

The Power of the Patient

As patients move from recipients to participants, the industry needs to align strategies to pull them into the focus of future business models.

A recent PwC report describes a new health economy on the horizon, one in which technological advances, empowered consumers, disruptive new entrants, and rising demand by an aging population are ushering in a new era in healthcare. The report, *Healthcare's New Entrants: Who will be the industry's Amazon.com?*, says the industry is at the tipping point as these emerging trends create a rapid shift in where dollars are being spent, triggering major changes in patient behavior and fundamentally altering the business landscape. Within this new health economy, patients will be consumers first, with both the freedom and responsibility that comes with making more decisions and spending their own money, the report says.

As consumers become increasingly more engaged in their own healthcare decision-making, healthcare stakeholders must evolve their strategies to address the needs of patients as consumers. They will seek solutions, tools, and information that help them focus on costs, quality, and convenience. In the very near future, consumers will be taking much more control over their healthcare, our experts predict.

"I prefer the words choice and influence over control," says Roslyn Schneider, M.D., global patient affairs lead, Pfizer Medical, Pfizer. "And we're definitely seeing growing trends in that direction. As a result, we should use language and behaviors that emphasize the importance of collaboration in medicine development and shared decision making among patients and their healthcare teams in their individual care."

At Sanofi, company leaders acknowledge that consumers are taking a much more proactive role in their care, with technology serving as the key enabler to empower consumers and providers with the right information, at the right time.

"The consumerization of care is gaining momentum in North America, and the trend is accelerating in Europe and emerging markets as well, representing a profound evolution for stakeholders in healthcare delivery," says Paul Sekhri, senior VP, integrated care, Sanofi. "As consumers increase their proactive role, we also anticipate an increased willingness to pay for out-of-pocket costs. These evolving economics represent a significant opportunity for the most patient-centric and forward-thinking organizations."

One such opportunity can be found in patient education. Providing education will allow consumers to make better decisions and ultimately lead to more control on their part, says Dan Piggott, CEO, Ashfield Commercial, Clinical and Medical Information.

"With the education being provided today, it is safe to say patients are becoming more empowered to make decisions relative to their treatment," he says.

The benefit of education is two-fold: patients with a solid education to back their healthcare needs will have greater control over their health and will commit greater adherence to their therapy.

"It appears that healthcare is moving to where it is less about the physician recommending a drug for treatment and to where the patient or caregiver is having a much more direct and reasonable say in their treatment," Mr. Piggott says.

The increased availability of online infor-



“Focusing on the needs of the patient creates an alignment of purpose among R&D players and thus is the most cost-effective way to further science.”

JOAN BACHENHEIMER / BBK

mation plus improvements in search over the last decade have enabled patients to become educated, engaged, and empowered over their healthcare.

"Patients are no longer recipients of healthcare, they are active participants," says Patrick Homer, principal industry consultant, global practice, health and life sciences, SAS. "Patients used to listen to physicians, now they interact."

Gamification's Role in Adherence, Education, and Marketing



BORIS KUSHKULEY

Executive VP
Intouch Solutions

Behavior economics, including gamification techniques, can dramatically change patient healthcare outcomes. The education of consumers needs to be coupled with goal setting, motivation, and peer pressure.

A better understanding of mechanisms of diseases and recognition of the systemic nature of disease conditions elevates the importance of patients' commitment to their health. A large number of risk factors can be controlled by the conscious decision of individuals to exercise, eat healthier, stop smoking, etc. Medications will become just a part of the comprehensive prevention and treatment paradigm.

We know that knowledge of what needs to be done not always translates into actual behaviors. Carefully constructed comprehensive treatment programs are the answer. Some people call them pill-plus, programs that combine education, treatment, and a communication layer all geared towards behavior modification.



JULIE ROSS

Executive VP
Advanced Clinical

The gamification movement is notably changing how patient engagement strategies are used in pediatric clinical research trials. Motives for patient participation and interaction have long been generated using elements of gamification,

In addition to the traditional methods to understand patient centricity, the industry needs to evaluate how to access the "new voice of the patient," with their participation in social channels, Mr. Homer says. Social media content generated by patients is proliferating at a magnitude that is becoming a cornerstone of the big data movement in pharma. However, the challenge lies in developing the strategy to access this new pool of intelligence about patients, their concerns and needs, which is all available in social media.

"Pharma needs to figure out the right key to unlock this rich treasure chest of insight, and the answer goes well beyond basic social listening capabilities," he says.

The average healthcare consumer is far more sophisticated than those of earlier generations, and is far more likely to turn to friends, experts, and technology to gather information, says Nick Colucci, CEO, Publicis Healthcare Communications Group. Thanks to years of concerted efforts to make patients

specifically incentive, challenge and reward. Now by applying such elements to digital technologies, we are educating and engaging pediatric patients in trials with greater success. Adults are more capable of understanding disease, logistics of a trial, and the intrinsic value of participating in clinical research, while children may understand little. This explains why study-specific messaging in pediatric trials is traditionally targeted towards parents/caretakers. Yet with the use of digital gamification technologies, this distinction has been transformed. We are now educating and motivating children directly through gaming, rather than bypassing comprehensive study information through their parents/caretakers. Digital games provide a platform for communication directly to pediatric patients that is natural, motivating and most importantly, educating future generations about the significance of clinical research in their overall healthcare.



PAUL SEKHRI

Senior VP, Integrated Care
Sanofi

Gamification in healthcare is at its core an alternative modality for patients to enhance their health literacy. Gameplay is a great way to engage patients, as it provides a built-in reward mechanism, stimulating further play and greater understanding of health conditions. The positive impact of gamification on patient engagement, health literacy and adherence is well established and very much consistent with what we're seeing in our own offerings at Sanofi.

feel more comfortable in discussing their health, the stigma of many health concerns is breaking away.

"For example, cancer is no longer said in a whisper and mental illnesses are increasingly dealt with as a disease, rather than as personal failings," Mr. Colucci says. "These factors empower consumers and allow them to take action, especially when aided by technology."

Patients are evolving into proactive healthcare consumers and seeking to manage their own outcomes; they are studying their family history for disease risks, practicing primary prevention by modifying diet and lifestyle, seeking secondary prevention with advanced diagnostic and genetic tests, as well as evaluating personal healthcare economics.

"This transformation from reactive patient to proactive consumer takes place against a backdrop of impactful socio-demographic trends, such as an aging population that is increasingly well-connected and informed," says John Doyle, Dr.P.H., senior VP and managing



"It will take courageous leadership to address changes in patient engagement."

LOUIS SANQUINI
QualityHealth



"Talking with patients starts with listening to what they are thinking, feeling, and doing when it comes to their condition."

KRISTIN LABOUNTY PHILLIPS
Patient Experience Project

director, consulting, value and outcomes center of excellence, Quintiles. "Healthcare stakeholders are taking notice and placing the patient at the center of the ecosystem, giving the patient more control than ever before."

To meet this patient need, consumer-facing companies such as Walgreens and CVS Health are transforming themselves from being the corner drugstore to conveniently offering a variety of health services right in people's neighborhoods, says Rich Scarfo, director of the mHealth Summit and VP of the Personal Connected Health Alliance.

"We are just at the very beginning of seeing how the collaborations between mobile operators and technologists with pharma and other service companies are moving toward putting the patient first," Mr. Scarfo says. "These companies are starting to help patients and consumers to live longer, healthier, and more productive lives by driving improved reporting and clinical trial support as well as improved adherence, disease management, and patient engagement."

In this new health environment, taking responsibility for one's own health has never been easier or more productive, with increased emotional and psychological benefits, says Robert Palmer, executive VP, managing director, digital and video, Juice Pharma Worldwide. Online tools and resources have given consumers

great capabilities to research, consider, and purchase goods and services; social media enhances those capabilities by allowing consumers to interact with peers who have similar needs. Healthcare professionals are learning to let go of traditional notions regarding their interactions with patients and caregivers, becoming more comfortable acting as advisors and counselors to patients who walk in their door armed with information about a particular disease or treatment.

“Digital and social resources have bolstered patients’ confidence, many times resulting in much more productive and satisfying relationships with their HCPs even as time with the doctor has decreased,” he says.

However, payers will still have a major influence in what medication is reimbursable and for that reason, it is difficult to say where control will truly lay in future healthcare delivery, Mr. Piggott adds.

“Control varies now and will continue to do so based on the type of disease and where treatments reside on formularies,” he says. “The recent trend toward step edits and prior approvals on new therapies requires the pa-

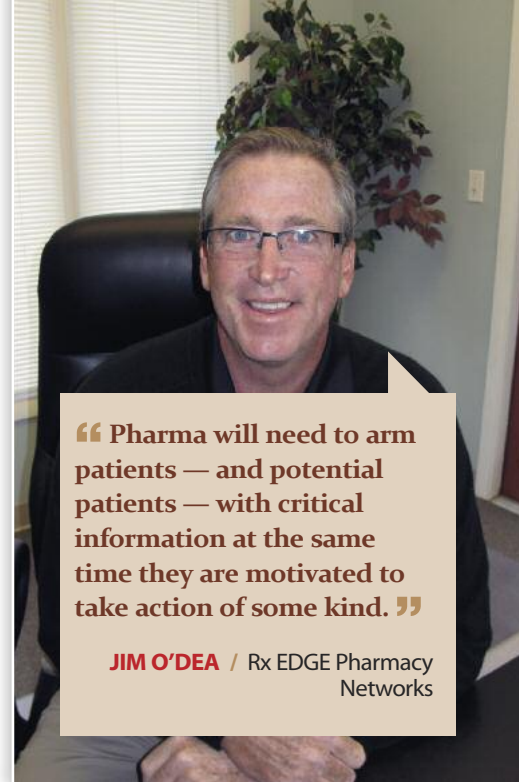
tient and physician to be more active in going above and beyond to pursue the latest therapies.”

For that reason, pharma must find a way to stay relevant in a world where patients pay more and more, closed network plans are on the rise, and payers and providers will start to question whether they should continue to cover a therapy, says Julie Papanek, principal at Canaan Partners. And the most important choice that consumers face today is what healthcare insurance to buy.

“As a result, there are opportunities for new digital health and service investments that empower pharma to stay relevant when negotiating with payers and PBMs and help patients stay on therapy despite rising out-of-pocket costs,” Ms. Papanek says.

Harnessing big data and making it usable will be critical in allowing consumers to understand their health and the factors that are impacting their health.

“With more available data and the context for putting it to use, we expect that consumers will find it simpler to have a deeper involvement in making decisions with their



“Pharma will need to arm patients — and potential patients — with critical information at the same time they are motivated to take action of some kind.”

JIM O'DEA / Rx EDGE Pharmacy Networks

healthcare providers and may be motivated to take a more proactive role in their health overall,” says Amy Grogg, Pharm.D., president, consulting services at AmerisourceBergen. “The continued availability of genomic information will also allow consumers to think more about prevention and proactive healthcare that gives people control even before they experience a health issue.”

Credible and predictive information will be increasingly available to guide healthcare and life decisions, says Kim Johnson, president of Palio+Ignite, an inVentiv Health Company.

“As patients become more empowered to make informed decisions, many analysts predict that better outcomes will result,” she says. “Empowered patients can make behavior change modifications, understand the consequences of treatment non-adherence and navigate the reimbursement environment, in addition to reducing disease and co-morbidity risk with aggressive prevention methods.”

Putting Patients at the Center of Strategies

There has been a growing realization in the industry that companies require efforts beyond just individual business model innovation to focus the health ecosystem around the patient.

“Putting the patient at the center means listening to them — individually or collectively — having them involved in many design decisions and focusing on their own patient experience,” says Patrick Flochel, global pharmaceutical leader at EY. “More and more companies have therefore started involving patients in clinical trial design to measure what really matters to patients in their own life with

Changing the Model of Patient Engagement

Americans are busier than ever, multi-tasking has become normal and expectations have been set for immediate responsiveness from services, including healthcare.

According to Louis Sanquini, executive VP, business development and marketing, QualityHealth, 34% of consumers want self-service options to resolve their issues themselves, and they have high expectations from mobile and social technologies to meet their needs.

“High-deductible health plans are contributing to the need for low-cost, self-service healthcare options,” he says. “Importantly, as health plans evolve and communication channels continue to fragment, the need for alternative healthcare solutions is expected to grow significantly.

“As an industry, we have to seriously change how we address this patient population,” Mr. Sanquini says. “As we move forward, broad-based DTC promotion that raises awareness about a condition or a brand may be rendered highly inefficient and ineffective. We need to redefine how we can help patients find the right care, within the right location with the right products and services at the right price.”

He suggests marketers think about the large and growing number of relevant local offers from Groupon, Amazon, Living Social, and others.

“Wouldn't it be nice to be more local, selective, and specific in our health marketing efforts to boost utilization among those who can take advantage of brands and services?” Mr. Sanquini asks. “Who will become the Groupon for health? Who will bring immediate and low cost options for healthcare, such as tele-health, to the masses? How will patients unintentionally or intentionally bypass the existing payer system to take advantage of the benefits offered by brands and services?”

Traditional physician practices may not be where everyday healthcare is dispensed in the future. Already patient volume is being diverted to alternative channels like telemedicine and low-cost retail pharmacy clinics and PA practices. The burgeoning health ecosystem holds a growing volume of providers bypassing the payer framework altogether.

“This group may become a powerful stakeholder,” Mr. Sanquini says. “We need courageous leadership to address these changes.”



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KURT MUELLER / PulseCX

the illness, and not just the clinical output of the regimen and in focusing on a day in the life of a patient when they develop their value proposition on the new medicine they are preparing to launch. These efforts should extend beyond the patient to the family and other caregivers.”

“To truly make a difference for patients, companies need to shift from a medicine- or physician-focused approach to a patient-centered approach,” says Dr. Anne Beal, chief patient officer at Sanofi. “The first step in doing this is gaining a deep understanding of the patient experience and their condition across different patient types and demographic groups, and then using these insights to inform and shift the company’s culture to produce products and solutions that really work for patients, and address their various needs.”

Employees in a patient-centered culture recognize how their daily work impacts the lives of patients and their families, and become even more driven to develop products and solutions that impact and improve patient outcomes.

“At Sanofi, we have been hosting internal ‘Zoom In’ sessions with patients, doctors, and key opinion leaders to gain a better understanding first-hand of the patient experience in different disease areas,” Dr. Beal says. “These conversations have been a great way for us to hear patients’ stories and understand their real-life needs and challenges.”

Dr. Beal goes on to say patient centricity requires more than simply gaining insights from patients; it also includes a focus on meeting patients’ needs and translating the insights

from patient meetings to products that improve outcomes, including those that matter most to patients.

“While we have made progress and have the patient’s interests at heart we need to more systematically operationalize the integration of patient-reported experiences and preferences into the development of medicines and in healthcare,” Dr. Schneider says.

“We need to work together across companies, initiatives, and stakeholders to outline how we can narrow the gaps and align our approach,” she adds. “Several patient, industry, and regulatory collaborative groups in the United States, EU, and elsewhere are doing just that. We will only know that we are truly putting patients at the center when we have measurable outcomes, and patients, caregivers, and advocates see our decisions and behaviors as patient-centric.”

Disrupting the existing dysfunctional process, and changing the mindset of how healthcare is “supposed” to be delivered to patients is key in providing a patient focus.

“If we were to redesign care — forgetting about the legacy structure — we would never design it how it is today,” says Diego Miralles, M.D., global head of innovation at Janssen Pharmaceuticals. “We would design a system where patient health and convenience were the top priority and the financial incentives of hospitals, payers, and providers would be focused on keeping people healthy. But the existing fee-for-service structure prevents patients from always getting the most rational or efficient care, and that is intrinsically the problem.”

In today’s consumer-driven world, patients need and want to have easy access to their personal healthcare data. Technology now enables patients to upload, store, and manage their own healthcare data and to share across various studies or doctor offices, therefore, according to Clare Grace, Ph.D., VP, site and patient access, at INC Research, pharma and CRO partners need to recognize the need to support patients by providing greater access to both consolidated and personal trial data.

“With emerging technologies granting patients the ability to perform personal assessment tests — like using a SmartPhone application to take a pulse — trials can be designed to be much more patient-centric and reduce the amount of time in the doctor’s office,” Dr. Grace says. “We need to make sure these technologies and applications are built into our trials moving forward so that the patients experience a reduction in the intense impact a trial can have on them.”

Patient-centered research should prioritize patients’ unmet needs and their lived experience with disease. Pharmaceutical and service companies should connect with patients directly to learn what symptoms most affect their quality of life and how they measure improvement. The Michael J. Fox Foundation for Parkinson’s Research understands there are gaps between what researchers focus on and what patients deem important. For example, in Parkinson’s disease, improving motor symptoms is the focus of much of the attention from the research community. However, many patients report that their nonmotor symptoms, such as sleep disorders and constipation, may be as bothersome as their motor symptoms.



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Triple Threat Communications



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JAY CARTER / AbelsonTaylor

“These types of conversations can influence areas of research and study design,” says Todd Sherer, Ph.D., CEO, The Michael J. Fox Foundation for Parkinson’s Research. “Companies can put the patient in the center of care by incorporating their input in study concept and design.”

Ongoing research into the voice of the customer will help companies stay up to date with patients’ needs after the trial, says Ingrid Blair, business director, 3M Drug Delivery Systems.

“Many insights can be gained by asking patients what they want and also by closely observing how they use current treatments,” she says. “For example, if most patients think they use a treatment correctly, but observation shows they do not, then companies have an opportunity to address the issue and help the patient be more successful.”

Lissette Linares, senior VP at Spectrum, says the focus on personalized or precision medicine will compel the industry to put the patient at the center of care and drug development more than ever. Biopharmaceutical companies have begun to explore ways to integrate the patient voice in clinical trial design, but they need to engage with patients long before the commercialization stage.

“It needs to be all about the patient, even at early stages of clinical development,” Ms. Linares says. “It’s about understanding how a medicine fits into the treatment paradigm and the impact it can have on an individual suffering from a specific disease. Education and engagement are keys in really shaping and designing programs that encourage a dialogue

and exchange. We’re not just pushing out messages, but understanding patients and disease at a new level.”

There is no question that consumers have been driving major healthcare shifts, says Joan Bachenheimer, founding principal, BBK Worldwide.

“Applying tried-and-true marketing principles and most importantly understanding the protocol from a patient recruitment perspective is a key step in engaging patients in your trial,” she says. “With so many competing priorities for mindshare when conducting a clinical trial, focusing on the needs of the patient creates an alignment of purpose among all R&D players, and thus is the most cost-effective way to further science.”

Marketing to the New Patient Consumer

On the marketing end, pharmaceutical and service companies need to reassess how they distribute their patient research budgets. According to Malcolm MacKenzie, senior VP, strategic planning/business development, Juice Pharma Worldwide, the current focus is to invest heavily in segmentation studies and other quantitative research and this short changes an important aspect of patient understanding. Marketers need to know more than what decisions patients are making; they also need to know why they make the decisions that they do, and this is frequently a missing piece of research.

“Decision-making is a complex undertaking; we know from experience that our targets

often have trouble telling us why they really made a decision,” Mr. MacKenzie says. “Insight shines a light on why decisions are made by taking the entire person into account to uncover the essence of decision-making.”

“If we truly want to put the patient in the center of care, our marketing efforts need to start with their journeys, their perspectives, and the insights that drive their attitudes and behaviors regarding our brands, says Jay Bolling, CEO at PulseCX.

“Too often, pharmaceutical and service companies plan their consumer/patient campaigns as a derivative of their professional campaign,” he says. “They understand consumers/patients are different, but their hope is typically to find synergy in the campaigns to ensure consistency at the point of prescription or that physician/patient interaction. A drawback of this approach is that the patient is truly never in the center of care, they’re often viewed as one more influencer on the prescribing habits of physicians.”

As consumers become more active participants in their own healthcare, marketers will need to be much more strategic in how, where, and when to reach them. Otherwise, the marketing efforts will have minimal impact.

“Pharma will need to arm patients, and potential patients, with critical information when they are motivated to take action of some kind and are ready to have a meaningful consultation with a healthcare provider,” says Jim O’Dea, president and CEO, Rx EDGE Pharmacy Networks — a business unit of LeveragePoint Media. “If people have a need — in the form of symptoms, general concerns, or a



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KIM JOHNSON / Palio+Ignite



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MALCOLM MACKENZIE
Juice Pharma Worldwide



“Providing education will allow consumers to make better decisions and ultimately lead to more control on their part.”

DAN PIGGOTT / Ashfield Commercial

current known condition — they will take notice. We call it the mindset moment, which refers to gaining consumers' attention when they are thinking about their healthcare.”

The pharmaceutical industry will be increasingly challenged to define and deliver value to consumers and patients. In a consumer-centric world where patients have more financial stake in the game, pharma will need to continue to evolve the manner in which it differentiates and delivers value to support the use of ethical products.

Richard Dudek, senior VP, marketing practice, at TGaS Advisors predicts that this challenge of engaging patients within the constraints of a highly regulated environment will be perhaps the most fascinating trend and value proposition for the industry overall.

“For me, that emphasis falls in the digital and social media space,” Mr. Dudek says. “Technologies are evolving rapidly, information sources have increased dramatically, and consumers are seeking not just information, but dialogue.”

“The way companies reach and interact with patients is in a state of great flux,” says Jay Carter, senior VP, director of strategy services, at AbelsonTaylor.

Traditionally, the patient who the pharmaceutical industry reaches is 55 and over. That is where the greatest drug expense lies, Mr. Carter says. This demographic is still most easily reached using broadcast advertising. That's

why all three new agents for atrial fibrillation are spending tens of millions to sell a product that costs \$5 per day.

“This paradigm will change completely in the next 10 years, as the ‘sweet spot’ demographic becomes more and more Internet savvy,” he says. “The Internet is where the future of cost-effective interaction lies.”

The best social media initiatives integrate campaigns and leverage best practices from all channels, including print, digital, and social, says Kurt Mueller, chief innovation officer at PulseCX.

“The most successful initiatives focus on the specific needs of different customer segments at each particular point in their journeys through the channels they prefer,” he says. “The ideal formula for developing an effective social media strategy pairs brand awareness — grounded in the unmet needs of customers — with a wide variety of delivery channels, allowing customers to control and drive their interactions with the brand through the specific content and experiences that provide meaning to their journeys.”

Making connections with patient advocacy groups is another great way to gain insights from more than a single patient. As is engaging with unaffiliated patients, who are not actively engaged with an advocacy group, but who have created an organic community through social media or other online channels, Dr. Beal of Sanofi says. There are many ways to

reach patients, whether it be in the drug development process through to when the medicine is on the market.

The best way to reach patients is to stop talking to them and start talking with them, says Kristin LaBounty Phillips, director, patient experience strategy and program design, The Patient Experience Project.

“Talking with patients starts with listening to what patients are thinking, feeling, and doing when it comes to their condition,” she says. “An in-depth understanding of the patient experience brings empathy to your content, so it resonates with your audience.”

Collaborating with patients to co-create programs and communications goes a step further, and results in authentic, peer-to-peer content that patients want to engage with and want to share with others. Co-creation fosters meaningful relationships between the brand and patients, which breeds brand loyalty.

New Technologies Improve Adherence

Medication adherence will continue to be one of the more difficult challenges in pharmaceutical development, with major therapeutic and economic consequences.

Today, advances in digital medicine or smart pills enable accurate and timely insight into medication adherence data during a clinical trial, with data fed directly into electronic



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DR. ANNE BEAL / Sanofi



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RICHARD DUDEK / TGaS Advisors



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“ Advances in digital medicine or smart pills enable accurate and timely insight into medication adherence data during clinical trials. ”

JAMES STREETER
Oracle Health Sciences

data capture systems, says James Streeter, senior director, life sciences product strategy, Oracle Health Sciences.

“This helps researchers to more easily and more quickly determine the optimum range between the dose-response curves for both desirable drug effect and unwanted drug toxicity, and promotes greater compliance with the clinical trial protocol,” he says.

The industry needs to stand ready to unleash the potential of technology to enhance care and how it reaches people, Dr. Miralles says.

“Healthcare companies need to step back and not think about ‘how can we decrease cost’ because that won’t deliver the best care,” he ex-

plains. “Consumers can do so much now and are using technology to better engage within other industries. However, the life-sciences industry is limited by regulations and cultural restrictions, not by technology. Innovation is not about ideation; it’s about experimentation and execution. We need to be experimenting with engaging the patient so they have a much better understanding of their condition and want to invest in their own health. This will be the key to unlocking adherence and compliance.”

Sanofi’s Mr. Sekhri predicts a surge in adherence solutions, due to an increased interest in healthcare applications by consumer technology providers and consumers.

“With the cost of technology continuing to decline, and mass distribution on the rise, consumers are more connected now than ever and have a wealth of healthcare information available at their fingertips. We should see a remarkable proliferation of solutions that enhance patient engagement, health literacy and adherence,” he says. “These solutions will generate a tremendous amount of real-world data, which can be leveraged to fundamentally enhance outcomes.”

GSK and Community Care of North Carolina have partnered to co-develop and test prescriptive analytic tools, based on GSK’s experience with CMM and data analytics with the goal of assisting healthcare professionals in medication-related problems, reports Jon Easter, senior director, delivery and payment reform, GSK.

“Findings from this pilot revealed a ‘near sick’ population, one that is dealing with chronic disease but are highly functional and therefore only visit the doctor once a year on



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DR. AMY GROGG / AmerisourceBergen

average,” Mr. Easter says. “This near sick population, though, visits their pharmacy about 30 times a year. This presents a major opportunity for better medication management across large populations, one patient at a time, and potentially provides pharmacists with a significant role to intervene and help patients manage their medications.”

Mr. Easter adds that holistic comprehensive medication management (CMM) strategies involving clinically trained pharmacists or a patient’s primary care providers can be very successful. In fact, pharmacists can play an increasingly powerful role in helping patients comply with their physician’s orders.

To drive such patient engagement and adherence, Walgreens recently launched the first personalized immunization app and widget to track the user’s immunization history and provide “smart” recommendations based on CDC



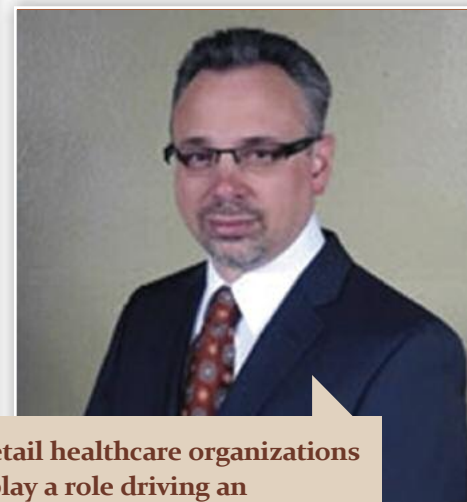
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DR. ROSLYN SCHNEIDER / Pfizer



“ Retail healthcare organizations can play a role driving an omnichannel approach to population health, specifically in the area of prevention. ”

ADAM PELLEGRINI / Walgreens

guidelines. According to Adam Pellegrini, divisional VP, digital health at Walgreens, retail healthcare organizations can play a role driving an omnichannel approach to population health, specifically in the area of prevention. For example, managing a condition like dia-

Quantifying Patient Journey Remains a Challenge

Polling from a recent IMS Patient Journey webinar indicates that incorporating the physician, payer, and patient into a single view and quantifying the patient journey remains a big challenge in the industry.

Polling Question: Where do you see your biggest area of challenge in building and using the Patient Journey?

Quantifying the Patient Journey	28.5%
Incorporating the patient payer and physician into a single view	24.2%
Identifying all potential opportunities and challenges	15.7%
Ensuring connection between objectives and execution	12.8%
Understanding the potential evolution in future	11.4%
Tracking against objectives	7.1%

Source: IMS Patient Journey white paper. For more information, visit imsconsultinggroup.com

betes, a patient may visit a pharmacy regularly, and use other resources such as mobile apps, websites, and wearables.

“Our industry is well-positioned to promote the use of rewards incentives, connectivity, and evidenced based interventions to improve outcomes and adherence,” Mr. Pellegrini says.

“The industry is on the cusp of a revolution in how patients interact with therapy and options for improving health and wellness due to the communications power of new and emerging technologies,” says Paul O’Neill, president at Ogilvy CommonHealth Wellness Marketing, part of Ogilvy CommonHealth Worldwide.

While many of these technologies will provide meaningful ways to prompt and monitor adherence and compliance behaviors, the most exciting aspect of these technologies is their ability to fundamentally change how people view their bodies and the impact of therapy on their physiology. Linking positive or negative behavior to understandable and visualizable results within the body will provide powerful incentives for patients to engage in their health and wellness in a profoundly different way.

Technology is key in detecting, documenting, and messaging non-adherence issues in near real-time and has also been shown to be effective in delivering tailored interventions to patients.

However, even with technological advances, the problem of non-adherence is as

prevalent as ever, says Christian Nimsch, chief strategist, SAS Center for Health Analytics and Insights. At times, there are easy to understand reasons for observed nonadherence and compliance, such as a lack of efficacy, safety concerns, or financial considerations. More often nonadherence/compliance is a symptom of a greater challenge: the lack of engagement with health in general.

“Research has shown that patients who are actively engaged in their health are also more adherent to recommended therapies,” he says. “Technology aimed at general health engagement will likely be more successful in driving results than technologies solely focused on adherence and compliance,” he says.

According to Bob Hogan, director of consumer services, at Triple Threat Communications, the time has come for patient education and technology to mash up in way that provides the right education to the right patient at the right time.

“In our world, healthcare providers, pharma, and health insurance companies all want to ‘educate’ large numbers of people about drugs and disease management,” Mr. Hogan says. “But we still do that by dumping truckloads of self-serving ‘support’ on them, telling patients what we want them to know or what we think they need to know. I call that ‘information therapy.’ It’s time to marry the best practices of e-learning with creativity and behavioral science to deliver interactions that actually move the adherence needle ahead.” PV

SAVE YOUR BRAND THROUGH REFORMULATION

How creative life-cycle management can protect your bottom line

By Nelly Edmondson

Drug reformulation can be a successful — and profitable — way to extend the life of brand-name pharmaceutical products. Reformulated drugs that better meet patients' clinical needs or reduce side effects and/or toxicity, for example, often achieve success in the marketplace. So can reformulations that significantly enhance efficacy and compliance or preserve efficacy while lowering drug dosages.

Reformulation is especially important now, thanks to the much-discussed "patent cliff," a metaphor for what occurs when established drugs go off patent, leading to potentially steep drops in revenue. Indeed, the patent cliff is "one of the biggest drivers of reformulation," said Anil Kane, PhD, MBA, Executive Director and Global Head of Formulation Sciences Pharmaceutical Development Services at Patheon, Inc. "Loss of patents means huge business losses, unless the brand-name drugs are substituted with other drugs in the pipeline or are reformulated."

Reformulation 101

When considering reformulation strategies, companies sometimes utilize "older drugs that can be delivered in new ways," noted Charles Grudzinskas, PhD, founder of NDA Partners, a global strategy consulting firm specializing in expert product development. Transdermal patches, intranasal and sublingual options, as well as dissolvable film strips, are all finding acceptance from physicians and patients. Some companies are even making it a priority to design patient-friendly delivery systems for people who are unable or unwilling to undergo injections, or who have difficulty swallowing. (See sidebar, "An easier way to deliver.")

Other popular reformulation strategies include developing pediatric line extensions and controlled-release formulations. Although pediatric products command a smaller market segment than products for adults, producing them often makes sense from a regulatory and market perspective, because launching a pediatric version of a drug can get a company a six-month patent extension, thereby delaying the entry of competitive products into the market. Companies can take the same approach with controlled-release formulations, which sometimes offer compliance benefits or a better side effects profile than the original version.

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*Dave Savello, PhD,
NDA Partners*

Another strategy being looked at is different dosage strengths. Newer technologies can allow manufacturers to lower dosage strength while showing similar or better clinical efficacy, and/or fewer side effects. "These technologies may not have been explored when the drug was first looked at," Dr. Kane said. Reformulation can be an opportunity "to revisit" the issue, and has been used — or is being considered — for a variety of indications. An obvious case in point is so-called "low dose" oral contraceptives,

which are as effective as their higher-dose fore-runners but are associated with a lower risk of stroke, heart attack and other serious side effects. Indeed, clinical practice has shifted from reserving low-dose OCs for specific patient populations to using them as first-line therapy.

Creative combinations

To create favorable synergistic clinical effects, savvy reformulators are also developing novel drug combinations. For example, several years ago, Bristol-Myers Squibb Co. and Astra-Zeneca teamed up to create Kombiglyze XR to improve glycemic control in adults with type 2 diabetes. The once-daily tablet contains saxagliptin and extended-release (XR) Metformin. The U.S. Food and Drug Administration (FDA) approved Kombiglyze XR in 2010. Metformin has also been combined with Actos, Avandia, glimepiride, Januvia, and Prandin, among others.

Combination drugs are also being used in other therapeutic areas, such as cardiovascular disease, women's health — including oral contraceptives and hormone replacement therapy — and HIV infection. "Fixed dose combos are on the rise," Dr. Kane said. "There have been lots of good data in the past 10 years, and we have seen tremendous growth in FDA approvals of fixed-dose combinations."

In the HIV area, three and even four drugs are being combined to produce one-pill-a-day treatment regimens: In July 2006, the FDA approved Atripla, a single-tablet regimen for HIV that combines efavirenz, emtricitabine, and tenofovir disoproxil fumarate, which is manufactured by Gilead Sciences. In 2012, the FDA approved Gilead's Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate), a once-a-day combination pill designed to treat HIV-1 in adults who have never before been treated for HIV infection.

Making old drugs new again

Dr. Kane, whose company is currently working with some 300 clients, describes yet another reformulation technique. "We see a number of existing molecules being used for completely new indications," he said. Since these existing molecules are generic and can be utilized by any group, the drugs being used for new indi-



cations may not have been discovered or manufactured by the same sponsor that is developing the reformulated drugs.

As a case in point, Tonix Pharmaceuticals in New York City is in the process of developing new treatments for challenging chronic pain disorders of the central nervous system (CNS), including two diagnoses that have been very much in the news lately: fibromyalgia and post-traumatic stress disorder (PTSD). To do this, the company is using new formulations of the FDA-approved generic muscle relaxant cyclobenzaprine. Other companies currently market cyclobenzaprine, which works by blocking nerve impulses sent to the brain.

"We tried a number of reformulation strategies," explained Seth Lederman, MD, the company's Co-founder, CEO and Chairman. Eventually, Tonix came up with a sublingual tablet that is taken once daily at bedtime. Designed to disintegrate under the tongue and to cross sub-mucosal membranes, Dr. Lederman says it achieves "faster absorption and faster uptake into the brain" than other forms of cyclobenzaprine.

Dr. Lederman adds that this treatment is non-addictive, and that the once-daily dosing schedule will help patients with long-term compliance. "Our product is a new class of medication that targets sleep quality," he said, noting that patients with fibromyalgia and PTSD often have difficulty getting enough sleep. "By having patients take the medication at bedtime, you are also helping them establish a nighttime ritual – good sleep hygiene – that will help them plan their day and then sleep for a reasonable period of time."

If all goes well, Tonix is hoping for FDA approval for both indications in 2017. "The area we are working in is one that big pharmaceutical companies don't want to get involved in," Dr. Lederman said, "because chronic pain patients often have suicidal thoughts. What we're doing for chronic pain is, arguably, comparable to what Gilead did for AIDS." Many big pharma companies, he added, thought AIDS was too controversial — so they let Gilead have the entire field. "Since then, Gilead has taken an intractable problem and made substantial improvements in treatment."

No matter which reformulation strategy is chosen, timing is key. According to formulation expert Dave Savello, Ph.D., a scientist at NDA Partners, it is important for manufacturers to launch a new formulation well in advance of patent loss to allow physicians time to switch.

"Although every drug and every marketplace are different," he continued, "you really have to take a reformulated product out there at least a year or two before patent loss, because converting physicians and patients is going to take time."

Speed to market

In the past, pharmaceutical companies that discovered new molecules often developed many formulations and dosage points upfront. Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) taken or applied to reduce inflammation and as a pain-reduction therapy for certain conditions. Originally developed by Ciba-Geigy (now Novartis) in 1973, diclofenac was first approved for use in the United States in 2007, and is now supplied as, or contained in, medications under a variety of trade names. When it was first discovered, Ciba-Geigy developed a sodium salt, a potassium salt, an enteric-coated tablet, an extended-release capsule, and a powdered form to be mixed with water.

Today, fewer companies are introducing multiple formulations and dosages upfront. "Now, speed to market is very much the priority," Dr. Kane said. "Companies want to take a product to market, launch the product, generate revenues and, in parallel, look for other routes of administration."

Making money quickly is key, he said, because the financial investment required to bring a molecule to market is higher than ever, and competition and pressures are rising. Companies do look at different dosages and forms of administration to delay generic competition, Dr. Kane added, "but at a later stage as a life-cycle management strategy."

Challenges ahead

None of this means that successful reformulation is easy. Pharmaceutical companies attempting to reformulate their products face stiff challenges in today's difficult sales environment. Healthcare payers, focused on cost cutting, are becoming increasingly reluctant to pay for reformulated medications that aren't demonstrably superior clinically – and just as cost-effective – as existing options. And they demand hard, real-world outcomes data to back any claims about a reformulated medicine's supposed advantages. "Payers are becoming very touchy," Dr. Savello said. "Because of costs, many big pharma companies are relying on specialty pharma to take the risk of reformulating old drugs."

Also adding to the mix is a rapidly changing healthcare landscape, declining R&D productivity, and fierce competition from generics, all of which are "conspiring to produce lower growth and slimmer profit margins for the pharmaceutical industry," Dr. Savello added.

In fact, a recent study by IMS Health estimated that between 2011 and the end of 2015, drugs falling off the patent cliff will have cost pharmaceutical manufacturers \$120 billion in lost sales.

Never too soon

Perhaps the most important thing pharmaceutical manufacturers can do to safeguard the bottom line is to review the reformulation possibilities and challenges early in a brand's life cycle, and then decide which approach is best for each specific product. "There is no one answer," Dr. Kane concluded. "With different drug candidates, different approaches can be successful. It depends on the drug candidate and its properties." ●

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