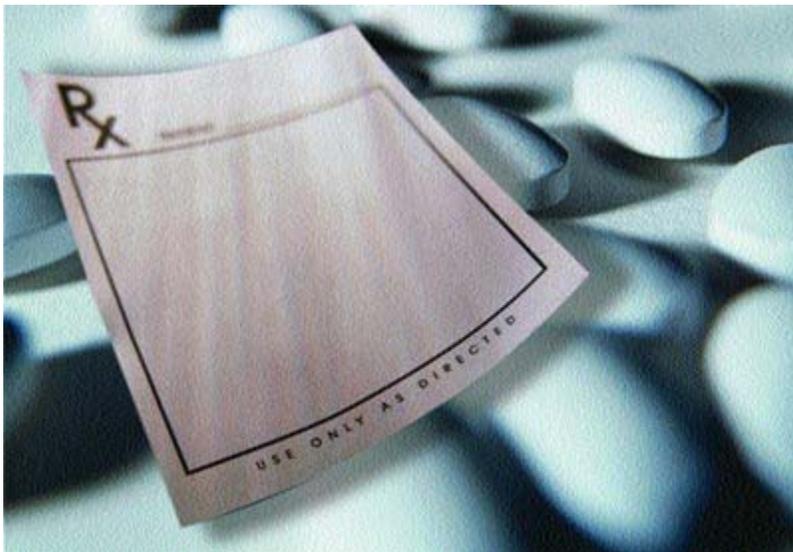


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DTC's New Job: Boosting Compliance

By Dorothy Smith

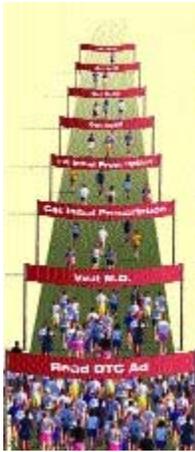
Refills, not office visits, should be the goal of consumer communications.



Imagine a footrace. A hundred runners assemble at the starting line, but when the starter's pistol goes off, ten of them change their minds and don't run at all. At the first turn, another dozen drop out: They're too far behind, and they feel like they can never catch up. Halfway into the race, still more quit: They're tired, they're sore, and they don't think they can make it. With the finish line in sight, still more grind to a halt: They haven't paced themselves, and they can't go on. By the time the runners reach the finish line, only a handful are left.

In real life, races don't usually work that way, partly because of good coaching. Runners are motivated by their coaches to train and prepare for the race. They learn how to handle the obstacles of the course and develop a frame of mind so that they can endure. They prepare not just for the starter's gate, but for the entire course.

Getting patients to comply with treatment isn't quite the same as a race. There's no single winner-anyone who stays the course comes out on top. And for patients with chronic diseases, there's no finish line. They must stick with a treatment indefinitely. But in one way, the patient compliance effort is a lot like our



hypothetical race: Most patients drop out. And only a handful keep going long enough to really benefit from the drugs they've been prescribed.

This article addresses pharma's equivalent of coaching: patient information, especially in the form of DTC advertising. It shows how DTC ads can reinforce pharma company messages when patients enter the long-term treatment cycle, help patients stay with that treatment as long as the condition persists-and increase pharma's profits.

Running the Race A 2003 survey conducted by Prevention magazine tested consumer awareness of DTC advertising for 13 medicines prescribed for chronic conditions such as arthritis, high blood pressure, and depression. The data showed that eight of every 100 people who read a DTC ad received a prescription.

But how many persist in taking the medication? An earlier Prevention survey paints a striking picture. In that 1999 survey, seven patients out of 100 received a prescription. Six filled it. Four made it to the first refill. But by the fourth or fifth refill, only one was still taking the medication.

Think of it another way: If all six patients who filled their prescriptions made it to the fourth refill, the manufacturer would have made 30 sales-six patients times five visits to the pharmacy. In fact, the manufacturer makes only 16 sales, a loss of almost 50 percent.

But that scenario applies only to the fourth or fifth refill. Medications for chronic conditions could be prescribed for months or years. If patients can be persuaded that it is in their best interest to refill the prescription and stay on the therapy as prescribed, the product's return on investment (ROI) would skyrocket. Patients who remain in therapy and manage their medications correctly also have a better clinical response and physicians are more inclined to prescribe the medication to other patients.

Why do patients drop out of therapy prematurely? The 2003 Prevention survey lists several reasons: failure to remember; started feeling better; forgot to get refill; cut recommended dose because medicine is too strong; took less so prescription would last longer; and side effects. Perhaps some of those reasons would be eliminated if pharmaceutical patient communications focused more on health literacy as part of their patient compliance strategies.

Reducing the Dropout Rate Pharma companies have good reason to be concerned that so many patients with chronic conditions are dropping out of therapy prematurely. Not only does that drastically decrease the campaign's potential ROI, but a commonly used advertising statistic maintains that it costs six times more to gain a new patient than to retain a current one.

Yet, there is no quick fix. To persuade patients to remain in therapy, pharma marketers must develop a compliance strategy that meets the varying needs of consumers, patients, and health professionals through all stages of treatment. It must take into account the specific product, disease, and patient population. A patient compliance strategy must be part of the DTC program and subsequent patient information materials.

Three-Step Program When DTC is conceptualized as the first stage of a larger patient compliance program, the stage is set for educational messages that can help patients answer three key questions:

Should I fill this prescription? Patient compliance literature during the last 20 years has shown that patients never fill 10–20 percent of all initial prescriptions because they are not convinced they need the medication. According to a 1999 FDA report titled "Managing the Risks for Medical Product Use," patients must decide if the benefits of the medication are greater than the risks. When their own health is at stake, they will do all they can to protect it.



The Prevention study found that providing risk information in a DTC message may actually increase consumer confidence in the advertised product. And if patients trust what the DTC promotion says, they are more likely to fill the initial prescription. Compliance also increases when patients feel they are part of the decision-making process. Because DTC programs target people as they are about to make a therapeutic decision and encourage them to become more informed, they have the potential to improve initial prescription fill rates.

To make an accurate risk/benefit assessment, consumers must be able to understand the information presented. There is a wide disparity in the quality of materials distributed to patients, according to an eight-state study published in the May/June 2003 issue of the Journal of the American Pharmacists Association. And many materials fail to inform patients. A survey conducted by the Department of Psychiatry at Louisiana State University Medical Center in 2000 showed that almost half of all patients were unable to understand pharmacy printouts.

Many companies still use the highly technical "brief summary" with consumer materials, but the FDA-approved patient package insert (PPI) is easier to understand and should become the foundation of all patient information programs, including DTC ads. (See "Words to the Wise.")

How do I take this medication? At least 50 percent of the people who get prescriptions for chronic medications do not take them correctly. That is usually because they do not receive enough information, they fail to understand the information the pharmacy provides, or they choose to ignore it. If the patient makes an error, the drug will not be as effective as it should be, often leading the doctor to switch the patient to another medication.

Prevention's 1999 survey found that three in ten patients already taking a product said they were more likely to take the prescribed medicine after seeing it advertised. The magazine's 2003 survey suggests that DTC advertising might make consumers feel better about the safety and effectiveness of the medicines they are taking, but the survey did not address the impact of this effect on compliance.

Why should I refill my prescription? Patients decide if they're going to finish-or lengthen-their course of therapy, based on their symptoms, side effects, and feedback from health professionals.



Many studies demonstrate that compliance for patients with chronic conditions is extremely poor. After three months of treatment, the patient dropout rate for anti-hypertensives and cholesterol-lowering products is as high as 50 percent. For cholesterol agents, 25 percent of patients stopped therapy in the first month and 50 percent quit within three months of starting treatment. The Saskatchewan Health Services Utilization and Research Commission compiled actual clinical practice data and reported that 75 percent of new patients taking cholesterol agents had dropped out of therapy after one year. In fact, the dropout rate after the initial prescription was also extremely high.

DTC programs tied to an overall patient compliance strategy can help improve refill compliance and increase patient retention. In the 1999 Prevention survey, one third of patients said DTC ads reminded them to refill their prescriptions. And consumers who see a DTC ad for a product they currently take are significantly more likely than others to say the ad made them more confident about their medication.

On their own, DTC ads will never improve refill compliance. Because patients experience side effects and drug interactions, the issue is far too complicated to be addressed by ads alone. But they can play a reinforcing role. The goal is to convince patients with chronic conditions to develop habits that help them manage their medications correctly. Once patients have taken their medications correctly for one year, their chances of being compliant thereafter are significantly increased. Thus, the goal should be to get patients through the first year so they will remain on the medication for as long as necessary.



Staying the Course An effective patient compliance strategy can take a DTC program to the next level and improve prescription refills. But to do that, it is critical at the outset for companies to communicate with patients differently than they do with traditional medical communications and continuing medical education (CME) programs. The reason so many patients drop out of therapy is that they are simply being given information-much of which they cannot understand. Companies must create programs that teach patients to modify their behavior-and convey information in language that patients can understand. (See "Voices of Experience.") The DTC ad can become a very effective first step to winning the person's trust and helping the physician and pharmacist persuade the patient that the medication has value.

But patient retention programs must go far beyond DTC advertising and address the problems patients face as they try to make treatment decisions. What are the side effects and are they manageable? Does the medication change the effectiveness of other prescriptions they are currently taking? Is the medication easy

to take on a regular schedule? Anyone who has counseled patients in clinical settings knows that when patients make mistakes, it is usually not their fault. They just didn't have the information they needed to make a better decision.

Programs will work only if the content

- provides patients with information they need to manage the medication safely and wisely
- helps build confidence and trust in the medication
- is provided in language the average consumer can understand
- is reinforced with an effective design based on health literacy principles.

To create an effective patient retention program, companies must develop materials in the following order:

1. Patient Compliance Strategy. Before developing content or design, it is essential for companies to:

- Identify-through research on the disease, its therapies, and the target population-all the other potential compliance programs patients may encounter.
- Identify the barriers that health professionals are most likely to encounter when answering patients' questions about a company's DTC campaign or patient compliance tools.
- Determine which patient counseling techniques and programs are successful in overcoming each patient compliance barrier. Sometimes that means patients must keep personal progress journals so they can self-monitor and remain motivated. At other times, a clinic and pharmacy reminder program will help.
- Apply behavior modification models that work with different types of information at each stage of patients' decision making process: the DTC campaign, initial prescriptions, and refill prescriptions. That will help drug makers connect with patients at an emotional level and deal with their fear, anger, denial, concern about side effects and worry about the therapy's cost as well as its impact on their family and lifestyle.
- Identify behavior modification techniques tailored to the medical condition and product. Patients with obsessive-compulsive disorders require different approaches than patients taking long-term antihypertensives. Identify self-monitoring and interactive tools that will help patients follow their own progress so they are motivated to continue taking the medication.

2. Content. Once a patient compliance strategy has been developed, pharma companies must incorporate it into all DTC materials, on websites, and in health screening tools, patient pamphlets, patient videos, product launch kits, starter packs, and health professional counseling tools.

The foundation of a strong patient compliance program and strong DTC promotion is the FDA-approved PPI, which replaces the brief summary on the back of DTC print ads and helps ensure that consumers understand the medication's benefits and risks.

The PPI should be the basis for all future DTC collateral education programs and patient counseling tools for physicians and pharmacists as well as for the product's website.

Then the company is ready to:

- Develop easy-to-understand content at the fourth- or sixth-grade reading level. Even if a pamphlet is written at the sixth-grade level, however, there is no guarantee that consumers will understand it. Studies show that some people do not understand such terms as "red meat," "orally," and "high-fat diet."
- Translate side effects into symptoms that patients can understand. Patients must be able to recognize the early warning signs of side effects, know how to manage symptoms, and know when to seek medical attention if side effects become too severe. When the information is communicated properly, patients are less likely to drop out of treatment prematurely.
- Use strategies that persuade patients to fill the initial prescription and remain in treatment. Patients must see value in taking a medication as well as the need to make lifestyle changes. Companies should use behavior modification strategies that fit each specific stage of therapy. Patients need different information when they receive the initial prescription than they do for refilling a prescription at one month, three months, six months, or more.

- Demonstrate empathy. Patients must believe that the pharma company cares about, and wants to improve, their quality of life. When they see the company's educational materials, their reaction should be, "That's exactly how I feel."

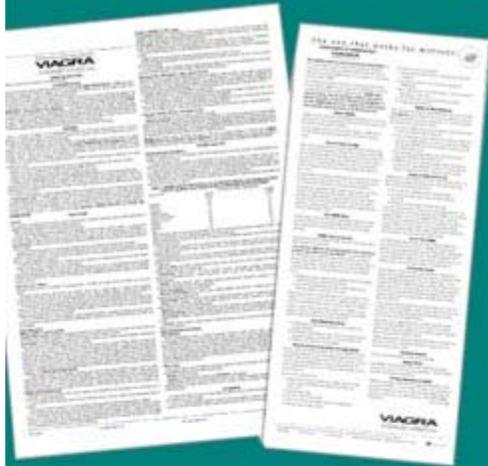
3. Design. The design of a full compliance program begins during the content development stage. Whenever a message can be more clearly conveyed through a photograph, chart, illustration, or other visual medium, it should be. The key is to ensure that the design reinforces the written content, increases comprehension, and speaks directly to the patient's condition and symptoms. (See "His Heartburn is My Heartburn.")

Here's how:

- Simplify medical illustrations so they are consumer friendly and easy to understand.
- Select colors, fonts, type sizes, and paper that meet patients' needs. For example, blue and green should not be used together for a diabetic audience, because many diabetic patients who have undergone laser surgery for retinopathy cannot distinguish between the two colors.
- Reinforce the brand identification so consumers easily recognize the product each time they see a DTC ad or collateral materials about it.
- Convey a sense of empathy with patients throughout the design in a way that will be acceptable to patients, consumers, and caregivers.

Long-Term Success For most patients, the success of drug therapy hinges on how well they understand and believe the information they receive. For a pharma company, the success of DTC advertising campaigns for drugs that treat long-term conditions may have less to do with the size of the ad budget and more to do with understanding how to deliver information in a way that meets the customer's self-care needs. Although patient noncompliance is a major problem for pharma, it also presents one of the industry's greatest opportunities for growth.

Words to the Wise



VIAGRA BRIEF

SUMMARY:

"Serious cardiovascular events, including myocardial infarction, sudden cardiac death, ventricular arrhythmia, cerebrovascular hemorrhage, transient ischemic attack and hypertension, have been reported post-marketing in temporal association with the use of VIAGRA. Most, but not all, of these patients had preexisting cardiovascular risk factors."

VIAGRA PPI:

"Heart attack, stroke, irregular heart beats, and death have been reported rarely in men taking VIAGRA. Most, but not all, of these men had heart problems before taking this medicine."

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materials, but the the FDA-approved patient package insert (PPI) is easier to understand and should become the foundation of all patient information programs, including DTC ads.

His Heartburn is My Heartburn

AstraZeneca's Prilosec (omeprazole) DTC ad showing a man with heartburn is a good example of a successful DTC ad, one which consumers can readily identify.

FREQUENT HEARTBURN SUFFERERS:

If your heartburn medicine works so well, why do you keep getting heartburn?

ASK YOUR DOCTOR ABOUT PRILLOSEC

Just one capsule of PRILLOSEC daily can provide 24-hour acid control.

If your heartburn is persistent and occurs on two or more days a week, you probably don't have ordinary heartburn.

You may have a potentially serious condition called acid reflux disease (also known as gastroesophageal reflux disease, or GERD). Today doctors can help by prescribing PRILLOSEC. It's highly effective in controlling acid production for 24 hours—comes about once, not all night, two—two, just one capsule a day.

Available only by prescription. Ask your doctor if PRILLOSEC is right for you.

PRILLOSEC is generally well tolerated, but it is not for everyone. The most common side effects are headache (13%), diarrhea (12%), and abdominal pain (12%).

Please read important information on the adjacent page and discuss it with your doctor.

www.acidcontrol.com

FREE INFORMATION KIT
1-800-338-4443

You will receive FREE a booklet about heartburn, acid reflux disease, and PRILLOSEC (one a person benefits daily, and a special combination to help you sleep better).

ASK YOUR DOCTOR ABOUT 24-HOUR ACID CONTROL
PRILLOSEC
OMEPRAZOLE 20 MG ONCE DAILY

ASTRA
AstraZeneca



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