HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

December 20, 2016

Honorable Donald J. Trump
President-Elect
1717 Pennsylvania Avenue, NW
Washington, DC 20006

Dear Mr. President-Elect:

On behalf of the Healthcare Supply Chain Association (HSCA), I write to congratulate you on your recent election as the 45th President of the United States. We look forward to working with you and your Administration to improve the nation's healthcare delivery system.

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 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. The value that GPOs deliver allows healthcare providers to focus on their core mission: providing first-class patient care.

At a moment of great change for the healthcare system, American hospitals and their patients face uncertainty and significant new challenges. The American Hospital Association (AHA) and Federation of American Hospitals (FAH) recently estimated that the financial impact on hospitals of repealing the Affordable Care Act (ACA) without a replacement and without eliminating scheduled reimbursement reductions could be hundreds of billions of dollars. We believe that Congress and the Administration should carefully consider the full range of consequences of repealing the ACA without a simultaneous replacement plan that continues to provide coverage to consumers and does not disrupt state budgets.

Especially during this time of transition, HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. GPOs advocate for common-sense, innovative, market-based solutions to help providers confront the myriad challenges facing the healthcare supply chain. I wanted to bring to your attention several policy priorities that HSCA supports that will help reduce costs and increase competition and innovation in the healthcare market.

Generic Drug Price Spikes

As you know, prescription drug prices have been one of the leading drivers of overall healthcare costs. Patients have long relied on generic drugs to reduce costs and increase access to essential medications.

Recently, however, significant price spikes for some generic drugs have begun to jeopardize patient access to affordable healthcare. We applaud your recent statements underscoring the need to address this public health crisis and we look forward to working with you specifically on this issue given our previous work to address price spikes and our unique expertise in health care supply chain costs, including pharmaceutical costs.

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. The current backlog for abbreviated new drug applications (ANDAs) at the U.S. Food and Drug Administration (FDA) has exacerbated the problem of price spikes. The median review time for product approval has consistently grown – from 30 months prior to 2011, to 36 months in 2013, to an estimated 42 months in 2014. A three- or four-year wait time for approval stifles the ability of manufacturers who want to introduce competition in the generic market.

HSCA and its members have and will continue to advocate for policy solutions that would mandate priority review of ANDAs for products when significant price spikes occur. **Specifically, mandatory priority review should occur when a product's price increases at a rate of more than five times the percent change that occurred in the Prescription Drugs Index of the Consumer Price Index for the previous year.** The marketplace responds best when more than two manufacturers compete to create a natural price reduction for consumers. We look forward to working with your Administration, and specifically with the FDA to advance this pressing policy priority and help spur competition through market-based solutions.

Drug Shortages

Despite a decline in new drug shortages, existing and ongoing prescription drug shortages continue to be a public health crisis and jeopardize patient access to essential medications. The FDA, Government Accountability Office (GAO), Congress, academia, and others, have thoroughly examined the issue of drug shortages and identified manufacturing problems, quality control issues, and barriers to getting new suppliers online as the primary causes of shortages.

GPOs are industry leaders in addressing drug shortages and are currently working collaboratively with hospitals, manufacturers, distributors, the Department of Health and Human Services (HHS) and the FDA to ensure that hospitals and patients have access to the life-saving drugs they need.

HSCA and its members are taking a number of innovative steps to help combat shortages. GPOs operate as an advance warning system to the supply chain with respect to drug shortages. They track data on drug shortages and strategize with their hospital members when there is potential for supply disruption. GPOs help lessen hospital exposure to shortages by evaluating manufacturer reliability when awarding contracts, and work to identify additional manufacturers who can reliably produce the needed supply. In the event of shortages, GPOs help hospitals locate, source and safely migrate to alternative products where possible. GPOs work with their supplier partners to communicate product demand so they have advance notice to plan for production capacity.

GPO contracts are voluntary, competitively negotiated, and provide predictability and stability to both hospitals and suppliers. Hospitals and other providers are always free to purchase outside of their GPO arrangement and frequently do. When manufacturers experience shocks to production, such as higher input price, they regularly work with GPOs to adjust contract pricing.

Biosimilars

Biosimilar drugs have the potential to increase patient access to life-saving treatments and to reduce costs for the entire healthcare system. One recent study projected that biosimilars would save the system $250 billion over ten years. HSCA and its members are working with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies.

HSCA believes that reference biologics and their biosimilars should share the same International Nonproprietary Name (INN). The FDA has proposed unique suffixes for biosimilars; however, HSCA is concerned that suffixes might lead to clinician confusion and hinder adoption of biosimilars by creating the mistaken impression that a biosimilar product will behave differently than its originator.

The ability to safely substitute FDA-approved biosimilars for reference biologics will be critical to realizing the full cost-savings and access potential of biosimilars. It is important for the FDA to issue clear and robust guidance on the requirements for a biosimilar product to obtain an "interchangeable" designation. FDA's guidance on interchangeability will have an impact on state level substitution and, ultimately, provider and patient access to biosimilars.

Risk Evaluation and Mitigation Strategies (REMS) Program and the "CREATES" Act (S. 3056)

The FDA's Risk Evaluation and Mitigation Strategies (REMS) program serves a compelling public good by ensuring that the benefits of a drug outweigh its safety risk and by making important information available to patients and providers. However, some brand pharmaceutical manufacturers have exploited a loophole in the law to impede patient access to generic medicines and increase healthcare costs.

HSCA supports the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act," (S. 3056) which would help give generic and biosimilar manufacturers a clear and efficient pathway to market. The bill targets two forms of anticompetitive behavior: refusal to provide adequate samples to gain provide approval and denying generic and biosimilar access into an FDA approved single-shared REMS program. Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset.

We appreciate the opportunity to provide you and your healthcare team with information on our industry, policy priorities, and commitment to reducing costs and increasing competition and innovation in the market. We would welcome the opportunity to meet with the appropriate members of your transition team and we look forward to working with your Administration to confront the challenges facing the healthcare system.

We have enclosed for your review information about our members. If you would like any additional information, or if we can be a resource to your Administration, please do not hesitate to ask your staff to contact me directly. HSCA would very much welcome the opportunity to participate in a Healthcare Listening Session with transition officials. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org.

Sincerely,

Todd Ebert

Todd Ebert, R.Ph.
President and CEO