

The Honorable Mark Kirk
United States Senate
524 Hart Senate Office Building
Washington, D.C. 20510

Dear Senator Kirk,

The undersigned patient advocacy organizations write to you regarding the “Reliable and Effective Growth for Regenerative Health Options that Improve Wellness,” or the “REGROW Act” (H.R. 4762 / S. 2689). Many of us have engaged in productive dialogue with your office and the Bipartisan Policy Center, and we look forward to continued collaboration. However, we have concerns about the most recent draft of this legislation that was shared with us on June 1st.

If passed, this bill would amend the Food, Drug, & Cosmetic Act to create a new pathway for “regenerative therapeutic products” to be approved by the Food and Drug Administration (FDA). While we support regenerative medicine research and policies that enable patients to access the therapies they need to live their best lives, we cannot support the current path outlined in REGROW. The field of regenerative medicine, including cell and gene therapies, shows potential for treating, and potential for curing, a number of diseases and conditions for which there are currently no treatments, or for which current treatments are inadequate. However, for patients to have confidence that these new treatments are safe and effective, FDA’s standards of approval and regulatory authority must remain intact. We are concerned that the REGROW Act will lower the FDA’s current standard for approval in a way that would rush new treatments to market without sufficient proof of safety and efficacy. This could adversely affect public health and safety and slow research progress.

We share your urgency to find new and innovative treatments and cures for the life-changing and life-threatening diseases that beset Americans every day, but we cannot lend our support to this legislation at this time. We urge you to continue to bring all of the stakeholders together, including the FDA, until a mutual agreement is reached on the best way to bring safe and effective regenerative therapeutic products to market. We feel that the patient voice needs to be at the forefront of this conversation, as they will be the ones utilizing these innovative treatments.

Thank you for your attention to this matter. For any questions or comments, please contact John Wylam at john.wylam@nmss.org or (202) 408-0679.

CC:

The Honorable Mitch McConnell
Majority Leader
United States Senate
317 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Lamar Alexander
Chair
Health, Education, Labor &
Pensions Committee
455 Dirksen Senate Office Building
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The Honorable Harry Reid
Minority Leader
United States Senate
522 Hart Senate Office Building
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The Honorable Patty Murray
Ranking Member
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