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November 25, 2014

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

Following enactment of the Drug Quality and Security Act (P.L. 113-54), the Food and Drug Administration (FDA) issued guidance in July of 2014 regarding enforcement of Section 503A of the Federal Food, Drug, and Cosmetic Act. The guidance stated in relevant part that the “FDA expects state boards of pharmacy to continue their oversight and regulation of the practice of pharmacy, including pharmacy compounding.”

However, a letter dated September 15, 2014, from Thomas Kraus, Associate Commissioner for Legislation, in response to a letter from Members of Congress (including myself), states that “with respect to drugs for office use, section 503A requires that to qualify for exemptions from certain requirements, such as having to submit a new drug application, a compounder must obtain a prescription for an individually identified patient...The Agency intends to continue to exercise its authority, as appropriate, to protect the public health.”

If the FDA has indicated via its July 2014 guidance that state boards of pharmacy should continue their oversight and regulation of compounding pharmacies, in what areas does the Agency intend to continue to exercise its authority? Does action in those circumstances indicate that the FDA is preempting the state law and that the corresponding regulation by the state boards of pharmacy is effectively void?

Thank you for your attention to this matter, and I look forward to your response.

Sincerely,

J. RANDY FORBES
Member of Congress