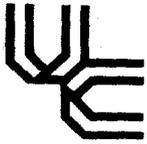


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Anthony F. Guanciale, M.D.
Assistant Professor

Director
Orthopaedic Spine Surgery

December 17, 1999

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 sincerely hope that you will not allow corporate profiteering actions taken by Sulzer Spine-Tech to create a situation where allograft materials become regulated and further restrict the practice of medicine. Enclosed are copies of correspondence related to this issue. I'm sure you will find them interesting.

I appreciate your involvement regarding this issue.

Sincerely,

Anthony F. Guanciale, M.D.

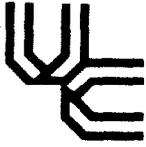
AFG/gj

Attachments

97N 484S

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September 24, 1999

P. Richard Lunsford, Jr.
General Manager
Sulzer Spine-Tech
7375 Bush Lake Road
Minneapolis, MN 55439-2027

**RE: Reports of Sulzer Spine Tech Initiating Action by the FDA in Regards to
Regulation of the Use of Threaded Cortical Bone Dowels.**

Dear Mr. Lunsford,

I find your letter dated August 16, 1999 and the enclosed letter by Mr. Rich Jansen dated July 16, 1999 to be very concerning and disheartening. I am a University based Orthopaedic Spine Surgeon and an Assistant Professor of Orthopaedics at the University of Cincinnati. I base my patient treatment on many factors, none of which involves the politics which are clearly at play between your corporation and Danek. I believe that the current recent series of events that have obviously occurred behind the backs of most spine surgeons between your corporation and Danek, to be very damaging. I certainly find it difficult to support the current stance of Sulzer Spine-Tech.

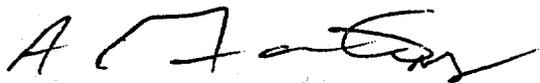
Despite the statement that you made in your letter of August 16, 1999, "Please be assured that Sulzer Spine Tech is not interested in restricting your access to technology which could benefit your patients", it is clear that the contrary has occurred. This is clearly born out in the letter of Mr. Rich Jansen to Mr. Mark Melkerson, of the FDA, which is dated July 16, 1999. This letter clearly supported the issue of regulating bone products for surgical application. As a matter of fact, this letter states the following, "I believe the real issue is the application of bone products in orthopaedic surgery and which of these products may require regulatory oversight.", and to continue, "causing it to cross over into a regulated product", and to continue further it goes on to state, "If threaded bone dowels are expected to function

Letter to P. Richard Lunsford, Jr.
Page 2

like fusion cages, they are more than minimally manipulated and should be regulated like devices". This letter is without doubt attempting to regulate the use of bone dowel products in spine surgery and to have it regulated by the FDA.

Mr. Lunsford, I find such corporately motivated attempts at bringing even further FDA regulation into the practice of spine surgery to be frankly, disgusting. I certainly will not hesitate to share these views with my fellow members of the North American Spine Society and the American Academy of Orthopaedic Surgery. I indeed will send a copy of this letter to both societies in regards to my views on this very unfortunate series of events.

Sincerely,



Anthony F. Guanciale, M.D.

AFG/gj

CC: General Council, North American Spine Society
General Council, American Academy of Orthopaedic Surgery
Mark Melkerson, Branch Chief, Orthopaedic Branch, FDA

SULZER MEDICA

Sulzer Spine-Tech

7375 Bush Lake Road
Minneapolis, MN 55435-2027

Phone 612-832-6600
Fax 612-832-6620

July 16, 1999

Mr. Mark Melkerson, Branch Chief
Orthopaedics Branch
Office of Device Evaluation
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Dear Mr. Melkerson:

Since I will be unable to attend the FDA Orthopaedics Advisory Panel meeting on July 27th to discuss regulation of bone dowel, I am submitting this letter to be read into the record.

The issue listed on the agenda is too narrow for adequate discussion. I believe the real issue is the application of bone products in orthopaedic surgery and which of these products may require regulatory oversight. Bone in various shapes has been used for decades. More recently, some bone banks have begun machining bone to function more like a mechanical device, i.e. placing threads on dowels to be screwed into a prepared opening.

The real issue is when are changes to bone products more than minimal manipulation of the bone, causing it to cross over into a regulated product.

Threaded bone dowels are machined to specific industry tolerances. One must ask what standards are they being compared to? What is the torsional strength of threaded bone dowels? What is the compressive strength of this product over time?

If threaded bone dowels are expected to function like fusion cages, they are more than minimally manipulated and should be regulated like devices. One must look beyond the source of the material, and also consider the anticipated function and mechanical properties and claims.

Thank you for your consideration of these issues.

Best regards,



Rich Jansen
Vice President
Regulatory and Clinical Affairs

SULZERMEDICA

Sulzer Spine-Tech

7375 Bush Lake Road
Minneapolis, MN 55439-2027

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16 August 1999

Dear Doctor:

Last week you may have received a letter from Ron Pickard, the president of Sofamor Danek regarding Sulzer Spine-Tech's position on the regulation of allograft bone as a device. This correspondence incorrectly states that Sulzer Spine-Tech supports such regulation. Sulzer Spine-Tech is not advocating the further regulation of allograft bone and has made this position clear with the FDA in a letter dated 20 July 1999. Please be assured that Sulzer Spine-Tech is not interested in restricting your access to technologies which could benefit your patients.

We at Sulzer Spine-Tech value our relationship with Physician's and are committed to working together for the advancement of spinal care. Should you have further questions regarding this issue, please contact me directly at (612) 830-6274 or by e-mail at richl@spinctech.com.

Sincerely,



P. Richard Lunsford, Jr.
General Manager
Sulzer Spine-Tech

send a copy of this letter



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