Firms Warn of Delays from FDA Scrutiny

By **ALICIA MUNDY**

Medical-device makers including Johnson & Johnson are warning of delays in device approvals after the Food and Drug Administration announced a major review of the process that has allowed quick clearance for thousands of products.

An internal FDA memo suggests that the tightening of the abbreviated process known as 510k is beginning already, before the review has been completed.

"It's Autumn, and change is in the air. This is particularly true for our 510k program," said Donna-Bea Tillman, head of the device evaluation office, in an email to her staff late Friday that was reviewed by The Wall Street Journal.

Dr. Tillman said in the memo that she needed to "get a better lay of the land" and called on branch chiefs to inform her when they were asked to clear a new "indication" or use "that you have never cleared for that device type." FDA reviewers typically don't run such individual applications by an official at Dr. Tillman's level, according to two FDA scientists.

Dr. Tillman didn't respond to requests for comment. The FDA said in a statement that her memo "reflects and is a furtherance of [FDA head Peggy Hamburg's] new direction."

The FDA's action came after it found "definite threats" to the integrity of its approvals in the case of a knee device approved last year that was the target of intensive lobbying by Democratic politicians. Dr. Tillman's role in the approval was critiqued in the FDA report on the episode.

The FDA has also commissioned an outside group to look into the issue.

The reviews "could have an impact now, in that they may lead FDA reviewers to be more conservative or more cautious in 510k reviews," said Jeffrey Gibbs, a Washington lawyer who advises device makers on FDA issues. "It's a very nervous time for the device industry."

A Johnson & Johnson spokeswoman defended the current 510k process, which streamlines clearance for products deemed "substantially equivalent" to devices already on the market. Carol Goodrich said the process "builds on ever-expanding knowledge" and accelerates innovation. Requiring more evidence for approval through the 510k process "would raise development costs substantially while also creating barriers to market entry that would reduce competition," she said.

At J&J, about $23 billion of the company's $64 billion in world-wide sales in 2008 came from the medical devices and diagnostic equipment division.

The FDA's Dr. Tillman said in her memo that the agency has set up a working group on 510k matters in her unit, and she called for extra scrutiny of certain applications.

She said the new scrutiny is "just the first of what I am sure will be many things that we will be doing to strengthen the 510k and all of our other programs in the months ahead."

The FDA's moves came in the wake of other potentially bad news for the industry in Washington. Leading Democrats have included a tax on device makers in health-overhaul legislation that would raise $40 billion over 10 years. Companies are fighting on Capitol Hill to stop or reduce those taxes.

Companies have valued the 510k process because it doesn't normally require lengthy clinical trials, allowing them to get their products to market sooner. Some members of Congress and some FDA device reviewers say the process is used too often for complex products that need more testing for safety and efficacy.

The Advanced Medical Technology Association, the industry's lobbying group, has met with members to discuss how to get their concerns reflected in the reviews at the FDA.

The association's executive vice president, David Exon, said the industry supports the reviews and is open to changes, so long as the "standards are reasonable and applied with consistency and transparency."

But Mr. Exon said he fears the multiple reviews could have a "chilling effect now" on FDA staff.

—*Nomaan Merchant contributed to this article.*

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