S 2516

Food and Drug Administration Safety and Innovation Act

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 7, 2012
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 389. (May 7, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/2516

Sponsor

Name: Sen. Harkin, Tom [D-IA]
Party: Democratic • **State:** IA • **Chamber:** Senate

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported Original Measure	May 7, 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 HR 5334	Related bill	**May 11, 2012:** Referred to the Subcommittee on Health.
112 S 2289	Related bill	**Apr 17, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
112 S 2236	Related bill	**Mar 26, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
112 HR 4087	Related bill	**Feb 24, 2012:** Referred to the House Committee on Energy and Commerce.
112 HR 3988	Related bill	**Feb 10, 2012:** Referred to the Subcommittee on Health.

Summary (as of May 7, 2012)

Food and Drug Administration Safety and Innovation Act - Amends the Federal Food, Drug, and Cosmetic Act to reauthorize and establish new Food and Drug Administration (FDA) prescription drug user-fee programs and revises requirements relating to: (1) prescription, pediatric, and generic drugs; (2) medical devices; (3) biosimilar biological products; (4) new infectious disease drugs; and (5) drug manufacturer reporting.

Prescription Drug User Fee Amendments of 2012 - Extends through FY2017 the authority of the Secretary of Health and Human Services (HHS) to assess and collect prescription drug fees to support the FDA drug development and human drug application review process.

Medical Device User Fee Amendments of 2012 - Extends through FY2017 the authority of the Secretary to assess and use fees for expediting the review process for medical device applications and for assuring the safety and effectiveness of such devices.

Generic Drug User Fee Amendments of 2012 - Directs the Secretary to assess and collect human generic drug user fees through FY2017, including a fee for drug applications pending on October 1, 2012, a drug master file fee, a generic drug facility fee, and an active pharmaceutical ingredient facility fee.

Biosimilar User Fee Act of 2012 - Establishes a new program to assess and use fees to expedite the review process for biosimilar biological product applications.

Makes permanent programs to study and provide extended exclusivity periods for new drugs for use in pediatric populations.

Permits the FDA to change a classification of a medical device through an administrative order rather than by regulation.

Expands reporting requirements for manufacturers of prescription drugs.

Provides incentives for the development of new qualified infectious disease products, including: (1) an additional five-year market exclusivity period, and (2) eligibility for priority and fast track review.

Requires the Secretary to: (1) expedite the development and review of new drugs designed to treat a serious or life-threatening disease, and (2) include a risk-benefit analysis in the regulatory decision-making process for prescription drugs.

Revises requirements for the reporting by drug manufacturers to HHS of a discontinuance or interruption in the production of life saving drugs. Requires the Secretary to establish a task force to develop and implement a strategic plan for enhancing the Secretary's response to preventing and mitigating drug shortages.

Extends until October 1, 2017, the deadline for applications for elections relating to marketing exclusivity for certain drugs containing single enantiomers.

Extends through FY2017 the authorization of appropriations for Critical Path Public-Private Partnerships to implement the FDA's Critical Path Initiative.

Provides for the regulation of medical gas products.

Directs the Secretary to: (1) issue guidance explaining FDA policy for promoting FDA-regulated medical products using

the Internet and social media; (2) report to Congress on initiatives to combat prescription drug abuse; (3) reconsider tanning bed labeling requirements; and (4) submit an integrated management strategy identifying goals for the FDA Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health.

Actions Timeline

- **May 7, 2012:** Introduced in Senate
- **May 7, 2012:** Committee on Health, Education, Labor, and Pensions. Original measure reported to Senate by Senator Harkin. Without written report.
- **May 7, 2012:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.