HR 1576

Generic Complex Drugs Safety and Effectiveness for Patients Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 24, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 27, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/1576

Sponsor

Name: Rep. Burgess, Michael C. [R-TX-26]
Party: Republican • **State:** TX • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Ashford, Brad [D-NE-2]	D · NE		Mar 24, 2015
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Mar 24, 2015
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Mar 24, 2015
Rep. Pompeo, Mike [R-KS-4]	R · KS		May 1, 2015
Rep. Kinzinger, Adam [R-IL-16]	R · IL		May 21, 2015
Rep. Hudson, Richard [R-NC-8]	R · NC		Nov 5, 2015
Rep. Collins, Chris [R-NY-27]	R · NY		Nov 19, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 27, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 24, 2015)

Generic Complex Drugs Safety and Effectiveness for Patients Act of 2015

This bill requires the Government Accountability Office (GAO) to study whether generic versions of certain complex drugs or certain biological drugs face significantly different challenges in meeting the approval standards of the Food and Drug Administration (FDA) than generic versions of small-molecule drugs. (Complex drugs and biological drugs can be composed of large molecules that are more difficult to fully characterize than small molecules, so it can be more difficult to demonstrate that generic versions of these drugs are the same as the brand name versions.)
If the GAO determines that these generic drugs face significantly different challenges, then the GAO must also determine: (1) the evidence that should be required to demonstrate that one of these generic drugs is sufficiently similar to the brand name drug in safety, composition, and activity; (2) whether the Federal Food, Drug, and Cosmetic Act should be amended to address the approval of these generic drugs; and (3) whether the FDA should develop a policy document on the evidence that is necessary to obtain approval of these generic drugs.

Actions Timeline

- **Mar 27, 2015:** Referred to the Subcommittee on Health.
- **Mar 24, 2015:** Introduced in House
- **Mar 24, 2015:** Referred to the House Committee on Energy and Commerce.