Advancing Transfusion and Cellular Therapies Worldwide

AABB Center for CELLULAR THERAPIES

September 26, 2016

Leslie Kux
Associate Commissioner for Policy
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-3581 for ''Draft Guidances Relating to the Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Extension of Comment Periods''

Dear Ms. Kux,

AABB appreciates the opportunity to provide comments on three of the four draft guidance documents – "Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue Based-Products," "Same Surgical Procedure Exception Under 21 CFR 1271.15(b): Q & A Regarding the Scope of the Exception," "Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products," and "Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations" – that are open for comment.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

In general, AABB applauds FDA for its efforts to thoughtfully regulate the HCT/P industry in order to maintain patient access to safe and effective cellular therapies.

Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue Based-Products

AABB requests clarification on two sections of this draft guidance: the working definition of minimal manipulation and the list of examples characterized as cells or nonstructural tissues. Regarding the working definition of minimal manipulation, there are methods of processing that may be considered more than minimal manipulation, depending on the final product. These include, among others, cutting, grinding, shaping, culturing, enzymatic digestion or de-cellularization. For cord tissue that is stored and will subsequently be used as a source of mesenchymal stromal cells, **would any of the processing methods used for cryopreservation be defined as more than minimal manipulation?**

With respect to the list of examples characterized as cells or nonstructural tissues, AABB understands that the list is not meant to be exhaustive. However, as lymph nodes were included in this list, **AABB asks the**

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Agency to clarify whether thymic tissue or the thymus gland also qualify as a cells or nonstructural tissues?

Same Surgical Procedure Exception Under 21 CFR 1271.15(b): Q & A Regarding the Scope of the Exception, Homologous Use of HCT/Ps

AABB requests clarification on the requirements for intra-establishment transfer of HCT/Ps. The guidance states that the same surgical procedure (SSP) exception applies when HCT/Ps are for autologous use, implanted in the SSP and remain in their original form with maintenance of safety and sterility. Temporary storage between the time of collection and utilization, occurring at the same establishment, would qualify for the SSP exception as long as the HCT/P is not manipulated other than rinsing, cleansing, sizing and labelling. **Is the SSP exception applicable if the stored HCT/Ps are transported from one building or facility to another building or facility within the same business establishment?**

Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products

AABB requests that FDA revise the guidance on homologous use of HCT/Ps by:

1) Including examples that address the use of whole bone marrow (BM) aspirates, or enriched concentrates of bone marrow-derived stem cells and blood or BM-derived platelet rich plasma (PRP).

2) Clarifying whether the effects of the platelet derived growth factors in PRP are considered to have systemic effects, and therefore do not meet the criteria for regulation solely under Section 361 of the PHS act and 21 CFR 1271.10(a)(4)?

Should you have any questions regarding these comments or would like additional information, please contact me at nkamani@aabb.org.

Sincerely,

Naynesh Kamani, MD
Vice President, Center for Cellular Therapies & Research
AABB

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