CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

NEIL L. BRADLEY
EXECUTIVE VICE PRESIDENT &
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May 20, 2019

The Honorable Thom Tillis
United States Senate
Washington, DC 20510

The Honorable Bill Flores
U.S. House of Representatives
Washington, DC 20515

The Honorable Patrick Leahy
United States Senate
Washington, DC 20510

The Honorable David Cicilline
U.S. House of Representatives
Washington, DC 20515

Dear Senators Tillis and Leahy and Representatives Flores and Cicilline:

The U.S. Chamber of Commerce commends your efforts to reduce prescription drug prices, while preserving a system of innovation for new cures. In that context, the Chamber supports both the Hatch-Waxman Integrity Act of 2019 and the CREATES Act of 2019.

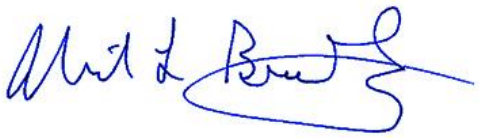
The 1984 Hatch-Waxman Act created a pathway for expedited approval and market entry of generic medicines, leading to a market for prescription medicines that is ninety-percent supplied by lower cost generics, while preserving the innovator rights that have made the United States the world leader in the delivery of new, life-saving medicines. Subsequently, the America Invents Act of 2011 created the inter partes review, or ("IPR"), process as an administrative alternative to the courts for challenges to the validity of a patent in any industry sector.

The Hatch-Waxman Integrity Act of 2019 ("HWIA") would amend the Federal Food, Drug, and Cosmetic Act and the Securities Exchange Act of 1934 to require a generic manufacturer wishing to challenge a bio-pharmaceutical patent to choose between the Hatch-Waxman framework, which affords certain advantages, such as being able to rely on the drug innovator's safety and efficacy studies for FDA approval, and the IPR, which is cheaper and faster than Hatch-Waxman litigation, but does not provide the advantages of a streamlined generic approval process. The legislation would preserve Hatch-Waxman as the standard path for generic manufacturers to challenge innovator's patents, while retaining IPR as an option, eliminating the costs and uncertainty associated with redundant challenges.

The Creating and Restoring Equal Access to Equivalent Samples Act of 2019 ("CREATES") would further promote competition in the market for drugs and biological products by facilitating the prompt entry of lower-cost generic and biosimilar versions of those drugs and biological products through ensuring the timely availability of innovator drug samples for generic manufacturers on commercially reasonable terms.

Taken together, these two bills enhance the strengths of, and address imbalances in, the innovator-generic pathway to promote access to innovative and affordable medicines. The Chamber looks forward to working with you and other Members of Congress to advance these goals.

Sincerely,



Neil L. Bradley