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Shifting the Responsibility for Medical Decisions

Ever since its inception, the Food and Drug Administration (FDA) has served as the watchdog for the American public, and its approval of medical devices has been a guide to the profession in its efforts to avoid exposing patients to products that may not be safe and efficacious. Although the process may not be entirely foolproof, in most instances it has been effective and, when it is not, the agency has taken action to remove the product from the market and send out appropriate warnings to the profession. This was true in the instance of the Teflon/Proplast (Vitek Inc, Houston, TX) fiasco, which not only resulted in the interpositional implant being taken off the market, but also in a ban on the use of all available total temporomandibular joint (TMJ) prostheses except for the acrylic-on-metal type that had been on the market prior to May 1976. The latter product preceded the amendment to the law that empowered the FDA to oversee medical devices and it was allowed to be sold until the agency could evaluate it and make a final determination.

In February 1999 a premarket approval application (PMA) for a TMJ metal-on-metal total joint replacement prosthesis was filed with the FDA by the same company and, after consideration by the Dental Products Panel, it was classified as a Class III device (requiring additional evidence to demonstrate safety and effectiveness) and approval was given to begin commercial distribution. However, sale of the fossa-eminence prosthesis for use against the natural condyle was not allowed because it was considered a separate device in such usage. A PMA was filed for this prosthesis in June 2000 and in October 2000 it was reviewed by the Dental Products Panel, which unanimously recommended to the FDA that it not approve the device for marketing.

At that meeting the FDA staff presentation expressed concern regarding the lack of data on the effect of the natural condyle articulating against a metal fossa, the limited number of patients with long-term follow-up, and the broad diagnosis of internal derangement as an indication for its use. The panel expressed similar concerns about these issues, as well as the fact that the registry data provided in support of the product did not include all the patients treated and the sample size was insufficient for each of the individual indications. They recommended clarification of the patient inclusion criteria in the clinical study, evaluation of failures and additional patient follow-up, more clearly defined indications for use of the device, and that a power analysis of the clinical data be done to place the PMA in an approvable form. However, despite these criticisms, and the panel's opinion that adequate safety and effectiveness data for the given surgical indications were lacking, the device was approved by the FDA for distribution in February 2001.

This precedent-setting decision was based on a new FDA Center for Devices and Radiologic Health standard that requires full disclosure labeling of a device's limitations, as well as the availability of nondevice alternative therapies, and then places the burden of deciding whether or not to use the device on the shoulders of the doctor and the patient. The decision to perform surgery has always been based on a discussion between the doctor and the patient but, until now, one could rely on the FDA to critically evaluate the clinical evidence and determine safety, efficacy, and appropriate use of devices. To make such an independent judgment requires broad expertise that is available in an agency, but is not possessed by any single person. It also requires that adequate information is provided to the decision-makers. For example, how reliable are clinical data based on a registry that did not include all patients treated with the device, in which there was a very small number of total patients with serial data and even smaller numbers in each diagnostic subcategory, and where in 1 group of 97 patients with a diagnosis of internal derangement and/or inflammatory arthritis, only 30% (12 subjects) had a follow-up of 3 or more years and 70% were either lost to follow-up, withdrawn, or potentially lost to follow-up. How can one make an informed decision with such information?

These criticisms are not meant to imply that the TMJ fossa-eminence prosthesis is unsafe or ineffective, because there is still insufficient data to answer that question. However, it is now available on the market and the decision concerning its use and the responsibility for any future problems are ours. As noted by the Director of the FDA Office of Device Evaluation in a 2/28/01 article posted on Dickinson's FDA Webview (www.fdaweb.com), "We'll discuss [the] information in the labeling and we'll let the

doctors and the patients decide whether they want to use the device—we won't decide for them." Under these circumstances, until adequate information to truly make an informed decision becomes available in the literature, those deciding to use the device need to read the labeling carefully, and be sure their patients read and understand it as well, before proceeding. One can no longer use the issue of FDA approval as an excuse if a device eventually proves to be ineffective.

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