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HSCA STATEMENT ON SENATE HELP COMMITTEE HEARING ON GDUFA AND ACCESS TO GENERIC DRUGS

*Healthcare Supply Chain Association Urges Congress to Grant FDA Authority to Expedite Review of
Drugs with Potential to Mitigate or Avoid Price Spikes*

Washington, DC (January 28, 2016) –Healthcare Supply Chain Association ([HSCA](#)) President and CEO Todd Ebert, R.Ph., today released the following statement about the Senate Health, Education, Labor, and Pensions (HELP) Committee’s hearing “Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs” featuring Janet Woodcock, Director of the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA):

“We applaud the Senate HELP Committee for their commitment to mitigating price spikes in the generic drug market – a trend that poses enormous risk to public health by jeopardizing patient access to affordable healthcare. While the Generic Drug User Fee Act (GDUFA) was designed to speed public access to – and reduce costs of – generic drugs, since its implementation the FDA backlog for new generic drugs has grown, and some opportunistic suppliers have driven up their prices as a result of little-to-no competition. It is essential that new manufacturers are able to enter the market in a timely manner to help increase competition and reduce costs. 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.”

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 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 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.

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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

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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.

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