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## **Members of Congress Introduce Legislation That Would Support Development of Life-Saving Combination Therapies**

**WASHINGTON, D.C.** — The [Melanoma Research Foundation](#) (MRF) applauds new proposed legislation that would incentivize the development of combination therapies to treat life-threatening diseases like melanoma. [Congressman Brian Bilbray](#) (R-CA), [Congresswoman Carolyn Maloney](#) (D-NY) and [Congresswoman Rosa DeLauro](#) (D-CT) are co-sponsors on the Life-Threatening Diseases Compassion Through Combination Therapy Act of 2012, designed to address barriers and jump-start the development of new combination therapies.

MRF appreciated the opportunity to work with Congressman Bilbray and the bill's sponsors on identifying the impediments and incentives to creating drug combinations. Broad agreement exists across the scientific community that combining two or more drugs is the only way to help people with melanoma live longer and better, much like combination therapies have revolutionized treatment for diseases like human immunodeficiency virus (HIV) or tuberculosis (TB). Yet MRF learned from launching the [Melanoma Research Foundation Breakthrough Consortium](#) (MRFBC) that securing biopharmaceutical participation for combinations of drugs is challenging, particularly if the drugs are early in their development – prior to at least one drug's approval – or when the drugs were owned by different companies. This bipartisan effort identified incentives that would favor early development of promising combinations for life-threatening diseases such as melanoma and is consistent with recent FDA regulatory guidance on early development of combinations.

“These trials simply have not come together quickly enough for those people fighting for their lives,” said Timothy J. Turnham, executive director of the MRF. “This bill reflects a smart assessment of those realities and will be critical to encouraging more successes.”

In addition to this legislation, MRF recognizes the role of other stakeholders in supporting the development of these critical trials. The FDA took an important step in 2010 when it issued draft guidance for industry on the conduct of combination trials. Final guidance from the agency will provide much-needed clarity about effective collaboration among industry partners.

“Finding treatments and cures for life-threatening diseases requires a true collaboration among all parties, including researchers, the biopharmaceutical industry and the FDA. This legislation goes a long way toward ensuring the active participation of all parties in finding these essential treatments,” said Turnham.

To bridge communication between industry, academia and government, MRF launched the MRFBC in 2010 to design and implement high-impact clinical trials using two or more drugs. The MRFBC is initiating multiple combination trials that will answer important questions not being addressed in other trials.

MRF commends Reps. Bilbray, Maloney and DeLauro for recognizing the immediate need to create additional momentum around the development of combination therapies in order to meet the pressing needs of those with melanoma and other cancers.

### **About the Legislation**

The bi-partisan legislation encourages collaboration among biopharmaceutical companies, researchers, and government agencies to develop and create access to investigational new drugs (IND) for life-threatening diseases. The legislation will provide benefits for companies who engage in preclinical and clinical combination studies early, when the treatments are not yet approved, if certain criteria put forth by the FDA are met. It will grant a six-month extension of market exclusivity as well as expedite priority review to qualifying therapies.

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### **About Melanoma**

Melanoma is one of the fastest growing cancers in the United States and can strike men and women of all ages, all races and skin types. With a one in 50 lifetime risk of developing melanoma, nearly 76,000 Americans are expected to be diagnosed with the disease in 2012, resulting in over 9,000 deaths. Melanoma is the most common form of cancer for young adults 25- to 29-years-old and the second most common cancer in adolescents and young adults 15- to 29-years-old.

The majority of melanomas occur on the skin; in fact, melanoma is the most serious type of skin cancer. Melanoma can also occur in the eye (ocular, or uveal melanoma), in mucous membranes (mucosal melanoma), or even beneath fingernails or toenails.

### **About Melanoma Research Foundation**

The Melanoma Research Foundation (MRF) is the largest independent, national organization devoted to melanoma in the United States. Committed to the support of medical research in finding effective treatments and eventually a cure for melanoma, the MRF also educates patients and physicians about prevention, diagnosis and the treatment of melanoma. The MRF is an active advocate for the melanoma community, helping to raise awareness of this disease and the need for a cure. The MRF's website is the premier source for melanoma information seekers. More information is available at [www.melanoma.org](http://www.melanoma.org).