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Document Management Branch
(HFA-305) Food and Drug Administration
5630 Fishers Lane, Room 1061
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Dear Gentleman,

I had recently come to my attention that there is a possibility of the FDA regulating bone allograft as a medical device.

I have used bone allograft in several thousand cases during my lifetime as a neurosurgeon and have yet to have had a reaction or infection as a result of it.

It is my opinion, therefore, that there is really no need to add restrictive regulations to a product that has proven to be safe and effective through the years. I believe in doing so, it would only further add to the burgeoning cost of medical care and not really be of any help.

Sincerely yours,



Dale K. Johns, M.D.

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