Invitrx Therapeutics

September 4, 2017

Invitrx applauds FDA's recent promise (Statement from FDA Commissioner Scott Gottlieb, August 28, 2017) to more clearly define their regulatory oversight of stem cell therapies and regenerative medicine. FDA has promised to do all they can to bring patients more quickly innovative, scientifically proven regenerative cell therapies. This fall they will advance a comprehensive policy to establish clearer lines around when these regenerative medicine products have sufficient complexity to fall under the agency's current authority and then define an efficient process for how these products should be evaluated for safety and effectiveness. This new policy will also serve to fully implement provisions of the 21st Century Cures Act that define the Regenerative Medicine Advanced Therapy (RMAT) designation. FDA promises to develop a novel approach to product approval that will allow very small product developers to gain all the benefits of FDA approval through a process that is minimally burdensome and less costly.

Invitrx eagerly awaits further definition of this new regulatory framework as we continue to build on our firm commitment to produce safe and effective regenerative medicine products under the most rigorous cGMP conditions as described in current FDA regulation and guidance documents.

Invitrx is presently expanding its manufacturing operations in Irvine through the purchase of a new10,000 sq.ft building. The facility will house three Class 7 cleanrooms each populated with two Class 5 biosafety hoods and be fully validated and operational by 1st quarter 2018.