ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

February 23, 2015

Ms. Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

In Re: Docket No. FDA-2014-D-1696-0001: Comments to the Draft Guidance Document Titled Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Draft Guidance for Industry and Food and Drug Administration Staff (December 2014)

Submitted electronically at www.regulations.gov

Dear Associate Commissioner Kux;

The Alliance of Wound Care Stakeholders ("Alliance") is submitting the following comments in response to the FDA draft guidance document on "***Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Draft Guidance for Industry and Food and Drug Administration Staff*** **(December 2014)".** The Alliance is a nonprofit multidisciplinary trade association representing 16 physician and clinical organizations whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research. A list of our members can be found on www.woundcarestakeholders.org.

The Alliance has two very specific areas of concern:

Period of Time To Comment Is Too Short

First, while we appreciate the opportunity to offer our comments, we are very disappointed in the short amount of time that the FDA allowed to respond to this very dense document that is so critical to wound care stakeholders. Since we do not believe there has been enough time to give this important document the careful consideration that it needs, we are submitting these comments, but intend to supplement our filing as we receive more information from our members. There are scientifically incorrect statements within this document that need careful consideration. The time frame for public comment given the complexity and complete overhaul of tissue regulations is far too short.

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Draft Guidance is Inappropriate – Proposed Regulation Should Have Been Issued

Secondly, we believe that utilizing a draft guidance document rather than a proposed regulation is inappropriate. This guidance document is a significant departure from current law and as such a formal proposed regulation should have been issued which is more appropriate given the significant implications and changes to current regulations. A guidance document is intended to provide guidance. Yet, the significant changes that this document proposes renders it more than just guidance. This document not only proposes changes in the way that tissue products are and will be regulated, but also adds new requirements and introduces new terminology all within the guise of a guidance document.

Under the approach outlined in the draft guidance document, the FDA has intimated that specific tissues have specific relevant characteristics independent of their use. As such, it is likely that many HCT/P products will be considered more than minimally manipulated – a key component in the regulations - and, thus, subject to regulation beyond section 361 of the PHS and 21 C.F.R. Part 1271, irrespective of how they are processed. As such, this draft guidance document could render more HCT/Ps subject to regulation as drugs, devices, or biologics under Section 351 of the PHS Act, the FDCA, and the applicable regulations. These products would be subject to the more stringent regulatory requirements as a result.

Given the expanded definition of minimal manipulation to rely upon the "main function" in order to determine whether a tissue type is considered structural or non structural imposes new limitations under the current 21 CFR Part 1271 regulation. As such, this draft guidance should have been issued in accordance with the notice-and-comment proceedings required by the APA. Section 553 of the APA requires the publication of proposed agency rules be followed by a period of time for consideration and comment by the public. A notice-and-comment period is not required if an agency issues an interpretive rule or general statement. This guidance document is not an interpretive rule nor is it a general statement. Rather it is a material change to an existing regulation with additional requirements being imposed.

As a result, the Alliance recommends the following:

1. The FDA meet with affected stakeholders either through workshops or public meetings and subsequently issue a proposed rule instead of moving forward with this guidance document.
2. formally withdraw this guidance document
3. Issue a proposed regulation which provides appropriate notice and comment period.
4. Address the following issues within the proposed regulation:

- Provide the scientific basis for the various tissue categories (e.g., selection of skin versus dermis or epidermis);
- Provide a scientific accounting of the function or functions of all tissue categories;
- Provide the scientific rationale for selecting one of the functions as the main function for each of the tissue categories;
- Provide the scientific rationale for shifting the focus of the utility of the tissue from its function in the

recipient to the function in the donor;

- Provide the scientific rationale for "locking in" only one main function for a tissue category and not examining how it is utilized in the recipient; and

5. · Provide the distinction between the term "main function" and the term "homologous use."

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In conclusion, the Alliance is concerned that the FDA, in issuing this guidance document, significantly changed the processes and requirements by which a HCT/P comes to market. We are concerned about the products that we will have access to treat our patients and how this new regulation impacts those that are already in the marketplace.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director