HR 4156

EXPERRT Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 7, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 9, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/4156

Sponsor

Name: Rep. Markey, Edward J. [D-MA-7]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (22 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Marino, Tom [R-PA-10]	R · PA		Mar 7, 2012
Rep. Stearns, Cliff [R-FL-6]	R · FL		Mar 7, 2012
Rep. Bachus, Spencer [R-AL-6]	R · AL		Mar 28, 2012
Rep. Dent, Charles W. [R-PA-15]	R · PA		Mar 28, 2012
Rep. Fleming, John [R-LA-4]	R · LA		Mar 28, 2012
Rep. Murphy, Tim [R-PA-18]	R · PA		Mar 28, 2012
Rep. Myrick, Sue Wilkins [R-NC-9]	R · NC		Mar 28, 2012
Rep. Pascrell, Bill, Jr. [D-NJ-8]	D · NJ		Mar 28, 2012
Rep. Pastor, Ed [D-AZ-4]	D · AZ		Mar 28, 2012
Rep. Cassidy, Bill [R-LA-6]	R · LA		May 8, 2012
Rep. Coble, Howard [R-NC-6]	R · NC		May 8, 2012
Rep. Doyle, Michael F. [D-PA-14]	D · PA		May 8, 2012
Rep. Filner, Bob [D-CA-51]	D · CA		May 8, 2012
Rep. King, Peter T. [R-NY-3]	R · NY		May 8, 2012
Rep. McGovern, James P. [D-MA-3]	D · MA		May 8, 2012
Rep. Mulvaney, Mick [R-SC-5]	R · SC		May 8, 2012
Rep. Tonko, Paul [D-NY-21]	D · NY		May 8, 2012
Rep. Welch, Peter [D-VT-At Large]	D · VT		May 8, 2012
Rep. Wolf, Frank R. [R-VA-10]	R · VA		May 10, 2012
Rep. Lofgren, Zoe [D-CA-16]	D · CA		Jun 21, 2012
Rep. Walden, Greg [R-OR-2]	R · OR		Jun 21, 2012
Rep. Castor, Kathy [D-FL-11]	D · FL		Nov 29, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 9, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 2281	Related bill	**Mar 29, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Mar 7, 2012)

Expanding and Promoting Expertise in Review of Rare Treatments Act of 2012 or EXPERRT Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS) to establish a program for consultation with external experts to inform and strengthen the Food and Drug Administration's (FDA's) review of drugs and biologic products for rare diseases and drugs and biologic products that are genetically targeted.

Requires, under such program, each review division within the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research to seek the opinion of external experts on topics that may include: (1) rare diseases; (2) the severity of rare diseases; (3) the unmet medical need associated with rare diseases; (4) the willingness and ability of individuals with a rare disease to participate in clinical trials; (5) an assessment of the benefits and risks, including side effects, of current and investigational therapies; (6) the design of clinical trials for rare disease populations and subpopulations; and (7) demographics and the clinical description of patient populations. Allows external experts to request the opportunity to meet with a review division regarding any such topic. Authorizes the Secretary to determine the timing of each consultation, which may occur prior to, or following, the filing of an investigational new drug application, a new drug application, or a biologies license application.

Requires the experts consulted to be considered special government employees.

Actions Timeline

- **Mar 9, 2012:** Referred to the Subcommittee on Health.
- **Mar 7, 2012:** Introduced in House
- **Mar 7, 2012:** Referred to the House Committee on Energy and Commerce.