Midwest Stem Cell Therapy Center—A Unique Initiative

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Joint Meeting
Committee on Public Health and Welfare, Kansas Senate
Committee on Health and Human Services, Kansas House
March 10, 2014

The Distinguished Chairs and Honored Members of the Committee.

I am a cell biologist, currently working for a policy think tank in Washington, D.C. and as an adjunct professor at a local university. For the previous 20 years, I was Professor of Life Sciences at Indiana State University and Adjunct Professor of Medical & Molecular Genetics at Indiana University School of Medicine, and I have done federally-funded laboratory research, lectured, and advised on these subjects extensively, in the U.S. and internationally. I was selected by the Bush President's Council on Bioethics to write the comprehensive review of adult stem cell research for the Council's 2004 publication "Monitoring Stem Cell Research". I am proud to be a native Kansan, born in La Crosse, Kansas, raised near Parker, Kansas, with my degrees (B.S. and Ph.D.) from the University of Kansas.

Thank you for the opportunity to testify to you on the progress of the Midwest Stem Cell Therapy Center, a unique Kansas initiative. I was honored to assist with development of the Kansas stem cell center, and testified before you last year in favor of the bill, SB199, that made the Center a reality. Thank you for your support of this idea. Currently I serve as a member of the Center's Advisory Board.

As a brief review, we had previously discussed how stem cell treatments using adult stem cells from bone marrow, umbilical cord blood, and other sources have become a cutting-edge technology in medicine, poised to revolutionize therapy for dozens of diseases and conditions. Over 2,800 clinical trials using adult stem cells are currently listed in the NIH/FDA-approved database,[1] and over 60,000 people around the globe now receive adult stem cell transplants each year. Application of adult and cord blood stem cells in clinical therapy is rapidly blooming. The KU Cancer Center itself last year did over 300 marrow and blood stem cell transplants for cancer treatments, over 30% more than the previous year, with over 1,360 transplants done since 2006. Moreover, there is therapeutic promise for diseases where there has previously been no available treatment option. The published scientific literature now documents therapeutic success of adult stem cells for patients with heart damage, stroke, sickle cell anemia, spinal cord injury, multiple sclerosis, juvenile diabetes, and dozens of other conditions. Further, a growing number of adult stem cell transplants use cells from sources such as mesenchymal (connective) tissue, adipose (fat) tissue, and even nasal tissue, and there is the promise of even more sources such as the solid portion of the umbilical cord (Wharton's jelly), amniotic fluid, and others. A published estimate is that here is a 1 in 200 chance that you or I, or anyone living in the U.S., will undergo an adult stem cell transplant during our lifetime.[2]

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[1] Search term: http://www.clinicaltrials.gov/ct2/results?term=adult+stem+cell+transplants&type=Intr accessed March 8, 2014.

[2] Nietfeld JJ *et al.*, Lifetime Probabilities of Hematopoietic Stem Cell Transplantation in the U.S., *Biology of Blood and Marrow Transplantation* 14, 316-322, 2008

The **Midwest Stem Cell Therapy Center (MSCTC)** at KUMC is already beginning to take advantage of this promise, treating patients, running clinical trials for new treatments, and developing collaborations for future therapies. I will leave the details of the Center's accomplishments in its first few months of existence to Dr. Buddhadeb Dawn, the distinguished Director of the MSCTC.

The Midwest Stem Cell Therapy Center is a unique, comprehensive center. It is focused on patients. This focus includes not only current therapies and trials, but also advancing the frontier of research and therapies to help even more people, providing clinical-grade stem cells for treatments and trials, educating the public as well as professionals about current and developing treatments, and serving as a global resource for patients and physicians.

The unique, comprehensive nature of the Center can be characterized in the word TREAT:

T **Treat** patients for diseases and injuries
R **Research** to understand and develop further stem cell therapies, *and*
Resource for patients & physicians (clinical grade stem cells, database, information)
E **Educate** public including school children, professionals, policymakers, *and*
Ethical and non-controversial stem cell therapies and research
A **Access** for patients, professionals to information as well as clinical trials
T **Train** physicians and scientists

In contrast to the MSCTC, most "stem cell centers" focus on basic research with little or no clinical component. Further, most "stem cell treatment centers" tend to emphasize certain clinical treatments but do not educate the public or physicians. According to one source I found, there are around 53 programs nationwide doing research in the stem cell field. Here are some of these stem cell centers, for comparison. Some of the funding information is unavoidably vague due to the lack of transparency at the institutions.

The **Oklahoma Center for Adult Stem Cell Research (OCASCR)** is a virtual center. It was established in 2010 by the Oklahoma legislature with $5.5 million from the Oklahoma Tobacco Settlement Endowment Trust. The principal activities of the Center are to promote adult stem cell research in Oklahoma, and to educate the public about adult stem cells. These goals are accomplished primarily by giving out grants for basic research.

The **Regenerative Medicine Program at the University of Nebraska Medical Center** was formally established in 2010 with the naming of a Director for the Program. Funding was reallocated to the Program, apparently by the University of Nebraska Medical Center, for recruiting up to four additional faculty, and the press release noted that they were hopeful to generate more support through private donations. While the Nebraska Medical Center does approximately 150 bone marrow transplants per year, the clinical program is not coordinated with the Regenerative Medicine Program, which does basic stem cell research. The Nebraska legislature in 2008 prohibited use of state funds or facilities for embryo destruction or creation, including cloning (somatic cell nuclear transfer), and provides up to $500,000 in state tobacco settlement funds as matching research grant funds each year for non-embryonic stem cell research.

The **Center for Regenerative Medicine and Cell Based Therapies at Ohio State University** was officially opened in 2012. The focus of the center is to develop research on regenerative medicine and cell-based therapies, and it is solely involved in basic research. The center itself is administrative space, with the actual laboratories scattered across the campus. Funding for the research activities comes from the academic colleges; the College of Medicine provides an annual budget of $500,000 and six other colleges within the University contributed $515,000 to cover initial operating costs including office equipment and personnel for a total of $1,015,000.

The **National Center for Regenerative Medicine at Case Western Reserve University** is a collaboration between Case Western, the Cleveland Clinic, Ohio State University, University Hospitals at Case Western, and the adult stem cell company Athersys. The Center was created in 2003 with a $19.4 million award from the Ohio Third Frontier, a state-sponsored technology innovation fund. The Center's efforts focus on non-embryonic stem cell research and the clinical components of the collaboration do some transplantations, though much of the work coordinated by the Center is in the basic science area. Since its establishment, the Center has received over $19 million in grants and awards, primarily from state programs.

The **Tulane Center for Stem Cell Research and Regenerative Medicine** was founded in 2000. The Center was initially supported by funding from the state of Louisiana via the Louisiana Gene Therapy Research Consortium and the Louisiana Board of Regents, from the Tulane University Health Sciences Center, the HCA - Healthcare Company and several private foundations. The Center is presently supported by research funds from the federal government via National Institutes of Health, National Science Foundation and Department of Defense grants. The Center opened a Good Manufacturing Practice (GMP) facility to process cells for transplant, and does some clinical work though most of the resources are directed toward basic research.

The **McGowan Institute for Regenerative Medicine at the University of Pittsburgh Medical Center** was founded in 2001, focused primarily on artificial organs and supporting technologies. Currently it has approximately 230 faculty in 31 academic departments. The majority of the work is basic research, though significant translational research does take place as well as clinical trials. In 2012, the University of Pittsburgh Cancer Center did 287 adult stem cell transplants. The McGowan Institute's annual budget is not divulged by the University. One report indicated that in 2001 the initial research annual budget was less than $1 million per year, but that the annual budget was $27 million in 2011. Funding comes primarily from grants and contracts for faculty members from federal agencies such as the National Institutes for Health, the National Science Foundation and Department of Defense. Between fiscal year 2004 and fiscal year 2011, these grants accounted for $85.6 million, according to the institute's 10-year progress report. Another $19.8 million came from gifts and philanthropy, $15.65 million from University of Pittsburgh Medical Center, and $4.84 million from the University of Pittsburgh.

The **Stem Cells and Regenerative Medicine (STaR) Center of Baylor College of Medicine** was founded in 2005. It is targeted toward basic research into fundamental questions, such as understanding how stem cells are stimulated to regenerate tissues, with a focus on enhancing basic research and developing training programs in stem cells. No budget information was available.

The Midwest Stem Cell Therapy Center compares favorably against all of these and other "stem cell centers" around the country. The Kansas Center is unique, comprehensive, focused on the patients first and the potential benefits for patients are incalculable. It encompasses clinical treatments, basic and translational research, education and training, and a resource for cell processing and information, including development of a one-of-a-kind database. It is already on the path to becoming a focal point for adult stem cell therapies, trials, and collaborations, as well as for education and training.

Kansas can be the leader in providing adult stem cell treatments and information to physicians and patients around the world.