

December 12, 2016

Vice President-elect Mike Pence
Chairman- President-Elect Trump's Transition Team
1800 F Street NW
Washington, DC 20006

Dear Vice President-elect Pence:

The undersigned organizations represent patient advocates, physicians, pharmacists, and other healthcare providers who are united in a mission to preserve patient safety and access to needed compounded medications, pursuant to state and federal laws and regulations. Since 2014, our organizations have been meeting and working together as part of a coalition of over 30 organizations (the DQSA Coalition) to provide input to the FDA, to State Boards of Pharmacy, and to the Congress about our concerns with the Agency's implementation of the *Drug Quality and Security Act* ("DQSA", P.L. 113-54) and to seek solutions that maintain a balance between public safety and patient access to compounded medications.

We write today to offer our assistance to the transition team as a resource on issues related to FDA's implementation of this important law. During a time of rising drug prices and increasing shortages, it is paramount that patient access be preserved for compounded medications. We are concerned that the FDA is implementing the DQSA in a way that is negatively impacting patient access to medications and subjecting state-licensed compounding pharmacies to FDA oversight and manufacturer standards in a way that exceeds the authority given to the Agency by Congress. Unfortunately, FDA's actions in implementing the DQSA have been just one component of a larger pattern of regulatory overreach by the Agency that has involved the use of "guidance documents," often still in draft form, and not finalized. We believe that these types of important policy decisions by the FDA should be done through the formal Administrative Procedure Act rulemaking process, and should be consistent with the clear intent of Congress when the law was passed. Although this coalition and many other stakeholder groups and individuals have weighed in with the Agency regarding our concerns about how implementation of the law is affecting patient access, we have not seen evidence that the Agency is hearing those concerns.

As you work to transition to the new administration's leadership within HHS and FDA, our coalition of organizations stands ready to serve as a resource on these issues related to patient access to safely compounded medications. In the meantime, we ask for your support in encouraging the FDA to cease using un-finalized non-legally binding guidance documents in their enforcement actions as if they have the weight of law or regulation, and in preventing the finalization of any pending draft guidance documents between now and the end of the current administration. Should the FDA move forward with finalizing these guidance documents, we believe the new administration should give consideration to rescinding them and reconsidering the policies contained therein in light of the new administration's policy priorities. Specifically, we are concerned about the following pending draft or interim guidance documents:

- [Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration](#)
- [Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#)
- [Insanitary Conditions at Compounding Facilities](#)
- [Compounded Drug Products That are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#)
- [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#)
- [Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities](#)
- [Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application](#)

Thank you for the opportunity to bring these matters to your transition team's attention. Again, we stand ready to serve as a resource to your team on these issues, and to the new administration's health policy team when appropriate.

Sincerely,

Alliance for Natural Health (ANH)
 Ambulatory Surgery Center Association (ASCA)
 American Academy of Dermatology Association (AADA)
 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)
 American Society for Dermatologic Surgery Association (ASDSA)
 American Society of Mohs Surgery (ASMS)
 Central Admixture Pharmacy Services (CAPS)
 Fagron
 International Academy of Compounding Pharmacists (IACP)
 National Alliance of State Pharmacy Associations (NASPA)
 National Community Pharmacists Association (NCPA)
 National Home Infusion Association (NHIA)
 PCCA

cc:

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