

## HR 2182

Generating Antibiotic Incentives Now Act of 2011

**Congress:** 112 (2011–2013, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Jun 15, 2011

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Jun 16, 2011)

**Official Text:** <https://www.congress.gov/bill/112th-congress/house-bill/2182>

### Sponsor

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**Name:** Rep. Gingrey, Phil [R-GA-11]

**Party:** Republican • **State:** GA • **Chamber:** House

**Cosponsors** (46 total)

Cosponsor	Party / State	Role	Date Joined
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Rep. Eshoo, Anna G. [D-CA-14]	D · CA		Jun 15, 2011
Rep. Green, Gene [D-TX-29]	D · TX		Jun 15, 2011
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Jun 15, 2011
Rep. Shimkus, John [R-IL-19]	R · IL		Jun 15, 2011
Rep. Whitfield, Ed [R-KY-1]	R · KY		Jun 15, 2011
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Rep. Latta, Robert E. [R-OH-5]	R · OH		Jul 26, 2011
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Jul 28, 2011
Rep. Brady, Robert A. [D-PA-1]	D · PA		Sep 23, 2011
Rep. Murphy, Christopher [D-CT-5]	D · CT		Oct 3, 2011
Rep. Markey, Edward J. [D-MA-7]	D · MA		Oct 12, 2011
Rep. Keating, William R. [D-MA-10]	D · MA		Oct 13, 2011
Rep. Carney, John C., Jr. [D-DE-At Large]	D · DE		Oct 25, 2011
Rep. Inslee, Jay [D-WA-1]	D · WA		Oct 25, 2011
Rep. Meehan, Patrick [R-PA-7]	R · PA		Oct 25, 2011
Rep. Miller, Brad [D-NC-13]	D · NC		Oct 31, 2011
Rep. Burton, Dan [R-IN-5]	R · IN		Nov 10, 2011
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Nov 10, 2011
Rep. Guthrie, Brett [R-KY-2]	R · KY		Nov 10, 2011
Rep. Cassidy, Bill [R-LA-6]	R · LA		Nov 16, 2011
Rep. McCaul, Michael T. [R-TX-10]	R · TX		Nov 16, 2011
Rep. Brooks, Mo [R-AL-5]	R · AL		Nov 30, 2011
Rep. Broun, Paul C. [R-GA-10]	R · GA		Dec 2, 2011
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Dec 13, 2011
Rep. Himes, James A. [D-CT-4]	D · CT		Dec 15, 2011
Rep. McHenry, Patrick T. [R-NC-10]	R · NC		Dec 19, 2011
Rep. Walden, Greg [R-OR-2]	R · OR		Dec 19, 2011
Rep. Tsongas, Niki [D-MA-5]	D · MA		Feb 2, 2012
Rep. Matheson, Jim [D-UT-2]	D · UT		Feb 7, 2012
Rep. Gonzalez, Charles A. [D-TX-20]	D · TX		Feb 15, 2012
Rep. Matsui, Doris O. [D-CA-5]	D · CA		Feb 29, 2012
Rep. Latham, Tom [R-IA-4]	R · IA		Mar 5, 2012
Rep. Barrow, John [D-GA-12]	D · GA		Apr 17, 2012
Rep. Filner, Bob [D-CA-51]	D · CA		Apr 17, 2012

Cosponsor	Party / State	Role	Date Joined
Rep. Miller, Gary G. [R-CA-42]	R · CA		Apr 17, 2012
Rep. Kinzinger, Adam [R-IL-11]	R · IL		Apr 24, 2012
Rep. Benishek, Dan [R-MI-1]	R · MI		Apr 27, 2012
Rep. Ross, Mike [D-AR-4]	D · AR		May 7, 2012
Del. Christensen, Donna M. [D-VI-At Large]	D · VI		May 8, 2012

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 16, 2011

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

Bill	Relationship	Last Action
112 S 1734	Identical bill	<b>Oct 19, 2011:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## Summary (as of Jun 15, 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

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- **Jun 16, 2011:** Referred to the Subcommittee on Health.
- **Jun 15, 2011:** Introduced in House
- **Jun 15, 2011:** Referred to the House Committee on Energy and Commerce.