March 1, 2022

Robert Califf, M.D. Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Alliance for Pharmacy Compounding
Formerly IACP

Dear Commissioner Califf:

Congratulations on your nomination and confirmation as U.S. Food & Drug Administration commissioner. We welcome you back to the agency's helm.

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. You're likely familiar with pharmacy compounding from your time with the Duke University Medical Center. The hospital's Duke Compounding Facility provides 500,000 doses a year to Duke Hospital. DCF may well have provided compounded Del Nido Cardioplegia recovery solution or sterile Glutaraldehyde for cardiac patients you treated there. It certainly provides many ready-to-administer anesthesia and pain medications used in the OR and during recovery. We share that to emphasize that without compounding, all hospitals, not just Duke, would struggle to provide effective patient care. Likely, you already recognize the important role that pharmacy compounding plays in the American healthcare system and drug supply chain and the good it does for millions of patients nationwide.

FDA policy and rulemaking profoundly affect our members' ability to serve their patients and for patients to have access to compounded therapies. That's why we write to encourage you to follow closely our conversations with Director Gail Bormel and her team in FDA's Office of Compounding Quality and Compliance.

While we disagree on many issues, Director Bormel has demonstrated an openness to hearing and considering our views that is refreshing and, we believe, productive. Via that dialogue, we believe there is potential to find middle ground that can help the agency achieve some of its patient safety-focused policy aims regarding compounding while also elevating the practice of pharmacy compounding and its rightful place in the drug supply chain and American healthcare system.

Among the issues on which we think there is common ground to be found are these:

1. **Compounded hormone therapies**
   The agency has indicated publicly and in correspondence with members of Congress that it intends to base its next steps on compounded hormone therapies on a deeply flawed report FDA commissioned from the National Academies of Science, Engineering & Medicine – a report marked by the demonstrable absence of scientific rigor and which FOIA data show was not independent but affected by bias and conflicts of interest. Our ask is for the agency to slow down and allow the industry to gather reliable data, including patient outcomes data, and that FDA base any evaluation of compounded hormones on rigorous scientific evidence and patient outcomes.

2. **Animal compounding from bulk ingredients and draft GFI #256**
   Draft guidance was published in the *Federal Register* on November 20, 2019, and has raised very serious concerns from veterinarians, veterinary pharmacists, pet owners, and animal caretakers since then. GFI #256 proposes drastic changes in the way compounded animal drugs are produced and sold that would have the harmful impact of increasing the price and reducing the safety of these drugs. The FDA guidance would require veterinary compounders to use finished drug products, as opposed to bulk

substances, in certain critical compounded medications, increasing the price of these medications by 300% or more. We believe using finished drugs in compounded medications introduces unnecessary and potentially unsafe excipients into compounded medications, impacting their administration and the animals' health outcomes. That's why we urge you to ensure that CVM publish the next version of GFI #256 in draft – not final – form due to the concerns raised.

3. **A robust, state-based compounded medications adverse event reporting framework**
   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 a proposed framework.

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 Director Bormel and her team that we consider introducing a minor amendment to DQSA that would eliminate the MOU and in its place mandate reporting to state boards of pharmacy by any 503A that ships fifty percent or more of its compounded preparations out of state. This would eliminate both the need to plead with states to sign the MOU and the onerous five percent cap on out-of-state shipments in states that don't sign. It would also resolve a fractious disagreement between FDA and the industry over the substance of the MOU as finalized.

5. **A Narrow Urgent-Use Pathway for 503As to Source Shortage Drugs**
   H.R. 3662 (Cuellar/Griffith) 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. 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 short-term drug shortages, and even to consider enacting it via GFI rather than legislation.

On each of these issues, we would be happy to provide you a briefing on the substance of our concerns and our ideas and hopes for workable solutions. Short of that, we have learned from precious commissioners that industry concerns about the agency's compounding-related policies are not always shared up the leadership chain to the commissioner. We respectfully ask that you make a point to be briefed ongoing on issues related to pharmacy compounding and your team's interactions with the compounding industry.

We stand ready to assist you in any way you deem appropriate, and we thank you for your service to our nation. Please contact me at scott@a4pc.org if you have questions or need information.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
ALLIANCE FOR PHARMACY COMPOUNDING