Support a Senate Companion Letter to the House of Representatives Letter to the Food and Drug Administration (FDA) Expressing Congressional Intent to Allow Office-Use Compounding

During the passage of the Drug Quality and Security Act (DQSA), six bipartisan and bicameral Congressional Statements were read into the record establishing congressional intent that the practice of a State licensed pharmacist providing compounded medications to a physician or other practitioner for administration to a patient (often called office-use compounding) was to remain allowable under the DQSA.

Following FDA’s actions which have ignored these Statements on the Record, Congress took many steps to reinforce the bipartisan and bicameral intent for office-use compounding to continue where authorized by State law.

- Questions for the Record were submitted from the House Energy and Commerce Committee following a House Energy and Commerce Hearing entitled, “Reviewing FDA’s Implementation of FDASIA.”
- Questions for the Record were submitted by House Energy and Commerce Members following a Hearing entitled “Improving Predictability and Transparency in DEA and FDA Regulation.”
- A Congressional Letter led by Congressman Burgess and Congressman Morgan Griffith and signed by over 30 Representatives was sent to FDA regarding office-use and repackaging.
- A Congressional Letter led by Congressman Buddy Carter to the FDA following-up on office-use compounding questions which were asked during prior House Education and Workforce Committee hearing.
- Congressional appropriations report language within the 2016 Omnibus instructed FDA, within 90 days of enactment, to issue guidance allowing State-licensed compounding pharmacies to provide compounded medications to physicians and providers to be administered to patients.

Despite all these actions by Congress, FDA released draft guidance on April 15, 2016 entitled “Prescription Requirement under Section 503A of the Food, Drug, and Cosmetic Act” which expressly prohibits all 503A pharmacies from providing physicians and other practitioners compounded medications to administer to patients. Instead, FDA states within the guidance, the physician will have to send the patient to the pharmacy to pick up the medication and return on a second visit to the physician for the administration of the medication, therefore drastically decreasing patient safety and convenience and increase patient and healthcare costs. It is unacceptable the FDA would ignore Congress and continue to take the position that Section 503A prohibits office-use compounding despite clear congressional intent.

In order to hold FDA accountable for implementing the DQSA in accordance with Congressional intent and preserve patient safety and access to vital medications, please support a Senate companion letter to the House of Representatives bipartisan letter instructing FDA to allow States to continue to possess jurisdiction over office-use compounding.

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