

Rx Price Watch Report: Retail Prices for Widely Used Brand Name Drugs Increase Considerably Prior to Generic Competition

AARP's Public Policy Institute finds that retail prices for brand name prescription drugs widely used by Medicare beneficiaries increase considerably in the years prior to generic entry. Furthermore, the retail prices of brand name drug products continue to increase after patent expiration, indicating that generic competition has little or no impact on costs for consumers who choose to continue taking the brand name product.

Introduction

AARP's Public Policy Institute has been tracking price changes for widely used prescription drug products since 2004, with quarterly and annual results reaching back as far as 2000.¹ Previous studies have used a market basket of drugs based on actual drug utilization in a Medicare Part D plan during calendar year 2006. Our reports on price changes have included the overall price change across all types of drug products in our market basket as well as specific analysis of the retail price changes found for each of the drug subgroups—brand name, generic, and specialty drugs.²

This report focuses on changes³ in the retail prices⁴ for brand name drug products widely used by Medicare beneficiaries. In particular, the report examines changes in the retail prices of brand name drugs both before and after patent expiration to see how the change in patent status affects retail prices.

Even before brand name drugs come on the market, they are typically covered by one or more patents or other types of market exclusivity.⁵ Over time, patent-protected brand name drug products will typically go off patent and face generic competition.⁶ Since 2006, 85 of the 217 drug products in the Rx Price Watch brand name market basket have gone off patent and faced generic competition. We have chosen to keep these off-patent brand name drugs in our market basket, since they are still being sold, albeit at considerably lower volumes. Another 11 brand name drug products were already off patent in 2006, but the brand name product remained widely used for a variety of reasons.⁷ Eventually, the remaining 121 brand name drug products in the market basket are expected to go off patent and face generic competition, with several losing their patent protection in the next few years.⁸

In an effort to better understand the implications of patent protection and subsequent generic competition, this report examines retail price changes both before and after patent expiration for all of the off-patent drug products in the Rx Price Watch brand name market basket. The 96 off-patent brand name drug products were combined to create the dataset of off-patent brands used in this analysis. For comparison purposes, the report also examines the retail prices of the remaining 121 drug products that continue to have

patent protection and market exclusivity and, therefore, have not yet faced price competition from generics.

FDA Drug Approval Process

All new drugs must be reviewed and approved by the U.S. Food and Drug Administration (FDA) in order to enter the U.S. prescription drug marketplace. The approval process includes preclinical research, various clinical studies to demonstrate safety and effectiveness, and submission of a new drug application or abbreviated new drug application for review by FDA.

Brand Name Drugs

Overall, the discovery and development of a new (brand name) medicine is estimated to take 10 to 15 years.⁹ Many patents are granted by the U.S. Patent and Trademark Office before a drug is approved for marketing by the FDA. Consequently, it is not unusual for a few years to pass from the time a drug product is awarded its first patent until it receives FDA approval to market the drug. To compensate for some of the time lost while developing the product and awaiting FDA approval, the Hatch-Waxman Act provides for patent restoration by extending the patent's life.

Once the FDA has approved the drug, the pharmaceutical company is usually able to market it without any direct price competition—that is, the brand name drug has a monopoly. On average, brand name drug manufacturers do not face competition until 11 to 13 years FDA approval,¹⁰ although some may not face generic competition for 20 years or more after filing for the first patent owing to the effect of multiple patents and other factors.¹¹ The length of a drug product's monopoly period is attributable mainly to multiple patents, patent restoration,¹² other forms of market exclusivity, and delays caused by intellectual property litigation.

Generic Drugs

All of the relevant patents and exclusivity periods for a brand name drug product must expire before the FDA can approve generic manufacturers' versions of the drug. Generic manufacturers must demonstrate that their products have the same active ingredient, route of administration, dosage form, strength, and proposed labeling as the reference-listed (brand name) drug. The generic drug manufacturer must also demonstrate that their product is "bioequivalent," or exhibits the same rate and extent of absorption, as the relevant branded product. However, generic manufacturers are allowed to rely on the FDA's previous findings of safety and effectiveness for the drug molecule, and they do not have to perform their own clinical studies, thus saving them substantial time and development costs.

Sometimes the first generic manufacturer to file for FDA approval is granted a 180-day exclusivity period that briefly protects the first generic drug product from competition with other generic versions.¹³ After that period expires, the FDA may approve all generic versions of a drug product that meet FDA requirements.

The Impact of Generic Competition

Over time, multiple generic manufacturers can enter the market, creating substantial competition that drives down the prices of the generic versions.¹⁴ In combination with the

less costly approval process, this competition can lead to generic drug prices that are, on average, 85 percent lower than the price of the brand name counterpart before it went off patent.¹⁵

Strong price competition among generics can quickly reduce a brand name manufacturer's market share from 100 percent to as low as 10 percent,¹⁶ impacting the manufacturer's revenue substantially. Some brand name drug manufacturers postpone the entry of generic competition by entering into what are known as "pay for delay" agreements with the first generic manufacturer to file for FDA approval. The Federal Trade Commission has observed that the number of such agreements has been growing in recent years and that the estimated cost of these agreements to the American public is \$3.5 billion a year due to delay of price competition from other generics.¹⁷ Brand name drug manufacturers may also try to minimize, delay, or prevent generic price competition by creating an "authorized generic" or new versions of the drug in a different strength, dosage form, molecular form, or other minor variations.¹⁸

The marketplace price competition of generics will become increasingly challenging for brand name manufacturers as more and more blockbuster drugs go off patent. Over the next two years, six of the ten top-selling products on the U.S. market are expected to face generic competition, and many more are expected to go off patent over the next several years.¹⁹ Many brand name manufacturers are struggling to develop new blockbusters, making it even more difficult for them to replace the revenue from blockbusters that presently or soon will face generic competition.²⁰

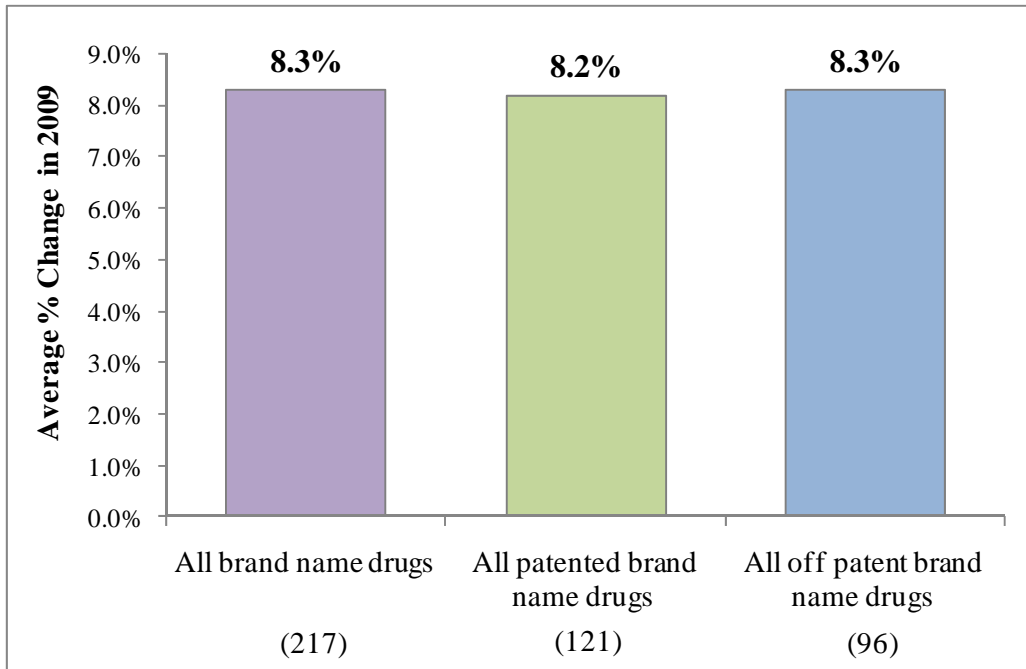
Retail Price Changes among Off-Patent Brand Name Drugs

Since 2006, 85 of the 217 drug products in the Rx Price Watch brand name market basket have gone off patent and faced generic competition.²¹ Another 11 brand name drug products were already off patent in 2006 but remained widely used for a variety of reasons. These 96 off-patent brand name drug products were combined to create the dataset used in this analysis. We compared price changes for these off-patent brands with the remaining 121 brand name drug products in the market basket that remain patent protected.

Annual Percent Change in Retail Prices

The AARP Public Policy Institute's most recent Rx Price Watch report found that retail prices for the 217 brand name drug products most widely used by Medicare beneficiaries rose 8.3 percent in 2009.²² When this finding is broken down by patent status, there was very little difference, on average, in the price increases experienced by widely used patented versus off-patent brand name drug products in 2009.²³ The 96 off-patent drug products in the brand name market basket experienced an average annual retail price increase of 8.3 percent, while the average annual retail price increase for the remaining 121 brand name drug products (i.e., brand name drug products that are still under patent) was essentially the same, at 8.2 percent (Figure 1).

Figure 1: Average Annual Percent Change in Retail Prices for Widely Used Brand Name Drugs Is Essentially the Same Regardless of Patent Status in 2009



Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

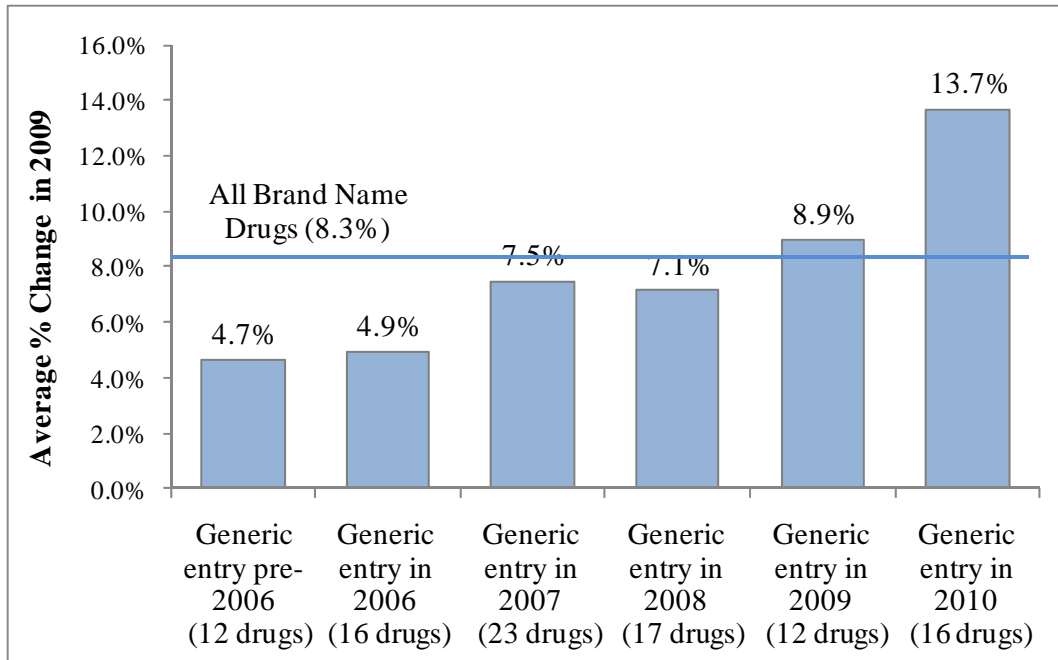
Annual percent change in retail prices by year of generic entry

While the average annual retail price increase for the 96 off-patent brand name drug products in the AARP market basket (8.3 percent) was equal to the overall average annual price increase for brand name drug products (8.3 percent) in 2009, a large degree of variation emerges when the data are examined by year of actual or expected generic entry and weighted by actual sales (2006) to Medicare Part D beneficiaries.

In 2009, average annual retail price increases were notably higher among the brand name drugs closest to experiencing generic competition. For example, brand name drug products that faced generic entry in 2009 and 2010 experienced average annual retail price increases of 8.9 percent and 13.7 percent, respectively. In contrast, brand name drug products that faced generic competition prior to 2009 experienced average annual retail price increases of less than 7.5 percent (ranging from 4.7 percent to 7.5 percent) over the same period (Figure 2).

The average annual retail price increases for brand name drug products facing generic competition in 2009 (8.9 percent for 12 drugs) and 2010 (13.7 percent for 16 drugs) also greatly exceeded the overall annual retail price increase for the whole market basket of widely used brand name drug products in 2009 (8.3 percent for 217 drugs). The brand name drugs facing generic competition in 2009 and 2010 also had a higher average annual retail price change than the patented brand name drugs (8.2 percent for 121 drugs).

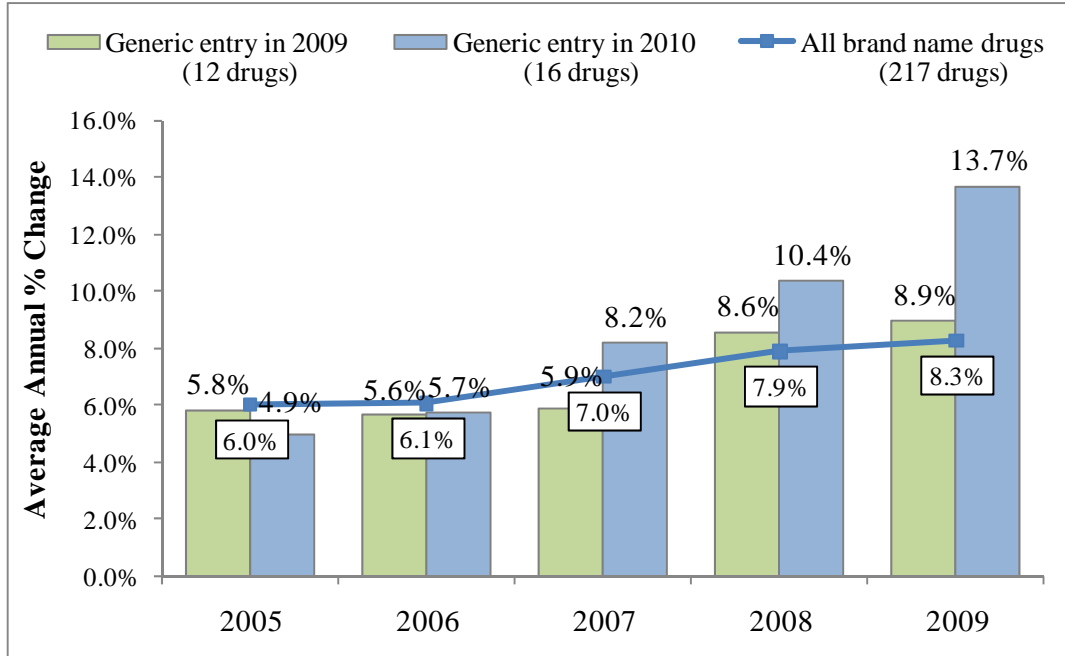
Figure 2: Average Annual Percent Changes in Retail Prices for Brand Name Drugs Facing Generic Competition in 2009 and 2010 Greatly Exceed Overall Average Annual Percent Change for All Brand Name Drugs in 2009



Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

The markedly higher average annual retail price increases seen in 2009 among brand name drugs facing generic entry in 2009 and 2010 are not atypical, and instead represent a trend of consistent retail price increases for brand name drugs in the years immediately prior to patent expiration. For example, the average annual retail price change for the 12 brand name drug products that faced generic competition in 2009 increased by more than one and one-half times (8.9 percent vs. 5.8 percent) the rate found in 2005—five years prior to generic entry (Figure 3). Similarly, the average annual retail price increase for the 16 brand name drug products that faced generic competition for the first time in 2010 was almost three times higher in 2009 than it was in 2005 (13.7 percent vs. 4.9 percent) (Figure 3).

Figure 3: Average Annual Percent Change in Retail Prices for Brand Name Drugs Accelerates in Years Immediately Prior to Patent Expiration



Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

Five-Year Cumulative Percent Change in Retail Prices by Year of Generic Entry

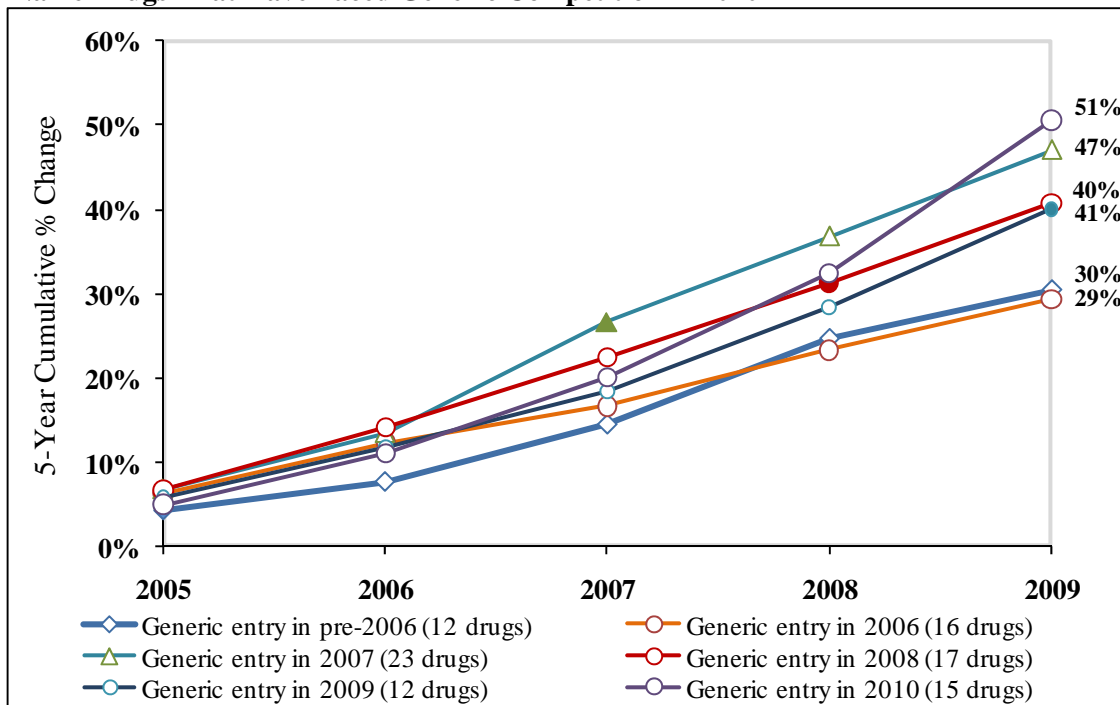
All but one of the 96 off-patent drugs in the brand name market basket has been on the market from December 31, 2004, through December 31, 2009. The one exception, Ambien CR 12.5 mg tablets, entered the market in September 2005. Over the five-year period, the average retail price increase for the remaining 95 off-patent brand name drug products was 42.6 percent, compared with 41.5 percent for the overall brand name market basket. Much like the average annual percent change, the five-year cumulative percent change from December 31, 2004, to December 31, 2009, reveals a large degree of variation when the data are examined by year of generic entry (Figure 4):

- The retail prices of the 15 brand name drugs that faced generic competition in 2010 rose by 51 percent over the entire five-year period. It is notable that this group’s retail price increases accelerated most rapidly in the two years before generic entry (i.e., 2008 and 2009).
- The retail prices of brand name drugs that faced generic competition in 2008 and 2009 each increased cumulatively by approximately 40 percent between the end of 2004 and the end of 2009. For brand name drug products that faced generic competition in 2009, almost one-half of the cumulative increase took place in 2008 and 2009. In contrast, brand name drug products that faced generic entry in 2008 have experienced fairly steady average annual increases of around 7 percent since 2006.

Brand Name Drug Prices Increase Prior to Generic Competition

- The retail price of brand name drugs that faced generic entry in 2007 increased by 47 percent between 2005 and 2009. Much of this increase was due to an unusually high average annual retail price increase (11.6 percent) in 2007, which was driven by retail price increases of almost 27 percent for Ambien 5 mg and 10 mg tablets.
- The retail prices of brand name drugs that faced generic competition pre-2006 and in 2006 each increased cumulatively by approximately 30 percent between 2005 and 2009. The average annual retail price increases for these drug products were notably lower than for brand name drug products that faced generic competition in later years, averaging roughly 5.5 percent. Nonetheless, these brand name drugs showed continued retail price increases five or more years after generics had entered the market.

Figure 4: Five-Year Cumulative Percent Change in Retail Price Is 51 Percent for Brand Name Drugs That Have Faced Generic Competition in 2010



Note: Solid markers indicate the year when the drug products faced generic competition.

Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

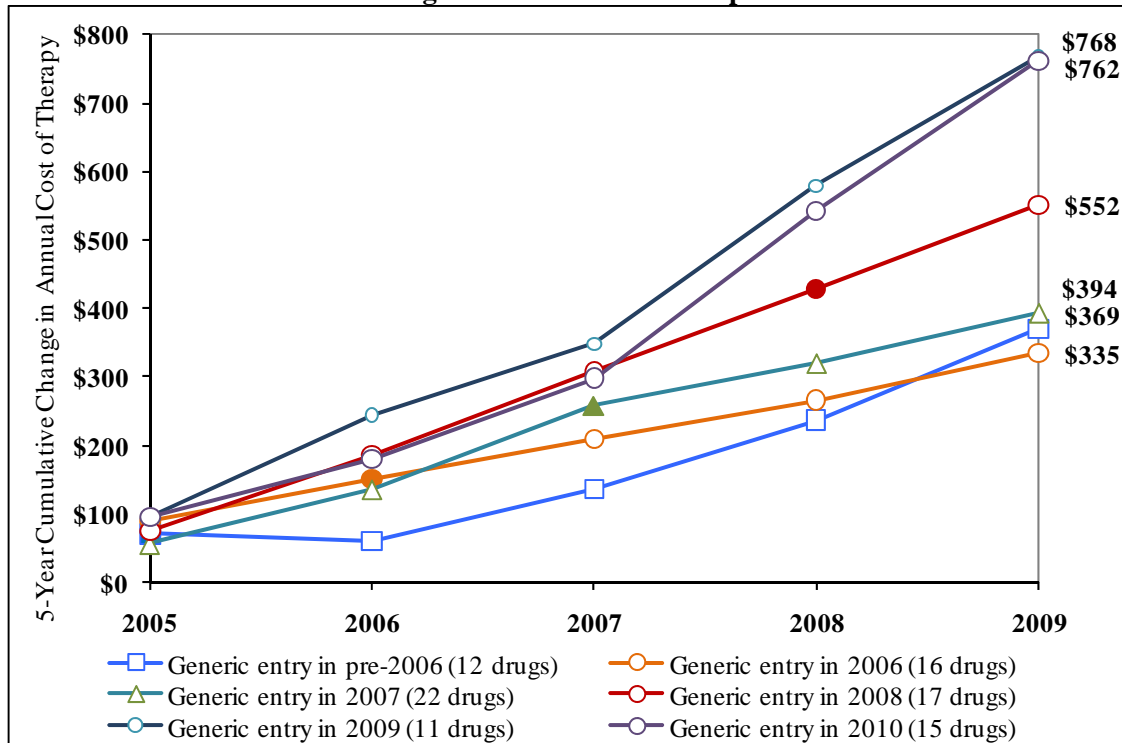
Five-Year Cumulative Dollar Change in Annual Retail Cost of Therapy by Year of Generic Entry

All but 2 of the 95 off-patent brand name drug products that have been on the market since the end of 2004 are used to treat chronic conditions.²⁴ The retail prices for the 93 chronic brand name drug products were translated into average annual costs of therapy.²⁵ Figure 5 shows the five-year (December 2004 to December 2009) cumulative change in cost of therapy due to retail prices for off-patent brand name drug products.

Brand Name Drug Prices Increase Prior to Generic Competition

- The annual retail cost of therapy for brand name drug products that went off patent in 2009 rose by \$768 (from \$1,842 to \$2,610) between the end of 2004 and the end of 2009. It is notable that the majority of this \$768 five-year increase took place in 2008 and 2009.

Figure 5: Five-Year Cumulative Dollar Change in Annual Retail Cost of Therapy Accelerates for Brand Name Drugs Prior to Generic Competition



Note: Solid markers indicate the year when the drug products faced generic competition.
 Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

- Similarly, the average annual retail cost of therapy for drug products that have gone off patent in 2010 rose by \$762 over the five-year period ending in 2009. These brand name drugs facing patent expiration in 2010 experienced an increase from \$1,320 per year at the end of 2004 to \$2,082 per year at the end of 2009. More than half of this \$762 increase took place in 2008 and 2009, the two years before patent expiration.
- The average retail price for a one-year supply of brand name drug products that faced generic competition in 2008 rose by more than \$550 between the end of 2004 and the end of 2009. At the end of 2004, the average annual retail price for brand name drug products that went off patent in 2008 was \$1,338; by the end of 2009, the retail price for these same drugs had increased to \$1,890.
- The average annual retail cost of therapy for brand name drug products that faced generic entry prior to 2008 had five-year cumulative price increases ranging from \$335 to \$395 from the end of 2004 to the end of 2009.

Conclusion

The retail prices for the overall market basket of 217 brand name drug products that are widely used by Medicare Part D enrollees increased by 8.3 percent in 2009. The retail prices for brand name drug products that were still on patent (121 drugs) after 2010 increased 8.2 percent in 2009. Retail prices for the drug products that were off patent and faced generic competition in 2010 or before (96 drugs) increased 8.3 percent in 2009.

The brand name drugs that went off patent in 2009 and 2010 experienced substantial retail price increases in 2009 (8.9 percent and 13.7 percent, respectively). Inclusion of only these 2009 and 2010 off-patent brand name drugs (28 drugs) could have resulted in a modest overstatement of the retail price increase shown for the entire market basket of brand name drugs. However, the method used for the Rx Price Watch study also included the 68 brand name drugs that went off patent prior to 2009, which had retail price increases in 2009 ranging from 4.7 percent to 7.5 percent. Therefore, inclusion of the 68 brand name drugs that went off patent prior to 2009 more than offset the effect of the brand name drugs that went off patent in 2009 and 2010. In fact, inclusion of all 96 drugs that went off patent in 2010 or before in the overall market basket of 217 brand name drugs resulted in essentially the same retail price increase in 2009 as that experienced by only the 121 brand name drugs still on patent after 2010 (8.3 percent versus 8.2 percent).

The cumulative effect of these retail price increases for individual brand name drugs just prior to patent expiration can be quite substantial. The retail price of brand name drugs that have faced generic competition in 2010 rose by 51 percent (from \$1,842 to \$2,610 for a year of therapy, an increase of \$762) between the end of 2004 and the end of 2009; much of this increase took place in the two years before generic entry (i.e., 2008 and 2009). In contrast, brand name drug products that faced generic competition in 2008 or earlier experienced average cumulative retail price increases of approximately 30 percent (increases of \$335 to \$394 for a year of therapy) over the same period.

The retail price increases for brand name drugs just prior to patent expiration may be due to many factors. Anticipated price competition from generics and the resulting reduction in market share for the brand name drug could prompt rapid price hikes just before patent expiration. A previous Rx Price Watch report found that the retail prices of brand name drugs widely used by Medicare beneficiaries increased more in 2009 than in the previous four years; notably, 2009 was the year preceding passage of the Affordable Care Act, which contained several provisions that could impact drug manufacturers' revenues.²⁶ Drug manufacturers may also have been responding to price pressure from cost containment measures currently being implemented in many European Union countries.²⁷ Yet another factor is the unprecedented number of drugs that will be going off patent and facing generic price competition in next few years,²⁸ which may have led some manufacturers to increase their prices in an effort to maintain corporate revenue and profits.

Nevertheless, these findings make it clear that, regardless of the cause, the retail prices of brand name drugs increased markedly just prior to patent expiration and continue to increase post-patent expiration, albeit at substantial but less rapid rates. Thus, consumers who choose to continue taking a brand name product are not likely to experience any price relief at patent expiration, and will instead continue to experience the effects of retail price increases for the brand name drug.

Importantly, consumers who need a patent-protected brand name drug at any time before that patent expires do not have a lower cost generic alternative available. If they cannot afford that patent-protected brand name drug, it is not reasonable to expect them to wait a year or two, or even a decade or more, for the generic version in order to afford treatment for their medical condition.

Retail price increases translate into higher out-of-pocket costs for those beneficiaries who pay a percentage of drug costs (coinsurance) rather than a fixed dollar amount (copayment). Higher prices also push more Medicare Part D enrollees into the “doughnut hole”—the gap in coverage when enrollees have to pay all, or most, of their drug costs—each year. And, once in the doughnut hole, enrollees feel the full effect of the higher retail prices for patented and off-patent brand name prescription drugs.

The recently passed health care reform legislation has provisions that will phase out the Medicare Part D coverage gap through discounts to consumers on brand name, biologic, and generic prescription drugs. However, Part D enrollees will continue to be exposed to the effects of the doughnut hole until the legislation’s provisions are fully implemented in 2020. Furthermore, the value of consumer discounts provided to beneficiaries who reach the doughnut hole, while substantial, could be eroded over the years if substantially escalating drug prices, such as those seen in 2009, are not addressed.

Insight on the Issues 49, March, 2011

Written by Stephen Schondelmeyer^b and Leigh Purvis^a

^aAARP Public Policy Institute

^bPRIME Institute, University of Minnesota, Minneapolis, MN 55455
601 E Street, NW, Washington, DC 20049

www.aarp.org/ppi

202-434-3890, e-mail: ppi@aarp.org

© 2011, AARP, reprint only with permission.

¹ Previous reports from this series can be found on the AARP Web site at <http://www.aarp.org/rxpricewatch>.

² Two drug industry-sponsored publications (a report by E. Berndt and M. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Hatch-Waxman Legislation*, September 2010; and an article from the American Enterprise Institute, J. E. Calfee, *Why the AARP Reports Are Misleading or Worse*, AEI Outlook Series, No. 4, October 2010) erroneously state that the AARP Rx Price Watch reports do not reflect the impact of generic drugs. In fact, the AARP drug pricing report series has consistently analyzed price trends among widely used brand name, generic, and specialty prescription drugs both separately and collectively. When the three market baskets are combined, the results have consistently demonstrated that the substantial price increases for widely used brand name and specialty prescription drugs more than offset the price decreases commonly found among widely used generic drugs.

³ Calculated as a rolling average and weighted by actual 2006 sales to Medicare Part D enrollees. See detailed methodology in Appendix A of the AARP Public Policy Institute’s August 2010 report, *Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Medicare Beneficiaries, 2004 to 2009*, for details.

Brand Name Drug Prices Increase Prior to Generic Competition

⁴ The retail price tracked and analyzed for this report was based on consumers age 50 and older enrolled in employer-sponsored health plans, as reported by the Thomson Reuters MarketScan® Research Databases.

⁵ Individual drug products may have multiple patents on the same product. For example, the once-popular drug product Prilosec (the “purple pill”) had at least 12 different patents, which collectively provided its manufacturer with more than 12 years on the market without any price competition from FDA-approved generic equivalents. Other major brand name drug products in the AARP market basket for brand name drugs that have reported multiple patents to the FDA in recent years include Evista (18), Kaletra (13), Paxil (10), Norvir (10), Wellbutrin (9), Zyprexa (9), Prevacid (8), Fosamax (8), and Lipitor (6), among others (based on data compiled by the *PRIME* Institute at the University of Minnesota from data found in various annual editions of the FDA Orange Book). Various types of market exclusivity may be awarded to a drug product based on (1) the conduct of studies on pediatric populations, (2) designation by FDA as an orphan drug, or (3) other statutory and regulatory criteria.

⁶ Blockbuster brand name drugs tend to lose market share quickly once generic versions are on the market. For example, when generic versions of Zolofit became available in August 2006, the brand name product lost 85 percent of its overall market share in the first 30 days. Similarly, generic statin-dispensing rates almost doubled in the three months after the products entered the market (Medco, 2007 Drug Trend Report, 2008; and Caremark, “Blockbuster Launches of 2006,” *TrendsRx Quarterly*, December 2006). Lower volume brand name drugs also experience market share loss to lower cost generic versions, but at slower rates of decline than blockbuster brands.

⁷ Six of the drug products are widely considered to be narrow therapeutic index drugs, or drugs for which small changes in systemic concentration can lead to significant changes in pharmacodynamic response. This designation can make some prescribers hesitant to switch patients from the brand name drug to the generic version. The remaining drug products do not have generic equivalents or have generic equivalents that were substantially delayed in reaching the market.

⁸ K. Method, “Going, Going, Gone: Patents Set to Expire Soon on Many Brand-Name Drugs,” *Drug Topics Supplements*, August 10, 2009.

⁹ Pharmaceutical Research and Manufacturers of America, *Industry Profile 2010*, July 2010.

¹⁰ H. Grabowski et al., “Generic Competition and Market Exclusivity Periods in Pharmaceuticals,” *Managerial and Decision Economics* 28 (4–5): 491–502. See also E. C. Seoane-Vazquez, S. W. Schondelmeyer, and S.L. Szeinbach, “Drug Patent Life and Generic Competition: Analysis of New Molecular Entities Approved by the FDA Between 1980 and 1999,” *Journal of Pharmaceutical Finance, Economics & Policy*, 16 (4), 67–85.

¹¹ For example, the brand name drug known as Norvasc (amlodipine) tablets had 24.9 years of protection from the time of filing for the first patent to expiration of all forms of patent coverage, patent restoration, and pediatric exclusivity. Norvasc had 13.2 years on the market (post-FDA approval) before a generic version was approved. The average time from “first right of priority to file a patent” to “expiration of the first patent and any other market exclusivity periods” was reported to be 23.7 years for the 186 new molecular entities (NMEs) approved by the FDA between 1995 and 1999. (Seoane-Vazquez, Schondelmeyer, and Szeinbach, “Drug Patent Life.” The same research article showed that NMEs approved between 1995 and 1999 had effective post-NDA market exclusivity time (including patent extensions and market exclusivity) that averaged 12.4 years (± 1.1 years).

¹² C. Clift, “The Value of Patent Term Extensions to the Pharmaceutical Industry in the USA,” *Journal of Generic Medicines* 5 (3): 201–8.

¹³ The Hatch-Waxman Act provides a 180-day marketing exclusivity period to the first generic drug manufacturer that seeks FDA approval by challenging the validity of patents prior to the expiration of patents relating to the brand name drug product. No other generic manufacturer may obtain FDA approval to market its product until the first generic has sold its product for 180 days or has forfeited its exclusivity period.

¹⁴ There is a strong association between the number of generic entrants and the degree of drug price competition. The average generic-to-brand price ratio a year after the first generic entry for drugs with at least 20 generic suppliers is 20 percent; by contrast, this ratio is 65 percent for drugs with two or fewer

Brand Name Drug Prices Increase Prior to Generic Competition

generics by the end of the first year (A. Saha, H. Grabowski, H. Birnbaum, P. Greenberg, and O. Bizan, "Generic Competition in the US Pharmaceutical Industry," *International Journal of the Economics of Business*, 13 (1): 15–38.

¹⁵ Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010.

¹⁶ Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, January 2010.

¹⁷ Ibid.

¹⁸ The process of making minor modifications to an existing product in order to obtain additional patents on a drug product, and thus extend its patent life, is more commonly known as evergreening. A commonly cited example of evergreening involves the acid-reflux drugs Prilosec and Nexium. When Prilosec faced generic competition, its manufacturer introduced a slight molecular variant called Nexium and began campaigning to switch consumers to the "new" product. The manufacturer also introduced an over-the-counter version of Prilosec at a much lower price. Similarly, an extended-release product (Seroquel XL) was introduced to replace the original immediate release product of Seroquel, an antipsychotic drug, just before the original product was going to lose its patent. Another manufacturer introduced a tablet version of Tricor to replace the original capsule version of Tricor prior to expiration of the patent on the tablet version. The manufacturer also changed the labeled strength of the product over time from 200 mg to 160 mg and later to 145 mg. Shortly after the new strength product was put on the market, the old strength product was withdrawn from the market. Another strategy is to create a combination drug product with a new patent to replace the patent-expiring single-drug product. An example of this strategy was the introduction of Fosamax D, which is Fosamax combined with vitamin D.

¹⁹ IMS Health, "IMS Forecasts Global Pharmaceutical Market Growth of 5–8% Annually through 2014; Maintains Expectations of 4–6% Growth in 2010," Press Release, April 20, 2010.

²⁰ L. Lentini, "Pharma Industry Enters Critical Phase as Patent Cliff Looms Large, Hastening Consolidation," *FiercePharma*, May 19, 2010.

²¹ We have chosen to keep these off-patent drugs in our market basket, since they are still being sold, albeit at considerably lower volumes.

²² S. W. Schondelmeyer and L. Purvis, *Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Medicare Beneficiaries, 2005 to 2009*, AARP Public Policy Institute, August 2010.

²³ The Government Accountability Office has also reported that on-patent and off-patent brand name drugs experience similar price changes. Government Accountability Office, *Prescription Drugs: Trends in Usual and Customary Prices for Commonly Used Drugs*, February 2011.

²⁴ There were two off-patent drug products that are typically used to treat acute conditions, or for less than one year's duration: Lamisil 250 mg tablets and Valtrex 1 Gm caplets.

²⁵ The figures in this section reflect the total retail price (employer plus consumer cost) for prescriptions provided to consumers enrolled in employer-sponsored health plans and not simply the out-of-pocket cost a consumer would face at the pharmacy.

²⁶ D. Wilson, "Drug Makers Raise Prices in Face of Health Reform," *New York Times*, November 15, 2009.

²⁷ L. Taylor, "EU Govts Warned Over 'Enforced, Unpredicted' Rx Price Cuts," *Pharma Times Online*, March 31, 2010.

²⁸ Method, "Going, Going, Gone."