PATIENT SAFETY BLOG

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Should You Take Lipitor or a New Generic? Lots of Questions as a Big Drug Loses Its Patent

January 22, 2012 by Patrick A. Malone

When patents expire on profitable brand-name prescription drugs, patients and their insurance companies usually both catch a break on the price as generic manufacturers move in with cheaper versions of the same drug. That's happening now with Lipitor, the most prescribed brand name drug in the U.S., but the usual rules on pricing may be broken.

Every day 3.5 million people take Lipitor to control cholesterol. Since its debut in 1997, Lipitor has lined the coffers of Pfizer to the tune of \$81 billion. It's the best-selling prescription drug ever, and its patent protection ended in November.

A few months ago we wrote about how pharmaceutical companies whose patents are expiring for prescription drugs sometimes go to great—and questionable—lengths to prevent other manufacturers from making a generic version that costs a lot less. So it seems counterintuitive that a member of Big Pharma would celebrate the end of a drug protection period by lowering its cost below that of a generic.

But that's exactly what's going on with Lipitor.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) In order to maintain loyalty among those customers who otherwise might have a choice (depending on their health plan coverage) often driven by cost. Pfizer cut deals with insurers and pharmaceutical plan brokers to price Lipitor at or below the cost of generic competitors. The company has even lobbied patients directly to

take Lipitor instead of other atorvastatin-based compounds.

As reported in the Los Angeles Times, "It was an unprecedented effort, but the motivation was clear: When a

drug loses its patent protection, more than 80 percent of its prescription sales are replaced by generics within

six months..."

Often, patients are forced by their insurance plans to switch to generics when their drugs go off patent. Often,

the transition is smooth, but sometimes generics are metabolized differently from the brand, and patients and

their doctors prefer the status quo. Sometimes the generic is equally or more effective, and patients welcome

the opportunity to choose.

Although brand and generic drugs share the chemical or biological agent responsible for addressing the

problem, the other ingredients in the compound can be different, and the body can react differently. That's why

all drugs with the same primary agent don't always have the same effect.

So how does the Lipitor situation affect you? The L.A. Times provided an excellent primer for what you need to

know in a time of drug transition that will affect millions of people.

Is atorvastatin as good as Lipitor?

Pharmacologists don't anticipate trouble with atorvastatin; Lipitor may not be much different from other statins

now sold as generics. Generic statins are just as good for 95 in 100 people. They include lovastatin (Mevacor),

pravastatin (Pravachol) and simvastation (Zocor).

I have a prescription for atorvastatin, but I was given Lipitor. Why can't I get the generic?

Pfizer made a deal with your insurance companies and/or pharmacy benefit managers (PBMs). Usually, one

drug maker gets exclusive rights to make the low-cost generic version of a medication for the first six months

after it goes off patent. Then additional generic drug makers enter the market, prices drop more and demand

for the brand-name drug withers.

To prevent that with Lipitor, Pfizer agreed to pay rebates to insurers and PBMs to eliminate the cost advantage

of atorvastatin. So some companies offer only Lipitor.

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Is that legal?

No laws that govern how generics enter the market have been broken, according to Erik Gordon, an attorney

and professor at the University of Michigan's Ross School of Business. But Pfizer's actions do raise questions

about whether antitrust laws, which aim to keep market competition fair, have been violated.

Pfizer, the biggest drug maker in the world, seems to be using its muscle to make deals with the aim of

undercutting the sale of generic Lipitor and limiting consumers' access to it, Gordon told The Times.

What's odd here is that although Big Pharma often uses rebates to woo PBMs and influence insurance plan

coverage, Pfizer's Lipitor rebates are helping to make a brand name less expensive than a generic. Usually

rebates afford an advantage to one or two comparable drugs in the same therapeutic class.

Is it normal for drug companies to do this kind of thing?

Drug makers have a long history of using rebates to influence PBMs and insurance plans as they decide which

medications to cover, said Timothy Wentworth, group president of employer accounts with Medco Health

Solutions, a large pharmacy benefit manager. What makes this situation unusual is that Pfizer's rebates are

helping to make a brand-name drug cost less than a generic. Normally, rebates give an edge to one of two

comparable drugs in the same therapeutic class.

Dave Marley, president and founder of the advocacy group Pharmacists United for Truth and Transparency.

Marley said this practice is longstanding and prompted insurers including Cigna, Community Care Rx,

Coventry and AARP to reject generic prescriptions for brand-name drugs, including Zyprexa (for schizophrenia

and bipolar disorder), Nitro-Dur (to prevent chest pain) and Protonix (for gastroesophageal reflux disease, or

GERD).

What else is Pfizer doing to keep patients on Lipitor?

The company offers discounts to patients through its Lipitor for You program, bringing the drug's monthly co-

pay to as little as \$4. Pfizer pays as much as \$50 to cover the difference between the \$4 minimum and a

patient's usual co-pay for a preferred brand-name drug, which averages \$25.

Enroll in Lipitor for You by linking here. Select "For Lipitor Patients" and click on "Lipitor for You." Or call (866)

354-7486. The deal is supposed to be good through the end of 2012.

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pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) What if I don't have health insurance?

Buy atorvastatin. Prices vary by pharmacy, but a 30-day supply of 20-milligram pills ranges from \$80 to \$130.

Uninsured patients may take part in Lipitor for You and save \$50 on the brand-name drug. At a cost of

approximately \$165 a month for a 30-day supply of either 20 mg or 40 mg pills, that might make Lipitor the less

expensive option.

I don't want Lipitor. Can I get the generic?

It depends on the arrangements your insurance company has made. Some say they cover both Lipitor and

atorvastatin. But Lipitor costs less for members at the pharmacy. Some insurers declined to participate in

Pfizer's rebate program and require most members to switch to the generic. Some insurers will continue allow

Lipitor at the cost of the generic co-pay for their Medicare patient.

If my generic prescription is filled with brand-name Lipitor, does that mean I'll pay more?

Not if your insurer has cut a deal with Pfizer; you'll pay the generic co-pay, about \$10 for a 30-day supply, on

average. For many patients, that's a price cut. And you might be able to lower the cost further via Lipitor for

You.

What if I'm on Medicare?

Several pharmacy benefit managers and health plans say they'll continue to dispense brand-name Lipitor but

charge a generic co-pay to people with a Medicare Part D prescription drug plan.

But you might pay more in the long run. People with Part D plans hit the so-called "doughnut hole" after

accumulating \$2,930 in drug costs this year; after that, their drug costs rise. When these patients get Lipitor,

the drug's full cost is added to their tally, not the generic. So even with an immediately discounted co-pay, they

reach the doughnut hole faster.

Medicare Part D plans are supposed to report rebates they get from drug makers to the government so that the

Medicare program and its beneficiaries see cost savings as well. But a report last year by the Office of the

Inspector General reviewed some Part D plan sponsors that received rebates when they encouraged patients

to use certain drugs. It found that some plans passed along the rebate money and some didn't.

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