Got teammates who aren't APC members?

a4pc.org/join

APC COMP PAC

It's how we cultivate compounding champions in Congress

Invest:
a4pc.org/comppac

Got patients whose lives have been enhanced by cBHT?

Ask them to share their story at compounding.com

Mike Blaire

APC President

Thank you to our conference sponsors!

PCCA

Letco MED LET US HELP.

MEDISCA years of EXCELLENCE

SteriTek Expert Sterilization Services

Compounder's International Analytical Laboratory

International Filter Products

George & Lucy Malmberg

Advocacy Champion Award 2021

ISSUE BRIEFING:

Preparing You for Meetings with Members of Congress

David Pore
Scott Brunner

DOWNLOAD SLIDES:

a4pc.org/cch

Learning Objectives:

At the conclusion of this program, the participating pharmacist or technician will be able to:

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 Capitol Hill meetings.**

The Federal Court ruling against FDA on the MOU is one thread in a broad fabric of FDA overreach.

- *FDA's manipulation of research to restrict cBHT*
- *FDA reluctance to support permanent path for 503A sourcing of shortage drugs*
- *Lack of specific authorization for CVM's vet compounding GFI*

Why *these issues?*

They demonstrate a pattern of FDA overreach.

Why Congress?

It holds the pursestrings and the influence. Congress trumps FDA.

Why *now?*

To parlay the court victory on MOU into a broader conversation.

TIPS:*

** Keep these in mind as we go through the issues today. How will you tell this story to someone who doesn't understand pharmacy, much less compounding?*

1. **Remember who you're talking to … and summarize.**
   - Except for Buddy Carter and Diana Harshbarger, members of Congress and their staffers are laymen, not clinicians. 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).
2. **Tell stories that illustrate the issues. *Short* stories. Share examples.**
   - Cover the bases, but emphasize the impact on you and your patients.
   - Get quickly to the ask. Don't get bogged down. Your time with them is very short.

(You need not explain every nuance of every compounding issue – and you shouldn't try, for compounding is complicated, and you risk confusing or overwhelming non-pharmacist Members of Congress and their staffers. This message should be the theme of your conversations with them – the one take-away you'll want to state clearly and reiterate in each meeting, the one thing you'll want them to remember.)

Our 4-Point Message:

1. Compounding is a highly regulated profession, just as it should be, so that patients are protected.
2. *Congress specifically authorized pharmacy compounding in the Food, Drug, and Cosmetic Act, but FDA has mounted a years-long effort to marginalize and restrict compounding in ways Congress did not authorize or intend.*
3. The recent Federal Court ruling against FDA – related to how FDA did not go through proper rulemaking procedures in launching its MOU on interstate shipments of compounded meds – validates our view that FDA is overreaching in its efforts to restrict pharmacy compounding.
4. Let us tell you very briefly about some other issues on which FDA is working to restrict patients' access to compounded medications that in the judgment of a prescriber, those patients need: the threat to cBHT, animal compounding from pure ingredients, and urgent use / shortage drug compounding legislation

- **IN FOLDER:** Briefing paper + supporting documents on each issue
- **FOR YOU:** Talking points cheat sheet

A4PC.org/issuebriefs

1. Last month the Federal District Court agreed with compounders: FDA cut corners with its MOU.

* Starting with this particular point is the gateway to discussing our three other issues: The court has validated our concerns about overreach.

1. The court agreed: FDA cut corners in drafting and finalizing the MOU.

IN SHORT:

- 1997: Congress directed FDA, via rule-making, to create a standard MOU with states for reporting interstate distributions of compounded medications above a certain threshold
- Reporting threshold was to be set by FDA; In states that did not sign: statutory 5% cap on interstate distributions of compounded meds
- October 2020: FDA finalized MOU – without notice-and-comment rulemaking, without following Regulatory Flexibility Act – and set deadline for states to sign
- October 2020: 7 compounding pharmacies sue FDA

1. The court agreed: FDA cut corners in drafting and finalizing the MOU.

IN SHORT:

- Summer 2021: With many states threatening not to sign, FDA extends signing deadline by an additional year
- September 2021: Federal District Court rules in part in favor of compounder plaintiffs and remands MOU back to FDA. (Rachael Pontikes will discuss in here session later today.)
  - Court said plaintiffs had standing (FDA had argued they did not)
  - Court said FDA broke law in not adhering to Regulatory Flexibility Act
  - Court did not rule on plaintiff's substantive concerns about FDA's conflation of "distribute" and "dispense"

1. The court agreed: FDA cut corners in drafting and finalizing the MOU.

THE POINT YOU SHOULD MAKE:

- Compounders have been decrying FDA overreach and corner-cutting on a range of issues for years.
- Now the Federal District court agrees.
- **But the MOU is certainly not the only issue in which FDA is cutting corners and stacking the deck against pharmacy compounding.**

2. FDA has stacked the deck against compounded hormone therapy. The agency's implicit threat to restrict cBHT based on an FDA-manipulated report will deprive millions of patients of therapies that work for them.

* The MOU isn't the only example of FDA shenanigans. They've even gone so far as to manipulate research in an effort to restrict certain compounded therapies!

2. They've stacked the deck against cBHT

The issue:

– FDA has a longstanding, documented position against compounded hormones.

– FDA commissioned a study of cBHT, pre-ordained the outcome*, and now hints it will use that manipulated report to enact restrictions on cBHT.

– That FDA-commissioned report **recommends across-the-board restriction of compounded hormone therapy "unless safety and effectiveness can be proven."**

– It's a stunning conclusion by an FDA-chosen panel of "experts" who had little expertise and who didn't even study a majority of the most prescribed compounded hormones.

* A FOIA request by the Reed Smith law firm, representing a group of compounding pharmacies, shows clear manipulation of the structure of the committee, evidence it reviewed, and recommendations it made regarding compounding hormones. A third-party, independent analysis of the FDA-commissioned NASEM report (available at compounding.com) documents egregious shortcomings of the study structure, process and recommendations.

2. They've stacked the deck against cBHT

THE ASK:

– Since FDA has yet to take formal action on cBHT, use this virtual visit to educate the MOC about cBHT and (briefly!) the problems with the NASEM report. Let them know millions of Americans benefit from cBHT, and those patients will respond in anger if FDA attempts to restrict cBHT in a way that denies them access.

– Direct them to compounding.com to read patient stories (from the MOC's own stats!) and learn more.

– **Ask your Member of Congress to sign the bipartisan House letter to FDA on cBHT led by Reps. Herrera-Beutler (R) and Wexton (D). A Senate letter may be coming soon!**

3*. FDA authorized COVID shortage drug compounding under pandemic temporary guidance**, but now opposes legislation to create a permanent path for that kind of shortage-drug compounding.

* Link this conversation to the clear problems with America's drug supply chain that the pandemic revealed. Our legislation is one necessary fix.

** The point to make here is that FDA is inconsistent: They are opposing legislation that in effect does what FDA has allowed under temporary guidance.

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

The issue:

– In pandemic, drug supply chain failed to assure that hospitals and clinics had the drugs they needed to treat the most seriously ill COVID-19 patients.

– FDA issued temporary guidance allowing 503A pharmacies to prepare 13 COVID drugs to hospitals – under very tight regulatory guidelines – when those drugs are unavailable from manufacturers or 503Bs.

– APC survey shows that 87 503As sourced drugs for hospitals under that guidance.

– Spring 2021: Cuellar/Griffith introduce bipartisan bill to make permanent the ability of 503As to source drugs to hospitals and specialty clinics when those drugs are unavailable from manufacturers or 503Bs – HR 3662

– October 2021: FDA opposes HR 3662 in memo to Energy & Commerce Comm

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

WHAT THE BILL DOES*:

– Two components:

- Urgent Use
- Shortage Drugs

* To be clear: FDA's temporary guidance does not address urgent use, only COVID shirtage drugs. However, our bill applies same principles to urgent-use situations.

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

WHAT THE BILL DOES:

– Urgent Use
- Modifies the patient prescription requirement.
- Requires prescriber to certify they are unable to obtain the drug as an FDA-approved product or from a 503B entity.
- Only allows for compounding of limited quantities of the drug.
- Only allows the compounded drug to go to the prescriber (not to the patient).
- Only allows the administration of the drug by a licensed prescriber in a clinical setting.

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

WHAT THE BILL DOES:

– Urgent Use (continued)
- Ensures that patient information is later married with the compounded drug information by requiring:
  – The compounder to label the drug to request the patient information (within 7 days of administration or 7 days of patient discharge).
  – That the compounder couple the compounded drug information with the patient information, once received.
  – That the compounded product be labeled with a BUD (per USP).
- Requires that the compounder and prescriber report adverse events to the FDA.

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

WHAT THE BILL DOES:

– Shortage Drugs
- Modifies the patient prescription requirement (when necessary).
- Ensures, when the patient prescription requirement is waived, that the patient information is later married with the compounded drug information
- Requires that the compounded product be labeled with a BUD (per USP).
- Expands the definition of shortage to include drugs listed *on the FDA or ASHP lists*.
- Requires that the compounder and prescriber report adverse events to the FDA.

3. FDA okayed COVID shortage-drug compounding – but opposes HR 3662?

THE ASK:

– HR 3662 was introduced in June by lead sponsors Henry Cuellar (TX) and Morgan Griffith (VA).

– They're seeking additional cosponsors now.

– The bill is bipartisan and should not be controversial. Despite FDA's position on it, the bill helps prevent the kind of supply chain problems we saw in treating COVID patients during the pandemic, and expands it to include any drugs that FDA or ASHP says are in shortage.

– Ask your U.S. Representative to sign-on as a co-sponsor of HR3662.

A word about this from our friends at The Mercatus Institute

4. FDA seeks to restrict animal compounding from pure ingredients – to the detriment of animal patients – on shaky authority.

4. Limiting animal compounding from pure ingredients

THE ISSUE:

– Based on shaky authority at best, Autumn 2019 proposal from CVM would greatly restrict animal drug compounding from bulk ingredients, limit animal patient access to critical medications, and interfere with the practice of veterinary medicine.

– Would limit the ingredients used to compound drugs for veterinarians for office administration to a positive list developed by FDA, with a very high bar for inclusion on the list – akin to new drug approval.

– GFI #256 would require animal compounding only from FDA-approved drugs unless the veterinarian indicates a clinical need for the compounded animal drug to utilize bulk ingredient. The vet will be required to justify, a requirement not asked of other prescribers.

4. Limiting animal compounding from pure ingredients

OUR CONCERNS:

– FDA CVM has no statutory authorization for this guidance. They base it on a misinterpretation of the AMDUCA section on extra-label use.

– Requirement that vet must justify medical necessity for use of bulk API supercedes a vet's medical judgment about how to best treat their animal patients – and is not required of any other medical professional.

– In requiring compounding from FDA-approved drugs, GFI #256 will almost certainly drive up costs for pet owners – and give compounders less certainty about potency of the animal drugs they compound.

4. Limiting animal compounding from pure ingredients

THE STRATEGY:

– APC anticipates proposing to FDA this month a marked-up version of the GFI that would be acceptable to AVMA and APC.

THE ASK:

– No ask at present. But alert members of Congress that it's yet another example of FDA acting with out clear statutory authority to advance its own anti-compounding agenda – and advise them briefly about our strategy above.

Overriding theme:

Despite the crucial role compounders' preparations play in keeping millions of Americans healthy, FDA continues to stack the deck against us – and our patients – and it's time Congress did something about it.

Next up:

APC Corporate Patron Showcase

MEDISCA®
YOUR TRUSTED PARTNER IN COMPOUNDING

Got teammates who aren't APC members?

a4pc.org/join

APC COMP PAC

It's how we cultivate compounding champions in Congress

Invest:
a4pc.org/comppac

Got patients whose lives have been enhanced by cBHT?

Ask them to share their story at compounding.com

VISIT LOGISTICS AND PROTOCOLS:

In the pandemic era,
New rules + old rules apply.

Some rules:

1. Wear the damn mask.

Some rules:

2. Time will be short: maybe 20 minutes. Don't be distracted. Use it well.

- – Staff will be hovering, checking their watches, etc.
- – Be clear and concise, prepare, and know **exactly** what you want to say and accomplish.
- – Keep small-talk brief. You don't have much time. Get to the meat of our message quickly.
- – State your name, pharmacy name, and town when you speak. *Briefly* tell about your market presence in the district or state if you have one. How many patients do you serve? How many prescribers do you work with?

Some rules:

3. The Process

- – APC will have scheduled the meeting, and you represent APC.
- – **Some in-person, some virtual.** ALMOST EVERYONE should have at least ONE in-person meeting
- – You'll be meeting with the Member of Congress and/or his/her staffer(s).
- – Each meeting needs a spokesperson who will facilitate discussion.
- – Don't small-talk to much. Get to the meet of our message quickly.

Some rules:

3. APC has prepared folders with talking points and one-page issue briefs.

- – Share one folder with each Member of Congress or his/her staff.
- – **PLEASE stick to the message points**. No speeches, no tirades, no anger, no tangents.
- – Close by restating the the theme: FDA overreach persists, and only Congress can reign them in.

4. Follow-up

- – Send an email saying thanks – and inviting the Member of Congress to visit your pharmacy or facility.
- – Know that APC and its partners' lobbyists will be following-up as well. You'll lay the foundation for those follow-ups

Here's Janet,
to help
manage expectations …

CONGRESSIONAL PHARMACY VISITS:

1. Great relationship-building opportunity.
2. During recess periods, when they're home.
3. Invite them early – 4-to-6 weeks out.
4. Contact APC for latest talking points.
5. Give a tour and share your challenges.
6. Take pictures and send to local newspaper (and to APC!)

Lessons from a former Hill staffer:
A conversation with Amy Shank

A compounder running for Congress:

A word from Rich Moon

Next up:

APC Corporate Patron Showcase

PCCA

Got teammates who aren't APC members?

a4pc.org/join

APC COMP PAC

It's how we cultivate compounding champions in Congress

Invest:
a4pc.org/comppac

Got patients whose lives have been enhanced by cBHT?

Ask them to share their story at compounding.com

CE: The Legal Update – Profiles in FDA Overreach

with Rachael Pontikes, partner, Reed Smith LLP

The Legal Update

A Profile in FDA Overreach

Rachael G. Pontikes, Partner, Reed Smith LLP

Alliance for Pharmacy Compounding

What is FDA Overreach?

- FDA operating outside the authority granted to it by Congress in its governing statute (Section 50A or 503B of the FDCA)
- FDA violating the Administrative Procedure Act (APA)
- FDA violating federal obligations (Federal Advisory Committee Act)

So what?

What's the big deal?

Recent Examples of FDA Overreach

- FDA disregarded Section 503A in issuing the Final Standard MOU
- FDA will violate the Federal Advisory Committee Act (FACA) if FDA adopts or uses the NASEM report on cBHRT

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Background

- Seven plaintiff pharmacies (Belmar, ChemistryRX, Hartley, Medquest, VLS Pharmacy, Wellness, Women's International Pharmacy) filled suit against FDA
- Plaintiffs alleged FDA overreach—FDA failed to follow Section 503A and the Regulatory Flexibility Act in issuing the MOU
- How?
  - FDA failed to follow the "shall issue regulations" command in Section 503A and promulgate the MOU via regulation;
  - FDA failed to conduct a Regulatory Flexibility Act analysis (analyzing the MOU's impact on small business entities) which is required for legislative rules;
  - FDA exceed its statutory authority by defining the statutory terms "distribution" and "inordinate amount" to include dispensing.

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Court Ruling (Holding)—Part I

Plaintiffs are entitled to be in Court

- Plaintiffs' claims are ripe;
  - The dispute is not hypothetical or remote;
  - So, the Court can hear the Plaintiffs' claims.
- Plaintiffs have standing
  - Plaintiffs are impacted by FDA issuing MOU;
  - So, the Court can proceed.

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Court Ruling (Holding)—Part II

FDA Overreached In Issuing the MOU

- The MOU is a legislative rule
  - The MOU defines key terms in 503A (distribution to include dispensing);
  - Draws the line in a statute that carries both civil and criminal penalties.
- FDA failed to comply with the Regulatory Flexibility Act (RFA) and do an analysis of the MOU's impact on small business
  - Legislative rules requires compliance with RFA;
  - No analysis of MOU impact on small business was done;

Federal Court Finds FDA Overreached in Issuing The MOU – *Wellness Pharmacy Inc. v. Becerra*

Court Ruling (Holding)—Part II (Continued)

FDA Overreached In Issuing the MOU

- MOU remanded to FDA to:
  - Prepare a regulatory flexibility analysis OR
  - To certify that the MOU will not have a "significant impact on small entities."
  - "Small business" in this context means that a pharmacy is considered "small" if it has $30 million or less in annual gross receipts, according to the standard established by the Small Business Administration.
- FDA to submit a progress report to the Court by November 22, 2022

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

What is FACA?

- FACA is a federal statute that formally recognizes the importance and value of federal advisory committees to agencies;
- FACA allows agencies the benefit of the expertise of the public on a broad range of issues;
- FACA puts restrictions on recommendations from the National Academy of Sciences.

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

What are FACA's restrictions?

- FACA prohibits an agency from using any advice or recommendation that was developed a committee that was subject to ***actual management or control by an agency***;
- FDA cannot use any conclusion or recommendation by NASEM if they are the result of a NASEM committee that was unduly influenced by FDA.

FDA will violate FACA if it adopts or uses NASEM's Report on cBHRT

FDA unduly influenced the NASEM report

- Ms. Axelrad former, lead on pharmacy compounding evidenced that FDA had strong command over the outcome;
- FDA submitted its own data and forced NASEM to evaluate cBHRT under new drug approval standards;
- FDA and NASEM collaborated consistently over substance aspects of the report;
- FDA was handed the pen to revise the report before it was published—also violating NASEM rules.

Rachael G. Pontikes
Reed Smith Partner
Chicago
+1 312 207 2857
rpontikes@reedsmith.com

Rachael's broad experience covers the full range of issues that arise for health care companies in life sciences, most prominently with entities involved in the compounding of drugs across both the human and animal health spheres. Rachael has notable strength in representing health care facilities in high-stakes Federal Food and Drug Administration, (FDA), Drug Enforcement Administration (DEA), and state agency investigations and related litigation, as well as acting as regulatory counsel for large-scale, high-profile transactions involving major healthcare players in the compounding space. Widely regarded as a thought leader on current issues facing the compounding sector, Rachael is called upon to represent coalitions of compounding pharmacies and outsourcing facilities to challenge FDA, state regulators, or other regulatory bodies on critical issues defining the industry.

A recognized national authority, Rachael is the leading health care partner in our Chambers-ranked Illinois Health Care group, and is personally ranked by Chambers USA in Band 1 for the Illinois Healthcare: Pharmaceutical/Medical Products Regulatory category. Clients describe her as "quick to understand and support the perspective of the business, allowing her to help formulate business solutions that fit into the regulatory framework of our industry" and say "[h]er intellect, measured responses, written expertise and work ethic are unsurpassed."

Got teammates who aren't APC members?

a4pc.org/join

APC COMP PAC

It's how we cultivate compounding champions in Congress

Invest:
a4pc.org/comppac

Got patients whose lives have been enhanced by cBHT?

Ask them to share their story at compounding.com

APC Briefing:

- *New Pharmacy/Facility Memberships*
- *2022 cBHT campaign*
- *USP & BUDs*

Sponsored by

Letco MED
LET US HELP.

Save these dates!

EduCon 2022

February 3–4, 2022
Virtual

EDUCON 2022 VIRTUAL

Owner Summit 2022

March 24–26, 2022
Hilton Scottsdale Resort

2022 COMPOUNDING PHARMACY OWNER SUMMIT

Coming Q1 2022 …

NEW: Pharmacy/Facility Membership

- **Rate includes membership for all employees, PLUS value-add services that might include:**
  - Free access to APC Compounded Preparation Pricing Calculator **AGREED**
  - 24/7 online access to *NABP's State Survey of Pharmacy Law, a state-by-state compendium of pharmacy law and regulation* ***($195 value)*** **AGREED**
  - Annual subscription to the *USP Compounding Compendium* ***($150 value)*** **IN DISCUSSION**
  - Enrollment in The Alliance for Patient Medication Safety® (APMS®) program, which helps community pharmacies implement and maintain continuous quality improvement programs to comply with state and federal requirements and improve patient care. ***($300 value)***
  - **$1,000 discount** on PCAB accreditation from ACHC **AGREED**
  - One trial subscription to *The Pharmacist's Letter* **IN DISCUSSION**
  - A free one-hour consultation annually, plus a reduced hourly rate with attorneys at Bendin, Sumrall & Ladner, a law firm specializing in compounding law and compliance. **AGREED**
  - Weekly Kosar Report on proposed state legislation and regulation **AGREED**
  - Store(s) listed in APC's Compounding Pharmacy Locator and NOTED with an APC-MEMBER logo
  - FREE access to APC archived training webinars one year old or more (no CE credit) **AGREED**

Coming Q1 2022 …

NEW: Pharmacy/Facility Membership

- **TIERED COMPANY DUES** based on # of pharmacists+technicians employed
  - Dues likely $1,600 for 1-5 employees
  - Up to $12,000 dues for 60+ pharmacists/technicians
- **MULTI-STORE OWNERS** get aggregate rate, with each store listed in APC Pharmacy Locator
- **AUTO-RENEWS** annually
- **PAYMENTS IN INSTALLMENTS** quarterly for 13-30-employee category or more
- **INDIVIDUAL MEMBERSHIPS** will continue to be available for non-company members.

Alliance for Pharmacy Compounding

Fighting for cBHT: Year One

3 YEARS
$3,000,000

YEAR 1 IN REVIEW
Raised: $1,500,000

WHAT DID THESE FUNDS GO TO?

Media	$500,000
Agency Professional Services *(Strategic Planning, Media Buying, Reporting, Optimizations, Social Media, Fundraising, Member Growth Campaigns)*	$474,400
Podcasting & Influencer Marketing	$215,600
Video Production *(4 testimonials, testimonial teaser, :60, :30, :15 Joy of Living spots)*	$160,000
Ad Creative & Photography	$70,000
Marketing Technology	$50,000
Compounding.com	$30,000

Fighting for cBHT: Year One

Wins

TOTAL REACH:
25,000,000+
patients, prescribers & pharmacists

TOTAL ENGAGED:
300,000

ASSETS CREATED

- Compounding.com
- Four testimonial videos
- One testimonial teaser video
- Joy of Living videos (for APC, for APC members)
- Posters & in-store materials for pharmacists
- 3rd party review of NASEM report
- Articles published in STAT News, Everyday Health
- Letters to Congress
- Change.org Petition
- 100 podcast episodes

Top Engagement/Congressional Campaign:

- → U.S. Senate
- → FDA
- → Bernie Sanders
- → Jamie Raskin
- → Jim Hines for Congress
- → U.S. House of Representatives
- → Elect Adam Smith
- → Ed Markey
- → Bera for Congress
- → Martin Heinrich

- Engaged 9,100 people associated with targeted Congressional accounts
- We now have a testimonial from every state in the U.S.
- Total messages to Congress sent via compounding.com: 531

YEAR 2:

FDA Overreach/Manipulation/Corner-Cutting/Inconsistency

1. Continue the fight for Compounded Hormones
2. Prescriber Campaign
3. Broaden campaign to include other aspects of compounding (Compounding the Joy of Living)

OPPORTUNITIES:

- → Celebrity Spokesperson
- → PBS Viewpoint with Dennis Quaid
- → Improved & expanded Compounding.com

THE ASK:
$850,000

1. compounding.com
2. 

USP and BUDs

- USP published updated proposed chapters 795 and 797 on 9/1/2021
- APC had 10 minutes to present a brief synopsis of our opinion, along with FDA, at a meeting in October
  - FDA remains opposed to pharmacies being able to extend BUDs beyond the defaults
- The main objections appear to be of the 797 revisions
  - USP did provide a pathway, per our suggestion, to extend BUDs of CSPs by creating a "category 3"
  - However, they proposed a batch size limitation of 250 units and the maximum BUDs are too short to justify the costs associated with the increased EM and stability studies required
  - This will deprive patients of important CSPs that are going to be impossible for pharmacies to continue to compound, or pharmacies will make smaller, more frequent, untested batches of CSPs
    - Using inappropriate terminal sterilization or frozen storage to get longer BUDs
- Our ask
  - Make comments to USP before the January 31, 2022 deadline
  - PATIENT ACCESS ISSUE STORIES would be very helpful in these comments, and to give to APC to include in our comments as well
  - Get prescribers and patients involved - their stories hold great weight

DEEPER DIVE INTO OUR USP RECS FOLLOWS HERE

USP and BUDs

Background

- United States Pharmacopeia (USP) General Chapters 795 (Nonsterile) and 797 (Sterile) were established in 2004 to provide quality practice standards for compounded medication produced at pharmacies. Current Chapters 795 and 797 were last updated in 2014 and 2008, respectively.
- USP standards on their own are not regulations, however nearly every state has incorporated the standards found in chapters 795 and 797 into their state pharmacy regulations.
- Since 2012 USP's Compounding Expert Committee (CEC) has been working to make revisions to chapters 795 and 797, with the most significant revisions being changes to sterile compounding standards.
- In June 2019 USP issued "final" versions of revised 795 and 797 standards that imposed significant restrictions to compounders' ability to assign Beyond Use Dates (BUDs) that meet the practical needs of practitioners, particularly sterile compounds. Stakeholders appealed these 2019 revisions and won their appeal, with USP remanding both chapters back to the CEC to reevaluate the BUD standards based on improved engagement with stakeholders.
- On September 1, 2021 USP issued revised drafts of 795 and 797 with a public comment period extending until January 31, 2022.
- While the CEC greatly increased its stakeholder engagement and incorporated some of the suggested changes proposed by APC, the BUD limitations proposed in the draft chapters, especially those proposed in <797>, remain overly restrictive.

USP and BUDs

Anticipated Timing

USP's Process for Finalizing and Publishing General Chapters

- Once the comment period closes (January 31, 2022), USP's CEC will review submitted comments and consider any revisions to the chapter based on these comments. USP is then permitted to publish final versions of both chapters. USP has no standard timeline for this step and it is dependent on the number and content of comments submitted.
- Once a final version of a USP general chapter is published, stakeholders have a minimum of six months to come into full compliance with the standards of the chapter though USP may allow a longer period for compliance.

USP and BUDs: Chapter 795 Proposed

Proposed Changes to Nonsterile Compounding Standards with the Highest Potential Impact

- USP default BUD for non-aqueous oral liquids (i.e. oil-based oral solutions and suspensions) is being reduced from 180 days to 90 days.
- Default BUDs for all nonsterile compounds would be:

Type of Preparation	BUD (days)	Storage Temperature
Aqueous Dosage Forms		
Non-preserved aqueous dosage form	14	Refrigerated
Preserved aqueous dosage form	35	Controlled room temperature or refrigerator
Nonaqueous Dosage Forms		
Oral liquids (nonaqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms	180	Controlled room temperature or refrigerator

- Stability studies will now be required to extend the BUD of any nonsterile compound beyond the USP default BUD.
- All nonsterile compounds (even those with stability studies) will be limited to a maximum 180 day BUD.

USP and BUDs: Chapter 797 Proposed

Proposed Changes to Sterile Compounding Standards with Highest Potential Impact

- All sterile item batches would be limited to producing no more than 250 units.
- USP default BUDs for sterile compounds (Category 2 CSPS) vary depending on sterilization method and storage temperature:

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed	No	4 days	10 days	45 days
	Yes	30 days	45 days	60 days
Terminally sterilized	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

- The above BUDs can be assigned to sterile compounds without performing stability studies.

USP and BUDs: Chapter 797 Proposed

Proposed Changes to Sterile Compounding Standards with Highest Potential Impact (continued)

- Category 3 CSPs are sterile compounds that can be assigned BUDs beyond the default BUDs when:
  - Stability studies are performed to support the extended BUD.
  - Personnel competencies are evaluated every three months (currently every six months)
  - Viable air sampling is conducted monthly (currently every six months) and viable surface sampling inside the ISO 5 hood is conducted after each batch (currently every six months).
- Even with the above in place, sterile compound BUDs cannot be extended beyond the following:

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days

USP and BUDs:

Potential Impact – Nonsterile Items

The BUD standards proposed in the revised 795 would impact compounded nonsterile preparations in the following ways:

- Compounds currently assigned BUDs of greater than 180 days would require a reduction in BUD to no greater than 180 days.
- Oral oil liquids assigned the current USP's default BUD of 180 days would require either a reduction in BUD to 90 days to use the new USP default BUD, or would require stability studies to justify a BUD greater than the default 90 days.
- Items currently assigned an extended BUD greater than the default USP BUDs would require either stability studies to support their current BUDs (up to 180 days) or would require a BUD reduction down to the new USP default BUD.

USP and BUDs:

Potential Impact – Category 2 Sterile Items

- When the time to obtain passing sterility test results is factored in (assuming a minimum of 14 days), the maximum usable shelf life (maximum BUD remaining when the compound is dispensed) for Category 2 CSPs would be:

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed	No	4 days	10 days	45 days
	Yes	16 days	31 days	46 days
Terminally sterilized	No	14 days	28 days	45 days
	Yes	31 days	46 days	76 days

- An aseptically processed CSP stored at room temperature and sterility tested would spend half of its BUD sitting in quarantine awaiting sterility test results.
- A terminally sterilized CSP NOT sterility tested would essentially have the same usable shelf life as an aseptically processed CSP that has passed sterility testing.
- The only practical way to provide a patient with a month's supply of a Category 2 CSP would be to refrigerate or freeze it.
- All sterile item batches would be limited to producing no more than 250 units

USP and BUDs:

Potential Impact – Category 3 Sterile Items

- When the time to obtain passing sterility test results is factored in (assuming a minimum of 14 days), the maximum usable shelf life for Category 3 CSPs would be:

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	46 days	76 days	106 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	76 days	106 days	166 days

- All sterile item batches would be limited to producing no more than 250 units

USP and BUDs:

Category 2 CSPs vs. Category 3 CSPs

To extend the BUDs of Category 3 CSPs beyond those established for Category 2 CSPs, compounders are required to perform stability studies and increase the frequencies of environmental monitoring. But when we compare the maximum *usable shelf life* of Category 3 CSPs to those of Category 2 CSPs, we see:

- An aseptically processed Category 3 CSP stored at room temperature has essentially the same usable shelf life (46 days) as:
  - An aseptically processed Category 2 CSP (with or without sterility testing) stored frozen
  - A terminally sterilized Category 2 CSP without sterility testing stored frozen
  - A terminally sterilized Category 2 CSP sterility tested stored refrigerated
- An aseptically processed Category 3 CSP stored at room temperature has a shorter usable shelf life (46 days) than a terminally sterilized Category 2 CSP sterility tested stored frozen (76 days)
- An aseptically processed Category 3 CSP stored refrigerated has the same usable shelf life (76 days) as a terminally sterilized Category 2 CSP sterility tested stored frozen.
- A terminally sterilized Category 3 CSP stored at room temperature has the same usable shelf life (76 days) as a terminally sterilized Category 2 CSP sterility tested stored frozen.

USP and BUDs – What you can do:

COMMENT.

Got teammates who aren't APC members?

a4pc.org/join

APC COMP PAC

It's how we cultivate compounding champions in Congress

Invest:
a4pc.org/comppac

Got patients whose lives have been enhanced by cBHT?

Ask them to share their story at compounding.com