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Food and Drug Administration
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Rockville, Maryland 20852

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Reference: Docket No. 97N-484S

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To whom it may concern:

As an academic spine surgeon at a teaching university, I am writing this letter concerning the FDA's efforts to allow FDA regulation of allograft bone tissue as medical implants. Allograft tissues have been in use for a long time and have reliably proved to be an important tool in our armamentarium against spinal disorders. Increasing FDA regulation of these tissues will result in greater difficulty in obtaining them, greater cost, and increased litigation. Allograft is frequently modified in the operating theater for the intended purpose using tools at hand. More recently, some companies have machined some of the grafts ahead of time, thus saving time in the operating room. If regulation of these companies is increased I believe that many of them will simply stop providing these products and will focus on more profitable, but not necessarily better products. Please contact me if you wish to discuss this issue further. Thank you.

Sincerely,

Mitchell F. Reiter, MD

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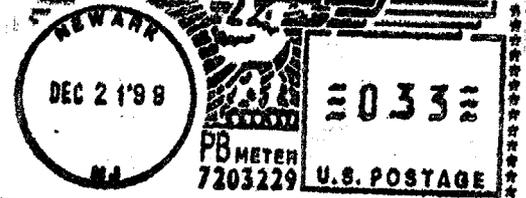
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