

January 19, 2021

President-elect Joe Biden
1401 Constitution Ave., NW
Washington, DC 20230

Dear President-elect Biden:

The undersigned organizations represent patient advocates, physicians, pharmacy organizations, and other healthcare providers who are united in a mission to preserve patient access to quality compounded medications. Since 2014, our groups have been working together as part of a coalition of over 30 organizations (the DQSA Coalition) to provide input to the Administration (including the Food and Drug Administration or FDA/Agency), State Boards of Pharmacy, and Congress to seek policy solutions to protect patient access to compounded medications while ensuring patient safety. We write today to offer our assistance to the transition team as a resource on issues related to compounded medications.

During the current public health emergency (PHE), compounded medications have served as a vital resource for patients to address regional and national shortages of critical medical resources – from medications to assist with ventilated COVID patients to ensuring an adequate supply of hand sanitizer. Given the critical value of these guidance documents, we urge the Agency to extend them beyond the PHE. As part of our partnership with the Agency, we have been involved in conversations regarding the implementation of the necessary flexibilities and system checks to ensure that all patients can receive their medications. **We look forward to engaging in further dialogue with the FDA to extend these flexibilities for those patients who may need critical compounded medications in an office setting for an urgent or emergency use.**

We share a mutual interest in ensuring that all Americans are able to receive appropriate healthcare, including medications tailored to meet their unique medical needs. For some patients, especially those with special needs, a prescribing clinician may opt to order a compounded drug: (1) when the drug is in shortage to ensure continued patient access to the medication, (2) if the patient has an allergy or otherwise cannot tolerate excipients, or (3) if the patient cannot take the medication in its manufactured dosage form (e.g., an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form). One key tool for ensuring patients have access to these critical medications is ensuring compounders' access to active pharmaceutical ingredients (API, also called pure ingredients), which allows a pharmacist to avoid excipients (such as dyes or allergens like corn or gluten), ensure appropriate chemical formulation of the final dosage (such as dissolving in a lotion base), and address any issues with drug shortages. Given these key issues, we want to be a resource for your administration and to help support the FDA's role in the oversight of drug compounding, in partnerships with the States. **We also look forward to working with your Administration to better understand the reimbursement challenges for compounded medications, given that patients need continuing access to medications from pure ingredients because of unique medical needs.**

In October, in the midst of the pandemic, the U.S. Food and Drug Administration started a 365-day clock requiring states to decide whether to sign a Memorandum of Understanding

Addressing Certain Distributions of Compounded Human Drug Products (“MOU”). The Agency has asserted it will enforce a strict limit on the compounded medications that can be sent to out of state patients if the states do not sign onto this MOU within the allotted 365 days. In response, several pharmacies from states across the nation filed suit raising both procedural and substantive challenges to the MOU. **We urge the Agency to pause further implementation of the MOU and work with stakeholders to resolve its procedural and substantive defects.** If the Agency continues to implement the MOU, patients through the United States will no longer be able to get the compounded medications they need, from the pharmacy of their choice. The MOU will have a dramatic effect on patient access to critical medications, especially given that certain patient populations rely upon a limited number of compounding pharmacies. Moreover, the MOU adds additional regulatory burdens for the States and, by extension, local pharmacies, and those additional requirements add unnecessary burden at a time when state resource are already stretched thin.

Lastly, we wish to bring to your attention concerns related to the July 2020 report from the National Academies of Sciences, Engineering, and Medicine (NASEM) titled *The Clinical Utility of Compounded Bioidentical Hormone Therapy: A Review of Safety, Effectiveness, and Use*. According to the document, “[m]illions of men and women use cBHTs to alleviate symptoms associated with age-related hormone changes, such as hot flashes in menopause, or low muscle mass due to decreased testosterone.” NASEM’s report has the potential to influence future FDA policy and constrain patient access to compounded bioidentical hormone therapies (cBHT). The recommendations, if adopted, would limit prescribing guidelines and severely restricts the availability of cBHT by placing these hormones on the Agency’s Difficult to Compound List. **Many patients, especially women, have worked with their providers to find a customized hormone preparation that works for them, and therefore, as the FDA reviews the NASEM recommendations, we urge the Agency to ensure that all treatment options are preserved without limitation.**

Thank you for the opportunity to bring these patient access concerns to your transition team’s attention. We look forward to working with you to ensure that patients continue to receive their personalized compounded medications, as prescribed by their doctor. Again, we stand ready to serve as a resource to your team and to the new administration. Thank you for your consideration.

Sincerely,

Alliance for Natural Health (ANH)

Alliance for Pharmacy Compounding (APC)

American Academy of Ophthalmology (AAO)

American Association of Naturopathic Physicians (AANP)

American Pharmacists Association (APhA)

American Society of Cataract and Refractive Surgery (ASCRS)

American Society of Consultant Pharmacists (ASCP)

Empower Pharmacy

Letco Medical

MEDISCA

National Alliance of State Pharmacy Associations (NASPA)

National Community Pharmacists Association (NCPA)

OSRX Inc.

PCCA