

Midwest Center for Stem Cell Therapy
Testimony in support of SB 199
by Buddhadeb Dawn, M.D.

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Chairman Crum and members of the Committee, thank you for the opportunity to testify on this important topic.

I am the Maureen and Marvin Dunn Professor and Director of the Division of Cardiovascular Diseases at the University of Kansas Medical Center. I am also the Director of the Cardiovascular Research Institute and Vice Chairman for research in the Department of Medicine at KUMC. I am a Fellow of the American Heart Association, the American College of Cardiology, and the American College of Physicians. I serve on various scientific committees, grant review panels, and editorial boards of several prominent cardiovascular journals. I have authored more than 100 original scientific papers, review articles, editorials, and book chapters, including many focused on adult stem cell research and therapy. I am a clinician-scientist with research interests focused primarily on heart repair by adult stem cells. The research conducted in my laboratory has been funded by the National Institutes of Health and the American Heart Association. Having performed extensive and critical analysis of data from numerous clinical trials of heart repair with adult bone marrow cells, I am very familiar with various aspects of such therapy. In addition, I am currently the site principal investigator for an ongoing clinical trial of CD34+ bone marrow cell therapy in patient with heart attacks. I am also the principal investigator on a planned clinical trial with bone marrow cell therapy in patients with critical limb ischemia, which we hope to begin in the near future.

As we presented and discussed in our previous testimony to the joint committee on Feb 7 and 8, an increasing number of patients are being treated with various types of adult stem cells all over the world. These cells include adult bone marrow cells, cardiac stem cells, adipose stem cells, and other types of tissue-specific progenitor cells. Research with cells from cord blood and related tissues also seems very promising.

Although adult bone marrow cell therapy significantly improves outcomes in heart patients, such treatments for various diseases currently occur only in the form of clinical trials. Although there are many centers outside the US for stem cell therapy, there is a severe lack of access to such therapy for patients in Kansas and other adjoining states. The creation of a center for adult stem cell therapy will obviate the travel to distant countries and related difficulties to receive stem cell therapy. Moreover, such therapy outside the US is not regulated by the FDA. Ideally, similar clinical trials and treatments can be and should be performed using the appropriate cells and following Good Manufacturing Practices and safe methods on the US soil, in Kansas.

The above provides a convincing rationale to create a center that will facilitate adult stem cell therapy and research in the Midwest. It is important to note that the center will facilitate treatment and research with adult stem cells, the only type of stem cell that has shown promise for organ repair in patients thus far. Therefore, focusing on adult stem cell research will greatly facilitate faster translation of such therapy in patients in a safe manner. Given the high incidence of heart disease and other diseases that may potentially benefit from adult stem cell therapy in Kansas, it makes excellent fiscal sense to invest in cells with the greatest potential for use in patients in the near future.

Since I have been an active participant in this initiative to create a center for adult stem cell therapy, I have given much thought to the organizational structure of this center and its various operations. I believe the

center will benefit from a director, who is very familiar not only with adult stem cell research, but also stem cell therapy in patients. These qualities will be important as the director will be responsible for evaluating and selecting the various available therapies and clinical trials that will benefit patients.

The responsibilities of the center director will touch upon all aspects of center operations, and can be divided broadly into administrative, fiscal, and scientific domains. Administratively, the director will report to and work closely with the Executive Vice Chancellor of the University of Kansas Medical Center. The director will also work closely with the advisory board members to incorporate suggestions into the operational plan as appropriate. The center is envisioned to be modular in nature – starting with a smaller operation and then adding components as the operations grow. In this regard, the director will determine the need for expansion of center operations and the need for recruiting additional scientific as well as support personnel for center operations. With the expected growth in operations, the center director will increasingly rely on section directors in specific areas (for example, scientific director), who will manage the day-to-day operations.

With help from a financial assistant, the center director will be responsible for preparing and managing the budget for the entire operation. In this role, the director will work with the state treasurer and the director of accounts and reports for transactions concerning the fund created for the center. The director will work with the KUMC Research Institute and the KU Endowment Association for the management of study budgets, personnel salary, various income accounts, and related matters.

The center director will work with the clinical trial division and various centers and institutes within KU Medical Center to facilitate the selection and initiation of clinical trials with adult stem cells for various diseases. The director will work with the principal investigators to ensure the use of appropriate methods and protocols for various trials.

In collaboration with the scientific director of the cell processing facility, the center director will ensure timely processing and manufacturing of clinical grade adult stem cells, the need for new personnel hire, purchase of equipment and services, and infrastructural changes. As for research on adult and nonembryonic stem cells, the center will recruit well trained stem cell scientists, who will conduct basic research and train fellows. In collaboration with the educational team, the center director will oversee the preparation and dissemination of educational materials, and courses and seminars on adult stem cells for physicians, fellows, and community members.

We would like to emphasize that we fully intend to utilize various existing expertise and resources within the KU Medical Center. However, because of the current economic environment and existing commitments, it will be impossible for the KU Medical Center to bear the costs of this endeavor entirely. Considering the various components that need to be in place for successful operation, we believe approximately \$1.3 million will be necessary in the first year.

We sincerely hope that this investment, although substantial in the current era of economic austerity, will very likely generate tremendous returns for Kansans in need of stem cell therapy for numerous diseases.

Thank you very much for this opportunity to testify.

Respectfully submitted,

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