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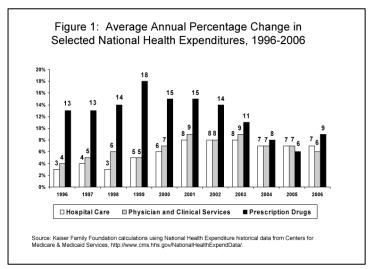
Prescription Drug Trends

Overview

Prescription drugs are vital to preventing and treating illness and in helping to avoid more costly medical problems. Rising costs and implementation of the Medicare Part D drug benefit in 2006 have highlighted the need for a better understanding of the pharmaceutical market and for new approaches to address increasing prescription costs.

Rising Expenditures for Prescription Drugs

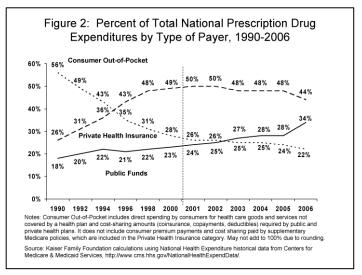
Spending in the US for prescription drugs was \$216.7 billion in 2006, more than 5 times the \$40.3 billion spent in 1990.¹ Although prescription drug spending has been a relatively small proportion of national health care spending (10% in 2006, compared to 31% for hospitals and 21% for physician services), it has been one of the fastest growing components, until recently growing at double-digit rates compared to single-digit rates for hospital and physician services. In 2006, the annual rate of increase in prescription spending was 9%, compared to 7% for hospital care and 6% for physician services² (Figure 1).



Prescription spending growth slowed from 1999 to 2005 because of the increased use of generic drugs, the increase in tiered copayment benefit plans, changes in the types of drugs used, and a decrease in the number of new drugs introduced.

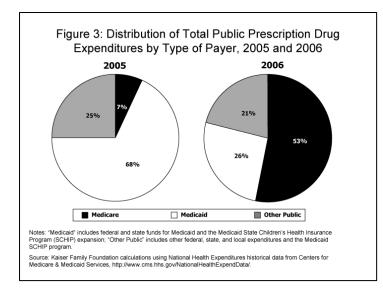
The growth in drug spending in 2006 resulted from 1) increased use of prescription drugs, attributed to the implementation of Medicare Part D, new indications for existing drugs, strong growth in several therapeutic classes, and increased use of specialty drugs; 2) lower rebates from drug manufacturers; and 3) changes in the therapeutic mix of drugs.³

The share of prescription drug expenses paid by private health insurance increased substantially over the past sixteen years (from 26% in 1990 to 44% in 2006), contributing to a decline in the share that people paid out-of-pocket (from 56% in 1990 to 22% in 2006). The government's share of expenditures remained fairly constant. However, the implementation of the Medicare Part D drug program in 2006 substantially changed the mix of funding sources, as the government's share rose from 28% in 2005 to 34% in 2006, the private insurance portion fell from 48% to 44%, and the consumer out-of-pocket share declined from 24% to 22% (Figure 2).



Within public funds, the funding shares changed from 7% Medicare and 68% Medicaid in 2005, to 53% Medicare and 26% Medicaid in 2006 (Figure 3).

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Factors Driving Changes in Prescription Spending

Three main factors drive changes in prescription drug spending: changes in the number of prescriptions dispensed (utilization), price changes, and changes in the types of drugs used.

Utilization. From 1997 to 2007, the number of prescriptions purchased increased 72% (from 2.2 billion to 3.8 billion), compared to a US population growth of 11%. The average number of retail prescriptions per capita increased from 8.9 in 1997 to 12.6 in 2007.⁴ The percent of the population with a prescription drug expense in 2005 was 59% for those under age 65, and 91% for those 65 and older; the proportions of these populations with a drug expense has changed little since 1997, when they were 59% and 86%, respectively.⁵

Price. Prescription drug prices increased at the same rate in 2006 as in 2005 (3.5%).⁶ Retail prescription prices⁷ (which reflect both manufacturer price changes for existing drugs and changes in use to newer, higher-priced drugs) increased an average of 6.9% a year from 1997 to 2007 (from an average price of \$35.72 to \$69.91), more than two and a half times the average annual inflation rate of 2.6% over the same period. The average brand name prescription price in 2007 was over 3 times the average generic price (\$119.51 vs. \$34.34). Of the average retail prescription price of \$69.91, manufacturers received 78%, retailers received 19%, and wholesalers received 4% in 2007.⁸

Changes in Types of Drugs Used. Prescription drug spending is affected when new drugs enter the market and when existing medications lose patent protection. New drugs can increase overall drug spending if they are used in place of older. less expensive medications; if they supplement rather than replace existing drugs treatments; or if they treat a condition not previously treated with drug therapy. New drugs can reduce drug spending if they come into the market at a lower price than existing drug therapies; this can occur when a new drug enters a therapeutic category with one or two dominant brand competitors. New drug use is affected by the number of new drugs (new molecular entities) approved by the US Food and Drug Administration; approvals have fluctuated over the past decade, with 39 approvals in 1997, 27 in 2000, 20 in 2005, and 18 in 2006.⁸

Drug spending is also typically reduced when brand drugs lose patent protection and face competition from new, lower cost generic substitutes. FDA analysis shows that generic competition is associated with lower drug prices: on average, the first generic competitor prices its product only slightly lower than the brand-name manufacturer; the second generic manufacturer reduces the average generic price to nearly half the brand name price; prices continue to fall but more slowly as additional generic manufacturers market the product. For products with a large number of generics, the average generic price falls to 20% of the branded price and lower.¹⁰

Approximately three-quarters of FDA-approved drugs have generic counterparts. In 2007, 21% of total prescription drug sales and 65% of total prescriptions dispensed were generic medicines. Generic sales grew 8% from 2005 to 2006.¹¹ Federal legislation allowing FDA approval of generic substitutes for brand name biologic drugs was introduced in 2007 but has not as yet been enacted.

Advertising. Both prescription use and shifts to higher-priced drugs can be influenced by advertising. After increasing every year since 1996, the total amount manufacturers spent on advertising declined from 2004 to 2005 (from \$11.9 billion to \$11.4 billion), rose to \$12.0 billion in 2006, and fell to \$10.4 billion in 2007. The share directed toward consumers (through advertising on television, radio, magazines, newspapers, and outdoor advertising) decreased from 2006 to 2007 (from \$4.8 to \$3.7 billion), and the share directed toward physicians (through the sales activities of pharmaceutical representatives and through professional journals) also decreased (from \$7.2 to \$6.7 billion). Spending for consumer advertising in 2007 was over 4 times the amount spent in 1996 (\$3.7 billion vs. \$0.8 billion), while 2007 physician advertising was almost 2 times the 1996 amount (\$6.7 billion vs. \$3.5 billion).¹² The FDA and Congress are considering changes to prescription advertising rules.

Profitability. From 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry (profits as a percent of revenues). They ranked 3rd in profitability in 2003 and 2004, 5th in 2005, 2nd in 2006, and 3rd in 2007, with profits of 15.8% compared to 5.7% for all Fortune 500 firms in 2007.¹³ Prescription drug sales were \$286.5 billion in 2007, an increase of 3.8% over 2006, the smallest growth rate since 1961. IMS Health attributes slower sales growth to loss of exclusivity of brand name medicines, fewer new product approvals, the leveling of year-over-year growth from the Medicare Part D program, and the impact of safety issues.¹⁴

Insurance Coverage for Prescription Drugs

Lack of insurance coverage for prescription drugs can have adverse effects. An April 2008 survey found that uninsured nonelderly adults (ages 18-64) are more than twice as likely as insured nonelderly adults to say that they or a family member did not fill a prescription (45% vs. 22%) or cut pills or skipped doses of medicine (38%vs.18%) in the past year because of the cost.¹⁵

Prescription drug coverage comes from a variety of private and public sources:

Employer Coverage. Employers are the principal source of health insurance in the United States, providing coverage for 177 million (59%) of Americans in 2007.¹⁶ Sixty percent of employers offered health insurance to their employees in 2007, and 65% of employees in those firms are covered by their employer's health plan.¹⁷ Other employees may have obtained coverage through a spouse. Nearly all (98%) of covered workers in

employer-sponsored plans had a prescription drug benefit in 2007.¹⁸

Medicare. Prior to January 1, 2006, the traditional Medicare program (the federal health program for the elderly and disabled) did not provide coverage for outpatient prescription drugs. As a result, about one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage in 2003.¹⁹ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a voluntary Medicare outpatient prescription drug benefit (known as Part D), effective January 1, 2006, under which the 44 million Medicare beneficiaries can enroll in private drug plans. These plans vary in benefit design, covered drugs, and utilization management strategies.

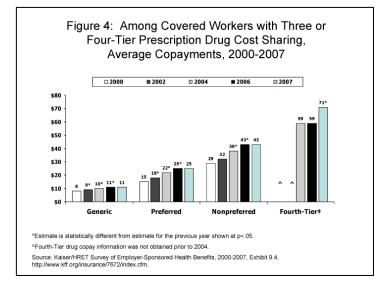
Department of Health and Human Services (HHS) data show that as of January 2008, approximately 90% of Medicare beneficiaries had drug coverage: 25.4 million beneficiaries had Medicare Part D drug coverage from either a stand-alone prescription drug plan (17.4 million, including 6.2 million low-income seniors and people with disabilities, known as dual eligibles, who were transferred from Medicaid drug coverage to Medicare Part D drug coverage), a Medicare Advantage drug plan (7.6 million), or other Medicare health plan types (0.4 million). Another 10.2 million beneficiaries had coverage from creditable employer or union retiree plans including FEHB and TRICARE retiree coverage. And an estimated 4.0 million beneficiaries had creditable drug coverage from the VA and other sources. About 4.6 million beneficiaries did not have creditable coverage (were not enrolled in a Part D drug plan or a source of creditable coverage).²⁰

Medicaid. Medicaid is the joint federal-state program that pays for medical assistance to 60 million low-income individuals and is the major source of outpatient pharmacy services to the lowincome population. All state Medicaid programs provide coverage for prescription drugs, although there are important differences in state policies with regard to copayments, preferred drugs, and the number of prescriptions that can be filled. Approximately 6 million dual eligibles were transferred from Medicaid drug coverage to Medicare Part D drug coverage in January 2006; they represented an estimated 14% of Medicaid beneficiaries and accounted for about 45% of Medicaid prescription drug spending in FY2003.²¹ Since January 1, 2006, states have been required to make payments to Medicare to help finance Medicare drug coverage for the transferred and future dual eligibles.

Responses to Increasing Prescription Costs

A variety of public and private strategies have been implemented to attempt to contain rising costs for prescription drugs, as described below.

Utilization Management Strategies. Health plans have responded to increasing prescription drug costs by excluding certain drugs from coverage, using quantity dispensing limits, and increasing enrollee cost-sharing amounts. In 2007, three-guarters (75%) of workers with employersponsored coverage had a cost-sharing arrangement with 3 or 4 tiers, over 21/2 times the proportion in 2000 (27%).²² Copayments for nonpreferred drugs (those not included on a formulary or preferred drug list) increased 48% from an average of \$29 in 2000 to \$43 in 2007. Copayments for preferred drugs (those included on a formulary or preferred drug list, such as a brand name drug without a generic substitute) increased by 67%, from an average of \$15 in 2000 to \$25 in 2007 (Figure 4).



Discounts and Rebates. Private and public drug programs negotiate with pharmaceutical manufacturers (often using contracted organizations known as pharmacy benefit managers) to receive discounts and rebates which are applied based on volume, prompt payment, and market share. Manufacturers who want their drugs covered by Medicaid must provide rebates to state Medicaid programs for the drugs they purchase; many states have also negotiated additional rebates, known as supplemental rebates.

Several government agencies, including the Department of Veterans Affairs, the Defense Department, the Public Health Service, and the Coast Guard, participate in a program known as the Federal Supply Schedule through which they purchase drugs from manufacturers at prices equal to or lower than those charged to their "mostfavored" nonfederal purchasers. In order to participate in Medicaid, another program, the Section 304B Program, requires manufacturers to provide drugs to certain nonfederal entities (such as community health centers and disproportionate share hospitals) at reduced prices. Federal legislation to expand this program was introduced in 2007 but has not as yet been enacted.

Medicaid. Historically, prescription drugs have been one of the fastest-growing Medicaid services. The Deficit Reduction Act of 2005 gave states more authority to control Medicaid drug spending through increased cost sharing for non-preferred drugs, changes in the way Medicaid pays pharmacists, allowing pharmacists to refuse prescriptions for beneficiaries who don't pay their cost sharing, and inclusion of authorized generic drugs in the calculation of "best price" for drugs. A 2006 survey of 50 states+DC found that more than half had Medicaid pharmacy cost containment measures in place in FY2006, including preferred drug lists and prior authorization programs (about 75% of states), supplemental rebates from manufacturers (about 70% of states), and state Maximum Allowable Cost programs for generic and multi-source brand drugs (about 60%); smaller proportions of states were members of multi-state purchasing coalitions (about 25%) or had limits on quantities dispensed per prescription (about 20%).²³ BY 2007, most states had already implemented many of these approaches, so new action to control drug spending slowed.24

The Centers for Medicare & Medicaid Services issued a rule (known as the AMP Rule) in July 2007 that would have set limits on federal government reimbursements to states for Medicaid prescriptions; however, in December 2007, a US District Court issued a preliminary injunction against this change. Several bills have been introduced in Congress to address this issue.

Medicare. The Medicare Part D drug benefit shifted spending from the private sector and Medicaid to Medicare, making Medicare the nation's largest public payer of prescription drugs in 2006, when Medicare spending rose to 18% of total US prescription spending from 2% in 2005.²⁵ Under the Medicare Part D legislation, Medicare is prohibited from directly negotiating drug prices or rebates with manufacturers, but will rely on the private Part D drug plans to negotiate these discounts/rebates. In early 2007, the 110th Congress considered but did not pass legislation to allow or require Medicare to negotiate drug prices with drug makers.

Purchasing Pools. Some public and private organizations have banded together to form prescription drug purchasing pools to increase their purchasing power through higher volume and shared expertise. Examples include joint purchasing by the Department of Defense and VA; multi-state bulk buying pools through which states purchase drugs for their Medicaid, state employees, senior/low-income/uninsured pharmacy assistance programs, or other public programs; and individual state purchasing pools.²⁶

Consumers. Consumers are turning to a variety of methods to reduce their prescription costs,²⁷ including requesting cheaper drugs or generic drugs from their physicians and pharmacies, using the Internet and other sources to make price comparisons, using the Internet to purchase drugs, buying at discount stores, buying over-the-counter instead of prescribed drugs, buying drugs in bulk and pill-splitting, using mail-order pharmacies,²⁸ and using pharmaceutical company or state drug assistance programs. Over half of physicians say they frequently talk with patients about the out-of-pocket costs of medicines they prescribe, 62% say they switch patients to less expensive drugs, and 58% say they give patients office samples.²⁹

Importation. The high cost of prescriptions has led some to suggest that individuals be permitted to purchase prescription products from distributors in Canada or other countries (called "importation,"

or "reimportation" if the drug is manufactured in the US). Although it is generally not lawful for individuals or commercial entities such as pharmacies or wholesalers to purchase prescription drugs from other countries, the government does not always act to stop individuals from purchasing drug products abroad. Importation of pharmaceutical products from Canada through Internet sales and travel to Canada totaled about \$700 million in sales in 2003, or 0.3% of total US prescription sales. An equivalent amount of prescription drugs was estimated to have entered the US from the rest of the world, mostly through the mail and courier services.³⁰ P.L. 109-295 (enacted in 2006) allows US residents to transport up to a 90-day supply of qualified drugs from Canada to the US. Actual savings amounts, drug safety, and marketplace competition and pricing are importation issues being debated.

Outlook for the Future

HHS projects US prescription drug spending to increase from \$216.7 billion in 2006 to \$515.7 billion in 2017, a 138% increase in 11 years. The average annual increase in drug spending from the previous year is projected to drop from 8.5% in 2006 to 6.7% in 2007 because of a deceleration in drug price growth, and then rise to 9.6% in 2017, or an 8.2% average annual increase over the 11-year period. Drug spending as a percent of overall health spending is projected to increase from 10% in 2006 to 12% in 2017. HHS projects that over the next decade, drug spending growth will accelerate due to a leveling off of growth in the use of generic drugs, rising utilization rates, and a mild acceleration in new drugs coming onto the market.³¹

http://www.cms.hhs.gov/NationalHealthExpendData/.

¹ All spending amounts in this report are in current dollars (i.e., not adjusted for inflation).

² Centers for Medicare & Medicaid Services, National Health Expenditure Accounts, Historical,

³ Aaron Catlin et al., "National Health Spending In 2006: A Year Of Change For Prescription Drugs," *Health Affairs* 27, no. 1, (January/February 2008).

⁴ Kaiser Family Foundation calculations using data from IMS Health, <u>http://www.imshealth.com</u> (About Us, Press Room, US Top-Line Industry Data), and Census Bureau, <u>http://www.census.gov</u>. The per capita number may differ from the number reported at KFF's website <u>www.statehealthfacts.org</u> because of differing data sources which use different retail pharmacy definitions (e.g., IMS Health includes mail order, Verispan does not).

⁵ Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey Component Data, "Prescription Medicines – Mean and Median Expenses per Person With Expense and Distribution of Expenses by Source of Payment," table 2, 1997 and 2005, http://www.meps.ahrg.gov/mepsweb/.

⁶ Aaron Catlin et al., "National Health Spending In 2006: A Year Of Change For Prescription Drugs," Health Affairs 27, no. 1, (January/February 2008).

Retail prescription prices reflect the prices paid by insured and uninsured patients, and do not reflect rebates, discounts, and other payments that in effect lower the cost of prescriptions.

Kaiser Family Foundation calculations using data from the National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," http://www.nacds.org (based on data from IMS Health), and Consumer Price Index, US City Average, All items, from the Bureau of Labor Statistics, http://www.bls.gov.

⁹ US Food and Drug Administration, http://www.fda.gov/cder/rdmt/; 2004-2007 data include new BLAs (biologic license applications) for therapeutic biologic products transferred from FDA's Center for Biologics Evaluation and Research to its Center for Drug Evaluation and Research.

¹⁰ US Food and Drug Administration, Center for Drug Evaluation and Research, "Generic Competition and Drug Prices,"

http://www.fda.gov/cder/ogd/generic competition.htm. Generic Pharmaceutical Association,

http://www.gphaonline.org/Content/NavigationMenu/AboutGenerics/St atistics/default.htm

IMS Health, http://www.imshealth.com (About Us, Press Room, 2007 US Top-Line Industry Data); Kaiser Family Foundation, Prescription Drug Trends, a chartbook, (July 2000), ex. 3.13,

http://www.kff.org/rxdrugs/3019-index.cfm. The data on spending for advertising directed towards physicians excludes the retail value of drug samples left at sales visits to physicians' offices, which totaled about \$16 billion in 2004, the last year such data were available online from IMS Health.

³ Fortune 500 online,

http://money.cnn.com/magazines/fortune/fortune500/2008/performers/i ndustries/profits/index.html, and personal communication; April issues of Fortune magazine.

"Moderating Growth Reflects Impact of Patent Expirations, Fewer Product Approvals, Maturing Medicare Part D Program, and Safety Issues," IMS Health Press Release (March 12, 2008),

http://imshealth.com/ims/portal/front/articleC/0,2777,6599 3665 83470 <u>499.00.html</u>. ¹⁵ Kaiser Family Foundation, Kaiser Public Opinion Survey Brief,

Economic Problems Facing Families (April 2008), p. 4, http://www.kff.org/kaiserpolls/upload/7773.pdf.

US Census Bureau, Income, Poverty and Health Insurance Coverage in the United States: 2007 (August 2008), Table C-1, p. 61, http://www.census.gov/prod/2008pubs/p60-235.pdf

Kaiser Family Foundation and Health Research and Educational Trust, Employer Health Benefits 2007 Annual Survey (September 2007), pp. 36 and 51,

http://www.kff.org/insurance/7672/upload/76723.pdf

 ¹⁸ Ibid, p. 134, <u>http://www.kff.org/insurance/7672/upload/76723.pdf</u>.
¹⁹ Dana Gelb Safran et al., "Prescription Drug Coverage And Seniors: Findings From A 2003 National Survey," Health Affairs, Web Exclusive (April 19, 2005): W5-160,

http://www.kff.org/medicare/med041905pkg.cfm. ²⁰ Kaiser Family Foundation, *The Medicare Prescription Drug Benefit*, (February 2008), http://www.kff.org/medicare/upload/7044_08.pdf.

Kaiser Family Foundation calculations using data from John Holahan and Arunabh Ghosh, Dual Eligibles: Medicaid Enrollment and Spending for Medicare Beneficiaries in 2000 (Kaiser Commission on Medicaid and the Uninsured, July 2005), 8,10,21, http://www.kff.org/medicaid/7346.cfm

Kaiser Family Foundation and Health Research and Educational Trust, op. cit., Ex. 9.1,

http://www.kff.org/insurance/7672/sections/ehbs07-9-1.cfm. 23 Kaiser Family Foundation calculations using data from Vernon Smith et al., Low Medicaid Spending Growth Amid Rebounding State Revenues: Results from a 50-State Medicaid Budget Survey, State Fiscal Years 2006 and 2007 (Kaiser Commission on Medicaid and the Uninsured, October 2006), 39, fig. 24,

http://www.kff.org/medicaid/upload/7569.pdf.

²⁴ Kaiser Commission on Medicaid and the Uninsured, *Few Options for* States to Control Medicaid Spending in a Declining Economy (April 2008), p. 3, http://www.kff.org/medicaid/upload/7769.pdf.

Aaron Catlin et al., op.cit., ex. 4, p. 19.

²⁶ National Conference of State Legislatures, "Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans, 2008 edition" (Updated May 8, 2008), <u>http://www.ncsl.org/programs/health/bulkrx.htm</u>. ²⁷ Devon Herrick, National Center for Policy Analysis, *Shopping for*

Drugs: 2004, National Center for Policy Analysis, Policy Report No. 270 (October 2004), http://www.ncpa.org/pub/st/st270

²⁸US mail services sales have increased 54% since 2003, though their share of total US prescription sales has increased only slightly -- 2007: \$44.6 billion in sales, 16% of total prescription sales; 2003: \$28.9 billion in sales, 13% of total prescription sales. IMS Health, http://www.imshealth.com (About Us, Press Room, US Top-Line Industry Data, 2007 U.S).

Kaiser Family Foundation, Prescription Drugs: Advertising, Out-of-Pocket Costs, and Patient Safety from the Perspective of Doctors and Pharmacists (November 2006),

http://www.kff.org/kaiserpolls/upload/7583.pdf.

US Department of Health and Human Services Task Force on Drug Importation, Report on Prescription Drug Importation (December 2004), ix, http://www.hhs.gov/importtaskforce/Report1220.pdf.

Sean Keehan et al., "Health Spending Projections Through 2017: The Baby-Boom Generation Is Coming To Medicare," Health Affairs, Web Exclusive (February 26, 2008), w145-w155.

For More Information:

In addition to the Kaiser Family Foundation reports found in the Endnotes above, this Fact Sheet (#3057-07) and the following reports are available on the Foundation's website at www.kff.org: Trends and Indicators in the Changing Health Care Marketplace (#7031), Prescription Drug Trends—A Chartbook Update (#3112), Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature (#7295), Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain (#7296), Medicare Prescription Drug Benefit Fact Sheet (#7044-08), Medicare Payments and Beneficiary Costs for Prescription Drug Coverage (#7620), Resources on the Medicare Prescription Drug Benefit, Medicaid and Outpatient Prescription Drugs (#1609-03), Federal Policies Affecting the Cost and Availability of New Pharmaceuticals (#3254), and Retiree Health Benefits Examined: Findings from the Kaiser/Hewitt 2006 Survey on Retiree Health Benefits (#7587). See also www.statehealthfacts.org for state-specific prescription drug utilization and sales (under Health Costs & Budgets); www.kaiserEDU.org (Prescription Drugs) for a Tutorial, Issue Modules, and SmartLinks on prescription drugs; and http://facts.kff.org/ (search for Prescription Drugs) for Fast Facts about prescription drugs.

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