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December 16, 1999

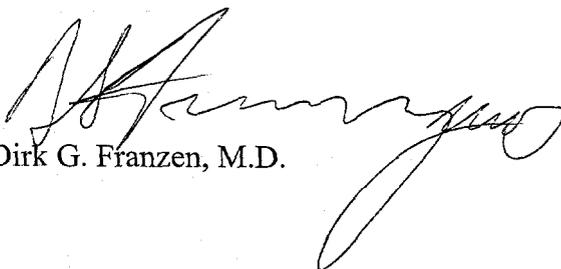
Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484S

To whom it may concern,

I am writing to voice my most strong objection to the proposal to reclassify some types of allograft as medical devices. This would almost certainly lead to a shortage, or total unavailability, of some of these products upon which our patients depend. This would force us to either use a less optimal product, or to subject the patient to harvesting of their own tissue, an unpleasant procedure to which they would not have otherwise been subjected. Lets not fix a problem where one does not exist, especially when it's to the detriment of our patients.

Sincerely,



Dirk G. Franzen, M.D.

97N 484S

31-E Wiley Parker Road, Jackson, TN 38305
901 660-2911 901 660-4604 Fax

C258



Dirk G. Franzen, M.D.
31-E Wiley Parker Road
Jackson, TN 38305



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

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