

*Orthopedic and Hand Surgery
Micro Surgery
Fractures
Arthroscopy
Sports Medicine*

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

Re: Docket #97N-484S

it is my understanding, although I have not read the FDA regulation that appeared in September 30, 1999 Federal Register, that bone use for grafting in orthopedic procedures is under review by the **FDA**.

It is my opinion after 40 years of use of **bone** products that the FDA should not be involved with the regulation of the usage of bone or the registration of bone products.

Bone-grafting is a very specific technique used in very specific cases for very specific reasons and **cannot be regulated by the FDA inasmuch** as patients differ in their capacities and their needs, and to have regulations that curtail my usage of bone is improper.

I am against any regulation.

Sincerely yours,



Robert H. Horne, M.D.
RHH:iws

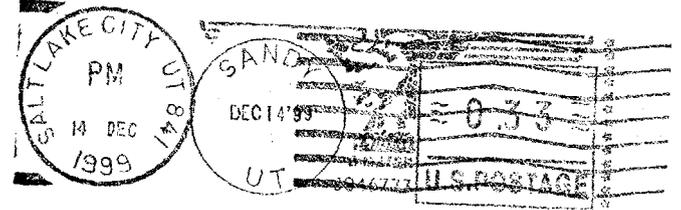
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