

Rx Watchdog Report
Trends in Manufacturer Prices of Prescription
Drugs Used by Medicare Beneficiaries
2008 Year-End Update

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Research Report

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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.

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EXECUTIVE SUMMARY

AARP's Public Policy Institute finds that average manufacturer price increases for brand name and specialty prescription drugs widely used by Medicare beneficiaries have continued to far outstrip the price increases for other consumer goods and services. In 2008, the average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for 219 brand name prescription drugs was 8.7 percent, or more than twice the general inflation rate of 3.8 percent. Similarly, the average annual increase in manufacturer prices for 144 brand and generic specialty prescription drugs was 9.3 percent in 2008, or almost two and a half times the general inflation rate. In contrast, average manufacturer prices for 185 generic drugs fell by 10.6 percent during the same 12-month period.

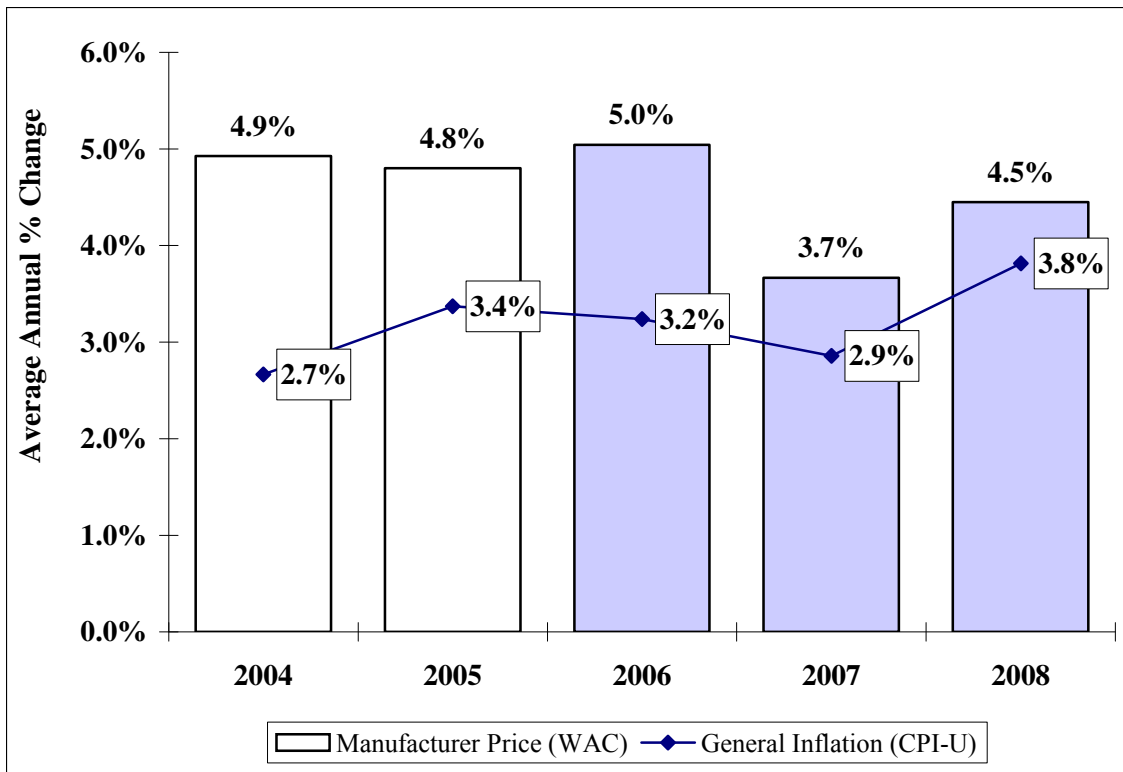
This report presents our most recent findings on the pattern of price increases for brand name, generic, and specialty drugs widely used by Medicare Part D beneficiaries. The three market baskets in this report series are analyzed and reported on separately because they are typically made by different drug manufacturers and their prices are subject to different market dynamics, pricing, and related behaviors.

Specifically, this report compares prescription drug price changes to the rate of general inflation from one year to the next. The report focuses on changes in prices that drug manufacturers charge to wholesalers and other direct purchasers. The manufacturer's charge for the drug product itself is the most substantial component of the total cost to the consumer. Data in this report do not include drug rebates that Part D plans are able to negotiate with manufacturers—such rebates are typically confidential and are not usually passed on to the Medicare beneficiary. Since we examine the change in drug prices over time, the lack of rebate data should not prove to be a major bias. When manufacturers change their price to wholesalers or other direct purchasers, the new cost of the drug is generally passed on to insurers or consumers as a similar increase or decrease in prescription price.

Findings

When combined, the average annual increase in manufacturer prices for all of the market baskets has consistently exceeded the rate of general inflation. In 2008, the average annual rate of increase for widely used brand name, generic, and specialty prescription drugs was 4.5 percent, or 1.2 times the general inflation rate of 3.8 percent, as price growth in the brand and specialty market baskets more than offset substantial price decreases in the generic market basket.

Average Annual Percent Change in Manufacturer Prices for Most Widely Used Prescription Drugs Increases in 2008



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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health, Inc., April 2009).

Brand name market basket

- In 2008, the average annual increase in manufacturer prices charged to wholesalers (and other direct purchasers) for the 219 most widely used brand name prescription drugs (8.7 percent) was substantially higher than the rates of increase for manufacturer prices in the prior six years, which ranged between 5.3 percent and 7.4 percent during the years 2002 to 2007.
- For a consumer who takes three brand name prescriptions on a chronic basis, the average increase in the cost of therapy for the drug products used to treat chronic conditions rose by almost \$2,100 between 2002 and 2008.
- All but 7 of the 219 brand name prescription drug products in the study's market basket had manufacturer price increases during 2008. Nearly all (93 percent) of these increases exceeded the rate of general inflation during the year.

Generic market basket

- The manufacturer prices of a majority of the generic drug products in the market basket do not change. However, when list price changes do occur, they are usually substantial.
- On average, manufacturer prices for the 185 generic drug products most widely used by Medicare beneficiaries fell by 10.6 percent in 2008. This was the largest average decrease in generic drug prices for this market basket since at least 2003.

Specialty market basket

- In 2008, the average annual increase in manufacturer prices charged to wholesalers (and other direct purchasers) for the 144 most widely used specialty prescription drugs (9.3 percent) was almost two-and-a-half times the rate of general inflation (3.8 percent).
- For a consumer who takes a specialty prescription on a chronic basis, the average increase in the cost of therapy for the drug products used to treat chronic conditions rose by more than \$9,258 between 2004 and 2008.
- About two-thirds (64 percent or 105 of 144 drug products) of the specialty drug products had manufacturer price increases that exceeded the rate of general inflation during 2008. Only 8 of the 144 specialty drug products had a decrease in price, and all the drug products with price decreases were generics.

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, Prevacid (lansoprazole) 30 mg, delayed-release capsule, bottle of 100, Abbott Pharmaceuticals).

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 charged by drug manufacturers to wholesalers and other direct purchasers were measured using changes in the wholesale acquisition cost (WAC) as published by the Medi-Span Price-Chek PC database. The average annual change in prices was calculated for each individual drug product as a 12-month rolling average. Aggregate estimates of price or change in drug 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 in earlier years. These trend analyses are based solely on the new (i.e., Medicare Part D plan provider) market basket.

Concluding Observations

The findings of this report shows that average annual increases in manufacturer prices charged to wholesalers and other direct purchasers for widely used brand name and specialty prescription drugs have continued to consistently exceed the rate of general inflation. In contrast, manufacturer prices for widely used generic drugs have declined.

Manufacturer drug price increases can have a direct impact on the costs borne by Medicare Part D enrollees. Manufacturer price increases to the provider or pharmacy result in higher out-of-pocket costs for those beneficiaries who pay a percentage of drug costs (coinsurance) rather than a fixed dollar amount (copayment). The effect of higher drug manufacturer prices on the total price to the end payer means that Part D enrollees will get to the “donut hole”—the gap in coverage when enrollees have to pay all of their drug costs—much quicker. And, once enrollees are in the donut hole, they directly absorb the entire effect of the higher drug manufacturer prices on the prescription price to the end payer.

Higher drug manufacturer prices to retail pharmacies result in higher costs to drug plans, unless plans are able to negotiate higher rebates from drug manufacturers to account for these costs or lower prices from pharmacies (thereby forcing the pharmacies to absorb the cost of the manufacturer's price increase). Higher costs to plans likely result in reduced benefits and/or higher premiums to enrollees.

RX WATCHDOG REPORT: TRENDS IN MANUFACTURER PRICES OF BRAND NAME PRESCRIPTION DRUGS USED BY MEDICARE BENEFICIARIES 2008 YEAR-END UPDATE

AARP's Public Policy Institute finds that average manufacturer price increases for brand name drugs continued to far outstrip the price increases for other consumer goods and services in 2008. These increases are consistent with the pattern that we have seen since initiating our ongoing series of studies on brand name prescription drug prices in 2004.¹ In 2008, the average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for 219 brand name prescription drugs widely used by Medicare beneficiaries was 8.7 percent, or more than twice the general inflation rate of 3.8 percent.

These reports focus on changes in the prices that drug manufacturers charge to wholesalers and other direct purchasers for their sales to retail pharmacies. The manufacturer's charge to wholesalers is the most substantial component of a brand name prescription drug's retail price. Data in this report do not include drug rebates that Part D plans are able to negotiate with manufacturers—such rebates are typically confidential and not passed on to the pharmacy or consumer. Since we examine trends over time, the lack of rebate data should not prove to be a major bias in reporting the rate of price change. When manufacturers increase their price to wholesalers for a brand name drug, the added cost is generally passed on in the retail price to most prescription purchasers.² Changes in drug manufacturers' prices are measured by changes in the wholesale acquisition cost (WAC) published in the Medi-Span Price-Chek PC database.³

This report presents annual and seven-year cumulative price changes through the end of 2008, using both rolling average and point-to-point estimates (see methodological appendix).⁴ The first set of findings shows *annual* rates of change in manufacturers' prices

¹ Previous reports from this series can be found on the AARP Web site at www.aarp.org/research/health/drugs/rx_watchdog.html.

² Rebates generally do not benefit retail pharmacies, drug prices paid by Medicare Part D enrollees, or cash-paying consumers (i.e., people who pay up front for their prescriptions when they are in the Medicare Part D coverage gap or who have no drug coverage or have indemnity insurance).

³ 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, www.medispan.com.) “WAC represents the catalog price, as reported to Medi-Span by a manufacturer, at which wholesalers may purchase drug products from that manufacturer.” (Wolters Kluwer Health AWP Policy, August 23, 2007, www.medispan.com/marketing/Common/PDF/Marketing/WKH_AWP_Policy.pdf)

⁴ A brief description of the methodology used to produce these findings is provided in the methodological appendix. For a more detailed description of the methodology for the baseline study, including the rolling average approach, see Appendix A in D. Gross, S. Schondelmeyer, and L. Purvis, *Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002*

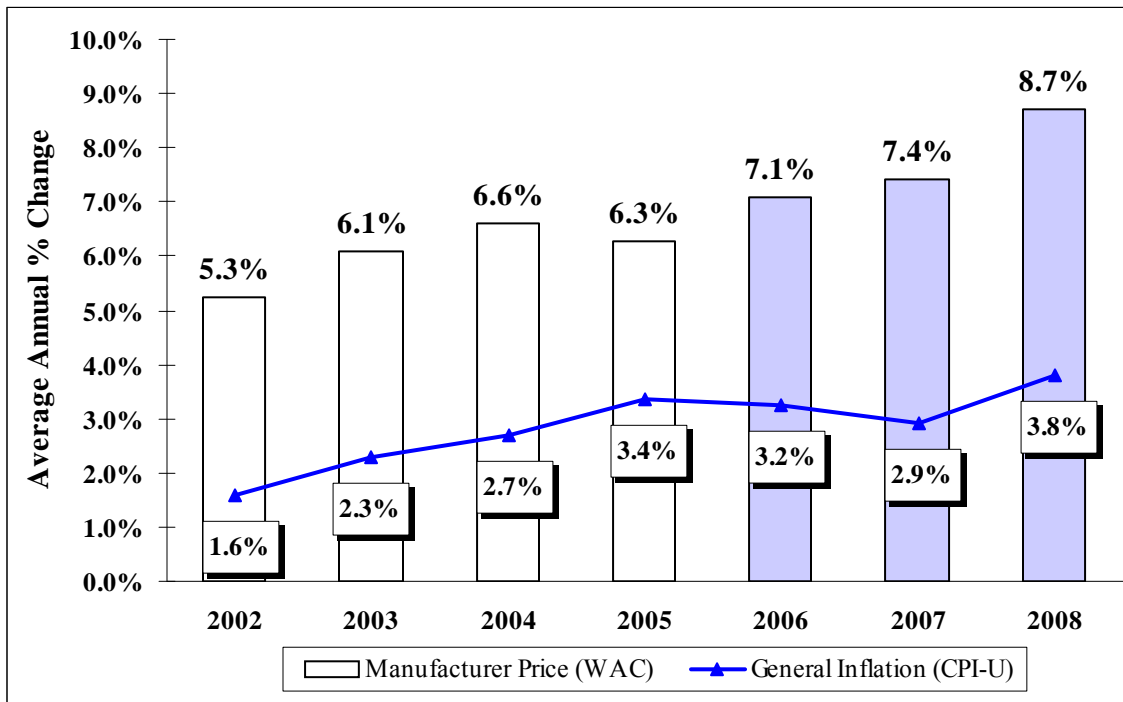
for widely used brand name drugs from 2002 through 2008, using both rolling average and point-to-point measures. The rolling average measure also is used to examine the distribution of price changes as well as differences in average percentage price changes by manufacturer and by therapeutic category. The second set of findings summarizes the *cumulative* impact of manufacturer drug price increases that have taken place during the seven-year period from December 31, 2001 to December 31, 2008.

FINDINGS

I. Annual Trends in Manufacturer Price Changes for Most Widely Used Brand Name Prescription Drugs

Annual percent change in manufacturer prices

Figure 1: Average Annual Percent Change in Manufacturer Prices for Widely Used Brand Name Prescription Drugs Continues to Grow in 2008



Average increases for 2008 exclude Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008.

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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health, Inc., March 2009).

- Manufacturer prices for the brand name drug products most widely used by Medicare beneficiaries rose 8.7 percent in 2008 when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries (figure 1). This rate of increase was more than twice the rate of general inflation in 2008 (8.7 percent vs. 3.8 percent).
- The average annual increase in 2008 was substantially higher than the rates of increase for manufacturer prices in the prior six years. The average manufacturer price increase for this market basket ranged between 5.3 percent and 7.4 percent during the years 2002 to 2007.

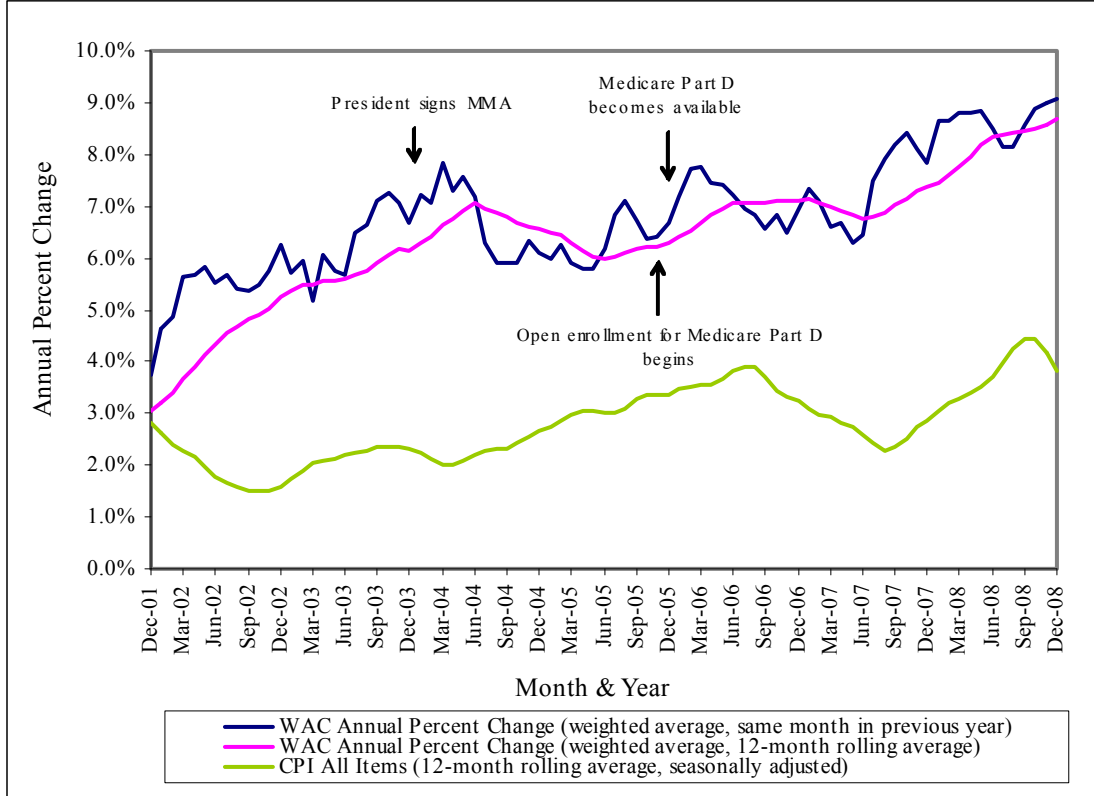
Notably, the average annual price changes for brand name drug products has continued to increase despite a sizable number of widely used brand name drugs going off patent in the past two years. Since 2006, 58 of the 219 drug products in the brand name market basket have had generic versions introduced to the market.⁵ These drugs represent 25.5 percent of 2006 brand name drug sales to Medicare Part D beneficiaries. We have chosen to keep these off-patent drugs in our market basket, since they are still being sold, albeit at considerably lower volumes.⁶

The average annual price change reported in figure 1 is a conservative measure that, by averaging annual point-to-point price changes for each month in a 12-month period (referred to as a *rolling average* change), smoothes over the entire year the annual amount of change in manufacturer 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 has been plotted along with the 12-month rolling average to allow more detailed examination of the rate and timing of price changes over the entire study period (figure 2).

⁵ One drug, Zyrtec 10 mg tablets, began to be sold over-the-counter, or without a prescription. As over-the-counter drugs do not accurately reflect price changes in prescription drugs, it was dropped from the analysis.

⁶ 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 Manufacturer Prices for Widely Used Brand Name Prescription Drugs Consistently Increase Between 2002 and 2008



Average increases for 2008 exclude Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008.

Note: MMA is the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

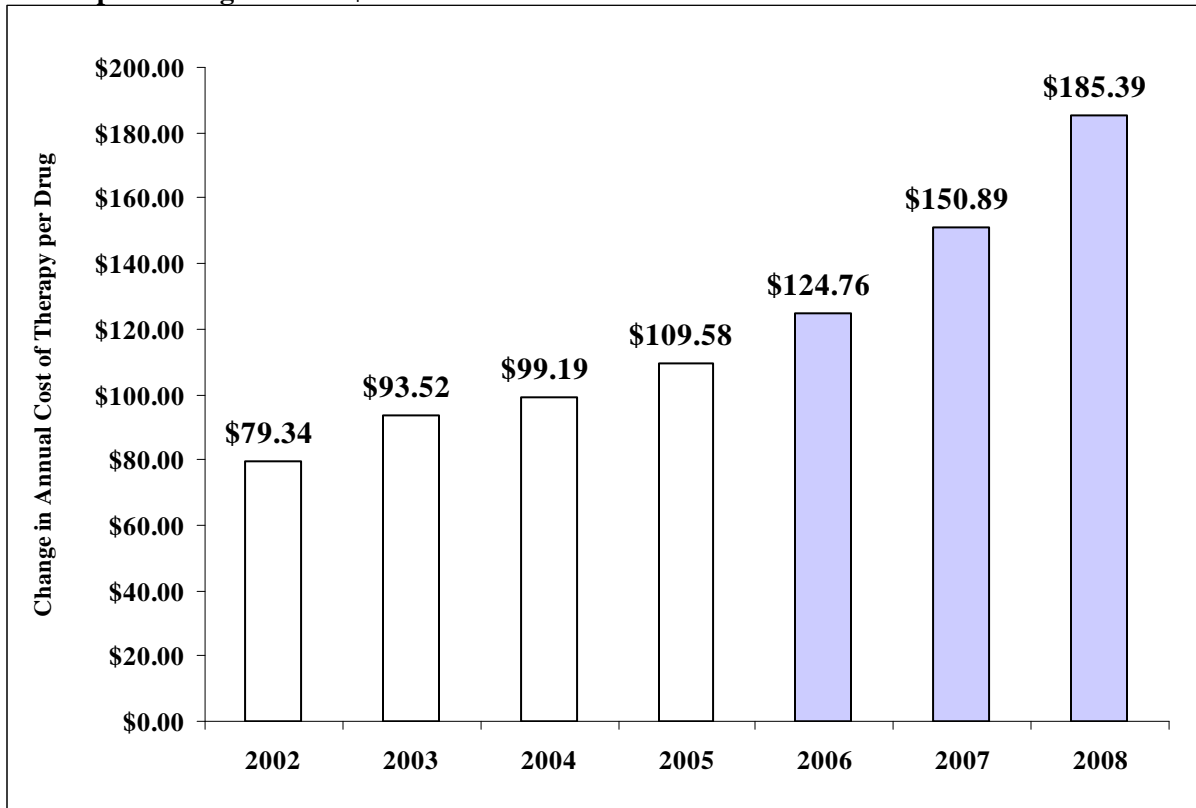
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Figure 2 shows that the point-to-point annual change in prices accelerated rapidly at three specific times since Medicare beneficiaries were first able to choose Part D plans in the fall of 2005: (1) December 2005 through February 2006, (2) December 2006 through January 2007, and (3) July 2007 through October 2007. Further, the rolling average indicates that brand name drug prices have been increasing steadily since July 2007. Throughout the entire time the Medicare Part D prescription drug program has been in operation: (1) the price level of brand name drug products has steadily increased rather than decreased; (2) the rate of increase in brand name drug prices has continued to accelerate; and (3) the price increases have been well above (usually two-fold or more) the rate of general inflation.

Change in annual cost of therapy

Manufacturer price increases for the 211 most widely used brand name drugs used for treating chronic conditions (out of a total market basket of 219 drugs)⁷ were translated into increases in the average annual cost of therapy (figure 3).⁸

Figure 3: Average Change in Annual Cost of Therapy for Most Widely Used Brand Name Prescription Drugs is Over \$185 Per Year in 2008



Average increases for 2008 exclude Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008.

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

Does not include eight 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

- The average increase in the cost of therapy was more than \$185 per year per prescription drug in 2008, roughly 70 percent higher than the average annual increase the year before Medicare Part D was implemented (i.e., 2005).

An older American who takes three prescription drugs is likely to have experienced an average increase in the annual cost of therapy of more than \$556 in 2008, assuming that

⁷ Drug products typically used to treat acute conditions or for less than one year's duration include: Lidoderm 5%, Levaquin 250 mg, 500 mg, and 750 mg, Patanol 0.1%, Avelox 400 mg, Lamisil 250 mg, and Valtrex 1 Gm.

⁸ Note that the figures in this section reflect manufacturer prices and not necessarily the prices a consumer would face at the drugstore.

the consumer uses brand name drugs for chronic conditions and that the manufacturers' price increases were passed on in the form of higher prices. While insurance would cover much of this cost for some beneficiaries, it would not cover the costs for Medicare Part D enrollees in the "donut hole"⁹ (the period when beneficiaries pay 100 percent of their prescription costs).¹⁰

II. Seven-Year Cumulative Impact of Manufacturer Price Changes for Widely Used Prescription Drugs, 2002-2008

AARP has tracked manufacturers' brand name drug price changes for the seven-year period from December 31, 2001, to December 31, 2008. More than three-fourths (168 of 219) of the most widely used drugs in the market basket for this analysis have been on the market for the entire seven-year period (the end of 2001 through the end of 2008). The cumulative effect of price changes over this seven-year period is reported.

Seven-year cumulative percent change in manufacturer prices

- More than three-fourths (168 of 219) of the most widely used drugs in the market basket for this analysis have been on the market for the entire seven-year period from the end of 2001 through the end of 2008. Cumulatively, the average manufacturer price increase for these 168 brand name drug products was 63.8 percent, compared with 19.2 percent for general inflation—or more than 3 times the rate of general inflation.¹¹
- Figure 4 illustrates the cumulative effect of manufacturer price changes between the end of 2001 and the end of 2008 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:
 - Nexium 40 mg capsules (AstraZeneca)—used in the treatment of acid reflux disease;
 - Lipitor 20 mg tablets (Pfizer)—used to treat high cholesterol;
 - Aricept 10 mg tablets (Eisai)—an anti-Alzheimer's drug;
 - Fosamax 70 mg tablets (Merck)—used to treat osteoporosis; and

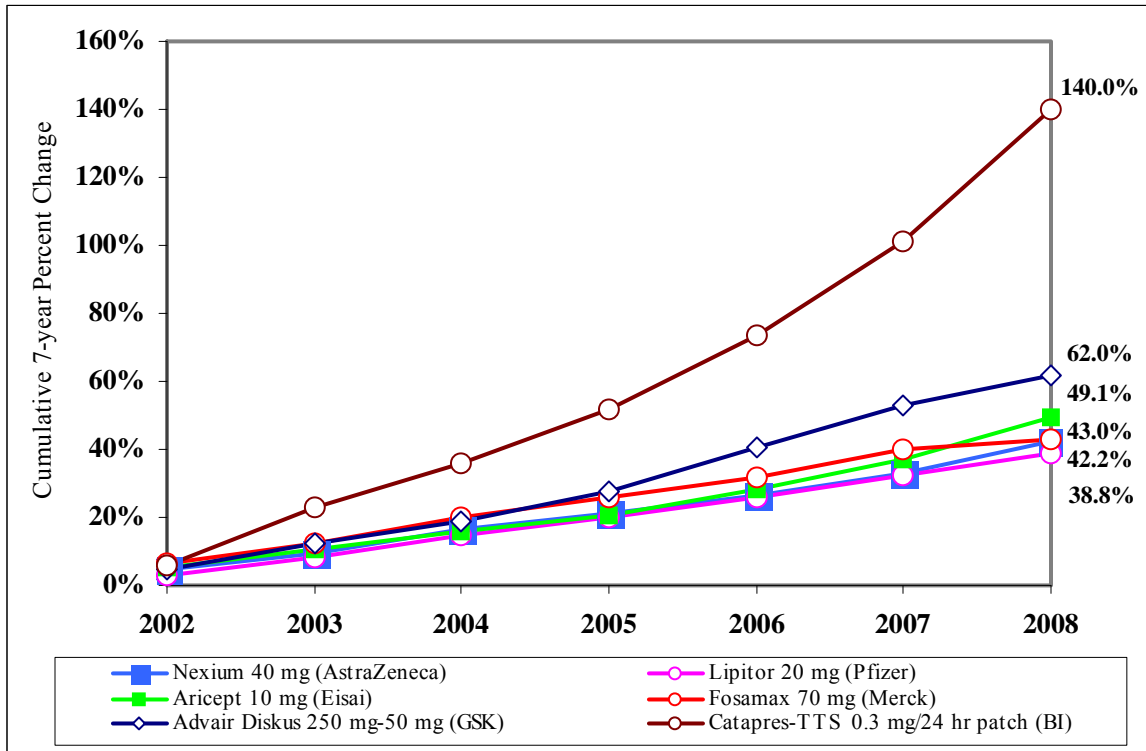
⁹ The cost impact on beneficiaries is based on the continued use of the brand name drug product. Seventy-three percent of the brand name drug products in this index (160 of 219) do not have therapeutically equivalent generic alternatives. For the remaining 27 percent of these brand name drug products, the beneficiary could save money by switching to a less-expensive generic drug product.

¹⁰ This "gap" in coverage generally begins after the beneficiary has \$2,700 (in 2009) in total drug costs and continues until the beneficiary spends \$4,350 in out-of-pocket drug costs. The Henry J. Kaiser Family Foundation, "The Medicare Prescription Drug Benefit," Fact Sheet, March 2009. Some plans might offer some coverage in the gap, and some low-income beneficiaries also have gap coverage.

¹¹ The seven-year average cumulative growth rate for all drugs in the market basket was 65.4 percent. This number was calculated by compounding the average annual growth rate for each year from 2002 to 2008.

- Advair Diskus 250 mg-50 mg (GlaxoSmithKline)—a respiratory inhaler.
- The sixth drug, Catapres-TTS 0.3 mg/24 hr patch (Boehringer Ingelheim), which is used to treat high blood pressure, was chosen because it had the largest percent price increase in 2008 among the drug products that have been on the market since the end of 2001.

Figure 4: The Seven-Year Cumulative Percent Change in Manufacturer Price is 140 Percent for the Brand Name Drug with the Largest Percent Price Increase in 2008



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).

- The seven-year (i.e., December 31, 2001 to December 31, 2008) cumulative percent change in manufacturer prices for six specific drug products is shown in figure 4:
 - The manufacturer price of Catapres-TTS 0.3 mg/24 hr patch rose by 140 percent over the entire seven-year period, when measured as a 12-month rolling average change. This cumulative growth was more than seven times the rate of growth in general inflation.
 - The manufacturer price of Advair Diskus 250 mg-50 mg increased cumulatively by 62 percent, and the manufacturer price of Aricept 10 mg tablets increased by nearly 50 percent over the seven-year period.

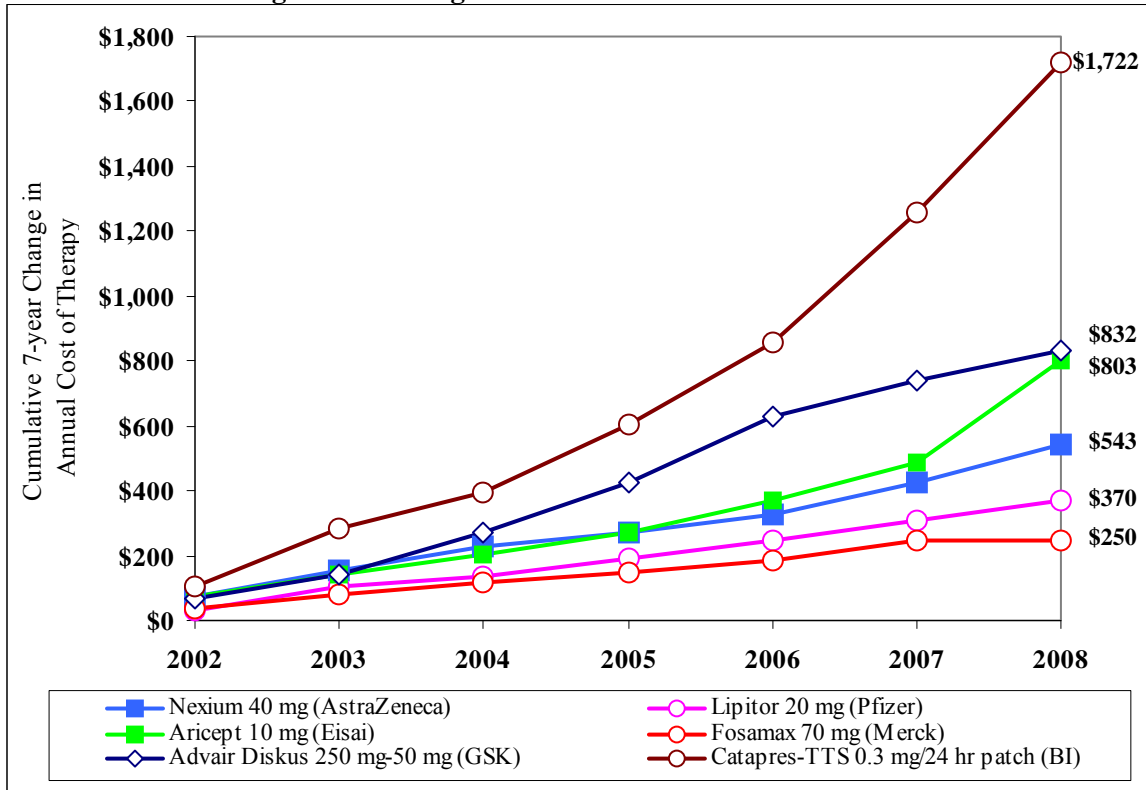
- The manufacturer prices of Nexium 40 mg capsules and Lipitor 20 mg tablets each increased cumulatively by approximately 40 percent between the end of 2001 and the end of 2008.
- The manufacturer price of Fosamax 70 mg tablets also increased by approximately 40 percent between the end of 2001 and the end of 2008, even with the introduction of a generic equivalent in February 2008.

Seven-year cumulative change in annual cost of therapy

- All but 8 of the 168 brand name drug products that have been on the market since the end of 2001 are used to treat chronic conditions. By the end of 2008, the average annual cost of therapy for these brand name drug products was \$699 higher than seven years earlier, assuming that manufacturers' price increases were passed along to the consumer as a higher price¹² and that the consumer used these brand name drugs for chronic conditions. For a consumer who takes three brand name medications, this translates into an average increase in annual brand name therapy costs of \$2,097 between December 31, 2001 and December 31, 2008.
- The seven-year (2001 to 2008) cumulative change in brand name cost of therapy due to manufacturer prices for six specific drug products is shown in figure 5.
 - Manufacturer prices for a one-year supply of Catapres-TTS 3 mg/24 hr patch have risen more than \$1,700 between the end of 2001 and the end of 2008.
 - Manufacturer prices for a one-year supply of Advair Diskus 250 mg-50 mg and Aricept 10 mg tablets have risen more than \$800 between the end of 2001 and the end of 2008.
 - Manufacturer prices for a one-year supply of Nexium 40 mg capsules have risen more than \$500 by the end of the seven-year period (2001 to 2008).
 - Manufacturer prices for a one-year supply of Lipitor 20 mg tablets had risen almost \$400 and a one-year supply of Fosamax 70 mg tablets had risen almost \$250 by the end of the seven-year period (2001 to 2008). Again, it should be noted that the manufacturer price for Fosamax 70 mg tablets was likely impacted by the introduction of a generic equivalent in February 2008.

¹² The actual amount that an individual consumer pays out-of-pocket may depend on a variety of factors.

Figure 5: The Seven-Year Cumulative Change in Cost of Therapy is More Than \$1,700 for the Brand Name Drug with the Largest Percent Price Increase in 2008



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).

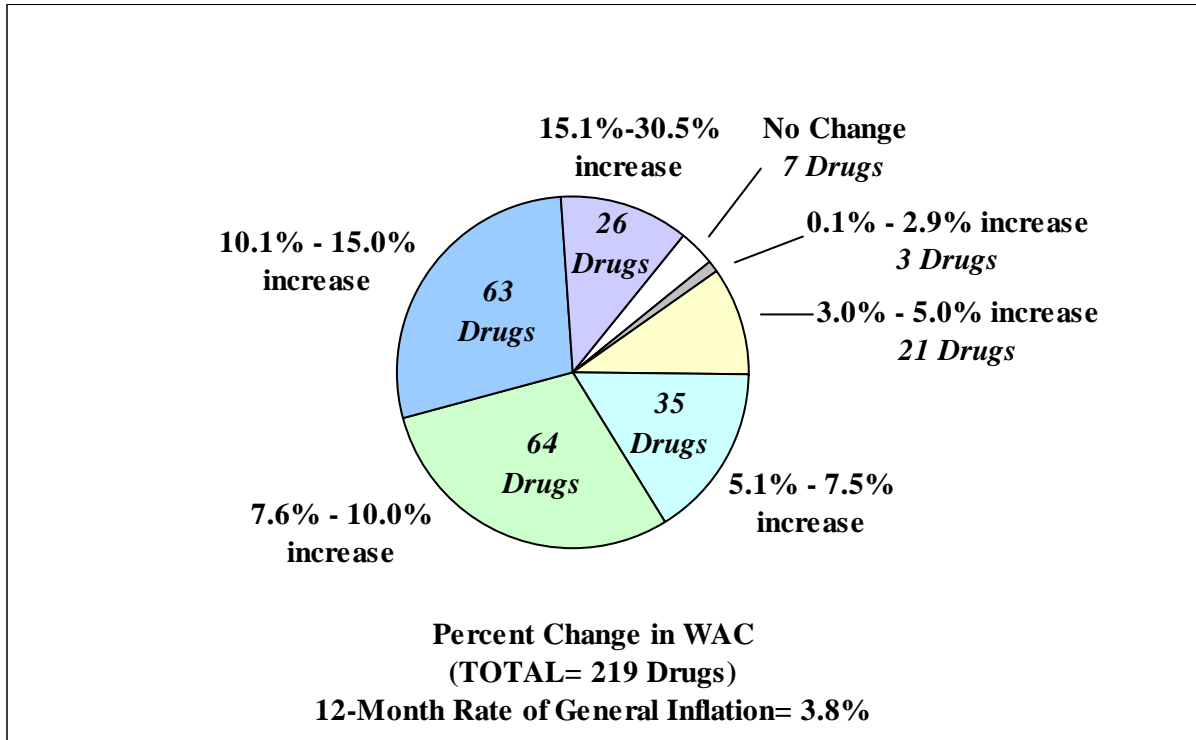
III. Manufacturer Price Changes for Most Widely Used Brand Name Prescription Drugs in 2008

Distribution of manufacturer price changes

All but 7 of the 219 (96.8 percent) most widely used brand name prescription drug products in this study's market basket had manufacturer price increases during 2008, when measured as a 12-month rolling average (figure 6).

- Annual manufacturer price increases for 203 (92.7 percent) of the 219 drug products exceeded the rate of general inflation (3.8 percent) in 2008.
- Annual manufacturer price increases for 188 (85.8 percent) of the 219 brand name drug products in the market basket increased more than 5.0 percent in 2008, including 64 (29.2 percent) with a price increase between 7.6 percent and 10.0 percent, 63 (28.8 percent) with a price increase between 10.1 percent and 14.9 percent, and 26 (11.9 percent) with a price increase of more than 15.2 percent.

Figure 6: Over Two-Thirds of the Most Widely Used Brand Name Prescription Drugs Had Manufacturer Price Increases That Were Over Twice the Inflation Rate in 2008



Note: Excludes Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008.

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).

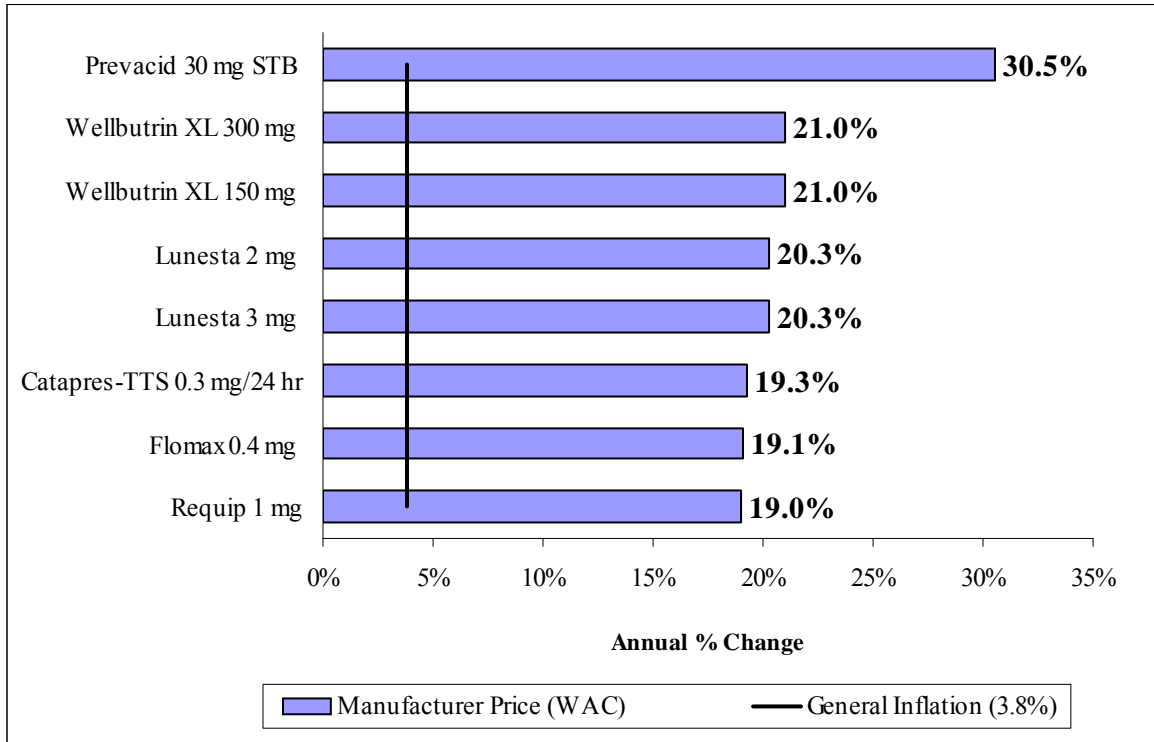
Nearly one-half (108 of 219) of the drug products had more than one manufacturer price increase during 2008. Two drugs—Flomax 0.4 mg capsules and Prevacid 30 mg STB tablets—had three price increases during 2008.

- Six of the seven brand name drug products with no change in manufacturer price for 2008—Zocor 10, 20, 40, and 80 mg tablets, Proscar 5 mg tablets, and Flonase 0.05% nasal spray—have generic equivalents on the market.
- One final drug product that did not have a change in manufacturer price in 2008—Xenaderm 90 units/gm ointment—is no longer covered by Medicare Part D.¹³

Eight of the brand name drug products had manufacturer price increases that were at least five times the rate of general inflation, ranging from 19.0 percent to 30.5 percent (figure 7). All eight of these brand name drug products were among the 108 drug products that had more than one price increase in 2008.

¹³ Healthpoint, “Questions and Answers about Xenaderm Ointment,” 2007, at www.healthpoint.com/divisions/tm/XenadermQuestionsAnswers.pdf.

Figure 7: Five Widely Used Brand Name Drugs Had Manufacturer Price Increases of Over 20 Percent in 2008



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).

Nearly all (23 of 25) of the brand name drug products with the greatest sales in 2006 had manufacturer price increases during 2008. Most (21 of 25) of the top-selling 25 brand name drug products had an increase that exceeded the rate of general inflation in 2008 (3.8 percent). Eleven of the top 25 brand name drug products had annual manufacturer price increases that met or exceeded twice the rate of general inflation (table 1).

Table 1: Nearly All of the Top 25 Brand Name Prescription Drug Products Had a Manufacturer Price Change in 2008

Rank by Sales among Study Market Basket*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	Annual Percent Change in WAC
1	Nexium 40 mg capsule	30	AstraZeneca	Ulcer Drugs (PPIs)	6.9%
2	Plavix 75 mg tablet	90	Bristol-Myers Squibb	Anticoagulants	8.4%
3	Prevacid 30 mg DR capsule	100	Takeda Pharmaceuticals	Ulcer Drugs (PPIs)	7.3%
4	Protonix 40 mg tablet	90	Wyeth	Ulcer Drugs (PPIs)	3.9%
5	Lipitor 20 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.0%
6	Lipitor 10 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.0%
7	Aricept 10 mg tablet	30	Eisai	Antidementia Agents	8.8%
8	Fosamax 70 mg tablet	4	Merck	Osteoporosis Agents	2.2%
9	Norvasc 10 mg tablet	90	Pfizer	Antihypertensives (CCBs)	8.9%
10	Advair Diskus 250-50 mist	60	GlaxoSmithKline	Respiratory Agents	5.9%
11	Lipitor 40 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.0%
12	Actonel 35 mg tablet	4	Procter & Gamble	Osteoporosis Agents	8.6%
13	Norvasc 5 mg tablet	90	Pfizer	Antihypertensives (CCBs)	8.9%
14	Celebrex 200 mg capsule	100	Pfizer	Anti-Inflammatory Agents	10.7%
15	Namenda 10 mg tablet	60	Forest	Antidementia Agents	8.4%
16	Singulair 10 mg tablet	30	Merck	Respiratory Agents	7.0%
17	Flomax 0.4 mg capsule	100	Boehringer Ingelheim	Prostatic Hypertrophy Agents	19.1%
18	Zetia 10 mg tablet	30	Merck/Schering-Plough	Cholesterol Agents (HMG CoA)	8.8%
19	Lexapro 10 mg tablet	100	Forest	Antidepressants (SSRIs)	6.9%
20	Lantus 100/ml inj	10	Sanofi-Aventis	Antidiabetics (Insulins)	14.9%
21	Zocor 20 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	0.0%
22	Ambien 10 mg tablet	100	Sanofi-Aventis	Sedatives	3.0%
23	Seroquel 200 mg tablet	100	AstraZeneca	Antipsychotics	12.2%
24	Zocor 40 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	0.0%
25	Avandia 4 mg tablet	30	GlaxoSmithKline	Antidiabetics (Oral)	4.5%
General rate of inflation (as measured by growth in CPI-U)					3.8%

*Ranking based on prescriptions processed by the Medicare Part D plan provider during 2006.

See Appendix B for explanation of therapeutic category acronyms.

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).

- Boehringer Ingelheim's Flomax 0.4 mg capsules had the highest annual percent change (19.1 percent) in manufacturer price during 2008 among the top 25 brand name drug products with the greatest sales in 2006.
- Three of the top 25 drug products had annual changes in manufacturer price of more than three times the rate of general inflation (11.4 percent). In addition to Boehringer Ingelheim's Flomax 0.4 mg capsules, the other drug products were Sanofi-Aventis' Lantus 100 ml/inj and AstraZeneca's Seroquel 200 mg tablets.
- Merck's Zocor (20 mg and 40 mg) had no manufacturer price change in 2008. Merck's Fosamax 70 mg tablets had an increase of 2.2 percent and Sanofi-Aventis' Ambien 10 mg tablet had an increase of 3.0 percent in 2008. All four of

- Three other drugs in the top 25 brand name drug products with the greatest sales in 2006 recently faced their first generic competition: Wyeth's Protonix 40 mg tablets EC in January 2008 and Pfizer's Norvasc (5 and 10 mg tablets) in March 2007. These drug products experienced manufacturer price increases in 2008 that ranged from 3.9 percent to 8.9 percent.

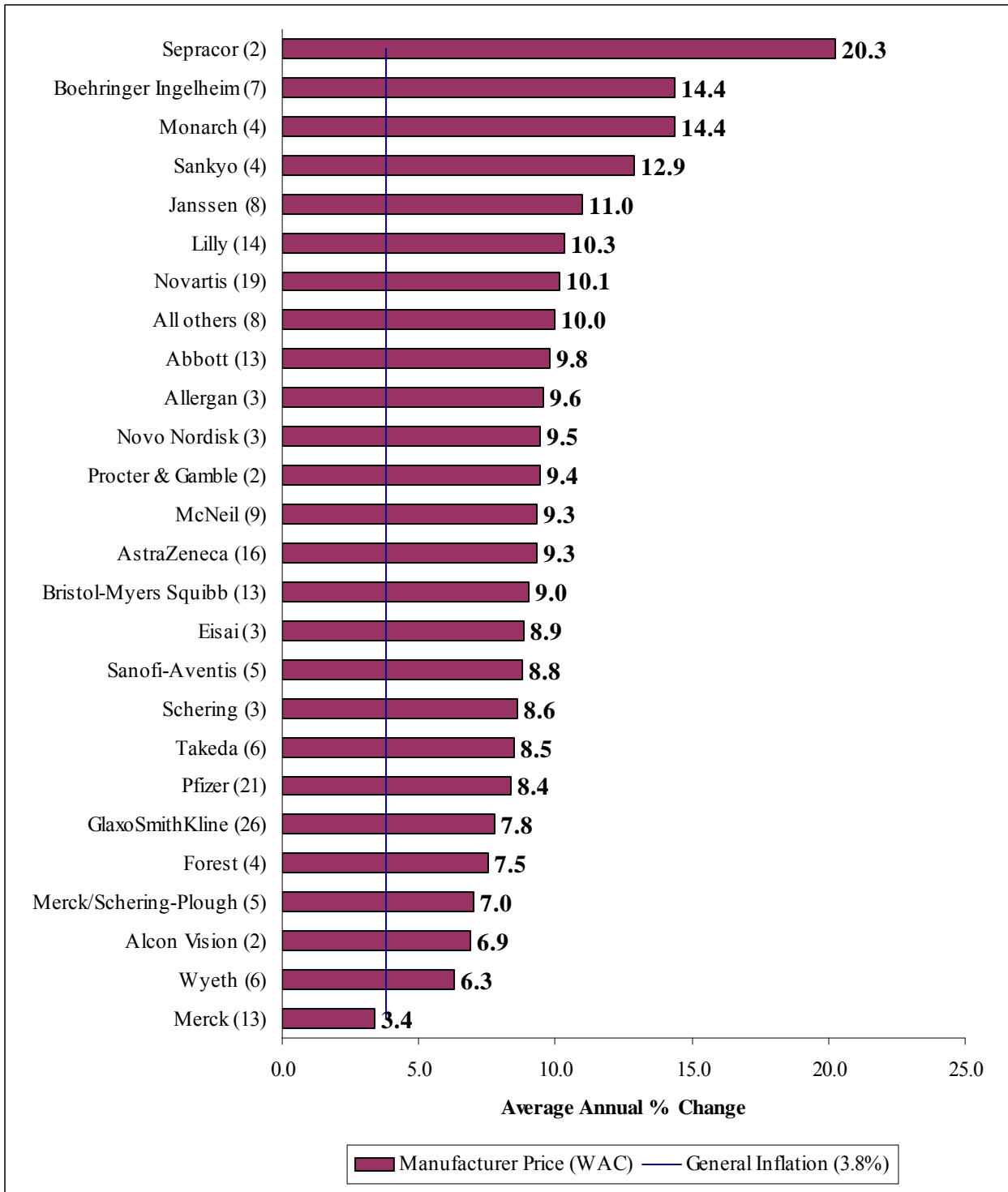
IV. Manufacturer Price Changes for Most Widely Used Brand Name Prescription Drugs by Manufacturer and by Therapeutic Category

Twenty-five drug manufacturers had at least two drug products in the study's market basket of widely used brand name drugs. The weighted average annual increase in price for all but one of the 25 drug manufacturers exceeded the rate of general inflation in 2008 (figure 8).

- Three manufacturers—Sepracor, Boehringer Ingelheim, and Monarch—had average annual price increases for the drug products in the market basket of more than three times the rate of general inflation (i.e., greater than 11.4 percent) during 2008. One manufacturer (Sepracor) had an average annual price increase of 20.3 percent, or more than five times the rate of general inflation (3.8 percent).
- Nearly all drug manufacturers (20 of 25) had weighted average annual price increases that were at least twice the rate of general inflation during 2008 (i.e., equal to or greater than 7.6 percent or two times 3.8 percent).
- The lowest average price increase was for Merck. The average 2008 price increases for this manufacturer was 3.4 percent, slightly lower than the rate of general inflation. Notably, over one-half of the drug products in the market basket that are manufactured by Merck have gone off-patent since 2006.

¹⁴ U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *First Time Generic Drug Approvals*, at www.fda.gov/cder/ogd/approvals/default.htm.

Figure 8: All But One Drug Manufacturer Increased Their Prices for Widely Used Brand Name Drugs by More Than the Rate of General Inflation in 2008



Average increase for “Pfizer” excludes Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008.

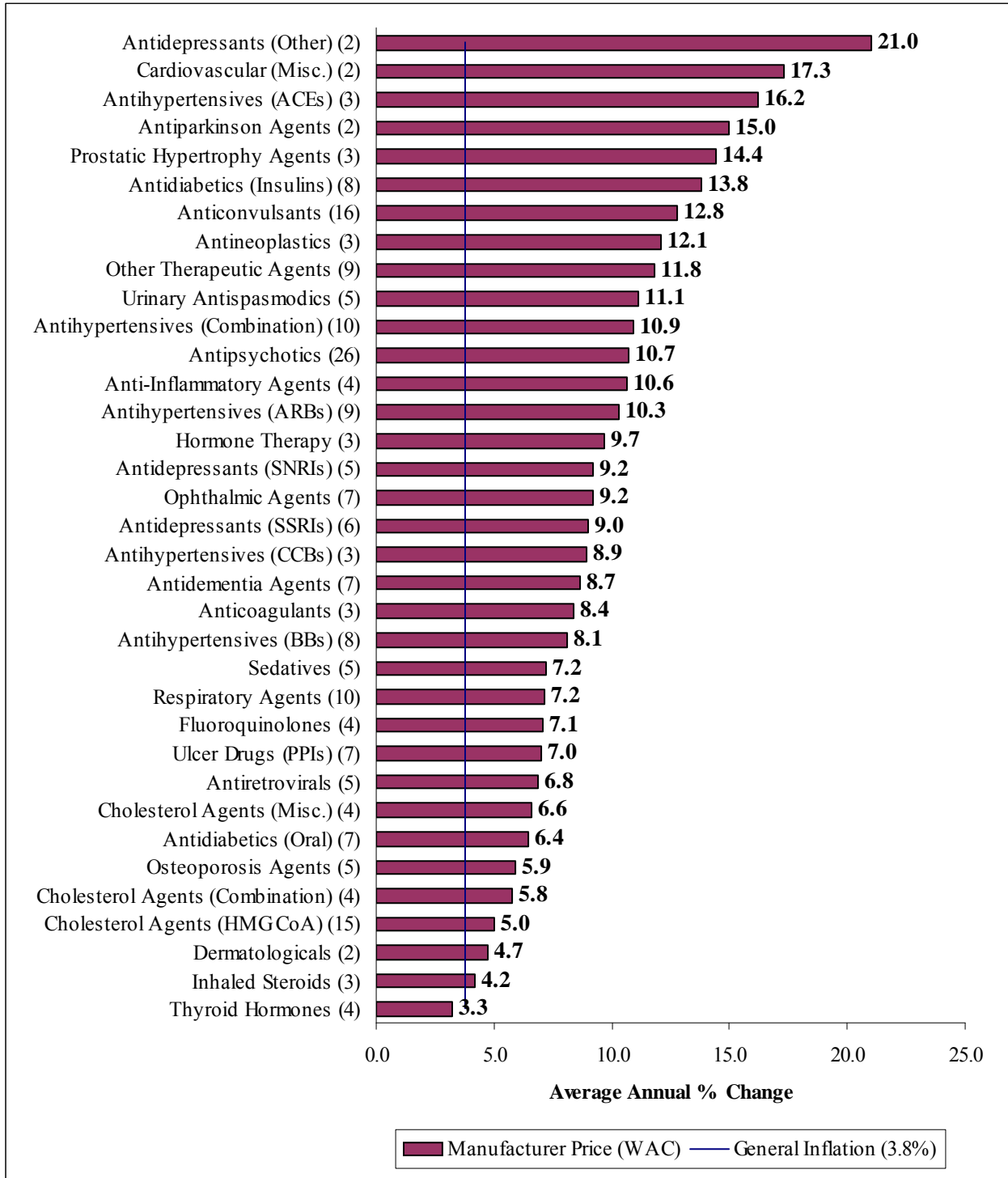
Manufacturers with fewer than two drug products in the 2006 market basket of most widely used brand name prescription drugs are included in the “All Others” category. The number in parentheses after a manufacturer’s name indicates the number of drug products in the market basket for that manufacturer. 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

All but one of the 35 therapeutic categories of brand name drug products had average annual manufacturer price increases that met or exceeded the rate of general inflation (3.8 percent) in 2008 (figure 9).

- The therapeutic category with the highest manufacturer price increase—antidepressants (other)—had an average annual manufacturer price increase of 21.0 percent in 2008—more than five and one-half times the rate of general inflation in 2008. Three therapeutic categories, including the antidepressants (other) category, had average annual price increases of more than four times the rate of general inflation (i.e., more than 15.2 percent per year).
- Twenty-two of the 35 therapeutic categories had average annual manufacturer price increases that exceeded twice the general inflation rate during 2008 (i.e., greater than 7.6 percent).
- Only one therapeutic category—thyroid hormones—had an average price increase of less than the rate of general inflation in 2008. Manufacturer prices for anticoagulants increased 3.3 percent, on average, in 2008.

Figure 9: All But One Therapeutic Category Had Manufacturer Price Increases That Exceeded the Rate of General Inflation in 2008



Average increase for “Antihistamines (Non-Sedating)” is no longer provided due to the removal of Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008. The other drug in the therapeutic category, Clarinex 5 mg tablets, was moved to the “Other Therapeutic Agents” category.

See Appendix B for explanation of therapeutic category acronyms.

Therapeutic categories with fewer than two drug products in the 2006 market basket of most widely used brand name 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

CONCLUDING OBSERVATIONS

Manufacturer drug price increases can have a direct impact on costs borne by Medicare Part D enrollees. Manufacturer price increases result in higher prices at the pharmacy and in higher out-of-pocket costs for beneficiaries who pay a percentage of drug costs rather than a fixed copayment. The effect of higher drug manufacturer prices on the total retail price also means that enrollees will get to the “donut hole”—the gap in coverage where enrollees have to pay all of their drug costs—much sooner. And once enrollees are in the donut hole, they directly absorb the entire effect of the higher drug manufacturer prices on the retail price.

Higher drug manufacturer prices to retail pharmacies result in higher costs to drug plans, unless plans are able to negotiate higher rebates from drug manufacturers to account for these costs or lower prices from pharmacies (thereby forcing the pharmacies to absorb the cost of the manufacturer’s price increase). Higher costs to plans likely result in reduced benefits and/or higher premiums to enrollees.

Drug manufacturers have substantially raised prices of brand name prescription drug products that Medicare beneficiaries use since the implementation of the Medicare drug benefit. Average annual increases in manufacturer prices charged to wholesalers (and other direct purchasers) for the 219 most widely used brand name prescription drugs continued to substantially exceed the rate of general inflation. The average annual increase in 2008 (8.7 percent) was substantially higher than the rates of increase for manufacturer prices in the prior six years, which ranged between 5.3 percent and 7.4 percent during the years 2002 to 2007.

The cumulative effect of these manufacturer price increases can be substantial. On average, manufacturer prices of the 168 most widely used prescription drug products that have been on the market since the end of 2001 have increased by 63.8 percent during the subsequent seven-year period (2002 through 2008), compared with a general inflation rate of 19.2 percent. For a consumer who takes three brand name prescriptions on a chronic basis, the average increase in the cost of therapy for the drug products used to treat chronic conditions rose by almost \$2,100 during this seven-year period.

All but 7 of the 219 brand name prescription drug products in the study’s market basket had manufacturer price increases during 2008. Nearly all (93 percent) of these increases exceeded the rate of general inflation during the year. Average annual drug manufacturer price increases in 2008 exceeded the rate of general inflation for all but one of the manufacturers with at least two drug products in the market basket, and for all but one therapeutic category.

APPENDIX A: BRIEF METHODOLOGY

The list of 219 brand name 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.¹⁵ 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 during 2006. Each drug product represents a unique combination of active chemical ingredient, strength, dosage form, package size, and manufacturer (for example, Prevacid (lansoprazole) 30 mg, delayed-release capsule, bottle of 100, Takeda Pharmaceuticals).

Products are identified by a unique 11-digit National Drug Code (NDC) identifier. In this analysis, when a manufacturer discontinues a NDC code for a particular product but assigns a new NDC to a product with the same chemical ingredient, strength, dosage form, and similar or identical package size as the product with the discontinued NDC, the products are considered the same for the purposes of tracking price per unit (i.e., tablet, capsules, etc.). Products are included in the analysis only for the time period that they were on the market.

Although the market basket of drugs studied was constructed using data from a Medicare Part D plan provider for 2006, the price changes by drug manufacturers were measured using Wholesale Acquisition Cost (WAC) data published in the Medi-Span Price-Chek PC database.¹⁶ According to Medi-Span, the WAC represents “the reported cost at which wholesalers purchase drug products from a manufacturer and is provided by the manufacturer. WAC may not represent *actual* acquisition cost as wholesalers may obtain discounts through volume purchases or special deals.” WAC is a publicly available price that is the closest published price to the actual transaction price between a manufacturer and the wholesaler or other direct purchaser of a drug product. Although drug wholesalers may receive “discounts or special deals” for some drug purchases, the wholesaler’s price to the retail class of trade is typically based on, or is a function of, WAC.¹⁷ Therefore, a change in WAC generally results in a similar percent change in price to most prescription purchasers, including “cash pay” customers as well as private and public third-party programs such as Medicare Part D drug plans and Medicare Part D enrollees in the coverage gap.

This report calculates average drug price changes in the following ways:

¹⁵ Although the original sample contained 220 brand name prescription drugs, Zyrtec 10 mg tablets went over-the-counter in January 2008. As a result, only 219 drugs are analyzed for any period that includes January 2008 or subsequent months.

¹⁶ Price-Chek PC is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health, Inc., and is based on data from the Master Drug Database (MDDB®).

¹⁷ Wholesalers often receive prompt pay discounts, but these discounts typically are not passed on to their customers.

- The 12-month *rolling average* percent price change is calculated by taking the average of the point-to-point changes over the preceding 12 months. Thus, for example, the average annual price changes for 2008 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2008 through December 2008 compared with the same months in the previous year.
- The annual *point-to-point* percent change in 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 2008 vs. January 2007, February 2008 vs. February 2007).

When aggregate estimates of price or change in drug prices were calculated for this study, each drug product's value was weighted by the 2006 sales for a Medicare Part D plan provider. The Medicare Part D plan provider weights were used as a proxy for average drug use for all Medicare beneficiaries.

To assess the impact of price changes on dollars spent, an annual cost of therapy was calculated for each drug product. This analysis excludes the eight products in the sample that are used primarily for treatment of acute conditions and typically taken for a limited period of time. The amount of a drug that an average adult person would take on a daily basis was determined using the "usual daily dose" reported in the Medi-Span Price-Chek PC database or, when this information was not available from Medi-Span, using dosing information in the U.S. Food and Drug Administration (FDA)-approved labeling for the drug product.

Analyses of manufacturer price changes are presented by drug manufacturer and by therapeutic category. The analysis of drug manufacturers reported separately on the 25 manufacturers with at least two drug products, accounting for 211 of the drug products among the 219 most widely used brand name drugs. Eight additional drug products from eight drug firms with one drug product per firm were grouped together in an "All Others" category, resulting in a total of 26 reported drug manufacturer categories. There were 34 therapeutic categories, each containing two or more drug products from the market basket, which together accounted for 211 of the total 219 drug products in the market basket. The remaining eight drug products with other therapeutic uses were grouped together in an "Other Therapeutic Agents" category, resulting in a total of 35 reported therapeutic categories.

APPENDIX B: THERAPEUTIC CATEGORY ACRONYMS

Therapeutic Category	Definition
Antidepressants (SNRIs)	SNRI – Serotonin-Norepinephrine Reuptake Inhibitors
Antihypertensives (ACEs)	ACE – Angiotensin-Converting Enzymes
Antihypertensives (ARBs)	ARB – Angiotensin II Receptor Blockers
Antihypertensives (BBs)	BB – Beta Blockers
Antihypertensives (CCBs)	CCB – Calcium Channel Blockers
Cholesterol Agents (HMG CoA)	HMG CoA – HMG CoA Reductase Inhibitors
Ulcer Drugs (PPIs)	PPI – Proton Pump Inhibitors

RX WATCHDOG REPORT: TRENDS IN MANUFACTURER PRICES OF GENERIC PRESCRIPTION DRUGS USED BY MEDICARE BENEFICIARIES 2008 YEAR-END UPDATE

AARP's Public Policy Institute finds that manufacturer prices for generic drugs fell on average in 2008; this is consistent with the pattern that we have seen since initiating our ongoing series of studies on prescription drug prices in 2004.¹ In 2008, the average annual rate of change in manufacturer prices² charged to wholesalers and other direct purchasers for 185 generic prescription drugs widely used by Medicare beneficiaries fell by 10.6 percent. The general inflation rate, according to the Consumer Price Index for all items,³ was 3.8 percent during the same 12-month period.

Generic drugs have long been a means of helping consumers and third-party payers reduce prescription drug costs.⁴ Generic drugs account for about two-thirds of all retail prescriptions in the United States, but because they are priced substantially below their therapeutically equivalent brand name counterparts, they account for a much smaller dollar share (about 20 percent) of U.S. retail prescription drug purchases.⁵ The availability of lower-cost generic drugs is particularly important in view of rapid health care cost increases of recent years, a substantial share of which is attributed to prescription drugs.

This report presents the results of an analysis of changes in manufacturers' prices set for drugs sold to wholesalers and other direct purchasers for the generic prescription drugs most widely used by Medicare beneficiaries. These price changes represent changes in manufacturers' *list prices* for generic drugs, which can affect the level of payment by

¹ Previous reports from this series can be found on the AARP Web site at www.aarp.org/research/health/drugs/rx_watchdog.html.

² The manufacturer price tracked and analyzed for this report was the wholesale acquisition cost (WAC), which is a list price reported by the manufacturer and used by manufacturers on their invoices to wholesalers or other direct purchasers. The actual net transaction price from the manufacturer to the wholesaler or other direct purchaser may be less than the WAC as a result of discounts and rebates. There are no consistent, comprehensive, and publicly reported data sources for this discount and rebate information.

³ The general inflation rate, for purposes of this report, is measured by the Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) and published by Bureau of Labor Statistics series CUSR0000SA0 (CPI-U).

⁴ A generic drug is defined by the U.S. Food and Drug Administration (FDA) as a "chemical clone" that has the same active ingredients as its FDA-approved brand name counterpart and that can be expected to have the same therapeutic effect as its brand name counterpart (FDA, Center for Drug Evaluation and Research, *From Test Tube to Patient: Improving Health through Human Drugs*, September 1999). For the purposes of this analysis, a generic drug is any FDA-approved product that is therapeutically equivalent to a product marketed by the original new drug application (NDA) holder. For the most part, this includes products with an abbreviated NDA (ANDA). It also includes some products that have an NDA that was not the original NDA for the chemical entity, as well as "branded generics," that is, generic drug products that are marketed using a brand name (e.g., Levoxyl 100 mcg tablets).

⁵ Generic Pharmaceutical Industry Association, *Generic Pharmaceutical Association: Statistics*, www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm (accessed March 18, 2008).

third-party payers and consumers and which almost always link pharmacy reimbursement to list prices,⁶ but may not reflect discounts or rebates that generic drug manufacturers provide to wholesalers and other direct purchasers.⁷ As a result, the price changes reported in this study represent an upper bound of manufacturer price changes. Changes in drug manufacturers' prices are measured by changes in the wholesale acquisition cost (WAC) published in the Medi-Span Price-Chek PC database.⁸

This report presents annual and six-year cumulative price changes through the end of 2008, using both rolling average and point-to-point estimates (see methodological appendix).⁹ The first set of findings shows *annual* rates of change in manufacturers' prices for widely used generic drugs from 2003 through 2008, 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 price changes by manufacturer and by therapeutic category. The second set of findings summarizes the *cumulative* impact of manufacturer drug price changes that have taken place during the six-year period from 2003 through 2008.

⁶ U.S House of Representatives, Committee on Oversight and Government Reform, Majority Staff, *Private Medicare Drug Plans: High Expenses and Low Rebates Increase the Costs of Medicare Drug Coverage*, October 2007, ii, 15. This congressional report found that "In almost all cases, the private (Part D plan) insurers use pricing formulas that pay pharmacies the drug manufacturers' full list prices minus a fixed percentage and a small dispensing fee. These formulas have resulted in drug prices that are generally no lower than those already available through discount pharmacies and on-line drugstores, while leaving beneficiaries and taxpayers vulnerable to repeated increases in list prices by the drug manufacturers... With only two exceptions, the Part D insurers established drug pricing formulas that pay pharmacies the manufacturers' published 'Average Wholesale Prices,' which are the manufacturers' list prices, minus a fixed percentage (on average 15%), plus a small dispensing fee (on average \$2.10 per prescription)." The report goes on to say, "One consequence of these pricing formulas is that increases in manufacturer list prices are passed through to beneficiaries."

⁷ *Ibid.* The congressional report found that "When the Part D insurers obtain rebates, however, they do not pass them through to beneficiaries by reducing drug prices in coverage gaps like the 'donut hole.'"

⁸ 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, www.medispan.com.) "WAC represents the catalog price, as reported to Medi-Span by a manufacturer, at which wholesalers may purchase drug products from that manufacturer." (Wolters Kluwer Health AWP Policy, August 23, 2007, www.medispan.com/marketing/Common/PDF/Marketing/WKH_AWP_Policy.pdf)

⁹ A brief description of the methodology used to produce these findings is provided in the methodological appendix. For a more detailed description of the methodology for the baseline study, including the rolling average approach, see Appendix A in D. Gross, S. Schondelmeyer, and L. Purvis, *Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007*, AARP Public Policy Institute Research Report #2008-05 (Washington, DC: AARP), March 2008, at www.aarp.org/research/health/drugs/rx_watchdog.html.

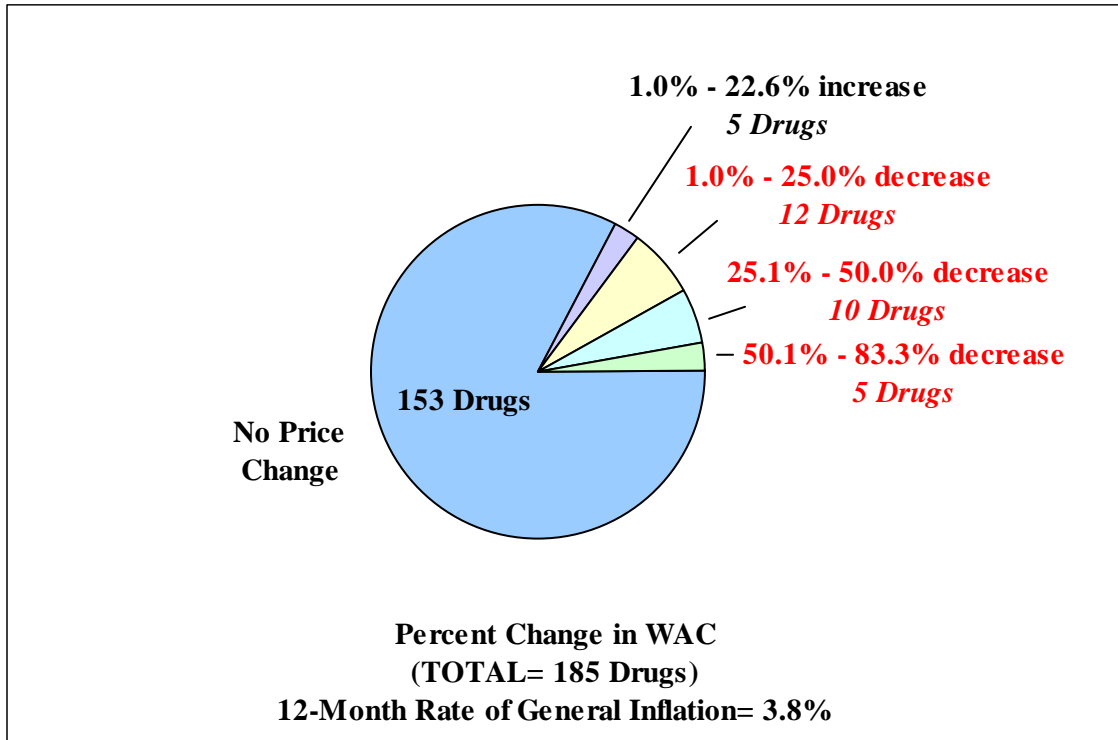
FINDINGS

I. Manufacturer Price Changes for Most Widely Used Generic Prescription Drugs in 2008

Distribution of manufacturer price changes

Although manufacturer prices of generic drugs decreased *on average* in 2008, most generic drugs—153 (82.7 percent) of the 185 generic drugs in the market basket—had no change in price during the year. However, some of the changes in price in 2008 were quite substantial, and most—but not all—of these changes were *decreases* in price (see figure 1).

Figure 1: The Vast Majority of Most Widely Used Generic Prescription Drugs Did Not Have a Manufacturer Price Change in 2008

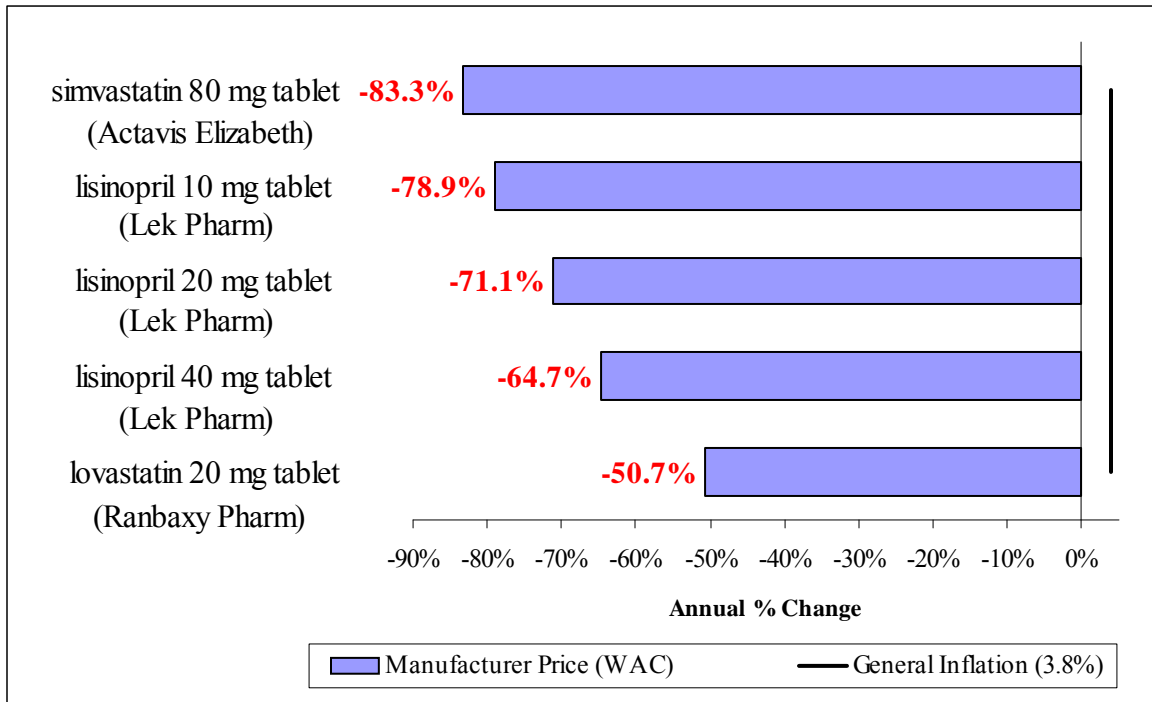


Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

- Twenty-seven (14.6 percent) of the 185 generic drug products experienced *decreases* in manufacturer price in 2008, including 12 with decreases between 1.0 percent and 25.0 percent, 10 with decreases between 25.1 percent and 50.0 percent, and 5 with decreases of more than 50.1 percent.
- Five (2.7 percent) of the 185 drug products experienced *increases* in manufacturer price in 2008. Four generic drug products had increases of at least three times the rate of general inflation; these changes ranged from 12.3 percent to 22.6 percent.

The five generic drugs with the greatest average annual decreases in manufacturer price in 2008 are shown in figure 2. These drugs are used to treat high cholesterol (simvastatin and lovastatin) and high blood pressure (lisinopril).

Figure 2: Five Widely Used Generic Drugs Experienced Manufacturer Price Decreases of More Than 50 Percent in 2008



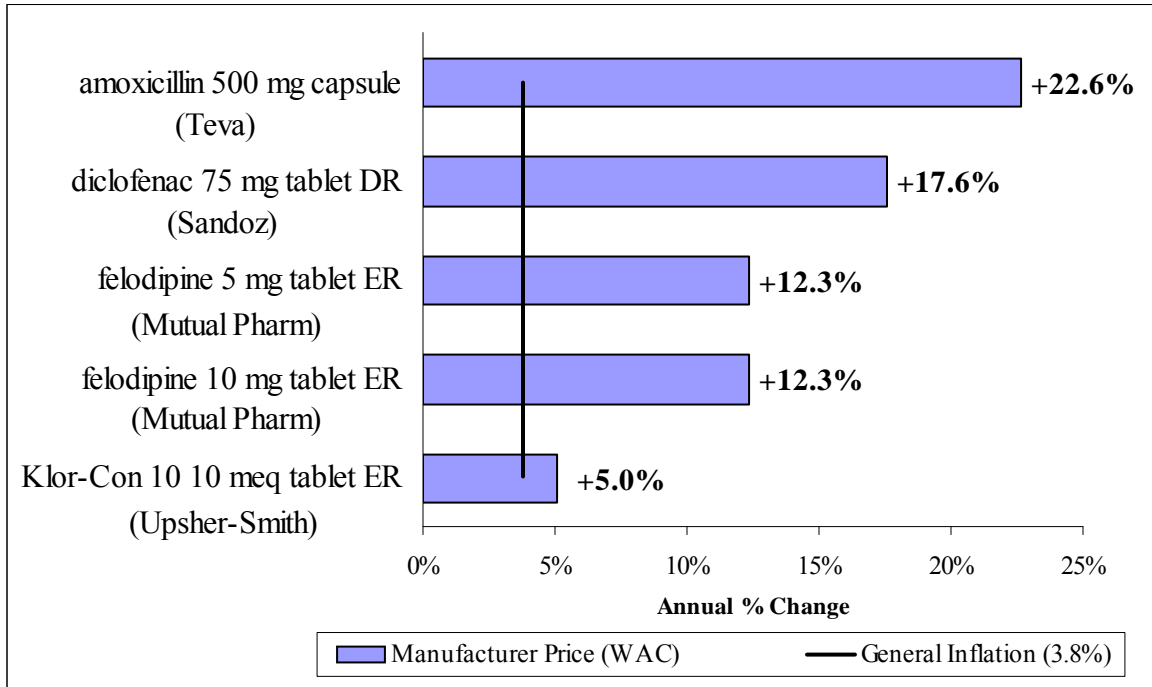
The general inflation rate is based on CPI-U.

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).

The five generic drugs with increases in manufacturer price in 2008 are shown in figure 3. These drugs are used to treat infections (amoxicillin), inflammation (diclofenac), heart disorders (felodipine), and low potassium (Klor-Con 10).

- Teva's amoxicillin 500 mg capsules experienced an annual manufacturer price increase of close to six times the rate of general inflation in 2008 (22.6 percent vs. 3.8 percent).

Figure 3: Four Widely Used Generic Drugs Had Manufacturer Price Increases of More Than Three Times the Rate of General Inflation in 2008



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).

Table 1 shows a similar trend in price changes among the 25 generic drug products with the greatest sales in 2006. Fewer than one-half of these drugs (10 of 25) had price changes during 2008. Of those drugs that had changes in manufacturer price in 2008, all had decreases.

- Lek Pharmaceuticals' lisinopril 10 mg tablets had the greatest annual percent decrease (-78.9 percent) in manufacturer price in 2008 among the top 25 generic drug products with the greatest sales in 2006.
- Eight of the 10 generic drug products that had decreases in annual manufacturer price in 2008 had decreases of more than 30 percent. In fact, four of the five generic drug products with the largest price decreases in 2008 are among the top 25 generic drug products with the greatest sales in 2006.
- Sixty percent (15 of 25) of the 25 generic drug products with the greatest sales in 2006 did not experience a manufacturer price change in 2008.

Table 1: Fewer Than One-Half of the Top 25 Generic Prescription Drug Products Had Manufacturer Price Changes in 2008

Rank by Sales among Study Market Basket*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	Annual Percent Change in WAC
1	simvastatin 20 mg tablet	30	Teva	Cholesterol Agents (HMG Co-A)	-38.6%
2	simvastatin 40 mg tablet	90	Teva	Cholesterol Agents (HMG Co-A)	-38.6%
3	omeprazole 20 mg capsule	1000	Sandoz	Ulcer Drugs	-23.5%
4	metformin 500 mg tablet	100	Ivax	Antidiabetics, Oral	0.0%
5	fentanyl 100 mcg/hr patch	5	Sandoz	Analgesics, Opioid	0.0%
6	gabapentin 300 mg capsule	100	Greenstone	Anticonvulsants	0.0%
7	lisinopril 20 mg tablet	100	Lek Pharmaceuticals	Antihypertensives (ACEs)	-71.1%
8	fexofenadine 180 mg tablet	100	Teva	Antihistamines, Non-Sedating	0.0%
9	Klor-Con M 20 meq tablet ER	100	Upsher-Smith	Minerals & Electrolytes	0.0%
10	pravastatin 40 mg tablet	90	Teva	Cholesterol Agents (HMG Co-A)	0.0%
11	azithromycin 250 mg tablet	6	Greenstone	Antibiotics	0.0%
12	fentanyl 50 mcg/hr patch	5	Sandoz	Analgesics, Opioid	0.0%
13	lisinopril 40 mg tablet	100	Lek Pharmaceuticals	Antihypertensives (ACEs)	-64.7%
14	lisinopril 10 mg tablet	100	Lek Pharmaceuticals	Antihypertensives (ACEs)	-78.9%
15	megestrol acetate 40 mg/ml susp	240	Par	Antineoplastics	0.0%
16	sertraline 100 mg tablet	30	Teva	Antidepressants (SSRIs)	-45.1%
17	sertraline 50 mg tablet	30	Teva	Antidepressants (SSRIs)	-45.1%
18	gabapentin 600 mg tablet	100	Greenstone	Anticonvulsants	0.0%
19	fentanyl 75 mcg/hr patch	5	Sandoz	Analgesics, Opioid	0.0%
20	metformin 1000 mg tablet	100	Sandoz	Antidiabetics, Oral	-11.2%
21	amiodarone 200 mg tablet	60	Eon Laboratories	Other, Antiarrhythmics	0.0%
22	propoxyphene-N/APAP 100-650 tablet	500	Teva	Analgesics, Opioid Combinations	0.0%
23	lovastatin 20 mg tablet	60	Actavis Mid Atlantic/Eliz.	Cholesterol Agents (HMG Co-A)	-50.7%
24	hydrocodone/APAP 5-500 mg tablet	500	Mallinckrodt Pharm.	Analgesics, Opioid Combinations	0.0%
25	tramadol HCl 50 mg tablet	1000	Pliva	Analgesics, Opioid	0.0%
General rate of inflation (as measured by growth in CPI-U)					3.8%

*Ranking based on prescriptions processed by the top Medicare Part D plan provider during 2006.

See Appendix C for explanation of therapeutic category acronyms.

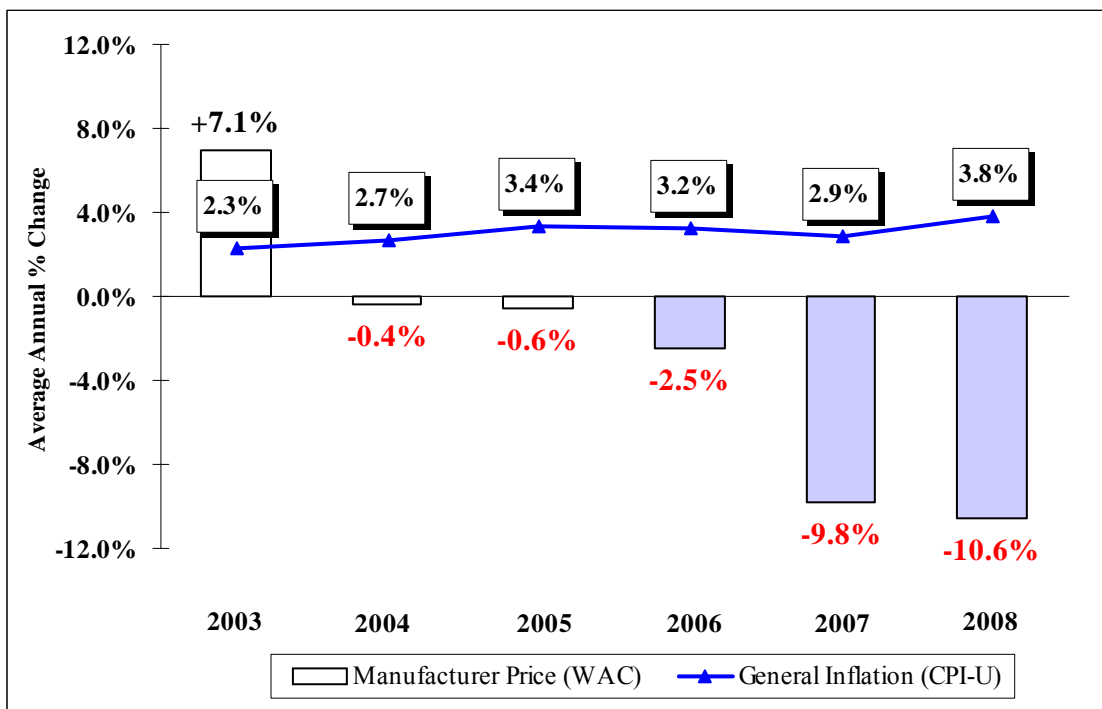
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

II. Annual Trends in Manufacturer Price Changes for Most Widely Used Generic Prescription Drugs, 2003-2008

Annual percent change in manufacturer prices

On average, manufacturer prices for the generic drug products most widely used by Medicare beneficiaries fell by 10.6 percent in 2008, when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries. This was the largest average decrease in generic drug prices for this market basket since at least 2003 (figure 4).

Figure 4: The Average Annual Percent Change in Manufacturer Prices for Most Widely Used Generic Prescription Drugs Decreased in 2008



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

Differences between the data reported here and in the previous Rx Watchdog (generic) report are due to drug products with NDCs that have gone inactive. See detailed methodology for additional details.

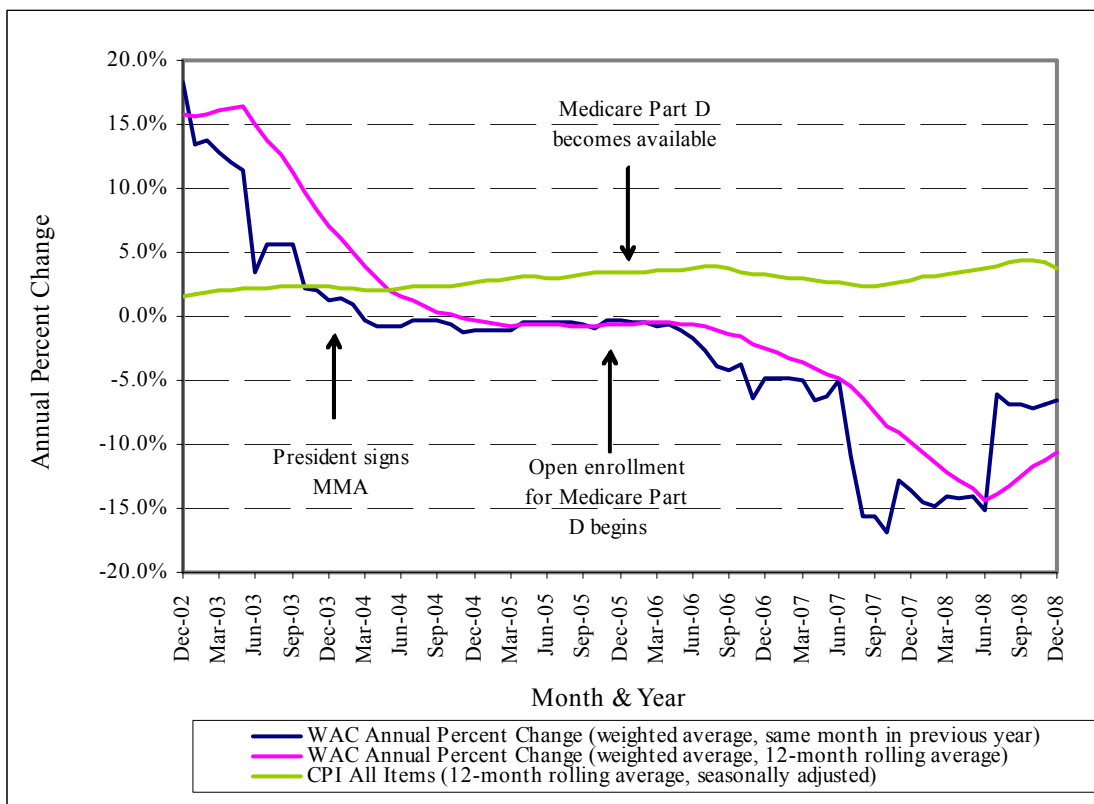
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health, Inc., March 2009).

- The average annual price changes in 2007 and 2008 (-9.8 and -10.6 percent, respectively) were substantially lower than the rates of change for manufacturer prices for generic prescription drugs in the prior four years. By contrast, the average manufacturer price for this market basket increased by 7.1 percent in 2003, and fell by only 0.4 percent in 2004, 0.6 percent in 2005, and 2.5 percent in 2006.
- Furthermore, the average annual decreases in price from 2004 through 2008 occurred during a period of increases in the rate of general inflation. The annual

rate of general inflation ranged from 2.7 percent to 3.8 percent during this five-year period.

The average annual changes in price reported in figure 4 reflect a conservative measure that, by averaging annual point-to-point price changes for each month in a 12-month period (referred to as a *rolling average* change), smoothes over the entire year the annual amount of change in manufacturer 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 has been plotted along with the 12-month rolling average to allow more detailed examination of the rate and timing of price changes over the entire study period (figure 5). Figure 5 shows that, except for a dramatic decrease in June 2007, average manufacturer prices for generic drugs have steadily declined (that is, had an average negative change in the WAC) since March 2004. Throughout the entire time the Medicare Part D prescription drug program has been in operation, the rate of change in manufacturer prices for generic drugs has been well below zero.

Figure 5: Manufacturer Prices Have Been Dropping for Most Widely Used Generic Drugs, Far Below the Rate of Inflation

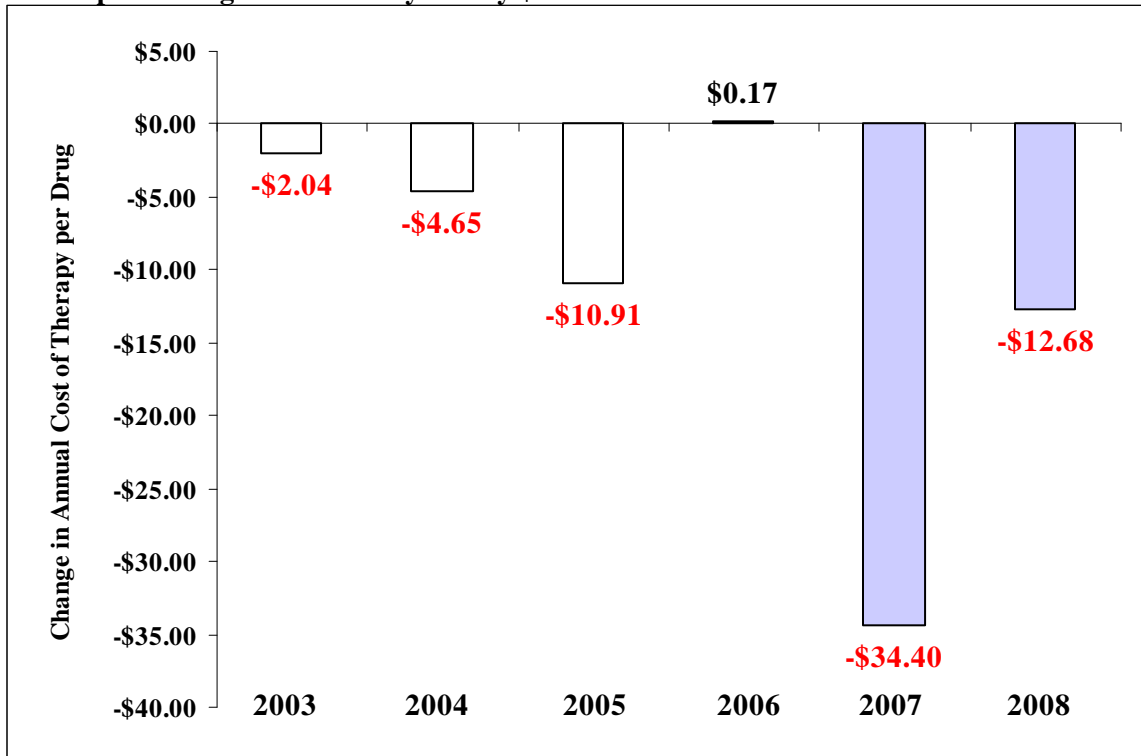


Note: MMA is the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Change in annual cost of therapy

Manufacturer price changes for the 154 most widely used generic drugs for treating chronic conditions (out of a total market basket of 185 drugs) were translated into changes in the average annual cost of therapy (figure 6).¹⁰

Figure 6: The Average Change in Annual Cost of Therapy for Most Widely Used Generic Prescription Drugs Decreased by Nearly \$13 in 2008



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

Differences between the data reported here and in the previous Rx Watchdog (generic) report are due to drug products with NDCs that have gone inactive. See detailed methodology for additional details.

Does not include 31 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

- The average annual cost of therapy decreased by nearly \$13 for each generic prescription drug in 2008, assuming that the changes in price were passed on in the form of lower prices. This decrease was substantially less than the average annual decrease in 2007, which was more than \$34.
- Decreases in the average annual cost of therapy ranged from just over \$2 per year to nearly \$11 per year between 2003 and 2005, followed by a slight increase of \$0.17 in 2006.¹¹

¹⁰ Note that the figures in this section reflect manufacturer prices and not necessarily the prices a consumer would pay at the pharmacy. In addition, they do not capture the impact of a consumer's switching from a brand name drug to a generic product once the brand name drug loses its patent.

An older American who takes three generic prescription drugs is likely to have experienced an average decrease in the annual cost of therapy of more than \$38 in 2008, assuming that the consumer uses generic drugs for chronic conditions and that the decreases in price were passed on in the form of lower prices. While the Medicare Part D plan would benefit from this reduction in cost for some beneficiaries, Medicare Part D enrollees might also benefit if their total costs move them into the “donut hole,” which is the period when beneficiaries pay 100 percent of their prescription costs.¹² One-quarter of the stand-alone Medicare Part D drug plans and one-half of the Medicare Advantage plans cover generic drugs even in the donut hole. Only 7 percent of enrollees in stand-alone Medicare Part D plans have any form of coverage in the gap. In contrast, 63 percent of Medicare Advantage plan enrollees have some form of gap coverage.¹³

III. Six-Year Cumulative Impact of Manufacturer Price Changes for Widely Used Generic Prescription Drugs, 2003-2008

Six-year cumulative percent change in manufacturer prices and annual cost of therapy

- More than two-thirds (125 of 185) of the most widely used drugs in the market basket for this analysis have been on the market for the entire six-year period from the end of 2002 to the end of 2008. Cumulatively, the average change in manufacturer prices for these 125 generic drug products was -17.9 percent, compared with +16.3 percent for general inflation.¹⁴

Seventy-five percent (94 of 125) of the generic drug products that have been on the market since the end of 2002 are used to treat chronic conditions. By the end of 2008, the average annual cost of therapy for these drug products was \$70 lower than six years earlier, assuming that manufacturers’ price decreases were passed along in the form of lower prices¹⁵ and that the consumer used these generic drugs for chronic conditions. For a consumer who takes three generic medications, this translates into an average decrease in therapy costs of \$210 between December 31, 2002, and December 31, 2008. This

¹¹ The average annual cost of therapy in 2006 was heavily influenced by some drug products that had very large increases in list price in dollar terms relative to the smaller dollar decreases in list prices of other generic drug products. Similarly, despite an average manufacturer list price *increase* of 7.1 percent in 2003, the average cost of therapy *decreased* by more than \$2. This finding was due to some drug products having very large decreases in list price in dollar terms relative to smaller dollar increases in list prices of other generic drug products.

¹² This “gap” in coverage generally begins after the beneficiary has \$2,700 (in 2009) in total drug costs and continues until the beneficiary spends \$4,350 in out-of-pocket drug costs. The Henry J. Kaiser Family Foundation, “The Medicare Prescription Drug Benefit,” Fact Sheet, March 2009. Some plans might offer some coverage in the gap and some low-income beneficiaries also have gap coverage.

¹³ The cost impact on beneficiaries is based on the continued use of the generic drug product. J. Hoadley, J. Thompson, E. Hargrave, J. Cubanski, and T. Neuman, *Medicare Part D 2009 Data Spotlight: The Coverage Gap*, (Menlo Park, CA, The Henry J. Kaiser Family Foundation, November 2008).

¹⁴ The six-year average cumulative growth rate for all drugs in the market basket was 56.3 percent. This number was calculated by compounding the average annual growth rate (as shown in figure 4) for each year from 2003 to 2008.

¹⁵ The actual amount that an individual consumer pays out-of-pocket depends on a variety of factors.

decrease in therapy cost does not capture the substantial savings a consumer receives initially by switching from a brand-name product to a generic product once the brand-name drug loses its patent. As noted earlier, the data for this study showed that, on average, generic prescriptions for Medicare beneficiaries had a price that was about 80 percent less than the price of patented brand name prescriptions.

IV. Manufacturer Price Changes for Most Widely Used Generic Prescription Drugs by Manufacturer and by Therapeutic Category, 2008

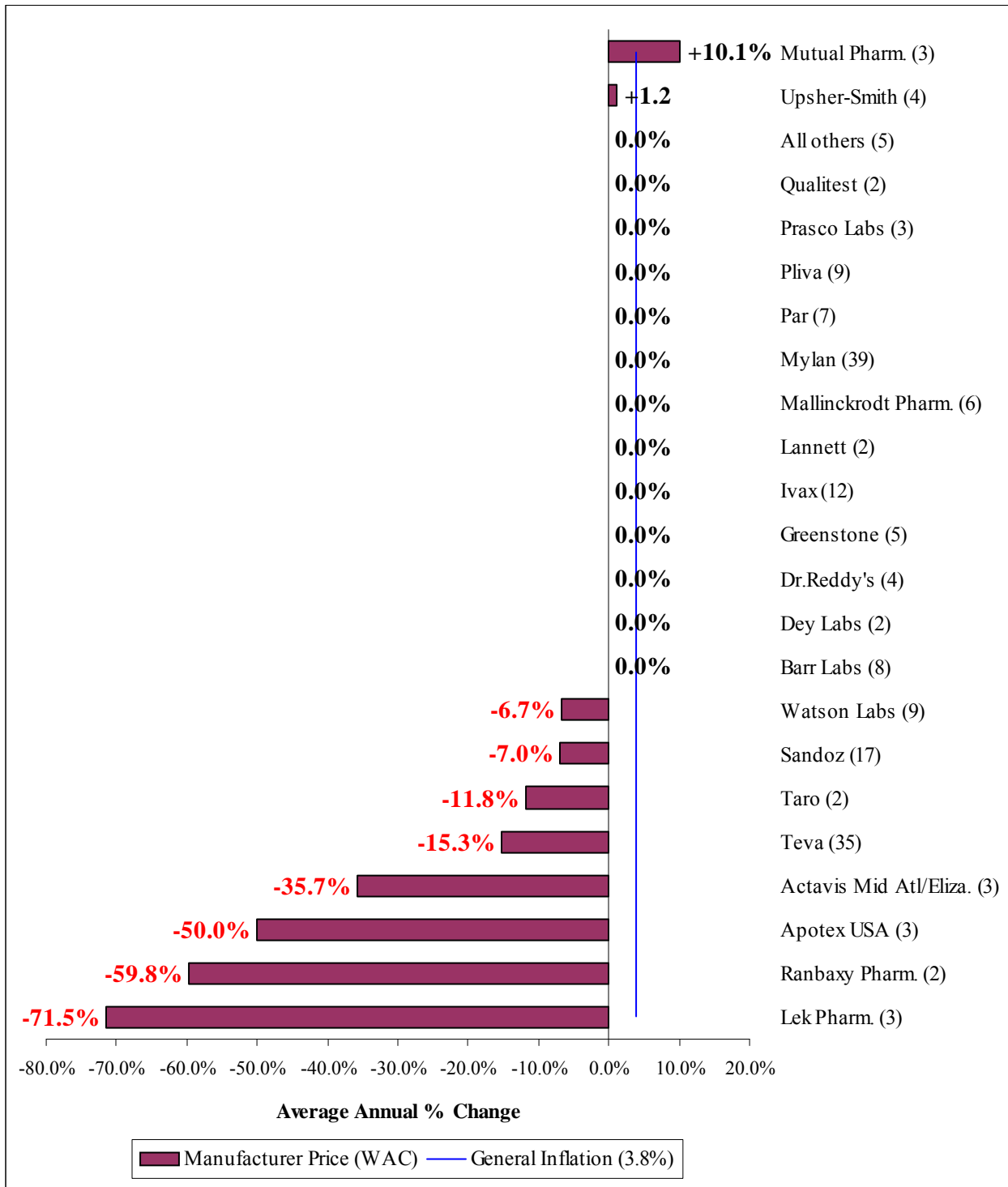
There were 22 generic drug manufacturers¹⁶ with at least two drug products (at the NDC level) among the 185 most widely used generic drugs. These 22 manufacturers supplied 180 drug products that accounted for more than 97 percent of drug sales and prescriptions dispensed among the overall market basket of 185 generic drugs. Five other drug products from five different generic drug firms with one drug product per firm were grouped together in an “All Others” category, resulting in a total of 23 reported drug manufacturer categories.

Twenty-two drug manufacturers had at least two generic drug products in the study’s market basket of widely used generic drugs. The weighted average annual change in price decreased or remained unchanged for all but two drug manufacturers in 2008 (figure 7).

- One of the two generic manufacturers with an average annual increase in prices—Mutual Pharmaceuticals—had an average annual increase in price of 10.1 percent, or more than two and one-half times the rate of general inflation (3.8 percent). The second manufacturer—Upsher-Smith—had an increase for the drug products in the market basket of 1.2 percent, or less than one-third the rate of general inflation during 2008.
- More than one-half of the drug manufacturers (13 of 23)—including the “All Others” drug manufacturer category—had no change in prices in 2008 for their generic drug products in the market basket.
- The greatest average decreases in price were for Apotex USA, Ranbaxy Pharmaceuticals, and Lek Pharmaceuticals. The average 2008 decreases in price for these generic drug manufacturers were 50.0, 59.8, and 71.5 percent, respectively.

¹⁶ A generic drug manufacturer is defined as a firm marketing the drug product under its corporate name in 2006. If a listed manufacturer is a division of another firm, its drugs are defined as being manufactured by the parent firm. This includes cases where the firm marketing a drug product may have changed over time due to mergers and acquisitions, divestitures of specific drug products, or other reasons.

Figure 7: Three Drug Manufacturers Had Average Manufacturer Price Decreases of More Than 50 Percent for Widely Used Generic Drugs in 2008



Note: Manufacturers with fewer than two drug products in the 2006 market basket of most widely used generic 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

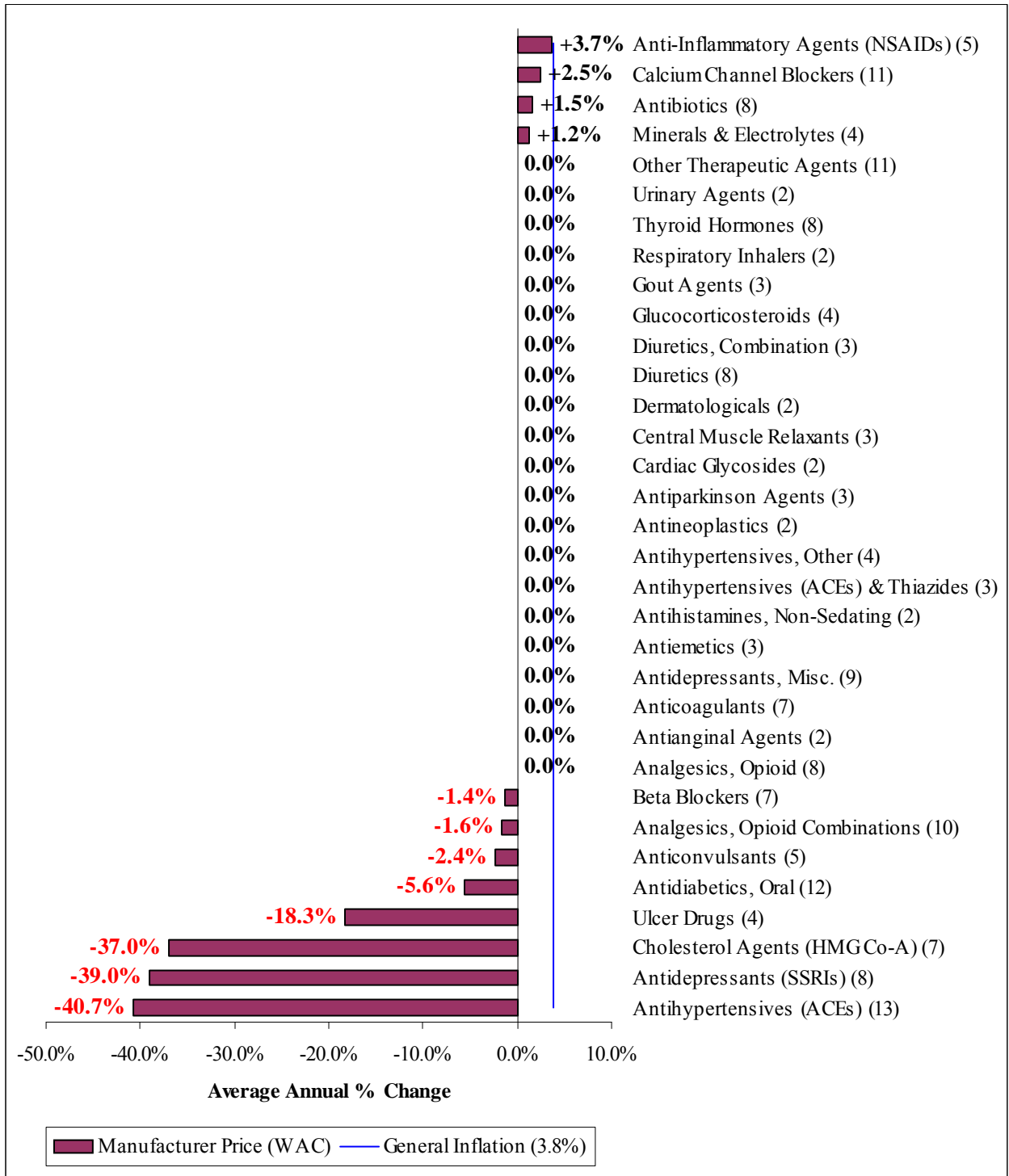
Thirty-two therapeutic categories,¹⁷ each containing two or more drug products from the market basket, together accounted for 174 of the total 185 drug products in the market basket. The remaining 11 drug products with other therapeutic uses were grouped together in an “Other Therapeutic Agents” category, resulting in a total of 33 reported therapeutic categories.

Four of the 33 therapeutic categories of generic drug products in the market basket had increases in average manufacturer prices in 2008. However, none of these categories had price increases that exceeded the rate of general inflation (3.8 percent) during the same period (figure 8).

- Twenty-one therapeutic categories did not have any change in manufacturer reported list prices during 2008.
- Eight of the 33 therapeutic categories had decreases in average manufacturer prices during 2008.
- The four therapeutic categories with the greatest decreases—ulcer drugs, cholesterol agents (HMG Co-A), antidepressants (SSRIs), and antihypertensives (ACEs)—had average decreases in prices that ranged between 18.3 percent and 40.7 percent in 2008.

¹⁷ The therapeutic categories used in this study were assigned based on an intermediate level of the Generic Product Identifier (GPI) code that specifies the groupings of similar chemical entities, such as “Calcium Channel Blockers.” When two or more drug products at the NDC level in the market basket were in the same intermediate GPI code category, the category was reported separately in the therapeutic category analysis.

Figure 8: Eight Therapeutic Categories Had Decreases in Average Manufacturer Price in 2008



Note: See Appendix C for explanation of therapeutic category acronyms. Therapeutic categories with fewer than two drug products in the 2006 market basket of most widely used generic 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

CONCLUDING OBSERVATIONS

The findings of this report show that the manufacturer prices of a majority of the generic drug products in the market basket do not change. However, when list price changes do occur, they usually decrease, and the decreases can be quite substantial.

Manufacturer drug price changes can have a direct impact on costs borne by Medicare Part D plans and enrollees. Lower-cost generic drugs help consumers and third-party payers reduce their prescription drug costs, particularly when prices remain stable or are decreasing. The availability of these therapeutically equivalent substitutes is especially important in view of the rapid health care cost increases of recent years, a substantial share of which is attributed to prescription drugs.

On average, manufacturer prices for the 185 generic drug products most widely used by Medicare beneficiaries fell by 10.6 percent in 2008. This was the largest average decrease in generic drug prices for this market basket since at least 2003.

Average annual drug manufacturer price increases in 2008 exceeded the rate of general inflation for only one of the manufacturers with at least two drug products in the market basket, and for none of the therapeutic categories.

APPENDIX A: BRIEF METHODOLOGY

The list of 185 generic name prescription drugs 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, simvastatin 20 mg tablet, bottle of 30, Teva Pharmaceuticals).

Products are identified by a unique 11-digit National Drug Code (NDC) identifier. In this analysis, when a manufacturer discontinues an NDC code for a particular product but assigns a new NDC to a product with the same chemical ingredient, strength, dosage form, and similar or identical package size as the product with the discontinued NDC, the products are considered the same for the purposes of tracking price per unit (i.e., tablet, capsules, etc.). Products are included in the analysis only for the time period when they were on the market.

Although the market basket of drugs studied was constructed using data from a Medicare Part D plan provider for 2006, the price changes by drug manufacturers were measured using Wholesale Acquisition Cost (WAC) data published in the Medi-Span Price-Chek PC database.¹ According to Medi-Span, the WAC represents “the reported cost at which wholesalers purchase drug products from a manufacturer and is provided by the manufacturer. WAC may not represent *actual* acquisition cost as wholesalers may obtain discounts through volume purchases or special deals.” WAC is a publicly available price that is the closest published price to the actual transaction price between a manufacturer and the wholesaler or other direct purchaser of a drug product. Although drug wholesalers may receive “discounts or special deals” for some drug purchases, the wholesaler’s price to the retail class of trade is typically based on, or is a function of, WAC.² Therefore, a change in WAC generally results in a similar percent change in price to most prescription purchasers, including “cash pay” customers as well as private and public third-party programs such as Medicare Part D drug plans and Medicare Part D enrollees in the coverage gap.

This report calculates average drug price changes in the following ways:

- The 12-month *rolling average* percent price change is calculated by taking the average of the point-to-point changes over the preceding 12 months. Thus, for

¹⁸ Price-Chek PC is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health, Inc., and is based on data from the Master Drug Database (MDDB®).

¹⁹ Wholesalers often receive prompt pay discounts, but these discounts typically are not passed on to their customers.

example, the average annual price changes for 2008 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2008 through December 2008 compared with the same months in the previous year.

- The *annual point-to-point* percent change in 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 2008 vs. January 2007, February 2008 vs. February 2007).

When aggregate estimates of price or change in drug prices were calculated for this study, each drug product's value was weighted by the 2006 sales for a Medicare Part D plan provider. The Medicare Part D plan provider weights were used as a proxy for average drug use for all Medicare beneficiaries.

To assess the impact of price changes on dollars spent, an annual cost of therapy was calculated for each drug product. This analysis excludes the 31 products in the sample that are used primarily for treatment of acute conditions and typically taken for a limited period. The amount of a drug that an average adult would take on a daily basis was determined using the "usual daily dose" reported in the Medi-Span Price-Chek PC database or, when this information was not available from Medi-Span, using dosing information in the U.S. Food and Drug Administration (FDA)-approved labeling for the drug product.

Analyses of manufacturer price changes are presented by drug manufacturer and by therapeutic category. The analysis of drug manufacturers reported separately on the 22 manufacturers with at least two drug products, accounting for 180 of the drug products among the 185 most widely used generic drugs. Five other drug products from five drug firms with one drug product per firm were grouped together in an "All Others" category, resulting in a total of 23 reported drug manufacturer categories. There were 32 therapeutic categories, each containing two or more drug products from the market basket, which together accounted for 174 of the total 185 drug products in the market basket. The remaining 11 drug products with other therapeutic uses were grouped together in an "Other Therapeutic Agents" category, resulting in a total of 33 reported therapeutic categories.

APPENDIX B: STUDY METHODS AND LIMITATIONS

A detailed description of the study methods and data limitations is presented 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*. The price changes for generic prescription drugs have been analyzed and reported separately from price changes for brand name and specialty drugs because generic drugs are subject to different market dynamics, pricing, and related behaviors. Appendix A to the AARP Public Policy Institute's May 2008 report, "Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries, 2003 to 2007" provides an overview of the market dynamics for generic drug products.

The analysis of manufacturer price changes for generic drug products in this particular study is limited because of the lack of publicly available data that capture all of the discounts and rebates that generic drug manufacturers sometimes provide to wholesalers and other direct purchasers. These discounts and rebates can be quite substantial for generic drug products, such that increases in manufacturer list prices may overstate increases in net transaction prices, or no change in manufacturer prices may mask decreases in generic drug product prices. As a result, the findings presented here represent an *upper bound* of net transaction price increases by generic drug manufacturers.

Furthermore, the manufacturer price for generic drugs often represents a smaller component of the retail prescription price than does the manufacturer price for brand name drugs. Therefore, consumers may have experienced changes in retail prescription prices for generic drug products that differ from the patterns and trends reported here.

APPENDIX C: THERAPEUTIC CATEGORY ACRONYMS

Therapeutic Category	Definition
Antidepressants (SSRIs)	SSRI – Selective-Serotonin Reuptake Inhibitor
Antihypertensives (ACEs)	ACE – Angiotensin-Converting Enzyme
Cholesterol Agents (HMG Co-A)	HMG Co-A – HMG Co-A Reductase Inhibitor
Anti-Inflammatory Agents (NSAIDs)	NSAID - Non-Steroidal Anti-Inflammatory Drug

RX WATCHDOG REPORT: TRENDS IN MANUFACTURER PRICES OF SPECIALTY PRESCRIPTION DRUGS USED BY MEDICARE BENEFICIARIES 2008 YEAR-END UPDATE

AARP's Public Policy Institute finds that price increases for specialty drugs have continued to far outstrip price increases for other consumer goods and services in 2008. In 2008, the average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for 144 brand and generic specialty prescription drugs widely used by Medicare Part D beneficiaries was 9.3 percent, or almost two and one-half times the general inflation rate of 3.8 percent. In contrast, brand name non-specialty drugs widely used by Medicare beneficiaries experienced an 8.7 percent increase in 2008, and generic non-specialty drugs widely used by Medicare beneficiaries experienced a 10.6 percent decrease. Especially notable is the even steeper price increases among specialty prescription drugs during the first three years of the Medicare Part D program, which covers drugs 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.¹ They are expected to be the fastest growing group of drug products in the decade ahead.²

Specialty drug products often flow through different channels of distribution than typical outpatient drugs (i.e., directly from the manufacturer to the physician's office to the patient or, alternatively, to pharmacy benefit manager (PBM)-owned specialty pharmacies), and many of them are initiated and administered by specialist physicians in clinics or hospitals. This report focuses on changes in the prices that drug manufacturers charge direct purchasers such as physicians' offices, clinics, hospitals, or specialty pharmacies. The manufacturer's charge for the drug product itself is the most substantial component of the total cost to the consumer for a specialty drug. Data in this report do not include drug rebates that Part D plans may be able to negotiate with manufacturers—such rebates are typically confidential and are not usually passed on to the Medicare beneficiary.³ However, because we examine trends over time, the lack of rebate data should not prove to be a major bias, because when manufacturers increase their price to wholesalers or other direct purchasers for a specialty drug, the added cost is generally

¹ L.E. Perry, "Specialty Pharmacy: A New Class of Trade?" *Drug Topics*, November 6, 2006.

² Express Scripts, *2007 Drug Trend Report*, April 2008.

³ U.S. House of Representatives, Committee on Oversight and Government Reform, *Medicare Part D: Drug Pricing and Manufacturer Windfalls*, July 2008.

passed on in the insurer's or consumer's cost for the specialty drug.⁴ Changes in drug manufacturers' prices are measured by changes in the wholesale acquisition cost (WAC) published in the Medi-Span Price-Chek PC database.⁵

This report presents annual and five-year cumulative price changes through the end of 2008, using both rolling average and point-to-point estimates (see methodological appendix).⁶ The first set of findings focuses on *annual* rates of change in manufacturers' prices for widely used specialty drugs from 2004 through 2008, 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 price changes by manufacturer and by therapeutic category. The second set of findings summarizes the *cumulative* impact of manufacturer drug price increases that have taken place during the five-year period from 2004 through 2008.

⁴ Rebates to Medicare Part D plans generally do not benefit retail pharmacies and are not typically passed on to the Medicare beneficiary or to cash-paying consumers (i.e., people who pay up front for their prescriptions when they are in the Medicare Part D coverage gap or who have no drug coverage or have indemnity insurance).

⁵ 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, www.medispan.com.) "WAC represents the catalog price, as reported to Medi-Span by a manufacturer, at which wholesalers may purchase drug products from that manufacturer." (Wolters Kluwer Health AWP Policy, August 23, 2007, www.medispan.com/marketing/Common/PDF/Marketing/WKH_AWP_Policy.pdf).

⁶ A brief description of the methodology used to produce these findings is provided in the methodological appendix. For a more detailed description of the methodology for the baseline study, including the rolling average approach, see Appendix A in D. Gross, S. Schondelmeyer, and L. Purvis, *Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007*, AARP Public Policy Institute Research Report #2008-05 (Washington, DC: AARP), March 2008, at www.aarp.org/research/health/drugs/rx_watchdog.html.

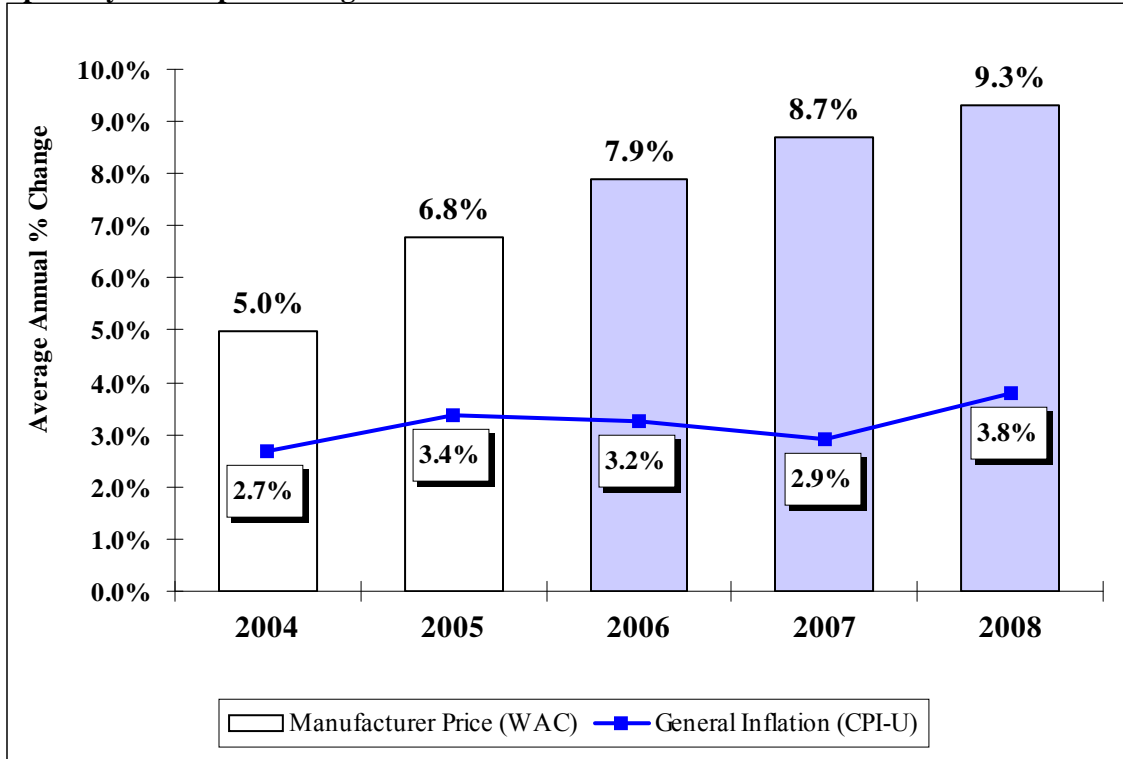
FINDINGS

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

Annual percent change in manufacturer prices

- Overall, manufacturer prices for the specialty drug products most widely used by Medicare beneficiaries have been consistently rising since the implementation of Medicare Part D. Manufacturer prices for widely used specialty drug products rose 9.3 percent in 2008, 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 Manufacturer Prices for Widely Used Specialty Prescription Drugs Continues to Grow in 2008



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

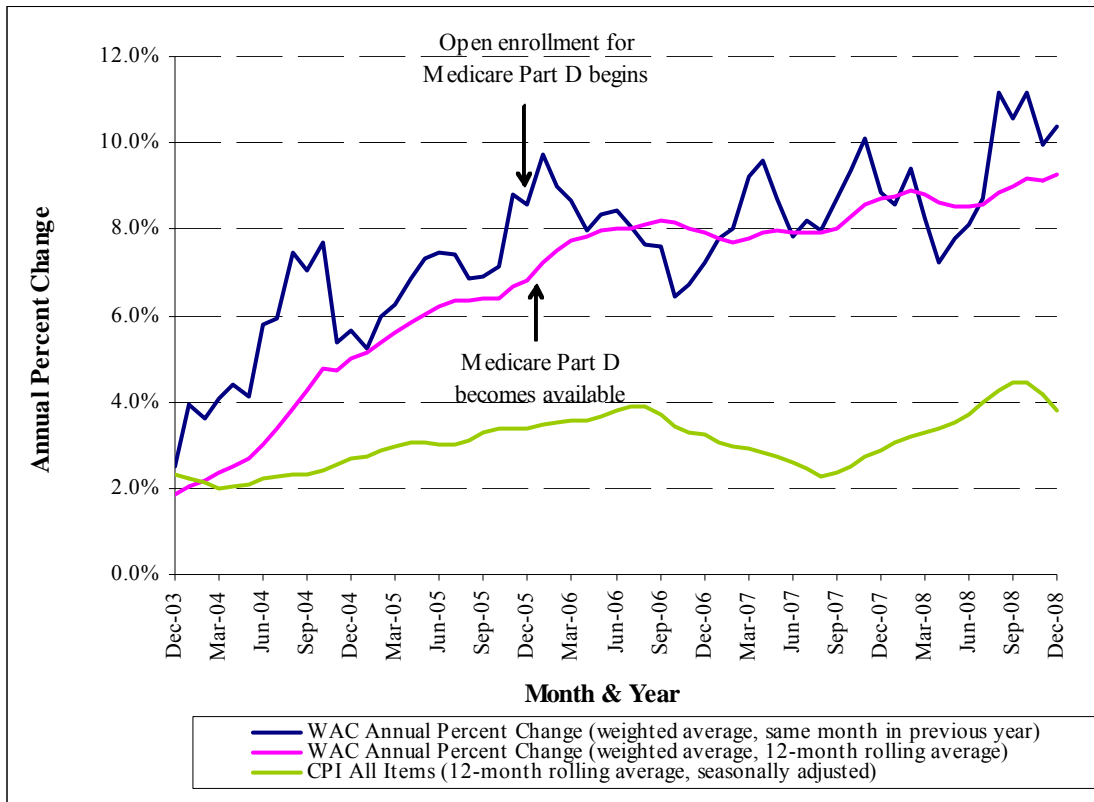
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health, Inc., March 2009).

- In contrast, manufacturer prices for the non-specialty brand name drug products most widely used by Medicare beneficiaries rose by 8.7 percent in 2008, and manufacturer prices for non-specialty generic drug products fell by 10.6 percent in the same year.
- The average annual increases since 2006, which have ranged from 7.9 percent to 9.3 percent, are substantially higher than the rates of increase for manufacturer prices in the prior two years. The average manufacturer price increase for this market basket was 5.0 percent in 2004 and 6.8 percent in 2005.
- The rate of specialty drug price increases in 2008 was almost two and one-half times the rate of general inflation (as measured by the Consumer Price Index-All Urban Consumers, or CPI-U)⁷ (9.3 percent vs. 3.8 percent); and in 2007 the rate of specialty drug price increases was three times the rate of general inflation (8.7 percent vs. 2.9 percent).

The average annual price change reported in figure 1 is a conservative measure that, by averaging annual point-to-point price changes for each month in a 12-month period (referred to as a *rolling average* change), smoothes over the entire year the annual amount of change in manufacturer 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 has been plotted along with the 12-month rolling average to allow more detailed examination of the rate and timing of price changes over the entire study period (figure 2). Figure 2 shows that both the point-to-point and the rolling average annual change in prices have consistently been increasing. Throughout the time the Medicare Part D prescription drug program has been in operation, the rate of increase in specialty drug prices has been well above (usually two-fold or more) the rate of general inflation.

⁷ 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.

Figure 2: Rolling Average and Point-to-Point Changes in Manufacturer Prices for Widely Used Specialty Prescription Drugs Consistently Increase Between 2004 and 2008



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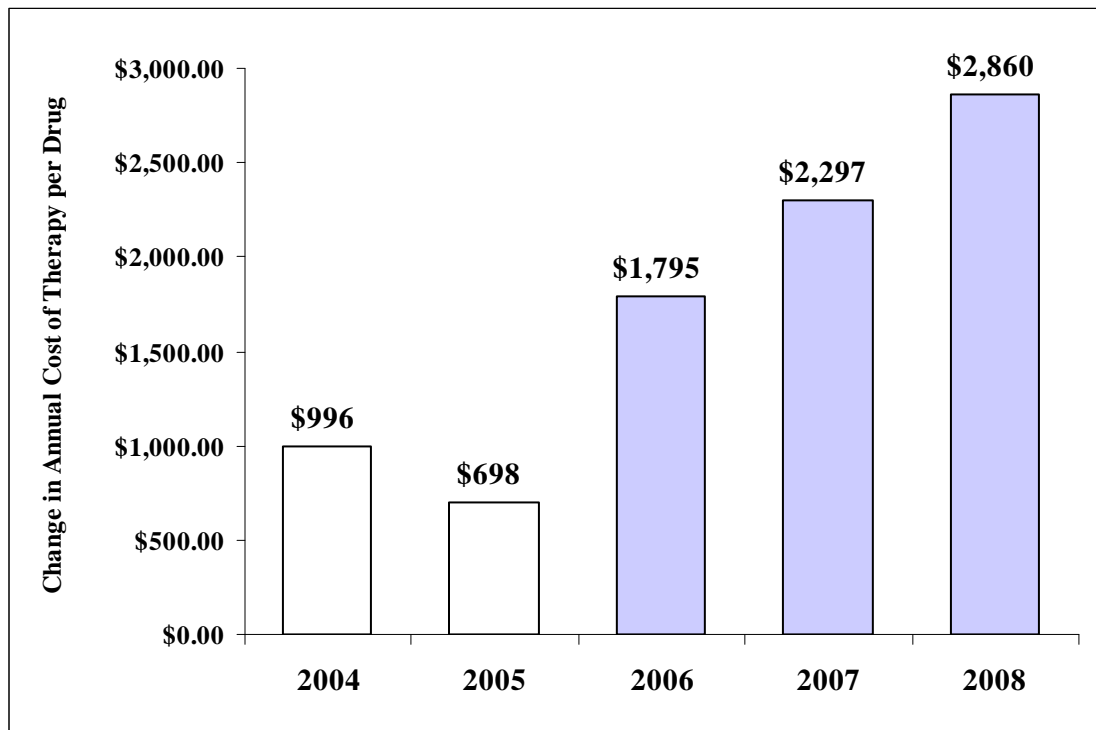
Change in annual cost of therapy

Manufacturer price increases for the 95 most widely used specialty drugs for treating chronic conditions (out of a total market basket of 144 drugs) were translated into increases in the average annual cost of therapy (figure 3).⁸

- An older American who takes a specialty prescription drug is likely to have experienced an average increase in the annual cost of therapy of \$2,860 in 2008, assuming that the consumer uses the specialty drug for a chronic condition and that the price increases were passed on in the form of higher end-payer prices. In 2006 and 2007, average increases in the annual cost of therapy were \$1,795 and \$2,297, respectively. These amounts were substantially higher than the average annual increases prior to the implementation of Medicare Part D, which had been about \$1,000 per year in 2004 and \$700 per year in 2005.

⁸ The figures in this section reflect manufacturer prices and not necessarily the prices a consumer would face at the drugstore.

Figure 3: Average Change in Annual Cost of Therapy for Most Widely Used Specialty Prescription Drugs is Over \$2,800 Per Year in 2008



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

Does not include 49 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Since most Part D plans (and many private plans) require substantial cost sharing for specialty drugs, these price increases are likely to affect consumers directly and substantially.⁹ They also could lead to a substantial increase in the number of Part D enrollees who reach the coverage gap (the period when beneficiaries are responsible for 100 percent of their prescription drug costs) and catastrophic coverage levels.¹⁰ Moreover, the relatively high prices of specialty drugs compared with other prescription drugs are likely to push beneficiaries beyond the coverage gap and into catastrophic coverage, where they are yet again responsible for a percentage of their drug costs, fairly quickly, further exposing them to price increases.

⁹ The cost impact on beneficiaries is based on continued use of the specialty drug product. Seven of the 107 brand name drug products in the specialty market basket are off-patent, making it possible for the beneficiary to save money by switching to a less expensive, therapeutically-equivalent generic drug product.

¹⁰ Under Part D, catastrophic coverage kicks in after the beneficiary has incurred \$4,350 in out-of-pocket drug costs. The Henry J. Kaiser Family Foundation, “The Medicare Prescription Drug Benefit,” Fact Sheet, March 2009. After this point, consumers pay roughly 5 percent of the cost of their prescription drugs.

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

The products in the specialty market basket were approved by the U.S. Food and Drug Administration (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. Seventy-five of the 144 drug products in the specialty drug market basket were approved under an NDA, 31 under a BLA, and 38 under an ANDA. One BLA-approved drug product, Baxter Bio-Science's Gammagard SD 10 Gm, had a large price decrease in 2005. Because this unusual price change was an extreme outlier and distorted the overall BLA trends, this drug product has been excluded from the analyses by FDA approval process.¹¹ Therefore, the BLA group used to track manufacturer prices in this section, and subsequent data reported by FDA approval process, includes 30 drug products.

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

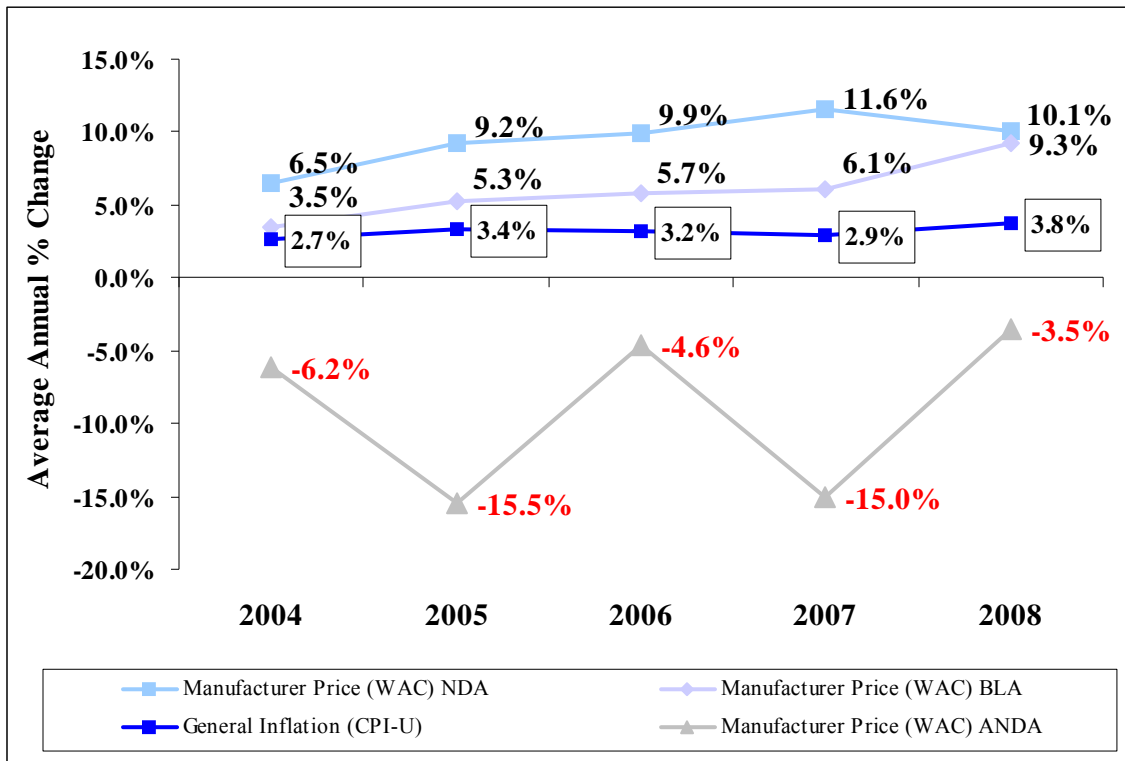
Annual percent change in manufacturer prices

- Manufacturer prices for ***NDA-approved specialty drug products*** most widely used by Medicare beneficiaries rose by an average of 10.1 percent in 2008, or more than two and one-half times the rate of general inflation (3.8 percent) when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries. In 2006 and 2007, manufacturer prices for these products rose by 9.9 percent and 11.6 percent, respectively. The increases since 2006 were substantially higher than the average increases in the two years prior to implementation of Medicare Part D (figure 4).
- Manufacturer prices for ***BLA-approved specialty drug products*** most widely used by Medicare beneficiaries increased by an average of 9.3 percent in 2008, or almost two and one-half times the rate of general inflation (3.8 percent). This increase was considerably higher than the average manufacturer price increases seen in the previous four years, which ranged from 3.1 percent to 6.5 percent. These average percentage increases, while lower than those for the NDA-approved specialty drug product group, most likely resulted in a larger change in dollar amount paid because BLA-approved specialty drug products tend to have relatively higher prices than NDA-approved specialty drug products. Further, unlike most NDA-approved specialty drugs, the FDA currently lacks the ability to approve generic equivalents for BLA-approved specialty drugs, leaving manufacturers free to continue charging the same or even higher prices.

¹¹ Gammagard SD 10 Gm is ranked number 96 in the market basket of 144 widely used specialty prescription drugs, sorted by 2006 sales in the Medicare Part D plan provider's drug plans.

- Manufacturer 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 9.8 percent in 2007 and 9.9 percent in 2008. In contrast, manufacturer prices for brand name non-specialty drug products most widely used by Medicare beneficiaries increased by an average of 7.4 percent and 8.7 percent, respectively, in those years.
- In contrast, manufacturer prices for *ANDA-approved specialty drug products* most widely used by Medicare beneficiaries have consistently *decreased* over the past five years, with average annual decreases of more than 15 percent both in 2005 (before implementation of Part D) and in 2007 (after implementation of Part D). The average annual decrease in 2008 was substantially less than the average annual decrease in 2007 (3.5 percent vs. 15.0 percent, respectively).

Figure 4: Marked Increase in Average Manufacturer Prices Among Most Widely Used BLA-Approved Specialty Prescription Drugs in 2008



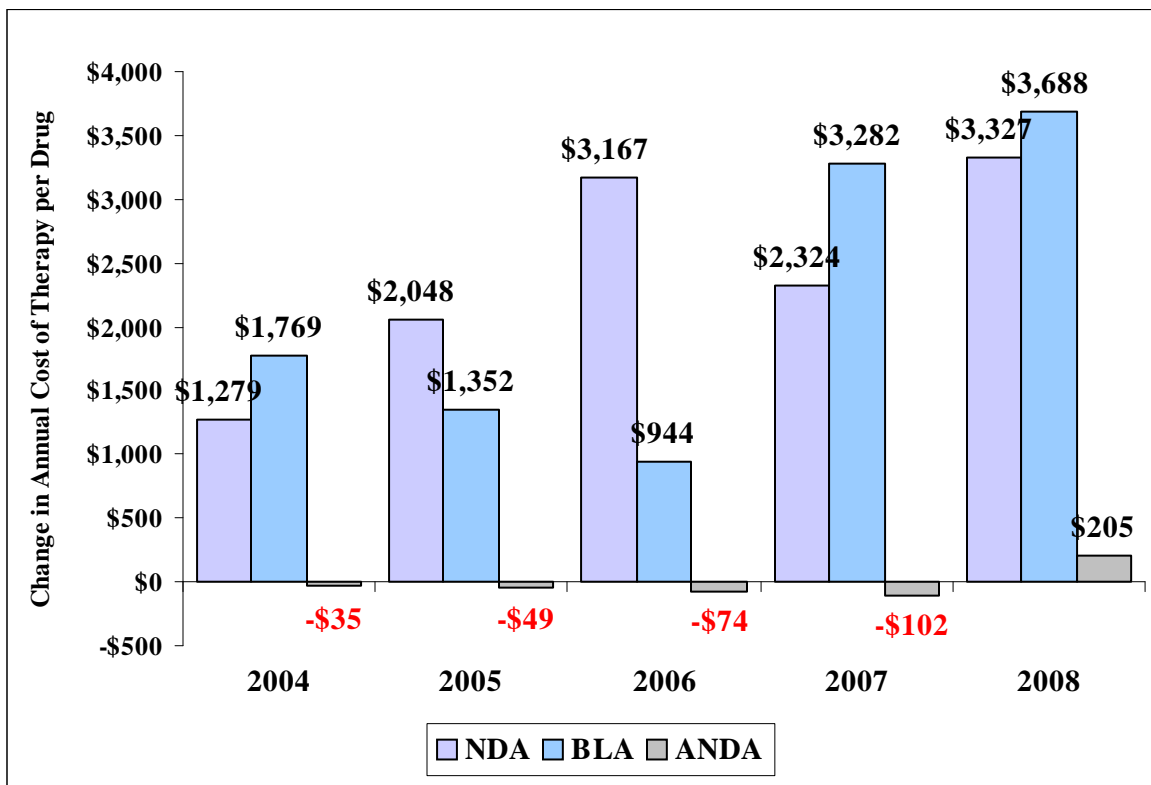
Note: BLA calculations do not include Gammagard SD 10 Gm.
 Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Change in annual cost of therapy

Manufacturer price changes for the most widely used specialty drugs for treating chronic conditions were translated into changes in the average annual cost of therapy (figure 5). Of the 94 drugs in the market basket that were used to treat chronic conditions,¹² 48 were NDAs, 29 were BLAs, and 17 were ANDAs.

- An older American who takes a **BLA-approved specialty prescription drug** is likely to have experienced an average increase in the annual cost of therapy of \$3,688 in 2008, assuming that the consumer uses the specialty drug for a chronic condition and that the price increases were passed on to the end payer in the form of higher prices. This amount is slightly higher than the average annual change in 2007 (\$3,282) and substantially higher than the average annual changes in previous years, which ranged from an increase of \$944 in 2006 to an increase of \$1,769 in 2004.

Figure 5: The Average Annual Cost of Therapy Increased for Most Widely Used NDA-, BLA-, and ANDA-Approved Specialty Prescription Drugs in 2008



Note: BLA calculations do not include Gammagard SD 10 Gm.

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).

¹² Not including Gammagard SD 10 Gm.

- The average annual cost of therapy for *NDA-approved specialty prescription drugs* increased by \$3,327. This is the highest increase in the average annual cost of therapy since at least 2004.
- The average annual cost of therapy increased by almost \$205 for the typical *ANDA-approved specialty prescription drug* in 2008, assuming that the changes in price were passed along to the end payer in the form of higher prices. This is a reversal from 2004 through 2007, when the average annual cost of therapy *decreased* between \$35 and \$102.¹³

III. Five-Year Cumulative Impact of Manufacturer Price Changes for Widely Used Specialty Prescription Drugs, 2004-2008

- More than three-fourths (112 of 144) of the most widely used drugs in the market basket for this analysis have been on the market for the entire five-year period from 2004 through 2008. Cumulatively, the average manufacturer price increase for these 112 specialty drug products was 60.2 percent, compared with 14.0 percent for general inflation—or more than four times the rate of general inflation.¹⁴
- Figure 6 illustrates the cumulative effect of manufacturer price changes between 2004 and 2008 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 (Aventis)—a blood thinner
 - Humira 50 mg/ml kit (Abbott)—used to treat inflammatory and immunological disorders
 - Procrit 40,000 U/ml injection (Ortho Biotech)—used to treat anemia
 - Forteo 250 mcg/ml solution (Lilly)—used to treat osteoporosis
- The sixth drug, heparin sodium 10,000 U/ml injection (APP Pharmaceuticals), a blood thinner, was chosen because it had the largest percent price increase in 2008

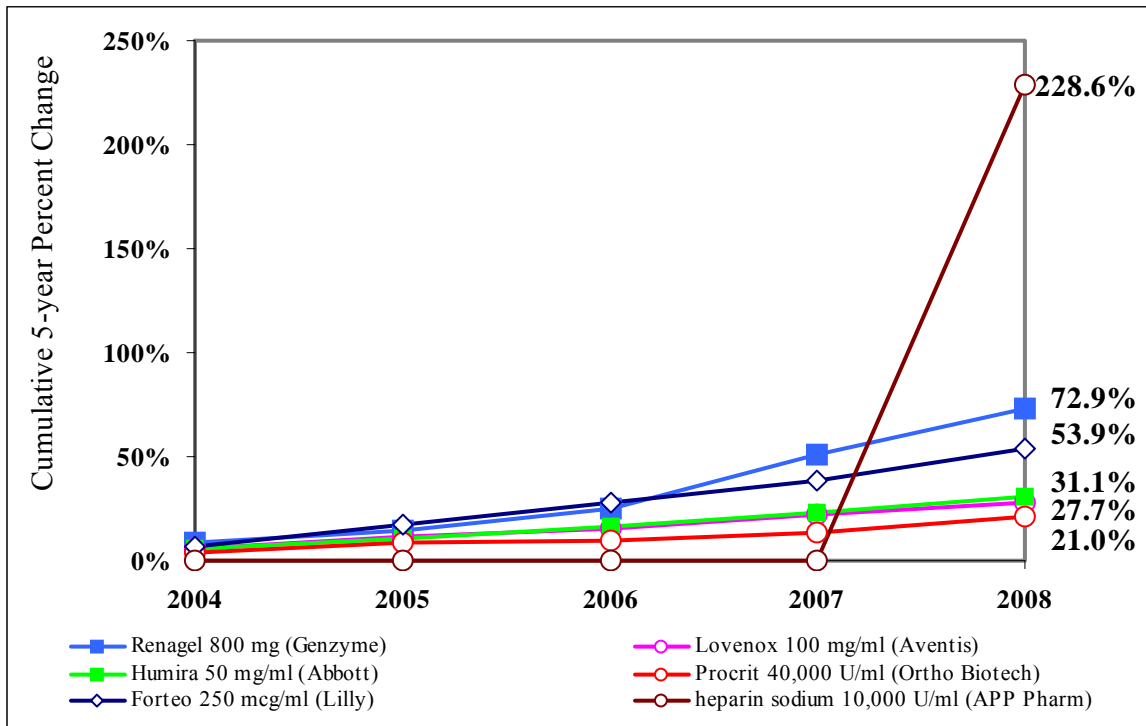
¹³ This change is mostly attributable to notable price increases in 2008 for two ANDA-approved drug products: APP Pharmaceutical's heparin sodium 10,000 U/ml injection and Ivax Pharmaceutical's cromolyn sodium 10 mg/1 ml nebulizer.

¹⁴ The five-year average cumulative growth rate for all drugs in the market basket was 69.1 percent. This number was calculated by compounding the average annual growth rate for each year from 2004 to 2008.

among all drug products in the market basket. Interestingly, heparin sodium is a generic drug yet still had the highest percentage price increase over the period.¹⁵

- The five-year (2004 to 2008) cumulative percent change in manufacturer prices for six specific drug products is shown in figure 6:
 - The manufacturer price of heparin sodium 10,000 U/ml injection did not change between 2004 and 2007, but rose 229 percent in 2008, when measured as a 12-month rolling average change. This one-year growth was more than 60 times the rate of general inflation in 2008.
 - The manufacturer price of Renagel 800 mg tablets increased cumulatively by 73 percent, and the manufacturer price of Forteo 250 mcg/ml injection increased by 54 percent over the five-year period.

Figure 6: The Five-Year Cumulative Percent Change in Manufacturer Price is Nearly 230 Percent for the Specialty Drug with the Largest Percent Price Increase in 2008



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).

¹⁵ 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-sulfated derivative of chondroitin sulfate, a shellfish-derived supplement often used for arthritis (U.S. Department of Health and Human Services, Food and 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.

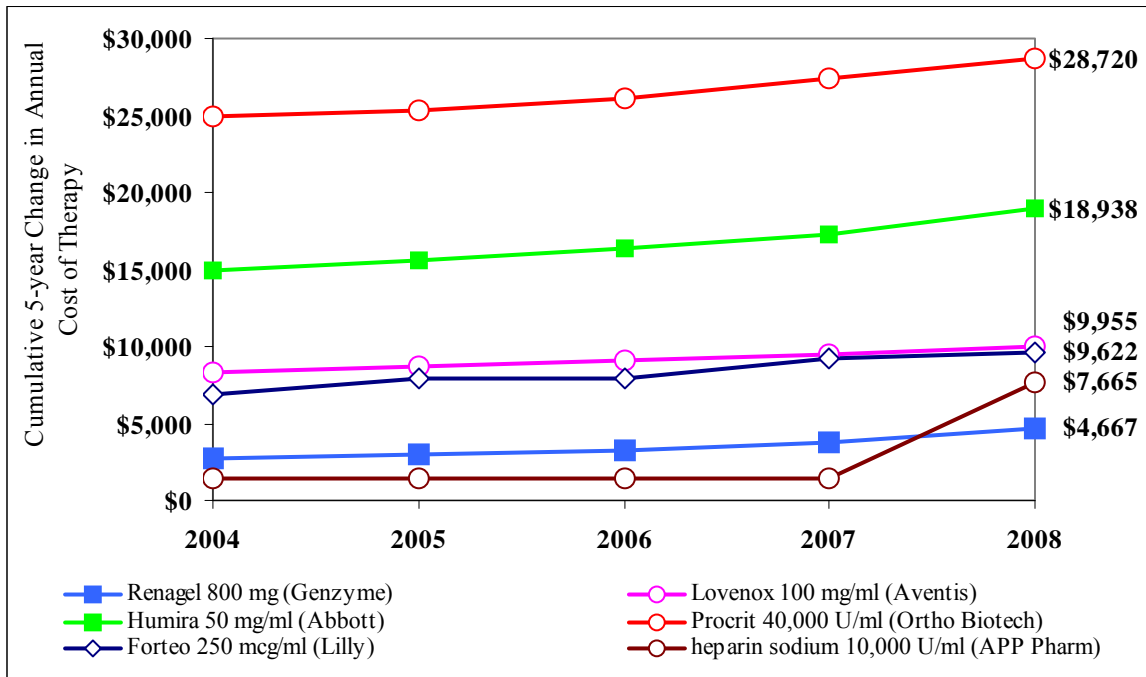
- The manufacturer prices of Humira 50 mg/ml injection and Lovenox 100 mg/ml injection increased by approximately 30 percent between 2004 and 2008.
- The manufacturer price of Procrit 40,000 U/ml injection increased cumulatively by 21 percent over the five-year period.

Five-year cumulative change in annual cost of therapy

- Sixty-seven of the 112 drug products that have been on the market since the end of 2003 are used to treat chronic conditions. By the end of 2008, the average annual cost of therapy for these drug products was more than \$9,258 higher than five years earlier, assuming that manufacturers' price increases were passed along in the form of higher prices¹⁶ and that the consumer used these specialty drugs for chronic conditions.
- The five-year (2004 to 2008) cumulative change in cost of therapy due to manufacturer prices for six specific drug products is shown in figure 7:
 - Manufacturer prices for a one-year supply of Procrit 40,000 U/ml injection rose by nearly \$29,000 between the end of 2003 and the end of 2008, while manufacturer prices for a one-year supply of Humira 50 mg/ml injection rose by almost \$19,000.
 - Manufacturer prices for a one-year supply of Lovenox 100 mg/ml injection and Forteo 250 mcg/ml injection rose by nearly \$10,000 between the end of 2003 and the end of 2008.
 - Manufacturer prices for a one-year supply of Renagel 800 mg tablets rose by more than \$4,600 by the end of the five-year period (2004 to 2008).
 - The generic drug heparin sodium 10,000 U/ml injection had the largest one-year percentage increase in 2008, which increased the manufacturer price for a one-year supply of this drug by more than \$7,600 by the end of the five-year period spanning from the end of 2003 to the end of 2008.

¹⁶ The actual amount that an individual consumer pays out-of-pocket may depend on a variety of factors.

Figure 7: The Five-Year Cumulative Change in Cost of Therapy is Nearly \$29,000 for the Specialty Drug with the Largest Percent Price Increase in 2008



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).

IV. Manufacturer Price Changes for Most Widely Used Specialty Prescription Drugs in 2008

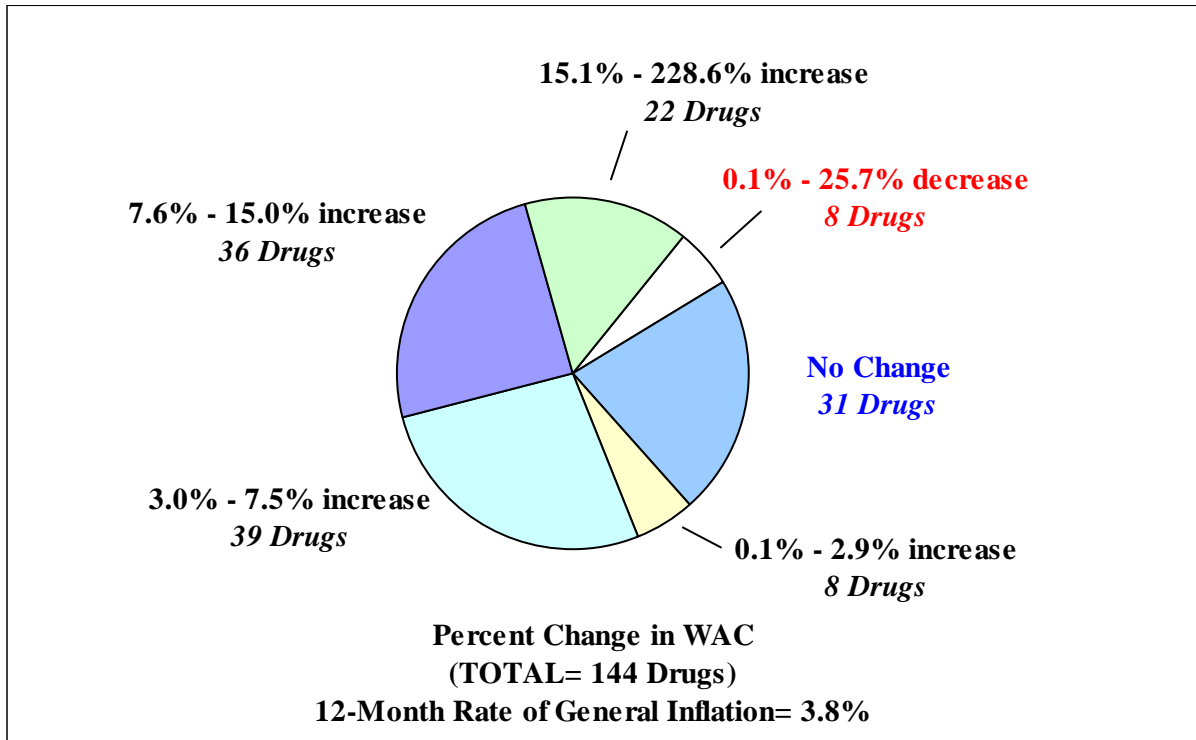
Distribution of manufacturer price changes

Seventy-three percent (105 of 144) of the most widely used specialty prescription drug products in this study's market basket had manufacturer price increases during 2008, when measured as a 12-month rolling average (figure 8).

- Annual manufacturer price increases for 92 (63.9 percent) of the 144 drug products exceeded the rate of general inflation (3.8 percent) in 2008.
- Annual manufacturer price increases for 76 (52.8 percent) of the 144 drug products increased more than 5.0 percent in 2008, including 36 (25.0 percent) with a price increase of between 7.6 percent and 15.0 percent, and 22 (15.3 percent) with a price increase of more than 15.0 percent.
- Almost four-fifths (31 of 39) of the specialty drug products that had no price change or a manufacturer price decrease in 2008 were ANDA-approved (i.e., generic). In contrast, only 7 percent (7 of 105) of the specialty prescription drug products that had a manufacturer price increase in 2008 were ANDA-approved.

More than one-third (49 of 144) of the drug products had more than one manufacturer price increase in 2008. One drug—Gamunex 10% injection—had four price increases in 2008. Two other drugs—Infergen 30 mcg/ml injection and heparin sodium 10,000 U/ml injection—had three price increases in 2008.

Figure 8: Over One-Third of the Most Widely Used Specialty Prescription Drugs Had Manufacturer Price Increases of More Than Twice the Rate of Inflation in 2008

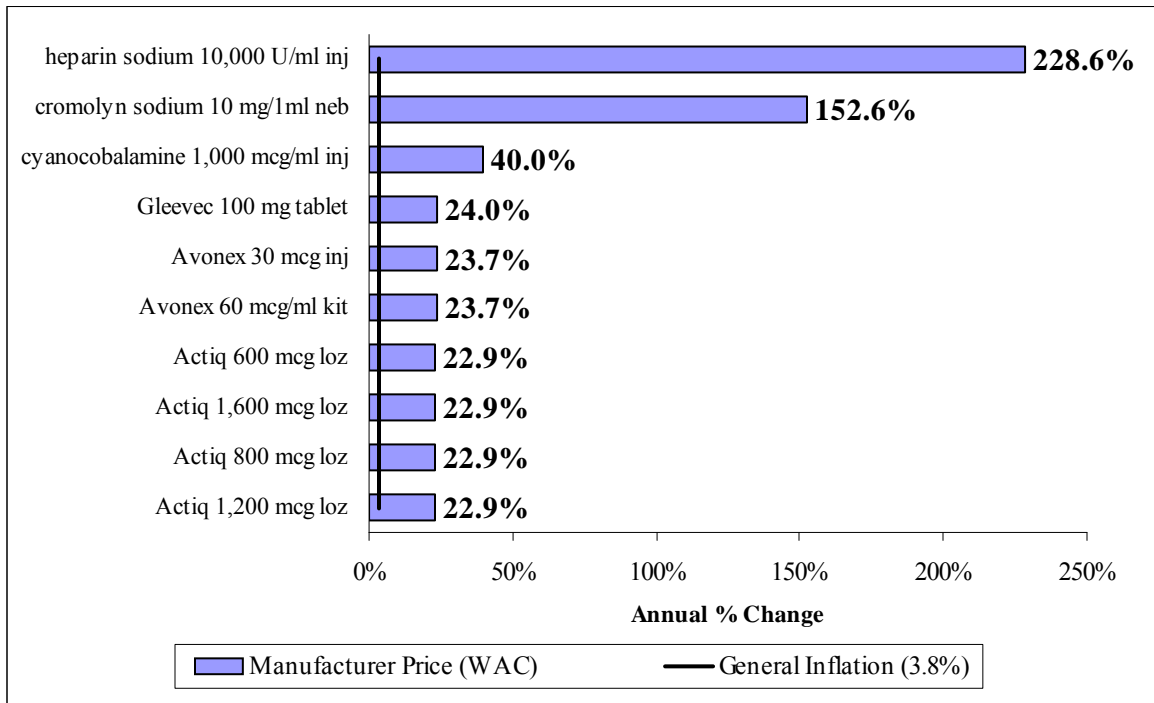


Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Ten specialty drug products had increases in manufacturer price of at least six times the rate of general inflation, ranging from 22.9 percent to 228.6 percent (figure 9). Seven of them were among the 49 drug products that had more than one price increase in 2008, while two others (Gleevec 100 mg tablets and cromolyn sodium 10 mg/1ml nebulizer) had a greater than 22.9 percent increase with a single change in price in 2008. The final drug, cyanocobalamine 1,000 mcg/ml injection, did not experience a price change in 2008, but did increase 56 percent in June of 2007 that produced a 40 percent change in the annual rolling average price change for 2008.¹⁷ Interestingly, the three drugs with the highest percentage price changes are generic versions of specialty drugs.

¹⁷ This finding is the result of the use of a rolling average to calculate annual changes. Cyanocobalamine 1,000 mcg/ml injection experienced a 56.0 percent price increase in 2007.

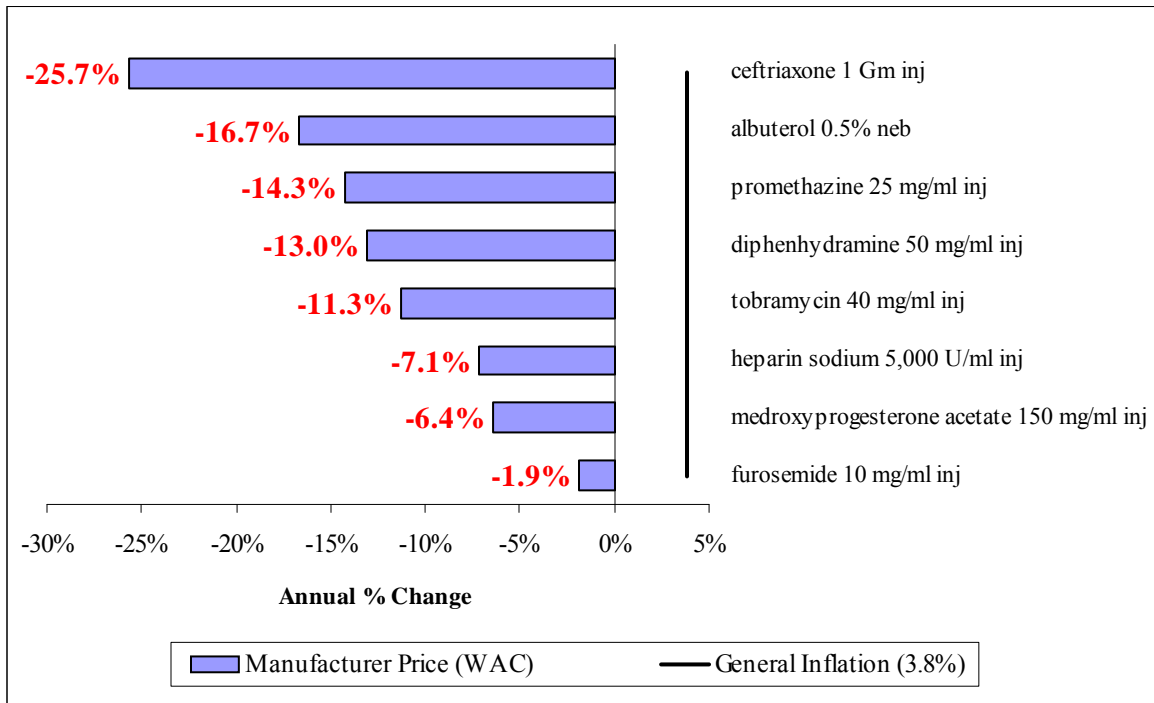
Figure 9: Two Widely Used Specialty Prescription Drugs Had Average Manufacturer Price Increases of More Than 100 Percent in 2008



Note: The general inflation rate is based on CPI-U.
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Annual manufacturer prices *decreased* for 8 (5.6 percent) of the 144 drug products, with price decreases that ranged from 1.9 percent to 25.7 percent (figure 10). All the drug products with a decrease in manufacturer price for 2008 were generics.

Figure 10: Five Widely Used Specialty Prescription Drugs Had Average Manufacturer Price Decreases of More Than 10 Percent in 2008



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).

More than 95 percent (24 of 25) of the specialty drug products with the greatest sales in 2006 had manufacturer price increases during 2008. All but one of these top-selling 25 drug products had an increase that exceeded the rate of general inflation in 2008 (3.8 percent). The remaining 23 drug products had annual manufacturer price increases that exceeded the rate of general inflation, including five drug products that had price increases more than four times the rate of general inflation (15.2 percent) (table 1).

Table 1: Almost All of the Top 25 Specialty Prescription Drug Products Had a Manufacturer Price Change in 2008

Rank by Sales among Study Market Basket*	Product Name, Strength, and Dosage Form	Package Quantity and Size	Manufacturer	Therapeutic Class	Annual Percent Change in WAC
1	Renagel 800 mg tablet	1 x 180	Genzyme	Phosphate Regulation	14.2%
2	Lovenox 100 mg/ml inj	10 x 0.4	Aventis	Anticoagulants	5.0%
3	Enbrel 50 mg/ml inj	4 x 1	Amgen	Arthritis, Severe	7.0%
4	Humira 50 mg/ml kit	2 x 1	Abbott	Arthritis, Severe	6.2%
5	Procrit 40,000 U/ml inj	4 x 1	Ortho Biotech	Erythropoietins	6.6%
6	Forteo 250 mcg/ml soln	1 x 28	Lilly	Calcium Regulators	11.1%
7	Copaxone 20 mg/ml kit	1 x 30	Teva Neuroscience	Multiple Sclerosis Agents	22.1%
8	Avonex 60 mcg/ml kit	4 x 1	Biogen Idec	Multiple Sclerosis Agents	23.7%
9	Tracleer 125 mg tablet	1 x 60	Actelion Pharmaceuticals	Pulmonary Hypertension	9.1%
10	Reyataz 150 mg capsule	1 x 60	Bristol-Myers Squibb	Antiretrovirals	6.0%
11	Procrit 20,000 U/ml inj	6 x 2	Ortho Biotech	Erythropoietins	6.6%
12	Tarceva 150 mg tablet	1 x 30	Genentech	Cancer Agents	10.2%
13	Gleevec 400 mg tablet	1 x 30	Novartis	Cancer Agents	11.0%
14	Procrit 10,000 U/ml inj	6 x 1	Ortho Biotech	Erythropoietins	6.6%
15	Betaseron 0.3 mg inj	15 x 1	Bayer Pharmaceutical (Berlex)	Multiple Sclerosis Agents	20.5%
16	Risperdal 50 mg inj	1 x 1	Janssen	Tranquilizers	1.8%
17	Sensipar 30 mg tablet	1 x 30	Amgen	Calcium Reduction	8.4%
18	Zyvox 600 mg tablet	1 x 20	Pfizer U.S.	Antibiotics, Misc.	7.1%
19	Enbrel 25 mg inj	4 x 1	Amgen	Arthritis, Severe	7.0%
20	Trizivir 300 mg-150 mg-300 mg tablet	1 x 60	Glaxo Smith Kline	Antiretrovirals	4.9%
21	Sensipar 60 mg tablet	1 x 30	Amgen	Calcium Reduction	8.4%
22	Byetta 250 mcg/ml inj	1 x 60	Amylin Pharmaceuticals	Diabetes Care	8.8%
23	Thalomid 50 mg capsule	10 x 28	Celgene Corp	Leprosy Agents	22.3%
24	ipratropium 0.02% soln	25 x 2.5	Dey Labs	Bronchial Dilators	0.0%
25	Rebif 88 ml inj	12 x 1	Serono	Multiple Sclerosis Agents	18.8%
General rate of inflation (as measured by growth in CPI-U)					3.8%

*Ranking based on prescriptions processed 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

- Biogen Idec's Avonex 60 mcg/ml kit had the highest annual percent increase (23.7 percent) in manufacturer price during 2008 among the top 25 specialty drug products with the greatest sales in 2006.
- Four of the top 25 drug products had annual changes in manufacturer price of more than 19 percent—or more than five times the rate of general inflation. In addition to Biogen Idec's Avonex 60 mcg/ml kit, the other drug products were Teva Neuroscience's Copaxone 20 mg/ml kit, Bayer Pharmaceutical's Betaseron 0.3 mg injection, and Celgene Corporation's Thalomid 50 mg capsules.

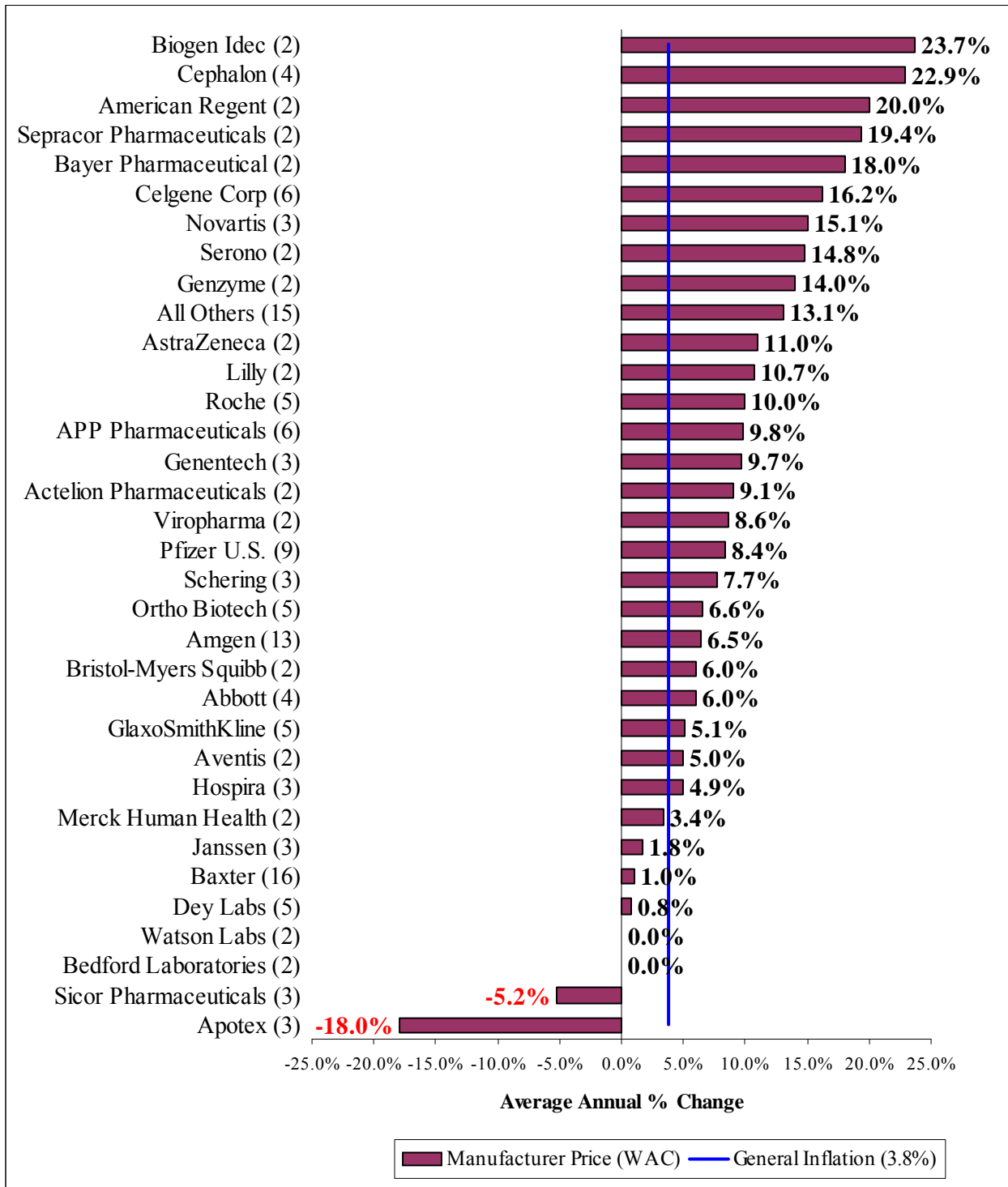
- Dey Labs' ipratropium's 0.02% solution was the sole drug product among the top 25 specialty drug products that did not have a change in manufacturer price in 2008. Ipratropium is also the only generic drug among the top 25 specialty drug products with the greatest sales in 2006.

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

Thirty-three 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 price for 25 of the 33 drug manufacturers exceeded the rate of general inflation in 2008 (figure 11).

- Four manufacturers—Biogen Idec, Cephalon, American Regent, and Sepracor Pharmaceuticals—had average annual price increases for the drug products in their market basket of more than five times the rate of general inflation (i.e., greater than 19.0 percent) during 2008.
- More than one-half of the drug manufacturers (18 of 33) had weighted average annual price increases that were at least twice the rate of general inflation during 2008 (i.e., equal to or greater than 7.6 percent, or twice the rate of general inflation at 3.8 percent).
- Two manufacturers—Watson Labs and Bedford Laboratories—did not change prices for widely used specialty drugs in 2008. Both of these manufacturers produce generic drug products.
- Two manufacturers—Sicor Pharmaceuticals and Apotex—had average annual price *decreases* in 2008. The average 2008 price changes for these manufacturers were -5.2 percent and -18.0 percent, respectively. All of the drug products from these manufacturers were generic.

Figure 11: Three Manufacturers Increased Their Prices for Widely Used Specialty Prescription Drugs by 20 Percent or More in 2008



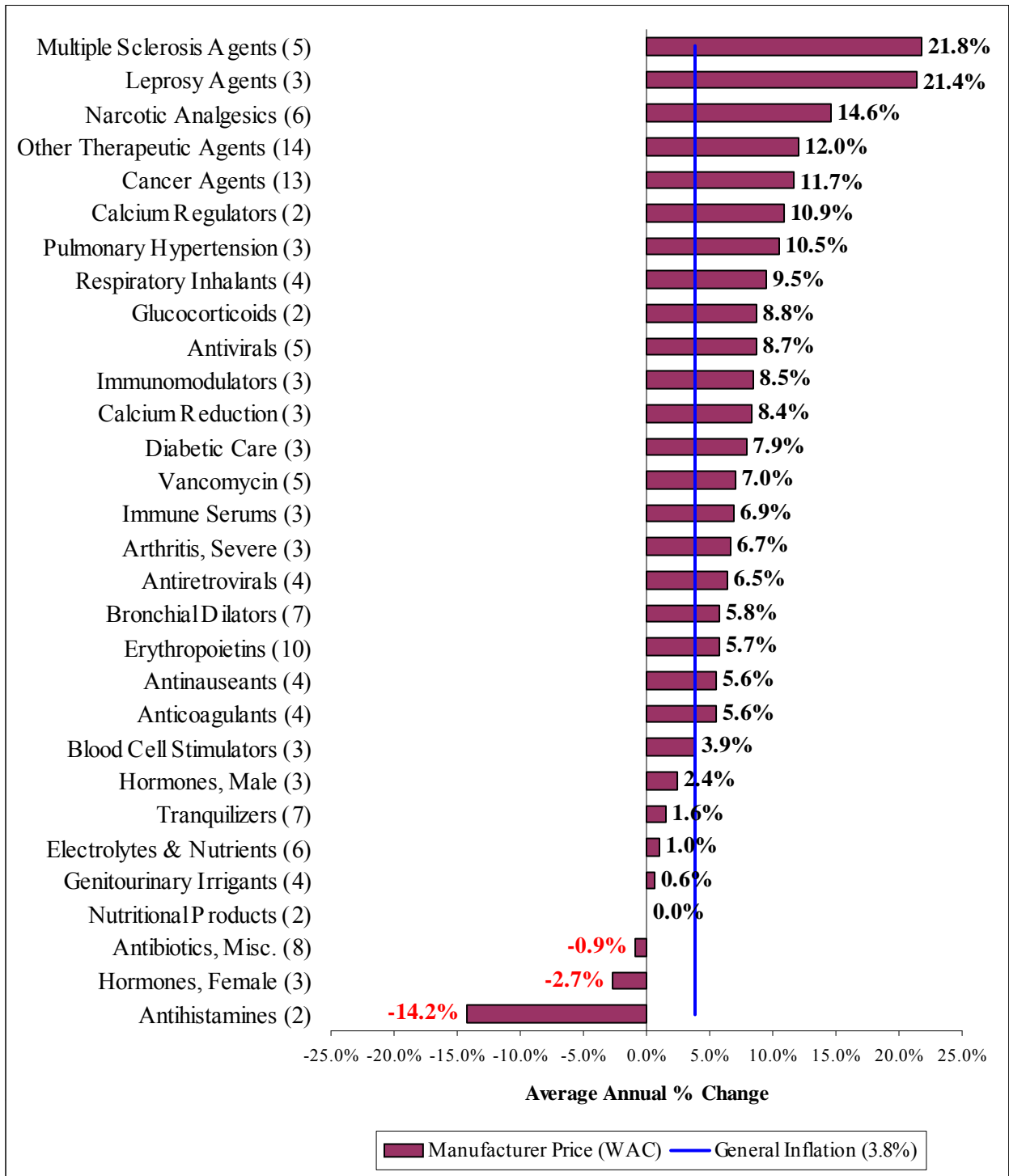
Notes: Manufacturers with fewer than two drug products in the 2006 market basket of most widely used specialty prescription drugs are included in the "All Others" category. The number in parentheses after a manufacturer's name indicates the number of drug products in the market basket for that manufacturer. 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 Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., March 2009).

Twenty-two of the 30 therapeutic categories of specialty drug products had average annual manufacturer price increases that exceeded the rate of general inflation (3.8 percent) in 2008 (figure 12).

- The two therapeutic categories with the highest manufacturer price increases—multiple sclerosis agents and leprosy agents—had average annual manufacturer price increases of more than five times the rate of general inflation in 2008 (i.e., more than 19.0 percent).
- Thirteen of the 30 therapeutic categories had average annual manufacturer price increases that met or exceeded twice the general inflation rate during 2008 (i.e., equal to or greater than 7.6 percent).
- Three therapeutic categories—miscellaneous antibiotics, female hormones, and antihistamines—had average annual price *decreases* in 2008. Manufacturer prices for these categories decreased by 0.9 percent to 14.2 percent.
- Four therapeutic categories—male hormones, tranquilizers, electrolytes and nutrients, and genitourinary irrigants (used for irrigation)—had average price increases that were less than the rate of general inflation in 2008. Another therapeutic category, nutritional products, had no change in average price for 2008.

Figure 12: Multiple Sclerosis Agents and Leprosy Agents Had the Highest Average Annual Percent Increases in Manufacturer Prices in 2008



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).

CONCLUDING OBSERVATIONS

Specialty drug expenditures are growing faster than other segments in the pharmaceutical market. This growth can be due to increased utilization, high introductory prices, and high rates of price increases. This study focused on the manufacturer drug price changes for specialty drug products. Manufacturer drug price increases for specialty drugs can have a direct impact on costs borne by Medicare Part D enrollees. These increases result in higher prices at the pharmacy level and result in higher out-of-pocket costs for beneficiaries who pay a percentage of drug costs rather than a fixed copayment. The effect of higher drug manufacturer prices on the total end-payer price also means that enrollees will get to the “donut hole”—the gap in coverage where enrollees have to pay all of their drug costs—much faster. The higher prices also more quickly push Part D enrollees through the donut hold and into catastrophic coverage, thereby increasing the burden on the taxpayers who help subsidize these costs. These effects are particularly pertinent for specialty drugs, which are typically expensive and often subject to co-insurance.

Drug manufacturers have raised prices of specialty prescription drug products used by Medicare beneficiaries substantially since the implementation of the Medicare drug benefit. Average annual increases in manufacturer prices charged to wholesalers (and other direct purchasers) for the 144 most widely used specialty prescription drugs continued to substantially exceed the rate of general inflation. The 2008 average rate of increase (9.3 percent) was almost two and one-half times the rate of general inflation (3.8 percent). In contrast, brand name non-specialty drugs widely used by Medicare beneficiaries experienced an 8.7 percent increase in 2008, and generic non-specialty drugs widely used by Medicare beneficiaries experienced a 10.6 percent decrease.

About two-thirds (64 percent or 105 of 144 drug products) of the specialty drug products had manufacturer price increases that exceeded the rate of general inflation during 2008. More than one-third (49 of the 144 drug products) had more than one manufacturer price increase during 2008. Only 8 of the 144 specialty drug products had a decrease in price, and all the drug products with price decreases were generics. Average annual drug manufacturer price increases in 2008 exceeded the rate of general inflation for 25 of 33 manufacturers with at least two drug products in the market basket, and for 22 of 30 therapeutic categories with at least two drug products in the market basket.

The cumulative effect of these manufacturer price increases can be substantial. On average, manufacturer prices of the 112 most widely used prescription drug products that have been on the market since the end of 2003 have increased by more than 60.2 percent during the subsequent five-year period (2004 through 2008), compared with a general inflation rate of 14.0 percent. For a consumer who takes a specialty prescription on a chronic basis, the average increase in the cost of therapy for the drug products used to treat chronic conditions rose by more than \$9,258 during this five-year period.

APPENDIX A: BRIEF METHODOLOGY

The list of 144 specialty 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 during 2006. Each drug product represents a unique combination of active chemical ingredient, strength, dosage form, package size, and manufacturer (for example, Enbrel (etanercept) 50 mg/ml injection, package of four syringes, Amgen).

Products are identified by a unique 11-digit National Drug Code (NDC) identifier. In this analysis, when a manufacturer discontinues a NDC code for a particular product but assigns a new NDC to a product with the same chemical ingredient, strength, dosage form, and similar or identical package size as the product with the discontinued NDC, the products are considered the same for the purposes of tracking price per unit (i.e., tablet, capsules, etc.). Products are included in the analysis only for the time period that they were on the market.

Although the market basket of drugs studied was constructed using data from a Medicare Part D plan provider for 2006, the price changes by drug manufacturers were measured using Wholesale Acquisition Cost (WAC) data published in the Medi-Span Price-Chek PC database.⁵⁴ According to Medi-Span, the WAC represents “the reported cost at which wholesalers purchase drug products from a manufacturer and is provided by the manufacturer. WAC may not represent *actual* acquisition cost as wholesalers may obtain discounts through volume purchases or special deals.” WAC is a publicly available price that is the closest published price to the actual transaction price between a manufacturer and the wholesaler or other direct purchaser of a drug product. Although drug wholesalers may receive “discounts or special deals” for some drug purchases, the wholesaler’s price to the retail class of trade is typically based on, or is a function of, WAC.⁵⁵ Therefore, a change in WAC generally results in a similar percent change in price to most prescription purchasers, including “cash pay” customers as well as private and public third-party programs such as Medicare Part D drug plans and Medicare Part D enrollees in the coverage gap.

This report calculates average drug price changes in the following ways:

- The 12-month *rolling average* percent price change is calculated by taking the average of the point-to-point changes over the preceding 12 months. Thus, for

²¹ Price-Chek PC is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health, Inc., and is based on data from the Master Drug Database (MDDB®).

²² Wholesalers often receive prompt pay discounts, but these discounts typically are not passed on to their customers.

example, the average annual price changes for 2008 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2008 through December 2008 compared with the same months in the previous year.

- The *annual point-to-point* percent change in 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 2008 vs. January 2007, February 2008 vs. February 2007).

When aggregate estimates of price or change in drug prices were calculated for this study, each drug product's value was weighted by the 2006 sales for a Medicare Part D plan provider. The Medicare Part D plan provider weights were used as a proxy for average drug use for all Medicare beneficiaries.

To assess the impact of price changes on dollars spent, an annual cost of therapy was calculated for each drug product. This analysis excludes the 49 products in the sample that are used primarily for treatment of acute conditions and typically taken for a limited time. The amount of a drug that an average adult person would take on a daily basis was determined using the "usual daily dose" reported in the Medi-Span Price-Chek PC database or, when this information was not available from Medi-Span, using dosing information in the U.S. Food and Drug Administration-approved labeling for the drug product.

Analyses of manufacturer price changes are presented by drug manufacturer and by therapeutic category. The analysis of drug manufacturers reported separately on the 33 manufacturers with at least two drug products, accounting for 129 of the drug products among the 144 most widely used brand name drugs. An additional 15 drug products from 15 drug firms with one drug product per firm were grouped together in an "All Others" category, resulting in a total of 34 reported drug manufacturer categories. There were 29 therapeutic categories, each containing two or more drug products from the market basket, which together accounted for 130 of the total 144 drug products in the market basket. The remaining 14 drug products with other therapeutic uses were grouped together in an "Other Therapeutic Agents" category, resulting in a total of 30 reported therapeutic categories.