

Summary and Recommendations for Reform of the Device Approval Process

The statement of The TMJ Association documents in detail the past failings of device manufacturers, health professionals, and the Food and Drug Administration at all stages of the device approval and monitoring process—from design and manufacture through safety and efficacy testing and post-market surveillance, and even in recalls. The result has been a human disaster affecting thousands of patients who have been harmed physically, emotionally, and financially—individuals who are now worse off in the severity of their pain and jaw dysfunction as well as suffering serious systemic complications, even death.

FDA – Transparency and Communication

The convening of a hearing to examine the device approval process and propose reforms comes at a time of change within the FDA, which augers well for the future. Over the past decade The TMJ Association made several unsuccessful attempts to meet with the Director of the Center for Devices and Radiological Health (CDRH) to discuss TMJ issues. All the more reason, then, that we applaud Dr. Shuren's eagerness to hear from all stakeholders in the device arena. Several weeks after Dr. Shuren assumed that Directorship, I, as President of The TMJ Association, was invited to participate in a conference call with him and other advocates to discuss our concerns with the Center. Several other conference calls followed. On July 10, 2010, I asked to meet with Dr. Shuren. He immediately responded and accommodated my scheduled visit to Washington. Since he became CDRH director he has held Town Hall meetings throughout the country at which patients have had a voice. However, the challenge for FDA is to give equal voice and participation to all stakeholders. For example, last year I watched the Institute of Medicine meeting webcast on the 510K process. In the room were 399 representatives of the device industry and one representative of the consumer. In a letter to Dr. Shuren I asked him to "please remember we are greatly outnumbered and greatly outspent by those who have the most to gain financially from devices." Yet it is we the patients who have the most to gain or lose from devices—our quality of life, even our lives.

The Future of TMJ Devices: A Paradigm Shift

On February 7, 2011 the FDA ordered the manufacturers of TMJ implant devices to conduct Postmarket Surveillance studies and to submit protocols within 30 days. A few days after the order was issued, The TMJ Association received a question from a patient, "Why should we believe the data the manufacturers will present when we were led to believe they had scientific data 10 years ago?" That question provoked much thought and discussion within The TMJ Association, which led us to the conclusion that we could no longer accept the status quo for TMJ patients. As we viewed the recent directive from the FDA we saw an opportunity for a major paradigm shift. We would propose a formal agreement to work together with all interested parties to ensure that the best clinical and bioengineering science, based upon robust scientific principles and good manufacturing practices, will be directed toward the implant patients and their devices. Collaboration would take the form of a **TMJ Device Round Table** where all stakeholders could come

together to discuss how to build a body of data on implant performance, patient satisfaction, side effects and complications—data which could better guide patients’ health care decisions as well as future device designs to yield optimal patient outcomes.”²⁵ The Round Table will include manufacturers, bioengineers, clinical, basic, and bioengineering scientists, representatives from FDA and NIH, surgeons, registry experts, and The TMJ Association. On March 9, 2011 we presented our concept to Dr. Shuren and his staff. They responded with enthusiastic support and intent to participate. The manufacturers have also been positive in their response. We look forward to the challenges of this new approach and are optimistic that results will benefit all stakeholders, especially TMJ patients.

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The TMJ Association submits the following recommendations to reform the Medical Device Approval Process:

Rec. 1: Review the classification process for all medical devices to assure that the classification is conducted in a timely manner and reflects the degree of harm that can result from device failure.

Rec. 2: Establish a TMJ Implant Registry.

A medical implant registry should be mandatory, independently monitored, include representation by all stakeholders, and include a process for device retrieval and analysis. It should be internationally compatible. Data analysis should enable detection of problems in time to minimize the number of people who could be damaged by the device and thus prevent future suffering and save lives. The registry would also be a means of assessing the success rates for implants and gleaning information on the scale of device problems from minor to major.

Rec. 3: Assure FDA Monitoring of Postmarket Surveillance.

If a device manufacturer is ordered to continue a clinical study following approval, it is FDA’s obligation to see to it that the study is being conducted appropriately, and that the required reports are received by FDA on schedule.

Rec. 4: The FDA should have mechanisms in place to assure that manufacturers comply with device-tracking requirements.

The Food and Drug Administration requires manufacturers to track certain devices upon order from the agency. Tracking is intended to facilitate notification and recall in the event a device presents a serious health risk to the patient health that requires prompt attention. Temporomandibular Joint (TMJ) prostheses, glenoid fossa prostheses, and mandibular condyle prostheses are among devices that the FDA has ordered manufacturers to track. But many patients have told The TMJ Association that they had never been contacted by the manufacturer of their device in an attempt to keep the patients’ contact information current. Moreover, when the TMJ Association asked FDA staff if assessing compliance of the tracking system was part of the FDA inspection process, the reply was no.

Rec. 5: If a company is unable to fulfill its responsibilities in the event of a recall of one its products, a system should be in place allowing FDA to conduct the recall promptly and efficiently.

The FDA became the responsible party to conduct the Class I Recall of the TMJ Vitek implant but was ill prepared to carry out that recall.

Rec. 6: The MedWatch and Medical Device Reporting systems must be improved. The FDA should conduct an awareness campaign to educate health professionals and the public of the importance of reporting device-related adverse events to the agency.

MedWatch is a voluntary reporting system in which professionals and the public can report a serious adverse event from a medical device, drug, biologic, dietary supplement or cosmetic. In 1986, the FDA was informed of adverse problems related to the Vitek implant but because of problems with the Medical Device Report (MDR) program, the reports were dismissed. Over the years MedWatch reports have been filed on all TMJ devices. In July 2010 The TMJ Association asked FDA officials how many reports had to be filed before FDA took action, since in addition to those submitted by the Association there were many others submitted by individual patients. We asked the FDA to review all MedWatch reports on TMJ devices over the years. Responding to The TMJ Association's request, FDA analyzed TMJ implant-related adverse event reports submitted between April 30, 2004 and Aug. 17, 2010. The analysis found 52 percent of TMJ patients had their implants removed three years or less after surgery because of extreme pain. This is considerably shorter than the expected minimum five-year life span of the device, based on premarket mechanical testing. What is important to note is that this analysis was conducted only *after* The TMJ Association pointed out the problems to the FDA.