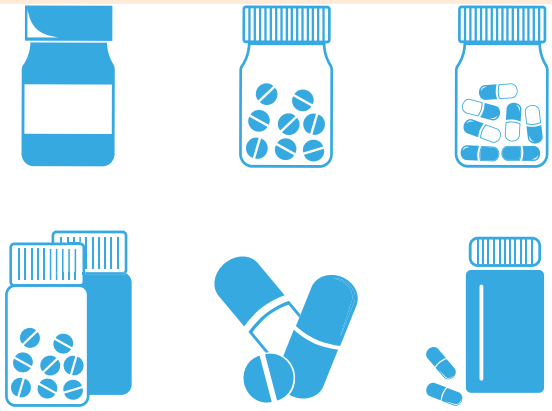
BlueCross BlueShield Association



Congress Should Pass the CREATES Act to Improve Access to Lower-Cost Rx Drugs

Bipartisan legislation – the CREATES Act (H.R. 2211/ S. 974) – would bring lower-cost generics to consumers.

KEY FACTS

CBO estimates the CREATES Act will produce **$3.8B** IN SAVINGS to the federal government.

Average cost of generic drugs is **80-85%** LOWER than the brand-name product.

Savings from generics totaled **$1.67** TRILLION from 2007-2016

BCBSA RECOMMENDS

BCBSA urges Congress to act quickly to pass the CREATES Act as an important step in improving consumer access to generic drugs by discouraging abuses in the prescription drug market. Action is needed now because:

1 DOZENS OF DRUG MANUFACTURERS ARE BLOCKING GENERICS

- Generic drug manufacturers need access to brand products to develop safe, effective and lower-cost generic alternatives and receive FDA approval.
- The FDA cited more than 40 brand drug manufacturers that are inappropriately refusing to sell, collectively, more than 50 drugs to generic manufacturers – preventing competition and impeding consumer access to lower-cost medicines. These manufacturers raised their drug prices by double-digits since 2012 and delayed generic completion, resulting in Medicare and Medicaid spending $12 billion in 2016 on these drugs alone.

2 A COMPETITIVE MARKET BRINGS SAVINGS FOR FAMILIES, EMPLOYERS, AND TAXPAYERS

- Consumers expect clinicians to be able to prescribe and health plans to cover lower-cost generics, but that access is not possible if some drug manufacturers use tactics that delay entry of generic medicines to the market.
- Consumers will realize lower drug costs and more drug choices and the federal government will see significant cost savings when manufacturers compete fairly in the market.

3 FEDERAL AGENCIES AGREE A SOLUTION IS NEEDED

- FDA Commissioner Scott Gottlieb has called on drug manufacturers to "end the shenanigans" that delay generics from entering the market, including manufacturer tactics that "frustrate or block the sale of a branded drug to a generic firm." Another FDA official testified to Congress that they have received 150 "inquiries" from generic product developers stating difficulty in purchasing brand drugs.
- FTC Chairwoman Edith Ramirez indicated that "this conduct undermines the careful balance created by the Hatch-Waxman Act to encourage generic entry, and may violate the antitrust laws."

4 THE CREATES ACT PROVIDES A SAFE, EFFICIENT PATHWAY TO END ANTI-COMPETITIVE PRACTICES

- The CREATES Act requires the FDA to grant authorization to access brand drug samples only to those generic manufacturers that demonstrate patient safety protections are in place.
- This bill creates a narrow, legal avenue for generic manufacturers to seek injunctive relief and capped monetary damages when a brand company refuses to sell its product. Generic manufacturers will develop lower cost alternatives and consumers will benefit when brand manufacturers are forced to the table.