Activity Outline
FDA Grand Rounds: Are Stem Cells Ready for Prime Time? A Look at FDA Research Advances in Regenerative Medicine
March 8, 2018
White Oak Building 2: Room 2031

Series Description
The FDA Grand Rounds is webcast every other month to highlight cutting-edge research underway across the agency and its impact on protecting and advancing public health. Each session features an FDA scientist presenting on a key public health challenge and how FDA is applying science to its regulatory activities.

Lecture Description
Stem cell-based cellular therapies are being actively developed and hold tremendous promise for treating a wide variety of medical conditions, from diabetes to heart disease and joint repair. However, the use of stem cell-based products is new and characterizing the product is challenging. Specifically, FDA is conducting research into identifying cell therapy product characteristics that will predict the reliably of the performance of cell-based therapies in humans. In many cases, this is a challenge that is largely unresolved.

FDA is concerned with lot release characteristics of identity, purity, and potency, which constitute quality attributes. Ideally, these attributes are related to a given cell preparation's ability to perform the desired biological function--and result in the intended clinical effect.

For many investigational stem-cell based products, we currently don't know if the measurements we use to characterize products will predict their clinical effectiveness. For stem-cell-based clinical trial proposals submitted to FDA, the products are characterized using a small number of cell surface markers and simple measures of cell product activity.

The regulatory science question is whether or not the characteristics that are measured in product testing are predictive of clinical outcomes. This presentation will describe FDA's multipotent stromal cell (MSC) Consortium and our research efforts to develop strategies that will result in cell characterization methods that can predict quality, potency, and safety of MSCs. This could have implications for other types of stem cells and cell-based products in general.

References

- Reisman M., Adams, K. (2014) Stem Cell Therapy: a Look at Current Research, Regulations, and Remaining Hurdles. Pharmacy and Therapeutics (P.T) 39 (12) 846-847, 854-857 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4264671/
- Robbins, Reiesha., et al, (2010) Inducible pluripotent stem cells: Not quite ready for prime time? Current Opinions Organ Transplant 15 (1): 61-67 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3617582/
- 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
- Improved proteomic profiling of the cell surface of cultureexpanded human bone marrow multipotent stromal cells. 2013. Samuel T. Mindaye, Moonjin Ra, Jessica Lo Surdo, Steven R. Bauer, Michail A. Alterman. J Proteomics 78: 114.
- 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

Series Objectives

- Discuss the research conducted at the FDA
- Explain how FDA science impacts public health

Learning Objectives After completion of this activity, the participant will be able to:

- Explore measurements currently used to characterize products to predict clinical effectiveness.
- Describe FDA’s multi-potent stromal cell (MSC) Consortium and our research efforts to develop strategies that will result in cell characterization methods that can predict quality, potency, and safety of MSCs

Target Audience
This activity is intended for physicians, pharmacists, nurses, and other scientists within the agency external scientific communities.

Agenda

Lecture 1 March 8, 2018

Time	Topic	Speaker
12:00 - 1:00 PM	Are Stem Cells Ready for Prime Time? A Look at FDA Research Advances in Regenerative Medicine	Steven Bauer, Ph.D.

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1.00 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)* ™ . Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-18-037-L04-P for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacy participants: partial credit cannot be awarded, therefore you must attend the entire activity to receive CPE credit. No exceptions. Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit. Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Bauer, Steven, Ph.D., Chief, Cell and Tissue Therapies Branch, FDA/CBER/OTAT/DCGT - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Lee, Christine - nothing to disclose
- Parish, Eileen, MD, Medical Officer, FDA/OC/OCS/OSPD - nothing to disclose
- Wheelock, Leslie, MS, RN, Director, OSPD, FDA, OC, OCS, OSPD - nothing to disclose

CE Consultation and the Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary; therefore, refunds are not applicable.

Remote Access Instructions ***Webcast Registration:*** To register for the webcast, please click the link below and then follow the instructions on the registration page. After you register you will receive a link via email to access the live webinar. You must log in with your username and password which you create when you register. Please pre- register at least one day before the event to ensure you receive the access link email and outlook invitation for the session.

LINK TO REGISTER for WEBCAST:

https://collaboration.fda.gov/grmarch8reg/event/registration.html

For technical assistance please contact Jeffery Rexrode at Jeffery.Rexrode@fda.hhs.gov.

HHS/LMS Registration Link for FDA employees
https://lms.learning.hhs.gov/Saba/Web/Main/goto/RegisterCatalog?offeringId=class000000000132585&oneClickLearningON=true

Reasonable Accommodations
The FDA provides reasonable accommodations for all individuals with disabilities who apply for training or developmental opportunities. If you need a reasonable accommodation for any part of the training application process, please notify the training contact for this particular event. Reasonable accommodation requests are granted on a case-by case basis. Should you need sign language interpretation to attend this event, please send the request to Interpreting.Services@oc.fda.gov.