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Food and Drug Administration  
5630 Fishers Lane, Room 106 1  
Rockville, Maryland 20852

**Docket #97N-484S**

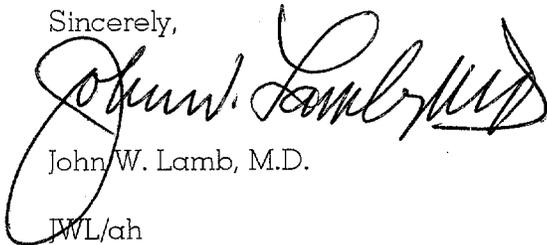
Dear Sirs:

As an orthopaedic surgeon who has treated a number of trauma patients and done a number of reconstructive procedures requiring bone grafts from the bone bank, I would strongly urge the FDA not to choose to regulate allograft of bone, tendon or connective tissues as devices.

First of all, they have been used safely for a number of years with care to preserve the tissue in a similar fashion to the way the blood banks preserve blood cells and plasma. There certainly have been some tragedies, as there have been in the blood bank, but the risk in recent years has been minuscule and the benefit has been substantial when bone grafts can be taken from the tibia of one person and used to reinforce the deficient femur in another person who is having revision of a hip replacement. Allograft bone is also extensively used in spinal surgery and if there are complex regulations, it is very reasonable to believe that the price will significantly increase and patients will suffer.

Finally, as blood is clearly a tissue and is currently not classified as a device, I believe it is reasonable to continue to allow tissue grafts without excessive new regulation.

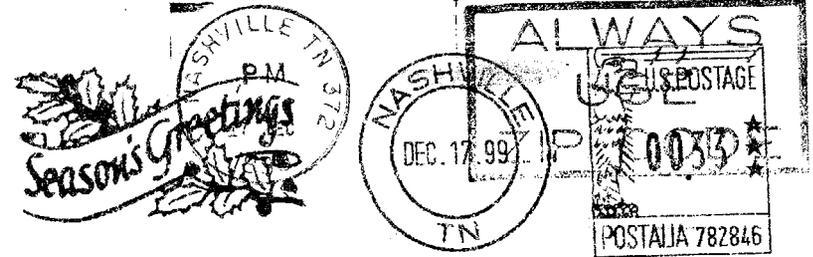
Sincerely,



John W. Lamb, M.D.  
JWL/ah

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