

Moving Beyond the “Beyond the Pill” Conversation



In today's value-based environment, providing services is critical to company and patient success.

The pursuit of better outcomes from all sides of the healthcare equation is driving the creation of more and more digital treatments and supplemental services as drug companies strive to prove, and increase, the value of their drugs — to payers, physicians, and patients. The value-add of these digital and mobile services can impact payers' willingness to reimburse drugs, physicians' willingness to prescribe treatments, and patients' ability to adhere to treatments in the appropriate manner — all leading to more positive healthcare outcomes.

In today's environment, a company must decide if its purpose is to provide health or to provide medications, says Shideh Sedgh Bina, founding partner, Insigniam, and 2016 PharmaVOICE 100 honoree. This is a conversation that cannot be ignored for much longer, she says, adding “If a company decides its mission is to provide health, it needs to move beyond the pill. And if its purpose is to provide pills and medication than it should focus on excelling in that area. However, it is likely it will face competition from other healthcare opportunity sets in the future.”

Every day there is news of how the market is changing — for example, the merger between CVS and Aetna, or the JP Morgan, Berkshire Hathaway, and Amazon collaboration to form a healthcare company to explore technological solutions to reduce costs — and changing dynamically. Disruptive alliances, innovations, and collaborations are forcing traditional “healthcare” companies to bring patient services to the forefront.

“There was a time when cutting-edge solutions to a health problem were pills and medications,” Ms. Sedgh Bina says. “Today, we have so many other resources and tools available to us as a society to improve health.”

The pharmaceutical industry has begun to adopt a move beyond the pill strategy to ensure its medicines are used to their fullest potential, hopefully resulting in better outcomes for patients and physicians alike, says Matt Clemente, chief technology officer, Lilly connected solutions platform, delivery and device research and development, Lilly Diabetes.

“Pharmaceutical companies are collaborating with both medical and digital technology companies to develop new holistic, connected solutions, which has been coined connected care or connected health,” Mr. Clemente says. “These solutions come in various forms, including wearables, digital pills that can track whether a medication was taken, and apps that make treatment simpler and more effective.”

Lilly Diabetes is currently developing a variety of connected health solutions, with the most advanced being its Connected Diabetes Ecosystem. In its first generation, it will have three core components: insulin, smart devices, and evidence-based dosing algorithms built into its software. These components will analyze blood sugar trends in response to insulin dose changes and capture people's behaviors to give them actionable insights for simpler, more effective diabetes management.

At AstraZeneca, providing value beyond the pill is top of mind and is built on its legacy of supporting patients in this way, says Olivier Nataf, VP, U.S. oncology, AstraZeneca.

"It is our day-to-day mode of operation, and we applaud all efforts across the industry to improve patient outcomes through holistic patient-support programs," he says.

The industry as a whole has expanded efforts to develop complementary support programs, customized to help ensure patients have the best possible experience. These endeavors include programs to help patients and healthcare providers manage treatment by helping navigate health insurance and affordability challenges, matching patients with clinical trials, supporting coordinated care across provider and care settings, and offering resources post-treatment.

"We recognize no two patients are the same, and different treatments pose unique challenges for patients, providers, and caregivers," Mr. Nataf says. "The key to creating these programs in a way that truly benefits healthcare providers and patients is collaboration, particularly with the patient advocacy community."

A few examples of efforts supported by AstraZeneca in the lung cancer space include: Lung Cancer Alliance's LungMATCH, which helps eligible patients identify clinical trials through one-on-one connection with a specialist and an online tool; the Bonnie J. Addario Lung Cancer Foundation's Centers of Excellence program, which seeks to establish coordinated, multi-disciplinary care in community hospitals across the United States; and LUNGevity's HOPE Summit, a survivorship conference that enables patients and caregivers to connect and share resources for living with or beyond their disease. (See box for more of AstraZeneca's patient-services programs.)

"At the core of the movement is a commitment to patients, and a desire to support patients, caregivers, and healthcare providers in every part of their healthcare journey," Mr. Nataf says. "We view this as more than a passing trend, but rather a way of doing business; patients are, and should remain, at the center of everything we do."

To be successful today, the focus needs to



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SHIDEH SEDGH BINA
Insigniam



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Ayogo



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ADELE GULFO
Formerly with Mylan

tor that we have influence over are the things that will impact human behavior," he says.

If pharma companies don't provide services for the patient,

another industry will, and the pharma industry will lose out.

"The industry is becoming increasingly aware that it's actually in the behavior business, whether it likes it or not," says Mr. Fergusson, who is a 2012 PharmaVOICE 100 honoree.

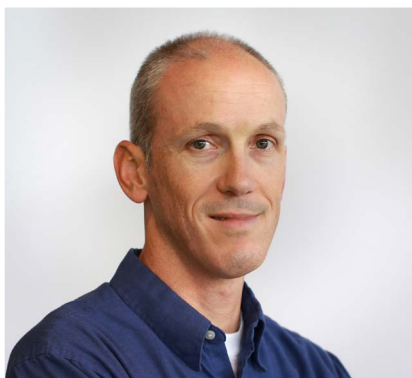
The shift to value-based reimbursement will drive a greater focus on closing the gaps in care and prioritizing wellness, says PharmaVOICE 100 honoree 2007 and 2016 Adele Gulfo, former executive VP, global commercial development and chief strategy officer, Mylan. "There is no lack of mobile health tools and digital service technologies, the key for pharma companies will be to find partners that are willing to invest in conducting clinical studies to demonstrate the value that can be created or the waste that can be eliminated," she says.

However, as long as the healthcare system

be much more on patient and physician behavior than on product benefit and features, says Michael Fergusson, CEO of Ayogo, a patient engagement software company.

"There is actually a complete, absolutely unequivocally necessary component to getting a positive health outcome that can't be put into a bottle," Mr. Fergusson says. "Even if the behavior is just as simple as opening the bottle, taking a pill out, and swallowing it."

The push from payers for outcomes-based value has made the behavioral component increasingly important. Human behavior is the only avenue that can be influenced to provide a better outcome. Patients need to take the medication exactly as prescribed and in some cases, depending on the medication, this can be a complex process for patients. "A medication will perform roughly the same way in the absence of other factors and the only other fac-



Pharma needs to realize the potential of beyond-the-pill services.

ROB PETERS
MicroMass

is out of alignment around incentives to support chronic care management, as well as to promote wellness and prevention in general, reimbursement for digital technology tools will struggle in a world of fee-for-service instead of fee-for-value or outcomes-based care.

“Some companies are focused on finding solutions to deliver better health, especially in chronic disease areas where we know a combination of drug therapy and digital therapy can lead to better outcomes,” Ms. Gulfo says. “Companies are starting to focus on identifying the right healthcare solutions, services, and technologies to complement their vast product portfolios and franchises.”

The pharma industry is focusing on value beyond the pill on multiple fronts and there are two key areas emerging, says Pratik Maroo, chief digital officer, life sciences, Cognizant. First is a focus on outcome commitment for newly launched drugs. “For the majority of specialty products, it is now a clear expectation that manufacturers will commit to programs to improve outcomes and that link to health benefits,” he says.

Historically, patient-centric initiatives started with HUB services that focused on reimbursement support and typical call center activities. Over the years, HUB has matured to offer services such as drug adherence, financial assistance, onboarding, and patient training. “Now the industry is starting to evolve into health management services, which will entail pharma playing a larger role in health management,” Mr. Maroo says.

Nelia Padilla, VP, consulting services, IQVIA, notes that HUB services have grown to include more services, and help patients navigate through the increasing complexity around pre-authorizations, step-edits, and other payer requirements for access to medi-



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STEPHANIE TILENIUS
Vida Health



Beyond-the-pill service is becoming an important element of achieving differentiation in the competitive market.

PRATIK MAROO
Cognizant

cations. Centralizing services allow for ease of access and reimbursement is very helpful to patients. One pharma company that is utilizing this method is Genzyme. It is employing strong patient-support programs that typically include case managers, charitable access programs, and other co-pay or financial assistance for qualifying patients.

“The industry is taking many different approaches to providing value to patients and physicians, and is increasingly turning to digital modalities,” Ms. Padilla. “For example, digital tools are extremely useful for capturing patient symptoms, improving medication adherence, monitoring activity and other elements that when charted or tracked provide critical insights to patients, caregivers, and healthcare professionals.”

Ms. Padilla offers two examples of companies using these types of service: Otsuka’s Abilify MyCite and Roche’s acquisition of MySugr. The recently approved Abilify MyCite for schizophrenia involves a sensor in the medication to help track adherence. This enables individuals with the disorder to better understand the circumstances, days, or conditions under which they are less likely to take their medication as directed and potentially take actions to be more adherent.

The other often-mentioned example in this

space is Roche’s acquisition of MySugr, which allows diabetes patients to better manage their disease.

Roche’s purchase of MySugr is a clear indication of where the industry is headed, according to Mr. Fergusson of Ayogo. Roche already had a sophisticated digital innovation organization, and the company’s decision to buy a diabetes management company further demonstrates the industry’s realization how crucially important behavior is to improve patient outcomes.

Mr. Fergusson predicts that there will be a whole wave of acquisitions of behavioral health companies. He also sees a shift in what pharma companies are asking for in terms of solutions and digital innovation. Companies are seeking turnkey solutions instead of wanting to be a part of the building or designing of the program or app.

Previously, pharma companies would come to the table with a concept for a disease management app or program, and ask for assistance in producing such tools. Now, they want companies such as Ayogo to handle the whole process and provide more turnkey solutions.

Stephanie Tilenius, co-founder of digital therapeutics and health coaching company Vida Health, predicts a day when physicians will prescribe mobile apps as part of a patient’s treatment.

“The digital therapeutic space is evolving,” she says. “Doctors will begin to prescribe apps and digital tools that patients can carry with them that allow them to interact with coaches and therapists, and manage and overcome health conditions. The consumerization of healthcare is emerging and with it the notion of managing conditions in a way that is unique from the methods in the past.”

Going forward, she predicts, care will change from the traditional reactive model to a

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more continuous care model that is predictive, preventive, and personalized and incorporates all the data collected from mobile devices. “We’re moving into a new world; we expect to see a predictive care model that will include genetics data as well,” Ms. Tilenius says.

Patient Services are Critical Market Differentiators

Our experts say providing patient services is critical for companies to stay relevant in today’s marketplace. Especially since technology continues to advance facilitating the evolution of connected devices and decision-making support for chronic disease management.

“At Lilly, we’re excited about the connected health solutions we may be able to deliver,” Mr. Clemente says. “Harnessing in the right way, these technologies can help improve the long-term health of people managing chronic diseases, and we see a huge opportunity to marry Lilly’s background in therapeutics with technology to create innovative solutions that seamlessly integrate the two.”

Beyond-the-pill services have become essential today because many pharmaceutical products are not highly differentiated from their competitors based on clinical data alone, says Rob Peters, executive VP, strategy, MicroMass. “These services enhance value, provide a competitive edge for the product, and increase confidence for a desirable outcome,” he says. “They also demonstrate how to minimize the burden for the patient and his or her healthcare provider.”

Mr. Peters says beyond-the-pill services are becoming an important element of achieving differentiation in the competitive market.

“We expect that these types of tools and services will become an even more important part of the commercialization plan for new therapies,” he says. “For most of the high-cost therapies, value-add services and outcome commitment will be basic expectations from patient and payers respectively.”

Beyond-the-pill services also complement newer, more targeted therapies by helping to ensure patients receive an optimal balance of clinical and non-clinical treatment to meet their specific needs, Mr. Peters says.

Capturing data is as critical for pharma companies as it is for healthcare providers. Pharma companies can institute a feedback loop that funnels hard data about patient experiences and successes back to the provider. This would reinforce prescriber decisions and lead to future prescriptions.

“The data are overwhelmingly positive that when patients are actively engaged in their disease, they have much better outcomes,” Ms. Gulfo says. “Combine this with a

Vida Health App for Post-Heart Attack Recovery Shows Positive Results

Two years ago, digital health therapeutics and coaching company Vida Health and AstraZeneca teamed up to launch an app for recovering heart attack patients to help them recover faster. The app was tested in a study of 21 participants through Duke University.

The study found a statistically significant increase in pre- and post-intervention Patient Activation Measure (PAM) scores in 10 cardiac patients using Vida’s coaching app on their smartphones. Prior research showed that an increase in PAM scores of this magnitude were associated with increased medication adherence and reduced hospital utilization.

Ten patients and 11 caregivers completed the four-week intervention. The mean age of patients was 57, and 20% were women; caregivers had a mean age of 54 and the majority (88%) were women. On average, participants engaged in one live video/phone consultation per week and opened the Vida app five times per week. Patients sent texts an average of 24 times per week and caregivers sent texts an average of eight times per week.

The app walks patients through the recovery process using live digital coaches and educational materials, such as videos, articles, and food journals to help patients

implement lifestyle changes and adhere to their new drug regimen. The unbranded app was designed to focus on the patient, regardless of what drugs are prescribed.

AstraZeneca covered the cost for all users participating in the program. The effort was designed to give the pharmaceutical company a better idea of how it can engage with consumers beyond their daily dosages, as well as gain insights into how patients are using daily medications during recovery.

After the four-week coaching intervention in the post-MI cohort, patients were significantly more likely to agree with the statements: “I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising,” and “I know what treatments are available for my heart attack.” Eight out of 10 patients (80%) said they would go to cardiac rehab after coaching, compared with the traditional 25% of post-MI patients who participate in cardiac rehab.

Participants reported high levels of satisfaction with the program, with an average satisfaction rating of 8.3/10 across the patient and caregiver cohorts, and an average net promoter score of 61%, which is comparable with customer satisfaction levels for Apple’s iPhone.

connection back to the healthcare provider and we can really make an impact.”

The aging population of baby boomers and the growing number of adults who have chronic diseases will drive the need for innovative and supportive initiatives.

“For products in therapeutic areas with a lot of competition and that are expensive and/or complex to administer, beyond-the-pill services can be quite important,” IQVIA’s Ms. Padilla says.

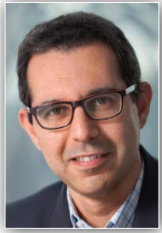
For example, an independent study looked at the best support-service program in a given category. In addition to physician and patient satisfaction with the program, there were significant reductions (i.e., >20%) in overall and diseases-specific medical spend when the services were used. More importantly, the long-term persistence on medication was shown to be substantial, with more than 90% of patients still on medication at 12 months.

“We have seen products that improve connectivity with humans as consumers of healthcare close the gap between simple data collection, product promotion, and clinical decision making, triggering changes in care management that ultimately enhances patient outcomes,” Ms. Padilla says.

“Understanding the underlying psychology that drives the behavior of an individual person is where we need to get to in order to build really effective programs,” Mr. Ferguson adds. “I see us all moving toward a kind of precision psychology in the same way we are beginning to use precision medication.”

The opportunity for these services lies in every disease state from over-the-counter products to chemotherapy and for every patient population, he says. “We even see applications in surgery prep. Device manufacturers are coming to us and asking for help in designing behavioral interfaces to their products.”

AstraZeneca Oncology Programs Support Patients



OLIVIER NATAF
VP, U.S. Oncology, AstraZeneca

AstraZeneca believes our support programs provide important services to patients to improve their health and well-being before, during, and after treatment with our medicines.

AstraZeneca has initiated a series of oncology programs that support patients and their healthcare providers. According to Olivier Nataf, VP, U.S. oncology, AstraZeneca, these efforts provide important services to patients to improve their health and well-being before, during, and after treatment with their medicines.

LIGHTHOUSE

AstraZeneca launched the Lighthouse program to support cancer patients through medically trained professionals, available at any time of day. Patients are assigned their own personal advocate, ensuring that they talk to the same person regularly. Advocates help a patient remember to take his or her medication at the correct times, address questions about treatment 24/7, and provide ongoing support even if a patient chooses to stop treatment. The program also includes a tool to help patients keep track of their treatment experience and communicate pertinent informa-

Source: Olivier Nataf, VP, U.S. Oncology, AstraZeneca

tion to their doctor to help manage adverse events as soon as possible before becoming more serious and possibly causing treatment to be stopped.

ONCOLOGY NURSE EDUCATORS

Education is a critical element of support, particularly in immuno-oncology, an area of cancer treatment that is relatively new. In bringing these new therapies to market, AstraZeneca realizes physicians and patients need support to better understand immuno-oncology treatment, including how these medicines differ from traditional treatments. AstraZeneca's oncology nurse educators, stationed across the United States, provide on-site education to healthcare providers, patients, and caregivers; facilitate communications between patients and their doctors through a personalized patient-care team; and help educate patients to early identification of adverse events.

ACCESS TO MEDICINES

For some patients, the healthcare costs associated with treating and managing their disease can present a financial burden, and AstraZeneca is committed to helping ensure that patients who need its medicines have access to them. For example, its Access 360 program helps patients access the care they need. Once patients are prescribed one of its medicines and give consent, Access 360 reimbursement counselors provide assistance to patients and their providers with coverage and reimbursement

support. The program connects eligible patients to affordability programs, informs on insurance requirements and when appropriate, provides referrals to nurse assistance or educational support programs.

The company also supports copay assistance programs for eligible, commercially insured patients across the specialty oncology portfolio. Additionally, AstraZeneca has one of the longest standing patient assistance programs in the industry, AZ&ME, which provides eligible patients with AstraZeneca medicines at no cost. AstraZeneca provided prescription savings to 4.5 million patients across the United States and Puerto Rico over the past 10 years.

PATIENT COMMUNITIES & ADVOCACY PARTNERSHIP

A healthier world begins with education to help individuals make informed decisions and navigate available tools and resources, and AstraZeneca believes that creating awareness through community is key. As a result, in partnership with patient advocacy groups, it has created online platforms for patients facing certain advanced types of cancer. For example, AstraZeneca's My MBC Story offers a community for metastatic breast cancer patients to share stories and offer tips. Similarly, AstraZeneca created LVNG With, a community of people living with lung cancer who are inspiring each other.

Driving Momentum to Patient Services

A number of factors are driving the momentum, namely the need for better chronic care management in areas such as diabetes, COPD, and cardiovascular disease where pharmaceutical interventions are best combined with behavior changes and a higher degree of connectivity to care outside the physician office.

Initially, mobile health apps that entered the market were designed for the "worried well." Now, more digital therapeutics and solutions are geared toward helping patients with chronic disease.

"Studies continue to show that the combination of remote monitoring, behavior modi-

fication, and provider-supported interventions all outside the physician office can improve patient outcomes and lower the total cost of care," Ms. Gulfo says. "These results are starting to get the attention of payers, specifically accountable care organizations. The more robust the data to support a favorable outcome, the greater chance of reimbursement."

The increased scrutiny on pricing for drugs is one component driving the industry toward more patient services, Ms. Padilla says. However, she says pharma companies are using the wrong yardstick to measure results. Most companies are seeking to compare their beyond-the-pill services with their competition. The better benchmark is to provide services that achieve real-world results that are as close as possible to clinical trials results.

Mr. Clemente from Lilly Diabetes sees the ultimate driver as consumer demand.

"All stakeholders are searching for more holistic, connected solutions that improve adherence and outcomes," he says. "Insulin has been available for almost 95 years and there have been advances in diagnostics and therapies, yet managing diabetes remains a complex puzzle. With the evolution of connected devices and decision-making support for chronic disease management, people with diabetes may soon be able to leverage technology to achieve better outcomes."

Moving beyond the pill and toward a connected care model can reduce many burdens, improve patient engagement, and allow physicians to focus on the most important clinical decisions. **PV**