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April 11, 2016

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:


The Society for Women's Health Research (SWHR®) is pleased to submit a response to the U.S. Food and Drug Administration (FDA) request for comments on "Human Cells, Tissues, and Cellular and Tissue-Based Products: Draft Guidance for Industry." SWHR, a national non-profit organization based in Washington, D.C., is widely recognized as the thought leader in promoting research on sex differences and is dedicated to improving women's health through advocacy, education, and research.

We are pleased to see FDA address the issue of adipose tissue transplantation, as breast reconstruction and liposuction are two common procedures performed on women in the United States every year. FDA staff have developed a thoughtful approach to ensuring the re-use of such tissues are regulated and deemed to be safe and effective for patients.

However, SWHR asks FDA staff to consider the implications of creating new requirements to deem certain commonly practiced procedures as more than "minimally manipulative." SWHR respectfully requests FDA staff to partner with clinician groups, such as the American Society of Plastic Surgeons, and American College of Surgeons, Academy of Medical-Surgical Nurses, American Society of Plastic Surgical Nurses, and other relevant organizations as well as manufacturers to ensure that final guidance may not adversely affect regular clinical practice. Developing new requirements in partnership with groups that are directly impacted by such guidance will ensure that any potential complications are addressed in the outset and ensure women and men have timely access to appropriate surgical procedures when needed.

Thank you for the opportunity to comment on such important guidance for industry and clinicians.

Sincerely,



Andrea L. Lowe, MPH, CPH
Health Policy and Public Health Liaison