



March 27, 2019

The Honorable Frank Pallone
Chairman
Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20510

The Honorable Greg Walden
Ranking Member
Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20510

Dear Chairman Pallone and Ranking Member Walden,

I am writing to you on behalf of the Healthcare Supply Chain Association (HSCA) to thank you for your continued leadership on the important issue of drug pricing and the pressing need to stop anti-competitive abuses that keep drug prices high. HSCA shares your belief that a competitive marketplace will lower the price of generic drugs and help ensure that price spikes for critical generic drugs do not jeopardize patient access to care.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,000+ 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.

HSCA and its members consistently advocate for policy solutions that lower costs and increase competition and innovation in the healthcare marketplace. Two years ago, HSCA advocated for priority U.S. Food and Drug Administration's (FDA) review of abbreviated new drug applications (ANDAs) for drugs with three or fewer approved alternatives, which was subsequently included as provision in the FDA Reauthorization Act of 2017. The provision allows more generic drugs to enter the marketplace at a faster pace, providing patients with more affordable alternatives to brand name medications. The expedited ANDAs review was an important step; however additional actions by Congress are still necessary to increase competition in the generic drug market.

Given our unique line of sight over the entire health care supply chain, HSCA and its member GPOs respectfully recommend the following:

HSCA MEMBER COMPANIES



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HSCA Supports the ‘Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act’ (H.R. 965) to End REMS Loopholes and Increase Generic Drug Access

Some brand name drug manufacturers are currently exploiting a loophole in the FDA Risk Evaluation and Mitigation Strategy (REMS) program to prevent 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,” the Agency currently does not have the authority to prevent the abuse of REMS and restricted access programs.

HSCA supports the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 965), bipartisan legislation that will increase competition and patient access to safe and affordable generic and biosimilar medicines. 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. 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 Supports the ‘Protecting Consumer Access to Generic Drugs Act of 2019’ (H.R. 1499) to Combat Manufacturer Pay-for-Delay Tactics

We also support the Protecting Consumer Access to Generic Drugs Act of 2019 (H.R. 1499) to help end manufacturer pay-for-delay tactics. Some brand name pharmaceutical manufacturers are attempting to pay manufacturers of the first generic alternative not to enter the market – i.e., “pay-for-delay” – thereby allowing the brand name drug to remain the only product on the market. This lack of competition delays patient access to cheaper alternatives. The Protecting Consumer Access to Generic Drugs Act would eliminate the tactics that allow brand name manufacturers to prevent or delay generic manufacturers from entering the marketplace with competitor products. Once again, we urge the Committee to mark-up the bill and move it to the House floor in a timely manner.

Please let us know if HSCA can be a resource to you and your staff in regard to these issues, and we appreciate the opportunity to provide our perspective. We look forward to continuing to work with you and your office to help shape the right kind of healthcare reforms that will increase the quality of care and reduce costs across the board.

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.

HSCA MEMBER COMPANIES





Sincerely,

Todd Ebert, R.Ph.
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Healthcare Supply Chain Association

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