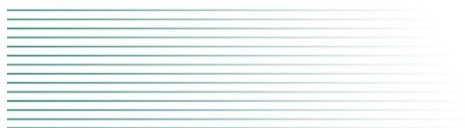


# Outsourcing Facilities Association (OFA) Presentation for RIN: 0910-A131, Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act

September 11, 2023



# Agenda

- Introduction to OFA
- OFA's Interest in learning more about the proposed rule
- Impact of drug shortages
- 503B and 503A – different capabilities



# OFA's Mission



- The Outsourcing Facilities Association (OFA) is the trade association representing multiple FDA-registered 503B facilities
  - OFA members work with patients, healthcare providers and healthcare facilities to ensure the specific needs of both providers and patients are satisfied by providing safe and effective compounded and repackaged medications
- OFA will continue to work with industry, governmental agencies and healthcare providers to educate and advocate for outsourcing facilities and their ability to meet the critical need of patients and providers to access medications



# OFA's Interest in learning more about the proposed rule



# Title: Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act

## **Abstract:**

Compounded drug products must satisfy the conditions of section 503A or section 503B of the FD&C Act to qualify for certain statutory exemptions listed under each section. Both sections 503A and 503B provide that a compounded drug is not eligible for those exemptions if it is identified by FDA as presenting demonstrable difficulties for compounding. FDA is proposing to establish the criteria by which it would evaluate drug products and categories of drug products for inclusion on the list of drug products and categories of drug products that present demonstrable difficulties for compounding under section 503A and/or under section 503B. Based on the results of its evaluation of nominated categories of drug products to date, as well as consultation with the Pharmacy Compounding Advisory Committee (PCAC), FDA is also proposing to include certain categories of drug products on these lists.

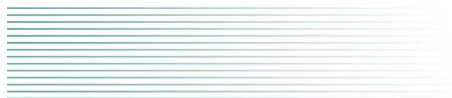


# Impact on drug shortages



# Impact on drug shortages

- 503B outsourcing facilities are REGISTERED with the FDA, unlike traditional 503A compounding pharmacies
  - 503B outsourcing facilities are registered and are subject to routine FDA oversight similar to traditional manufacturers
- 503B outsourcing facilities are the only FDA-regulated firm that Congress envisioned to mitigate drug shortages
  - **Ability to mitigate drug shortages is directly linked to having access to compound a drug**



# Impact of Drug Shortages





# Impact of Drug Shortages

- **Economic:** Drug shortages lead to higher drug prices. Analysis of the data showed a 16.6 percent increase in the price of drugs in shortage, driven mostly by an increase in the price of generics (14.6 percent). *See* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Impact of Drug Shortages on Consumer Costs. May 2023. <https://aspe.hhs.gov/>
- **Health Outcomes:** Drug Shortages are significantly associated with increased mortality among patients. *See* Vail E, Gershengorn HB, Hua M, Walkey AJ, Rubenfeld G, Wunsch H. Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 2017;317(14):1433–1442. doi:10.1001/jama.2017.2841



# Negative Impact of Lists on Drug Shortages



# Lists Negatively Impacting Drug Shortages – Select Examples

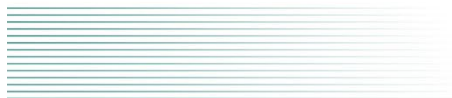
Bulk Drug Substances Not Included on the 503B Bulks List	Drug Products containing the Bulk Drug Substance on the FDA Drug Shortage List
Diazepam	Diazepam Rectal Gel (Currently in Shortage)
Dipyridamole	Dipyridamole Tablets (Discontinuation)
Dobutamine hydrochloride	Dobutamine Hydrochloride Injection (Currently in Shortage)
Dopamine hydrochloride	Dopamine Hydrochloride Injection (Currently in Shortage)
Edetate calcium disodium	Edetate Calcium Disodium Injection (Currently in Shortage)
Glycopyrrolate	Glycopyrrolate Inhalational Solution (Discontinuation)
Mannitol	Mannitol Injection (Currently in Shortage)
Nicardipine hydrochloride	Cardene IV (nicardipine hydrochloride) 0.2 mg/mL in 5% Dextrose (Discontinuation)
Potassium acetate	Potassium Acetate Injection (Currently in Shortage)
Procainamide hydrochloride	Procainamide Hydrochloride Injection (Discontinuation)
Sodium bicarbonate	Sodium Bicarbonate Injection (Currently in Shortage)
Verapamil hydrochloride	Verapamil Hydrochloride Tablets (Discontinuation)

# Differences between 503A and 503B



# Differences between 503A and 503B

- Quality standard:
  - 503A = USP
  - 503B = current Good Manufacturing Practices (same standard as conventional drug manufacturers)
- Different standards = Different capabilities
- Different capabilities should = different lists



# Questions?

