



July 18, 2017

Scott Gottlieb, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

**Re: Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting [Docket No. FDA-2017-N-3615]**

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments on increasing competition in the generic drug market as part of the U.S. Food and Drug Administration's (FDA) meeting, "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access."

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,700+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. We help our healthcare provider partners leverage their purchasing volume to negotiate competitive prices on healthcare products and services, helping to lower costs for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. [One report](#) estimated that between 2013 and 2022, GPOs will reduce healthcare spending by up to \$864 billion, while [an analysis](#) by former Federal Trade Commission Chair Jon Leibowitz recently found that GPOs reduced costs and promoted competition in the market for procurement services. GPOs deliver critical cost savings that allow healthcare providers to focus on their core mission: providing first-class patient care.

Significant price spikes for critical generic drugs and ongoing prescription drug shortages are jeopardizing patient access to care. Patients have long relied on generic drugs to reduce costs and increase access to essential medications, and price spikes for commonly used drugs create hardship for patients and providers alike.

HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. Given our unique line of sight over all aspects of the healthcare supply chain, HSCA suggests the following administrative and policy solutions to help increase access to generic drugs, to lift unnecessary regulatory burdens, and to streamline the FDA approval process.

**Generic Drug Price Spikes**

Price spikes often occur when a lack of competition among manufacturers allows high prices to go unchecked. To help increase competition in the market and prevent price spikes, HSCA supports prioritized FDA review of abbreviated new drug applications (ANDAs) for drugs with three or fewer

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approved alternatives. HSCA has supported proposed legislative solutions, including the bipartisan “Making Pharmaceutical Markets More Competitive Act” (S.1115), which would give priority review to ANDAs with not more than three alternatives and help streamline the process of additional manufacturers entering the generic drug market.

We applaud FDA’s recent action to increase generic drug competition by giving priority review to ANDAs for which there are three or fewer approved alternatives. As FDA takes additional steps to increase competition, we ask you to consider implementing a more specific timeline for such expedited reviews.

### **Shortages of Generic Injectable Drugs**

Generic injectable drugs are the workhorses of acute care facilities. Shortages for these drugs in particular cause significant challenges for patients and providers, and are exacerbated by the FDA backlog of ANDAs, which can delay product review by up to four years. As with generic drug price spikes, we encourage FDA to utilize its current authority to fast-track generic drugs, guaranteeing review of completed ANDAs and eliminating the backlog of ANDAs that have not yet been reviewed.

### **Manufacturing Shutdowns**

Due to the nature of generic injectable drugs, they require a rigorously-maintained manufacturing process. Manufacturers of these drugs sometimes shut down plants or specific lines for FDA-mandated CGMP improvements or 483 observations, even in instances where only small issues need improvement and where the remaining areas are functioning successfully. These shutdowns can lead to price spikes and shortages for drugs ranging from saline to chemotherapy treatments. Improved coordination between divisions at the FDA and a more rapid review of corrective actions taken by manufacturers would help moderate fluctuations in the supply and price of these necessary drugs.

### **Pay For Delay**

Some brand name pharmaceutical manufacturers are attempting to pay the manufacturer of the first generic alternative not to enter the market – i.e., “pay for delay” – thereby allowing the brand name drug to remain the only product on the market. This lack of competition delays patient access to cheaper alternatives. HSCA supports a legislative solution (S.124, “Preserve Access to Affordable Generics Act.”) that would eliminate the tactics that allow brand name manufacturers to prevent or delay generic manufacturers from entering the marketplace with competitor products.

### **Biosimilar Nomenclature**

Current FDA regulations allow for a unique four-digit suffix in the naming of biosimilar products. This arbitrary suffix may lead to clinician confusion and hinder the adoption of biosimilars by creating the mistaken impression that they will behave differently than their originator. We encourage FDA to eliminate the four-digit suffix for biosimilar products to promote competition in the market and reduce the possibility of confusion for clinicians and patients.

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### Supplemental Manufacturing Requests

Supplemental manufacturing requests – including requests to improve, modernize, or expand manufacturing – are currently treated as ANDAs, which significantly delays their review and approval. Additionally, the FDA has sometimes been unresponsive to questions and requests about the pending applications, which further slows down the approval process. Supplemental manufacturing requests should be handled separately from ANDAs, and should only be evaluated on the areas that will be changed or enhanced. By expediting these supplemental requests, manufacturers will be able to produce drugs more efficiently.

### FDA and REMS Loopholes

Some brand name drug manufacturers are exploiting a loophole in the FDA’s Risk Evaluation Mitigation Strategies (REMS) program to prevent generic and biosimilar manufacturers from accessing the product samples they need to obtain FDA approval and market entry. HSCA supports policy solutions, including the “FAST Generics Act of 2017” (H.R. 2051) and the “CREATES Act” (S.974), that provide generic and biosimilar drug manufacturers with a clear and efficient pathway to obtain samples and to combat these anticompetitive practices, and empower courts to award damages to the affected generic and biosimilar manufacturers.

We appreciate the opportunity to provide our perspective and we look forward to continuing to work with FDA to increase generic drug competition. Please do not hesitate to contact me directly should you have any questions or if HSCA can be a resource in the future. I can be reached at (202) 629-5833 or [tebert@supplychainassociation.org](mailto:tebert@supplychainassociation.org).

Sincerely,

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Healthcare Supply Chain Association

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