Pharma companies active in the US market recognize the declining importance of physicians compared to the increased clout of payers, provider organizations and patients. Many have moved toward new commercial models and repositioned sales resources to achieve greater scale and efficiency through Integrated Delivery Networks (IDNs). Others have attempted to implement geographically dispersed organizational strategies or geographic “archetypes” that require differing levels and types of sales investment.

In pursuit of this objective, managers have looked to the traditional metrics of market share and Tier 2 access to identify where to invest or, failing that, on how to reduce sales force and promotional spend. But the world has changed. Reliance on these tools – applied almost uniformly throughout big Pharma for the past 20 years – is no longer sufficient to ensure a profitable brand, let alone a sustainable business. In fact, the old standards may be having a reverse effect: in sales territories dominated by powerful payers or expanding Medicaid enrollments, continued deployment of traditional volume and access metrics could prompt companies to maintain investments in geographic markets that end up being the least profitable.

Put simply, it’s time for a new set of metrics that will allow pharma companies to align their strategies around the push for greater profitability, putting them on the right track for growth – right to the end of the product cycle. Precisely targeted data linked to method of payment, insurance coverage and geographic footprint are now available from both internal and external sources. When combined with insights from anonymous patient longitudinal data (APLD), these new information products can help management to be more confident in deciding where and when to expand, redeploy or reduce costly staffing of sales professionals among specific market geographies. Considering that field force expenditures comprise the third biggest discretionary investment that big Pharma makes after access rebates and R&D, the efficiencies achieved can be considerable.

Specifically, the application of these new metrics will enable management to move along three important vectors of performance simultaneously:

1. From measuring Volume to measuring Net Margin.
2. From measuring Quantity of Preferred Formulary Lives to measuring Quality of Access.
3. From measuring Drivers and Barriers to Performance at the National level to the Local level.

The following detailed explanations highlight why each of these three transitions is critical to helping companies maximize the effectiveness and impact of their promotional resources in the midst of mounting competitive market pressures.

Margins Matter

When the multi-billion dollar blockbuster model was ascendant, growing market share was the standard benchmark to evaluating the success of a new product launch. Management could pay for all sales and marketing investments, including an expanded field force, with the additional sales volume.

Exhibit One: New Performance Vectors
that resulted; all told, the strategy tended to yield very high gross profit margins. Today, in an industry where legacy blockbusters are in their last years of life, net margin must be measured at a granular geographic level to ensure that incremental sales are actually “accretive” – i.e. adding to the profitability of the company and covering any costs associated with adding sales volume. When a brand completes this analysis, factoring in the costs identified in Exhibit One, management will often find significant geographic differences in net margins. Such differences, once exposed, can help impact a decision on whether the company can afford to risk additional resources in a sales territory.

For example, there are a number of mandated new reductions to net revenue, like the offset of 50 percent of the “doughnut hole,” legislated in the Affordable Care Act (ACA). For the products we have reviewed, this can be as high as 12 to 15 percent of Gross Sales over the course of a year. Surprisingly, our review finds that this expense is geographically concentrated in a few areas of the country – the Midwestern states, New York, and California—where there are more CMS “Standard Eligible” patients.

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An even more important indicator of exposure to margin erosion, particularly for mature brands, is the rebate level paid to the Medicaid program, Part D Plans, Commercial Plans and PBMs – and also now directly to patients through coupon offset savings programs. The toll is cumulative and extensive: years of double-digit price increases have created CPI penalties in Medicaid that can often lead to reimbursement which is less than the cost of goods sold for products in their last years of patent life. According to IMS Health research, about five percent of all branded Medicaid prescriptions are reimbursed at only one cent per Rx due to cumulative CPI penalties that exceed 100 percent of the product’s Wholesale Acquisition Cost (WAC).

The minimum access rebate for each new product launch, which due to therapeutic competition often means a marginally differentiated product, is now going up every year. According to a recent report by Credit Suisse, for in-market brands, voluntary extension of “price protection” clauses in Medicare Part D, along with recent demands by large commercial payers to get the same type of protection in that channel, drove the average gross to net margin ratio down by at least seven points between 2008 and 2012.

Likewise, the expense of patient support programs is compressing margins – some 400 products had a co-pay offset, coupons or evouchers in 2013 and most of them also contracted for formulary access simultaneously. This can drive up the gap for lower cost prescriptions. For example, paying down an ARB co-pay to $5 from a Tier 3 average patient out-of-pocket (OOP) charge can knock 40 percent out of a brand’s net revenues. If the manufacturer had already contracted in the geography and patients use the co-pay cards to pay down a preferred OOP, virtually all the margin in that market can disappear. In 2014, as much as five billion dollars will be spent on co-pay support in the US, but the money will not be spread evenly. Rather, it will concentrate in places where high deductible plans and co-insurance are prevalent. In some sales territories, manufacturers with specialty pharmaceuticals will spend more this year on co-pay support than all other sales and marketing expenses combined.
One final margin consideration is the regional differences in patient adherence. With the breadth of longitudinal data now available, brands can calculate adherence at a local level and thus place more value on new patient starts in one area of the country over another. For example, in the DPP4 diabetes market, there is a 25 percent difference in expected days of therapy when measured across the US geography. In other words, as indicated by Exhibit Two, all patients are valuable—but some are more valuable than others.

**Access: Quality not Quantity**

Patient compliance to therapy is a consequence of many factors, but the most consistent driver, across all therapeutic classes, is patient OOP. Since 2006, many pharma companies have seen that the quality of access for patients who have qualified for the government Low Income Subsidy [LIS] is unsurpassed in any other patient population. LIS patients will pay only $6.35 in 2014 for any branded product on either Tier 3 or Tier 2 and may use many more days of therapy in a year than a standard eligible patient. Once their total drug spend exceeds $6,455 in a calendar year, their cost sharing per prescriptions goes to zero. In chronic care therapeutic classes, it is not unusual to see 50 percent or more of transactions in the catastrophic phase of coverage in Part D for prescriptions filled in the second half of the year. Thus, LIS patients, who need no co-pay support, will generate many more net revenue dollars than other Part D patients.

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The conclusion from this data? Using Tier 2 access, specifically the percentage of lives with preferred formulary status, as a proxy for market attractiveness, is no longer meaningful. Preferred formulary status is not helpful if the patient has a $50 co-pay or if the brand is classified as a stepped therapy, behind a generic. Worse yet, more benefit designs now have coinsurance and higher deductibles that can put a damper on patient adherence or can drive continuing patients into switching to generics early in the calendar year. The good news is it is now possible to measure the actual co-pay exposure and benefit designs of patients on a geographic basis and to incorporate that into the calculation of brand opportunity. Each brand and therapeutic class has a price sensitivity threshold, perhaps $40 for many cardiovascular and metabolic products, where the evidence reveals patients will abandon a prescription at the pharmacy counter. For specialty products in MS or oncology, that patient threshold will be higher.

It follows that pharmaceutical manufacturers must incorporate this understanding of the patient response to cost sharing or utilization management techniques, so that they know where they have a high level and quality of access to them. This makes it easier to demonstrate that additional sales effort will actually succeed in turning that written prescription into a filled – and refilled – prescription.

**Think Nationally...but Invest Locally**

Today, the impact of different standards of care or treatment protocols can also be measured. The nature of the delivery system and the conditioning of the providers within it can either dampen or amplify the profitable, high quality access that a brand will command. A number of large pharmaceutical companies have made changes to their commercial model around the idea that IDNs as well all other variables affecting patient uptake must be isolated in order to identify additional competitive advantage.

In a number of recent projects, where the quality of access could be taken out of the equation for suc-
cess, our research has discovered clear geographic patterns in the standard of pharmaceutical care. These patterns can be measured and translated into a sales opportunity. For example, there are clear differences between northern and southern regions in the US on the length of time a patient stays on metformin before adding an alternative diabetes therapy. The same is true for methotrexate use prior to and/or concomitant with a TNF inhibitor.

This can make Seattle or Boston far more interesting to some treatments, and Birmingham and Miami less so. By the same token, Boston can be considered “scorched earth” for many manufacturers who will have to get their products stepped through multiple generics before being eligible to be prescribed. The insurance formulary may say that all the brands in a class are covered, but the practice of writing generics first is deeply embedded in all training and practice in the Boston area.

Existing data sources, when married to physician practices affiliated with individual IDNs, will allow manufacturers to measure and compare the impact of individual networks for a given insurer, and vice versa. In the example in Exhibit 3, all physicians associated with five IDNs in Chicago appear to be impacted by United Healthcare’s formulary restrictions on the diabetes product, Januvia. Nationally, this formulary action moved 35 points of market share to the preferred products [Onglyza and Tradjenta]. It proved to be one of the payer actions with the highest impact in 2013.

The same outcome occurred with unaffiliated physicians, but to varying degrees. The decline in share among physicians affiliated with a rival IDN, Presence, was less significant compared to the drop for another competitor, Dupage Medical. Knowing whether to invest in resources to move entire blocks of physicians to amplify the formulary advantage or dampen the impact of the restriction can only come from connecting this granular performance data in real time physician practices.

**The clean cut**

As we move into the next phase of change in pharmaceutical marketing and sales management, more sophisticated tools and measurements need to be adopted to ensure that companies continue to invest in the most profitable geographic opportunities. The traditional measurements – quantity of formulary lives and volume, are just too imprecise for making disruptive, time consuming and largely irreversible cuts in long-standing sales investments. A new set of metrics, which provide a proxy for “gross to net margin” at a local level, must be deployed across the industry. Metrics that provide better indicators of branded growth potential – whether these measure quality of access or the power of local influences – should be identified in each therapeutic class.

Accuracy in evaluating the growth and profitability potential of each market, incorporating new insights that have only recently been extracted from performance, affiliation and longitudinal data, will be critical to ensuring that cuts in resources, when they do happen – as they must – can be focused on the markets where this will matter least. As in crafting a suit that fits, bespoke is best. And to do that, managers would be wise to measure twice, so they only have to cut once.

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