FDA Acknowledges Deviations in Menaflex Knee Device Clearance

Written by Paul T. Kim

September 25, 2009

In an unusual "preliminary report" released yesterday, the Food and Drug Administration (FDA) admitted to "multiple departures from processes, procedures, and practices" in the 510(k) clearance of ReGen Biologics' Menaflex knee repair implant, which "leave[s] the basis for a review decision in question." The report, authored by FDA Acting Chief Counsel Michael Landa, Acting Chief Scientist Jesse Goodman, and Associate Commissioner for Policy and Planning Jeffrey Shuren, recommends an independent science-based reevaluation of the Menaflex 510(k) clearance decision.

Background

In December 2008, the FDA cleared the Menaflex device – formerly known as the Collagen Scaffold (CS) – under the 510(k) premarket notification process, which permits manufacturers to market devices that are established to be substantially equivalent to previously-cleared devices (known as predicate devices). Questions were then raised as to whether FDA's decision was influenced by inquiries from Members of the New Jersey congressional delegation on behalf of ReGen, a constituent company. These questions culminated in a May 11, 2009 letter to FDA from senior members of the House Energy and Commerce Committee, requesting that the agency investigate the Menaflex clearance history. In response, the FDA launched an investigation, leading to yesterday's report.

FDA Menaflex Report

The report found that "external considerations affected the decision-making process and possibly the review decisions of the ODE Director." (Report at 21.) This failure, the report states, "constitutes a clear deviation from the principles of integrity used in this review and undermines the ability of the agency to counter the suggestion that lobbying on behalf of ReGen affected the decision. Beyond all that, because the 510(k) review process relies on predicate devices, this failure to sufficiently explain and document the basis for clearing the CS device will almost certainly affect subsequent review decisions." (*Id.* at 1.)

The Menaflex report is the latest of a series of high-level critiques of the 510(k) premarket notification process and of the FDA's Center for Devices and Radiological Health (CDRH), which regulates medical devices. Dr. Daniel Schultz, the Director of CDRH, resigned in August after Schultz and Commissioner Margaret Hamburg determined that his departure "would be in the best interest of the center and the agency." (August 11 Resignation Memo from Schultz to FDA Staff.) Schultz had been criticized by some Members of Congress and was subject to anonymous internal accusations concerning the integrity of device reviews.

In 2007, to address consumer advocates' criticism of the 510(k) process, the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) included a provision requiring the Government Accountability Office (GAO) to conduct a study of the 510(k) clearance process. The GAO report, released in January of this year, did not propose fundamental changes to the process but did identify certain weaknesses. The FDA addressed many of the weaknesses in an April 2009 order requiring the submission of safety and effectiveness information for older devices, but the Menaflex report goes much farther in critiquing the 510(k) process.

Perhaps most significantly, the Menaflex report concludes that "the predicate system, as implemented, appears to perpetuate questionable review decisions," and recommends an independent review of the 510(k) program. (Report at 15.) Such a review was initiated this week when FDA formed an internal 510(k) task force and also asked the independent Institute of Medicine (IOM) to conduct a study of the 510(k) process and issue a report and recommendations by March 2011. It is notable that the agency's charge to the IOM is broad and affords substantial discretion in how far the recommendations will extend; the FDA asks IOM "what legislative, regulatory, or

administrative changes are recommended to achieve the goals of the 510(k) process?"

Agency Coordination

The FDA is not the only agency focusing on ReGen's Menaflex device. Earlier this month, the Centers for Medicare & Medicaid Services (CMS) announced plans to initiate a national coverage determination (NCD) on Menaflex to dictate Medicare coverage for the device on a national level. The issuance of an NCD is notable as such determinations are made by CMS only about 18-24 times per year. Additionally, the timing of this announcement indicates that the FDA and CMS are coordinating their efforts with respect to Menaflex. It is also noteworthy that Jeffrey Shuren, Associate Commissioner for Policy and Planning at FDA and co-author of the Menaflex report, is the former Director of the Division of Items and Devices in the Coverage and Analysis Group at CMS.

Conclusion

The Menaflex report is an exceptional example of critical FDA self-scrutiny, and will undoubtedly be the subject of continuing congressional oversight. It is also a signal of Commissioner Hamburg's commitment to renewing public confidence in the agency's credibility and product reviews. More specifically, the report will lend further support to the calls for reevaluation and potential revamping of the 510(k) process as a whole. It remains to be seen whether the resulting FDA task force report, IOM study, and reevaluation of the Menaflex clearance will lead to legislative reforms in the 111th Congress or during the next user fee reauthorization cycle in 2012.

RELATED INDUSTRIES

- Life Sciences
- Healthcare

RELATED PRACTICES

- Federal Government Strategies
