

Drug prices to plummet in wave of expiring patents

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In this June 6, 2011 photo, Ray and Jo Kelly relax on a swing in front of their home in Conklin, Mich., where they live in retirement. The two both take Lipitor and look forward to having extra money when the drug is replaced with a generic in the fall. (AP Photo/Adam Bird)

The cost of prescription medicines used by millions of people every day is about to plummet. The next 14 months will bring generic versions of seven of the world's 20 best-selling drugs, including the top two: cholesterol fighter Lipitor and blood thinner Plavix.

The magnitude of this wave of expiring drugs patents is unprecedented. Between now and 2016, blockbusters with about \$255 billion in global annual sales are set to go off patent, notes EvaluatePharma Ltd., a London research firm. Generic competition will decimate sales of the brand-name drugs and slash the cost to patients and companies that

provide health benefits.

Top drugs getting generic competition by September 2012 are taken by millions every day: Lipitor alone is taken by about 4.3 million Americans and Plavix by 1.4 million. Generic versions of big-selling drugs for blood pressure, asthma, diabetes, depression, high triglycerides, HIV and bipolar disorder also are coming by then.

The flood of generics will continue for the next decade or so, as about 120 brand-name prescription drugs lose market exclusivity, according to prescription benefit manager Medco Health Solutions Inc.

"My estimation is at least 15 percent of the population is currently using one of the drugs whose patents will expire in 2011 or 2012," says Joel Owerbach, chief pharmacy officer for Excellus Blue Cross Blue Shield, which serves most of upstate New York.

Those patients, along with businesses and taxpayers who help pay for prescription drugs through corporate and government prescription plans, collectively will save a small fortune. That's because generic drugs typically cost 20 percent to 80 percent less than the brand names.

Doctors hope the lower prices will significantly reduce the number of people jeopardizing their health because they can't afford medicines they need.

Dr. Nieca Goldberg, director of The Women's Heart Program at NYU Langone Medical Center in Manhattan, worries about patients who are skipping checkups and halving pills to pare costs.

"You can pretty much tell by the numbers when I check the patient's blood pressure or cholesterol levels," that they've not taken their medications as often as prescribed, she says.

Even people with private insurance or Medicare aren't filling all their prescriptions, studies show, particularly for cancer drugs with copays of hundreds of dollars or more.

The new generics will slice copayments of those with insurance. For the uninsured, who have been paying full price, the savings will be much bigger.

Daly Powers, 25, an uninsured student who works two part-time jobs at low wages, says he often can't afford the \$220 a month for his depression and attention deficit disorder pills. He couldn't buy either [drug](#) in June and says he's struggling with his Spanish class and his emotions. He looks forward to his antidepressant, Lexapro, going generic early next year.

"It'd make all the difference in the world," says Powers, of Bryan, Texas.

Generic medicines are chemically equivalent to the original brand-name drugs and work just as well for nearly all patients.

When a drug loses patent protection, often only one generic version is on sale for the first six months, so the price falls a little bit initially. Then, several other generic makers typically jump in, driving prices down dramatically.

Last year, the average generic prescription cost \$72, versus \$198 for the average brand-name drug, according to consulting firm Wolters Kluwer Pharma Solutions. Those figures average all prescriptions, from short-term to 90-day ones.

Average copayments last year were \$6 for generics, compared with \$24 for brand-name drugs given preferred status by an insurer and \$35 for nonpreferred brands, according to IMS Health.

Among the drugs that recently went off patent, Protonix, for severe heartburn, now costs just \$16 a month for the generic, versus about \$170 for the brand name. And of the top sellers that soon will have competition, Lipitor retails for about \$150 a month, Plavix costs almost \$200 a month and blood pressure drug Diovan costs about \$125 a month. For those with drug coverage, their out-of-pocket costs for each of those drugs could drop below \$10 a month.

Jo Kelly, a retired social worker in Conklin, Mich., and her husband Ray, a retired railroad mechanic, each take Lipitor and two other brand-name medicines, plus some generic drugs. Both are 67, and they land in the Medicare prescription "doughnut hole," which means they must pay their drugs' full cost, by late summer or early fall each year. That pushes their monthly cost for Lipitor to about \$95 each, and their combined monthly prescription cost to nearly \$1,100.

Generic Lipitor should hit pharmacies Nov. 30 and cost them around \$10 each a month.

"It would be a tremendous help for us financially," she says. "It would allow us to start going out to eat again."

For people with no prescription coverage, the coming savings on some drugs could be much bigger. Many discount retailers and grocery chains sell the most popular generics for \$5 a month or less to draw in shoppers.

The impact of the coming wave of generics will be widespread - and swift.

Insurers use systems that make sure patients are switched to a generic the first day it's available. Many health plans require newly diagnosed patients to start out on generic medicines. And unless the doctor writes "brand only" on a prescription, if there's a generic available, that's almost

always what the pharmacist dispenses.

"A blockbuster drug that goes off patent will lose 90 percent of its revenue within 24 months. I've seen it happen in 12 months," says Ben Weintraub, a research director at Wolters Kluwer Pharma Solutions.

The looming revenue drop is changing the economics of the industry.

In the 1990s, big pharmaceutical companies were wildly successful at creating pills that millions of people take every day for common conditions, from heart disease and diabetes to osteoporosis and chronic pain. Double-digit quarterly profit increases became the norm.

But the patents on those blockbusters, which were filed years before the drugs went on sale, last for 20 years at most, and many expire soon.

In recent years, many drug companies have struggled to develop new blockbuster drugs, despite multibillion-dollar research budgets and more partnerships with scientists at universities and biotech companies. The dearth of successes, partly because the "easy" treatments have already been found, has turned the short-term prognosis for "big pharma" anemic.

"The profit dollars that companies used to reinvest in innovation are no longer going to be coming," warns Terry Hisey, life sciences leader at consultant Deloitte LLP's pharmaceutical consulting business. He says that raises "long-term concerns about the industry's ability to bring new medicines to market."

But pharmaceutical companies can save billions when they stop promoting drugs that have new generic rivals, and U.S. drug and biotech companies are still spending more than \$65 billion a year on R&D.

The 20 new drug approvals in the U.S. this year, and other important ones expected in the next few years, eventually will help fill the revenue hole.

For now, brand-name drugmakers are scrambling to adjust for the billions in revenue that will soon be lost. Many raise prices 20 percent or more over the last couple years before generics hit to maximize revenue. Some contract with generic drugmakers for "authorized generics," which give the brand-name company a portion of the generic sales.

Brand-name companies also are trimming research budgets, partnering with other companies to share drug development costs and shifting more manufacturing and patient testing to low-cost countries.

Pharmaceutical companies have cut about 10 percent of U.S. jobs in four years, from a peak of about 297,000 to about 268,000, according to Labor Department data. Nearly two-thirds of the cuts came in the last 1 1/2 years, partly because of big mergers that were driven by the need to shore up pipelines and boost profit in the short term by slashing overlap.

Drug companies also are trying to stabilize future sales by putting more sales reps in emerging markets such as China and India, and diversifying into businesses that get little or no generic competition. Those include vaccines, diagnostic tests, veterinary medicines and consumer health products.

As the proportion of prescriptions filled with generic drugs jumped to 78 percent in 2010, from 57 percent in 2004, annual increases in prescription drug spending slowed, to just 4 percent in 2010. According to the Generic Pharmaceutical Association, generics saved the U.S. health care system more than \$824 billion from 2000 through 2009, and now save about \$1 billion every three days.

The savings are only going to get greater as our overweight population ages. People who take their medicines regularly often avoid costly complications and hospitalizations, says AARP's policy chief, John Rother, bringing the system even bigger savings than the cheaper drugs.

In addition, many patients taking a particular brand-name drug will defect when a slightly older rival in the same class goes generic.

Global sales of Lipitor peaked at \$12.9 billion in 2006, the year Zocor, an older drug in the statin class that reduces bad cholesterol, went generic. Lipitor sales then declined slowly but steadily to about \$10.7 billion last year. That still makes Lipitor the biggest drug to go generic.

For patients, it's a godsend.

Douglas Torok, 59, of Erie, Pa., now spends nearly \$290 every three months for insulin for his Type 2 diabetes, plus four daily pills, including Lipitor, Plavix and two generics, for his blood pressure and cholesterol problems. The \$40,000-a-year foundry supervisor fears not being able to cover the out-of-pocket costs when he retires and doesn't have a generous prescription plan.

In the meantime, once Lipitor and Plavix get generic competition his copayment will plunge from the current \$1 per day for each.

"I will pay \$16 for 90 days" for both, says Torok, who hopes to travel more. "It's a big deal for me on my income."

More information:

Brand-name drugs going off patent through 2015:

www.medcohealth.com/art/corpor...rsttime-generics.pdf

Brand-name and generic drug price comparisons:

www.flrx.com/calculator/generi...nced-calculator.html

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