

Kevin Jon Lawson M.D.
Spinal Surgery, Spinal Deformity and General Orthopedics

00 JUL 20 P1:39



530 243-5700
2662 Edith Ave.
Redding, CA. 96001

Kathy Eberhart
Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Suite 200 North
Rockville, Maryland 20852-1448
HFM42

July 7 , 2000

Dear Ms. Eberhart & FDA Regulatory Personnel:

As a practicing orthopedic spinal surgeon, I would like to again voice my concerns about changing the regulation of Allograft human tissue into a new category equivalent to the way orthopedic and spinal implants are regulated. I wrote also last year on this same issue which is up for public comment in August.

I understand clinical use of Allograft bone products has some overlap with that of metallic devices and other surgical implants. However, I think it would be unwise to modify the existing regulations of Allograft tissue. The current quality and availability of bone-back tissue is excellent in so far as disease transmission and graft tracking. I think that additional regulation to these products would be unwise at this time. I believe it would most likely make allograft tissue scarce for patients with bone defects/fusion needs while not improving clinical outcomes.

I think xenograft cortical implants could be useful, and would appropriately be assessed as implants after machining and processing, but current allograft human tissue regulation I believe is appropriate.

Thank you for your time and consideration of my opinion.

Sincerely,

Kevin Jon Lawson MD

00N-1380

C2

Kevin Jon Lawson, M. D.
2662 Edith Ave
Redding, CA 96001



HEM-49

FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
1401 ROCKVILLE PIKE, SUITE 200 NORTH
ROCKVILLE, MARYLAND 20852-1448
HEM42

ATTN: KATHY EBERHART

20852/1448

