

Alliance for Cell Therapy Now Commends Congress for Regenerative Medicine and Cell Therapy Provisions in FY 2021 Spending Bill

Additional Support for Clinical Trials for COVID Patients is Still Needed

Washington, DC (December 30, 2020) – Leaders of [Alliance for Cell Therapy Now](#) (ACT Now)—including representatives of academic and medical institutions, industry innovators, and patients—applaud Congress for its inclusion of important provisions in the final FY 2021 omnibus spending bill that encourage the National Institutes of Health (NIH) to expand its support for clinical research on regenerative medicine and cell therapies (RMCTs) for patients in need. ACT Now also encourages federal funding support for clinical trials that explore the use of RMCTs for seriously ill patients with COVID-19.

Support for Regenerative Medicine and Cell Therapies in Omnibus Spending Bill

Specifically, the spending bill (including the related House Report):

- Encourages the NIH—in coordination with the Food and Drug Administration (FDA) and the Health Resources and Services Administration (HRSA)—to explore the feasibility and utility of an outcomes database for adult cellular therapies that are FDA-approved or being administered under FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE) protocols, engaging experts and stakeholders to define data types and standards necessary for such a database.
- Encourages the NIH to support:
 - Basic and translational discoveries—including regenerative medicine—to support research related to cerebral palsy;
 - A robust and coordinated portfolio of research related to traumatic brain injury that includes research on regenerative medicine;
 - Acceleration of research in regenerative medicine for patients with heart disease; and
 - An already robust regenerative medicine research portfolio in the field of regenerative medicine to improve dental, oral, and craniofacial health.

“We are delighted to see Congress’ recognition of the need for additional federal funding and support for clinical research and collaborative evidence development for regenerative medicine and cell therapies,” said Janet Marchibroda, President of ACT Now, “the lack of federal funding for large-scale, randomized, placebo-controlled clinical trials in this area serves as a primary barrier to bringing promising treatments to patients in need.”

Funding for RMCT Clinical Trials for Seriously Ill COVID Patients is Still Needed

Early results from clinical studies indicate that RMCTs—and in particular, mesenchymal stromal cells (MSCs)—can play a key role in helping severely ill patients with COVID-19, given their immunomodulatory and anti-inflammatory characteristics.

In its most severe form, COVID-19 leads to acute respiratory distress syndrome (ARDS)—a life-threatening lung injury that allows fluid to leak into the lungs and makes it difficult for patients to breathe. According to the [Centers for Disease Control and Prevention](#) (CDC), anywhere from 67

to 85 percent of patients admitted to the ICU develop ARDS, and 39 to 72 percent of patients admitted to the ICU die. There is a need for additional therapies for severely ill patients in the ICU who are on ventilator support.

[ACT Now's research](#) indicates that at least 100 clinical studies exploring the use of RMCTs for COVID-19—79 of which are specifically focused on MSCs—are listed on www.clinicaltrials.gov. Early results from 21 clinical studies—as well as insights shared through at least 100 published review articles—show promise for the use of RMCTs for COVID patients.

“[Our analyses](#) of clinical trials exploring the use of MSCs show a trend toward improved pulmonary function, reduced severe lung inflammation, and reduced mortality for patients with ARDS, a major complication for patients with COVID-19,” said Wenchun Qu, MD, PhD, Associate Professor, Mayo Clinic College of Medicine and Director, Regenerative Pain Medicine at Mayo Clinic Florida. Dr. Qu, as well as other researchers from Mayo Clinic, Emory University, Duke University, Case-Western University, and the University of Miami, [have called for](#) the rapid commencement of large-scale, confirmatory clinical trials to build on the existing evidence base, to pave the way toward another treatment option for seriously ill patients with COVID-19.

While early results from clinical studies are promising, larger-scale, randomized, placebo-controlled clinical trials that take into account the evolving standard of care and current mortality rates, are urgently needed to confirm early results and rapidly bring safe and effective FDA-approved treatments to patients in need.

The key barrier to conducting such trials is lack of federal funding. While more than \$10 billion of supplemental funding was previously appropriated by Congress to BARDA and the NIH for vaccines and therapies, [no funds](#) were directed towards clinical trials for these promising therapies for COVID patients, other than one small Phase 1 trial funded through the National Cancer Institute. In addition, no funding was specifically directed towards clinical trials focused on RMCTs or any other types of therapies for COVID patients in the \$1.4 trillion spending package passed by Congress last week and signed into law by the President earlier this week.

More than 19.5 million Americans have tested positive for COVID-19 and more than 335,000 Americans have died. The number of hospitalizations in the U.S. has hit an all-time high—[nearly 125,000](#)—exceeding 100,000 every day since the beginning of December.

As Congress considers additional COVID legislation and as the Administration establishes its priorities for new funds brought about by the just-released FY 2021 spending package, ACT Now urges policymakers to direct funding to large-scale, randomized, controlled trials exploring the use of RMCTs for seriously ill patients with COVID-19.

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About Alliance for Cell Therapy Now

Alliance for Cell Therapy Now (ACT Now) is an independent, non-profit organization guided by leaders representing academic and medical institutions, industry innovators, and patients, that is working to advance safe and effective regenerative medicine and cell therapies for patients in need. See www.allianceforcelltherapynow.org