FOOD AND DRUG ADMINISTRATION

Center for Biologics Evaluation and Research
121st Meeting of the Blood Products Advisory Committee
Tommy Douglas Conference Center
New Hampshire Avenue
Silver Spring, MD 20903

November 22, 2019

Committee Members	**FDA Participants**
Evan Bloch, M.D., M.S.#	Anne Eder, M.D., Ph.D.
Barbara Bryant, M.D., F.C.A.P, F.A.S.C. P	Monique Gelderman, Ph.D.
Alfred DeMaria, Jr., M.D.	Orieji Illoh, M.D.
CDR Michael DeVan, M.S., M.D., F.C.A.P.##	Wendy Paul, M.D.
Miguel Escobar, M.D.#	Nicole Verdun, M.D.
LCDR Jefferson Jones, M.D., M.P.H.	Carlos Villa, M.D., Ph.D.
Andrei Kindzelski, M.D., Ph.D.	
Roger Lewis, M.D., Ph.D., F.A.C.E.P.#	**Guest Speakers**
Thomas Ortel, M.D.,Ph.D.##	COL Andrew Cap, M.S., M.D., Ph.D., F.A.C. P
Elena Perez, M.D., Ph.D., F.A.A.A.A. I	Donald Jenkins, M.D., F.A.C. S
Amy Shapiro, M.D.	Philip Spinella, M.D., F.C.C. M
Martin Schreiber, M.D., #	Moritz Stolla M.D., Ph.D.
Jack Stapleton, M.D.	Geir Strandenes, M.D.
	James Stubbs, M.D.
Chair	Darrell Triulzi, M.D.
Richard M. Kaufman, M.D.	
	Consumer Representative
Temporary Voting Members	Judith Baker, DrPH, MHSA
Joel Bennett, M.D.	
Kenichi Tanaka, M.D., MSc.	**Industry Representative**
Charity Morgan, Ph.D.##	Susan Stramer, Ph.D.
Designated Federal Official	**Committee Management Specialists**
Christina Vert, M.S.	Joanne Lipkind, M.S.
	Monique Hill, M.P.H.
# Did not attend	
## Attended by phone	

These summary minutes for the November 22, 2019 meeting of the Blood Products Advisory Committee were approved on February 14, 2020.

I certify that I participated in the November 22, 2019 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

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Christina Vert, M.S.	Richard Kaufman, M.D.
Designated Federal Official	Chair

The Chair, Dr. Richard Kaufman, called the meeting of the Blood Products Advisory Committee to order at 8:30 a.m. EST on November 22, 2019. The Chair invited the members, temporary members, and other participants seated at the table to introduce themselves. The Designated Federal Official (DFO), Christina Vert, made administrative remarks and read into the official record the conflicts of interest statement pertaining to the meeting participants. The meeting was held in an open session in its entirety. There were no waivers issued for conflicts of interest for this meeting. After the conflicts of interest statement was read for the public record by the DFO, the presentations began.

QUICK SUMMARY

Topic: Considerations for Cold Stored Platelet Products Intended for Transfusion

The meeting topic was introduced by Dr. Carlos Villa from the Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) after which, Dr. Darrell Triulzi from the University of Pittsburgh presented on "Platelet Transfusion Practice in the US." This presentation was followed by a presentation on the "Regulatory Approaches to the Evaluation of Platelet Products and *In vitro* Characterization of Platelets," given by Dr. Monique Gelderman from OBRR, CBER, FDA. Then, Dr. Moritz Stolla from Bloodworks Northwest presented on "*In vitro*, Preclinical, and *in vivo* Recovery and Survival Studies of Cold-Stored Platelets." After the presentations were completed, clarifying questions were asked of the four speakers.

After the morning break, the second set of speakers presented. The first presentation was given by Dr. Geir Strandenes from the Norwegian Armed Forces Medical Services who presented on "Implementation Strategy Whole Blood and Cold Stored Platelets." The second speaker, Dr. James Stubbs from the Mayo Clinic, presented on "Cold-Stored Platelets: Hospital-Based Blood Bank Experience." The final morning speaker was Dr. Donald Jenkins from University of Texas San Antonio Health who presented on the "Role of Cold Stored Platelets in Clinical Care in the General Population." After questions were answered by the three speakers, the committee adjourned for lunch.

The committee reconvened after lunch to listen to the presentation by COL Andrew Cap from the U.S. Army Institute for Surgical Research on the "US DOD Cold Stored Platelet Experience." The final speaker for the day was Dr. Philip Spinella from Washington University who presented on the "Chilled Platelet Study: CHIPS Bonus: Microfluidic Models of Hemostasis."

Following questions of the two speakers, an Open Public Hearing (OPH) was held between 2:45 p.m. and 3:45 p.m. Dr. Richard Kaufman, Chair, read the OPH statement for the record.

The following individuals presented during the OPH:

1. Dr. Mike Fitzpatrick, Ph.D., President and Director of R&D, Cellphire Inc., *statement*
2. Mr. Michael Parejko, President, Americas Blood Centers (ABC), *statement*
3. Dr. Beth Shaz, M.D. President AABB, *joint statement* representing AABB, American Red Cross, and ABC
4. Dr. Jose A. Cancelas, M.D., Ph.D., Professor of Pediatrics, Hoxworth Blood Center, University of Cincinnati, *presentation*
5. Ms. Elizabeth Waltman, Chief Operating Officer, South Texas Blood and Tissue Center, *presentation*
6. Dr. Richard Benjamin, MBChB, Ph.D., FRCPath, Chief Medical Officer, Cerus Corporation, *presentation*

At the conclusion of the OPH, the committee discussed the questions posed by FDA.

Dr. Kaufman presented the following questions to the committee.

Question 1:
Please comment on the available data on cold stored platelets, including discussion of knowledge gaps and potential need for preclinical or clinical studies, with respect to the following:

a) Length of storage beyond 3 days
b) Indications for use (such as treatment of active bleeding)
c) Differences in collection platforms and storage media
d) Pathogen reduction

Question 2:
Please comment on the design of any additional clinical studies needed to evaluate the safety and hemostatic efficacy of cold stored platelets to support their widespread use in the United States.

The committee discussed the following:

- In general, the committee supported further studies on the safety and efficacy of cold stored platelets in active bleeding populations.

- Members supported allowing the current use of cold stored platelets for the treatment of active bleeding in settings with logistical constraints leading to limited platelet availability (battlefield use, specific rural US settings) while necessary clinical trials are conducted and ongoing to further assess safety and efficacy.

- Most committee members encouraged FDA to consider granting variance requests for the use of cold stored platelets with dating beyond 3 days for the treatment of active bleeding in settings where conventional platelets are not available, such as in remote, rural settings. Several members encouraged data collection and surveillance systems in these settings to monitor for safety signals.

- With respect to clinical trials, committee members discussed challenges with assessing hemostatic efficacy of cold stored platelets *in vivo*. Several members commented on the utility of studies in the cardiac surgery population, while others also commented on the use of studies in patients needing reversal of anti-platelet medications for the treatment of head bleeds and studies in other neurosurgery populations.

- Some members commented that it would be important to study cold stored platelets manufactured using different collection platforms and media, as well as pathogen reduced cold stored platelets. Certain members advocated for more basic and translation research in the area of cold stored platelets and discussed the value of a surrogate marker that could correlate with clinical outcomes.

- Members discussed certain *in vitro* tests that have the potential to be helpful in studying cold stored platelets. Members also discussed the variability seen with some of the in vitro parameters and the additional challenge of correlation of in vitro data with clinical outcomes.

- While the committee acknowledged dating of cold stored platelets beyond 3 days is necessary from a practical standpoint, the committee did not agree on an optimal dating period and encouraged clinical trials. Members discussed that more safety and efficacy data is needed prior to widespread use of cold stored platelets beyond 3 days.

- Some members supported dating of cold stored platelets for 5-7 days, but questioned efficacy after 7-10 days. Other members supported dating out to 14 days for an indication of active bleeding. Several members discussed the need for clinical trials to fully assess dating of cold stored platelets and supported the adaptive design trial presented to the committee as a start.

- Members commented on the potential challenges of maintaining a dual inventory of conventional and cold stored platelets.

Following the open committee discussion, the meeting was adjourned at 4:45 p.m.

Additional information and details may be obtained from the transcript and the recordings of the webcast of the meeting that may be viewed at:

https://www.fda.gov/advisory-committees/blood-products-advisory-committee-november-22-2019-meeting-announcement-11222019-11222019