**The REGROW Act- an urgent demand for a new FDA regulatory pathway to accelerate safe cell therapies**

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| |  | | --- | | Why does cell therapy need a new regulatory pathway?   Because it is a unique form of treatment that does not appropriately belong in either of the FDA’s two approval pathways: the practice of medicine or the development of biologics and drugs. The FDA currently regulates cell therapy as a drug.  Requiring all therapeutic cell products to go through the lengthy and expensive Biologics Licensing Application (BLA) process and initial Phase 3 trials is too high a regulatory bar, especially since some forms of cell therapy, such as bone marrow transplants, have been in use for decades and have been proven safe.    Even more to the point, after 15 years of requiring cell therapy developers to pursue approval through the BLA process, the FDA has not yet issued a single approval. This bottleneck has real-world consequences for patients every day who cannot receive new treatments that could alleviate suffering or even cure their conditions.   This is not just some ivory tower academic debate about the power and reputation of the FDA. This is not about the bottom line for a few companies and their minions that have decided that they have vested financial interest in maintaining the status quo. Here’s the reality: Some patients die waiting.   I’ve been working as an advocate for cell therapies for 14 years, and I have never seen the convergence of technologies and progress that we see today in areas such as imaging, nanotechnology, gene editing and cell reprogramming. We have largely moved beyond the societal debate about embryonic versus adult, or tissue-specific, stem cells. Today we understand that all of these cells hold promise in different ways as valuable tools in the clinical toolkit. | |

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| |  | | --- | | We are at an important juncture and the time to move forward is now. The U.S. is lagging behind other nations that have already developed accelerated approval pathways for cell therapy. The FDA is arguably the world’s most important regulatory agency, and should seize the opportunity to guide the appropriate development of this emerging field. The innovation and cross-disciplinary work being done in the lab should be a model for our regulatory and legal systems.   I am not advocating that we compromise safety. Far from it. We must have appropriate standards and boundaries. And that is why we need an innovative approval pathway designed specifically for cell therapy. We must be smart about preparing for the era of precision medicine and the sweeping changes regenerative cell therapy will bring.   Recently I’ve been studying and writing about important patient advocacy movements. In the mid-20th century, medical philanthropist and health activist Mary Lasker, who said she was “opposed to heart attacks and cancer and strokes the way [she was] opposed to sin,” fostered important medical research and revolutionized the American Cancer Society. Polio vaccines were a giant clinical trial, and parents in the 1960s offered up their children as research subjects to help face down a health emergency. The AIDS/HIV epidemic was eventually addressed and the field advanced after public protests gained national attention. Breast cancer research was underfunded until public advocacy campaigns brought about change.   I believe that regenerative medicine represents the next consumer movement, and the REGROW Act gives us a foundation to build on. Public awareness and coalition-building will help move the needle on this, and advance the field of medicine, just as it has in the past. | |

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