HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION

July 25, 2017

Hon. Tom Marino
Chair, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Re: HSCA Support for H.R. 2212, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of the Healthcare Supply Chain Association (HSCA), I am writing in support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), bipartisan legislation that will increase competition and patient access to safe and affordable generic and biosimilar medicines. We applaud you for your leadership on this critical issue and urge the Committee to mark-up the bill and move it to the House floor promptly.

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. GPOs deliver critical cost savings that allow healthcare providers to focus on their core mission: delivering first-class patient care.

Significant price spikes for critical generic drugs are jeopardizing patient access to care. HSCA and its members have a unique line of sight over all aspects of the healthcare supply chain, and we advocate for policy solutions that lower costs and increase competition and innovation in the healthcare marketplace.

Some brand name drug manufacturers are currently exploiting a loophole in the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) program to prevent

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generic and biosimilar manufacturers from accessing the product samples they need to obtain FDA approval and market entry. The impact of this practice is to hinder competition and prevent safe, affordable generic and biosimilar medicines from entering the market at the earliest possible date.

Although the FDA has identified this anti-competitive practice as "a problem" that "delays the availability of generics,"[1] the Agency currently does not have the authority to prevent the abuse of REMS and restricted access programs.

Congressional action is necessary to ensure that a small handful of brand manufacturers do not prevent generic drug developers from obtaining the samples necessary to bring new accessible generic and biosimilar drugs to patients and payers. The bipartisan CREATES Act (H.R. 2212) would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics.

Thank you for holding this important hearing. We appreciate the opportunity to provide our perspective. Please do not hesitate to contact me directly should you have any questions or if HSCA can be a resource. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org.

Sincerely,

Todd Ebert

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

[1] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.