Rx Watchdog Report

Shining a light on the cost and quality of prescription drugs

Brand Name And Specialty Drug Prices Continue To Climb

At the same time that Congress was putting the final touches on health care reform, manufacturers of brand-name and specialty prescription drugs were raising their prices at record rates. Despite a near-zero rate of inflation for all consumer goods and services, manufacturer prices for widely used brand name and specialty drugs rose by more than 9 percent, on average, in the twelve month period ending with March 2010, according to the AARP Public Policy Institute's most recent *Rx Watchdog Report*. In contrast, manufacturer prices for widely used generic drugs fell by an average of over 9 percent during the same time period. The report showed findings through the first quarter of 2010 on the pattern of manufacturer price changes for brand name, specialty, and generic drugs widely used by Medicare Part D beneficiaries.

Brand Name Drugs

Manufacturer prices for brand name drugs are clearly on an upward trend—the report found the highest percentage increase for brand name prescription drugs since the AARP Public Policy Institute began publishing the *Rx Watchdog* reports (see Figure 1). More specifically, the manufacturer prices of the brand name prescription drugs most widely used by Medicare beneficiaries increased by an average of 9.7 percent in the 12 months ending with March 2010. This far exceeded the rate of increase observed during any of the prior eight years, which ranged from 5.3 percent to 9.3 percent, and would be even higher if the analysis had excluded brand name drugs that are off patent. For the consumer, this is not good news. An older

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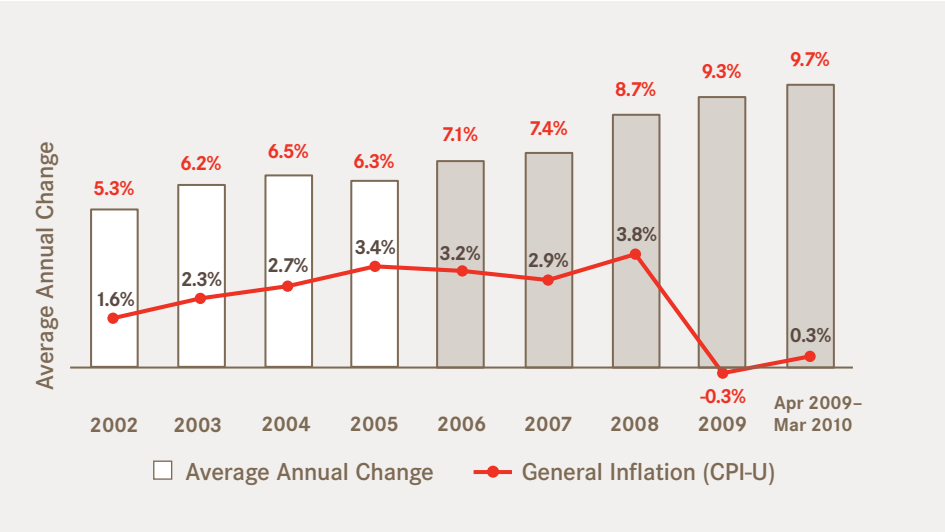
Figure 1. Average Annual Percentage Change in Manufacturer Prices for Widely Used Brand Name Prescription Drugs Continues to Increase in 2010



Note: Analyses for 2008, 2009, and 2010 exclude Zyrtec 10 mg tablets, which began to be sold over the counter, without a prescription in January 2008. Shaded bars indicate years when Medicare Part D was operational.

Health Reform To Reduce Drug Costs For Many Americans

Attention to the new health care reform legislation has largely focused on coverage and rather than cost control. But a vital part of the new law involves reducing the cost of prescription drugs for American consumers. Advocates working to lower drug costs achieved a number of victories: the Medicare Part D doughnut hole will be phased out; cost sharing on prescription drugs will be eliminated for chronically ill low-income Medicare beneficiaries; and the U.S. Food and Drug Administration (FDA) will now be allowed to approve lower-priced generic versions of biological drugs.

However, some goals were not achieved. Even after health reform legislation was signed into law, Medicare is still banned from directly negotiating with drug manufacturers for lower prescription drug prices in Part D; Americans still cannot legally import prescription drugs from other countries; and biologic drugs will not face competition for a longer period of time than many feel is necessary.

Good News: Closing the Part D Doughnut Hole

Each year millions of those covered by Medicare's Part D prescription drug program have medication costs so high that they hit the infamous **gap in coverage known as the** "doughnut hole." The doughnut hole is a gap in Medicare Part D coverage where enrollees are responsible for 100 percent of their prescription drug costs. In 2010, once an enrollee's total spending on prescription drugs reaches $2,830, the gap begins—Part D benefits are suspended and enrollees bear the full cost of their medications. After spending a total of $4,550 out-of-pocket for prescription drugs (including the deductible and cost sharing during the initial coverage period), the enrollee emerges from the gap and their Medicare benefits start again.

Under the new Health Care and Education Affordability Reconciliation Act of 2010, the

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Table 1: All of the Top 25 Brand Name Prescription Drug Products Experienced a Manufacturer Price Change in The Past Year

Rank by Sales among Study Market basket*	Product Name, Strength, and Dosage Form	Package Size	Manufacturer	Therapeutic Class	% Change in WAC, Apr 2009–Mar 2010
1	Nexium 40 mg capsule	30	AstraZeneca	Ulcer Drugs (PPIs)	7.4%
2	Plavix 75 mg tablet	90	Bristol-Myers Squibb	Anticoagulants	10.5%
3	Prevacid 30 mg DR capsule	100	Takeda Pharmaceuticals	Ulcer Drugs (PPIs)	8.1%
4	Protonix 40 mg tablet	90	Wyeth	Ulcer Drugs (PPIs)	9.3%
5	Lipitor 20 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
6	Lipitor 10 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
7	Aricept 10 mg tablet	30	Eisai	Antidementia Agents	13.9%
8	Fosamax 70 mg tablet	4	Merck	Osteoporosis Agents	6.7%
9	Norvasc 10 mg tablet	90	Pfizer	Antihypertensives (CCBs)	5.0%
10	Advair Diskus 250-50 mist	60	GlaxoSmithKline	Respiratory Agents	7.0%
11	Lipitor 40 mg tablet	90	Pfizer	Cholesterol Agents (HMG CoA)	5.5%
12	Actonel 35 mg tablet	4	Warner Chilcott Pharm	Osteoporosis Agents	9.3%
13	Norvasc 5 mg tablet	90	Pfizer	Antihypertensives (CCBs)	5.0%
14	Celebrex 200 mg capsule	100	Pfizer	Anti-Inflammatory Agents	5.0%
15	Namenda 10 mg tablet	60	Forest	Antidementia Agents	7.6%
16	Singulair 10 mg tablet	30	Merck	Respiratory Agents	9.7%
17	Flomax 0.4 mg capsule	100	Boehringer Ingelheim	Prostatic Hypertrophy Agents	27.6%
18	Zetia 10 mg tablet	30	Merck/Schering-Plough	Cholesterol Agents (HMG CoA)	10.8%
19	Lexapro 10 mg tablet	100	Forest	Antidepressants (SSRIs)	6.4%
20	Lantus 100/ml inj	10	Sanofi-Aventis	Antidiabetics (Insulins)	7.5%
21	Zocor 20 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	6.3%
22	Ambien 10 mg tablet	100	Sanofi-Aventis	Sedatives	13.9%
23	Seroquel 200 mg tablet	100	AstraZeneca	Antipsychotics	15.6%
24	Zocor 40 mg tablet	30	Merck	Cholesterol Agents (HMG CoA)	6.3%
25	Avandia 4 mg tablet	30	GlaxoSmithKline	Antidiabetics (Oral)	11.6%
General rate of inflation (as measured by growth in CPI-U)					**0.3%**

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

American who takes three brand name medications on a chronic basis is likely to have experienced an average increase in the cost of therapy of more than $700 during the 12 months ending in March 2010, assuming that the manufacturers' price increases were passed along in the form of higher prices.

The report also found that 192 of the 219 brand name drugs (88%) in the market basket experienced a manufacturer price increase in the 12-month period. Twenty-seven (12%) of the 219 brand name drugs products had no change in price during the same period; only two of these products were still under patent (see Table 1). All of the 25 most widely used brand name drug products had price increases of at least 5 percent, including 7 that had double-digit price increases. This indicates that manufacturer price increases for brand name drugs tend to slow or stop once they face generic competition.

Specialty Drugs

The manufacturer prices of 144 specialty prescriptions most widely used by Medicare beneficiaries increased by an average of 9.2% in the 12 months ending with March 2010 (see Figure 2). If the 52 drug products in the specialty market basket that are off-patent are excluded from the analysis, the average manufacturer price change is actually 9.8% over

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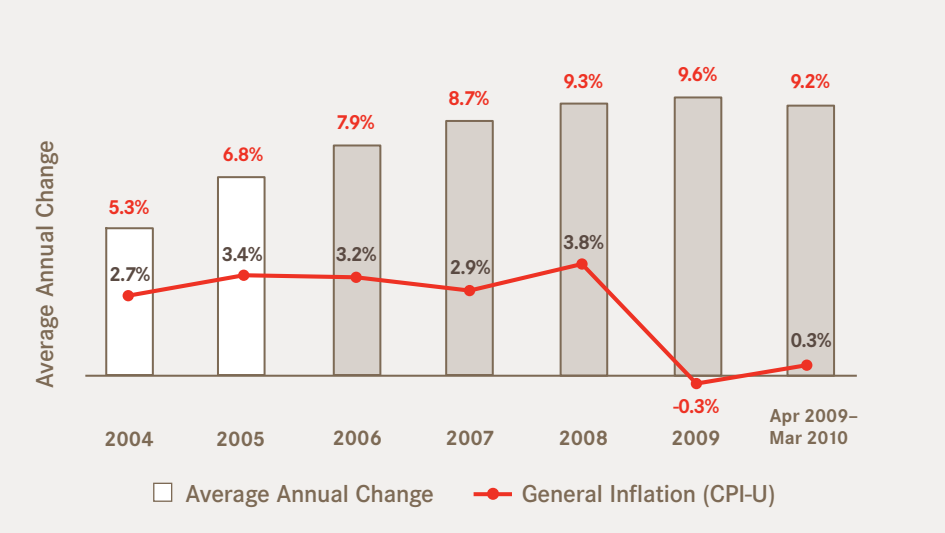
Figure 2: Average Annual Percent Change in Manufacturer Prices for Widely Used Specialty Prescription Drugs Remain High in 2010



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

this time period. A specialty drug is one that is often used to treat chronic illness, such as multiple sclerosis or cancer, and is typically very expensive.

An example of a specialty drug is the newly approved Provenge, which is used to treat prostate cancer. Each infusion of Provenge will cost $31,000, bringing the full cost of treatment for three infusions to $93,000. According to experts, the drug will cost an average of about $23,000 per month of life extension, based on the Phase II study that found the drug extended life by 4.1 months. Additionally, Dendreon, the drug's manufacturer, said that initially the demand will outpace the supply as they build their out their manufacturing sites.

90 of the 144 (about two-thirds) drug products in the specialty market basket experienced a manufacturer price increase in the 12-month period ending with the first quarter of 2010. Two of the 144 specialty drug products had a decrease in price; both of these were generics. One-third (52 of 144) of the specialty drug products had no change in price in the same period; most of the drug products with no price change were generics or off-patent brands.

Generic Drugs

The good news is that the manufacturer prices of generic prescription drugs widely used by Medicare beneficiaries decreased by an average of 9.7 percent in the 12 months ending with March 2010. For an individual who takes three generic prescriptions on a chronic basis, the average cost of therapy decreased by $51 in the 12 months ending with the first quarter of 2010, assuming that the price decreases were passed along in the form of lower prices.

"The good news is that the manufacturer prices of generic prescription drugs widely used by Medicare beneficiaries decreased by an average of 9.7 percent in the 12 months ending with March 2010."

Combined Market Basket

When combined, the average annual rate of increase for all of the drugs analyzed —brand, specialty and generic—was 5.3 percent in the 12 months ending with the first quarter of 2010. This combined rate of growth for drug prices is attributable to continuing high levels of manufacturer price growth among brand name and specialty drugs that more than offset the substantial price decreases among generic drugs.

The Impact Of Higher Drug Pricing

Higher drug prices can raise Medicare beneficiaries' costs, particularly for those beneficiaries who pay a percentage of drug costs, referred to as a coinsurance, rather than a fixed amount, known as a copayment.

Higher drug prices also push more Part D enrollees into the dreaded "doughnut hole"—the gap in coverage when enrollees have to pay 100 percent of their prescription drug costs every year. And, once in the doughnut hole, enrollees pay for the full effects of the higher manufacturer prices. Furthermore, if escalating drug prices are not addressed, the substantial value of closing the doughnut hole could be eroded over the years.

Also, higher prices to retail pharmacies are generally passed on as higher costs to consumers and drug plans. Higher drug costs to plans may also result in reduced benefits and higher premiums for enrollees.

The impact of manufacturer price increases will be substantial for those persons taking brand name medications which have grown in price by an average of 9.7 percent in the 12 months ending with the first quarter of 2010. Even more challenging will be affording the price of high-cost specialty drugs which have grown in price by an average of 9.2 percent over the same period. And even though generic drug prices have decreased by an average of 9.7 percent, it is not sufficient to offset price increases of brand and specialty medications.

For the full AARP Public Policy Institute *Rx Watchdog Report* "Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate" go to: **www.aarp.org/research/ppi/health-care/medicare/articles/rx_watchdog.html** ■

doughnut hole will gradually be eliminated. As the first step, Part D enrollees who hit the doughnut hole in 2010 will receive a $250 rebate check.

This $250 payment could be made to about 4 million Medicare beneficiaries this year. While the Centers for Medicare and Medicaid Services (CMS) have not finalized the process, it is anticipated that checks will be issued automatically after an individual enters the doughnut hole.

Low-income Medicare Part D enrollees who receive the Low-Income Subsidy (also known as "Extra Help") will **not** receive the $250 rebate since their costs are already covered by the federal government. However, while CMS has not issued final rules, it is expected that Part D enrollees whose cost-sharing is paid for by State Pharmaceutical Assistance Programs (SPAPs) will receive the $250 payment after they enter the doughnut hole, even if the SPAP pays some or all of their prescription drug costs while they are in it.

The real action on closing the doughnut hole, however, starts in 2011. Beginning that year, drug manufacturers will be required to provide 50 percent discounts to Part D enrollees while they are in the doughnut hole. In addition, the Medicare program will provide a 7 percent discount on generic prescription drugs for Part D enrollees while they are in the doughnut hole. Starting in 2013, Medicare will also begin providing a discount on brand-name drugs. Medicare will gradually increase its discounts on generic and brand-name drugs each year, so that by 2020 Part D enrollees will only be responsible for 25 percent of their prescription drug costs while they are in the doughnut hole. Thus, enrollees will have the same level of coverage from the time they meet their deductible to the time they reach catastrophic coverage.

Another change in Medicare Part D is the elimination of out-of-pocket drug costs for chronically ill Part D enrollees who are also enrolled in Medicare and who receive home and community based services rather than going into a nursing home. If these enrollees were in a nursing home, they would pay nothing for Part D drugs. This new provision gives the same protection to beneficiaries who are similarly sick or incapacitated but are able to remain in their own homes.

More Good News: Cheaper Biologics—in the Long Run

Another health reform victory for consumers is a provision that finally creates a system for the FDA to approve generic versions of biologic drugs, or "biosimilars". Biologic drugs differ from conventional pharmaceuticals in that they are derived from living organisms, rather than from chemical compounds. Once prescribed to treat only rare genetic diseases, biologics have rapidly become a more common treatment option for people with conditions such as multiple sclerosis, diabetes, cancer, and rheumatoid arthritis. They are also typically expensive: some treatments can cost tens to hundreds of thousands of dollars per year. Although European countries have successfully been using biosimilars for several years, in the U.S. there was virtually no legal mechanism for the FDA to approve similar drugs. But thanks to the new law, the FDA will be able to approve them. However, brand name biologic manufacturers will be protected from competition with 12 years of market exclusivity, during which no lower-priced biosimilars may be sold. It will take a while to get the approval process started, and experts don't expect the first biosimilar drugs to be on the market for several years. (For more information about the issue of market exclusivity for biologic drugs, see the May 2009 and August 2009 issues of AARP's *Rx Watchdog Report* at **www.aarp.org/watchdog**.)

The Bad News: Some Savings Were Left on the Table

Even with these victories, the health reform bill doesn't contain everything that consumers wanted. For example, although drug manufacturers will be providing discounts to Medicare beneficiaries who fall into the doughnut hole, there won't be any constraints on far much manufacturers can raise their prices. During the 12 months ending March 31, 2010, manufacturers raised prices on brand-name drugs by an average of 9.7 percent (see lead article), continuing an upward trend in drug price increases. Across Part D plans, even enrollees who do not fall into the coverage gap still face cost-sharing for brand-name drugs of $40 to $95 per prescription, excluding "specialty tier" drugs which have cost-sharing of 30 to 40 percent or more.

The health reform law did not include two tools that could have been used as leverage to get lower prices from manufacturers. First, the law keeps in place a provision that prohibits Medicare from negotiating directly with drug manufacturers to achieve lower prices for Medicare Part D enrollees. Second, the law does not include a provision to allow safe importation of prescription drugs from countries such as Canada and European Union members.

In addition, some observers believe that the law gives excessive protections to manufacturers of brand name biologic drugs. While many advocates, including AARP, sought to limit market exclusivity, the drug industry was still able to obtain 12 years of market exclusivity. Such a long period of exclusivity also contradicted the findings of the Federal Trade Commission, which concluded that brand name biologic manufacturers did not need any market exclusivity, and that 12 years actually negatively impacts innovation. "This means extra years that consumers, insurers, and Medicare will be paying incredibly high prices for these drugs," said AARP Executive Vice President John Rother.

"Health reform clearly means lower drug costs for consumer," Rother continued, "but our work isn't over. There is still a lot of room to improve the market even more, and that's why AARP will continue to fight for Medicare negotiating authority and safe drug importation." ■

Ed Dale contributed to this article

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