



Workers Compensation Prescription Drug Study 2006 Update

Background

The nation's drug cost acceleration is finally moderating. Nationwide prescription drug spending for all payers (including Group Health and Workers Compensation) increased 8.2% in Calendar Year 2004. This is down from the 10.2% increase in 2003 and 14.0% increase in 2002.¹

The Centers for Medicare and Medicaid Services, Office of the Actuary cites several contributing factors to this slowing growth in prescription drug spending, including:

- Rapid growth in the use of lower-priced generic drugs through tiered benefit plans
- Increased over-the-counter use of antiulcerants and antihistamines
- A shift towards greater mail order dispensing
- Reduced consumption of certain drugs due to concerns about their safety²

Despite a slowing trend, the prescription drug issue remains at the forefront of political and media attention. Current hot topics include the importation of prescription drugs from foreign countries, Medicare's coverage for prescription drugs, and the potential for additional health risks from formerly popular drugs such as Celebrex[®], Vioxx[®], and Bextra[®].

Has the rate of increase of workers compensation (WC) drug spending also slowed? This is the focus of our ongoing research. We are currently collecting more recent WC data to address this and other current issues pertaining to prescription drugs. In the interim, this study uses the most recently compiled data^a to revisit several issues discussed in the first two NCCI studies (on ncci.com) and to examine additional items of interest to the WC industry.

¹ Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Tables, <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>

² Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditure Historical Data, Highlights, http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage

Prescription Drug Study 2006 Update—Key Findings

- WC prescription drugs' share of total medical costs continues to grow—estimated ultimate share rising from 12.1% in Injury Year 1998 to 13.4% in 2003, with the most recent year potentially signaling the beginning of a slowdown
- Six of the ten states in the study have prescription drug to medical costs ratios close to the overall 2003 average of 13.4%, while two states have somewhat higher ratios and two states have somewhat lower ratios
- The percentage of times a generic drug was prescribed when available rose further in Service Year 2003—89% compared to 86% in 2002
- Anti-inflammatories/painkillers remained the top drug group, representing 52% of total prescription drugs paid in 2003, with eight out of the top ten drugs in this group

Discussion of Findings

Prescription Drugs' Share of Medical Costs

This year's study shows continued growth in prescription drugs' share of total WC medical costs by accident year.

Prescription Drug Costs/Total Medical— All Study States* Combined (Estimated at Ultimate)	
Injury Year ^b	Prescription Drug Share
1998	12.1%
1999	12.4%
2000	12.7%
2001	13.0%
2002	13.3%
2003	13.4%

* States included in the study: CA, CO, FL, IL, KY, MA, NC, OR, TN, and TX.

Individual State Results

Analysis of individual state results for prescription drug costs relative to total medical costs revealed some interesting outcomes. For a majority of the states in the study (60%), the ratios were close to the average ratios for all states. Two of the states had ratios above average, while two states were below average.

- Above Average (greater than 15%): FL, KY
- Average (10% to 15%): CA, CO, MA, NC, TN, TX
- Below Average (less than 10%): IL, OR

Case Study: Florida and Illinois

NCCI analyzed the data for two key states—Florida (above average) and Illinois (below average)—to help explain the differences in results. Our research has concluded that there are both distinct behavioral and cost patterns associated with these two states leading to such divergent results.

Our analysis identified the percentage of claims that include prescription drugs as the most significant driver of

the difference in prescription drug to medical costs ratios between Florida and Illinois. About one in six claims includes costs for prescription drugs in Illinois, compared to about one in three claims in Florida (and all states in the study combined).

The following may also be contributing factors to the difference in results for these two states:

- The average price per unit for a given drug is usually higher in Illinois.
- Less expensive drugs, particularly generics, are a greater percentage of all prescriptions in Illinois. As a result, the average price per unit for all drugs combined is lower in Illinois than in Florida.
- OxyContin[®], a relatively expensive drug, is prescribed more often relative to all drugs in Florida.
- Managed-care controls are not as prevalent in Illinois as in other states; thus, costs for many nonprescription medical services are higher.
- About 93% of medical costs are paid within 96 months of the injury year in Illinois, compared to about 70% in Florida.

Drug Costs Breakdown

This year’s analysis of the change in drug costs from Service Year 2002 to 2003 shows utilization continuing to have a greater impact on costs than price.

Factors Affecting Change in WC Drug Costs			
Service Years	Drug Price Impact	Utilization Impact	Total Impact
1998–1999	1.120	1.173	1.314
1999–2000	1.096	1.204	1.320
2000–2001	1.091	1.233	1.345
2001–2002	1.079	1.209	1.304
2002–2003	1.100	1.109p	1.220p

p Preliminary, most recent service year is subject to material reporting lag, resulting in increases in both the utilization and total impacts at subsequent maturities.

Prescribing Patterns

The percentage of times a generic drug prescription was written when a generic drug was available increased from the previous year, rising from 86% in service year 2002 to 89% in 2003. The remaining potential for savings from generic drugs was about 8% of total WC prescription drug costs in 2003. Although generic prescriptions represented 66% of the number of prescriptions written in 2003, they accounted for only 43% of total WC prescription drug costs.

Anti-inflammatories/painkillers remained the top drug group in this year’s study based on amounts paid, followed by muscle relaxants, and antidepressants. As we look at individual year results, we see some interesting changes taking place with respect to drug group percentages of total prescription drug paid. The anti-inflammatories/painkillers as well as anti-infective agents experienced a significant decrease in the percentage of total prescription drug from 1998 to 2003. In contrast, the muscle relaxants, central nervous system drugs, and gastrointestinal agents had significant increases in percentage of total prescription drug paid during that same period.

Drug Group	Share of Total Prescription Drug Paid by Service Year						
	1998	1999	2000	2001	2002	2003	All Yrs.
Anti-Inflammatories/Painkillers	60%	59%	59%	58%	55%	52%	55%
Muscle Relaxants	15%	17%	17%	18%	20%	21%	19%
Central Nervous System (CNS) Drugs*	8%	10%	12%	12%	12%	12%	12%
Gastrointestinal Agents	3%	3%	3%	4%	5%	7%	5%
Anti-Infective Agents	8%	6%	4%	4%	4%	3%	4%
Topical Products**	3%	2%	2%	2%	2%	3%	2%
Other	3%	3%	3%	2%	2%	2%	3%

* Includes antidepressants, hypnotics, antianxiety agents, antipsychotics, stimulants/antiobesity/anorexiant, miscellaneous psychotherapeutic and neurological agents, and certain sedatives.

** Topical medications include balms, creams, gels, oils, lotions, patches, ointments, and other products applied to skin.

The following exhibit shows the top 20 prescribed drugs by total paid in WC for years 2001 to 2003 separately, and 1998–2003 combined, sorted by rank in 2003.

Top 20 Prescribed Drugs by Total Paid in WC (Baseline—Service Year 2003)					
Drug Name	FDA Approval	Ranking			
		2003	2002	2001	1998–2003
Celebrex®	12/98	1	1	1	1
Hydrocodone/Acetaminophen	7/85	2	3	4	3
Carisoprodol	<1/82	3	6	6	6
OxyContin®	12/95	4	4	3	4
Neurontin®	12/93	5	5	5	5
Vioxx®	5/99	6	2	2	2
Ranitidine HCL	7/97	7	9	20	9
Bextra®	11/01	8	8	—	14
Naproxen®	3/94	9	7	8	7
Duragesic®	8/90	10	14	15	16
Skelaxin®	4/64	11	13	12	13
Ambien®	12/92	12	11	11	12
Cyclobenzaprine HCL	5/89	13	10	9	8
Tizanidine HCL	6/02	14	22	—	21
Tramadol HCL	6/02	15	23	—	24
Lidoderm®	3/99	16	25	49	22
Ibuprofen	8/85	17	15	14	15
Propoxyphene/Acetaminophen	<1/82	18	12	10	11
Ultracet®	8/01	19	18	101	20
Actiq®	11/98	20	28	88	27

Note: Drugs listed without registered trademark symbol are generics.
Source for FDA approval dates: FDA Electronic Orange Book.³

³ US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Pharmaceutical Science, Office of Generic Drugs, Electronic Orange Book, <http://www.fda.gov/cder/ob/default.htm>

A more detailed look at the top 20 prescribed drugs by total paid in 2003 shows:

- The top 20 prescribed drugs by total paid in 2003 represented 64% of the total prescription drugs paid in that year
- Anti-inflammatories/painkillers represented 70% of the top 20 drugs
- Nine of the top 20 prescribed drugs were generics

Top 20 Prescribed Drugs by Total Paid in WC—Service Year 2003		
Drug Name	% of Total Prescription Drug Paid	Brand vs. Generic
Celebrex [®] (anti-inflammatory)	6.2%	Brand (generic not available)
Hydrocodone/Acetaminophen (painkiller)	6.0%	Generic
Carisoprodol (muscle relaxant)	5.6%	Generic
OxyContin [®] (painkiller)	5.5%	Brand (generic available 3/04)
Neurontin [®] (painkiller)	5.5%	Brand (generic available 9/03)
Vioxx [®] (anti-inflammatory)	5.1%	Brand (generic not available)
Ranitidine HCL (H2-Blocker*)	3.9%	Generic
Bextra [®] (anti-inflammatory)	3.5%	Brand (generic not available)
Naproxen (anti-inflammatory)	3.2%	Generic
Duragesic [®] (painkiller)	2.3%	Brand (generic available 1/05)
Skelaxin [®] (muscle relaxant)	2.0%	Brand (generic not available)
Ambien [®] (sedative)	2.0%	Brand (generic not available)
Cyclobenzaprine HCL (muscle relaxant)	2.0%	Generic
Tizanidine HCL (muscle relaxant)	1.7%	Generic
Tramadol HCL (painkiller)	1.7%	Generic
Lidoderm [®] (painkiller)	1.6%	Brand
Ibuprofen (anti-inflammatory)	1.6%	Generic
Propoxyphene/Acetaminophen (painkiller)	1.6%	Generic
Ultracet [®] (painkiller)	1.5%	Brand
Actiq [®] (painkiller)	1.5%	Brand (generic not available)

* H2-Blocker: blocks the action of histamine on stomach cells, thus reducing stomach acid production.

Noteworthy Changes in Rankings

The pain medication Actiq[®] continues to climb the rankings—moving from #88 (0.1% of total prescription drug paid) in the 2001 data to #20 (1.5% of total prescription drug paid) in the 2003 data.

We also see further evidence of generics being prescribed more often in place of brand-name drugs as generic drug ranitidine HCL moves from #20 (of total prescription drug paid) in 2001 to #7 in 2003, while Zantac[®] drops from #201 to #367. Ranitidine HCL is an H2 Blocker* and a generic version of Zantac[®]. The movement in rankings of these two drugs indicates a

substitution of a generic for a brand taking place over time.

OTHER ITEMS OF INTEREST

Current Status on Celebrex[®], Vioxx[®], and Bextra[®]

It will be interesting to see what effect the recent actions taken by the FDA and the makers of Celebrex[®] (Pfizer), Vioxx[®] (Merck & Company), and Bextra[®] (Pfizer) will have on drug group distributions and individual drug rankings. These three drugs represented 15% of amounts paid for prescription drugs in WC in 2003. They are in the top 10 by total paid over the period reviewed, with the exception of Bextra[®], which didn't receive FDA approval until November 2001.

Due to concerns regarding the potential side effects and health risks associated with selective COX-2 inhibitors^c (all three of these drugs are in this class), the following actions have taken place:

- September 30, 2004—Merck & Company voluntarily withdrew Vioxx[®] from the market
- April 7, 2005—At the request of the FDA, Pfizer voluntarily suspended sales of Bextra[®]
- April 7, 2005—The FDA allowed Pfizer to keep Celebrex[®] on the market, but with expanded risk information included in the labeling

Questions remain as to what will occur in the coming years following these developments. Will demand increase for Celebrex[®]—currently the only remaining selective COX-2 inhibitor available? Will other drugs currently in the pipeline take the place of all selective COX-2 inhibitors currently on the market? Will future tests prove the associated risks are acceptable given the benefits these drugs have to offer?

Average Wholesale Price Issue—Revisited

There was testimony at a recent hearing of the House Energy and Commerce Subcommittee on Health that the federal and state governments pay too much for prescription drugs in the Medicaid program, with markups the highest on generic drugs.⁴

State Medicaid agencies, pharmacy benefit managers, and other third-party payers frequently use the average wholesale price (AWP^d) to set payment rates for retail pharmacy prescription drugs. The AWP is a suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider, but it is not the actual price that wholesalers charge.⁵

A Department of Health and Human Services analysis⁵ comparing average sales price^e (ASP) to AWP for 2,077 national drug codes found that the ASP was substantially

lower than the AWP. The median percentage difference was 49%, with the difference being the greatest for generic drugs. For drug codes in the analysis, the ASP was 26% below AWP at the median for single-source brand codes, 30% below for multisource brand codes, and 68% less for generic national drug codes.

Relationship of ASP to AWP	
Type of Drug Codes	Percent ASP Below AWP at the Median
All	49%
Single Source Brand Codes	26%
Multisource Brand Codes	30%
Generic National Drug Codes	68%

The Congressional Budget Office (CBO) reported that the difference (or “mark-up”) between what Medicaid paid the pharmacy for a prescription and what the pharmacy or wholesaler paid for the drug increased an estimated 79% per prescription between 1997 and 2002. Committee vice chairperson, US Rep. Michael Bilirakis, stated “It is clear to me that the use of AWP-based reimbursement as a payment benchmark under Medicaid is fatally flawed.”⁴

As reported in NCCI’s 2004 prescription drug study update (see ncci.com for complete study), all 28 states identified as having some type of workers compensation prescription drug reimbursement schedule also use AWP as a mechanism for prescription drug reimbursement.

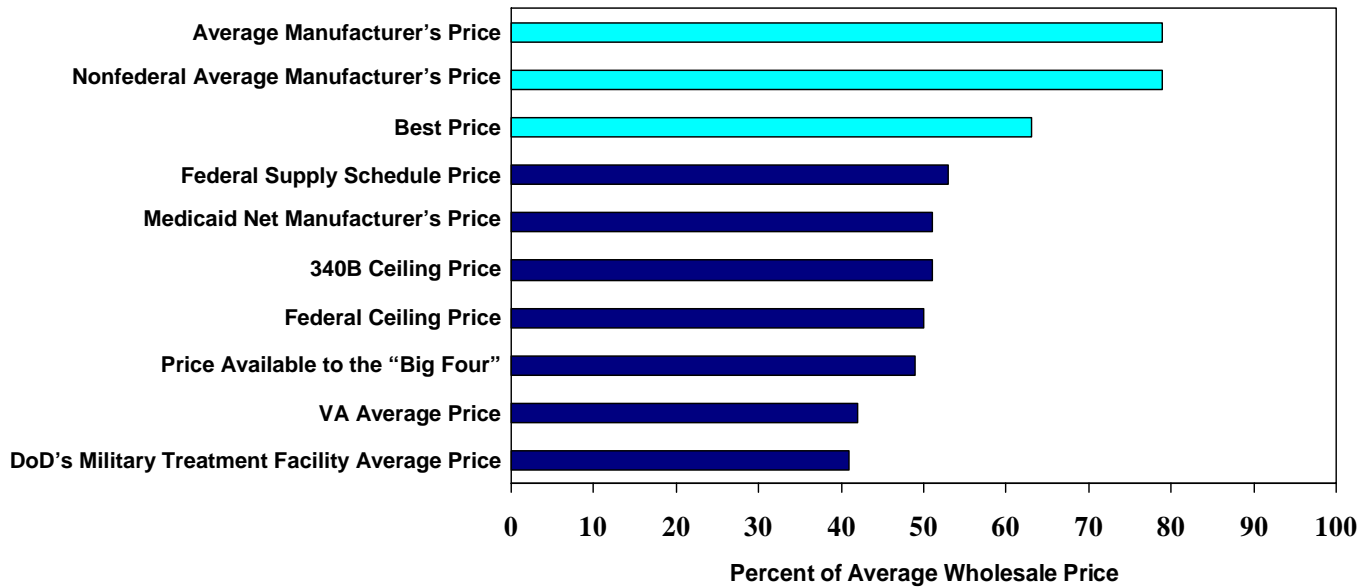
In our 2003 study we stated that the 2001 data showed WC pays (on average for all drugs) roughly 125% of the AWP of prescription drugs, while group health pays only 72%. A recent CBO paper on brand-name prices⁶ gives us a better idea of what others may be paying relative to AWP. As displayed in the following chart, the selected average prices are all less than 80% of AWP.

⁴ Medicaid Drug Costs Artificial, Stunningly High; Markups Greatest on Generics, Committee Told, The Committee on Energy and Commerce, US House of Representatives, Testimony, June 23, 2005, http://energycommerce.house.gov/108/News/06232005_1567.htm

⁵ Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price, Department of Health and Human Services, Office of the Inspector General, June 2005

⁶ Prices for Brand-Name Drugs Under Selected Federal Programs, Congressional Budget Office, June 2005

Estimated Prices Paid to Manufacturers, Relative to AWP*, For Brand-Name Drugs Under Selected Federal Programs, 2003



Source: Congressional Budget Office.

* AWP – Average Wholesale Price

The first three bars in the figure are manufacturer-reported private-sector prices.

The study sample includes 130 single-source brand-name prescription drugs that accounted for about 50 percent of U.S. sales through retail pharmacies and about 70 percent of U.S. sales of brand-name drugs through retail pharmacies in 2003. The estimates of average price are based on the quantities of those drugs sold in the United States and, with the exception of the federal ceiling price (FCP), are for the third quarter of 2003. (The FCP is calculated annually, so the estimate of average price is for calendar year 2003.) Results for other quarters in 2003 are similar. Prices exclude dispensing costs.

The "Big Four" are the four largest federal purchasers of pharmaceuticals: the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service, and the Coast Guard.

Note: See appendix for descriptions of prices and associated federal program.

Despite its name, evidence suggests that the average wholesale price does not accurately reflect either the average price or the wholesale price. Yet AWP is used as a benchmark for prescription drug reimbursement by payers throughout the healthcare industry, including WC. AWP is a price derived from self-reported drug manufacturer data, and:

- There is no requirement that it reflect the price of any actual sale of drugs by a manufacturer, or be updated at regular intervals
- It is not defined in law or regulation
- It fails to account for discounts available to various payers⁷

⁷ Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?, Dawn M. Gencarelli, National Health Policy Forum, The George Washington University, Washington DC, NHPF Issue Brief, No. 775, June 7, 2002

After years of study and much controversy, a growing number of payers are beginning to investigate alternatives to AWP as a mechanism for prescription drug reimbursement. In January 2005, Medicare began paying for most Part B drugs using a new pricing methodology based on ASP.⁸ Perhaps policymakers of WC may join this trend.

Limitations on Use of Some Drugs

The US Congress recently voted to exclude Medicare and Medicaid drug coverage for drugs prescribed for the treatment of impotence like Viagra®, Cialis®, and Levitra®. Medicaid was spending approximately \$15 million a year on these drugs.⁹

⁸ Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs, US Department of Health and Human Services, Office of Inspector General, February 2006

⁹ House Rejects Medicare, Medicaid Viagra Coverage, New York Times News Service, June 24, 2005

Impotence drugs are included in a long list of drugs typically defined as “lifestyle.” Also included in this category are hair-growth stimulants like Propecia[®], smoking-cessation agents like Nicotrol[®] or Zyban[®], weight-loss agents like Meridia[®], cosmetic applications like Botox[®], and certain dermatologic agents for the treatment of acne and rosacea.¹⁰

In addition to public programs, the private sector is also starting to take steps to curb payments for lifestyle drugs. Results of a 2004 PricewaterhouseCoopers survey of 174 large, multinational businesses on their strategies to fight rising healthcare costs showed that 15% of the companies that responded had either reduced or eliminated coverage for lifestyle drugs from the previous year.¹⁰

WC pays for some drugs typically associated with treatment of conditions that may be considered related to quality of life. Although drugs in this category represented a small percentage (0.5%) of total prescription drug paid in our study data, this may be another area to investigate for possible further cost containment.

NCCI will continue to monitor and report on prescription drugs and other important issues that affect the WC industry.

CREDITS

Contributors to this study are Lou Brown, John Robertson, Brett King, and Delano Brown of Actuarial and Economic Services; James Bonk of Data Quality Research; and Barry Llewellyn and Jim Stevens of Regulatory Services.

¹⁰ Plans Seek Ways to Control Use of Hard-to-Define “Lifestyle Drugs,” AISHealth.com, February 11, 2005

APPENDIX

Description and Estimates of Prices Paid to Manufacturers, Relative to AWP, for Brand-Name Drugs Under Selected Federal Programs, 2003		
Price	Description of Price and Associated Federal Program	Average Price as a % of AWP
Average Wholesale Price (AWP)	The AWP is a publicly available, suggested list price for sales of a drug by a wholesaler to a pharmacy or other provider. It is not the actual price that wholesalers charge but serves more like a sticker price in the automobile industry. It was chosen as the reference price for this analysis because it is commonly used in pharmaceutical transactions.	100
Average Manufacturer Price (AMP)	The AMP is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The AMP is the average price paid to a manufacturer for drugs distributed through retail and mail-order pharmacies. The AMP does not include rebates paid by the manufacturer to third-party payers. Both the AMP and the nonfederal average manufacturer price exclude sales to direct federal purchasers.	79
Nonfederal Average Manufacturer Price (Non-FAMP)	The non-FAMP is used to calculate the maximum price that manufacturers can charge the "Big Four"—the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service (PHS), and the Coast Guard—for brand-name drugs. The non-FAMP is the average price paid to the manufacturer by wholesalers (or others who purchase directly from the manufacturer) for drugs distributed to nonfederal purchasers, taking into account any cash discounts or similar price reductions given to those purchasers, but not taking into account any prices paid by the federal government. The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers.	79
Best Price	The best price is used to calculate the rebates that manufacturers are required to give to federal and state governments for sales to Medicaid beneficiaries. The best price is the lowest price paid by any private-sector purchaser for the drug product, and it includes discounts, rebates, chargebacks, and other pricing adjustments.	63
Federal Supply Schedule (FSS) Price	All direct federal purchasers of pharmaceuticals can purchase drugs at prices listed in the Federal Supply Schedule for pharmaceuticals (FSS prices). The VA negotiates FSS prices with manufacturers on the basis of the prices that manufacturers charge their most-favored commercial customers under comparable terms and conditions. Furthermore, during a multiyear contract period, those FSS prices may not increase faster than inflation.	53
Medicaid Net Manufacturer Price	The Omnibus Budget Reconciliation Act of 1990 requires manufacturers to pay a rebate to the Medicaid program. For brand-name drugs, the basic rebate is equal to the greater of 15.1% of the AMP or the difference between the AMP and the best price. There is an additional rebate if the AMP rises faster than inflation. The Medicaid net manufacturer price is the AMP minus all rebates.	51
340B Ceiling Price	Section 340B of the Public Health Service Act of 1992 extends the Medicaid drug rebate program to PHS-funded clinics and disproportionate share hospitals. Eligible entities are free to negotiate steeper discounts than the Medicaid rebate amount. Not all eligible entities choose to participate in the program, however.	51
Federal Ceiling Price (FCP)	The FCP is the maximum price that manufacturers can charge the Big Four for brand-name drugs. It is calculated annually. In the first year of an FSS contract, the FCP equals 76 % of the previous fiscal year's non-FAMP minus an additional discount if the non-FAMP rises faster than inflation. In subsequent years of a multiyear contract, the FCP also cannot exceed the previous year's FSS price, increased by inflation.	50

Price	Description of Price and Associated Federal Program	Average Price as a % of AWP
Price Available to the Big Four	Under the federal ceiling price program, the Big Four purchase brand-name drugs at a price that cannot exceed the FCP. About two-thirds of the brand-name drug products on the FSS have one FSS price (which cannot exceed the FCP). The remaining one-third of the brand-name drug products have both an FSS price, offered to all non-Big Four purchasers, and an FSS Big 4 price, offered to the Big Four. The price available to the Big Four is the FSS Big 4 price when it exists and is the FSS price offered to all federal purchasers otherwise.	49
Veterans Affairs (VA) Average Price	The VA average price for a drug may be lower than the price available to the Big Four because the VA negotiates further price reductions using its preferred formulary. The VA average price takes into account all the various pricing schedules and contracts under which VA purchases drugs, and it includes discounts from the prime vendor that averaged about 3% of the contract price in 2003, or about 1.4% of the AWP.	42
DoD's Military Treatment Facility (MTF) Average Price	The DoD military treatment facility average price for a drug may be lower than the price available to the Big Four because DoD negotiates further price reductions using its preferred formularies. The MTF average price takes into account all the various pricing schedules and contracts under which DoD purchases drugs.	41

Source: Congressional Budget Office.

Notes: In this analysis, the list price is the average wholesale price

The study sample includes 130 single-source brand-name prescription drugs that accounted for about 50% of US sales through retail pharmacies and about 70% of US sales of brand-name drugs through retail pharmacies in 2003. The estimates of average price are based on the quantities of those drugs sold in the United States and, with the exception of the FCP, are for the third quarter of 2003. (The FCP is calculated annually, so the estimate of average price is for Calendar Year 2003.) Results for other quarters in 2003 are similar. Prices exclude dispensing costs

^a Injury years 1998 to 2003 evaluated as of July 1, 2004. Additionally, service year figures include data from injury years prior to 1998.

^b WC looks at costs by accident year (the year of injury) because insurance coverage continues (potentially for many years) following the date of injury in WC. This “long-tail” feature of WC is distinct from most other lines of insurance coverage, which are normally confined to the 12-month calendar year (or service year) for which premium is charged. As a result, other types of insurance coverage are much more sensitive to short-term increases in costs, while WC is subject to substantial long-term cost pressures.

^c Selective COX-2 Inhibitors are nonsteroidal anti-inflammatory drugs (NSAIDs) designed to perform the functions of an anti-inflammatory and painkiller (like traditional NSAIDs), while minimizing the potential for gastrointestinal side effects.

^d **Average Wholesale Price (AWP)** is the most commonly used price benchmark for ingredient cost. The total price of a prescription is: Ingredient Cost (which includes the costs of R&D, marketing and profit) + Dispensing Fee + Tax. AWP's are reported by drug manufacturers to organizations that publish the data in compendia (e.g., Red Book), which are used by Medicare and other third parties to calculate prescription drug reimbursement. The AWP is not the acquisition cost paid by suppliers and physicians, as it does not reflect rebates and discounts. AWP is not defined by law or regulation.

^e **Average Sales Price (ASP)** is a manufacturer's unit sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of drug units sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program. Certain sales are exempt from the calculation of ASP, including sales at a nominal charge. Manufacturers report ASPs to the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis by national drug code. This method of calculation is described in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and the Social Security Act.⁷

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