HR 6502

Life-Threatening Diseases Compassion through Combination Therapy Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 21, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Sep 26, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/6502

Sponsor

Name: Rep. Bilbray, Brian P. [R-CA-50]
Party: Republican • **State:** CA • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeLauro, Rosa L. [D-CT-3]	D · CT		Sep 21, 2012
Rep. Maloney, Carolyn B. [D-NY-14]	D · NY		Sep 21, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Sep 26, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Sep 21, 2012)

Life-Threatening Diseases Compassion through Combination Therapy Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to authorize the Secretary of Health and Human Services (HHS) to designate a combination of drugs as a significant drug combination if such combination: (1) includes two or more drugs or biological products that, when used in combination, offer the potential to significantly advance treatment for a serious or life-threatening disease and, in combination, meet the criteria for co-development of drug combinations in Food and Drug Administration (FDA) guidance; and (2) includes at least two drugs that are not approved.

Requires the Secretary to develop, publish, and revise annually a list of combinations of two or more drugs designated as significant drug combinations.

Extends the market exclusivity for a drug by six months if it is designated as a significant drug combination before it is approved as a new drug.

Requires the Secretary to review and take action on a drug in a significant drug combination designated under this Act within six months after receiving an application for approval of a new drug application or licensure of a biosimilar biological product.

Requires the Secretary, at the request of the sponsor of a drug, to expedite development and review for designated drug combinations.

Requires the Secretary to establish an interagency task force to encourage the co-development of drugs in significant drug combinations. Requires the task force to develop, revise in response to public comments, and update annually a list of types of drug combinations it recommends that the Secretary designate as significant drug combinations.

Directs the Secretary to study the impact of the extension of market exclusivity under this Act.

Actions Timeline

- **Sep 26, 2012:** Referred to the Subcommittee on Health.
- **Sep 21, 2012:** Introduced in House
- **Sep 21, 2012:** Referred to the House Committee on Energy and Commerce.