Statement of Senator Patrick Leahy (D-Vt.)
Ranking Member, Senate Judiciary Committee
Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on
"The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition"
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In recent months, the high cost of prescription drugs has been front and center in national news. Last year, American consumers learned of the unconscionable price-hike by Turing of their drug for HIV patients. New owners of that company increased the price of their medicine from $13.50 to $750 per pill overnight, an increase of 5000 percent. Think for a moment about the impact of a price hike like that on the family of a patient facing a life-threatening illness. Across the country, hard-working Americans feel like the system is rigged against them by corporations that are looking to make a profit at any price. With examples like Turing, it is no wonder they feel that way.

The legislation I have introduced with Senators Grassley, Klobuchar and Lee addresses anticompetitive conduct that helped Turing drive up its prices. Our CREATES Act targets predatory delay tactics that some brand-name drug manufacturers are using to block competition from more affordable generic drugs.

The first delay tactic addressed by the CREATES Act involves the withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition. The FDA has reported receiving more than 100 inquiries from generic product developers who were unable to access samples of a brand-name drug to compare their generic product.

The second delay tactic addressed by the CREATES Act involves the development of shared safety protocols. For some high-risk drugs, federal law requires a generic drug manufacturer to join the brand-name drug manufacturer in a single, shared safety protocol for distribution of the drug. Despite this requirement, some brand-name companies are refusing to negotiate a shared safety protocol with potential generic competitors, again undermining those competitors' ability to gain FDA approval for their generic version of the drug.

The practices addressed by the CREATES Act thwart competition and deny consumers the benefit of lower drug prices. They also undermine the careful balance created in the Hatch-Waxman Act and the more recent Biologics Price Competition and Innovation Act, which are designed to reward and incentivize innovation while ensuring that consumers ultimately benefit, after a certain time, from the entry of generic or biosimilar versions of a drug.

Pharmaceutical companies should be compensated for their important work developing life-saving treatments. But when companies engage in predatory practices at the expense of consumers, we must act. Our bill creates a sensible, efficient way for generic drug manufacturers to address these delays without jeopardizing patient safety or creating protracted litigation in the courts.

I share the concerns of Vermonters and Americans across the country that many prescription drugs are simply too expensive for consumers. When brand companies can drive up the price of drugs by using predatory practices, patients suffer. Illnesses get worse. Families, government programs, and other payers in the healthcare system ultimately bear those added, unnecessary costs.

The CREATES Act is supported by consumer groups, physicians, pharmacists and hospitals who all see firsthand the impact of the high costs of prescription drugs. I thank them for working with us on this legislation, as well as the antitrust experts and medical professionals who helped ensure it is an effective, narrowly-tailored bill.

Unfortunately, this legislation is not a silver bullet to address all of the complex problems driving the high costs of medications. In addition to the delayed entry of generic drugs, I am troubled by the rising cost of treatments for opioid overdoses, which remain expensive for local law enforcement even though there are generic competitors. In Vermont, many patients are grappling with the extremely high cost of a new drug for Hepatitis C that will likely have years of market exclusivity before generic alternatives can be made. The Judiciary Committee has jurisdiction over intellectual property policy, and we recognize the importance of ensuring that pharmaceutical companies can recoup the expensive costs of their research so they can continue to develop new treatments. We also recognize that other participants in the supply chain and other factors contribute to the high cost of prescription drugs. But patients are struggling. We must find thoughtful solutions to address the impossibly high prices of some prescription drugs.

With the CREATES Act, the bipartisan leaders of the Judiciary Committee and its Subcommittee on Antitrust, Competition Policy and Consumer Rights are contributing one piece of the puzzle by addressing anticompetitive behavior that delays the creation of affordable generic drugs. I hope other members both on and off this Committee will work with us on thoughtful, bipartisan solutions to address the high costs of prescription drugs.

I thank Senators Grassley, Klobuchar and Lee for joining me in this effort and for holding this hearing on our bill. I look forward to the witnesses' testimony.

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