HR 6151

Responsibility in Drug and Device Advertising Act of 2008

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: May 22, 2008
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (May 22, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/6151

Sponsor

Name: Rep. DeLauro, Rosa L. [D-CT-3]
Party: Democratic • **State:** CT • **Chamber:** House

Cosponsors (8 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Emerson, Jo Ann [R-MO-8]	R · MO		May 22, 2008
Rep. DeFazio, Peter A. [D-OR-4]	D · OR		Jun 19, 2008
Rep. Doggett, Lloyd [D-TX-25]	D · TX		Jun 23, 2008
Rep. Filner, Bob [D-CA-51]	D · CA		Jul 23, 2008
Rep. Lee, Barbara [D-CA-9]	D · CA		Jul 30, 2008
Rep. Lipinski, Daniel [D-IL-3]	D · IL		Sep 10, 2008
Rep. McCollum, Betty [D-MN-4]	D · MN		Sep 10, 2008
Del. Christensen, Donna M. [D-VI-At Large]	D · VI		Nov 19, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	May 22, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 22, 2008)

Responsibility in Drug and Device Advertising Act of 2008 - Amends the Federal Food, Drug, and Cosmetic Act to prohibit direct-to-consumer advertising in the first three years after approval of a new drug or device. Authorizes the Secretary of Health and Human Services to: (1) waive such prohibition if such advertising would have an affirmative value to public health; and (2) continue such prohibition in subsequent years if the drug or device has significant adverse health effects.

Requires any direct-to-consumer advertisement to include a fair balance of the benefits and risks associated with the drug or device.

Deems a drug to be misbranded if a direct-to-consumer television advertisement for such drug does not prominently display a statement encouraging individuals to report negative side effects of prescription drugs to the Food and Drug Administration (FDA). Requires the Secretary to discontinue the study designed to determine if such a statement is appropriate for television advertisements.

Deems a device to be misbranded if a direct-to-consumer television advertisement for such device does not include a statement encouraging individuals to report negative side effects of medical devices to the FDA.

Sets forth civil monetary penalties for violations relating to the advertising and promotion of a drug or device. Allows the Secretary to order the distribution of materials to notify the public and the medical community of such a violation and to provide corrective information.

Requires the Secretary to conduct an education campaign to increase public awareness of risks that, for some patients, may outweigh the benefits of using a particular drug or device.

Authorizes additional appropriations to regulate direct-to-consumer drug and device advertisements.

Actions Timeline

- **May 22, 2008:** Introduced in House
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