

COMPREHENSIVE CARE
OF THE BRAIN AND SPINE

Adult and Pediatric

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RE: Docket No. 97N-484S

Dear Sirs:

I am a spine surgeon and would like to comment on the proposed FDA regulation of banked bone in spine surgical procedures.

At the present time, allograft bone has been widely used in the cervical spine and, to a lesser extent, the thoracic and lumbar spine for fusion procedures. Recently, milled allograft bone has become available to help us in these surgical procedures. Prior to the milled bone being available, we had to resort to our own free-hand cutting and shaping of the allograft bone. Milled bone, in my experience, is clearly preferable to what we had previously been doing on our own in the operating room. In the event that milled bone became subject to FDA regulation, we would have to go back to doing the procedures we did previously. I don't believe any regulation of bone would in any way change usage of it in spine procedures, but would only add one additional layer of regulation.

I hope that the temptation to extend FDA regulation in this area is resisted.

With Best Regards:



Peter V. Hall, M.D.

PVH/pab

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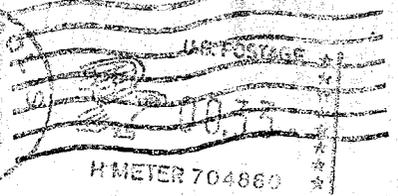
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