NABP
National Association of Boards of Pharmacy

Prescription Drug Shortages

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NABP Mission, Vision, and Purpose

NABP Mission Statement

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial Association that assists its member boards in protecting the public health.

Vision Statement

Innovating and collaborating today for a safer public health tomorrow.

NABP Purpose

Founded in 1904, the purpose of the Association is to provide for interstate and interjurisdictional transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation, and to improve the standards of pharmacist education, licensure, and practice by cooperating with state, national, and international governmental agencies and associations having similar objectives.

Member Boards

NABP's member boards of pharmacy are grouped into eight districts that include all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, and 10 Canadian provinces. The Association is governed by its Executive Committee, whose officers and members are elected during the Association's Annual Meeting.

Current Active Members: All 50 states, District of Columbia, Guam, Puerto Rico, and the Virgin Islands

Current Associate Members: Bahamas and all 10 Canadian provinces

Active vs Associate Members

Active Members

- Participate in Electronic Licensure Transfer Program® (eLTP) and NABP Clearinghouse
- Serve on NABP standing committees
- May propose resolutions and amendments to the *NABP Constitution and Bylaws*
- Privilege of the floor at the Annual Meeting
- Vote at the Annual Meeting
- Eligible to serve on NABP Executive Committee

Associate Members

- Not required to participate in eLTP or Clearinghouse
- Privilege of the floor at the Annual Meeting
- No vote at the Annual Meeting
- Not eligible to serve on NABP Executive Committee

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Drug Shortage Factors

- Approximately 87% of prescriptions are dispensed as generics[1]
- Approximately 88% of dollars are spent on brands (biologics, specialty drugs, etc.) [1]
- Generic prices have fallen by approximately 20% since 2019[1]
- Low drug prices of generics have contributed to ANDA holders not launching approved drugs to market, limiting suppliers of inexpensive generics in both solid dosage forms and injectables
- Since 2013, 42% of injectables receiving approved ANDAs have not be launched
- Manufacturing problems shutting down one generic manufacturer can reduce supplies drastically
- Injectables are by nature, difficult to make, further limiting firms entering the marketplace

[1] IQVIA - HDA DMC 3/12/2024

FDA

“There are fewer firms making older sterile injectable drugs, and there are a limited number of production lines that can make these drugs. The raw material suppliers the firms use are also limited in the amount they can make due to capacity issues at their facilities. This small number of manufacturers and limited production capacity for older sterile injectables, combined with the long lead times and complexity of the manufacturing process for injectable drugs, results in these drugs being vulnerable to shortage. When one company has a problem or discontinues, it is difficult for the remaining firms to increase production quickly and a shortage occurs.”

https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages

FDA – Report on Drug Shortages

https://www.youtube.com/watch?v=u4Pe3bfcr7I

- The report identifies three root causes for drug shortages:
  - Lack of incentives for manufacturers to produce less profitable drugs;
  - The market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues; and
  - Logistical and regulatory challenges make it difficult for the market to recover from a disruption.
- Limited number of major players in the generic drug market

Stimulant Shortages

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search

Morbidity and Mortality Weekly Report (*MMWR*)

Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021

Weekly / March 31, 2023 / 72(13);327–332

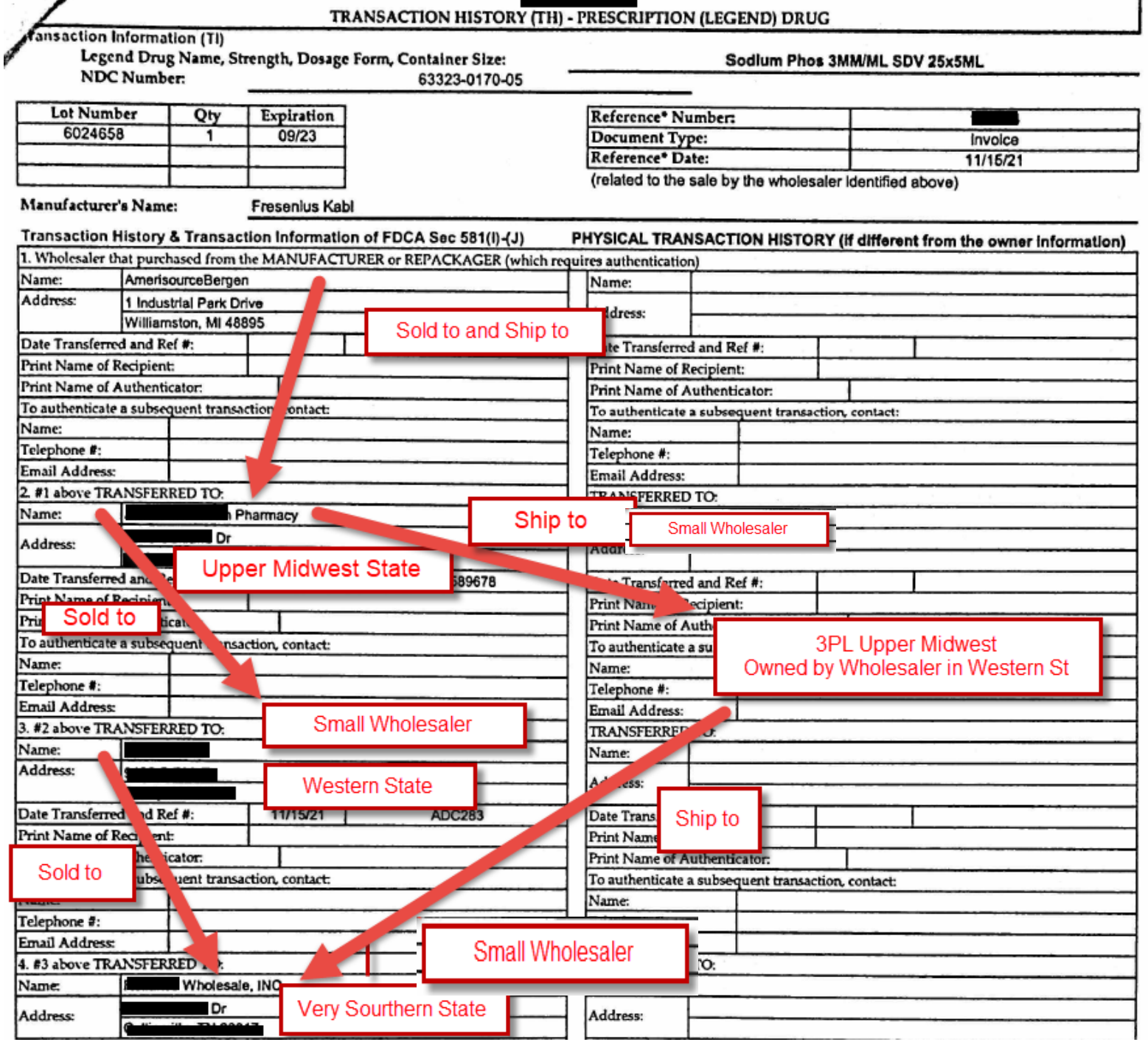
Melissa L. Danielson, MSPH[1]; Michele K. Bohm, MPH[2]; Kimberly Newsome, MPH[1]; Angelika H. Claussen, PhD[1]; Jennifer W. Kaminski, PhD[2]; Scott D. Grosse, PhD[3]; Lila Siwakoti, MPH[2]; Aziza Arifkhanova, PhD[2]; Rebecca H. Bitsko, PhD[1]; Lara R. Robinson, PhD[1] (VIEW AUTHOR AFFILIATIONS)

Stimulant Shortages

- Increase in demand
  - Relaxed telehealth policies (no in-person visit)
  - Increased access to mental health care through telehealth
- Established patients at pharmacies seeking prescriptions elsewhere due to the shortage, resulted in established patients at those pharmacies with fewer supplies
- Nonpayment for branded stimulants
- Imbalance of DEA-allocated raw active pharmaceutical ingredients
- Manufacturers not utilizing allocated resources (2022 & 2023)

DEA Response to Stimulant Shortage

- August 28, 2023, DEA made changes to the allocation quota process
  - Reduced the amount of drug inventory required to be on hand at manufacturers
  - Adjusted the process for manufacturers to voluntarily relinquish their quota allotments to shift allotments to other manufactures
- November 1, 2023, DEA announced steps to increase manufacturer transparency and receive real-time data on the status of drug production
  - Required drug manufacturers to submit anticipated production timelines in advance of receiving their quotas
  - Moved the quota application process to quarterly instead of annually
  - Monthly reporting by manufactures and distributors on the amount of drug product being produced and shipped
  - Specifying whether drug product allotment is domestic or imported



Drugs sold/ship to Pharmacy by Big 3 (WD-1)

Drug shipped to 3PL by Pharmacy. Drug sold to WD-2 that owns 3PL.

WD-2 that bought the drug from Pharmacy sells to another WD-3. 3PL ships drug to WD-3

WD-2 Business Model is buying drugs from pharmacies that purchase a couple of vials that are on allocations from the WD. This exacerbates the shortage when the WD buys hundreds vials from many pharmacies.

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Questions?