

Sports Medicine

James R. Bocell, Jr., M.D.
William Jay Bryan, M.D.
Omer A. Ilahi, M.D.
David M. Lintner, M.D.
Walter R. Lowe, M.D.
Mark W. Maffet, M.D.
J. Bruce Moseley, M.D.

Primary Care

Lon A. Castle, M.D.

Research

Harold W. Kohl, III, Ph.D.

Executive Director

Dennis W. Pullin

**HopeStar Orthopedic
Group, L.L.P.**

**Arthritis Surgery
& Joint Replacement**

George H. Lane, M.D.
David R. Lionberger, M.D.
Kenneth B. Mathis, M.D.
Hugh S. Tullos, M.D.

Foot & Ankle Surgery

John V. Marymont, M.D.
Saul G. Trevino, M.D.

**Hand & Upper
Extremity Surgery**

Gerard T. Gabel, M.D.
David H. Hildreth, M.D.
David M. Lichtman, M.D.
Brian Tobias, D.O.

General

Orthopedic Surgery

Robert A. Fulford, M.D.
Henry D. Wilde, Jr., M.D.

**Surgery of the Spine
& Scoliosis**

Jesse H. Dickson, M.D.
Stephen I. Esses, M.D.
William R. Francis, Jr., M.D.
Michael Heggeness, M.D., Ph.D.
Michael G. Kaldis, M.D.
Ronald W. Lindsey, M.D.
Barry A. Nelms, M.D.
R. Craig Ponder, M.D.

Orthopedic Research

Philip C. Noble, Ph.D.

0406 '99 DEC 28 10:24

December 7, 1999

Document Management Branch
(HFA-305) Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, Maryland
20852

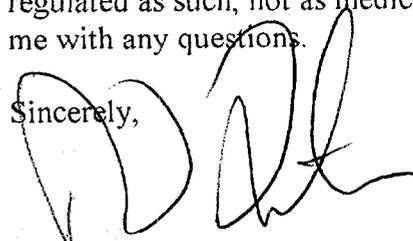
Re: Docket #97N-484S

To whom it may concern:

It has come to my attention that the FDA is proposing to regulate some types of tissue allograft as a medical device. Currently, bone banks provide bone as tissue, which is already under FDA regulation. This is certainly appropriate since bone is, in fact, a tissue. Allograft bone and tendon grafts are commonly used in my practice (Sports Medicine, knee and shoulder reconstruction) and I am concerned that the higher level of regulation, paperwork, etc. will result in higher costs and thus decreased availability of the grafts. There is already some difficulty in obtaining tissue grafts because of limited availability, with many patients on extended waiting lists already. I expect this to only get worse if the change occurs.

Bone and other allograft tissues are exactly that: tissues. They should be regulated as such, not as medical devices. Please do not hesitate to contact me with any questions.

Sincerely,



David M. Lintner, M.D.

DML:dk

97N 484S

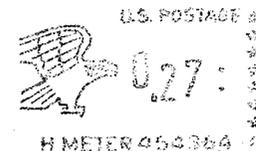
C 189

**BAYLOR SPORTS
MEDICINE INSTITUTE**

David M. Lintner, M.D., Orthopedic Surgeon
6560 Fannin • Suite 400 • Houston, Texas 77030

MAILED AT 770 12/22/99

REGISTERED
FIRST CLASS



Document Management Branch
(HFA-305) Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, Maryland
20852

20852-0001

