

# U.S. Rep. Sensenbrenner: Bipartisan drug pricing bills clear House Committee unanimously

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**Washington, D.C.** - During today's markup, the House Judiciary Committee passed two bills sponsored by Congressman Jim Sensenbrenner [WI-05] aimed at lowering drug costs. The CREATES Act and Stop STALLING Act both passed out of the committee unanimously.

**Rep. Sensenbrenner:** *"I'm proud to be a leader in this bipartisan push to lower drug prices and bring relief to the American people. By holding accountable those who game the system, we can find market-based solutions that make prescription medicines more affordable. I thank Chairman Cicilline and Congressman Jeffries for joining me in this effort."*

## **Background on the legislation courtesy of the House Judiciary Committee:**

### **H.R. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act**

(Sponsored by Congressmen Jim Sensenbrenner and David Cicilline [RI-01])

In order for a generic or biosimilar prescription to have FDA approval, the generic manufacturer must be able to compare its product to the brand-name product. Simply put, if the product is as safe and effective as the label, then the FDA can approve the generic.

Some generic manufacturers, however, have difficulty obtaining samples of

medication from the brand-name company. This is because brand-name companies have an incentive to make it difficult for generic producers to obtain their brand-name products.

The CREATES Act gives generic manufacturers the ability to bring actions in federal court against brand-name companies that refuse to provide samples of their products for purchase and use in the generic approval process. In so doing, the CREATES Act helps to increase the likelihood of a generic product coming to the market so consumers have more affordable options.

The CREATES Act also gives the FDA more discretion for approving alternative safety protocols that meet the statutory standards already in place. This helps the FDA more efficiently process generic applications. In the end, this helps consumers, who will have greater choice when selecting their medications.

According to a Congressional Budget Office estimate, the CREATES Act will save the federal government \$3.9 billion on prescription spending.

More than 90 organizations representing consumers, physicians, pharmacists, hospitals, insurers, antitrust experts, and other support the CREATES Act. Supporters include AARP, Campaign for Sustainable Rx Pricing, Consumer Reports, Public Citizen, American Hospital Association, America's Health Insurance Plans, Patients for Affordable Drugs, and the Coalition for Affordable Prescription Drugs.

### **H.R. 2374, the Stop Significant and Time-wasting Abuse Limiting Legitimate Innovation of New Generics (Stop STALLING) Act**

(Sponsored by Congressmen Jim Sensenbrenner and Hakeem Jeffries [NY-08])

Individuals or companies can submit citizen petitions to voice concerns about a drug that could receive FDA approval. Because the FDA must respond to every petition it receives, bogus petitions often delay a generic drug from coming to market.

When used appropriately, citizen petitions allow all Americans to raise legitimate health and safety concerns, but prescription drug companies game the system by submitting numerous or baseless bogus citizen petitions to protect their market share unfairly. The Stop STALLING Act clarifies that such anticompetitive petitions are illegal under the Federal Trade Commission (FTC) Act.

The Stop STALLING Act also strengthens the FTC's ability to challenge bogus

petitions in court. This allows citizen petitions to continue serving their intended purpose while simultaneously deterring anticompetitive delays in the form of citizen petitions.