FDA LISTENING SESSION:
Hospital and Health System Organizations
June 19, 2018
3:00PM-4:00PM

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 in hospitals and health systems. 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 from hospital and health systems on compounding under the federal Food, Drug, and Cosmetic Act (the "Act"). As FDA is aware, compounding is an important part of pharmacy practice at hospitals and other sites of care because it permits patients with unique medical needs to have access to vital medications when commercially available dosage forms do not exist. APhA appreciates FDA granting some flexibility to hospitals and health systems, through enforcement discretion, in distributing compounded drug products prior to a patient-specific prescription as announced in the April 2016 *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, Draft Guidance*[1]. In addition, in the Agency's January 2018 *Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, *Guidance for Industry, Final Guidance,* FDA stated it "…is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance or rulemaking."[2]

FDA's proposed 1-mile flexibility helps prevent some scenarios which would hurt patient access to needed compounded medications in hospitals and health systems. However, APhA has heard from members the 1-mile exception is still problematic for some health systems. Arbitrary distance limitations could prevent the most qualified pharmacy/ pharmacist from providing these medications. Accordingly, APhA recommends FDA return to its previous interpretation and enforcement of section 503A(a)(2) of the Act and allow licensed pharmacists to compound "limited quantities" in advance of a prescription when there is an existing relationship, as long as

[1] FDA. Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act. Guidance for industry. Draft Guidance. April 2016. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496287.pdf
[2] FDA. Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act. Final Guidance. January 2018. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf

it is allowed by state laws and regulations and in compliance with recognized professional standards and guidelines.

In separate final guidance,[3] FDA asserted that hospitals, clinics, and health care facilities can rely on 503B facilities to obtain their office use compounded products. However, while hospitals and health systems can obtain a portion of their products from 503B facilities, 503B facilities cannot supply all their compounding products because compliance with CGMP requirements makes it cost and/ or time prohibitive, which is the reason many 503B facilities have defined formulary lists.[4] As stated previously, 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.). Therefore, rather than provide a narrow exception for hospitals and health systems, APhA, strongly urges FDA to follow its previous long-standing policy, as well as the clear intent of Congress,[5] to continue to allow pharmacists compounding under 503A to compound "limited quantities" without a patient-specific prescription and defer to states for statutory or regulatory authority over pharmacies' office use compounding.

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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[3] FDA. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act. December 29, 2016. Final Guidance. Available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf

[4] *See* SCA Pharmaceuticals. Product Catalog. 2016; Cantrell Drug Company. Product Catalog. 2016; and Leiter's Compounding Product Catalog, 2016.

[5] *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