

Office of the Assistant Secretary for Health Washington ,D.C.20201

MAY- T 2015

Jay Menitove, M.D.
Chair, Advisory Committee on Blood and
Tissue Safety and Availability
637 W 57th Terrace
Kansas City, MO 64113

Dear Dr. Menitove:

Thank you for the leadership you provided during the Committee's recent discussions of tissue tracking and traceability. I appreciate the guidance you provided during the meeting which resulted in the thoughtful recommendations developed by the Committee.

The Committee recommendations illuminate the importance and complexity of creating interoperable standards for tissue tracking and traceability. As was discussed in the meeting, the tissue industry involves independent, geographically dislocated recovery organizations, processing centers, distribution services and transplant clinics, hospitals, and dental businesses. With over 1.5 million tissue grafts that are distributed from deceased donors to healthcare facilities each year, and with up to 50 grafts processed from a single donor, it is clear that challenges can arise for effective tissue tracking and traceability. Biovigilance of all biological products, including human tissue and tissue products is a part of our mission at the Department of Health and Human Services and we are committed to ensuring the continued safety of these products. The conscientious and dedicated work the Committee put into this meeting is evident in the recommendations you developed, which will provide an important starting point for our discussions.

I am forwarding a copy of the recommendations to the Secretary for internal discussion with the relevant Operating Divisions within the Department. Please express to the Committee my appreciation for their service and valued recommendations. I look forward to the upcoming Committee meeting in November, 2015.

Sincerely yours,

Wc:lhda K Jont£DrPH Principal **Dep** Assistant Secretary for Health