

LA JOLLA ORTHOPAEDIC SURGERY

JAMES R. MOITOZA, M.D.

Diplomate American Board of Orthopaedic Surgery

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Special Interests:

Arthroscopic Surgery
Sports Medicine
Pediatric Orthopaedics
Foot Surgery
Hip & Knee Arthroplasty
Complex Gait Analysis

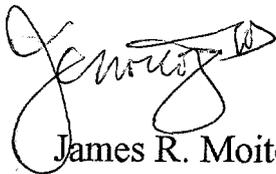
Document Management Branch (FHA305)
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, Md 20852

RE: Docket # 97N-484S

Gentlemen:

A proposed FDA regulation that appeared in the Federal Register, September 30th, 1999, would regulate bone allograft tissue as medical devices. We have been utilizing bone **allografts** for Orthopedic surgery for many years. The **affordability** of this tissue is very important and this type of regulation would greatly increase the cost. Bone banks that harvest and provide these tissues would have a very difficult time sponsoring the clinical trials and the lengthy regulatory documents that would be required under this proposed legislation. Since this is natural human tissue, I don't see how this could be construed as a manufactured medical device in any way. Certainly the sterility, biological safety, and the mechanisms of harvesting should be regulated and there are established procedures for this industry. I would strongly urge you to reconsider this regulation as unnecessary.

Sincerely,



James R. Moitoza, M.D.

JRM:cw

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9900 GENESEE AVENUE - SUITE C - LA JOLLA, CALIF. 92037-1273

Telephone: (858) 643-5650 - Fax: (858) 643-5660

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La Jolla Orthopaedic Surgery
JAMES R. MOITOZA, M.D.
9900 Genesee Ave. Suite C
La Jolla, California 92037



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