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Reprint # 310-05

Will COX-2 Inhibitors Crash and Burn?

By **John Mack**

The headlines say it all (see box). After the fall of Vioxx, Merck is suffering mightily: 42% loss of market share, downgraded credit ratings, lost revenue, congressional scrutiny, etc. But worse still, the entire class of COX-2 inhibitors is under increased scrutiny and the credibility of Merck, the FDA, and the entire drug industry is in question as revelations about who knew what, when are announced almost daily.

the 'Me-Too Drug Domino Effect'") seems to be unfolding before our very eyes.

Soon after Vioxx was withdrawn Pfizer announced in a letter to doctors that one of its own COX-2 inhibitors—Bextra—was associated with an increase in heart attacks and strokes in two studies of patients taking the drug after heart bypass surgery.

Meanwhile an unpublished study presented at the American Heart Association annual meeting found 2.19 times the number of heart attacks or strokes among patients given Bextra, compared with those given placebos. Dr. Curt Furberg, an FDA advisory panel member who helped conduct the study, said "Basically, we showed that Bextra is no different than Vioxx, and Pfizer is trying to suppress that information." Pfizer called the findings "unsubstantiated."

Trouble at FDA

Two days after Dr. Furberg's remarks were published in the New York Times the FDA "disinvited" him from an advisory panel meeting scheduled for next February to examine the safety of Cox-2 inhibitors. FDA said Dr. Furberg could not be expected to be objective and Pfizer said it had nothing to do with his removal. The FDA has had problems with other physicians on its staff and has been accused of dragging its feet regarding studies of Vioxx and other Cox-2 inhibitors.

What About the Effect on Physicians' Prescribing Behavior

How has the Vioxx withdrawal affected the writing of prescriptions for pain killers by physicians? Data from ImpactRx, a company that tracks New Written Prescription (NWRx) data in real time (see "The New Written

Recent Headlines

"Merck Announces Voluntary Worldwide Withdrawal Of VIOXX," WSJ: September 30, 2004

"Pfizer Warns Of Bextra Heart Risk," WSJ: October 18, 2004

"Pfizer To Sponsor Major New Celebrex Clinical Trial," WSJ: October 18, 2004

"A New Trial of Celebrex, and Questions on Its Timing," NYT: October 19, 2004

"FDA Says It Is Too Soon to Tell If Vioxx's Risks Apply to Class," WSJ: October 19, 2004

"European Medicines Agency To Review COX-2 Inhibitors," WSJ: October 22, 2004

"FDA Seeks More Information On Merck Pain Drug Arcoxia," WSJ: October 29, 2004

"E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage," WSJ: November 1, 2004

"Canadian Officials Say Six Deaths May Have Been Linked to Celebrex," WSJ: November 4, 2004

"Did FDA Staff Minimize Vioxx's Red Flags?" WSJ: November 10, 2004

"Senate Panel Sets Nov. 18 Hearing On Vioxx Withdrawal," WSJ: November 10, 2004

"New Study Links Pfizer's Bextra, Similar to Vioxx, to Heart Attacks," NYT: November 10, 2004

The Me Too Domino Effect

What I described as the "Me Too Domino Effect" in a recent opinion piece (see "Vioxx Withdrawal and

company that tracks New Written Prescription (NWRx) data in real time (see "The New Written

Prescription: Leveraging Technology to Measure Change in Physician Behavior as it Occurs,” [PMN Reprint #33-06](#)), show that soon after Vioxx was withdrawn, there was a dramatic increase in new scrips written for Bextra, Celebrex, and especially for Mobic, a “traditional” NSAID (see CHART 1 on next page). Within a few days, however, new scrips for Celebrex and Bextra declined to the levels seen before Vioxx was withdrawn. Mobic, however, maintained its new level.

ImpactRx also tracks share of attention—i.e., a product’s share of all sales representatives’ details

to physicians (see CHART 2 below). These data show that Celebrex and Mobic were being detailed more aggressively to physicians after the withdrawal of Vioxx. No doubt this increase in detailing was responsible for driving some of the new scrips for these products. Note, however, that even with continued increased share of details devoted to Celebrex, the volume of new scrips written for that drug feel back to previous levels (see CHART 1). Physicians, it seems, are losing faith in COX-2 inhibitors and shifting patients to traditional NSAIDs like Mobic.

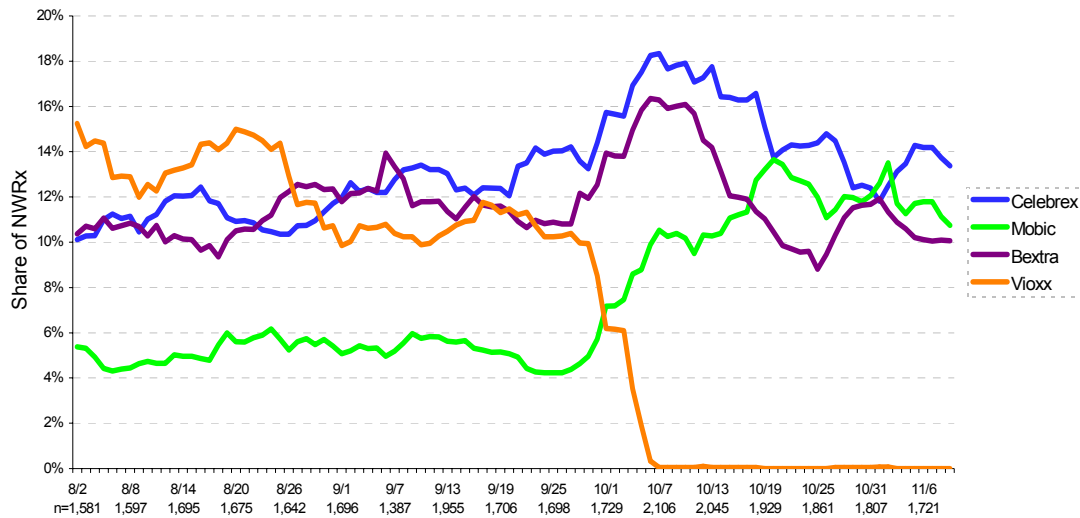


CHART 1: Share of New Written Prescription Starts (NWRx). The share of New Written Prescription Starts (NWRx). Includes prescriptions for newly diagnosed patients and previously diagnosed patients with a change in medication only. Source: ImpactRx

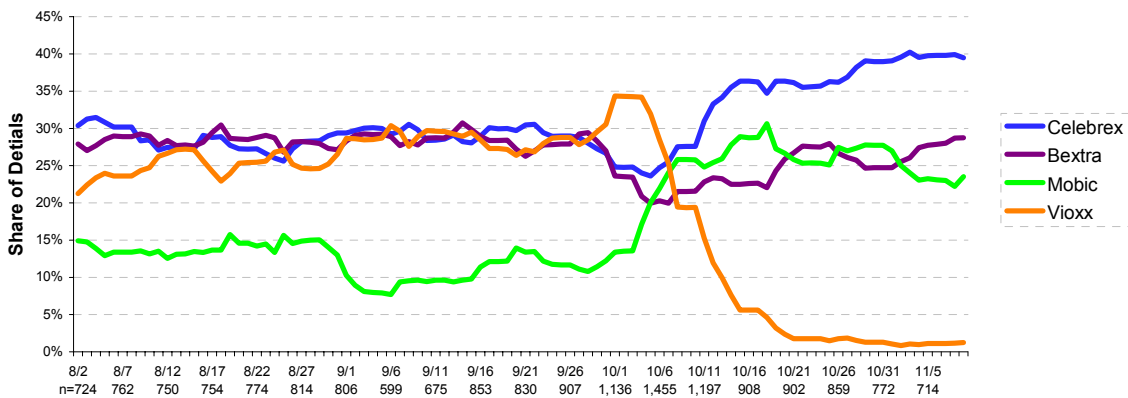


CHART 2: Share of Attention – Details. The product’s share of all sales representatives’ details. Source: ImpactRx

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Pfizer: Crazy or What?

Practically simultaneous with its Bextra announcement, Pfizer also announced plans to fund a large-scale clinical trial of Celebrex's ability to prevent heart attacks and strokes in patients with serious cardiovascular disease. Some experts suspected the timing of this announcement was calculated to divert attention away from the Bextra situation. Some even wondered if such a trial was ethical given the problems with Vioxx and Bextra.

"This kind of trial makes a lot of sense," said Steven K. Galson, acting director of the FDA's Center for Drug Evaluation and Research. "Given the question about whether we are seeing a class effect or something unique to Vioxx, there won't be a definitive answer until there has been an additional long-term study," he said. "I believe Pfizer understands that."

To see what we could learn from other experts about Pfizer's reasoning behind this announcement, we conducted an online survey of Pharma Marketing News subscribers between October 18, 2004 and November 24, 2004. The survey, titled "Is Pfizer Crazy or What?", asked just two questions:

1. In your opinion, why is Pfizer doing this?

- It's a gamble, but Pfizer has no choice: to protect Celebrex sales, it must be shown that Celebrex is cardioprotective, not just that it does no cardiovascular harm.
- Pfizer is too smart to gamble. The trial is not long term, consequently it is more likely to show a benefit than a problem as far as cardiovascular effects go.

2. Make a prediction. What will be the fate of Celebrex?

- It will crash and burn, just like Vioxx!
- It will prevail, be shown to be different than Vioxx and Bextra (i.e., cardioprotective), and sales will increase!
- It will hang in there, regardless of the outcome of the new trial, but sales will remain flat or decrease.

Survey Results

Seventy people responded to the survey. Respondents included 16 pharmaceutical company employees (23% of respondents), 23 marketing professionals from outside agencies or consultancies (33% of respondents), and 13 pharmaceutical market research professionals not employed at pharmaceutical companies (19% of

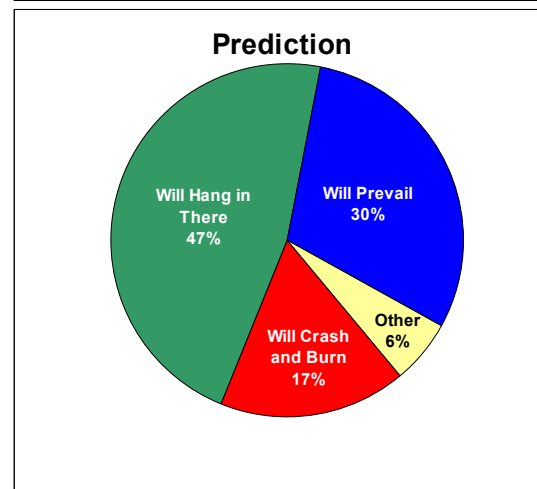
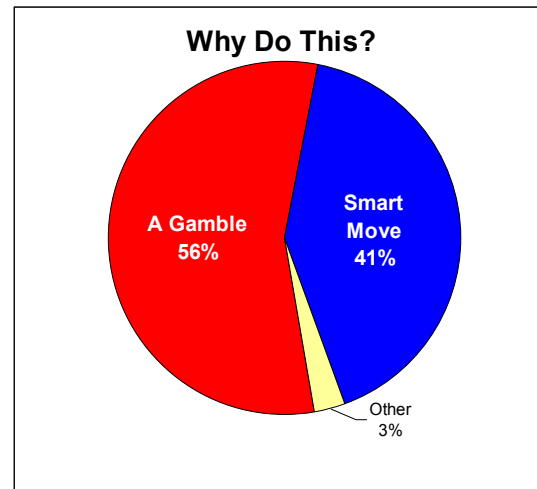
respondents). The following charts summarize the responses from all respondents.

Smart or Not?

A majority (56%) of respondents felt that Pfizer was making a gamble. This consensus was consistent among different types of respondents – pharma insiders as well as outside marketers and others. About the same percent of pharma respondents as non-pharma respondents felt Pfizer made a smart move (44% vs. 41%, respectively).

Will Celebrex Crash and Burn?

Surprisingly, a higher percent of pharmaceutical company respondents thought that Celebrex would "crash and burn" like Vioxx than did non-pharma respondents (25% vs. 15%, respectively). None of the marketing agency/consultant respondents and very few (8%) of the market research/consultant respondents thought that Celebrex would crash and burn.



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Selected Comments from Respondents

Several respondents added comments, a few of which are reproduced here.

“Pfizer has no choice but to address the spill over safety concerns from Vioxx. They are smart to position this research as a study to show potential benefit—a positive connotation for Celebrex. [This will have a] positive impact until safety data is available. The data will determine future market share.” – a strategic marketing manager at a pharma/biotech company

“Pharmaceutical companies are known to power the design of clinical trials to show favorable outcomes...and Pfizer can be expected to do the same to protect sales.” – a pharmaceutical company respondent.

“I think Pfizer has already reviewed post-approval data and knows that Celebrex is either (1) cardioprotective or (2) will not induce stroke or MI” – a market research professional respondent.

“[Pfizer] pretends to do the 'right' thing. Gets immediate publicity. Results are a long way away, good or bad. Who really needs cox-2s anyway?” – a marketing agency/consultant respondent.

“It's the responsible thing to do because it should answer any questions. If it comes out negatively, then a proper response should follow. If it comes out positive, then a huge marketing advantage is obtained.” – a marketing agency/consultant respondent.

“At very least, running this trial will inoculate Pfizer from any of the liability arrows that are already being aimed at Vioxx and Merck.” – a market research professional respondent.

You can see more results of the survey and look at responses from different segments of respondents by pointing your browser to <http://www.surveymonkey.com/Report.asp?U=67590467301>.

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