# ‘FAST’ Generics Act Seeks to Thwart Abuse of FDA Safety Programs

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A bipartisan House bill introduced on Friday seeks to stop pharmaceutical companies from blocking generic competitors by abusing US Food and Drug Administration (FDA) safety programs.

The “Fair Access for Safe and Timely Generics Act of 2017,” or “FAST Generics Act of 2017,” introduced by Reps. David McKinley (R-WV) and Peter Welch (D-VT) would amend the Federal *Food, Drug, and Cosmetic Act* to ensure that eligible generic and biosimilar developers have competitive access to drugs and biologics so they can develop and test their new generic products.

Closing this loophole would likely lead to lower pharmaceutical costs, particularly as companies abuse FDA safety programs by withholding access to drug samples for generic manufacturers, often resulting in increased costs.

As Janet Woodcock, director of FDA’s Center for Drug Evaluation and Research, noted in testimony (http://docs.house.gov/meetings/IF/IF14/20170302/105631/HHRG-115-IF14-Wstate-WoodcockJ-20170302.PDF) before a House committee in March, there are several factors that can delay timely consumer access to these less expensive generic medicines, including:

- the inappropriate use of statutory requirements regarding single-shared Risk Evaluation and Mitigation Strategies (REMS) to delay generics entry to the market;

- delaying or denying generic companies' access to reference listed drug products, thereby preventing the companies from conducting studies required for approval; and
- misuse of FDA's citizen petition process to block generic approvals.

On the citizen petition front, the Federal Trade Commission has been cracking down on such abuses, and most recently went after (http://www.raps.org/Regulatory-Focus/News/2017/02/07/26775/FTC-Shire-ViroPharma-Abused-FDA-Citizen-Petition-Process-Delaying-Generics/) Shire ViroPharma for blocking and delaying the marketing of generic versions of its antibiotic Vancocin (vancomycin) after filing 24 different citizen petitions, among other submissions to FDA.

The bill, meanwhile, would make clear that "no aspect of such a REMS shall be construed or applied by the REMS product's license holder in a way that prohibits or restricts the supply, at commercially reasonable, market-based prices."

Eligible generics companies will also be entitled to obtain from a license holder of a covered product subject to a REMS impacting distribution, sufficient quantities of the covered product for purposes of development and testing.

"Our bipartisan bill will allow more people to access generic alternatives by providing competition in the marketplace and removing unnecessary bureaucratic delays from the federal government," McKinley added in a statement. (https://mckinley.house.gov/press-releases/mckinley-welch-introduce-bill-to-increase-consumer-access-and-drive-down-costs-for-generic-drugs/)

Supporters of the bill include the Pharmaceutical Care Management Association, the Association for Accessible Medicines, the Academy of Managed Care Pharmacy, Public Citizen and the Blue Cross Blue Shield Association.

Bill Text (http://freepdfhosting.com/7c07f4d41e.pdf)

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