



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

March 23, 2007

Mr. Jon Hamilton
National Public Radio
635 Massachusetts Ave., NW
Washington, DC 20001-3753

Dear Mr. Hamilton:

The American Academy of Orthopaedic Surgeons (AAOS) representing 17,000 board-certified orthopaedic surgeons has serious concerns with your story, “Researcher Finding Ways to Sterilize Transplants.” The safety and welfare of our patients is of paramount importance to the AAOS and we believe that for appropriate patients, musculoskeletal allografts represent a beneficial therapeutic treatment provided those tissues are acquired from facilities that use the highest standards of tissue banking and are in compliance with federal laws. The AAOS is concerned that your story did not provide a more balanced representation of proven allograft processing methods which also have exemplary records of safety. Many tissue processors have validated sterilization processes, as defined by the Food and Drug Administration (FDA), including the use of chemical washes and radiation.

Essentially, your story was presented as a promotional piece for one tissue manufacturer in particular, which is a for-profit company and stands to benefit from championing tissue sterilization. While the company has a unique processing method which is proprietary, there are other well established approaches to providing safe and effective tissues. The important focus of the story really should be centered on Mahmoud Radwan’s return to normal life following an altruistic donation of an anterior cruciate ligament.

The AAOS recommends¹ that surgeons only use tissue from American Association of Tissue Banks (AATB) accredited tissue banks which adhere to stringent tissue safety standards. Mandatory and consistent donor screening – utilizing past medical history, serologic and bacteriologic tests and, when available, autopsy findings – is imperative to eliminate potentially harmful transmittable diseases. By following AATB standards, and FDA regulations, disease transmission rarely occurs. Tissue transplantation has a remarkable safety record with over 10 million allografts (bone and tissue) being implanted over the last decade with only a few cases of disease transmission having occurred.



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

6300 North River Road
Rosemont, Illinois 60018

P. 847.823.7186
F. 847.823.8125

www.aaos.org

With regard to the Biomedical Tissue Services recall, according to the FDA and the Centers for Disease Control and Prevention (CDC), there are no cases of confirmed disease transmission related to that recall, to date.

In 2001, the Lykins donor did not fall within acceptable AATB accredited standards for donor suitability. By all accounts, the Lykins case was a tragedy. Subsequently, the federal government finalized rules for donor suitability and good tissue practices in 2005. The tissue bank that supplied the Lykins tissue was not AATB accredited at the time of his death.

The AAOS questions the statement by Dr. Archibald regarding the lack of a surveillance system for musculoskeletal allograft tissues as the FDA operates an adverse event reporting system, named MedWatchⁱⁱ. The FDA's reporting system was in place during the Lykins investigation in 2001.

Under the circumstances, we look forward to following up with you on another more balanced story that would highlight the enormous benefits that patients receive from allograft tissues.

Sincerely,

James H. Beaty, M.D.
President, American Academy of Orthopaedic Surgeons

ⁱ Use of Musculoskeletal Tissue Allografts. American Academy of Orthopaedic Surgeons, December 2006 <http://www.aaos.org/about/papers/advistmt/1011.asp>

ⁱⁱ MedWatch. Food and Drug Administration <http://www.fda.gov/medwatch/>