



**U.S. HOUSE ENERGY AND COMMERCE  
HEALTH SUBCOMMITTEE  
“Examining Implementation of the Compounding Quality Act.”  
Tuesday January 30, 2018  
11:00AM  
Statement for the Record  
The American Pharmacists Association**

The American Pharmacists Association (APhA) appreciates the opportunity to submit the following Statement for the Record for today’s U.S. House Energy and Commerce Health Subcommittee hearing “Examining Implementation of the Compounding Quality Act.”

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.

APhA would like to thank Subcommittee Chair Burgess and Ranking Member Green for holding a hearing to gather Agency and stakeholder input on drug compounding as part of the Committee’s ongoing oversight of the FDA’s mission to ensure drug quality and security as the provision of safe, effective medications, including compounded medications, which is of paramount importance to APhA members and a goal shared by everyone here today. APhA 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 our comments. 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**

APhA supports FDA finalizing an MOU which aligns with the congressional intent of the DQSA. The plain language of the Food, Drug and Cosmetic (FD&C) Act directs FDA to develop

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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>

an MOU that addresses “the distribution of inordinate amounts of compounded drug products interstate.”<sup>2</sup> While DQSA does not explicitly define “distribution,” the statutory text differentiates between “distribution” and “dispensing” in a number of places—a clear indication that Congress ascribed different meanings to the two terms.<sup>3</sup> Historically, the terms “dispense” and “distribute” refer to two different activities. In both FD&C<sup>4</sup> and the Controlled Substances Act,<sup>5</sup> Congress and FDA expressly recognized the different usage of “dispense” and “distribute,” defining “dispensing” as something that is intrinsically clinical in nature, while defining “distribution” as the act of shipping or delivering a medication outside of the patient-provider relationship. To treat “distribution” and “dispensing” as interchangeable only in the context of DQSA not only creates confusion, it also implies that FDA is entering into the regulation of clinical decision-making related to prescribing—an area meant to be governed by states. Thus, in keeping with congressional intent, we believe that a final MOU should only address “distribution” of compounded medications across state lines and should have no effect on dispensing of prescriptions for identified patients by pharmacies compounding under section 503A. Congress noted that for the MOU, “inordinate” amounts or quantities refers to “amounts typically associated with ordinary commercial drug manufacturing.”<sup>6</sup> It would be helpful for the Committee to clarify congressional intent with the FDA during today’s hearing.

### **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>7</sup> While the FDA has indicated that office use compounded products should be fulfilled by outsourcing facilities, due to the cost and/ or time to comply with CGMP, 503B facilities cannot meet all the product demands of patients and providers. This is why many 503B facilities have defined formulary lists.<sup>8</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>9</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

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<sup>2</sup> See 21 U.S.C. § 353a(3)(B). Available at: <https://www.law.cornell.edu/uscode/text/21/353a>

<sup>3</sup> See e.g., *id.* at (3)(B)(ii) (differentiating the “dispensed” and “distributed” through the use of the disjunctive “or”, indicating that the terms are not interchangeable).

<sup>4</sup> Drug Supply Chain Security Act, §581(5) (2013) (defining distribute as “the sale, purchase, trade, delivery, handling, storage, or receipt of a product”, but stating that it “does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b)”).

<sup>5</sup> See 21 U.S.C. §802(10)-(11). Available at: <http://www.deadiversion.usdoj.gov/21cfr/21use/802.htm> ; See also 21 C.F.R. §208.3 defining “distribute” as “the act of delivering, other than by dispensing, a drug product to any person”, thereby expressly excluding dispensing from the act of distribution). Available at: <https://www.law.cornell.edu/cfr/text/21/208.3>

<sup>6</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>7</sup> See, 21 USC 353a. SEC. 503A. PHARMACY COMPOUNDING. Available at: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm376733.htm>

<sup>8</sup> See SCA Pharmaceuticals. Product Catalog. 2016; Cantrell Drug Company. Product Catalog. 2016; and Leiter’s Compounding Product Catalog, 2016.

<sup>9</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>

strongly urges Congress to ensure that FDA follows its previous long-standing policy, as well as existing statute and the intent of Congress, and continue to allow pharmacies compounding under section 503A 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>10</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>11</sup> because FDA is now attempting to define “limited quantity,” we believe it is minimizing the value and benefit of anticipatory compounding.

### **Inspections**

Finally, APhA was initially pleased with FDA’s recent July 2016 "Notice" that starting August 1, 2016, FDA inspectors would make a "preliminary assessment" of whether pharmacies are in compliance with 503A before applying 503B standards in "Form FDA-483" investigations and would not include observations in its Form-483 based "solely" on CGMP under section 503B.<sup>12</sup> However, APhA has received multiple Form FDA-483s dated post-July 2016 regarding inspections of pharmacies compounding under section 503A, which indicate that FDA inspectors continue to inspect pharmacies, not outsourcing facilities under 503B, and cite CGMP noncompliance. APhA continues to have serious concerns that the pharmacies being cited are not 503B and are incorrectly being cited by FDA for CGMP. Accordingly, we are pleased that the 2017 appropriations legislation signed into law also requires FDA to recognize that federal oversight of pharmacies compounding under section 503A 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>13</sup> We strongly urge the Committee to clarify to FDA the congressional intent of this language during today’s hearing.

In addition, we have heard from nuclear pharmacies, which are exempt from the DQSA for the preparation of radiopharmaceuticals,<sup>14</sup> that FDA is inspecting these facilities based on these draft

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<sup>10</sup> See 21 U.S. Code § 353a - Pharmacy compounding. Available at: <https://www.law.cornell.edu/uscode/text/21/353a>

<sup>11</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.

<sup>12</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>13</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>

<sup>14</sup> See 21 U.S.C. §353a(e). ““(e) Application.--This section shall not apply to-- “(1) compounded positron emission tomography drugs as defined in section 201(ii); or “(2) radiopharmaceuticals.” Available at: <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec353a.pdf>

guidances, not statutes, and then issuing Form FDA-483s for observations that are not applicable. While compounding creates what are essentially new drug products designed to meet patient needs, most nuclear pharmacies are preparing radiopharmaceuticals from kits that are FDA-approved—activity that falls outside of the FD&C’s definition of compounding. We would appreciate the Committee inquiring why FDA is inspecting nuclear pharmacies as compounders when Congress specifically exempted them from the DQSA.

APhA would like to close by thanking the Committee 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 Congress and 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.

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