

**Food and Drug Administration
Center for Biologics Evaluation and Research
Cellular, Tissue and Gene Therapies Advisory Committee
Meeting # 64, February 16, 2016
FDA White Oak Conference Center
Great Room, Salon C
Silver Spring, MD**

SUMMARY MINUTES OF OPEN SESSION

Committee Members

Timothy P. Cripe, M.D., Ph.D., Chair
Dale Ando, M.D.*
David Bartlett, M.D.+
Catherine Bollard, M.D., MBChB, FRACP+
William Bugbee, M.D.
Barry J. Byrne, M.D., Ph.D.
Leisha Emens, M.D., Ph.D.
John D. Gearhart, Ph.D.+
Ole Isacson, M.D., Ph.D.
Grace E. Pluhar, D.V.M., Ph.D., DACVS
Stephen M. Rose, Ph.D.**+
Robert F. Willenbacher, M.D., M.B.A.***+
Janet Wittes, Ph.D.
Ann C. Zovein, M.D.

FDA Participants

Carolyn Wilson, Ph.D., Associate Director for Research
Celia Witten, Ph.D., M.D., Director, Office of Cellular, Tissue, and Gene Therapies (OCTGT)
Suzanne Epstein, Ph.D., Associate Director for Research for OCTGT
Raj Puri, M.D., Ph.D., Director, Division of Cellular and Gene Therapies (DCGT), OCTGT
Steven Bauer, Ph.D., Chief, Cellular, and Tissue Therapy Branch, DCGT, OCTGT

* Industry Representative

** Consumer Representative

*** Alternate Industry Representative

+ Not Attending

The summary minutes for the February 16, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) were approved on _____.

I certify that I attended the February 16, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee and that this report accurately reflects what transpired.

_____/s/_____
Timothy P. Cripe, M.D., Ph.D., Chair
Cellular, Tissue and Gene Therapies
Advisory Committee, FDA

_____/s/_____
Janie Kim, Pharm.D., Designated Federal Officer
Cellular, Tissue and Gene Therapies
Advisory Committee, FDA

The Cellular, Tissue and Gene Therapies Advisory Committee met by teleconference on February 16, 2016. Dr. Timothy Cripe, Chair, opened the meeting. The Designated Federal Officer made the roll call and read a statement into the public record that the February 16 meeting topic is determined to be a non-particular matter and the Committee discussion presented no potential for a conflict of interest. The Committee Members and FDA participants were introduced. Time was allotted during the meeting for public comment. No individuals from the public requested time at the meeting to address the Committee.

Open Session

In open session, the Committee heard presentations on the following:

- Overview of research and regulatory activities in the Center for Biologics Evaluation and Research (CBER), FDA by Dr. Carolyn Wilson
- Overview of research and regulatory activities in the Office of Cellular, Tissue and Gene Therapies (OCTGT) and research programs, CBER, FDA by Dr. Raj Puri
- Summary of an individual research program in the Tumor Vaccines and Biotechnology Branch (TVBB) by Dr. Raj Puri
- Summary of individual research programs in the Cell and Tissue Therapies Branch (CTTB) by Dr. Steven Bauer

Following the presentations and the open public hearing the open session was adjourned at 3:55 pm.

For more detailed information concerning the open session presentations and committee discussions summarized above, please refer to the meeting transcripts available on the FDA [website](#). Please submit all external requests to the FDA Freedom of Information Office.