HR 3737

ULTRA

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Dec 20, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Dec 23, 2011)
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Sponsor

Name: Rep. Stearns, Cliff [R-FL-6]
Party: Republican • **State:** FL • **Chamber:** House

Cosponsors (13 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Towns, Edolphus [D-NY-10]	D · NY		Dec 20, 2011
Rep. Benishek, Dan [R-MI-1]	R · MI		Jan 25, 2012
Rep. Roskam, Peter J. [R-IL-6]	R · IL		Feb 9, 2012
Rep. Andrews, Robert E. [D-NJ-1]	D · NJ		Feb 28, 2012
Rep. Bartlett, Roscoe G. [R-MD-6]	R · MD		Feb 28, 2012
Rep. Rothman, Steven R. [D-NJ-9]	D · NJ		Feb 28, 2012
Rep. Velazquez, Nydia M. [D-NY-12]	D · NY		Feb 28, 2012
Rep. Ribble, Reid J. [R-WI-8]	R · WI		Mar 6, 2012
Rep. LoBiondo, Frank A. [R-NJ-2]	R · NJ		Mar 29, 2012
Rep. DeFazio, Peter A. [D-OR-4]	D · OR		Apr 16, 2012
Rep. Harris, Andy [R-MD-1]	R · MD		Apr 16, 2012
Rep. Meehan, Patrick [R-PA-7]	R · PA		Apr 26, 2012
Rep. Barletta, Lou [R-PA-11]	R · PA		May 29, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Dec 23, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Dec 20, 2011)

Unlocking Lifesaving Treatments for Rare-Diseases Act or ULTRA - Amends the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services (HHS) to approve an application for a drug as a fast track product using a surrogate endpoint, based on the existence of reasonable scientific data that support and qualify the relevance of such endpoint to the disease state and treatment, if the Secretary: (1) makes an initial determination that the drug is eligible for approval as a drug designated for a rare disease or condition (orphan drug) and as a fast track product, and (2) determines that the drug is a treatment for a disease or condition that affects a small number of patients in the United States. Prohibits the Secretary from requiring clinical treatment or other historical clinical data on such endpoint as a prerequisite to assessment of that endpoint if such scientific data is not available.

Directs the Secretary to issue guidance providing details and options for qualifying surrogate endpoints without clinical data, taking into account and balancing: (1) the unmet need served by the drug and the adverse effects of the rare disease or condition on quality and length of life, (2) the very low likelihood that clinical data would exist or that clinical studies would be completed to support a surrogate endpoint due to the small size of the U.S. patient population and other significant barriers inherent in performing such studies due to the prevalence of the disease or related factors, and (3) the full scope of available basic scientific data and information that the Secretary deems reasonably predictive of a clinical benefit in the absence of clinical data.

Actions Timeline

- **Dec 23, 2011:** Referred to the Subcommittee on Health.
- **Dec 20, 2011:** Introduced in House
- **Dec 20, 2011:** Referred to the House Committee on Energy and Commerce.