celltherapynow

Take Action to Bring Regenerative Cell Therapy to Americans

Please contact your U.S. Senators and Representatives and ask them to co-sponsor the *Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act (*S. 2689 / H.R. 4762), introduced in the by Senators Mark Kirk (R-IL), Joe Manchin (D-WV) and Susan Collins (R-ME); and Representatives Mike Coffman (R-CO), Mark Takai (D-HI), and Morgan Griffith (R-VA). Regenerative medicine provisions have now been included in the House-passed *21st Century Cures Act* (H.R. 6) and the *FDA and NIH Workforce Authorities Modernization Act* (S. 2700) as marked-up by the Senate Health, Education, Labor, and Pensions (HELP) Committee, providing an opportunity to incorporate the REGROW Act as medical innovation legislation advances in Congress.

What the bill would do: The REGROW Act would help to advance safe and effective regenerative cell therapies through the FDA approval process and to the market so that patients can benefit from them.

Why this is important:

Cell therapy—which involves the use of cells to restore healthy function in the human body—represents one of the most promising areas for the next generation of groundbreaking treatments. Cell therapies have been shown to halt the progression of degenerative joint disease in the knee or hip and restore function to a failing heart or damaged cornea. Scientific advances in the field include applications in cardiology, neurology, oncology, ophthalmology, and orthopedics and there have been promising studies for those with Alzheimer's disease, Parkinson's disease, diabetes, and cancer. Cell therapies are different from drugs in that they attempt to address the root cause of disease, rather than simply treating the symptoms of disease.

Despite the benefits of these treatments, cell therapies are generally not accessible to patients in the United States. This is primarily due to an outdated approach toward regulation within the U.S. Food and Drug Administration (FDA). Currently the FDA treats the approval of cell therapies much like it treats the approval of drugs. As a result, it takes on average more than $1 billion and ten years of investment in development before cell therapies can be brought to patients. Europe and Japan have outpaced the United States in their policies to grant patient access to safe cell therapies. As a result, patients in the U.S. are flocking to other countries to gain access to these treatments, and U.S. companies that are innovating in cell therapy are also making their investments in other parts of the world.

Recognizing the benefits of cell therapies, numerous organizations and experts including the Regenerative Medicine Foundation, the Alliance for the Advancement of Cellular Therapies, and experts and leaders involved in the Bipartisan Policy Center, have called for a new framework to accelerate the availability of safe and effective cell therapies to Americans in need and improve U.S. competitiveness in the global marketplace.

What you can do to help: send a letter, make a phone call and/or schedule a meeting with your Member of Congress or their staff to ask that they co-sponsor the REGROW Act (S. 2689/H.R. 4762) and support its inclusion in, and passage as part of, any medical innovation legislation advancing through Congress in 2016.