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Format: Campaign Profile-A two-page summary of a Silver-Anvil Award of Excellence winner, addressing research, planning, execution and evaluation.

Title: “Helping Americans Save Billions With Generic Medications”

Silver-Anvil Award of Excellence Winner

Express Scripts, Inc., Padilla Speer Beardsley Inc., **2007**

Summary: 2007 Silver Anvil Award of Excellence Winner – Marketing Consumer Products – Healthcare Services

Advances in medicine have allowed Americans to live healthier lives. But many families and employers are strained to afford promising new treatments. Express Scripts (ESI), one of the country’s largest pharmacy benefit management companies, saw an unprecedented opportunity in 2006 to help plan members save millions without sacrificing quality: generic anti-cholesterol medication was about to hit the market. But moving patients onto different medications is a difficult undertaking. ESI successfully launched an integrated campaign that increased generic anti-cholesterol medication use from 8 percent to 40 percent and saved patients and employers \$126 million in 2006.

Full Text: OVERVIEW

In the United States, heart disease is a leading cause of death. Statins, which are used to manage cholesterol, promise to cut the risks of heart disease by preventing blockage of the arteries.

But the drugs are costly. In 2005, statins made up 12 percent of pharmacy spending, totaling \$1 of every \$8 spent on pharmaceuticals and making statins the top-selling drug class. At the same time, use of these medications was increasing about 15 percent per year, creating a “perfect storm” of expense.

Express Scripts (ESI) is one of the country’s largest pharmacy benefit management companies, which negotiate discounts from pharmacies and manufacturers and promote cost-effective prescription drug use. ESI is dedicated to encouraging employer, union, managed care and government plan sponsors to substitute generics whenever possible to hold down spiraling costs. In general, for every percentage point increase in generic use, a plan sponsor can reduce drug costs by a percent.

In 2006, an unprecedented opportunity arose to help plan sponsors and patients save millions without sacrificing quality: The patent for Zocor® would expire in June. Generic Zocor®, simvastatin, would soon hit the market joining lovastatin and pravastatin. Except for the relatively small number requiring a high-potency brand medication, patients would have three low-cost generic alternatives to fight cholesterol.

Persuading patients to use a different medication is complex, especially when they had been using the top-selling drug, Lipitor®. “Express Scripts has yanked the beard of the biggest lion,” observed Barron’s. But ESI’s focus on generics compelled it to use this opportunity to encourage patients to choose the new options, and educate the public about the potential for savings through generic drugs.

RESEARCH

Research served two purposes critical to the success of this persuasion campaign:

1. Gauge Americans’ acceptance of generic drugs as effective replacements for higher-cost branded drugs, as a baseline for awareness-building.
2. Build a proof case for greater generics use that addressed both the cost savings and the concern over whether generics worked as well as major brands.

Generic Drug Acceptance

Secondary research in health care journals revealed uneven understanding and acceptance among Americans of generics as the treatment equivalent to branded drugs.

Proof Case for Generics

Secondary research, including a Kaiser Permanente report, revealed that more than 70 percent of anti-cholesterol prescriptions in 2004-5 could have been filled by a generic with no compromise to health outcomes.

Primary research, including 100 independent and 75 ESI-led studies, made the economic case for generics:
o Americans could have saved more than \$25 billion in 2006 with greater use of generics; \$10 billion of that with

generic statins.

- o Generic statins have the potential to fill 85 percent of statin prescriptions.

PLANNING

Overall Goal: Help patients and employers save money through increased generic drug use, using the arrival of generic statins as a “triggering event.”

Campaign Objectives:

1. Assist ESI’s clients in making the formulary change with minimal difficulties as measured by:
 - o Timely, comprehensive communication with all target audiences.
 - o Key messages evident in all media.
 - o No loss of plan sponsor clients due to employee pressure not to adopt ESI’s recommended formulary.
2. Use the arrival of generic statins to raise awareness of the potential for billions in savings by switching to equivalent generic medications, as measured by:
 - o Positive media attention for the use of generic medications from at least one national news service, two major TV outlets, two major daily newspapers, and 25 ESI client markets.
 - o The percentage of ESI patients using a generic medication post-campaign.
3. Increased usage of lower-cost, high potency brands Vytorin® and Crestor®. Reduction in the use of higher-cost Lipitor® among ESI plan members as measured by:
 - o Greater than average national conversion rates.

Target Audiences:

ESI analyzed a variety of audiences (see supporting materials) and chose as its primary targets:

- o ESI employees with direct client contact.
- o ESI clients, who may have been concerned about resistance from change-averse employees and might choose not to adopt ESI’s recommended formulary.
- o Consultants and brokers as client gatekeepers.
- o Patients, each of whom had to agree with any medication change.
- o Physicians, who often continue to prescribe branded drugs even when generics are available.
- o Retail pharmacists, who interface with patients and can educate them about lower-cost alternatives and encourage them to speak with their doctors.
- o News media, as a conduit to above audiences.

Strategies & Tactics:

The possibility that brand manufacturers would defend their drugs publicly and aggressively was real. That “noise” could blunt the effectiveness of ESI’s education effort to show that generics were clinically sound and to communicate the enormous savings. But ESI also had relationships to preserve with the brand manufacturers with whom it contracted for the hundreds of drugs within its plans. Presenting generic facts with due respect to these companies and deftly executing on the campaign plan would achieve ESI’s objectives. Anything less could backfire and actually slow the rate of generic adoption.

Strategy One: Inform ESI clients about the formulary change and encourage them to take steps to move members from high-cost to lower-cost medications.

- o Train ESI account management executives to communicate changes and encourage implementation of tools to “ease into” generics such as step-therapy.
- o Host Web cast and provide content for employee newsletters and Intranet sites.

Strategy Two: Recruit top physicians and researchers to serve as non-paid, independent spokespeople in support of greater generics use.

- o Research and select spokespeople, and provide them with ESI and independent background.

Strategy Three: Inform patients of the potential generic savings at each point-of-contact including:

- o Patient, physician notification letters and phone calls.
- o Web pop-up window and “Price Check” price difference chart displayed on Web site when patient refills prescription.
- o “On hold” phone message describing savings.

Strategy Four: Inform American workers of the potential cumulative savings through greater use of generics, in order to reinforce what they were hearing from their doctors and pharmacists (or to trigger the conversation about generics in the first place):

- o Conduct nationwide studies to determine the potential savings in 2005 and 2006.
- o Release study results nationally with news release, video news release and media outreach.

Strategy Five: Educate physicians about clinical alternatives and appropriately moving patients to a lower-cost medication in accordance with benefit designs.

- o Provide background sheet ranking drugs by potential to lower cholesterol.
- o Outreach to health care trade media.

Budget: PR agency fees: \$115,620; ESI internal budget: proprietary.

EXECUTION

ESI began executing its communication strategy in June 2005, with internal training of sales executives. In August 2005, it began informing clients about recommended changes to the 2006 formulary (moving Lipitor® off the formulary and encouraging use of Zocor® in preparation for new generic statin). By October, the Associated Press was on the story of ESI's major formulary change. ESI put its media strategy in place, working hand-in-hand with the AP and other major news outlets including Reuters, St. Louis Post-Dispatch, Bloomberg, St. Louis Business Journal, Drug Industry Daily, Washington Post, New York Times, Barrons and Dow Jones Newswire. The goal was to focus on the savings potential for patients and plan sponsors rather than differences between pharmacy benefit managers like ESI and brand manufacturers.

ESI continued its tactical execution. In late October 2005 it released the "2004 Generics Usage Report," which showed that Americans could have saved \$20 billion that year with greater use of generics. In June 2006, the study was updated to show a \$25 billion savings opportunity. The media outreach included national and local markets, a comprehensive online media kit, and expert interviews. Video and audio news releases were also available.

EVALUATION

The campaign was an unprecedented success, exceeding all objectives:

Objective 1: Successful formulary change.

- o All communications were executed according to plan despite a tight timeframe, and included key messages, including 1.2 million patient letters, 100,000 educational conversations with patients and 25,000 interactive voice recognition messages.
- o Nearly all clients adopted the recommended formulary.
- o ESI lost no clients over the formulary change.

Objective 2: Capitalize on generic statins' arrival to raise awareness of cost-savings nationwide and to increase ESI patients' generic statin usage post-campaign.

- o More than 270 media outlets around the country reported on ESI's generics savings report, totaling more than 100 million media impressions. Coverage included AP, Bloomberg, Health Day News and UPI news services; national media outlets such as ABC News, CBS News, CNN, NBC News, Fox News, New York Times, Wall Street Journal, Los Angeles Times, National Public Radio; and more than 200 local television and print outlets in ESI client markets.
- o By the end of 2006, 40 percent of all anti-cholesterol drug prescriptions at Express Scripts were for generics, up from 8 percent at the beginning of that year. This type of dramatic increase in the generic fill rate within this therapy class had never been achieved previously.

Objective 3: Increase share of lower cost, high potency anti-cholesterol brands.

- o Lipitor® use among ESI plan members dropped 21 percent in 2006. This was more than double the 8.7 percent decrease seen nationally. Crestor® usage increased 5.2 percent vs. 2.2 percent nationally and Vytorin® usage increased 4.5 percent vs. 2.5 percent nationally.

Most importantly, ESI clients and patients saved \$126 million on anti-cholesterol medications alone in 2006.

October 15, 2005

Lipitor or Generic? Billion-Dollar Battle Looms

By [ALEX BERENSON](#)

The Lipitor war is about to begin.

Starting next June, insurers and government agencies will have the opportunity to save billions of dollars by moving patients from Lipitor, a [cholesterol](#)-lowering drug by [Pfizer](#) that is the world's top-selling medication, to an inexpensive generic version of Zocor, a similar but less potent drug now made by [Merck](#).

Some insurers are already planning ways to move patients from Lipitor to generic cholesterol drugs after Zocor loses its patent protection. But Pfizer, which plans to use marketing muscle and clinical data to fight that migration, says that Lipitor has unique benefits and is worth a premium price, especially for patients at high risk of heart attacks.

Both medicines belong to a class of drugs known as statins, which are the nation's best-selling medications, with almost 150 million prescriptions expected to be filled this year at a cost of \$16 billion. The insurers, and some cardiologists, say that switching patients from Lipitor to generic Zocor will be a safe way to cut costs in an era of skyrocketing pharmaceutical prices.

In many cases, they say, patients who now take the most commonly prescribed dosage of Lipitor - 10 milligrams daily - can reduce their cholesterol just as much with Zocor. Lipitor costs \$2 or more a day, while generic Zocor will probably cost 35 cents or less.

"If I was taking a statin, I'd want to take the cheapest one, as long as I get to the goal that I wanted to get to," said Dr. Scott Grundy, a researcher who has consulted for both Merck and Pfizer. Dr. Grundy led a federal panel that in 2001 wrote guidelines for treating people with high cholesterol.

But other doctors and epidemiologists say that Lipitor may be the best drug for many patients. "It would not be good medicine to go to a cheaper medicine that has less efficacy in our high-risk patients," said Dr. Robert Vogel, a cardiologist at the University of Maryland, who has been paid by Pfizer to help conduct a clinical trial of Lipitor.

Pfizer says it will fiercely defend Lipitor. "By taking any dose of Lipitor, you will reduce the risk of a cardiovascular event faster and to a greater degree than you will with any other medicine," said J. Patrick Kelly, Pfizer's president of United States [pharmaceuticals](#).

The fight over Lipitor involves a collision of fundamental forces in American health care. Spending on prescription drugs has jumped from \$40 billion in 1990 to almost \$250 billion this year, and continues to rise faster than overall inflation. But while many Americans say they believe that prescription drugs cost too much, they rarely want to accept generic medicines for themselves instead of more expensive drugs that may be only marginally better - especially since insurers or government agencies pay nearly 70 percent of all drug costs.

Dr. JoAnne Foody, a practicing cardiologist and a professor at Yale University School of Medicine, said she expected to continue prescribing Lipitor for her high-risk patients, who need the maximum possible reduction in cholesterol.

But she said she would be inclined to switch other patients off Lipitor onto generic Zocor, also called simvastatin, if the price difference was significant.

"There are a very large portion of patients where the data for simvastatin are equivalent and sometimes better than the data for Lipitor," Dr. Foody said.

But convincing American patients to give up a brand-name medicine and take a generic drug is not easy, said Albert Rauch, a drug industry analyst at A. G. Edwards, a regional brokerage firm based in St. Louis.

For example, even though the antacid Prilosec is available in an inexpensive over-the-counter form, people prefer three very similar but higher-priced prescription antacids - Prevacid, Nexium and Protonix. Those three will have \$10 billion in United States sales this year.

"Therapeutic substitution - substituting one product for another in the same class - just hasn't happened yet," Mr. Rauch said.

And Lipitor has more than Pfizer's marketing dollars working for it. Last month, an analysis of 14 clinical trials by Oxford University and the University of Sydney in Australia found that the more potent the statin and the greater the cholesterol reduction, the lower the risk of [heart disease](#).

Dr. Colin Baigent, who oversaw the analysis, did not directly endorse Lipitor but said he believed that statins were not interchangeable.

"The aim should be to get their LDL cholesterol as low as possible," Dr. Baigent said, referring to low-density lipoprotein, or LDL, cholesterol - commonly called bad cholesterol. "There is potential for many patients benefiting more."

Statins work by interfering with the liver's ability to synthesize LDL cholesterol. All statins are chemically similar, although Lipitor, whose active ingredient is called atorvastatin, is more potent than Zocor, or simvastatin.

The highest dosage of Lipitor (80 milligrams) can reduce cholesterol as much as 57 percent in an average patient, while the highest dosage of simvastatin lowers cholesterol 47 percent. But because most patients are not placed on the highest dosages, the two drugs can achieve comparable cholesterol-lowering results in many cases.

Several large clinical trials have shown that statins reduce the risk of heart attacks and strokes. And statins appear to be safe for most patients, although they can cause muscle weakness in some people and occasionally lead to severe muscle damage.

As a result, statins have become among the most commonly prescribed drugs. This year's forecast of 150 million statin prescriptions in this country is up from 82 million in 1999, according to [IMS Health](#), a Pennsylvania company that compiles data about drug usage.

About half of those prescriptions will be for Lipitor, which is taken by 12 million Americans a year, at a cost of about \$8 billion. Worldwide, Lipitor sales are forecast to top \$12 billion this year, making the drug by far the best-selling prescription medicine.

Prescription drugs are protected by patents that give their inventors the exclusive right to sell them for up to 20 years, though they usually must spend part of that time gaining federal approval. The patent protection enables the drug maker that discovered the drug to earn back its development costs and make a profit. Otherwise, other companies could make and sell identical versions of the medicine, undercutting the company that invented it.

But when a patent expires, the legal protection disappears. At that point any company can make the drug, as long as it proves to the Food and Drug Administration that its version is identical to the original. The patent on Lipitor is to expire in 2011, but that patent has been challenged.

Zocor will lose its patent protection next June 23, and be opened to competition. [Ivax](#), a generic drug company, has already said it will produce a generic version of the drug, and other companies plan to follow. As more generics enter the market, the price of generic simvastatin could fall to 35 cents a pill or less, compared with \$3 or more now, according to Richard T. Evans, a drug industry analyst at Sanford C. Bernstein & Company.

Merck will lose billions of dollars in annual sales and profits when Zocor loses its patent protection. To recoup its profits, Merck has introduced another anticholesterol drug, Vytorin, which combines Zocor with Zetia, a medicine from [Schering-Plough](#) that is not a statin but also reduces cholesterol.

Vytorin is about as effective as Lipitor at lowering cholesterol, so both Merck and Pfizer have a stake in convincing doctors and insurers that they should pay extra for the increased potency their drugs offer over generic Zocor. But because Lipitor is so much more popular than Vytorin, Pfizer has more to lose than Merck and Schering-Plough if generic simvastatin becomes a standard treatment.

Last week, Express Scripts, a Missouri company that helps companies design drug benefit plans, said it would drop Lipitor from its list of preferred drugs. Instead, Express Scripts has devised a plan that will offer patients taking generic simvastatin a much lower co-payment on their prescriptions.

Steve Littlejohn, a spokesman for Express Scripts, said simvastatin was a viable alternative to Lipitor for most patients.

At its minimum 10-milligram dose, Lipitor reduces bad cholesterol an average of 39 percent. In contrast, a 40-milligram dose of simvastatin cuts cholesterol by as much as 41 percent. For patients who need a higher-potency statin, Vytorin will be available, Mr. Littlejohn said. "Consumers and physicians and employers have seen the steady, almost inexorable rise in pharmacy costs, and said nothing can be done," Mr. Littlejohn said. "We're saying something can be done."

Other insurers also say the Zocor patent expiration is an opportunity to reduce drug spending. Robert Seidman, the chief pharmacy officer for WellPoint, the nation's largest publicly traded health insurer, estimated that wide use of simvastatin could reduce the nation's drug costs by \$2 billion or more a year. To encourage patients to switch from Lipitor, WellPoint plans to offer members four to six months of free simvastatin as soon as generic versions are available, he said.

But Pfizer is fighting back. To demonstrate Lipitor's benefits in different kinds of patients, Pfizer has conducted 400 clinical trials on Lipitor, covering 80,000 people. Lipitor's edge over other statins goes beyond its superior ability to lower cholesterol, said Mr. Kelly.

The data from those clinical trials has enabled Pfizer to repeatedly broaden Lipitor's label of approved uses, changes that must be approved by the F.D.A. Last month, the F.D.A. said Pfizer could begin to market Lipitor for the prevention of heart attacks and strokes in [diabetics](#). To build brand loyalty, Pfizer also has thousands of sales representatives discussing Lipitor with doctors and spends at least \$60 million annually to advertise Lipitor to consumers, according to Brandweek magazine. Pfizer declined to discuss how much it spends to market Lipitor.

Dr. David Hyman, professor of medicine at Baylor College of Medicine in Houston, said he did not expect many patients to be switched off Lipitor. He pointed to drugs that lower [blood pressure](#), where expensive branded medicines dominate cheaper generics despite extensive research showing the generics work as well. "So much of the market is really not price-responsive."

But other experts on drug benefits said they believed that generic simvastatin might put a dent in Lipitor's sales, because companies, government agencies and patients had become so concerned about drug costs.

"It's very likely that a large portion of the market, especially those covered by managed care organizations, will switch to generic Zocor," said Albert Wertheimer, a professor of pharmacy at Temple University. "It seems like a reasonable thing to try."