Robin Robinson

YEAR IN PREVIEW: PAYERS

Addressing the Needs of Payers

Helping payers contain costs and improve outcomes becomes paramount for pharma in the healthcare reform future.

ccording to an EY report, the majority of payers in the United States and Europe believe that drug adherence solutions and data that pharma

companies possess are vital to lowering healthcare costs and improving outcomes. However, the pharma industry will need to change its model of interaction with payers in order to earn payers' trust and gain traction for their beyond-the-pill adherence programs.

"More than ever, payers today need to help with implementing healthcare reforms," says Patrick Flochel, global pharmaceutical leader at EY. "While pharma companies have useful data and potential solutions in areas such as drug adherence, payers simply don't trust that they have the impartiality required. The good news is that payers are open to evolving the types of interactions they have with pharma companies from simple negotiations around access and price to more strategic, enduring relationships around their biggest challenges."

The payer landscape is complex and fragmented across geographies, but two major needs rise above all others for payers of all types. Mr. Flochel says the first is to ensure that costs are put on a sustainable trajectory and second is to enable better outcomes.

Consequently, pharma companies must ensure that their solutions revolve around these two goals. To address these needs, there is a need to design customer-centric solutions that span the patient's journey through the health ecosystem going beyond individual products and services.

"Companies can use their expertise and real-world and comparative effectiveness data to complete the picture, enabling better selection of treatments while targeting pockets of patient populations that drive the biggest costs," he says. "However, the industry must also work on restoring trust since without trust, pharma companies' data and solutions will get little traction with payers." At GSK, this has meant working across the company to review data and incorporating the payer voice earlier in the R&D process, including payer advisory boards that provide feedback before medicine candidates reach Phase II development.

"Specifically, GSK focuses on comparators, endpoints, and target populations from a payer lens," says Mark Johnson, VP of payer marketing, policy, payer, and vaccines division of GSK. "Payers are operating in an increasingly challenging environment with greater pressure to contain costs. This makes it more important than ever for pharmaceutical companies to deliver medicines of value to the payer, the patient, and the physician."

Addressing Costs

Many major pharma companies are altering their R&D strategies to respond to pricing pressure from payers. This has led to some striking innovations in corporate structures and organizations, especially in pharma companies' relationships with outsourcing partners, says Michael Griffith, executive VP, in-Ventiv Health, and president, inVentiv Health Commercial.

"The purpose is to increase the drug maker's flexibility in deploying investment capital, advanced R&D tools, human expertise, and other resources," Mr. Griffith says. "Large pharma companies today manage a dozen or more key research and manufacturing partnerships, each of which entails countless high-level conversations and negotiations. The complexity of these relationships slows down operations, adds inefficiencies, and increases costs."

In 2015, however, the major pharma players will seek partnerships with larger, more diversified outsourcing partners that can help them streamline this overhead, while shifting costs from fixed to variable, reducing operating costs, raising research productivity, and



" The pressure is on pharma to show real results, and companies must shift their mindsets from providing pills to providing surround-sound solutions. "

WENDY BLACKBURN / Intouch Solutions

thus responding more effectively to pricing requests from payers. Relying on comprehensive partnerships with CROs, CMOs, and with a newer type of contract arrangement covering commercial services, pharma companies will be able to expand or contract their pools of expert resources and execute at greater or lesser scale as the market requires, Mr. Griffith says.

"Companies need to be cognizant of the fiscal realities, and the resources available to provide treatment to patients, when considering how their product will be sourced, manufactured, and administered," says Zami Aberman, CEO, Pluristem Therapeutics. "If different cell therapies can be produced from one cell source, or if an efficient manufacturing process is developed, this further reduces the costs of effective therapies."

According to Steve Stefano, managing director, Ashfield Market Access, the best way to address the needs of payers is to price medicines commensurate with their value.

"Payers need to understand the value of the medicines they are reimbursing, so this pricing needs to be supplemented with the best data available as it relates to comparative studies, health outcomes, and pharmacoeconomics," he says.

Companies that fail to deliver HEOR that justifies the value of their products and meets the needs of payers could face formulary exclusion by the more sophisticated payers, therefore, biopharmaceutical companies will need to develop new, targeted strategies to meet payers' demands for this valuable information, says Robert Shewbrooks, principal

Cost is No. 1 Payer Concern

EY conducted a survey of U.S. and European payer organizations and pharmaceutical companies and determined the following:

- Payers are focused on cost containment and budgetary predictability over outcomes-based approaches.
- While prescription drugs only account for about 10% of healthcare expenditures, payers see curbing rising drug costs as a more important business challenge than non-drug costs.
- » 88% of payers strongly or somewhat agreed that "drug prices are a major driver of healthcare cost increases," while only 42% of pharma respondents reported the same.
- >> 78% of payers agree that "boosting drug adherence is a critical component of lowering healthcare costs" and 57% agree that "pharmaceutical companies have data that is vital for measuring and improving outcomes."
- » Only 43% of payers agree that pharma's data are credible for measuring and improving outcomes.
- » Most payers do not think that pharma companies developing beyond-the-pill services can be unbiased between their products and those of competitors, with only 15% of respondents even somewhat agreeing with that statement.

Source: EY. For more information, visit ey.com

66 Creating powerful value propositions is the catchphrase of the day, but the task is easier said than done. **))**

ANNA MCCLAFFERTY / TGaS Advisors

and practice leader, syndicated research, at HealthStrategiesGroup.

"Payer use of HEOR varies based on the availability of data and cost pressures within each category and drug exclusions, which will become more common in competitive therapeutic categories," he predicts. "Health plans use comparative effectiveness studies to make formulary decisions for hepatitis C agents, anticoagulants, breast cancer agents, rheumatoid arthritis treatments, and other high-cost categories."

Building Value for Payers

More than ever, meeting the needs of payers is a primary focus for pharma, says Anna McClafferty, senior VP, executive commercial operations practice, TGaS Advisors.

"However, companies are also taking a fresh and intensified look at how they can better engage with organized customer groups as the influence of these corporatized providers increases," she says.

In a recent landscape benchmark, TGaS found that more than 80% of mid- and largetier companies are piloting or implementing new approaches to resonate with, deliver value to, and allocate promotional resources to this growing customer segment. These efforts truly qualify as a new commercial model, requiring unprecedented teamwork and insights generation capabilities across marketing, sales, and managed markets functions.

"Creating powerful value propositions is the catchphrase of the day, but the task is easier said than done," Ms. McClafferty says. "Tradition and process that focus heavily on

Containing costs and enabling better outcomes are the two major payer needs that emerge above all others across geographies. J

PATRICK FLOCHEL / EY



44 Observational studies and comparative effectiveness research have become critical means to describe clinical practice and to measure safety and value. **33**

> DR. ANNETTE STEMHAGEN United BioSource Corp.

establishing efficacy and safety, barriers to transparent and timely discussion with payers about products in development, and disconnects between R&D and commercial are just a few of the challenges companies face. Developing and funding new mindsets, business processes, ways of working and decision approaches across R&D and commercial are all essential to success."

Beginning as early as clinical trial design, pharma companies must communicate value and at every step in the process of drug development, not only at the time of launch. This

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Health systems are looking for new approaches to disease intervention and patient population management, and pharma companies can deliver these through tailored patient-centric programs.

ERIN CURCIO / Daiichi Sankyo

approach allows a pharma company to add value by addressing payer concerns that go beyond the product, says Jonathan Wilson, president of the strategic communications firm Spectrum. Lack of adherence to medication is a chief payer concern and to address this, pharma must demonstrate its dedication to providing services that will increase adherence, with the use of digital tools and other creative approaches to connect with patients, and to ultimately increase the value of the medication.

"We can learn from industry experience in the EU, particularly in Germany and the UK, where payer demand has resulted in infrastructures geared to longer-term positive outcomes that prove economically efficient," Mr. Wilson says.

As payers undergo a transformation that materially impacts the way they evaluate medications and develop formularies, pharmaceutical companies also need to adapt to the changing needs of payers to continue to be successful in the ever-changing healthcare landscape.

"Value propositions for medications must continue to clearly articulate core payer elements such as safety, efficacy, and appropriate patient populations," says Richard Black, executive director health systems marketing at Astellas Pharma US. "However, due to changing needs of the payer, value propositions must also establish relevancy for the medication via linkages to quality measures and health economics outcomes research as well as real-world evidence evaluations."

For example, Astellas has achieved great success with non-pill payer solutions focused on quality measures, he says. Tools to help payers evaluate their quality measure performance versus their competitors, as well as discrepancies in quality measure attainment across various geographic areas, have offered meaningful metrics to further discussions around improving quality of patient care.

GlaxoSmithKline has also taken steps to offer healthcare services beyond the pill. In 2012, the company implemented a Patient Centered Medical Home pilot with its own employees in North Carolina with Community Care of North Carolina (CCNC).

According to Martin Marciniak, VP of US health outcomes and medical policy at GSK, Patient-Centered Medical Momes allow a patient's primary care physician to coordinate with the patient's various other providers using health information technology, best practices, and care managers.

And in 2013, GSK collaborated with CCNC on a pilot to co-develop prescriptive analytics tools that identify patients at risk for medication challenges in real time to help providers determine effective ways to overcome barriers to quality care.

"Counter to healthcare trends focused on big data, this pilot's small data approach focuses on integrating analytics into practice with relatively small data requirements, such as a patient's prescription fill history and hospital admission and discharge data, to help prevent negative health outcomes, all while protecting the patient's information and privacy," Mr. Marciniak says.

JACKIE KWONG / Daiichi Sankyo

44 Research investments made by pharmaceutical companies must generate data that are relevant to healthcare payers. **33**

Jackie Kwong, senior director, health economics and outcomes research at Daiichi Sankyo, says engaging healthcare stakeholders by seeking their perspectives during early stages of clinical development can build value for healthcare decision makers.

"In conjunction with the regulatory evidentiary needs, payer perspectives should also be considered when designing clinical trials such that a relevant comparator is included, and data that are meaningful to the payer audience, such as hospitalizations, are collected," she says. "As funding for comparative effectiveness research increases, research activities proliferate, and the era of evidence-based medicine prospers, it is very important to make sure that research investments made by pharmaceutical companies will generate data that are relevant to healthcare payers so that they can be useful to inform reimbursement policy and healthcare decisions."

Furthermore, during a product's lifecycle, pharmaceutical companies can collaborate with health plans and institutional healthcare providers, for example, accountable care organizations and integrated delivery networks, to conduct outcomes research to assess treatment effectiveness in the real-life setting, Ms. Kwong adds. In addition, pharmaceutical companies can work with healthcare stakeholders to understand any potential challenges associated with the use of therapy in different healthcare settings, such as medication nonadherence or inappropriate use, and jointly develop solutions to overcome these challenges.

Payers must make informed choices regard-



44 An open dialogue with realistic expectations and demonstrated benefit to the health system helps both payer and the perceived value of the brand. **33**

RUSSELL POWTER / Cello Health Consulting



Manufacturers need to find a legitimate way to promote the effectiveness of their drugs that includes the type of information payers need.

RICHARD TREZZA Ogilvy CommonHealth Payer Marketing



44 Companies need to be cognizant of the fiscal realities when considering how their products will be sourced, manufactured, and administered. **37**

ZAMI ABERMAN / Pluristem



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STEVE STEFANO / Ashfield Market Access

ing the reimbursement of novel medicines or medical devices that balance significant drug acquisition costs with care outcomes, including patient safety and effectiveness. To inform these often difficult decisions, payers require tangible and robust, real-world evidence of benefit and, increasingly, of incremental benefit versus the standard of care. Study designs tailored to evaluate patterns and outcomes of care are clearly warranted.

"Observational studies and comparative effectiveness research (CER) have thus become a critical means to describe clinical practice and to measure safety and value, the latter encompassing aspects of clinical, economic, and patient-reported outcomes," says Annette Stemhagen, DrPH, senior VP, safety, epidemiology, registries, and risk management, United BioSource Corp. "Payers welcome thought leadership and multi-disciplinary expertise in market access strategy, safety and risk management, real-world study design, and streamlined global clinical operations."

In their role as population managers, payers need more information about how the drug supports the health of their patient or member populations in achieving better health outcomes at a lower cost; for example, data that determine what patient subgroups the drug works best for or how can the use of the drug be maximized by improving patient engagement and adherence or how can use of the drug support quality and outcomes measures, which often have financial implications.

According to Richard Trezza, general manager, Ogilvy CommonHealth Payer Marketing and Ogilvy Healthworld Payer Marketing, part of Ogilvy CommonHealth Worldwide, manufacturers need to find a legitimate way to



44 Innovative programs that improve adherence through the discipline of health psychology ultimately lead to better outcomes.**?**

> DR. SCOTT GUERIN Atlantis Healthcare

promote the effectiveness of their drugs that includes this type of information.

"Pharma medical, regulatory, and legal teams need to find a way to create, support, and disseminate these types of information and value propositions in a way that FDA allows," he says.

Overall, the pressure is on pharma companies to show real results, and the industry must shift its mindset from providing pills to providing surround-sound solutions, says Wendy Blackburn, executive VP, Intouch Solutions.

"This is the right thing to do for payers, professionals, and patients," she says. "We are really just beginning to see built-for-ACA programs emerge."

In this new environment, patient support programs take on even bigger meaning and adherence programs are getting smarter about making a difference. But the mandate, Ms. Blackburn says, is to tie them to outcomes real results — meaning beyond-the-pill solutions must have their own data sets and proof points and that means planning carefully from the early beginnings of a program.

Innovative Programs and Strategies to Advance Health Outcomes

In response to health reform's focus on outcomes, many pharma companies have been experimenting with services and solutions that expand beyond the pill and there are several innovative programs that are making a difference.

For instance, Daiichi Sankyo has created eResources4Health, an unbranded health education Web-based tool that contains more than

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11 In 2015, pharma will seek partnerships with companies that can reduce operating costs and thus respond more effectively to pricing requests from payers.**)**

> MICHAEL GRIFFITH inVentiv Healthcare

100 unbranded, customizable health resources.

"The solution is intended to educate people with chronic diseases with appropriate selfmanagement tools and help them work more closely with their healthcare providers," says Erin Curcio, director, payer marketing, Daiichi Sankyo. "Healthcare reform has forced many providers and health systems to build better capabilities to effectively deliver on population health goals, and some of those capabilities are areas in which pharmaceutical companies can offer assistance, such as improved patient engagement, transitions of care, and disease management. These are areas in which pharma has expertise, which lends to our credibility in providing better solutions."

As health systems are looking for new approaches to disease intervention and patient population management, pharma companies can deliver more tailored patient-centric programs and protocols through their access to robust data sets.

For example, providers are consistently looking for ways to improve patient satisfaction and pharmaceutical companies can support them by providing broad-based patient engagement programs to ensure their populations understand their conditions and get the support and resources they need to stay compliant. Pharmaceutical companies also have worked across multiple settings of care and through their extensive market research, understand certain patient pathways and emotional triggers better than many providers.

"These insights can serve as an opportunity



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> ROBERT SHEWBROOKS HealthStrategiesGroup

to provide best practices and help inform better patient treatment throughout the care continuum," Ms. Curcio says.

The search for long-term, sustainable solutions remains strong among payers. Innovative programs to improve adherence through the discipline of health psychology are designed to address patient barriers, beliefs, and perceptions about their disease and treatment. Such interventions, grounded in scientific rigor, focus on behavior change to help patients selfmanage their condition and follow prescribed treatment, are ultimately leading to better outcomes, says Scott Guerin, Ph.D., health psychology specialist, Atlantis Healthcare.

"It's one thing to demonstrate effective outcomes in clinical trials with controlled protocols and adherence monitoring, but results often change post-launch when a drug is available to patients in less controlled environments," Dr. Guerin says. "As a result, payers are looking for ways to enhance adherence, get the most value from their pharmacy spend, and reduce overall medical costs."

Pharma will need to adjust its strategies for communicating with payers to align with the new era of healthcare reform and payer's evolving needs. According to Russell Powter, managing consultant at Cello Health Consulting, payers and other stakeholders typically respond well to situations where they feel they have influence on critical elements of significant access challenges. An overall approach would be to engage payers — with healthcare practitioners when appropriate — in the creation of solutions and win-win propositions.

"Co-creation workshops building consensus on unmet need and barriers help everyone to identify common ground and objectives,



44 Payers and pharma can learn a lot from each other when it comes to real-world evidence and outcomes research. **33**

> JAMIE POWERS SAS Health Analytics Practice



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JONATHAN WILSON / Spectrum

develop aligned strategies and tactics, and even integrate clinical champions to drive studies with downstream payer engagement," Mr. Powter says. "An open dialogue with realistic expectations and demonstrated benefit to health systems helps both payers and the perceived value of brands."

Pharma companies will also need to ensure collaboration early on in the process.

"Payers and pharma companies can learn a lot from each other when it comes to realworld evidence and outcomes research," says Jamie Powers, DrPH, senior industry consultant, SAS Health Analytics Practice. "Specifically, how can evidence generation be tailored to the needs of payers; and, how can payers learn from the development process to understand how and why decisions are made?"





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Payer Partnerships Require Innovative Business Model

Pharma must provide programs beyond the pill today, not tomorrow.

he Wharton's Mack Institute for Innovation Management held a workshop earlier this year that examined pharma's urgent need to develop beyond-the-pill solutions as a way to meet the

many new challenges currently facing the industry. The workshop panel reported that the time for beyond-the-pill solutions has come, and the pharmaceutical industry has to show leadership and courage in innovating its business model.

While the Affordable Care Act brought challenges to the industry, it also brought an opportunity to play a bigger role in improving patient outcomes and enhancing the efficiency of healthcare delivery. With a shift to value and quality, the healthcare ecosystem is increasingly appreciating the importance of prevention, care coordination, and care management in controlling healthcare costs and keeping people healthy.

"Pharmaceutical companies are uniquely situated to establish new and unique payer partnerships due to their long-standing relationships with both large and small payers," says Richard Black, executive director, health systems marketing, at Astellas Pharma US. "New opportunities exist to forge partnerships with payers due to their heightened focus on quality and outcomes."

Focused on reducing cost of care while improving quality outcomes for patients, biopharma must strive to construct a value argument measured in clinical and economic terms, ensuring that new drugs meet the needs of payers, patients and physicians alike, says John Doyle, Dr.P.H, senior VP and managing director, consulting value and outcomes center of excellence at Quintiles.

"As stakeholders become more interconnected and patients become more savvy healthcare consumers, biopharma will need to look holistically at patients and incorporate educational areas such as diet, exercise, and health screening to focus more holistically on health thereby building consumer communities to drive better patient and population outcomes," Dr. Doyle says. "Programs that empower patient consumers with more accurate and reliable information about their diagnosis, treatment, and outcomes will enable consumer-driven healthcare to thrive, ensuring that the right patient receives the right drug at that right time, for the right duration of care."

According to Amy Grogg, Pharm.D., president, consulting services, at AmerisourceBergen, the most promising adherence strategies are customized to the patient's individual needs and characteristics.

One example is Care Pathway, Lash Group's proprietary approach for optimizing patient adherence. This approach focuses on developing patient confidence and skills, as well as efficient use of resources that requires targeting those patients who need more help and are not as able to self-manage as others. The Care Pathway is personalized to a patient's medication knowledge, skill, and confidence. It is implemented with communications by certified nurses and executed with education and outreach interventions along the way.

"Pharmaceutical manufacturers are looking for opportunities to partner with payers to demonstrate outcomes and make populationbased decisions," Dr. Grogg says.

To assist in that goal, Xcenda pioneered the development of the first Outcomes Analyzer and continues to refine and enhance its use in even more specialty disease areas. Outcomes Analyzers use a payer's own data to help identify areas for quality improvement and, more importantly, to easily measure the effectiveness of those quality improvement programs. Outcomes Analyzers are very pow-

Consider Needs of Payers in Beyond-the-Pill Programs

The best pill-plus programs extend their influence beyond the patient taking the drug, and support payers by:

- Improving population health. Pharmaceutical manufacturers can support population health by disseminating pertinent clinical data that identify both responders and nonresponders.
- Improving the patient experience. Regardless of the drug, patient adherence principles are universal, but their implementation requires support. Manufacturers are often cited as experts in persuading physicians to prescribe their drug. Similar behavioral change principles could be applied to patients, including using various media to convey important information across all patient interfaces, for example in-patient and out-patient physicians, pharmacist, case managers, etc., in a coordinated manner.
- Reducing per capita costs. Manufacturers can use their resources to collect, organize, analyze, and report financial results of their programs in conjunction with the IT and managerial systems at payer organizations.

Source: Richard Trezza, general manager, Ogilvy CommonHealth Payer Marketing and Ogilvy Healthworld Payer Marketing, part of Ogilvy CommonHealth Worldwide



44 We are seeing the best results from programs that bring together key aspects of condition management into a single service. **37**

TIM DAVIS / Exco InTouch

erful tools in helping payers to improve quality and reduce costs across a variety of disease states.

"Early development of the outcomes analyzers were targeted to chronic conditions such



If The most promising adherence strategies are customized to the patient's individual needs and characteristics.

DR. AMY GROGG / AmerisourceBergen

as asthma, diabetes, depression, and osteoporosis," Ms. Grogg says. "However, they are now being developed for oncology and other highcost therapeutic areas."

The best programs to expand pharmaceuti-

Best Practices for Beyond-the-Pill Programs

Pharma has started targeting patient assistance and patient engagement programs and focusing on delivering a pill-plus-service model, or beyond-the-pill solutions (BTPS). Every pharma brand has developed a patient journey. Now companies have to look at all aspects of the patient journey and find opportunities to make the patients' interactions with the healthcare ecosystem easier. Best practices include:

- Compare drugs and not placebos. Payers want to see clinical data that compares multiple drugs in market and not just the drug to a placebo.
- Prove long-term cost value of the drug. Pharma companies must also answer how

their drug reduces costs over time. Even if the cost of the drug at the pharmacy is more expensive, the long-term care cost must be lower.

- Prove value across multiple demographics. Payers want an even representation across age, ethnicity, genetic predisposition, and gender. Many times certain segments of the population are underrepresented during patient recruitment.
- Compare data with their own claims data. Some payers extract data from clinical trials and combine that with their own claims data to develop their own comparative effectiveness models.



44 As stakeholders become more interconnected and patients become more savvy healthcare consumers, biopharma will need to look holistically at patients. **39**

DR. JOHN DOYLE / Quintiles

cal offerings beyond the pill may be those that value passive data collection. The success of evidence-based medicine will rely on the accuracy of that evidence.

"We've known for a long time that it's hard to get patients to adhere to a treatment plan; people have busy lives, and it's hard to get professionals to force anything else into their overcrowded work and personal lives," says Nick Colucci, CEO, Publicis Healthcare Communications Group. "If pharmaceutical companies can develop tools that give us greater insight but require less effort from the patient or the healthcare providers, that will provide true value beyond the pill."

"We are seeing the best results from programs that bring together key aspects of condition management into a single service," says Tim Davis, CEO and founder, Exco InTouch. Therefore, rather than focusing on medication reminders, informational content, or goals setting in isolation, companies need to create services that use all these aspects, and more, in conjunction to provide support and motivation for the patients and their caregivers and healthcare providers. Additionally, this needs to be done through a simple interface, so it is really easy for patients to interact when they need to.

"These are the types of programs that are realizing the best results and will make the beyond-the-pill movement a sustainable strategy," he says.