January 15, 2025

Brian Blase, PhD
Agency Lead
President-elect Trump's transition team: U.S. Department of Health and Human Services (HHS)

Dear Dr. Blase,

The undersigned organizations represent patients, pharmacists, pharmacy organizations, and other healthcare providers united in a mission to preserve patient access to quality compounded medications prepared in state-licensed pharmacies and FDA-registered outsourcing facilities.

Compounding pharmacists create customized medications for patients pursuant to a prescription. Pharmacists' ability to compound medications is authorized in federal law.

We write to offer our assistance to the transition team as a resource on issues related to compounded medications.

The FDA exceeds its statutory authority to regulate certain aspects of pharmacy compounding by 503A pharmacies and 503B outsourcing facilities. This overreach has often resulted in litigation – multiple lawsuits, the outcomes of which have not been favorable to the Agency. We urge the Administration to ensure that FDA operates consistently within its statutory authority and in line with Congressional intent.

Critical Issues the Compounding Industry is Confronting

Urgent-Use and Drug Shortage Compounding

Record numbers of drug shortages persist in the United States, with traditional compounding pharmacies often stepping in to fill gaps in the supply chain and ensure continuity of patient care when drugmakers cannot supply certain medications. We strongly encourage the Administration to support policy efforts to ensure timely access to compounded medications in shortage situations. Please refer to this issue brief on drug shortages for detailed recommendations.

We urge the Administration to consider the positive and necessary role traditional compounding pharmacies can play, within very tight regulatory guardrails, in meeting immediate, short-term gaps in drug supply when a drug is added to the shortage list and 503Bs have not completed testing necessary to ramp up production. Precedent for this is FDA's temporary guidance during the COVID pandemic, when it allowed traditional 503A compounding pharmacies to prepare 13 urgently needed COVID drugs to hospitals while those drugs were unavailable form manufacturers or 503B outsourcing facilities. FDA says not a single adverse event was reported as a result of that flexibility. We believe the FDA's guidance utilized during COVID should be the model for handling shortages moving forward and not put the Agency in the position of having to issue guidance documents each time a need arises.

We note that there are legislative proposals currently pending before Congress that we also encourage the Administration to support. We support H.R. 10239/S. 5368, the *End Drug Shortages Act*, a bipartisan, bicameral bill that would help FDA more quickly identify emerging drug shortages.

Preserving Access to Active Pharmaceutical Ingredients (API)

We urge your Administration to reject pharmaceutical companies' requests that FDA add certain APIs to the FDA's Demonstrably Difficult to Compound (DDC) List without any legitimate scientific justification. It is unlawful to compound with API included on the DDC list, so approving the requests will significantly disrupt treatment options for millions of patients. Our position is detailed further in this issue brief (DDC Issue Brief) and in this submission to the FDA's rulemaking docket.

In addition, we ask that the Administration scrutinize FDA's proposed rule creating criteria for the 503A and 503B Demonstrably Difficult to Compound Lists. This is an example of the type of regulatory overreach mentioned above, in which the agency is attempting to include "categories" of drugs on the 503A list, even though the enabling legislation authorizes only specific drug "products." FDA's proposal sets up the agency to be able to prohibit entire categories of compounded medications, something the statute clearly does not empower it to do for 503A pharmacies.

Related, we also strongly encourage your Administration to reject FDA's reliance on a discredited report the agency commissioned in 2020 from the National Academies of Sciences, Engineering, and Medicine (NASEM) regarding compounded bioidentical hormone therapy. If fully implemented, the recommendations of that report would restrict essential therapies for millions of men and women by adding more than ten commonly compounded hormones to the DDC list. Indeed, an independent analysis of the NASEM report, which drew from FDA documents obtained in an FOIA request, has raised questions about the process used to produce it. [Link to analysis: bit.ly/NASEM-Analysis] Further discrediting the report is an article published in the April 2022 *Menopause*, the peer-reviewed journal of the North American Menopause Society (NAMS), which found that available evidence provides meaningful data regarding the safety and efficacy of compounded hormones. In short, any agency action on compounded hormones needs to be based on real science and thorough analysis.

Implementation of the Drug Quality and Security Act (DQSA)

Our organizations have closely followed the implementation of the *Drug Quality and Security Act* ("DQSA", P.L. 113-54), and engaged Congress and the Administration on several key policy areas where we believe the FDA has overstepped its authority. Following are two troubling examples we would like to work with you to rectify:

- The FDA has taken the position that the definition of "distribution" under the agency's "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between [insert State] and the U.S. Food and Drug Administration" (MOU) would combine the statutory definition of "dispensing" and "distributing." These are separate and distinct activities in the pharmacy profession that must not be conflated. Title II of the DQSA (Sec.581(5)) clearly defines distribution and states that distribution does not include the dispensing of a product pursuant to a prescription.

- Through nonbinding Agency guidance documents, the FDA has taken the position that an "applicable" United States Pharmacopeia (USP) monograph is limited to only those USP monographs in the drug section of USP and not those in the dietary supplement section of USP. This interpretation has disallowed important ingredients from being lawfully compounded and disrupted patient care. Notably this has threatened access to methylcobalamin for patients with autism spectrum disorder and glutathione for patients facing cystic fibrosis or to help try to prevent chemotherapy induced peripheral neuropathy in patients being treated for cancer.

Coverage and Financial Access Barriers to Compounded Medications

Coverage and reimbursement also affect patient access to compounded medications, specifically, those that are prepared from "bulk substances," or active pharmaceutical ingredients (API). Medicare Part D reimburses when a compound is made using finished pharmaceutical products, but not from API. This limitation is particularly problematic for beneficiaries that face certain conditions (e.g., eczema, psoriasis) where the FDA-approved therapy is insufficient or poorly tolerated and their healthcare provider determines that a compounded medication is the appropriate option. In addition, drug shortages have continued to plague the United States and compounders have been helping to fill those gaps when the drugs are not available. However, because Medicare does not cover compounded drugs formulated from bulk ingredients, beneficiaries must either pay out-of-pocket for their medication or forgo treatment altogether. Indeed, when a finished pharmaceutical product is on the FDA drug shortage list, clearly it cannot be used in a compounded medication. We are working closely with Rep. Neal Dunn, MD (R-FL) on draft legislation that would close this gap in access for medications in shortage. We urge your support of it.

Animal Drug Compounding

Compounded medications are essential in veterinary care, enabling customized treatments when FDA-approved drugs are unavailable or unsuitable. We urge the Administration to support policies that preserve access to veterinary compounding while maintaining appropriate oversight.

In 2023, FDA's Guidance for Industry (GFI) #256 took effect. It requires veterinarians and compounding pharmacies to justify the need for compounded medications by submitting detailed formulations and evidence to the FDA, including demonstrating the necessity and quality of specific compounded formulations, as only bulk drug substances on an FDA-approved list may be used

Of the roughly 300 drugs submitted for FDA review by veterinarians, pharmacists and others, nearly 93 percent have been rejected, often contradicting veterinarians' professional judgment and compromising patient care.

We believe these actions undermine veterinarians' ability to provide timely and effective care, ultimately harming animal health.

The Pharmacy Compounding Advisory Committee

We have deep reservations about FDA's Pharmacy Compounding Advisory Committee process and composition, and we urge reforms that can make it a more effective advisory body to FDA. Our concerns

are enunciated in comment letters here and here. In short, current processes preference FDA staff testimony and inhibit substantive discussion (especially the input of outside groups and individuals). Moreover, compounding pharmacists with current patient-facing experience are under-represented on the panel; FDA has previously considered such persons to have a conflict of interest because they actually work for a pharmacy. We believe a complete revamping of that group would provide the FDA with a richer, more informed stream of advice on pharmacy compounding matters.

Conclusion

Thank you for considering these critical issues. We look forward to working with your Administration to enhance medical freedom, patient access to personalized compounded medications, and regulatory transparency. **We would be happy to provide your transition team or your designated FDA officials a more thorough briefing on the issues enunciated here.** Our organizations stand ready to serve as a resource for your transition team and Administration.

Sincerely,

Alliance for Pharmacy Compounding
Fagron North America
National Community Pharmacists Association
Professional Compounding Centers of America

CC: Heidi Overton, Department Project Manager
May Mailman, DCOS Lead
John Brooks, JD, HHS Landing Team