



Rx Price Watch Report

January 2012

Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009

Stephen W. Schondelmeyer
PRIME Institute, University of Minnesota

Leigh Purvis
AARP Public Policy Institute

Rx Price Watch

Rx Price Watch Report

January 2012

Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009

By

Stephen W. Schondelmeyer
PRIME Institute, University of Minnesota

Leigh Purvis
AARP Public Policy Institute

AARP's Public Policy Institute informs and stimulates public debate on the issues we face as we age. Through research, analysis and dialogue with the nation's leading experts, PPI promotes development of sound, creative policies to address our common need for economic security, health care, and quality of life.

The views expressed herein are for information, debate, and discussion, and do not necessarily represent official policies of AARP.

#2012-01

January 2012

© 2012, AARP.

Reprinting with permission only.

AARP Public Policy Institute
601 E Street, NW, Washington, DC 20049
<http://www.aarp.org/ppi>

This Rx Price Watch report is a new iteration of our Rx Watchdog report series that has been tracking *manufacturer* price changes for widely used prescription drugs since 2004. The new name for this report series (i.e., Rx Price Watch) marks our switch to *retail* prices—or the amount that is actually charged to consumers (and/or insurers)—as our primary data source. Thus, while our market basket of specialty prescription drugs widely used by Medicare Part D enrollees remains unchanged, our findings for this and future reports will be based on changes in the prices charged to consumers ages 50 and older enrolled in employer-sponsored health plans, as reported by the Thomson Reuters MarketScan® Research Databases. The addition of retail prices to our analyses will allow the AARP Public Policy Institute to assess what prices are being paid by consumers and whether the rebates and discounts often given to payers are being passed along to their clients.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	IV
FINDINGS.....	2
I. ANNUAL TRENDS IN RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS	2
II. ANNUAL TRENDS IN RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY FDA APPROVAL PROCESS	6
III. FIVE-YEAR CUMULATIVE IMPACT OF RETAIL PRICE CHANGES FOR WIDELY USED SPECIALTY PRESCRIPTION DRUGS, 2005-2009.....	8
IV. RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS IN 2009.....	12
V. RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY MANUFACTURER AND BY THERAPEUTIC CATEGORY	17
CONCLUDING OBSERVATIONS.....	21
APPENDIX A: DETAILED METHODOLOGY AND DESCRIPTION OF RETAIL PRICE DATA	23

LIST OF FIGURES

FIGURE 1: AVERAGE ANNUAL PERCENT CHANGE IN RETAIL PRICES FOR WIDELY USED SPECIALTY PRESCRIPTION DRUGS CONTINUED TO GROW IN 2009	2
FIGURE 2: ROLLING AVERAGE AND POINT-TO-POINT CHANGES IN RETAIL PRICES FOR WIDELY USED SPECIALTY PRESCRIPTION DRUGS WERE WELL ABOVE INFLATION BETWEEN 2005 AND 2009.....	4
FIGURE 3: THE AVERAGE ANNUAL RETAIL COST OF THERAPY FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS WAS ALMOST \$29,000 PER YEAR IN 2009	5
FIGURE 4: MARKED INCREASE IN AVERAGE RETAIL PRICES AMONG MOST WIDELY USED BLA-APPROVED SPECIALTY PRESCRIPTION DRUGS IN 2009	7
FIGURE 5: THE AVERAGE ANNUAL COST OF THERAPY INCREASED FOR MOST WIDELY USED NDA-, BLA-, AND ANDA-APPROVED SPECIALTY PRESCRIPTION DRUGS IN 2009.....	8
FIGURE 6: THE FIVE-YEAR CUMULATIVE PERCENT CHANGE IN RETAIL PRICE IS 326 PERCENT FOR THE SPECIALTY DRUG WITH THE LARGEST PERCENT PRICE INCREASE IN 2009	10

FIGURE 7: FIVE-YEAR CUMULATIVE CHANGE IN ANNUAL RETAIL COST OF THERAPY ACCELERATES FOR SPECIALTY DRUGS..... 11

FIGURE 8: NEARLY ONE-THIRD OF THE MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS HAD RETAIL PRICE INCREASES OF GREATER THAN 10 PERCENT IN 2009 13

FIGURE 9: SIX WIDELY USED SPECIALTY DRUGS HAD RETAIL PRICE INCREASES OF OVER 25 PERCENT IN 2009..... 14

FIGURE 10: SIX WIDELY USED SPECIALTY PRESCRIPTION DRUGS HAD AVERAGE RETAIL PRICE DECREASES OF MORE THAN 15 PERCENT IN 2009..... 15

FIGURE 11: RETAIL PRICES FOR WIDELY USED SPECIALTY DRUG PRODUCTS FROM ONE DRUG MANUFACTURER INCREASED BY MORE THAN 75 PERCENT IN 2009..... 18

FIGURE 12: A MAJORITY OF THERAPEUTIC CATEGORIES HAD RETAIL PRICE INCREASES THAT EXCEEDED THE RATE OF GENERAL INFLATION IN 2009 20

LIST OF TABLES

TABLE 1: ALL BUT ONE OF THE TOP 25 SPECIALTY PRESCRIPTION DRUG PRODUCTS HAD RETAIL PRICE INCREASES IN 2009 16

EXECUTIVE SUMMARY

AARP's Public Policy Institute finds that retail price increases for specialty prescription drugs widely used by Medicare beneficiaries far outstripped the price increases for other consumer goods and services between 2005 and 2009; this is consistent with the pattern that we have seen since we first started tracking manufacturers' prescription drug prices in 2004.

In 2009, the average annual increase in retail prices for 112 brand and generic specialty prescription drugs widely used by Medicare Part D beneficiaries was 8.9 percent, while the general inflation rate was -0.3 percent over the same time period.

In contrast, retail prices for brand name non-specialty drugs widely used by Medicare beneficiaries experienced an 8.3 percent increase in 2009, and retail prices for generic non-specialty drugs widely used by Medicare beneficiaries experienced a 7.8 percent decrease. Especially notable is a persistent trend of steeper price increases among specialty prescription drugs in the years following the implementation of the Medicare Part D program, which provides prescription drug coverage for Medicare beneficiaries.

This report presents our findings on the pattern of price changes for specialty drug products, a group that includes products sometimes referred to as biotech drugs or biopharmaceuticals. Specialty drugs have not been precisely and consistently defined elsewhere but generally include drugs that are used to treat complex, chronic conditions and require special administration, handling, and care management. Many of these drugs are used to treat conditions that often affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis.

Specialty drugs are also among the most expensive drugs on the market, with prices that can reach hundreds of thousands of dollars per year. They are expected to be the fastest growing group of drug products in the decade ahead.

This report presents annual and five-year cumulative price changes through the end of 2009, using both rolling average and point-to-point estimates (see Appendix A). The first set of findings shows *annual* rates of change in retail prices for widely used specialty drugs from 2005 through 2009, using both rolling average and point-to-point measures. The rolling average measure also is used to examine the distribution of price changes as well as differences in average percentage retail price changes for drug products from individual manufacturers and for specific therapeutic categories. Additional findings summarize the *cumulative* impact of retail drug price increases that have taken place during the five-year period from 2005 through 2009.

Findings

- In 2009, the average annual increase in retail prices for the 112 most widely used specialty prescription drugs (8.9 percent) was notably higher than the rates of

increase for retail prices in the prior five years, which ranged between 6.5 percent and 8.5 percent during the years 2005 to 2008.

- On average, retail prices for 98 specialty drugs that have been on the market since the beginning of the study (December 2004) increased 50.4 percent by December 2009, compared to the general inflation rate of 13.3 percent during the same period.
- The average annual retail cost for a specialty medication was about \$29,000 in 2009. For a consumer who takes a specialty drug on a chronic basis, the average annual cost of therapy for the drug products used to treat chronic conditions rose by almost \$11,000 between 2004 and 2009.
- Retail prices for 87 of the 112 specialty prescription drug products in the study's market basket increased during 2009. All of these increases exceeded the rate of general inflation during the same time period.
- Twenty-one of the 29 drug manufacturers with at least two drug products in the study's market basket of widely used specialty drugs had average increases in retail price that exceeded the rate of general inflation (-0.3 percent) in 2009. Nine manufacturers—plus the “All Others” category— had average annual retail price increases of 10 percent or more during 2009.
- Twenty of the 26 therapeutic categories of specialty drug products had average annual retail price increases that exceeded the rate of general inflation in 2009, ranging from 1.0 percent to 23.5 percent.

Concluding Observations

The findings of this report show that average annual increases in retail prices charged for widely used specialty prescription drugs have continued to consistently exceed the rate of general inflation.

Retail drug prices have a direct impact on costs borne by Medicare Part D enrollees. Since most Part D plans (and a growing number of private plans) require substantial cost sharing for specialty drugs, retail price increases are likely to affect consumers directly and substantially.

Rising drug prices can also increase the number of Part D enrollees who reach the coverage gap, where they directly absorb the effect of higher retail prescription prices. Moreover, the relatively high prices of specialty drugs compared to other prescription drugs are more likely to push beneficiaries beyond the coverage gap and into catastrophic coverage, where they are responsible for a percentage of their drug costs, fairly quickly, further exposing them to price increases. This would also cause Medicare spending to increase, as it covers 80 percent of Part D enrollees' costs once they enter catastrophic coverage.

The recently-passed health care reform legislation will gradually phase out the Medicare Part D coverage gap through discounts 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. In addition, the value of closing the doughnut hole, while substantial, could be eroded over the years if escalating drug prices are not addressed.

Methodology

The list of prescription drugs that are widely used by Medicare beneficiaries is based on the 300 most widely dispensed drug products (including both generic and brand name drugs), the 300 drug products with the highest sales levels, and the 300 drug products with the highest number of days of therapy provided among the prescriptions adjudicated by a Medicare Part D plan provider. UnitedHealthcare-PacifiCare provided Medicare Part D coverage in 2006, and is also the organization that insures the AARP Medicare Rx plans. This Medicare Part D plan provider supplied data for all prescriptions provided to Medicare Part D enrollees in 2006. Each drug product represents a unique combination of active chemical ingredient, strength, dosage form, package size, and manufacturer (for example, Nexium (esomeprazole magnesium) 40 mg, capsule, bottle of 30, AstraZeneca).

The three market baskets that are used in this report series (brand name, generic, and specialty drugs) account for 81.6 percent of all prescription drug expenditures, 79.2 percent of all prescriptions dispensed, and 91.2 percent of all days of therapy provided in 2006 by a Medicare Part D plan provider.

Although the market basket studied was identified using data from a Medicare Part D plan provider, changes in prices were measured using retail prices as published by the Thomson Reuters MarketScan® Research Databases. The average annual change in retail prices was calculated for each individual drug product as a 12-month rolling average. Aggregate estimates of retail price or change in retail prices were calculated for this study by weighting each drug product's value by its share among the Medicare Part D plan provider's 2006 annual sales. The number of drugs included in the analysis for a given year varies because not all drugs in the sample were on the market prior to 2006.

This Rx Price Watch report is a new iteration of our Rx Watchdog report series that has been tracking *manufacturer* price changes for widely used prescription drugs since 2004. The new name for this report series (i.e., Rx Price Watch) marks our switch to *retail* prices—or the amount that is actually charged to consumers (and/or insurers)—as our primary data source. Thus, while our market basket of specialty prescription drugs widely used by Medicare Part D enrollees remains unchanged, our findings for this and future reports will be based on changes in the prices charged to consumers ages 50 and older enrolled in employer-sponsored health plans, as reported by the Thomson Reuters MarketScan® Research Databases. The addition of retail prices to our analyses will allow the AARP Public Policy Institute to assess what prices are being paid by consumers and whether the rebates and discounts often given to payers are being passed along to their clients.

**RX PRICE WATCH REPORT:
TRENDS IN RETAIL PRICES OF SPECIALTY
PRESCRIPTION DRUGS USED BY MEDICARE BENEFICIARIES
2005 TO 2009**

AARP's Public Policy Institute finds that retail price increases for specialty prescription drugs widely used by Medicare beneficiaries far outstripped the price increases for other consumer goods and services between 2005 and 2009; this is consistent with the pattern that we have seen since we first started tracking manufacturers' prescription drug prices in 2004.

In 2009, the average annual increase in retail prices charged for 112 brand and generic specialty prescription drugs¹ widely used by Medicare Part D beneficiaries was 8.9 percent, while the general inflation rate was -0.3 percent over the same time period.

In contrast, retail prices for brand name non-specialty drugs widely used by Medicare beneficiaries experienced an 8.3 percent increase in 2009, and retail prices for generic non-specialty drugs widely used by Medicare beneficiaries experienced a 7.8 percent decrease.² Especially notable is a persistent trend of steeper price increases among specialty prescription drugs in the years following the implementation of the Medicare Part D program, which provides prescription drug coverage for Medicare beneficiaries.

This report presents our findings on the pattern of price changes for specialty drug products, a group that includes products sometimes referred to as biotech drugs or biopharmaceuticals. Specialty drugs have not been precisely and consistently defined elsewhere but generally include drugs that are used to treat complex, chronic conditions and require special administration, handling, and care management. Many of these drugs are used to treat conditions that often affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis.

Specialty drugs are also among the most expensive drugs on the market, with prices that can reach hundreds of thousands of dollars per year.³ They are expected to be the fastest growing group of drug products in the decade ahead.⁴

¹ Although the original sample contained 144 specialty prescription drugs, 32 of the drug products were excluded from the market basket and related analysis due to insufficient price data.

² S. 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," August 2010; and S. Schondelmeyer and L. Purvis, "Rx Price Watch: Trends in Retail Prices of Generic Prescription Drugs Widely Used by Medicare Beneficiaries, 2005 to 2009," July 2011. Available on the AARP website, <http://www.aarp.org/rxpricewatch>.

³ J. Appleby, "Workers Squeezed As Employers Pass Along High Costs Of Specialty Drugs," *Kaiser Health News*, August 22, 2011.

⁴ Medco, *2011 Drug Trend Report*, May 2011.

This report presents annual and five-year cumulative price changes through the end of 2009, using both rolling average and point-to-point estimates (see Appendix A). The first set of findings shows *annual* rates of change in retail prices for widely used specialty drugs from 2005 through 2009, using both rolling average and point-to-point measures. The rolling average measure also is used to examine the distribution of price changes as well as differences in average percentage retail price changes for drug products from individual manufacturers and for specific therapeutic categories. Additional findings summarize the *cumulative* impact of retail drug price increases that have taken place during the five-year period from 2005 through 2009.

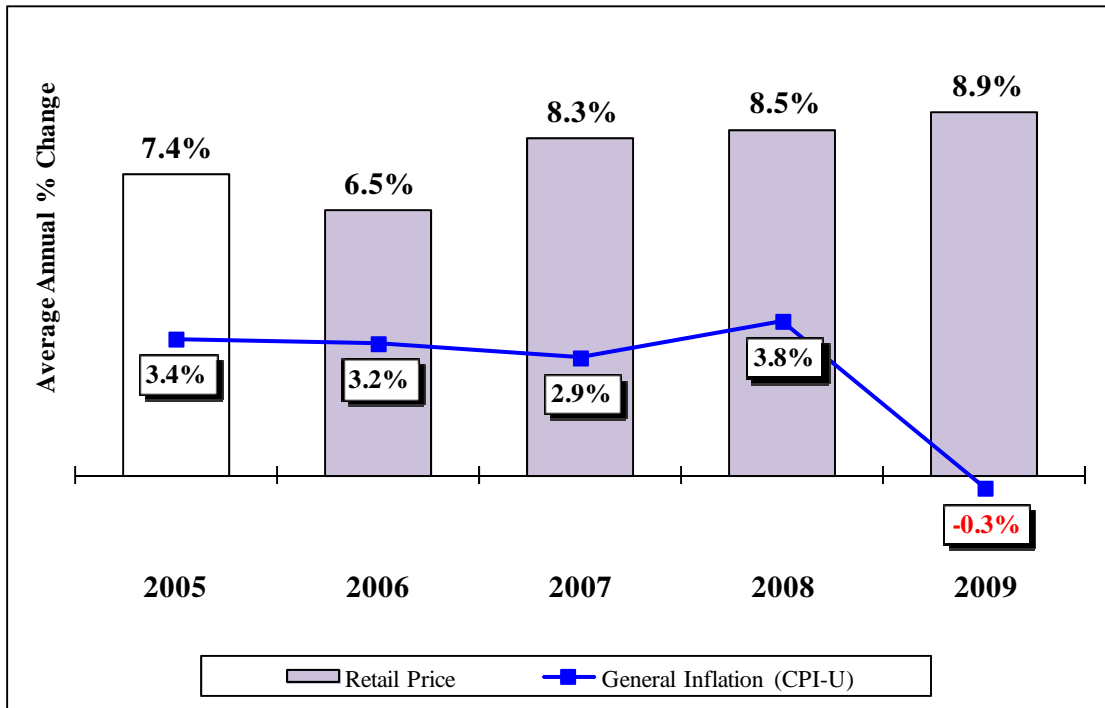
FINDINGS

I. Annual Trends in Retail Price Changes for Most Widely Used Specialty Prescription Drugs

Annual percent change in retail prices

- Retail prices for the specialty drug products most widely used by Medicare beneficiaries rose 8.9 percent in 2009, when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries (Figure 1).

Figure 1: Average Annual Percent Change in Retail Prices for Widely Used Specialty Prescription Drugs Continued to Grow in 2009



Note: Shaded bars indicate years when Medicare Part D was operational.

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

- In contrast, retail prices for non-specialty brand name drug products most widely used by Medicare beneficiaries rose by 8.3 percent in 2009, and retail prices for non-specialty generic drug products fell by 7.8 percent in the same year.⁵
- The average annual increases since 2007, which have ranged from 8.3 percent to 8.9 percent, are substantially higher than the rates of increase for retail prices in 2005 and 2006 (7.4 percent and 6.5 percent, respectively).
- The average annual retail price increase in 2009 for these specialty prescription drug products was substantially higher than the rate of general inflation⁶ (8.9 percent vs. -0.3 percent); in 2008, the rate of specialty price increase was more than twice the rate of general inflation (8.5 percent vs. 3.8 percent).

Notably, the average annual retail price changes for specialty drug products has continued to increase despite a number of widely used specialty drugs going off patent in the past few years. Between 2006 and 2009, 7 of the 85 brand name drug products in the specialty market basket had generic versions introduced to the market. These drugs represent 3.6 percent of 2006 specialty drug sales to Medicare Part D enrollees. We have chosen to keep these off-patent drugs in our market basket, since they are still being sold, albeit at considerably lower volumes.⁷ If these drug products were excluded from the analysis, the average annual retail price increase for the remaining drug products (i.e., brand name drug products that do not have generic competition and drugs that were already generic in 2006) is 9.0 percent in 2009. This indicates that the off-patent products in our market basket actually lower the average annual price change, making our results an underestimate of retail price changes for specialty drug products.

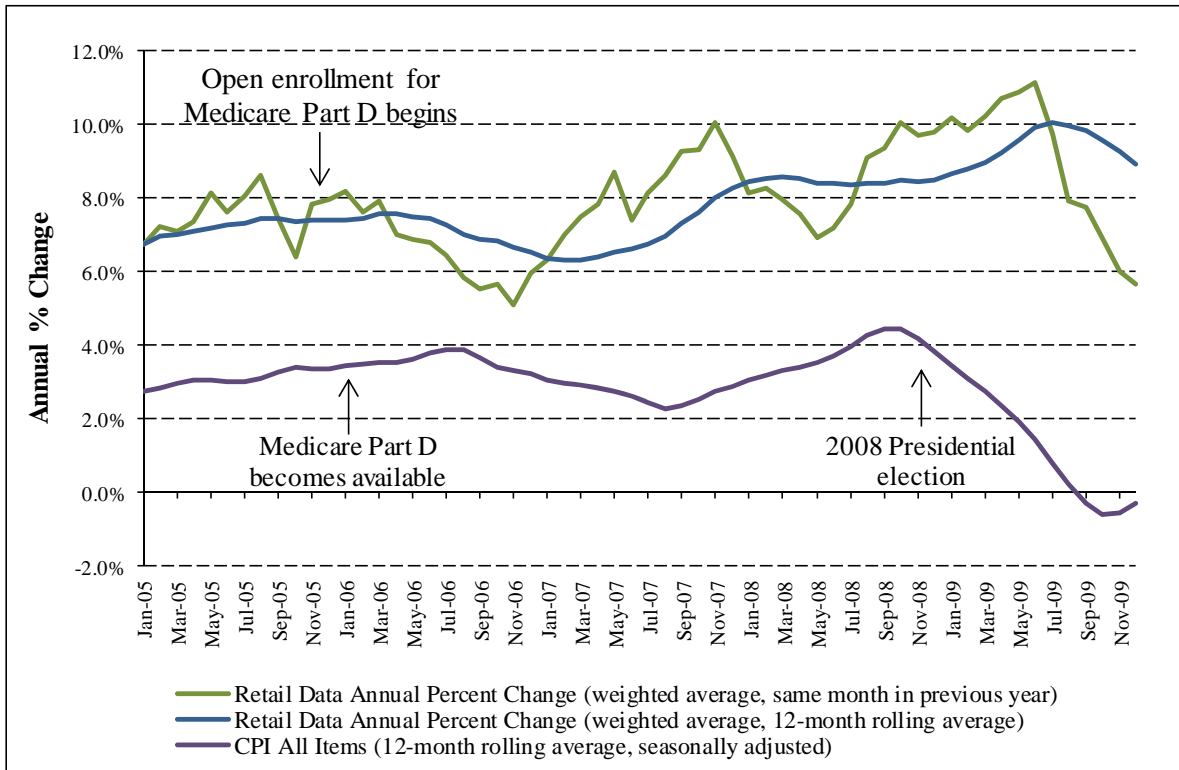
By averaging annual point-to-point price changes for each month in a 12-month period (referred to as a *rolling average* change), the average annual retail price change reported in Figure 1 smoothes over the entire year the annual amount of change in retail price that occurs for a single month (referred to as an annual *point-to-point* change). The percent change in price compared with the same month in the previous year is plotted along with the 12-month rolling average to allow more detailed examination of the rate and timing of retail price changes over the entire study period (Figure 2).

⁵ S. 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," August 2010; and S. Schondelmeyer and L. Purvis, "Rx Price Watch: Trends in Retail Prices of Generic Prescription Drugs Widely Used by Medicare Beneficiaries, 2005 to 2009," July 2011. Available on the AARP website, <http://www.aarp.org/rxpricewatch>.

⁶ The general inflation rate reported is based on the average annual rate of change in the Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) (CPI-U), Bureau of Labor Statistics series CUSR0000SA0.

⁷ Brand name drugs tend to lose market share quickly once generic versions are on the market. For example, when generic versions of Zoloft 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.

Figure 2: Rolling Average and Point-to-Point Changes in Retail Prices for Widely Used Specialty Prescription Drugs Were Well Above Inflation Between 2005 and 2009



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

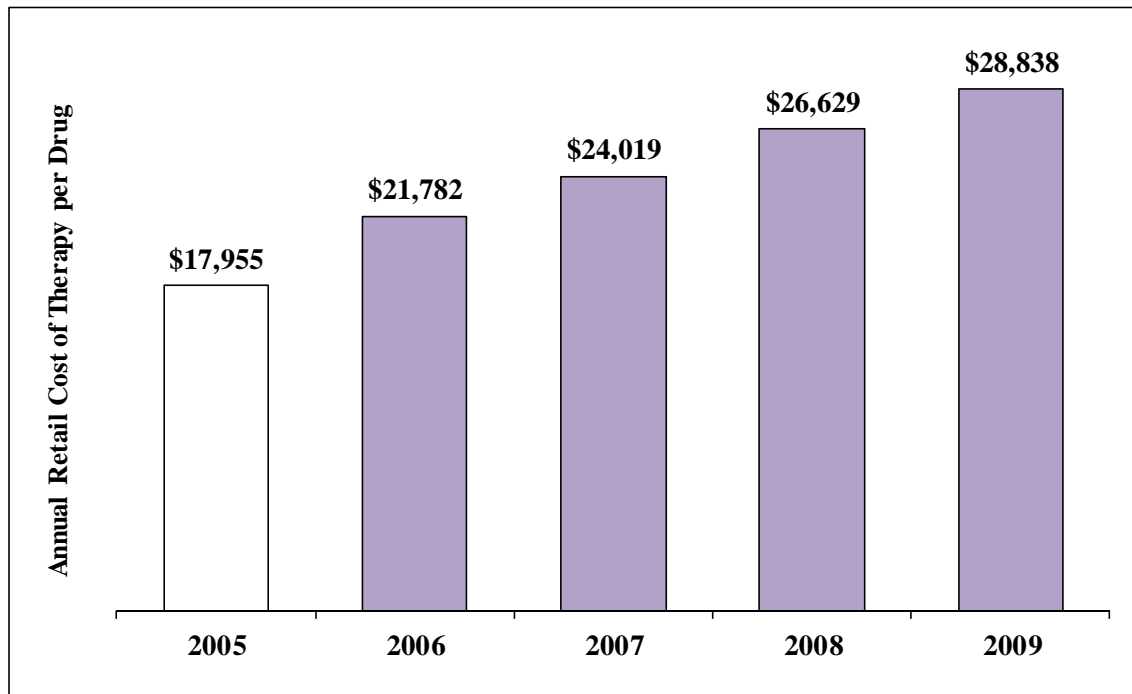
Figure 2 shows that the point-to-point annual change in retail prices accelerated rapidly at two specific times since Medicare Part D became available in January 2006: (1) November 2006 through November 2007; and (2) May 2008 through May 2009. The rolling average indicates that specialty drug prices have been increasing fairly steadily since March 2007. Two broad trends have been observed throughout the entire time the Medicare Part D prescription drug program has been in operation: (1) the retail price level of specialty drug products has steadily increased rather than decreased; and (2) the retail price increases have been well above (usually two-fold or more) the rate of general inflation.

Annual retail cost of therapy

Retail prices for the 78 most widely used specialty drugs used for treating chronic conditions (out of a total market basket of 112 drugs) were translated into average annual costs of therapy (Figure 3).⁸

⁸ The figures in this section reflect the total retail price for consumers enrolled in employer-sponsored health plans and not simply the out-of-pocket cost a consumer would face at the drugstore.

Figure 3: The Average Annual Retail Cost of Therapy for Most Widely Used Specialty Prescription Drugs Was Almost \$29,000 per Year in 2009



Note: Shaded bars indicate years when Medicare Part D was operational. Does not include 34 drug products typically used for acute conditions or for less than one year.

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

- The average annual retail cost of therapy was almost \$29,000 per year per prescription drug in 2009, roughly 61 percent higher than the average annual retail cost in the year before Medicare Part D was implemented (i.e., 2005).

An older American who takes a specialty prescription drug is likely to have experienced an average annual retail cost of therapy of \$28,838 in 2009, assuming that the consumer uses specialty drugs for these chronic conditions. The annual cost of therapy was substantially higher (60.6 percent) than the average annual retail cost in the year prior to the implementation of Medicare Part D, or about \$17,955 per year in 2005. While insurance may cover much of this cost for some beneficiaries, it would not cover the costs for Medicare Part D enrollees in the “doughnut hole”⁹ (the period when beneficiaries were traditionally responsible for 100 percent of their prescription costs).¹⁰

⁹ The cost impact on beneficiaries is based on the continued use of the specialty drug product. Seven of the 85 brand name drug products in the specialty market basket had generic equivalents introduced to the market between 2006 and 2009, making it possible for the beneficiary to save money if he or she switched to a less expensive, therapeutically-equivalent generic drug product.

¹⁰ This “gap” in coverage generally begins after the beneficiary has \$2,930 (in 2012) in total drug costs and continues until the beneficiary spends \$4,700 in out-of-pocket drug costs. Centers for Medicare & Medicaid Services, “Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” April 4, 2011. Some plans might offer some coverage in the gap, and some low-income beneficiaries also have gap coverage. As part of the recently-passed Affordable Care Act, in 2011, non-low-income Part D enrollees began receiving a 50

II. Annual Trends in Retail Price Changes for Most Widely Used Specialty Prescription Drugs by FDA Approval Process

The products in the specialty market basket were approved by the FDA using one of the following processes: (1) a new drug application (NDA); (2) a biologic license application (BLA); or (3) an abbreviated new drug application (ANDA). NDAs and ANDAs apply to drug products and medical devices, and BLAs apply to biological products. Sixty-four of the 112 drug products in the specialty market basket were approved under an NDA, 21 were approved under a BLA, and 27 under an ANDA.

NDA and BLA-approved drugs are brand name drugs, while ANDA-approved drugs are generic drugs. The differences between NDA-, BLA-, and ANDA-approved drugs are evident in their annual percent change and annual change in cost of therapy.

Annual percent change in retail prices

- Retail prices for ***NDA-approved specialty drug products*** most widely used by Medicare beneficiaries rose by an average of 9.5 percent in 2009, substantially more than the rate of general inflation (-0.3 percent) when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries. Annual retail price increases between 2005 and 2008 ranged from 8.2 percent to 10.6 percent (Figure 4).
- Retail prices for ***BLA-approved specialty drug products*** most widely used by Medicare beneficiaries increased by an average of 9.4 percent in 2009, in contrast to a rate of general inflation of -0.3 percent. This increase was considerably higher than the average retail price increase in 2008 (8.8 percent) and considerably higher than the average annual retail price increases seen in 2005 through 2007, which ranged from 5.5 percent to 5.6 percent. Furthermore, unlike most NDA-approved specialty drugs, the U.S. Food & Drug Administration has yet to begin approving generic equivalents or biosimilars for BLA-approved specialty drugs, leaving manufacturers free to continue charging the same or higher prices after patents expire.¹¹
- Retail prices for ***all brand name specialty drug products*** (i.e., NDA- and BLA-approved drug products) most widely used by Medicare beneficiaries increased at an average rate of 9.1 percent in 2008 and 9.5 percent in 2009. In contrast, retail prices for brand name non-specialty drug products most widely used by Medicare

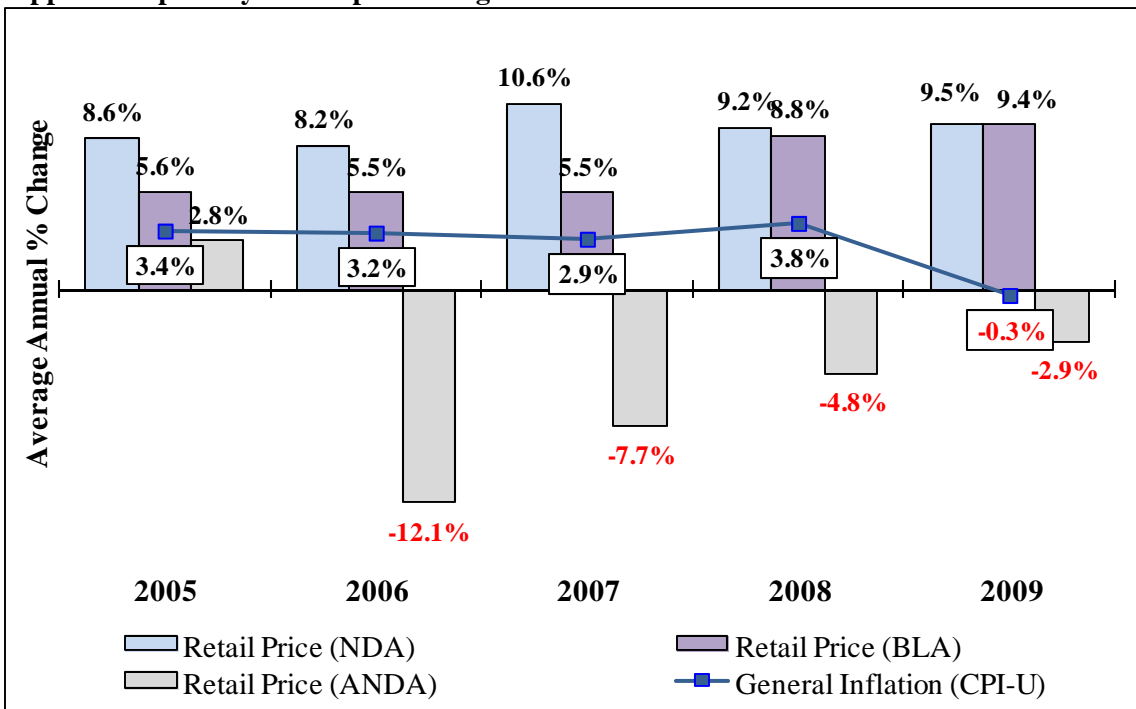
percent discount on their brand name and biologic prescription drugs and a 7 percent discount on their generic prescription drugs while they are in the coverage gap. These discounts will continue growing until, in 2020, Part D enrollees are responsible for 25 percent of all of prescription drug costs while they are in the coverage gap.

¹¹ The FDA was granted the authority to approve generic versions of BLA-approved specialty drugs as part of Affordable Care Act. However, the FDA has yet to exercise this authority.

beneficiaries increased by an average of 7.9 percent and 8.3 percent, respectively, in those years.¹²

- In contrast, retail prices for *all generic specialty drug products* (i.e., ANDA-approved drug products) most widely used by Medicare beneficiaries have consistently *decreased* over the past four years. The average annual decrease in 2006 was substantially less than the average annual decrease in 2009 (12.1 percent vs. 2.9 percent, respectively).

Figure 4: Marked Increase in Average Retail Prices Among Most Widely Used BLA-Approved Specialty Prescription 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.

Annual retail cost of therapy

Retail price changes for the widely used specialty drugs for treating chronic conditions were translated into average annual cost of therapy (Figure 5). Of the 78 drugs in the market basket that were used to treat chronic conditions, 46 were NDAs, 20 were BLAs, and 12 were ANDAs.

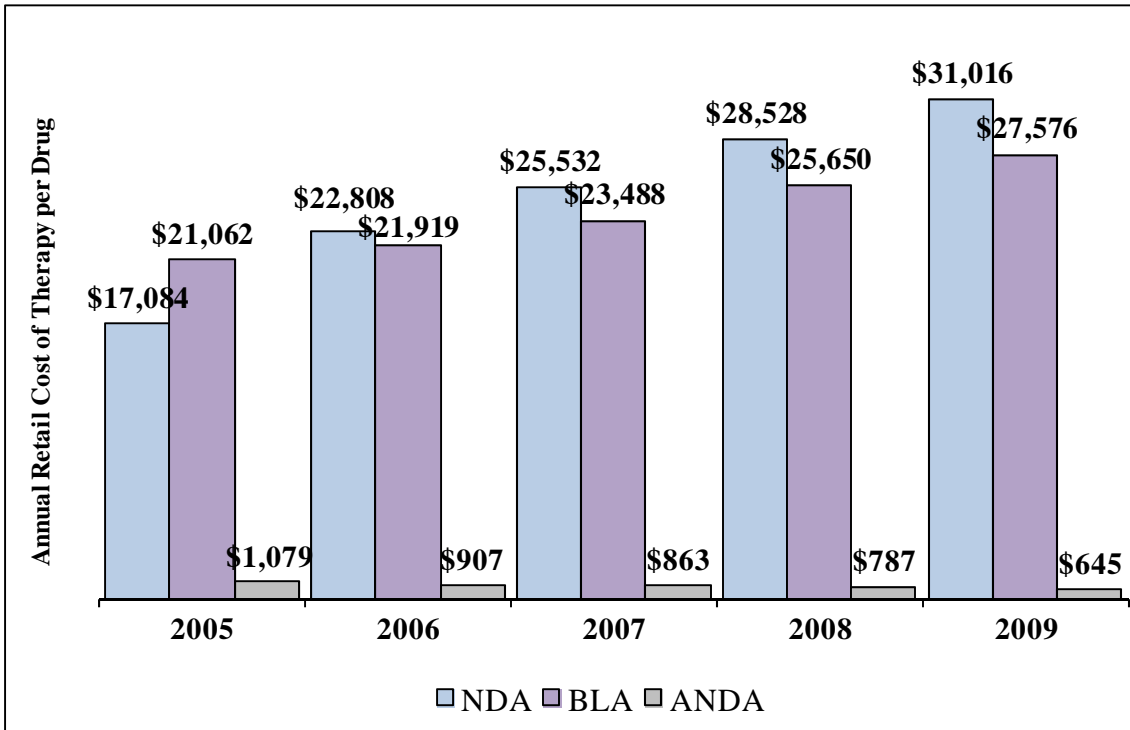
- An older American who takes an *NDA-approved specialty prescription drug* had an average annual cost of therapy of \$31,016 in 2009, assuming that the consumer uses the specialty drug for a chronic condition. The average annual cost of therapy

¹² S. 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,” August 2010. Available on the AARP website, <http://www.aarp.org/rxpricewatch>.

for NDA-approved specialty drugs has increased by more than 80 percent since 2005.

- The average annual cost of therapy for **BLA-approved specialty prescription drugs** was \$27,576 in 2009. This is the highest average annual cost of therapy since at least 2005.

Figure 5: The Average Annual Cost of Therapy Increased for Most Widely Used NDA-, BLA-, and ANDA-Approved Specialty Prescription 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 average annual cost of therapy was \$645 in 2009 for the typical **ANDA-approved specialty prescription drug**. This average annual cost of therapy for ANDA-approved specialty drugs consistently decreased between 2005 and 2009.

III. Five-Year Cumulative Impact of Retail Price Changes for Widely Used Specialty Prescription Drugs, 2005-2009

AARP has tracked specialty drug retail price changes for the five-year period from December 31, 2004, to December 31, 2009. Nearly all (98 of 112) of the widely used drugs in the specialty market basket have been on the market for the entire five-year period (the end of 2004 through the end of 2009). The cumulative effect of retail price changes over this five-year period is reported.

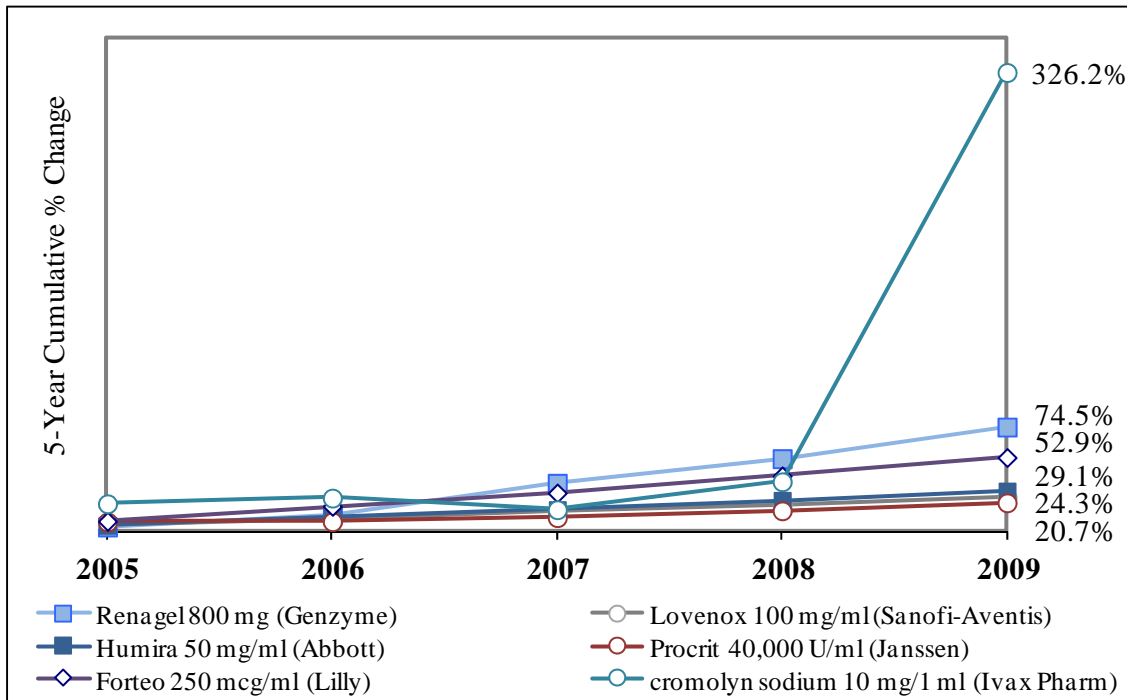
Five-year cumulative percent change in retail prices

- Cumulatively, the average retail price increase for the 98 widely used specialty drug products that have been on the market from the end of 2004 through the end of 2009 was 50.4 percent, compared with 13.3 percent for general inflation—or nearly 4 times the rate of general inflation.¹³
- Figure 6 illustrates the cumulative effect of retail price changes between the end of 2004 and the end of 2009 for six specific drug products. Five of these drug products were chosen because they are among the 25 most widely used drugs in the market basket and are from a variety of therapeutic classes:
 - Renagel 800 mg tablets (Genzyme)—used in the treatment of kidney disease
 - Lovenox 100 mg/ml injection (Sanofi-Aventis)—a blood thinner
 - Humira 50 mg/ml kit (Abbott)—used to treat inflammatory and immunological disorders
 - Procrit 40,000 U/ml injection (Janssen)—used to treat anemia
 - Forteo 250 mcg/ml solution (Lilly)—used to treat osteoporosis
- The sixth drug, cromolyn sodium 10 mg/1 ml nebulizer (Ivax), which is used to treat asthma symptoms, was chosen because it had the largest percent price increase in 2009 among the drug products that have been on the market since the end of 2004.¹⁴

¹³ The average cumulative growth rate in retail prices for all specialty drugs in the market basket was 68.6 percent. This number was calculated by compounding the average annual growth rate for each year from 2005 to 2009.

¹⁴ Notably, multiple manufacturers of cromolyn sodium 10 mg/1 ml nebulizer exited the market in 2008.

Figure 6: The Five-Year Cumulative Percent Change in Retail Price is 326 Percent for the Specialty Drug with the Largest Percent Price Increase in 2009



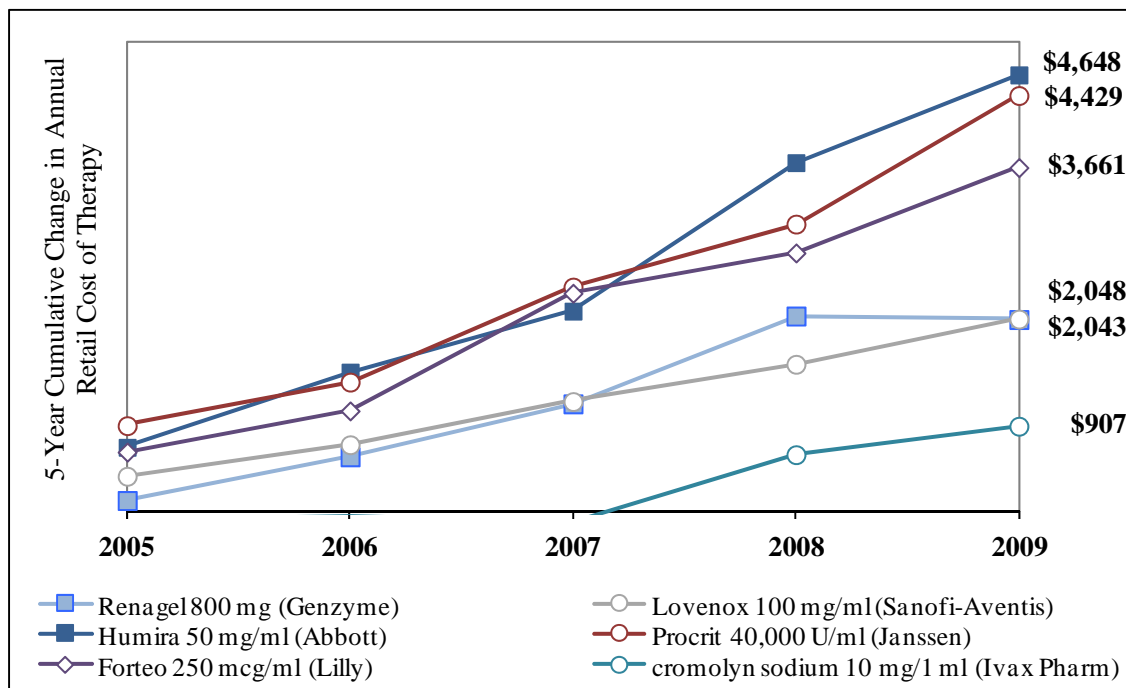
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

- The five-year (i.e., December 31, 2004 to December 31, 2009) cumulative percent change in retail prices for six specific drug products is shown in Figure 6.
 - The retail price of cromolyn sodium 10 mg/1 ml rose by 326 percent over the entire five-year period, when measured as a 12-month rolling average change. It is notable that this product’s retail price increases accelerated most rapidly in the two years after other manufacturers of the product exited the market.
 - The retail price of Renagel 800 mg tablets increased cumulatively by approximately 75 percent over the five-year period, and the retail price of Forteo 250 mcg/ml solution rose cumulatively by 53 percent over the same time period.
 - The retail price of Lovenox 100 mg/ml increased cumulatively by 29 percent, and the retail price of Humira 50 mg/ml increased by 24 percent between the end of 2004 and the end of 2009.
 - The retail price of Procrit 40,000 U/ml increased by approximately 21 percent between the end of 2004 and the end of 2009. This product faced increased competition from Aranesp (Amgen) over this time period.

Five-year cumulative change in annual retail cost of therapy

- 67 of the 98 specialty drug products that have been on the market since the end of 2004 are used to treat chronic conditions. By the end of 2009, the average annual retail cost of therapy for these specialty drug products was \$9,607 higher than five years earlier, assuming that the consumer used these specialty drugs for chronic conditions.
- The five-year (2005 to 2009) cumulative change in specialty cost of therapy due to retail prices for six specific drug products is shown in Figure 7.

Figure 7: Five-Year Cumulative Change in Annual Retail Cost of Therapy Accelerates for Specialty Drugs



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

- The retail price for a one-year supply of Humira 50 mg/ml, which was \$20,606 in 2009, rose by \$4,648 between the end of 2004 and the end of 2009.
- Similarly, the retail price for a one-year supply of Procrit 40,000 U/ml rose by \$4,429 over the five-year period ending in 2009, increasing from \$26,066 per year to \$30,494 per year.
- The retail price for a one-year supply of Forteo 250 mcg/ml rose by \$3,661 between the end of 2004 and the end of 2009. At the end of 2004,

the retail price for a one-year supply of Forteo 250 mcg/ml was \$7,262; by the end of 2009 the retail price had increased to \$10,923.

- The retail prices for a one-year supply of Renagel 800 mg tablets and Lovenox 100 mg/ml rose by nearly \$2,050 by the end of the five-year period (2005 to 2009). In 2009, the retail price of a one-year supply of Renagel 800 mg tablets was \$4,883 and the retail price of a one-year supply of Lovenox 100 mg/ml was \$10,974.
- The retail price for a one-year supply of cromolyn sodium 10 mg/1 ml was \$1,436 by the end of 2009, an increase of \$907 from the end of 2004.

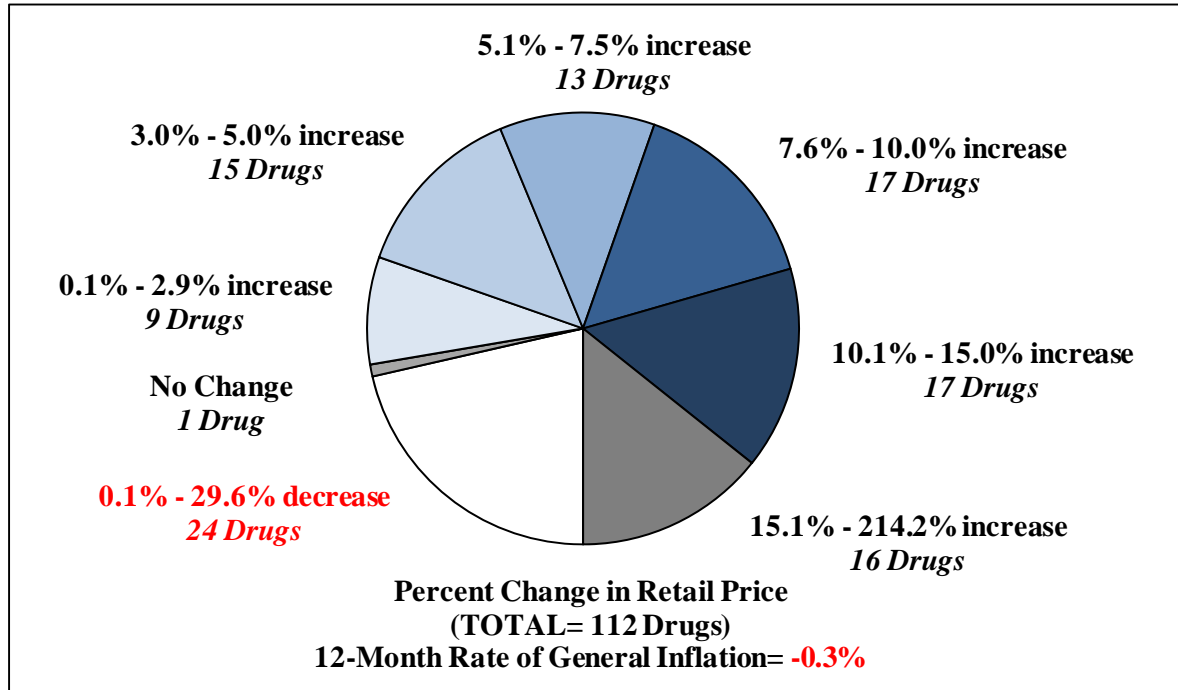
IV. Retail Price Changes for Most Widely Used Specialty Prescription Drugs in 2009

Distribution of retail price changes

89 of the 112 (79.5 percent) most widely used specialty prescription drug products in this study's market basket had retail price changes that met or exceeded the rate of general inflation (-0.3 percent) in 2009 (Figure 8).

- Annual retail price changes for 87 (77.7 percent) of the 112 specialty drug products had retail price increases in 2009, when measured as a 12-month rolling average.
- Annual retail price changes for 89 (79.5 percent) of the 112 drug products met or exceeded the rate of general inflation (-0.3 percent) in 2009.
- Annual retail price increases for 63 (56.3 percent) of the 112 specialty drug products in the market basket increased more than 5.0 percent in 2009, including 17 (15.2 percent) with a price increase between 7.6 percent and 10.0 percent, 17 (15.2 percent) with a price increase between 10.1 percent and 15.0 percent, and 16 (14.3 percent) with a price increase of more than 15.1 percent.

Figure 8: Nearly One-Third of the Most Widely Used Specialty Prescription Drugs Had Retail Price Increases of Greater Than 10 Percent in 2009

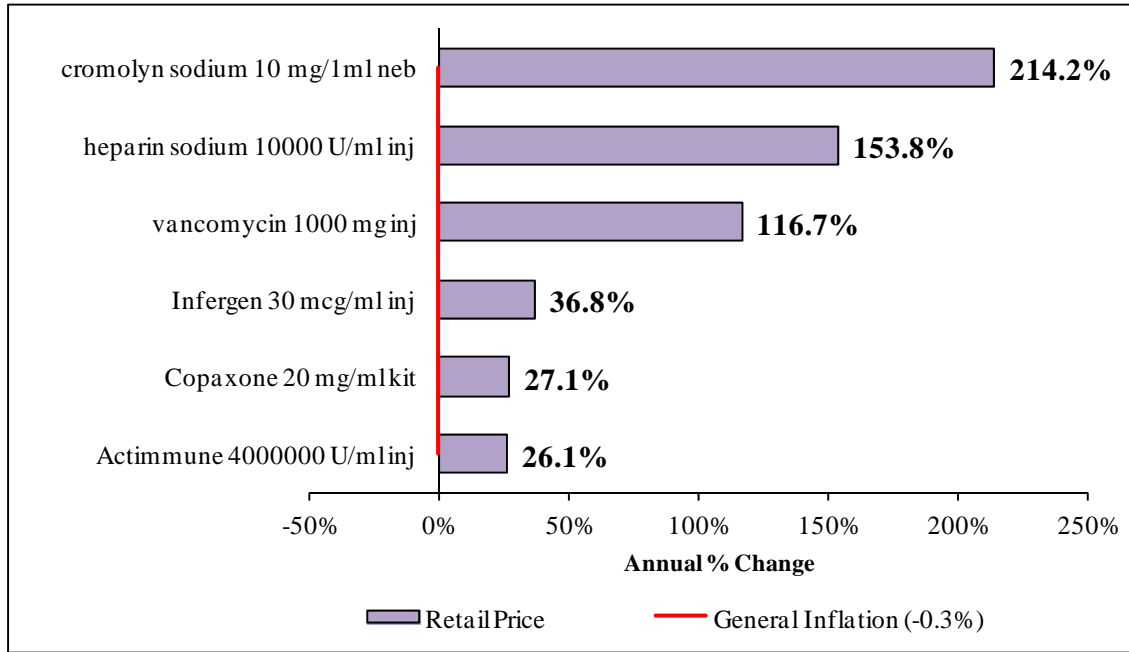


Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

Six of the specialty drug products had retail price increases that were greater than 25 percent in 2009 (Figure 9). Notably, the three products with the highest retail price increases were generic drugs that have recently experienced market disruptions.¹⁵

¹⁵ Multiple manufacturers of cromolyn sodium 10 mg/1 ml nebulizer exited the market in 2008. In addition, in early 2008, heparin sodium was subject to a wide-ranging recall after raw heparin stock that had been imported from China was found to be contaminated. The contaminant was identified as an over-sulphated derivative of chondroitin sulfate, a shellfish-derived supplement often used for arthritis (U.S. Department of Health and Human Services, Food & Drug Administration, “Information on Heparin,” 2009). This recall resulted in a shortage of the drug, and led to a corresponding increase in heparin sodium’s price. Finally, vancomycin HCL 1000 mg/inj is currently in extremely short supply in the United States.

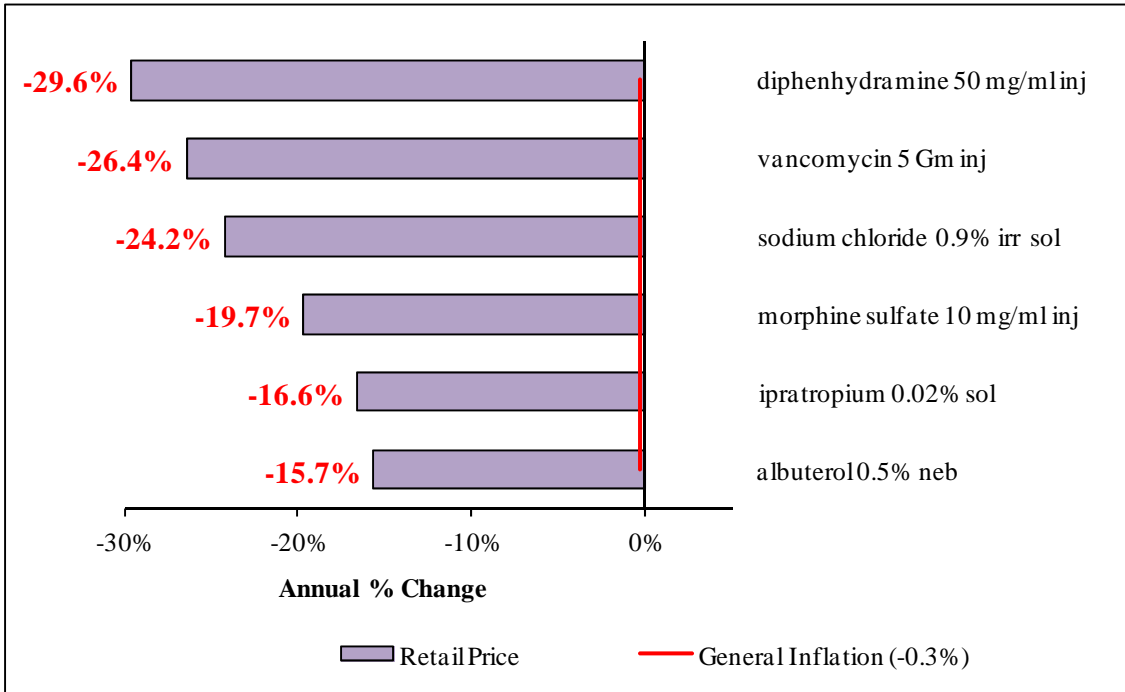
Figure 9: Six Widely Used Specialty Drugs Had Retail Price Increases of Over 25 Percent in 2009



The general inflation rate is based on CPI-U (See Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) (CPI-U), Bureau of Labor Statistics series CUSR0000SA0). Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

Six of the specialty drug products had retail price decreases in 2009 that were greater than 15 percent, with price decreases that ranged from 15.7 percent to 29.6 percent (Figure 10). All of the drug products with a decrease in retail price of 15 percent or more in 2009 were generics.

Figure 10: Six Widely Used Specialty Prescription Drugs Had Average Retail Price Decreases of More Than 15 Percent in 2009



Note: The general inflation rate is based on CPI-U.

Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

All but one of the 25 top-selling specialty drug products with the greatest sales in 2006 had retail price increases during 2009. Most (18 of 25) of the drug products had annual retail price increases of over 5 percent; nine of the Top 25 drug products had annual retail price increases of over 10 percent (Table 1).

Table 1: All But One of the Top 25 Specialty Prescription Drug Products Had Retail Price Increases in 2009

Rank by Sales among Study Market Basket*	Product Name, Strength, and Dosage Form	Package Quantity and Size	Manufacturer	Therapeutic Class	Retail Price Per Day	Annual Percent Change in Retail Price
1	Renagel 800 mg tablet	1 x 180	Genzyme	Phosphate Regulation	\$13.38	14.8%
2	Lovenox 100 mg/ml inj	10 x 0.4	Sanofi-Aventis	Anticoagulants	\$30.06	4.6%
3	Enbrel 50 mg/ml inj	4 x 1	Amgen	Arthritis, Severe	\$57.55	8.0%
4	Humira 50 mg/ml kit	2 x 1	Abbott	Arthritis, Severe	\$56.45	5.4%
5	Procrit 40,000 U/ml inj	4 x 1	Janssen	Erythropoietins	\$83.55	4.9%
6	Forteo 250 mcg/ml soln	1 x 28	Lilly	Calcium Regulators	\$29.93	9.4%
7	Copaxone 20 mg/ml kit	1 x 30	Teva Neuroscience	Multiple Sclerosis Agents	\$86.56	27.1%
8	Avonex 60 mcg/ml kit	4 x 1	Biogen Idec	Multiple Sclerosis Agents	\$86.26	20.3%
9	Tracleer 125 mg tablet	1 x 60	Actelion Pharmaceuticals	Pulmonary Hypertension	\$176.38	15.3%
10	Reyataz 150 mg capsule	1 x 60	Bristol-Myers Squibb	Antiretrovirals	\$29.82	3.5%
11	Procrit 20,000 U/ml inj	6 x 2	Janssen	Erythropoietins	\$42.05	4.8%
12	Tarceva 150 mg tablet	1 x 30	Genentech	Cancer Agents	\$132.25	8.8%
13	Gleevec 400 mg tablet	1 x 30	Novartis	Cancer Agents	\$132.05	15.6%
14	Procrit 10,000 U/ml inj	6 x 1	Janssen	Erythropoietins	\$21.14	4.5%
15	Betaseron 0.3 mg inj	15 x 1	Bayer Healthcare Pharmaceutical	Multiple Sclerosis Agents	\$90.76	24.0%
16	Risperdal 50 mg inj	1 x 1	Janssen	Tranquilizers	\$36.49	0.4%
17	Sensipar 30 mg tablet	1 x 30	Amgen	Calcium Reduction	\$11.96	7.9%
18	Zyvox 600 mg tablet	1 x 20	Pfizer U.S.	Antibiotics, Misc.	\$152.21	6.7%
19	Enbrel 25 mg inj	4 x 1	Amgen	Arthritis, Severe	\$57.20	7.9%
20	Trizivir 300 mg-150 mg-300 mg tablet	1 x 60	Viiiv Healthcare	Antiretrovirals	\$43.76	6.2%
21	Sensipar 60 mg tablet	1 x 30	Amgen	Calcium Reduction	\$24.00	8.2%
22	Byetta 250 mcg/ml inj	1 x 60	Amylin Pharmaceuticals	Diabetes Care	\$8.44	10.7%
23	Thalomid 50 mg capsule	10 x 28	Celgene Corp	Leprosy Agents	\$238.65	12.3%
24	ipratropium 0.02% soln	25 x 2.5	Dey Labs	Bronchial Dilators	\$1.65	-16.6%
25	Rebif 88 ml inj	12 x 1	Serono	Multiple Sclerosis Agents	\$91.26	16.3%
General rate of inflation (as measured by growth in CPI-U)						-0.3%

*Ranking based on prescription payments made by the Medicare Part D plan provider during 2006.

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

- Teva's Copaxone 20 mg/ml kit had the highest annual percent change (27.1 percent) in retail price during 2009 among the top 25 specialty drug products with the greatest sales in 2006.
- Three of the top 25 drug products had annual changes in retail price of more than 20 percent. In addition to Teva's Copaxone 20 mg/ml kit, the other drug products were Biogen Idec's Avonex 60 mcg/ml kit and Bayer Healthcare's Betaseron 0.3 mg inj.

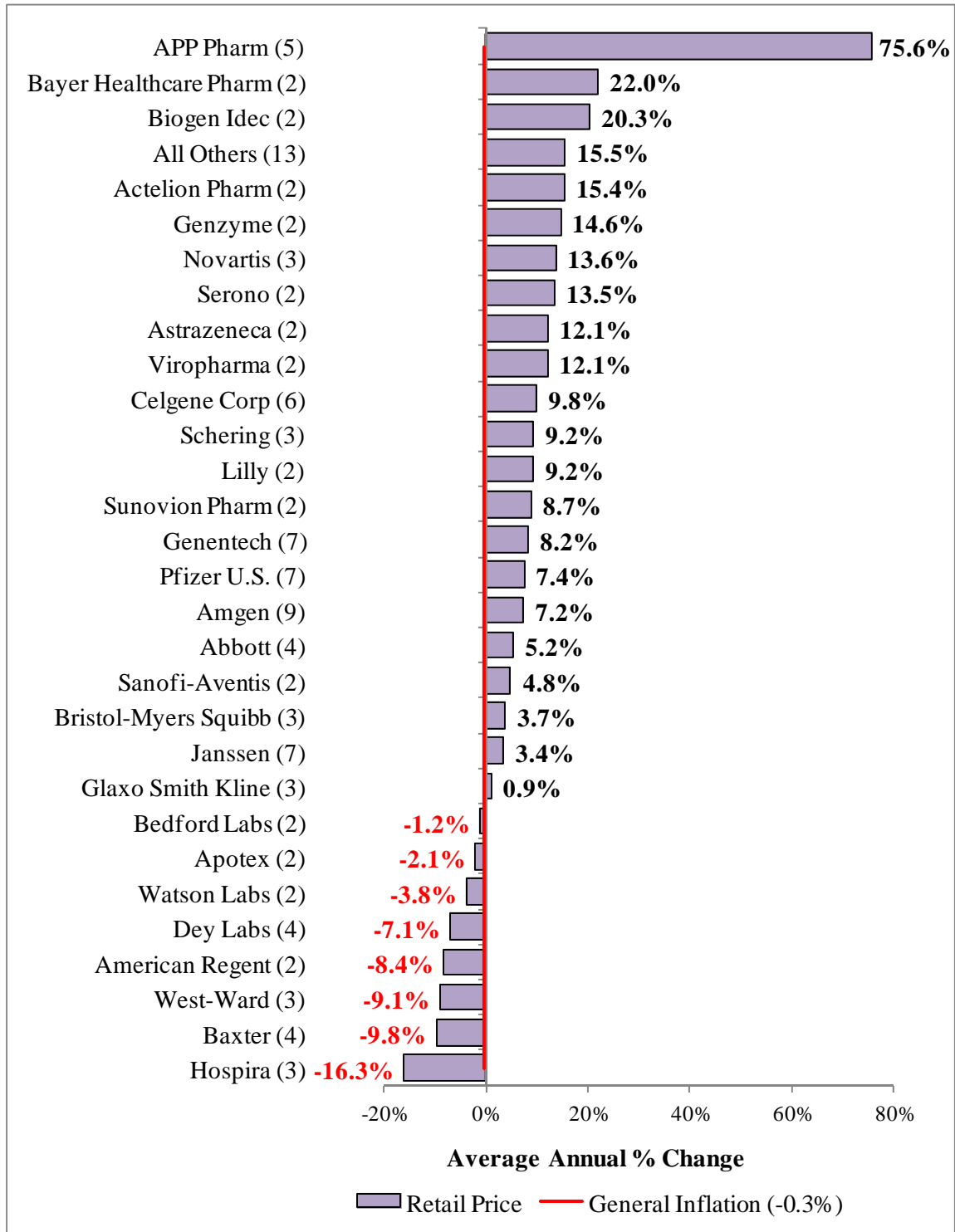
- Dey Labs' ipratropium's 0.02% solution was the sole drug product among the top 25 specialty drug products that experienced a decrease in retail price in 2009. Ipratropium is also the only generic drug among the top 25 specialty drug products with the greatest sales in 2006.

V. Retail Price Changes for Most Widely Used Specialty Prescription Drugs by Manufacturer and by Therapeutic Category

Twenty-nine drug manufacturers had at least two drug products in the study's market basket of widely used specialty drugs. The weighted average annual increase in retail price for the drug products from 21 of the 29 drug manufacturers exceeded the rate of general inflation in 2009 (Figure 11).

- Nine manufacturers—plus the “All Others” category—had average annual retail price increases of 10 percent or more during 2009. One manufacturer's drug products (APP Pharmaceuticals) had an average annual retail price increase of 75.6 percent.
- Nearly all of the drug manufacturers with an average annual increase in retail price (17 of 21)—plus the “All Others” category—had weighted average annual retail price increases of more than 5 percent.
- Eight manufacturers had average annual retail price *decreases* in 2009 that ranged from 1.2 percent (Bedford Labs) to 16.3 percent (Hospira).

Figure 11: Retail Prices for Widely Used Specialty Drug Products from One Drug Manufacturer Increased by More Than 75 Percent in 2009

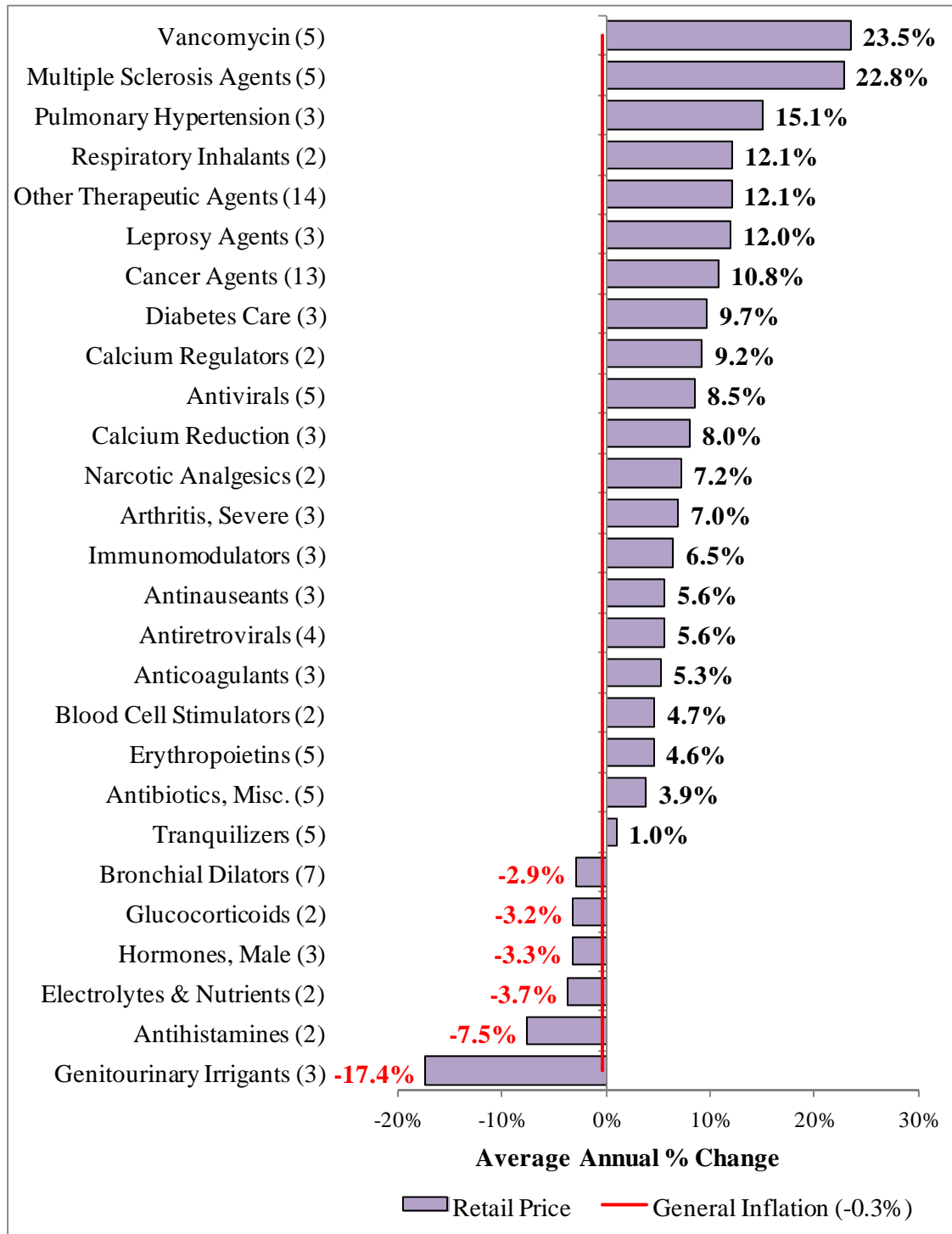


Note: Manufacturers with fewer than two drug products in the 2006 market basket of most widely used specialty prescription drugs are included in the “All Others” category. The number in parentheses after a manufacturer’s name indicates the number of drug products in the market basket for that manufacturer. The general inflation rate is based on CPI-U. Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Thomson Reuters MarketScan® Research Databases.

Twenty of the 26 therapeutic categories with at least two drug products in the study's market basket of widely used specialty drugs had average annual retail price increases that exceeded the rate of general inflation (-0.3 percent) in 2009 (Figure 12).

- The two therapeutic categories with the highest retail price increases—vancomycin and multiple sclerosis agents—had average annual retail price increases of 23.5 percent and 22.8 percent, respectively, in 2009.
- Seven therapeutic categories, including vancomycin, multiple sclerosis agents, and the “Other Therapeutic Agents” category had average annual price increases of more 10 percent in 2009. Another ten therapeutic categories had average annual retail price increases of between 5 percent and 10 percent.
- Five of the 26 therapeutic categories had average annual retail price *decreases* in 2009 that ranged from 2.9 percent to 17.4 percent. A majority of the drug products in these therapeutic categories were generic.

Figure 12: A Majority of Therapeutic Categories Had Retail Price Increases That Exceeded the Rate of General Inflation in 2009



Note: Therapeutic categories with fewer than two drug products in the 2006 market basket of most widely used specialty prescription drugs are included in the “Other Therapeutic Agents” category. The number in parentheses after a therapeutic category indicates the number of drug products in the market basket for that therapeutic category. The general inflation rate is based on CPI-U.

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

CONCLUDING OBSERVATIONS

Specialty drug expenditures are one of the fastest growing segments of the pharmaceutical market, much of which is attributable to price growth.¹⁶ This study examined specialty drug price changes over time. Retail prices have increased substantially for specialty prescription drug products that are used by Medicare Part D prescription drug program enrollees. Average annual increases in retail prices for the 112 most widely used specialty prescription drugs continued to substantially exceed the rate of general inflation. The average annual increase in 2009 (8.9 percent) was substantially higher than the rates of increase for retail prices in the prior five years, which ranged between 6.5 percent and 8.5 percent during the years 2004 to 2008.

The cumulative effect of these retail price increases can be substantial. On average, retail prices of the 98 most widely used prescription drug products that have been on the market since the end of 2004 have increased by 50.4 percent over the subsequent five-year period (2005 through 2009), compared with a general inflation rate of 13.3 percent. For a consumer who takes a specialty prescription drug on a chronic basis, the average annual retail cost of therapy rose by more than \$10,000 during this five-year period.

More than three-quarters (79.5 percent, or 89 of 112 drug products) of the specialty drug products had retail price increases that met or exceeded the rate of general inflation during 2009. 24 of the 112 specialty drug products had a decrease in price. Average annual retail price increases in 2009 exceeded the rate of general inflation for 21 of 29 manufacturers with at least two drug products in the market basket, and for 20 of 26 therapeutic categories with at least two drug products in the market basket.

Retail drug prices have a direct impact on costs borne by Medicare Part D enrollees. Since most Part D plans (and a growing number of private plans) require substantial cost sharing for specialty drugs,¹⁷ retail price increases are likely to affect consumers directly and substantially. They can also increase the number of Part D enrollees who reach the coverage gap, where they directly absorb the effect of higher retail prescription prices. Moreover, the relatively high prices of specialty drugs compared to other prescription drugs are more likely to push beneficiaries beyond the coverage gap and into catastrophic coverage,¹⁸ where they are responsible for a percentage of their drug costs,¹⁹ fairly quickly, further exposing them to price increases. This also impacts Medicare spending,

¹⁶ Medco, *2011 Drug Trend Report*, May 2011.

¹⁷ J. Appleby, "Workers Squeezed As Employers Pass Along High Costs Of Specialty Drugs," *Kaiser Health News*, August 22, 2011.

¹⁸ Government Accountability Office, "Medicare Part D: Spending, Beneficiary Cost Sharing, and Cost-Containment Efforts for High-Cost Drugs Eligible for a Specialty Tier," Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, January 2010.

¹⁹ In 2011, catastrophic coverage kicks in after a Part D enrollee has incurred \$4,550 in out-of-pocket drug costs. After this point, enrollees pay roughly 5 percent of the cost of their prescription drugs. Centers for Medicare & Medicaid Services, "Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 5, 2010.

as the program covers 80 percent of Part D enrollees' costs once they enter catastrophic coverage.

The health care reform legislation will gradually phase out the Medicare Part D coverage gap through discounts on brand name, biologic, and generic prescription drugs. 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. However, the value of closing the doughnut hole, while potentially substantial, could be eroded over the years if escalating drug prices are not addressed.

APPENDIX A: DETAILED METHODOLOGY AND DESCRIPTION OF RETAIL PRICE DATA

AARP's Public Policy Institute has been publishing a series of reports that track manufacturers' price changes for the prescription drug products most widely used by older Americans with annual and quarterly results of these price changes reaching as far back as 2000. Since 2008, these reports have focused on price changes for three market baskets—brand, generic, and specialty drugs. Separate analyses of the price changes for these three groups are reported because they are typically made by different drug manufacturers and their prices are subject to different market dynamics, pricing, and related behaviors. In addition, a combined market basket (i.e., brand, generic and specialty) was recently added to the series, which is useful to view the price change trend across all types of prescription drugs.

The AARP Public Policy Institute and the University of Minnesota's PRIME Institute have collaborated to report an index of manufacturers' drug price changes based on the Wholesale Acquisition Cost (WAC) from the Medi-Span Price-Chek PC database.²⁰ Recently, AARP and the PRIME Institute have created an additional drug price index based on retail prices from the Thomson Reuters MarketScan® Research Databases.²¹ Thus, we have used the same market basket of prescription drugs widely used by Medicare Part D enrollees to examine both manufacturer-level prices and retail prices charged to consumers ages 50 and older who are enrolled in employer-sponsored health plans. The addition of retail prices to our analyses will allow the AARP Public Policy Institute to assess what prices are being paid by consumers and/or insurers and whether the rebates and discounts sometimes given to payers are being passed along to the covered individuals. This new retail data was used as the primary data source for AARP's Rx Price Watch reports beginning with the brand drug report²² and moving forward. As

²⁰ Medi-Span is a private organization that collects price and other clinical and drug-related data directly from drug manufacturers and wholesalers. Price-Chek PC is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health, Inc., and uses data from the Master Drug Database (MDDDB®). This commercial drug database has been published for more than 25 years and provides “comprehensive, integratable drug databases to healthcare professionals worldwide. The Medi-Span product line is an accurate and trusted drug information source that integrates with healthcare software applications.” (Open Letter to Pharmaceutical Manufacturers, Distributors and Re-packagers, Re: Pharmaceutical Product Pricing Information for the Medi-Span Drug File [MDDDB®], July 2003, published on the Medi-Span Website: <http://www.medispanspan.com>.)

²¹ The Thomson Reuters MarketScan® Research Databases, a family of databases, contains individual-level healthcare claims, lab test results, and hospital discharge information from large employers, managed care organizations, hospitals, Medicare, and Medicaid programs. The Healthcare & Science business of Thomson Reuters constructs the MarketScan® Research Databases by collecting data from employers, health plans, and state Medicaid agencies and placing them into databases. D.M. Adamson, S. Chang, and L.G. Hansen, “White Paper: Health Research Data for the Real World: The MarketScan Databases,” Thomson Healthcare, January 2008.

²² The first AARP Rx Price Watch Report to use the retail price data was “Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Medicare Beneficiaries 2005 to 2009,” Stephen W. Schondelmeyer and Leigh Purvis, AARP Public Policy Institute, Report # 2010-06, August 2010, which can be found at: <http://www.aarp.org/rxpricewatch>.

in the past, the series will include separate data sets and reports for brand name, generic, and specialty drugs, and also for the combined market basket.

This appendix describes the characteristics of the market baskets used in the Rx Price Watch reports, as well as how the new retail data were refined and incorporated into the analysis.

Market Basket Characteristics

The AARP Public Policy Institute has been reporting manufacturer drug product price changes annually and quarterly since 2004. Previous reports by AARP were based on a market basket of retail and mail-order prescriptions provided to about two million people age 50 and older who used the AARP Pharmacy Service. Following the implementation of the Medicare Part D program, we chose to develop a new market basket of drugs based on actual drug use in Medicare Part D plans during calendar year 2006. This new market basket has been used for all AARP price trend reports published since 2007.

The brand name market basket for this price change study is composed of 220 drug products.²³ These 220 drug products accounted for 84.6 percent of all brand name (both brand single source and brand multiple source) prescription expenditures, 82.7 percent of all brand name prescriptions and 84.2 percent of all brand name days of therapy provided.

The generic market basket is composed of 185 widely used generic drug products. These drug products represent 89.0 percent of sales, 91.6 percent of prescriptions, and 91.5 percent of days of therapy provided.

The specialty market basket for this price change study is composed of 144 widely used specialty drug products.²⁴ These 144 drug products represented 91.4 percent of all specialty drug expenditures, 87.6 percent of all specialty drug prescriptions, and 93.7 percent of all specialty drug days of therapy provided.

²³ Although the original sample contained 220 brand name prescription drugs, Zyrtec 10 mg tablets went over-the-counter in January 2008 and was subsequently excluded from the market basket and related analysis. In addition, Risperdal 0.25 mg tablets and Risperdal 4 mg tablets were excluded due to insufficient price data.

²⁴ Although the original sample contained 144 specialty prescription drugs, 32 of the drug products were excluded from the market basket and related analysis due to insufficient price data.

There are 549 drug products in the overall (combined) market basket (220 brand name, 185 generic, and 144 specialty drug products).²⁵ Brand name prescription drugs consumed the majority of the expenditures (70.4 percent), while generic drugs were the majority of prescriptions dispensed (58.3 percent). Specialty drugs, not including any payments that were made under Medicare Parts A and B,²⁶ represented 7.4 percent of the Medicare Part D plan's expenditures and 1.3 percent of the plan's prescriptions. This combined market basket represented the vast majority of the outpatient prescription drug market for Medicare recipients, accounting for 81.6 percent of all outpatient prescription drug expenditures under Medicare Part D, 79.2 percent of all outpatient prescriptions dispensed, and 91.2 percent of all days of therapy provided in outpatient settings.

A more detailed explanation of the process used for determining the market basket of drug products to be tracked is available in Appendix A of the AARP Public Policy Institute's March 2008 report, "Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007."²⁷

Monitoring Retail Drug Prices

Historically, the Rx Watchdog reports have been based on market baskets of drugs constructed using data from a Medicare Part D plan provider for 2006 and manufacturer drug price changes measured using WAC data from the Medi-Span Price-Chek PC database. The AARP Public Policy Institute and the University of Minnesota's PRIME Institute recently collaborated to develop a retail drug price index to be known as the Rx Price Watch reports based on retail prescription prices from the Thomson Reuters MarketScan® Research Databases. This new retail price index will allow the AARP Public Policy Institute to assess retail prices actually being paid by consumers and/or insurers and whether or not the rebates and discounts sometimes given to pharmacy benefit managers, Part D drug plans, and payers are being passed along to the covered individuals.

Retail Data Description

The Thomson Reuters MarketScan® Research Databases are comprised of eight fully integrated claims databases, and are one of the nation's largest collections of patient data. The warehouse features an opportunity sample from multiple sources (employers, states, health plans), over four billion patient records, and 69 million covered lives.²⁸ The data used in the Rx Price Watch analyses are drawn from the Thomson Reuters MarketScan®

²⁵ In order to measure the impact of changes in retail price alone, the weights for drug products in this market basket are fixed over time. Drug products that enter the market as generics after 2006 will not be included in this index. If drug products are withdrawn from the market, they will be dropped from the market basket in subsequent periods and the weights of other drugs will be proportionately adjusted.

²⁶ Since the specialty market basket does not include drugs that fall under Medicare Parts A and B, these numbers do not reflect total specialty drug utilization and spending among Medicare beneficiaries.

²⁷ Available on the AARP website, http://www.aarp.org/health/medicare-insurance/info-04-2009/rx_watchdog.html.

²⁸ D.M. Adamson, S. Chang, and L.G. Hansen, "White Paper: Health Research Data for the Real World: The MarketScan Databases," Thomson Healthcare, January 2008.

Commercial Database and the Thomson Reuters MarketScan® Medicare Supplemental Database.

The Thomson Reuters MarketScan® Commercial Database consists of employer- and health plan-sourced data containing medical and drug data for several million individuals. Nearly 18 million individuals are included in the database, encompassing employees, their spouses, and dependents that are covered by employer-sponsored private health insurance. Healthcare for these individuals is provided under a variety of fee-for-service, fully capitated, and partially capitated health plans, including preferred and exclusive provider organizations, point of service plans, indemnity plans, health maintenance organizations, and consumer-directed health plans.

The Thomson Reuters MarketScan® Medicare Supplemental Database is composed of data from retirees with Medicare supplemental insurance sponsored by employers or unions. In 2007, 23% of the 44 million Medicare beneficiaries received their drug benefits through an employer or union-sponsored health plan.²⁹ The Thomson Reuters MarketScan® Medicare Supplemental Database includes the Medicare-covered portion of payment, the employer-paid portion, and any patient out-of-pocket expenses. The database provides detailed cost and use data for healthcare services performed in both inpatient and outpatient settings.

The retail price data drawn from the Thomson Reuters MarketScan® Commercial Database and Thomson Reuters MarketScan® Medicare Supplemental Database had to meet several conditions in order to be included in the analysis:

1. Claimant must be age 50 and older
2. Claim must have a value of greater than zero in the following fields:
 - a. Total payment amount
 - b. Metric quantity
 - c. Ingredient cost
 - d. Days supply
 - e. Average wholesale price.
3. Metric quantity value must fall within pre-defined ranges developed using reference data from the Medi-Span Price-Chek PC database.
4. Claim must come from a non-capitated health plan.

Thomson Reuters then combined the two databases and provided the AARP Public Policy Institute with datasets that included the monthly median (as well as the 10th, 25th, 75th and 90th percentile) retail price from January 2004 through December 2009 for all of the drug products in the Rx Price Watch market baskets. The monthly median retail prices were compiled in spreadsheets and utilized to track price changes among all of the drug products in the AARP market baskets.

²⁹ D.M. Adamson, S. Chang, and L.G. Hansen, "White Paper: Health Research Data for the Real World: The MarketScan Databases," Thomson Healthcare, January 2008.

Calculating Annual Price Changes for Each Drug

This Rx Price Watch report calculates average retail price changes for drug products in the following ways:

- The *annual point-to-point* percent change in retail price is calculated as the percent change in price for a given month compared with the same month in the previous year (e.g., January 2009 vs. January 2008, February 2009 vs. February 2008).
- The 12-month *rolling average* percent change in retail price is calculated by taking the average of the point-to-point changes over the preceding 12 months. Thus, for example, the average annual retail price changes for 2009 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2009 through December 2009 compared with the same months in the previous year.

To aggregate retail price changes across multiple drugs, a weighted average of price changes was calculated by weighting each drug's annual price change (calculated using retail price data from the Thomson Reuters MarketScan® Commercial Database and the Thomson Reuters MarketScan® Medicare Supplemental Database) by its share of the Medicare Part D plan provider's total 2006 prescription sales among its given market basket (e.g., brand name, generic, specialty, or combined).

The weights used for all years in this study were based on 2006 sales from the largest Medicare Part D plan provider, which included the AARP Plans. The 2006 weights were used and held constant over time in the market basket so that change in the price indices would be a function of price changes alone and not a function of changes in mix within the market basket(s).

However, some drugs that were in the sample in 2006 were not on the market in all earlier years. As a result, drug products were dropped out of the analysis in the month before they entered the market and for all previous months, and the weights of the products present in the market during each month prior to 2006 were recalculated to reflect their relative share of the total sales as adjusted to reflect only drugs in the market during that period.

A more detailed description of the methods used for calculating various measures of the change in prices and study limitations is provided in Appendix A of the AARP Public Policy Institute's March 2008 report, "Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007."³⁰

³⁰ Available on the AARP website, http://www.aarp.org/health/medicare-insurance/info-04-2009/rx_watchdog.html.



Public Policy Institute

601 E Street, NW | Washington, DC 20049
202-434-3840 PH | 202-434-6480 F | www.aarp.org/ppi

