FDA LISTENING SESSION, June 17, 2022

SCOTT: Good morning.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers. We have about 2,200 members and represent about 600 businesses.

The most important thing we have to say here is that we think there is common ground to be found in dealing with a range of pharmacy compounding issues. That common ground can help FDA achieve its policy objective of keeping patients safe, while also preserving patient access to essential compounded medications. And it's a much better alternative than ongoing head-butting, overreach, and litigation.

I'm here with our Board Chair Michael Blaire and our President-Elect Anthony Grzib. We are in full agreement with the concerns raised by our sister associations APhA and NCPA, as well as by PCCA.

In addition to the concerns they have raised or will raise in this session, the three of us would like to mention a few areas where APC has concerns and on which we think we can work with the agency to craft a way forward.

1. **I'll begin with the need for a robust, state-based adverse event reporting framework for compounded medications**
   We recognize a need for a consistent and effective adverse event reporting framework for compounded medications that is state-based, properly defines "adverse event" in the context of compounded medications, and requires reporting directly to the pharmacy itself as well as to the state board of pharmacy. APC has recommended to Director Bormel that FDA – as well as the National Association of Boards of Pharmacy – join with us in developing such a framework. We think this is important for patient safety, as well as for the aim of some consistency across the states. We also think it's important for the reputation and credibility of pharmacy compounding. While unexpected adverse reactions to compounded medications are absolutely the exception to the rule – and certainly occur less on average

than adverse reactions to manufactured drugs – APC is nevertheless concerned that the absence of a proper, rigorous adverse events reporting framework in the states hurts the reputation and credibility of the compounding professionals we represent. Simply put, it's in our interest to have a good system for reporting compounding adverse events – but the definitions and details matter. We don't want a system imposed upon us; rather, we seek to work with FDA and state regulators in creating a system that works for us all – especially patients.

2. **The PCAC process**
   Having witnessed over the past three weeks the process that culminated in PCAC's meeting last week, I want to express our serious concerns about the entire PCAC process. What we saw was not timely, fair or informed, and we believe that it's not helpful to FDA or the public for such important decisions to be made via such a shabby process. You have heard or will hear it here from others: Providing materials – voluminous documents that require careful scrutiny – only a few days before the meeting doesn't allow proper time for review by the committee itself, much less by stakeholders. As AJ Day noted in his presentation on glutathione last week, there was too little time to even schedule experts to present to the committee. And then to only allow a brief time for presenters to make a case for a certain substance is flatly unfair, especially when no such time constraints are put on FDA presenters. Lastly, the complete absence of an actual discussion or deliberation by the committee absolutely influences outcomes, and not in a helpful way. In last week's meeting, the chairman's concern about ending on time seemed to trump any desire for substantive scrutiny and deliberation by the committee of the proposed substances or the presentations they had heard. An up-or-down vote without discussion is little more than a beauty contest. To our thinking, it must change, and we ask that the agency proactively look at the broken process and fix it.

I'll now turn to APC Board chair Mike Blaire to discuss a couple of issues. Mike:

3. **Closing 483 files more timely**
   We have mentioned this issue to you previously and would be interested in knowing what steps the agency has taken to see that pharmacy compounders 483 files are closed more expeditiously. As of last year,

according to a law firm who did the research, the average amount of days an FDA 483 or warning letter file remained open was more than 900 days. We understand then need for diligence and follow-up by the agency, but here again arises a fundamental issue of fairness: Compounding pharmacies remain under a shadow as long as a 483 file remains open – and especially if all mitigation required to rectify the issues raised in the 483 has been done. As you know, compounding pharmacies with open 483 files are largely disqualified from getting LegitScripts and NABP dot-pharmacy accreditations if they have an open 483 file, even if mitigation is complete. I understand this is a listening session, but given that we've raised this matter a couple of times before, I respectfully ask the agency to fill us in on its perspective on this problem. Thank you.

4. **FDA's MOU with states regarding interstate shipments of compounded medications**
   After 24 years, numerous stops and starts, multiple iterations, and now litigation, we believe it is time to discuss an alternative to the MOU. APC has proposed to the CDER team that it consider a different approach for accomplishing what FDA had sought from the 1997-mandated MOU. You've heard us say before; APC is not opposed to mandated reporting to state boards of pharmacy by any 503A that ships fifty percent or more of its compounded preparations out of state. We would cheer for a solution that eliminates both the need to plead with states to sign a problematic MOU and the onerous five percent cap on out-of-state shipments in states that don't sign that MOU.

I'll now turn to APC President-elect Anthony Grzib to discuss a couple of additional issues. Anthony:

5. **A Narrow Urgent-Use Pathway for 503As to Source Shortage Drugs**
   You're aware, of course, of the APC-supported H.R. 3662, legislation that would make permanent the sort of pathway FDA created via pandemic-era temporary guidance for 503As to source 13 specific shortage drugs to hospitals when those drugs cannot be obtained from manufacturers or from 503B outsourcing facilities. The legislation would expand that authority to include any drugs on FDA's or ASHP's shortage lists. It would also allow short-term 503A sourcing to medical clinics when those clinics

cannot get office-administration medications from manufacturers or from 503B outsourcing facilities. In a technical memo, CDER has indicated to the House Energy & Commerce Committee that it does not think the legislation is needed, that 503Bs can fill the gap for urgent-need medications in shortage. But in fact that's not what has occurred during the pandemic. I'd like to ask one of our APC members and also a member of the virginia Board of Pharmacy, Cheri Garvin of Leesburg, Virginia, to share a bit of anecdotal perspective on this issue, because I think you need to know what's happening out in the real world, so to speak. Cheri?

CHERI: [90 seconds]

Thanks, Cheri. We'd urge the agency to take another look at this issue, to see it as a safe, effective and *narrow* supply chain fix for very real, very concerning short-term drug shortages, and even to consider enacting it via GFI rather than legislation.

6. Concerns about ambiguity in FDA's Insanitary Conditions Guidance

We continue to have serious concerns about the lack of definitive standards in the agency's Insanitary Conditions guidance. The GFI is little more than a list of examples, with a sentence tacked on that says other things may be considered insanitary conditions as well. Because the agency is enforcing via that ambiguous GFI – versus a formal rule that adheres to the notice-and-comment requirement in law – compounding pharmacies have no standard for compliance or what exactly would constitute a violation. This is both illegal and unfair. In one very recent instance, the agency demanded a full recall of a pharmacy's non-sterile preparations based on 483 findings that focused on areas well outside the pharmacy's compounding areas, none of which violated applicable USP standards. Unless there can be developed standards for compliance and clear delineation of what is a violable standard, we fear this issue, too, will result in litigation.

SCOTT: That concludes our planned remarks. I want to reiterate that we sincerely appreciate this opportunity to share perspective with you. We do hope we've raised concerns on which the agency will engage with us, with

the aim of accomplishing its policy objectives without marginalizing or stigmatizing the practice of pharmacy compounding.