EBOOK FROM THE EDITORS OF Pharmaceutical Executive

CHANGING CONTOURS OF DRUG COMMERCIALIZATION

UBM

TOC | CHANGING CONTOURS


PATIENT VALUE
PAYER VALUE
Payers and other stakeholders who influence utilization must be assured of a new pharmaceutical's clinical and economic value in addition to its safety and efficacy. HEOR experts apply evidence-based strategies to demonstrate value and support a product's differentiation within a crowded market. Securing successful coverage and formulary positioning takes retrospective database analysis and prospective studies. It takes strategic foresight and real-world evidence to establish a product's value for both payers and patients. It takes a committed commercialization partner. It takes AmerisourceBergen.
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REIMBURSEMENT

New Payment Models:

THE TIME TO MOVE IS NOW

BY STACIE HELLER, PETER WEISSBERG

Fundamental changes in the US access and reimbursement landscape are accelerating for the vast majority of public and commercial stakeholders. Often characterized as accountable care organizations (ACOs) or medical homes, these changes are indicative of the larger trend of payers using a variety of payment models to drive an overall behavior change among healthcare professionals and patients. Whether it's the traditional fee-for-service system which serves as the basis for some new payment models or a new bundled/episodic payment model, pharmaceutical manufacturers need to have a clear line of sight into how each model may impact their specific product portfolios in order to ensure commercial success. As such, the era of simple surveillance is over.

Two-pronged mission

Though data on new payment delivery models are mixed, payers are betting on these new approaches to improve quality and corral costs. The goal of simultaneously improving patient outcomes while also reducing costs is seen as a realistic achievement. Ultimately,

Pharmacy Engagement and Prescription Drug Management in ACOs

	Private (N=140)	Medicare (N=111)
At least one accountable care contract including pharmacy spending in calculation of total cost	76.8%	1.8%
Near complete ability to e-prescribe and confirm fill	53.4%	37.3%
Near complete ability to maintain a list of diagnoses and medications in EHR	59.8%	51.0%
Near complete ability to intergrate inpatient and outpatient data in EHR, including medication data from ACO providers	41.9%	37.9%
Near complete ability to provide patients with electronic chart or discharge information	58.6%	49.5%

J Manag Care Spec Pharm. 2015 Apr, 21(4): 338-344

The "Private" column refers to ACOs whose contracts include commercial as well as Medicare and Medicaid. The "Medicare" column refers to ACOs whose contracts include Medicare and Medicaid, but do not include private payers.

pharmaceutical manufacturers need to understand how to navigate the behavior changes brought by various payment models (see table) by anticipating implications and adjusting commercialization strategies accordingly.

The inflection point for pharmaceutical manufacturers occurred once drug benefits were included as part of the new payment models in a way they hadn't been before. Recall that the first wave of CMS-sponsored ACOs excluded drug treatment from the overall program design. Now we are seeing examples such as those from Houston, TX, which saved the municipality an estimated $42 million in healthcare costs over the past three years through the use of ACOs and narrow networks. By pushing to keep city employees to a small ACO and switching to 87% generic drugs, Houston simultaneously promoted wellness overall and reigned in costs.

Cancer pilot study

A recent pilot program conducted by United Healthcare and published in the Journal of Oncology Practice illustrates where the industry is headed through the lens of an oncology bundled payment model.

ACO Characteristics and Engagement with Outpatient Pharmacy

Some numbers have been rounded.
J Manag Care Spec Pharm. 2015 Apr, 21(4): 338-344

3 Manufacturer Musts

It's a safe bet that payment models will continue to evolve, reimbursement will continue to be a challenge, and medication will continue to play a role in improved outcomes and cost savings. There are clear steps to take to ensure products are positioned to add value regardless of the payment models to ensure patient access, adherence, and quality care outcomes for patients. Manufacturers should therefore:

1. **Dedicate a strategic imperative within each brand's business plan to ensure the impact of each of these models on brand performance is well understood and senior management is educated appropriately**

2. **Invest in the development of educational, promotional, and training resources that provide details on the specific implications of each model.**

3. **Continue to monitor both public and private payers and calibrate activities along the implementation timelines for newer models that are able to deliver concrete results.**

In doing so, manufacturers can successfully pivot towards proactive engagement in our new reimbursement reality and sidestep the pitfalls which are sure to ensnarl the passive watchers. The commercial success of your products is what hangs in the balance.

The study, conducted over three years, rewarded physicians for focusing on best treatment practices and health outcomes while simultaneously removing the financial incentives associated with drug acquisition. Data illustrated an overall savings, despite an increase in drug utilization and costs, without compromising quality and outcomes. These successes will add wind to the sails of other initiatives such as WellPoint's Cancer Quality Care and Cigna's Collaborative Care which aim to use incentives to engage healthcare professionals and help drive improved health, affordability, and patient experience.

The implementation of these pilots illustrates that even specialty disease categories such as oncology, which once were deemed strictly off limits to new models, are now clearly in play. These new models will be additive to traditional models such as fee-for-service, further illustrating the need to deeply understand unique program design when developing differentiated commercialization strategies. Consider that the fee-for-service model is in fact the ideal design for immunizations. Physicians are rightly incentivized to immunize more patients because it a) creates an overall

healthier population and enhances quality care outcomes and b) aligns to financial goals. The challenge for manufacturers will be to not only surveil the multiple models that exist (see figure), but rather to recognize and act upon how these models will ultimately impact the performance and success of their assets.

Payment models will continue to evolve as payers gather more data and continue to work to improve outcomes while reducing costs. Manufacturers can't wait for change to slow before reacting and planning as market changes can and do impact patient access to branded treatments and overall utilization patterns. For example, the Affordable Care Act's Health Insurance Exchange plan models' bronze, silver, and gold levels all carry with them different formulary structures. Astute manufacturers will not only know where their products fall on formularies for each level of plan, they must (or will) build financial models to ensure appropriate funding for patient assistance and co-pay programs to account for coverage dynamics. The most progressive executives then leverage this data to develop tools and training for field representatives so they can confidently address heathcare professional (HCP) inquiries and build credibility with increasingly sophisticated provider audiences.

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DATA

THE NEW METRICS OF MARKET SUCCESS

BY MASON TENAGLIA

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 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.

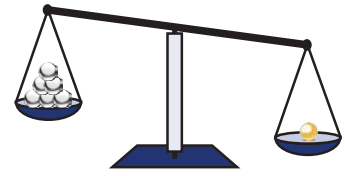
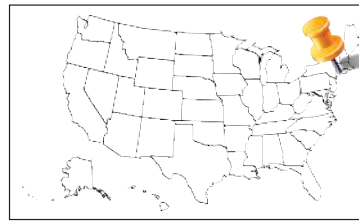
Volume → Margin	Quantity → Quality	National → Local
		
▪ Medicaid % of Total Volume ▪ Average Medicaid Rebate/Rx ▪ Part D Standard Eligible % of Part D ▪ Average Coverage Gap Utilization per Patient ▪ Contracted Part D and Commercial Sales % ▪ Average Commercial Rebate, Part D Rebate /Transaction ▪ Co-pay or Evoucher Penetration/Rx ▪ Co-pay or Evoucher cost per Rx ▪ Total Co-Pay Support/Year ▪ 340b Sales/Total Sales ▪ Average Days of Therapy/New Patient Starts	▪ % LIS Transactions/Total Part D ▪ % Patient Co-Pays under $15 Commercial ▪ % Patient OOP >$40 ▪ Average Deductible in Commercial Plan ▪ % Patients having Co-Insurance for Rx Benefit ▪ Average Co-Insurance % ▪ % PA/ST Rejections ▪ % PA/ST Rejections – Overcome	▪ Generic Fill Rate All Brands or Benchmark (ARBs?) ▪ % New Patient Starts on "generics first" in Therapeutic Area ▪ % Transactions passing through IDN Network ▪ % of Transactions from Exchange Plans ▪ % New to Brand Prescribed by Specialists (ie. Endos,Rheums) ▪ % Mail Order of Commerical&Part D

Exhibit One: New Performance Vectors

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 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.

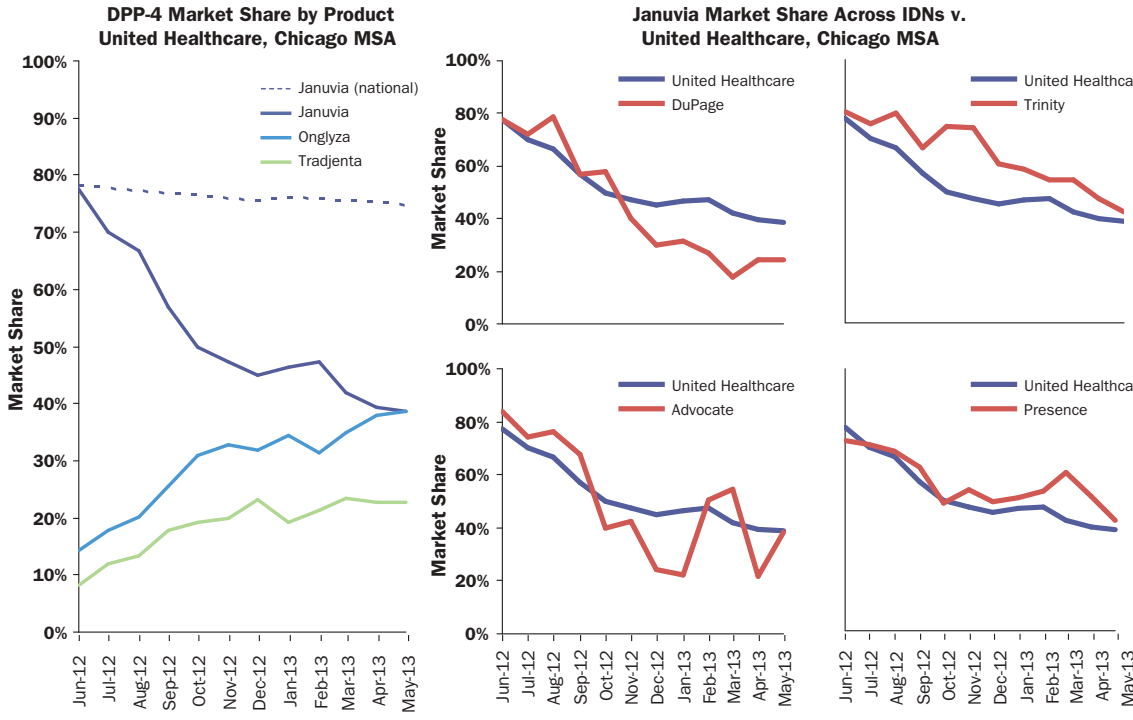
For example, there are a number of mandated new reductions to net revenue, like the offset of 50 percent of the "doughnut hole," legislated in the Affordable Care Act (ACA). For the products we have reviewed, this can be as high as 12 to 15 percent of Gross Sales over the course of a year. Surprisingly, 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.

> "A NEW SET OF METRICS IS NEEDED THAT WILL ALLOW PHARMA COMPANIES TO ALIGN THEIR STRATEGIES AROUND THE PUSH FOR GREATER PROFITABILITY"

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 a 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.



Source: IMS FIA+APLD dataset; Amundsen Group analysis

Exhibit Three: A Local IDN Strategy can Amplify or Dampen Payer Actions.

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.

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 success, 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.

> “CLEAR GEOGRAPHIC PATTERNS EXIST IN THE STANDARD OF PHARMACEUTICAL CARE THAT CAN BE MEASURED AND TRANSLATED INTO A SALES OPPORTUNITY”

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 formulaly 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 comet 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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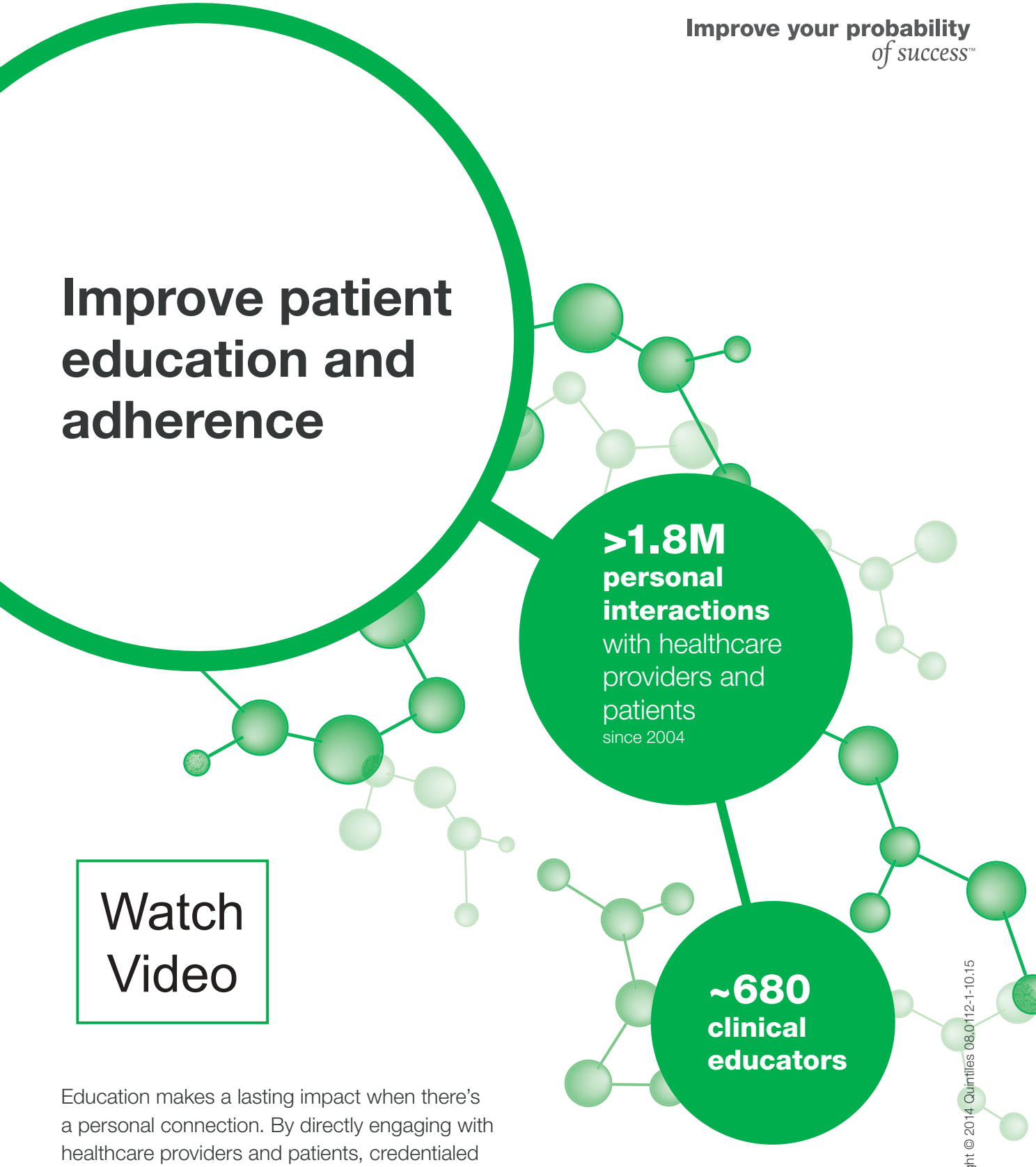

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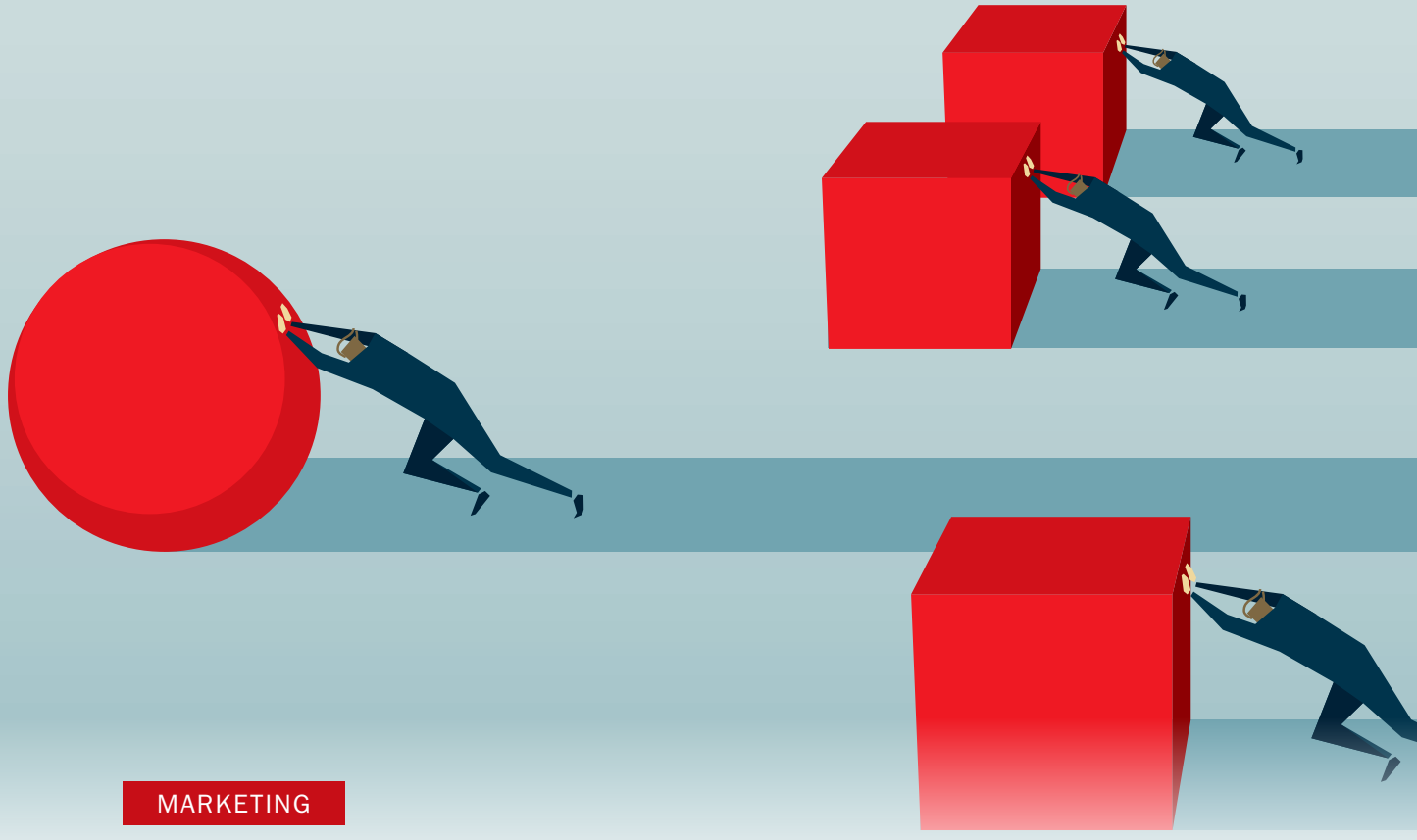

MARKETING

RETHINKING PRODUCT LIFECYCLE MANAGEMENT

BY STAN BERNARD, MD

Imagine if physicians only treated people as if their lives began at age 18 and stopped treating them at age 65. This approach would essentially ignore the early development years of youth and the late maturity years of seniors, which also happen to be the peak periods of demand for the physicians' services. Sound preposterous? Not in the pharmaceutical industry. Pharmaceutical marketing professionals primarily focus on the middle years of a product's commercial life, commonly referred to as the "product lifecycle," which begins with regulatory approval and ends with expiration of the patent. The conventional practice is to apply a product lifecycle management (LCM) strategy that entails making critical investments corresponding to four commercial stages of a product's lifecycle: introduction; growth; maturity; and decline (Figure 1).

While LCM is adaptable to many types of manufactured products, it is not applicable to drugs. Drugs are unique products which have not one lifecycle but rather three different life periods: an extensive early development period; a highly competitive mid-life period; and a significant late post-patent period. These three periods together constitute the real life of a drug, running from bench to bedside (Figure 2). Unlike most products, drugs have a lengthy, closely regulated, and complex

PRODUCT LIFECYCLE MANAGEMENT PHARMACEUTICAL LIFECYCLE CURVE

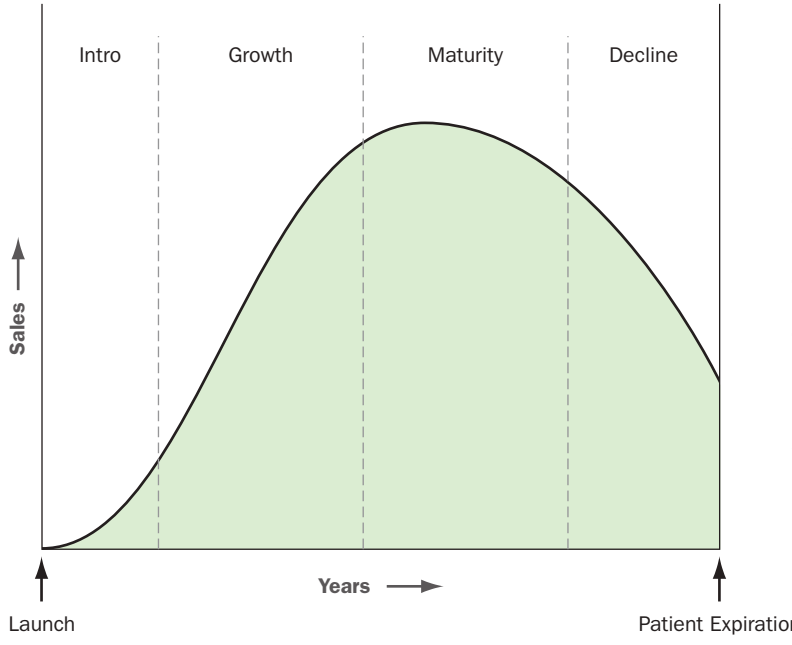

Figure 1: Many pharmaceutical professionals use the standard product lifecycle management approach to make important commercial choices. Unfortunately, this limited methodology focuses primarily on the middle years of a product's commercial life, commonly referred to as the product lifecycle, often resulting in flawed business decisions.
Source: Stan Bernard, Bernard Associates, LLC, 2013

developmental pre-marketing phase usually lasting a decade or longer. During this period of scale up toward commercialization, drugs are influenced by an extremely diverse group of customers and stakeholders, each of which can dramatically alter the conditions of access, utilization, pricing, and sales. And unlike most other products, pharmaceuticals are treated as a public good, usually financed by governments or third-party entities. This is reinforced by global, regional, and national intellectual property laws which frequently determine the timing and impact of generic competition in the product's later years.

Consequently, applying the limited LCM approach to pharmaceutical products can lead to flawed assumptions, unrealistic strategies, and value-destroying execution. Pharmaceutical professionals are advised instead to consider the concept of Drug Life Optimization (DLO), which enables pharmaceutical professionals to view the entire life—not just the lifecycle—of a product in order to make more appropriate, timely, and strategic decisions through each of a product's three life periods. DLO is an all-encompassing business approach to manage the complete set of product information, processes, and resources in order to maximize the longest, full life potential of a drug.

More life than you think

DLO is a disruptive innovation because it requires a transformational change in the mindset of every pharmaceutical professional. In contrast to LCM, DLO:

Incorporates early-stage development planning. The early period is a way to showcase not only the clinical but also the commercial market potential of a new product. During this foundational period, pharmaceutical planners are tasked with making crucial business planning decisions that will determine the ultimate sales, profitability, and therapeutic impact of the new agent, over a

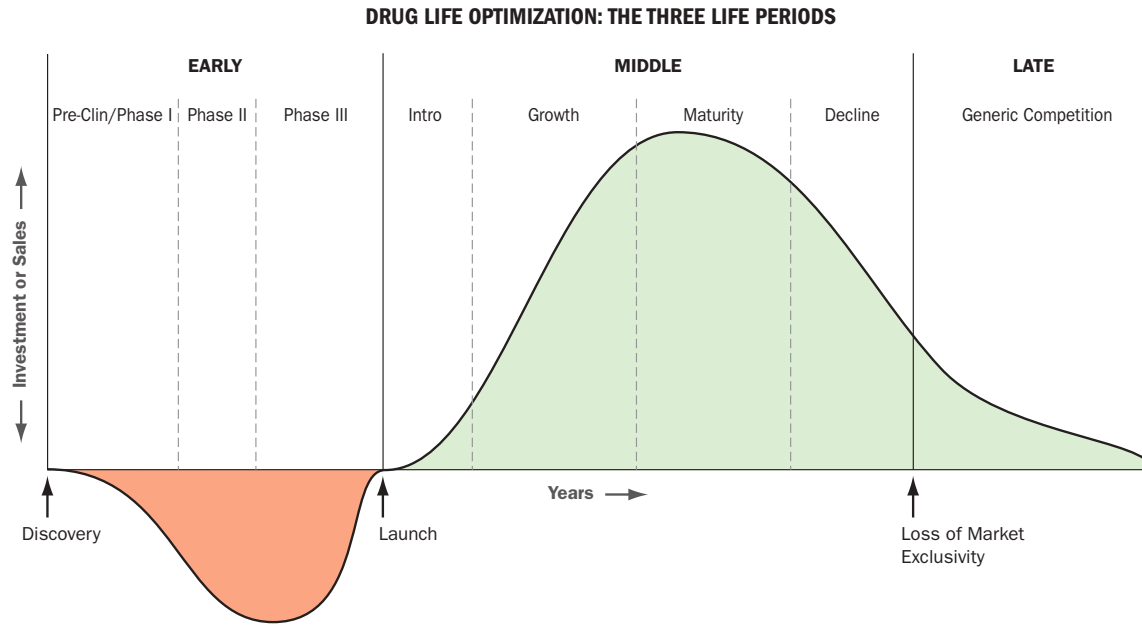

Figure 2: Drug Life Optimization enables pharmaceutical professionals to view the entire life—not just the lifecycle— of a product and to make more appropriate, timely, and strategic decisions to maximize cumulative, lifetime sales, represented as the area under the curve in green.
Source: Stan Bernard, Bernard Associates, LLC, 2013

period of decades. The early period also requires a forward looking accounting of the full range of investments to position the drug for market success.

Includes the late generic period. Unlike the LCM curve, the DLO curve does not end with product patent expiration but includes the late period beginning with the loss of market exclusivity and initial generic competition. DLO recognizes that patent expiry is not necessarily the demarcation line for an abandonment of product support, since generic competitors are now entering the market to grab brand share prior to patent expiration. Moreover, there is no longer a single, primary patent or patent expiration date, even in the same market. Innovators utilize various types of patents (e.g., composition of matter, method, formulation, etc.), which generic companies can challenge in different markets.

Realizes cumulative product sales. DLO focuses on maximizing product sales throughout the entire life of the product, including the post-marketing exclusivity period. Consequently, the DLO approach assumes there is real business opportunity even for products facing generic competition, in contrast to the historical practice of withdrawing support from products as LOE approaches. A 2011 Leerink-Swann investor analysis reveals that innovative companies can capture as much as 20 to 30 percent of the total value of an innovative product after patent expiration and the onset of generic competition, by considering a wide range of cost-effective actions.

Encourages a holistic business approach. LCM is preoccupied with winning during the middle years of the LCM curve; it relies on traditional marketing and sales promotion channel strategies to compete. However, DLO offers many other ways to win, involving the application of regulatory and legal tools; manufacturing, distribution, and formulation changes; partnerships, mergers

and acquisitions; public policy, public relations, and stakeholder reputation advocacy; portfolio management; and other actions. Execution of DLO strategies thus demands an integrated, multi-disciplinary and cross-functional team approach to manage things through the entire life of the drug.

Like LCM, DLO has several limitations. Different types of products, such as acute care products or vaccines, will have different life curve "shapes." Because there are so many pharmaceutical stakeholders and market influences, the shape and duration of the life curve for any given product is highly unpredictable. For example, new clinical data, regulatory requirements, or market access can dramatically alter the drug's life. While the LCM and DLO curves are typically used cumulatively to reflect total sales across geographies, the curves for a particular drug can be applied to a specific market. Unlike LCM, the DLO curve includes the drug's pre-launch clinical and commercial investment, which represents only a relative estimation of actual costs.

Where to focus

Pharmaceutical professionals who apply DLO are demonstrating dramatically better commercial success and competitive advantages for their products and companies. The benefits of the DLO versus the LCM approach are highlighted in three critical events during a product's life:

Product launches. Pharmaceutical professionals using the LCM focus their efforts in succeeding during the launch year, the first year of the traditional product lifecycle. However, in today's highly competitive pharma industry, just winning the launch year is far too late. It's like a presidential candidate trying to win the election a year after it is held. In contrast, DLO users—like presidential campaign teams—realize that successful launches are actually won in the pre-launch years, usually in clinical Phases II and III, during the early period of a product's life.

> "THE VALUE OF A MEDICINE, STARTING FROM DISCOVERY TO THE POINT WHERE IT IS REPLACED BY SOMETHING ELSE MUCH GREATER THAN WHAT IS CURRENTLY TAKEN INTO ACCOUNT BY REGULATORS"
>
> —Stephen Whitehead, ABPS

In fact, IMS data has shown that the ultimate sales trajectory of a new chronic-care medicine is determined in the first 12 weeks as opposed to the first 12 months after launch. Applying DLO enables professionals to plan and execute pre-launch activities much earlier to position the product and generate stakeholder awareness and demand. Moreover, it enables the commercial launch team to preempt counter-launches, brand pre-positioning, and unfavorable messaging from competitors seeking to thwart the new product in the pre-launch years. It is analogous to a presidential candidate who begins the competitive campaign three to four years before the election by fixing an election strategy, communicating a platform, and establishing relationships with key constituencies before competitors can frame an alternative negative message about the candidate's platform and character.

Generic competition. A 2009 Thomson Reuters survey revealed most pharma professionals wait too late to prepare for generic competition, usually only a few years instead of the eight to 10

years before a product's patent expiration. Innovator professionals utilizing DLO initiate generic competitive planning prior to their brand's market launch, at the same time as generic companies typically start their planning by procuring the brand's active pharmaceutical ingredients. Earlier competitive planning is essential since increasingly aggressive generic companies are no longer waiting for patent expiration to enter the market. Teva has launched over a dozen products "at risk" in the United States prior to patent expiration. Many other generic companies have launched products prior to patent expiry in Europe and in some cases prior to the innovator's own product launch, as occurred with Amgen/Pfizer's rheumatoid arthritis agent Enbrel in China.

Recalculating product valuations. Business development professionals can utilize the DLO framework to properly value in-licensing and out-licensing opportunities by accounting for the full value of a product's life, not just during those middle years when the product stands front and center in the market. In fact, companies can use DLO to persuade payers on how innovative brand medicines can serve as a source of long-term value, setting prices in the context of a long duration of exposure to patients and the market. Stephen Whitehead, chief executive of the Association of the British Pharmaceutical Industry (ABPI), has used this DLO argument to expedite the adoption of novel products by payers in the UK healthcare system. He is determined to get the National Health Service authorities to stop thinking about the product lifecycle as the patent lifecycle, because the cumulative life of a product extends far beyond that—closer to 40 years. "The value of a medicine, starting from discovery to the point where it is replaced by something else is much greater than what is currently taken into account by regulators," he says.

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ADVERTORIAL

MAXIMIZING PATIENT VALUE

Benefits of Patient Education, Engagement and Support Solutions

***Pete Megronigle**, Vice President, Integrated Market Access, Quintiles*

Biopharmaceutical manufacturers' focus on new patient acquisition has historically been a mainstay of marketing and sales efforts. However, in the current, rapidly evolving healthcare environment, an initial diagnosis and treatment decision is but a first step in achieving a positive patient and healthcare provider (HCP) experience with a particular product.

Today's focus has shifted to achieving lower costs, better care and driving patient outcomes. Success in the marketplace now requires a more comprehensive and innovative approach inherent in a multi-channel marking and sales strategy. An approach that can pull through the demand of a drug, engage patients throughout the entirety of their treatment journey and educate healthcare providers to the true value of a therapy.

Pete Megronigle, Vice President, Integrated Market Access, NA, Quintiles

An emphasis on patient outcomes shines a spotlight on adherence. The two go hand in hand when assessing treatment efficacy, according to the World Health Organization (WHO), which states: "The population health outcomes predicted by treatment efficacy data cannot be achieved unless adherence rates are used to inform planning and project evaluation."

Too often, however, patient support is sub-optimal, which can result in poor compliance, a challenge across all therapeutic categories. According to Dr. Chowdhury et al. at the Centers For Disease Control and Prevention (CDC), an estimated 20–30% of prescriptions are never filled, and medication is not continued as prescribed in about 50% of cases. Only 51% of Americans treated for hypertension are adherent to their long-term therapy, and some 25–50% of patients discontinue statins within one year of treatment initiation.

What exactly does adherence mean? The WHO definition extends beyond the taking of a prescribed medicine to include (among other determinates) "a cluster of behaviors that are simultaneously affected by multiple factors," which also takes into account the relationship between the patient and the healthcare provider. Be it physician, nurse or other health practitioner, the WHO states that the relationship should be mutually beneficial and more like a partnership that draws on the abilities of each party. In 2003, the WHO's adherence project adopted the following as its official policy definition: "The extent to which a person' s behavior—taking medication, following a diet, or making healthy lifestyle changes—corresponds with agreed-upon recommendations from a health-care provider." [1]

Overall, between one-third and one-half of patients with long-term conditions fail to adhere to therapy—for reasons relating to the healthcare system, patient, therapy, condition, and socio-

economic status—regardless of the severity of the condition. In addition to significant health impacts, non-adherence is linked to direct costs of $100 billion to $289 billion annually.[2]

Intervention: The key to improving adherence

Against this backdrop, innovative healthcare solutions and patient support services are called for. Inherent in multi-channel marketing and sales strategies are Clinical Educators (also known as Clinical Nurse Educators, Nurse Advisors or Health or Medical Educators).

Clinical Educators (CEs) are credentialed healthcare providers (i.e., nurses). Highly trained, CEs have a minimum of 2–3 years of experience in managing patients with a specific chronic disease. CEs are, therefore, qualified to work directly in a practice. Perfectly positioned, CEs serve to increase brand adoption and support sales force objectives. In addition, CEs can improve a HCP's understanding of the clinical aspects of a brand, drive accuracy in diagnosing patients and successfully engage patients and care-partners in improved treatment regimens. In short, CEs have the power to drive brand adoption and adherence, and maximize brand ROI. (Figure 1)

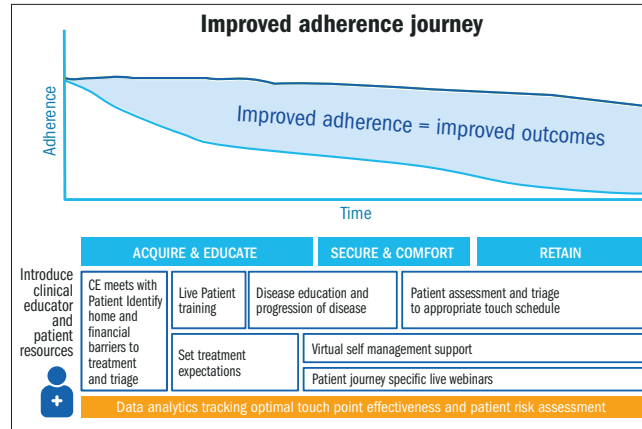

Figure 1 Illustrative example

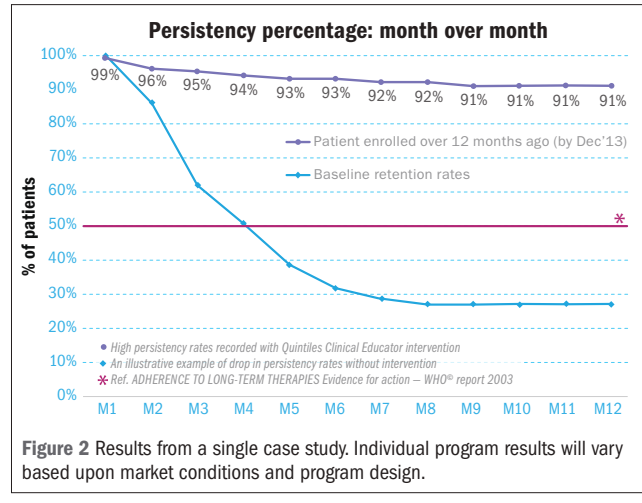

Figure 2 Results from a single case study. Individual program results will vary based upon market conditions and program design.

When it comes to patients, CEs employ their considerable skills in disease management to increase patient engagement. CEs provide patients with disease and treatment education, help accelerate program shifts, improve and monitor treatment regimes to enhance adherence, and facilitate ways for patients to connect with other people living with the same condition.

CE programs represent a powerful differentiator for both physicians and patients. Many therapeutic categories can benefit from the intervention of CEs, including chronic conditions such as diabetes, asthma, multiple sclerosis, oncology and immune disorders, as well as rare diseases and challenging-to-diagnose conditions.

Nurses are highly respected in the US. They have the highest honesty and ethical standards ratings of any professional, according to Gallup. This only adds to a CEs' effectiveness in the eyes of a patient. CEs involvement in a patient's treatment represents changing healthcare provider behaviors. For example, CEs offer a mutually beneficial partnership in our relationship with a patient similar to the one the WHO referred to as being necessary in driving health outcomes.

Impact of Clinical Educator program as a sales strategy

At Quintiles, our CE program functions as part of a multi-channel sales strategy and serves to increase the size of a product's overall market through awareness and advocacy. In particular, Quintiles' CE program serves to maximize sales force effectiveness. Its impact is demonstrated by data showing sales representatives gaining increased access to difficult-to-see HCPs who have opted into the program. CEs also provide access as well as selling opportunities for representatives. Using peer-to-peer knowledge, they help educate HCPs as to the clinical aspect of a therapy with peer-to-peer knowledge of the brands while improving patient care and treatment.

As part of any CE program, Quintiles offers a range of patient support interventions delivered face to face, virtually or telephonically. These can be on a full-time, part-time or Per Diem basis. CE resources added and integrated into a program to improve adherence, further educates patients (with print or online materials), and can remind patients of their treatment regime. Market access solutions to facilitate payment and speed-to-therapy for patients are also available.

To demonstrate the overall impact of their CE program, Quintiles points to a recent case study that made use of Clinical Nurse Educators (CNEs)—to positively improve patient adherence, from less than 50% to more than 90% at 12 months. The program itself was credited to playing an integral part in product growth over the past three years. (Figure 2)

Conclusion

Developed and deployed correctly, patient engagement programs involving Clinical Nurse Educators support the entire patient journey. Such ongoing support ensures that the patient has the tools and support necessary to obtain maximum benefit from the treatment prescribed. And perhaps just as important, CE's, by way of their patient engagement, their attention and sheer presence can create that positive treatment "atmosphere" the WHO described in its adherence definition. An atmosphere that provides patients, so often isolated by their disease, with a feeling they are not alone, that they have someone in their corner watching out for them.

FOR FURTHER INFORMATION: To find out about customized solutions to improve patient adherence and outcomes, contact: patientcentric@quintiles.com

(1) Sabaté E, editor. , ed. Adherence to Long-Term Therapies: Evidence for Action. Geneva, Switzerland: World Health Organization; 2003.
(2) Ho, 2009, Circulation; Levine et al. 2013, Annals of Neurology

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LAUNCH

THE SEVEN DEADLY SINS OF PRODUCT LAUNCHES

BY STAN BERNARD

The pharma world is currently composed of the "haves" and the "have nots." The haves recognize that the industry has transitioned from the Commercialization Stage ("Pharma 1.0") to the Competitive Stage ("Pharma 2.0") of its lifecycle and have adopted dramatically new and different ways to win. The have-nots continue to compete the same old way, effectively using yesterday's battle plans and approaches to try to win today's brand wars.

Nowhere is this more evident than in product launches. In my experience as a competition consultant, I work with companies and brand teams who consistently launch blockbuster products by leveraging Product Launch 2.0 approaches. Unfortunately, I also witness many other companies who repeatedly make the same launch mistakes. Here is what I refer to as the "Seven Deadly Sins of Product Launches."

Sin #1

Seeking to win the launch year. Most brand teams still try to "win the Launch Year" by conducting a military-style campaign. Once a company receives regulatory approval for their new product, they send waves of infantry-like sales professionals supported by heavy air promotional cover into physicians' offices to battle the competitors' beefed up front-line field forces. At the end of one year, the launch company analyzes IMS sales data to determine the ultimate trajectory of the new product's sales in that market.

Unfortunately, in today's competitive environment, seeking to win the launch year is often two to three years too late. The most successful launch teams conduct an election-style campaign by seeking to win the "Pre-Launch Years." In late Phase II or early Phase III of clinical development, these teams will initiate an election-style campaign to maximize the awareness, advantages, and advocates for their "drug candidate." They create a crescendo of positive perceptions of their new agent to ensure high customer anticipation and demand. Upon approval, doctors and patients cast their votes for the challenger agent with prescriptions to the pharmacy. Today's launch teams can typically project the ultimate sales of a new launch product 12 weeks —not 12 months— after launch.

One of the strongest examples of such an election launch campaign was Gilead Sciences' launch of its hepatitis C virus (HCV) drug Sovaldi. Gilead built up so much pre-launch buzz and excitement for Sovaldi that many physicians were withholding HCV patients from marketed treatments and "warehousing" them in order to wait to prescribe this new agent.

Sin #2

Trying to win by differentiating your product. In the majority of US Presidential elections, very few voters know the numerous details or specifics of a candidate's policies; they typically vote based on how they generally feel about the candidate and the campaign agenda. Consequently, the most successful campaign parties use a two-step campaign approach. First, they seek to convince the electorate and constituents to focus on their carefully-selected campaign platform issues, particularly the perception of how their candidate would handle these issues. Then they campaign to create the optimal perception of how their party candidate would be best at handling these issues while serving in this leadership role. Essentially, by taking the lead on the campaign agenda, they force rivals to play their game.

Launch teams that create a clear, concise campaign communication platform for their drug candidate usually perform dramatically better than those focusing on countless

> "LAUNCH TEAMS THAT CREATE A CLEAR, CONCISE CAMPAIGN COMMUNICATION PLATFORM FOR THEIR DRUG CANDIDATE USUALLY PERFORM DRAMATICALLY BETTER THAN THOSE FOCUSING ON COUNTLESS PRODUCT DETAILS AND MESSAGES"

product details and messages the current environment, pharmaceutical launch teams that force competitors to play their game—according to their own issues, rules, criteria, and timetable—usually win the game. Unfortunately, the vast majority of brand launch teams are still fixated on product differentiation. For example, over the last few years rival novel oral anticoagulant brand teams have focused first on differentiating their agents based on traditional efficacy and safety parameters. In stark contrast, Janssen Pharmaceuticals has forced rivals to play an "indication game." Their launch team campaigned first on the critical importance of demonstrating multiple indications of oral anticoagulants across diverse healthcare settings. Janssen then successfully positioned its new drug candidate Xarelto (which it licensed in the US from Bayer) as "the first and only novel oral anticoagulant with six indications approved by the FDA." As a result of this two-step election-style campaign, Xarelto became the No. 1 prescribed novel oral anticoagulant in the US.

Sin #3

Electric numbers Using outdated marketing tools and tactics. Many pharmaceutical companies and their partner agencies deploy obsolete launch techniques and promotional tactics. For example, numerous launch teams continue to rely on lengthy product positioning statements, product messages, and sales aids. However, in today's text-heavy, six-second video world, these protracted approaches are tuned out. Doctors, patients, and other constituents today simply cannot keep up with the overwhelming number and amount of different products, trials, data, and details. Consequently, these stakeholders form an overall perception of the different products and select the product with which they feel most comfortable.

Brand teams need to use simpler, more concise communications to convey the optimal perception of a product instead of the details. For example, Janssen used three short "i-Bites" instead of messages to promote Xarelto on its website and elsewhere: "proven efficacy across multiple patient types;" "demonstrated safety profile;" and "convenient oral dosing." Launch teams that create a clear, concise campaign communication platform for their drug candidate usually perform dramatically better than those focusing on countless product details and messages.

Sin # 4

Focusing on traditional customers. Election strategists know that they cannot win by simply focusing on voters; they have to impact voter influencers or campaign constituents such as the media, political pundits, and major campaign contributors. Similarly, product launch teams need to focus beyond their traditional customer triad of physicians, patients, and payers to engage many other stakeholders. Stakeholders can be defined as those constituents who can influence the perception, access, and utilization of pharmaceutical products.

Stakeholder Management 2.0 consists of several key principles. First, there are numerous types of stakeholders, including but not limited to government agencies, patient advocacy groups, media, analysts, regulatory authorities, politicians, policymakers, professional and lay associations, and many others. Second, their influence can be very different in diverse competitive landscapes and lifecycle stages. For example, Pre-Launch stakeholders are often very different from Post-Launch stakeholders.

Most importantly, today's pharma stakeholders do not exist in silos but rather in a "Stakeholder Ecosystem." They routinely influence and are influenced by other types of stakeholders. Sharing of extensive product information and perceptions has been cultivated by the Internet, which breaks down traditional stakeholder silos and offers timely, comprehensive data to all audiences. The most successful launch teams identify, prioritize, and address the stakeholder segments and networks most vital to the launch of their and their competitors' products.

Sin #5

Not anticipating competitive counter-launches. In elections, it is typical for opponents to attack their rivals preemptively, especially early in the campaign when voters are beginning to form their initial impressions of candidates. In fact, many candidates will seek to be the first to pre-position and create a negative impression of their opponent(s), often by negative campaigning and pulling proverbial skeletons out of their rival's closet.

Not surprisingly, the same occurs in new pharmaceutical product launch campaigns. Savvy, aggressive companies—most notably Bristol-Myers Squibb and Novo Nordisk—form teams and plans to "counter-launch" against potential new products that threaten their current or future product sales and market shares. Most commonly, rivals will try to form the early first perception of a competitive product by pre-positioning the product in a negative light. Counter-launching companies may deploy many other strategies or actions to preempt new product launches, including legal, regulatory, or payer limitations on market access or specific stakeholder communications and activities.

Many launch teams fail to anticipate these counter-attacks until it's too late. In many cases, launch teams and their partners erroneously want to wait until they have completed most of their clinical trials or product positioning studies before establishing their communication campaign or product positioning. Unfortunately, competitors will not wait to pre-position their new rival. In fact, these counter-launch attacks may come as early as late Phase II or early Phase III of a new product launch. It is essential to prepare for and counter these assaults as early as possible.

Sin #6

Failure to pressure-test the pre-launch plan. One essential way to prepare for counter-launches and overall product launch success is to conduct a series of competitive simulations or business war games 2.0. The new competitive simulations go way beyond traditional war games to incorporate multiple issues, competitors, landscapes, stakeholders, and market factors. Brand teams role-play their competitors and themselves to identify not only competitive insights but—more importantly—a few prioritized strategies and executable action steps to help launch products win in the market.

The best pharma competitors start conducting these simulations in late Phase II trials or early Phase III and continue to conduct them every three to six months in key markets to ensure that the entire, extended launch team is fully prepared for both the launch and competitive counter-launches. These companies usually take a "Multi-Level Competition" approach by considering

ways not only to win at the brand level but also at their or their competitors' franchise, portfolio, and corporate level. They may also use simulations for global, regional, or local markets; specific situations, such as the release of new clinical data or a major professional conference; or with certain departments/functions or stakeholder groups, such as medical affairs or payers.

Sin #7

Failing with "Launch Excellence Programs." The most egregious sin of all is companies and consulting firms that actively perpetuate and promote the first six sins in so-called "Launch Excellence Programs." Increasingly, companies are recognizing that many of their product launches have failed to meet corporate and market expectations. As a result, they hire consulting firms or initiate internal launch excellence centers to try to counter this trend. These training programs often teach and embed across the organization the very Pharma 1.0 launch strategies and tactics that caused previous product launches to fail. Consequently, many of these "Launch Excellence Programs" are in actuality "Launch Failure Programs."

Pharma professionals and brand teams that avoid or at least learn from these seven potential sins will dramatically enhance product launch success. As Malcolm Forbes so eloquently stated, "Failure is success if we learn from it."

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Conquering the Oncology Marketspace

Matt Sarnes, PharmD – Senior Vice President, Commercial Consulting

How Xcenda helped a biotech manufacturer with a total strategy for market entry

The Need

A biotech manufacturer with more than 10 years of success with injectables in the acute-care market was preparing to enter the oncology space with a new delivery technology for an existing, well-established generic. The company needed a comprehensive and cohesive reimbursement, pricing, and payer strategy.

The Xcenda Solution

Our managed markets experts developed value messaging based on the agent's improved safety and tolerability compared to competing products. Our economic modeling and medical communications teams created a cost-effectiveness model, a value dossier, and a publications strategy designed to raise stakeholders' awareness. Additionally, a reimbursement and patient access plan was created that addressed:

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‘‘ With Xcenda’s help, we not only successfully entered the oncology space. We defined and promoted our unique value in an extremely short time frame. This was a true partnership in excellence.’’

– Brand Manager, Biotech Manufacturer

- Payer segmentation and recommendations
- Analysis of the total cost of care for the Centers for Medicare & Medicaid Services (CMS)
- CMS economic impact analysis
- Successful J-code submission

Tactical elements included provider and payer mailings and advisory boards. Additionally, a reimbursement education program for the manufacturer's account managers and provider customers was developed and administered.

The Outcome

The manufacturer realized measurable results in the 12 months leading up to the product's FDA approval and in the 6 months following it. Based on favorable reimbursement and coverage decisions supported by the value messaging, appropriate patients were able to access this innovative product.

Injecting New Life Into a Generic Oncolytic.

Taking on a 2-pronged challenge was critical for this biotech manufacturer—not only were they trying to raise new awareness by innovating an existing product, but they were also entering an oncology market dominated by more-established companies.

The client used a generic base compound and combined it with a new delivery technology to create a product that produced fewer and less-severe side effects than competing products. Although the product improved clinical efficacy and safety for many patients receiving this type of therapy, the manufacturer still faced several issues prior to product launch.

With FDA approval 12 months away, the manufacturer had no brand recognition or company name recognition among stakeholders in the oncology space. Generic and branded competitors were well established. And both time and budgets were limited.

Putting the Right People – and Plan – Together.

Delving deep into the client's specific needs and putting together a targeted, multi-phase plan commenced with a day one meeting, where Xcenda did a full needs and market assessment, including competitor analysis.

From this, the right team was created that combined Xcenda's managed markets experts, health outcomes specialists, medical services personnel, and creative staff to develop an evidence-based, value-driven reimbursement, pricing, and payer strategy, as well as tactical tools.

The implementation plan would be centered around evidence generation, optimized patient access, and education—starting with the discovery that a large segment of the market was unaware of the total cost and burden associated with the product's competition.

Based on this finding, our managed markets experts developed value messaging for the product that centered on its overall clinical and economic impact, including the significant value provided by its improved safety and tolerability compared to competing products. Even though the acquisition cost of the product itself was higher, these efforts demonstrated that the product reduced the overall cost of care and improved patients' quality of life compared to "less expensive" competitors.

Our economic modeling and medical communications teams then put these value messages into action by creating a cost-effectiveness model, a value dossier, and a publications strategy designed to raise awareness among stakeholders. From a reimbursement and patient access perspective, Xcenda provided strategic counsel that included:

- Payer segmentation and recommendations
- Coding assessment
- Analysis of total cost of care for CMS
- CMS economic impact analysis
- Successful J-code submission

Advisory boards were conducted, and, additionally, Xcenda's creative team designed an awareness campaign promoting value-specific messaging, including provider and payer communications. A reimbursement education campaign and materials were also developed and administered to the manufacturer's account managers and provider customers.

Helping Patients – and Manufacturers – Succeed.

The manufacturer realized measurable results in the 12 months leading up to the product's FDA approval and in the 6 months following it.

Value Messaging and Evidence That Supported Pricing. The manufacturer was able to demonstrate the costs associated with the toxicity burden of its competitors and compared this to the product's documented clinical and pharmacoeconomic value.

Successful Coverage Through CMS and Commercial Payers. The product launched with favorable reimbursement, including a unique C-code and a J-code that allows a separate and more-beneficial pricing scenario than the pricing of similar generic products.

Improved Patient Access to a Clinically Superior Product. Based on the favorable reimbursement and coverage decisions supported by the value messaging, appropriate patients were able to receive this innovative product in a timely manner, with fewer barriers to access.

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STRATEGY

3 CAPABILITIES YOU MUST BUILD TODAY TO ENSURE MARKET ACCESS TOMORROW

BY HOWARD DEUTSCH

Oncology-market access doesn't "just happen" anymore. As competition in the U.S. health-care market only continues to intensify, oncology-drug companies will need a good corporate strategy to ensure physicitan uptake and payer coverage of therapies. Having strong clinical data isn't enough, especially as stakeholders grow ever more sophisticated, weigh more options—and have more leverage to demand data and deals for contracts, discounts and rebates.

Oncology-drug companies can't wait until these new demands are right at their doorstep. They must start working today to ensure they have solid yet adaptable market access capabilities for tomorrow. Good market access can't be achieved on the fly. It can't be cookie-cutter or static. **Here are three core capabilities to begin building now:**

1. The ability to engage with a range of stakeholders

At one time, oncology companies promoted their products mainly to oncologists. But now,

oncologists are not the only (nor even always the primary) decision makers when it comes to treatment choices and the stakeholder ecosystem will continue to grow in complexity. So companies need to map out the stakeholders and develop a strategy to address all of these decisions makers effectively.

The stakeholder map will vary widely by geography: In Boston, for instance, hospital groups predominate; in Texas and Florida, broad oncology practices are more common.

Companies need a deep understanding of these stakeholders and a stakeholder-specific strategy for engaging each in the field. They also need the right personnel, in both number and skills. These personnel need to understand stakeholders' motivations and engage with them—and sooner rather than later.

2. The ability to design contracting and discounting strategies

Although pharmaceutical giants may have extensive experience in contracting and discounting strategies for general medicine, they are often unlikely to know how to design and evaluate contracting and discounting strategies specific to oncology. And oncology-focused companies need to build new capabilities altogether. All companies need to understand the tradeoffs among oncology treatment options. For example, they need to understand where payer contracting is appropriate, how much to rebate payers and what terms to negotiate. Some of the contract structures that emerge may also differ from the predominant flat or share-based rebates that we have long observed in general medicines. Companies may need to explore innovative ideas like indication-specific contracts for oncology drugs that could be used for a variety of patient types, each with different competition.

Pharmaceutical companies also need to account for the fact that the data used for evaluating strategies is typically spottier in oncology than in other therapeutic areas, requiring them to use analytics and triangulation from multiple sources to arrive at the right levels of contracting and discounting.

3. The ability to operate contracting and discounting strategies

Once companies have a solid understanding of the stakeholder ecosystem and developed specific strategies, they need practical ways to make their contracting and discounting strategies work. Those with a legacy in general medicine have related experience in other therapeutic areas—but they need to adapt those abilities for the unique environment of oncology. And oncology-specific companies often need to build them from scratch.

At issue are tactical capabilities. Once contracts are signed, how will companies deliver on the terms? They will need to undertake several tasks—collecting data from payers, GPOs and other integrated providers; validating the information; paying rebates, and others—all at once, and carry them out seamlessly.

These three capabilities aren't the only ones needed for successful market access, of course, but they do represent some of the fundamental, ongoing changes oncology-drug companies are facing.

What other capabilities are key to maintaining and strengthening market access—now and in the future?

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PHARMA PRICING

STRIKING A POST-ACA BALANCE

BY DAVID ORMESHER

Even as evidence grows that we have begun to bend the US healthcare cost curve and reduce the inexorable rise in national healthcare expenses, there is a lot of talk about pricing, particularly pharmaceutical pricing. For pharmaceutical executives, engaging in this conversation is long overdue. Healthcare pricing poses a potential threat because people may get priced out of the market. And it's not just drugs and medical devices, but pricing for medical procedures, physician visits, and hospitalization are also under scrutiny.

How the ACA affects costs

The goal of the Affordable Care Act (ACA) was to slow the rise in the overall cost of healthcare and expand health insurance coverage to more Americans. Constraints on costs are expected to come from three primary market forces. First, broadening insurance coverage enlarges the

risk pool and gets healthcare services to uninsured people before their illness gets too serious (and expensive).

Secondly, by moving from a fee-for-services model to a pay-for-outcomes model, the financial incentives for healthcare providers shifts to quality and coordinated care to keep people healthy and out of the hospital. Finally, as consumers begin to bear more of the direct cost of insurance and out-of-pocket co-pays, there will be additional pressure on pricing.

In our free-market economic system, we've been reticent to tell private-sector producers of products or services what they can sell a product for, leaving it to customers and competition to rationalize pricing. The ACA largely left drug pricing to the market, assuming supply, demand, transparency and outcomes data would identify the right price ranges for most products.

> "THE VALUE HAS TO BE MEASURABLE—PHARMACEUTICAL PRODUCTS WILL NEED TO JUSTIFY THEIR PRICE WITH OUTCOMES DATA"

Pay now or pay later

However, healthcare is a special case. Unlike most consumer products and services, healthcare is rarely a discretionary purchase. We either buy health services (e.g., physician office visit, lab test, drug therapy) today when we need it—when it is the most effective to treat or cure—or we, or society-at-large, will ultimately pay for it later when the situation is likely more acute and the cost of treatment is much higher. It makes sense that we do whatever we can to offset that higher risk tomorrow by providing access to health services today.

Offsetting future financial risk requires two inputs—universal access and measurable quality. We need to cover as many people as we can to insure that everyone has adequate access to healthcare products and services—but not just any products and services. Patients need access to quality care that results in positive outcomes.

A business model transformation

In this model, insurers provide the universal patient access and providers and pharmaceutical, diagnostic, and device companies deliver the quality outcomes. However, the financial lubrication in this complex workflow will require a new approach to balancing cash flow between healthcare entities. In fact, we are in the middle of a massive restructuring of risk, payments and health accountability.

With the introduction of universal insurance coverage and new incentives for cost containment and improved health outcomes, the ACA disrupted the long-standing business model that governed cash flow and profitability among the various healthcare entities.

The ACA has forced the national conversation to shift from one about pricing to one about value. When you really unpack the philosophy behind the ACA, it is a philosophy of value: We're going to pay for outcomes, not just for procedures or services.

Is value-based pricing the answer?

Framed as value, the question then is about efficacy. Whether it's a pharmaceutical therapy,

hospital stay, or a medical procedure, did it fix the problem? Did we get the kinds of long-term, healthy outcomes we're looking for? And if so, if we're able to reduce hospitalization or arrest a chronic decline in health, then the result—the value of costs saved and future productivity secured—should be factored into the acceptability of the price of achieving this outcome.

But the question remains, is there a price point that is unacceptable, regardless of the long-term value?

Do cures deserve a premium price?

Gilead's Sovaldi has become a lightning rod for this discussion. Sovaldi, which can cure hepatitis C virus (HCV) for 80% to 100% of patients who take it, carries a retail price of $84,000 for a 12-week regimen. Private payers, states insurers, and Medicare and Medicaid are up in arms at the cost. Hence, the moves by the major pharmacy benefit managers (PBMs) to cut exclusive deals with the makers of the new HCV drugs in exchange for discounts.

But on the other hand, Sovaldi is curing people, which very few drugs actually do. Compare the long-term cost of someone who has HCV, who will be on drugs and in and out of the hospital for the rest of his or her life, to a short-term spend of $84,000, and you'll recognize that while there's certainly short-term pain, there's huge long-term value.

We either pay for it now or we pay for it later. It becomes a time-value of money question.

The time-value of money

Insurance companies were built on an actuarial model of paying for chronic illness over time. There hasn't been a financial scenario that assumes there is a cure that will end treatment costs for a chronic illness, short of death. Insurers are accustomed to paying relatively smaller bills over long periods of time, not a large one-time payout.

However, if you step back from the intimidating numbers of three million HCV patients at a cost of $84,000 per patient and consider the literature that predicts treating the old way is on a path to rise from $30 billion a year to $85 billion a year over the next 20 years (complications, liver transplants costing more than $550,000 each), and that the number of new cases of HCV is falling (now only 20,000 new patients annually), not even taking into account the quality of life and productivity of those cured citizens, there is an actuarial risk/financial model that makes sense, even at a high short-term cost.

Total cost of ownership

As healthcare leaders, we need to reframe this argument in terms of total cost of ownership. There is a total cost of health in this country, and if by investing in innovative solutions today we can improve long-term cost and wellness tomorrow, then that is a move that makes sense.

The technology industry held a similar conversation 20 years ago when software and hardware manufacturers like Microsoft and IBM introduced the concept of total cost of ownership to chief information officers (CIOs). While the initial costs to outfit your entire company with IBM computers or a new Microsoft operating system might be high, if you looked at the total cost of ownership of that technology amortized over three to five years and analyzed the improved productivity and lower

maintenance costs from the investment, it was actually quite affordable.

We need to look at healthcare in a similar fashion. We need to factor in the total cost of ownership—the total cost of the therapy and procedure and the total outcomes benefits—before we take severe measures like restricting access to certain types of care based on price or introducing price controls on pharmaceutical companies.

Amidst the feverish debate over pricing in healthcare, the industry needs to focus on the value that healthcare can provide to patients and let that calculation dictate relative costs. The value has to be measurable—pharmaceutical products will need to justify their price with outcomes data—but that's part of the enlightened conversation that will lead to a more rationale social and economic contract between healthcare suppliers, providers, patients, and payers.

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HEALTH CARE

3 KEY OBAMACARE ACTIONS FOR RX MANUFACTURERS IN 2015

BY TOM NORTON

At first glance Obamacare developments for the American Rx industry in 2015 appear fairly benign. However, digging deeper suggests that each, in its own way, could cause various actions with potential for substantial uncertainty for the U.S. pharmaceutical industry next year. If your response to this profound observation was, "Really, what's new?" — read on.

Here are three examples of the key changes which may lead to significant, yet uncertain impact on the American prescription drug business:

1 The Personal Mandate

The personal mandate requiring all Americans to have insurance went into effect on January 1, 2014. It directed that all citizens present proof of having a "minimum essential healthcare coverage" on their 2014 IRS filing. On April 15, 2015, for the first time, all individuals must pay up, one way or the other. If citizens don't have valid "minimum essential healthcare coverage", they face the following penalties:

- In **2014**, the penalty for not having a qualified health insurance plan is 1% of your annual income or $95 per adult, whichever is higher. If you have children, the penalty for uninsured

children in 2014 is $47.50 per child, with a maximum per-family penalty of $285.

- And, if you don't sign up by February 15, 2015, these are the penalties that await you in your 2015 IRS filing:
- In **2015**, the penalty increases to the higher of 2% of your annual income or $325 per adult.
- By **2016**, the penalty goes up to 2.5% of income or $695 per adult, and max $2,085 per family.
- So, given the rising formula of the Obamacare penalty, we can anticipate that only the most ardent Obamacare resistors will not decide to join the program this year or next.

So, What does this mean for U.S. Rx care?

As the penalties cause the number of Obamacare participants to grow, (and likely the bulk of these who are now joining will be less well off, younger citizens), the statistics show that most of the new, lower income Obamacare patients will be signing up for the lower cost "Silver Plans". It makes sense. These are "minimum" healthcare insurance products that charge lower premiums, but the plans do exact very high utilization copays from those new patients who select them.

In these new 2015 Silver Plan offerings, Rx care needs to be very carefully evaluated by all new Obamacare sign ups. As Kev Coleman, head of Research & Data at HealthPocketpointed out more than a year ago:

"About 70 percent of Americans use prescription drugs, and they are going to need to pay very, very close attention to what plans offer to minimize out-of-pocket increases for medications… When it comes to drug costs and changes in our newly reformed health care system, the fine print really matters."

sIndeed, if most new patients are signing up either for the lowest cost "Bronze Plan", or in the majority of cases, for the Silver Plan options, the formulary offerings of these programs will very likely drive the new patients to almost exclusive use of generics. At best, they would access the limited number of "preferred" brand name drugs, and even these will carry substantial, additional copay costs. All other indicated products provided to these new Obamacare signups are going to demand prohibitively high copays. Some "specialty drugs" copays are listed as high as 40% of the retail cost, according to Healthpocket.

All of this, of course, is not really unique news for the American brand name industry. This trend towards almost 100% generic offerings in health insurance plans has been growing for several years.

Take Away

Therefore, as the impact of the Obamacare individual mandate and penalties are fully felt on April 15, 2015, and millions of the lower income, younger, healthier Obamacare patients are swept into the program, the likelihood of the success for American innovator Rx's in Obamacare for 2015 will only get more difficult.

2 Comingling or Separate Medical/Rx Deductibles?

A separate, but related private market challenge that Obamacare presents in 2015 is the new,

mandated implementation of higher Maximum Out of Pocket (OOP) charges. Although this applies to both the public and private sector, the impact of this rule appears to be having a greater in the more established private sector plans. Here's why: Beginning on January 1, 2015, all "minimum essential health benefits (EHB)", including Rx's, must operate within these mandated OOP limits:

- The maximum deductible/OOP costs for an individual is $6,600.
- The total for a family is $13,200.

All of this seems straight forward enough, and, yes, there are going to be substantial variations in the way that employers go at this. But, generally, what is not clear is how the PBMs and private health plans are actually going to cooperate in administering this. According to the law, the PBMs and health plans can either "comingle" or "separate" the application of the medical and Rx deductibles. And ultimately, this determination will be made by the private employer who is paying for the bulk of the premium for the health plan.

So, what could this mean to the industry?

Given the numerous iterations this could take, here are some general possibilities:

- Comingling. In the case of the "comingle" approach, any combination of OOP utilization of EHB's, whether for Rx care or other EHB medical services that gets the individual to the new maximum deductible, is acceptable. The only requirement is that the total OOP cap be $6,600. In a purely theoretical example, OOPs for drug usage could be designated to go all the way to the $6,600.00 maximum deductible if the employer directed that to occur. If this were to occur, given that the 2013 estimated average for annual individual Rx deductibles was about $800, this would definitely not be great news for the patient. Even at half the maximum OOP deduction of $3,300 for drug copays, it would be big trouble for the patient. Why? Because the patient would end up paying out thousands more in OOPs to meet his overall maximum deductible as compared to his earlier private healthcare plans. We can anticipate that the patient, faced with these huge OOP costs, will opt for the lowest cost Rx possible and that will lead them to generic products for every script. For the innovator brand company, this result is obvious. If the patient is strapped with massively higher Rx copays, this would likely preclude the use of new, higher cost Rxs. Will employers actually go for 100% Rx OOPs to meet their deductibles? I doubt it, but even if they set the Rx OOPs maximums at, say, $1500, considering HealthPocket's $800 average, that would be nearly a 100% increase in OOP cost versus that which the patient had previously been managing.
- Separated Maximums Separated Rx and medical services maximums could be interesting. Let's say, hypothetically that an employer, working with a medical plan decided the firm would go with a $1000 Rx OOP max, and $5,600 for all other EHB medical services. For the Rx marketers, such an outcome is probably about the best that can be hoped for since the patient's OOP would be satisfied much more quickly, would likely be much more predictable and the prospect for at least partial reimbursement for the use of higher priced drugs may be much better.

Take away

All and all, the new Obamacare mandates on maximum allowable OOP EHB costs presents a growing unknown for the Rx industry which is compounded many times over by the thousands of deals that employers, health plans, and PBMs are concluding at as they attempt to meet the new $6,600.00 mandated OOP limit. Clearly, Rx managers trying to "plan" estimated sales and Rx charges in the midst of this new OOP mandate face a daunting task.

3 The Number of Obamacare Insurers Increased by 25%

In the second full year of Obamacare coverage, the number of insurance offerings has increased by 25% with some 77 insurers now participating in the state exchange and federal exchange coverage. This includes the greatly enhanced presence of United Health Care, thelargest healthcare insurer in the country. This fact alone must be viewed as a significant competitive development for Obamacare.

So what does this mean for the industry?

Obviously, more insurers will lead to competition, which is good for the Obamacare patients. But this increase in competition no doubt will also put increased pressure on Rx manufacturers to provide ever lower prices on individual and, in particular, bundled product offerings that they provide to the 77 insurers.

Take away

Particularly for those Rx firms hoping to access the Bronze and/or Silver markets, the combination of increasing numbers of younger patients signing up for these coverages, the increased maximum OOPs, and the large increase in the number of insurers participating in the market, can only translate into heighten pricing tensions for the Rx industry. Getting your drug accepted on just about any formulary in this environment is going to present serious challenges in 2015.

PHOTO/JOHN HALPERN

OPERATIONS

Biopharma's Engine Room:

A PHARM EXEC INNOVATION ROUNDTABLE

BY WILLIAM LOONEY

Two words define the future of commercialization project management: Faster and Better

Payer pressures to slow volume growth and drive down margins, a continuing wave of patent expiries, and fewer ripe targets for drug development have left biopharma companies with one ready remedy for hard times that is uniquely within their own sphere of control: finding better ways to manage those internal

Roundtable Participants

William Looney, Editor-in-Chief, Pharmaceutical Executive
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Amit Tangri, Vice-President, UMT Consulting

operations and processes that produce products. Project and process engineering is attracting more attention from the "c-suite," while technology is unlocking the many efficiencies latent in the vast stores of information that companies collect on the long road to commercialization. In other words, it's time to declare process innovation in drug development and commercialization as a strategic capability—when done well, it can spell all the difference in launching a new product, between life cycle hegemony and that hardly-worth-a-ripple "ho hum."

To shed light on what works and what doesn't, Pharm Exec convened a prominent global operations strategy consultant, UMT, and four big Pharma practitioners of the art of commercial effectiveness to discuss what makes their days a constant challenge in turning a world of multiplying left-field risks into manageable routines. If you are looking to find synergies in the research arts of serendipity, this group can.

—William Looney, Editor-in-Chief

PE: *The objective of today's biopharmaceutical enterprise is to move seamlessly from the R&D phase to commercialization: accelerating development time to market; executing a strong global launch program, across geographies; building market share against the competition; and sustaining that lead right through the end of the product life cycle. Attaining this objective is easier said than done. Why—and how—does a commitment to functional integration help management navigate that often unforgiving transition from registration to the real-world battle for clinical acceptance and market share?*

Amit Tangri, UMT Consulting: A distinguishing characteristic of the industry over the last 15 years is the growing gap between expectations and performance. Drug development times and R&D costs are rising, while the number of approved NMEs and utilization of branded innovative drugs, as a percentage of total scrips, is declining. The contrast leads to a singular conclusion: this is an industry that needs to be more efficient. It has to create process improvements that allow for greater selectivity in the products being pushed down the pipeline, at lower cost. That is a difficult change to accomplish, for two reasons. First, it requires a harmonization of functions across the entire organization, not just R&D, even though in practice such functions tend to be heavily siloed. Second, we see today a far more disruptive external environment that prevents the business from relying on a neat sequential path to commercialization, as was common in the past. It's no longer possible to move a compound down the pipeline by just checking the boxes starting from preclinical, Phase III, and regulatory submission followed in close order by market access, promotion, and sales. The pace is variable and the spaces where you engage are blurred; product teams have to be ready to address anything, at every stage of the process.

Scientific steeplechase

According to the FDA Center for Drug Evaluation and Review (CDER), the number of approved NMEs has averaged about 22 over each of the past 10 years. During the same period, company applications for market authorization have remained static, which has prompted CDER to state

that it does not expect to see a significant year-to-year rise in new drug approvals. The numbers also show some big year-to-year contrasts in approvals, such as the drop from 32 approved NMEs in 2004 to only 20 in 2005 (see chart below). Here, the culprit was the fallout from Merck's withdrawal of Vioxx, which considerably reduced the tolerance of regulators and industry for risk. Taken together, the approvals data suggest that, however good the science of drug discovery may be, there are an increasing number of hurdles that expose the industry to greater uncertainty, which given the long lead times in biopharmaceuticals, always must be expressed in terms of costs. To survive, industry has no choice but to raise its game internally.

PE: *Isn't demonstrating improvement in health outcomes an additional factor that requires drugmakers to focus on functional and process efficiencies if they want a product to succeed in the marketplace?*

Tangri: Acceptance of a medicine is now built around a value-based model rather than the evidence-based approach, where all you had to do was meet the [randomized clinical trial] endpoints set by the FDA. Demonstrating value is a formidable task that, again, cannot be handled sequentially. Different functions—clinical development, P&R, marketing, sales, and medical affairs—all have to come together, starting from the very moment testing begins in human patients. We have strong evidence of system and process failures due to the many drugs that pass muster at the FDA and then founder as payers and providers hesitate to embrace the product under real-time market conditions. Why? Because the products usually have little to offer beyond proof of safety and efficacy. The people and capabilities best able to make that broader proposition were not in the room at critical stages of their evolution into products. Innovation—the way regulators might define it—is not enough. Operational excellence through functional integration is the pre-condition for success; without it, innovation remains an abstract concept rather than a driver of competitive advantage.

Leading edge lessons

PE: *What is the most essential factor in overcoming these persistent barriers to operational excellence? How do you execute for success?*

Farouk Rhymaun, UMT: Our projects with client companies have yielded two examples that resolve some of the tensions inherent to operating in this new commercial environment. The first involved a company with eight new products it was preparing to launch over the next several years. It had no process in place to manage the abundance of assets, a task which for that company was unprecedented in its scale and complexity. The key flaw we identified was the absence of an information tool that would permit all the participants in the launch process to interact, share, and collaborate among the various strands of work, in real time.
Hence, we designed with the company an operational management approach and a system that helped different functions, with multiple assignments, to immediately understand what they were doing both in the context of their brand or function as well as relative to other brands or

functions. Instead of dispensing raw data, we opted for a visualization platform that enabled the teams to actually see the connections needed at each stage of the product journey. It was designed around accessibility in interpreting information, for data alone is useless unless it can be transposed into the knowledge required to make good decisions.

The second example of a process challenge is a company that went from managing about a dozen clinical trial programs per year to more than 100. As the data management requirements became vastly more complex, the company realized its existing clinical trial management system infrastructure was inadequate. Specifically, there was no cross fertilization between internal activities and the inputs from CROs handling the trial sites. To address this, we built what we call a "clinical explorer" solution that consolidated reams of information from different sources into one central repository, accessible to all. This considerably reduced the time spent searching through different systems to obtain data, making it faster to track the asset as it moved through the stages of a trial.

Both cases respond to this central problem in managing an asset, for the long term: maximizing available resources, removing organizational silos, and, by bringing useful information together in one place, extending the bounds of what is feasible through collaboration. There was a major time-saving component, particularly in expediting answers to questions from senior company management.

Matthew Portch, Pfizer: Consolidating and enhancing the usefulness and accessibility of key data is undeniably important, but how do you take that extra step in understanding factors like anticipating actions on market access that often play out only over a period of years?

Tangri: Making sure information is "fresh" demands a cultural change in organizations, because people tend to be protective about sharing information within their control. Breaking that bond demands a system of governance that has buy-in from the very top of the organization. The other element to keep ahead of the game is generating constant feedback from stakeholders that can influence an asset's long-term prospects in the market. It's the only way to guarantee information is constantly updated and replenished.

Rhymaun: I'd add another element. By extending the reach of useful data to more people, we broaden the scope of decision-making. It actually facilitates different conversations—conversations that in a silo information system don't take place. This provides an extra measure of exposure to perspectives beyond the current status quo—alternatives that may make the future slightly more predictable.

The default option: Simplify

PE: *Now that we have identified information management as a critical process challenge, what other issues are shaping your capacity to innovate in bringing products from the bench to the bedside? Where are the opportunities and risks?*

Timothy Phelan, Merck & Co.: Complexity is the dominant issue we confront on a daily

basis. Whether it is the outcomes research required to demonstrate value to a growing list of stakeholders, the intensifying competition that demands unrelenting focus on the customer, or meeting the stringent safety and efficacy mandates imposed by regulators, the stark reality is our work is getting progressively harder. Standing in place is not an option.

It may be counter-intuitive, but Merck believes the best way to fight complexity is to simplify. One key change is trimming responsibility for new product development to a core group of seven individuals with carefully defined functional coordination responsibilities, covering clinical science, regulatory affairs, clinical safety, value evidence, supply chain, commercial, and project and portfolio management, respectively. The group is empowered to make and move decisions on behalf of the entire organization, and is accountable to three "c-suite" executives: the heads of R&D, commercial, and manufacturing, who act much like a investment committee that decides where the company should place its bets, allocating resources accordingly. The objective is to simplify layers of governance to enable our product teams to react to shifts in the external environment more quickly.

PE: *Does simplification mean in practice fewer people?*

Phelan: Yes. We are driving decision-making further down in the organization and making the functional areas accountable for their deliverables. A smaller team is also likely to be able to respond quickly to changes at every step of the program, whether it is nuances in trial design that affect the trial protocol, adjusting to regulatory mandates, or responding to the competition. And we are giving them the ability to access top management to drive a quick resolution.

Culture of small

Caroline Saxton, Regeneron: Regeneron has the advantage of still being relatively small, so teams have ready access to decision makers to address issues and bring them to resolution. Our greatest challenge going forward is balancing our strong science-driven culture while driving value as we commercialize new medicines. To maintain innovation, it's important that science and business operate separately while creating synergies among them that accelerate time to market. Will Mongan, AstraZeneca: My group is geared to providing a commercial perspective throughout the entire product development process. As an asset moves through the R&D pipeline, there are periodic touch points with us, where we strive to ensure that the asset is best positioned to meet the needs of patients, providers, and payers in the marketplace. We monitor progress and constantly update our estimates about commercial potential as new information becomes available. The challenge here is making sure we have the right information at the right time so we are not blindsided or surprised by something out of left field.

PE: *How does the trend toward a more global approach to commercialization affect your responsibilities? Doesn't this impose yet another layer of complexity on the process?*

Phelan: A global strategy means that nothing is done in a narrow or sequential fashion anymore. This means you have to make more choices as to where and how to deploy your resources.

It also requires initiating the development and commercialization process much earlier; it's that early start that enables you to make those choices. And perhaps the biggest choice you have to make is what you are NOT going to do. Or to choose where to launch first, in order to apply learnings progressively, from one launch market to the next. It is surprising what you can accomplish with the gift of time; to have a plan ready to go—before you need it. For example, just by having some deep conversations with the manufacturing supply chain teams, we can define very precisely just how much capacity we will need to meet our launch obligations. That alone creates a cost advantage when we go to execute.

PE: *Where does market access fit in the process?*

Portch: Market access is essential and here, too, the work has to be initiated very early. First and foremost is determining the value proposition around the asset and then considering whether that is something people will pay for. Handling this task well requires tapping a lot of stakeholders for insight that often cannot be found internally. It's very different from the former days of the blockbuster, when the only decision was how many hundreds of field force reps you wanted to deploy on behalf of the product. An additional factor is extending these insights out in time—what is the commercial environment going to look like in two, three, or five years? The US market is fascinating in this regard, because forecasting now involves assessing a customer's ability to take on exposure risk: should we double up on our value proposition for the Aetna's who are taking on a lot of new ACA exchange enrollees with scant prior-claims history? Or is the patient likely to bear much of the cost burden, which entails a very different calculation of value? It's very complex. The pitch to the paying customer is looking very different than the case we make to the FDA.

Saxton: Satisfying market access and the regulatory authorities is challenging enough without accounting for differing requirements from country to country. In addition to this, frequent changes in the landscape (competitive, regulatory, political etc.) make a "one size fits all" global strategy a remnant of the past. The key is for the development teams to define the strategy, together with commercial, very early in the clinical development process.

Do playbooks make sense?

PE: *Many organizations have adopted a "playbook" approach to add more structure and predictability to the process of integrating all the necessary steps toward commercialization.*
Phelan: A playbook can certainly be useful, particularly as a source of milestones and helping teams navigate through the organization, but care must be taken to ensure it does not become unduly prescriptive. Process can be an impediment to the flexible responses that allow companies to seize a competitive advantage. We must not let process trump the product.

Portch: We find the playbook hard to square with the constant changes taking place in our market environment. It can miss important things, especially when the playbook is designed to

guide decisions around global commercialization and launch. You'd have to build a pretty nimble document to track that.

Phelan: Another trend challenging the playbook is the desire of customers to have a dialogue that involves the entire drug portfolio. Formerly, the conversation focused on a single product. No more. It's all about establishing value to the customer by leveraging the full assets of the company. And if you fail to expose your R&D teams to this expectation from the very beginning, there is a large handicap that is hard to surmount at later stages of the dialogue.

Portch: Yes. R&D people are passionate about a product they may have spent years creating in the laboratory. It's hard to be objective about that customer across the table who just wants to know if he has to spend a nickel or a dollar to get it. This is all about building capabilities: do you have people on board prepared to relate to both science and the market? It's the cross-cultural approach required to prevail in the new market environment.

Mongan: AstraZeneca has a tool we call enterprise leadership, the essence of which is being able to eliminate silos¬—to change swim lanes. The premise is anticipating and understanding the environment you don't know, because that is where you are most vulnerable. Relying on a playbook, by definition, means you are always facing backwards because it is based on learned experience. At AstraZeneca, we see the playbook as more of a checklist. It's a tactical instrument, not a strategy blueprint.

Saxton: A key competency for teams in navigating through change is how effectively they deal with operational ambiguity. A playbook can be useful as a general guide, but teams need to be agile and empowered to adjust and refocus quickly when the changes require them to move in a different direction.

PE: *Is the classic CEO-led change management initiative still useful in creating this cultural mindset?*

Portch: Pfizer has such a program. It's called OWN IT, and CEO Ian Read put it in place when he assumed the top job three years ago. OWN IT has worked because it is being consistently applied. The imperative, to be responsible to yourself in actions with others, is now part of performance reviews and career development plans. Colleagues are free to start an open conversation about something that he or she believes needs to be fixed without being tagged as a bad news maven or a troublemaker.

Mongan: Personally, I believe change management is passé for most companies. At AstraZeneca, change is accepted as a given so there is no need to create any branded program—we are changing all the time.

Rhymaun: Many companies put the focus on behavioral changes through a culture that embodies

a few transcendently clear management principles. It leads from the top, not spreads from the bottom. It is aware that running a business is all about people. And what people want most of all is certainty as an alternative to disorder. People wish to feel comfortable in dealing with uncertainty. That means management must be more tolerant of failure. There is an alternative formula called "conditions of satisfaction" that grants managers more leeway to define their own pace in getting to the right place.

Phelan: When Merck decided to simplify decision-making and empower teams to act and execute, the process started with two people: the heads of R&D and commercial. They met with SVP positions with oversight over key functions. The SVPs then worked out what specifically they expected the product teams to deliver to them. Once they were aligned, the expectations filtered down throughout the organization—here is what we want, and this is how we need you to behave. It's a living dialogue—oral feedback in real time. The process has worked.

PE: *Are there particular process issues or challenges in moving from the strategy phase to execution?*

Portch: Such a transition can be very complicated when you define the value proposition for an asset and then try to motivate the field force to engage around it. Many of our sales representatives were educated to sell in a different way; today, it's all about plying the customer with hard evidence to justify the sale, in terms of superior health outcomes versus the competition. The reps have to be told why this is important and to understand the "big picture," which from the customer perspective is critical to closing the deal. Pfizer has found this demands a lot more time spent in telling the sales force "why," in addition to how.

Information: From silos to synergies

PE: *Do you have examples from your work on how the vast amounts of information now available about customer habits and orientation can be applied to leverage commercial success?*

Mongan: Tackling the data revolution starts with awareness that the human part of the solution is as important as the technology. AstraZeneca is zeroing in on all these new information capabilities to better assess how our employees in different functions interact with the customer. We have our field force, our medical reps, and the key account teams in managed care markets—each of these groups have different touch points with customers. How do we bring all the interactions together and turn these into insights that will help us move market share? The learnings can be quite powerful when everyone has access to them, and so we are spending significant amounts of time and money to make that happen. In fact, we recently made a decision to consolidate all our IT activities to be managed internally instead of being outsourced. That's because we now see IT as a strategic asset.

PE: *What is most necessary to making information really work for you in the project management field?*

Saxton: The key to making information work for collaboration and communication is establishing an unequivocal "single version of the truth." It is also important to define who owns that information and the business rules around how it is used across the organization, as well as deciding who can have access to it. Moreover, the concept of data pools—or data lakes—gives us powerful methods to glean real insights from available data. Certainly, technology can be a useful tool, but it is critical to ensure that your IT initiatives are driven by the business.

Phelan: Commercialization proceeds on the basis of a series of "go/no go" decisions. Good information can tell us what else might be going on that could affect our decisions. The last thing a project team wants to find out is that a decision should have gone differently if other information was more widely known. It provides the opportunity to hold off on that decision and wait for these other identified risks to play out. The capacity to scan more widely for alerts is one area where we can increase our effectiveness in using IT.

Benoit Millet, UMT: Another way of referencing this is what we call peripheral vision. Information should be available in real time, but often it is not, so a way to compensate is to work for that broader context, shifting away from the predictable center, gazing instead to the left and right. People can be very myopic, so there is real value in being able to access information that is not entirely visible through your own function.

Phelan: Structures tend to channel how the information actually gets used. Hence, we fall back on the best attributes of a project manager. First, they should value the contributions of every functional expert in the team. What these people do, they tend to do very well, so don't get in their way. Second, they need to be aware of the interdependencies among them; this is where a good project manager can bring the organization to a higher level of performance. Third, they must pay attention to the "white space," where one task is in transition to another. If you can reduce that time and effort, you get a pay off in terms of everything from speed to a reputation of being a great partner. Everyone wants to work with an organization known for executing well—many companies will pay a premium to work with that "partner of choice."

Partnering as a process

PE: *One response to the complexity of development and commercialization is sharing the burden with external partners. How does the imperative to "partner well" figure in cross-functional process innovation?*

Mongan: It's essential. The distance between program management in drug development and business development—M&A and licensing—has gotten a lot shorter. Partners are also savvier about extracting tangible commitments. Just trusting our good judgment doesn't work. Of course, every deal is unique and there are lots of qualifications. But you are rarely going to slip if you follow the golden rule— treat any partner as you would like to be treated.
Phelan: Potential partners are interested in assessing Merck's capabilities, so we are working

closely with business development colleagues to help address their questions. For example, when we license out an asset, partners want to know the level of support we can give them since we had the head start in developing the asset. Being able to give that out-licensing partner a good development plan is absolutely critical to sealing the deal.

PE: *For those of you in big Pharma, has consolidation through larger mergers changed the environment for project management and process innovation? What's the impact been on your work?*

Phelan: At Merck, our role has expanded. Earlier this year, we acquired Idenix, a small biotech where innovation is core to their DNA. This was a great opportunity for us to inventory all their ideas and spread them across our enterprise. While most people play in one segment, we are expected to work across all therapies and functions. There are lots of hidden gems in even the smallest of acquisitions. We find them, and fuse their creative DNA to ours.

Portch: This is also true at Pfizer. Our early acquisitions were mainly about the product assets. Now, it's about the human capital and cultural attributes as well. The combination with Wyeth is especially telling, as Pfizer deliberately kept many of their key people in leadership roles and thus helped transpose much of that company's culture. The result is that Pfizer today is a more open environment.

Keeping vendors close

PE: *How do you manage key vendor relationships today?*

Mongon: Compared to other industries, commercialization in biopharmaceuticals is expensive. Management tends to see-saw between trying to cut the number of vendors—many doing the same things—and adding them back. The latter happens after the cuts leave you with only one or a few vendors, who exploit that privileged position by raising fees. So it's a constant cycle of expand and contract. But the motivation is always to take costs out of the commercial side of the business, wherever possible.

Portch: There is also the fact that relying on one vendor per assignment diminishes the diversity of perspectives you need to render the best decision. Vendors can be helpful, too, in helping to implement strategic program changes that the regular organization might resist. But the value is often over-stated, as vendors also carry an instinct for self-preservation with the people who pay their fees.

PE: *Is the global supply chain an integral element of process innovation?*

Mongon: It's high on the agenda. A decade ago, the supply chain was an operational, not a strategic, issue. Costs were immaterial because nearly all medicines were small molecule and easy to manufacture and distribute. This is no longer the case: biologics are hard to replicate and

production must proceed in small batches requiring significant monitoring and oversight. Costs of manufacture have risen, so this is getting the attention of people at the top.

Phelan: Biologic drugs require mastery of both upstream and downstream production capabilities. There is a lot that can be learned, even in the formulation process, by people with extensive downstream experience. You need to incorporate that experience to succeed in biologics. Process innovation in this world is actually just as important as the product. A decade ago, what we did was create a medicine and then build a plant to make it. It was a single supply chain. Now everything—from the API to the pill coating to the replication and synthesis of living organisms like proteins—comes from multiple sources and destinations, all merging at once in a networked chain of logistics. That requires strong management.

Valuing IP

PE: *Another objective is wresting maximum value through the end of the product life cycle. With that in mind, what is uppermost in managing the intellectual property portfolio?*

Mongon: Our industry is IP. It is still rare to see know-how being resourced for commercial purposes outside the scope of the traditional patent. In the larger tech world, the value of IP is not always connected to a particular asset. In biopharmaceuticals, that link is still clear and strong.

Phelan: IP is being managed more intensively in the context of active, anticipatory planning around loss of exclusivity. Companies used to simply accept a loss of exclusivity (LOE) without proactively seeking to manage the transition. Today, considering how to maintain the status of the brand begins very early, because we have discovered that LOE doesn't necessarily mean loss of revenue. It's also true that in a global market, LOE rarely occurs all at once, so you can apply different revenue retention strategies for different countries.

Portch: It's important to address this question globally. Our branded off-patent business is booming in Asia, even as revenues drop precipitously when LOE occurs in the US or other mature markets.

Millet: As biologic drugs begin to dominate the market, it is getting difficult to set a specific metric or value around IP. The molecular composition of these products and the diversity of the science behind them make any such calculation quite complex. In addition, many new products are the outcome of a shared effort, where big Pharma provides the process expertise while smaller biotechs create the technology. Partners have to figure out how to divide the IP: who owns which part?

Project management: The next wave

PE: *To sum up, how does each of you see your role in your company changing over the next three to five year planning cycle? What needs to change to help you fit better into the new—and still rather shapeless—business model for tomorrow's pharma?*

Portch: Rather than changing significantly, I think the mandate of project and process management will be reinforced. There is a critical need for direction, clarity, and scale in taking limited resources and deploying these —surgically—to develop and sell our products. One urgent theme here in the US is looking at our sales and account management resources to apply these human assets effectively in managing the mix of tools—like rebates and samples and co-pay cards and coupons—to bring down expenses while raising our game in providing greater access to our medicines and ultimately generating revenues. We know that achieving this will depend on being able to adapt to different realities, because what works in Minnesota or Boston will not succeed in Florida and Texas. And that requires not just superior logistics and organization but the interpretive skills, buttressed by constant feedback, that enable us to be first, before the competition. We have to apprise the ROI from virtually every action we take in the field. Analytics is going to be a bigger part of the job.

Mongon: Program and project management is blessed with a simple, self-evident mission: to help the entire organization make the best decisions. The challenge is commensurate with the growth of IT over the next few years. Taking the cue from Murphy's Law, there will a constant doubling of data available to us. Applying that information to make it quality information, relevant to the business, is more important than ever in dealing with an abundance of risk and uncertainty in the market.

Saxton: Project and program management will continue as a critical function in driving organization value and effectiveness, ensuring communication and cross-functional integration and doing this while sustaining a culture of scientific innovation to keep up with the competition. But this level of effectiveness cannot be realized if the end game isn't clear. That involves the creation of better ways for people across the business to talk to each other, connect their work to the rest of the enterprise, and make better decisions more quickly. It will also continue to be important that the function be close to decision-makers at the top; as their buy-in has always been vital to the success of the project managers' mission.

Phelan: The imperative over the next few years is twofold: (1) ensure our corporate leaders have the right information in making difficult choices; and (2) rally the entire organization around the choices they make, and execute quickly around them. I agree with the others, too: we need to stick close to the senior leadership.

Millett: This function is going to grow in stature. The commercial environment in biopharmaceuticals today is like warfare, where success depends on trained multi-functional product units that can operate independently, act rapidly, with a singular focus around a clear objective. Other sectors like automobiles have already moved decisively in this direction, with more operational autonomy for those elite teams tagged with developing a new car platform in a six or seven-year cycle time. That time frame is longer for biopharmaceuticals, so the challenge is to keep the team active and knowledgeable for the duration, from R&D to market launch and beyond. Maintaining that balance between autonomy and control will test every project manager

and the leadership team. The bright spot is our industry is increasingly willing to look outside for ideas on how to do that. Industry practices are more open today than they have ever been.

A future left curve?

PE: *What about potential disruptive threats? Can you identify any big intangibles that will require a decisive response from you and other process experts?*

Portch: The commercial model in the US is undergoing a radical shift, to one that demands much more from our market access capabilities. Access decisions taken by providers will follow risk; the upshot is the providers will end up owning that risk. It's a very different calculation than what exists for insurers and PBMs, whose perspective concerning the patient is very short-term. If we handle this institutional change well, and extend our partnering reach to include ACOs and integrated care companies, then it could be a net positive for us. That's because the providers carry a risk exposure that incentivizes them to consider patient health over time. Wellness, total cost of care and health outcomes associated with keeping patients out of hospitals really matters to them.

Mongon: There is also an implicit threat in the abundance of information about every aspect of health care financing and delivery. The burden is on our industry to ensure the information benefits patients rather than to curtail use of medicines.

Portch: The truth is the five major health systems and three dominant PBMs that cover more than 150 million insured lives in the US possess more information about our brands than we do. What they do with that knowledge is a strategic issue for us.

Phelan: Balancing size and science is another imperative. The global burden of disease is very large. It is logical that companies whose business it is to address that burden be large as well. It pays to be large—we face significant commercialization costs due to the longest development cycle times of any industry. Yet medicines discovery itself proceeds in small, incremental steps; big Pharma has to fill its pipeline by being as nimble as the smallest biotech. And there is no management theory to show how to navigate successfully between these two opposites. Lots of small innovative science based teams tied to a big footprint: the company that does that well is well positioned for the future.

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