HR 6331

Generating Antibiotic Incentives Now Act of 2010

Congress: 111 (2009–2011, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 29, 2010
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (Sep 29, 2010)
Official Text: https://www.congress.gov/bill/111th-congress/house-bill/6331

Sponsor

Name: Rep. Gingrey, Phil [R-GA-11]
Party: Republican • **State:** GA • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeGette, Diana [D-CO-1]	D · CO		Sep 29, 2010
Rep. Green, Gene [D-TX-29]	D · TX		Sep 29, 2010
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Sep 29, 2010
Rep. Whitfield, Ed [R-KY-1]	R · KY		Sep 29, 2010

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Sep 29, 2010

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Sep 29, 2010)

Generating Antibiotic Incentives Now Act of 2010 - Amends the Federal Food, Drug, and Cosmetic Act to: (1) extend for five years the exclusivity period for the first licensure of a qualified infectious disease product; (2) grant priority review to an application for approval or licensure of a qualified infectious disease product (i.e., review and action on such application not later than six months after receipt); and (3) deem a qualified infectious disease product as a fast track product, for review and approval purposes. Defines "qualified infectious disease product" as an antibiotic drug, or a diagnostic test including a point-of-care diagnostic test, for treating, detecting, preventing, or identifying a qualifying pathogen.

Requires the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to review the guidelines of the Food and Drug Administration (FDA) for the conduct of clinical trials for antibiotic drugs and revise such guidelines to reflect developments in medical information and technology. Allows the sponsor of a drug intended to be used to treat, detect, prevent, or identify a qualifying pathogen, as defined by this Act, to request that the Secretary provide written recommendations for nonclinical and clinical investigations before such drug may be approved for use or licensed.

Actions Timeline

- **Sep 29, 2010:** Introduced in House
- **Sep 29, 2010:** Referred to the House Committee on Energy and Commerce.

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