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

RE: Docket No. 97N-484S

Dear Sirs:

I am writing because of Ron Pickard's mass mailing urging surgeons to protest the proposed regulation of some types of allograft as medical devices. In my opinion, Mr. Pickard's appeal is inappropriate and serves only the self-interest of his company at the expense of the general public.

The Federal Food, Drug, & Cosmetic act of 1976 defines a medical device as "... an implant ... or related article. ... intended to affect the structure or function of the body which is not dependent upon being metabolized for the achievement of any of its principle intended purposes." Although this is a perfectly workable definition, physicians, industry leaders, and the FDA all understand that many devices do have a biologic objective that must be met in order for the patient to achieve clinical success. Thus, all of the current cage implants for interbody fusion must achieve a stable mechanical environment and also a proper biologic construct. Unless bony healing is achieved, the objective of fusion will not occur, and the device will fail. Each cage is constructed from a block of titanium or reinforced polymer and is machined to exact dimensions in order to achieve a specific mechanical performance. In spite of the biologic requirement, cage function is primarily mechanical, and no one questions that cages are primarily devices and should be regulated as such.

In comparison, allograft bone is primarily a commodity tissue product used for a biological objective, even though it may have a secondary mechanical function. Each allograft must be cut into smaller blocks since it is not reasonable to preserve and deliver an entire cadaver to the operating room. The blocks must be processed by cleaning to remove protein material, preservation such as with freeze drying, and sterilization to remove bacteria and viruses. These are all biologic steps that overshadow in significance the simple cutting of blocks. Thus when tricortical iliac crest blocks or femoral ring allografts are delivered to the operating room for interbody fusion, they are primarily biologic products and are appropriately regulated as such.

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The decision whether a specific implant product should be regulated as a device or as a tissue product should be made according to which characteristics are most prominent. Several companies are now selling allograft tissue for interbody lumbar fusions. In contrast to the traditional allografts, these new products are machined to very exact dimensions and include threaded or serrated surfaces, slots or hollow areas to accept autologous bone graft, and are intended to be used with device-specific surgical tools designed for their insertion. Because the mechanical characteristics predominate, and because these machined allografts cannot reasonably be called a tissue commodity, they are primarily devices and should be so regulated.

Some companies have raised the issue that non-regulation of machined, threaded allografts is "unfair" to those who have borne the time and expense of IDE studies, and that the allografts need to be regulated in order to "level the playing field." While this argument has merit, the real reason these allograft devices should be regulated is to protect the public.

I have done extensive study in this area and have published research that shows that interbody lumbar fusion with allograft has about a 60% fusion success rate (Spine 19: 1271-1279) and that the compression strength of allograft is unpredictable and in many cases insufficient to meet the mechanical needs of interbody fusion (Spine 18: 1213-1221). If the distributors of machined allograft have not found a way to overcome these problems with their products, the products should be banned. If the distributors have overcome these problems, documentation of these and other aspects should be presented to demonstrate that the products are safe and effective. There is a mechanism for this process, and it's called an IDE under the established FDA device regulations.

Practicing surgeons can be easily deceived by slick marketing and promotion. Thus, numerous patients are currently being subjected to surgical implant procedures whose success rates and complications are simply unknown. This is morally, ethically, and legally unacceptable. By normal legal theory, a manufacturer is liable for injuries caused by an unfit product. The companies selling these machined allografts are inviting enormous liability.

I believe that FDA has not only the authority but also the obligation to protect the public from these untested devices.

Sincerely yours,



John W. Brantigan, M.D.



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