

Research Report

Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2013

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**Public Policy
Institute**

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

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Executive Summary

Retail prices for widely used specialty prescription drugs increased substantially faster than general inflation in every year from 2006 to 2013. In 2013, retail prices for 115 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, increased by an average of 10.6 percent. In contrast, the general inflation rate was 1.5 percent over the same period.

Specialty drugs have never been precisely and consistently defined. The definition of specialty prescription drugs used throughout this report is a prescription drug that is: administered by injection; has a total average prescription cost greater than \$1,000 per prescription; or has a total average cost per day of therapy greater than \$33 per day.

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

Increases in the retail price of specialty prescription drugs have a corresponding impact on the cost of drug therapy for the individual and for all other payers. In 2013, the average annual retail cost of prescription drug therapy for one specialty drug, based on the market basket in this study, was \$53,384 per year. This average annual cost was greater than the median US household income (\$52,250). It was also more than twice the median income for Medicare beneficiaries (\$23,500) and almost three and a half times higher than the average Social Security retirement benefit (\$15,526) over the same time period.

Until recently, relatively few patients have used specialty drugs. However, there are strong indications that a much larger share of the population will use specialty prescription drugs in the future. If recent trends in specialty drug prices

and related price increases continue unabated, an increasing number of older Americans will be unable to afford necessary specialty medications. Such developments will lead to poorer health outcomes and higher health care costs in the future.

OVERVIEW OF FINDINGS

- In 2013, retail prices for 115 widely used specialty prescription drugs increased by 10.6 percent, similar to the rates of increase observed during the prior 7 years (i.e., 2006 to 2012), which ranged from 7.5 percent to 12.1 percent.
- Specialty drug prices increased more than seven times faster than general inflation in 2013 (10.6 percent vs. 1.5 percent).
- The average annual cost for one specialty medication used on a chronic basis was more than \$53,000 in 2013. The average annual cost of therapy for the specialty drug products used to treat chronic conditions rose by more than \$35,000 between 2006 and 2013.
- In 2013, the average annual price of therapy for specialty prescription drugs was 18 times higher than the average annual price of therapy for brand name prescription drugs (\$53,384 vs. \$2,960, respectively) and 189 times higher than the average annual price of therapy for generic prescription drugs (\$53,384 vs. \$283 respectively).
- Retail prices for 64 chronic use specialty drugs that have been on the market since the beginning of the study (i.e., between January 2006 and December 2013) increased cumulatively by an average of 161.0 percent over 8 years. In contrast, general inflation in the US economy rose 18.4 percent during the same 8-year period.
- Retail prices increased in 2013 for 87 percent (100 of 115) of the widely used specialty prescription drug products in the study's market basket. All but nine of these retail price increases (91 of 115) exceeded the rate of general economic inflation in 2013.

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- Retail prices for almost three-quarters of the drug manufacturers with at least one specialty drug product in the study's market basket increased faster than the rate of general inflation (1.5 percent) in 2013. Twenty drug manufacturers had average annual price increases for their specialty drugs of 10 percent or more during 2013, or more than six times the rate of general inflation in 2013.
 - All but 4 of the 46 therapeutic categories of specialty drug products had average annual retail price increases that exceeded the rate of general inflation in 2013. Price increases by therapeutic category ranged from 1.7 percent to 77.2 percent.

SPECIALTY PRESCRIPTION DRUG PRICE INCREASES AFFECT INDIVIDUAL CONSUMERS AND PUBLIC INSURANCE PROGRAMS

Until recently, relatively few patients used specialty drugs. However, there are strong indications that a much larger share of the population will use specialty prescription drugs in

the future. This report shows that average annual increases in the retail prices of widely used specialty prescription drugs have consistently exceeded the general inflation rate. In addition, the retail prices associated with these products now outstrip what many families earn in a year.

It is important to note that patients are not the only ones affected by specialty prescription drug prices. Higher prescription drug prices are usually passed along to everyone with health coverage in the form of increased health care premiums, deductibles, and other forms of cost sharing. Prescription drug price growth also increases spending for taxpayer-funded health programs like Medicare and Medicaid, which will eventually affect all Americans in the form of higher taxes, cuts to public programs, or both.

Policy makers interested in reducing the impact of prescription drug prices should focus on options that drive innovation while also protecting the health and financial security of consumers and taxpayer-funded programs like Medicare and Medicaid.

1. Introduction

AARP's Public Policy Institute finds that average price increases for specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, far outstripped the price increases for other consumer goods and services between 2006 and 2013. Specialty drug prices have routinely increased much faster than general inflation over the more than 10 years that this report series has been tracking prescription drug prices.¹

In 2013, the average annual increase in retail prices² for 115 specialty prescription drugs (some are brand name and some are generics) widely used by older Americans, including Medicare beneficiaries, was 10.6 percent. The average annual increase in 2013 was similar to the rates of increase observed during the prior 7 years (i.e., 2006 to 2012), which ranged from 7.5 percent to 12.1 percent. In contrast, the rate

of general inflation in the US economy was 1.5 percent in 2013.

Previous Rx Price Watch reports found that retail prices for brand name non-specialty drugs widely used by older Americans experienced a 12.9 percent increase in 2013, and retail prices for generic non-specialty drugs widely used by older Americans experienced a 4.0 percent decrease.³

Specialty drugs have never been precisely and consistently defined but generally include drugs used to treat complex, chronic conditions and require special administration, handling, and patient care management. The definition of specialty prescription drugs used throughout this report is a prescription drug that is: administered by injection; has a total average prescription cost greater than \$1,000 per prescription; or has a total average cost per day of therapy greater than \$33 per day.

- 1 The AARP Public Policy Institute in its Rx Price Watch series provides reports with separate analyses of the price changes for three different segments of the pharmaceutical market: brand name, generic, and specialty drug products. These three market baskets are important because a different mix of drug manufacturers typically makes the drug products in each segment and the drug products are subject to unique market dynamics, pricing, and related behaviors. In addition, the Rx Price Watch series also reports the price change for an overall market basket (i.e., brand name, generic, and specialty drug products combined) to reflect the overall market impact of drug price changes. Some critics have argued that the brand name price index report alone overstates the effect of drug price changes on the overall prescription drug market. Those critics argue that an overall measure should include the effect of generic prescription drug price competition and the impact of generic substitution. This is precisely why the AARP Rx Price Watch series of reports also provides an overall market basket (including brand name, generic, and specialty drug products) to examine the price change impact for the overall prescription drug market. While this overall perspective is useful for those interested in understanding the industrial economics of the entire prescription drug market, consumers typically are considerably more interested in the price trend for the specific products that they are taking as an individual rather than all drug products on the market. In addition, separate analyses of the different market segments (i.e., brand name, generic, and specialty drug products) is important because they represent very unique and distinct segments in the prescription drug market and they provide an indication of policy changes that may be warranted in the various market segments. Previous reports from this series are on the AARP website at http://www.aarp.org/health/medicare-insurance/info-04-2009/rx_watchdog.html and <http://www.aarp.org/rxpricewatch>.
- 2 The retail prices used in this report are drawn from Truven Health's MarketScan® Commercial Database and MarketScan® Medicare Supplemental Database (Truven Health MarketScan® Research Databases). The prices reflect the total price for a specific prescription that a pharmacy benefit manager (PBM) bills to a specific health plan for consumers enrolled in employer-sponsored or government-sponsored (i.e., Medicare or Medicaid) health plans and not simply the out-of-pocket cost (such as the copay) that a consumer would pay at the pharmacy. These amounts may or may not reflect what the PBM paid the pharmacy or the usual and customary price that a pharmacy would charge a cash pay consumer for the same prescription. Specialty drug products are often provided through PBM-owned specialty pharmacies, although these specialty drug products may also be provided through other types of specialty pharmacies or pharmacies in a retail network. Therefore, in the context of this report, the term "retail price" refers to the price for a specialty drug product that may have been provided by a PBM-owned specialty pharmacy or other types of specialty pharmacies rather than traditional retail pharmacies.
- 3 S.W. Schondelmeyer and L. Purvis, "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Medicare Beneficiaries, 2006 to 2013," AARP Public Policy Institute, November 2014; and S.W. Schondelmeyer and L. Purvis, "Rx Price Watch Report: Trends in Retail Prices of Generic Prescription Drugs Widely Used by Medicare Beneficiaries, 2006 to 2013," AARP Public Policy Institute May 2015. Available on the AARP website, <http://www.aarp.org/rxpricewatch>.

One of the most notable characteristics of specialty drugs is their cost; specialty drugs are among the most expensive drugs on the market, with prices that can reach hundreds of thousands of dollars per year.⁴ They are also widely expected to be the fastest growing group of drug products in the decade ahead.⁵ Experts have projected that specialty drug spending will increase by more than 16 percent annually between 2015 and 2018, and will comprise more than 50 percent (\$235 billion) of total drug spending by 2018.⁶

Until recently, relatively few patients used specialty drugs. However, the US population is steadily aging and older adults typically use more specialty medications than younger populations.⁷ In addition, specialty drugs are increasingly being used to treat common chronic conditions that affect millions of Americans.⁸ Drug manufacturers are also developing more specialty drugs, which now represent 42 percent of the late stage research and development pipeline.⁹ Overall, these trends indicate that a much larger share of the population will use specialty prescription drugs in the future.

Increases in the retail price of specialty prescription drugs have a corresponding impact on the cost of drug therapy for the individual and all other payers. In 2013, the average annual

retail cost of prescription drug therapy for a specialty drug, based on the market basket in this study, was \$53,384 per year. This average annual cost was greater than the median US household income (\$52,250).¹⁰ It was also more than twice the median income for Medicare beneficiaries (\$23,500),¹¹ and almost three and a half times higher than the average Social Security retirement benefit (\$15,526)¹² over the same time period. For a consumer who takes a specialty drug on a chronic basis, the average annual cost of therapy for the specialty drug products used to treat chronic conditions rose by more than \$35,000 between 2006 and 2013.

Prescription drug price increases also affect employers, private insurers, and taxpayer-funded programs like Medicare and Medicaid. For example, the Medicare Payment Advisory Commission recently attributed the majority of “excess” growth in Medicare Part D spending to growth in the average price of drugs provided to enrollees.¹³ Spending increases driven by high and growing drug prices will affect all Americans in some way. Those with private health insurance will pay higher premiums and/or cost sharing for their health care coverage.¹⁴ Similarly, spending by government health programs will grow faster than the tax-based revenue that supports them, leading to higher taxes and/or cuts in public health or other programs.

4 I. Spatz and N. McGee, “Health Policy Brief: Specialty Pharmaceuticals,” *Health Affairs* (2013).

5 IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shift: A Review of the Use of Medicines in the U.S. in 2014*, April 2015.

6 A.M. Lotvin, W.H. Shrank, S.C. Singh, B.P. Falit, and T.A. Brennan, “Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs,” *Health Affairs* 33, no. 10 (2014): 1736–44.

7 Ibid.

8 Ibid.

9 IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shift: A Review of the Use of Medicines in the U.S. in 2014*, April 2015.

10 A. Noss, “Household Income: 2013, American Community Survey Briefs,” ACSBR/13-02, US Census Bureau, September 2014.

11 G. Jacobson, J. Huang, T. Neuman, and K.E. Smith, “Income and Assets of Medicare Beneficiaries, 2013–2030,” Kaiser Family Foundation, January 2014.

12 The average monthly Social Security retirement benefit in 2013 was \$1,294 per month. Social Security Administration, *Annual Statistical Supplement to the Social Security Bulletin, 2015*, 2015, <https://www.socialsecurity.gov/policy/docs/statcomps/supplement/2015/5b.html#table5.b8>.

13 Medicare Payment Advisory Commission, “Report to the Congress: Medicare Payment Policy, Chapter 14: Status Report on Part D,” March 2014.

14 D.I. Auerbach and A.L. Kellermann, “A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average U.S. Family,” *Health Affairs* 30, no. 9 (2011): 1630–36.

This report presents *annual* and 8-year cumulative price changes through the end of 2013. The first set of findings shows annual rates of change in retail prices for widely used specialty drugs from 2006 through 2013, using both rolling average and point-to-point methods (see Appendix A). The rolling average measure is used to examine the distribution

of retail price changes as well as differences in average percentage price changes for individual manufacturers and therapeutic categories. The second set of findings summarizes the *cumulative* impact of specialty drug price changes that have taken place across the entire 8-year period from 2006 through 2013.

2. Findings

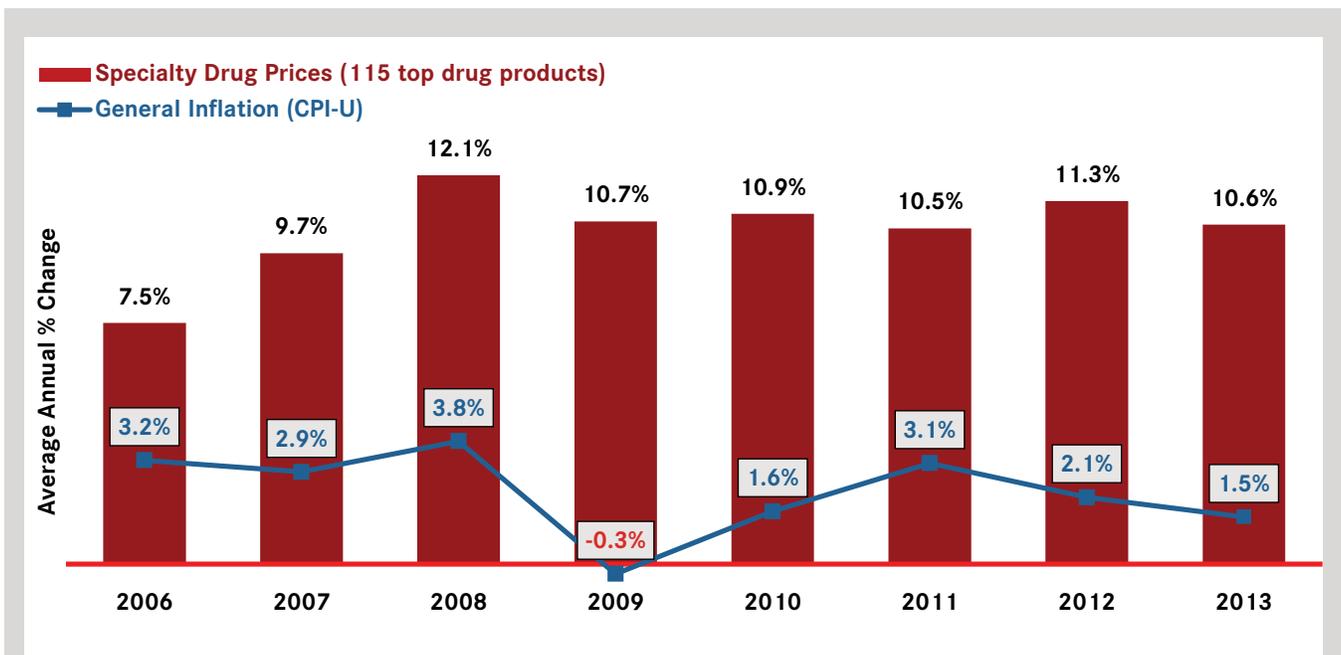
2.1. SPECIALTY PRICE TRENDS FOR MOST WIDELY USED PRESCRIPTION DRUGS

The annual percent change in prices for specialty prescription drugs has consistently increased substantially faster than general inflation in recent years.

- Retail prices for the 115 specialty drug products¹⁵ most widely used by older Americans rose 10.6 percent in 2013 (Figure 1).¹⁶
- The average annual retail price increase in 2013 for these specialty prescription drug products was just over seven times higher than the rate of general inflation (10.6 percent vs. 1.5 percent).¹⁷
- In contrast, retail prices for traditional (non-specialty) brand name drug products most widely used by older Americans rose by 12.9 percent in 2013, and retail prices

Figure 1

Annual Specialty Drug Price Changes Remained Substantially Higher than General Inflation in 2013



Note: Calculations of the average annual specialty drug price change include the 115 drug products most widely used by older Americans (see Appendix A).

Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

- 15 The market basket for this analysis had 115 specialty prescription drug products. Some critics of the Rx Price Watch reports have suggested that brand name drug products in our market basket that subsequently face generic competition should be excluded from this analysis because they may be skewing the results upward. However, when the 86 specialty drug products with no generic competition are analyzed separately, the average annual price change was 10.9 percent in 2013—higher than the 10.6 percent price trend shown in this report.
- 16 When measured as a 12-month rolling average and weighted by actual 2011 retail prescription sales to older Americans ages 50 and above, including Medicare beneficiaries.
- 17 The general inflation rate used in this report 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.

for traditional (non-specialty) generic drug products fell by 4.0 percent in the same year.¹⁸

The annual retail price change for specialty drug products reported in Figure 1 is a rolling average change. We calculate the change in specialty drug prices for each month compared with the same month in the previous year (referred to as an annual point-to-point change). We then average all the annual point-to-point price changes for each of the 12 months to produce a rolling average change.

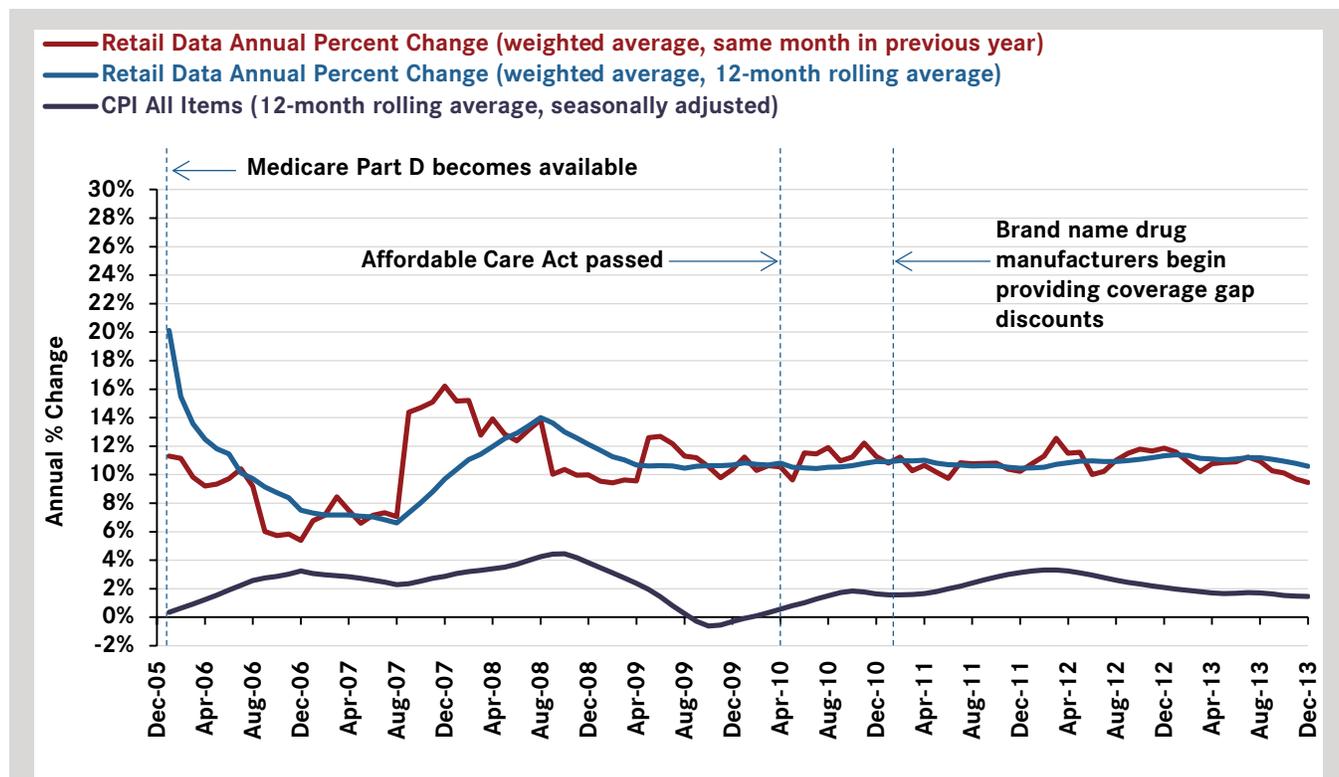
Figure 2 shows the percent change in specialty drug prices for each month compared with the same month in the previous year. This trend is

shown alongside the 12-month rolling average to allow more detailed examination of the rate and timing of specialty drug price changes over the entire study period. This analysis reveals three broad trends since implementation of the Medicare Part D program:

- The retail prices of specialty drug products have consistently increased since 2006;
- Specialty drug price increases at the retail level have been substantially higher than the rate of general inflation; and
- The gap between the rate of specialty drug price change and the rate of change in general

Figure 2

Rolling Average and Point-to-Point Changes in Retail Prices for Most Widely Used Specialty Prescription Drugs Were Well above Inflation from 2006 to 2013



Note: Calculations of the average annual specialty drug price change include the 115 drug products most widely used by older Americans (see Appendix A).

Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

18 Schondelmeyer and Purvis, “Rx Price Watch Report: Brand Name Prescription Drugs”; Schondelmeyer and Purvis, “Rx Price Watch Report: Generic Prescription Drugs.” <http://www.aarp.org/rxpricewatch>.

inflation has fluctuated but remained sizeable over the period from 2006 to 2013. This gap has ranged from less than a 3-fold difference to more than a 10-fold difference.

The cost of specialty drug therapy reached \$53,384 per drug per year in 2013.

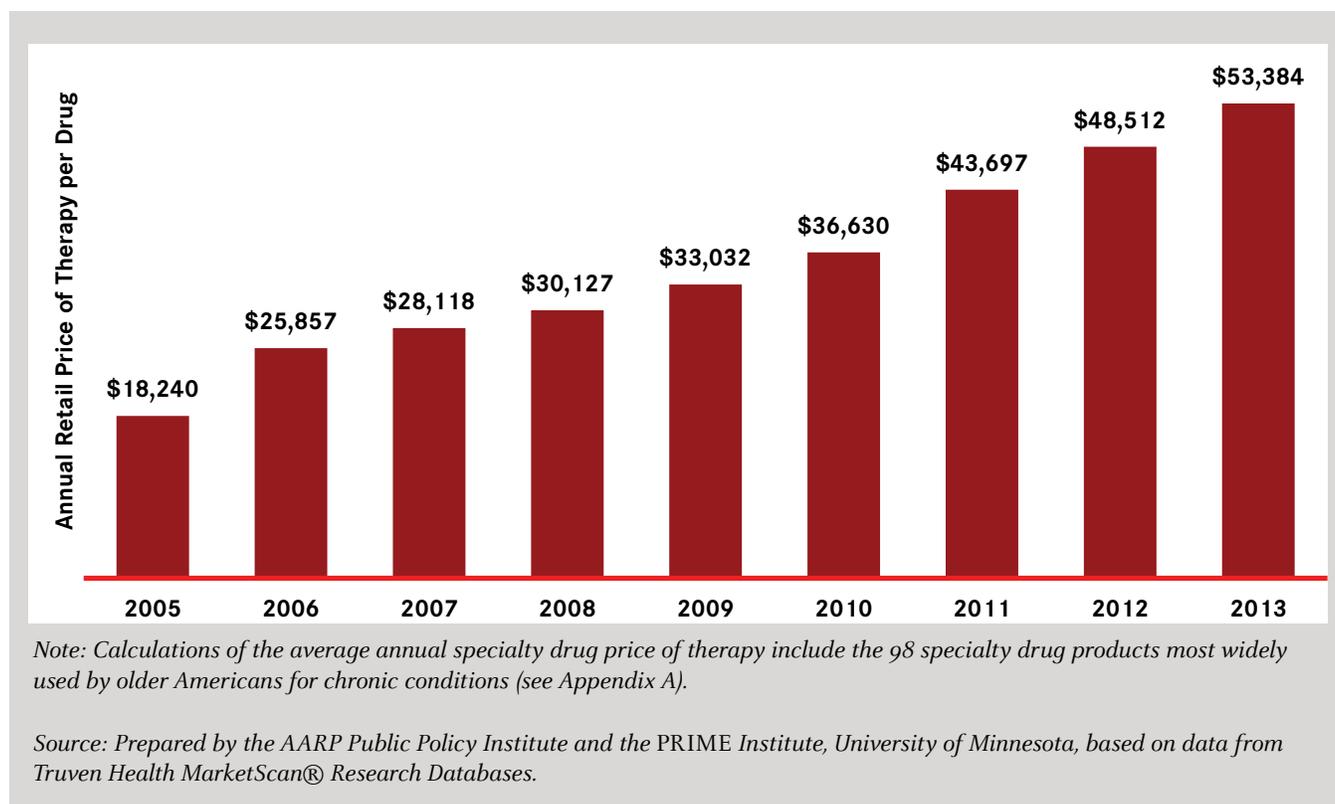
Figure 3 presents the retail price for 98 widely used specialty drugs indicated for treating chronic conditions when the price is expressed as an average annual cost of therapy per drug.

- The average cost of therapy was more than \$53,000 per drug per year for specialty prescription drugs at the end-payer (retail) level in 2013.
 - This average annual cost (\$53,384) is more than double the average annual cost (\$25,857) for a specialty drug in 2006, the year Medicare implemented Part D.

- The average annual cost of therapy for one specialty drug in 2013 (\$53,384) was greater than the median US household income (\$52,250), more than twice the median income for a Medicare beneficiary (\$23,500), and over 40 times higher than the average Social Security retirement benefit (\$1,294) over the same time period.¹⁹

It is noteworthy that the average annual retail price of therapy for widely used specialty drugs is considerably higher than the average annual retail cost of therapy for widely used brand name and generic drugs. Further, the price differential between these three market baskets is growing rapidly. In 2013, the average annual price of therapy for specialty prescription drugs was 18 times higher than the average annual price of therapy for brand name prescription drugs (\$53,384 vs. \$2,960 respectively) and 189 times higher than the average annual price of therapy

Figure 3
The Average Annual Price of Specialty Drugs Grew Substantially between 2005 and 2013



19 Noss, "Household Income"; Jacobson, Huang, Neuman, and Smith, "Income and Assets; Social Security Administration, *Annual Statistical Supplement*.

for generic prescription drugs (\$53,384 vs. \$283, respectively).²⁰

Figure 4 shows the annual price of therapy for specialty, brand name, and generics in the past 4 years (2010 to 2013). While the average annual generic price of therapy has declined by about 50 percent (\$551 to \$283), the average annual brand name price of therapy has increased by about 50 percent (\$2,068 to \$2,960) and the average annual specialty price of therapy has increased by almost 46 percent (\$36,630 to \$53,384).

It is notable that, despite typically having smaller average annual percentage increases in retail prices than non-specialty brand name drugs between 2010 and 2013, specialty drugs had a larger dollar change over the same time period

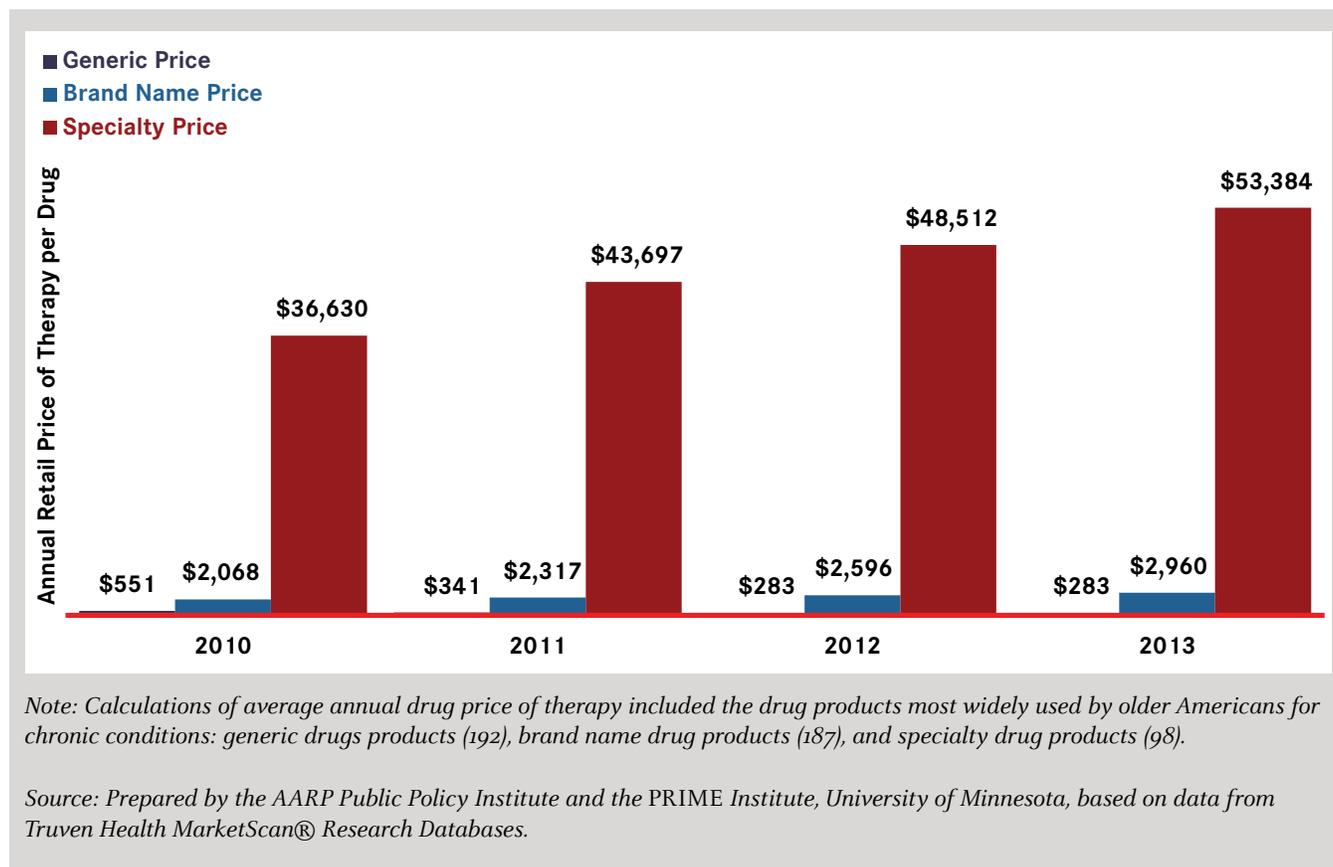
(\$16,754 vs. \$892 for brand name drugs). This inconsistency is due to the markedly higher price level of specialty drug products (e.g., a 10 percent price increase for a \$10,000 drug product is \$1,000, while the same percentage price increase for a \$1,000 drug product is \$100).

2.2. ANNUAL TRENDS IN PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY FDA APPROVAL PROCESS

The products in the specialty market basket were approved by the US 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

Figure 4

The Average Annual Retail Price of Therapy for Specialty Drugs Is Substantially Higher than the Average Annual Retail Price of Therapy for Brand Name and Generic Drugs in 2013



20 Schondelmeyer and Purvis, "Rx Price Watch Report: Brand Name Prescription Drugs"; Schondelmeyer and Purvis, "Rx Price Watch Report: Generic Prescription Drugs." <http://www.aarp.org/rxpricewatch>.

devices, and BLAs apply to biological products. Seventy-nine of the 115 drug products in the specialty market basket were NDA-approved, 27 were BLA-approved, and 9 were ANDA-approved.

NDA and BLA-approved drugs are new brand name drugs, while ANDA-approved drugs are generic drugs. Drug products approved as NDAs, BLAs, and ANDAs differ considerably in their annual percent change and their annual change in cost of therapy.

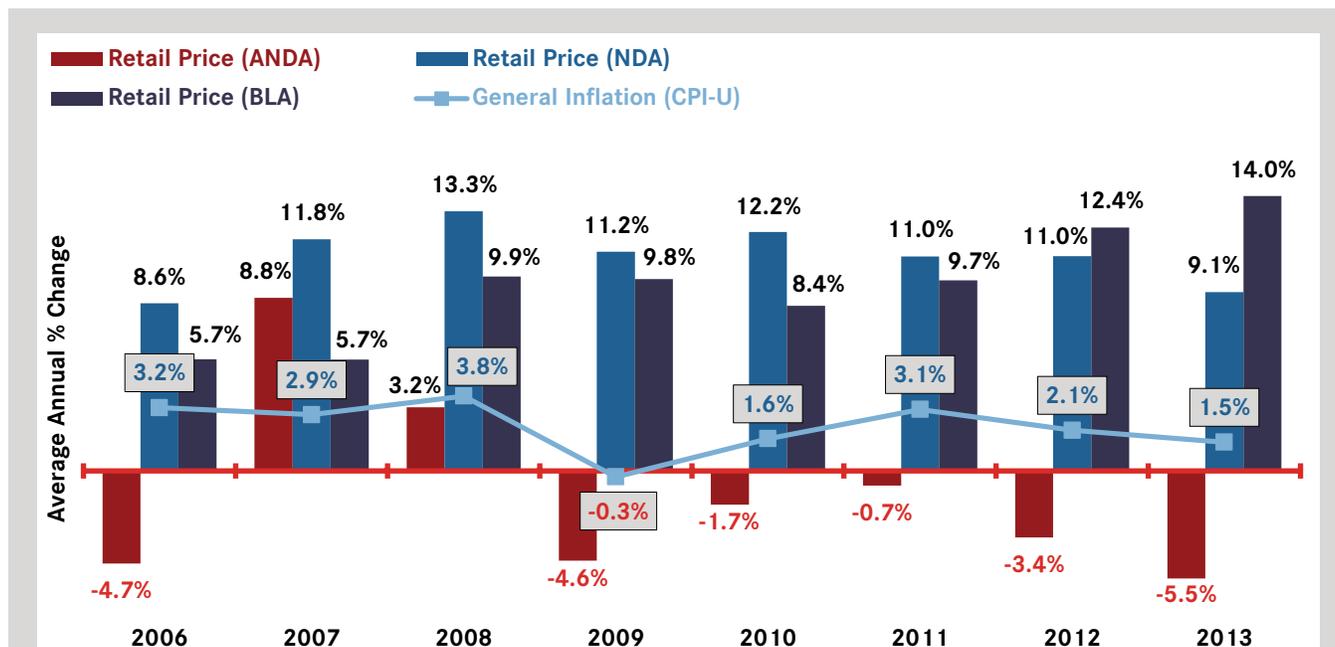
Annual percent change in retail prices

- Retail prices for *NDA-approved specialty drug products* most widely used by older Americans rose by an average of 9.1 percent in 2013. This rate of increase was more than six times higher than the rate of general inflation

(1.5 percent) when measured as a 12-month rolling average and weighted by sales to older Americans ages 50 and above. Annual retail price increases between 2006 and 2012 ranged from 8.6 percent to 13.3 percent (Figure 5).

- Retail prices for *BLA-approved specialty drug products* most widely used by older Americans increased by an average of 14.0 percent in 2013, more than nine times higher than the rate of general inflation (1.5 percent).²¹
- Retail prices for *all brand name specialty drug products* (i.e., NDA- and BLA-approved drug products) most widely used by older Americans increased at an average rate of 11.4 percent in 2012 and 10.7 percent in 2013. In contrast, retail prices for brand name non-specialty drug products most widely used by

Figure 5
Marked Increase in Average Retail Prices among Most Widely Used BLA-Approved Specialty Prescription Drugs in 2013



Note: Calculations of average annual specialty drug price change include 115 drug products most widely used by older Americans: ANDAs (9); NDAs (79), and BLAs (27).

Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

21 The Affordable Care Act of 2010 contained a provision that granted FDA the authority to approve less expensive generic (biosimilar or interchangeable) versions of BLA-approved specialty drugs. However, FDA has yet to finalize all of the regulations needed to fully implement this new authority. Thus, biologic drug manufacturers still do not face meaningful generic competition after biologic patents expire.

older Americans increased by an average of 12.3 percent and 12.9 percent, respectively, in those years.²²

- In contrast, retail prices for *all generic specialty drug products* (i.e., ANDA-approved drug products) most widely used by older Americans decreased by 5.5 percent in 2013. Similarly, retail prices for generic non-specialty drug products most widely used by older Americans decreased by an average of 4.0 percent over the same time period.²³

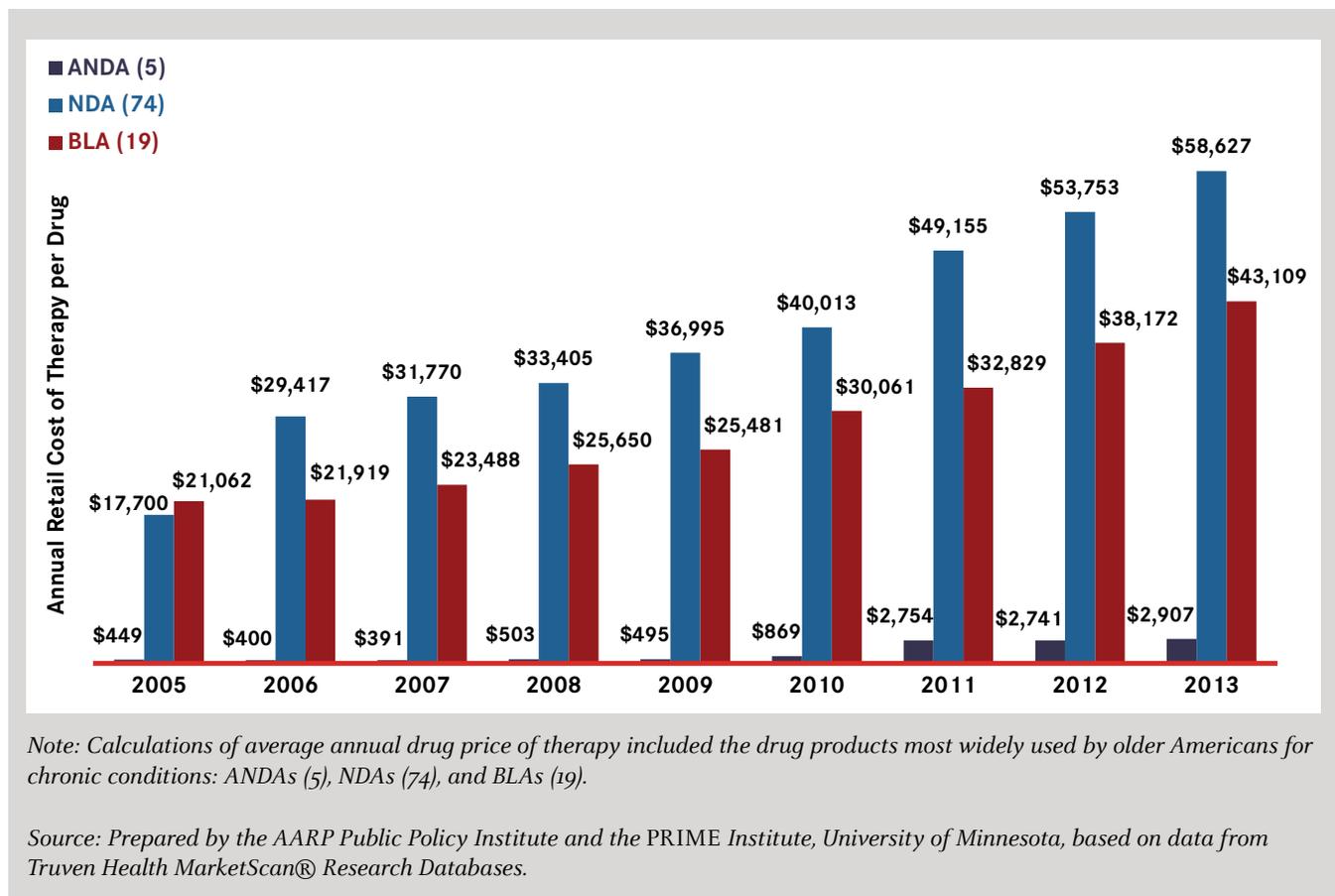
Annual retail cost of therapy

We translated retail price changes for the widely used specialty drugs for treating chronic conditions into average annual cost of therapy (Figure 6). Of the 98 drugs in the market basket used to treat chronic conditions, 74 were NDAs, 19 were BLAs, and 5 were ANDAs.

- A person who took an *NDA-approved specialty prescription drug* had an average annual cost of therapy of \$58,627 in 2013, assuming that the consumer used the specialty drug for a chronic condition. The average annual cost of therapy for NDA-approved specialty drugs

Figure 6

The Average Annual Cost of Therapy Increased by Almost 100 Percent for Widely Used NDA-Approved Specialty Prescription Drugs between 2006 and 2013



22 Schondelmeyer and Purvis, “Rx Price Watch Report: Brand Name Prescription Drugs”; Schondelmeyer and Purvis, “Rx Price Watch Report: Generic Prescription Drugs.” <http://www.aarp.org/rxpricewatch>.

23 Schondelmeyer and Purvis, “Rx Price Watch Report: Brand Name Prescription Drugs”; Schondelmeyer and Purvis, “Rx Price Watch Report: Generic Prescription Drugs.” <http://www.aarp.org/rxpricewatch>.

increased by 99 percent since 2006, the year Medicare implemented Part D.

- The average annual cost of therapy for *BLA-approved specialty prescription drugs* was \$43,109 in 2013. This average annual cost of therapy has increased substantially since 2006. The average annual cost of therapy for BLA-approved specialty drugs has increased by 121 percent since 2006.
 - The average annual cost of therapy for ANDA-approved specialty prescription drugs was \$2,907 in 2013. The average annual cost of therapy for ANDA-approved specialty drugs (generics) increased substantially (627 percent) since the implementation of Medicare Part D in 2006.

2.3. EIGHT-YEAR CUMULATIVE RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS, 2006 TO 2013

This AARP report tracked specialty drug prices at the retail level for the 8-year period from

December 31, 2005, to December 31, 2013. Fifty-six percent (64 of 115) of the widely used drugs in the original specialty market basket were on the market for the entire 8-year period (i.e., the end of 2005 through the end of 2013).

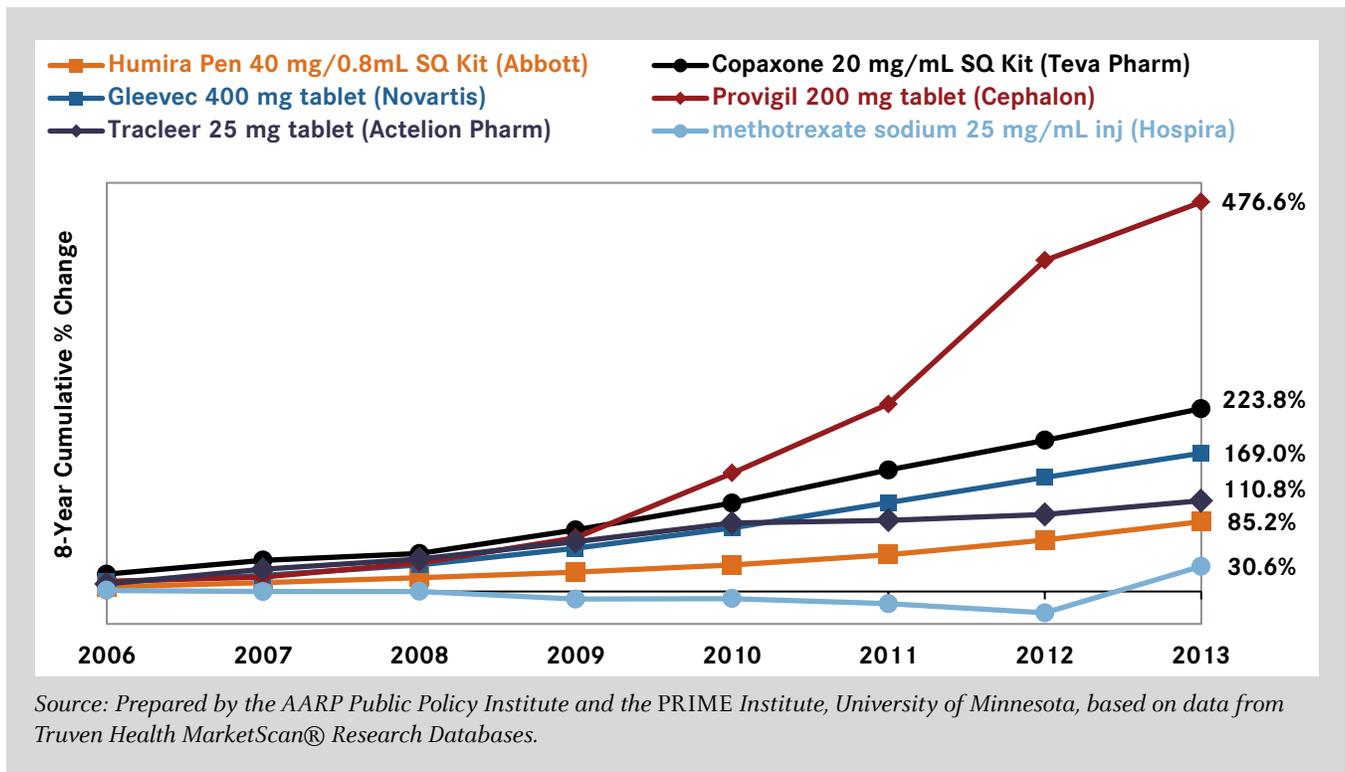
Cumulatively, the average retail price for these 64 widely used specialty drug products increased 161.0 percent over 8 years, compared with an 18.4 percent increase in general inflation in the same period. This means that specialty drug prices increased almost nine times more than the rate of general inflation during this time period.

Eight-year cumulative retail price changes are substantial.

Figure 7 presents the 8-year cumulative effect of drug price changes from the end of 2005 to the end of 2013 for six specific specialty drug products. We chose 5 of these drug products because they are among the 25 most widely used drugs in the market basket and are from a variety of therapeutic classes:

Figure 7

Eight-Year Cumulative Percent Change in Retail Price Is Almost 500 Percent for Provigil 200 mg Tablets



- Humira Pen 40 mg/0.8mL SQ Kit (Abbott)—used in the treatment of inflammatory and immunological disorders;
- Copaxone 20 mg/ml SQ Kit (Teva Pharmaceuticals)—used to treat multiple sclerosis;
- Gleevec 400 mg tablets (Novartis)—used to treat cancer;
- Provigil 200 mg tablets (Cephalon)—used to treat excessive sleepiness; and
- Tracleer 25 mg tablets (Actelion Pharmaceuticals)—used to treat pulmonary arterial hypertension

We included the sixth drug, methotrexate sodium 25 mg/mL injection (Hospira), used to treat cancer and inflammation, because it had the largest percent price increase in 2013 among the specialty drug products that have been on the market since the end of 2005.

Figure 7 shows the eight-year (i.e., December 31, 2005 to December 31, 2013) cumulative percent change in retail prices for six specific drug products:

- Provigil 200 mg tablets had a price increase of 476.6 percent over the 8-year study period ending in 2013.
- Copaxone 20 mg/mL SQ Kit had a price increase of 223.8 percent over the 8-year study period ending in 2013.
- Gleevec 400 mg tablets had an 8-year price increase of 169.0 percent over the entire 8-year study period ending in 2013.
- Tracleer 25 mg tablets had an 8-year price increase of 110.8 percent over the entire 8-year study period.
- Humira Pen 40 mg/0.8mL SQ Kit increased in retail price by 85.2 percent over the 8-year study period.
- Methotrexate sodium 25 mg/mL injection had an 8-year retail price increase of 30.6 percent.

The retail price for this product increased cumulatively solely because of a 77.2 percent retail price increase in 2013—the product experienced multiple price decreases between 2006 through 2012.

Eight-year cumulative change in annual specialty drug cost of therapy is considerable.

Of the specialty drug products in the AARP market basket that have been on the market since the end of 2005, 89 percent (57 of 64) treat chronic conditions.²⁴ The remaining seven drug products treat acute or intermittent conditions.

The average annual retail cost of drug therapy for specialty drug products on the market since the end of 2005 and used to treat chronic conditions was \$42,255 in 2013, which is an increase of \$24,015 over the 2006 annual cost of \$18,240.

The annual cost of Gleevec 400 mg tablets grew by more than \$50,000 over 8 years.

More than one-half (30 of 57) of the specialty drugs used for chronic conditions that have been on the market since the end of 2005 had annual cost of therapy increases of more than \$10,000 during the 8-year period ending in 2013.

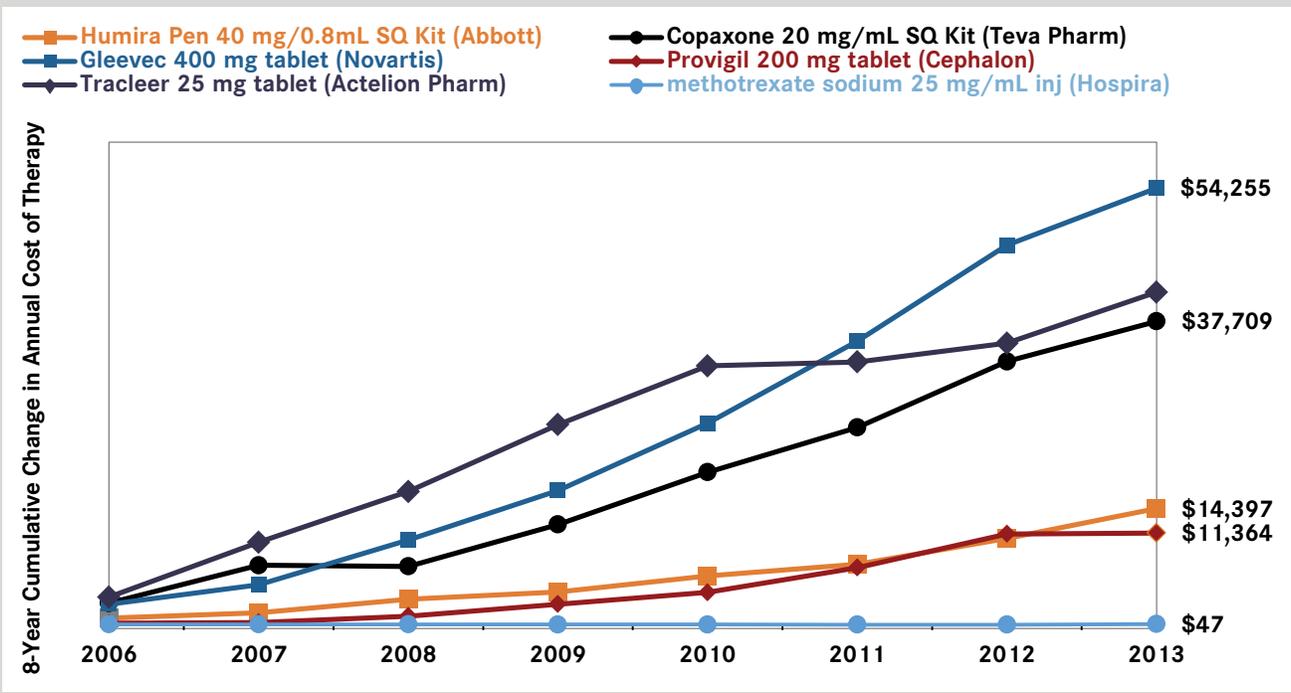
Figure 8 shows the 8-year cumulative change in cost of therapy (based on retail prices) for six widely used specialty drug products.

- The retail price for a 1-year supply of Gleevec 400 mg tablets increased by \$54,255 over an 8-year period ending in 2013. The price rose from \$31,521 per year at the end of 2005 to \$85,775 by the end of 2013.
- The retail price of Tracleer 25 mg tablets jumped by \$41,325 from \$40,134 at the end of 2005 to \$81,459 by the end of 2013. This substantial price hike took place despite relatively small price increases in 2011 and 2012.
- The retail price of a 1-year supply of Copaxone 20 mg/mL SQ Kit increased by \$37,709 in the 8-year period ending in 2013. The price for a

24 The drug products in our study market basket were classified based on whether the primary indication for use was for a chronic condition or an acute (or intermittent) condition.

Figure 8

Eight-Year Cumulative Change in Annual Cost of Therapy Is More than \$50,000 for Gleevec 400 mg Tablets



Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

1-year supply of this specialty drug increased from \$19,023 in 2006 to \$56,731 in 2013.

- The retail price of a 1-year supply of Humira Pen 40 mg/0.8mL SQ Kit increased by \$14,397 in the 8-year period ending in 2013. The retail price for a one-year supply of this drug rose from \$16,636 in 2006 to \$31,033 in 2013.
- The retail price of a 1-year supply of Provigil 200 mg tablets increased by \$11,364 in the 8-year period ending in 2013. The retail price for a one-year supply of this drug rose from \$2,674 in 2006 to \$14,037 in 2013.
- The annual retail price of methotrexate sodium 25 mg/mL injection increased by \$47 between the end of 2005 and the end of 2013. After experiencing retail price decreases every year from 2007 through 2012, the retail price of this drug product increased from \$100 at the end of 2012 to \$185 at the end of 2013.

2.4. FOUR OUT OF FIVE WIDELY USED SPECIALTY DRUGS INCREASED IN PRICE MORE THAN GENERAL INFLATION IN 2013

Four out of five (91 of 115) of the most widely used specialty drug products had retail price increases greater than the rate of general inflation (1.5 percent) in 2013. Eighty-seven percent (100 of 115) of the most widely used specialty prescription drug products had an increase in price in 2013 (Figure 9).

Among the 43 percent (50 of 115) of specialty drug products with annual price increases of 10.0 percent or more in 2013:

- Thirty-four (30 percent) increased by 10.0 percent to 14.9 percent;
- Ten (9 percent) increased by 15.0 percent to 19.9 percent; and

- Six (5 percent) increased by 20.0 percent or more with the highest increase as much as 77.2 percent.

Retail prices for 6 of the 115 widely used specialty drug products increased by more than 20 percent in 2013 (Figure 10). The retail price of one specialty drug product (methotrexate sodium 25 mg/mL injection) rose by 77.2 percent between 2012 and 2013.

Twelve of the 115 top specialty drug products were generics. Ten of the 12 generic specialty drug products had either a price decrease (8 drug products) or a price increase less than the general rate of inflation (2 drug products). However, the other two specialty generic drug products had the highest annual percent increase in 2013 among all of the products in the specialty drug market basket.

Figure 9
Retail Prices for 80 percent of Most Widely Used Specialty Drugs Increased Faster than General Inflation in 2013

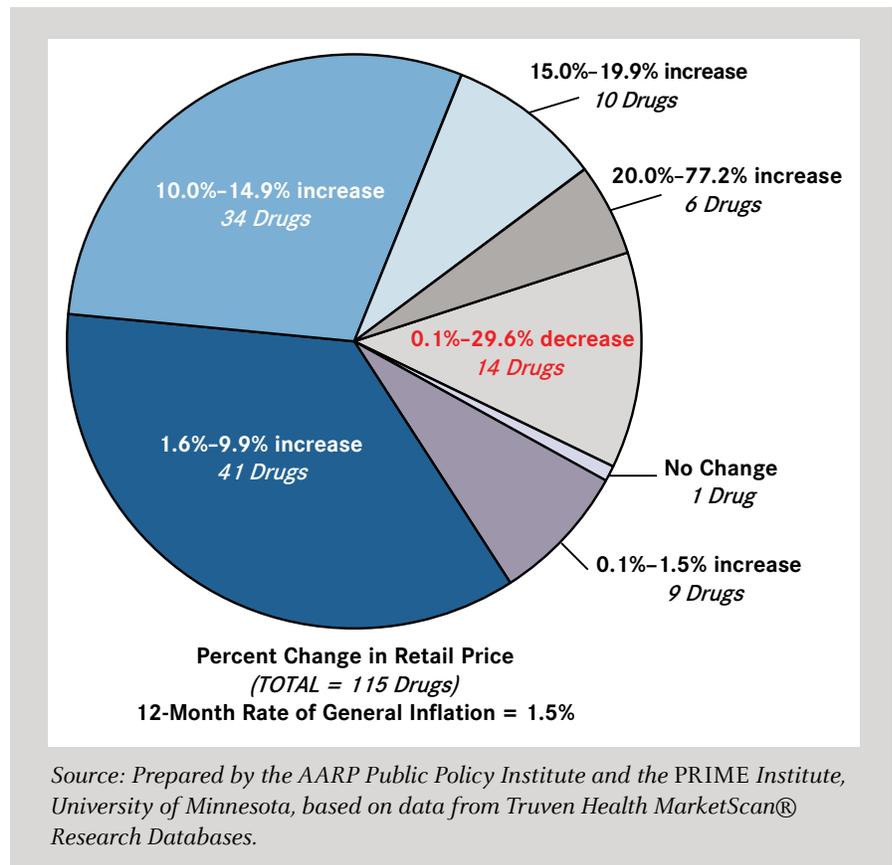
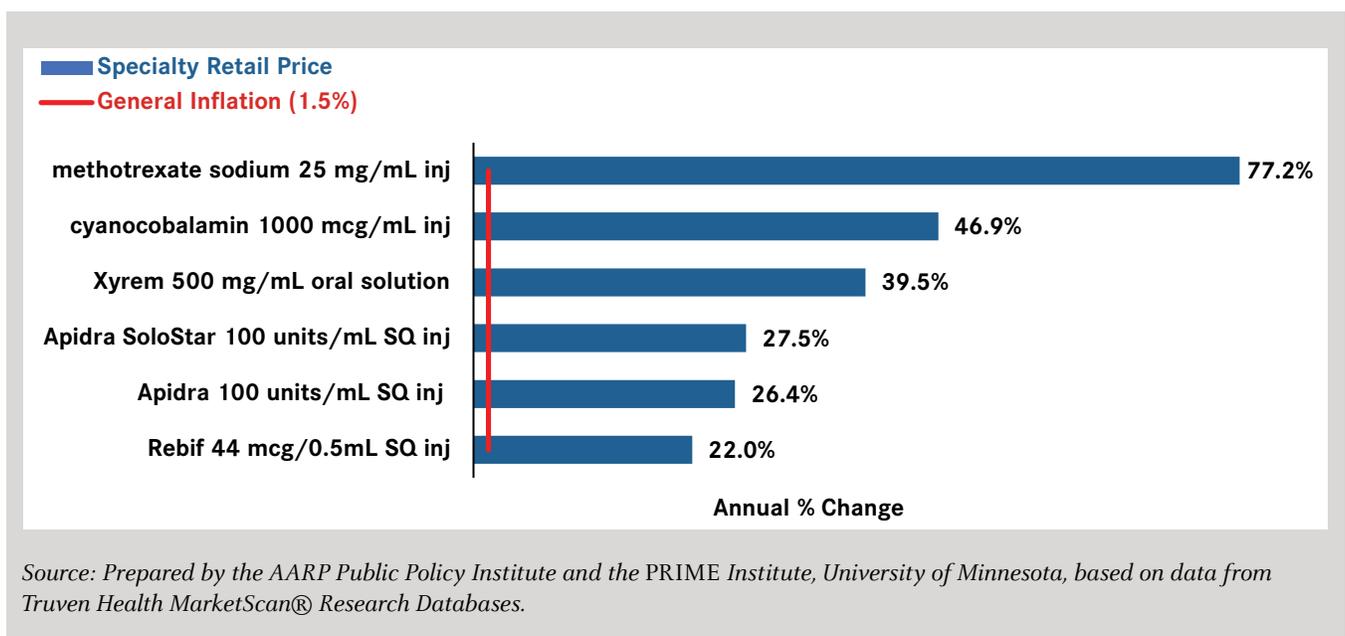


Figure 10
Retail Prices for Six Widely Used Specialty Drugs Increased by More than 20 percent in 2013



Retail prices for five of the most widely used specialty drug products decreased by more than 10 percent in 2013, with price decreases that ranged from 10.3 percent to 30.8 percent (Figure 11). Four of the five specialty drug products with retail price decreases of more than 10 percent in 2013 were generic drug products. The fifth drug product was a brand name flu vaccine (Fluzone Preservative Free Injection).

All of the 30 top-selling specialty drug products in the market basket had retail price increases in 2013 when compared with 2012 (Table 1). Eighty-seven percent (26 of 30) of these top-selling specialty drug products had a price increase that was higher than the rate of general inflation (1.5 percent) in 2013.

Six of the top 30 specialty drug products had retail price increases of 15.0 percent or more in 2013—at least 10 times the rate of general inflation. The highest retail price increase among the top 30 specialty drug products in 2013 was 22.0 percent for Serono’s Rebif 44 mcg/0.5 mL SQ inj.

2.5. RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY MANUFACTURER

Forty-seven drug manufacturers had at least one drug product in the study’s market basket of 115 widely used specialty drugs. The average annual increase in retail price for almost three-quarters (34 out of 47) of these drug manufacturer categories exceeded the general inflation rate in 2013 (Figure 12), suggesting that the specialty drug price trends in this report likely reflect price trends for the entire specialty drug industry.

- Twenty-nine of the drug manufacturers (62 percent) had weighted average annual specialty drug price increases of more than 5 percent in 2013—more than three times the rate of general inflation (1.5 percent) in 2013.
- Twenty drug manufacturers (41 percent) had weighted average specialty drug price increases of more than 10 percent in 2013, or more than six times the rate of general inflation (1.5 percent) in 2013.
 - These 20 drug manufacturers represent 41 percent (47 of 115) of the specialty drug products in the market basket in 2013.
- Seven drug manufacturers had weighted average specialty drug price increases of at

Figure 11
Retail Prices for Five Widely Used Specialty Prescription Drugs Decreased by More than 10 percent in 2013

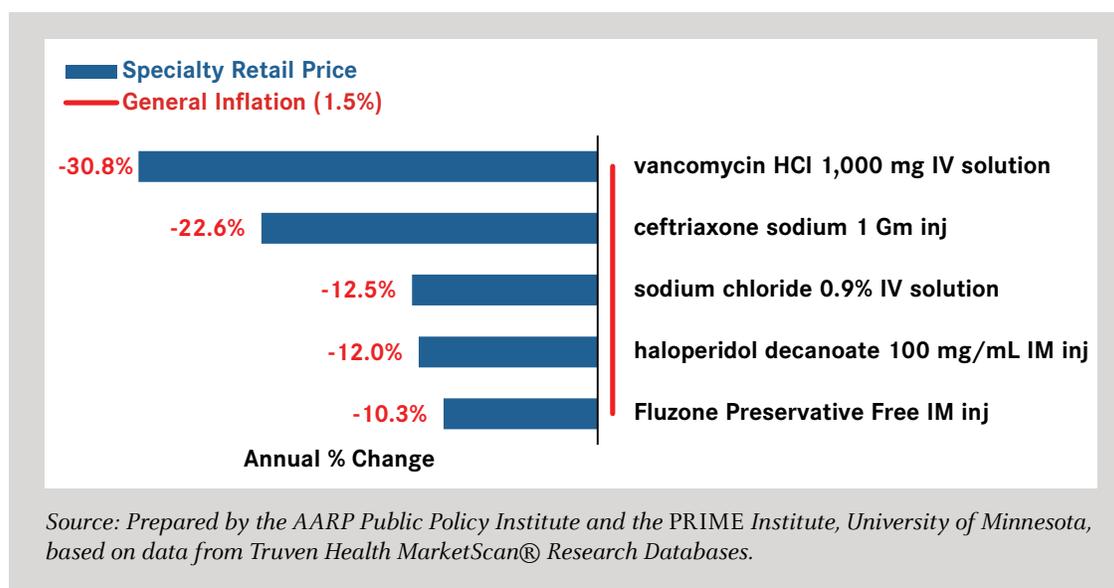


Table 1

All of the Top 30 Drug Products in the Specialty Market Basket Had Retail Price Increases in 2013

Sales Rank*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	2013 Retail Price/Day	Annual % Change
1	Enbrel SureClick 50 mg/mL SQ inj	4 x 0.98	Amgen	Anti-Inflammatory Agents (Disease Modifying Anti-Rheumatic Drugs)	\$85.72	15.0%
2	Humira Pen 40 mg/0.8mL SQ inj Kit	2 x 1	Abbott	Anti-Inflammatory Agents (Disease Modifying Anti-Rheumatic Drugs)	\$85.02	13.8%
3	Copaxone 20 mg/mL SQ Kit	1	Teva Neuroscience	Multiple Sclerosis Agents	\$155.43	13.6%
4	Avonex Prefilled 30 mcg/0.5mL IM Kit	1	Biogen Idec	Multiple Sclerosis Agents	\$164.42	14.5%
5	Gleevec 400 mg tablet	30	Novartis	Antineoplastics (Oral)	\$235.00	12.4%
6	Revlimid 10 mg capsule	100	Celgene Corp	Antineoplastics (Oral)	\$430.93	7.9%
7	Provigil 200 mg tablet	30	Cephalon	Wakefulness Agents	\$38.46	14.1%
8	Tracleer 125 mg tablet	60	Actelion Pharm.	Pulmonary Arterial Hypertension	\$223.18	8.6%
9	Forteo 600 mcg/2.4mL SQ inj	2.4	Lilly	Other Therapeutic Agents	\$46.99	11.5%
10	Atripla 600-200-300 mg tablet	30	Bristol-Myers Squibb/Gilead	Antiretrovirals	\$63.65	6.9%
11	Rebif 44 mcg/0.5mL SQ inj	12 x 0.5	Serono	Multiple Sclerosis Agents	\$164.04	22.0%
12	Incivek 375 mg tablet	168	Vertex Pharm.	Antivirals	\$811.83	16.6%
13	Betaseron 0.3 mg SQ inj	14 x 1	Bayer Healthcare Pharma	Multiple Sclerosis Agents	\$154.83	15.8%
14	Victoza 18 mg/3mL SQ inj	3	Novo Nordisk	Antidiabetics (Other Inj.)	\$17.97	10.2%
15	Truvada 200-300 mg tablet	30	Gilead Sciences	Antiretrovirals	\$41.56	4.8%
16	Revlimid 25 mg capsule	21	Celgene Corp	Antineoplastics (Oral)	\$428.93	5.1%
17	Byetta Pen 10 mcg/0.04mL SQ inj	2.4	Amylin Pharmaceuticals	Antidiabetics (Other Inj.)	\$12.01	12.8%
18	Zyprexa 20 mg tablet	30	Lilly	Antipsychotics (Atypical)	\$37.72	0.6%
19	Seroquel 300 mg tablet	60	AstraZeneca	Antipsychotics (Atypical)	\$17.09	7.6%
20	Tarceva 150 mg tablet	30	Genentech	Antineoplastics (Oral)	\$197.77	11.2%
21	Zyprexa 10 mg tablet	30	Lilly	Antipsychotics (Atypical)	\$19.23	0.6%
22	Revlimid 5 mg capsule	100	Celgene Corp	Antineoplastics (Oral)	\$422.66	7.9%

continued on page 18

continued from page 17

Table 1

All of the Top 30 Drug Products in the Specialty Market Basket Had Retail Price Increases in 2013

Sales Rank*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	2013 Retail Price/Day	Annual % Change
23	Revlimid 15 mg capsule	21	Celgene Corp	Antineoplastics (Oral)	\$407.15	2.4%
24	Zyprexa 15 mg tablet	30	Lilly	Antipsychotics (Atypical)	\$28.60	0.2%
25	Isentress 400 mg tablet	60	Merck Sharpe & Dohme	Antiretrovirals	\$36.63	4.7%
26	Xeloda 500 mg tablet	120	Genentech	Antineoplastics (Oral)	\$139.87	15.2%
27	Seroquel 400 mg tablet	100	AstraZeneca	Antipsychotics (Atypical)	\$20.32	3.8%
28	Opana ER 40 mg tablet (12 Hour, crush resistant)	100	Endo Pharmaceuticals	Analgesics (Opioid)	\$27.58	1.3%
29	Revatio 20 mg tablet	90	Pfizer U.S.	Pulmonary Hypertension	\$65.50	15.9%
30	Gleevec 100 tablet	90	Novartis	Antineoplastics (Oral)	\$195.45	12.0%
General rate of inflation (as measured by growth in CPI-U)						1.5%

least 15.0 percent in 2013, or more than 10 times the rate of general inflation (1.5 percent) in 2013.

- Three of the drug manufacturers had weighted average annual specialty drug price increases at the retail level of more than 20 percent in 2013, or more than 13 times the rate of general inflation (1.5 percent) in 2013. All three manufacturers had only one product in the study's market basket.
 - American Regent had a weighted average annual price increase of 46.9 percent in 2013, or more than 30 times the rate of general inflation.
 - Jazz Pharmaceuticals had a weighted average annual price increase of 39.5 percent in 2013, or more than 26 times the rate of general inflation.
 - Serono had a weighted average annual price increases of 22.0 percent in 2013, or nearly 15 times the rate of general inflation.
- Nine manufacturers (about 20 percent) had weighted average annual price *decreases* in 2013 that ranged from 0.3 percent (Astellas) to 22.6 percent (Wockhardt).

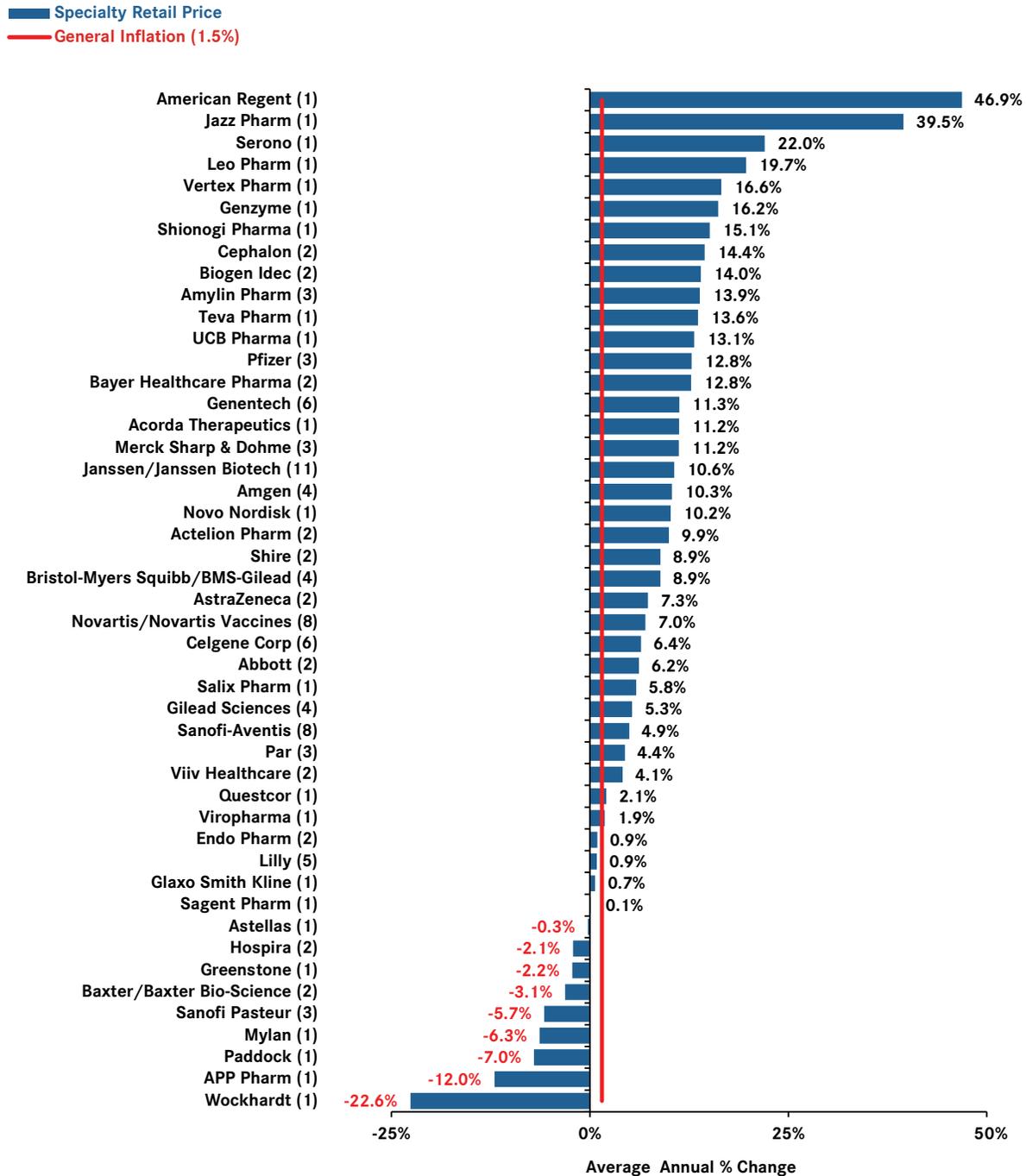
2.6. RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY THERAPEUTIC CATEGORY

Specialty drug prices at the retail level increased faster than the rate of general inflation (1.5 percent) in 2013 for 87 percent (26 of 30) of the therapeutic categories examined in this study (Figure 13). Twenty-one therapeutic categories had average annual price increases of 5.0 percent or more—more than three times the rate of general inflation in 2013.

- Three therapeutic categories had average annual price increases that were more than 39 percent or more than 25 times the rate of general inflation in 2013.
 - The therapeutic category with the highest specialty drug price increase—antineoplastics (other), used to treat cancer—had an average annual retail price increase of 77.2 percent in 2013. The only specialty drug product in this therapeutic category was a generic drug product (i.e., methotrexate sodium 25 mg/mL injection).
- Twenty percent (6 of 30) of the therapeutic categories for specialty drugs had weighted average annual retail price increases of more

Figure 12

Retail Prices for Widely Used Specialty Drug Products Increased by More than 5 percent for the Majority of Drug Manufacturers in 2013

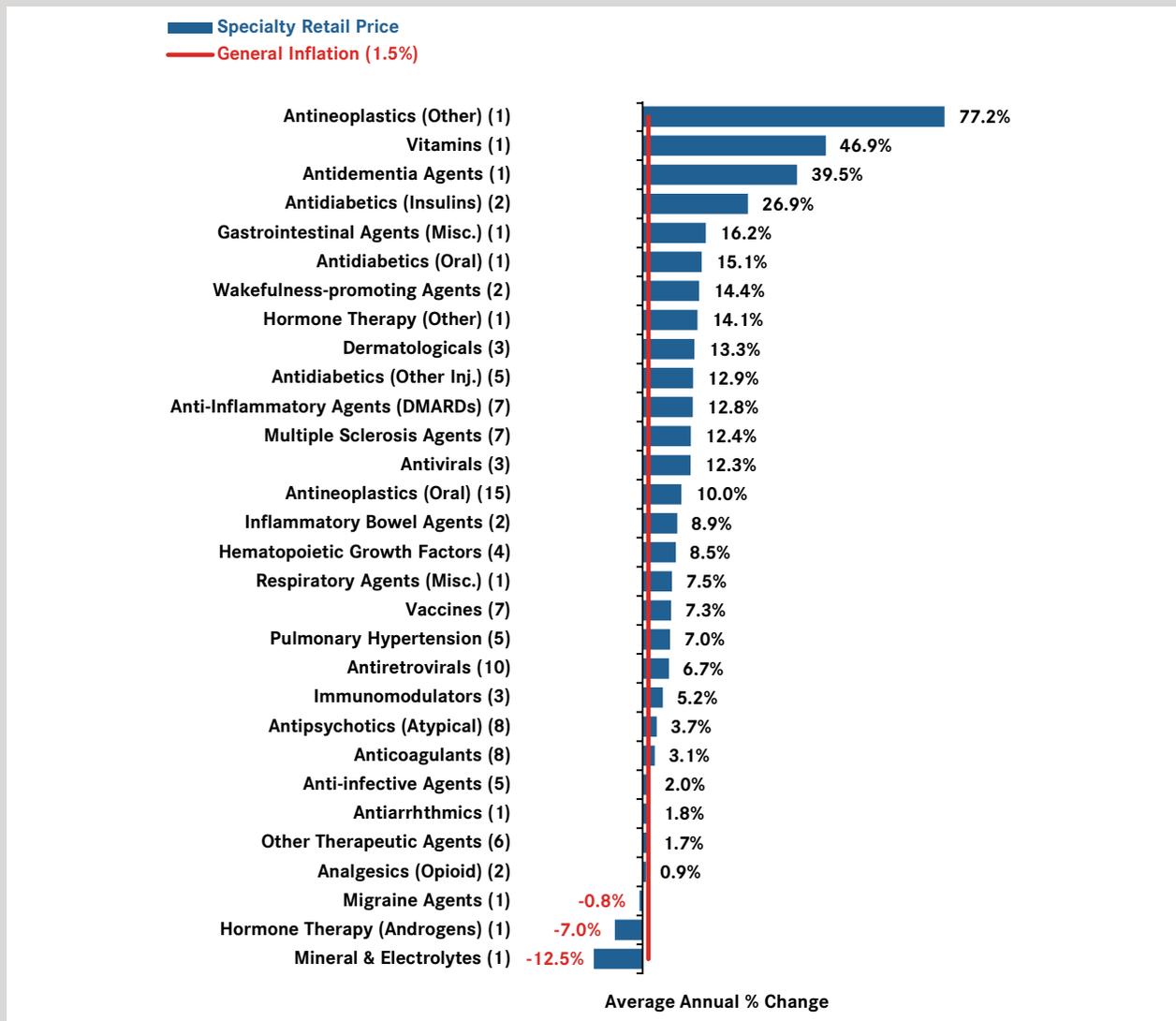


Note: Calculations include the 115 specialty prescription drug products most widely used by older Americans (see Appendix A). The number in parentheses after a manufacturer's name indicates the number of drug products in the market basket for that manufacturer. The general inflation rate is based on CPI-U for 2013.

Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Figure 13

All but Four Therapeutic Categories for Specialty Drugs Had Retail Price Increases That Exceeded the Rate of General Inflation in 2013



Note: Calculations include the 115 specialty prescription drug products most widely used by older Americans (see Appendix A). Some therapeutic categories with only one drug product in the market basket were grouped together 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 the CPI-U for 2013.

Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

than 15 percent in 2013—more than 10 times the rate of general inflation.

- Three of the 30 therapeutic categories had average annual retail price decreases in 2013 with decreases that ranged from 0.8 percent to

12.5 percent. All of the specialty drug products in these three therapeutic categories with an annual average price decrease were generic drug products.

CONCLUDING OBSERVATIONS

Specialty drug prices have routinely increased much faster than general inflation over the more than 10 years that this report series has been tracking prescription drug prices. In 2013, the average annual increase in retail prices for 115 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, was 10.6 percent. In contrast, general inflation in the United States rose by 1.5 percent in 2013.

Increases in the retail price of specialty prescription drugs affect both patients and the larger economy. In 2013, the average annual retail cost of drug therapy for a prescription drug, based on the market basket in this study, was \$53,384 per year. This price exceeds the median US household income (\$52,250).²⁵ It also greatly exceeds the median income for Medicare beneficiaries (\$23,500)²⁶ and the average Social Security retirement benefit (\$15,524)²⁷ over the same time period.

There are strong indications that a much larger share of the population will be using specialty

prescription drugs in the future. If recent trends in specialty drug prices and related price increases continue, it will almost undoubtedly become more difficult for patients to access and afford necessary specialty medications. This will lead to poorer health outcomes and higher health care costs in the future.²⁸

Spending increases driven by high and growing specialty drug prices affects all Americans in some way. Those with private health insurance will pay higher premiums and/or cost sharing for their health care coverage²⁹ and government programs will grow faster than the tax-based revenue that supports them, leading to higher taxes and/or to cuts in public health or other programs.

Policy makers interested in reducing the impact of prescription drug prices should focus on options that drive innovation while also protecting the health and financial security of consumers and taxpayer-funded programs like Medicare and Medicaid.

25 Noss, "Household Income."

26 Jacobson, Huang, Neuman, and Smith, "Income and Assets."

27 The average monthly Social Security retirement benefit in 2013 was \$1,294 per month. Social Security Administration, *Annual Statistical Supplement*.

28 Z.A. Marcum, M.A. Sevick, and S.M. Handler, "Medication Nonadherence: A Diagnosable and Treatable Medical Condition," *Journal of the American Medical Association* 309, no. 20 (2013): 2,105–06.

29 Auerbach and Kellermann, "A Decade of Health Care Cost Growth."

Appendix A: Detailed Methodology and Description of Retail Price Data

This appendix describes in detail how brand, generic, and specialty drugs are defined in this study; how the study identified the market basket (i.e., sample) of drugs; how it measured prices; and how it calculated weighted average price changes. In addition, it describes methods and assumptions used to determine prices and price changes by drug manufacturer and by therapeutic category.

OVERVIEW

AARP's Public Policy Institute has been publishing a series of reports that track price changes for the prescription drug products most widely used by older Americans with annual and quarterly results reaching as far back as 2000. Since 2008, these reports have focused on price changes for three market baskets—brand, generic, and specialty drugs. In addition, a combined market basket (i.e., brand, generic, and specialty) has been added to the series, which is useful to view the price change trend across all types of prescription drugs in the U.S. market. While this overall perspective is useful for those interested in understanding the industrial economics of the entire prescription drug market, consumers have proven to be considerably more interested in the price trend for the specific products that they are taking as an individual rather than all drug products on the market.

The AARP Public Policy Institute and the University of Minnesota's *PRIME* Institute originally collaborated to report an index of manufacturers' drug price changes based on the Wholesale Acquisition Cost (WAC) from the Medi-Span Price-Chek PC database.³⁰ In 2009, AARP and the *PRIME* Institute created an additional drug price index based on retail prices³¹ from Truven Health's MarketScan® Commercial Database and MarketScan® Medicare Supplemental Database (Truven Health MarketScan® Research Databases).³² Thus, the report series uses the same market basket of prescription drugs widely used by older Americans to examine both manufacturer-level prices and retail-level prices in the market. The addition of retail-level prices allows the AARP Public Policy Institute to assess what prices payers (i.e., insurers, consumers or government programs) are paying and whether rebates and other types of discounts have been passed along to payers and their covered members.

Recently, the AARP Public Policy Institute and the University of Minnesota's *PRIME* Institute collaborated again to develop a new market basket of widely used prescription drugs based on 2011 data provided by the Truven Health MarketScan® Research Databases and a Medicare Part D plan provider. UnitedHealthcare provides

30 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 (now Price Rx®) 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 35 years. See <http://www.medispan.com>.

31 The retail prices used in this report series reflect the total price for a specific prescription that a PBM bills to a specific health plan for consumers enrolled in employer-sponsored or government-sponsored (i.e., Medicare or Medicaid) health plans and not simply the out-of-pocket cost (such as the copay) which a consumer would pay at the pharmacy. These amounts may or may not reflect what the PBM paid the pharmacy or the usual and customary price that a pharmacy would charge a cash-pay consumer for the same prescription.

32 The Truven Health MarketScan® Research Databases, a family of databases, contain individual-level health care claims, lab test results, and hospital discharge information from large employers, managed care organizations, hospitals, Medicare, and Medicaid programs. Truven Health constructs the MarketScan® Research Databases by collecting data from employers, health plans, and state Medicaid agencies and placing them into databases. E. Danielson, "White Paper: Health Research Data for the Real World: The MarketScan® Databases," Truven Health Analytics, January 2014.

Medicare Part D coverage and is the organization that insures the AARP Medicare Rx plans. This Medicare Part D plan provider supplied data for all prescriptions provided to its Medicare Part D enrollees in 2011. This Rx Price Watch reports used the 2011 market basket. As in the past, the series will include separate data sets, analyses, and reports for brand name, generic, and specialty drugs, as well the overall combined market basket.

DEFINING BRAND, GENERIC, AND SPECIALTY PHARMACEUTICALS

A brand name drug is defined as a product marketed by the original holder of a new drug application (NDA) or biological license application (BLA) (or related licensees) for a given drug entity. A generic drug is defined as any drug product marketed by an entity other than the NDA or BLA holder or related licensees.

The market conditions and pricing behavior for brand name and generic drugs are quite different. For example, brand name drugs have a monopoly based on patents and other forms of exclusivity for a number of years after market entry,³³ and they do not experience typical price competition from therapeutically equivalent drug products that can be routinely substituted at the pharmacy level. On the other hand, generic drug products face price competition from the time the generic first enters the market when there are two or more therapeutically equivalent drug products (as evaluated by the Food and Drug Administration [FDA] and reported in the Orange Book), including the brand name product. However, certain generic drugs—that is, those for which the manufacturer files a paragraph IV certification of patent non-infringement—may receive 180 days of exclusivity as the sole generic after this first generic drug product is approved. In cases where there is only one generic drug product on the market, the level of economic competition may be somewhat limited until other generics enter the market.

Specialty pharmaceuticals are drugs that treat complex, chronic conditions and that often require special administration, handling, and care management. Specialty drugs are expected to be

the fastest growing group of drug products in the next decade. This important group of drugs and biologicals is not precisely defined, but it includes products based on one or more of the following: (1) how they are made, (2) how they are approved by the FDA, (3) conditions they treat, (4) how they are used or administered, (5) their cost, and (6) other special features. The operational definition of specialty drugs for this study is further described in a later section of the methodology.

CREATING THE MARKET BASKET OF DRUGS

The AARP Public Policy Institute has been reporting prescription drug product price changes since 2004. The original reports were based on a market basket of retail and mail-order prescriptions provided to about two million people ages 50 and older who used the AARP Pharmacy Service in 2003. Following the implementation of the Medicare Part D program, we chose to develop a new market basket of drugs using 2006 data provided by UnitedHealthcare–PacifiCare, now UnitedHealthcare, which is also the organization that insures the AARP Medicare Part D plans. All AARP price trend reports published between 2007 and 2012 used this market basket.

Subsequently, we updated the AARP market baskets again using 2011 data provided by Truven Health MarketScan® Research Databases and the same Medicare Part D plan provider that was used for the 2006 market basket. We weighted the data from the Medicare Part D plan provider by Part D enrollment and the Truven Health MarketScan® data by the 50 plus population less Part D enrollment, based on data from the Centers for Medicare and Medicaid Services and the U.S. Census. We then merged the weighted data to develop and rank a weighted master list by prescription volume and sales at the National Drug Code (NDCs) level for the new AARP market baskets.

Our selection of the market basket of drugs to track in the price index was a multi-step process. First, prescriptions covered and adjudicated by the commercial entities included in the merged data set were grouped by NDC number. The NDC

33 The average market exclusivity period for a brand name drug is almost 13 years. H. Grabowski, G. Long, and R. Mortimer, “Brief report: Recent trends in brand-name and generic drug competition,” *Journal of Medical Economics*, Vol. 17(3) (2014): 207-214.

is a number that refers to a specific drug product presentation with a unique combination of active chemical ingredient, strength, dosage form, package type and size, and manufacturer (e.g., Nexium [esomeprazole magnesium] 40 mg, capsule, bottle of 30, AstraZeneca). As a result, some drug entities (i.e., molecules) could appear more than once among the widely used drug products e.g., when there are different strengths, such as Lipitor 10 mg, Lipitor 20 mg, and Lipitor 40 mg). For each NDC, we calculated total sales revenue from adjudicated prescription claims, including the patient cost-sharing amount, as well as the total prescriptions dispensed, the total units supplied, and the total days of therapy provided during 2011.

The next step involved merging the use and expenditure data from the Truven Health MarketScan® Research Databases and the Medicare Part D plan provider by NDC code and then linking the data with descriptive information from Medi-Span's Price Rx® drug database,³⁴ using the NDC number as the key linking variable. The descriptive data from Price Rx included drug product information such as brand name, generic name, manufacturer, patent status, package size, route of administration, usual dose, therapeutic category, usual duration, and each drug product's price history.

All NDCs were classified by the patent status of the drug product presentation—that is, patented brand name (i.e., brand single source [SS]), off-patent brand name (i.e., brand multiple source [BMS] or innovator multiple source [IMS]), and off-patent generic (i.e., generic multiple source [GMS] or non-innovator multiple source [NMS]). We then grouped all NDC numbers by the Generic Product Indicator (GPI) code into GPI-patent status groups using the GPI code from Price Rx®. The GPI combines drug products into a common group when they have the same active ingredients, dosage form, and strength—a single GPI includes the NDCs for any package type and size and from all manufacturers. When patent status is combined with the GPI categories, each GPI will typically be either a single source GPI (GPI-brand-single source) or a multiple source GPI with both a GPI-brand multiple source group and a GPI-generic multiple source group.

The next step involved summing the total expenditures, number of prescriptions dispensed, and days of therapy provided across all NDCs within each GPI-patent status group. The NDCs within each GPI-patent status group were then rank ordered based on total annual expenditure for each NDC. The designated “representative NDC” was the NDC that had the highest level of expenditure within each GPI-patent status group. If the NDC with the greatest expenditure level was inactive, the NDC with the next highest level of expenditure became the representative NDC.

This analysis excluded less than 0.5 percent of the expenditures and the prescriptions because they were for non-drug items. These non-drug items included devices, medical and diabetic supplies, syringes, compounding service fees, and other professional services. After exclusion of non-drug items, the 2011 data set contained 35,119 NDCs grouped into 6,710 GPI-patent status categories.

We then coded all GPIs to distinguish the specialty prescription drugs from other regular prescription drugs. The definition of specialty prescription drugs used here is a prescription drug that is: (1) administered by injection, such as intravenous, intramuscular, sub-cutaneous, or other injection site (not including insulin); (2) any dosage form that has a total average prescription cost greater than \$1,000 per prescription; or (3) any dosage form that has a total average cost per day of therapy greater than \$33 per day. The drugs meeting this definition were considered “specialty drugs” and all other prescription drugs were considered “regular” or “non-specialty drugs.” Throughout this report, references to the market basket of drugs refer to the regular (non-specialty) drugs unless otherwise indicated. Only specialty drugs provided through a Medicare Part D program or under a prescription drug benefit program are included. The specialty drugs provided under Medicare Part B, or under a commercial health plan and administered in a clinic or physician's office and billed as a medical claim, are not included in this data set or this analysis.

All NDCs were classified by the patent status of the drug product presentation—that is, patented brand name (or SS), off-patent brand name (or IMS), or off-

34 Price Rx® 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®).

patent generic (NMS). We classified both the regular and the specialty drug data sets by patent status.

We sorted the list of all GPI-patent status groups in the merged data set for 2011 by three criteria: (1) total prescription expenditures, (2) number of prescriptions dispensed, and (3) days of therapy provided. The top 400 GPI-patent status categories were identified for each of these three criteria. Since some GPI-patent status groups appeared in more than one of these top 400 lists, the combined list of all GPI-patent status groups totaled to 627 GPI-patent status groups. There were 227 brand name GPI-patent status groups (i.e., both brand single source and brand multiple source) and 283 generic GPI-patent status groups. Another 115 GPI-patent status groups in this combined top 400 list were classified as specialty drugs.

The three market baskets (brand name, generic, and specialty drugs) combined accounted for 83.0 percent of all prescription drug expenditures and 82.8 percent of all prescriptions dispensed.

MONITORING RETAIL DRUG PRICES

The original Rx Watchdog reports were based on market baskets of drugs constructed using data from a Medicare Part D plan provider for 2006 and manufacturer drug price changes measured using WAC data from the Medi-Span Price-Chek PC database. The AARP Public Policy Institute and the University of Minnesota's *PRIME* Institute collaborated to develop a new retail drug price index known as the Rx Price Watch reports based on retail-level prescription prices from the Truven Health MarketScan® Research Databases. This retail price index allows the AARP Public Policy Institute to assess retail prices actually paid by consumers or insurers and whether the rebates and discounts sometimes given to payers are being passed along to their clients.

Retail Data Description

The Truven Health MarketScan® Research Databases are comprised of 12 fully integrated claims databases, and contain the largest and oldest collection of privately and publicly insured, de-identified patient data in the United States.³⁵ The warehouse features an opportunity sample from multiple sources (employers, states, health plans), more than 20 billion patient records, and 196 million covered lives since 1995.³⁶ The data used in the Rx Price Watch analyses are drawn from the Truven Health MarketScan® Commercial Claims and Encounters Database (Commercial Database) and the Truven Health MarketScan® Supplemental and Coordination of Benefits Database (Medicare Supplemental Database).

The Truven Health MarketScan® Commercial Database consists of employer- and health plan-sourced data containing medical and drug data for several million individuals annually. It encompasses employees, their spouses, and dependents covered by employer-sponsored private health insurance. Health care for these individuals is available under a variety of fee-for-service (FFS), fully capitated, and partially capitated health plans. These include PPOs and exclusive provider organizations (EPOs), POS plans, indemnity plans, HMOs, and consumer-directed health plans.³⁷

The Truven Health MarketScan® Medicare Supplemental Database is composed of data from retirees with Medicare supplemental insurance sponsored by employers or unions. In 2010, 14 percent of the 46.5 million Medicare beneficiaries received their drug benefits through a retiree coverage plan.³⁸ The Truven Health MarketScan® Medicare Supplemental Database includes the Medicare-covered portion of payment, the employer-paid portion, and any patient out-of-pocket expenses. The database provides detailed cost and use data for health care services performed in both inpatient and outpatient settings.

35 E. Danielson, "White Paper: Health Research Data for the Real World: The MarketScan® Databases," Truven Health Analytics, January 2014.

36 Ibid.

37 Ibid.

38 Ibid.

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

1. Claimant must be age 50 and older;
2. Claim must have a value of greater than zero in the following fields;
 - a. Total payment amount
 - b. Metric quantity
 - c. Ingredient cost
 - d. Days' supply
 - e. Average wholesale price
3. Payment amount cannot be less than 100 percent of the ingredient cost;
4. Metric quantity value must fall within pre-defined ranges developed using reference data from the Price Rx Pro database; and
5. Claim must come from a non-capitated health plan.

Truven Health Analytics then combined the two databases and provided the AARP Public Policy Institute with datasets that included the monthly median (as well as the 25th and 75th percentile) retail price from January 2005 through December 2013 for all of the drug products in the Rx Price Watch market baskets. We then compiled the monthly median retail prices in spreadsheets designed to track price changes among all of the drug products in the AARP market baskets.

CALCULATING ANNUAL PRICE CHANGES FOR EACH DRUG

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

- The *annual point-to-point* percent change in retail price is the percent change in price for a given month compared with the same month in the previous year (e.g., January 2013 vs. January 2012, February 2013 vs. February 2012).

- The 12-month *rolling average* percent change in retail price is the average of the point-to-point changes over the preceding 12 months. For example, the average annual retail price changes for 2013 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2013 through December 2013 compared with the same months in the 2012.

We calculated average annual price changes for each drug product for each year that the drug was on the market from 2006 to 2013. The first step was to calculate the annual point-to-point percent change for each month by comparing the price in a specific month with the same month in the previous year (e.g., January 2013 vs. January 2012, February 2013 vs. February 2012). The next step was to calculate the average of these annual point-to-point changes for the 12 months in each calendar year. For example, average annual price changes for 2013 refer to the average of the annual point-to-point price for each of the 12 months in 2013. This 12-month rolling average tends to be a more conservative estimate of price changes than the point-to-point method (that is, a simple percentage change for a single month from the same month in the previous year), and it accounts for seasonal variations in drug manufacturers' pricing policies.

Table A-1 shows how 12-month rolling average price changes are calculated. Suppose, for example, that drug A had the following pattern of price changes in 2013 when compared to the same month in 2012.

In this example, the retail price of drug A was 2 percent higher than the price for the same months in the previous year, for the period from January through April 2013. A price hike in May increased the percentage difference to 3 percent for each of the subsequent months in 2013. The 12-month average of these price differences is

$$(2.0+2.0+2.0+2.0+3.0+3.0+3.0+3.0+3.0+3.0+3.0+3.0)/12, \text{ or } 2.67 \text{ percent.}^{39}$$

39 If the drug was introduced to the market in July of the previous year, then the price change for the given year is averaged using only the 6 months that the product was on the market in the previous year (i.e., July-December).

Table A-1

Average Annual Percent Change in Price for Hypothetical Prescription Drug A, 2013

Jan 12-13	Feb 12-13	Mar 12-13	Apr 12-13	May 12-13	Jun 12-13	Jul 12-13	Aug 12-13	Sep 12-13	Oct 12-13	Nov 12-13	Dec 12-13	Average
2.0	2.0	2.0	2.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	2.67

CALCULATING AGGREGATE AVERAGE PRICE CHANGES ACROSS MULTIPLE DRUGS

To aggregate price changes for multiple drugs, we calculated a weighted average of price changes by weighting each drug's annual price change (calculated from the Truven Health MarketScan® Commercial Database and the Truven Health MarketScan® Medicare Supplemental Database, as shown in the hypothetical example in Table A-1) by its share of total 2011 prescription sales within its given market basket (i.e., brand name, generic, specialty, or combined). As an example, Table A-2 shows that the sample from which drug A was drawn has 10 drugs (we chose this small sample size to simplify this illustrative example). The second column of Table A-2 gives the average annual price change for each of these drugs, denoted as drugs A-J. A straight (or unweighted) average, which adds up individual values and divides by the number of drugs, would result in an average annual price change of 4.76 percent for the drugs in this hypothetical sample. Assuming the hypothetical changes in the dollar cost of therapy for these drugs, shown in the third column, the straight average change in the annual cost of therapy would be \$236.13.

A *straight* average, however, distorts the actual impact of price changes because it does not account for each product's "weight" within the sample (that is, it gives equal weight to price changes of both commonly used drugs and drugs that are used less frequently). As a result, it does not accurately capture the average impact of price changes in the marketplace. In Table A-2, drugs with low price increases in percentage terms (drugs E and J) account for a small share (7 percent) of total 2011 sales for the specific group of drugs analyzed. By contrast, drugs with the highest percentage changes (drugs B, D, and I) account for a much larger share (37 percent) of sales. To reflect the relative importance of each drug's price change in

the market basket of products, we weighted each annual price change by the drug's share of total 2011 sales. In this simple example, the weighted average price increase in 2007 is the sum of:

$$\begin{aligned} & (\text{Unweighted average price change for drug A} \times \\ & \quad \text{drug A's share of total sales}) \\ & \quad + \\ & (\text{Unweighted average price change for drug B} \times \\ & \quad \text{drug B's share of total sales}) \\ & \quad + \\ & (\text{Unweighted average price change for drug C} \times \\ & \quad \text{drug C's share of total sales}) \\ & \quad + \dots + \\ & (\text{Unweighted average price change for drug J} \times \\ & \quad \text{drug J's share of total sales}) \end{aligned}$$

or,

$$(2.67 \times 0.15) + (10.0 \times 0.14) + (2.67 \times 0.07) + \dots + (1.0 \times 0.02).$$

The results of this calculation are in the fifth column of Table A-2, which shows that the weighted annual average price change for drugs is 5.22 percent, or approximately one-half percentage point higher than the unweighted average of 4.76 percent. The weighted dollar change in the annual cost of therapy would be \$251.07, compared to an unweighted average dollar change of \$236.13.

CALCULATING AVERAGE PRICE CHANGES ACROSS MULTIPLE DRUGS FOR YEARS BEFORE 2011

The process for aggregating price changes for multiple drugs pre-2011 is similar to that for 2013. Average price changes for 2006 through 2010 were derived by first calculating the rolling-average annual price change for each drug (as shown in Table A-1), then weighting each drug's price change by its share of total sales in the sample. The weights used for all years in this study are from 2011 sales from the Medicare Part D plans of a Medicare

Table A-2

Average Changes in Price and Cost of Therapy for 10 Hypothetical Prescription Drugs, 2013

Drug Name	Unweighted Average Annual Price Change (%)	Unweighted Average Change in Cost of Therapy (\$/year)	Share of Total Sales	Weighted Average Annual Price Change (%)	Weighted Average Change in Cost of Therapy (\$/year)
A	2.67%	\$623.48	15%	0.40%	\$93.52
B	10.00%	\$108.68	14%	1.40%	\$15.22
C	2.67%	\$433.68	7%	0.19%	\$30.36
D	8.00%	\$54.08	10%	0.80%	\$5.41
E	1.50%	\$162.76	5%	0.08%	\$8.14
F	4.33%	\$54.08	14%	0.61%	\$7.57
G	6.40%	\$216.84	2%	0.13%	\$4.34
H	3.25%	\$433.68	18%	0.59%	\$78.06
I	7.80%	\$27.04	13%	1.01%	\$3.52
J	1.00%	\$247.00	2%	0.02%	\$4.94
TOTAL	4.76%	\$236.13	100%	5.22%	\$251.07

Part D plan provider, including the AARP plans, as well as from the Truven Health MarketScan® Commercial Database, and the Truven Health MarketScan® Medicare Supplemental Database. The 2011 weights keep the market basket constant over time so that the change in prices would be a function of price changes alone and not a function of changes in market basket.

However, some drugs that were in the 2011 sample were not on the market in all earlier years. We dropped these drug products out of the analysis in the month before they entered the market and for all previous months, and recalculated the weights of the products present in the market prior to 2011 to reflect their relative share of the total sales as adjusted to reflect only drugs on the market during that period.

For example, suppose that drugs I and J in Table A-2 were not on the market in 2008. Furthermore, assume that total drug spending in 2011 was \$100,000. To capture the loss of drugs I and J from the analysis for 2008, the weights are redistributed across the drugs that remain in the analysis (drugs A through H); the new weights are still based on their 2011 sales but as a share of total sales for the smaller number of drugs in the analysis for the year. In this example, the total 2011 sales would be \$85,000 without drugs I and J. Drug A's \$15,000 in sales, which represented 15 percent of sales for all 10 drugs, rises to

18 percent of sales when I and J are excluded. This weight, along with the analogous weights for drugs B-H, was used to derive the weighted average price change for 2008 (see Table A-3).

Weighting the previous years' price changes by 2011 sales potentially creates a bias relative to using each specific year's sales as the basis for assigning weights for that year. Using 2011 sales gives more weight to drugs that, relative to other drugs, had high rates of sales growth in 2011 or earlier years compared to the year analyzed. In general, however, newer drugs initially have higher rates of sales growth, but relatively lower rates of price growth, than do older drugs. This pattern occurs both because newer drugs may have been introduced at higher prices and because price increases for brand name drugs tend to accelerate in rate and amount closer to the end of a product's effective patent life.

CALCULATING ANNUAL COST OF THERAPY FOR A DRUG PRODUCT

To assess the impact of price changes on dollars spent, we calculated an annual cost of therapy for each drug product. This annual cost of therapy analysis excludes drug products in the market basket that are used primarily for treatment of acute conditions and are typically taken for a limited period of time. The amount of a drug that an average adult would take on a daily basis

Table A-3

Recalculating Weights When Prescription Drugs Drop out of the Sample

Drug Name	2011 Weights		2008 Weights	
	Share of 2011 Sales	Dollar Value of 2011 Sales	Dollar Value of 2008 Sales	Share of 2008 Sales
A	15%	\$15,000	\$15,000	18%
B	14%	\$14,000	\$14,000	16%
C	7%	\$ 7,000	\$ 7,000	8%
D	10%	\$10,000	\$10,000	12%
E	5%	\$ 5,000	\$ 5,000	6%
F	14%	\$14,000	\$14,000	16%
G	2%	\$ 2,000	\$ 2,000	2%
H	18%	\$18,000	\$18,000	21%
I	13%	\$13,000	–	–
J	2%	\$ 2,000	–	–
TOTAL	100%	\$100,000	\$85,000	100%

was determined using the “usual daily dose” reported in the Medi-Span Price Rx® database. When this information was not available from Medi-Span, we used dosing information in the FDA-approved labeling for the drug product. The weighted average annual cost of therapy was also calculated using the 2011 sales volumes to weight the annual cost of each drug product to produce the aggregate annual cost of therapy across all drug products in the study’s market basket.

DEFINING MANUFACTURER

We defined a drug manufacturer as the firm marketing the drug product under its corporate name in 2013. If a listed manufacturer is a division of another firm, we defined its drugs as 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 for other reasons. The analysis of drug manufacturers reported separately on manufacturers with at least one drug product (at the NDC level) among the most widely used drugs.

DEFINING THERAPEUTIC CATEGORY

Drug products can be classified by the therapeutic purpose for which they are used. If a drug has multiple uses, the most common indication typically becomes the classifier. To group drug products in this study into similar therapeutic categories, we used Medi-Span’s therapeutic coding scheme known as the GPI (or generic product indicator) code.

The therapeutic categories used in this study use an intermediate GPI level code that specifies the groupings of similar chemical entities such as “Proton Pump Inhibitors.” A therapeutic category may include drug products that are brand single-source or brand multiple-source.

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