VS Thomas Global Health Strategy Consulting

Pharmaceutical & Life Sciences: Companion Diagnostics

Growth in partnerships spurred by payor demands for treatment stratification but challenges abound

With health care budgets under increasing pressure and concerns over the affordability of new health care technologies, drugs manufacturers have been increasingly faced with demands to employ stratifying mechanisms that identify those patients most likely to benefit. Diagnostic tests are looked upon as one of the key tools available to achieve health system goals. But challenges abound with the effort to integrate the different development and commercialization models of diagnostic and biopharmaceutical manufacturers as well as the manner in which revenue will be shared.

Observing the denoument of the pharmaceutical blockbuster, the industry has begun a slow repivot, finally discerning the potential to sustain traditional earnings and growth via targeted therapies. They have been urged further down this path by payors who, faced with a deteriorating macro-economic environment and declining budgets for health care expenditures, have increasingly sought mechanisms to increase the efficiency of their spending on medicines. „Stratifying mechanisms" allow effective patient targeting and have already been employed in various forms for a number of years (e.g., ranibizumab for wet age-related macular degeneration) to reduce side effects and maximize efficacy. Stratified medicines are envisioned to be a major area of robust future growth and industry partnerships and new business models have been formally encouraged, e.g., Technology Strategy Board in the UK.

As payors spell out the increasingly constrained parameters within which they will agree to premium prices for medicines, biopharmaceutical manufacturers have turned at a greater rate to diagnostic companies to help them build tests to meet these constraints. This has created a virtuous circle driving Companion Diagnostic partnerships, which tripled in 2010, continuing apace in 2011 and 2012. The two industry sectors have not proven easy bedfellows though, and collaborations have provided for a variety of challenges. Biopharmaceutical manufacturers are inherently wary of diagnostic tests, viewing tests as constraining drug development plans and a priori limiting the revenue potential of their new therapies. Two of the key challenges in this space are how best to incentivize the development of diagnostic tests to complement medicines and how to appropriately distribute the rewards across the value chain. The latter, as it turns out, significantly influences the former.

Payors have evaluated and contracted with diagnostic versus pharmaceutical manufacturers in very different ways to now. Although the real and potential monetary value assigned to diagnostic tests has risen dramatically in recent years (particularly in markets such as the U.S.), reimbursed prices for diagnostic tests still tend to be low, reflecting product cost rather than value; as well as the flimsy protection of intellectual property rights and a lack of exclusivity, which in turns leads to supply outstripping demand. Additionally, automation has driven down costs.. Perhaps more critically, there are few if any direct schemes for reimbursing diagnostics – even with the development of the Diagnostic Evaluation Program by NICE in the UK in 2012. In contrast, the process for pricing and reimbursing medicines, although admittedly challenging, rewards innovation and value, and tends to be quite transparent.

Payor evaluations of diagnostics tend to revolve around two key questions (beyond the standard consideration of validity and clinical utility): which tests are true cost savers? and does a test alter treatment decision-making? In order for testing to be effective, it is necessary to enforce the appropriate use and follow-up of tests. Even at low-cost, tests that are frequently utilised can also generate budgetary concerns. Further, the returns to testing do not accrue immediately for all diseases, thereby fragmenting the value proposition for payors in non-integrated or multi-payor systems.

Potential cost-savings and cost-effectiveness from testing may therefore not be discernible until the test has been on-market and in-use for some time. Payors might therefore be inclined to delay adoption (reimbursement and recommendation) until an adequate demonstration of value has been achieved. In response, "demonstration programs" are springing up: from Rule 137E in Germany to makeshift agreements in Canada.

For the investment in companion diagnostic partnerships to bear fruit, payors must be convinced of the value in the product combinations. Payors will demand the accurate identification of a target (i.e., limited) patient population – and are unwilling to pay for mere treatment guidance. Finding a way forward that mutually rewards diagnostic and drug manufacturers is laden with challenges though.

Prices for medicines are ever-increasing for novel therapeutic agents, and payors struggle to rein in price growth. The most important concern for payors is that of improved patient health outcomes. Diagnostics that can help to deliver on such efficiency goals should receive an appropriate distribution of the rewards to the therapeutic/diagnostic combination. Large diagnostics manufacturers currently earn their revenue primarily from the test machines they build. With shabby IP protection on test technology, manufacturers compete on price and practically give away tests (even highly innovative tests) to laboratory customers as sweeteners to retain contracts for their machines.

In contrast, there is less intense price competition in the pharmaceutical industry due to the protection of IP and the duration of differential product advantages. Some diagnostic manufacturers have demanded up-front payments from the drug manufacturer, effectively holding it to ransom. At the other end of the spectrum, some struggling diagnostic companies have indentured themselves to pharmaceutical partners, turning themselves into subcontractors in exchange for an immediate cash-flow, and thereby giving away virtually all future rights to equitable revenue-sharing or potentially even the commercialization of their tests as stand-alone products.

Biopharmaceutical manufacturers might prefer to provide diagnostic tests as tradeables in negotiations of the price for the drug, but this does not represent a sustainable business model from the perspective of diagnostic companies or payors. Despite the promise of targeted medicines and drug-test combinations, the practicalities of doing business suggest a tortured path ahead.

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