American Hospital Association

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June 14, 2016

The Honorable Patrick Leahy
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Ranking Member Leahy,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) is pleased to support the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016.

Achieving fair and sustainable drug pricing is a priority for the AHA. Patients must have access to needed medication, and the inability to afford that medication because of high prices charged by drug manufacturers is a real and growing problem. We continue to hear from hospitals and health systems across the country about sharply rising drug prices and the financial stress it puts on patients and hospitals.

Last August, the Centers for Medicare & Medicaid Services estimated that the annual rate of increase in national spending on drugs accelerated to 12.6 percent higher in 2014 than the previous year. In May, the IMS Institute for Healthcare Informatics estimated that drug spending nationwide increased by 8.5 percent in 2015 over 2014 – more than any other year in the past decade except for the double-digit spike in 2014.

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.

The CREATES Act allows a generic drug manufacturer facing one of these delay tactics to bring an action in federal court for injunctive relief (such as to obtain the sample it needs or to enter court-supervised negotiations for a shared safety protocol). The bill also authorizes a judge to award damages to deter future delaying conduct.

America's hospitals appreciate your 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 work as this bill moves to Committee mark-up and floor consideration.

If you have any questions, please contact Robyn Bash, vice president for government relations and public policy operations, at rbash@aha.org or (202) 626-2672.

Sincerely,

/s/

Tom Nickels
Executive Vice President