EMORY HEALTHCARE

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

Re: Docket # 97N-484S
FDA Proposal to Regulate Allograft Tissue

Dear Sirs:

As an orthopaedic surgeon, and especially as a spine surgeon, I am alarmed to learn that the Food and Drug Administration is contemplating regulation of allograft tissues along the same lines as other manufactured surgical implants. In previous reports/proposals comments have been made regarding nonhomologous applications of bone as an excuse for the FDA to impose regulatory oversight. Equally, the manipulation of bone with regard to size and shape has been used as a justification for imposing regulatory oversight. This reasoning leads to nothing but detrimental influence on the quality and availability of patient care in this country.

Those of us familiar with the pedicle screw debacle need not remind you of the 1976 regulations that came into place. Even if one were to construe allograft bone or other tissues as some kind of surgical device (which is a stretch in and of itself), such tissues have been in use for many decades prior to the 1976 Device Amendment Act. Based on that you have no authority whatsoever to impose any kind of premarket approval regulatory oversight. Second, it is actually the rule rather than the exception that allograft tissues are used in a nonhomologous location. It is rather unusual for them to be used in a homologous location, especially with regard to the spine, as circumstances in which spinal allograft bone would be used in a spinal application are virtually nonexistent. From the very beginning of such applications in the spine, bone has typically been harvested from the iliac crest, fibula, femur or long bones. Third, "manipulation" of these bones to different shapes and dimensions in a sterile processed environment by skilled craftsmen is actually a bonus to patient care. Typically, such "customizing" of bone has been done in the operating room on the back table by surgeons using far cruder materials. As well, the

ambient environment in which such manipulations are performed in the operating room is far less sterile than the clean room environments in which bone banks prepare tissues at this time.

Please be advised that as Professor of Orthopaedic Surgery and Director of the Spine Fellowship Program at Emory University School of Medicine, I speak on behalf of my spine specialist colleagues as well as the rest of us in the Departments of Orthopaedic Surgery and Neurosurgery. The proposed regulatory oversight by the FDA on allograft tissues is unreasonable, ill-considered and probably unlawful. It will have nothing but a negative impact on the quality of care for American citizens. I urge you in the strongest terms to abandon this course of action which is fraud from its outset.

Respectfully yours,

John G. Heller, M.D.
Professor of Orthopaedic Surgery

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