FDA LISTENING SESSION: Drug Compounding
June 19, 2018
8:30am – 10:30am

Statement by the American Pharmacists Association

The American Pharmacists Association (APhA) is pleased to submit our comments to FDA for its June 19th listening session on compounding. APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 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 FDA for holding its annual listening session to gather stakeholder input on drug compounding as part of the Agency's efforts to ensure the provision of safe, effective medications, including compounded medications, which is of paramount importance to our members. We continue to have concerns with some of FDA's compounding regulatory activity on which we previously commented. Areas of concern include:

- Revised draft memorandum of understanding (MOU) between FDA and the states;
- Prohibition of office use/ stock;
- Definition of "anticipatory compounding"; and
- FDA's inspections of pharmacies.

APhA would like to note that legislation providing appropriations to the federal agencies for Fiscal Year (FY) 2019 passed the House of Representatives Appropriations Committee on May 16, 2018 includes report language/ instructions to FDA addressing many of these concerns.[1] The legislation provides instructions to FDA to clarify congressional intent with regard to the Drug Quality and Security Act (DQSA). Specifically, the new language for FY 2019, states Congress:

- Expects "FDA will clarify the distinction between distribution and dispensing activities," and "…any new draft MOU should be open for comment given the significance of this provision to patient access to medications from the pharmacy of their choice";

[1] The FY 2019 language supplements FY 2018 report language. *See,* H. Rept. 115-232 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2018. Available at: https://www.congress.gov/congressional-report/115th-congress/house-report/232/1. Available at: https://docs.house.gov/meetings/AP/AP00/20180516/108312/HRPT-115-HR-FY2019-Agriculture.pdf.Also, *See,* RULES COMMITTEE PRINT 115–66 TEXT OF THE HOUSE AMENDMENT TO THE SENATE AMENDMENT TO H.R. 1625. March 2018. Available at: https://docs.house.gov/billsthisweek/20180319/BILLS-115SAHR1625-RCP115-66.pdf. Also, See, The Explanatory Statement to Ag/FDA division of FY18 Omnibus Appropriations Act. "The House and Senate report language that is not changed by the explanatory statement is approved and indicates congressional intentions." Available at: https://docs.house.gov/billsthisweek/20180319/DIV%20A%20AG%20SOM%20FY18%20OMNI.OCR.pdf

- "[E]ncourages FDA to either prescribe a pathway for limited, safe, and controlled office-use, or hold a public meeting so that FDA can clearly explain to the respective stakeholders the legal rationale for disallowing office-use", and, within 90 days, "…explain how the agency will implement any applicable changes in its use of guidances to ensure consistency…" with the "…January 2018 Memorandum issued by the Associate Attorney General that prohibits the DOJ from using civil enforcement authority to convert agency guidance documents into binding rules[2]";
- "[E]xpects that, at the earliest possible date, whether filling open positions or replacing existing members [for the Pharmacy Compounding Advisory Committee (PCAC)], the FDA shall appoint voting members with recent, actual, and diverse experience in the preparation, pre-scribing, and use of compounded medications;" and
- "…FDA should be interpreting Section 503A of the FDCA to allow the compounding of product under the standards contained in the United States Pharmacopeia Convention (USP) for sterile and non-sterile pharmaceutical compounding or other applicable pharmacy inspection standards adopted by state law or regulation", as "…these particular compounding pharmacies are not drug manufacturers, but rather, 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."[3]

Furthermore, APhA strongly urges FDA to follow its previous long-standing policy concerning compounding products for office use/ stock, as well as the intent of Congress, as stated under recent report language signed into law, where:

> *The Committee directs the FDA to rescind this GFI ["Prescription Requirement Under Section 503A of the FDCA"] which expressly prohibits office-use compounding]and issue a proposed rule, subject to the notice and comment provisions in the Administrative Procedure Act. The proposed rule should be consistent with Congressional intent as stated in both Appropriations Reports and the DQSA, and that also allows for office-use compounding as authorized by state law. In the proposed rule, FDA should lay out the means by which office use is permissible while addressing such critical safety matters, such as maintaining controls on quantity and safety issues such as those related to office stock shelf life. Lastly, FDA's clarification on the line between traditional compounding and outsourced compounding will support state regulators, outsourcing facilities, and traditional compounders in their efforts to ensure that patients have access to safe compounded drugs while reducing the risks associated with sterile drugs produced in bulk.*[4]

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[2] *See,* U.S. Department of Justice. MEMORANDUM FOR HEADS OF CIVIL LITIGATING COMPONENTS UNITED STATES ATTORNEYS. Re: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases. January 25, 2018. Available at: https://www.justice.gov/file/1028756/download

[3] *See,* H. Rept. AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2019. Available at: https://docs.house.gov/meetings/AP/AP00/20180516/108312/HRPT-115-HR-FY2019-Agriculture.pdf.

[4] *See,* H. Rept. 115-232 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2018. Available at: https://www.congress.gov/congressional-report/115th-congress/house-report/232/1. Available at: https://docs.house.gov/meetings/AP/AP00/20180516/108312/HRPT-115-HR-FY2019-Agriculture.pdf. Also, *See,* RULES COMMITTEE PRINT 115–66 TEXT OF THE HOUSE AMENDMENT TO THE SENATE AMENDMENT TO H.R. 1625. March 2018. Available at: https://docs.house.gov/billsthisweek/20180319/BILLS-115SAHR1625-RCP115-66.pdf. Also, *See,* The Explanatory Statement to Ag/FDA division of FY18 Omnibus Appropriations Act. "The House and Senate report language that is not changed by the explanatory statement

In closing, APhA thanks FDA for its work with stakeholders in an effort to construct a framework to ensure patients have access to safe and effective compounded medications. We look forward to being part of ongoing discussions on this topic and serving as a resource for FDA. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

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