September 2007

MEDICAL DEVICES

FDA's Approval of Four Temporomandibular Joint Implants

GAO Accountability · Integrity · Reliability

Highlights

Highlights of GAO-07-996, a report to congressional requesters

Why GAO Did This Study

It is estimated that over 10 million people in the United States suffer from jaw joint and muscle disorders. Artificial temporomandibular joint (TMJ) implants have been used to replace the jaw joint in some patients in an effort to decrease pain and increase jaw function. The safety and effectiveness of these implants, like other medical devices, is overseen by the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS). Two implants used in the 1970s and 1980s that were later removed from the market caused severe side effects for some patients. In 1998, FDA began to require certain TMJ implant manufacturers sponsoring these devices to demonstrate the implants' safety and effectiveness before receiving approval. Since 1998, four TMJ implants from three sponsors were approved.

In response to your request, GAO described (1) the types of concerns raised by FDA and how it addressed these concerns for the implants approved since 1998 and (2) how FDA has monitored sponsors' compliance with conditions of approval. GAO examined documentation related to the four TMJ implants approved by FDA since 1998 and sponsors' annual reports, which FDA uses to monitor compliance with conditions of approval. GAO also interviewed FDA officials, TMJ implant sponsors, and patient advocacy groups.

www.gao.gov/cgi-bin/getrpt?GAO-07-996.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

FDA officials raised concerns during the approval process that were similar for all four TMJ implants. These concerns generally involved the adequacy of the sponsors' clinical study protocols, patient follow-up, engineering testing, and other matters, such as device labeling. FDA addressed many, but not all, concerns upon approval. Some concerns were addressed by obtaining additional information from sponsors to clarify and supplement data contained in their device applications before approval. Other concerns were addressed when FDA approved the implants but required sponsors to comply with certain conditions of approval, such as continuing clinical studies postmarket and collecting patient data. Because FDA staff, who review the device applications, and FDA management, who approve the devices for marketing, held differing views as to whether the implants' health benefits outweighed its risks, they did not agree on the approval decisions of two of the four TMJ implants. FDA management acknowledged that the concerns raised about the implants were legitimate. However, they ultimately concluded that the benefits provided by these two devices outweighed the concerns and approved both devices to help patients obtain relief from chronic pain.

FDA monitored sponsors' compliance with conditions of approval by evaluating information contained in their annual reports. FDA often required additional actions by the sponsors to resolve questions that were raised through its review of these reports. However, GAO found that not all annual reports were received by FDA. At the time GAO conducted its work, FDA had only received 13 of 18 required reports. One implant sponsor did not submit 5 of 7 required annual reports. FDA has requested these reports and has issued draft guidance on annual report submissions to all medical device sponsors. In addition, when reviewing the available annual reports to determine if sponsors were complying with conditions of approval, many of the submitted reports did not provide FDA with sufficient information to assess compliance. FDA required these TMJ implant sponsors to provide additional information to address this lack of sufficient information. In most instances, once FDA received additional information from the sponsors, the annual reports were considered adequate. However, one sponsor submitted several annual reports for both of its devices that FDA said lacked sufficient information regarding patient follow-up and also underreported problems experienced by patients associated with the devices. FDA notified the sponsor that it must address these concerns, but the sponsor repeatedly provided inadequate responses. This situation ultimately led FDA to inspect the sponsor's records and file an administrative complaint for civil monetary penalties against the sponsor for failure to file certain reports with FDA. On July 6, 2007, an administrative law judge ruled in favor of FDA.

In commenting on a draft of this report, HHS provided clarification on postmarket requirements for approved devices and updated information on the administrative complaint for civil monetary penalties.