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Media Contact: Vanessa Descalzi
202-759-9614
VanessaDescalzi@rational360.com

HSCA URGES CONGRESS TO TAKE ACTION TO ADDRESS GENERIC DRUG PRICE SPIKES

HSCA Sends Letters to Senate Aging and HELP Committees Calling for FDA Authority to Expedite Review of Drugs with Potential to Mitigate or Avoid Price Spikes

Washington, DC (December 1, 2015) – The Healthcare Supply Chain Association ([HSCA](#)) today urged Congress to address price spikes in the generic drug market by granting the U.S. Food and Drug Administration (FDA) authority to expedite review and approval of new drug applications for products where there are two or fewer manufacturers, or in instances where there have already been price spikes. HSCA recently [sent letters to the Senate Special Committee on Aging](#) and [the Senate Health, Education, Labor, and Pensions \(HELP\) Committee](#) encouraging Congress to take specific action to help ensure a healthy generic market and safeguard patient and provider access to essential medications.

“Significant recent price spikes in the generic drug market are an enormous risk to public health and are jeopardizing patient access to affordable healthcare,” said HSCA President and CEO Todd Ebert, R. Ph. “HSCA and its member group purchasing organizations are committed to lowering costs and increasing competition in the healthcare marketplace. We urge Congress to give FDA authority to expedite review and approval for new generic drugs that have the potential to mitigate price spikes and help ensure access to critical medications for healthcare providers and the patients they serve.”

HSCA members have recently seen price spikes for many widely used generic drugs. In less than two years, for example, the price of two important generic cardiac drugs increased by over 2,700 percent. Additionally, one generic anti-parasitic compound recently surged to a 4,522 percent price increase.

“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 exacerbate the ongoing problem of drug shortages,” said Ebert in the HSCA letter to the Senate Special Committee on Aging.

The current backlog of Abbreviated New Drug Applications (ANDA) at the FDA is compounding the problem of price spikes. 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 ANDAs was 30 months. In FY2013, that

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time had risen to 36 months, and in FY2014 was estimated to be 42 months. A wait time of 3-4 years stifles the ability of some manufacturers who want to reintroduce competition to the generic market.

“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,” added Ebert in the HSCA letter to the Senate Special Committee on Aging.

“We applaud [the Senate HELP Committee] for your previous efforts to address critical drug shortages, including giving FDA the authority to ‘fast track’ new drug applications to help mitigate or prevent shortages. We urge you to pass legislation granting FDA the same authority for generic drugs experiencing price spikes or those for which there are only one or two manufacturers. Doing so will help increase competition, reduce costs for providers, and preserve access in the generic drug market,” said Ebert in the HSCA letter to the Senate HELP Committee.

To view the full letters click [here](#) and [here](#).

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About the Healthcare Supply Chain Association (HSCA)

The Healthcare Supply Chain Association (HSCA) represents the nation’s leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America’s hospitals, nursing homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers, to increasing competition and innovation in the market, and to being supply chain leaders in transparency and accountability. For more information, visit www.supplychainassociation.org. Follow HSCA on Twitter @HSCA.