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To Whom It May Concern:

As a surgeon, I am deeply concerned about the proposed new regulation being considered during the public meeting "Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair". It is imperative that it be understood that human allografts have been in clinical practice and have been used in multiple procedures for decades. Transplantation of human allograft bone has yielded excellent results while maintaining a sterling safety record. As a physician, I feel that any interference by government regulation is not only an intrusion on an already established practice, but it is an invasion of the doctor-patient relationship.

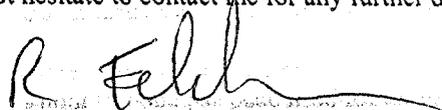
The following summarizes my position regarding the manipulation and homologous use of human bone grafts in the spine and during orthopedic reconstruction and repair:

- Allograft bone has been used for decades and is a safe and efficacious product. The risk-benefit ratio is negligible.
- Appropriate regulations for infectious disease testing, donor screening and record keeping currently exist.
- The use of allograft bone significantly minimizes surgical time, as well as the pain and hardship typically associated with autograft procedures.
- Any change in the classification of human allografts from their current status would significantly decrease the availability of these much needed tissues to physicians and their patients, as well as increase the financial burden on an already overburdened health care delivery system.
- The proposed reclassification of human allografts will stifle innovations towards safer and more effective allografts.
- There has been no correlation drawn between the proposed regulatory terms, "more than minimally manipulated" and "non-homologous use" with any increase in risk to the patient.
- Additionally, the terms "more than minimally manipulated" and "non-homologous use" are too vague and subjective to be of any value.

I strongly encourage FDA to consider these points prior to taking any further regulatory action dealing with the processing of human allograft tissue. I recommend that the proposal to regulate bone allografts as medical devices be completely dismissed.

Please do not hesitate to contact me for any further discussion on this matter.

Sincerely,



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