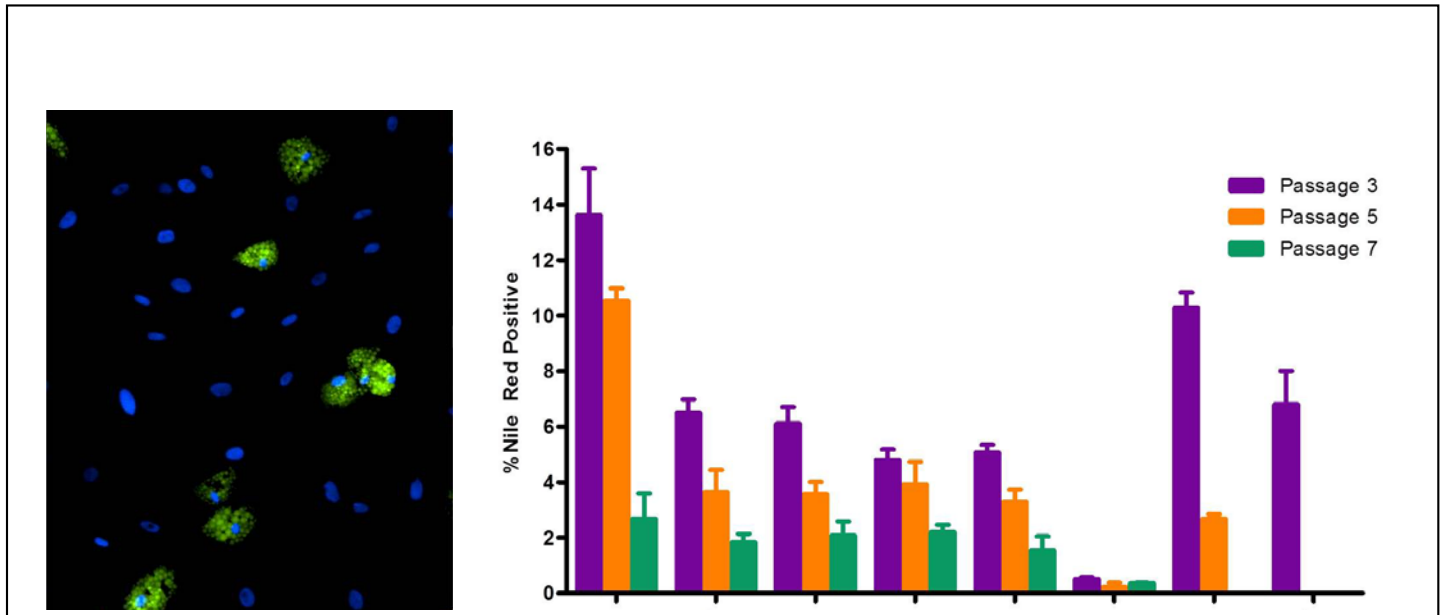




2015 Science Writers Symposium Lab Tour: Improving Stem Cell Characterization

Steven R. Bauer, Ph.D. Chief, Cellular and Tissue Therapies Branch

Center for Biologics Evaluation and Research
Office of Cellular, Tissue, and Gene Therapies



Left panel: Shows mesenchymal stem cells (MSCs) after treatment to induce fat cell formation. Blue indicates cell nuclei; green indicates the presence of fat revealed by a dye called Nile Red. Right panel: MSCs treated to make fat cells were counted to determine how many—using different donors—were successful in transforming and how long the cultures lasted (a concept known as passage). Passage refers to the duration of cell culture. The graph shows that the number of MSCs that can turn into fat decreases over time. Also, the ability of MSCs to turn into fat is different between MSCs from different donors.

Cell-based therapies show great promise for repairing, replacing, restoring, or regenerating damaged cells, tissues and organs. Researchers are working to develop cell-based treatments that are both effective and safe.

Many cell-based therapies use mesenchymal stem cells that are removed from the body and put into cultures in the laboratory, where they multiply before being infused into the patient. MSCs can generate several tissues including fat, bone, and cartilage. They can also suppress immune responses.

Despite the huge amount of clinical research to date, MSC-based products have not reached the market. One reason may be that MSC preparations appear to be a mixture of different cells—and the mixture varies in MSC isolates from different people and changes during manufacturing. The current methods to

characterize these cells typically do not measure this heterogeneity of cells in an MSC preparation.

The FDA's MSC Consortium is a group of eight scientists who are trying to develop better ways to understand MSCs. The group uses a variety of cutting-edge methods to characterize MSCs and then determines if any of these characteristics can predict the behavior of the cells in biological assays or in animal models. The group has published multiple papers on their work. The next step will be to determine if any characteristics they measure will predict the safety or effectiveness of stem-cell based products in patients.

Questions? Contact FDA's Office of Media Affairs at 301-796-4540 or fdaoma@fda.hhs.gov.

MSC Consortium Publications

- **Differentiation**

- Quantitative Approaches to Detect Donor and Passage Differences in Adipogenic Potential and Clonogenicity in Human Bone Marrow-Derived Mesenchymal Stem Cells. 2012. Lo Surdo, JL, and Bauer, SR. *Tissue Engineering: Part C* 18: 877–889.
- Automated Microscopy as a Quantitative Method to Measure Differences in Adipogenic Differentiation in Preparations of Human Mesenchymal Stem Cells. 2013. Lo Surdo, JL, Millis, B. and Bauer, SR: *Cytotherapy*. 2013 15: 1527–40

- **Proteomics**

- Improved proteomic profiling of the cell surface of culture-expanded human bone marrow multipotent stromal cells. 2013. Samuel T. Mindaye, Moonjin Ra, Jessica Lo Surdo, Steven R. Bauer, Michail A. Alterman. *J Proteomics* 78: 1–14.
- Global proteomic signature of undifferentiated human bone marrow stromal cells: Evidence for donor-to-donor proteome heterogeneity. Mindaye, ST, Ra, M, . Lo Surdo, JL, Bauer, SR, and Alterman, MA. 2013.. *Stem Cell Research* 11: 793–805

- **Immunomodulation**

- Assessment of immunosuppressive activity of human mesenchymal stem cells using murine antigen specific CD4 and CD8 T cells in vitro. 2013. Nazarov, C., Lo Surdo, J.L., Bauer, S.R., Wei, C-H. *Stem Cell Research & Therapy* 4:128.

- **Genomics**

- Gene markers of cellular aging in human multipotent stromal cells in culture. 2014. Ian H Bellayr, Jennifer G Catalano, Samir Lababidi, Amy X Yang, Jessica L Lo Surdo, Steven R Bauer and Raj K Puri. *Stem Cell Research & Therapy*, 5:59 (online)

- **Epigenetics**

- Chromatin Changes at the PPAR- γ 2 Promoter During Bone Marrow-Derived Multipotent Stromal Cell Culture Correlate With Loss of Gene Activation Potential. Lynch, PJ, Thompson, EE, McGinnis, K, Rovira-Gonzalez, YI, Lo Surdo, JL, Bauer, SR, Hursh, DA. *Stem Cells* 33: 2169–2181.

- **Sector Overview**

- MSC-based product characterization for clinical trials: An FDA Perspective. 2014. Mendicino, M, Bailey, AM, Wonnacott, K, Puri, RK., and Bauer, S.R. *Cell Stem Cell* 14:141–145