Pharmaceutical manufacturers face an increasing drug utilization dilemma— not related to formulary acceptance—in the US marketplace regarding patent expiration and biotechnology products. Current business transaction platforms, such as health insurance plans, have created different barriers to the entry of products and to their routine use that traditional pharmaceutical marketing has yet to effectively address. Health benefit coverage decision makers are disrupting the traditional pharmaceutical channel, emphasizing the absence of a compelling pharmaceutical value proposition to the buyer (ie, patient and benefits community), while exposing a critical weakness for managed market coverage and utilization. Despite manufacturers’ efforts in traditional channels to achieve sales or market share, the current managed market channels can eliminate a product’s marketplace value within weeks. In addition to research and development investment, harnessing 21st-century technologies and a better understanding of the new healthcare customer channels may prove to be the best investment a manufacturer can make. [AHDB. 2010;3(3):225-230.]

For example, we have populations of patients with cardiovascular disease or diabetes who are at risk for a heart attack or a glycemic event, but are generally not screened for these events or often not detected in the current healthcare system.1 In contrast, better screening and detection programs can identify people for inclusion in drug and nondrug therapies to facilitate the prevention of a potentially serious illness and costly hospitalization.

This represents a true value proposition opportunity not only for health plan payers or sponsors but also for influencers in the US healthcare system, such as patients and providers. In fact, true value-based offerings supported by pharmaceutical manufacturers may deliver the opportunity for alignment of interests for improving health in contrast to the current pharmacy distribution channel’s focus and health plan coverage in the marketplace (Figure 1).

The Value Proposition in Current Healthcare

Another difficulty in the current healthcare system is understanding what aspect of the drug product is of value, and to whom, and what determines value. There is no single definition of value consistently used in the marketplace or in the literature to date. Furthermore, the use of value in combination with various applications (eg, value-based purchasing, value-based benefits, value-based insurance design, and quality-adjusted life-
The healthcare market today is focused on medical practices and regulatory oversight, rewarding reactive management/delivery of services.

Reimbursement decision makers should be considered by pharmaceutical manufacturers with regard to their product pipeline.

The absence of a compelling value proposition to healthcare buyers, including patients and payers, is a significant weakness for product coverage and utilization.

Successfully implementing a new market-channel strategy necessitates a well-orchestrated approach to integrating the manufacturer’s marketing issues.

Drug manufacturers are beginning to address disease states and drug classes/categories from an employer’s or a buyer’s perspective.

Those in charge of benefit design and their influencers are currently disrupting the traditional pharmaceutical sales and distribution channels that are still relying on traditional physician-focused marketing efforts.

The price for failing to implement change in addressing new channels can be more costly than the investment toward facilitating change.

**KEY POINTS**

- The healthcare market today is focused on medical practices and regulatory oversight, rewarding reactive management/delivery of services.
- Reimbursement decision makers should be considered by pharmaceutical manufacturers with regard to their product pipeline.
- The absence of a compelling value proposition to healthcare buyers, including patients and payers, is a significant weakness for product coverage and utilization.
- Successfully implementing a new market-channel strategy necessitates a well-orchestrated approach to integrating the manufacturer's marketing issues.
- Drug manufacturers are beginning to address disease states and drug classes/categories from an employer’s or a buyer’s perspective.
- Those in charge of benefit design and their influencers are currently disrupting the traditional pharmaceutical sales and distribution channels that are still relying on traditional physician-focused marketing efforts.
- The price for failing to implement change in addressing new channels can be more costly than the investment toward facilitating change.

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**Figure 1** View of the Marketplace

Channels driving decisions on coverage include:

- Manufacturer
- Distributor
- Dispenser (pharmacy)/administering professional (eg, Medical Director)
- Patient, purchaser (employer, government, union), and payer (health plan, PBM)

PBM indicates pharmacy benefit manager.

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year analysis) has contributed to increased confusion among stakeholders seeking to find a common ground. Fundamental to the understanding of value is the relationship between economic value and the individual stakeholder perspective. Key stakeholders include patients, physicians, health plans, and plan sponsors (eg, employers, union trusts).

Various value-driven product coverage or utilization decisions have been emerging from the traditional cost-only (unifactorial) decision system as a result of finally recognizing that multiple factors are responsible for driving up the total cost of healthcare, including more sophisticated medical treatments and an aging population that will consume ever-more services. Consequently, even modest savings from this new value-based benefit design strategy can be significant for struggling employers, municipalities, and patients who are the key payers in our economically strained modern healthcare system. Value-based benefit design incorporates cost-efficiency with alignment of corporate business goals and objectives that should be reflective in the company’s health plan (Figure 2).

The continuing absence of a compelling value proposition to the buyer (ie, patients and the health benefits payer community) has exposed a significant weakness for product coverage and utilization, despite some modifications to traditional pharmaceutical marketing practices. As seen in the October 2008 congressional votes authorizing “bail out” funding toward solving the economic crisis, Congress members could not fail to address the changes through funds that can lead efforts toward restoring the economy.

In the healthcare marketplace, the price for failure to change product-marketing efforts by addressing new drug distribution decision-making channels is going to be more costly than the relatively modest investment toward facilitating change to achieve marketplace success.

**System Dysfunction versus Cost-Efficiency**

Affordability and effectiveness are 2 components of value for health insurance payers. As an example, employers have used value-based purchasing strategies for many disparate services over the years, akin to the collective purchasing power by hospitals, health plans, and even pharmacy chains. This represents a unit cost-focused decision approach similar to cost minimization in pharmacoeconomic terms. However, a November 2007 survey of employers showed that as a whole, employers do not appear to be implementing health-related programs in line with value-based purchasing ideals that include affordability and cost-effectiveness.3,4

Even when using available health plan level quality information—such as HEDIS (Healthcare Effectiveness Data and Information Set) and eValue8—the information is used by less than two thirds of benefit design decision makers and less than one quarter of medical providers.3,4 However, existing sources of quality data, with their inherent limitations or usefulness, are not factored into many pay-for-performance programs and decisions.

This gap stems from the difficulty in executing a fully electronic exchange of patient-centered information at the time of service, along with traditional reimbursement programs that are not incented to align across different areas of coverage. For example, medical and pharmacy...
services are typically handled under different benefit design and coverage rules, making it difficult for providers to treat a patient independent of what service or product may be covered under their area of the benefit design.

For pharmaceutical product coverage and purchasing decisions in the traditional pharmacy channel, misaligned incentives between quality (ie, performance) and cost means that key decisions for branded products with (an actual or perceived) low or marginal health improvement could be placed in a higher copayment or coinsurance tier, or not be covered without prior approval. Therefore, quality outcomes that are researched in the absence of economic impacts may fail to influence actual physician prescribing, plan coverage, or use by patients.

Different industry, accounting, and benefit consulting organizations indicate that although employers as a whole are not ready to adopt even value-based purchasing, such a strategy has the potential to lower costs and improve quality. For example, despite a 2001 report from the RAND Corporation that healthcare spending could be reduced by nearly 30% without adversely affecting health, as well as evidence from the health literature from the past 20 years, employers still maintain their deep-rooted ambivalence regarding the reality that value-based purchasing is limited in its potential to contain healthcare costs.

The importance of these emerging trends for pharmaceutical marketers and executives is in the rapidly evolving need to better align the value proposition of a drug product with all stakeholders and influencers. Such an approach requires looking beyond any perceived clinical need, US Food and Drug Administration (FDA) approval, or drug price to address the issues of the payer or consumer as buyer in a product’s value proposition.

Rethinking the Process

One approach would be to look to the marketplace to address how pharmaceutical manufacturers, especially biotechnology-based companies, establish a value proposition to stakeholders beyond just clinical data and rethinking the traditional pharmaceutical strategic planning process (situational analysis, strategic development and planning, implementation). Several examples during the past 2 years have been reported in business and industry publications, suggesting that pharmaceutical industry executives, including GlaxoSmithKline Chief Executive Officer Andrew Witty, have held product pipeline meetings with insurance carrier payers and European regulators to gain feedback on marketplace needs as well as issues related to new or future product acceptance.

Expanding the individual situational analysis to the broader marketplace perspective requires a translational utilization (ie, applying data such as comparative effectiveness research into benefit decisions) of traditional differentiating drug data. For example, when developing a new drug, the developer considers clinical parameters toward the FDA approval requirement and provider acceptance, whereas benefit plan managers are looking for the product’s value in their covered population and to their operational bottom line. Including the perspectives of the new buyers and influencers of buying decisions, such as employers or unions, in strategic planning and implementation requires a more robust understanding of all those stakeholders, along with the different drivers influencing their decision making for health benefits coverage.

Validation and strategy refinement in working with buyer segments, such as employers, need to be accomplished before consideration of a new product launch.
Companies are beginning to address disease states and classes or categories of drugs from an employer’s or a buyer’s perspective. Buyer-specific tools, models, and materials require more of an outsourced and independent business solution.

Companies are beginning to address disease states and classes or categories of drugs from an employer’s or a buyer’s perspective. Buyer-specific tools, models, and materials require more of an outsourced and independent business solution, because of the negative perceptions or distrust that commercial plan sponsors (including employers, unions, and municipalities) have of manufacturer-supplied programs. Benefit decision makers are skeptical of manufacturer-driven or -developed programs and instead tend to rely on their trusted network of consultants or brokers for their benefit design and formulary decisions.

In addition, adequate development budgets are needed for entry into the employer markets, because there is currently a dearth of independently developed tools for these commercial buyers of healthcare services. Traditional efforts by manufacturers have focused on physician organizations and health plans, yet it is the commercial plan sponsors along with government programs (ie, Medicare, Medicaid) that are becoming increasingly important in driving demand for preventive and new products that will improve health. This effort goes along with established patient advocacy trends, direct-to-consumer campaigns, and recognizing a changing business environment. Overall, realigning resources (ie, field and research personnel and funding), tools, models, and nonbranded support materials needs to be included when addressing this (ie, employers) market channel.

The Emerging 21st-Century Technology

The emergence of the human genome, and the resultant biologic- or biotechnology-based diagnostic and medication products is a cutting-edge 21st-century product technology. Manufacturers need to look beyond vendors in the marketplace—such as pharmacy benefit managers (PBMs) and health plans/managed care—and the current vendor-only business model(s) for manufacturers to sell their product. Current influencers on a buyer’s decision makers that are invisible to manufacturers include health benefit consultants and brokers. Of more interest for successful market behavior change are the reimbursement platform technology and money flows that have not changed since the past century.

To date, drug manufacturers maintain their traditional channel focus on access (ie, formulary acceptance) or copay modifications through managed care vendor relationships to include expensive rebates to intermediary health plans. These efforts that focus solely on product costs ignore the marketplace need for vendors in providing value to buyers, and do not offer an improved transaction platform or money flow that could be used to create a winning business-to-business product solution to buyers (ie, patients and providers) that would allow opportunities such as creating brand value beyond a product’s patent life.

For pharmaceutical marketers, not establishing a money-flow product value proposition to buyers in a new business transaction environment can result in market share losses to evolving benefit design policy decisions. For example, the allergic rhinitis drug category represents a large pharmacy cost, but more significantly, an important asset in the management of a disease that represents a high-frequency and high-spending category for buyers.

Managed care plans to date have focused on generic substitution by default as a way to control costs, because of the obvious benefit influencers (ie, PBMs, health plans) and money-flow managers (including healthcare providers) who gain the most from that practice. However, generic substitution alone is a self-limiting value proposition from an employer total-cost management perspective and ignores the bigger value proposi-
tion of managing a disease risk for a buyer, which is where the manufacturer and employer are in alignment.

In addition, a new electronic communication platform for evolving information transactions can lead to more effectively addressing adherence that can amortize investment costs made but lost through patient behavior or market forces.

Disrupting Channels
Contemporary health benefit design decision makers and their influencers are disrupting the traditional pharmaceutical sales and distribution channels, along with demand control, whereas manufacturers are still relying on traditional physician-focused marketing efforts for demand creation, with little focus on utilization or product pull-through. Several limitations to changing healthcare decisions exist, including, for example, patient or employee confidentiality, union-negotiated restrictions on benefit changes, and specified services contracts. In addition, health benefit brokers who represent vendors, or benefit consultants who represent purchasers, may not be the solution for manufacturers seeking advocacy as a result of conflicts of interest.

Further exacerbating product use problems are the current managed market coverage and reimbursement platforms that have created ever-changing or varying barriers to product entry and utilization. This is what pharmaceutical marketing and senior sales executives continue to find difficult to understand or to successfully address.

Conclusion
To date, the lack of a compelling value proposition to patients and to the health benefits payer community exposes a weakness for product coverage and utilization, despite talk of changing from traditional pharmaceutical marketing practices. As seen in the banking and finance industry, the cost for failure to implement change in addressing new channels can be more costly than the investment toward facilitating change. For some pharmaceutical companies, the risk may be no less than failure of the product or the failure to survive as a business.

Contemporary health benefit design decision makers and their influencers are disrupting the traditional pharmaceutical sales and distribution channels, along with demand control.

Despite the best efforts in traditional market channels by marketers and their vendors to achieve sales goals or market share, the new buyer channels for pharmaceuticals can effectively neutralize potential gains and eliminate a product’s clinical value in the marketplace. The new road map for success will require systems, processes, and tools that are aligned with the customers in the marketplace. Training and development of personnel also require a change, to implement, sustain, and hold onto marketplace achievements. Harnessing 21st-century technologies, and better understanding new customer channels, may prove to be the best investment by a manufacturer aside from applied research.

References

STAKEHOLDER PERSPECTIVE
The Many Challenges of Pay-for-Performance Programs

In his article, Dr Vogenberg challenges pharmaceutical manufacturers to consider new strategic approaches to the marketplace. Acknowledging the leverage that managed care organizations (MCOs) and pharmacy benefit managers (PBMs) can have in the marketplace, Dr Vogenberg challenges pharmaceutical manufacturers to think about the multiple stakeholders in healthcare and how a new product will be perceived by those different stakeholders. In other words, new pharmaceutical products will be judged and accepted based on the clinical and economic value they may bring to health plans, patients, employers, and physicians.

From the managed care perspective, we continue to
struggle to manage the rising costs of medical care, and pharmaceutical products continue to be an area of major focus. According to an Associated Press article from April 1, 2010, “Growth in US sales of pharmaceuticals bounced back last year, as rebates and low-cost generic drugs drove an increase in the number of prescriptions filled, according to data tracking firm IMS Health.” In addition, US drug sales “climbed 5.1 percent to $300.3 billion in 2009, after two prior years of slower growth.” The report also notes that generic drug sales “made up 75 percent of all prescriptions filled last year,” compared with 57% of all sales in 2004.

On May 18, 2010, the AARP reported that “manufacturer prices for brand-name drugs widely used by Medicare enrollees rose 9.7 percent in the 12 months that ended in March….The increase was the largest twelve-month spike since AARP began tracking drug prices in 2002.”

With the cost of pharmaceuticals still a concern for their customers, MCOs are looking for ways to actively manage their drug benefit and to narrow formularies in categories where there are valid generic options or where there are choices of clinically equivalent branded options. Pharmacy & Therapeutics (P&T) committees are increasingly looking to find true innovation in the products they review. Such things as combinations of existing generic agents remarked as a branded agent, new longer-acting formulations of existing products, and branded agents in the “me-too” category are coming under intense review by P&T committees; often the discussion revolves not only around what clinical value does this product bring to the market, but on what is the economic value, and how does the new medication bring additional value to the specific MCO and its clients.

As Dr Vogenberg points out so accurately in his article, failure to recognize this dynamic, and failure to demonstrate this value to the MCO or the PBM client can result in an unsuccessful product launch. From the MCO perspective, I agree with Dr Vogenberg that going forward, manufacturers must understand what the value equation is for the MCOs, and they must also understand the unmet needs in the MCO marketplace early in the drug development cycle to have successful product launches in the future.


Gary M. Owens, MD
President, Gary Owens Associates
Philadelphia, PA