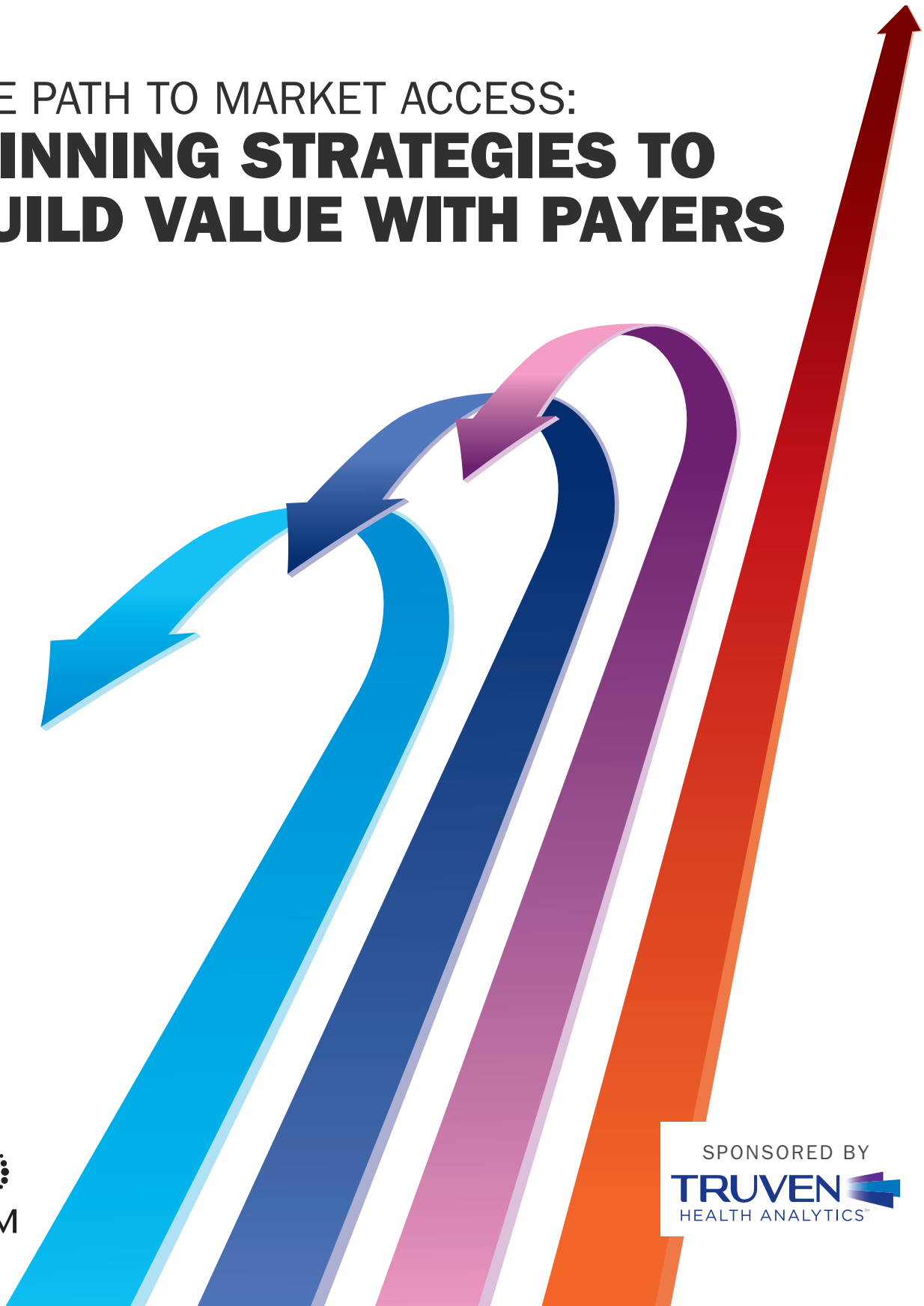
EBOOK FROM THE EDITORS OF Pharmaceutical Executive

THE PATH TO MARKET ACCESS: WINNING STRATEGIES TO BUILD VALUE WITH PAYERS



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Interacting With Payers in Value Evidence Development

In today's rapidly changing market access world, it's not just about developing solid evidence of the value of your product. Understanding your product's value through the eyes of payers and crafting your value communication around the needs and concerns of market access stakeholders is critical for success. Regardless of the constituency, you need to know 1) who the decision makers are; 2) their issues and concerns; and 3) how to actively use this information to develop and package your evidence effectively.

At a recent international health economic and outcomes research (HEOR) conference, a speaker from a U.S. health plan commented on his experience receiving 'variable quality' economic models. He offered an open invitation to industry model developers to provide feedback on draft economic models to help manufacturers improve their ability to communicate their value story in a meaningful way. So how often are models informed by stakeholder input during development?

Proactive dialogue with market access stakeholders, within the bounds of promotional and approval regulations, through face-to face meetings, and, more economically, through virtual advisory boards, must be part of a best-practice market access process. Clinical, HEOR, and Market Access staff who develop and prepare evidence for value dossiers, economic models, and published research need to know the profiles of key decision-making stakeholders and engage in meaningful interaction with them to ensure value demonstration evidence and communications are on target.

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MARKET ACCESS

CAN PAYERS AND DRUG INDUSTRY AGREE ON REAL VALUE?

BY ED SCHOONVELD

Recent developments in the pharmaceutical industry give the strong impression that both payers and industry are struggling to understand what represents "value" to our customers. The epicenter of many value discussions has been the United Kingdom, where three years of intensive discussions have sought to quantify the value of prescription drugs through Value-Based Pricing (VBP). However, the discussions halted abruptly over a rejection of the concept during a public consultation process, leaving the health economist community wondering what is next.

Value by numbers

Value is often said to be in the eye of the beholder. Perception of value can be very different between individuals with different functional perspectives (physician, patient, payer or other) and even between individuals with the same functional perspective. Value of health is very emotional and personal. Under the VBP concept, National Health Service (NHS) England and the National Institute for Health and Care Excellence (NICE) have been trying to essentially represent drug value in a single number in order to calculate a price. The initiative was intended to modify the existing cost per quality-adjusted life years (QALY) metric to incorporate a societal perspective. Arguing that one member of society qualifies less for treatment than others, on the basis of, for example, age, may remind some of the U.S. discussion of death panels.

After an initial broad discussion over the implementation of VBP (who would disagree with the concept of pricing on the basis of value?), the discussion evolved to building an analytical algorithm. Although scientifically perhaps sound, it has become very apparent that many of our customers will not accept an algorithm to decide on value and patient access to treatments in life-and-death situations. This has been the issue in many countries with cost-effectiveness cutoffs in the first place, as evidenced by rejection of this principle in the United States and Germany, and continuing challenges in France to making it a central component of coverage decision making. Adding an even more complicated multiplier further disconnects decision making from what we emotionally feel as important.

Customer value

What does constitute value to patients, physicians and payers? Particularly, the value to patients should be a critical driver in decision making. Payers and physicians should ideally have only patient value in mind when they make trade-offs in allocation of resources. They usually consider long-term outcomes the most significant measure of value. Surrogate end points, such as complete response rates in solid tumor treatments, are generally not proven a reliable predictor of overall survival. Payers therefore tend to insist on specific longer-term evidence of patient improvement, such as reduction in cardiovascular events for diabetes patients and LDL-lowering treatments or overall survival for cancer treatments. However, long-term outcomes data are not always easily obtained with the strict clinical trial guidelines from the Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Value demonstration at launch

At launch, we usually have only efficacy and safety data from randomized controlled clinical trials, rather than real-life effectiveness data that demonstrate actual value and cost-effectiveness. Most payers are fairly comfortable to judge value on the basis of head-to-head efficacy and safety data, but questions with respect to longer-term outcomes often remain. For example for anticancer drugs, median overall survival data supporting strong improvements may be only available several years after launch. Simply speaking, it is hard to provide data on the average survival of your treatment cohort when more than half are still alive! In few cases, payers are willing to provide market access on the basis of compelling surrogate end-point data, usually linked with agreements on further data collection. However, most payers are concerned that they will not be able to reverse availability of an expensive treatment when conclusive evidence of long-term effectiveness fails to materialize.

MA&P challenges

Pharmaceutical companies face significant challenges in meeting evolving and sometimes sudden new payer evidence requirements, which can result in suboptimal launch or even failure to launch in some markets. One of the more public examples of industry frustration has been the withdrawal of Trajenta by Boehringer Ingelheim and Lilly from the German market after introduction of Germany's price control law AMNOG. However, there have been many less

prominent examples in Germany and other global markets. A lack of mutual understanding between industry and payers drives much of this. What can payers and industry do to resolve this?

What can industry and payers do to reach out and improve the situation, so that patients get access to the most innovative proven treatments within a reasonable time frame?

Value and the drug industry

Payers often criticize drug companies for failing to generate meaningful evidence of health improvement claims. Many payers have recently tightened evidence requirements, for example the insistence of head-to-head clinical trials versus a meaningful treatment comparator in France and Germany. What can and should drug companies do to address this?

Payers have seemingly reasonable evidence requirements, but often also a very poor understanding of the drug development process and the implications of their demands on the likelihood of a new drug reaching their market. Many research organizations have a relatively poor understanding of payer perspectives and requirements, as well as strong incentives to ignore them as they may hurt timing to the next development gate and the probability of clinical success.

Based on the above, the drug industry would benefit from the following changes:

1. Ensure a stronger corporate-wide understanding of payers and market access and pricing limitations in key global markets. Functional organizations in big pharma tend to have a good understanding of the environment, but fundamentally impacting critical drug development decisions is often too tall an order.
2. The drug industry should engage closer with the payer community, explaining the trade-offs that companies have in drug development decision making, and the impact that payer requirements in individual countries can have on this decision making.

Value and payer decision making

Given the limited health-care resources available, how should payers make their trade-off decisions? Payer systems and priorities are very different from country to country and region to region. It is probably unrealistic to suggest a single solution, but I would propose some principles that allow for value to be included in decision making:

1. Evaluating value of a new drug treatment is complex and requires consideration of patients, physicians and payers. Given the multitude of stakeholders, a consensus-driven decision-making process is appropriate. Next to payers and physicians, patients and the pharmaceutical industry should be included. Patient organizations usually, at most, have an observing role in decision making, while they are the most direct representation of interest in the value offered. Pharmaceutical companies are generally absent, but should at least be able to provide information and perspective. Payers often complain that they have very little time to study a drug dossier in comparison with the multiple years that drug company staff has worked on the drug. Including the drug industry in the discussions may be useful to reach informed decisions.
2. Evaluations to support decision making should include an analysis of patient benefits across

the approved indication. Evidence should include what can be reasonably proven at time of regulatory approval; payer systems should allow for post-launch evidence gathering to further provide evidence of the benefits over time in appropriate cases.

3. Multiple-criteria decision analysis (MCDA) can be an interesting methodology to support decision making. At least in theory, it allows for a multifaceted review. As long as payers can resist the temptation to express the results in a single number, it can be a useful approach to support decision making.
4. Perspectives of value should ideally be societal, but at least include a long-term healthcare perspective, including long- and short-term medical and pharmaceutical interventions and patient outcomes. Pharmacy-cost-only silos still exist in many countries, including the United States, where pharmacy benefit managers (PBMs) can be the toughest negotiators on coverage.
5. Payers should have the discipline to control only drug reimbursement or coverage, rather than price. The pharmaceutical market is globally very interlinked through price referencing and parallel trade. Localization of pricing is only sustainable when price referencing and parallel trade mechanisms are abandoned or circumvented. Individual governments often struggle to see this.

The suggested solutions in this article are not all easy to achieve. At the very least, however, they could be part of a much needed discussion between industry and the payer community.

ED SCHOONVELD is Managing Principal at ZS Associates.

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PAYER LANDSCAPE

MASTERING THE LANGUAGE OF PAYERS

BY SYDNEY RUBIN

The first rule of effective communications — whether speaking to a beloved offspring or an important customer — is to know your audience. We must understand what motivates the listener, what they care about, what language will most likely persuade. Don't expect an argument on the importance of retirement savings to convince your teenage daughter not to buy a pair of costly jeans, and don't think that those making decisions on drug reimbursement will be persuaded by the traditional forms of drug advertising used to reach patients and physicians.

In today's world, payers lie at the center of a rapidly changing healthcare marketplace, increasingly empowered to make decisions affecting which drugs and treatments are prescribed. Their growing influence explains why old marketing communications models no longer get the best results. Market success now depends to a great extent on reaching and persuading payers. It is a business imperative, yet in some ways reaching this market remains an afterthought.

Market research studies by CAM and IMS Health reveal that most monitored promotional spending still goes toward detailing and samples for physicians, even though GPs in particular have lost influence over market access decisions. A survey conducted last year of

pharmaceutical marketing directors showed they were still allocating about 75% of their total budget to healthcare professionals and 25% to consumers. Pharmaceutical companies spend large sums of money on payer rebates without investing the time or resources needed to understand payer priorities and decision-making processes.

To prosper in today's environment, pharmaceutical companies should be investing the same effort and budget to gain insights into payers as they once devoted to physicians. We need a clear understanding of the payer as customer.

The good news is that we already have all the skills required to deliver persuasive payer communications. We're experts in market research and healthcare communications, we're scientists experienced in developing data and we know all about diseases and patients. Now we must translate everything we do into language linked entirely to value as it is defined by people deciding what products to reimburse and how much each is worth.

This is translation destined for an audience unlike any other. The number and variety of stakeholders within the payer community continues to expand with new players such as accountable care organizations (ACOs), medical home plans, integrated delivery networks, and new risk-sharing HMOs joining the traditional payers, public and private organizations, employers and individuals who buy healthcare products and services. Each has its own particular needs.

And even within each of these diverse organizations that are sub-groups, departments within payers with their own goals. Often operating in silos, these departments may not all have equal access to information on benefit and cost required to make formulary decisions and may be focused single-mindedly on their own departmental bottom-line. Successful commercialization means not only understanding the differing needs of each payer group, but also having insights into the internal operations of each. Only through this sort of insight can we know what form of communications is most appropriate and effective.

One thing all payers have in common, though, is the need to deliver value, defined as better outcomes at a lower cost. All payers are faced with reducing spend while costs continue to rise faster than their ability to increase premiums. Understanding the specific pressures they face is the place to start developing messages.

Messages today are a long way from the "old" days when payers only needed to know that a drug was effective to add it to their formulary. Now, we must demonstrate value in both the short- and long-term using comparative data, such as head-to-head studies and real-world results, which is more meaningful for this audience than data from controlled clinical trials.

Payers have been quite clear in their demand for comparative effectiveness data and analysis. Many contend that the data they receive from manufacturers is not sufficient to show real evidence of value. Like everything else in the current marketplace, beneath the surface, the commitment of both sides around data-driven evidence tends to be fuzzy and contingent. Although payers and pharmaceutical manufacturers are publicly open to more dialogue, privately there are still numerous conflicting agendas. Payers want to maintain as much flexibility as possible in making reimbursement and formulary decisions and have little interest in any proscribed, rigid definition of value. Industry is still not organized institutionally to guarantee outcomes and is concerned why it bears all the risk if it cannot demonstrate unequivocal results. Despite feelings of ambiguity,

payers are demanding information companies must work harder to build their in-house expertise on comparative effectiveness.

Comparative effectiveness research isn't new. Most companies have health economics departments that gather it. Until now, however, these researchers often had little interaction with the customer-facing side of the business. That's changing. Pharmaceutical executives are starting to tap into this research and combine it with Big Data, often from government research, to deliver budget impact modeling and richer communications.

Such aggregated data is useful, but even better in demonstrating ultimate effectiveness and cost in a value equation is the research we do ourselves. In countries like England and Germany, with single-payer systems, this research is routinely done. In the United States, we have been less diligent in delivering original research that shows the ultimate value of our therapies – so payers press us for discounts as the shortest path to savings.

It is imperative that we begin including value outcomes in early clinical study design. If we develop a drug that will decrease hospitalization, we have to include this in the pivotal trial. Adding value outcomes to approval trials gives us credible data to deliver to payers, helping them do their jobs and make good decisions for patients, while supporting our own formulary goals and market success.

A few companies have begun investing heavily in payer research groups and risk modeling. They recognize the importance of knowing the decision makers for a product, understanding what they specifically care about and building the tactics likely to produce desired results. Armed with data showing how a drug saves in other healthcare costs, they are well positioned to make a persuasive argument for the price of a drug or device.

And we're all seeing how this can be done within the FDAMA 114 guidelines that:

- Acknowledge that discussions about drugs are different with payers than with healthcare professionals;
- Allow for conversations about the broader impact of a drug based on reliable data that makes direct comparisons;
- Are not a license to talk off label, but do allow discussions about value.

One final note: In our efforts to better reach payers, we must not lose focus on physicians. Some of the new providers in U.S. healthcare, like ACOs, encourage teams of physicians and hospitals to coordinate their efforts on behalf of health consumers. Physicians' opinions still matter and they, too, are looking for dramatic improvements in clinical outcomes.

Payer and market access strategy should be approached with the same rigor and processes as traditional commercial strategy. Market access strategy must be developed in close coordination with brand strategy from the outset. We must have deep familiarity with the needs of payers and a mastery of the language that matters. In short, to succeed, we must speak payer.

SYDNEY RUBIN is the Chief Communications Officer of inVentiv Health.

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COMMERCIALIZATION

THE END OF PHARMA MARKETING—OR A NEW BEGINNING?

BY SUSAN MCDONALD, SANJIV SHARMA

FDA licensing approval is often touted as the essential marker of a new drug's success—but what counts far more is the skill of the developer in ensuring physicians, patients, and insurers know about the product to the point they are willing to do three things: prescribe it, pay for it, and use it. Making this connection is the function of the marketer, whose arts of persuasion are being tested by intensifying therapeutic class competition, disclosure rules on promotional spend, and access and reimbursement controls driven by a selective—and often contradictory—definition of "value." In the following Q&A, *Pharm Exec* Editor-in-Chief William Looney talks to two prominent commercial marketing experts, Susan Schwartz McDonald and Sanjiv Sharma, on how this mission critical function must change to stay relevant in bringing the next generation of therapies to the patients who need them.

PE: Disruptive change is the central dynamic that drives virtually everything in today's go-to-market toolkit. Can you trace the evolution of how we got to this situation, where the only certainty is uncertainty?

Sanjiv Sharma: Pharmaceutical history's "modern age" began in the 1970s when a shift from the traditional "sales model" to a "marketing model" converged with an era of exciting science. The next several decades saw a cavalcade of market-leading therapies that revolutionized modern medicine—iconic drugs like Inderal or Mevacor that have been all but forgotten by later generations of marketers who cut their teeth on the fourth-in-class therapies that followed. The word "innovation" wasn't yet in vogue, but those days were, in many ways, the best of times.

Looking back, it might be tempting to conclude that early blockbusters of the '80s and '90s were good enough to "sell themselves," but it took genuine marketing vision to make investments in critical outcomes research and blaze the trail for game-changing strategies like DTC. Subsequent decades put marketing to the tougher challenge of promoting drugs whose margins of improvement were more nuanced, but those efforts were still handsomely rewarded so long as healthcare spending remained unchecked.

Susan McDonald: In today's more austere budget environment, customer willingness to pay for minute distinctions is diminishing, while market access trumps marketing savvy as the driver of sales. We might almost be ready to say a eulogy for the very concept of "marketing," were it not for several other equally important trends, including the growing power of the patient, the role of digital technology, and the potential for new paths or processes to speed the transition from bench to clinic. At this watershed moment, we need to be thinking hard about how marketing must be redefined to remain relevant.

PE: Posing questions about the "end of marketing" suggests you both are a bit pessimistic about the future of traditional practices in marketing new medicines. Is there a right philosophical and tactical approach for an industry confronting challenges like these?

Sharma: Our question is inspired less by a sense of pessimism than by a recognition of opportunity, and at the same time, a concern that marketers may not be adapting fast enough to some of the new realities. The signs are everywhere—we're in a period of transition even more profound than that shift 30 years ago from the sales model to the marketing model. The industry is already bidding farewell to the "blockbuster" as we once defined it—i.e., drug therapy for common ailments or widespread prevention—and embracing the concept of niche market products, often priced at a much higher premium. We also know that the regulatory environment will be increasingly inhospitable to drugs that have small incremental benefits; it's clear that payers are looking for differentiating value that they can measure right out of the gate. That explains the swelling ranks of orphan drugs (nearly 200 of which could be approved in the next few years alone), and it also accounts for a new interest in drugs that work very well on only small sub-populations of diagnosed patients. Everyone understands that they need to reframe what commercial success looks like and rethink how to get there. It's not so much that we are defining unmet medical need differently; it's that we are defining solutions differently, in terms of a higher certainty of benefit or showcasing a solution that carries a unique value proposition.

"There is probably no other market with more complex mediation between manufacturer and end-user than the healthcare sector."

—Sanjiv Sharma, InflexionPoint LLC

McDonald: We actually think there is plenty to be upbeat about. One cause for optimism is the science—which ultimately drives everything. Strides in cell biology and advances in proteomics are helping us reconceive big diseases as a series of smaller targets that we aim to hit with greater precision. Science, social policy, and economics are all leading us fundamentally in the same direction—toward a new way of thinking about the drug-value proposition. "Marketing 2.0" in the pharmaceutical industry is no longer about just saying that our product is different and hoping customers will see it that way. It's very much about making it so—and then about finding our way at launch to customers with a "conversation" that actually helps create the value rather than just promoting it. All of which means we need to develop new, end-to-end processes that shape both the "genetics" of our new drugs and the "epigenetics" of the launch environment.

PE: What is the single most important change needed in our industry to create that value and realize the potential of "Marketing 2.0?"

McDonald: Given that much of the marketing cycle is now focused on launches, you've got to start the discussion by talking about the "epigenetic" factors that influence the health of a brand. By Phase III, the drug development process has pretty much dealt you a hand and now you have to play it.

So what must pharma marketers today do differently? The single most important change requires a transformative, born-again credo that replaces traditional "product-focused" marketing with a "customer-focused" model. Customer focus is something that receives much lip service but is actually challenging to adopt and execute with consistency. It's not enough to just say it; you have to live it. To walk that walk, companies, need to be rethinking not only about how they go to market, but just as much, how they are organized to develop and launch their products. Customer focus is something that has to be embedded in the business culture.

In a product-focused marketing model, everything is all about you— what your product does and how it suits you to deliver your product and your message. A customer-focused marketer takes a hard look at what customers want and need, really assimilates it, and then looks closely at his own way of operating through that customer lens. Customer-focused marketing is not just about looking for points of existing alignment or trying to change the customer so he fits your world, which has been the defining modus operandi of traditional product-focused marketing.

"The sales force has been a very good hammer for our industry, but we are starting to recognize that not every sales problem is the same sort of nail—or needs to be hit quite so many times."

—Susan McDonald, NAXION

The first thing it requires is listening to, and really hearing customers, even when what they tell you seems at odds with your conception of commercial success. Simply calling your market research "customer insight"—which has been all the rage since the start of the millennium—doesn't get you all the way there. It's what you do with the answers. People have a tendency to keep asking the same question over and over until they get an answer they like. In our travels, we've both seen many valid insights discarded or ignored because they didn't fit the marketing team's aspirational view of the market, and it seemed too hard to make good use of them. Part of the problem, of course, is that our end-user, the patient, really doesn't want to take medication. It feels like a form of bondage. Patients complain about that sense of diminished autonomy all the time and they often abandon therapy simply to regain their "freedom." As a result, we have gotten used to discounting some important things our customers have been telling us all along.

The concept of customer focus is an especially complex and challenging one in the pharmaceutical industry because we have less freedom with respect to how we "engineer" our solutions and what we say about them. And if you try to take a lesson from Steve Jobs' missionary approach to innovation in the digital space, you have to acknowledge that there is always a paradox between giving customers what they appear to want or say they want, and giving them what you know they ought to want, or what they really will want once you use innovative technology to retrain them. In other words, you have to be sensitive to the risks that customer focus, if not applied imaginatively, will perpetuate the status quo in a way that profits no one.

If years ago, we had actually listened to customers when they told us that they didn't like monthly dosing because it was too hard to remember, we'd have really missed the boat. Some people did miss it. The trick is to hear what customers want to experience since they can't always evaluate the mechanisms you are developing to get them there. That is precisely what Steve Jobs understood better than most people. Whether or not he did market research was beside the point; he knew what to look and listen for when he thought about "customer needs."

PE: What does "customer focus" mean in a complicated market ecosystem like healthcare, with different types of customers who don't necessarily have the same agendas or priorities?

Sharma: By the time you get to market, the DNA of a drug is already fixed, but there is still a great deal we can do to influence the customer experience at launch and after. The question is: what and who is meant by "customer?" There is probably no other market with more complex mediation between manufacturer and end-user than the healthcare sector. Clearly both payers and clinicians continue to control market access, though in very different ways. But the single biggest change we've seen in this market is the growing power of the patient, who is now very much in the conversation, thanks to digital information and social media.

Another critical change is dwindling sales access to providers, and looking ahead, a future in which they will have less decision-making latitude than today. (We're going to set aside payers for the moment because their definition of value is relatively straightforward, even though their calculations are sometimes opaque.) The theme, of course, is clear. Information delivery is changing everything. Information is no longer just about the product; it is an integral part of the product, and it is even an integral part of the distribution system, too. That's true in just about any market we can think of.

But because we are talking about an alignment of needs between pharmaceutical marketers and multiple customer groups who interact in complex ways, we need to be thinking not just in terms of traditional product positioning—i.e., what is the most persuasive thing we can say about our product?—but rather, we need to be thinking about "value zones" drawn more broadly and more holistically, based on how the overall product proposition maps to the complex profile of customer needs, objections, and routine behaviors. It is not just about identifying key benefits; it is also about understanding and dealing with limitations in a constructive and realistic way. That requires us to look for the areas of easy alignment and—potentially even more important—pay close attention to those borderline areas where alignment in any direction could conceivably be improved if we're willing to revisit our assumptions or adjust the solution we offer customers. Ethnographic insight on provider environments and patient lifestyles can play a key role here, but really, value-zone modeling is not about a method of research, it's about a method of thinking.

To set the stage, we have to develop a dynamic market map for every product depicting those alignments and anticipating how different customer groups will enable or impede one another. That allows us to devise a unique customer value strategy for every launch that reflects the interplay of patient, provider, and payer. Every new product needs one of those models, built on market intelligence that predicts vectors of influence and patterns of alignment across the market, because different customer groups overhear what we say and react very much to one another. This new world is multi-dimensional, not flat.

PE: What are the practical implications of using this kind of" value zone map" to guide launch strategy?

Sharma: What ties it all together is, of course, communications. For marketers living in the information age, that's the critical tool in the kit. If we think in terms of customer solutions, then how and when we communicate about our product, and what sort of ongoing dialogue we have with customers, are not just tactics—they are value drivers that differentiate our brand.

Everyone agrees that the patient is increasingly at the center of this ecosystem because the patient is clearly more engaged. They are accessing more information on their own, and shouldering more of the cost. Patients need to be made aware of their options and supplied with the kind of information that pertains directly to them and their treatment before they leave the provider's office with a script or a recommendation in hand. The data suggest that patients are far more likely to do a drug search after an MD visit than before, and that what they learn in those searches will influence the rate of script fulfillment.

Just as important—maybe even more so—is what happens after the script is filled. We believe that pharma manufacturers have to be thinking in terms of customer relationship management (CRM) as a strategy, beginning with the information they deliver at launch, the co-pay subsidies they offer, and the ongoing support they provide to patients in order to cultivate loyalty. Sanofi now has a chief patient officer. We believe that this sort of thinking, and the willingness to translate it into organizational structure, is critical.

One key challenge is that patients have traditionally "trusted" pharmaceutical companies less than many other information sources because they believe them to be self-interested. And it happens that the pharmaceutical industry as a whole has never done a very good job of image management. The industry has been so busy managing its relationship with regulators that it has never paid serious attention to the broader public in a way that some other industries have done. Ironically, it's partly because the pharma industry refuses to recognize that patients are as scared and resentful about drugs as they are grateful for them—again, the "bondage" idea.

But one dynamic in this new environment is the potential to redress that balance. Payers are increasingly going to take a lot of heat for "withholding" premium therapies which patients might want but can't afford. Co-pay support and patient engagement programs have the potential to change that, and help patients believe that pharmaceutical manufacturers are looking out for their interests. We don't need to be the villain in the piece anymore.

In order to make this work on the individual brand level, you've got to structure your launch in a way that optimizes the "value zone map" and then you've got to engage with patients immediately after launch to understand how the experience is unfolding for them so you can remap based on in vivoexperience, if you need to. Even within the first few months of launch, you need to seek out patients who have failed to fill scripts or abandoned therapy to get the best shot at early course correction—whether it's access issues (including distribution), titration challenges, or critical information gaps. Companies can't be afraid of adverse event reporting here or they will miss a very important opportunity.

PE: Given the importance of communication as a CRM platform, what is the right role for the sales force in a new digitally enabled environment—especially since provider autonomy will almost certainly diminish in the coming years?

McDonald: Clearly, we need to think about communications as the key to CRM with all our customers, which means we also need to rethink how we engage with providers too—not just because we're resource-constrained, but because we need to optimize their experience. As

we've said, information is a critical component of that experience. The sales force has been a very good hammer for our industry, but we are starting to recognize that not every sales problem is the same sort of nail—or needs to be hit quite so many times. Personal promotion is never going to be completely replaceable in our industry, but what we are seeing now is a long overdue correction. The future of marketing in our industry requires us to think strategically about where the sales force can be most effective—for instance, in introducing paradigm shifts—and where other tools, especially digital channels, can deliver better ROI. That can mean shifting resources away from traditional selling to digital communication serving up information when customers really want it, and not when it's convenient to deliver. Several successful launches, including the first major launch in the woman's healthcare space in many years, have used that to very good advantage.

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Digital selling also gives us the agility to manipulate messages and formats, and then track the results with analytic tools that link click-through messaging (patients) or online details (providers) to prescribing trends by community. Nimble communications represent a win-win that can bring customers and marketers into the same value zone. And we'll get better at it if we use digital channels as a way of learning about marketing effects, not just as a way of disseminating our messages. Digital strategies are not just megaphones, they're telescopes.

The use of more cost-effective and convenient methods of communication with customers can only become more critically important as networks become more accountable for cost of care, and individual providers themselves justify less direct investment. We are, by now, quite accustomed to pleading our case and cutting deals with payers. Once provider networks assume more of the cost and risk, we can expect a more centralized, cost-based decision-making process from them too—but structures, philosophies, and cultures will differ. It's very early days, and we need to be studying their evolution like good anthropologists so that we can decipher patterns of internal influence within, and respond appropriately. Long term, this trend may create new opportunities for influence mapping within large organizations, and inspire an approach to sales force deployment that places greater priority on institutional knowledge than specialized product knowledge. Specialized product knowledge can be delivered in a variety of ways once we know the lay of the land.

PE: Do the same rules apply for more specialized therapies, like orphan drugs, or in oncology, where evidenced-based principles appear to leave much less room—or need—for new ways of thinking about customer value?

Sharma: It's true that drug marketing inhabits a therapeutic continuum from "authoritarian"

science on one end to customer "democracy" and self-direction on the other. Sometimes the evidence is so clear and the clinical constraints or obligations so compelling, that marketing has only a small corner seat at the table. No one is going to argue that a drug that meaningfully extends life for melanoma or ovarian cancer patients will owe its commercial success to marketing. Even so, we are seeing evidence that drugs which extend life are sometimes being rejected by patients because the cost-benefits are not persuasive—whether the calculus is based on financial considerations or quality of life. Oncologists tell us that these conversations are occurring more often in their office, which means, in effect, that every aspect of the customer's own micro-environment will influence their experiences and their therapy choices. Information and empowerment are going to become increasingly important there too. The entire business model of the Cancer Centers of America hangs on that understanding.

PE: Looking back upstream, to earlier stages in the commercialization process, what needs to change there in order to get a head-start on customer-focused launch marketing?

McDonald: In consumer products marketing, we preach the gospel that marketing needs to guide product development, not merely optimize it. And of course, it's much easier to do that with engineered technologies where more can be controlled. For years, the industry has been mindful about the potential for guiding clinical trials by using marketing intelligence to value alternative indications or endpoints, and some companies are more proactive than others, but the process, overall, has lacked consistency, discipline, and coordination. So the time has come to really walk that walk too—by shifting from a discovery mindset to an engineering mindset, where everything comes together sooner in a more coherent, systematic way. We certainly can't de-risk the process entirely, but our preclinical molecular screenings need to be more ambitious so we can really advance the best compounds with improved candidate selection and better molecular engineering.

We also need to make some critical organizational changes by restructuring our commercial and clinical functions so that they are truly integrated, not just "collaborative." Too often, there is both a commercial team and a clinical development team and the two may seem to walk down the path arm in arm but in practice, those teams are not always thinking or seeing quite the same things.

More work also has to go into the development of a disciplined minimum acceptable product profile (MAPP) and target product profile (TPP) in the earliest clinical stages. Even Phase II profiles need to be modeled in ways that give us greater clarify of understanding around what it might mean to miss or exceed the mark. The quality of that research is often subpar for a variety of reasons: poor internal communication, poor communication with research consultants, and poor planning, among other things. Some of our newer techniques allow us to build models with smaller sample sizes but in order to take advantage of those tools, you need a team that is thinking very hard in a structure that maximizes information exchange, candor, and collaboration.

This shift from discovery to engineering mindset will also be enabled by sophisticated biomarker technology and better biochemistry screening to tailor drugs very early on for

appropriate subgroups and market applications. We're going to have to think about this in reverse—not developing drugs and looking to biomarkers to confirm benefit, but developing biomarkers to guide our development path. To get full ROI on our investments, we need clinical trial strategies that shift from one-size-fits-many to a more segmented approach, in which you prove higher, or more predictable, value for smaller groups of patients. There is much talk about personalized medicine these days but at the moment, that's really a misnomer. To borrow an old marketing term, it's really about segmented medicine—deconstructing the market into clinical subgroups with biomarkers suggestive of a particular therapeutic solution.

PE: Does the credo of "customer focus" mean that pharma companies need to reinvent themselves more broadly to become "healthcare solutions" providers—and, if so, what scope of innovation is required to accomplish it?

McDonald: Frustration is inspiring a lot of creative thinking about what pharma companies should really be in the business of selling. It's one thing to say that you are going to provide data and tools that support your drug, and quite another to say you are going to manage patient health solutions with a portfolio of drug and service options, including behavioral interventions. Are pharma companies properly structured and situated to design those holistic solutions, or do they really need to focus on designing the "plug-in" technologies that support broader health initiatives? Is the pharmaceutical company of the future an Apple that creates environments or an Intel that powers them?

The answer depends on whether, as an industry, we are willing to broaden our innovation mandate and make it our business, literally, to scan the environment for disruptive technologies that restructure various aspects of healthcare delivery. Once again, that kind of disruption is not going to come from bench science, it's going to come from bioinformatics.

Consider the call by the XPrize for smartphone-enabled diagnostics that match or improve on physicians' clinical assessments. That challenge is the logical extension of a trend we are already seeing among consumers: evidence of a growing appetite for information about their bodies that they can use to guide daily decisions or second-guess professional ones. Digital measurement and data modeling technologies that can routinely measure and interpret physical information blurs the line between patient and consumer—and it will extend their autonomy whether or not the healthcare system or its regulators think that's a good idea. Information, including esoteric information, gets cheaper and more accessible by the day. All the stakeholders in this system will need to think about how to organize themselves around new channels and vectors of information that bypass established authority and release patients from that sense of bondage they experience. At the top of the old-fashioned benefit ladder for consumers is control over the destiny of their bodies. We've been hearing customers say it for years but we never paid serious attention to it.

Sharma: There is an important message here for pharmaceutical companies of the 21st century. Already the big companies are leaving much of the drug discovery process to smaller, more nimble organizations. Part of their mandate needs to be scanning the environment for disruptive technologies and thinking about ways of integrating them with products they bring to

market. IBM Watson-type computing has the potential to truly customize dosing, for instance, in a way that gives reality to personalized medicine. The possibilities are as numerous as the number of disruptive technologies we can spot, and the odds of success are daunting—especially in a regulated industry where optimal consumer health is the ultimate benchmark of success.

Still, this puts the onus on pharmaceutical companies at the highest level of management to be on the look-out for relevant technologies of all kinds and be organized to make the most imaginative commercial use of innovation—platform as well as product; and digital as well as clinical. This way of thinking and behaving is what we will need to get past this emerging era of Marketing 2.0 to the next quantum leap—which is quite likely to require the reinvention of the pharmaceutical company. Whatever enabling technologies drive that reinvention, we can be assured that delivery of enhanced customer experience in the very broadest sense will be both the driver and the measure of success.

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STRATEGY

THREE 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 physician 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.

HOWARD DEUTSCH, Associate Principal, ZS

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