Since the onset of healthcare reform, the role and power of payers have been growing steadily and has reached a point of painful reality for the industry.

Starting today, companies need to abandon knee-jerk approaches to coping with the burden of proving value to payers, such as tacking on payer messaging efforts to an existing brand strategy. Instead, companies need to start from scratch and incorporate the payer perspective throughout all top-to-bottom decision-making.

According to a report by strategy consulting firm Monitor, most pharma companies have responded to the new payer environment from the bottom up, developing regional account sales teams to cultivate closer ties with payers. Others have tried to become more familiar with payers’ decision-making processes or have incorporated performance-based contracts with payers. While beneficial, these efforts are not enough to meet all of the challenges confronting pharmaceutical companies today.

To succeed, companies must overhauls the way they develop and market drugs by putting market access planning at the heart of their organization, and by balancing clinical and economic value in both product development and commercialization decisions. Our forum experts discuss the challenges, changes, and blunders the industry is experiencing as it moves closer to the core of market access within managed markets.

Proving Value is About More Than Price

There are many ways for manufacturers to prove meaningful clinical and economic value of their products to managed markets, but the key is in learning how to communicate the value effectively. Our experts suggest starting early, combining health economics and improved health outcomes data, and creating a targeted effort focused only on managed markets.

In summary:
1. It’s not just about the money; it’s about patients
2. Increasing nonpersonal and digital payer engagements can help
3. Sales: Don’t “show up and throw up”

 JOHN GUARINO. PALIO. There are roughly 350 commercial payers in America. But the top 28 plans cover more than 80% of the covered lives. So manufacturers segment the space, measure their resources, and draw a line where they stop proactively calling on plans.

The problem with this approach is that reimbursement is like politics: it’s all local. If you are a sales rep with a small regional plan that is not covering your product, that problem couldn’t be bigger. The best companies are creating digital and non-personal engagements for the other 300 payers. Payer websites and landing sites, banner ads, direct mail, journal ads, and supplements are all examples of tactics they use to provide air coverage for the small regional payers. Other companies have identified reps within regions for training on the basics of payer coverage and use them as triage for the broader payer organization.

 ROSHAWN BLUNT. Eisai. The discipline of pharmacoconomics and its associated tools, for example health technology assessments, budget impact modeling, evidence-based medicine, and so forth, have flourished in recent years. When applicable, it is a respected path to prove a product’s clinical and economic advantages to payers. Unfortunately, there isn’t a universally accepted framework. Different payers tend to prefer one model over an-
Pharmaceutical companies must develop the appropriate economic and clinical evidence that helps address the specific perspectives of payers, providers, and patients.

ROSHAWN BLUNT / Eisai

The challenge for marketers is that they now have to make a collaborative — rather than a competitive — case for their brands.

MICHELLE O’CONNOR / CMR Institute

other, based on what they believe are the most important factors. Furthermore, many payers want to see the analysis developed using their own member data only. This can be costly and cumbersome to a manufacturer. Moving forward, I believe it’s important for product development teams to design Phase II and Phase III clinical studies in a way so that one of the study’s goals includes the collection of the clinical and economic inputs needed to develop a strong health economics dossier. We should never forget, however, that health economics is only one part of a picture. Ultimately, we are analyzing whether lives are improved or saved — not just the dollars and cents of a clinical intervention. Therefore, I would obtain input from patients and their advocacy groups about a therapeutic area and use those insights as part of the total ‘incremental value story’ that is provided to payers.

JOE FALCON, TGA ADVISORS. The surest way to prove meaningful outcomes is to collaborate with payers during Phase II of development so that new products are introduced with the evidence payers require. Often, companies generate their health economics and outcomes research (HEOR) evidence too late, and they attempt to do it in a vacuum. Unless manufacturers involve payers in the research design and execution, payers can easily perceive a potential bias in the results. The burden of proof is made even more onerous by the fact that payers do not have a precise and consistent definition of, or way to measure, the value of life-extending or life-saving products. Consequently, each payer uses a different estimation of value.

DR. JOHN DOYLE, QUINTILES. Comparative effectiveness translates a product’s potential to real-world value. To formulate CER strategies, brand managers will need to understand their customers’ needs and appraise the market as a dynamic system of interdependent players. In

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ROSHAWN BLUNT. Market Access and Reimbursement, Eisai Inc., a research-oriented, global pharmaceutical company committed to addressing unmet medical needs. For more information, visit eisai.com/us.

JOHN DOYLE, DR. PH., M.P.H. Managing Director and Practice Leader of Market Access, Quintiles, an integrated bio/pharmaceutical services provider offering clinical, commercial, consulting, and capital solutions. For more information, visit quintiles.com.

JOE FALCON. VP, Managed Markets Practice Leader, TGA Advisors, a division of KnowledgePoint360, is a provider of benchmark and advisory services for pharmaceutical companies that enable them to evaluate their commercial operations against a confidential industry peer-set. For more information, visit tgas.com.

JOHN GUARINO. Senior VP, Managed Markets and Payer Strategy, Palio, an inVentiv company, is a full-service healthcare communications agency. For more information, visit palio.com.

MICHELLE O’CONNOR, M.ED., CMR. President, CEO, CMR Institute, a nonprofit, 501(c)3, independent educational organization that provides non-branded, unbiased, and applicable education to pharmaceutical, biotech and medical device and diagnostics professionals. For more information, visit cmrinstitute.org.
Marketing efforts of drug companies must keep pace with how healthcare delivery is changing. 

JOHN GUARINO / Palio

The best way to prove meaningful product advantages is to first think about the treatment process from the payer perspective.

DR. JOHN DOYLE / Quintiles

addition to developing their customer/market appraisal skills, they will also need to conceive how to measure their product’s real-world performance in an accurate, practical, and transparent manner to ensure they can demonstrate sustainable value to payers.

MICHELLE O’CONNOR. CMR INSTITUTE. Payers and integrated delivery models, such as ACOs, are gaining more access to data, thanks to electronic health records (EHRs) and other health information technologies. With access to their own outcomes data, customers will no longer rely solely on data from manufacturers or third parties to make their formulary decisions. Over time, they will gain an even greater understanding of their patient populations and may come to manufacturers for specific solutions targeting a patient subset, for example, elderly patients who are readmitted for pneumonia. Therefore, instead of proving the advantages of their products for all patients, manufacturers should focus on helping payers define the problem areas where they might offer solutions.

First Challenge: Changing the Mindset

According to the Monitor report, Big Pharma’s Market Access Mission, pharmaceutical executives need to rebalance the time and attention they spend on payers and specifically commit to rebuilding the drug commercialization process to address a new market reality. They have to make market access planning an integral part of their organization, placing clinical and economic value at the center of all their efforts. Inaccurate, under-resourced by marketing, and relegated to being contract deliverers. So the challenge has been, and remains, to change how we engage payers. The days of the 60-page payer deck or an account manager bringing a sales resource developed for physicians and intended to influence physician-prescribing behavior are over. Formulary decision makers need tailored information to help them make very different decisions than physicians make. If the drug company marketing efforts don’t keep pace with how healthcare delivery is changing, they will continue the account manager march into the pharmacy director’s office, and begin the contract negotiation. Payer-cost analysis abilities are becoming more sophisticated. But pharma feeds the monster of the payer organization preferring the cheapest drug in a class instead of the one that delivers the best value by moving immediately to cost instead of value.

ROSHAWN BLUNT. Eisai. Physicians and patients remain, and always will be, critical constituents to the pharmaceutical industry. We cannot shift our attention solely to payers at the expense of other core groups. Thus, the challenge is not to shift the focus, but of adding an additional perspective that we must speak to in the launch of our products. The perceived incremental value a therapy provides to a payer, provider, and patient is the key to a product’s success. In other words, manufactur-

MEETING PAYERS’ VALUE NEEDS

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<th>Overall Avg.</th>
<th>Large Tier % Agree</th>
<th>Mid Tier % Agree</th>
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Both large- and mid-tier companies believe HEOR for existing products is deficient...will future product needs “really” be met?

Source: TGaS Advisors. For more information, visit tgas.com.
ers must first demonstrate the significant unmet need and then price the therapy based on a realistic appraisal of the current market’s perception of that need. Payers have a strong voice in determining whether they agree with the value of a manufacturer’s offering. They also have the ability to place limitations on therapy use if they believe the price and the value of the product are not aligned. That being said, payers are not deaf to the informed opinions of providers and patients. In this regard, the U.S. market is still somewhat different from countries where access is based primarily on the manufacturer’s ability to demonstrate quantifiable improvements over the standard of care to economic purchasers. Therefore, whether it’s in the United States or abroad, a pharmaceutical company must develop the appropriate economic and clinical evidence that helps address the specific perspectives of payers, providers, and patients. And, this is typically done without a great deal of additional budget.

**JOE FALCON.** TgaS ADVISORS. We know from TGaS Advisors’ annual executive landscape report, Future Issues of Managed Markets, managed markets leaders are concerned primarily with addressing the changes being introduced through healthcare reform — starting with understanding specifically how their customer base will change as a result. Companies want to be able to prepare and align their organizations accordingly. The second-biggest issue is in ensuring their products achieve optimal access in the market. This is directly related to the ability to demonstrate that their products produce better outcomes and/or are more cost-effective than other treatment options. Respondents had a rather dim view of how well their products’ value propositions met payers’ needs today, and only about half were optimistic they could do so with products in the pipeline.

**MICHICLL O’CONNOR.** CMR INSTITUTE. The challenge for marketers is that they will have to make a collaborative — rather than a competitive — case for their brands. That’s because we’re already seeing payers become more integrated with hospitals and physicians through accountable care organizations (ACOs). In such models, the pharmacy decision makers will want to know how a drug is best able to assist in a total treatment program — for example, how it can help shorten postsurgical recovery time or assist in presurgical physical therapy. This means marketers will need strategies that help demonstrate their brand can achieve an end result. It’s a different mindset from the past, when marketers just focused on comparing their brand with other drugs.

**DR. JOHN DOYLE. QUINTELS.** The best way for manufacturers to prove meaningful product advantages is to first think about the treatment process from the payer perspective, diagnosing key decision nodes in that process that influence care efficiency and effectiveness, and then think about how their product can be adopted to optimize the treatment process. Payers think about incremental value when evaluating new products for coverage and payment decisions. Accordingly, they will consider pharmacy budget impact and medical budget impact. Persuasive value demonstration is underpinned with clinical, economic, and humanistic data describing the new product in relative terms to the existing standard of care.

“Unless manufacturers involve payers in the research design and execution, payers can easily perceive a potential bias in the results.”

**JOE FALCON / TgaS Advisors**

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**FUTURE ISSUES OF MANAGED MARKETS**

Rating the degree of integration of HEOR into brand strategy

TGaS Advisors’ annual executive landscape report, Future Issues of Managed Markets, illustrates some pressing issues the industry must prepare for. For example, below, TGaS discovered that many companies generate HEOR evidence too late in the game.

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<th>Excellent integration</th>
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Wide range of responses related to successful HEOR integration

**DO YOU ACTIVELY PURSUE COLLABORATIONS WITH PAYERS IN THE DEVELOPMENT OF CLINICAL ECONOMIC EVIDENCE FOR YOUR:**

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<th>Pipeline products</th>
<th>In-line products</th>
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**Blunders Lead to Best Practice**

Understanding how to address payer needs and how they differ from providers is critical. Missing the mark with payers means missing the boat on market access. Our experts discuss some of the mistakes they have observed in the industry regarding marketing practices to payers.

**In summary:**

1. Too much focus on pricing
2. Failure to include the total treatment in plan
3. Lack of designated payer marketing organizations

**ROSHAWN BLUNT.** EISA. The biggest mistake is pricing a product based on opinion rather than fact. It’s very easy to get too close to one’s own product. Bringing a therapy to market is a time-consuming, costly, and risky endeavor for a manufacturer. A potential product’s value can become clouded if it is defined solely as a means to achieve an appropriate return on investment. Similarly, a manufacturer must be sure that the value perceived by the external marketplace is not discounted in
Optimizing Marketing Using Managed Care Influence

The current pharmaceutical brand has seen an evolution of healthcare stakeholders, their influence and market forces that make it necessary to consider more of an integrated view across payer markets, and marketing and sales to determine which mix of tactical levers could be “pulled” locally to optimize predicted brand share.

For example, for a local area where the brand has limited managed care access, it may be a waste of resources and dollars for the brand to spend heavily on sampling, detailing, or direct-to-consumer promotion. Conversely, examining the promotional effort and mix per region may give a more informed look at which managed care contracts are not performing in exchange for the access the brand paid for in the managed care contract. Understanding and acting on this balance point across plan geographies can lead to a more efficient promotional mix deployment and better managed care contracting. With a more efficient promotional plan and managed care contracts, the brand can expect both improved revenues and profit.

Source: Dan Barton, IMS Health

favor of the company’s internal, long-held biases for a product’s profile. When either scenario happens, a therapy could be priced at a level that is too high and does not accurately reflect the value to which payers, physicians, or patients ascribe. Payer restrictions and/or a negative response from physicians and patients due to what may be perceived as high co-payments can detail a product’s launch and make it almost impossible for the brand to recover. Throughout a product’s development, marketers should employ market research to ensure they have a constant and realistic pulse on where their product will fit in the market, and these are the data that should be used to establish price, positioning, strategy, and tactics.

MICHELLE O’CONNOR. CMR INSTITUTE. Failure to understand what drives payers is one of the biggest blunders, and the issue only becomes more complicated with the advent of ACOs. The payers, hospitals, and physicians in ACOs only benefit if quality of care and total cost savings goals are met. In other words, the context for judging which drugs are most cost-effective will become broader. When developing their brand strategy, marketers will need to focus on their drugs role in the total treatment program. In addition, issues such as appropriate use and compliance may become more important, because they impact the overall success of the treatment.

DR. JOHN DOYLE. QUINTILES. The fundamental difference in marketing to a payer versus physician is that payers make policy decisions at the population level and physicians make decisions at the patient level. Consequently, marketing needs to ensure they are developing the appropriate evidence package with requisite product performance metrics and tailoring messages to facilitate decisions that relate to representative populations. One common pitfall in this area is assuming clinical trial patient populations are representative of managed care populations. Patient populations that ultimately receive a product in the community tend to be older and sicker than RCT patients, which may undermine a treatment’s risk-benefit. They also don’t adhere to their prescribed medication as well as clinical trial patients, compounding the uncertainty of real-world treatment effectiveness.

JOHN GUARINO. PALIO. The biggest blunder, and the cause of most of the others, is not having a payer marketing organization. If you are a multi-product pharmaceutical manufacturer and you don’t invest in this way, you are being penny wise and pound foolish. Think about how much money you invest in your contracts — millions even billions. But somehow an investment in being good at delivering messages that ground the cost conversation is viewed as extravagant or unnecessary. What we don’t understand, we don’t value; and the sad truth is that brand marketers run most companies. Managed markets was always something they knew was important but was too specialized to deeply understand and, as a result, they avoid it. Most manufacturers’ account managers stop at the office of the pharmacy director. But many points of receptivity for marketing messages exist within payer organizations. The problem is that each focuses on a different part of the decision process. Effective payer marketing creates one succinct message or story that includes all the information that is most critical to high-level decision makers, as well as creates deliverables that laser focus on specific areas of decision making. That’s because a pharmacy director wants high-level clinical information and a deeper dive into cost and value issues. Too often sales and marketing organizations — both HCP and payer — feel compelled to say every positive thing about their brand that they can. They think more is better, but a pharmacy director at an ad board described this as ‘showing up and throwing up.’ However, a clinical pharmacist writing the monograph that will inform the P&T committee needs a much more thorough deep dive. The point is, you can’t use the same resource or visual aid with each, and you certainly can’t use the same resource the sales reps are using in the physician field. Some progressive organizations are asking their account managers to go broader and deeper in the payer organization, but as the old pharma adage goes, you can’t sell from an empty bag. In today’s regulated world, manufacturers must fully understand the degree of engagement that their account managers can legally have, and train them to know when the discussion has moved beyond things they should be talking about. Strong alignment with the HECON group and medical liaisons ensures that an account manager understands when to leverage support. If they don’t, they will automatically go to where they are familiar and empowered and comfortable: contract conversations. The best organizations realize that this selling process is complicated and each team member plays a part. They allow the medical and HECON teams to develop their own relationships with payers to ensure the firewall is not breached.

JOE FALCON. TGAS ADVISORS. Pharmaceutical companies could work with payers to generate economic evidence following the same model they use in working with CROs to generate clinical evidence. They could confer with payers in Phase II to determine what information is needed and then fully outsource and/or partner with them to execute the research. Not all payers, of course, have the ability to take this on, but many do. It would certainly remove the stigma that comes with data produced exclusively by pharma.
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Value Proposition Marketing Requires NEW SKILLS

In today’s evolving managed market landscape, brand managers need to fully understand and take advantage of CER.

With comparative effectiveness research (CER) at the forefront of payer decision making, being able to work with payers to secure reimbursement and market access for products is more complicated than ever, and because of this, the nearly ignored managed markets function has gained new status in the industry, along with new pressures and challenges. CER is critical to the long-term success of moving payers to more informed decisions about treatment options within a class or disease state and may open up lines of communication that brings more value-based information to payers.

Back in 1997, the Food and Drug Administration Modernization Act (FDAMA), section 114, tried to create a path for delivery of salient cost-effectiveness comparisons, but it was never widely understood or adopted by manufacturers as it resides within the same legislation that the FDA uses to rein in off-label and inappropriate marketing practices, according to John Guarino, senior VP, managed markets and payer strategy, Palio.

“As a company’s medical, legal, and regulatory restrictions dramatically increased, payers were left with little input from manufacturers regarding the true cost of therapies,” Mr. Guarino says. “As a result, we wind up with WAC-to-WAC comparisons and that being the case, the only value is placed on the size of the discount.”

However, Mr. Guarino believes the implementation of CER now offers pharma a chance to re-launch FDAMA 114 and be a part of advancing value proposition marketing and communications as a place that will be much more valuable for payers. He fears though that CER will mostly be conducted by the government and may not focus on comparing value in a way that is helpful to payers, and ultimately may become underfunded.

“I encourage my clients to mine their HECON groups and see what types of data already exist, as well as begin to conduct their own CER studies and communicate them via FDAMA 114,” he says.

Robert Temple, M.D., Deputy Center Director for Clinical Science Center for Drug Evaluation and Research Food and Drug Administration, clarified how this information could be communicated during a recent presentation: “…FDAMA 114 allows manufacturers to provide healthcare economic information not in labeling to formulary committees and similar entities. This is a limited, but potentially important exception that has some potential relation to CER.”

The managed care model has seen huge growth in the pharmaceutical industry in the United States. It is estimated that 85% of all prescription drugs are today reimbursed through a managed care plan, and the remaining 15% of cash paid prescriptions is still shrinking. This proportion is even higher for expensive new specialty pharmaceuticals. These changes increase the need for managed markets experts to help shape decisions that are made early in the development of products, therapy area business strategies, and business development.

One of the foremost challenges is getting a handle on the scope of both the clinical evidence and health economics data, and being able to turn that into a story that will prove value to payers.

Not having a clear appreciation for the differences and how payers and clinicians will receive those data can lead to a less than optimal

“Understanding the limitations or opportunities your specific evidence provides is critical to marketing success.”

ROSHAWN BLUNT / Eisai

“When managed markets marketing teams function apart from the brand and HEOR teams, brand planning takes place without the proper degree of integration.”

JOE FALCON / TGap Advisors
outcome. Ideally, brand managers will be fluent in the language used to promote a product and conversant in the languages of research and development, medical affairs, reimbursement and health economics. The traditional path to brand management — typically through field sales and an MBA degree — may need to be augmented by spending time in managed markets, health economics, or medical affairs, says Roshawn Blunt, market access and reimbursement at Eisai Inc.

“[I] frequently question whether the best advanced degree for pharmaceutical marketing is an MBA, MPH, RPh, or Ph.D.,” she says. “Understanding the hierarchy of evidence and the limitations or opportunities your specific evidence provides is critical to marketing success. A downstream marketer may have limited ability to influence study design and thus the data used to commercialize the product. But, once the data are received, it is imperative that a marketer understands the implications of a case matched approach versus a cohort study.”

Michelle O’Connor, MEd, CMR, president, CEO, CMR Institute agrees that brand managers will also need the skills to interpret both humanistic and clinical findings and craft them into meaningful value statements for payers seeking to manage their patient populations. Studies will also have to be designed with this goal in mind.

“To fill the need for the data, more studies may need to include outcomes research relative to a patient’s emotional well-being and ability to perform daily activities following treatment.”

Thought leader John Guarino, senior VP, managed markets and payer strategy, at Palio presents five blunders to avoid when communicating with payers.

1. Repurposing physician-targeted visual-aids. There are many versions of this blunder. Some as literal as the actual rep piece, but also just rehashing the physician messages in a vis-aid that says “payer” on it can be almost as bad. Doctors treat patients, health plans cover members. You are trying to get a doctor to choose your product over all others and prescribe it for a particular patient. Payers are trying to determine if they need to make your product available for prescribing to a group of members. What is the best way to ensure that coverage is appropriate.

2. Using the 60-page payer deck. You wouldn’t dream of sending a rep into a doctor’s office with a giant clinical deck, yet that happens all the time with payers. The majority of the time, decks are bad marketing, their roots in the payer space comes from the reliance on some payer sales organizations to rely heavily on the medical group to communicate your clinical info. A pharmacy director once told me when I was an account director: “…you can tell how bad a company’s offer is going to be by how many slides he shows before he presents the offer.” If you have to have a deck, make it a good one — short, succinct messages and information directed at the audience. Then create a companion vis-aid. MLR loves decks and IVAs because you can’t leave them behind. Payers hate them for this reason. They are suspicious of marketing that they can’t have.

3. Using inappropriate messages. Convenience is not a compelling message for payers. Nor is adherence, unless you have data to show that there is a documented improved outcome. Sometimes manufacturers provide info to help portray what a particular patient type would be like a patient profile. Single patient examples for payers are not helpful and may actually harm your cause by limiting the payer’s perception of everyone who may benefit. Payers don’t see your co-pay card as aacea for people get their medicine; they see them as you trying to circumvent an important utilization management tool they use to try to direct members to therapies they prefer.

4. Using overly preachy messaging. Payers don’t want to be sold; they want to be informed. The tonality of payer messages needs to be more reserved and data-driven. Don’t put pictures of pharma beach on payer resources. Good data visualization and messaging that drives directly into the decision the payer will face are best practices to avoid these blunders. A big mistake that agencies make is thinking that they can throw a copywriter from the brand side on payer work and away they go. It is a specific skill set and one that takes time to learn and be good at.

5. Don’t abandon good marketing practices. There is a misperception that payer marketing isn’t sexy because we don’t draw pictures. There is a perception that agencies throw the baby out with the bath water and abandon good marketing to just dull down payer pieces. This marketing can be elegant and offers amazing opportunities for data visualization, impactful copy messages, and a lot of really cool digital expressions of information analysis.
“Brand managers will need the skills to interpret both humanistic and clinical findings and craft them into meaningful value statements for payers.”

MICHELLE O’CONNOR / CMR Institute

managed marketing team functions apart from the brand and HEOR teams, so brand planning takes place without the proper degree of integration between the teams and without any shared accountability, according to Joe Falcon, VP, managed markets practice leader, TGA Advisors.

“It is no wonder that in these companies, brand teams don’t focus on managed markets issues or understand the role and value of the managed markets marketing functions,” Mr. Falcon says. “However, when the managed markets marketing team is staffed with professionals who have expertise in marketing as a discipline, familiarity with marketing sciences, and a deep knowledge of managed markets customers, the situation can be quite different.”

Within organizations, brand teams and managed market teams need to collaborate to combine their expertise to bring a successful differentiationation message to the customer. This leads to a managed markets group that is trusted to spearhead a well-coordinated and customer-centric approach to the product’s launch and life-cycle management.

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