

Statement on  
**Prescription Drug Price Inflation: Are Prices Rising Too Fast?**

Statement before  
**Subcommittee on Health  
Congress of the United States  
House of Representatives**  
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Statement of  
**Stephen W. Schondelmeyer, BS Pharm, MA Pub Adm, Pharm.D., Ph.D.**  
Professor of Pharmaceutical Management & Economics

Director, **PRIME Institute**  
College of Pharmacy  
University of Minnesota  
Minneapolis, Minnesota 55455

[schon001@umn.edu](mailto:schon001@umn.edu)  
(612) 624-9931

Thank you Representative Pallone and other members of the House Subcommittee on Health for this opportunity to provide information and insights on drug price inflation and its impact on the Medicare Part D drug program. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Director of the *PRIME* Institute. The *PRIME* Institute focuses its research on policy issues related to pharmaceutical economics and the management of drug expenditures at all levels in society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over thirty years. Previously, I have had the opportunity to serve Congress on the Prescription Drug Payment Review Commission that was established under the Catastrophic Coverage Act of 1988—a law that was repealed before the program was implemented—to provide prescription drugs to Medicare beneficiaries.

This hearing on drug price inflation and its impact on the Medicare Part D drug benefit provides a timely forum for examining the effect that drug prices have had on health care expenditures of both patients and payers. Also, this hearing provides an opportunity to look ahead to what we can expect as Congress crafts health market reform provisions that will be implemented and will shape our health care outcomes and expenditures for years to come. Today, I will briefly address findings related to recent changes in drug prices and the expected impact of these changes on the Medicare Part D drug program and health market reform.

### **Prescription Drug Coverage Under Medicare Part D**

First, let me begin by commenting that the Medicare Part D program has provided improved coverage of prescription drugs for many Medicare beneficiaries that did not have such coverage prior to 2006. The Medicare Part D program, in general, has been a major step forward for providing appropriate and accessible drug therapy to the nation's elderly and disabled. While some advocates and observers projected that the Medicare Part D program would introduce competitive forces that would restrain drug prices, others contended that the legislation did not contain adequate provisions for ensuring competition that would reduce, or even slow, the escalation of drug prices. The issue of drug prices was, and still is, both critically important and hotly debated. Drug prices continue to be a concern for government programs such as Medicare and Medicaid, for private market payers such as employers and unions, and for individuals including Medicare beneficiaries who pay for all, or part, of the cost of their drug therapy.

Realizing that drug prices were a major hot button issue for those who pay for their own prescriptions—many of whom are AARP members—the AARP determined that it should do something to keep the public informed about prescription drug prices. AARP followed the advice of former President Reagan with respect to nuclear disarmament when he declared that the U.S. should “trust and verify.” AARP entered into a dialogue

with the major pharmaceutical manufacturers asking, and trusting, that they would hold their price increases near the level of general inflation. At the same time, the AARP Public Policy Institute inaugurated a process in 2004 to monitor and verify changes in manufacturer's drug prices over time. The findings—both favorable and unfavorable—are routinely reported to AARP members and to the general public. Researchers at the AARP Public Policy Institute were aware of drug price studies that had previously been conducted by the PRIME Institute at the University of Minnesota under my direction and they invited me to collaborate with them to track drug prices in the period before Medicare Part D began and after the program was implemented.

### **Tracking Prescription Drug Prices**

The Rx Watchdog reports were designed to track changes in *manufacturer* prices for prescription drugs widely used by Medicare Part D beneficiaries over time. The market basket for the AARP price studies was designed so that manufacturer pricing patterns for specific segments of the pharmaceutical market could be examined either individually or in aggregate. For example, the market basket allows calculation of separate indices for: (1) brand name drug products; (2) specialty drug products, including both brand and generic versions of specialty drug products; (3) generic drug products; and (4) a combined market basket (i.e., brand, specialty and generic). No other measure of drug prices in the market provides this level of detail and insight into drug pricing patterns.

The Rx Watchdog reports are the only published reports that provide for analyses of price trends such as: (1) brand versus generic status of drug products; (2) traditional drug products versus specialty drug products; (3) specific therapeutic categories of drug products; (4) individual drug manufacturers; and (5) individual drug products.

The prescription drugs that are most widely used by Medicare beneficiaries served as the basis for the market basket used in the Rx Watchdog reports. The most widely dispensed drug products (including brand name, specialty and generic drugs), the drug products with the highest sales levels, and the drug products with the highest number of days of therapy were identified from among the prescriptions provided by the largest Medicare Part D plan provider. Details of the method used to identify the market basket of drugs are described in our previously published reports.<sup>1</sup>

The market basket used included 548 specific drug products with 219 brand name products, 144 specialty products, and 185 generic products. This combined market

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<sup>1</sup> See detailed methodology in Appendix A of the AARP Public Policy Institute's March 2008 report, "Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007" for details. Previous reports from this series can be found on the AARP Web site at [http://www.aarp.org/research/ppi/health-care/medicare/articles/rx\\_watchdog.html](http://www.aarp.org/research/ppi/health-care/medicare/articles/rx_watchdog.html).

basket accounted for 81.6% of all prescription drug expenditures, 79.2% of all prescriptions dispensed, and 91.2% of all days of therapy provided by a Medicare Part D plan provider in 2006.

Although the market basket studied was identified using data from a Medicare Part D plan provider, changes in prices charged by drug manufacturers to wholesalers and other direct purchasers were measured using changes in the wholesale acquisition cost (WAC) as published by the Medi-Span Price Rx® database.<sup>2</sup> Wholesale acquisition cost is a price set by, and reported directly by, drug manufacturers to the drug price databases such as MediSpan, First Data Bank (Blue Book), and Thomson Reuters (Red Book®). The average annual change in prices was calculated for each individual drug product as a 12-month rolling average. The aggregate estimates of price, or change in drug prices, were calculated for this study by weighting each drug product's value by its share among the Medicare Part D annual sales.<sup>3</sup>

## **Drug Price Trends By Market Segment**

What has the trend been for prescription drug prices in the past year? The trends reported here are annual price changes based on the 12-month period from October 2008 to September 2009. Recall that in the past year the general inflation rate as measured by the Consumer Price Index for All Items (CPI-U)<sup>4</sup> actually averaged negative 0.3% for the year and it was negative 1.3% for September 2009 versus September 2008. So let's examine price changes in each of the market segments.

### Brands Name Drugs

What happened with brand name prescription drug prices in 2009?

- Brand name drug prices, on average, increased 9.3% during the 12-months ending with September 2009.
- The 2009 increase (9.3%) in brand name drug prices was higher than the rate of increase observed during any of the prior seven years (i.e., 2002 to 2008) when brand name drug price increases ranged from 5.3% to 8.7%. (See Figure 1.)

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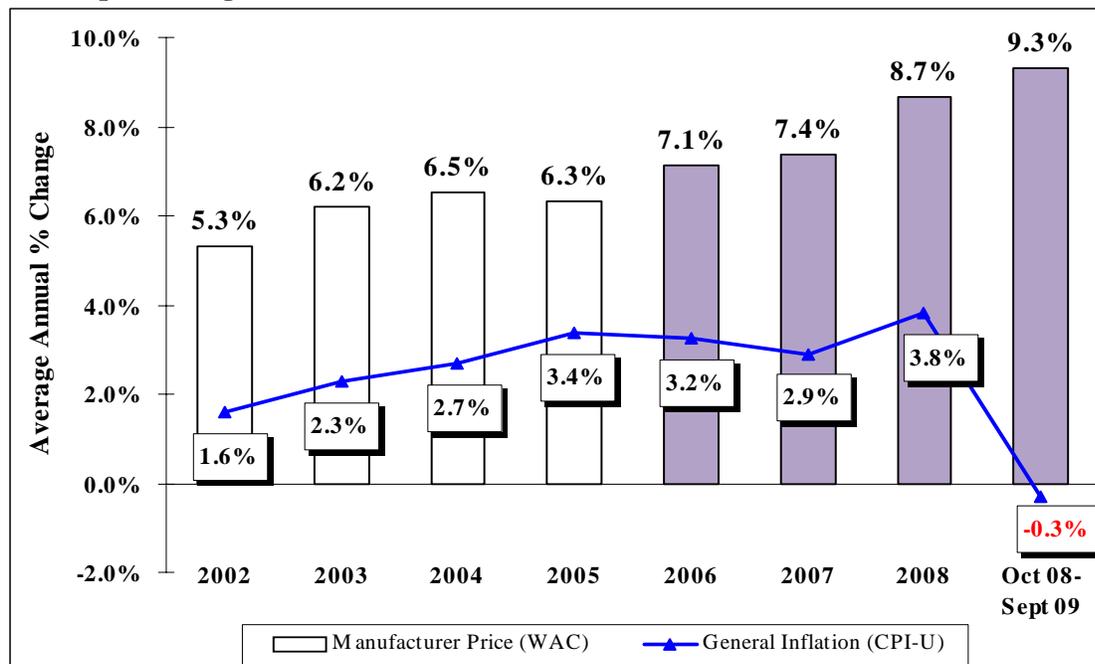
<sup>2</sup> Drug price data at the wholesale acquisition cost (WAC) level was obtained from the drug price database known as PriceRx© (Indianapolis, IN: Wolters Kluwer Health, Inc., Nov. 2008).

<sup>3</sup> The number of drugs included in the analysis for a given year varies because not all drugs in the sample were on the market in earlier years. For example, the analysis for 2004 includes 448 drug products representing 81.6% of the Medicare Part D drug expenditures.

<sup>4</sup> The general inflation rate, for purposes of this report, is measured by the Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) and published by Bureau of Labor Statistics series CUSR0000SA0 (CPI-U).

- The average annual cost for one brand name medication was about \$2,045 in the third quarter of 2009 and this was an increase of about \$202 per year for each chronic medication.
- A senior taking three chronic brand name drugs in 2009 would have total drug costs of about \$6,134—more than enough to push them into the doughnut hole.
- 96% (210 of 219) of the brand name drug products experienced a price increase in the previous 12-months. All of these price increases were greater than the CPI-Rx (2.7%). None of the brand name drugs decreased its price in 2009.
- Annual prices increases of individual brand name drugs that were notable include:
  - Ambien CR, a heavily advertised drug, increased 20.8%.
  - Aricept, an anti-dementia drug with generic competition, increased 17.2%.
  - Zetia, a drug with questionable value and efficacy, increased 14.3%.
  - Nexium, a heavily advertised drug with a patent until 2020, increased 7.1%.

**Figure 1: Average Annual Percent Change in Manufacturer Prices for Widely Used Brand Name Prescription Drugs Continues to Grow in 2009**



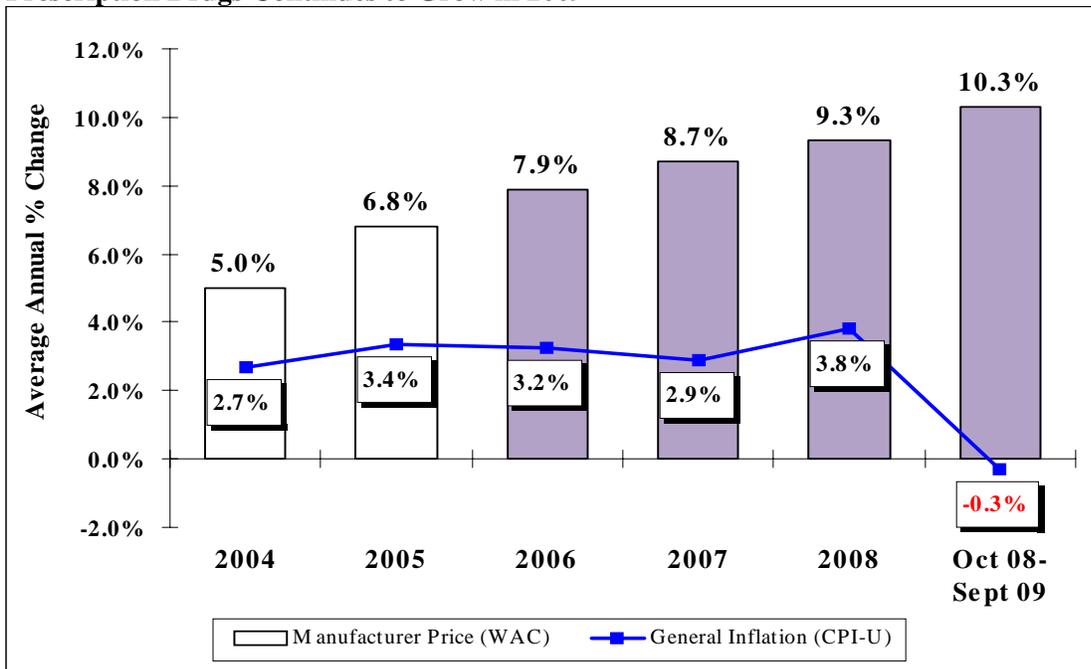
Note: Analyses for 2008 and 2009 exclude Zyrtec 10 mg tablets, which began to be sold over-the-counter (that is, without a prescription) in January 2008. Shaded bars indicate years when Medicare Part D was operational.

### Specialty Drugs

What happened with specialty prescription drug prices in 2009?

- Specialty drug prices, on average, increased 10.3% during the 12-months ending with September 2009. Brand name specialty drugs increased 19.2%.
- The 2009 increase (10.3%) in specialty drug prices was higher than the rate of increase observed during any of the prior five years (i.e., 2004 to 2008) when specialty drug prices increases ranged from 5.0% to 9.3%. (See Figure 2.)
- The average annual cost for one specialty medication was about \$32,735 in the third quarter of 2009 and this was an increase of about \$3,509 per year for each chronic specialty medication.
- 65% (94 of 144) of the specialty drug products experienced a price increase in the previous 12-months. 90% of specialty brand name drugs had a price increase in the previous year. 33% of the specialty drugs had no price increase and most of these were specialty generics. Two specialty generics had a decrease in price in 2009.
- Annual prices increases for individual specialty drugs that were notable include:
  - Infergen, an antiviral, increased 41.6%.
  - Betaseron, a multiple sclerosis drug, increased 28.2%.
  - All 5 multiple sclerosis drug products had price increases greater than 17.5%. (Range 17.5% to 28.2%)
  - All 12 cancer drugs had price increases greater than the CPI-Rx (2.7%) with price increases ranging from 4.9% to 20.8%. More than one-half (7 of 12) cancer drugs increased more than 4 times the CPI-Rx rate with increases ranging from 13.4% to 20.8%.

**Figure 2: Average Annual Percent Change in Manufacturer Prices for Widely Used Specialty Prescription Drugs Continues to Grow in 2009**



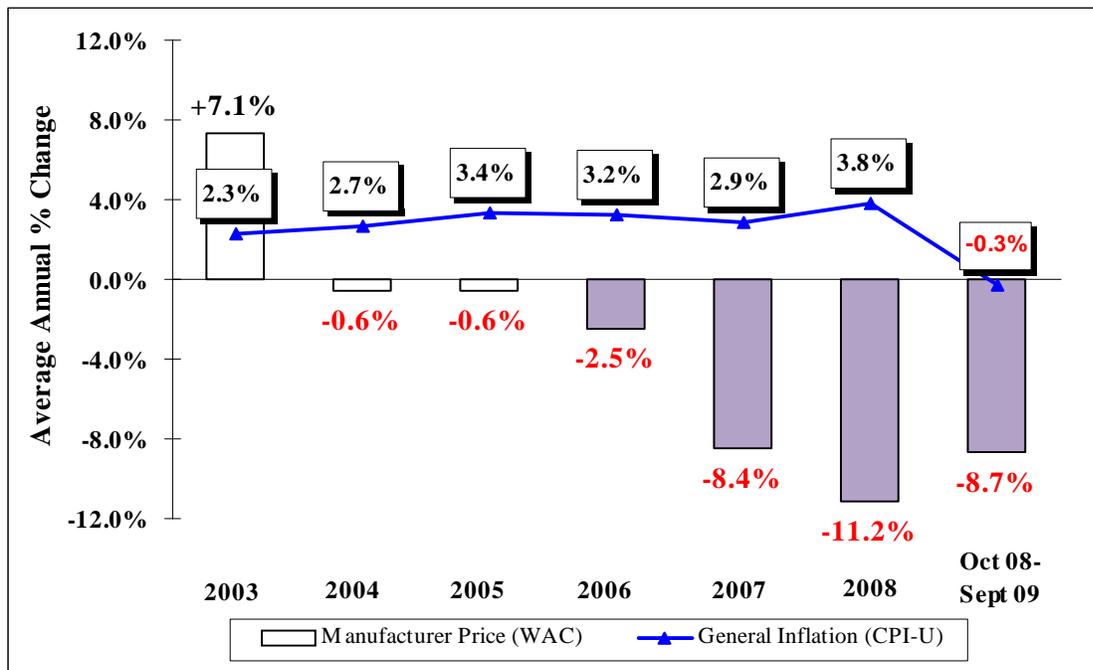
### Generic Drugs

What happened with generic prescription drug prices in 2009?

- Generic drug prices, on average, decreased 8.7% during the 12-months ending with September 2009.
- Generic drugs have had an average decrease in price every year since 2004 with these decreases ranging from -0.6% to -11.2%. (See Figure 3.)
- The average annual cost for one generic medication was about \$312 in the third quarter of 2009. This was a decrease of about \$21 per year for a chronic generic medication.
- 84% (155 of 185) of the generic drug products had no price increase in the previous 12-months while 15% (28 of 185) of generic drugs had a price decrease. Two generics had a price increase in the previous year.
- Prices changes for individual generic drugs that were notable include:
  - Simvastatin, an cholesterol lowering agent, decreased 79.8%.

- Metformin, an oral anti-diabetic drug, decreased 86.4%.
- Gabapentin, an anti-seizure drug, decreased 35.1%.
- Klor-Con, a branded generic potassium drug, had a price increase of 37.8%.

**Figure 3: The Average Annual Percent Change in Manufacturer Prices for Most Widely Used Generic Prescription Drugs Decreased More Slowly in 2009**



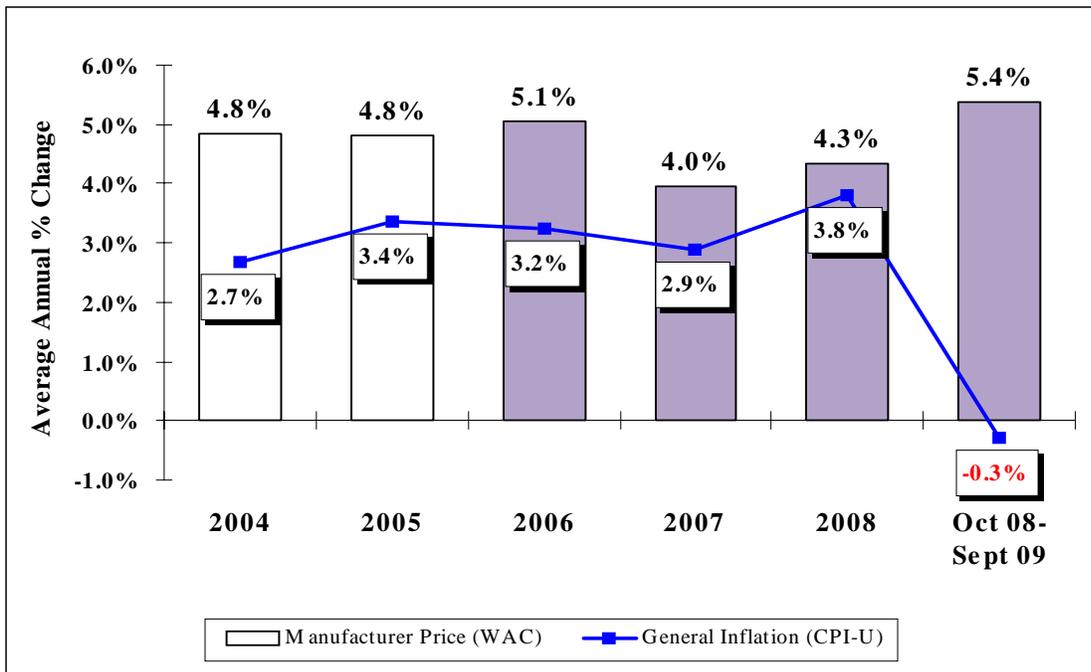
Note: Shaded bars indicate years when Medicare Part D was operational.

### Combined Market Basket

What happened with the drug prices for the combined market basket in 2009?

- When combined, the average annual rate of increase for all of the drugs analyzed (brand name, specialty, and generic) was about 5.4% during the 12-months ending with September 2009.
- The combined annual rate of growth for drug prices is attributable to the unusually high levels of price growth among brand name (9.3%) and specialty drugs (10.3%) despite the fact that generic drugs experienced a substantial price decrease of -8.7%. (See Figure 4.)

**Figure 4: The Average Annual Percent Change in Manufacturer Prices for Most Widely Used Prescription Drugs Continues to Increase in 2009**



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

### Different Measures for Different Questions

While there are several measures that track drug prices at the retail level, such as the Consumer Price Index for prescription drugs (CPI-Rx) or the National Health Expenditures (NHE) accounts, the Rx Watchdog series of studies was designed to report on trends in prices charged by drug manufacturers rather than prices at retail pharmacies. The question is not a matter of “Which is correct—The CPI-Rx or the AARP Watchdog index?” Rather, the more relevant question is “What can we learn from each of these measures of price change?” Another recent report<sup>5</sup> published by the AARP Public Policy Institute provides a comparison of the various measures available for tracking drug prices.

The overall price inflation rate reported by AARP Public Policy Institute is 5.4% which is a 12-month rolling average from Oct 2008 to Sept. 2009. The market basket for this price inflation measure included brands, specialty, and generic medications weighted by their relative contribution to total expenditures for those beneficiaries in Medicare Part D

<sup>5</sup> See Stephen W. Schondelmeyer, Leigh Purvis, and David J. Gross, *Comparative Measures of Price Change for Prescription Drugs and Other Good*, Rx Watchdog Report #2009-16, November 2009 which can be found at: <http://www.aarp.org/ppi>.

plans. The price changes were for manufacturer level prices and most of these medications are also widely used by persons of other age groups as well.

The CPI for prescription drugs (CPI-Rx) is not comparable to the AARP price index for several reasons: (1) different prices at different level of the market, (2) different patients and different drugs, (3) different methods.

First, these two indices measure *different prices at different levels of the market*. The inflation rate of CPI-Rx (2.7% in Sept. 2009) measured changes in retail prices from retail pharmacy outlets, while the inflation rate for the AARP price index (5.4% in aggregate for Sept. 2009) measured changes in manufacturer prices. A lower rate of retail-level price inflation (CPI-Rx) versus manufacturer-level price inflation (AARP price index) may result from retail price pressures that squeeze the margins of retail pharmacies but have little to no effect on manufacturer prices. In general, there has been continued downward pressure on retail prices and retail margins for the past two decades.

Second, the CPI-Rx considers *different patients and different drugs* than does the AARP price index. The CPI for prescription drugs is a more limited measure than the AARP combined price index for a variety of reasons as described in the AARP Rx Watchdog report<sup>5</sup>: "The CPI-Rx differs from the AARP price indices in several important ways. The CPI-Rx is a measure of retail price change for outpatient prescriptions used by urban consumers, while the AARP indices are measures of manufacturer price change for (outpatient) prescription drug products widely used by Medicare Part D enrollees. The CPI-Rx does not include rural U.S. residents, while the AARP indices do. The CPI-Rx also does not include specialty drugs, particularly those that are administered in physician's offices... While the AARP Rx Watchdog reports price change broken down to the level of specific manufacturers, therapeutic categories, brand versus generic drugs, traditional versus specialty drugs, or specific drug products, the CPI-Rx does not support reporting at the same level of specificity."

Third, different methodologies are used for calculating change in prices. The CPI for prescription drugs uses a methodology that incorporates factors that will typically lower the rate of inflation (e.g., substitution of generic prices for brand prices once a generic enters the market), but does not incorporate factors that would typically raise the rate of inflation (e.g., promotion and prescription of products resulting from patents on new strengths, dosage forms, or molecular manipulations for brands that go off patent). While the AARP Rx Watchdog reports price change broken down to the level of specific manufacturers, therapeutic categories, brand versus generic drugs, traditional versus specialty drugs, or specific drug products, the CPI-Rx does not support reporting at the same level of specificity.

## Rebates and Discounts: Where Did They Go?

Neither the CPI-Rx nor the AARP index of prescription price change account for the effect of rebates and discounts. Rebates and discounts may potentially result in lowering the cost of prescription drugs to patients and to taxpayers, but that effect depends on where the rebates and discounts go. Rebates and discounts to the Medicaid program are collected at the program level by state Medicaid programs. In contrast, rebates and discounts, if any, under Medicare may be passed on to the consumer as a lower prescription price or as a lower Part D plan premium.

So where do the rebates go? After implementation of the Medicare Part D program, the DHHS Office of the Inspector General (OIG) conducted a study to determine whether or not the Medicare Part D prescription prices were different from the former Medicaid prescription prices for dual eligibles. The OIG found that the Medicaid reimbursement amount was actually 0.6% less than the Part D amount for a set of single source drug products.<sup>6</sup> This analysis was before accounting for rebates that are collected by the state Medicaid program. The Medicaid drug rebate is estimated to have provided about 33% rebate from minimum rebates, best price rebates, and inflation adjustment payments.<sup>7</sup> This does not even include the effect of state supplemental rebates. Pharmaceutical companies received a windfall of revenue from decreased rebate payments when dual eligibles were shifted from Medicaid to Medicare Part D.

In contrast, rebates, if any, under the Medicare Part D plans go entirely to the Part D plan rather than to CMS. Rebates to Medicare Part D plans generally do not benefit retail pharmacies and are not typically passed on to the Medicare beneficiary or to cash-paying consumers.<sup>8</sup> A Congressional study has found that Part D drug plans, on average, have negotiated rebates for less than 10 percent of the drug products covered by Medicare Part D. Eleven of twelve Part D drug plans surveyed by a Congressional committee indicated that they “will not pass the drug rebates they receive in 2007 through to beneficiaries in the form of lower prices at the pharmacy counter.”<sup>9</sup>

Even though Medicare Part D plans do not generally pass rebates through to beneficiaries as a lower prescription price, they may use rebates to decrease the premiums for purchasing the Part D plan. Actual experience with Medicare Part D

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<sup>6</sup> Office of the Inspector General, Department of Health and Human Services, *Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid*, OEI-03-07-00350, February 2009.

<sup>7</sup> “Dueling for Duals,” *The RPM Report* (Windhover Information Inc.), Vol. 1, No.1 December 2005, pp.27-28.

<sup>8</sup> Rebates to Medicare Part D plans generally do not benefit retail pharmacies and are not typically passed on to the Medicare beneficiary or to cash-paying consumers (i.e., people who pay up front for their prescriptions when they are in the Medicare Part D coverage gap or who have no drug coverage or have indemnity insurance).

<sup>9</sup> United States House of Representatives, Committee on Oversight and Government Reform, *Medicare Part D: Drug Pricing and Manufacturer Windfalls*, July 2008. The reason such rebates have not been included in these AARP reports is not lack of interest, but rather lack of data. Absence of rebate data, however, has a limited effect on measures of change in prescription prices to Medicare Part D recipients.

premiums, however, over the past several years does not support that hypothesis. Part D premiums for 2010 have increased about 11% over 2009 Part D premiums.<sup>10</sup> Part D premiums also increased substantially (about 17%) in 2009 versus 2008. These increases in Medicare Part D premiums occurred at a time when drug utilization overall has leveled out or even declined slightly. Rebates, if they are having an effect on Part D premiums should lead to a reduction in premiums rather than an increase. If rebates are having an effect on Medicare beneficiaries or taxpayers, where did the rebates go? If rebates do not result in lower prescription prices or lower Part D premiums, their consideration in measuring price changes is not particularly relevant to the consumer or the taxpayer.

### **Forces Leading to Dramatic Drug Price Increases**

There are many important prescription drugs on the market today that are relatively safe and effective and that result in improved health through prevention and management of acute and chronic conditions. In fact, when marketed, prescribed, managed, and used properly many of these medications can improve health outcomes, save lives, or even save costs in the health care market. Well-controlled and documented studies have demonstrated this positive health and economic impact from appropriate use of specific prescription drugs. However, one should not over-generalize this principle to conclude that “all increased spending on prescription drugs is always good and will always save lives and reduce expenditures.” That over-generalization simply is not true.

Every drug, and its use, has an economic cost and as well it potentially has health benefits. Upon introduction the price of a new drug is established by the drug company and the drug product is monopoly protected by patents and other forms of exclusivity. In the U.S. market there is really no formal process for reviewing these prices to balance the costs and the benefits at a reasonable price. Irrespective of how the initial price is set, however, once the drug product is on the market, the beneficial effects of the drug are available to only those who have access to, and properly use, the drug product.

Once a drug product is on the market, any change in brand name prices (almost always an increase) at that point does not result in additional savings, but only in additional costs. For example, when the price of Zetia goes up 14.3% from Oct 2008 to Sept. 2009, the patient using this drug does not experience 14.3% in additional therapeutic benefit or 14.3% in reduced health care expenditures. The price change is entirely an added cost without added benefits from the use of that drug product. Indeed, there are serious concerns about over-promotion and over-use of prescription drugs that also raise questions about the use and value (therapeutic and economic) of many drugs

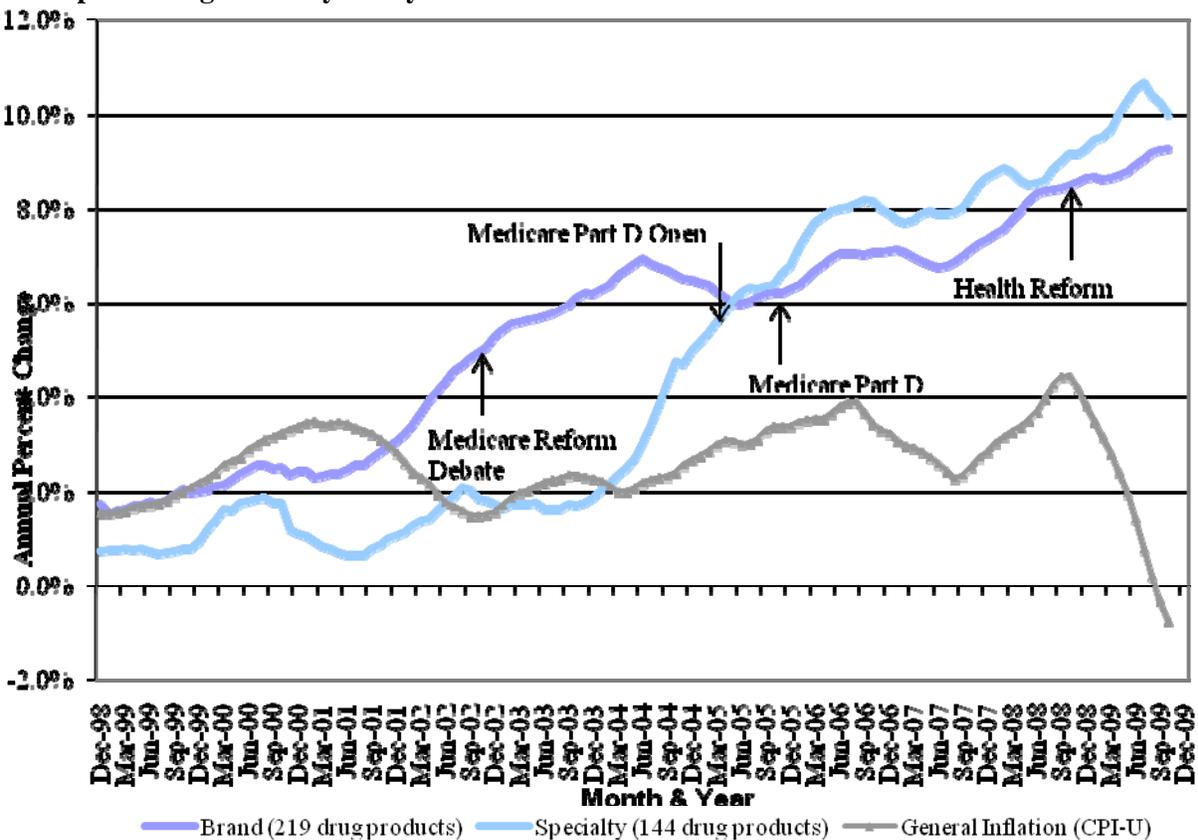
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<sup>10</sup> Jack Hoadley, J Cubanski, E Hargrave, L Summer, and T Neuman, *Part D Plan Availability in 2010 and Key Changes Since 2006*, November 2009, Kaiser Family Foundation, [www.kff.org](http://www.kff.org).

currently on the market. Zetia and Vytorin, for example, most recently have come into questions about their effectiveness compared to other drugs that have been on the market for many years and that are available at substantially lower costs. Similar concerns have been raised with respect to brand name drugs used for diabetes, arthritis, hypertension, gastroesophageal reflux disease, and other conditions.

Curiously, prescription drug prices appear to rise more rapidly in periods just prior to major policy changes. Brand name and specialty drug prices accelerated before the Medicare Part D program was enacted and implemented. Now that serious legislative action related to health market reform is being discussed, again we see a dramatic acceleration in brand name and specialty prescription drug prices. (See Figure 5).

**Figure 5: The Average Annual Percent Change in Manufacturer Prices for Most Widely Used Prescription Drugs and Key Policy Actions**



## **Concluding Observations**

The findings of the most recent AARP Watchdog report show that average annual increases in manufacturer prices charged to wholesalers and other direct purchasers for widely used prescription drugs have consistently and substantially exceeded the rate of general inflation. The combined set of manufacturer drug product prices grew at a faster rate in 2009 than in any of the previous 7 years. The overall drug price growth of 5.4% is attributable entirely to drug price growth among brand and specialty drugs that more than offset substantial price decreases among generic drugs.

Manufacturer drug price increases can have a direct impact on the costs borne by Medicare Part D enrollees, especially in a year when those living on Social Security income did not receive any Cost of Living Adjustment (COLA). Manufacturer price increases to the provider or pharmacy result in higher out-of-pocket costs for those beneficiaries who pay a percentage of drug costs (coinsurance) rather than a fixed dollar amount (copayment). The effect of higher drug manufacturer prices on the total price to the end payer means that Part D enrollees will get to the “donut hole”—the gap in coverage when enrollees have to pay all of their drug costs—much quicker. And, once enrollees are in the donut hole, they directly absorb the entire effect of the higher drug manufacturer prices on the prescription price to the end payer.