of the CA BOP.
 - For details: [Peter Koshland](#) or [Erin Michael](#)
- Compounding the Joy of Living / cBHT Campaign
 - Fundraising is flat
 - Focus on Geo-Fencing and the PBS video
 - 2024?
 - "Demonstrably difficult" rule?
 - Engaging prescribers
 - Compounding the Joy ...

The
compounded
hormones that
cleared your
brain fog?

Your access may
soon be restricted

JOIN THE FIGHT



Year 3: Total Campaign Results as of 2023 *(reduced media budget)*

40,167,888

Americans Reached

+ 62.79%
increase to 2022

499,640

Website Pageviews

(new home, patient and congress pages)

+ 73.36%
increase to 2022

5,157

Testimonials Submitted

+ 17.58%
increase to 2022

1,429

Congressional Offices
Reached

+ 194.03%
increase to 2022

5,388

Senders to Congress

+41.98%
increase to 2022



Purchasing Power

- New APC credit card processing deal with WorldPay
- Participation available only to PFM members
- The Processing Brokerage: customer service and onboarding
- Currently with WorldPay? You'll have to wait ...
- 2022 survey: On average, PFMs were paying 28¢ per transaction
- **Our deal starts at 11.5¢ for all participants** ... and that per-swipe fee will go down as volume and number of pharmacies in the GPO grows.
- *Note that some pharmacy software vendors already have a financial deal with particular credit card processors and these pharmacies will not be able to join APC GPO unless they change software or **use a stand-alone credit card processing setup that does not connect with software***

APC PRICING

# of Merchants		# of Transactions		Volume in \$		Proposed Pricing	
Lower Band	Upper Band	Lower Band	Upper Band	Lower Band	Upper Band	bps	per tran
0	5	0	180,000	\$0	\$18,000,000	0.011%	\$0.011
6	25	180,001	900,000	\$18,000,010	\$90,000,000	0.0975%	\$0.0975
26	50	900,001	1,800,000	\$90,000,100	#####	0.080%	\$0.080
51	100	1,800,001	3,600,000	#####	#####	0.070%	\$0.070
101	150	3,600,001	5,400,000	#####	#####	0.065%	\$0.065
151	200	5,400,001	7,200,000	#####	#####	0.060%	\$0.060
201	250	7,200,001	9,000,000	#####	#####	0.050%	\$0.050

Knowledge & Ethics



Alliance for
Pharmacy
Compounding

*The first step to truly helping your patients regain or maintain their health is not your depth of understanding of chemistry or pharmaceuticals or compounding. **It's trust.** We earn that trust through our actions, by consistently operating our pharmacies to the highest ethical, legal, and regulatory standards. Every day. With every prescription we fill.*

The Ethical, Legal, and Regulatory Foundations of Pharmacy Compounding

A 15-hour foundational curriculum aimed at equipping you to earn your patients' trust.

Earning their trust takes more than your technical expertise. It's equally important that patients know that you and your teammates have an essential understanding of the laws, regulations, and policies that govern pharmacy compounding. That you operate in compliance with those rules. It's critical for compounding well.

But you can't comply with rules and regulations that you don't know.



Taught by experienced professionals.

The faculty teaching this program have, collectively, decades of hands-on experience in compounding pharmacy and patient care. You will be learning from the best in the business.

Take the course. Earn their trust. Build your business.



Online. Affordable.

This is an online CE course, allowing you to complete the certificate at your own pace. It's also priced well below most CE courses. Every pharmacist and pharmacy technician involved in compounding should earn this essential certificate. Because it's that important.

PHARMACISTS/PHARMACY TECHNICIANS..... \$495/ea

PHARMACISTS/PHARMACY TECHNICIANS EMPLOYED BY AN APC PHARMACY/FACILITY MEMBER..... \$395/ea



Risk Management + Legal Protection



- APMS[®] uses data to create safe practice recommendations to help pharmacies reduce errors and positively impact patient care.
- PFM^s get FREE membership in AMPS, a patient safety organization, but only about 40% of PFM^s have registered.
- Why you should register:
 - **Compliance:** *Meets state BOP requirement that you have an active QA program*
 - **Legal Protection:** *Your pharmacy data collected within the PSO for patient safety improvement analysis is privileged and can be protected from discovery*
 - **Resources:** *Medication safety experts are available for data analysis and consultation, including guidance when conducting root-cause analysis*
- Visit Tara at her table here at CCH

State Influence 2023

- 12 states: AL, CA, DE, ME, MS, MT, NC, NY, OR, TN
- 16 comment letters^[L]_[SEP]
- 3 memos to all BOPs: USP 797, GFI 256, DTE^[L]_[SEP]
- 2 calls to action



Advising Prescribers

Prescriber Briefings: For APC members only

Use these to educate prescribers you work with about what compounders can (and cannot) do

The Truth About Pharmacy Compounding

A briefing for physicians and other prescribers

A highly regulated profession

Pharmacy compounding is not a new phenomenon. It goes back a thousand years or more to the very beginnings of pharmacy practice. In an ancient world in which standardized, mass-produced drugs were not yet developed, compounding was pharmacy — mixing ingredients to create a treatment for a specific person or animal.

Pharmacy practice has come a long way since then, and so has pharmacy compounding. While less consistent in the role of compounding in healthcare, these days, compounding is often used as a prescriber, traditional compounding pharmacies use raw ingredients to create customized medications for a specific patient or animal.

Pharmacy compounding for human patients has a long history that existed well before the establishment of mass-produced drugs and government regulation of those drugs. But being a legacy does not mean it's obsolete or unimportant. In fact, the American healthcare system depends on pharmacy compounding. Compounding is an appropriate and essential therapy option when, in the judgment of a prescriber, an FDA-approved, mass-produced drug is not suited to a specific human patient's need. This is why it is enshrined in the U.S. Food, Drug & Cosmetic Act and permitted so long as certain criteria are met.



From the simple addition of grape flavoring to a child's medication to the compounding of critical medications in shortage, compounding pharmacies are highly regulated, adhering to high standards of quality and compliance. Just as with pharmaceutical manufacturers, the active pharmaceutical ingredients — API — that compounding pharmacies use must come from FDA-registered facilities and manufacturers. Compounding labs and the equipment to them are subject to exacting regulation and are inspected by state boards of pharmacy and by the FDA. In addition, pharmacy compounders must adhere to state laws and regulations governing compounding as well as standards promulgated by the United States Pharmacopeia, the internationally recognized standards-writing organization. In fact, many (if not all) states have expressly adopted some or all USP standards directly into their laws.

The lives and health of millions of Americans are enriched daily by compounded medications created by a physician or other prescriber.



FDA's GFI #256 on Animal Compounding

Veterinarians must note medical rationale on prescription

According to the FDA Center for Veterinary Medicine's Guidance for Industry 256, effective April 1, 2013, veterinarians must provide a medical rationale when initially prescribing certain compounded medications, such as compounded drug prepared from pure ingredients that FDA reviewers identify to commercially available non-sterile drugs. When requested by your pharmacy to provide this information, one of the following rationales may be provided:

Commercial product would reduce compliance and/or is not effective for achieving medical outcome.

- Multiple tablets/tablets of high volume ML needed to dispense animal
- Active cannot be used orally, requires a topical dosage form
- Medications cannot be split appropriately (fragments of dose is unachievable)

Commercial product is not available and/or unable to source.

- The batch/lot/expiration
- Compounding readily available commercially
- Oral CE combination not available



Utilization of commercially available dosage form is unachievable or unsafe for patient.

- Creating a sterile ophthalmic suspension from a topical dosage form
- Creating a sterile injectable from a sterile dosage form
- For cost safety be done with approved dosage form

Patient and/or population has an intolerance, sensitivity, toxicity, or aversion to commercial product.

- Patient has severe fit against oral route, oral preferred
- Lactose intolerance
- Allergy sensitivity



Compounding Peptides: It's Complicated

A briefing for physicians and other prescribers

Compounding pharmacies frequently get requests from prescribers to compound a medication that is prohibited under Section 303A of the Federal Food, Drug, & Cosmetic Act. When a compounding pharmacist must decline to fill a prescription for a particular compounded medication, that's usually the reason.

A current "hot" product in the anti-aging and longevity medicine world is peptides, many of which were reclassified in March 2020 by federal law as biologics. Traditional compounding pharmacies cannot compound substances that are classified as biologics. In addition, most peptides do not meet any of the other legal requirements for compounding. Under federal law (Section 303A), to be eligible for use in a compounded product, an active ingredient must meet one of the following criteria:

- Be an active ingredient in an FDA-approved drug product.
- Have a USP or National Formulary drug monograph.
- Appear on the Section 303A Exempt or Exempt Bulk List published by FDA.

As a result, most peptides are off limits for traditional compounding, as they are either classified as biologics or don't meet one of the three criteria above. Unfortunately, that



March 2020 law reclassified both **tocopherol** and **HGH** as biologics, so they may no longer be compounded.

However, there are some peptides that, because of their smaller molecule size (specifically, 10 amino acids or fewer), do not meet the definition of a biologic, yet do meet one of the three legal criteria for use in compounding. One is **sermatropide**. Others include, for example, **sermorelin** and **hormel-oxide**. Sermatropide is the active ingredient in an FDA-approved drug product.

The law is complicated by the fact that a drug manufacturer now markets an FDA-approved sermatropide product, which may be protected by U.S. patents. Thus, compounding using sermatropide API, depending on the formulation, may be considered "essentially a copy" of an FDA-approved drug, and therefore impermissible for compounding. However, the FDA-approved sermatropide product has been on the FDA Drug Shortage List since March of 2022, which may render it preferable for use in compounding.



Compounding for Racehorses

An overview for veterinarians

Some compounding pharmacies are approached by veterinarians to prepare medications for racehorses. As a highly regulated sport, horse racing has specific rules and regulations regarding the use of drugs in horses. The new anti-doping and medication control programs launched by the Horseracing Integrity and Safety Authority (HISA) on March 27, 2023, addresses the use of human and non-approved substances in horseracing. However, it is important to note that compounded medications are not prohibited under the program.

Compounding and the HISA ADMC Program
Under the HISA ADMC program, Rule 411.36, HISA "non-approved substances," states that compounded products that comply with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (Compounding Animal Drugs from Bulk Drug Substances) are not prohibited. It is important for veterinarians to understand that they can continue to rely on compounding pharmacies to provide medications for their racehorses.

During a March 2023 phone conversation with APC staff, the Horseracing Integrity



William Witt (HISA) Chief of Science, Mary Scelley, emphasized the importance of compounded medications in the horseracing (HISA). She noted that compounding allows for customized medications to be tailored to each horse's specific needs. This is particularly important in horseracing, where each horse is unique and may require a different medication or dosage.

Conclusion
Compounded medications are not prohibited under the new HISA ADMC program. Rule 411.36 allows for the use of compounded products that comply with AMDUCA and GFI #256.

Compounding pharmacies play a critical role in providing customized medications for racehorses that meet their specific needs. As a result, it is important to understand the regulations around compounding and to rely on trusted compounding pharmacies to provide safe and effective medications for your racehorses.



Prescription Compliance: DEA's "Wet Signature" Requirement

A briefing for physicians and other prescribers

Physicians and other prescribers know they must manually sign paper prescriptions for controlled substances, including prescriptions generated by computer as a prescription application that are then printed or faxed. However, a great deal of confusion and misinformation exists about how the Drug Enforcement Agency's (DEA) "wet signature" requirement applies to electronic prescriptions for controlled substances ("EPCS").

Unfortunately, some prescribers and pharmacies may mistakenly believe that secure signature solutions like DocuSign comply with this requirement. Determining whether an application like DocuSign satisfies the law requires an understanding of the EPCS rules and the DEA's technical capabilities.

The DEA's "wet signature" rules for EPCS are primarily found in two relevant sections of the Code of Federal Regulations ("CFR"): 21 CFR § 1311.20 and 21 CFR § 1311.35. The rules are designed to ensure that prescribers of controlled substances are who they say they are.



To accomplish this goal, the EPCS rules require **two-factor authentication**, not just a secure signature.

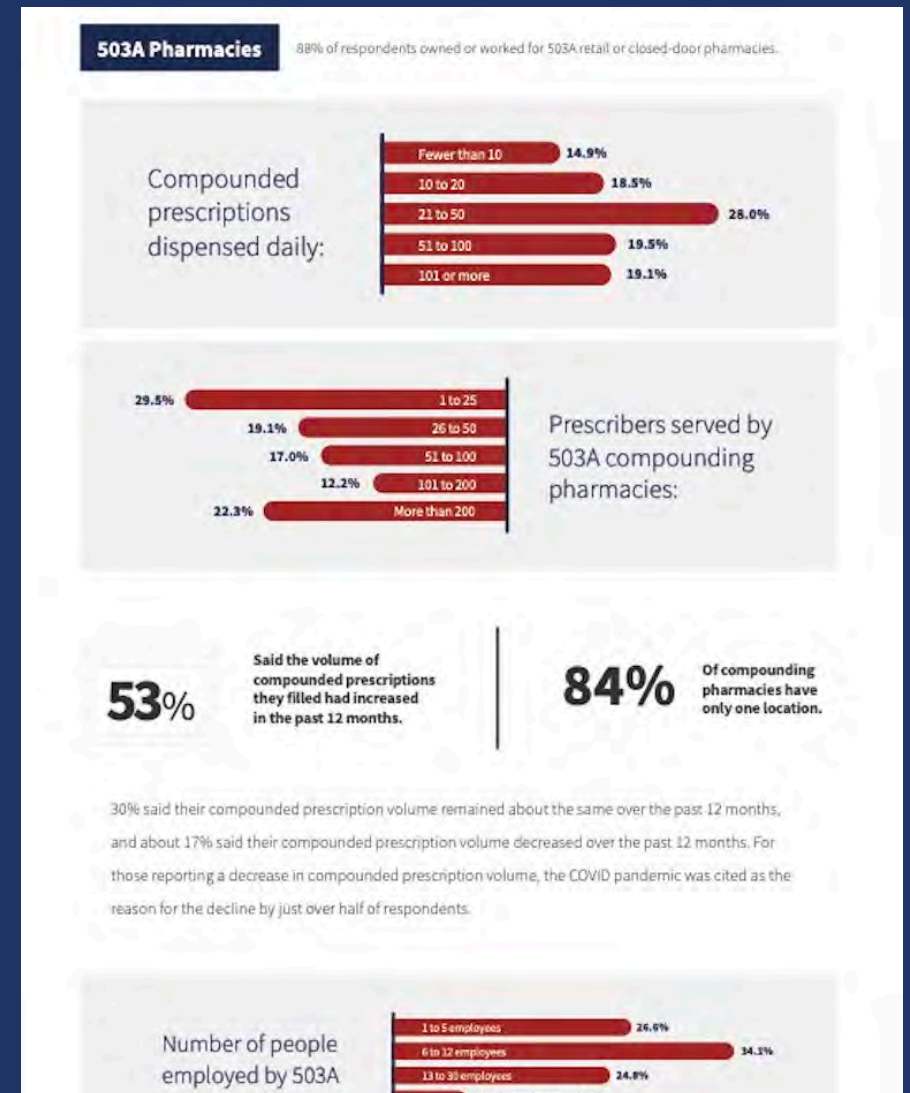
The electronic prescription application must accept **two-factor authentication** as required by § 1311.35 and require its use for signing controlled substance prescriptions and for approving data that is or change (audit) controls related to reviewing and signing controlled substance prescriptions. (emphasis added)



A4pc.org/prescriberbriefings

2023 Snapshot of Pharmacy Compounding

- 2023 survey of 15,000+ compounders launches next month
- Partnership between APC and University of Utah College of Pharmacy
- Support from Fagron, Medisca, PCCA
- By year-end: 2023 Snapshot, a demographic profile of the pharmacy compounding industry



Mitigating Regulatory Risk with DATA

What's in FDA's "Demonstrably Difficult" Rule?

- New criteria and new drug products adopted at same time?!
- But this should be a two-step process ...
- The threat to compounded hormones?

Standardized Data Collection: Patient Reported Outcomes



Why OutcomeMD?

- Validated measures: Same as FDA requires in NDA process
- Consistency: Ability to aggregate across pharmacies
- Coming soon: PCF-funded workflow/integration fixes what will make the process more turn-key
- FDA's demonstrably difficult rule and what may follow it: Time is short.



Pharmacy
Compounding
Foundation

Keep up. Fridays in your email box.



The voice for pharmacy compounding | 11 August 2023



Alliance for Pharmacy Compounding

Compounding the Joy of Living



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App Schedules and Logistics Overview



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Senator Ben Ray Luján

New Mexico

5:15p Reception • \$1,000



Cong. Richard Hudson

North Carolina

6:30p Dinner • \$1,000



Cong. Diana DeGette

Colorado

7:50a tomorrow





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2023



Ashley Berthelot

Professional Arts Pharmacy
Lafayette, Louisiana



CHAPTER FOUR

**We're Problem Solvers
... and We Can Fix This**





Amy Shank

PCCA Director of
Government Relations



David Pore

APC Governmental Affairs
Counsel





Amy Shank

PCCA Director of
Government Relations



David Pore

APC Governmental Affairs
Counsel



Amy & David slides here





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2023

What we'll discuss

- Compounded hormones
- Drug shortages & supply chain
- Coming attractions
- What's in your packets



The Threat to Compounded Hormones

- NASEM report
- Compounding.com
- **Senate ask:** Add your name to a letter to FDA led by Senators Baldwin (WI) and Marshall (KS)
- **House ask:** Contact the FDA to express concern about bias and lack of scientific rigor in the FDA-funded NASEM cBHT report. Forward the July 2023 House letter to the FDA with an expression of your support.



A Fix for Drug Shortage and Supply Chain Issues

- HR 167, the **Patient Access to Urgent-Use Pharmacy Compounding Act of 2023**, sponsored by Rep. Morgan Griffith (R-VA) and Henry Cuellar (D-TX), creates a permanent path for 503A pharmacies to provide urgent use and shortage drugs to hospitals and physicians when those drugs cannot be sourced from the manufacturer or a 503B outsourcing facility.
- **House ask:** Call the Energy & Commerce committee and ask that they include HR 167's provisions in any drug shortage or pandemic preparedness package
- **Senate ask:** Introduce a Senate companion bill to HR 167. Please sponsor an effort to include HR 167's provisions in any drug shortage or pandemic preparedness package.



Energy & Commerce Committee Members

- Cathy McMorris Rodgers, Washington
- Michael C. Burgess, Texas
- Bob Latta, Ohio
- Brett Guthrie, Kentucky
- Morgan Griffith, Virginia
- Gus Bilirakis, Florida
- Bill Johnson, Ohio
- Larry Bucshon, Indiana
- Richard Hudson, North Carolina
- Tim Walberg, Michigan
- Buddy Carter, Georgia
- Jeff Duncan, South Carolina
- Gary Palmer, Alabama
- Neal Dunn, Florida
- John Curtis, Utah
- Debbie Lesko, Arizona
- Greg Pence, Indiana
- Dan Crenshaw, Texas
- John Joyce, Pennsylvania
- Kelly Armstrong, North Dakota
- Randy Weber, Texas
- Rick Allen, Georgia
- Troy Balderson, Ohio
- Russ Fulcher, Idaho
- August Pfluger, Texas
- Diana Harshbarger, Tennessee
- Mariannette Miller-Meeks, Iowa
- Kat Cammack, Florida
- Jay Obernolte, California
- Frank Pallone, New Jersey
- Anna Eshoo, California
- Diana DeGette, Colorado
- Jan Schakowsky, Illinois
- Doris Matsui, California
- Kathy Castor, Florida
- John Sarbanes, Maryland
- Paul Tonko, New York
- Yvette Clarke, New York
- Tony Cárdenas, California
- Raul Ruiz, California
- Scott Peters, California
- Debbie Dingell, Michigan
- Marc Veasey, Texas
- Annie Kuster, New Hampshire
- Robin Kelly, Illinois
- Nanette Barragán, California
- Lisa Blunt Rochester, Delaware
- Darren Soto, Florida
- Angie Craig, Minnesota
- Kim Schrier, Washington
- Lori Trahan, Massachusetts
- Lizzie Fletcher, Texas



A look ahead

PHARMACY COMPOUNDING REPORTING ACT OF 2023

1. It would repeal a 1997 MOU requirement in the Food, Drug & Cosmetic Act – and the burden of FDA having to cajole states sign an MOU – and replace it with a requirement for reporting to state boards of pharmacy by all traditional compounding pharmacies that ship more than 50 percent of their compounded drugs out-of-state. This goes well beyond the reporting required under the 1997 MOU directive, to include reporting on compounded drugs dispensed pursuant to a patient specific prescription.
2. It would create a framework for mandatory reporting of serious adverse events by traditional compounding pharmacies – a requirement long sought by FDA.



In your leave-behind packet for members:

- Summary of Asks
- 3 issue one-pagers
- A comparison doc on HR 167
- *STAT* opinion piece on compounding and drug shortages
- Senate hormone letter (currently open)
- House hormone letter (just submitted in 2023)
- Snapshot of pharmacy compounding (2021)





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CHAPTER FIVE

We Are Science-Based ... and Also Innovative





Laura Bray

Founder, Angels for Change



Philip Smyth

Director of Global Public
Affairs, Medisca





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Senator Ben Ray Luján

New Mexico

5:15p Reception • \$1,000



Cong. Richard Hudson

North Carolina

6:30p Dinner • \$1,000



Cong. Diana DeGette

Colorado

7:50a tomorrow





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END OF DAY 1



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Ashley Berthelot

Professional Arts Pharmacy
Lafayette, Louisiana





Onyx Ahmad

Technical Sales & Quality Manager
International Filter Products



International Filter Products



Putting customers first, always!

- Instant Shipping from \$2.5M Inventory.
- Effortless E-commerce Experience.
- Inquiry Response in 24 hours.
- Consult Engineers for Tech Support.
- Data for Volume Range & Optimal Sizing.
- Plus: Exclusive Complimentary Services.

(Call or Email to Discover More)



Team Experience

Engineering

50+ Years of
Combined
Experience.

Technical Sales

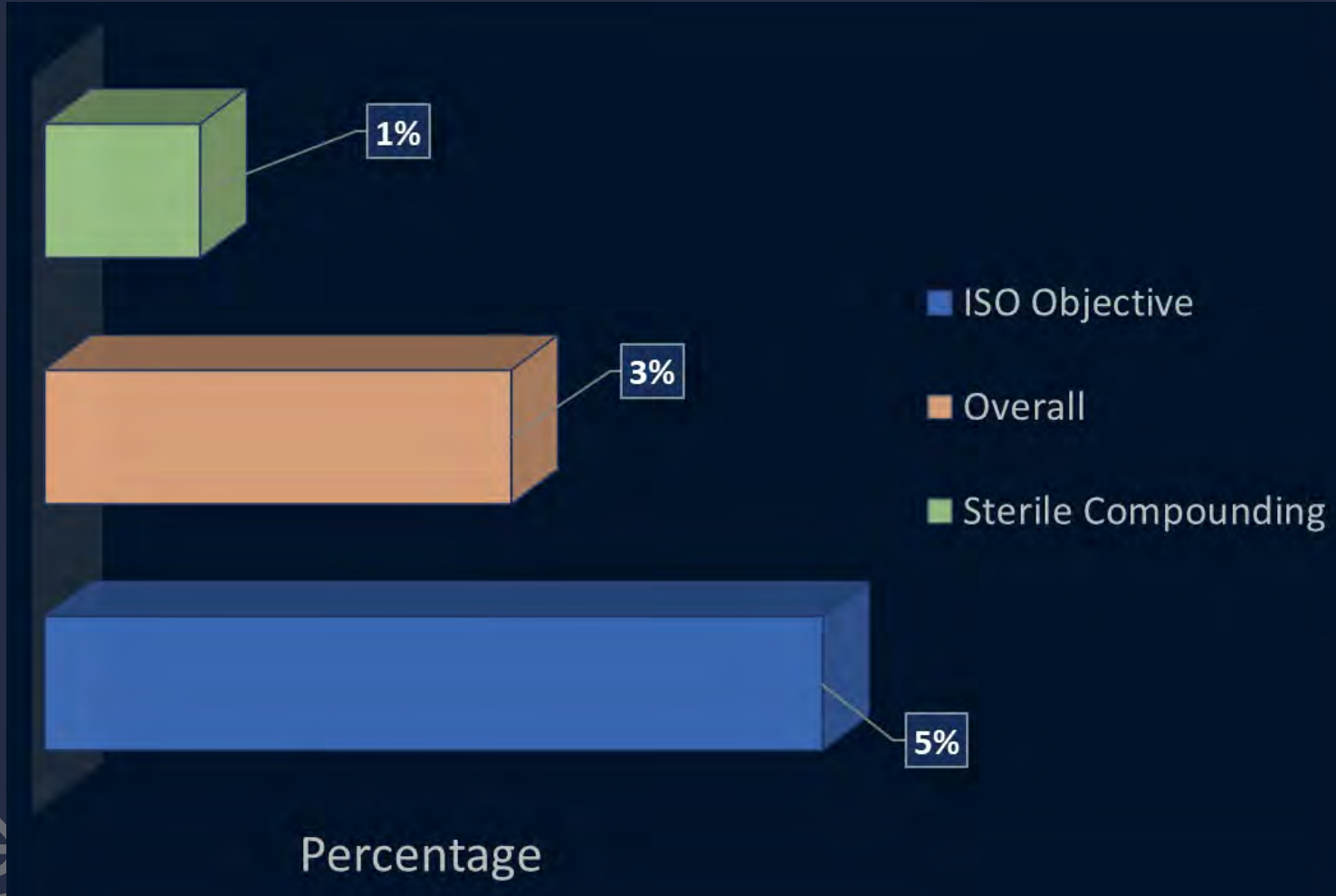
- Comprised of Engineers.
- Dedicated East Coast Representative Available.

Shipping & Handling

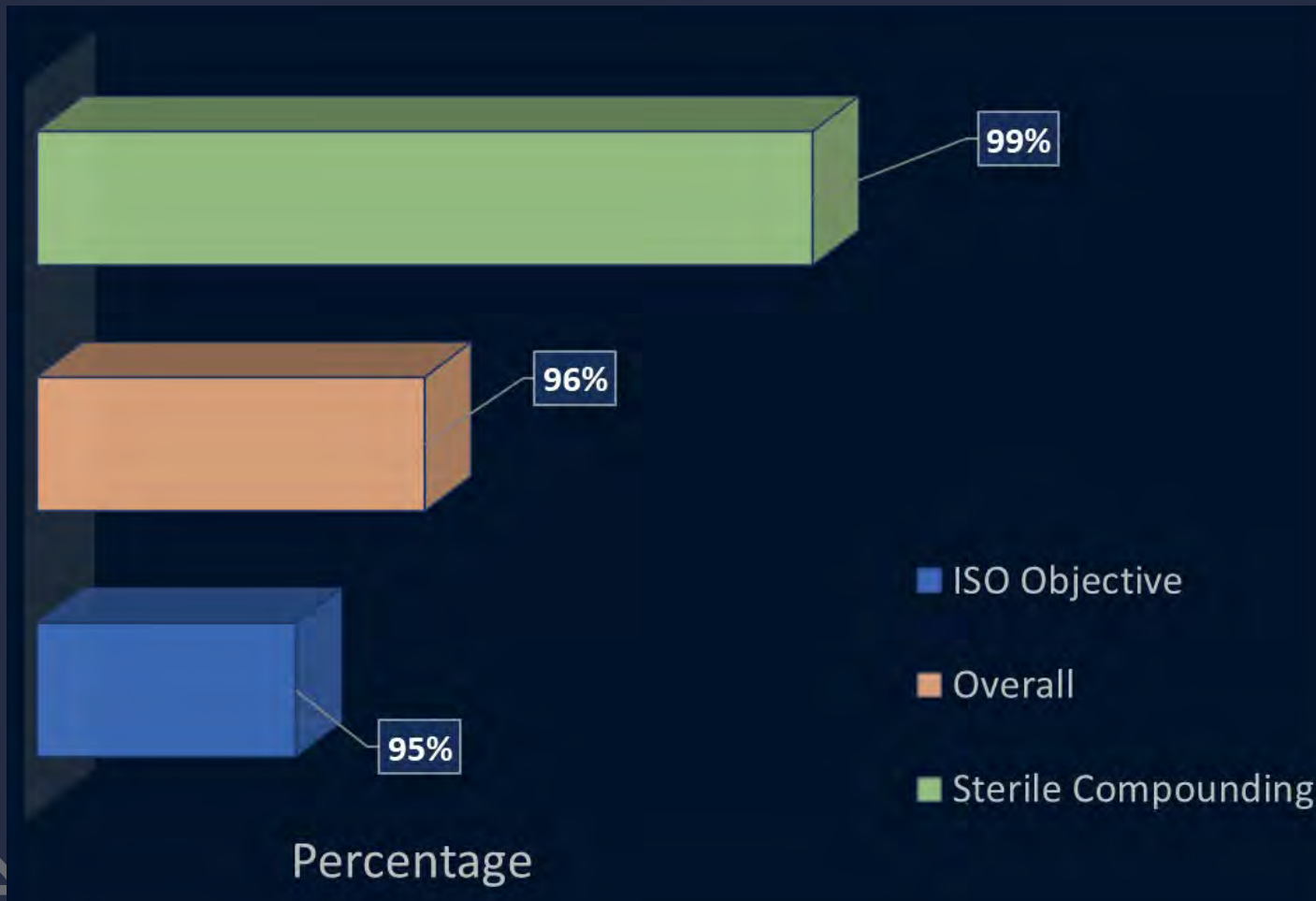
Adheres to ISO
9001:2015 for
Flawless Execution.



Order Processing Error



Customer Inquiries & Orders Acknowledged On-Time



Strengthening the compounding community with the Alliance for Pharmacy Compounding.



International Filter Products

Revolutionary systems for your industry



Bonus



Bubble Point Test

Detailed Guide Available.

Please Visit Our Booth





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2023

CHAPTER ONE

Excellence





The 2023
GEORGE AND LUCY MALMBERG
Compounding
Advocacy Champion





Please welcome

Lucy Malmberg





The 2023
GEORGE AND LUCY MALMBERG
Compounding
Advocacy Champion





Sue Horton, RPH

Central Iowa Compounding Pharmacy
Urbandale Iowa

**2023 George and Lucy Malmberg
Compounding Advocacy Champion**



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2023

**If I Can Do It,
So Can You.**

Ashley Berthelot

**Professional Arts Pharmacy
Lafayette, Louisiana**



Professional Arts Pharmacy



128 Curran Lane • Lafayette, LA 70506 • M-F 8am – 5:30pm



act of congress



THAT WHICH IS EXTREMELY DIFFICULT TO
ACHIEVE OR REQUIRES A LARGE AMOUNT
OF EFFORT OR PATIENCE TO ENACT
PRIMARILY HEARD



Before Your Meeting



Research the Congressional member



- *Prep work is VERY important to a successful outcome!*

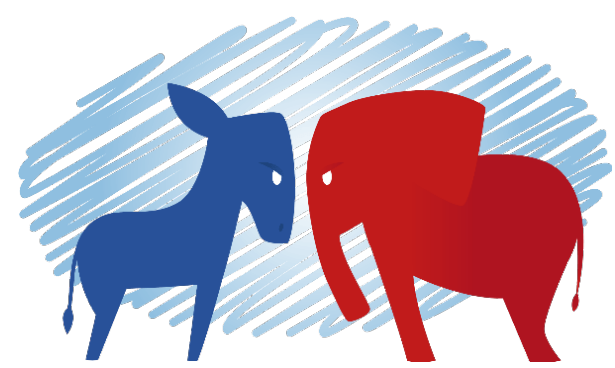


- Read their bio and have a general understanding of their viewpoints, status, influence, etc. *(In the Uber / Hallway)*



- Read through previous year's notes to build on your relationship. Pick up where you left off.

Before Your Meeting



Prepare for Political Pitfalls.

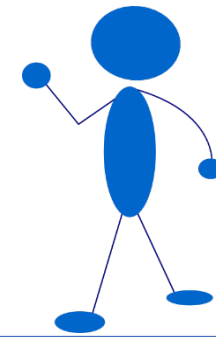
Expanded vs Limited Government

- Recognize that different parties have varying views on many issues, such as government agency involvement.

Hormones – **New* Sensitive Issue*

- You *may* have to explain that compounding pharmacists can and do provide hormones for transitioning individuals, though the vast majority of compounded hormone therapy is replacement for individuals going through menopause and andropause.

Reframe to non-partisan patient access!



Before Your Meeting

Memorize as much as possible about “the asks”

- **Figure out how to simplify the message**
- **Asks may be summed up by “Patient Access” barriers**

Correlate the asks to your business and explain the impact

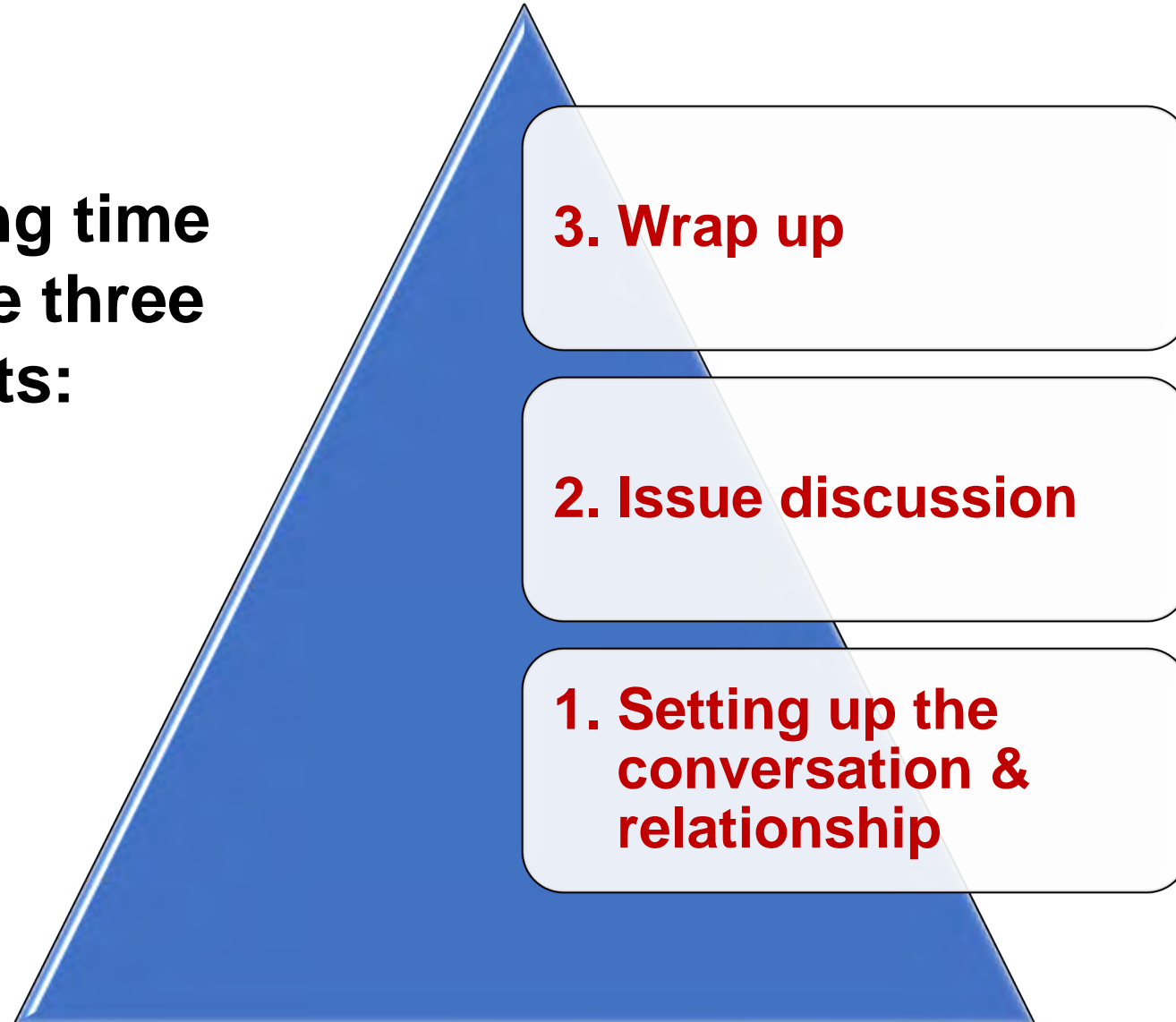
- ***Impact could be:***
- **Patients**
- **Physicians**
- **You**

Be prepared to show up as YOU

- **Constituent**
 - **Business owner**
 - **Patient**
 - **Person with needs**
- from the State/District**

During Your Meeting

Your meeting time should have three distinct parts:



Setting Up the Convo & Relationship



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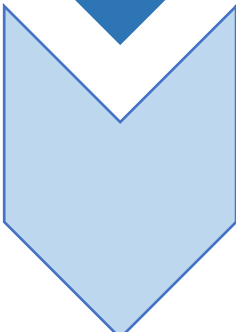
YELLOW PAGES

Setting Up the Convo & Relationship

Ask questions!!!! (SALES 101)

- 
- DO NOT show up and throw up!

- 
- **You ARE selling a story!**

- 
- Is your story compelling enough for them to BUY?
(aka: DO AN ACTION)

Setting Up the Convo & Relationship

ASK...

if they understand what compounding is.
Give a relatable explanation.
I use baking cookies vs buying chips ahoy off the grocery store shelf.

ASK...

if they or anyone close to them has ever used a compounded medication before,

or needed a medication problem solved.

THEN...

tell them what you do.
Fill in their gaps and have a patient story or two teed up.

Issue Discussion

- Have a common language conversation.
- Leave the lawyer sounding, bill language to the leave behinds, white papers, or your APC representative.
- You are there to tell a story and ask for help.

“We are here to talk to you today about some issues that we are having that really affect our pharmacy, our patients, and our doctors, and we’d like your help. It basically boils down to access issues that affect patient safety and ability to receive needed medications.”

1. STOP

2. COLLABORATE

3. LISTEN

**A PSA FROM VANILLA ICE
TO OUR GOVERNMENT**

ROFLBOT

IF THERE'S A PROBLEM

YO, I'LL SOLVE IT!

memegenerator.net

Wrap Up

Leave Behind

Pharmacy folder or marketing material

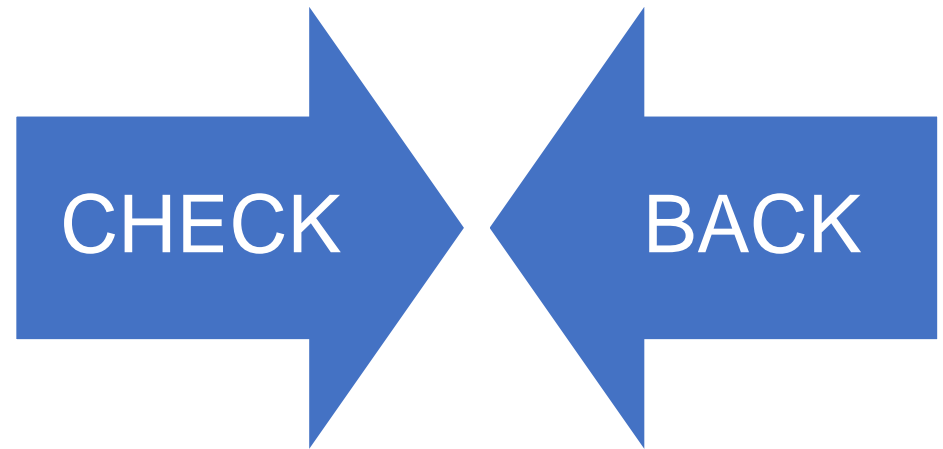
Business card for contact information

OFFER: (1) to be a district resource and (2) a tour of your pharmacy

Formal information on items discussed in PCCA folder

Offer APC's support for any specifics on current legislation

Wrap Up

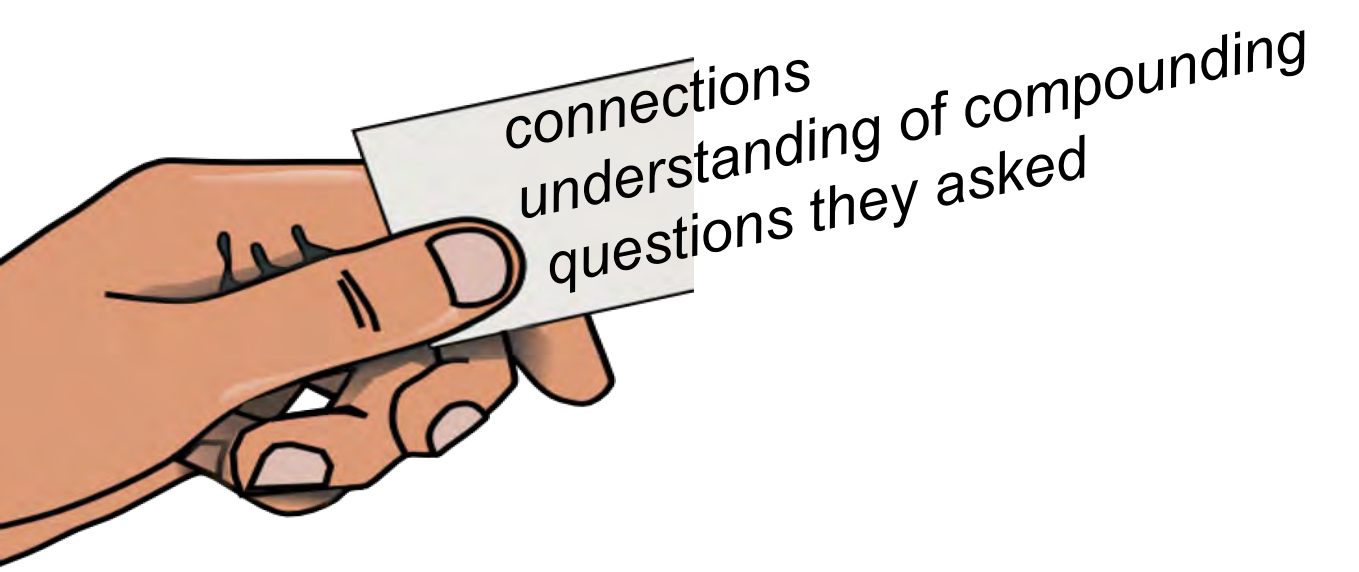


- Do they understand what you are asking of them?
- ASK where they think the member would stand on these issues

“What do you think the level of support or commitment could be? What type of follow up would you like? How can we help you help us?”

Wrap Up

- Thank them again for their time.
- Grab a business card for everyone that was present in your meeting.
- Write notes on the backs of all cards.



After Your Meeting

- Send a personal thank you note card.
 - This can also be done via email, especially highlighting the points you reviewed.
- Be prompt to send any follow up homework requested by the member or their staff!







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2023



Scott
Brunner, CAE
CEO





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Congresswoman Diana DeGette

Colorado





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