

Healthcare Supply Chain Association (HSCA) Position:

Patients have long relied on generic drugs to reduce costs and increase access to essential medications. However, significant price spikes for some generic drugs have begun to jeopardize patient access to affordable healthcare.

Price spikes often occur where there are two or fewer manufacturers for a given product in the market and where a lack of competition among manufacturers allows high prices to go largely unchecked. Limited manufacturing options also mean that quality control problems and disruptions to manufacturing can jeopardize supply and give rise to drug shortages, which allow opportunistic manufacturers to further drive up the price of common generic drugs.

Robust competition in the generic drug marketplace is critical to mitigating price spikes. HSCA and its healthcare group purchasing organization (GPO) members support common-sense policy solutions to help foster competition and speed up entry for new manufacturers. HSCA urges policymakers to mandate priority review by the U.S. Food and Drug Administration (FDA) for generic drugs with two or fewer manufacturers, particularly in the generic injectable market.

Significant Price Spikes for Some Generic Drugs Are Jeopardizing Patient Access to Affordable and Effective Healthcare

- ✓ Although healthcare providers and the patients they serve have long relied on generic drugs to reduce costs and increase access to essential medications, HSCA and its member GPOs are increasingly seeing **significant price spikes for some generic drugs**.
- ✓ According to [one industry analysis](#), price increases for the top 20 non-GPO contracted generic drugs (in terms of annual spend), increased by an average of 413 percent from 2013-2015, with **some spikes in the thousands of percent**.
- ✓ In 2015, Turing pharmaceuticals [increased the price](#) of newly acquired pyrimethamine by more than **5000 percent**. Also in 2015, Valeant Pharmaceuticals [increased the price](#) of two common cardiac drugs – isoproterenol from \$440 to \$2,700 per vial, and nitroprusside from \$215 to \$650.

Persistent Drug Shortages and Barriers to Market Entry for New Suppliers Allow Opportunistic Manufacturers to Further Drive Up Prices

- ✓ The [FDA has continually identified](#) **manufacturing and quality control problems** as the primary cause of drug shortages. Despite some progress in slowing the number of new shortages, ongoing critical prescription drug shortages remain a public health threat.
- ✓ The FDA's backlog of abbreviated new drug applications (ANDAs) and its median review time for product approval have consistently grown – from 30 months prior to 2011, to 36 months in FY2013, to an estimated 42 months in FY2014. Approval times of up to 42 months can be **prohibitive for new manufacturers** who want to enter the market for drugs in shortage.
- ✓ Drug shortage situations give opportunistic manufacturers who remain in the market an opportunity to **further drive up prices**.

Increased Competition in the Generic Drug Market is Critical to Mitigating Price Spikes

- ✓ A July 2016 [Journal of the American Medical Association \(JAMA\)](#) report found that **at least four generic competitors are needed to ensure healthy markets**, and that many treatment fields fall short of this threshold – for example, only two-thirds of cancer drugs have at least one generic.
- ✓ While FDA does expedite review of abbreviated new drug applications for generic drugs with only one manufacturer – sometimes called ‘sole source’ products – **more must be done to bring new competitors into the generic market** and safeguard access to essential medications.
- ✓ A July 2016 report from the U.S. Government Accountability Office (GAO), “[Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Health Challenge](#),” found that **manufacturing and quality control problems** are the primary cause of drug shortages; that **increased competition from suppliers is part of the solution** to persistent shortages; and that **FDA priority review of applications for sterile injectable drugs** has been effective in addressing some shortages.

HSCA Supports Common-Sense Policy Solutions to Increase Competition in the Market

- ✓ HSCA and its member GPOs are committed to reducing costs and increasing competition and innovation in healthcare. As the **sourcing and purchasing partners to virtually all of America’s 8,000+ hospitals**, as well as the majority of the 68,000+ non-acute care facilities such as nursing homes, clinics, home health providers and surgery centers, GPOs have a unique line of sight on the entire healthcare supply chain.
- ✓ HSCA member GPOs are working to **identify and bring additional generic manufacturers to the market**, including small and emerging suppliers, and are providing longer-term contracts that reduce the risk of market entry by ensuring consistent, predictable and recurring demand.
- ✓ HSCA provided [direct feedback to the FDA](#) regarding the **collection of quality metrics from drug manufacturers**. Using quality metrics to monitor establishments involved in the manufacture, preparation, propagation, or processing of drugs will empower FDA to make critical decisions about risk-based scheduling, prediction of drug shortages, and related price spikes.
- ✓ HSCA [sent letters](#) to both the [Senate Special Committee on Aging](#) and the [Senate Health, Education, Labor, and Pensions \(HELP\) Committee](#) urging Congress to grant the FDA authority to **expedite review and approval of new generic drug applications** for products where there are two or fewer manufacturers, or in instances where they have already been price spikes.
- ✓ HSCA supports the **Increasing Competition in Pharmaceuticals Act (S.2615)**, bipartisan legislation aimed at creating a more competitive generic drug marketplace by mandating priority review of abbreviated new drug applications (ANDAs) for generic drugs made by just one manufacturer.
- ✓ As future opportunities to consider enhancements or additions to S.2615 arise, HSCA encourages Congress to **mandate priority review for generic injectable drugs with two or fewer manufacturers**. Generic injectables are the workhorses of acute care facilities and bring tremendous value to healthcare providers and the patients they serve. In its [July 2016 drug shortage report](#), GAO found that unique characteristics of the sterile injectable drug market – including a small number of suppliers, production complexity, and the regulatory approval process – may make these drugs more susceptible to shortages.