

December 10, 2014

The Honorable Tom Harkin
Chairman
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: Maintaining Patient Access to Compounded and Repackaged Medications

Dear Chairman Harkin, Chairman Upton, Ranking Member Alexander, and Ranking Member Waxman,

Our organizations represent physicians, pharmacists, other healthcare providers, surgical centers, and patient advocates treating and providing care to patients with an array of conditions requiring a broad spectrum of treatments and also pharmacists that provide physicians, hospitals, and other health care professionals with compounded medications for administration to and treatment of patients within these practice settings (often called “office-use”). As such, we have been closely monitoring the Food and Drug Administration’s (FDA) implementation of the *Drug Quality and Security Act* (“DQSA”, P.L. 113-54) and remain concerned about the impact of the Agency’s actions on patient access to compounded medications.

We are deeply concerned about the implementation of the DQSA in regards to both compounded and repackaged medications for office-use. The most recent implementation actions of the FDA have resulted in decreased patient access to vital medications and have caused confusion amongst state boards of pharmacy, health care providers, pharmacists, and patients.

Many medical professionals rely on various types of repackaged and compounded medications to treat their patients -- whether it is in their office, on a crash cart in an emergency department, or in another medical setting. These medications are essential for emergency situations as well as to start treatment immediately in response to a medical condition. Medications, including some biologics, are compounded or repackaged in order to meet specific dosage needs and are critical to the timely treatment of many patients when a prescriber determines that a FDA-approved drug product is neither available nor appropriate to treat their condition.

Over the past year, access has declined for both repackaged and compounded medications, particularly those ordered without a patient-specific prescription and administered within a healthcare setting for “office-use.” Some examples of such care barriers include:

- Antibiotics for urgent and emergent use in treating ophthalmology patients;
- Buffered lidocaine for use in dermatology procedures;
- Vascular endothelial growth factor inhibitors used in treating age-related macular degeneration by ophthalmologists;
- Injection therapies used to treat erectile dysfunction in urology patients. Test injections are commonly administered in the doctor’s office to determine correct dosage;
- Cantharidin to treat viral skin conditions in office by dermatologists and pediatricians;
- Injectable methylcobalamin for the treatment of pernicious anemia and other vitamin B-12 deficiencies.

Maintaining access to essential repackaged and compounded medications for office-use is not only vital for patients, but is consistent with the legislative intent of the DQSA.^{1,2} While reinforcing Section 503A of the *Food, Drug and Cosmetic Act* (FDCA) through the passage of the DQSA, Congress came together in a bipartisan and bicameral fashion to make clear that pharmacists’ ability to provide compounded medications for a prescriber’s administration to or treatment of a patient within their practice should be left to the states -- office-use of compounded medications is currently regulated under state law.³

As with office-use, the DQSA did nothing to limit repackaging, and Congressional intent was that FDA would continue to allow the practice of repackaging of medications.⁴ Actions by FDA to limit access to repackaged medications, either by requiring a patient-specific prescription in all cases or by not allowing pharmacists to engage in repackaging, would have significant consequences for patients who rely on these

¹ Senator Isakson (GA), Senator Alexander (TN), and Senator Boozman (AR). “Drug Quality and Security Act.” *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

² Representative Griffith (VA), Representative Burgess (TX), and Representative Green (TX). “Drug Quality and Security Act.” *Congressional Record* p.H5963. Available from: Thomas.gov; Accessed 11/24/2014.

³ Senator Isakson (GA), Senator Alexander (TN), and Senator Boozman (AR). “Drug Quality and Security Act.” *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

⁴ Senator Harkin (IA), Senator Alexander (TN), and Senator Boozman (AR). “Drug Quality and Security Act.” *Congressional Record* 159: 164 (November 18, 2013) p.S8072. Available from Thomas.gov; Accessed 11/24/2014.

therapies.⁵ As the DQSA did not explicitly provide for repackaging by either 503A pharmacies or the newly-created 503B outsourcing facilities, physicians and patients are now forced to rely on the FDA for issuance of further guidance on this issue.

Congress' multiple statements in the *Senate Congressional Record* show clear and overwhelming intent that compounded preparations for office-use remain available after the passage of the DQSA. These numerous statements as well as strong urging from physician and pharmacy stakeholders, did not direct the agency to limit office-use medication preparation by 503A compounders. In addition, when FDA considered changes to the Compliance Policy Guide (CPG) for human compounding several years ago, the draft CPG specifically provided for office-use.⁶ Despite these statements and its own draft guidance, FDA stated in a September 15, 2014 response to a bipartisan letter from Congress that to comply with 503A, a compounding pharmacist may not dispense compounded medications for office-use, but rather, must obtain a prescription for an individually identified patient.⁷

Unfortunately, FDA's position interferes with the practice of medicine and decreases patient access to medications. In many situations, a provider must be able to have a compounded drug on hand in order to treat patients presenting with urgent or emergent conditions for which treatment delays may be extremely detrimental. In order to preserve patient access to medications, we ask that Congress address the concerns with office-use and repackaged compounded medications legislatively as soon as possible so that providers and patients can have access to these essential treatments and/or work with FDA on a responsible regulatory approach.

Sincerely Yours,

Alliance for Natural Health USA (ANH-USA)

Alliance of Independent Pharmacists of Texas (AIP)

⁵ Senator Isakson (GA), Senator Alexander (TN), Senator Harkin (IA), Senator Warner (VA), Senator Burr (NC), and Senator Boozman (AR). "Drug Quality and Security Act." *Congressional Record* 159: 164 (November 18, 2013) p.S8071. Available from Thomas.gov; Accessed 11/24/2014.

⁶United States. Department of Health and Human Services. Food and Drug Administration. *Pharmacy Compounding of Human Drug Products Under 503A of the Federal Food, Drug, and Cosmetic Act Draft Guidance*. Washington, DC: n.p., 2013. Print.

⁷ United States. Department of Health and Human Services. Food and Drug Administration. *Response to Congressional Letter on Office Use*. September 15, 2014.

Ambulatory Surgery Center Association (ASCA)
American Academy of Dermatology (AAD)
American Academy of Environmental Medicine (AAEM)
American Academy of Ophthalmology (AAO)
American Association of Naturopathic Physicians (AANP)
American College for Advancement in Medicine (ACAM)
American Medical Association (AMA)
American Pharmacists Association (APhA)
American Society of Cataract and Refractive Surgery (ASCRS)
American Society of Consultant Pharmacists (ASCP)
American Society of Retina Specialists (ASRS)
International Academy of Compounding Pharmacists (IACP)
International College of Integrative Medicine (ICIM)
International Hyperbaric Medical Association (IHMA)
International Organization of Integrative Cancer Physicians (IOIP)
National Alliance of State Pharmacy Associations (NASPA)
National Community Pharmacists Association (NCPA)
PCCA
The Integrative Medicine Consortium (IMC)
The Macula Society