

# THINKING PAST THE PILL

Pfizer is investing heavily in adherence, putting patient support programs on equal footing with some of its drugs, **Matthew Arnold** reports

**A**dherence is a pricey problem. Patients failing to take their meds as directed or at all costs us anywhere from \$170 billion to more than a quarter-trillion in added healthcare costs, depending on who you ask, and the data don't address the human toll. For drug companies in an era where maximizing profits from existing products is ever more vital, it's a big opportunity. And healthcare reform promises to scramble the incentive structure for other healthcare industry players in such a way that could give pharmaceutical-sponsored behavioral modification programs equal billing with the pills they augment.

That's how it looks to Pfizer, which has initiated a clinical trial on its Toviaz support plan, Your Way. If Pfizer can show a big boost to adherence through the program, that data could be trumpeted in professional marketing efforts, maybe even included in the label. In a category like overactive bladder, that data could be persuasive not only to physicians but also to increasingly powerful payers.

"When you talk about smoking cessation or any of these programs, we've been working on this for awhile, but the stars are aligning at the national level with healthcare

**Pfizer's Jim Sage, VP customer engagement and Adele Gulfo, president and general manager for US primary care**





**Pfizer's Get Quit program for Chantix features communications tailored to the user's triggers and anxieties about quitting. "What we've heard consistently from patients is that Chantix is a great medication but Get Quit is even better," says Pfizer's Jim Sage. Pictured below right, brochure for Pfizer's Your Way program for Toviaz**

reform, which is trying to take waste out of the system," says Adele Gulfo, president and general manager for US primary care at Pfizer. "And \$290 billion in waste is a big bucket of money."

A major theme of the Affordable Care Act that the president signed earlier this year is the effort to nudge the healthcare system from a fee for service model to an outcomes-based one that makes physicians and the healthcare systems they work for accountable for the quality of care. If a patient stops taking their meds and gets sicker, it'll cost the provider. Pfizer figures this sea change, coupled with the beefing up of healthcare IT mandated by the new law, will make patient support programs pay while bettering patient outcomes.

The company expects to have data from the clinical trial by the end of the year or early in 2011.

"The days of just selling the pill are over," says Gulfo. "As the number one player in primary care, we touch millions of patients, and we can take costs out of the overall healthcare system. It's an opportunity and a responsibility." Increasingly, says Gulfo, the government is demanding that companies demonstrate that their products provide economic as well as clinical benefits.

"The value equation has changed," says Jim Sage, VP of customer engagement at Pfizer. "It used to be that having a differentiated medicine was the value. That's changed. It's still part of the value, but now we also have the obligation and the expectation that we're going to make sure we follow through on that and support whoever takes those medicines in an appropriate way."

### Enter the "emotional concierge"

Some of the larger pharmas have been tinkering with patient support programs for years as a means of helping patients stay on their meds and take them as directed. These efforts have evolved from crude reminder messaging to elaborate relationship marketing efforts featuring multiple touchpoints and sophisticated behavioral modeling. Pfizer's Get Quit program for smoking cessation

treatment Chantix is actually featured in the company's marketing efforts for the drug.

"One of the hallmarks of the program is its interactivity," says Sage. Upon signing up, patients must answer questions about how they like to receive information, why they smoke, when they smoke, the sort of cravings they have and their concerns about quitting. Then they're assigned a Mayo Clinic-certified tobacco treatment specialist who will counsel them on how to overcome the challenges of quitting.

"It's built on a couple of important customer insights," says Sage. "The first is that smoking is not just a physical condition. It's also psychological, and you have to be able to treat both components. The second is that smokers don't need to be told what the health consequences are. They already know what's going to happen to them. They don't want to be preached to. What they want is support."

For its current Chantix consumer ad campaign, which debuted at the beginning of the year, Pfizer fired the tortoise and the hare and went instead with testimonials ripped from thank-you notes sent to the company unprompted.

Similarly, Roska Direct president and CEO Jay Bolling says his agency has realized 20% increases in persistency – patients continuing to take their medication – through the use of nurse counselors in patient support programs for high-cost therapies like biologics and oncology treatments, as well as chronic conditions like diabetes. It's not cheap, but it gets results.

"We've seen huge gains where we engage this third party and create a triad," says Bolling. "Where we're seeing the biggest difference is where we're able to provide emotional support and surround sound. There are so many issues where patients can fall through the cracks, and the nurse counselor fixes that. They're acting as an emotional concierge."

### Diabetes an adherence laboratory

The diabetes category has proven particularly fertile ground for innovation in patient support programs, in part because of the patient-directed nature of treatment. Lilly's Matt Beebe, global commercialization leader for diabetes, notes that the typical US patient spends less than an hour a year with their healthcare provider.

"Our focus had been to help support the healthcare provider, but we know that after a patient goes to see the doctor for 10-20





Lilly distributes L.L. Bean backpacks packed with educational materials at ADA- and DECCA-affiliated diabetes camps. “For many kids with type 1 diabetes, it’s the first time since they’ve been diagnosed that their parents have let them go away out of their control,” says Lilly’s Keith Johns



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minutes, they go home and spend the next 131,000 minutes living their life before they have another 20-minute intervention with their healthcare provider.”

One of the key lessons Lilly has learned in the space is of the need to provide bite-sized bits of information to just the right patient at just the right time. Lilly’s Humalog Small Steps effort, largely based on the Byetta By Your Side program, aims to support patients through the first few months of therapy through seven mailings calibrated to help patients through tough transition points in treatment – for example, the shift from basal insulin to mealtime insulin.

“It’s not everything you need to know about managing diabetes with an intense basal bolus regimen,” says Lilly senior director for insulin Keith Johns, “but rather, giving them small pieces of information they can act upon and make small changes in their lives.”

Lilly’s Play Forward Guide, for children with type 1 diabetes and their caregivers, aims to help families through the bewildering period after initial diagnosis by explaining how to manage birthdays, sports and sleepovers.

“That’s a time in a family’s life that truly rocks their world,” says Johns. “The guide is really trying to help children with type 1 diabetes still be kids, because the premise is, at the end of the day, you want your child to have the same hopes and dreams that any child has.”

## Recapturing Patients Following a Drug Holiday

Which types of patients can be recovered from “drug holidays” in specialty markets? With de-identified, longitudinal patient data from specialty pharmacy providers (SPPs), it is now possible to tell. IMS Health recently worked with a top-ten pharmaceutical company to analyze and understand adherence patterns for its specialty product.

Patients take drug holidays for a variety of reasons, including therapy failure, side effects, and cost factors, as well as physician-directed switches and the ironic situation where compliance drops as symptoms subside. For both its own and its competitors’ products, our client was interested in a range of information. When do patients return to the current brand and when do they switch? What are the unique patterns and interplay between therapy gaps and patient attributes? Are there any differences by physician specialty? Did patient gender and age, co-morbidity situations, or a change in co-pay impact adherence gaps?

Adherence is usually defined as a combination of patient persistence (remaining on the therapy as long as needed) and compliance (taking the drug as prescribed). Compliance studies have been conducted for years with data from retail pharmacies. Integrating data from SPPs offers the ability to more precisely analyze patients on specialty therapies. The database reveals patient demographics, brand performance, and compliance and persistence across patient groups. We analyzed a cohort of patients who were on therapy, dropped therapy for a period of time, and then returned.

### Bringing Back Patients

Fewer than 30% of all patients studied had an observed therapy gap—a not-atypical rate for a specialty drug in this category.

The gap was somewhat lower among new-to-brand patients, at 24%, indicating that those who had just started therapy were slightly less likely to take a holiday. Among new-to-brand patients who took a drug holiday, nearly 40% did so within 50 days of initiation. This suggested an issue at start-up, possibly related to the method of drug delivery.

Overall, patients using the client’s product had a higher rate of therapy gap relative to the competition and more instances of multiple therapy gaps. The majority of gaps lasted for an average of 75 days. Such

information led the company to consider: Might it be at a disadvantage based on efficacy or side-effect profile? Would some refinements to the patient assistance program yield better adherence? Primary research followed to explore such issues.

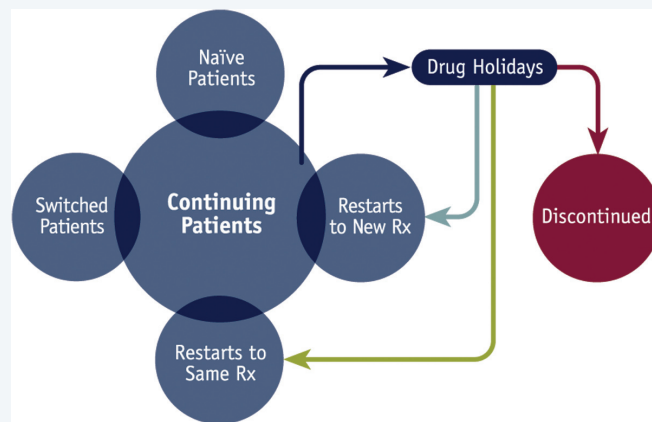
Patients treated by the majority prescribing specialty for both the client’s and the competitors’ products had slightly fewer therapy gaps compared with other specialties. Additionally, most therapy gaps were associated with either a co-morbidity event (as evidenced by the use of a drug in another therapeutic class) or a change event (with co-payment changes being the largest driver).

Based on this analysis, the client determined that true potential for recapturing business existed among 20% of the 30% of patients who went on holiday. The company estimated that, over the average 75-day holiday, this would amount to more than \$21,400 lost per patient (10.7 weeks at \$2,000 per patient)\*, and available for possible recapture.

Alan Hirshman is senior principal at IMS Health

\*These drug costs are illustrative only.

Figure 1: Patient Flow Model



The company has a big presence at diabetes camps, donating a backpack full of educational materials as well as products. Last summer, Lilly sponsored a tour of the camps by Olympic skier Chris Freeman. Lilly also runs the F.A.C.E. Diabetes program through black churches (F.A.C.E. stands for Fearless African Americans Connected and Empowered), which offers diet and lifestyle advice and has attracted star power from actor Anthony Anderson of *Law & Order* and R&B singer Angie Stone.

“The backdrop of how we approach it is that it’s not about changing your life for diabetes, but how you fit diabetes into your life,” says Johns.

That was the idea behind Sanofi-Aventis’ Go Meals app, a turbocharged calorie counter that has surpassed 100,000 downloads since its launch late last year. Around half of all users use it daily. An iPad version was released in July.

“A diagnosis of diabetes is traumatic at the start, but really after that is a 24-hour effort to manage a complex disease,” says Lynn Crowe, senior product manager, diabetes marketing at Sanofi-Aventis. “The more we understand what it’s like to walk through your day and then complicate it by adding diabetes to it, there’s some real obvious places to intervene, especially with mobile technology. The volume of apps would suggest that you’re not sitting home tending to your diabetes. You’ve got to take it with you.”

## Looping in other healthcare players

Pfizer is looking beyond patient support programs and reaching out to other healthcare industry players with a series of pilot programs. Last year, Pfizer ran a pilot program through 80 Walgreens pharmacies in New Jersey, providing educational materials on its products and sponsoring counseling by pharmacists. That program has been expanded to several other states.

Through a partnership with McKesson, the company offered one-on-one behavioral counseling through 2,000 pharma-

cies in support of Chantix, Detrol, Lyrica and Lipitor. That effort reached 15,000 patients. Pharmacist consultations for the company’s Get Quit program realized a “statistically significant” increase in refill rates.

“What’s working is having a personalized, one-to-one adherence program in a scalable way,” says Derek Rago, VP marketing for adherence solutions at McKesson. “And it works maybe for more complex disease states, more chronic conditions. What’s maybe not working as well is when you do the mass-market, one-size-fits-all approach and you just have one tool – say reducing copays. Those results become marginal because you really don’t address the complexity of adherence.”

Pfizer has also partnered with Wellpoint, Medco and other firms, even some large cardiovascular practices, on patient support programs for its products. The adoption of electronic medical records and healthcare IT infrastructure, already widespread in the west, will close the loop and amplify these efforts by allowing physicians to see when a patient has failed to refill their meds and anticipate non-compliant behavior in serial offenders.

“So if you’re writing me a script for hypertension, you may have the decision algorithm built in to know that I’m at high risk for non-compliance,” says Pfizer’s Gulfo. “It’s another point of intervention,” adds Sage. “The point of prescription becomes a teaching opportunity for the right patients. With healthcare reform and the incentives around accountability, more than likely we’ll be able to work not just at the individual doctor-patient level but in these systems with group practices to effect larger change.”

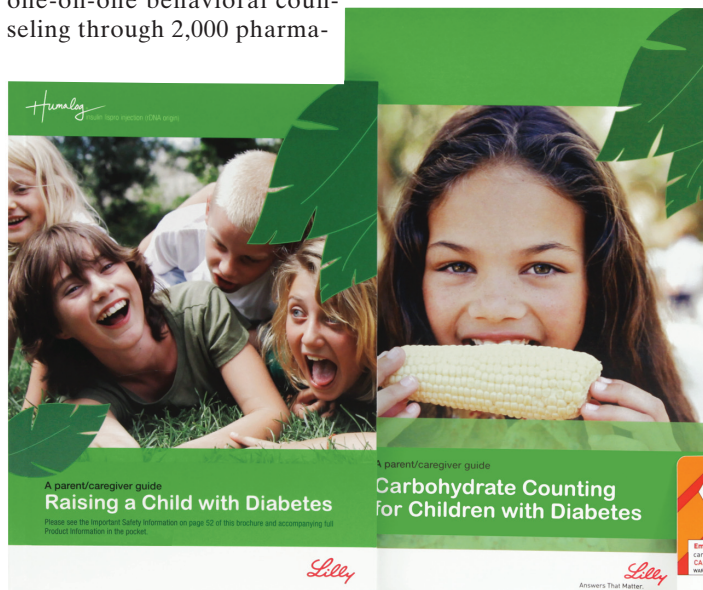
McKesson, which launched an adherence practice three years ago, approaches persistence as a plumbing problem.

“You try to aggregate where the bucket leaks most,” says Rago.

“If you started with 100 prescriptions at the physician’s office that they’re writing for a patient, on average, 70% arrive at the pharmacy, 30% don’t even get presented. And then 66% actually get out of the pharmacy, and that’s really an abandonment issue where they’re unclaimed. Either the patient doesn’t claim the prescription once they bring it to the pharmacy or a substitution is made at the point of sale. And then 25%-30% are taken properly when they get out of the pharmacy, and then you have leakage when they’re refilled, which is 15%-20%.” ■



**Sanofi-Aventis’ Go Meals app is a turbocharged calorie counter for diabetes patients on the go**



The premise behind Lilly’s pediatric starter kit and Play Forward Guide for children with diabetes and their caregivers, says Lilly’s Keith Johns, “is not an A-Z bible, it’s really taking some key moments in a family’s life that they’re going to have to learn to deal with so that their child can return to as normal a life with diabetes as possible”