HR 2841

FAST Generics Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 18, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 19, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/2841

Sponsor

Name: Rep. Stivers, Steve [R-OH-15]
Party: Republican • **State:** OH • **Chamber:** House

Cosponsors (9 total)

Cosponsor	Party / State	Role	Date Joined
Rep. McKinley, David B. [R-WV-1]	R · WV		Jun 18, 2015
Rep. Renacci, James B. [R-OH-16]	R · OH		Jun 18, 2015
Rep. Schakowsky, Janice D. [D-IL-9]	D · IL		Jun 18, 2015
Rep. Tiberi, Patrick J. [R-OH-12]	R · OH		Jun 18, 2015
Rep. Welch, Peter [D-VT-At Large]	D · VT		Jun 18, 2015
Rep. DeGette, Diana [D-CO-1]	D · CO		Jun 23, 2015
Rep. Cartwright, Matt [D-PA-17]	D · PA		Nov 4, 2015
Rep. Fortenberry, Jeff [R-NE-1]	R · NE		Nov 4, 2015
Rep. Kaptur, Marcy [D-OH-9]	D · OH		Nov 4, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 19, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jun 18, 2015)

Fair Access for Safe and Timely Generics Act of 2015 or the FAST Generics Act of 2015

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 the medication.

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

Actions Timeline

- **Jun 19, 2015:** Referred to the Subcommittee on Health.
- **Jun 18, 2015:** Introduced in House
- **Jun 18, 2015:** Referred to the House Committee on Energy and Commerce.

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