ALLIANCE for Regenerative Medicine

March 31, 2016

The Honorable Mark Kirk
Hart Senate Office Building
Washington, DC 20510

Dear Senator Kirk:

On behalf of the Alliance for Regenerative Medicine (ARM), I write to express our continued concerns with your legislation the "Reliable and Effective Growth for Regenerative Health Options that Improve Wellness" or the "REGROW Act" (S. 2689/HR 4762). I am referring to the draft marked Senate Legislative Counsel Draft Copy of O:\BOM\BOM16264.XML and dated 3/29/2016.

As the leading global advocate for the regenerative medicine and advanced therapies sector, ARM advocates for the acceleration of research, development, investment and commercialization of transformational treatments and cures for patients worldwide. ARM's members include over 250 member companies, academic institutions clinical centers, patient advocacy groups and investors.

We sincerely appreciate and support your efforts to advance this field and fundamentally share your goal to make safe and effective products available to patients as soon as possible. We remain interested in and committed to working with you to accomplish that goal. As you correctly point out, development of standards for regenerative medicine will go a long way to achieving that objective. To that end, we support your bill's provisions that require the Secretary to work with stakeholders to develop appropriate standards for manufacturing and other processes that directly impact the safety and reliability of cell and tissue-based products.

While we appreciate your intent and the changes that have been included in the bill since earlier versions, the legislation continues to contain provisions that we believe must be changed to make sure only safe and effective treatments reach patients quickly. For example, the bill as drafted will allow products to be marketed as "conditionally approved" under new and undefined standards such as "preliminary clinical evidence of safety, and a reasonable expectation of effectiveness". In addition, by calling into question whether Phase III trials should ever be required to receive this new type of "conditional approval" status, the bill potentially allows products on the market without necessary testing we believe to be required for complex products such as autologous cell therapies. Finally, the bill contains other provisions that we believe leave patients unnecessarily vulnerable and exposed to exploitation. In so doing, it could put patients at risk, put the hundreds of American companies that are developing drugs, biologicals, devices, and combination products according to the highest standards of FDA laws and regulations at a significant disadvantage and damage a very promising field of medicine before it has a chance to be properly recognized for its potential lifesaving value.

Other concerns include the bill's exclusion of therapies using genetically modified cells; these have tremendous promise. In addition, in the device section, the bill sets a precedent of codifying statutory classification requirements rather than through use of rulemaking, and takes away a sponsor's discretion regarding the approval pathway for cellular therapy combination products.

Consequently, we cannot support your bill as written. We would like to continue to work with you to advance policies that will support the regenerative medicine sector. We have attached a document with our specific concerns and possible solutions. We ask that you continue to dialog with us so we can develop alternative approaches that will provide access to these therapies in an accelerated way that does not compromise patient safety, efficacy and the public trust.

If you have any questions, please contact me at elanphier@sangamo.com or Michael Werner at 202-419-2515 or mwerner@alliancerm.org.

Sincerely,

Edward Lanphier

Edward Lanphier
Chair of the Alliance for Regenerative Medicine
President & CEO, Sangamo Biosciences, Inc.