S 1734

Generating Antibiotic Incentives Now Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Oct 19, 2011
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Oct 19, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/1734

Sponsor

Name: Sen. Blumenthal, Richard [D-CT]
Party: Democratic • **State:** CT • **Chamber:** Senate

Cosponsors (14 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Alexander, Lamar [R-TN]	R · TN		Oct 19, 2011
Sen. Bennet, Michael F. [D-CO]	D · CO		Oct 19, 2011
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		Oct 19, 2011
Sen. Coons, Christopher A. [D-DE]	D · DE		Oct 19, 2011
Sen. Corker, Bob [R-TN]	R · TN		Oct 19, 2011
Sen. Hatch, Orrin G. [R-UT]	R · UT		Oct 19, 2011
Sen. Roberts, Pat [R-KS]	R · KS		Oct 31, 2011
Sen. Kerry, John F. [D-MA]	D · MA		Feb 9, 2012
Sen. Chambliss, Saxby [R-GA]	R · GA		Feb 17, 2012
Sen. Isakson, Johnny [R-GA]	R · GA		Feb 17, 2012
Sen. Tester, Jon [D-MT]	D · MT		Apr 19, 2012
Sen. Begich, Mark [D-AK]	D · AK		Apr 23, 2012
Sen. Carper, Thomas R. [D-DE]	D · DE		May 7, 2012
Sen. Ayotte, Kelly [R-NH]	R · NH		May 22, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Oct 19, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 HR 2182	Identical bill	**Jun 16, 2011:** Referred to the Subcommittee on Health.

Summary (as of Oct 19, 2011)

Generating Antibiotic Incentives Now Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to extend the exclusivity period for a new prescription drug by five years for a drug that the Secretary of Health and Human Services (HHS) determines to be a qualified infectious disease product. Defines "qualified infectious disease product" to mean an antibiotic drug for treating, detecting, preventing, or identifying a qualifying pathogen (certain pathogens that are resistant to antibiotics). Excludes drugs that are: (1) a supplement to a new drug application for which an extension is in effect or has expired; or (2) a subsequent application for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or a modification to the structure of the product that does not result in a change in safety or effectiveness.

Extends such period of exclusivity an additional six months for a sponsor or manufacturer of a qualified infectious disease product that identifies a companion diagnostic test.

Requires the Secretary to give priority review to any drug determined to be a qualified infectious disease product.

Includes qualified infectious disease products as fast track products for which the Secretary shall facilitate development and expedite review.

Directs the Comptroller General to study the need for incentives to encourage the research, development, and marketing of qualified infectious disease biological products.

Requires the Secretary to: (1) review Food and Drug Administration (FDA) guidelines for clinical trials of antibiotic drugs; and (2) revise such guidelines, as appropriate, to reflect developments in scientific and medical information and technology and to ensure clarity regarding the procedures and requirements for approval of an antibiotic drug.

Actions Timeline

- **Oct 19, 2011:** Introduced in Senate
- **Oct 19, 2011:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.