HR 2051

FAST Generics Act of 2017

Congress: 115 (2017–2019, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 6, 2017
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 7, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/house-bill/2051

Sponsor

Name: Rep. McKinley, David B. [R-WV-1]
Party: Republican • **State:** WV • **Chamber:** House

Cosponsors (13 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Welch, Peter [D-VT-At Large]	D · VT		Apr 6, 2017
Rep. DeGette, Diana [D-CO-1]	D · CO		May 17, 2017
Rep. Schrader, Kurt [D-OR-5]	D · OR		May 17, 2017
Rep. Stivers, Steve [R-OH-15]	R · OH		May 17, 2017
Rep. Lipinski, Daniel [D-IL-3]	D · IL		May 25, 2017
Rep. Fortenberry, Jeff [R-NE-1]	R · NE		Jun 2, 2017
Rep. Schakowsky, Janice D. [D-IL-9]	D · IL		Jun 2, 2017
Rep. Renacci, James B. [R-OH-16]	R · OH		Jul 25, 2017
Rep. Cartwright, Matt [D-PA-17]	D · PA		Oct 3, 2017
Rep. Khanna, Ro [D-CA-17]	D · CA		Jul 26, 2018
Rep. Lujan Grisham, Michelle [D-NM-1]	D · NM		Sep 7, 2018
Rep. Joyce, David P. [R-OH-14]	R · OH		Sep 17, 2018
Rep. Bera, Ami [D-CA-7]	D · CA		Sep 27, 2018

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 7, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 6, 2017)

Fair Access for Safe and Timely Generics Act of 2017 or the FAST Generics Act of 2017

This bill amends the Federal Food, Drug, and Cosmetic Act to prohibit the license holder of a Food and Drug Administration (FDA)-approved drug or biological product from restricting availability of the medication for testing by a product developer seeking to develop a drug, generic drug, or biosimilar, including restricting availability with a risk evaluation and mitigation strategy (REMS).

Upon request, the license holder of a medication that is not subject to a REMS must provide a product developer with the medication for testing.

For a medication subject to a REMS, a product developer must have FDA authorization to obtain the medication before the license holder must provide it. The FDA may authorize a product developer to conduct testing and clinical trials with the medication.

A wholesaler or specialty distributor who receives a request from a product developer for a medication for testing may not disclose to the license holder the identity of the product developer.
The FDA may prohibit or limit transfer of a medication to a product developer if the transfer poses an imminent hazard to public health.

License holders are not liable for claims arising from a product developer testing a medication.

The FDA may waive the requirement that a medication use a single, shared system of elements to assure safe use with a comparable approved medication if the product developer is unable to finalize terms for a shared system with the license holder of the approved medication.

Actions Timeline

- **Apr 7, 2017:** Referred to the Subcommittee on Health.
- **Apr 6, 2017:** Introduced in House
- **Apr 6, 2017:** Referred to the House Committee on Energy and Commerce.