Drug industry's tough times aren't over

BY THERESA AGOVINO
ASSOCIATED PRESS

The pharmaceutical industry endured a disastrous 2004, and the aftermath will linger into the new year.

Regulators at the Food and Drug Administration were already expected to take a more cautious approach about new drug approvals in the wake of Merck's withdrawal from the market of its pain reliever Vioxx because it doubled patients' risk of heart attacks and strokes. Pressure on the FDA increased at year-end when Pfizer announced a study of its pain drug Celebrex showed it had similar problems at high doses. The two products are in the same class of drugs, known as Cox-2 inhibitors.

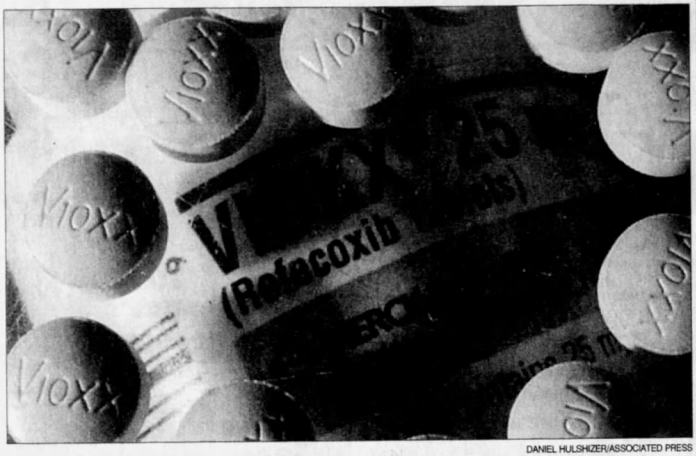
Questions still linger about whether Merck muzzled negative news about Vioxx in order to keep selling the drug. But the combination of problems with Vioxx and Celebrex is certain raise more questions about the safety of the drugs sold in the United States.

Drug makers already are struggling with growing generic competition and lackluster prospects for new medicines now in the pipeline. Some analysts believe further industry consolidation is likely because expense reductions resulting from mergers may be the key to increasing earnings at a time when revenues are stagnating.

"This has been a tough year, largely of their (the drug companies) own making," Catherine DeAngelis, editor in chief of the Journal of the American Medical Association, said. "Drug companies were not as honest and forthright as we expect them to be."

Besides the debacles at Merck and Pfizer, Chiron got a black eye earlier this year when products from the British plant where it was to produce half the country's flu vaccines were blocked by safety officials. Plus, the industry was buffeted by revelations drug companies had stifled negative clinical trial data from studies examining antidepressant use in children.

Those woes came amid mounting anger over the price of prescription drugs and increasing demands for the legalization of importing cheap drugs from Canada and Europe. And not to be outdone, a federal official testified before Congress the sale of five drugs approved by the FDA should be stopped or curtailed because they are unsafe.



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Merck's withdrawal of Vioxx from the market shook the company and the pharmaceutical industry.

THE STAR-LEDGER SOURCE: CBSMarketWatch

Stocks shriveled and reputations sank as few positives emerged to balance the negatives. As of Dec. 10, the S&P 500 Pharmaceutical Subindustry Index was down 12.8 percent for the year while the S&P 500 was up 6.8 percent.

Twenty-one new drugs were approved by the FDA through September, the last date available, including novel cancer treatments Avastin, made by Genentech, and Erbitux, from ImClone Systems and Bristol-Myers Squibb. Merck and Schering-Plough also got a green light for Vytorin, a cholesterol-lowering agent with blockbuster potential. But beyond those, analysts were hard pressed to name new products that were either major medical advances or potentially huge money makers.

Evidence the hurdles for drug approvals are going to get higher came in late October when the FDA said it wouldn't approve Arcoxia, Merck's successor drug to Vioxx, until it received additional information. And an FDA panel refused to recommend approval for a Johnson & Johnson patch to restore women's sex drive until more studies are conducted to determine its risks.

Carl Seiden, an analyst at UBS, said regulators may become more circumspect about approving any drug that is the third or fourth competitor in a class because it isn't filling a major void. And he predicted they won't okay any novel compound without vast safety data. Both will delay launches, depriving companies of revenues.

Generic competition has already caused problems for firms such as Bristol-Myers and Schering-Plough. Pfizer said it will lose $14 billion in sales in the next three years because of generic competition. But analysts say sales of Celebrex, and Bextra, Pfizer's other Cox-2 inhibitor, will slide steeply because of the recent study, causing more problems for the company.

Barbara Ryan, a managing director at Deutsche Bank Securities, said additional mergers are a possibility. "There is tremendous overcapacity in the industry," she said.

Analysts surveyed by Thomson First Call predicted overall industry earnings' growth of 8.37 percent this year, up from 4.75 percent in 2003. But growth rates are then likely to slow to the 7 percent range in 2005 and 2006, according to these forecasts.

Seiden noted after the industry reported single-digit growth in 1992 and 1993, there were six major mergers in 1994 and 1995.

The Vioxx disaster has some calling for a new agency to track drugs safety. Meanwhile, the 11 members of the International Committee of Medical Journal Editors said they won't publish studies unless all the trials are registered in a public repository when they begin. A public registry will make it more difficult to squelch negative studies.

Jeff Trewitt, a spokesman for the Pharmaceutical Research and Manufacturers of America, said he hopes this year's problems don't trigger new regulations and requirements that would place undue burdens on the industry.

While he acknowledged the industry needs to repair its damaged reputation, he said, "By and large the system works well."