



Regenerative Cell Therapies: Making Safe and Effective Treatments Available to Patients

Regenerative cellular therapies represent the next generation of groundbreaking treatments that are showing great promise in cardiology, neurology, oncology, orthopedics, ophthalmology, and other areas. Several well-designed clinical trials are being conducted under FDA investigational new drug (IND) protocols. At the same time, a handful of clinics have caused patient harm or made questionable claims, taking advantage of vulnerable patients and casting a negative light on this emerging, promising science and industry.

The 21st Century Cures Act contained several provisions to make safe and effective regenerative cellular therapies available to patients, including extending Food and Drug Administration (FDA) expedited programs to include regenerative therapies and providing funds for research through the National Institutes of Health (NIH). The FDA and NIH are taking several steps to advance and support the field.

Making safe and effective treatments available to patients requires several additional actions that build upon the Administration's activities and important provisions contained in the 21st Century Cures Act.

- Development, consensus, and adoption of standards and best practices to support improvements in development, manufacturing, and delivery.
- Launch of an outcomes database—or registry—to measure outcomes, advance the science, drive improvements in manufacturing and delivery, and inform regulatory evaluation and payment, as well as clinical and patient decision-making.
- Development of and support for workforce initiatives, including those in technical and community colleges, to build capacity and prepare the skilled, technical workforce for this emerging field.
- Additional funding support for research at the NIH.
- Increased capacity at the FDA to support both enforcement efforts and strategies to support academic and research institutions, as well as innovators, who need assistance in navigating FDA regulatory requirements.

About Alliance for Cell Therapy Now

Alliance for Cell Therapy (ACT) Now is a 501(c)6, independent, non-profit organization devoted to advancing the availability of safe and effective cell therapies for patients in need. ACT Now brings together experts and stakeholders—working in collaboration with other organizations that have a similar mission—to gain consensus on and advocate for sound policies that improve the development, manufacturing, delivery, and improvement of safe and effective regenerative therapies.