celltherapynow

Who We Are
Cell Therapy Now is a collaboration among organizations representing patients, providers, researchers, and thought leaders in the field of regenerative cell therapy.

Why We Need You
- Cell therapy – which involves the use of human cells to restore healthy function in the human body – represents one of the most promising areas for groundbreaking treatments.
- Unfortunately, most patients in the U.S. lack access to life-changing cell therapies, because of the way that they are regulated by the U.S. Food and Drug Administration (FDA).
- The current regulatory landscape means that cell therapies are either treated as the practice of medicine – and therefore not regulated – or as drugs, requiring a pathway lasting on average 10 years and costing more than $1 billion.
- Fortunately, the *Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act of 2016* (S. 2689 / H.R. 4762) – introduced 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) – would address this problem.
- The REGROW Act would create a new regulatory tool for FDA, providing a middle ground for certain cell therapies that are proven safe and show signs of efficacy, as an alternative to the "all or nothing" approach that is currently in place.

Cell Therapies are Not New
- Safe and successful uses of human cells for therapeutic purposes have been common medical practice for more than fifty years.
- Blood transfusions were the first type of cell therapy, and bone marrow transplantation has been the standard of care for patients with aggressive forms of cancer for decades.
- Scientific progress has advanced considerably; 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, heart disease, diabetes, and cancer.

Investment in the United States
- The U.S. is falling behind other countries in advancing the science and use of cell therapies.
- In 2014, Japan implemented a conditional approval system for cell therapies that allows a path to reimbursement while clinical trials are ongoing.
- The European Union has a regulatory exemption that allows patients to access cell therapies in hospitals under the exclusive professional responsibilities of treating physicians.
- Many patients are forced to receive treatments overseas, and companies are taking their investments to other parts of the world, due to the FDA's outdated regulatory framework.

Patients Can't Wait
- The scientific advances in cell therapy are significant and hold promise for those suffering from a multitude of conditions, including Alzheimer's disease, cancer, and diabetes.
- The U.S. lacks both the regulatory tools and the incentives to promote the advancement of cell therapies for Americans.
- Patients can't wait – *Congress should support and pass the REGROW Act (S. 2689 / H.R. 4762) to bring regenerative cell therapies to the United States.*