HR 4762

REGROW Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 16, 2016
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 18, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/4762

Sponsor

Name: Rep. Coffman, Mike [R-CO-6]
Party: Republican • **State:** CO • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Mar 16, 2016
Rep. Takai, Mark [D-HI-1]	D · HI		Mar 16, 2016
Rep. Rohrabacher, Dana [R-CA-48]	R · CA		Apr 18, 2016
Rep. Sensenbrenner, F. James, Jr. [R-WI-5]	R · WI		Jul 12, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 18, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 S 2689	Identical bill	**Mar 16, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Mar 16, 2016)

Reliable and Effective Growth for Regenerative Health Options that Improve Wellness or the REGROW Act

This bill amends the Public Health Service Act to require the Food and Drug Administration (FDA) to conditionally approve certain cellular therapeutic products without initiation of large-scale clinical trials. A conditionally approved cellular therapy may be marketed if certain conditions are met, including conditions on the source, processing, and function of the cells in the product.

The sponsor of a conditionally approved cellular therapy must apply for approval of the product as a biological product within five years. Unless the FDA has decided not to approve the product, the product may be marketed during this five-year period and the FDA may permit continued marketing while the application is being reviewed.

An individual administering a conditionally approved cellular therapy must inform the recipient regarding conditional approval.

The premarket report for a medical device used for cellular therapy must include specified information regarding the preparation or delivery of the cellular therapy.

The approval of a medical device that is a cellular therapy must be based on laboratory performance testing and not clinical trials.

A medical device used for cellular therapy is subject to medical device classification. The FDA must not limit the use of these devices to only specific cell types unless unique to the use of the device.

The Center for Biologics Evaluation and Research has primary jurisdiction for premarket review of combination products that act primarily through cellular components.
The Department of Health and Human Services must work with stakeholders to promote the development of standards for regenerative medicine products.

Actions Timeline

- **Mar 18, 2016:** Referred to the Subcommittee on Health.
- **Mar 16, 2016:** Introduced in House
- **Mar 16, 2016:** Referred to the House Committee on Energy and Commerce.