Kirk, Manchin, Collins Introduce Bill to Speed Development of Regenerative Medicine

March 16, 2016 By Cade Hildreth (CEO)

In major news released today, the Office of U.S. Senator for Illinois, Mark Kirk, announced the introduction of The REGROW Act, a bill designed

requires the "FDA to collaborate with stakeholders to develop standards that will lead to manufacturing processes and controls for safe regenerative medicine products."

The ability of stakeholders to work collaboratively with the FDA has been a major hot topic lately, with a FDA Public Hearing to review four draft guidances controlling the regulation of stem cells recently postponed due to an unexpectedly large number of registrations (approximately 600). It is my opinion – and one that is shared by most advocacy groups – that the large turn-out for this FDA public hearing was a successful effort to communicate patient concerns to the FDA and a way to indicate that more input is needed in the regulatory process.

Most impressively, the REGROW Act is supported by leading groups within the regenerative medicine space, including:

- National Stroke Association
- Alliance for Aging Research
- Regenerative Medicine Foundation
- Alliance for the Advancement of Cellular Therapies

To learn more, read the full press release below issued by the Office of Senator Mark Kirk.

REGROW Act Accelerates New Therapies to Help Patients Living with Disease; Stem Cell Therapies Help Alzheimer's, Parkinson's, Sickle Cell Patients

Wednesday, Mar 16, 2016 WASHINGTON – U.S. Senators Mark Kirk (R-Ill), Joe Manchin (D-W.Va.) and Susan Collins (R-Maine) today introduced The REGROW Act, S. 2689, bipartisan, bicameral legislation to reduce barriers to medical innovation and accelerate the development of new regenerative medicine treatments, which have the potential to restore or establish normal function in damaged human cells, tissues and organs.

"As a stroke survivor, I know how much potential new regenerative therapies have for the thousands of other stroke survivors nationwide," **Senator Kirk said.** "The REGROW Act provides clarity for companies and doctors who are developing breakthrough products and helping their patients. By expanding options for those living with Alzheimer's, Parkinson's, diabetes and stroke, we can help more patients live the life they want on their own terms."

"We must support important medical research to find cures and treatments to the many medical challenges we face," **Senator Manchin said**. "This bipartisan legislation will improve the approval process of low risk therapies that could have significant benefits to someone struggling with burns and wounds, arthritis, ALS, and may be able to be used to help people recover from stroke. I am glad to join my colleagues to ensure these

bipartisan REGROW Act will help make certain that the regulatory framework in the United States facilitates and helps support the development and continued progress in this important area of medicine."

"The development of regenerative medical treatments is one of the most exciting aspects of modern medicine. These products, developed from adult stem cells, show potential to fully restore or establish normal function in damaged human cells, tissues, or organs," **said U.S. Representative Mike Coffman (R-Colo.)**, who introduced companion legislation in the U.S. House of Representatives.

According to a recent U.S. Government Accountability Office (GAO) **report**, "virtually any disease that results from malfunctioning, damaged or failing tissues may be potentially cured through regenerative medicine treatments." Stem cell and tissue-based treatments have already proven to be successful in curing diseases **like sickle cell,** and recovering stroke victims have been helped during their rehab phase by utilizing stem cells to repair damaged brain tissue.

The promise of stem cell and tissue-based treatments is already evident in Illinois. In 2012, **Ieshea Thomas was successfully cured of sickle cell disease** after receiving a stem cell transplant at the University of Illinois at Chicago (UIC). Additional **patients** have been successfully treated by UIC, suggesting stem cell transplants are a viable alternative to

impediment to treatment development. Countries like Japan and England are outpacing the U.S. in regenerative medicine therapy development due to new regulatory policies that the U.S. has yet to mirror.

The REGROW Act addresses these issues by requiring the FDA to collaborate with stakeholders to develop standards that will lead to manufacturing processes and controls for safe regenerative medicine products. The legislation protects existing drug approval pathways under section 351 and 361 of the Public Health Service Act, while creating a new approval for regenerative medicine products. S. 2689 will allow the United States to regain prominence in the field of regenerative medicine science and bring therapies quickly to the patients that need it most.

In December 2015, the Bipartisan Policy Center published recommendations for advancing regenerative cellular therapies, which aim to "restore health rather than merely treat disease." The REGROW Act builds on that report by establishing a novel, conditional approval pathway that will ensure products are safe and effective before they can be marketed. It also includes post-market surveillance measures to ensure continued safety during the conditional use period.

The REGROW Act is supported by the Bipartisan Policy Center, National Stroke Association, Alliance for Aging Research, Regenerative Medicine

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