

NEW MEXICO SPINE

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December 20, 1999

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

re: Docket #97N-484S

Dear Sirs:

I have been made aware of the proposed FDA Regulation appearing in the September 30, 1999, issue of the Federal Register which would allow you to regulate some types of allograft as medical devices. I believe that such regulations would not be in the best interest of my patients. Specifically, having done anterior lumbar interbody fusions for years, in which I crafted the interbody plugs myself, there is no question that the precision and quality of dowels coming out of the certain providers is far and away more skillfully done than I could ever do. I see no reason, if I were not regulated in crafting such an interbody block, why companies should also be regulated.

This represents a significant waste of my tax money, of my patient's tax money, and would represent needless regulation blocking or regulating a product superior to anything that I or any other physician has used in years past.

Very truly yours,



Michael E. McCutcheon, MD

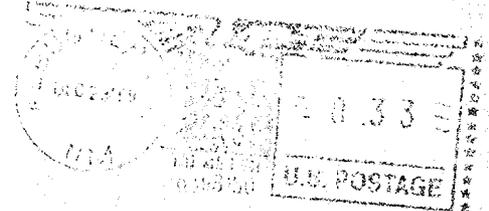
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