



November 19, 2015

Senator Susan Collins
Chairman
U.S. Senate Special Committee on Aging
413 Dirksen Senate Office Building
Washington, DC 20510

Senator Claire McCaskill
Ranking Member
U.S. Senate Special Committee on Aging
506 Hart Senate Office Building
Washington, DC 20510

Re: Generic Drug Price Spikes

Dear Chairman Collins and Ranking Member McCaskill:

We are writing in regard to recent price spikes in the generic drug market and their potential impact on healthcare providers and the patients they serve. We applaud your leadership in addressing this critical issue facing the healthcare supply chain.

The Healthcare Supply Chain Association's (HSCA) member group purchasing organizations (GPO) are crucial cost-savings and sourcing partners to America's hospitals, clinics, nursing homes, and surgery centers. GPOs leverage the buying power of members to secure significant discounts and obtain the best products at the best value on their behalf. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. We are concerned that generic price spikes and their effects – including making life-saving medications unaffordable for some patients – are an enormous risk to public health.

We have recently seen significant spikes for generic drugs where there are two or fewer manufacturers in the market, and where a lack of competition among manufacturers has allowed high prices to go largely unchecked. Limited manufacturing options also means that quality control problems and disruptions to manufacturing can jeopardize supply and give rise to drug shortage situations.

Compounding the problem of price spikes is the current backlog of new generic drug applications at the U.S. Food and Drug Administration (FDA). Since the Generic Drug User Fee Act (GDUFA) was negotiated in FY2011, the FDA's backlog has continually risen along with its median review time for product approval. A private sector survey revealed that prior to GDUFA, review time for an Abbreviated New Drug Application (ANDA) was 30 months. In FY2013, that time had risen to 36 months, and in FY2014 was estimated to be 42 months. A wait time of 3-4 years is currently stifling the ability of manufacturers who want to reintroduce competition to the generic market where there are currently limited manufacturers and help mitigate price spikes.

HSCA MEMBER COMPANIES

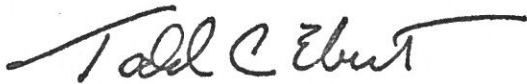


HSCA has been working with the Senate Committee on Health, Education, Labor and Pensions (HELP) as members address these important issues. Due to our unique role and position in the healthcare supply chain, our members often see early warning signs of potential price spikes. As a result, HSCA has proposed a set of practical measures to help mitigate spikes – specifically, giving FDA authority to expedite review of ANDAs in instances where there are only one or two manufacturers for a product or in instances where there have been recent spikes.

We look forward to working with you as the Aging Committee continues to examine this important policy concern. HSCA and its members have seen firsthand the effects and implications of price spikes on the overall healthcare delivery system. We support your search for potential solutions and believe that HSCA can be a valuable resource to help increase competition, reduce costs for providers, and help preserve patient access to affordable and life-saving medicines.

Please do not hesitate to contact me directly should you have any questions. I can be reached at 202.367.1162 or tebert@supplychainassociation.org.

Sincerely,

A handwritten signature in black ink that reads "Todd C. Ebert". The signature is fluid and cursive, with a long horizontal stroke at the end.

Todd Ebert, R. Ph.
President and CEO
Healthcare Supply Chain Association

cc: Members of the U.S. Senate Special Committee on Aging