

## Drug prices to plummet



July 25, 2011

By Linda A. Johnson

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Core/Group, Consumer Driven Health Care, Employer-paid

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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 will 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 benefits 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 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 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 pharmaceutical industry.

In the 1990s, big pharmaceutical companies were wildly successful at creating pills that millions of people take every day for long-term conditions, from heart disease and diabetes to osteoporosis and chronic pain. The drugs are enormously profitable compared with drugs that are prescribed for short-term ailments.

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

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biotech companies are still spending more than \$65 billion a year on R&D.

Drug companies have received U.S. approval for 20 drugs this year and expect approval for other important ones the next few years. Eventually, those 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. Typically, they raise prices 20 percent or more in the final years before generics hit to maximize revenue. Some also 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 bulk up drugs in development and boost profits in the short term by cutting costs.

Drug companies also are trying to grow sales by putting more sales reps in emerging markets, such as China and India, and by 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, which produces 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 will make 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 — 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 copayments will plunge.

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

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Brand-name drugs going off patent through 2015: [http://www.medcohealth.com/art/corporate/anticipatedfirsttime\\_generics.pdf](http://www.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf)

Brand-name and generic drug price comparisons: [https://www.flrx.com/calculator/generic/advanced\\_calculator.html](https://www.flrx.com/calculator/generic/advanced_calculator.html)

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**Estimated Dates of Possible First Time Generic/ Rx-to-OTC Market Entry**

Year	Period	Brand Name	Generic name	2009 US Retail Sales: (in millions)^
2011	1Q (Mar)	<i>Xalatan</i> <sup>®</sup>	latanoprost	\$520
2011	2Q (Apr)	<i>Aromasin</i> <sup>®</sup>	exemestane	\$129
2011	2Q (Apr)	<i>Femara</i> <sup>®</sup>	letrozole	\$462
2011	2Q (May)	<i>Concerta</i> <sup>®</sup>	methylphenidate extended-release tablet	\$1,327
2011	2Q (Jun)	<i>Nasacort AQ</i> <sup>®</sup>	triamcinolone nasal spray (previously approved, not launched 7/09)	\$272
2011	2Q (Jun)	<i>Levaquin</i> <sup>®</sup>	levofloxacin	\$1,633
2011	3Q (Jul)	<i>Uroxatral</i> <sup>®</sup>	alfuzosin extended- release tablet	\$196
2011	3Q (Jul)	<i>Anzemet</i> <sup>®</sup>	dolasetron	\$8
2011	4Q (Oct)	<i>Zyprexa</i> <sup>®</sup> and <i>Zyprexa</i> <sup>®</sup> <i>Zydis</i>	olanzapine	Zyprexa: \$1,968 Zydis: \$156
2011	4Q (Oct)	<i>Malarone</i> <sup>®</sup>	atovaquone/proguanil	\$60
2011	4Q (Nov)	<i>Solodyn</i> <sup>®</sup>	minocycline extended- release tablet (previously approved, briefly launched)	\$588
2011	4Q (Nov)	<i>Lipitor</i> <sup>®</sup>	atorvastatin	\$6,054
2011	4Q (Nov)	<i>Caduet</i> <sup>®</sup>	amlodipine/ atorvastatin	\$362
2011	4Q (Dec)	<i>Tazorac</i> <sup>®</sup>	tazarotene	\$111
2011	4Q (Dec)	<i>Combivir</i> <sup>®</sup>	lamivudine/zidovudine	\$280
2012	1Q (Jan)	<i>Clarinet</i> <sup>®</sup> & <i>Clarinet-D</i> <sup>®</sup> (planning OTC prior to generic availability) <sup>1</sup>	desloratadine and desloratadine/ pseudoephedrine	Clarinet: \$217 Clarinet D: \$39
2012	1Q (Mar)	<i>Lexapro</i> <sup>®2</sup>	escitalopram	\$2,557
2012	1Q (Mar)	<i>Seroquel</i> <sup>®</sup>	quetiapine	\$3,483

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Year	Period	Brand Name	Generic name	2009 US Retail Sales: (in millions)^
2012	1Q (Mar)	<i>Gabitrif</i> <sup>®</sup>	tiagabine	\$55
2012	1Q (Mar)	<i>Avandia</i> <sup>®</sup>	rosiglitazone	\$437
2012	1Q (Mar)	<i>Avandamet</i> <sup>®</sup>	rosiglitazone/ metformin	\$207
2012	1Q (Mar)	<i>Avandaryl</i> <sup>®</sup>	glimepiride/ rosiglitazone	\$48
2012	1Q (Mar)	<i>Avapro</i> <sup>®</sup>	irbesartan	\$414
2012	1Q (Mar)	<i>Avalide</i> <sup>®</sup>	irbesartan/ hydrochlorothiazide	\$359
2012	2Q (Apr)	<i>Provigil</i> <sup>®</sup>	modafinil	\$967
2012	2Q (May)	<i>Plavix</i> <sup>®3</sup>	clopidogrel (approved 1/06 and briefly launched 8/06)	\$4,563
2012	2Q (May)	<i>Viramune</i> <sup>®</sup>	nevirapine	\$109
2012	2Q (Jun)	<i>Lescol</i> <sup>®</sup> and <i>Lescol</i> <sup>®</sup> XL	fluvastatin	Lescol: \$32 Lescol XL: \$88
2012	3Q (Jul)	<i>Femcon</i> <sup>®</sup> Fe	ethinyl estradiol/ norethindrone	\$61
2012	3Q (Jul)	<i>Tricor</i> <sup>®</sup>	fenofibrate	\$1,350
2012	3Q (Aug)	<i>Singulair</i> <sup>®</sup>	montelukast	\$3,466
2012	3Q (Aug)	<i>Actos</i> <sup>®</sup>	pioglitazone	\$2,783
2012	3Q (Aug)	<i>Xopenex</i> <sup>®</sup> (not HFA) <sup>4</sup>	levalbuterol inhalation solution	\$477
2012	3Q (Sep)	<i>Revatio</i> <sup>®</sup>	sildenafil	\$182
2012	3Q (Sep)	<i>Diovan</i> <sup>®</sup> and <i>Diovan</i> <sup>®</sup> HCT <sup>5</sup>	valsartan and valsartan/ hydrochlorothiazide	Diovan: \$1,470 Diovan HCT: \$1,376
2012	3Q (Sep)	<i>Geodon</i> <sup>®</sup>	ziprasidone	\$976
2012	3Q (Sep)	<i>Detrol</i> <sup>®</sup>	tolterodine	\$46
2012	4Q (Nov)	<i>Lidoderm</i> <sup>®</sup>	lidocaine topical patch	\$1,065
2012	4Q (Dec)	<i>Atacand</i> <sup>®</sup> and <i>Atacand</i> <sup>®</sup> HCT <sup>®</sup> (16/12.5 and	candesartan and candesartan/	Atacand: \$157 Atacand HCT: \$73

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Year	Period	Brand Name	Generic name	2009 US Retail Sales: (in millions)^
		32/12.5 strengths)	hydrochlorothiazide	
2012	4Q (Dec)	<i>Evoxac</i> <sup>®</sup>	cevimeline	\$39
2012	4Q (Dec)	<i>Maxalt</i> <sup>®</sup> and <i>Maxalt-MLT</i> <sup>®</sup>	rizatriptan	Maxalt: \$272 Maxalt-MLT: \$229
2012	4Q (Dec)	<i>Actoplus Met</i> <sup>®</sup>	pioglitazone/ metformin	\$402
2013	1Q (Jan)	<i>Opana</i> <sup>®</sup> ER	oxymorphone extended-release tablet (previously approved, not launched 6/10)	\$269
2013	1Q (Jan)	<i>Zometa</i> <sup>®</sup>	zoledronic acid injection	\$5
2013	1Q (Mar)	<i>Lovaza</i> <sup>®</sup>	omega-3-acid ethyl esters	\$655
2013	1Q (Mar)	<i>Valcyte</i> <sup>®</sup>	valganciclovir	\$188
2013	2Q (May)	<i>Zomig</i> <sup>®</sup>	zolmitriptan	\$166
2013	2Q (Jun)	<i>Allegra-D</i> <sup>®</sup> 24 hr	fexofenadine/ pseudoephedrine	\$172
2013	2Q (Jun)	<i>Fosamax Plus D</i> <sup>™</sup>	alendronate / cholecalciferol	\$123
2013	2Q (Jun)	<i>Vivelle-DOT</i> <sup>®</sup>	estradiol extended- release film	\$174
2013	2Q (Jun)	<i>Rilutek</i> <sup>®</sup>	riluzole (generic approved, not launched 1/03)	\$35
2013	3Q (Aug)	<i>Temodar</i> <sup>®6</sup>	temozolomide (generic approved, not launched 3/10)	\$205
2013	3Q (Sep)	<i>Niaspan</i> <sup>®</sup>	niacin extended- release tablet	\$765
2013	3Q (Sep)	<i>Advicor</i> <sup>®</sup>	lovastatin/niacin	\$80
2013	4Q (Nov)	<i>AcipHex</i> <sup>®</sup>	rabeprazole (tablets approved but not launched 2/07)	\$1,160
2013	4Q (Dec)	<i>Cymbalta</i> <sup>®</sup>	duloxetine	\$2,621
2014	1Q (Jan)	<i>Rapamune</i> <sup>®</sup>	sirolimus	\$141

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Year	Period	Brand Name	Generic name	2009 US Retail Sales: (in millions)^
2014	1Q (Jan)	<i>Micardis<sup>®</sup> and Micardis<sup>®</sup> HCT</i>	telmisartan and telmisartan/ hydrochlorothiazide	Micardis: \$201 Micardis HCT: \$198
2014	1Q (Jan)	<i>Loestrin<sup>®</sup> 24 Fe<sup>7</sup></i>	ethinyl estradiol/ norethindrone	\$345
2014	1Q (Jan)	<i>Asacol<sup>®</sup></i>	mesalamine delayed- release tablet	\$541
2014	1Q (Feb)	<i>Renage<sup>®</sup></i>	sevelamer	\$322
2014	1Q (Mar)	<i>Evista<sup>®</sup></i>	raloxifene	\$521
2014	2Q (Apr)	<i>Viracept<sup>®</sup></i>	nelfinavir	\$62
2014	2Q (May)	<i>Nexium<sup>®</sup></i>	esomeprazole	\$5,551
2014	2Q (May)	<i>Celebrex<sup>®</sup></i>	celecoxib	\$1,581
2014	2Q (May)	<i>Lunesta<sup>®</sup></i>	eszopiclone	\$805
2014	2Q (Jun)	<i>Actonel<sup>®8</sup></i>	risedronate	\$762
2014	2Q (Jun)	<i>Xeloda<sup>®</sup></i>	capecitabine	\$294
2014	3Q (Aug)	<i>Teveten<sup>®</sup> and Teveten<sup>®</sup> HCT</i>	eprosartan and eprosartan/ hydrochlorothiazide	Teveten: \$7 Teveten HCT: \$5
2014	3Q (Sep)	<i>Avelox<sup>®</sup></i>	moxifloxacin	\$475
2014	3Q (Sep)	<i>Vigamox<sup>®</sup></i>	moxifloxacin ophthalmic solution	\$261
2014	4Q (Nov)	<i>Copaxone<sup>®</sup></i>	glatiramer injection	\$442
2015	1Q (Jan)	<i>Cipro<sup>®</sup> HC</i>	ciprofloxacin/ hydrocortisone otic suspension	\$42
2015	1Q (Jan)	<i>Norvir<sup>®</sup></i>	ritonavir	\$356
2015	1Q (Jan)	<i>Namenda<sup>®</sup></i>	memantine (generic approved 4/14/10, not launched)	\$711
2015	1Q (Feb)	<i>Lumigan<sup>®</sup></i>	bimatoprost ophthalmic solution	\$281
2015	1Q (Mar)	<i>Sustiva<sup>®</sup></i>	efavirenz	\$166

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2015	1Q (Mar)	<i>Renvela</i> <sup>®</sup>	sevelamer	\$132
2015	2Q (Apr)	<i>Oxytrol</i> <sup>®</sup>	oxybutynin extended-release film	\$31
2015	2Q (Apr)	<i>Abilify</i> <sup>®</sup>	aripiprazole	\$3,583
2015	2Q (May)	<i>Zyvox</i> <sup>®</sup>	linezolid	\$271
2015	2Q (May)	<i>Avodart</i> <sup>®</sup>	dutasteride	\$461
2015	2Q (Jun)	<i>Welchol</i> <sup>®</sup>	colesevelam	\$271
2015	2Q (Jun)	<i>Travatan</i> <sup>®</sup> and <i>Travatan Z</i> <sup>®</sup>	travoprost ophthalmic solution	\$328
2015	3Q (Jul)	<i>Aggrenox</i> <sup>®</sup>	aspirin/dipyridamole extended-release capsule	\$271
2015	3Q (Jul)	<i>Gleevec</i> <sup>®</sup>	imatinib	\$571
2015	3Q (Aug)	<i>Androgel</i> <sup>®</sup>	testosterone gel	\$652
2015	4Q (Oct)	<i>Aloxi</i> <sup>®</sup>	palonosetron	\$2
2015	4Q (Dec)	<i>Patanol</i> <sup>®</sup>	olopatadine solution	\$245
2015	4Q (Dec)	<i>Combivent</i> <sup>®</sup>	albuterol/ipratropium inhalation	\$649
2015	4Q (Dec)	<i>Fuzeon</i> <sup>®</sup>	enfuvirtide injection	\$26
2015	4Q (Dec)	<i>Coreg CR</i> <sup>®</sup>	carvedilol extended-release capsules	\$292
2016	2Q (May)	<i>Ortho Evra</i> <sup>®</sup>	ethinyl estradiol/norelgestromin transdermal system	\$130
2016	2Q (Jun)	<i>Focalin XR</i> <sup>®</sup>	dexmethylphenidate extended-release capsule	\$414
2016	3Q (Jul)	<i>Crestor</i> <sup>®</sup>	rosuvastatin calcium	\$2,626
2016	4Q (Oct)	<i>Benicar</i> <sup>®</sup> & <i>Benicar</i> <sup>®</sup> <i>HCT</i>	olmesartan & olmesartan/hydrochlorothiazide	Benicar: \$556 Benicar HCT: \$583
2016	4Q (Dec)	<i>Zetia</i> <sup>®</sup>	ezetimibe	\$1,111

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2017	1Q (Jan)	<i>Sandostatin</i> <sup>®</sup>	octreotide injection	\$39
2017	2Q (Apr)	<i>Spectracef</i> <sup>®</sup>	cefditoren pivoxil	\$15
2017	2Q (Apr)	<i>Vytorin</i> <sup>®</sup>	ezetimibe/simvastatin	\$1,233
2017	2Q (May)	<i>Relpax</i> <sup>®</sup>	eletriptan	\$234
2017	3Q (Sep)	<i>Cancidas</i> <sup>®</sup>	casprofungin injection	\$0.2
2017	4Q (Nov)	<i>Velcade</i> <sup>®</sup>	bortezomib injection	\$3
2018	2Q (Apr)	<i>Nasonex</i> <sup>®</sup>	mometasone nasal spray	\$1,098
2018	2Q (May)	<i>Cialis</i> <sup>®</sup>	tadalafil	\$681
2018	4Q (Oct)	<i>Nuvaring</i> <sup>®</sup>	ethinyl estradiol/ etonogestrel vaginal ring	\$383
2018	4Q (Oct)	<i>Sensipar</i> <sup>®</sup>	cinacalcet	\$371
2018	4Q (Nov)	<i>Tarceva</i> <sup>®</sup>	erlotinib	\$276
2019	1Q (Jan)	<i>Exelon</i> <sup>®</sup> Patch	rivastigmine extended- release film	\$267
2019	1Q (Jan)	<i>Hepsera</i> <sup>®</sup>	adefovir dipivoxil	\$99
2019	2Q (May)	<i>Vesicare</i> <sup>®</sup>	solifenacin	\$407
2019	2Q (Jun)	<i>Reyataz</i> <sup>®</sup>	atazanavir	\$616
2019	2Q (Jun)	<i>Lyrica</i> <sup>®</sup>	pregabalin	\$1,566
2019	4Q (Oct)	<i>Boniva</i> <sup>®</sup>	ibandronate	\$588
2020	2Q (Apr)	<i>Viagra</i> <sup>®</sup>	sildenafil	\$1,001
2020	2Q (Apr)	<i>Revlimid</i> <sup>®</sup>	lenalidomide	\$99
2020	2Q (May)	<i>Detrol</i> <sup>®</sup> LA	tolterodine	\$756
2020	2Q (Jun)	<i>Lialda</i> <sup>®</sup>	mesalamine delayed- release tablet	\$218

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2020	3Q (Jul)	<i>Byetta</i> <sup>®</sup>	exenatide injection	\$597
2020	4Q (Nov)	<i>Chantix</i> <sup>®</sup>	varenicline	\$493
2021	1Q (Feb)	<i>Sutent</i> <sup>®</sup>	sunitinib	\$138
2021	3Q (Aug)	<i>Crixivan</i> <sup>®</sup>	indinavir	\$9
2021	3Q (Sep)	<i>Truvada</i> <sup>®</sup>	tenofovir/emtricitabine	\$1,039
2023	1Q (Mar)	<i>Spiriva</i> <sup>®</sup>	tiotropium powder for inhalation	\$1,436
2023	4Q (Dec)	<i>Vyvanse</i> <sup>®</sup>	lisdexamfetamine	\$776
2023	4Q (Dec)	<i>Thalomid</i> <sup>®</sup>	thalidomide	\$172
2025	1Q (Jan)	<i>Trilipix</i> <sup>®</sup>	fenofibric acid	\$240
2026	4Q (Oct)	<i>Janumet</i> <sup>®</sup>	metformin/sitagliptin	\$431
2026	4Q (Oct)	<i>Januvia</i> <sup>®</sup>	sitagliptin	\$1,260

^ Dollar amount reflects combined sales of all strengths and formulations of the product, unless otherwise indicated; source IMS Health

<sup>1</sup> Several companies have announced the settlement of patent litigation relating to Desloratadine Tablets, 5 mg (Clarinet). Pursuant to these settlements, the generic manufacturers will have the right to market Desloratadine Tablets, 5 mg, in the U.S. on July 1, 2012, or earlier in certain circumstances. Clarinet and Clarinet D will likely be switched to OTC availability prior to generic availability.

<sup>2</sup> Lexapro's '712 patent was originally slated to expire in December 2009, which included an additional six months of pediatric exclusivity. The U.S. Patent & Trademark Office granted the patent an 828-day extension in March 2006. Therefore, the estimated date for generic availability changed to March 2012. A recent patent litigation decision has also sided with Forest, upholding the validity of a key patent on Lexapro and keeping generics off the market until patent expiration in 2012.

<sup>3</sup> Generic Plavix was approved 1/20/06 with paragraph IV certification giving Apotex 180-day exclusivity. Apotex launched their generic "at risk" on August 8, 2006. A preliminary injunction was granted on August 31, ordering Apotex to halt its sales of generic Plavix. The judge did not require Apotex to recall clopidogrel that had already

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been distributed. Bristol-Myers Squibb/Sanofi's patent infringement trial against Apotex began January 22, 2007.

<sup>4</sup> Mylan launched their first-time generic for Xopenex inhalation solution 0.25% with 180 day exclusivity in September 2009. In April 2008, Breath Limited received FDA approval for their generic Xopenex inhalation solution 0.021%, .0042%, and 0.0103%. Sepracor settled a patent dispute with them which will allow Breath to market generic versions of the drug beginning August 2012 with a 180-day exclusive license. In March 2009, Sepracor entered into a Settlement and License Agreement with Teva and Barr. The agreement permits Barr and Teva to launch generic versions of Xopenex inhalation solution dosages under terms of a non-exclusive license commencing on February 17, 2013.

<sup>5</sup> Diovan received pediatric exclusivity, extending the drug's patent protection in the US until September 2012.

<sup>6</sup> Patent litigation between Teva and Merck is ongoing. The U.S. Court of Appeals for the Federal Circuit court is reviewing an appeal by Merck. If the Appeals court agrees that Merck's patent is unenforceable, Teva may launch their generic at any time.

<sup>7</sup> Warner Chilcott sued Watson for patent infringement in 2006. A settlement was reached in January 2009. Warner Chilcott sued Lupin for patent infringement in September 2009.

<sup>8</sup> In October 2007, Teva received FDA approval of its ANDA for Actonel 5 mg, 30 mg, and 35 mg tablets but did not launch due to ongoing patent litigation. In February 2008, the U.S. District Court for the District of Delaware found Procter & Gamble's U.S. Patent No. 5,538,122 covering Actonel to be valid. Teva intends to appeal this decision.

<sup>9</sup> Boehringer Ingelheim sued Teva/Barr for patent infringement in July 2007. The companies announced a settlement agreement in August 2008.

Note: Pulmicort dry powder inhalation and Advair have been removed from the table. These both contain inhaled corticosteroids, and the FDA has not determined a standard for bioequivalence for inhaled corticosteroids in multi-dose inhalers (MDIs) or dry powder inhalers (DPIs). Therefore, generic availability may be significantly delayed. At this time, there is no estimated date of generic approval.

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