American Pharmacists Association

FDA Drug Compounding Annual Listening Session –
Pharmacy Groups
Compounding Core Group Chair-Elect Matt Martin, PharmD, BCSCP
June 15, 2023

- Thank you for the opportunity to represent our nation's pharmacists at today's compounding listening session.

- Briefly, I would like to touch on GFI 256 and compounding for animals. APhA would like to express its gratitude to the Center for Veterinary Medicine for its willingness to engage in a dialogue regarding GFI 256. It is helpful when discussions can be had with stakeholders. We remain concerned about various provisions of GFI 256 and think that more time should have been given prior to its use in inspectional activities as indicated in the letter sent to FDA earlier this year.

- I would like to focus our time on discussing FDA's response to the ibuprofen and acetaminophen shortages that recently occurred.

- In January of this year APhA sent a letter to FDA requesting FDA recognize the shortages of ibuprofen and acetaminophen oral suspensions by placing them on the FDA drug shortage list. Additionally, APhA requested temporary guidance to allow the compounding of these medications with enforcement discretion regarding the essential copies and prescription requirement provisions for these products until such time that sufficient supply is available across the country.

- We applaud FDA for responding quickly with guidance regarding ibuprofen suspension. APhA was also disappointed that the guidance did not address acetaminophen suspension or compounding of these medications by 503A pharmacies. The guidance initially described how 503B outsourcing facilities could make ibuprofen suspension for use in hospitals and was later revised to describe a pathway for 503B outsourcing facilities to provide ibuprofen suspension to other 503A facilities including community pharmacies.

- 503A pharmacies and their ability to compound drugs in shortage was addressed in the Questions and Answers on Compounded Oral Suspension Medications for Pain and Fever pointing to the ability of 503As to produce copies of manufactured as long as the compounding is not done "regularly or in inordinate amounts." While this is accurate according to the statutory language it does not address the fact that FDA's guidance on essential copies for 503A facilities provides enforcement discretion for up to 4 copies per month. Without FDA listing ibuprofen suspension on their drug shortage list, 503A pharmacies are very limited in the number of patients they could compound for ibuprofen suspension.

- FDA's guidance suggests 503B outsourcing facilities could produce the ibuprofen suspension and then provide it to 503A pharmacies for dispensing to patients with prescriptions. This concept is challenging on multiple levels. Pharmacies are not commonly purchasing compounded products from 503B outsourcing facilities for dispensing and don't know which of the approximately 75 outsourcing facilities to contact for ibuprofen suspension during a shortage.

- In addition, Section 503B of the Food Drug and Cosmetic Act (FDCA) also has a prohibition on wholesaling and the law requires labeling on all products produced by 503B facilities to include the statement "Not for resale." Many pharmacists would regard the sale of the compounded drug product by a 503B outsourcing facility to a 503A pharmacy as an act of wholesaling, and the label on that product would instruct the pharmacy not to resell it to the patient. Boards of pharmacy may also have questions or concerns regarding the interpretation of wholesaling by outsourcing facilities that would need to be addressed. APhA recommends FDA issue guidance on how it interprets the wholesaling provisions of 503B to assist pharmacy stakeholders.

- 503B outsourcing facilities must be willing and able to produce nonsterile products - and specifically ibuprofen suspension. There are a limited number of approximately 75 outsourcing facilities that produce nonsterile products. 503B outsourcing facilities are required to be engaged in the compounding of sterile drugs per the statute. Those 503B outsourcing facilities that do produce nonsterile products must analyze their current capacity and economic feasibility before taking on additional products.

- In addition to the 503A and 503B components – another barrier is requiring a prescription for what is typically available as an over-the-counter drug product. FDA guidance on the prescription requirement under Section 503A of the FDCA states that a prescription for a human compounded drug is required prior to that drug leaving the 503A pharmacy. Understandably, everyone involved in the triad of patient care is frustrated with the logistics involved and the delays generated by requiring a prescription for a common OTC product.

- In summary, while it may be viable for 503B outsourcing facilities to provide compounded medications to 503A pharmacies for dispensing this model is relatively new and was challenging to implement during a shortage along with questions as to how to interpret the wholesaling provisions. 503A pharmacies should be utilized to compound these medications in shortages as they are readily available to patients and caregivers in their communities to meet these needs. It may be of value to FDA to confer with Health Canada to learn more about their decision to allow pharmacies in Canada to compound

both ibuprofen and acetaminophen suspensions due to the shortages experienced in Canada.

- Thank you for the opportunity to provide our perspective to the FDA. We hope FDA considers these points as it crafts future policy and contacts APhA as a resource to ensure patients have appropriate access to compounded medications.