

January 24, 2017

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

Dear Dr. Ostroff:

We write today to express our strong disappointment with the final Guidance For Industry (GFI) issued by the Food and Drug Administration (FDA) on December 29, 2016, entitled “Prescription Requirement under 503A of the Food, Drug and Cosmetic Act”. The final GFI takes the position that state-licensed pharmacies cannot compound medications pursuant to state pharmacy laws for administration to patients in office or clinical settings (commonly referred to as “office-use compounding”).

Office-use compounding of medications is a common and often necessary medical practice that is authorized in some form by the vast majority of state pharmacy laws. Compounding for office-use done pursuant to state pharmacy laws does not make a pharmacy a drug manufacturer, and Congress never intended for the FDA to assert regulatory authority over the traditional practice of pharmacy, which has always been regulated at the state level.

The policies finalized in this GFI are contrary to the plain language of Section 503A as amended by the Drug Quality and Security Act (DQSA) and ignore clear, bipartisan, bicameral congressional intent expressed during passage of the bill. The FDA has unfortunately chosen to ignore broad and diverse stakeholder input, multiple congressional letters from both chambers, and clear directives in the House Report accompanying the FY2016 FDA appropriations legislation (House Report 114-205). More importantly, the FDA’s misinterpretation of the law and related enforcement actions against pharmacies are jeopardizing patients’ access to critical compounded medications. For these reasons, we respectfully request that the FDA immediately rescind this GFI and issue a proposed rule, with notice and stakeholder input as required by the Administrative Procedure Act, that is consistent with the DQSA and that allows for office-use compounding by state-licensed pharmacies where authorized by state pharmacy laws.

Particularly troubling is the fact that when finalizing this GFI from draft form, the FDA not only ignored congressional intent, stakeholder input, and clear directives in their FY16 funding legislation about office-use compounding, but also added new language not contained in the draft guidance that attempts to redefine the key and distinct terms “distribute” and “dispense”. It is astonishing that the agency would try to redefine these terms, which have commonly-accepted definitions both in existing law and in pharmacy practice, in a guidance document. This is a clear attempt by the FDA to assert unprecedented regulatory authority over the dispensing of medications and the traditional practice of pharmacy in a way that Congress never intended when passing the FDCA or its amendments in the DQSA. This regulatory overreach by the FDA and enforcement of the DQSA using guidance documents that don’t conform to the law is unacceptable and must stop.

In June of last year, sixty-one members of the House of Representatives, on a bipartisan basis, wrote to your predecessor Dr. Califf asking that the FDA finalize the draft GFI in a way that was consistent with the law and that protected both patient safety and access to critical medications compounded for office-use under state pharmacy laws. Unfortunately, the final GFI doubles-down on the FDA's misinterpretation of the statute and will further exacerbate the patient access problem as more state-licensed and compliant pharmacies are forced to cease compounding office-use medications to the providers in their communities who rely on them for their patients' needs.

We are hopeful that after rescinding this GFI, the incoming administration will re-evaluate the FDA's policy on this subject and issue a proposed rule that provides a meaningful opportunity for stakeholder input and that adheres to the plain language and congressional intent behind the underlying statute. We look forward to working with you during this process.