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March 22, 2016

The Honorable Sylvia Matthews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell:

Thank you for your testimony to the House Education and the Workforce Committee on Tuesday, March 15, 2016.

During the hearing, I questioned you about "office-use" compounding and the guidance, or lack thereof, by Food and Drug Administration (FDA) concerning the use of "office-use" compounding related to physician offices. I specifically asked whether the FDA was going to issue guidance on the current confusion with its interpretation and implementation of the Drug Quality and Security Act (DQSA) in regards to both compounded and repackaged medications for "office-use."

Over the last 18-months, the FDA has stated several times that a compounding pharmacist or physician may not dispense compounded medications for "office-use" without first obtaining or issuing a prescription for an individually identified patient. This move has caused many States to take action limiting "office-use" compounding. Your response to my questioning indicating that there is nothing preventing a 503A pharmacy from compounding for "office-use" purposes failed to address FDA guidance that has yet to clarify that 503A pharmacies will be exempt from individual prescription requirements. In addition, you omitted the fact that 503A pharmacies are currently being regulated under Good Manufacturing Practices (cGMPs) standards rather than U.S. Pharmacopeia (USP) Convention standards, which have been the standards for 503A pharmacies for years. As such, FDA has ignored that its actions have, in some cases, denied access to life-saving medications in a timely manner when manufactured products are unavailable or do not fit a patient's needs.

In addition, I am concerned the FDA's application of DQSA section 503A requirements to 503A pharmacies in the same manner as large outsourcing facilities is placing undue burden on 503A pharmacies and the patients they serve. Pharmacies that produce small amounts of compounded products in advance of receiving a patient-specific prescription and practice within States where "office-use" is authorized and regulated by State Boards of Pharmacy should not be the focus of FDA oversight. Oversight by FDA of 503A pharmacies is unreasonable and was not Congress' intent during passage of DQSA.

To address these concerns, please respond to the following questions:

1. It is my understanding that FDA is currently working on guidance to clarify that 503A pharmacies, who are regulated by State Boards of Pharmacy, will be exempt from DQSA requirements when participating in "office-use" compounding. When can we expect FDA to release this guidance?

2. For years, 503A pharmacies have operated under the standards contained in the U.S. Pharmacopeia (USP) Convention for sterile and non-sterile compounding. What prompted FDA to begin inspecting these 503A pharmacies under current Good Manufacturing Practices (cGMPs) as opposed to USP standards?

3. The FDA has begun inspecting state licensed 503A pharmacies using cGMP standards rather than USP standards or other applicable pharmacy inspection standards adopted by state law or regulation in the state where the pharmacy is licensed. Section 105 of DQSA states that any finding by the FDA must be turned over to the appropriate State Board of Pharmacy for review and consideration of corrective actions to bring the pharmacy back into compliance with state law. What authority, with clear congressional intent to state otherwise, does FDA have to inspect 503A pharmacies with cGMPs when federal oversight of 503A pharmacies was never the intent of Congress?

Thank you for your attention to this important matter. Please address the questions and topics set forth within 10 business days.

Sincerely,

Earl L. 'Buddy' Carter

Earl L. 'Buddy' Carter
Member of Congress