

0.32	38.78	84.20	75.50	120.57	8.27	21.57	91.27	26.07	70.13	59
1.06	-.71	-.22	+.28	+1.4	-.04	-1.71	-.95	-.03	+.54	+1

ZERO SUM



75	13.65	35.24	10.32	38.78	84.20	75.50	120.57	8.27	21.57	91.2
.12	-.09	-1.46	-1.06	-.71	-.22	+.28	+1.4	-.04	-1.71	-.9

GAME



The economics of the oncology industry have never been better, but changes are looming. A confluence of market forces is adjusting the commercial equation for oncology companies, rendering them potential victims of their own success. Pamela Santoni and Thomas Foster of IMS Health consider the unintended consequences of progress. [cont. on pg 14 >>](#)





Today, thanks to advances in diagnostic technology, pharmaceutical and radio therapy, we are making many advances in the treatment of major cancers. Indeed, the ‘business’ has never been better. Cancer, with its battery of tests, drugs and procedures, is among the richest in revenue opportunities of all illnesses to treat. Historically, almost every new product with any incremental benefit could expect a handsome return in the long run—which is why in the past five years alone the worldwide pharmaceutical oncology market has more than doubled, reaching \$35 billion in 2006. This represents a growth rate that is three times larger than that of the total pharmaceutical market. The continuation of this trend would make oncology the dominant pharmaceutical therapy area by 2010. As a result of these attractive market dynamics, over 40% of the pharmaceutical research and development pipeline of new drugs is dedicated to oncology.

But the current ‘hot’ economic environment for the business of cancer is beginning to threaten its future. The very headway we are making today may be significantly slowing our progress tomorrow. The forces driving this phenomenon are perhaps best explained through the lens of the standard economic equation: (volume x price) – cost = profit. When we consider its components, what this simple equation reveals is that just as we are beginning to win the cancer war on the scientific front, we are in danger of losing it on the commercial one.

Volume

Unlike diabetes or heart disease, cancer is not an epidemic. Cancer patient populations, as measured by both incidence and prevalence,

are currently growing only slightly faster than the overall population in the developed world; this is because of the ageing of the population. But better diagnostics and earlier, more aggressive treatments are expected to drive down the rate of growth of late-stage disease in many major cancers. Since late-stage disease is where most new therapies enter the market, these trends have the potential to change pharmaceutical company launch economics by limiting the supply of patients available for treatment.

Moreover, in order to satisfy market place demands for greater and more predictable efficacy, subpopulation analyses and biomarkers are becoming more commonplace. However, such data reduces the potential patient population for a given therapy and rarely results in a commensurate price premium. At the same time, whereas previously new products were able to grow the market since they were added to standard of care chemotherapy cocktails, going forward the introduction of directly competing products threatens to further divide the market. Take the case of Herceptin®—highly effective in women with the aggressive HER2 form of breast cancer but appropriate only for the 20%–25% of breast cancer patients in whom the HER2 gene is over-expressed, and now forced to compete with Tykerb® for a smaller piece of the pie (see Fig. 1).

We see a potentially similar competitive environment with Erbitux® and Vectibix™ in colorectal cancer (CRC), with Gleivec®, Sprycel® and Tasigna® in chronic myeloid leukemia (CML) and with Sutent® and Nexavar® in renal cell carcinoma (RCC), where the similarities in mechanism of action make the

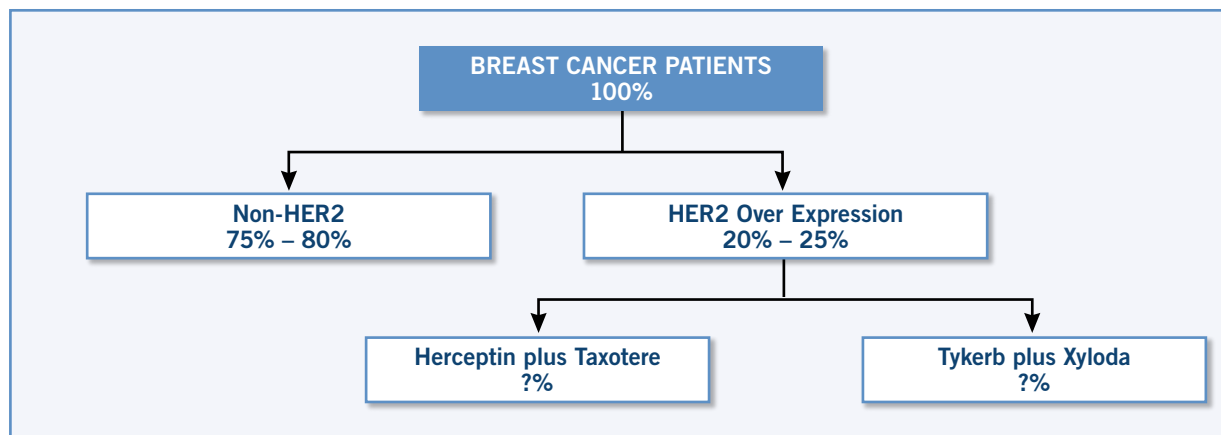
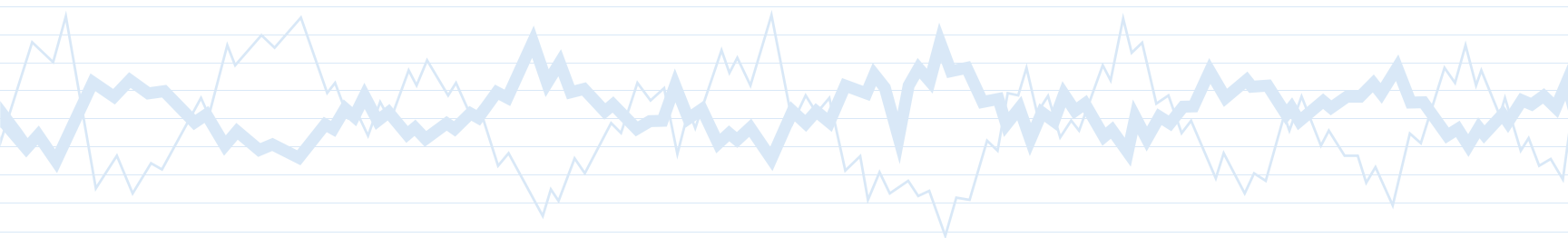


Figure 1. Targeted therapies and directly competing products have the potential to limit the size of the patient opportunity

...the oncology market, which could never have been said to be crowded or competitive in the past, is about to become so.

products more substitutable than complementary. In fact, with up to 55 new chemical entities (NCEs) entering the oncology market in the next five years, the potential for overlapping indications and mechanisms of action may further reduce the volume opportunities for these products.

Indeed, the oncology market, which could never have been said to be crowded or competitive in the past, is about to become so. Without significant increases in survival, the volume opportunity for new products will be diminished and divided. As a result, there will be pressure to push up prices in order to maintain revenue opportunities.

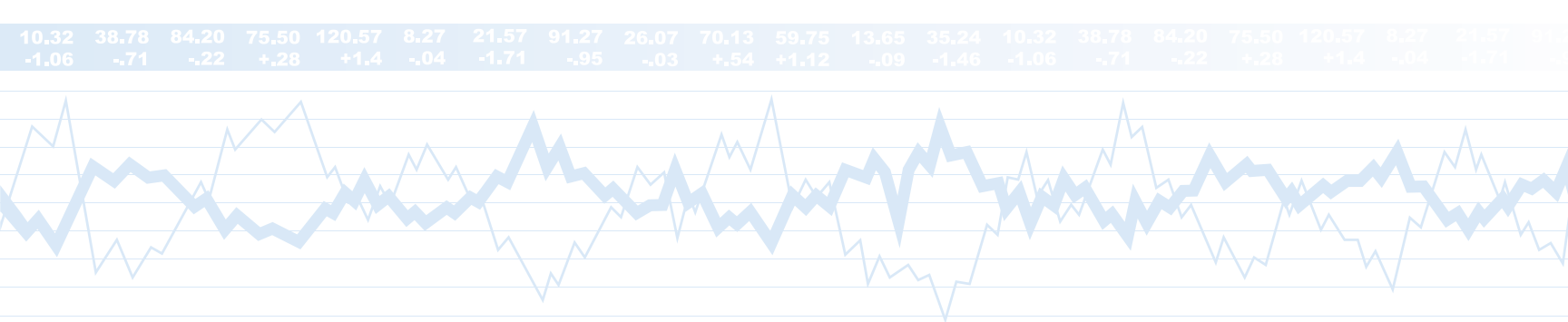
Volume x Price

Since the burden of illness in cancer is considered so significant and has proven so difficult to overcome, payers have thus far responded more to the benefits than the costs of new oncology products, allowing manufacturers more pricing latitude than in any other therapy area. As a result, payer budgets for oncology therapies have been growing consistently. Small wonder, then, that payers are beginning to react by re-evaluating historic

pricing freedom and imposing access restrictions on drug initiation and continuation.

Unsustainable pressure: US. In the US, health plans are still recommending ‘appropriate use’ for cancer drugs, rather than mandating outright restrictions, but it is a mistake to believe this will continue in perpetuity. In the past, because cancer is largely a disease in the elderly and oncology therapies were mostly given intravenously (IV), the burden of cost for these treatments was held by Medicare under Part B. Thus, health plans had very little financial motive to limit access to these therapies. However, the implementation of the Medicare oral drug benefit (Part D) coupled with the mounting use of oral oncology therapies makes health plans a more significant payer. Moreover, as these plans migrate their Medicare members from a drug only benefit (PDP) to the more profitable medical and drug benefit (MA-PD), thereby taking on the cost of IV therapies too, their exposure to the cost risk of oncology products increases further.

According to one MAPD medical director, “The oncology drug budget [cont. on pg 16 >>](#)



they will accept data. We also see payers and regulators holding pharma companies to more stringent levels of demonstrable value, thereby extending the time, complexity and costs of the trials themselves.

Biomarkers. As previously noted biomarkers have the potential to improve demonstrable value, but they reduce volumes and rarely obtain commensurate price premiums. In many cases, this places the onus on the pharmaceutical company to work with diagnostics counterparts in order to develop reliable and practical tests and to have them accessible and reimbursed simultaneous to the drug itself. In effect, this is tantamount to incurring the cost of developing, launching and supporting two products. And although payers appreciate the ability to ethically restrict access to expensive oncology therapies through diagnostic tests, they will, without hesitation, attempt to offload the cost of testing patients on to the pharmaceutical company.

Products without biomarkers are not off the hook. We believe post therapy monitoring will become more commonplace with payers in countries like Canada, Australia and Italy making reimbursement for certain oncology therapies contingent upon defined levels of patient response to therapy. Such an arrangement is currently being negotiated in the UK for Velcade® in multiple myeloma. Not only is this risky for pharmaceutical companies from a revenue standpoint, but it is also expensive to register patients and monitor and record their treatment and response level.

Adding insult to injury, as more new oncology products enter a market in which the growth rate of oncologists is stable, it is not

difficult to foresee pharmaceutical companies face increasing difficulties garnering the same level of attention to communicate and inform the market of the value of therapies. Historical methods of educating the market will likely become less efficient and require new approaches or risk a lower return on investment.

Zero Sum

As it has turned out, an erroneous assumption made by many in the cancer arena was that new drugs would be much like their predecessors, reaping huge rewards for bringing marginal improvement acceptable to all stakeholders in an area of very high unmet need. Based on that assumption, pharmaceutical companies set their pricing strategies and payers accepted them. Now, however, with payers under pressure, oncology budgets are no longer expanding at the rate of new drug introductions, and manufacturers may soon have to fight it out for a share of a relatively finite pie.

Manufacturers are not likely to stand by idly while payers decide their fate. Given the likelihood that progress in the battle to defeat cancer will markedly diminish the profits available for any one company, new business models will have to be created to deal with the emerging market realities of tomorrow. These adjustments may cut into present earnings but they could mean the difference between extinction and viability down the road. As the economics of oncology begin to show signs of weakness, we must either redefine the means to success or risk a tapering off of the future investment needed to close the door on this disease. And consensus might just work. But only 'might'. **PS TF**

About the Authors:

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