HR 3209

Premarket Predictability Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 14, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 18, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3209

Sponsor

Name: Rep. Shimkus, John [R-IL-19]
Party: Republican • **State:** IL • **Chamber:** House

Cosponsors (20 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Altmire, Jason [D-PA-4]	D · PA		Oct 14, 2011
Rep. Barton, Joe [R-TX-6]	R · TX		Oct 14, 2011
Rep. Bilbray, Brian P. [R-CA-50]	R · CA		Oct 14, 2011
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Oct 14, 2011
Rep. Burgess, Michael C. [R-TX-26]	R · TX		Oct 14, 2011
Rep. Cassidy, Bill [R-LA-6]	R · LA		Oct 14, 2011
Rep. Gingrey, Phil [R-GA-11]	R · GA		Oct 14, 2011
Rep. Guthrie, Brett [R-KY-2]	R · KY		Oct 14, 2011
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Oct 14, 2011
Rep. Latta, Robert E. [R-OH-5]	R · OH		Oct 14, 2011
Rep. Paulsen, Erik [R-MN-3]	R · MN		Oct 14, 2011
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Oct 14, 2011
Rep. Culberson, John Abney [R-TX-7]	R · TX		Nov 30, 2011
Rep. Walden, Greg [R-OR-2]	R · OR		Nov 30, 2011
Rep. Akin, W. Todd [R-MO-2]	R · MO		Dec 16, 2011
Rep. Benishek, Dan [R-MI-1]	R · MI		Dec 16, 2011
Rep. Mulvaney, Mick [R-SC-5]	R · SC		Jan 18, 2012
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Jan 23, 2012
Rep. Rokita, Todd [R-IN-4]	R · IN		Jan 25, 2012
Rep. Matheson, Jim [D-UT-2]	D · UT		Jan 31, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 18, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 14, 2011)

Premarket Predictability Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS) to assign a tracking number to a medical device upon submission of: (1) an application for an exemption of a device for investigational use, (2) a request to classify a device, or (3) a premarket report or notification related to a device. Requires the Secretary to use the tracking number to record interactions between the Secretary and applicant with respect to the device.

Directs the Secretary to: (1) assign a reviewer with prior review experience with the type of of device or technology involved or other relevant expertise to review an application for an exemption of a device for investigational use, and (2) evaluate whether the investigational study can be conducted ethically with reasonable risk in determining whether to grant an exemption for investigational use.

Prohibits the Secretary from disapproving an application because the investigation does not or may not meet any requirement relating to the approval or clearance of a device because the Secretary believes that a different clinical testing design or plan could produce data more relevant to an approval or clearance decision.

Revises the procedures relating to submission of an application to investigate a class II or a class III device, which may include a plan for determining whether the device is substantially equivalent to or is at least as safe and effective as a legally marketed device that is not subject to premarket approval requirements.

Sets forth requirements for the Secretary to meet in determining the least burdensome appropriate means of evaluating medical device effectiveness that would have a reasonable likelihood of resulting in approval.

Requires the Secretary to document the scientific and regulatory rationale for any significant decision of the Center for Devices and Radiological Health regarding device review, approval, or exemption. Sets forth appeal procedures. Requires the Secretary to regularly publish detailed decision summaries for each clearance of a device not requiring premarket approval.

Actions Timeline

- **Oct 18, 2011:** Referred to the Subcommittee on Health.
- **Oct 14, 2011:** Introduced in House
- **Oct 14, 2011:** Referred to the House Committee on Energy and Commerce.