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Asthma's New Expense

Phaseout of inhaler leaves patients gasping with sticker shock

By Marianne Lavelle
Posted 8/19/07

Like many asthma sufferers, Marty Marth was surprised to hear a news report months ago that her medication was being phased out because of its effect on the environment. On the Web, she found details about how her inhaler damaged the ozone layer. But the impact on her own life became clear only this summer, when she took her new prescriptions to a pharmacy near her Branford, Fla., home. "When they told me the price, I almost fell to my knees," she says.



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Instead of paying \$22 for generic albuterol, a 26-year-old drug that relaxes airway muscles, Marth faced a \$148 bill for two different medicines. The first was albuterol with a new ozone-friendly propellant, sold for \$36 under the brand name ProAir HFA.

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Even more damaging to her pocketbook was the second medication, Flovent HFA, with a hefty monthly cost of \$112; her doctor had used the Food and Drug Administration-driven switch as an opportunity to add that inhaled anti-inflammatory, to be used daily to reduce the need for albuterol, to her therapy plan. With no health insurance, the costs are all out of pocket for Marth, 59, a writer who lives on less than \$20,000 a year. "When you're asthmatic, you don't have a decision about whether or not you buy these things," she says. "It's buy it, or die. What choice do I have but to go into my savings and buy it?"

Marth is among those hardest hit by one of the few Bush administration decisions that environmentalists might laud. The FDA is, in effect, retiring the widely used, generic form of albuterol because its spray propellant contains chlorofluorocarbons. CFCs have been largely banned under the 1987 Montreal Protocol because they destroy the ozone that guards us against the sun's rays, but a few "essential uses" remain. In March 2005, the FDA said it would remove albuterol from that category because CFC-free versions were available—brand-name formulations that happen to have patent protection. The agency calculated that the change, which will go into full effect in December 2008 but is already being felt, will raise albuterol costs for patients and their insurers by \$1.2 billion per year.

That translates into a windfall for GlaxoSmithKline, Schering-Plough, Sepracor, and Teva Specialty Pharmaceuticals, the four manufacturers of CFC-free inhalers. More difficult to quantify are the additional brand-name drug sales that may occur as an indirect consequence of the FDA action, as doctors review patients' asthma control plans and—as in Marth's case—prescribe one of several newer preventive medications that are far more expensive than albuterol.

Health professionals generally believe too many patients relied on albuterol, even though it should be used only occasionally as a "relief" inhaler. They say albuterol offers quick but temporary help, leaving the underlying inflammation untreated and potentially leading to permanent airway damage.

More than 22 million Americans have the chronic airway inflammation known as asthma, with episodes of wheezing, coughing, and breathlessness. Each year, asthma causes 1.8 million emergency room visits, nearly 500,000 hospitalizations, and more than 4,000 deaths. Albuterol was a breakthrough for quelling asthma attacks when it debuted in 1981. But today, doctors emphasize the need for corticosteroids to reduce swelling long term and head off most acute episodes. No drug, however, wipes out the risk of attacks. So asthma patients keep albuterol close at hand, no matter how well their condition is controlled. "It is an incredibly important drug in the asthma market, because all patients—from those with mild intermittent to severe persistent cases—need it," says Vickie Lai, an analyst for the consulting firm Decision Resources.

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First to go. After the FDA approved generic albuterol in 1995, that low-cost alternative came to dominate the market. Such is the well-worn drug industry story line. But a rare plot twist came with the FDA's 2005 ozone move. Medical inhalers have been one of the few remaining uses of CFCs, eliminated from refrigerants and sprays years ago under the Montreal Protocol. The FDA has a duty to finger the therapies involving CFCs that are no longer medically necessary. It decided albuterol, the only inhaled asthma drug sold generically, would be the first to go. The amount of CFCs released from albuterol inhalers in the United States was small—about 1,200 tons per year, a tiny fraction of the 1.8 million tons of ozone-depleting substances emitted into the atmosphere prior to the treaty. But there's been an alternative since 1996, when Schering-Plough introduced Proventil HFA, which contains the ozone-benign propellant hydrofluoroalkane.

Proventil HFA and GlaxoSmithKline's

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Ventolin HFA, introduced in February 2002, lagged far behind the cheaper generic CFC albuterol in sales. So the FDA took action, saying: "This regulation is necessary because private markets are very unlikely to preserve levels of stratospheric ozone sufficient to protect the public health."

Two big patient advocacy groups, the American Lung Association and Allergy and Asthma Network Mothers of Asthmatics, support the FDA decision—and in fact helped spur it by filing a 2003 petition requesting CFC withdrawal. Both groups undertook CFC public awareness programs sponsored by drug companies. The ALA's "Time to Make the Switch" campaign was underwritten with \$1 million from Teva, maker of ProAir HFA. The AANMA promotes "Smart Moves to an HFA

Inhaler," sponsored by Sepracor. That company sells the albuterol-like drug levalbuterol as Xopenex HFA.

The groups maintain that patient concerns were foremost in their advocacy and that, in any case, dwindling global production of medical-grade CFCs would have sharply driven up the cost of CFC-based inhalers. "The fact we all have to face is that the CFC inhalers are going away," says Nancy Sander, AANMA's president and founder, who has owned Sepracor stock.

Alfred Munzer, a former ALA president and director of pulmonary medicine at Washington Adventist Hospital in Takoma Park, Md., says that competition among branded inhalers may soon begin to drive prices down. Indeed, Teva, known mainly as a generics firm, introduced ProAir HFA just prior to the FDA decision, pricing it slightly below Ventolin HFA and Proventil HFA. According to figures from IMS Health, a healthcare information company, ProAir HFA leapt to No. 1, with a 37.4 percent market share in early 2007. Munzer says negotiations between insurers and drug companies also will make a difference. For example, the nation's second-largest health insurer, UnitedHealth Group, in April struck a deal with Sepracor that moves Xopenex HFA from Tier 3 to Tier 1. That can shave the copayment from as much as \$50 to \$10, the same low sum patients previously paid for generic albuterol. The competing drugs remain in Tier 3.

Lai, the Decision Resources analyst, predicts that the FDA will feel pressure to accelerate approval of a generic form of CFC-free albuterol, perhaps by 2012. Meanwhile, GlaxoSmithKline says it has committed to freezing the price of Ventolin HFA until December 2008. It also emphasizes that the drug should be used no more than twice a week and that patients should instead be using the longer-acting preventive medications. GSK makes some of the most popular of those drugs, including Flovent and the blockbuster Advair. These drugs generally require high copayments.

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The move toward costlier drugs irks Marth, who has relied on albuterol as her sole inhaled medication since 1986. "I was able to have a completely asthma-free existence," she said. "It was like a miracle drug for me. But now they're saying, 'Don't use it preventively.' Well, I'm sorry, but it worked beautifully for me."



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Munzer says treatment of asthma has evolved greatly in recent years. "It has taken a long time for people to realize asthma is not just an intermittent, acute condition but a chronic condition," he says. But since many asthma patients experience

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the condition in episodes or seasonally, they often don't stay on the pricey long-term medication. The *Journal of Allergy and Clinical Immunology* recently reported asthma was not controlled in 55 percent of Americans with moderate to severe forms of the disease.

"It is a major challenge," says Munzer. "We talk about patients not being compliant, and we look for all sorts of reasons. Very often, the underlying reason is cost."

A Little Relief

Patients struggling to afford prescription drugs can find details on programs that provide free or low-cost medication at two clearinghouses, the **Partnership for Prescription Assistance** (www.pparx.org or 888-4PPA-NOW) and **RxHope** (www.rxhope.com). Programs offered by inhaler manufacturers include:

GlaxoSmithKline's Bridges to Access, www.bridgestoaccess.com or 866-728-4368.

Schering-Plough's SP-Cares, www.schering-plough.com/schering_plough/pc/sp_cares.jsp or 800-656-9485.

Sepracor Patient Assistance Program, www.sepracor.com/products/patientAssistance.html or 888-878-6266.

Teva Specialty Pharmaceuticals Patient Assistance Program, www.proairhfa.com/PatientAssistance.aspx or 866-482-9633.

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A 2005 FDA ruling mandated a gradual phaseout of a widely used inhaler. Now consumers must turn to pricier alternatives.

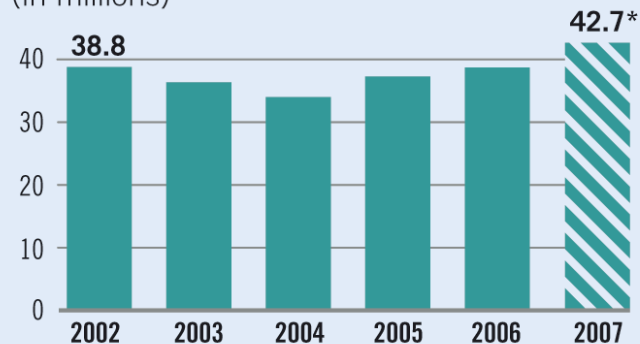
Generic albuterol	\$13.99
ProAir HFA	\$34.99
Proventil HFA	\$39.99
Ventolin HFA	\$37.63
Xopenex HFA	\$48.99

Sources: FDA, drugstore.com

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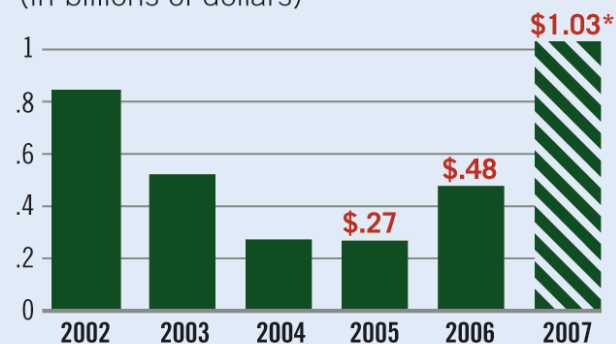
WHILE PRESCRIPTIONS HAVE INCREASED GRADUALLY, REVENUES HAVE SOARED

Number of prescriptions
(in millions)



*2007 projections by *U.S. News*, based on actual figures (17.8 million prescriptions, \$429.6 million in sales) for January to May 2007

Revenue from relief inhalers
(in billions of dollars)



Source: IMS Health