

TOP TWENTY PAY-FOR-DELAY DRUGS: HOW DRUG INDUSTRY PAYOFFS DELAY GENERICS, INFLATE PRICES AND HURT CONSUMERS

Too often, consumers are forced to shoulder a heavy financial burden, or even go without needed medicine, due to the high cost of brand-name drugs. Our research indicates that one significant cause is the practice called “pay for delay,” which inflates the drug prices paid by tens of millions of Americans.

In a pay-for-delay deal, a brand-name drug company pays off a would-be competitor to delay it from selling a generic version of the drug. Without any competition, the brand-name company can continue demanding high prices for its drug.

This list of 20 drugs known to be impacted by pay-for-delay deals represents the tip of the iceberg. Annual reports by the Federal Trade Commission (FTC) indicate that generic versions of as many as 142 brand-name drugs have been delayed by pay-for-delay arrangements between drug manufacturers since 2005.¹

However, because the details of these deals rarely become public, consumers have largely been kept in the dark about the extent of the problem. Information about these twenty specific drugs affected by pay-for-delay deals has been made public thanks to legal challenges brought by the FTC, consumer class action lawsuits, research by legal experts, and public disclosures by drug makers.

Key findings of our analysis of these 20 drugs impacted by pay-for-delay deals:

- This practice has held back generic medicines used by patients with a wide range of serious or chronic conditions, ranging from cancer and heart disease, to depression and bacterial infection.
- These payoffs have delayed generic drugs for **five years**, on average, and as long as nine years.
- These brand-name drugs cost **10 times more** than their generic equivalents, on average, and as much as 33 times more.
- Combined, these brand-name drug companies have made an estimated **\$98 billion** in total sales of these drugs while the generic versions were delayed.

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Community Catalyst is a national, non-profit consumer advocacy organization that works in partnership with national, state and local organizations, policymakers, and philanthropic foundations to ensure consumer interests are represented in communities, courtrooms, statehouses and on Capitol Hill. Our *Prescription Access Litigation* project has built a coalition of 130 consumer, senior and labor organizations that challenge drug industry practices that block consumer access to affordable medicines, including the pay-for-delay deals concerning Provigil, Cipro, K-Dur, and Tamoxifen. More information at www.communitycatalyst.org.

IMPACT OF PAY FOR DELAY ON CONSUMERS

While the specifics of pay for delay are only now beginning to be understood by the public, the consequences of this price-inflating practice are all too real for consumers and taxpayers.

The drug Provigil, prescribed for sleep disorders and multiple sclerosis-related fatigue, offers a case study: Experts expected a generic version of Provigil to go on the market in late 2005, but brand-name manufacturer Cephalon paid more than \$200 million to four different generic drug manufacturers, who kept their generics off the market until 2012.² In the meantime, many patients had to pay up to \$1,200 each month for the drug, or manage without it.

In 2010, the FTC estimated that a pay-for-delay deal for a single drug could cost an individual consumer and their health plan an extra \$4,590 over 17 months.³ Extended over the average five-year length of a pay-for-delay deal, that amounts to \$16,200 in wasteful spending per patient, per drug, due to pay for delay.

This not only forces consumers to pay higher premiums and out-of-pocket costs, it also means that taxpayers foot higher drug bills in Medicare and other programs. The FTC estimated in 2010 that these deals cost consumers and taxpayers \$3.5 billion each year in higher drug costs.⁴

But for drug companies, pay-for-delay deals can translate to a windfall in higher profits. As the CEO of Cephalon, the drug company that makes Provigil, reportedly said about the deal that kept generic Provigil off the market, “That’s \$4 billion in sales that no one expected.”⁵

METHODOLOGY:

Our list of the *Top Twenty Pay-for-Delay Drugs* details 20 drugs impacted by one or more known pay-for-delay deals which include a payment by the brand-name drug company in exchange for an agreement by the generic drug maker to delay bringing a generic to market. As described above and detailed in the endnotes, information about these 20 specific drugs affected by pay-for-delay deals has been made public thanks to legal challenges brought by the FTC, consumer class action lawsuits, research by legal experts, and public disclosures by drug makers.

When computing the average difference between brand-name and generic drugs, we included only those drugs for which there was both a brand-name and generic price available. We did not include the estimated prices for the five generic drugs that are currently delayed.

To estimate the combined total sales of these 20 brand-name drugs while the generic versions were delayed, we conservatively assumed a 10% annual growth rate in drug sales revenue for brand-name drugs before the generic entered the market. Starting from the most recent available sales revenue before generic entry, we then estimated sales for the previous years. For instance, with annual sales for Adderall XR at \$1.5 billion the year before generic entry, sales for the two previous years were estimated to be \$1.364 billion and \$1.239 billion, for a total of \$4.103 billion. We did not project sales revenue forward for drugs currently protected by pay-for-delay deals.

TOP 20 GENERICS DELAYED BY PAY-FOR-DELAY DEALS

Prescription Drug (and Drug Maker)	Condition the Drug is Commonly Prescribed to Treat	Annual Sales Before Generic (\$ millions) ^A	Year of Pay-for- Delay Deal	Length of Delay ^B	Price of Brand-name Drug ^C vs Price of Generic Drug (\$)	
					Brand-name Drug Price	Generic Drug Price
Adderall XR (Shire)	Attention deficit hyperactivity disorder (ADHD)	1,500 M	2006	3.0 years ⁶	238	102
Aggrenox (Boehringer Ingelheim)	Stroke risk, blood clots	331 M ⁷	2008	6.8 years ⁸	294	73†
Altace (Sanofi)	High blood pressure, heart failure	700 M ⁹	2006	3.0 years ¹⁰	115	12
AndroGel (Solvay Pharmaceuticals/ Abbott Laboratories)	Low testosterone in patients with AIDS, cancer and other conditions	1,332 M ¹¹	2006	8.7 years ¹²	379	96†
BuSpar (Bristol-Myers Squibb)	Anxiety	600 M ¹³	1994	6.25 years ¹⁴	not available ¹⁵	12
Caduet (Pfizer)	High cholesterol and coronary artery disease	266 M	2008	1.7 years ¹⁶	266	113
Cipro (Bayer)	Bacterial infection, anthrax exposure	1,300 M ¹⁷	1997	7.0 years ¹⁸	346	23
Effexor XR (Wyeth/Pfizer)	Major depressive disorder, anxiety and panic disorder	2,400 M	2005	4.7 years ¹⁹	194	17
K-Dur (Schering-Plough/Merck)	Low blood levels of potassium (hypokalemia)	250 M ²⁰	1997	4.0 years ²¹	not available ²²	21
Lamictal (GlaxoSmithKline)	Epilepsy, bipolar disorder, Lennox-Gastaut Syndrome	1,500 M	2005	3.0 years ²³	465	14
Lipitor (Pfizer)	High cholesterol, coronary artery disease	7,400 M	2008	1.7 years ²⁴	205	18
Nexium (AstraZeneca)	Gastroesophageal reflux disease (GERD), other digestive disorders	5,638 M ²⁵	2008	6.1 years ²⁶	222	56†
Niaspan (Abbott Laboratories)	High cholesterol, coronary artery disease	1,037 M ²⁷	2005	8.3 years ²⁸	122	30†
Nuvigil (Cephalon/Teva)	Narcolepsy, obstructive sleep apnea and hypnea syndrome	331 M ²⁹	2012	4.0 years ³⁰	450	113†
Nolvadex/Tamoxifen (AstraZeneca)	Breast cancer	400 M ³¹	1993	9.0 years ³²	99 ³³	20
Propecia (Merck)	Enlarged prostate, male pattern baldness	142 M ³⁴	2006	7.0 years ³⁵	89	72
Provigil (Cephalon/Teva)	Narcolepsy, multiple sclerosis-related fatigue	1,100 M ³⁶	2005	6.25 years ³⁷	1,213	520
Sinemet CR (Bristol-Myers Squibb)	Parkinson's disease	150 M ³⁸	1995	11.0 years ³⁹	39	13
Wellbutrin XL -150 mg (Biovail)	Major depressive disorder, seasonal affective disorder	835 M ⁴⁰	2006	1.0 years ⁴¹	250	29
Zantac (GlaxoSmithKline)	GERD, digestive disorders	2,900 M ⁴²	1995	2.0 years ⁴³	278	11

Notes on top 20 list:

^A Annual Sales are U.S. sales as reported at www.Drugs.com for the last full year before generic entry, unless otherwise indicated.

^B Unless otherwise indicated, the time between settlement and generic entry was calculated conservatively, rounding up the month of known settlements, and rounding down the month of generic entry. This length of time is assumed to be a reasonable proxy for the length of delay caused by pay-for-delay settlements.

^C Unless otherwise indicated, drug prices are as available at 14 CVS locations in Boston, MA, for the default dosage and quantity, as advertised at www.GoodRx.com on 6/10/2013 or 6/13/2013. These drug prices are typical of those available across the country.

[†] For drugs not yet available as generics, prices are conservatively estimated to be 25 percent of the brand-name price.

ENDNOTES:

- 1 Based on data compiled from annual Pharmaceutical Agreement Filings, FY2005-FY2012, posted on the FTC website at <http://www.ftc.gov/bc/healthcare/drug/index.htm>.
- 2 *FTC v. Cephalon*, Complaint, Feb. 13, 2008, at 3, available at <http://www.ftc.gov/os/caselist/0610182/080213complaint.pdf> (noting that “Cephalon bought off all four of its potential competitors” by “paying more than \$200 million collectively” in exchange for their agreement to delay generic “entry until April 2012.”)
- 3 *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, An FTC Staff Study, Jan. 2010, at page 4, available at <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>.
- 4 *Id.* at page 2.
- 5 Cephalon CEO Frank Baldino as quoted on the Provigil pay for delay deals in the Philadelphia Business Journal, *Hurdles ahead for Cephalon*, Mar 20, 2006, available at <http://www.bizjournals.com/philadelphia/stories/2006/03/20/story1.html>.
- 6 Scott Hemphill, *An Aggregate Approach to Antitrust Using New Data and Rulemaking to Preserve Drug Competition*, Columbia Law Review, Jan. 2009, at 11, Table 2: Settlements with Monetary Payment (reporting a settlement in 2006 that included payment and an agreed delay of generic entry for 3 years). However, because the first two generics introduced by Teva and Impax Labs were ‘authorized generics’ allowed under an exclusive licensing agreements provided in Teva’s pay-for-delay settlement, the delay of true generic competition and resulting lower prices was probably 5.8 years, until approx. June 2012. See Tracy Staton, *FDA hits Shire with early nod for Adderall XR copycat*, FiercePharma, June 25, 2012, available at <http://www.fiercepharma.com/story/fda-hits-shire-early-nod-adderall-xr-copycat/2012-06-25>. (noting FDA’s approval of a third generic of Adderall XR “ushers onto the market a lower-priced rival” to the first two generics).
- 7 2012 U.S. sales not publicly available; 2011 U.S. sales at https://host1.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf.
- 8 Adam Greene, *Analyzing Litigation Success Rates*, RBC Capital Markets Industry Comment, Jan. 15, 2010, at <http://amlawdaily.typepad.com/pharmareport.pdf>, at Appendix C (reporting a settlement in Aug. 2008 and anticipated generic launch in July, 2015, resulting in a delay from Sept. 2008 to June 2015); and Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 7 years).
- 9 2009 U.S. sales data not publicly available; listed data are for “the calendar year of settlement [2006] or the twelve months preceding settlement, or where unavailable, the closest available year” from Hemphill, *supra* note 6.
- 10 Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 3 years).
- 11 2012 U.S. sales, at <http://www.drugs.com/stats/top100/2012/sales>.
- 12 *FTC v. Watson Pharma*, 09-cv-00955 (N.D. GA), Second Amended Complaint, May 28, 2009, at para. 65 (disclosing that pay-for-delay agreements on September 13, 2006 included an agreed delay of generic entry until August 31, 2015) available at <http://www.ftc.gov/os/caselist/0710060/090528androgelfinalcmpt.pdf>. Thus pay-for-delay settlements delayed generic Androlog from at least Jan. 2007 to Aug. 2015, amounting to 104 months, or 8.7 years.
- 13 2000 U.S. Sales, at <http://www.ftc.gov/os/2003/03/bristolmyerscmp.pdf>, para. 4.
- 14 FTC enforcement action (*In the Matter of Bristol-Myers Squibb Company*, Docket No. C-4076, at <http://www.ftc.gov/os/2003/03/bristolmyerscmp.pdf>) reports a settlement on December 2, 1994, and generic entry in “late March 2001.” This equals a delay from approximately Jan. 1995 to March 2001 inclusive, equaling 75 months, or 6.25 years; See also Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 5 years).
- 15 The cost of brand-name Buspar is not available at website www.GoodRx.com, which lists prices and availability at 70,000 pharmacies nationwide.
- 16 Caduet has the same active ingredient as Lipitor, and is subject to the same patents. See Lipitor, note 24, below, and Greene, *supra* note 8, at Appendix A; See also Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 3 years).
- 17 1996 U.S. sales, see *Bayer Settles Cipro Patent Squabble*, ICIS Chemical Business, Jan. 27, 1997, available at <http://www.icis.com/Articles/1997/01/27/6512/bayer-settles+cipro+patent+squabble.html>.
- 18 Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 7 years); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323, 1130 (Fed. Cir. 2008)(noting at footnotes 7, 8 that multiple settlements on approximately Jan. 27, 1997 included payments totaling \$398 Million, and agreements to delay generic until entry until Jan. 2004) available at <http://www.ftc.gov/os/2010/04/100429ciprostatement.pdf>.
- 19 Greene, *supra* note 8, at Appendix C (reporting a settlement in Oct. 2005 and anticipated generic launch in July 2010, amounting to 56 months, or 4.7 years); See also Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 5 years).
- 20 2000 U.S. sales data not publicly available; listed data are for “the calendar year of settlement [1997] or the twelve months preceding settlement, or where unavailable, the closest available year” from Hemphill, *supra* note 6.
- 21 An FTC enforcement action reported pay-for-delay settlements in June 1997 delayed generic access until Sept 2001, resulting in a delay from at least July 1997 to at least Aug. 2001, amounting to 48 months, or 4 years. See <http://www.ftc.gov/opa/2001/04/>schering.shtm; See also Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 4 years).
- 22 The cost of brand-name K-Dur was not available at website listing prices and availability at 70,000 pharmacies nationwide. See www.GoodRx.com.
- 23 Hemphill, *supra* note 6 (reporting a settlement in 2005 that included payment and an agreed delay of generic entry for 3 years).
- 24 Delayed consumer access to a generic of Lipitor occurred from April 2010 to Nov. 2011, inclusive, amounting to a delay of 20 months, or 1.7 years, based on the expiration of the Pfizer patent on Lipitor’s active ingredient on approximately March 24, 2010 (see Patricia Hurtado, *Pfizer, Ranbaxy Sued Over Alleged Anti-Competitive Scheme*, Bloomberg News, February 09, 2012, available at <http://www.businessweek.com/news/2012-02-09/pfizer-ranbaxy-sued-over-alleged-anti-competitive-scheme.html>) and the generic entry on Nov. 30, 2011. Pfizer’s settlement on June 18, 2008 with Ranbaxy included a delay of generic launch until Nov 30, 2011. See *Pfizer and Ranbaxy settle Lipitor patent litigation worldwide*, Press Release, June 18, 2008, available at http://www.pfizer.be/sites/be/nl/media/press_bulletins/in_general/Pages/PfizerandRanbaxysettleLipitorpatentlitigationworldwide.aspx.
- 25 2012 U.S. sales, at <http://www.drugs.com/stats/top100/2012/sales>.
- 26 Estimated delay of 6.1 years based upon a pay-for-delay agreement on or about April 14, 2008, which delayed generic access from May 2008 to anticipated generic launch on May 27, 2014, inclusive. See *In re Nexium (Esomeprazole) Antitrust Litigation*, No. 12-md-02409-WGY (D. Mass.) Document # 95, filed Jan. 22, 2013, at page 27, available at <http://www.wexlerwallace.com/wp-content/uploads/2013/03/In-Re-Nexium-Esomeprazole-Ant.pdf>; See also Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 6 years).
- 27 2012 U.S. Sales, at <http://www.drugs.com/stats/top100/2012/sales>.
- 28 Greene, *supra* note 8 (reporting a settlement in April 2005 with anticipated generic launch in September 2013); Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 8 years). Generic entry was delayed from at least May 2005 to August 2013, amounting to 100 months, or 8.3 years.
- 29 2011 U.S. Sales from Medco/Express Scripts, at https://host1.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf.
- 30 *Teva settles Nuvigil litigation with Mylan*, April 30, 2012, Bloomberg, available at <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=acXtuf7zOK34> (reporting April 2012 settlement including delayed entry until June 2016 in exchange for exclusive licensing rights to Nuvigil).
- 31 2001 U.S. sales data are not publicly available; listed data are for 1993 “the calendar year of settlement or the twelve months preceding settlement, or where unavailable, the closest available year” from Hemphill, *supra* note 6.
- 32 Hemphill, *supra* note 6 (reporting a settlement in 1993 that included a payment and an agreed delay of generic entry for 9 years).
- 33 Nolvadex price is calculated as 50% of the price of \$197.23 for 60 tablets, as reported in *Bennish et. al v. Barr Labs*, 00-cv-74948 (E.D. MI) Doc #1, Complaint, Nov. 9, 2000, at para. 62, available through PACER.gov (citing a www.drugs.com price on Oct. 4, 2000).
- 34 2012 U.S. Sales not publicly available. 2011 U.S. Sales from Medco/Express Scripts, at https://host1.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf.
- 35 Hemphill, *supra* note 6 (reporting a settlement in 2006 that included payment and an agreed delay of generic entry for 7 years).
- 36 2011 U.S. Sales, at <http://www.drugs.com/stats/top100/2011/sales>, citing IMS Health.
- 37 Multiple pay-for-delay settlements starting in December 2005 allowed for generic entry in April 2012, causing a delay in generic access from Jan. 2006 to at least March 2012, inclusive, amounting to 75 months, or 6.25 years. Greene, *supra* note 8, at Appendix C; See also Hemphill, *supra* note 6 (reporting a 2006 settlement that included payment and an agreed delay of generic entry for 6 years).
- 38 2006 U.S. sales data not publicly available. Presented are for 1995 “Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or the twelve months preceding settlement, or where unavailable, the closest available year.” as reported in Hemphill, *supra* note 6.
- 39 Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 11 years).
- 40 Reported amounts are half of the 2006 U.S. sales for both for both 150mg and 300 mg doses of Wellbutrin XL were \$1,670,516 at http://www.drugs.com/top200_2006.html. This is a conservative estimate, because the 150mg dose is more commonly prescribed than the 300 mg dose.
- 41 Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 1 year).
- 42 1997 U.S. Sales data are not publicly available. Reported data are for 1995 “Annual U.S. sales, in millions of dollars, measured in the calendar year of settlement or the twelve months preceding settlement, or where unavailable, the closest available year” as reported in Hemphill, *supra* note 6.
- 43 Hemphill, *supra* note 6 (reporting a settlement including payment and an agreed delay of generic entry for 2 years).