

Many Health-Care Groups Laud Generics Bill

April 19, 2017

By [Christine Blank, Contributing Editor](#)

CVS Health, Express Scripts, and several other health-care groups or PBM, praised a bill in Congress that targets anticompetitive behavior by brand drug manufacturers; behavior intended to stifle generic and biosimilar competition.

The “Fair Access for Safe and Timely Generics Act of 2017” or the “FAST Generics Act of 2017” was introduced by Reps. Peter Welch (D-VT), and David McKinley (R-WV) in early April. Similar legislation had been introduced in Congress three times previously, but failed to pass.

CVS Health, Express Scripts, AARP, the Association for Accessible Medicines (AAM), the Academy of Managed Care Pharmacy, the Blue Cross Blue Shield Association, and other organizations wrote a [letter](#) in support of the bill to McKinley and Welch. “Certain companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to samples of brand products that are needed to obtain FDA approval and market entry,” they said in the letter. Nearly twenty companies or organizations involved in health care signed the letter.

“Many of these restricted distribution setups are implemented completely independently from FDA mandates, and exist solely to exert control of who purchases the product. These abuses are growing and the resulting delay in generic and biosimilars competition is costing patients, the federal government, and the health care system billions of dollars annually,” the letter said.

Abusing these restricted access programs to prevent generic competition costs the health-care system \$5.4 billion annually, including \$1.8 billion from the federal government, the letter stated, citing a 2014 analysis by Matrix Global Advisors. In addition, the Congressional Budget Office estimated that similar legislation would save government more than \$2 billion in direct savings over 10 years.

The FAST Generics Act targets two forms of anticompetitive behavior used by some brand manufacturers, according to the groups: refusal to provide adequate samples to gain approval, and denying generic and biosimilar access to an FDA-approved single shared risk evaluation and mitigation strategy program.

“Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset,” the letter noted. The legislation also aims to ensure patient safety “by requiring that only appropriate manufacturers receive these samples through an affirmative authorization from FDA that satisfies any relevant safety concerns, the letter said.

“This is a first step towards tearing down the walls blocking generic drugs from reaching patients and taking real action to lower costs,” Chester “Chip” Davis, Jr., president and CEO of AAM, said in a statement. Legislation such as the FAST Generics Act help to unleash the full

potential of the emerging biosimilars market, added Bruce Leicher, chair of The Biosimilars Council, a division of AAM.