

Rx Watchdog Report
Trends in Manufacturer Prices of Specialty
Prescription Drugs Used by Medicare Beneficiaries
2004 to 2007

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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

Introduction

This report presents our findings on the pattern of price changes for specialty drug products, a group of drugs that includes products sometimes referred to as biotech drugs or biopharmaceuticals. The term “specialty drugs” is defined differently across various Part D plans and private health plans, but generally includes prescription medicines that are used to treat complex, chronic conditions and require special administration, handling, and care management.

AARP’s Public Policy Institute finds that price increases for specialty drugs have greatly exceeded the price increases for other consumer goods and services between 2004 and 2007. In 2007, 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 8.7 percent, or three times the general inflation rate of 2.9 percent. In contrast, brand name non-specialty drugs widely used by Medicare beneficiaries experienced a 7.4 percent increase in 2007, and generic non-specialty drugs widely used by Medicare beneficiaries experienced a 9.6 percent decrease. Especially notable is that we see even steeper price increases among specialty prescription drugs during the first two years of the Medicare Part D program that covers drugs for Medicare beneficiaries.

Many of these drugs are used to treat conditions that often affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis. They are also among the most expensive drugs on the market, with costs that can reach hundreds of thousands of dollars per year. They are expected to be the fastest growing group of drug products in the decade ahead.

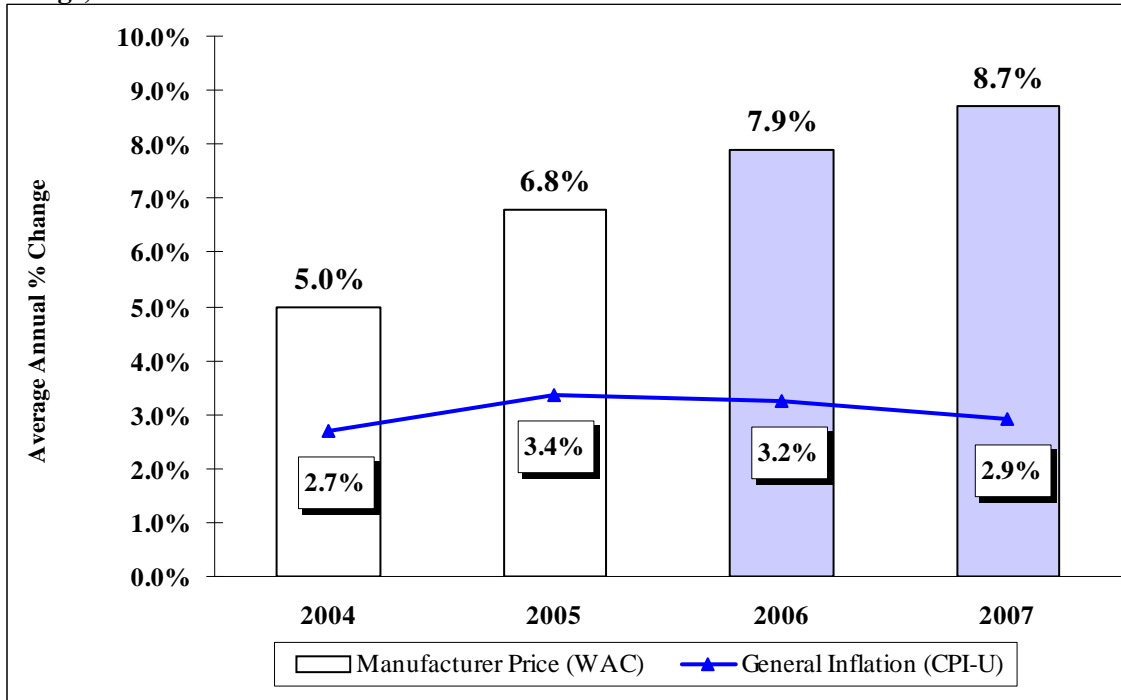
Specifically, this report compares specialty prescription drug price changes to the rate of general inflation and from one year to the next. The report also presents differences in average price changes by manufacturer and by major therapeutic category. The report focuses on changes in prices that specialty drug manufacturers charge to wholesalers for sales to direct purchasers and the retail class of trade. The manufacturer’s charge to wholesalers or direct providers is the most substantial component of a prescription drug’s price to the end payer. While this report does not provide data on drug rebates that plans are able to negotiate with manufacturers—such rebates are typically confidential and not passed on in lower prices to the consumer—when manufacturers increase their price to wholesalers or direct providers for a specialty drug, the added cost is generally passed on in the price to most prescription purchasers. Price increases are only one dimension of how much consumers pay for given specialty drug. The high price for many of these specialty drugs means that the cost to the end payer would be substantial even if the manufacturer’s price remained unchanged. Also, consumers may bear an increased share of costs due to placement of their drug on a specialty tier with high cost sharing.

Findings

- **Overview.** Manufacturers have raised prices of specialty prescription drug products used by Medicare beneficiaries substantially since the implementation of the Medicare drug benefit in 2006. 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 annual average rates of increase in 2006 and 2007 (7.9 percent and 8.7 percent, respectively) were substantially higher than the average annual increases found in the previous two years (5.0 percent in 2004 and 6.8 percent in 2005).

Average Annual Percent Change in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, 2004 to 2007



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., June 2008).

- **Cumulative change in manufacturer prices.** On average, manufacturer prices for 112 specialty drugs that have been on the market since the beginning of the study (December 2003) increased 42.9 percent by December 2007, compared to the general inflation rate of 14.1 percent during the same period.
- **Cumulative change in estimated dollar cost of therapy.** 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 almost \$5,800 between 2004 and 2007.
- **Annual price changes.** Of the 144 specialty prescription drug products in the study’s specialty market basket, 106 had manufacturer price increases during 2007. More than two-thirds (67 percent) of these increases exceeded the rate of general inflation during the year.
- **Differences by manufacturer and therapeutic category.** Average annual manufacturer drug price increases in 2007 exceeded the rate of general inflation for 25 manufacturers and for 21 therapeutic categories with at least two products in the market basket.

Methodology

The list of prescription drugs that are widely used by Medicare beneficiaries is based on the most widely dispensed drug products (including both generic and brand name drugs), the drug products with the highest sales levels, and the drug products with the highest number of days of therapy provided among the all prescriptions adjudicated by a Medicare Part D plan provider. UnitedHealthcare–PacifiCare provided Medicare Part D coverage in 2006, and it 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).

Three market baskets are used in this AARP Public Policy Institute series of studies: brand name, generic, and specialty drugs. Combined, they 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. Previous reports by the AARP Public Policy Institute have documented manufacturer price changes of specific *brand name* drugs and *generic* drugs that are widely used by Medicare beneficiaries.

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 were measured using changes in the wholesale acquisition cost (WAC) as published in 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 by weighting each drug product's value by its share among the Medicare Part D 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 Medicare Part D-based market basket. Analysis for 2004, the earliest year covered in this report, includes 112 drugs, representing 78 percent of the total study sample.

Concluding Observations

Manufacturer drug price increases can have a direct impact on costs borne by Medicare Part D enrollees. Manufacturer price increases to the provider or the 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 also means that enrollees will get more quickly to the “donut hole”—the gap in coverage where enrollees have to pay all of their drug costs. And once enrollees are in the donut hole, they directly absorb the entire effect of higher drug manufacturer prices on the price to the end payer. High manufacturer price increases are particularly relevant for patients on specialty drugs, which are typically quite expensive and are often subject to cost-sharing or placement on a specialty tier.

INTRODUCTION

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 defined elsewhere but generally include drugs that are used to treat complex, chronic conditions and require special administration, handling, and care management.

AARP's Public Policy Institute finds that price increases for specialty drugs have greatly exceeded the price increases for other consumer goods and services between 2004 and 2007. In 2007, 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 8.7 percent, or three times the general inflation rate of 2.9 percent. In contrast, brand name non-specialty drugs widely used by Medicare beneficiaries experienced a 7.4 percent increase in 2007, and generic non-specialty drugs widely used by Medicare beneficiaries experienced a 9.6 percent decrease.¹ Especially notable is that we see even steeper price increases among specialty prescription drugs during the first two years of the Medicare Part D program that covers drugs for Medicare beneficiaries.

Many of these drugs are used to treat conditions that often affect older populations, such as cancer, rheumatoid arthritis, and multiple sclerosis. They are also among the most expensive drugs on the market, with prices that can reach hundreds of thousands of dollars per year.² They are expected to be the fastest growing group of drug products in the decade ahead.³

Specialty drug products often flow through different channels of distribution than other 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. While this report focuses on manufacturer prices for specialty drug products, previous AARP reports have focused on manufacturer price changes among the more traditional *brand name* drugs and among the growing group of *generic* drugs.² Separate analyses of the price changes for these three groups—brand name drugs, generic drugs, and specialty drugs—are being reported because these three sets of drugs are typically made by different drug manufacturers and their prices are subject to different market dynamics, pricing, and related behaviors.

This report focuses on changes in the prices that drug manufacturers charge direct purchasers such as physician's 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

¹ 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," March 2008; and D. Gross, S. Schondelmeyer, and L. Purvis, "Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries, 2003 to 2007," June 2008. Available on the AARP website, http://www.aarp.org/research/health/drugs/rx_watchdog.html.

² L.E. Perry, "Specialty Pharmacy: A New Class of Trade?" *Drug Topics*, November 6, 2006.

³ Express Scripts, *2007 Drug Trend Report*, April 2008.

beneficiary.⁴ 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 passed on in the insurer's or consumer's cost for the specialty drug.⁵ Changes in drug manufacturers' prices are measured by changes in the wholesale acquisition cost (WAC) published in the Medi-Span Price-Chek PC database.⁶

SPECIALTY DRUGS DEFINED

The term "specialty drugs" is defined differently across Part D plans and private health plans. Although there is no clear consensus, this term generally refers to drugs that (1) are used to treat complex and chronic conditions; (2) involve special dosage forms (e.g., inhalation or injection), storage, and administration; (3) require special monitoring, patient education, and/or clinical support, (4) need frequent or careful dosage adjustments; or (5) have unusually high costs.⁷ For purposes of this study, a drug product was considered to be a specialty drug if it (1) is administered by injection, such as intravenous, intramuscular, sub-cutaneous, or other injection site (not including insulin); (2) has any dosage form with a total cost greater than \$1,000 per prescription⁸; (3) has any dosage form with a total cost of greater than \$33 per day of therapy, or (4) is commonly used as adjunctive therapy with other specialty medications.⁹ Some of the drug products that meet this definition are

⁴ United States House of Representatives, Committee on Oversight and Government Reform, *Medicare Part D: Drug Pricing and Manufacturer Windfalls*, July 2008.

⁵ 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).

⁶ 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 (MDDB®). 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 [MDDB®], July 2003, published on the Medi-Span website, <http://www.medispans.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, found at http://www.medispans.com/marketing/Common/PDF/Marketing/WKH_AWP_Policy.pdf).

⁷ For a discussion of variations in the definition of "specialty drugs," see the following articles: (1) D. Stern and D. Reissman, "Specialty Pharmacy Cost Management Strategies of Private Health Care Payers," *J Manag Care Pharm*, Vol. 12(9): 736-744, found at <http://www.amcp.org/data/jmcp/Nov-Dec06JMCP1.pdf>; (2) R.A.C. Opdycke, J.J. Ellis, and D.M. Kirking, *Specialty Drug Whitepaper*, Center for Medication Use Policy and Economics, College of Pharmacy, University of Michigan, August 24, 2007, found at <http://www.umich.edu/~benefits/forms/SpecialtyDrugReport.pdf>; (3) selecthealth, an Intermountain Healthcare Company, "Ask the Actuary & The Pharmacist: Managing Specialty Pharmacy," *employer QUARTERLY*, Spring 2007, found at <http://selecthealth.org/Static/Files/equarterlyspring07.pdf>; and (4) M. Tegenu, "Health Plan Approach to Operationalizing a Specialty Drug Management Program," *J Manag Care Pharmacy*, Vol. 14(4) Suppl: S17-S21, found at http://www.amcp.org/data/jmcp/JMCPSupp_S17-S21.pdf.

⁸ The Medicare Part D definition of specialty drugs is \$600 or more per prescription. If this study had used the \$600 per prescription criteria, only three additional drug products would have been included in the specialty market basket, since all injectables were already included regardless of price. Two of the three additional drug products were the higher strengths of Zyprexa (15 mg and 20 mg) which were included in our market basket of brand name drugs cited earlier. The third drug product was a combination-HIV medication (Truvada 200-300 mg).

⁹ Some medications are commonly used as an adjunct to other specialty medications. For example, sterile water for injection is required to dilute certain injectable medications such as a cancer drugs.

available as generics, which is somewhat unusual in many working definitions. However, these generic drug products are often provided along with other specialty drug products. Including these generic drug products reduces our estimate of the rate of price changes. When we remove the generic drug products from the market basket, the overall average annual percent change increases by approximately 1 percentage point, indicating that this makes the results more conservative.

Some, but not all, specialty drugs are also known as biotech drugs and biopharmaceuticals and have several features that distinguish them from conventional drugs. For example, in contrast to chemically synthesized conventional drugs, biotech drugs are typically derived using fermentation, cell cultures, and other techniques.

Specialty drugs are currently among the most expensive drugs on the market, with prices that can range from \$5,000 to more than \$300,000 per year.¹⁰ They are also the fastest growing segment of pharmaceuticals; expenditures are growing at 12 percent to 15 percent annually, or double the rate for conventional drugs.¹¹ A key factor in this growth is the number of approved and soon-to-be-approved drug products; since 1990, the number of approved biotech products alone has more than doubled every five years. Today, nearly 200 biotech medicines have been approved by the U.S. Food and Drug Administration (FDA) and an additional 800 are in development.¹²

An additional factor affecting specialty drug expenditures is utilization. Today, specialty pharmaceuticals are used to treat conditions that affect about 3 percent of the general population,¹³ but that number is expected to grow as new medications are approved. Furthermore, manufacturers are regularly expanding the indications for specialty drugs that are already on the market,¹⁴ meaning a larger proportion of the population could potentially benefit from the drugs that are already available.

A final factor in the rise in specialty drug spending is their price. The research, development, and manufacturing costs of specialty pharmaceuticals are typically spread over a limited patient population, leading to higher prices.¹⁵ This situation is exacerbated by the fact that most specialty drugs do not have biosimilars, generic equivalents, or substitutes to create competition and help lower their prices over time.

Instead of the traditional arrangements where patients pay a relatively low copayment for a prescription, Medicare Prescription Drug Plans (PDPs) and other health plans are now charging patients a percentage of the cost,¹⁶ with or without a maximum out-of-pocket amount. In 2008, 41 of

¹⁰ S.W. Schondelmeyer, "Specialty Pharmaceuticals: Benefit Coverage & Design, Overview of the Market, 2007," Presentation to health benefits department of a major employer, August 2007.

¹¹ C. Boorady, D.L. Weinswig, and C. Tang, *Riding the Specialty Pharmacy Wave: PBMs and Drug Retailers See a Big Swell Forming*, Citi, Health Care Distribution & Technology, October 8, 2007.

¹² Pharmaceutical Care Management Association, "Specialty Pharmacy Trends and Management Strategies," April 2006.

¹³ *Ibid.*

¹⁴ For example, Avastin, which was approved in 2004, has 23 potential additional indications under development. M. Said, C.-A. Brouwers, and P. Tollman, "Continued Development of Approved Biological Drugs," White Paper, The Boston Consulting Group, December 2007.

¹⁵ Pharmaceutical Care Management Association, "Specialty Pharmacy Trends and Management Strategies," April 2006.

¹⁶ Between 20 percent and 33 percent. G. Kolata, "Co-payments Soar for Drugs with High Prices," *The New York Times*, April 14, 2008.

47 national Medicare PDPs included a specialty tier for high cost or injectable drugs;¹⁷ 21 of those 41 had a co-insurance rate of 33 percent for specialty tier drugs while the others had specialty tier co-insurance rates ranging from 25 percent to 32 percent.¹⁸ This cost-sharing strategy is rapidly spreading to private insurance plans, exposing beneficiaries to a high share of the cost.

DEVELOPING THE MARKET BASKET OF WIDELY USED SPECIALTY DRUGS

The AARP Public Policy Institute has been reporting manufacturer drug product price changes annually and quarterly since 2004. Previous reports by AARP were based on a market basket of retail and mail-order prescriptions provided to about 2 million people ages 50 and older who used the AARP Pharmacy Service. The same market basket of drugs was used for all previously published AARP price trend reports. With the Medicare Part D program in its third year of operation, we chose to use a new market basket of drugs based on actual drug use in Medicare Part D plans during calendar year 2006.

One organization providing Medicare Part D prescription drug coverage in 2006 was UnitedHealthcare–PacifiCare, which also insures the AARP Medicare Rx plans. The combined enrollment of this Medicare Part D plan provider totaled 5.68 million for 2006 (4.46 million in stand-alone prescription drug plans and 1.22 million in Medicare Advantage plans), which represented 25.3 percent of all Medicare Part D enrollees for 2006. This Medicare Part D plan provider supplied data for all prescriptions provided during 2006 to this group of 5.68 million Medicare enrollees. The data set included NDC (National Drug Code) number, number of prescriptions, total expenditure, days of therapy, and units dispensed.

The Medicare Part D plan provider accounted for nearly \$12 billion in prescription drug expenditures and almost 175 million prescriptions in 2006. Specialty drugs, not including any payments that were made under Medicare Part B, represented 7.4 percent of the plan’s expenditures and 1.3 percent of the plan’s prescriptions.¹⁹ Brand single source prescriptions accounted for 52.8 percent of all specialty prescriptions and 89.8 percent of expenditures (see Table 1). This relationship is driven by an average price for a brand single source specialty prescription that was more than 12 times the average price of a generic multiple source specialty prescription.

Table 1: Characteristics of the Medicare Part D Plan Provider (Specialty Only)

| Type of Prescription | Share of Prescriptions | Share of Expenditures |
|-------------------------|------------------------|-----------------------|
| Brand single source | 52.8% | 89.8% |
| Brand multiple source | 3.0% | 3.9% |
| Generic multiple source | 44.2% | 6.2% |

Note: The expenditures and price per prescription referred to in this section represent the total amount paid to the pharmacy or provider (i.e., the sum of the Part D plan cost and the member cost sharing).

Source: PRIME Institute, University of Minnesota, based on 2006 data from the Medicare Part D plan provider.

¹⁷ E. Hargrave, J. Hoadley, K. Merrell, and J. Cubanski, *Medicare Part D 2008 Data Spotlight: Specialty Tiers*, The Henry J. Kaiser Family Foundation, publication #7711, December 2007.

¹⁸ Ibid.

¹⁹ Since the specialty market basket does not include drugs that fall under Medicare Part B, these numbers may not reflect total specialty drug utilization among Medicare beneficiaries.

Creating the list of widely used specialty drugs. The list of all drug product groups (i.e., Generic Product Indicator (GPI)-patent status groups²⁰) in the data set provided by the Medicare Part D plan provider for 2006 was sorted by three criteria: (1) total prescription expenditures, (2) number of prescriptions dispensed, and (3) days of therapy provided. There were a total of 1,134 specialty drug GPI-patent status groups in the entire data set for 2006, and these groups included 3,120 active NDCs and 485 inactive NDCs.²¹ All specialty drug GPI-patent status groups were sorted by three criteria: (1) total prescription expenditures, (2) number of prescriptions dispensed, and (3) days of therapy provided. The top 100 specialty GPI-patent status categories were identified by each of these three criteria. Since some specialty GPI-patent status groups appeared in more than one of these top 100 specialty drug lists, the combined list of all specialty drug GPI-patent status groups totaled to 150 GPI-patent status groups.

The 150 specialty drug GPI-patent status groups included 956 active NDCs and 112 inactive NDCs. However, 6 of the 150 GPI-patent status groups did not have price information (i.e., WAC) listed in 2006.²² As a result, this study is based on the 144 widely used specialty drug products for which WACs were reported in 2006.²³ These 144 drug products represented 91.4 percent of all specialty drug expenditures, 87.6 percent of all specialty drug prescriptions, and 93.7 percent of all specialty drug days of therapy provided.

Price changes were determined by comparing the price (WAC) for a drug product in a given month with the price for the same drug product in the same month in the previous year. A 12-month rolling average of these monthly price changes was then calculated to determine an average annual price change.

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

²⁰ GPI-patent status groups are the basic unit of analysis for grouping prescription drugs in this study. All prescription drug products have a unique NDC number. These drug products at the NDC level can be grouped so that all drug products with the same active ingredients, dosage form, and strength are grouped into a GPI group. Each GPI group includes all drug products at the NDC level with the same active ingredients, dosage form, and strength for any package type and size and from all manufacturers. Within a GPI group, the individual drug products at the NDC level may have a different patent status. If the patents and market exclusivity for the original drug product has not yet expired, then all NDCs within the GPI group will be brand single source drug products. However, if the original drug product no longer has a patent or market exclusivity, then the GPI group may contain both brand multiple source (or brand off-patent) drug products and generic multiple source drug products. The concepts of GPI groups and patent status groups were combined for purposes of this study to create GPI-patent status groups. Each drug product group was classified as one of the following GPI-patent status groups: (1) GPI-brand single source; (2) GPI-brand multiple source; or (3) GPI-generic multiple source.

²¹ Inactive NDCs are drug products that are no longer being actively marketed and sold by the manufacturer. In many cases, the manufacturer may be selling an identical, or very similar, drug product under a new NDC number.

²² Some drug manufacturers do not begin listing a WAC until months or years after the drug product is introduced to the market.

²³ In order to measure the impact of price changes alone, the weights for drug products in this market basket are fixed over time. Drug products that enter the market after 2006 will not be included in this index. If drug products are withdrawn from the market, these drug products will be dropped from the market basket in subsequent periods, and the weights of other drugs will be proportionately adjusted.

In contrast to previous AARP Public Policy Institute market baskets that contained brand name *or* generic drugs, the specialty market basket contains both brand name *and* generic prescription drugs. In addition, the specialty market basket contains both drug and biological products. The drug products in the specialty market basket were approved by the FDA using one of the following processes: (1) a new drug application (NDA); (2) a biologic license application (BLA); or (3) an abbreviated new drug application (ANDA). NDAs and ANDAs apply to drug products and medical devices; BLAs apply to biological products.

According to the FDA, “For both brand-name and generic drugs, FDA works with pharmaceutical companies to assure that all drugs marketed in the U.S. meet specifications for identity, strength, quality, purity and potency.”²⁴ An NDA or BLA is used to approve new drugs or biologicals when they are first introduced to the U.S. market. An ANDA is used to approve generic drug products and does not generally require duplication of previous research on the effectiveness and safety of the drug. However, the FDA does require rigorous tests and procedures to determine if the generic drug product is therapeutically equivalent to, and interchangeable with, the reference listed (brand-name) drug product. “Products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is a brand name or generic drug product.”²⁵ There is no abbreviated process for approval of generic versions of biological products.

NDA- and BLA-approved drug products represent almost three-quarters of the specialty drug market basket. The average daily cost for these specialty drug products is roughly 20 times higher than the average daily cost for ANDA-approved specialty drug products (see Table 2).

Table 2: Characteristics of Specialty Market Basket by FDA Approval Process

| Type of FDA Approval | Total Number of Drugs | Average Daily Cost | Average Annual Cost |
|----------------------|-----------------------|--------------------|---------------------|
| NDA | 75 | \$69.81 | \$25,481 |
| BLA | 31 | \$93.24 | \$34,032 |
| ANDA | 38 | \$4.07 | \$1,486 |

Note: Data are weighted by actual 2006 sales to Medicare Part D beneficiaries. Costs are as of December 2007.

Source: *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health, Inc., June 2008).

²⁴ Stuart L. Nightingale, M.D., Associate Commissioner for Health Affairs, U.S. Food & Drug Administration, *Therapeutic Equivalence of Generic Drugs, Letter to Health Practitioners*, January 28, 1998.

²⁵ *Ibid.*

FINDINGS

I. ANNUAL TRENDS IN MANUFACTURER PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS

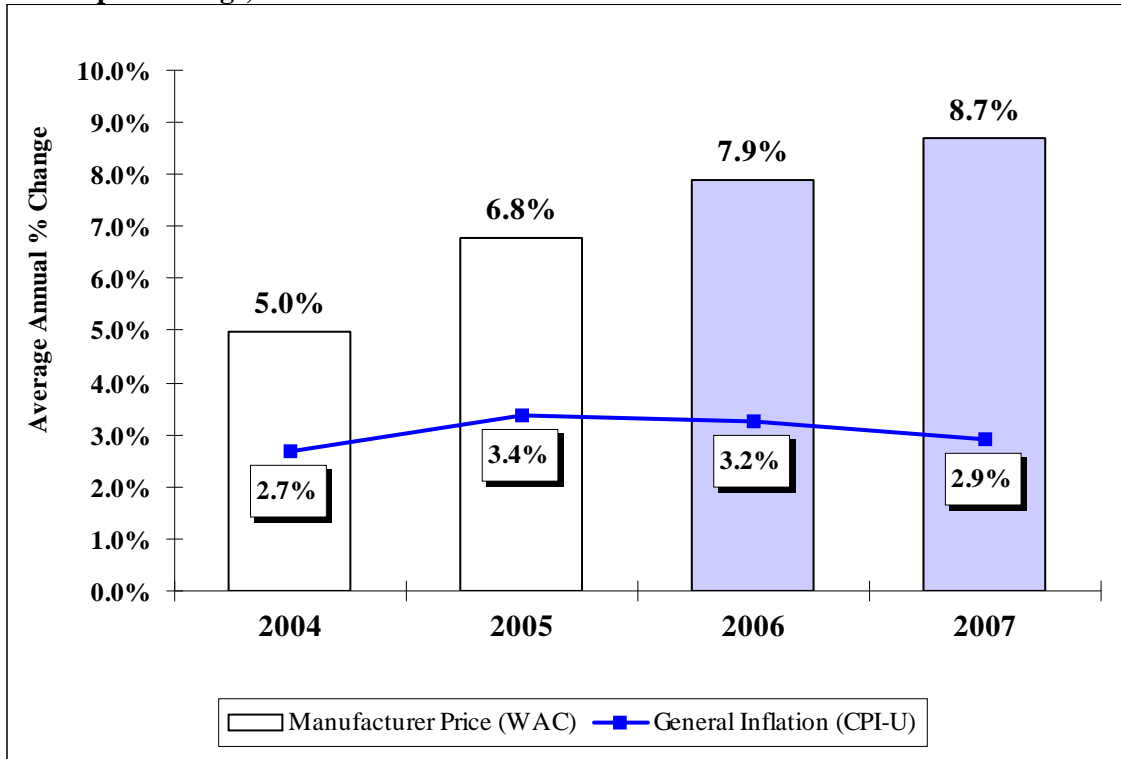
Annual percent change in manufacturer prices

- Manufacturer prices for the specialty drug products most widely used by Medicare beneficiaries rose 7.9 percent in 2006 and 8.7 percent in 2007, the first two years of operation of the Medicare Part D drug benefit, when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries (Figure 1).
- In contrast, manufacturer prices for non-specialty brand name drug products most widely used by Medicare beneficiaries rose by 7.1 percent in 2006 and 7.4 percent in 2007. Manufacturer prices for non-specialty generic drug products fell by 2.5 percent and 9.6 percent, respectively, in those years.²⁶
- The average annual increases in 2006 and 2007 (7.9 and 8.7 percent, respectively) were 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.
- Furthermore, the average annual price increase in 2007 for these specialty prescription drug products was three times the rate of general inflation²⁷ (8.7 percent vs. 2.9 percent); in 2006, the rate of specialty price increase was almost two and a half times the rate of general inflation (7.9 percent vs. 3.2 percent).

²⁶ 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," March 2008; and D. Gross, S. Schondelmeyer, and L. Purvis, "Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries, 2003 to 2007," June 2008. Available on the AARP website, http://www.aarp.org/research/health/drugs/rx_watchdog.html.

²⁷ 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 1: Average Annual Percent Change in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, 2004 to 2007

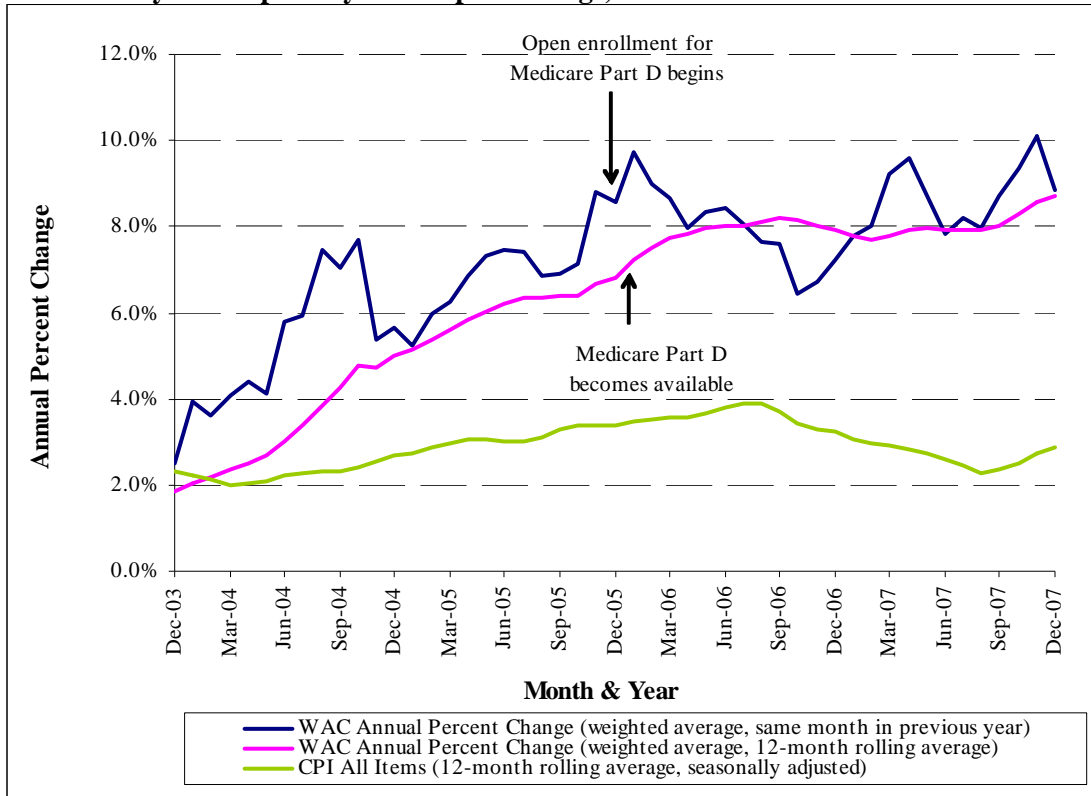


Note: Shaded bars indicate years when Medicare Part D was operational.

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., June 2008).

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 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.

Figure 2: Comparison of Rolling Average and Point-to-Point Changes in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, 2004 to 2007



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., June 2008).

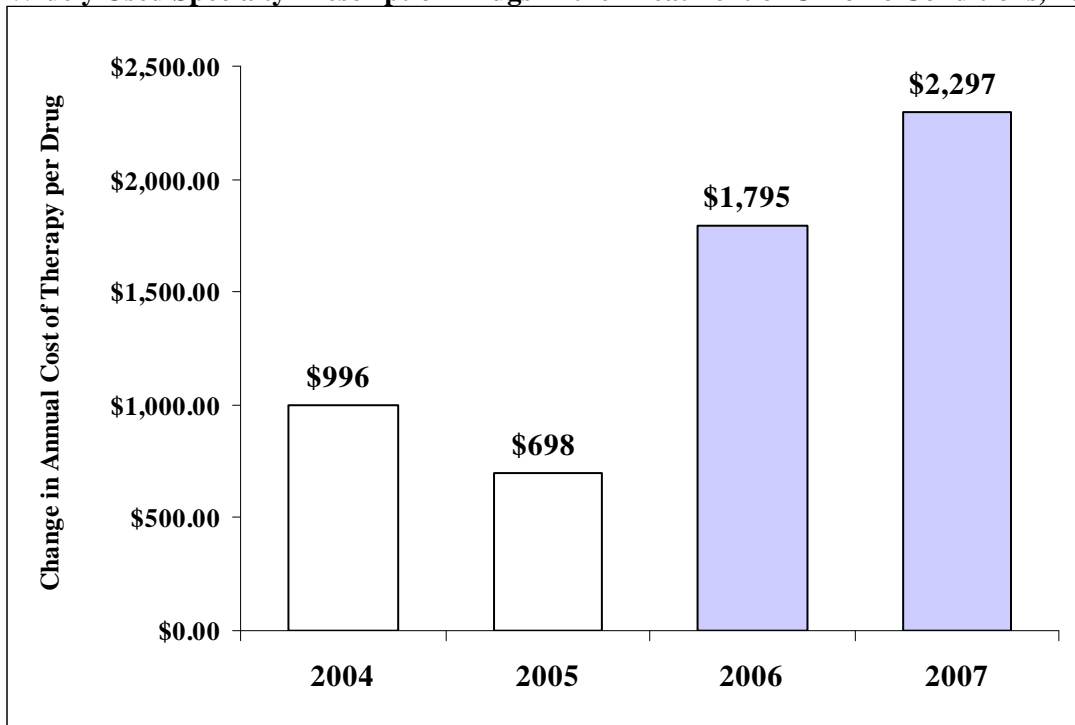
Change in annual cost of therapy

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).²⁸

- An older American who takes a specialty prescription drug is likely to have experienced an average increase in the annual cost of therapy of \$1,795 in 2006 and another \$2,297 in 2007, 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. These amounts were substantially higher than the average annual increases in previous years, which had been about \$1,000 per year in 2004 and \$700 per year in 2005.

²⁸ 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 Due to Manufacturer Price Changes for Most Widely Used Specialty Prescription Drugs in the Treatment of Chronic Conditions, 2004 to 2007



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., June 2008).

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.²⁹ 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.³⁰ Moreover, the relatively high prices of specialty drugs compared to other prescription drugs will likely push beneficiaries beyond the coverage gap and into catastrophic coverage fairly quickly, further exposing them to price increases.

²⁹ The cost impact on beneficiaries is based on the continued use of the specialty drug product. Five of the 107 brand name drug products in the specialty market basket are off-patent, making it possible for the beneficiary to save money if he or she switched to a less expensive, therapeutically-equivalent generic drug product.

³⁰ Under Part D, catastrophic coverage kicks in after the beneficiary has incurred \$3,850 in out-of-pocket drug costs. 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

As previously mentioned, the products in the specialty market basket were approved by the FDA using one of the following processes: (1) a new drug application (NDA); (2) a biologic license application (BLA); or (3) an abbreviated new drug application (ANDA). NDAs and ANDAs apply to drug products and medical devices, and BLAs apply to biological products. Seventy-five of the 144 drug products in the specialty market basket were approved under an NDA, 31 were approved 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.³¹ 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 change and annual change in cost of therapy.

Annual percent change in manufacturer prices

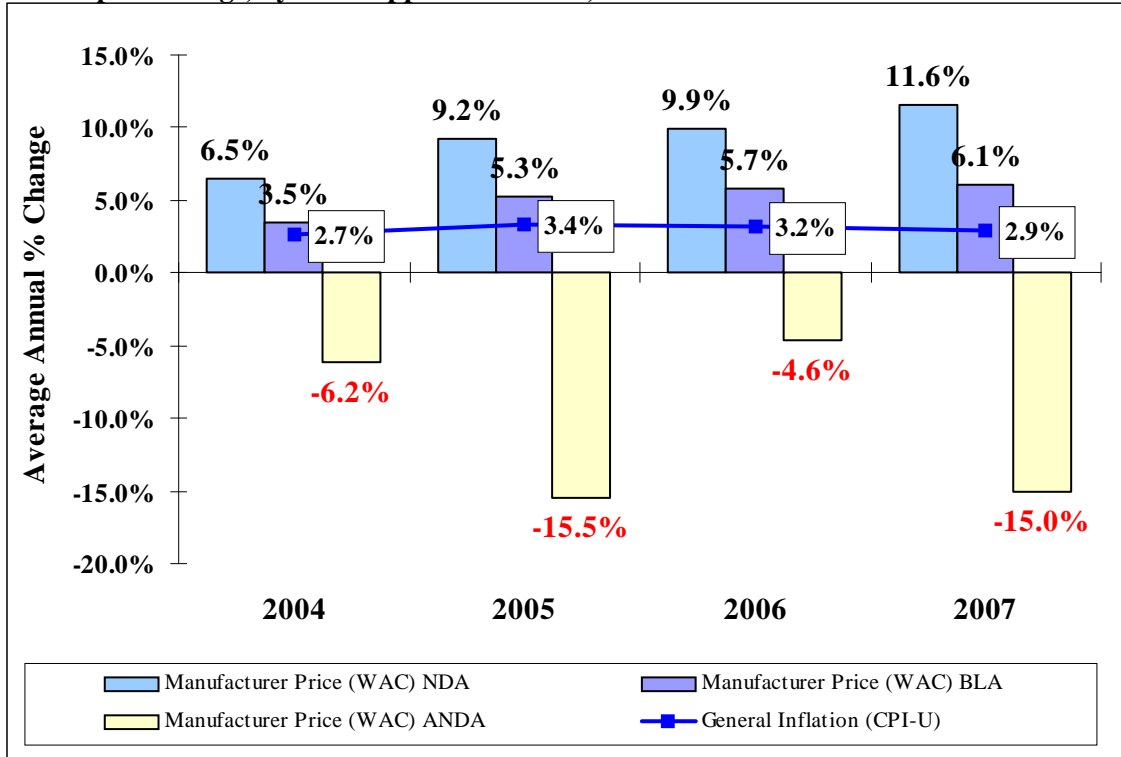
- Manufacturer prices for NDA-approved specialty drug products most widely used by Medicare beneficiaries rose by an average of 9.9 percent in 2006 and 11.6 percent in 2007, the first two years of operation of the Medicare Part D drug benefit, when measured as a 12-month rolling average and weighted by actual 2006 sales to Medicare Part D beneficiaries. These increases were substantially higher than the average increases in the two years prior to implementation of Medicare Part D. The average annual price increase in 2007 was four times the rate of general inflation (11.6 vs. 2.9 percent) (Figure 4).
- Manufacturer prices for BLA-approved specialty drug products most widely used by Medicare beneficiaries increased by an average 5.7 percent in 2006 and 6.1 percent in 2007. As was the case with NDA-approved specialty drugs, these increases were substantially higher than the average increases in the two years prior to implementation of Medicare Part D. The average annual price increase in 2007 for these drugs was more than twice the rate of general inflation (6.1 vs. 2.9 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.
- Manufacturer prices for 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 8.5 percent in 2006 and 9.8 percent in 2007. In contrast, manufacturer prices for brand name

³¹ 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. The impact of including Gammagard SD 10 Gm is shown in Figures A1 and A2 in Appendix A.

non-specialty drug products most widely used by Medicare beneficiaries increased by an average of 7.1 percent and 7.4 percent, respectively, in those years.³²

- In contrast, manufacturer prices for ANDA-approved specialty drug products most widely used by Medicare beneficiaries have consistently *decreased* over the past four 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).

Figure 4: Average Annual Percent Change in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, by FDA Approval Process, 2004 to 2007



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., June 2008).

Change in annual cost of therapy

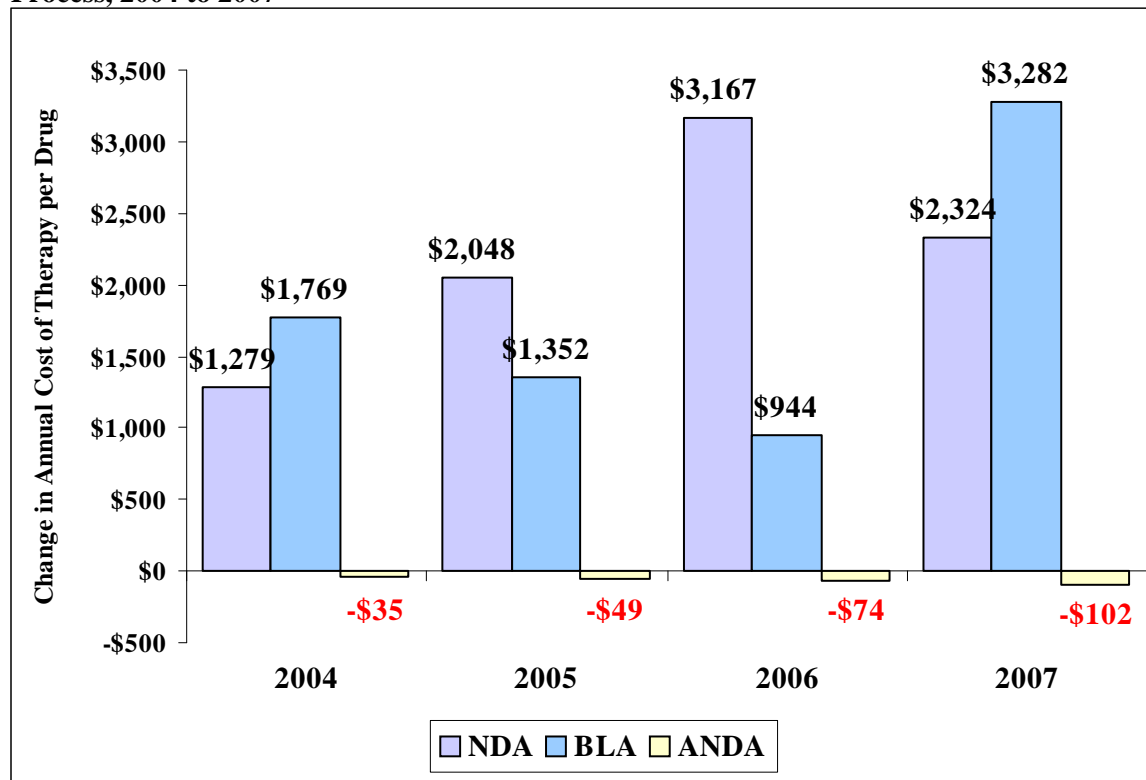
Manufacturer price changes for the widely used specialty drugs for treating chronic conditions were translated into changes in the average annual cost of therapy (Figure 5). Of the 94 drugs in the market basket that were used to treat chronic conditions,³³ 48 were NDAs, 29 were BLAs, and 17 were ANDAs.

³² 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," March 2008. Available on the AARP website, http://www.aarp.org/research/health/drugs/rx_watchdog.html.

³³ Not including Gammagard SD 10 Gm.

- 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 \$3,282 in 2007, 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 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.
- In contrast, the average annual cost of therapy decreased by more than \$102 for the typical ANDA-approved specialty prescription drug in 2007, assuming that the changes in price were passed on to the end payer in the form of lower prices. This decrease was substantially greater than the average annual decreases in previous years, which ranged from nearly \$35 per year to almost \$74 per year between 2004 through 2006.

Figure 5: Average Change in Annual Cost of Therapy Due to Manufacturer Price Changes for Most Widely Used Specialty Prescription Drugs in the Treatment of Chronic Conditions, by FDA Approval Process, 2004 to 2007



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., June 2008).

III. FOUR-YEAR CUMULATIVE IMPACT OF MANUFACTURER PRICE CHANGES FOR WIDELY USED SPECIALTY PRESCRIPTION DRUGS, 2004-2007

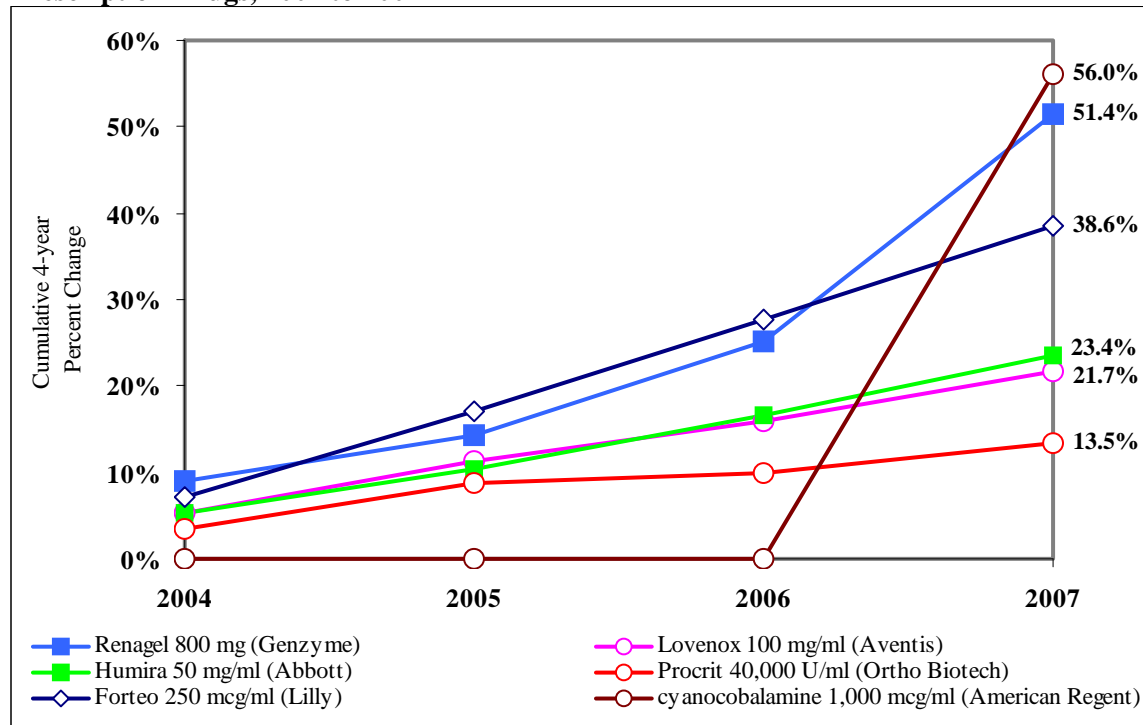
- More than three-fourths (112 of 144) of the most widely used drugs in the market basket for this analysis have been on the market for the entire four-year period from 2004 through 2007. Cumulatively, the average manufacturer price increase for these 112 specialty drug products

was 42.9 percent, compared with 14.1 percent for general inflation—or more than three times the rate of general inflation.³⁴

- Figure 6 illustrates the cumulative effect of manufacturer price changes between 2004 and 2007 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, cyanocobalamine 1,000 mcg/ml injection (American Regent), which is used to treat vitamin deficiencies, was chosen because it had the largest percent price increase in 2007 among all drug products in the market basket. Interestingly, cyanocobalamine is a generic drug, yet still had the highest price increase over the period.
- The four-year (2004 to 2007) cumulative percent change in manufacturer prices for six specific drug products is shown in Figure 6:
 - The manufacturer price of cyanocobalamine 1,000 mcg/ml injection did not change between 2004 and 2006, but rose 56 percent in 2007, when measured as a 12-month rolling average change. This one-year growth was nearly 20 times the rate of general inflation in 2007.
 - The manufacturer price of Renagel 800 mg tablets increased cumulatively by 51 percent, and the manufacturer price of Forteo 250 mcg/ml injection increased by nearly 40 percent over the four-year period.
 - The manufacturer prices of Humira 50 mg/ml injection and Lovenox 100 mg/ml injection increased by more than 20 percent between 2004 and 2007.
 - The manufacturer price of Procrit 40,000 U/ml injection increased cumulatively by 13.5 percent over the four-year period.

³⁴ The four-year average cumulative growth rate for all drugs in the market basket was 53.4 percent. This number was calculated by compounding the average annual growth rate for each year from 2004 to 2007.

Figure 6: Four-Year Cumulative Percent Change in Manufacturer Price for Six Widely Used Specialty Prescription Drugs, 2004 to 2007



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., June 2008).

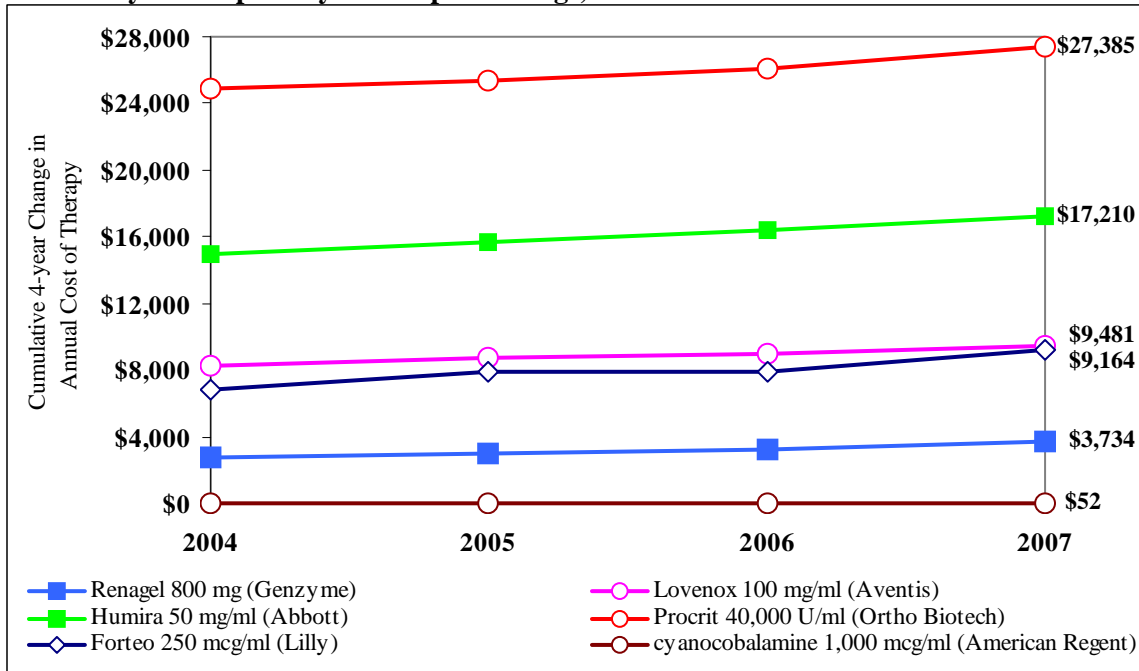
Four-year cumulative change in annual cost of therapy

- 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 2007, the average annual cost of therapy for these drug products was \$6,690 higher than four years earlier, assuming that manufacturers' price increases were passed along in the form of higher prices³⁵ and that the consumer used these specialty drugs for chronic conditions.
- The four-year (2004 to 2007) 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 more than \$27,000 between the end of 2003 and the end of 2007, while manufacturer prices for a one-year supply of Humira 50 mg/ml injection rose by over \$17,000.
 - Manufacturer prices for a one-year supply of Lovenox 100 mg/ml injection and Forteo 250 mcg/ml injection rose by more than \$9,000 between the end of 2003 and the end of 2007

³⁵ The actual amount that an individual consumer pays out-of-pocket may depend on a variety of factors.

- Manufacturer prices for a one-year supply of Renagel 800 mg tablets rose by almost \$4,000 by the end of the four-year period (2004 to 2007).
- Although the generic drug cyanocobalamine 1,000 mcg/ml injection had the largest one-year percentage increase in the four year period, the manufacturer price for a one year supply of this drug rose by only \$52 by the end of the four-year period spanning from the end of 2003 to the end of 2007.

Figure 7: Four-Year Cumulative Change in Cost of Therapy Due to Manufacturer Price Changes for Six Widely Used Specialty Prescription Drugs, 2004 to 2007



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., June 2008).

IV. MANUFACTURER PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS IN 2007

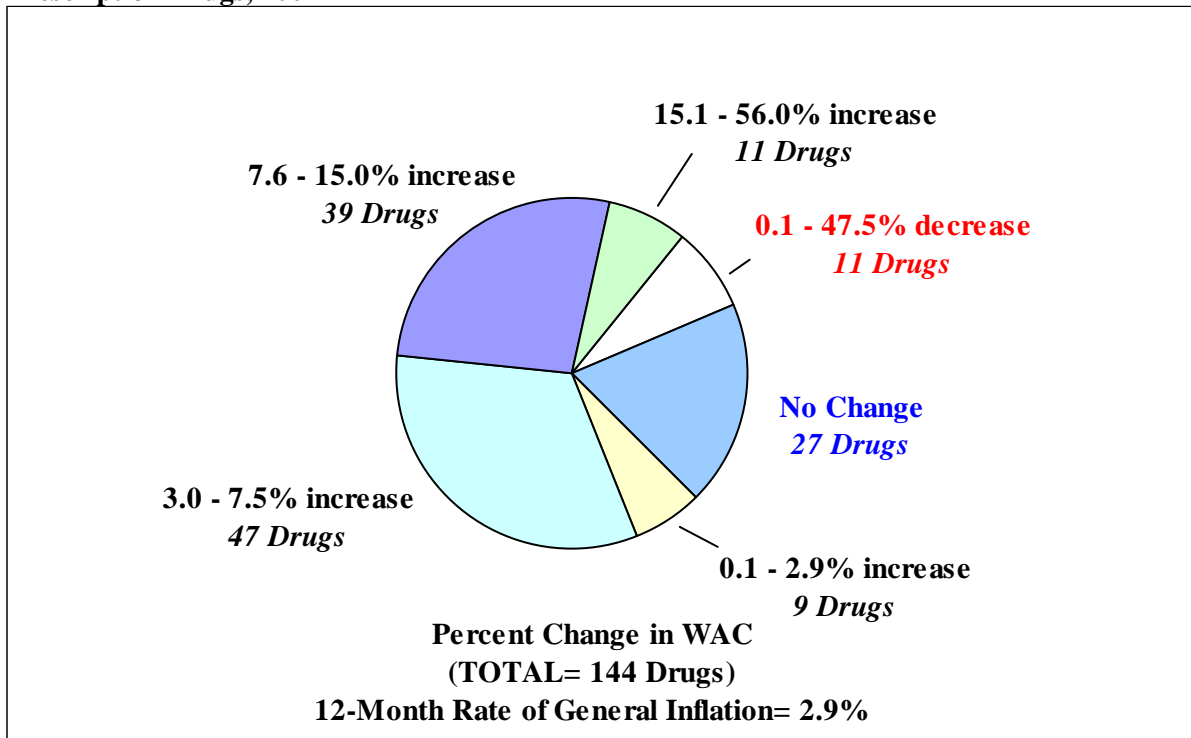
Distribution of manufacturer price changes

Seventy-four percent (106 of 144) of the most widely used specialty prescription drug products in this study's market basket had manufacturer price increases during 2007, when measured as a 12-month rolling average (Figure 8).

- Annual manufacturer price increases for 97 (67.4 percent) of the 144 drug products exceeded the rate of general inflation (2.9 percent) in 2007.
- Annual manufacturer price increases for 68 (47.2 percent) of the 144 drug products increased more than 5.0 percent in 2007, including 28 (19.4 percent) with a price increase between 7.6 percent and 10.0 percent, 11 (7.6 percent) with a price increase between 10.1 and 15.0 percent, and 11 (7.6 percent) with a price increase of more than 15.0 percent.

One-quarter (36 of the 144 drug products) had more than one manufacturer price increase during 2007. One drug—Gamunex 10% injection—had four price increases during 2007. Three other drugs—Avonex 60 mcg/ml kit, Rebif 88 ml injection, and Avonex 30 mcg injection—had three price increases in 2007.

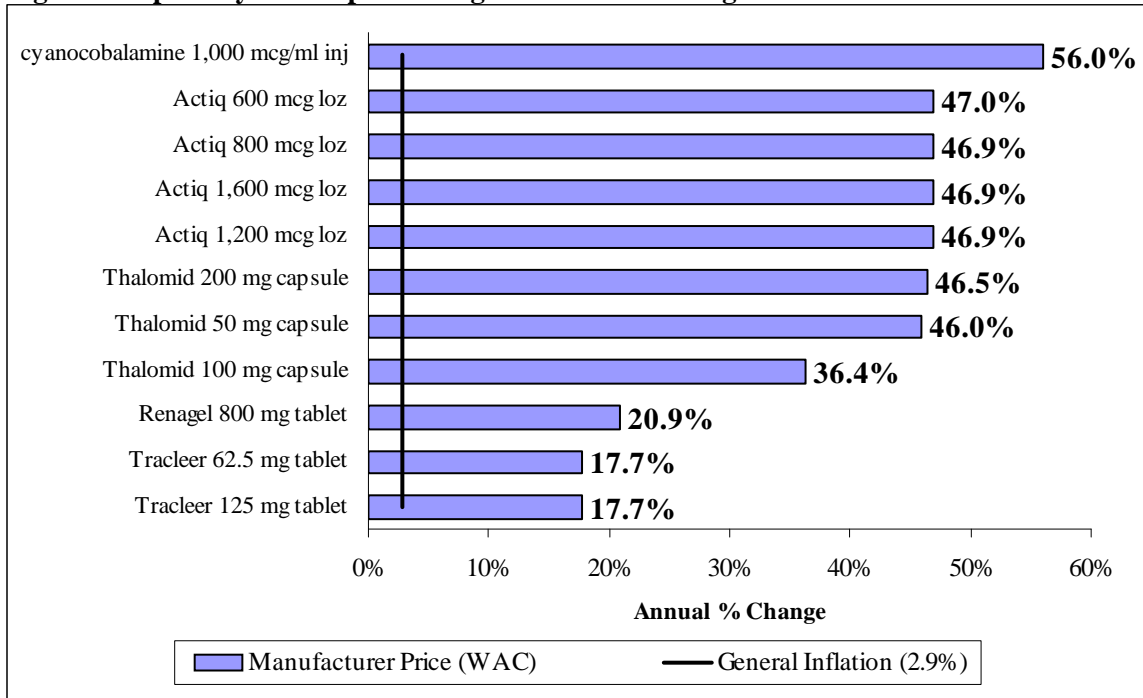
Figure 8: Distribution of Percent Changes in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, 2007



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., June 2008).

Eleven specialty drug products had increases in manufacturer price of at least six times the rate of general inflation, ranging from 17.7 percent to 56.0 percent (Figure 9). Five of them (Tracleer 62.5 and 125 mg tablet and Thalomid 50, 100, and 200 mg capsule) were among the 36 drug products that had more than one price increase in 2007, while the other six had a greater than 15 percent increase with a single change in price in 2007.

Figure 9: Specialty Prescription Drug Products with Largest Increases in Manufacturer Price, 2007



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

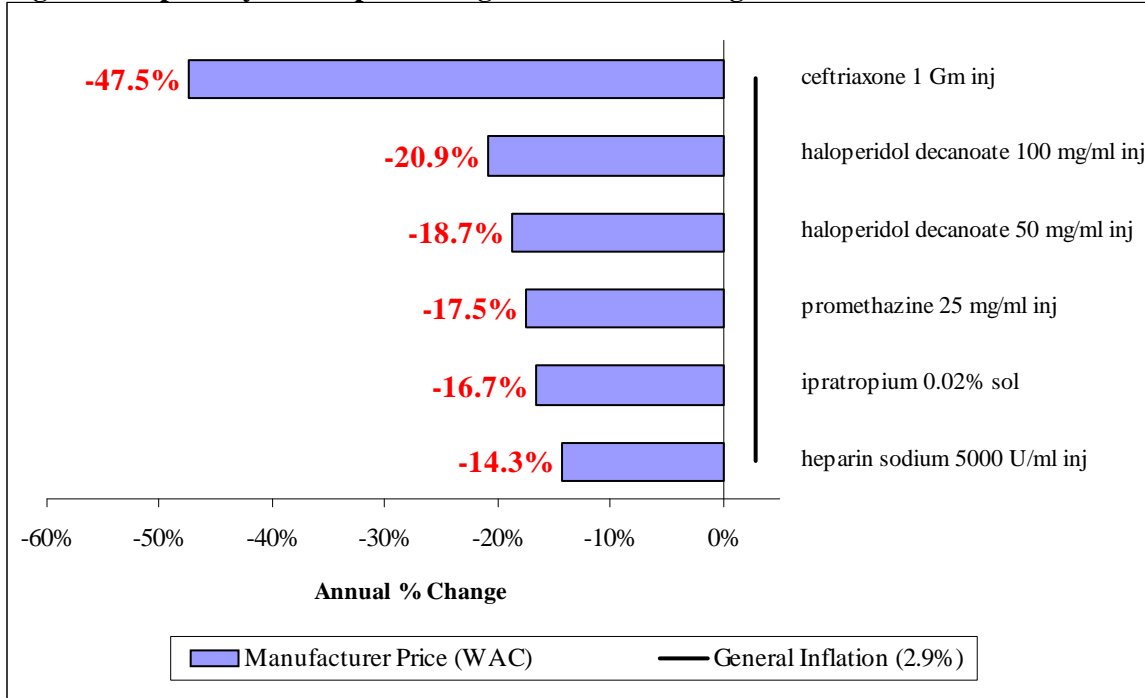
Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., June 2008).

Annual manufacturer prices *decreased* for 11 (7.6 percent) of the 144 drug products, with price decreases that ranged from 2.7 percent to 47.5 percent. All the drug products with a decrease in manufacturer price for 2007 were generics.

- One drug product—promethazine 25 mg/ml injection—had two price decreases in 2007.

The six specialty drug products with the largest decreases in manufacturer price had decreases ranging from 14.3 percent to 47.5 percent (Figure 10).

Figure 10: Specialty Prescription Drug Products with Largest Decreases in Manufacturer Price, 2007



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., June 2008).

More than 95 percent (24 of 25) of the specialty drug products with the greatest sales in 2006 had manufacturer price increases during 2007. All but one of these top-selling 25 drug products had an increase that exceeded the rate of general inflation in 2007 (2.9 percent). The remaining 23 drug products had annual manufacturer price increases that exceeded the rate of general inflation, including 8 drug products that had price increases more than four times the rate of general inflation (11.6 percent) (Table 3).

Table 3: Annual Percent Change in Manufacturer Prices for Top 25 Specialty Prescription Drug Products, 2007

| 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 | 20.9% |
| 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 | 5.8% |
| 4 | Humira 50 mg/ml kit | 2 x 1 | Abbott | Arthritis, Severe | 5.8% |
| 5 | Procrit 40,000 U/ml inj | 4 x 1 | Ortho Biotech | Erythropoietins | 3.2% |
| 6 | Forteo 250 mcg/ml soln | 1 x 28 | Lilly | Calcium Regulators | 8.5% |
| 7 | Copaxone 20 mg/ml kit | 1 x 30 | Teva Neuroscience | Multiple Sclerosis Agents | 14.4% |
| 8 | Avonex 60 mcg/ml kit | 4 x 1 | Biogen Idec | Multiple Sclerosis Agents | 13.0% |
| 9 | Tracleer 125 mg tablet | 1 x 60 | Actelion Pharmaceuticals | Pulmonary Hypertension | 17.7% |
| 10 | Reyataz 150 mg capsule | 1 x 60 | Bristol-Myers Squibb | Antiretrovirals | 5.3% |
| 11 | Procrit 20,000 U/ml inj | 6 x 2 | Ortho Biotech | Erythropoietins | 3.2% |
| 12 | Tarceva 150 mg tablet | 1 x 30 | Genentech | Cancer Agents | 12.3% |
| 13 | Gleevec 400 mg tablet | 1 x 30 | Novartis | Cancer Agents | 7.9% |
| 14 | Procrit 10,000 U/ml inj | 6 x 1 | Ortho Biotech | Erythropoietins | 3.2% |
| 15 | Betaseron 0.3 mg inj | 15 x 1 | Berlex | Multiple Sclerosis Agents | 13.3% |
| 16 | Risperdal 50 mg inj | 1 x 1 | Janssen | Tranquilizers | 2.0% |
| 17 | Sensipar 30 mg tablet | 1 x 30 | Amgen | Calcium Reduction | 8.2% |
| 18 | Zyvox 600 mg tablet | 1 x 20 | Pfizer U.S. | Antibiotics, Misc. | 12.2% |
| 19 | Enbrel 25 mg inj | 4 x 1 | Amgen | Arthritis, Severe | 5.8% |
| 20 | Trizivir 300 mg-150 mg-300 mg tablet | 1 x 60 | GlaxoSmithKline | Antiretrovirals | 6.9% |
| 21 | Sensipar 60 mg tablet | 1 x 30 | Amgen | Calcium Reduction | 8.2% |
| 22 | Byetta 250 mcg/ml inj | 1 x 60 | Amylin Pharmaceuticals | Diabetes Care | 8.4% |
| 23 | Thalomid 50 mg capsule | 10 x 28 | Celgene Corp | Leprosy Agents | 46.0% |
| 24 | ipratropium 0.02% soln | 25 x 2.5 | Dey Labs | Bronchial Dilators | -16.7% |
| 25 | Rebif 88 ml inj | 12 x 1 | Serono | Multiple Sclerosis Agents | 10.2% |
| General rate of inflation (as measured by growth in CPI-U) | | | | | 2.9% |

*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., June 2008).

- Celgene Corporation's Thalomid 50 mg capsules had the highest annual percent increase (46.0 percent) in manufacturer price during 2007 among the top 25 specialty drug products with the greatest sales in 2006.
- Three of the top 25 drug products had annual changes in manufacturer price of more than 15 percent—or more than five times the rate of general inflation. In addition to Celgene Corporation's Thalomid 50 mg capsules, the other drug products were Genzyme's Renagel 800 mg tablets and Actelion Pharmaceuticals' Tracleer 125 mg tablets.
- Dey Labs' ipratropium's 0.02% solution was the sole drug product among the top 25 specialty drug products that had a decrease (-16.7 percent) in manufacturer price in 2007.

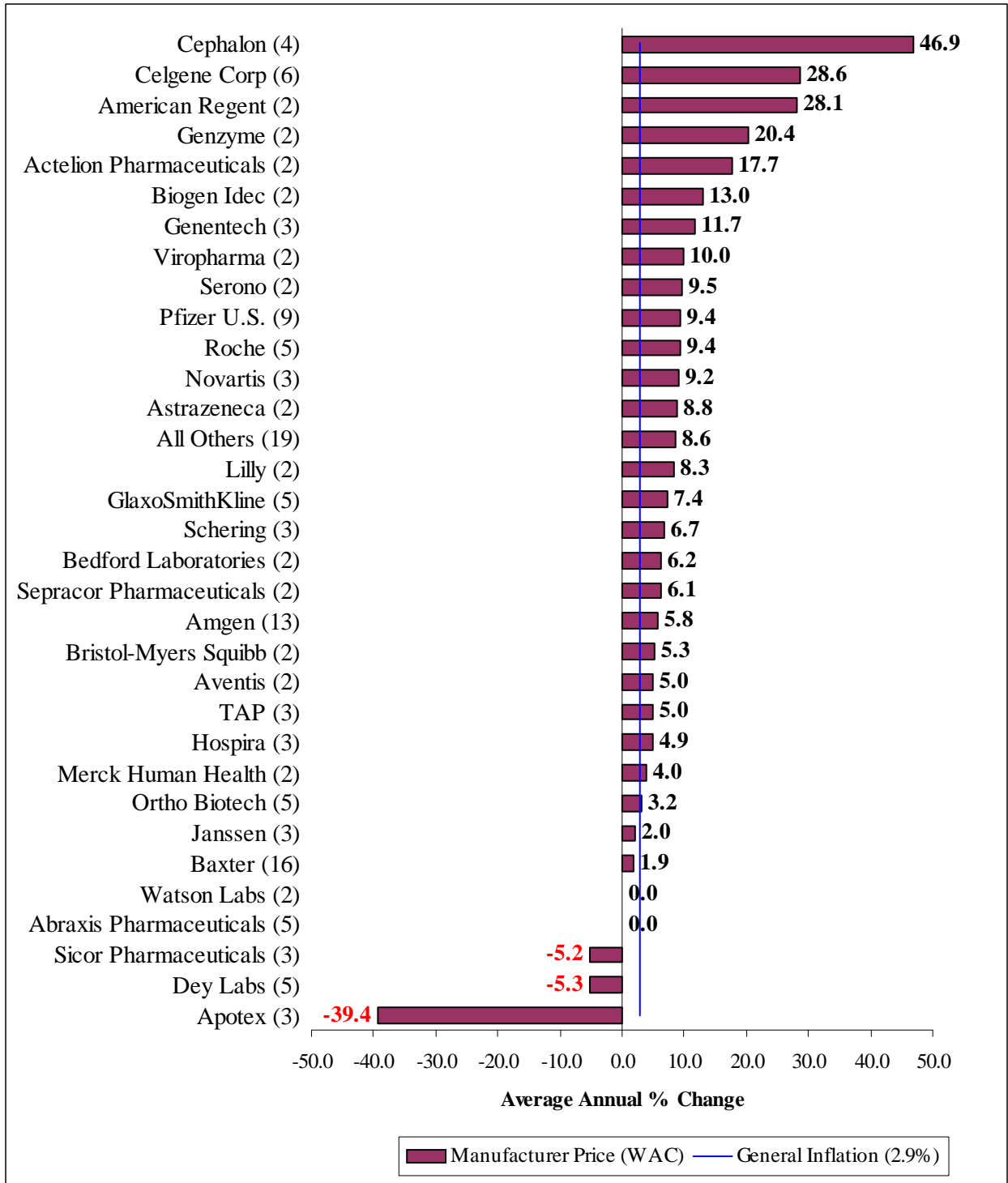
Ipratropium is also the only generic drug among the top 25 specialty drug products with the greatest sales in 2006.

V. MANUFACTURER PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY MANUFACTURER AND BY THERAPEUTIC CATEGORY

Thirty-two 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 32 drug manufacturers exceeded the rate of general inflation in 2007 (Figure 11).

- Three manufacturers—Cephalon, Celgene Corporation, and American Regent—had average annual price increases for the drug products in their market basket of more than nine times the rate of general inflation (i.e., greater than 26.1 percent) during 2007. Most notably, Cephalon had an average annual price increase of 46.9 percent, or more than 16 times the rate of general inflation (2.9 percent).
- More than half the drug manufacturers (19 of 32) had weighted average annual price increases that were at least twice the rate of general inflation during 2007 (i.e., equal to or greater than 5.8 percent, or twice the rate of general inflation at 2.9 percent).
- Two manufacturers—Watson Labs and Abraxis Pharmaceuticals—did not change prices for widely used specialty drugs in 2007.
- Three manufacturers—Sicor Pharmaceuticals, Dey Labs, and Apotex—had average annual price *decreases* in 2007. The average 2007 price changes for these manufacturers were -5.2 percent, -5.3 percent, and -39.4 percent, respectively. Most (9 of 11) of the drug products from these manufacturers were generic.

Figure 11: Average Annual Percent Change in Manufacturer Price for Specialty Prescription Drugs by Manufacturer, 2007



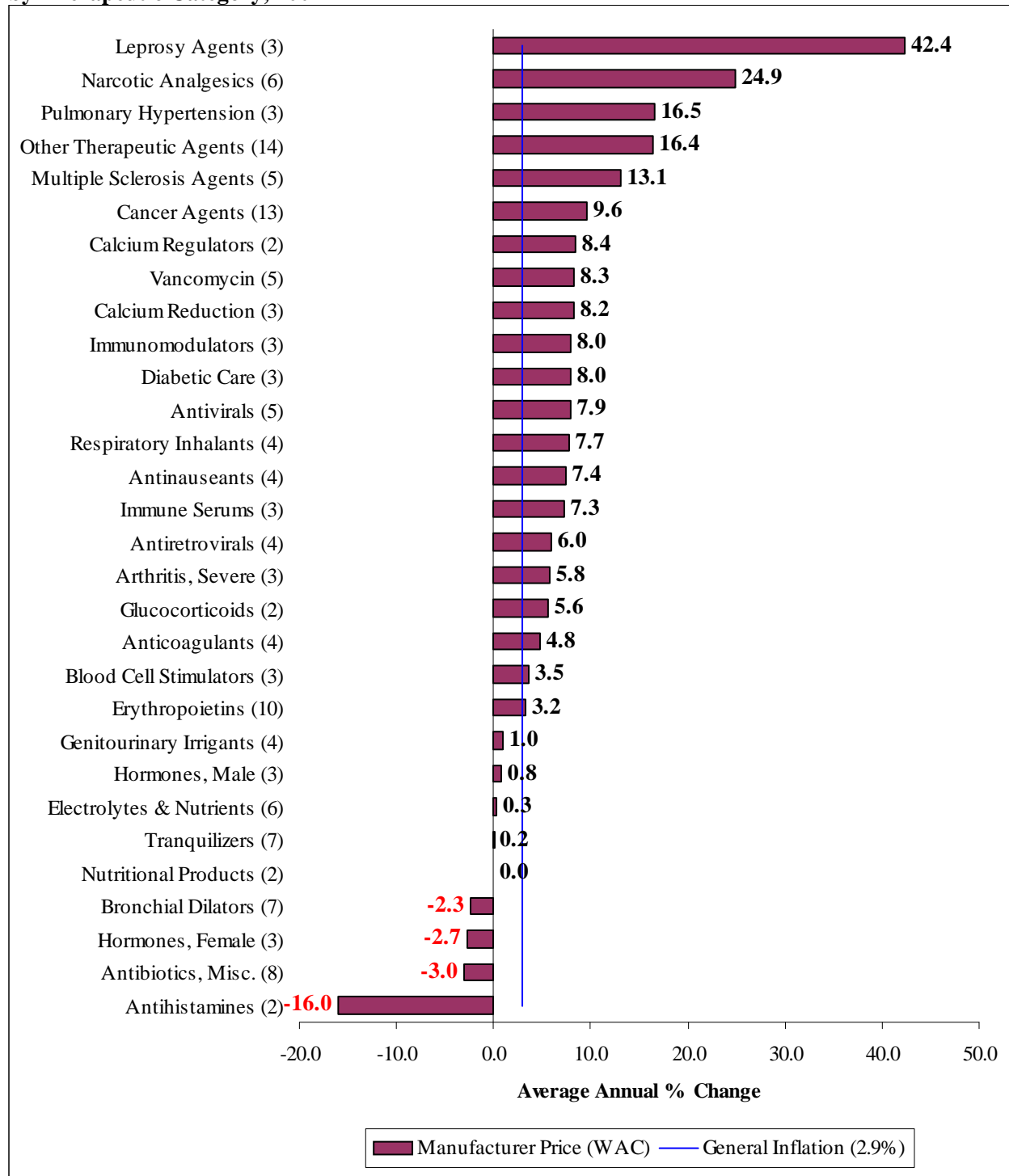
Notes: Manufacturers with fewer than two drug products in the 2006 market basket of most widely used specialty prescription drugs are included in the “All Others” category. The number in parentheses after a manufacturer’s name indicates the number of drug products in the market basket for that manufacturer. 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., June 2008).

Twenty-one of the 30 therapeutic categories of specialty drug products had average annual manufacturer price increases that exceeded the rate of general inflation (2.9 percent) in 2007 (Figure 12).

- The therapeutic category with the highest manufacturer price increase—leprosy agents—had an average annual manufacturer price increase of 42.4 percent in 2007—more than 14 times the rate of general inflation in 2007. Five therapeutic categories, including the leprosy agents, had average annual price increases of more than four times the rate of general inflation (i.e., more than 11.6 percent per year).
- Seventeen of the 30 therapeutic categories had average annual manufacturer price increases that met or exceeded twice the general inflation rate during 2007 (i.e., equal to or greater than 5.8 percent).
- Four therapeutic categories—bronchial dilators, female hormones, miscellaneous antibiotics, and antihistamines—had average annual price *decreases* in 2007. Manufacturer prices for these categories decreased by 2.3 percent to 16.0 percent.
- Four therapeutic categories—genitourinary irrigants (used for irrigation), male hormones, electrolytes and nutrients, and tranquilizers—had average price increases that were less than the rate of general inflation in 2007. Another therapeutic category, nutritional products, had no change in average price for 2007.

Figure 12: Average Annual Percent Change in Manufacturer Price for Specialty Prescription Drugs by Therapeutic Category, 2007



Notes: Therapeutic categories with fewer than two drug products in the 2006 market basket of most widely used specialty prescription drugs are included in the “Other Therapeutic Agents” category. The number in parentheses after a therapeutic category indicates the number of drug products in the market basket for that therapeutic category. The general inflation rate is based on CPI-U. Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Medi-Span Price-Chek PC (Indianapolis, IN: Wolters Kluwer Health Inc., June 2008).

CONCLUDING OBSERVATIONS

Specialty drug expenditures are growing faster than other segments in the pharmaceutical market. This growth can be due to several factors including 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 or provider 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 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.

Higher drug manufacturer prices to providers or 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 providers and pharmacies (thereby forcing the providers or 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.

Price increases are only one dimension of how much consumers pay for a given specialty drug. For example, the unusually high price for many of these drug products means that the ultimate cost would be substantial even if the manufacturer’s price remained unchanged. In addition, consumers may bear an increased share of costs due to changes in insurance coverage (e.g., coverage on a specialty tier with high cost sharing). While some insurers may be able to negotiate rebates from manufacturers, the Medicare Part D plans are not passing most of their rebates along to consumers. This report does not address the issue of policies that promote economic competition in the pharmaceutical market, although it is widely expected that proposals such as allowing generic biologic drugs would lead to more competitive pricing in the market. Finally, each of these factors may affect the ultimate amount that consumers will pay for their specialty drug product.

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 annual average rates of increase in 2006 (7.9 percent) and 2007 (8.7 percent) were substantially higher than the average annual increases of 5.0 percent and 6.8 percent in the previous two years. The 2007 average rate of increase (8.7 percent) was more than three times the rate of general inflation (2.9 percent). In contrast, brand name non-specialty drugs widely used by Medicare beneficiaries experienced a 7.4 percent increase in 2007, and generic non-specialty drugs widely used by Medicare beneficiaries experienced a 9.6 percent decrease.

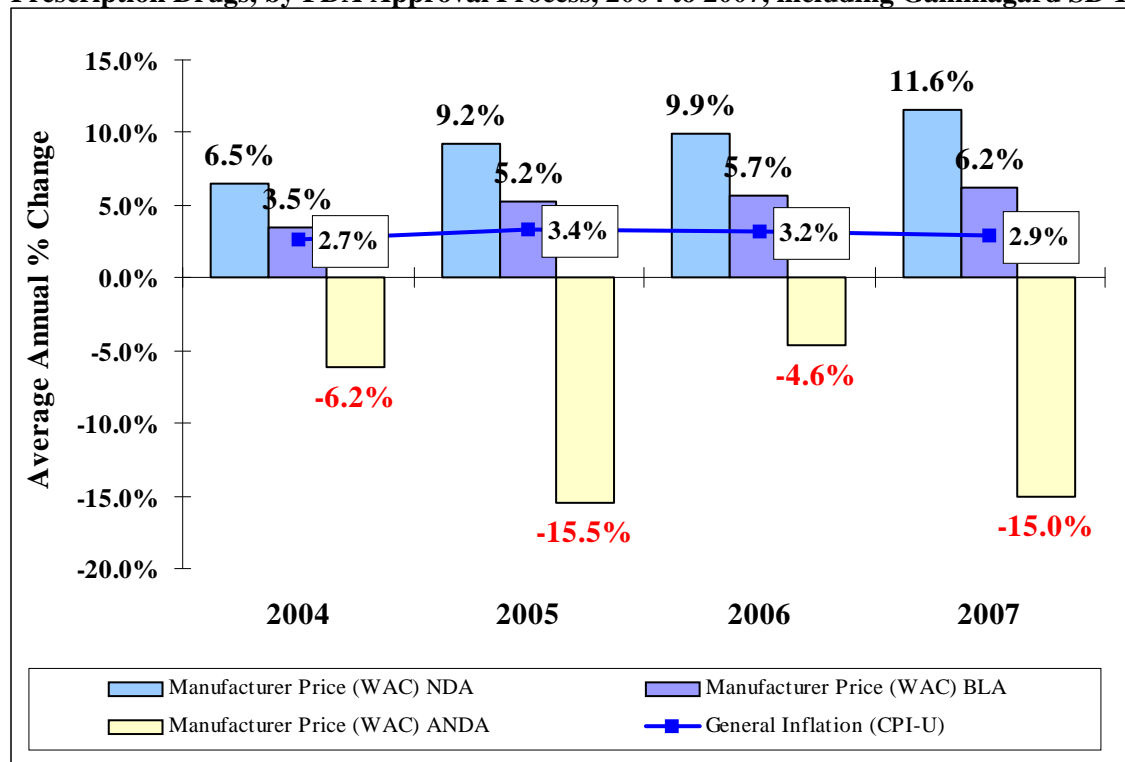
About two-thirds (67 percent or 97 of 144 drug products) of the specialty drug products had manufacturer price increases that exceeded the rate of general inflation during 2007. More than one-fifth (35 of the 144 drug products) had more than one manufacturer price increase during 2007. Only 11 of the 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 2007 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 29 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 42.9 percent during the subsequent four-year period (2004 through 2007), compared with a general inflation rate of 14.1 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 \$6,690 during this four-year period.

APPENDIX A: IMPACT OF GAMMAGARD PRICE CHANGE IN 2005 ON AVERAGE BLA-APPROVED SPECIALTY MANUFACTURER PRICE CHANGE

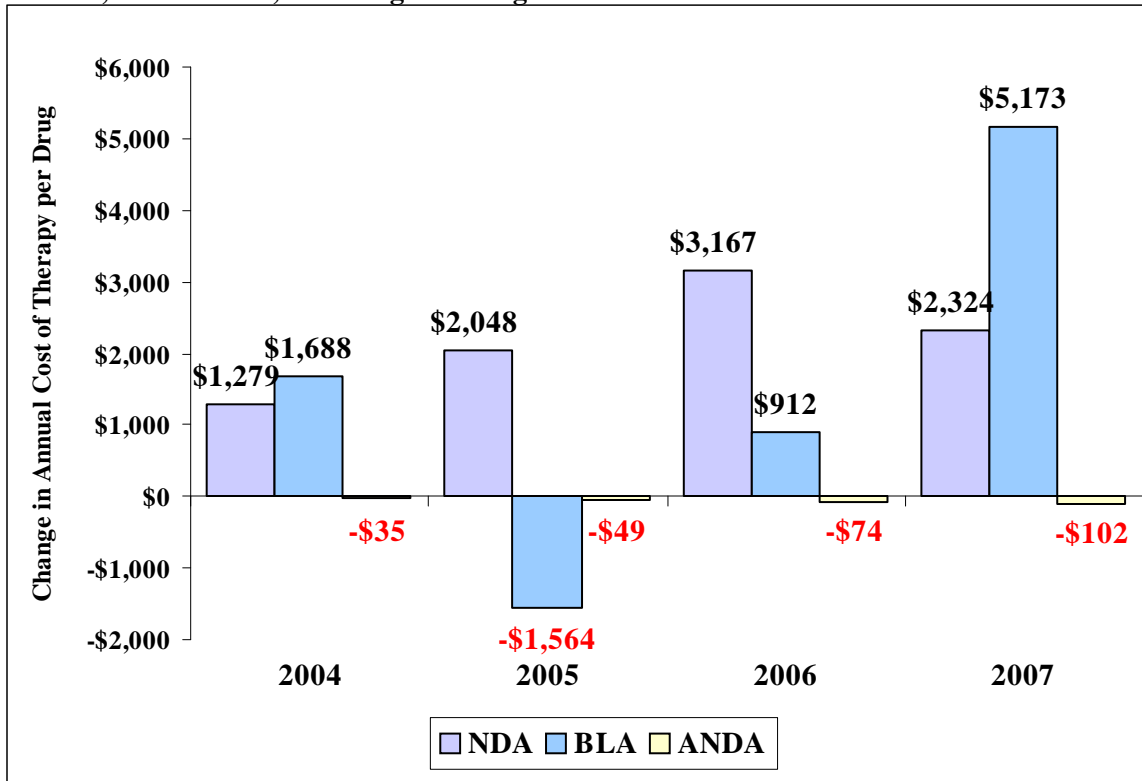
As noted in the main report, one drug product (Gammagard SD 10 Gm) had a one-time decrease in drug manufacturer price in 2005. Since this price change was an extreme outlier that substantially distorted the average price increase for 2005, Gammagard SD 10 Gm was excluded from the analyses by FDA approval process. Gammagard SD 10 Gm was ranked 96 among the 144 most widely used brand name prescription drugs when sorted by 2006 sales of a Medicare Part D plan provider. The impact of including Gammagard SD 10 Gm, shown in Figures A1 and A2, corresponds with Figures 4 and 5 in the main body of the report.

Figure A1: Average Annual Percent Change in Manufacturer Prices for Most Widely Used Specialty Prescription Drugs, by FDA Approval Process, 2004 to 2007, including 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., June 2008).

Figure A2: Average Change in Annual Cost of Therapy Due to Manufacturer Price Changes for Most Widely Used Specialty Prescription Drugs in the Treatment of Chronic Conditions, by FDA Approval Process, 2004 to 2007, including 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., June 2008).

APPENDIX B: MARKET BASKET OF SPECIALTY DRUG PRODUCTS MOST WIDELY USED BY MEDICARE BENEFICIARIES AND ANNUAL PERCENT CHANGE IN MANUFACTURER PRICES: 2007

| Rank by Sales among Study Market Basket* | Product Name, Strength, and Dosage Form | Package Quantity and Size | Manufacturer | Therapeutic Class | FDA Approval Process | 2007 Annual Percent Change in WAC |
|---|--|----------------------------------|--------------------------|---------------------------|-----------------------------|--|
| 1 | Renagel 800 mg tablet | 1 x 180 | Genzyme | Phosphate Regulation | NDA | 20.9% |
| 2 | Lovenox 100 mg/ml inj | 10 x 0.4 | Aventis | Anticoagulants | NDA | 5.0% |
| 3 | Enbrel 50 mg/ml inj | 4 x 1 | Amgen | Arthritis, Severe | BLA | 5.8% |
| 4 | Humira 50 mg/ml kit | 2 x 1 | Abbott | Arthritis, Severe | BLA | 5.8% |
| 5 | Procrit 40,000 U/ml inj | 4 x 1 | Ortho Biotech | Erythropoietins | BLA | 3.2% |
| 6 | Forteo 250 mcg/ml soln | 1 x 28 | Lilly | Calcium Regulators | NDA | 8.5% |
| 7 | Copaxone 20 mg/ml kit | 1 x 30 | Teva Neuroscience | Multiple Sclerosis Agents | NDA | 14.4% |
| 8 | Avonex 60 mcg/ml kit | 4 x 1 | Biogen Idec | Multiple Sclerosis Agents | BLA | 13.0% |
| 9 | Tracleer 125 mg tablet | 1 x 60 | Actelion Pharmaceuticals | Pulmonary Hypertension | NDA | 17.7% |
| 10 | Reyataz 150 mg capsule | 1 x 60 | Bristol-Myers Squibb | Antiretrovirals | NDA | 5.3% |
| 11 | Procrit 20,000 U/ml inj | 6 x 2 | Ortho Biotech | Erythropoietins | BLA | 3.2% |
| 12 | Tarceva 150 mg tablet | 1 x 30 | Genentech | Cancer Agents | NDA | 12.3% |
| 13 | Gleevec 400 mg tablet | 1 x 30 | Novartis | Cancer Agents | NDA | 7.9% |
| 14 | Procrit 10,000 U/ml inj | 6 x 1 | Ortho Biotech | Erythropoietins | BLA | 3.2% |
| 15 | Betaseron 0.3 mg inj | 15 x 1 | Berlex | Multiple Sclerosis Agents | BLA | 13.3% |
| 16 | Risperdal 50 mg inj | 1 x 1 | Janssen | Tranquilizers | NDA | 2.0% |
| 17 | Sensipar 30 mg tablet | 1 x 30 | Amgen | Calcium Reduction | NDA | 8.2% |
| 18 | Zyvox 600 mg tablet | 1 x 20 | Pfizer U.S. | Antibiotics, Misc. | NDA | 12.2% |
| 19 | Enbrel 25 mg inj | 4 x 1 | Amgen | Arthritis, Severe | BLA | 5.8% |
| 20 | Trizivir 300 mg-150 mg-300 mg tablet | 1 x 60 | GlaxoSmithKline | Antiretrovirals | NDA | 6.9% |
| 21 | Sensipar 60 mg tablet | 1 x 30 | Amgen | Calcium Reduction | NDA | 8.2% |
| 22 | Byetta 250 mcg/ml inj | 1 x 60 | Amylin Pharmaceuticals | Diabetes Care | NDA | 8.4% |
| 23 | Thalomid 50 mg capsule | 10 x 28 | Celgene Corp | Leprosy Agents | NDA | 46.0% |
| 24 | ipratropium 0.02% soln | 25 x 2.5 | Dey Labs | Bronchial Dilators | ANDA | -16.7% |
| 25 | Rebif 88 ml inj | 12 x 1 | Serono | Multiple Sclerosis Agents | BLA | 10.2% |
| 26 | Duoneb 2.5-0.5 mg/3ml soln | 30 x 3 | Dey Labs | Bronchial Dilators | NDA | 6.1% |
| 27 | Aranesp 200 mcg/ml inj | 4 x 1 | Amgen | Erythropoietins | BLA | 3.3% |

| Rank by Sales among Study Market Basket* | Product Name, Strength, and Dosage Form | Package Quantity and Size | Manufacturer | Therapeutic Class | FDA Approval Process | 2007 Annual Percent Change in WAC |
|--|---|---------------------------|-----------------------------|-----------------------------|----------------------|-----------------------------------|
| 28 | Valcyte 450 mg tablet | 1 x 60 | Roche | Antivirals | NDA | 8.8% |
| 29 | oxycontin 80 mg tablet CR | 1 x 100 | Purdue Pharma | Narcotic Analgesics | NDA | 4.3% |
| 30 | Gleevec 100 mg tablet | 1 x 100 | Novartis | Cancer Agents | NDA | 11.6% |
| 31 | Thalomid 100 mg capsule | 5 x 28 | Celgene Corp | Leprosy Agents | NDA | 36.4% |
| 32 | Fuzeon kit | 60 x 1 | Roche | Antiretrovirals | NDA | 7.6% |
| 33 | Xeloda 500 mg tablet | 1 x 120 | Roche | Cancer Agents | NDA | 14.0% |
| 34 | Sensipar 90 mg tablet | 1 x 30 | Amgen | Calcium Reduction | NDA | 8.2% |
| 35 | Aranesp 500 mcg/ml inj | 4 x 1 | Amgen | Erythropoietins | BLA | 3.3% |
| 36 | Vancocin HCl 250 mg capsule | 1 x 20 | Viropharma | Vancomycin | NDA | 10.0% |
| 37 | Risperdal 37.5 mg inj | 1 x 1 | Janssen | Tranquilizers | NDA | 2.0% |
| 38 | Revlimid 10 mg capsule | 1 x 100 | Celgene Corp | Immunomodulators | NDA | 9.9% |
| 39 | Risperdal 25 mg inj | 1 x 1 | Janssen | Tranquilizers | NDA | 2.0% |
| 40 | Xopenex 1.25 mg/3ml nebulizer | 24 x 3 | Sepracor Pharmaceuticals | Bronchial Dilators | NDA | 6.1% |
| 41 | Pegasys kit | 4 x 1 | Roche | Antivirals | BLA | 7.4% |
| 42 | Marinol 10 mg capsule | 1 x 60 | Unimed | Antinauseants | NDA | 9.0% |
| 43 | albuterol 0.083% nebulizer | 25 x 3 | Dey Labs | Bronchial Dilators | ANDA | -5.9% |
| 44 | Pulmicort 0.25 mg/ml susp | 30 x 2 | Astrazeneca | Respiratory Inhalants | NDA | 9.7% |
| 45 | Ceftriaxone 1 Gm inj | 10 x 1 | Apotex | Antibiotics, Misc. | ANDA | -47.5% |
| 46 | Revlimid 5 mg capsule | 1 x 100 | Celgene Corp | Immunomodulators | NDA | 9.9% |
| 47 | Tarceva 100 mg tablet | 1 x 30 | Genentech | Cancer Agents | NDA | 12.3% |
| 48 | Lovenox 150 mg/ml inj | 10 x 0.8 | Aventis | Anticoagulants | NDA | 5.0% |
| 49 | Nexavar 200 mg tablet | 1 x 120 | Bayer Pharmaceutical | Cancer Agents | NDA | 6.8% |
| 50 | Xopenex 0.21 mg/ml nebulizer | 24 x 3 | Sepracor Pharmaceuticals | Bronchial Dilators | NDA | 6.1% |
| 51 | Sutent 50 mg capsule | 1 x 28 | Pfizer U.S. | Cancer Agents | NDA | 3.0% |
| 52 | Serostim 6 mg inj | 7 x 1 | Serono | Growth Hormones | NDA | 7.7% |
| 53 | Exjade 500 mg tablet | 1 x 30 | Novartis | Antidotes, Chelating Agents | NDA | 8.6% |
| 54 | Atripla 600 mg 200 mg 300 mg tablet | 1 x 30 | Bristol-Myers Squibb/Gilead | Antiretrovirals | NDA | 3.1% |
| 55 | Zofran 8 mg tablet | 1 x 30 | GlaxoSmithKline | Antinauseants | NDA | 6.4% |
| 56 | Neupogen 600 mcg/ml inj | 10 x 1 | Amgen | Blood Cell Stimulators | BLA | 3.5% |
| 57 | Tracleer 62.5 mg tablet | 1 x 60 | Actelion Pharmaceuticals | Pulmonary Hypertension | NDA | 17.7% |

| Rank by Sales among Study Market Basket* | Product Name, Strength, and Dosage Form | Package Quantity and Size | Manufacturer | Therapeutic Class | FDA Approval Process | 2007 Annual Percent Change in WAC |
|--|---|---------------------------|---------------------------|---------------------------|----------------------|-----------------------------------|
| 58 | Revlimid 25 mg capsule | 1 x 100 | Celgene Corp | Immunomodulators | NDA | 1.8% |
| 59 | Aranesp 100 mcg/ml inj | 4 x 1 | Amgen | Erythropoietins | BLA | 3.4% |
| 60 | Revatio 20 mg tablet | 1 x 90 | Pfizer U.S. | Pulmonary Hypertension | NDA | 8.6% |
| 61 | Vancocin HCl 125 mg capsule | 1 x 20 | Viropharma | Vancomycin | NDA | 10.0% |
| 62 | Avonex 30 mcg inj | 4 x 1 | Biogen Idec | Multiple Sclerosis Agents | BLA | 13.0% |
| 63 | Thalomid 200 mg capsule | 3 x 28 | Celgene Corp | Leprosy Agents | NDA | 46.5% |
| 64 | Lupron Depot 30 mg inj | 1 x 1 | TAP | Cancer Agents | NDA | 5.0% |
| 65 | Vfend 200 mg tablet | 1 x 30 | Pfizer U.S. | Fungicides | NDA | 8.2% |
| 66 | Actiq 1,600 mcg lozenge | 1 x 30 | Cephalon | Narcotic Analgesics | NDA | 46.9% |
| 67 | Gamunex 10% inj | 1 x 100 | Talecris Biotherapeutics | Immune Serums | BLA | 3.4% |
| 68 | Gammagard 5 Gm/50ml inj | 1 x 50 | Baxter Bio-Science | Immune Serums | BLA | 10.0% |
| 69 | Actiq 1,200 mcg lozenge | 1 x 30 | Cephalon | Narcotic Analgesics | NDA | 46.9% |
| 70 | Neupogen 300 mcg/ml inj | 10 x 1 | Amgen | Blood Cell Stimulators | BLA | 3.5% |
| 71 | Actiq 800 mcg lozenge | 1 x 30 | Cephalon | Narcotic Analgesics | NDA | 46.9% |
| 72 | Neulasta 10 mg/ml inj | 1 x 0.6 | Amgen | Blood Cell Stimulators | BLA | 3.5% |
| 73 | Imitrex 12 mg/ml kit RF | 1 x 1 | GlaxoSmithKline | Migraine Headaches | NDA | 11.9% |
| 74 | Peg-Intron 300 mcg/ml kit RP | 1 x 1 | Schering | Antivirals | BLA | 8.0% |
| 75 | Lupron Depot 22.5 mg inj | 1 x 1 | TAP | Cancer Agents | NDA | 5.0% |
| 76 | Peg-Intron 240 mcg/ml kit RP | 1 x 4 | Schering | Antivirals | BLA | 8.0% |
| 77 | haloperidol decanoate 100 mg/ml inj | 1 x 5 | Apotex | Tranquilizers | ANDA | -20.9% |
| 78 | Xolair 150 mg soln | 1 x 1 | Genentech | Respiratory Inhalants | BLA | 4.3% |
| 79 | Actimmune 4,000,000 U/ml inj | 12 x 0.5 | Intermune Pharmaceuticals | Cancer Agents | BLA | 6.8% |
| 80 | Primaxin IV 500 mg inj | 25 x 1 | Merck Human Health | Antibiotics, Misc. | NDA | 4.0% |
| 81 | Mepron 150 mg/ml susp | 1 x 210 | GlaxoSmithKline | Antiparasitics | NDA | 6.9% |
| 82 | Remicade 100 mg inj | 1 x 1 | Centocor | Inflammatory Bowel Agents | BLA | 3.6% |
| 83 | Cubicin 500 mg soln | 1 x 1 | Cubist Pharmaceuticals | Antibiotics, Misc. | NDA | 7.9% |
| 84 | glucagon 1 mg kit | 1 x 1 | Lilly | Diabetes Care | NDA | 5.0% |
| 85 | Temodar 100 mg capsule | 1 x 20 | Schering | Cancer Agents | NDA | 2.8% |
| 86 | Aranesp 60 mcg/ml inj | 4 x 1 | Amgen | Erythropoietins | BLA | 3.3% |
| 87 | vancomycin 1,000 mg inj | 10 x 1 | Abraxis Pharmaceuticals | Vancomycin | ANDA | 0.0% |

| Rank by Sales among Study Market Basket* | Product Name, Strength, and Dosage Form | Package Quantity and Size | Manufacturer | Therapeutic Class | FDA Approval Process | 2007 Annual Percent Change in WAC |
|--|---|---------------------------|----------------------------|--------------------------|----------------------|-----------------------------------|
| 88 | Travasol 10% inj | 6 x 2,000 | Baxter Medication Delivery | Nutritional Products | NDA | 0.0% |
| 89 | Clinisol SF 15% inj | 6 x 2,000 | Baxter Medication Delivery | Nutritional Products | NDA | 0.0% |
| 90 | sodium chloride 0.9% inj | 80 x 100 | Baxter | Electrolytes & Nutrients | ANDA | 0.0% |
| 91 | Actiq 600 mcg lozenge | 1 x 30 | Cephalon | Narcotic Analgesics | NDA | 47.0% |
| 92 | Prograf 5 mg capsule | 1 x 100 | Astellas | Immunosuppressive Agents | NDA | 8.1% |
| 93 | Lupron Depot 7.5 mg inj | 1 x 1 | TAP | Cancer Agents | NDA | 5.0% |
| 94 | Procrit 4,000 U/ml inj | 6 x 1 | Ortho Biotech | Erythropoietins | BLA | 3.2% |
| 95 | Pulmicort 0.125 mg/ml susp | 30 x 2 | Astrazeneca | Respiratory Inhalants | NDA | 4.8% |
| 96 | Gammagard SD 10 Gm inj | 1 x 1 | Baxter Bio-Science | Immune Serums | BLA | 10.0% |
| 97 | Synvisc 8 mg/ml inj | 3 x 2 | Genzyme | Neuromuscular Drugs | BLA | 0.8% |
| 98 | Emend 80-125 mg-mg capsule | 1 x 3 | Merck Human Health | Antinauseants | NDA | 3.9% |
| 99 | Zofran ODT 8 mg tablet | 1 x 30 | GlaxoSmithKline | Antinauseants | NDA | 6.4% |
| 100 | Aranesp 500 mcg/ml inj | 1 x 1 | Amgen | Erythropoietins | BLA | 1.5% |
| 101 | Epipen 1 mg/ml inj | 1 x 0.3 | Dey Labs | Allergic Reactions | NDA | 4.0% |
| 102 | Infergen 30 mcg/ml inj | 6 x 0.5 | 3 River Pharmaceuticals | Antivirals | BLA | 2.5% |
| 103 | sodium chloride 0.9% irr soln | 24 x 250 | Baxter | Genitourinary Irrigants | ANDA | 0.0% |
| 104 | fluphenazine DE 25 mg/ml inj | 1 x 1 | Amerinet Choice | Tranquilizers | ANDA | 0.0% |
| 105 | Glucagen Diagnostic 1 mg inj | 1 x 1 | Bedford Laboratories | Diabetes Care | NDA | 7.7% |
| 106 | albuterol 0.5% nebulizer | 1 x 20 | Hi-Tech | Bronchial Dilators | ANDA | 0.0% |
| 107 | medroxyprogesterone acetate 150 mg/ml inj | 1 x 1 | Sicor Pharmaceuticals | Hormones, Female | ANDA | -6.4% |
| 108 | promethazine 25 mg/ml inj | 25 x 1 | Baxter Healthcare Corp. | Antihistamines | ANDA | -17.5% |
| 109 | Levaquin in D5W 5 mg/ml inj | 1 x 100 | Mcneil | Antibiotics, Misc. | NDA | 0.0% |
| 110 | Procrit 3,000 U/ml inj | 6 x 1 | Ortho Biotech | Erythropoietins | BLA | 3.2% |
| 111 | testosterone cypionate 200 mg/ml inj | 1 x 10 | Watson Labs | Hormones, Male | ANDA | 0.0% |
| 112 | Caverject 20 mcg kit | 2 x 1 | Pfizer U.S. | Impotence Agents | NDA | 7.6% |
| 113 | Vancocin HCl 5 mg/ml inj | 6 x 200 | Baxter Medication Delivery | Vancomycin | NDA | 0.0% |
| 114 | heparin sodium 5,000 U/ml inj | 25 x 1 | Baxter Healthcare Corp. | Anticoagulants | ANDA | -14.3% |
| 115 | vancomycin 5 Gm inj | 1 x 1 | Hospira | Vancomycin | ANDA | 7.0% |
| 116 | dextrose 5% in sodium chloride 0.45% inj | 14 x 1,000 | Baxter | Electrolytes & Nutrients | ANDA | 0.0% |
| 117 | sterile water irr soln | 24 x 250 | Baxter | Genitourinary Irrigants | ANDA | 0.0% |

| Rank by Sales among Study Market Basket* | Product Name, Strength, and Dosage Form | Package Quantity and Size | Manufacturer | Therapeutic Class | FDA Approval Process | 2007 Annual Percent Change in WAC |
|--|--|---------------------------|-------------------------|--------------------------|----------------------|-----------------------------------|
| 118 | haloperidol lactate 5 mg/ml inj | 10 x 1 | Sicor Pharmaceuticals | Tranquilizers | ANDA | 0.0% |
| 119 | haloperidol decanoate 50 mg/ml inj | 1 x 5 | Apotex | Tranquilizers | ANDA | -18.7% |
| 120 | ZMax 2 Gm susp | 1 x 1 | Pfizer U.S. | Antibiotics, Misc. | NDA | 5.0% |
| 121 | Depo-Testosterone 200 mg/ml inj | 1 x 1 | Pfizer U.S. | Hormones, Male | ANDA | 2.5% |
| 122 | Boniva 1 mg/ml kit | 1 x 1 | Roche | Calcium Regulators | NDA | 0.0% |
| 123 | gentamicin 40 mg/ml inj | 25 x 2 | Abraxis Pharmaceuticals | Antibiotics, Misc. | ANDA | 0.0% |
| 124 | dextrose 5% inj | 14 x 1,000 | Baxter | Electrolytes & Nutrients | ANDA | 0.0% |
| 125 | Renacidin irr soln | 1 x 500 | Guardian Laboratories | Genitourinary Irrigants | NDA | 7.4% |
| 126 | methotrexate 25 mg/ml inj | 10 x 2 | Bedford Laboratories | Cancer Agents | ANDA | 0.0% |
| 127 | sodium chloride 0.45% inj | 14 x 1,000 | Baxter | Electrolytes & Nutrients | ANDA | 0.0% |
| 128 | tobramycin 40 mg/ml inj | 1 x 30 | Sicor Pharmaceuticals | Antibiotics, Misc. | ANDA | -11.3% |
| 129 | lidocaine 1% inj | 25 x 10 | Abraxis Pharmaceuticals | Local Anesthetics | ANDA | 0.0% |
| 130 | Depo-Provera 150 mg/ml inj | 1 x 1 | Pfizer U.S. | Hormones, Female | NDA | 7.6% |
| 131 | testosterone enanthate 200 mg/ml inj | 1 x 5 | Watson Labs | Hormones, Male | ANDA | 0.0% |
| 132 | heparin sodium 10000 U/ml inj | 25 x 1 | Abraxis Pharmaceuticals | Anticoagulants | ANDA | 0.0% |
| 133 | acetic acid 0.25% irr soln | 12 x 1,000 | Baxter | Genitourinary Irrigants | ANDA | 0.0% |
| 134 | Kenalog-40 40 mg/ml inj | 1 x 5 | Bristol-Myers Squibb | Glucocorticoids | NDA | 7.4% |
| 135 | sodium chloride 0.9% inj | 25 x 30 | Hospira | Electrolytes & Nutrients | ANDA | 5.5% |
| 136 | morphine sulfate 10 mg/ml inj | 25 x 1 | Baxter Healthcare Corp. | Narcotic Analgesics | ANDA | 0.0% |
| 137 | sodium chloride 0.9% nebulizer | 100 x 3 | Dey Labs | Respiratory Inhalants | ANDA | 0.0% |
| 138 | furosemide 10 mg/ml inj | 25 x 4 | Hospira | Diuretics | ANDA | -5.6% |
| 139 | sterile water inj | 25 x 10 | Abraxis Pharmaceuticals | Electrolytes & Nutrients | ANDA | 0.0% |
| 140 | diphenhydramine 50 mg/ml inj | 25 x 1 | Baxter Healthcare Corp. | Antihistamines | ANDA | -2.7% |
| 141 | cromolyn sodium 10 mg/1ml nebulizer | 60 x 2 | Ivax Pharmaceuticals | Bronchial Dilators | ANDA | 0.0% |
| 142 | Depo-Estradiol 5 mg/ml inj | 1 x 5 | Pfizer U.S. | Hormones, Female | ANDA | 7.6% |
| 143 | cyanocobalamine 1,000 mcg/ml inj | 25 x 1 | American Regent | Vitamins | ANDA | 56.0% |
| 144 | dexamethasone sod. phosphate 4 mg/ml inj | 25 x 1 | American Regent | Glucocorticoids | ANDA | 0.0% |

* 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., June 2008).



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