ALLIANCE for Regenerative Medicine

Summary

Regenerative Medicine Promotion Act of 2014

The Regenerative Medicine Promotion Act of 2014 (S. 2126) launches a national initiative on Regenerative Medicine (RM). Senators Barbara Boxer (D-CA) and Mark Kirk (R-IL) introduced this vital legislation in the Senate on March 13, 2014. Representatives Erik Paulsen (R-MN) and Diana DeGette (D-CO) will reintroduce the legislation in the House shortly. The Act establishes a national strategy for regenerative medicine and related advanced therapies to ensure that the US remains a leader in research and commercialization of these innovative products. Specifically, the Act would do the following:

- Establish the Regenerative Medicine Coordinating Council within the Department of Health & Human Services;
- Establish a public-private Council to devise a national strategy for the promotion of research into regenerative medicine and the development of drugs, biological products, medical devices, and biomaterials; identify and recommend policies to overcome barriers in research and product development; and specify priorities for research into regenerative medicine and the awarding of grants under the Act, among other things;
- Require the Council to issue an annual report on the state of regenerative medicine; and
- Require the US Government Accountability Office (GAO) to analyze research gaps and other obstacles to commercialization of RM products. Note Senators Harkin, Isakson, Boxer, Hatch, Landrieu and Alexander requested that the GAO conduct a study of current federal activities that impact the field of RM as well as progress compared to national programs in other countries in November of 2013. This provision is included in the legislation to serve as a catalyst for the GAO to begin the study.

House Version of the Act Only:

- NIH Grants for Academic-Industry Collaboration - creates two translational research grant programs at NIH to nurture academic-industry collaboration in regenerative medicine.
- Funds for non-profits or institutions of higher education to conduct basic or preclinical research into regenerative medicine, if the research is partly funded by a private company.
- Grants to collaborative partnerships, which include a non-profit/institution of higher education and a private company, for R&D of regenerative medicine and the making of an investigational new drug (IND)/ investigational device exemption (IDE) application at FDA within 4-years.
- NIH Grants for Private Companies - to support product development in regenerative medicine through the existing Cures Acceleration Network. Grants will support basic research, pre-clinical studies and clinical trials for pre- and IND/IDE applications in regenerative medicine.
- FDA Grants for Regulatory Research - to foster development of a clear, predictable regulatory pathway to enable speedy approval of safe and effective products, the Act authorizes FDA to conduct regulatory research to help in the approval of regenerative medicine products. Research would be public-private partnerships.

The Act does not authorize any new funding.