



**American Hospital
Association®**

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April 27, 2017

The Honorable Patrick Leahy
Committee on the Judiciary
United States Senate
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Senator Leahy:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) is pleased to express our support the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017.

One of the AHA's top priorities is achieving fair and sustainable drug pricing. Access to medication for patients is critical, and the inability to afford that medication because of high prices charged by drug manufacturers is a fast growing problem. We regularly hear from hospitals and health systems across the country about sharply rising drug prices and the financial stress it puts on patients, hospitals and health systems.

The AHA supports policies to advance sustainable and fair drug prices while encouraging innovation of new therapies. These policies reflect our assessment that the challenge of high and rising drug prices is multi-faceted, and there is no one solution that will enable us to achieve the objectives.

Generic drugs are one tool for reducing drug prices, as they increase competition to the monopoly enjoyed by drug manufacturers after a drug's patent expires.

The CREATES Act targets two forms of anticompetitive behavior that are being used to block and delay entry of generic drugs. The first is known as sample-sharing. This occurs when brand-name drug companies refuse to sell samples of their product to potential generic competitors so the generic company cannot perform testing to show that its product is bioequivalent to the brand-name product, a prerequisite for approval by the Food and Drug Administration (FDA). The second involves participation in a shared safety protocol. This occurs when brand-name manufacturers whose products require a distribution safety protocol refuse to allow generic competitors to participate in that safety protocol, which is needed to gain FDA approval.



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The CREATES Act allows a generic drug manufacturer facing the sample-sharing delay tactic to bring an action in federal court for injunctive relief, such as to obtain the sample it needs. The bill also authorizes a judge to award damages to deter future delaying conduct.

America's hospitals appreciate your ongoing leadership on addressing the problem of drug prices. We are grateful for the willingness of the bill's authors and their staff to work with the health care field to find solutions, and we appreciate the opportunity to continue that critical work.

Please contact me if you have any questions or feel free to have a member of your team contact Robyn Bash, vice president for government relations and public policy operations, at rbash@aha.org or (202) 626-2672.

Sincerely,

//s//

Thomas P. Nickels
Executive Vice President