FDA'S MEDICAL DEVICE REVIEW PROCESS: 510 (K) PREMARKET NOTIFICATION PROCESS SCRUTINIZED

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As many know, on August 3, 2010, the Food and Drug Administration (FDA) released proposed reforms to the 510(k) premarket notification program. The 510(k) process, used to analyze whether certain medical devices may be marketed in the United States, has come under close scrutiny in recent years.

The impetus for the FDA's broad examination of the 510(k) review process appears to stem, in part, from the approval of the ReGen Biologics, Inc. Collagen Scaffold device used for knee repair, known as the Menaflex®, under somewhat questionable circumstances. After the device was approved for marketing via the 510(k) process in December 2008, this approval was subsequently called into question by members of the House Energy and Commerce Committee amid speculation that representatives and senators from New Jersey exerted undue influence over FDA review staff to approve the device, which is manufactured by a New Jersey-based company.

In September 2009, the FDA issued a report indicating "multiple departures" from its device approval process. While conducting the review of the Menaflex device, the FDA noted that its "inquiry inevitably involved some examination of 510(k) practices, procedures, and standards," which ultimately led to both its internal examination of the 510(k) process and its recommendation that an independent review be undertaken. Around that same time, the Institute of Medicine was asked to review the 510(k) program, and its report is due in March 2011.

The August 3, 2010, report released by the FDA contained numerous proposed changes, including:

- Requiring clinical information, post-market information, and manufacturing process information of 510(k) applications
- Creating a new class of devices, referred to as "class II b," for which there would be additional requirements
- Updating the "de novo" review process to address applicants' use of "split predicates" and "multiple predicates," whereby applicants would be prohibited from using split predicates

- Considering drafting regulations to address the FDA's authority to rescind approval of devices, including whether expanded authority is warranted

Hodgson Russ, as a member of MedTech, a vibrant bioscience industry group based in New York, participated in drafting the MedTech comments to the FDA's proposals. Generally speaking, the device industry has voiced concern over expanding the information that may be required of 510(k) applicants; prohibiting applicants from using split predicates, especially where a suitable single predicate does not exist; and generally blurring the line between the 510(k) process and the more rigorous premarket approval process.

On October 12, 2010, members of Congress requested that the FDA obtain additional information from stakeholders and provide Congress with more information before proceeding with what it called "five proposals … [that] should be considered controversial." Among these proposals was the FDA's expanded rescission authority. Nonetheless, on October 14, the FDA announced its rescission of clearance of the Menaflex device. This suggests that the FDA may not be waiting to proceed with specific reform proposals despite the request of Congress that the FDA provide it with "a detailed work schedule for implementing the recommendations of August 3." There is no indication that the FDA officially responded to the October 12 letter from Congress.

The medical device industry should be watching FDA actions carefully in the coming months and should expect that certain reforms will be implemented without the FDA affirmatively highlighting that the action is a change or that it is one of the FDA's proposed reforms. Piecemeal implementation of the FDA's recommendations and incremental changes are likely. We at Hodgson Russ are carefully monitoring 510(k) reform, and we will continue to provide updates as changes occur.

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