

Congress of the United States
Washington, DC 20515

June 20, 2016

Dr. Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

As the Congress considers appropriations for the Food and Drug Administration (FDA) for Fiscal Year 2017, we write to express our concern that the FDA has ignored a clear directive in the House Report accompanying the FY2016 FDA appropriations legislation (House Report 114-205). That report language directed the FDA, within 90 days of enactment, to issue a guidance document on how state-licensed compounding pharmacies can provide healthcare providers with compounded medications for administration to their patients in an office setting (commonly referred to as “office-use”) consistent with Section 503A of the Food, Drug and Cosmetic Act (FDCA). Instead of complying with this congressional directive, on April 15, 2016, the agency issued a Draft Guidance entitled “Prescription Requirement under Section 503A of the Food, Drug and Cosmetic Act” that expressly *prohibits* office-use compounding by 503A compounding pharmacies.

It is unacceptable that the FDA would ignore the Congress and continue to take the position that Section 503A specifically prohibits office-use compounding, despite clear congressional intent to the contrary and despite previous FDA actions that directly contradict that position, including the recent statement by Health and Human Services Secretary Burwell that also directly conflicts with FDA’s current position on “office-use”. For these reasons, the House Appropriations Committee on April 19, 2016, included report language in the FY17 FDA Appropriations legislation that passed out of the full committee acknowledging the Draft Guidance referenced above and directing that the Final Guidance document issued by the FDA allow for office-use compounding by 503A pharmacies.

Prior to the passage of the Drug Quality and Security Act (DQSA) of 2013, FDA circulated a draft Compliance Policy Guide (CPG) in 2012 to Congress that recognized office-use as legitimate and permissible and explained how compounding pharmacists can engage in office-use compounding before the receipt of a patient-specific prescription consistent with the provisions of 503A of the FDCA. The DQSA did not change the statutory language in 503A that was the basis of that CPG. During the consideration of the DQSA, six Members of Congress, on a bipartisan, bicameral basis, made statements in the Congressional record to clarify that the intent of the legislation was to preserve patient access to medications compounded for office-use.

The Congress has been very clear with the FDA in its intent behind the DQSA as it relates to office-use compounding by 503A pharmacies. Unfortunately, the FDA has to date ignored that congressional intent and substituted the agency’s own, incorrect interpretation of the law in implementing and enforcing the DQSA. We write to reiterate the directive contained in this year’s appropriations report for the FDA and now in the House committee-passed FY17 report to

issue a final guidance document on how office-use compounding can be done in a manner consistent with 503A and which protects both patient safety and patient access to critical medications. We look forward to your prompt response.

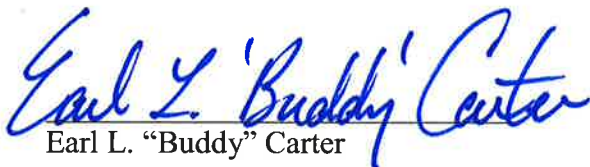
Sincerely,



Chris Stewart
Member of Congress



Pete Olson
Member of Congress



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Member of Congress



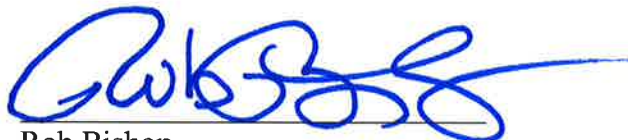
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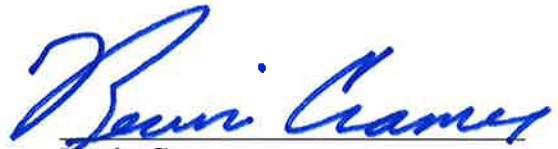
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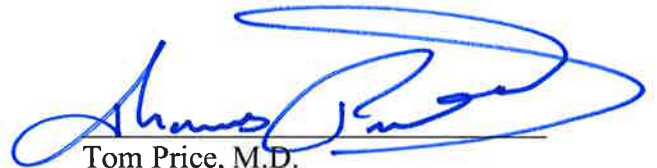
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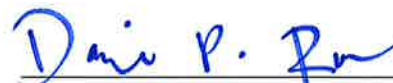
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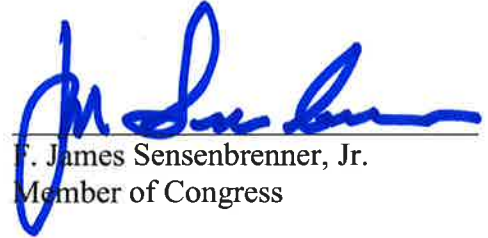
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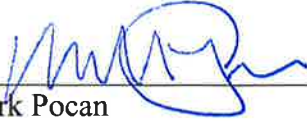
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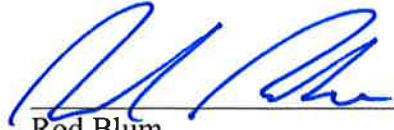
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