

## **Dental Products Panel Meeting**

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In 1992 I made my first visit to Congressman Ted Weiss's office to describe to his legislative staffer what I knew about the Vitek and Silastic TMJ implants. She asked me what I knew about other devices on the market and when I said, "not much," she admonished me, saying, "If you are going to be a patient advocate, you darn well better know everything about every device out there." That meeting led to the congressional hearings called: *Are FDA and NIH Ignoring the Dangers of TMJ Implants?* and the subsequent initiation of the classification process of these devices.

In the eight years since that congressional visit, I have made it my business to learn as much as I can about all TMJ devices. From the May 1999 Dental Products Panel Meeting I learned the following about the TMJ Implants, Inc. (Christensen) models. First, the testing data on all Christensen devices were woefully inadequate. Safety was not demonstrated due to testing with inadequate loads. [As an aside, at our Association's research meeting co-sponsored with the NIH last Spring, the experts noted that "the numerous failures of prosthetic treatments for TMJ disease indicate that our understanding of joint biomechanics is flawed... but it is probably both significant and more complex than was previously thought."] The May 1999 panel went on to say that evaluation of Christensen, Inc. clinical data was impossible as all Christensen products were blended into one reservoir of anecdotal, case study, and retrospective data--a body

of haphazardly collected information without the benefit of a clinical trial protocol. Over 80 percent of the patients were lost to follow-up.

Regarding the devices under discussion today, the TMJ Association has heard the following problems from patients: When the fossa eminence prosthesis is used, the patient suffers what surgeons refer to as condyle “shredding” or degeneration. Others have experienced fossa eminence prosthesis fracture. Of the all-metal total joint, the primary complaints are metallosis and shattering of the fossa piece. Screw loosening is a complaint common to all of these devices.

Conspicuous by its absence at this meeting is discussion of the Christensen polymethylmethacrylate (PMMA) condylar head device, on the market since 1961 and, following the recall of the Vitek devices in 1990, aggressively marketed. Compelling evidence of the safety and efficacy of this device was not presented at the May 1999 meeting. The PMMA shreds, leaving a nail-like projection to abrade against the metal fossa, which can then shatter. It is apparent that a PMA (premarket approval application) for this device has not been submitted by the manufacturer and the device is no longer being marketed. Where does this leave the patients who have been implanted with the device? If it is found to be unsafe, shouldn't the FDA initiate appropriate action, such as a recall, alert, or warning?

The most troubling information revealed at the May 1999 panel meeting was that the manufacturer received 361 MDR reports and determined that only 4 were device related

and reportable to the FDA. He blamed the remaining reports on the patients and surgeons. This is a chilling reminder to the patients of Dr. Charles Homsey's defense of the Vitek devices – he blamed the patients and the surgeons for the failures.

Upon hearing about the number of failures, we have to ask, who has the responsibility of determining the cause of failures of TMJ Implants, Inc. devices? Is it the manufacturer, someone within the company? Is it an independent monitor? Does the FDA agree with the company's definition of device failure? When the FDA learned that there had been 361 failures, did the agency investigate the reports? If they found the company responsible for the majority of failures, at what number does the FDA take action? If the device failures are due to surgeon error, shouldn't the company be responsible for surgeon training? If the failures are the patient's fault, are the patient selection criteria wrong? Was the diagnosis questionable? Was the use of the device for the patient's TMJ problem wrong? Or, is the problem that there are no uniform guidelines for aftercare for implant patients in the oral surgery and device community. Instead there are different directions given to patients by different doctors.

We know that some surgeons never file MDR or Medwatch reports, not just on these devices, but on any device. They either don't know they should, or they fail to comply, or their only criterion for failure is if the device breaks. One can only wonder how many more device failures exist that have never been reported. Patients hesitate to complain about their device problems to their surgeons for fear of antagonizing them. If they call

the manufacturer they are told to speak to their surgeon. If they call the FDA the agency is usually limited in what it can say.

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In their frustration, patients who experience local and systemic problems related to their TMJ air these problems online in chat rooms or listservs, in private conversations with each other or with The TMJ Association. It will be interesting to learn how many TMJ Implants, Inc.-related devices have failed since the May 1999 meeting. Our Association has heard from 34 patients since the May 1999 meeting. The gap between what patients are experiencing, what others tell them is happening, and what is officially reported about the devices is huge.

This panel has weighty matters to deliberate. Your charge is to decide whether the manufacturer has met the standards of safety and efficacy demanded of jaw devices. And you must do this cognizant of the sorry history of TMJ implants with their legacy of pain and suffering, of disability and financial ruin, of careers lost and families destroyed. To truly add insult to injury, implant patients have lost all faith in the system. They feel betrayed by their providers, dismissed by the manufacturers, and frustrated by government agencies. You can make a major contribution toward rebuilding patient confidence not only by addressing the specific issues related to TMJ Implants by remembering the words of the congressional staffer that “if it only happened to one person it is worth investigating”-- but also by recommending that an independently monitored TMJ implant registry be established, complete with explanted device analysis and direct patient input. Thank you.