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LIFECYCLES

Fast Followers

by Mike Luby

The unparalleled prosperity of the pharma industry in the 1980s and 1990s is best summed up as “the age of the blockbuster.” The billion-dollar drug moved from rarity to commonplace, as drug therapies replaced more intrusive measures. In 1977, Tagamet replaced surgery for ulcers. Capoten, approved in 1982, revolutionized the treatment of hypertension. And who can forget the breakthrough treatment for depression that turned the United States into “Prozac Nation?”

These breakout drugs and others defined two decades of pharma history. Each enjoyed at least four years of market exclusivity before the second prod-

uct with the same mechanism was introduced, giving manufacturers time to cash in on their innovations. But in each case, additional drugs in the same categories also achieved blockbuster status, including Zantac, Vasotec, Zocor, Lipitor, Paxil, and Zoloft, to name a few.

For the most part, the honeymoon enjoyed by innovator compounds is over. Second- and third-category entrants come to market faster today. Consider Cozaar, the first among new antihypertensives to reduce the side effects of ACE inhibitors. Cozaar launched in 1995, and was followed by Diovan in 1996. Diovan not only followed faster, it took over as market leader. Likewise, the breakthrough biologics, Enbrel and Remicade, received approval within one year of each other in the late 1990s.

Probably the most dramatic case of a “fast follower” in a breakthrough category was Celebrex, approved in December 1999, following the approval of Vioxx in May. One sees a similar situation emerging for Gardasil, Merck’s new cervical cancer vaccine, which is closely followed by a competing GlaxoSmith-Kline product. **CONTINUED ON PAGE 120**

Category (condition)	Innovator drug (year of US introduction)	Follow-on drug (year of US introduction)
H2 receptor antagonist (ulcer disease)	Tagamet (1977)	Zantac (1982)
ACE inhibitor (hypertension, heart failure)	Capoten (1982)	Vasotec (1987)
HMG Co-A reductase inhibitor (hypercholesterolemia)	Mevacor (1987)	Pravachol & Zocor (1991)
SSRI (depression)	Prozac (1988)	Paxil (1992)
Angiotensin II receptor blocker (hypertension)	Cozaar (1995)	Diovan (1996)
Anti-TNF (inflammation)	Enbrel (1998)	Remicade (1999)
Cox II (inflammation and pain)	Celebrex (January 1999)	Vioxx (June 1999)

LUBY CONTINUED The last quarter of a century shows that me-too drugs offer multiple benefits, including faster development, more options for patients, and, not least, a healthy level of competition to keep pricing in check.

Clinical Execution a Must

Follow-on drugs can dominate markets. The most notorious example is Lipitor, which is the fifth statin to market, following Mevacor, Zocor, Pravachol, and Lescol, but which became the number-one selling drug in the world. Today, being first is less important than being best, especially in clinical development and sales and marketing execution.

On the clinical side, the industry has improved its batting average with FDA approvals, and shortened cycle times for clinical programs. But mistakes have been costly. Procter & Gamble's Actonel had a sizeable lead on Merck's Fosamax in the race to treat osteoporosis with bisphosphonates in the US market. But sub-optimal dosages in several trials forced P&G to repeat several studies, which allowed Fosamax to get to market first—an execution misstep with a price tag of more than \$1 billion dollars.

Marketing Still Lags Behind

Pre-launch marketing plans are easy to write, the old joke goes, because they are all the same. You publish papers, go to congresses, develop opinion leaders, and so on. Marketers just change the product name and choose physician specialties to fit their new brand.

Indeed, while clinical development has advanced during the blockbuster era, sales and marketing practices have not. In the case of Tagamet, SmithKline had six years to iron out positioning and messaging before competition heated up. Today's manufacturers might have six months. A "miss" in positioning, messaging, or strategic implementation is costly, since follow-on entrants are in hot pursuit. Industry practices have not progressed much over the past 25 years, so the pharmaceutical industry needs to re-think the marketing process from pre-launch through the entire lifecycle, as the marketing stakes are higher now than ever before.