

April 26, 2016

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

Dear Senator Kirk:

On behalf of AABB, I am writing to thank you for your leadership in sponsoring legislation aimed at expediting patient access to cellular therapies. While AABB strongly supports the goal of S. 2689, the Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act<sup>7</sup> (as amended and marked BOM16344), we respectfully request that certain provisions in the bill be amended to better protect patients from receiving ineffective care.

AABB is an international, not-for-profit association representing individuals and institutions involved in the field of transfusion medicine and cellular therapies. The association is committed to improving health by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB membership consists of nearly 1,800 institutions and approximately 7,500 individuals, including physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers involved in all aspects of cellular therapies and transfusion medicine.

Cellular therapies hold tremendous promise for patients facing a wide range of severe or life-threatening medical conditions. AABB firmly advocates for efforts to expedite testing of therapies to improve patient access to these treatments and options for care. Improvements to the current regulatory pathways are needed to allow for more rapid introduction of life-saving therapies. We applaud your effort to enact legislation aimed at modifying the regulatory framework to decrease the time from novel laboratory discovery to the routine clinical application of these products.

However, AABB is concerned about the breadth of products that would be eligible for conditional approval under the REGROW bill. AABB is concerned with the inclusion of cells or tissues that are more-than-minimally manipulated for a **non-homologous use** in the conditional approval program. Use of more-than-minimally manipulated cells or tissues for non-homologous use could have unpredictable delayed consequences in the recipients and thus affect the risk-benefit ratio of these therapies. Clear demonstration of a favorable risk-benefit ratio, as assessed by randomized controlled trials, would address this concern and demonstrate that they are not only safe but effective as well. Otherwise, significant numbers of patients risk spending limited healthcare dollars on care that offers them no real hope of improvement. **In order to foster high quality patient care, AABB respectfully requests that the REGROW bill be amended to delete the clause “or non-homologous use” from the amended section 351B(c)(3)(B).**

In addition, AABB recommends another relatively minor change in language to ensure the safety of products eligible for conditional approval. **Under the amended section 351B(c)(2), we suggest adding the terms “and tumorigenicity” and “or other adverse” to require that eligible cells or tissues be “evaluated to examine immunogenicity and tumorigenicity and do not provoke a significant**



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**unintended immune or other adverse response in the recipient.”** This addition will help protect patients from being exposed to potentially oncogenic therapies.

Again, AABB appreciates your efforts to champion the advancement of regenerative medicine and cellular therapies. We respectfully urge you to consider the two above amendments aimed at ensuring high quality patient care. We welcome the opportunity to further discuss this issue with you and stand ready to work with you and our colleagues in the cellular therapy community to advance policy changes which will speed the delivery of safe and effective therapeutics. Please feel free to contact AABB Director of Public Policy Theresa Wiegmann (301-215-6554 or [theresa\\_w@aabb.org](mailto:theresa_w@aabb.org)) if you have questions or require additional information.

Sincerely,

Donna Regan, MT(ASCP)SBB  
President  
AABB