

Generic Prescription Drug Shortage Bills

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AAM's core mission is to improve patients' lives by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. AAM is the nation's leading trade association for manufacturers and distributors of generic and biosimilar prescription medicines. Our members provide more than 36,000 jobs at nearly 150 facilities, and manufacture more than 61 billion doses of prescription medicine in the US annually.

From 2010 to 2016, generic drug prices decreased 66%. Generic drugs saved the U.S healthcare system roughly \$2 trillion in the last decade.

- Generic drugs are particularly susceptible to drug shortages. Prices for generic products are decreasing, generic drug purchasers are becoming more concentrated, and the number of registered manufacturing sites are declining.
- Most generic companies manufacture a broad portfolio of products, including drugs that do not generate positive revenue, therefore, new product launches are the life-blood of the generic industry. When the ability to recoup investment in new products is difficult or is blocked, it becomes hard to justify the continued production of revenue-neutral or revenue-negative products.
- Drug shortages can directly affect patient and medical providers' ability to optimize patient care. Physicians may be forced to delay therapy or resort to less than optimal therapies to preserve supply, ultimately deciding patient care based on cost rather than standard medical practice.
- Former FDA Commissioner Gottlieb recently stated:
"The low-profit margins, and the significant cost of manufacturing these complex drugs, has resulted in consolidation in the industry. The only way to produce these low-margin products profitably is

to manufacture them at tremendous scale. This has resulted in fewer and fewer manufacturers for certain key products. The result is very little margin for error in this space."

- Drug shortages are most acute for sterile generic injectable products, but, other products are impacted as well including: oral solids, liquids, ophthalmic products, aerosols, powders, topical products, and suppositories.

Drug shortages can occur because of three categories of challenges:

1) Manufacturing / Regulatory:

- FDA Inspections and warning letters can delay manufacturing in facilities not linked to reports of drugs harming consumers.
- Insufficient supply of available raw materials and components reduce manufacturers' ability to respond to shortages or demand increases.
- The DEA's evaluation and approval process is slow and can result in manufacturer difficulty in obtaining and maintaining an adequate supply of active pharmaceutical ingredient (API).
- Challenges exist in maintaining a consistent supply including, but not limited to, quality compliance; limited production lines; complex manufacturing; and USP standard and monograph changes.

- Short shelf life (18-24 mos.) requirements for finished goods and wholesaler minimum shelf life requirement (12mos. at time of purchase) limit a manufacturers' ability to carry additional safety stock.

2) Market / Pricing Factors

- The generic drug market has more than 200 generic manufacturers, at times with as many as a dozen manufacturers making a given product.
- 90% of generic medicine purchasing for hospitals/clinics is controlled by 3 organizations, and 3 purchasing groups (wholesaler/retail chain combos) control 90% of the retail generic drug market.
- Generic price deflation is threatening generic sustainability. Today, generics launch at a greater discount off the brand price, lower prices more quickly, and have lower price points than at any time in the last 20 years.

3) Unsound Public Policy Can Exacerbate Drug Shortages

- State proposals aimed at regulating the price of generic drugs without considering the significant differences between branded and generic businesses can impact the sustainability of the generic drug market.
- State drug price transparency and other pricing proposals disproportionately impact generic drugs and fail to account for the regular price variability that exists within the generics market.
- State and local drug takeback mandates place the bulk of the financial burden on generic drugs. These efforts create additional costs on generic manufacturers exclusively related to the normal course of business and undermine the ability of generic manufacturers to remain in low-volume markets.
- The Medicaid inflation penalty will impact patient access because it subjects generic manufacturers to millions in "penalties" on products that have not had a price increase. This creates disincentives to enter the market and makes it more challenging for manufacturers to continue participating in the market.

Recommendations for State to Address Drug Shortages

Ensure robust access to generic medicines

States should be cautious of proposals that might create long-term barriers to robust generic competition. Consistent with Dr. Gottlieb's statement as noted above, we should "make sure we aren't discouraging investment for manufacturing drugs that are more likely to go into shortage, and thus working against our own goals." States must collaborate with industry, health care professionals, and patients to ensure robust coverage of generic medicines.