Public Citizen

PUBLIC CITIZEN FOUNDATION
Ralph Nader, Founder

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Dockets Management Branch (HFA-305)
Food and Drug Administration, rm. 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Reproposed Classification of Temporomandibular Joint Implants [Docket No. 93N-0470].

On behalf of Public Citizen Health Research Group, we submit the following comments regarding FDA's reproposed classification of the Mandibular Condoyle Prosthesis and the Glenoid Fossa Prosthesis, both temporomandibular joint (TMJ) implants, from class II (the manufacturer is not required to submit evidence of the device's safety and effectiveness to FDA), into class III (manufacturer must submit such evidence in order to market the device). The TMJ is the jaw joint - the hinge that connects the two main parts of the human skull, the cranium and the mandible. Its main purposes are to allow efficient chewing, and movements for speech.

We support the reproposed classification; however, a careful examination of the history of TMJ implants reveals that this action is long overdue in terms of protecting the public's health, due, in part, to FDA's incompetence. Hundreds of reports of injuries associated with TMJ implants, including skull perforation, infection, tissue breakdown, bone degeneration and disfigurement, have been submitted to FDA. In the past 2 years alone, FDA has received 108 reports of serious injuries associated with TMJ implants and sheeting materials used by oral surgeons in TMJ surgery.

THIS ACTION SHOULD HAVE BEEN TAKEN BY THE FDA
AT LEAST 5 IF NOT 10 YEARS AGO

An estimated 60,000-80,000 Americans have received artificial jaw joint implants since the early 1970s. Unfortunately for many of these people, the manufacturers never were required to or bothered to test the devices to determine how they would perform in

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a load-bearing joint such as the jaw. Jaw joint implants came on the market before the Medical Device Amendments of 1976, which first required manufacturers of medical devices to prove that their devices are safe and effective. The TMJ implants that were first marketed after 1976 were allowed on the market without testing, because of a legal loophole which required their manufacturers to prove only that the devices were "substantially equivalent" to pre-1976 devices.

Reports of TMJ failures began to accumulate at least 10 years ago. Clinicians were communicating with a manufacturer of TMJ Interpositional Implants (Vitek, Houston, Texas) as early as 1984 concerning biomechanical failure of the implants, as well as tissue reaction and bone resorption. The first published report concluding that silicone may not be a totally inert material and that its biomechanical properties may not be desirable for use in the TMJ appeared in 1985.[1] By the 1986 Annual Meeting of the American Association of Oral and Maxillofacial Surgeons (AAOMS), several clinicians reported biomechanical failure of Vitek Proplast disc replacement. They found that debris from failure and wear led to progressive macrophage and giant cell reaction causing pain, resorption of the jawbone, and malocclusion. Subsequent testing with Dow silicone rubber (Silastic) implants showed that particles of debris were associated with macrophage and foreign body giant cell response, from wearing, tearing, and fracturing of the implants' surfaces. After a review of the literature, and exhaustive in vitro and in vivo testing of Proplast Teflon and Silastic TMJ implants, researchers reported in the August 1991 Journal of Oral and Maxillofacial Surgery, that "[t]he use of alloplastic [inert metal or plastic] TMJ devices for use as an interpositional implant, either permanent or temporary, must be questioned. Thousands of these devices have been implanted because material components were believed to be biocompatible. However, the biomechanical performance of these implants and the service life under TMJ loading have not been adequately discussed or determined."[2]

One of the many reported problems associated with implant failure was skull perforation. The implants ate away at bone and tissue; in some cases making a cavity which went through the skull to the brain. Yet despite literature reports of such tragedies, the Federal Register reproposed rule (59 FR 6935) indicates that "[t]he TMJ prostheses were inadvertently omitted from the dental devices considered for reclassification" by the agency back in

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[1] Dolwick MF and Aufdemorte TB. Silicone induced foreign body reaction and lymphadenopathy after temporomandibular joint arthroplasty. Oral Surg 59:449, 1985.

[2] Fontenot MG, Kent JN. In vitro and in vivo wear performance of Proplast TMJ disc implants. 1991 Aug; J Oral Maxillofac Surg.

1987. In 1988, one manufacturer of TMJ implants (Vitek) stopped making its TMJ implants because it faced several hundred lawsuits as a result of damages to recipients. Curiously, at an April 1989 meeting of the FDA Dental Products Panel, again the Panel did not make a recommendation regarding the classification of the glenoid fossa or the mandibular condyle implants. In September 1990 FDA obtained a court order to seize all of Vitek's TMJ implants, manufactured and distributed by Vitek's shell company, Oral Surgery Marketing, Inc., because they were "dangerous to health." On December 28, 1990 FDA issued its own safety alert to oral and maxillofacial surgeons regarding the Vitek TMJ implant. In March of 1991, our organization petitioned the FDA to find patients implanted with the Vitek TMJ implants, in order to warn them of the serious risks associated with them, and the need for immediate medical evaluation. In October of 1991, FDA established a notification program for patients who had received Vitek implants.

At the very least, it would have been prudent for FDA to call for safety and effectiveness data from <u>all</u> TMJ implant manufacturers when problems first surfaced with the Vitek devices, and at least by 1987. Other TMJ implants, including the Silastic, have been found to have high failure rates. FDA has never recalled the Silastic implants. Dow Corning voluntarily removed them from the market in January 1993.

At a February 1993 meeting, the FDA Dental Products Panel finally recommended that the devices be classified into class III. It is now April of 1994, and manufactures of the mandibular condyle prosthesis and the glenoid fossa prosthesis will not be required to submit premarket safety and effectiveness data to FDA for at least another 2 1/2 years, and will be allowed to continue marketing them in the meantime.

THERE IS, AND NEVER HAS BEEN, SUFFICIENT INFORMATION TO DETERMINE THAT TMJ IMPLANTS ARE SAFE AND EFFECTIVE.

Too many lives have been destroyed by TMJ implants. Often, by the time clinical symptom of deterioration such as pain or deformity are noticed by the patient, the damage is well advanced. It is unfortunate that it has taken the FDA until now to take definitive steps to reclassify them. Hundreds of thousands of patients consult with oral surgeons each year, seeking relief for jaw pain, headaches, clicking and popping sounds in their ears, and other symptoms of TMJ syndrome. Usually, conservative treatment is indicated, and was recommended, but many of these dentists recommend that their patients undergo surgery for TMJ implants; thousands of these devices are therefore implanted into patients yearly. Considering the disfigurement and agony (not to mention financial ruin) experienced thus far by many recipients of various brands of these devices, it is inconceivable that TMJ implants were inadvertently omitted from the list of dental devices up for reclassification back in 1987, and that the situation has not begun

to be remedied until now.

Two additional firms, TMJ Implants, Golden, CO., and Techmedica, Inc., Camarillo, CA., began marketing their own fossa and condyle devices in the late 1980s. Although no long term studies have been performed, TMJ Implants, Inc. markets the products in journals such as the Journal of Oral and Maxillofacial Surgery. Their product literature recommends the metallic glenoid fossa implant for every kind of TMJ problem, from early internal derangements to advanced degenerative joint disease. Some doctors are placing these implants in large numbers of young patients.[3]

From October of 1991 through December of 1993, the FDA received 108 reports of serious injuries associated with TMJ implants and sheeting materials used by oral surgeons in TMJ surgery. Among the problems reported were severe pain, malocclusion, restricted opening and deformity. Considering the fact that conservative measures provide relief from TMJ symptoms for most people, and that in most cases the symptoms resolve spontaneously, there is no excuse for allowing the devices to be used in the absence of adequate safety and effectiveness data.

CONCLUSION

We support the classification of all TMJ implants into Class III, thus requiring manufacturers to submit proof of their safety and effectiveness to FDA. However, we believe that the action taken is too late, not only to protect the patients damaged thus far by the Vitek Proplast and Dow Corning Silastic implants, but to prevent thousands more patients who will be implanted with these inadequately tested devices over the next 2 1/2 years.

Sincerely,

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[3] Hutchinson J and Still B. The Truth About TMJ: How To Help Yourself. Reinhardt & Still Publishers, Winchester, VA. 1994, p. 38.