



# American Pharmacists Association<sup>®</sup>

Improving medication use. Advancing patient care.

**FDA LISTENING SESSION: Drug Compounding**  
**June 5, 2017**  
**11:00AM-1:00PM**

**Statement of the American Pharmacists Association**  
**Stacie S. Maass, BSPHarm, JD**  
**Senior Vice President, Pharmacy Practice and Government Affairs**

Good morning, I am Stacie Maass, Senior Vice President for Pharmacy Practice and Government Affairs for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

I would like to thank the FDA for holding a listening session to gather stakeholder input on drug compounding as part of FDA's efforts to ensure drug quality and security as the provision of safe, effective medications, including compounded medications, which is of paramount importance to our members and a goal shared by everyone in this room. I would also like to note that legislation<sup>1</sup> providing appropriations to the federal agencies was recently signed into law. This legislation included report language clarifying congressional intent with regard to the Drug Quality and Security Act (DQSA), which aligns with APhA and other pharmacy organizations' interpretation and my comments today. The language specifically:

- Calls on FDA to draft a Memorandum of Understanding (MOU) that addresses the "distribution" of compounded products over state lines;
- Calls on FDA to draft final guidance to allow pharmacists to compound for "office use" "in anticipation of receiving patient-specific prescriptions at a later time;" and
- Reminds FDA that pharmacies that compound under 503A are under the purview of state boards of pharmacy and are not to be held to current Good Manufacturing Practices (cGMPs).

## **MOU**

Regarding the draft MOU, APhA is supportive of a new draft, in keeping with congressional intent, that will only address "distribution" of compounded medications across state lines and should have no effect on "dispensing" of prescriptions for identified patients by 503A pharmacies. In addition, APhA continues to have issues with the 5%/ 30% limits set in the draft MOU; concerns which are exacerbated by the conflation of "distribute" and "dispense." Congress noted that for the MOU, "inordinate" amounts or quantities refers to "amounts typically associated with ordinary commercial

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<sup>1</sup> See, H. Rept. 114-531 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017. Available at: <https://www.congress.gov/congressional-report/114th-congress/house-report/531/1?q=%7B%22search%22%3A%5B%22H.+Rept.+114-531%22%5D%7D&r=1>

drug manufacturing,”<sup>2</sup> but the 5% / 30% limitations set forth in the draft MOU in no way resembles commercial drug manufacturing output, particularly because FDA would apply them to patient-specific prescriptions.

### **Office Use**

APhA reiterates its concern with FDA’s position in its recent final guidance prohibiting pharmacies from compounding for office use, despite existing federal law which states that a licensed pharmacist can compound “in limited quantities before the receipt of a valid prescription order for such individual patient” and a long history of the agency allowing the practice.<sup>3</sup> While the FDA has indicated that office use compounded products can and should be fulfilled by outsourcing facilities, due to the cost and/ or time to comply with cGMPs, 503B facilities cannot meet all the product demands of patients and providers. This is why many 503B facilities have defined formulary lists.<sup>4</sup> CGMP requirements include: procurement of bulk drug product(s) which meets CGMP; authoring procedures to compound the medication which meet CGMP; proper testing (validation, release testing, stability testing) and other requirements.<sup>5</sup> APhA members’ conversations with 503B facilities have confirmed the inability of these facilities to supply many small batch medications commonly associated with office use (e.g., numbing creams/sprays, etc.). In addition, because of the time required to meet CGMPs, including, but not limited to the testing requirements, 503Bs are unable to immediately meet the needs of providers and patients unless facilities are currently compounding the product(s). Therefore, APhA strongly urges FDA to follow its previous long-standing policy, as well as the intent of Congress, and continue to allow 503A pharmacies to compound limited quantities without a patient-specific prescription and defer to states for statutory or regulatory authority over pharmacies’ office use compounding.

### **Anticipatory Compounding**

Section 503A(a)(2) of the FD&C Act, allows a licensed pharmacist or licensed physician to compound “limited quantities”<sup>6</sup> before the receipt of a valid prescription order when there is a relationship between the prescriber and pharmacist or physician receiving the prescription, or the patient and pharmacist or physician receiving the prescription. In final guidance, FDA defined “limited quantity” as “a 30-day supply of a particular compounded drug” if that supply “is based on the number of valid prescriptions that the compounder has received for an identified individual patient in a 30-day period over the past year” (i.e., referred to as “anticipatory compounding”). While APhA appreciates FDA acknowledging “larger batch sizes can increase efficiency and reduce the likelihood of human error,”<sup>7</sup> because FDA is now defining “limited quantity,” we believe it is minimizing the value and benefit of anticipatory compounding.

### **Inspections**

APhA appreciates FDA’s recent July 2016 "Notice" that starting August 1, 2016, FDA inspectors will make a "preliminary assessment" of whether pharmacies are in compliance with 503A before applying 503B standards in "Form FDA-483" investigations and will not include observations in its Form-483

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<sup>2</sup> See, S. Rept. 105-43 - FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997. Available at: <https://www.congress.gov/congressional-report/105th-congress/senate-report/43/1>

<sup>3</sup> See, 21 USC 353a. SEC. 503A. PHARMACY COMPOUNDING. Available at: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm376733.htm>

<sup>4</sup> See SCA Pharmaceuticals. Product Catalog. 2016; Cantrell Drug Company. Product Catalog. 2016; and Leiter’s Compounding Product Catalog, 2016.

<sup>5</sup> See FDA. Guidance for Industry Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. July 2014. Available at:

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm403496.pdf>

<sup>6</sup> See 21 U.S. Code § 353a - Pharmacy compounding. Available at: <https://www.law.cornell.edu/uscode/text/21/353a>

<sup>7</sup> In addition, compounding larger supplies of products often encourages quality control testing because costs can be spread out among a larger number of products.

based "solely" on FDA's good manufacturing practice (CGMP) requirements under section 503B.<sup>8</sup> However, APhA has received multiple Form FDA-483s dated post-July 2016 regarding inspections of pharmacies compounding under 503A, which indicate that FDA inspectors continue to inspect pharmacies (not outsourcing facilities) and cite CGMP noncompliance. We continue to have concerns that the pharmacies being cited are not 503B and are incorrectly being cited for cGMP. We are pleased that the 2017 appropriations legislation signed into law also requires FDA to recognize that federal oversight of 503As was not the intent of Congress, and that compounding pharmacies are not drug manufacturers—rather, they are “state licensed and regulated health care providers that are inspected by state boards of pharmacy pursuant to state laws and regulations that establish sterility and other standards for the pharmacies operating within their states.”<sup>9</sup>

I would like to close by thanking FDA for continuing to work with APhA and other pharmacy stakeholders to construct a framework in accordance with current statutory authority and congressional intent that ensures patients have access to safe and effective compounded medications. APhA looks forward to being part of future discussions on this topic. We hope to be a resource for FDA and are happy to be of assistance in any way possible. Thank you again for the opportunity to provide comments on this important issue.

Thank you.

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<sup>8</sup> See FDA. Notice of Change in Process for Inspections of Certain Compounders. July 12, 2016. Available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM510684.pdf>

<sup>9</sup> See, H. Rept. 114-531 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017. Available at: <https://www.congress.gov/congressional-report/114th-congress/house-report/531/1?q=%7B%22search%22%3A%5B%22H.+Rept.+114-531%22%5D%7D&r=1>

## Addendum A

FDA has indicated it is not aware of specific drug products needed for office use that are not supplied by outsourcing facilities.<sup>10</sup> The below list contains examples of such products that we are aware 503B facilities can not/ will not/ do not provide. These examples were previously supplied to FDA at the June 6, 2016 listening session by APhA and other pharmacist organizations.

- Numbing agents: Benzocaine, Lidocaine, Tetracaine, Bupivacaine. Pharmacies compounding under 503A often get requests from Ear, Nose and Throat physicians (ENTs), dentists and medical facilities for various topical combinations that a 503B would never be able to provide. These doctors and facilities request small quantities and the strengths and combinations always vary. The ENTs want something that can be easily sprayed whereas the dentists want a thick flavored oral paste or gel (TAC Gel - 20% lidocaine, 2% tetracaine, 1% phenylephrine in a 2% hydroxyethylcellulose gel that pharmacists flavor for them to as a topical numbing agent for procedures instead of having to use numbing injections). It is very difficult for these providers to get these compounded products on patient-specific prescriptions as they do not know who needs them until they are literally in the chair. Many patients only need a small amount, but when a patient specific prescription is generated it is typically for 30 to 60 grams. Depending on the procedure the MD may only use 5 grams for the patient. Under the current FDA guidance, ENT patients receive no anesthesia, have to reschedule, or every patient gets a 30 cc bottle they need to pick up personally, when only 1-2 sprays in the nose are required.
- Erectile Dysfunction injections (Tri-mix, Quad-mix): The first dose of these medications is always given in the office to determine the best formulation and dosage. Now patients are forced to buy it before the physician has tried it. In addition, they have to transport it (sometimes refrigerated) to the office for their first dose. If the injection does not work, they have to buy another prescription. The importance of the physician-patient interaction, including counseling and education, at the time of the office visit necessitates the medication be on-hand to ensure access to the right dosage of medication, at the right time.
- Phenol and Cantharidin (both used in podiatry and dermatology): These are items, similar to anesthetic gels that physicians can easily keep in office when a patient presents and needs them. They use a very small amount on each patient. Having a patient-specific prescription for a whole bottle is wasteful and again causes delay in treatment.
- Ophthalmic injections and “emergency” eye drops. The physician does not know when a patient will present with a need for these items. Pharmacies often get frantic phone calls at the end of the day for these medications. Literally, waiting until the next day could cause the loss of vision in the person’s eye. Many times the MD is forced to admit the patient to the hospital if they cannot locate these items within a few hours.
- Iontophoresis solutions for use in physical therapy (Potassium Iodide, Dexamethasone): Pain creams for hand therapists in a Hand, Shoulder & Elbow Surgical group. Mostly Ketoprofen, Gabapentin, and Lidocaine.
- Children's dentistry (Hydroxyzine Pamoate Suspension for anxiety):
- Chemical peels for dermatologists.
- Anesthetics for numbing prior to laser resurfacing.
- Lidocaine/Oxymetazoline for nasal rinsing in office.
- Phenol for inner ear procedure.

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<sup>10</sup> See. FDA. Department of Health and Human Services. Fiscal Year 2018. Justification of Estimates for Appropriations Committees. Available at: <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM559923.pdf>