HR 3988

Generic Drug and Biosimilar User Fee Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 8, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 10, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3988

Sponsor

Name: Rep. Murphy, Tim [R-PA-18]
Party: Republican • **State:** PA • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Feb 8, 2012
Rep. Pitts, Joseph R. [R-PA-16]	R · PA		Feb 8, 2012
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Feb 8, 2012
Rep. Dingell, John D. [D-MI-15]	D · MI		Feb 21, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 10, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 3187	Related bill	**Jul 9, 2012:** Became Public Law No: 112-144.
112 HR 5651	Related bill	**Jun 4, 2012:** Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 420.
112 S 2516	Related bill	**May 7, 2012:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.

Summary (as of Feb 8, 2012)

Generic Drug and Biosimilar User Fee Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS), beginning FY2013, to assess and collect the following fees related to generic drugs: (1) a one-time backlog fee for abbreviated new drug applications pending on October 1, 2012; (2) a drug master file fee; (3) an abbreviated new drug application and prior approval supplement filing fee, as well as an additional fee for active pharmaceutical ingredient information not included by reference to Type II active pharmaceutical ingredient drug master file; and (4) a generic drug facility fee and active pharmaceutical ingredient facility fee. Provides that submission of an application for a positron emission tomography drug or active pharmaceutical ingredient for a positron emission tomography drug shall not require the payment of any fee. Sets forth provisions relating to fee amounts and due dates. Terminates the above provisions on October 1, 2017.

Requires the Secretary to report to Congress on the progress of the Food and Drug Administration (FDA) in achieving specified safety, access, and transparency goals with respect to generic drugs.

Biosimilar User Fee Act of 2012 - Directs the Secretary, beginning FY2013, to assess and collect the following fees related to biosimilar biological products: (1) biosimilar program development fees, encompassing an initial biosimilar biological development fee, an annual biosimilar biological product development fee, and a reactivation fee; (2) a biosimilar biological product application and supplement fee; (3) a biosimilar biological product establishment fee; and (4) a biosimilar biological product fee. Waives the above fees for the first biosimilar biological product application of a small business. Terminates the above provisions on October 1, 2017.

Requires the Secretary to report to Congress on the progress of the Food and Drug Administration (FDA) in achieving specified goals with respect to biosimilar biological products.

Actions Timeline

- **Feb 10, 2012:** Referred to the Subcommittee on Health.
- **Feb 8, 2012:** Introduced in House
- **Feb 8, 2012:** Referred to the House Committee on Energy and Commerce.