

Rx Price Watch Report

Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015

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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

This report on retail prices of specialty drugs is the latest in the AARP Public Policy Institute's *Rx Price Watch* series. Separate reports analyze retail price changes for widely used brand name and generic drug products. The series also analyzes the price changes 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.

Retail prices for widely used specialty prescription drugs increased substantially higher than general inflation in every year from 2006 to 2015. Between 2014 and 2015, retail prices for 101 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, increased by an average of 9.6 percent—the highest average annual increase since at least 2006. In contrast, the general inflation rate was 0.1 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 has one or more of the following characteristics: administered by injection; has a total average prescription cost greater than \$1,000 per prescription; has a total average cost per day of therapy greater than \$33 per day; or is in a therapeutic class where several other drugs in the class meet one or more of the previous criteria (e.g., HIV drugs).

Many specialty drugs treat conditions that often affect older and disabled 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. Expenditures for this group of specialty drug products are widely expected to be the fastest growing sector of pharmaceuticals 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 2015, the average annual retail cost of

prescription drug therapy for a single specialty drug, based on the market basket used in this study, was \$52,486 per year. This average annual cost was slightly less than the median US household income (\$55,775). The annual specialty drug cost was also more than twice the median income for Medicare beneficiaries (\$25,150) and more than three times higher than the average Social Security retirement benefit (\$16,101) over the same time period.

If recent trends in specialty drug price levels and related price increases continue unabated, an increasing number of older and disabled 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 2015, retail prices for 101 widely used specialty prescription drugs increased by 9.6 percent, continuing the upward trend of specialty drug price increases observed during the prior 9 years (i.e., 2006 to 2014), which ranged from 3.3 percent to 9.4 percent.
- Specialty drug prices increased more than 80 times faster than general inflation in 2015 (9.6 percent v. 0.1 percent).
- The average annual cost for a single specialty medication used on a chronic basis was more than \$52,000 in 2015. The average annual cost of therapy for the specialty drug products used to treat chronic conditions rose by almost \$35,000 between 2006 and 2015.
- In 2015, the average annual price of therapy for specialty prescription drugs was 9 times higher than the average annual price of therapy for brand name prescription drugs (\$52,486 v. \$5,807, respectively) and 100 times higher than the average annual price of therapy for generic prescription drugs (\$52,486 v. \$523 respectively).
- Retail prices for 29 chronic use specialty drugs that have been on the market since

the beginning of the study (i.e., between January 2006 and December 2015) increased cumulatively by an average of 177.3 percent over 10 years. In contrast, general inflation in the US economy rose 19.4 percent during the same 10-year period.

- In 2015, retail prices increased for 93 percent (94 of 101) of the widely used specialty prescription drug products in the study's market basket. All of these retail price increases exceeded the rate of general economic inflation in 2015.
- Retail prices for 94 percent (29 of 31) of drug manufacturers with at least one specialty drug product in the study's market basket increased faster than the rate of general inflation (0.1 percent) in 2015. Eleven drug manufacturers had average annual price increases for their specialty drugs of 10 percent or more during 2015—more than 80 times the rate of general inflation in 2015.
- All but 2 of the 22 therapeutic categories of specialty drug products had average annual retail price increases that exceeded the rate of general inflation in 2015. Price increases by therapeutic category ranged from 5.0 percent to 24.7 percent.

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

Until recently, less than one percent of 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 price associated with many specialty drug products now outstrip the total individual or family income earned in a given year.

Individual 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 in public program benefits, or both.

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

Introduction

AARP's Public Policy Institute finds that average retail 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 2015. Specialty drug prices have regularly increased much faster than general inflation over the past 12 years—the entire period since the beginning of our report series on prescription drug prices in 2004.¹ Between 2014 and 2015, the average annual increase in retail prices² for 101 specialty prescription drugs (some are brand name and some are generic) widely used by older Americans was 9.6 percent—the highest average annual increase since at least 2006. In contrast, the rate of general inflation in the US economy was 0.1 percent in 2015.

The market basket for these analyses originally included 102 specialty prescription drugs. However, one specialty drug product (Questcor's

HP Acthar Gel 80 unit/mL) had an extremely large one-time price increase (more than 1,300 percent) in 2007.³ Because this unusual price change was an extreme outlier and substantially distorted the overall trends, we excluded this drug product from all analyses. Therefore, the market basket for specialty drugs used to track retail drug prices in this and subsequent studies includes 101 specialty drug products. Figures C1, C2, and C3 in Appendix C show the impact of including HP Acthar Gel 80 unit/mL.

Previous *Rx Price Watch* reports found that retail prices for brand name traditional (non-specialty) drugs widely used by older Americans experienced a 15.5 percent increase in 2015, and retail prices for traditional (non-specialty) generic drugs widely used by older Americans experienced a 19.4 percent decrease.⁴

Specialty drugs have never been precisely and consistently defined but generally include drugs

- 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 have proved 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. 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 derived 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.
- 3 HP Acthar Gel 80 unit/mL was number 20 in the market basket of 102 widely used brand name prescription drugs when ranked by 2014 spending data provided by the Truven Health MarketScan® Research Databases and a large Medicare Part D plan provider.
- 4 Stephen W. Schondelmeyer and Leigh Purvis, "*Rx Price Watch* Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015," Washington, DC, AARP Public Policy Institute, December 2016; and Stephen W. Schondelmeyer and Leigh Purvis, "*Rx Price Watch* Report: Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2015," Washington, DC, AARP Public Policy Institute September 2017. <http://www.aarp.org/rxpricewatch>.

used to treat complex and chronic conditions; require special administration and handling; or patient care management. The definition of specialty prescription drugs used throughout this report is a prescription drug that has one or more of the following characteristics: administered by injection; has a total average prescription cost greater than \$1,000 per prescription; has a total average cost per day of therapy greater than \$33 per day; or is in a therapeutic class where several other drugs in the class meet one or more of the previous criteria (e.g., HIV drugs).

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.⁵ Expenditures for this group of specialty drug products are widely expected to be the fastest growing sector of pharmaceuticals in the decade ahead.⁶ Research indicates that spending on specialty drugs has tripled since 2003.⁷

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.⁸ In addition, specialty drugs are increasingly being used to treat common chronic conditions that affect millions of Americans.⁹ Drug manufacturers are also developing more specialty drugs, which represent a growing share of the late-stage research

and development pipeline.¹⁰ 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 2015, the average annual retail cost of prescription drug therapy for a specialty drug, based on the market basket used in this study, was \$52,486 per year. This average annual cost was slightly less than the median US household income (\$55,775).¹¹ It was also more than twice the median income for Medicare beneficiaries (\$25,150),¹² and more than three times higher than the average Social Security retirement benefit (\$16,101)¹³ 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 almost \$35,000 between 2006 and 2015.

Prescription drug price increases also affect employers, private insurers, and taxpayer-funded programs like Medicare and Medicaid. For example, the 2017 Medicare Trustees' Report noted that per capita benefits under Medicare Part D increased at a high rate in 2016 because of price increases for brand name drugs.¹⁴ 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

5 Bradford R. Hirsch, Suresh Balu, and Kevin A. Schulman, "The Impact of Specialty Pharmaceuticals as Drivers of Health Care Costs," *Health Affairs* 33, no. 10 (2014): 1714–1720.

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

7 Stacie B. Dusetzina, "Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003-14," *Health Affairs* 35, no. 7 (2016): 1241–46.

8 Alan M. Lotvin, William H. Shrank, Surya C. Singh, Benjamin P. Falit, and Troyen A. Brennan, "Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs," *Health Affairs* 33, no. 10 (2014): 1736–44.

9 Ibid.

10 Kelly Procallo, Cara Maxwell, and Kanika Kapoor, "Specialty Pharmacy: Trending to the Future," *Pharmacy Today*, October 2016.

11 Kirby G. Posey, "Household Income: 2015, American Community Survey Briefs," ACSBR/15-02, US Census Bureau, Washington, DC, September 2016.

12 Gretchen Jacobson, Shannon Griffin, Tricia Neuman, and Karen Smith, "Income and Assets of Medicare Beneficiaries, 2016–2035," Kaiser Family Foundation, Washington, DC April 2017.

13 The average monthly Social Security retirement benefit in 2015 was approximately \$1,342 per month. Social Security Administration, *Annual Statistical Supplement to the Social Security Bulletin, 2016*, (Washington, DC, Social Security Administration, 2016), <https://www.socialsecurity.gov/policy/docs/statcomps/supplement/2015/5b.html#table5.b8>.

14 Medicare Board of Trustees, *2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, (Washington, DC, Medicare Board of Trustees, July 2017).

and/or cost sharing for their health care coverage.¹⁵ Similarly, spending by government health programs will grow faster than the tax-based revenue that supports them, leading to higher taxes and/or cuts to public health or other programs.

This report presents annual and 10-year cumulative price changes through the end of 2015. The first set of findings shows *annual* rates of change in retail prices for widely used specialty drugs from 2006

through 2015, using both rolling average and point-to-point methods (see Appendix A). The point-to-point method examines the distribution of price changes and differences in average percent changes in retail prices for individual drug products, specific manufacturers, and specific therapeutic categories. The second set of findings summarizes the *cumulative* impact of retail price changes for specialty drugs that have taken place across the entire 10-year period from 2006 through 2015.

15 David I. Auerbach and Arthur 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; America’s Health Insurance Plans, *Factors Affecting Premiums in 2017 Individual Exchange Marketplace*, Issue Brief, America’s Health Insurance Plans, Washington, DC, May 2016.

Findings

I. SPECIALTY PRICE TRENDS FOR MOST WIDELY USED PRESCRIPTION DRUGS

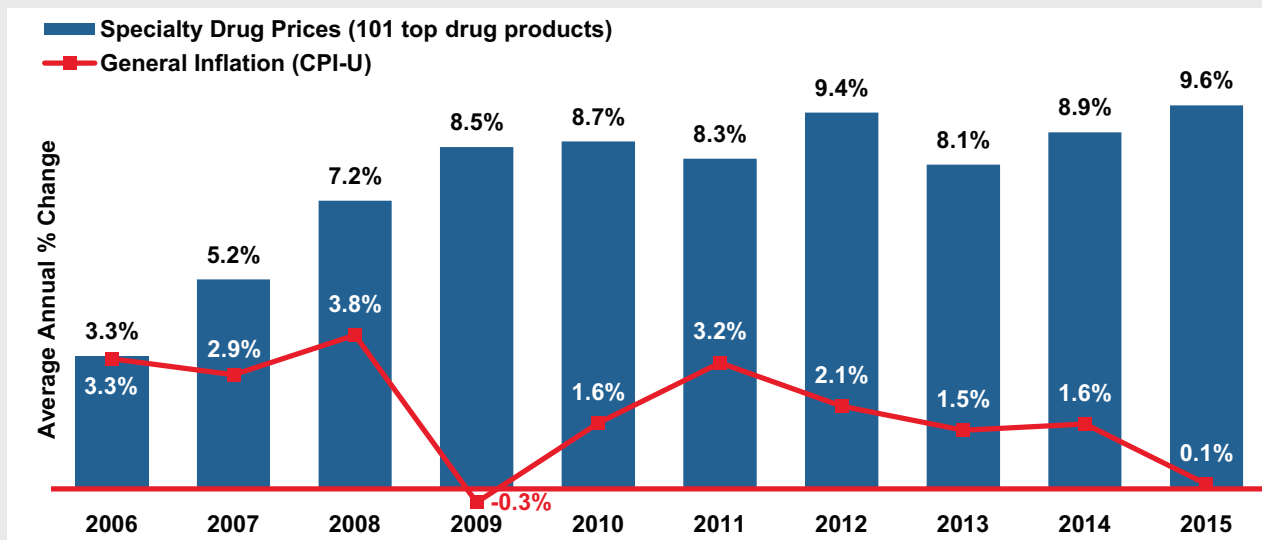
In recent years, the annual percent change in prices for specialty prescription drugs has consistently increased substantially faster than general inflation.

- Retail prices for the 101 specialty drug products¹⁶ most widely used by older Americans rose 9.6 percent in 2015 compared with 2014 prices (Figure 1).¹⁷ This was the highest average annual increase since at least 2006.

- The average annual retail price increase in 2015 for these specialty prescription drug products was more than 80 times higher than the rate of general inflation (9.6 percent vs. 0.1 percent).¹⁸
- In contrast, retail prices for traditional (non-specialty) brand name drug products most widely used by older Americans rose by 15.5 percent in 2015, and retail prices for traditional (non-specialty) generic drug products fell by 19.4 percent in the same year.¹⁹

The annual retail price change for specialty drug products reported in Figure 1 averages annual

FIGURE 1
Average Annual Specialty Drug Price Change in 2015 Is Highest Since at Least 2006



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

Note: Calculations of the average annual specialty drug price change include the 101 drug products most widely used by older Americans (see Appendix A).

16 The market basket for this analysis had 101 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 94 specialty drug products with no generic competition are analyzed separately, the average annual price change was 9.7 percent in 2015—higher than the 9.6 percent price trend shown in this report.

17 When measured as a 12-month rolling average and weighted by actual 2014 retail prescription sales to older Americans ages 50 and above, including Medicare beneficiaries.

18 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 (CPI-U; seasonally adjusted), Bureau of Labor Statistics series CUSR0000SA0.

19 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>.

point-to-point price changes for each month in the preceding 12-month period (referred to as a *rolling average* change), smoothing over the entire year the annual change in brand name drug price that occurs for a single month (referred to as an annual *point-to-point* 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 presented 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 in 2006:

- 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

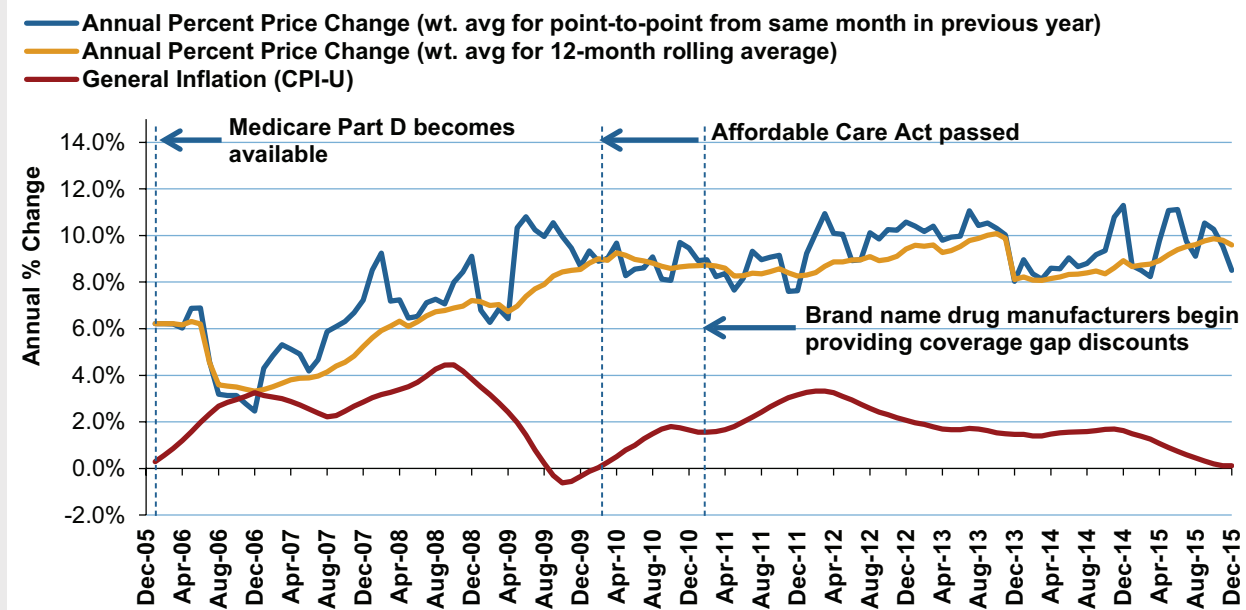
inflation fluctuated but remained sizeable over 2006 to 2015 period. This gap has ranged from a less than 2-fold difference to a more than 80-fold difference.

The cost of specialty drug therapy reached \$52,486 per drug per year in 2015.

Figure 3 presents the retail price for 49 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 chronic therapy was \$52,486 per drug per year for specialty prescription drugs at the retail level in 2015.
 - This average annual cost (\$52,486) is almost triple the average annual cost (\$17,838) for a specialty drug in 2006, the year Medicare implemented Part D.
 - The average annual cost of therapy for a single specialty drug in 2015 (\$52,486) was slightly less than the median US household income (\$55,775), more than twice the median income for a Medicare beneficiary

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 2015

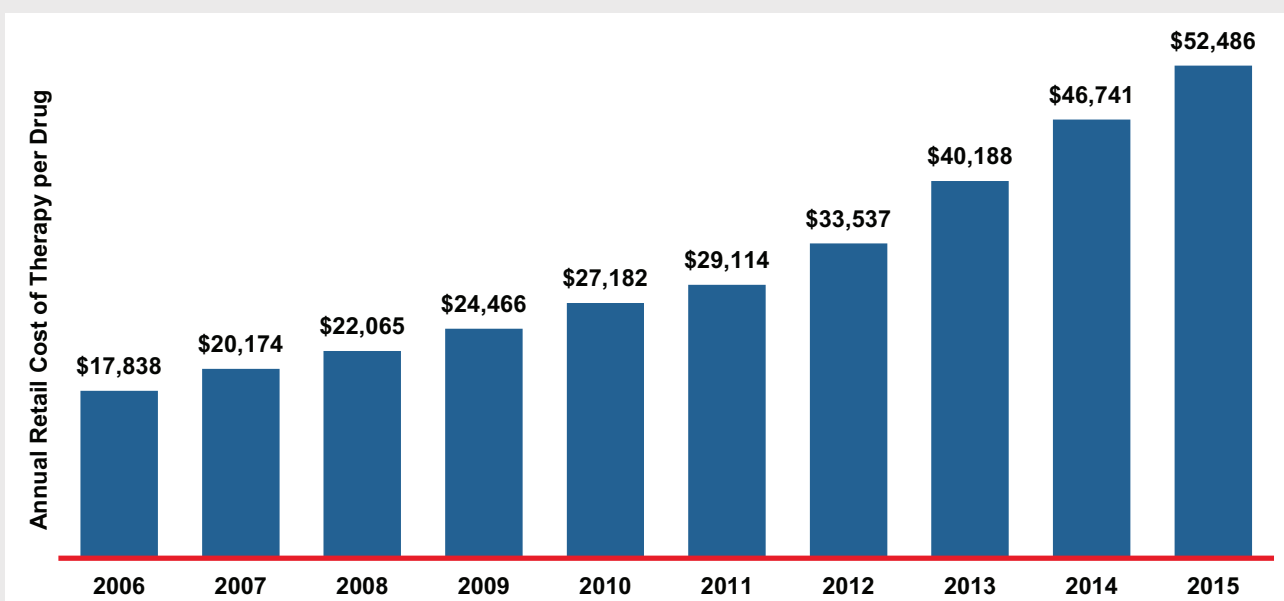


Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Note: Calculations of the average annual specialty drug price change include the 101 drug products most widely used by older Americans (see Appendix A).

FIGURE 3

The Average Annual Price of Specialty Drugs Almost Tripled between 2006 and 2015



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

Note: Calculations of the average annual brand name drug price change include the 214 drug products most widely used by older Americans for chronic conditions (see Appendix A).

(\$25,150), and over three times higher than the average Social Security retirement benefit (\$16,101) over the same time period.²⁰

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 traditional (non-specialty) brand name and generic drugs. Furthermore, the price differential between these three market baskets is growing rapidly. In 2015, the average annual price of therapy for specialty prescription drugs was 9 times higher than the average annual price of therapy for brand name prescription drugs (\$52,486 v. \$5,807, respectively) and 100 times higher than the average annual price of therapy for generic prescription drugs (\$52,486 v. \$523, respectively).²¹

Figure 4 shows the annual price of therapy for specialty, brand name, and generic drugs in the past six years (2010 to 2015). While the average

annual generic price of therapy has increased by 16.7 percent (\$448 to \$523), the average annual brand name price of therapy has more than doubled (\$2,698 to \$5,807) and the average annual specialty price of therapy has nearly doubled with an increase of more than 93 percent (\$27,182 to \$52,486).

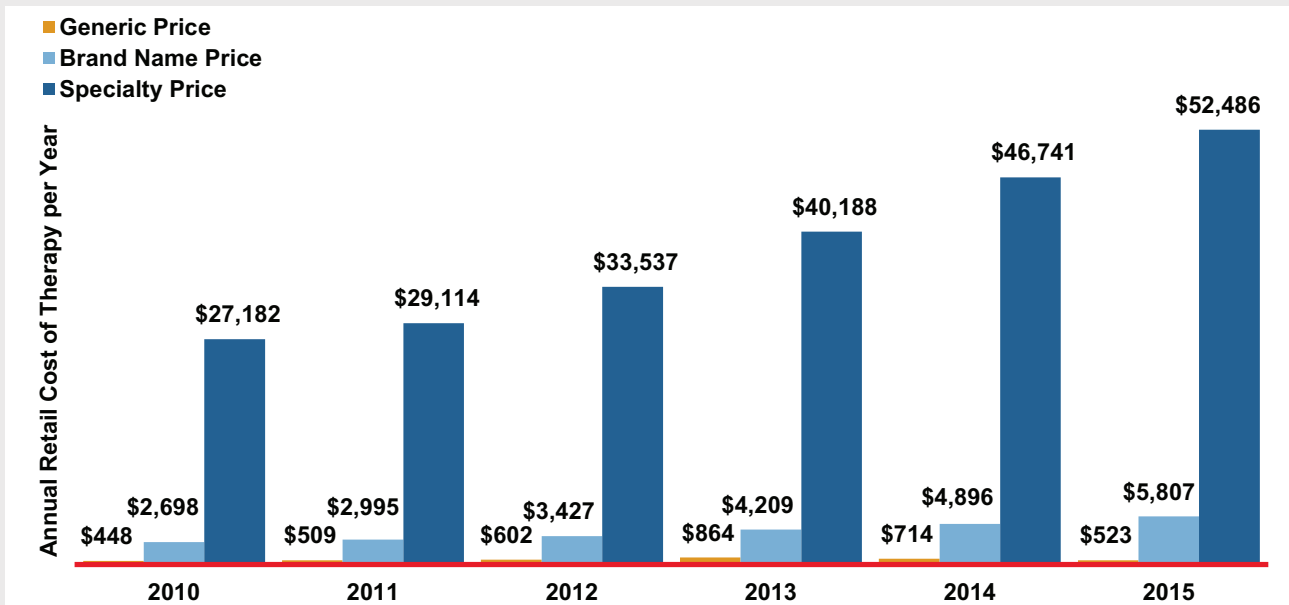
While brand name traditional (non-specialty) drugs had the highest percentage increase (115 percent vs. 93 percent for specialty drugs) between 2010 and 2015, the specialty drugs had a much more substantial increase in actual monetary value with a dollar increase from 2010 to 2015 of \$25,304. This very large difference in dollar change stems from the much higher initial price of specialty drugs as they enter the market. For example, a 10 percent price increase for a \$10,000 drug product is \$1,000, while the same percent price increase for a \$1,000 drug product is \$100.

20 Posey, "Household Income"; Jacobson et al., "Income and Assets"; Social Security Administration, *Annual Statistical Supplement*.

21 Schondelmeyer and Purvis, *Rx Price Watch Report: Brand Name Prescription Drugs*; Schondelmeyer and Purvis, *Rx Price Watch Report: Generic Prescription Drugs*.

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 2015



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

Note: Calculations of average annual drug price of therapy included the drug products most widely used by older Americans for chronic conditions: generic drugs products (266), brand name drug products (214), and specialty drug products (49).

II. 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 devices, and BLAs apply to biological products. Seventy-one of the 101 drug products in the specialty market basket were NDA-approved, 29 were BLA-approved, and 1 was 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 dollar change in cost of therapy.

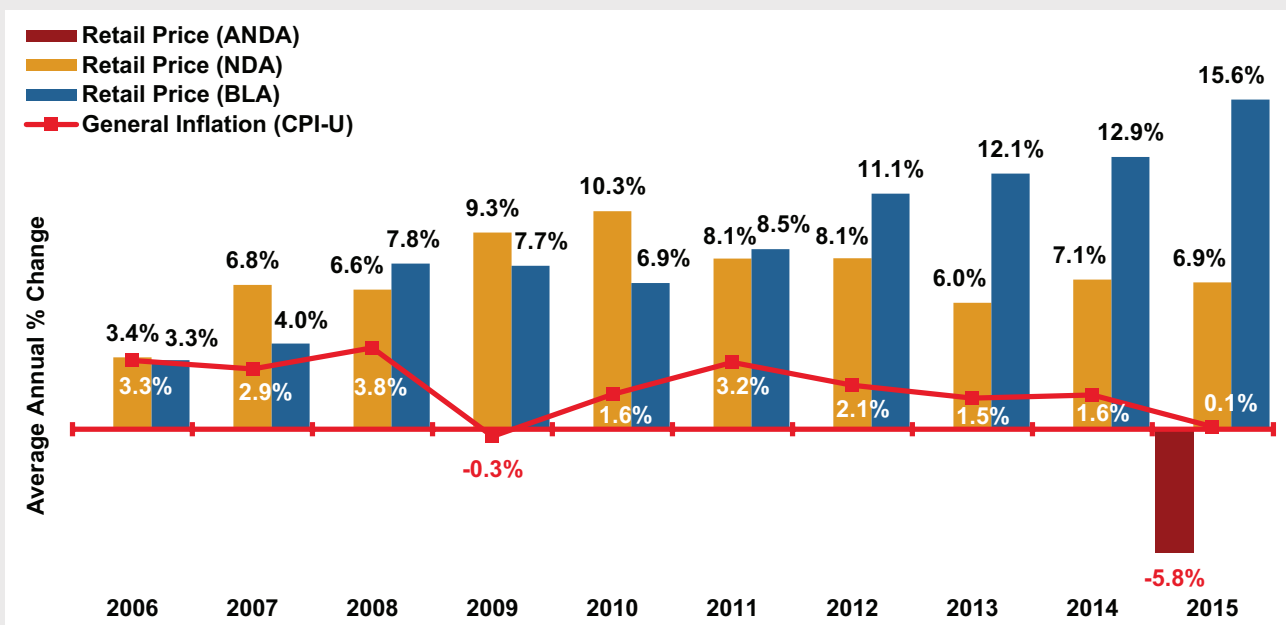
Annual Percent Change in Retail Prices

- Retail prices for **NDA-approved specialty drug products** most widely used by older Americans rose by an average of 6.9 percent in 2015. This rate of increase was almost 60 times higher than the rate of general inflation (0.1 percent) when measured as a 12-month rolling average and weighted by sales to older Americans ages 50 and above. Annual retail price increases for NDA-approved drug products between 2006 and 2014 ranged from 3.4 percent to 10.3 percent (Figure 5).
- Retail prices for **BLA-approved specialty drug products** most widely used by older Americans increased by an average of 15.6 percent in 2015, more than 130 times higher than the rate of general inflation (0.1 percent).²² Annual retail price increases for BLA-approved drug

22 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.

FIGURE 5

Marked Increase in Average Retail Prices among Most Widely Used BLA-Approved Specialty Prescription Drugs in 2015



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

Note: Calculations of average annual specialty drug price change include 101 drug products most widely used by older Americans: ANDAs (1); NDAs (71), and BLAs (29).

products between 2006 and 2014 ranged from 3.3 percent to 12.9 percent (Figure 5). The price increases of BLA-approved drug products have accelerated in the past 6 years (from 6.9 percent in 2010 to 15.6 percent in 2015) and have exceeded the price increases of NDA-approved drugs in each year since 2011

- 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 9.0 percent in 2014 and 9.7 percent in 2015. In contrast, retail prices for brand name non-specialty drug products most widely used by older Americans increased by an average of 16.1 percent and 15.5 percent, respectively, in those years.²³
- In contrast, the retail prices of the single **generic specialty drug product** (i.e., ANDA-approved drug product) most widely used by older Americans *decreased* by 5.8 percent in

2015. Similarly, the retail prices for generic non-specialty drug products most widely used by older Americans decreased, but even more dramatically at an average rate of 19.4 percent over the same time period.²⁴

Annual Retail Cost of Therapy

We translated retail price changes into average annual cost of therapy (Figure 6) for the widely used specialty drugs for treating chronic conditions. Of the 49 drugs in the market basket used to treat chronic conditions, 32 were NDAs, 17 were BLAs, and none were ANDAs.

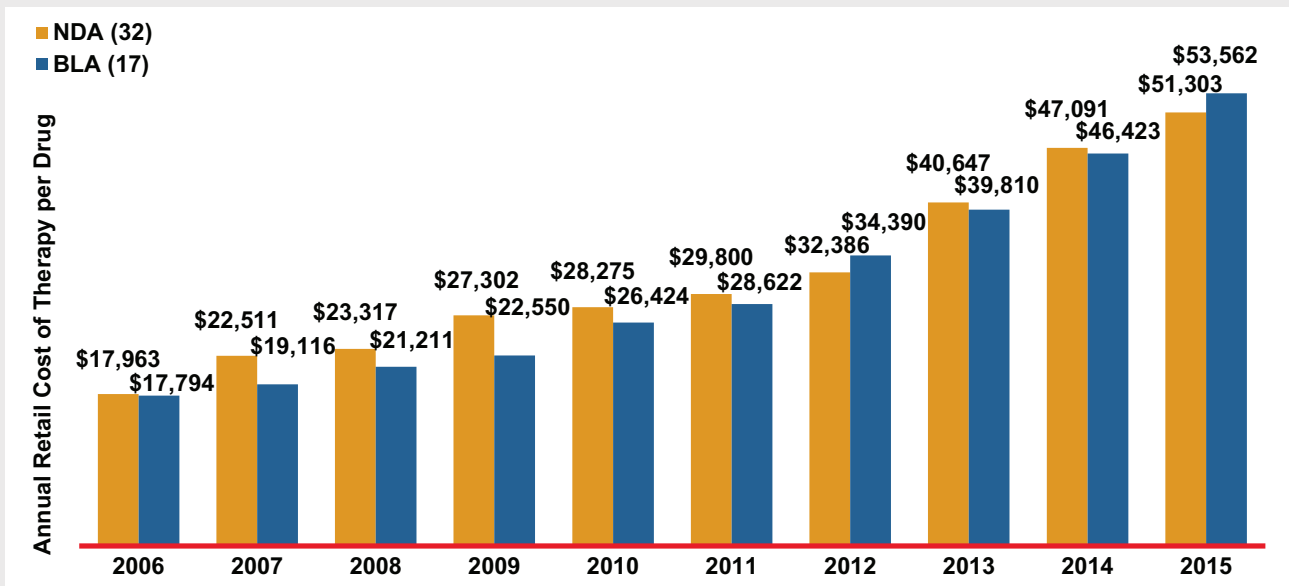
- A person who took an **NDA-approved specialty prescription drug** had an average annual cost of therapy of \$51,303 in 2015, assuming that the consumer used the specialty drug for a chronic condition. The average annual cost of therapy for NDA-approved specialty drugs increased by 186 percent since 2006, the year Medicare implemented Part D.

23 Schondelmeyer and Purvis, *Rx Price Watch* Report: Brand Name Prescription Drugs.

24 Schondelmeyer and Purvis, *Rx Price Watch* Report: Generic Prescription Drugs.

FIGURE 6

The Average Annual Cost of Therapy Increased by More than 200 Percent for Widely Used BLA-Approved Specialty Prescription Drugs between 2006 and 2015



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

Note: Calculations of average annual drug price of therapy included the 49 drug products most widely used by older Americans for chronic conditions: NDAs (32) and BLAs (17).

- The average annual cost of therapy for **BLA-approved specialty prescription drugs** was \$53,562 in 2015. The average annual cost of therapy for BLA-approved specialty drugs has increased by 201 percent since 2006. The year Medicare implemented Part D.

III. TEN-YEAR CUMULATIVE RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS, 2006 TO 2015

This AARP report tracked specialty drug prices at the retail level for the 10-year period from December 31, 2005, to December 31, 2015. Twenty-nine percent (29 of 101) of the widely used drugs in the specialty market basket were on the market for the entire 10-year period (i.e., the end of 2005 through the end of 2015).

Cumulatively, the average retail price for these 29 widely used specialty drug products increased 177.3 percent over 10 years, compared with a 19.4 percent increase in general inflation during the same period. This means that specialty drug prices

increased more than nine times faster than the rate of general inflation during this time period.

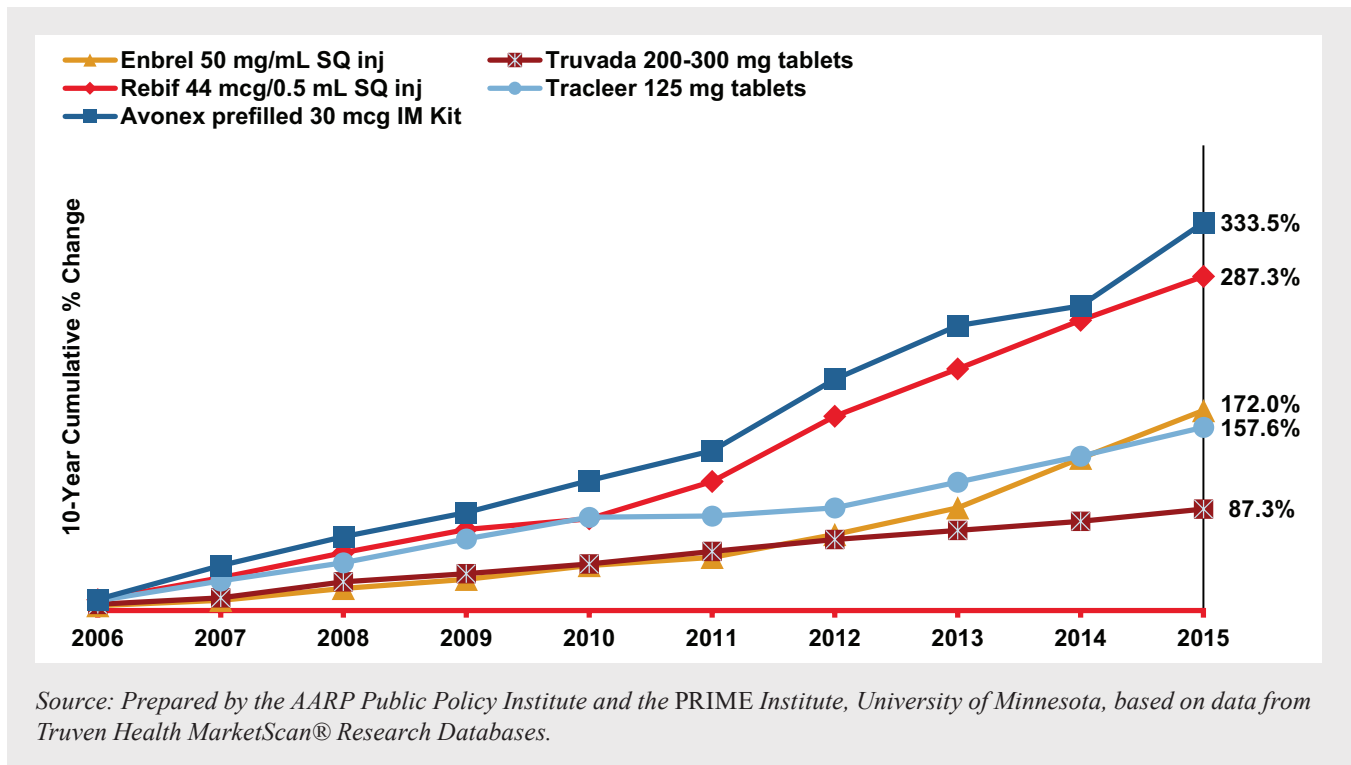
Ten-year cumulative retail price changes are substantial.

Figure 7 presents the 10-year cumulative effect of drug price changes from the end of 2005 to the end of 2015 for 5 specific specialty drug products. We chose 4 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:

- Enbrel 50 mg/mL SQ inj (Amgen)—used in the treatment of inflammatory and immunological disorders;
- Truvada 200-300 mg tablets (Gilead Sciences)—used to treat and reduce the risk of HIV infection;
- Rebif 44 mcg/0.5 mL SQ inj (Serono)—used in the treatment of multiple sclerosis; and
- Tracleer 125 mg tablets (Actelion Pharmaceuticals)—used to treat pulmonary arterial hypertension.

FIGURE 7

Ten-Year Cumulative Percent Change in Retail Price Is More than 300 Percent for Avonex 30 mcg IM Kit



We included the fifth drug, Avonex prefilled 30 mcg IM Kit (Biogen Idec), used to treat multiple sclerosis, because it had the largest percent price increase in 2015 among the specialty drug products that have been on the market for the 10 years since the end of 2005.

Figure 7 shows the 10-year (i.e., December 31, 2005, to December 31, 2015) cumulative percent change in retail prices for these five specialty drug products:

- Avonex prefilled 30 mcg IM Kit had a price increase of 333.5 percent over the 10-year study period ending in 2015.
- Rebif 44 mcg/0.5 mL SQ inj had a price increase of 287.3 percent over the 10-year study period ending in 2015.
- Enbrel 50 mg/mL SQ inj had a price increase of 172.0 percent over the entire 10-year study period ending in 2015.
- Tracleer 125 mg tablets had a 10-year price increase of 157.6 percent over the entire 10-year study period.

- Truvada 200 mg-300 mg tablets increased in retail price by 87.3 percent over the 10-year study period.

Ten-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, 55 percent (16 of 29) treat chronic conditions.²⁵ The remaining 13 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 \$52,386 in 2015, which is an increase of \$34,457 over the 2006 annual cost of \$17,929.

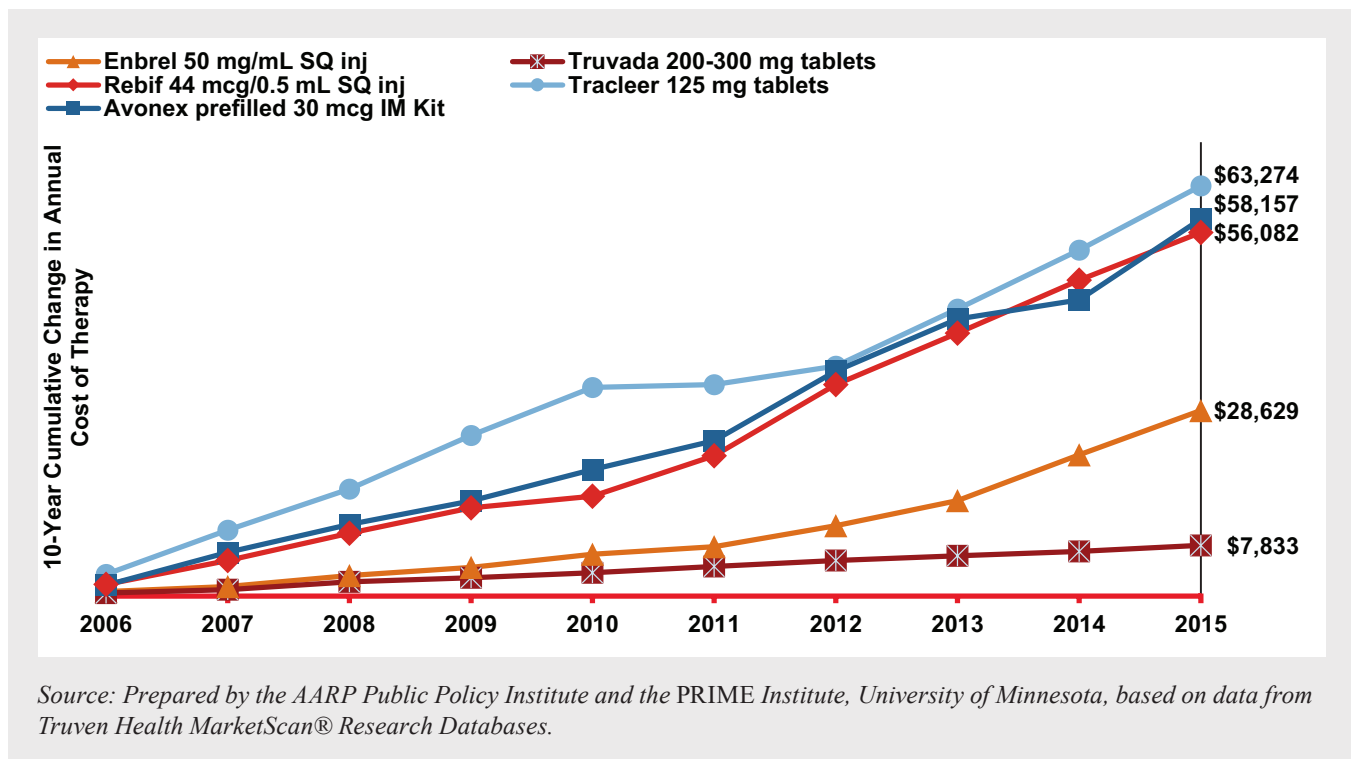
The annual cost of Avonex prefilled 30 mcg IM Kit grew by more than \$60,000 over the 10 years from 2006 to 2015.

More than two-thirds (11 of 16) of the specialty drugs used for chronic conditions that have been on the market since the end of 2005 had annual

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

FIGURE 8

Ten-Year Cumulative Increase in Annual Cost of Therapy Is More than \$60,000 for Tracleer 125 mg Tablets



cost of therapy increases of more than \$10,000 during the 10-year period ending in 2015.

Figure 8 shows the 10-year cumulative change in cost of therapy (based on retail prices paid) for five widely used specialty drug products.

- The retail price for a 1-year supply of Tracleer 125 mg tablets increased by \$63,274 over a 10-year period ending in 2015. The price rose from \$40,155 per year at the end of 2005 to \$103,429 by the end of 2015.
- The retail price of Avonex prefilled 30 mcg IM Kit jumped by \$58,157 from \$17,438 at the end of 2005 to \$75,595 by the end of 2015.
- The retail price of a 1-year supply of Rebif 44 mcg/0.5 mL SQ inj increased by \$56,082 in the 10-year period ending in 2015. The price for a 1-year supply of this specialty drug increased from \$19,520 in 2006 to \$75,603 in 2015.
- The retail price of a 1-year supply of Enbrel 50 mg/mL SQ inj increased by \$28,629 in the 10-year period ending in 2015. The retail price for a one-year supply of this drug rose from \$16,641 in 2006 to \$45,270 in 2015.

- The retail price of a 1-year supply of Truvada 200 mg-300 mg tablets increased by \$7,833 in the 10-year period ending in 2015. The retail price for a one-year supply of this drug rose from \$8,977 in 2006 to \$16,811 in 2015.

IV. MORE THAN NINE OUT OF TEN WIDELY USED SPECIALTY DRUGS INCREASED IN PRICE FASTER THAN GENERAL INFLATION IN 2013

Ninety-three percent (94 of 101) of the most widely used specialty drug products had retail price increases greater than the rate of general inflation (0.1 percent) in 2015. (Figure 9).

Among the 37 percent (37 of 101) of specialty drug products with annual price increases of 10.0 percent or more in 2015:

- Twenty-one (21 percent) increased by 10.0 percent to 14.9 percent;
- Thirteen (13 percent) increased by 15.0 percent to 19.9 percent; and
- Three (3 percent) increased by 20.0 percent or more.

The single highest retail price increase for a specialty drug product in the market basket was for Forteo (600 mcg/2.4mL injection, used to treat osteoporosis). Forteo’s retail price rose by 31.8 percent between 2014 and 2015 (Figure 10). The second highest retail price increase among the most widely used specialty drugs was Adcirca (20 mg tablets, used to treat pulmonary hypertension) had an annual price increase of 24.7 percent in 2015 compared to 2014. Gleevec (100 mg tablets, used for cancer) also had a price increase in 2015 of more than 20 percent.

One of the 101 top specialty drug products was a generic drug product. This generic drug (capecitabine 500 mg tablets, used to treat cancer) had a price decrease, along with 4 other drug products used to treat hepatitis B and hepatitis C (Figure 11). Two other drug products did not experience a price change between 2014 and 2015 (Tagretin 75 mg capsules, used to treat cancer, and Apokyn 10 mg/mL inj, used to treat Parkinson’s disease).

All but 3 of the 30 top-selling specialty drug products in the market basket had retail price increases in 2015 when compared with 2014 (Table 1). Each of these 27 top-selling specialty drug products had a price increase that was higher than the rate of general inflation (0.1 percent) in 2015.

Seven of the top 30 specialty drug products had retail price increases of 15.0 percent or more in 2015—at least 125 times the rate of general inflation. The highest retail price increase in 2015 among the top 30 specialty drug products was 31.8 percent for Lilly’s Forteo 600 mcg/2.4mL injection (Figure 10).

Three widely used specialty drug products—Sovaldi 400 mg tablets, Olysio 150 mg capsules, and Harvoni 90-400 mg tablets, used to treat hepatitis B and hepatitis C—experienced minimal (-0.5 percent to -1.4 percent) retail price *decreases* between 2014 and 2015.

FIGURE 9
Retail Prices for 93 Percent of Most Widely Used Specialty Drugs Increased Faster than General Inflation in 2015

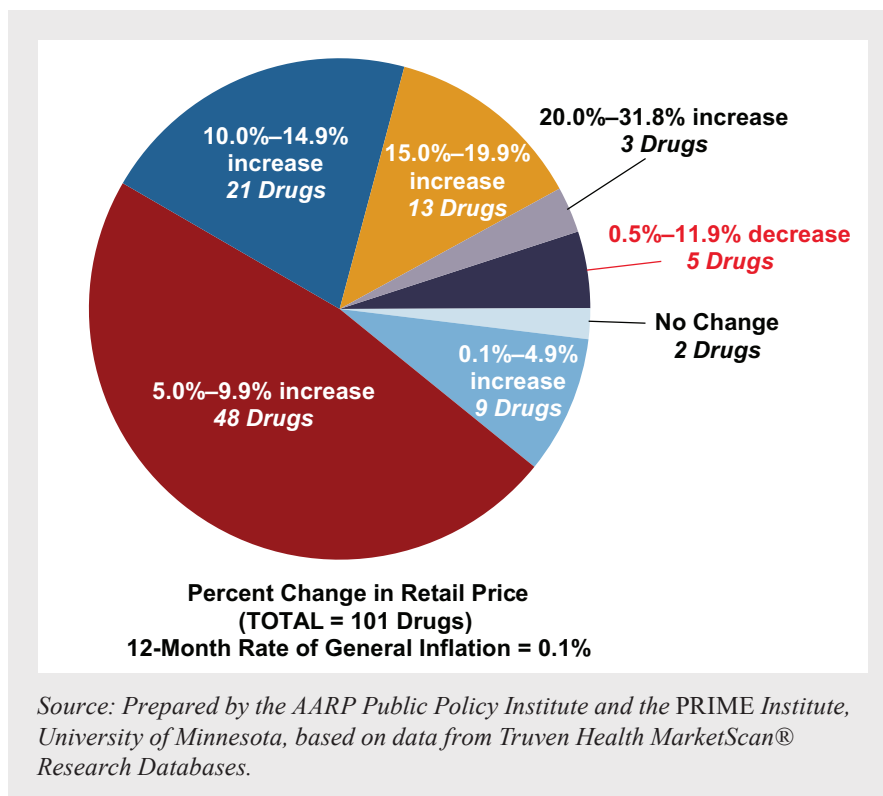


FIGURE 10
Retail Prices for Three Widely Used Specialty Drugs Increased by More than 20 Percent in 2015

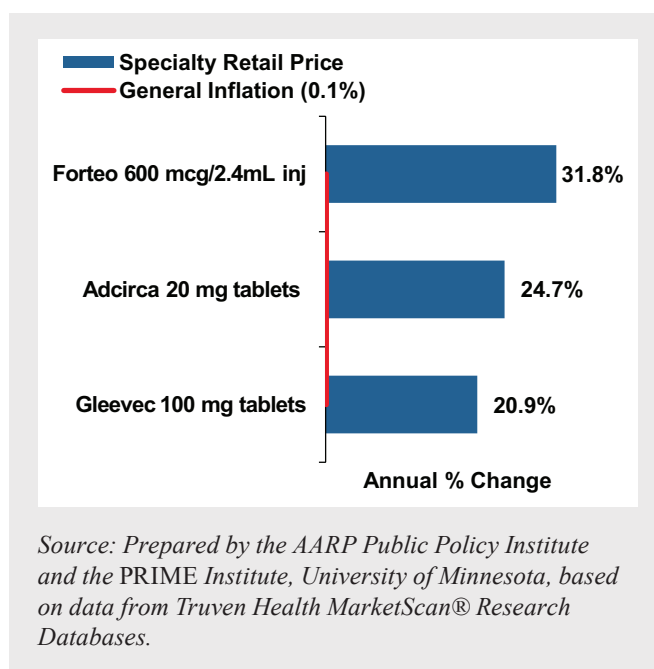


TABLE 1

All But 3 of the Top 30 Drug Products in the Specialty Market Basket Had Retail Price Increases in 2015

Rank by Sales among 2014 Market Basket*	Product Name, Strength, and Dosage Form	Pkg Size	Manufacturer	Therapeutic Class	2015 Retail Price per Day	Annual % Change in Retail Price
1	Sovaldi 400 mg tablets	28	Gilead Sciences	Hepatitis B & C	\$1,006.42	-0.7%
2	Humira Pen 40 mg/0.8mL SQ inj Kit	1	AbbVie	DMARD	\$123.98	17.5%
3	Enbrel SureClick 50 mg/mL SQ inj	0.98	Amgen	DMARD	\$123.98	17.6%
4	Gleevec 400 mg tablets	30	Novartis	Antineoplastic Agents	\$339.35	10.0%
5	Olysio 150 mg capsules	28	Janssen Products	Hepatitis B & C	\$796.32	-0.5%
6	Copaxone 20 mg/mL SQ Kit	1	Teva Neuroscience	Multiple Sclerosis Agents	\$200.86	7.6%
7	Tecfidera 240 mg DR capsules	60	Biogen Idec	Multiple Sclerosis Agents	\$194.21	10.8%
8	Harvoni 90-400 mg tablets	28	Gilead Sciences	Hepatitis B & C	\$1,127.44	-1.4%
9	Revlimid 10 mg capsule	28	Celgene Corp	Immunomodulators	\$510.23	7.1%
10	Enbrel 50 mg/mL SQ inj	0.98	Amgen	DMARD	\$124.03	17.8%
11	Copaxone 40 mg/mL SQ Kit	1	Teva Neuroscience	Multiple Sclerosis Agents	\$178.55	7.0%
12	Atripla 600-200-300 mg tablet	30	Gilead Sciences	Antiretroviral Combinations	\$74.47	7.2%
13	Zytiga 250 mg tablets	120	Janssen Biotech	Antineoplastic Agents	\$269.95	8.1%
14	Humira 40 mg/0.8mL SQ inj	1	AbbVie	DMARD	\$124.11	17.2%
15	Truvada 200 mg-300 mg tablets	30	Gilead Sciences	Antiretroviral Combinations	\$46.06	5.9%
16	Avonex Auto-injector Pen 30 mcg/0.5mL Kit	1	Biogen Idec	Multiple Sclerosis Agents	\$197.74	15.2%
17	Avonex Prefilled 30 mcg/0.5mL IM Kit	1	Biogen Idec	Multiple Sclerosis Agents	\$199.98	16.2%
18	Xtandi 40 mg capsules	120	Astellas	Antineoplastic Agents	\$298.79	5.5%
19	Forteo 600 mcg/2.4mL SQ inj	2.4	Lilly	Endocrine Drugs	\$83.07	31.8%
20	Revlimid 5 mg capsules	28	Celgene Corp	Immunomodulators	\$505.20	7.1%
21	Rebif 44 mcg/0.5mL SQ inj	0.5	Serono	Multiple Sclerosis Agents	\$207.13	10.8%
22	Revlimid 25 mg capsules	21	Celgene Corp	Immunomodulators	\$502.69	7.1%
23	Tracleer 125 mg tablets	60	Actelion Pharmaceuticals	Pulmonary Hypertension	\$283.37	10.6%
24	Stelara 90 mg/mL SQ inj	1	Janssen Biotech	Antipsoriatics	\$189.52	10.0%
25	Imbruvica 140 mg capsules	90	Pharmacyclics	Antineoplastic Agents	\$323.66	9.1%
26	Isentress 400 mg tablets	60	Merck Sharp & Dohme	Antiretrovirals - Integrase Inhibitors	\$40.45	6.0%
27	Betaseron 0.3 mg SQ inj	1	Bayer Healthcare Pharma	Multiple Sclerosis Agents	\$202.44	11.1%
28	Revlimid 15 mg capsules	21	Celgene Corp	Immunomodulators	\$377.02	7.1%
29	Tarceva 150 mg tablets	30	Genentech	Antineoplastic Agents	\$228.74	6.8%
30	Afinitor 10 mg tablets	28	Novartis	Antineoplastic Agents	\$378.94	8.6%
General rate of inflation (as measured by growth in CPI-U)						0.1%

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

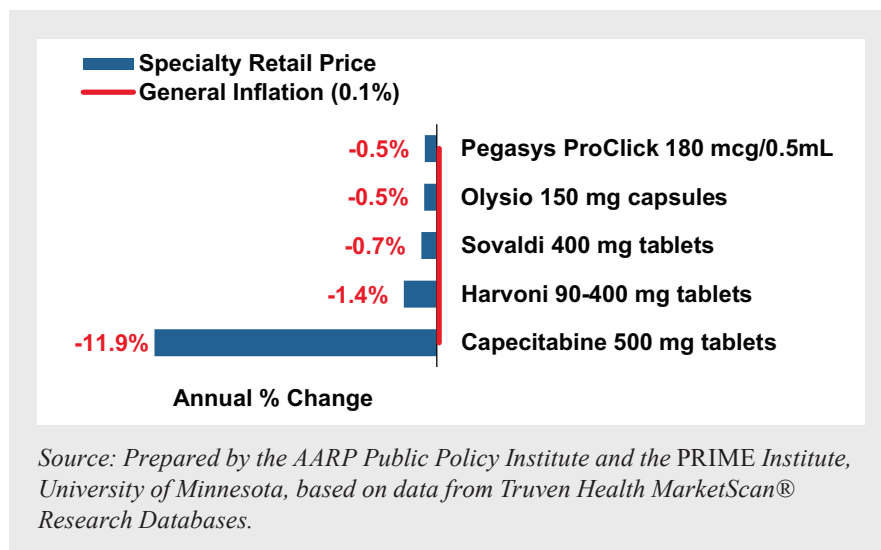
*Ranking based on 2014 spending data provided by the Truven Health MarketScan® Research Databases and a large Medicare Part D plan provider. See Appendix A.

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

Thirty-one drug manufacturers had at least 1 drug product in the study's market basket of 101 widely used specialty drugs. The average annual increase in retail price for 94 percent (29 out of 31) of these drug manufacturer categories exceeded the general inflation rate in 2015 (Figure 12), suggesting that there is a broad-based specialty drug price increase trend.

- Twenty-six drug manufacturers (65 percent) had weighted average annual specialty drug price increases of 5 percent or more in 2015—more than 40 times the rate of general inflation (0.1 percent) in 2015.
- Eleven drug manufacturers (35 percent) had weighted average specialty drug price increases of 10 percent or more in 2015—or more than 80 times the rate of general inflation (0.1 percent) in 2015.
 - These 11 drug manufacturers represent 37 percent (37 of 101) of the specialty drug products in the market basket in 2015.
- Three drug manufacturers had weighted average specialty drug price increases of more than 15.0 percent in 2015, or 125 times the rate of general inflation (0.1 percent) in 2015.
 - AbbVie had a weighted average annual price increase of 16.6 percent in 2015—or 140 times the rate of general inflation.
 - Amgen had a weighted average annual price increase of 16.9 percent in 2015—or more than 140 times the rate of general inflation.
 - Lilly had a weighted average annual price increase of 30.0 percent in 2015—or more than 250 times the rate of general inflation.
- Two drug manufacturers with only one product in the study's market basket—US Worldmeds and Valeant—had no change in their weighted average annual price in 2015.

FIGURE 11
Retail Prices for Five Widely Used Specialty Prescription Drugs Decreased in 2015



- One manufacturer (Janssen, 13 drug products) had a weighted average annual retail price increase of 5.8 percent in 2015. However, the pricing decisions of three divisions within the company were somewhat different in 2015, with Janssen Biotech (5 drug products) showing a 9.6 percent increase; Janssen (3 drug products) reporting an 8.9 percent increase; and Janssen Products (5 drug products) averaging a much lower 1.5 percent increase.

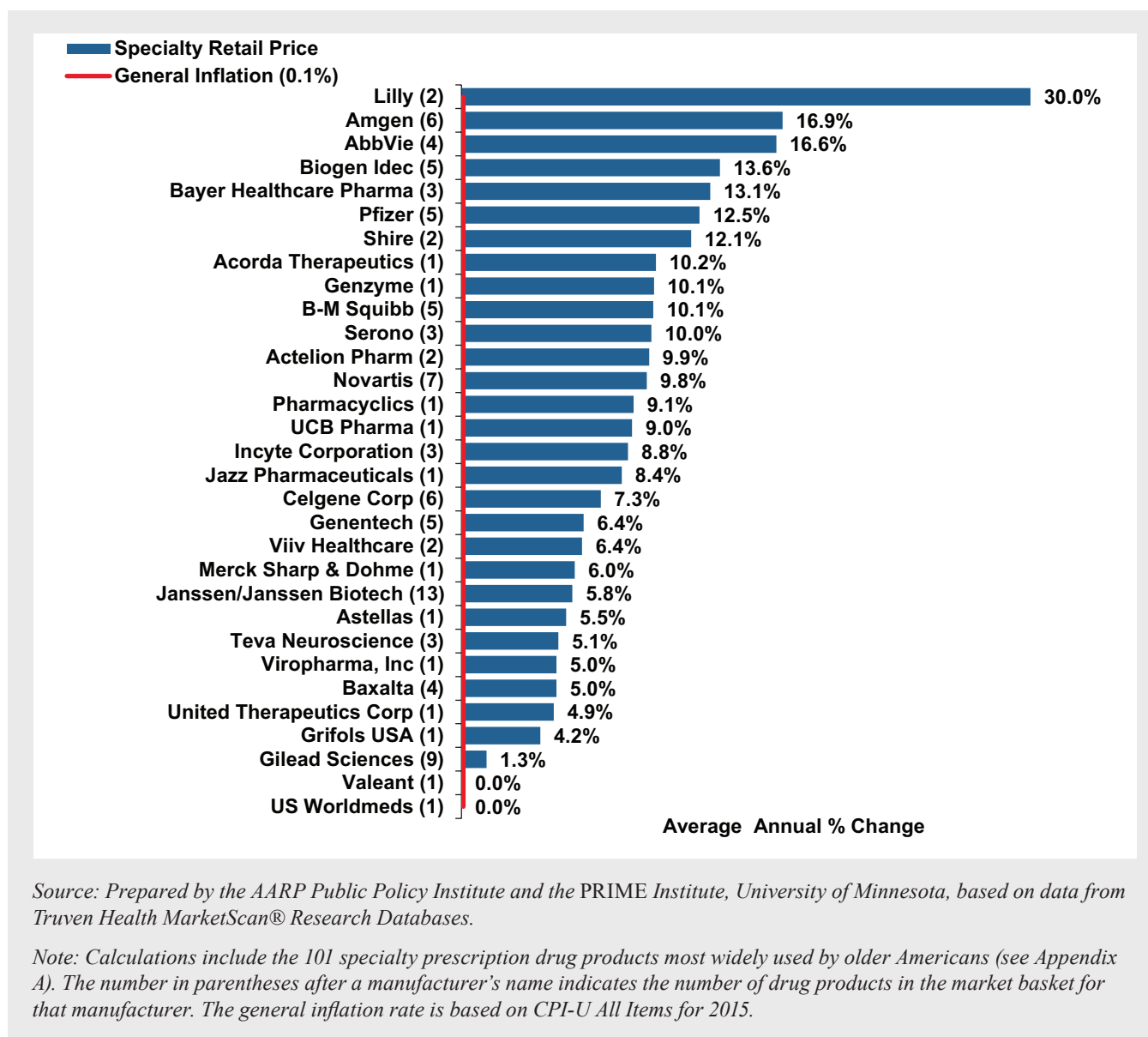
VI. RETAIL PRICE CHANGES FOR MOST WIDELY USED SPECIALTY PRESCRIPTION DRUGS BY THERAPEUTIC CATEGORY

Specialty drug prices at the retail level increased faster than the rate of general inflation (0.1 percent) in 2015 for 91 percent (20 of 22) of the therapeutic categories examined in this study (Figure 13). All 20 of the therapeutic categories with an increase in price averaged annual price increases of 5.0 percent or greater—more than 40 times the rate of general inflation in 2015.

- Five therapeutic categories had average annual price increases of 10 percent or higher—or more than 80 times the rate of general inflation in 2015.
 - The therapeutic category with the highest specialty drug price increase was endocrine drugs—used to treat hormonal imbalances—with an average annual retail price increase of 24.7 percent in 2015.

FIGURE 12

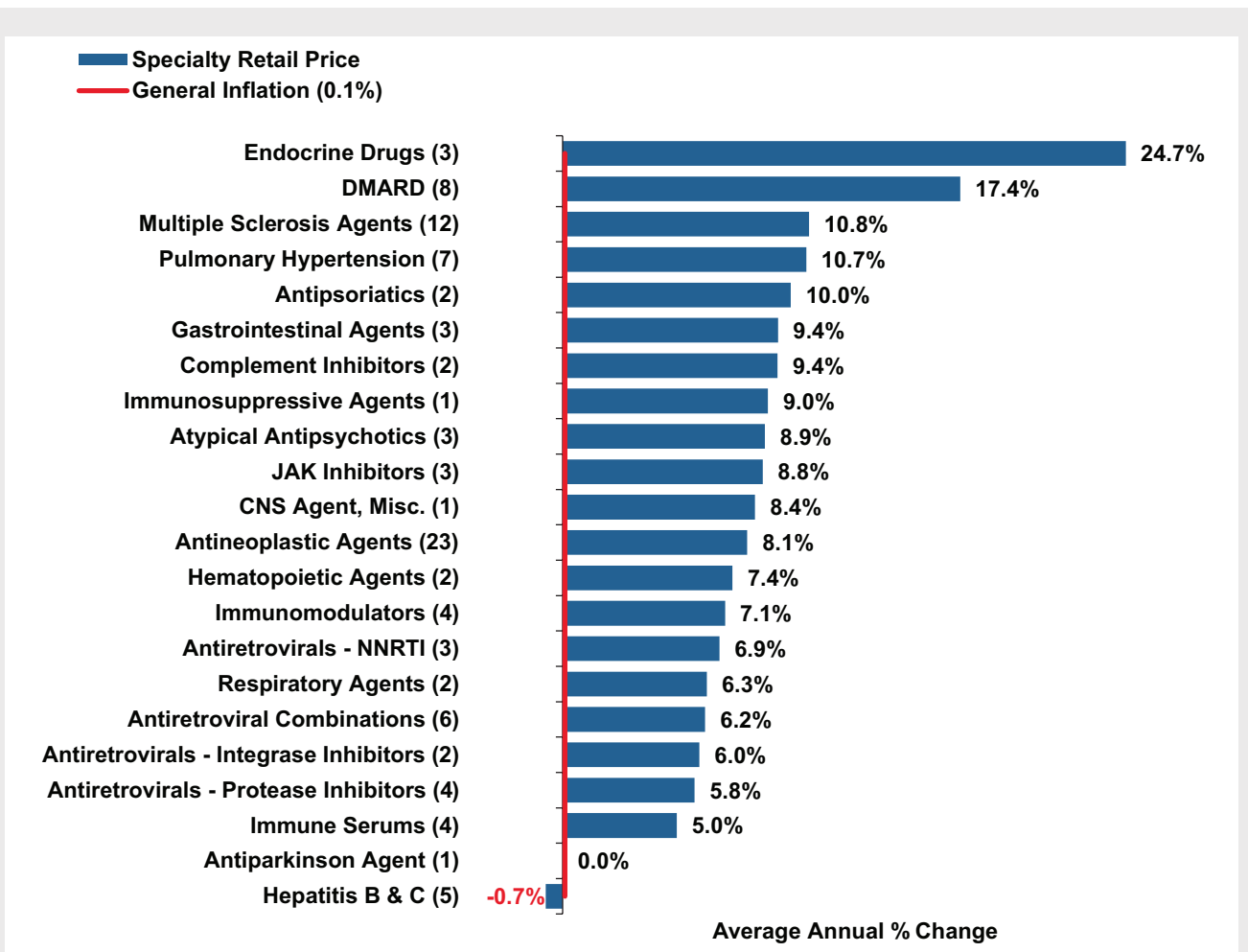
All But Two Drug Manufacturers Had Retail Price Increases That Exceeded the Rate of General Inflation in 2015



- The majority of this price increase stemmed from one specialty drug product (Forteo 600 mcg/2.4mL injection, used to treat osteoporosis). The retail price of this product rose by 31.8 percent between 2014 and 2015.
- The therapeutic category with the second highest average annual retail price increase in 2015 was the ‘Disease-Modifying Anti-Rheumatic Drugs’ (DMARDs), with a weighted average annual price increase of 17.4 percent.
- One of the 22 therapeutic categories (Antiparkinson Agent) did not experience any annual retail price change in 2015, and one therapeutic category (Hepatitis B & C) had a weighted average annual retail price decrease of -0.7 percent.

FIGURE 13

All but Two Therapeutic Categories for Specialty Drugs Had Retail Price Increases That Exceeded the Rate of General Inflation in 2015



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

Note: Calculations include the 101 specialty prescription drug products most widely used by older Americans (see Appendix A). See Appendix B for an explanation of therapeutic category acronyms. 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 All Items for 2015.

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 2015, the average annual increase in retail prices for 101 specialty prescription drugs widely used by older Americans, including Medicare beneficiaries, was 9.6 percent. In contrast, general inflation in the United States rose by 0.1 percent in 2015.

Increases in the retail price of specialty prescription drugs affect both patients and the broader economy. In 2015, the average annual retail cost of drug therapy for a specialty prescription drug, based on the market basket used in this study, was \$52,486 per year. This price is slightly less than the median US household income (\$55,775).²⁶ This annual cost also greatly exceeds the median income for Medicare beneficiaries (\$25,150)²⁷ and the average Social Security retirement benefit (\$16,101)²⁸ from the same time period.

While specialty drug products are used by a relatively small, but growing, share of the overall population, they account for the fastest growing portion of U.S. drug expenditures in recent years.²⁹ There are strong indications that specialty drugs

will become the largest share, and the majority, of drug expenditures in the next few years. 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. The pricing patterns (price levels and price increases) for specialty drugs will lead to serious problems with respect to access and affordability issues in the future.³⁰

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 coverage³¹ 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 health benefit programs.

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

26 Posey, "Household Income."

27 Jacobson, et al., "Income and Assets."

28 The average monthly Social Security retirement benefit in 2015 was approximately \$1,342 per month. Social Security Administration, *Annual Statistical Supplement*.

29 Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Observations on Trends in Prescription Drug Spending," ASPE Issue Brief, (Washington, DC, ASPE, March 8, 2016).

30 Aurel O. Iuga and Maura J. McGuire, "Adherence and Health Care Costs," *Risk Management and Healthcare Policy* 7 (2014): 35-44.

31 Auerbach and Kellermann, "A Decade of Health Care Cost Growth"; America's Health Insurance Plans, *Factors Affecting Premiums*.

Appendix A

Detailed Methodology and Description of Retail Price Data

This appendix describes in detail how brand name, 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, the appendix 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 outpatient prescription drugs in the US market. While this overall perspective is useful for those interested in understanding the industrial economics of the entire prescription drug market, consumers have proved to be considerably more interested in the price trend for the specific products that they are taking as individuals 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.¹ In 2009, AARP and the *PRIME* Institute created an additional drug price index based on actual retail prices² from Truven Health's MarketScan® Commercial Database and MarketScan® Medicare Supplemental Database (Truven Health MarketScan® Research Databases).³ Thus, the report series uses the same market basket of brand name 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 to develop a new market basket of widely used prescription drugs based on 2014 data provided by the Truven Health MarketScan® Research Databases and a large Medicare Part D plan provider. UnitedHealthcare provides Medicare Part D coverage and is the organization that insures the AARP Medicare Rx plans. This

- 1 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 Pro®) is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health Inc., and uses data from Medi-Span's Master Drug Database (MDDB®). This commercial drug database has been published for more than 35 years. See <http://www.medispans.com>.
- 2 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) 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.
- 3 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. Erica Danielson, "White Paper: Health Research Data for the Real World: The MarketScan® Databases," White Paper, Ann Arbor, MI, Truven Health Analytics, January 2014.

Medicare Part D plan provider supplied data for all prescriptions provided to its Medicare Part D enrollees in 2014. This *Rx Price Watch* report used the 2014 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 as 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 related licensees) or a 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 the 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,⁴ and they do not experience typical price competition from therapeutically equivalent (i.e., AB-rated generic equivalents) drug products that can be routinely and directly substituted at the pharmacy level. On the other hand, generic drug products typically 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 in which there is only one generic drug product on the market, the level of economic competition may be somewhat limited until other economically independent generic marketers 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 new 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 on 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 2 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 (formerly called PacifiCare), 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 US 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 (NDC) level for the new AARP market baskets.

This process was recently repeated using 2014 data provided by the same data sources. The 2014

4 The average market exclusivity period for a brand name drug is almost 13 years. Henry Grabowski, Genia Long, and Richard Mortimer, "Brief Report: Recent Trends in Brand-Name and Generic Drug Competition," *Journal of Medical Economics* 17, no. 3 (2014): 207–14.

market basket is the basis of this report, and the 2015 *Rx Price Watch* reports on generic, specialty, and the combined market basket.

Our selection of the market basket of drugs to track in the price index was a multistep process. First, prescriptions covered and adjudicated by the commercial entities included in the merged data set were grouped by NDC number. The NDC 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 (for example, 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 2014.

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 Pro® drug database,⁵ using the NDC number as the key linking variable. The descriptive data from Price Rx Pro 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 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 Pro®.

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, then 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 nondrug items included devices, medical and diabetic supplies, syringes, compounding service fees, and other professional services. After exclusion of non-drug items, the 2014 data set contained 36,866 NDCs grouped into 6,085 GPI-patent status categories.

We then coded all GPIs to distinguish the specialty prescription drugs from other regular, or traditional, 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) a drug product approved by the FDA through a BLA (biological license application); (3) any drug product that has a total average prescription cost greater than \$1,000 per prescription; or (4) any drug product that has a total average cost greater than \$33 per day of therapy. The drug products meeting this definition were considered “specialty drugs” and all other prescription drugs were considered “regular,” “traditional,” or “non-specialty” drugs. Throughout

⁵ Price Rx Pro® is a product of Medi-Span (Indianapolis, IN), a division of Wolters Kluwer Health, Inc., and is based on data from Medi-Span's Master Drug Database (MDDDB®).

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-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 2014 by three criteria: (1) total prescription expenditures, (2) number of prescriptions dispensed, and (3) days of therapy provided. The top 500 GPI-patent status categories were identified for each of these three criteria. Because some GPI-patent status groups appeared in more than one of these top 500 lists, the combined list of all GPI-patent status groups totaled to 627 GPI-patent status groups. There were 268 brand name GPI-patent status groups (i.e., both brand single source and brand multiple source) and 399 generic GPI-patent status groups. Also, there about 102 GPI-patent status groups in this combined top 500 list that 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 to those over age 50 in 2014.

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-Check 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 to determine whether the rebates and discounts sometimes given to payers are being passed along to consumers.

Retail Data Description

The Truven Health MarketScan® Research Databases are comprised of 12 fully integrated claims databases, and contain the largest collection of privately and publicly insured, de-identified patient data in the United States.⁶ 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 1995.⁷ 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 preferred provider organizations (PPOs) and exclusive provider organizations (EPOs), point of service (POS) plans, indemnity plans, health maintenance organizations (HMOs), and consumer-directed health plans.⁸

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

6 Danielson, "White Paper."

7 Danielson, "White Paper."

8 Danielson, "White Paper."

beneficiaries received their drug benefits through a retiree coverage plan.⁹ 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. 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 or 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; and
4. 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 2015 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 for each 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 2015 v. January 2014, February 2015 v. February 2014).
- 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 2015 refer to the average of the annual point-to-point price changes for each of the 12 months from January 2015 through December 2015 compared with the same months in 2014.

We calculated average annual price changes for each drug product for each month and year that the drug was on the market from 2006 to 2015. 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 2015 v. January 2014, February 2015 v. February 2014). 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 2015 refer to the average of the annual point-to-point price for each of the 12 months in 2015. This 12-month rolling average tends to be a more conservative estimate of price changes than the point-to-point method (i.e., 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

TABLE A-1
Average Annual Percent Change in Price for Hypothetical Prescription Drug A, 2015

Jan 14– Jan 15	Feb 14– Feb 15	Mar 14– Mar 1	Apr 14– Apr 15	May 14– May 15	Jun 14– Jun 15	Jul 14– Jul 15	Aug 14– Aug 15	Sep 14– Sep 15	Oct 14– Oct 15	Nov 14– Nov 15	Dec 14– Dec 15	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

⁹ Danielson, "White Paper."

changes in 2015 when compared with the same month in 2014:

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 2015. A price hike in May increased the percentage difference to 3 percent for each of the subsequent months in 2015. The 12-month average of these price differences is

$(2.0 + 2.0 + 2.0 + 2.0 + 3.0 + 3.0 + 3.0 + 3.0 + 3.0 + 3.0 + 3.0 + 3.0)/12$, or 2.67 percent.¹⁰

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 2014 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 through 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, does not account for the actual impact of price changes because it does not account for each product’s “weight” (or share) within the sample (i.e., 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 2014 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

TABLE A-2
Average Changes in Price and Cost of Therapy for 10 Hypothetical Prescription Drugs, 2015

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

10 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 six months that the product was on the market in the previous year (i.e., July through December).

the drug's share of total 2014 sales. In this simple example, the *weighted* average price increase in 2015 is the sum of

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

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 the drugs is 5.22 percent, or approximately one-half a 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 with the unweighted average dollar change of \$236.13.

CALCULATING AVERAGE PRICE CHANGES ACROSS MULTIPLE DRUGS FOR YEARS BEFORE 2014

The process for aggregating price changes for multiple drugs pre-2014 is similar to that for 2014. Average price changes for 2006 through 2013 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 2014 sales from the Medicare Part D plans of a Medicare 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 2014 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 utilization or mix.

However, some drugs that were in the 2014 sample were not on the market in all earlier years. We dropped these drug products from 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 2014 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 2011. Furthermore, assume that total drug spending in 2014 was \$100,000. To capture the loss of drugs I and J from the analysis for 2011, the weights are redistributed across the drugs that remain in the analysis (drugs A through H); the new weights are still based on their 2014 sales but as a share of total sales for the smaller number of drugs in the analysis for the

TABLE A-3
Recalculating Weights When Prescription Drugs Drop out of the Sample

Drug Name	2014 Weights		2011 Weights	
	Share of 2014 Sales (%)	Value of 2014 Sales (\$)	2014 Sales of Drugs on Market in 2011 (\$)	2014 Share of Drugs on Market in 2011 (%)
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%

year. In this example, the total 2014 sales of drugs on the market in 2011 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 through H, was used to derive the weighted average price change for 2011 (see Table A-3).

Weighting the previous years' price changes by 2014 sales potentially creates a bias relative to using each specific year's sales as the basis for assigning weights for that year. Using 2014 sales gives more weight to drugs that, relative to other drugs, had high rates of sales growth in 2014 or earlier years compared with 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 or that are typically taken for a limited period of time. The amount of a drug that an average adult would take on a daily basis was determined using the "usual daily dose" reported in the Medi-Span Price Rx Pro® 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 2014 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 2014. If a listed manufacturer is a division of another firm, we defined its drugs as marketed by the parent firm. This includes cases in which 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 two drug products (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 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 brand name therapeutic category may include drug products that are brand single source or brand multiple source.

Appendix B

Therapeutic Category Acronyms

Therapeutic Category	Definition
DMARD	DMARD – Disease-Modifying Anti-Rheumatic Drugs
Antiretrovirals – NNRTI	NNRTI – Non-Nucleoside Reverse Transcriptase Inhibitors
CNS Agent, Misc	CNS – Central Nervous System
JAK Inhibitors	JAK – Janus Kinase

Appendix C

Impact of HP Acthar Price Change in 2007 on Average Specialty Retail Price Change

As noted in the main report (footnote 3), one drug product (HP Acthar Gel 80 unit/mL) had a one-time increase in retail price of more than 1,300 percent in 2007. Since this price change was an extreme outlier that substantially distorted the average price increase for 2007 and 2008, we dropped HP Acthar Gel 80 unit/mL from the market basket for this study. HP Acthar Gel 80 unit/

mL was ranked number 20 among the 102 most widely used specialty prescription drugs based on 2014 spending data provided by the Truven Health MarketScan® Research Databases and a large Medicare Part D plan provider. The impact of including HP Acthar Gel 80 unit/mL, shown in Figures C1, C2, and C3, corresponds with Figures 1, 2, and 3 in the main body of the report.

FIGURE C1
Average Annual Percent Change in Retail Prices for Three Most Widely Used Specialty Prescription Drugs, 2006 to 2015, including HP Acthar Gel 80 unit/mL

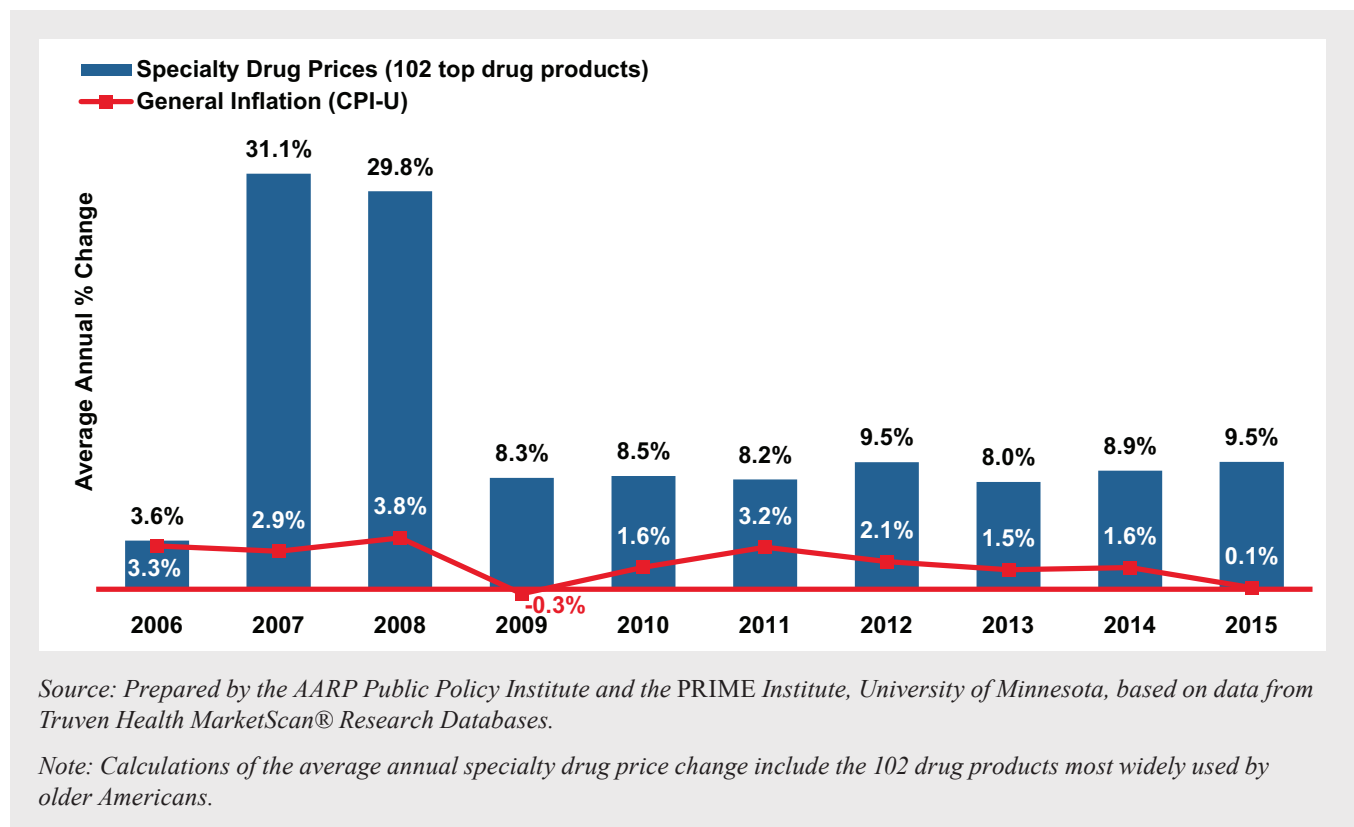
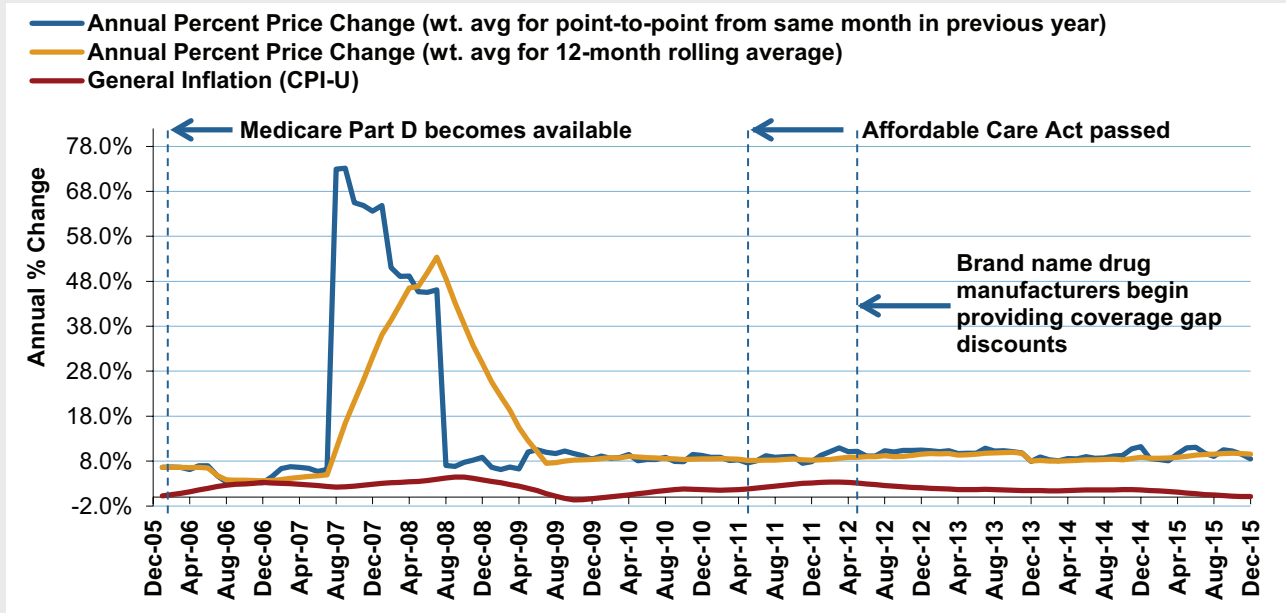


FIGURE C2

Comparison of Rolling Average and Point-to-Point Change in Retail Prices for Most Widely Used Specialty Prescription Drugs, 2006 to 2015, including HP Acthar Gel 80 unit/mL

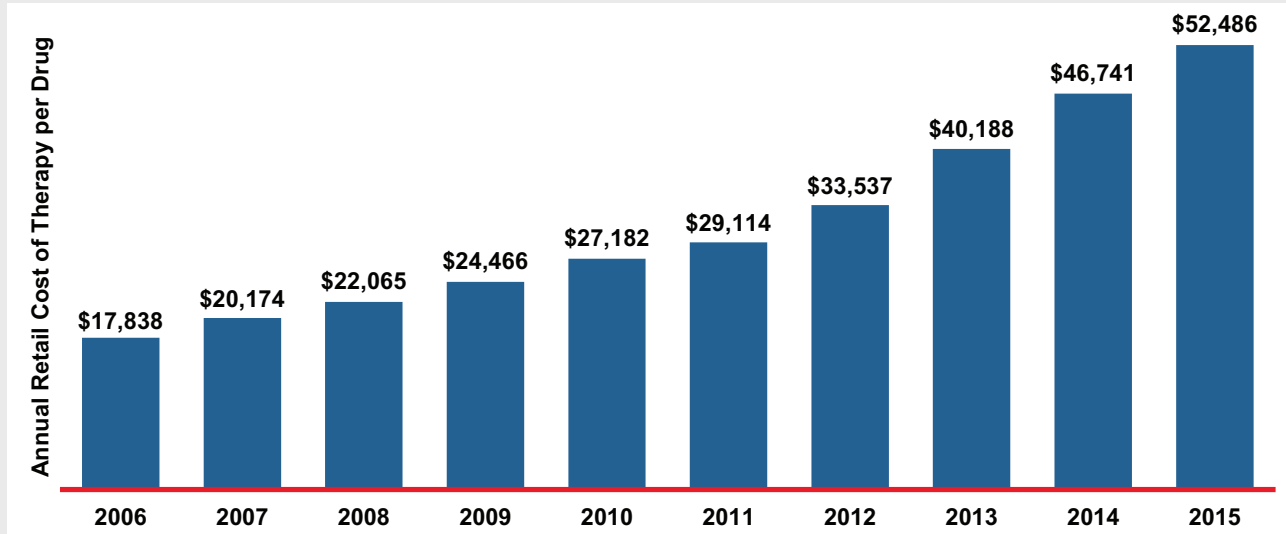


Source: Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases.

Note: Calculations of the average annual specialty drug price change include the 102 drug products most widely used by older Americans.

FIGURE C3

Average Change in Annual Cost of Therapy Due to Retail Price Changes for Most Widely Used Specialty Prescription Drugs Used in the Treatment of Chronic Conditions, 2006 to 2015, including HP Acthar Gel 80 unit/mL



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

Note: Calculations of the average annual specialty drug price change include the 102 drug products most widely used by older Americans. HP Acthar Gel 80 unit/mL was not included in these calculations since it is not used to treat chronic conditions, leaving the results unchanged from the main report.

Rx Price Watch Report 2017-06,
September 2017

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