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February 21, 2000

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

Re: Docket No. 97N-4842

Dear Sirs,

I read with some interest the comments by Dr. Brantigan concerning the recommendation that allografts should be regulated as devices. I have been doing posterior lumbar interbody fusions for over 25 years. I have used various devices including tricortical bone, the patient's own bone, and metallic titanium devices. I have been extremely impressed by the bone bank's continued identification of the problems we have had with previous grafts and their biologic properties and strength. As you are well aware, none of these allografts were ever conceived to represent a pure load bearing device but only load sharing, as they have all been shown to need supplemental instrumentation of some degree.

This has been a long learning process for surgeons that have been dealing with it over the last 20 years, as I have. I am sure this concern is what drove Dr. Brantigan to develop his carbon fiber Brantigan cage. With the associated research and development

that this required, I can understand his concerns that would invite further regulation of bone. I agree with him that these are considered biological implants, but they should not be considered devices since they are primarily harvested from cadaver bone which is not of human creation. We are basically using the natural biological architecture of bone and reshaping it to specific dimensions as many patients do not desire to have metallic carbon fiber implants placed in their body and wish only donor bone. This alternative needs to be maintained in its present status. I wish to applaud the particular distributors and companies that have been able to furnish us these allografts; although, as you are quite aware, the supply of these is quite limited. Therefore, we will to continue to have the problem of availability.

I believe this is an area that should be avoided by the Food and Drug Administration, and I disagree significantly with Dr. Brantigan's opinion. The FDA should not have the authority to supervene the operating surgeon's choice to use either an allograft or a metallic device. I totally disagree with his comment that the product should be banned because of the unpredictability of the mechanical loads placed on the interbody fusion. We are quite aware of the weakening of the allograft anywhere from three to five months, and that is the reason for supplementation of load sharing, either pedicular or facet screws. Thus far, in my practice, I have not seen this to be a problem.

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I appreciate any consideration you may give to my comments concerning this, but I do not support the regulation of allografts by virtue of the changes I have seen. The industry itself seems to be well-aware of this problem and, obviously, the product itself, and failure of the product will dictate its acceptability. Therein lies the risk that the company takes in not providing a graft strong enough to withhold the proposed standards that it sets for itself.

Sincerely,



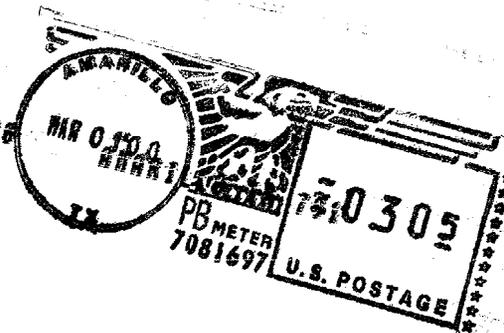
Wayne S. Paullus, Jr., M.D., F.A.C.S.

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FOOD AND DRUG ADMINISTRATION
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