

Prescription Drug Trends

a chartbook



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executive summary

Prescription drug coverage, expenditures, and prices are generating considerable interest. Although we increasingly look to medicines to maintain or improve our health, concerns are expressed about the rising cost of prescription drugs and its impact on health plans, employers, and uninsured individuals. Other issues include the lack of outpatient prescription drug coverage under Medicare (the nation's program of health coverage for the aged and disabled); methods for determining the price of drugs both nationally and internationally; and the development, approval process, and pricing for new drugs. This Chartbook provides information about the trends in prescription drug coverage, spending, prices, use, and industry structure. The Chartbook also includes a Glossary and a list of Sources of Information.

Insurance Coverage

- Just over three-quarters (77%) of the non-Medicare population had coverage for prescription drugs in 1996, primarily through employers (61%), followed by Medicaid (11%), private nongroup and other private coverage (4%), and other coverage (1%). Less than one-quarter (23%) of the non-Medicare population had no drug coverage in 1996.
- In contrast, almost a third (31%) of Medicare beneficiaries had no drug coverage in 1996.
 Coverage was primarily through employers (31%), followed by Medicaid (11%), individually purchased plans (10%), Medicare risk HMOs (8%), or other sources (9%).
 Only slightly more than half (53%) of Medicare beneficiaries had drug coverage for an entire year.
- The primary source of prescription drug coverage for most Americans (both non-Medicare and Medicare) is through their employers. About two-thirds of Americans have employment-based health care coverage, and prescription drug coverage is now the norm in these plans—99% of employees in employer plans have drug coverage.
- Medicaid is the largest source of public coverage for prescription drugs, covering just over a tenth (11%) of Americans in 1996.

- Expenditure increases for prescription drugs have been affected by a dramatic shift in the share of prescription expenditures paid for by private insurance (from 34% in 1990, to 51% in 1998), and a corresponding decrease in consumer out-of-pocket payments (from 48% to 28% over the same time period). Government programs have maintained a relatively steady share of payments (21% in 1998).
- Both the average number of prescriptions used and the average amount spent per prescription are higher among individuals with prescription coverage.

Expenditures

- Although national expenditures for prescription drugs (\$91 billion in 1998) still comprise a small proportion (9%) of total personal health care expenditures, they have been one of the fastest growing components of health care spending in the past decade, increasing 15% from 1997 to 1998 compared to 5% for all personal health care spending. In the past 5 years, the increases in prescription expenditures have been 2 to 4 times the percent changes in expenditures for most other health care services.
- Relative to expenditures for other household consumer goods and services, prescription and nonprescription drugs play a very small role (about 1.0%) in average out-of-pocket consumer spending each year, though they are more significant for seniors, rising to 2.7% of household spending by individuals aged 65 and older.
- Compared to other countries, the U.S. market (in terms of total prescription drug sales by manufacturers and wholesalers) is the largest. On a per capita or percentage of gross domestic product basis, however, U.S. spending is similar to other industrialized countries.

 Increases in prescription drug expenditures are influenced by three primary factors: price increases, utilization increases, and changes in the types of prescriptions used. Price changes for existing drugs have contributed less (18%) to the increases in prescription drug expenditures since 1993 than have increased utilization (43%) or changes in the types of drugs used (39%), with new and more expensive drugs typically replacing older drugs in the same therapeutic category.

Prices

- When a pharmacy sells a prescription to a consumer, on average about \$0.74 of each dollar in sales goes to the manufacturer that made the drug, \$0.03 to the wholesaler that distributes the drug, and \$0.23 to the pharmacy that sells the drug to the consumer.
- Retail prescription drug price increases differ from manufacturer price increases because retail price increases reflect not only manufacturer price increases for existing drugs but also shifts in use from older, less expensive drugs to newer, more expensive drugs over time.
- The average annual increase in the retail price of a prescription was 6.7% from 1991 to 1998, exceeding both general inflation (2.6% for the CPI) and medical care inflation (4.6% for the medical care component of the CPI). Prices of prescriptions for brand name drugs increased more rapidly (8.8% per year) than for generic drugs (6.5% per year).
- Average pharmaceutical manufacturer price increases have stood at less than 4% every year since 1992.
- Brand name drugs representing new approaches to treat diseases typically cost more than their precursors, and prescriptions dispensed for brand name drugs are, on average, 3 times more expensive than prescriptions for generic drugs.

Utilization

- On average, Americans use about 10 prescriptions per year.
- Utilization of prescription drugs has accelerated rapidly. Between 1992 and 1998, the number of prescriptions dispensed increased by 37%, compared to a 6% growth in the U.S. population. The increasing median age of the U.S. population with potential for increased drug use, plus an increasing number of licensed prescribers, have contributed to overall growth in prescription utilization.
- To stimulate the use of prescription drugs and, particularly, new therapies, manufacturers promote prescription drugs in several ways. The largest type of promotional spending is "detailing" (\$5.7 billion in 1998), where a company representative makes personal selling visits to physicians in offices and hospitals and leaves samples. Directto-consumer advertising (\$1.3 billion in 1998) is a relatively recent phenomenon that has grown dramatically, with nearly a 5-fold increase in spending overall since 1994, and nearly a 20-fold increase for television advertising since 1994. Many of the products with the most direct-to-consumer advertising are also among the top prescription drugs by sales and by number of prescriptions dispensed.

Types of Drugs Used

- New drugs receive considerable attention, and their use and popularity are important in maintaining revenue for manufacturers because considerable market erosion occurs when drug patents expire.
- Although almost 45% of all prescriptions dispensed are for generic drugs, they account for less than 20% of prescription sales in dollar terms because they are less expensive than brand name drugs. Sales of generic drugs have not kept pace with sales of brand name drugs, as new, innovative drugs carrying higher prices replace older drugs.

- Recent increases in average retail prescription prices are related more to changes in the type of drugs dispensed (to newer, higher cost drugs) than to year-to-year manufacturer price increases for existing drugs.
- Research and development activities of pharmaceutical manufacturers are a factor in the number of new drugs available each year, with research and development expenditures reaching \$21 billion, or 17% of prescription drug sales, in 1998.
- The average number of new drugs approved by the U.S. Food and Drug Administration (FDA) per year has increased (from 19 per year in the early 1980s to 38 per year in the late 1990s), and the length of time for FDA approval of new drugs has decreased (from an average of 33 months in 1986 to 12 months in 1998), contributing to the number of new prescription drugs on the market.

The Prescription Drug Industry

- Traditional measures of market structure and sales concentration suggest that pharmaceutical manufacturers are a relatively competitive industry. However, within many therapeutic categories, competition is limited to only a few firms, with the potential for considerable market power. Financially, pharmaceutical manufacturers have been the top ranking U.S. industry for profits as a percent of revenue throughout the past decade.
- In spite of being a very concentrated market as an industry, drug wholesalers have grown more efficient, with declining operating costs and relatively small gross margins and net profits.

 Overall, the retail pharmacy industry is a moderately concentrated market, with the top 8 firms representing almost half of all retail prescription sales nationwide. Mergers and acquisitions among chain pharmacies have increased this market concentration. Although the average retail prescription price has increased, pharmacy gross margins as a percent of sales have decreased, in part due to increased financial pressure from health plans with greater negotiating power than individual consumers.

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Trends in Insurance Coverage for Prescription Drugs

In the past decade, the proportion of prescription drug expenditures paid out-of-pocket by consumers has decreased, shifting instead to private insurers. This shift in insurer payment for prescription drugs has been an important factor influencing the growth of prescription use and expenditures, since increased insurance coverage (both new coverage for the uninsured and expanded coverage for those already insured) may encourage increased use of the health care service covered. However, almost a quarter of the non-Medicare population and almost a third of the Medicare population are still without prescription drug coverage.

Coverage Rates for Prescription Drugs

- Just over three-quarters (77%) of the non-Medicare population had prescription drug coverage in 1996, primarily through their employer (61%); the remainder were covered through Medicaid (11%), private nongroup and other private sources (4%), or other coverage (1%). Less than one-quarter (23%) of the non-Medicare population had no drug coverage in 1996, consisting mostly of those without any health insurance at all (exhibit 1.1). The near poor (between 100% and 200% of the Federal Poverty Level) are most likely to be without drug coverage.¹
- In contrast, almost a third (31%) of Medicare beneficiaries had no drug coverage in 1996. Because Medicare does not cover outpatient prescription drugs, coverage was primarily through employers (31%), followed by Medicaid (11%), individually purchased plans (10%), Medicare risk HMOs (8%), or other sources (9%) (exhibit 1.1). Although 69% of Medicare beneficiaries had drug coverage for at least one month in 1996, only slightly more than half (53%) were covered for the entire year.² Medicare beneficiaries who are near poor, very old, and living in rural areas are most likely to be without drug coverage.³

¹ U.S. Department of Health and Human Services, Prescription Drug Coverage, Spending, Utilization, and Prices – Report to the President, April 2000, pp. 34–35, based on the 1996 Medical Expenditure Panel Survey Household Component.

² Stuart, B. et al., Prescription Drug Costs for Medicare Beneficiaries: Coverage and Health Status Matter, The Commonwealth Fund, January 2000, p. 2.

³ U.S. Department of Health and Human Services, *Prescription Drug Coverage, Spending, Utilization, and Prices – Report to the President*, April 2000, pp. 25–33, based on the 1996 Medicare Current Beneficiary Survey Cost and Use File.

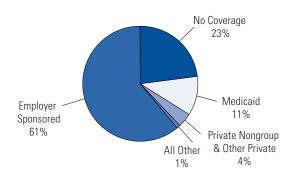
- The primary source of prescription drug coverage for most Americans (both non-Medicare and Medicare) is through their employers. About two-thirds of Americans have employment-based health care coverage, and prescription drug benefits are now nearly universal for employees of both small and large firms who are offered any health insurance at all (exhibit 1.2). The percent of insured workers with coverage for prescriptions increased from 91% in 1988 to 99% in 1999. About two-thirds of large employers (67%) provide health benefits to retirees aged 65 and older, and almost all large employers (98%) who provide health coverage to Medicare-eligible retirees include prescription drug benefits (small employers are less likely to provide coverage).4
- Medicaid is the largest source of public coverage for prescription drugs, covering just over a tenth (11%) of Americans in 1996 (exhibit 1.1). Although outpatient prescription drug coverage is optional under Medicaid, all states provide this benefit for families and children, and certain low-income Medicare beneficiaries may also qualify for Medicaid benefits.

⁴ Kaiser Family Foundation, Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits, prepared by Hewitt Associates, October 1999, pp. 4, 9.

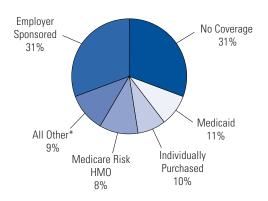
Insurance Coverage for Prescription Drugs, 1996 exhibit

1.1





Medicare Population (N=37.2 million)



note

*All Other within the Medicare population includes persons who switched coverage at some time during the year, totalling 7.3% of beneficiaries.

sources

Non-Medicare Coverage from U.S. Department of Health and Human Services, Prescription Drug Coverage, Spending, Utilization, and Prices, April 2000, based on data from the 1996 Medical Expenditure Panel Survey Household Component.

Medicare Coverage from Poisal, J.A. and Chulis, G.S., "Medicare Beneficiaries and Drug Coverage," Health Affairs, March/April 2000, pp. 248–256.

Coverage of Prescriptions for Insured Workers in Conventional, HMO, PPO, and POS Plans, by Employer Firm Size, 1988 and 1999

exhibit 1.2

	All Emp	loyers	All Small I (3–199 V	Employers Vorkers)	0	Employers Vorkers)
	1988	1999	1988	1999	1988	1999
Conventional Plans	91%	96%	90%	89%	94%	100%
HMO Plans	91%	99%	92%	92%	90%	100%
PPO Plans	93%	99%	80%	97%	99%	100%
POS Plans	N/A	99%	N/A	99%	N/A	99%
All Plan Types	91%	99%	89%	97%	94%	100%

notes

HMO = Health Maintenance Organization.

PPO = Preferred Provider Organization.

POS = Point-of-Service Plan.

N/A = Not asked in 1988 survey.

sources

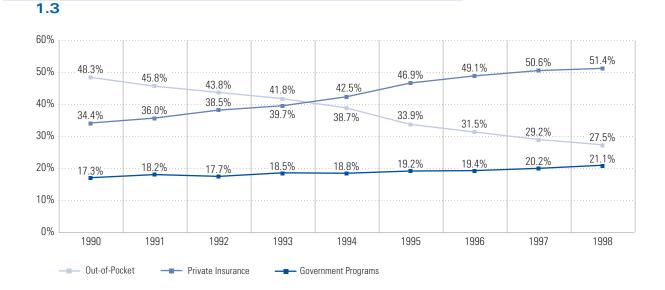
Kaiser Family Foundation/Health Research and Educational Trust Survey of Employer Health Benefits, 1999. KPMG Survey of Employer Health Benefits, 1988.

Prescription Drug Expenditures by Payer

- Since 1990, the proportion of drug expenditures paid out-of-pocket by consumers has decreased from 48% to 28% of total expenditures, with a corresponding increase from 34% to 51% in payments by private insurers (exhibit 1.3). The share of prescription drug payments by government programs has increased slightly since 1990, from 17% to 21%.
- Exhibit 1.4 compares the typical out-ofpocket costs paid for prescription drugs by "direct pay" private insured consumers and "cash" (uninsured and indemnity insured) consumers.⁵ "Direct pay" private insured consumers paid lower per prescription outof-pocket costs (i.e., their copayment or coinsurance amount) of about \$6 for generic drugs and \$10 for brand name drugs, compared to an average price of about \$31 paid by a "cash" consumer in 1997. Because they face a relatively low difference in outof-pocket costs (i.e., their copayment or coinsurance) between brand name and generic drugs, insured individuals may have less financial incentive to choose lower cost generic drugs, compared to uninsured individuals who face brand name prescription prices about 3 times higher, on average, than generic drug prescription prices (see exhibit 3.3). For consumers with indemnity coverage, even though their ultimate cost for prescriptions is only the unreimbursed portion of their total expenditure, the "pay and wait" aspect of their coverage can affect their sensitivity to the number and types of prescription drugs they obtain.
- In 1999, the prescription price paid by "cash" consumers (those without insurance and those covered by indemnity insurance) was typically 14.6% higher than the price paid by an insurer (excluding Medicaid) for the same prescription, excluding any rebates from manufacturers that insurers may also receive.⁶

⁵ "Direct pay" private insured are those covered under a "service benefit" plan, which typically includes first dollar coverage (no deductible) and direct payment from the plan to the pharmacy (thus the "direct pay" connotation); consumers are required to pay only a copayment or coinsurance amount when obtaining each prescription. "Cash" consumers are those who pay the full retail price for a prescription, including both the uninsured and those with indemnity coverage for prescriptions which typically requires consumers to pay the full charge for prescriptions and, after meeting a deductible, reimburses them for some portion of their expenditures.

⁶ U.S. Department of Health and Human Services, Prescription Drug Coverage, Spending, Utilization, and Prices – Report to the President, April 2000, p. 124, based on IMS Price Trak Report^w, 1999.



Percent of Total National Prescription Drug Expenditures by Type of Payer, 1990–1998

notes

exhibit

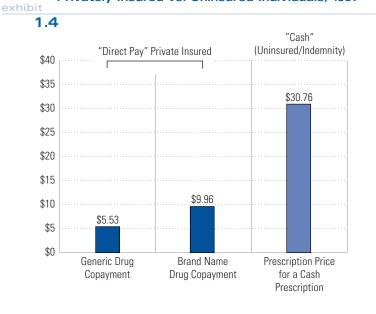
Out-of-Pocket Expenditures = all direct spending by consumers for prescription drugs, such as copayments, coinsurance amounts, deductibles, and amounts not covered by an insurer. Does not include out-of-pocket premiums for health insurance.

Government Programs = Federal, state, and local spending for prescription drugs, including Medicaid, Medicare, Department of Defense, Veterans Administration, Indian Health Service, and state and local hospitals and public assistance programs.

Private Insurance = payments made by private insurers for prescription drugs for covered beneficiaries.

source

Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, HCFA web site: www.hcfa.gov, last updated January 10, 2000.



Typical Out-of-Pocket Costs per Prescription for Privately Insured vs. Uninsured Individuals, 1997

notes

The Copayment amounts shown are average HMO copayments for generic and brand name drugs covered by a formulary. "Direct Pay" Private Insured includes persons with a service benefit prescription drug program (the insurer pays the pharmacy directly for the prescription claim, the patient pays only the copayment or coinsurance amount).

The Prescription Price shown is the average retail price (brand name and generic drug prescriptions combined) for a "cash" prescription in 1997. "Cash" prescriptions include those paid out-of-pocket at the pharmacy by both the uninsured and those with indemnity insurance. Persons with indemnity insurance are included because they pay the full price for the prescription at the time of dispensing (and thus in prescription audits are not distinguished from a "cash" customer). Indemnity insured currently represent only a small proportion (about 10%) of all prescriptions.

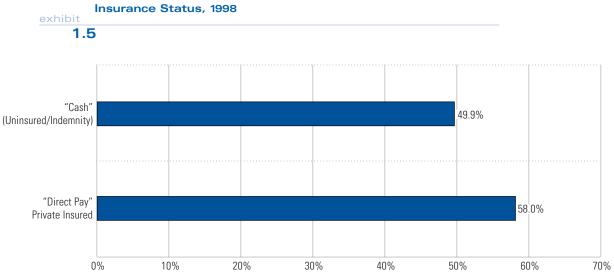
sources

Copayment data from Novartis Pharmaceuticals Corp., Novartis Pharmacy Benefit Report: Facts & Figures 1998 Edition, 1998.

Prescription price for uninsured prescriptions from National Association of Chain Drug Stores (NACDS), The Chain Pharmacy Industry Profile, 1999.

Impact of Insurance on Prescription Drug Use

- People with "direct pay" private insurance use brand name drugs at a higher rate (58%) than those who pay cash (50%) (exhibit 1.5), which may reflect, in part, the fact that prescription coverage helps to insulate these consumers from the additional costs of more expensive brand name drugs.
- Insurance coverage not only influences the types of drugs used, but also can improve access to drugs overall. Exhibit
 1.6 illustrates this impact for Medicare beneficiaries, almost a third (31%) of whom lack coverage for prescriptions. Comparing beneficiaries with prescription coverage to those without coverage, the number of prescriptions used (21 vs. 16) and the average per prescription expense (\$36.38 vs. \$28.92) per Medicare beneficiary are higher for beneficiaries with coverage.



Percent of Prescriptions for Brand Name Drugs by

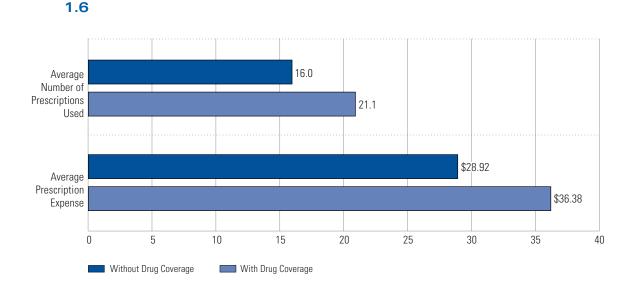
notes

"Cash" = all prescriptions paid out-of-pocket at the pharmacy by both the uninsured and those with indemnity insurance. Persons with indemnity insurance are included because they pay the full price for the prescription at the time of dispensing (and thus in prescription audits are not distinguished from a "cash" customer). Indemnity insured currently represent only a small proportion (about 10%) of all prescriptions.

"Direct Pay" Private Insured = prescriptions dispensed to persons with a service benefit prescription drug program (the insurer pays the pharmacy directly for the prescription claim, the patient pays only the copayment or coinsurance amount).

source

Scott-Levin, Source Prescription Audit (SPA), December 1999.



Number of Prescriptions and Average Prescription Expense per Medicare Beneficiary, by Insurance Status, 1996

notes

Medicare Beneficiaries with Drug Coverage includes all types of supplemental coverage for prescription drugs (i.e., Medicare risk HMO, Medicaid, employer-sponsored, and individually purchased plans).

The Average Prescription Expense is estimated as the annual prescription spending for Medicare beneficiaries divided by the number of prescriptions. It reflects the difference in the types of drugs used by beneficiaries with drug coverage vs. beneficiaries without drug coverage.

source

Poisal, J.A. and Chulis, G.S., "Medicare Beneficiaries and Drug Coverage," Health Affairs, March/April 2000, pp. 248–256, based on the 1996 Medicare Current Beneficiary Survey Cost and Use File.

Managing Prescription Drug Benefits

The nature of prescription drug benefits has changed in recent years due to:

- the spread of managed care plans with their efforts to control prescription drug costs through, for example, the use of formularies (see Glossary definition) to manage which drugs are prescribed, and their enrollee cost-sharing approach (a fixed copayment instead of a deductible and/or coinsurance, which may vary depending on whether the drug is brand name or generic); and
- the growth of pharmacy benefit managers (PBMs) - which are private firms that manage drug coverage programs for health plans, insurers, and employers - processing about 40% of all prescriptions dispensed in 1998 (exhibit 1.7). A primary PBM function is claims processing, but other related functions may include formulary management (selecting drugs for coverage), pharmacy network and payment administration (maintaining a panel of pharmacy providers and establishing payment rates), rebate negotiations and management (securing rebates from manufacturers for drugs used and directing rebates to plan sponsors), and patient compliance programs. In addition, many PBMs have mail order prescription service divisions. In 1998, the PBM market was dominated by 3 firms, Merck-Medco Managed Care, PCS Health Systems, and Express Scripts, Inc., that represented 64.2% of the PBM prescriptions processed and 27.1% of all U.S. prescriptions dispensed that year.

Prescription Volume and Market Share of the Top 10 Pharmacy Benefit Managers (PBMs), 1998

exhibit

PBM	1998 Prescription Volume (Million)	Market Share of All Prescriptions
Merck-Medco Managed Care (PAID Prescriptions, Inc.)	252.4	9.8%
PCS Health Systems	251.8	9.7%
Express Scripts, Inc.	196.3	7.6%
Wellpoint Pharmacy Management	45.4	1.8%
Advance Pharmacy Services/Paradigm	35.5	1.4%
Caremark Prescription Services	33.7	1.3%
Aetna Pharmacy Management	30.0	1.2%
National Prescription Administrators	28.0	1.1%
Preferred Solutions	26.4	1.0%
Provantage RX Management Services	19.5	0.8%
Other	172.6	6.7%
Total PBM Share of All Prescriptions	1,091.7	42.2%

note

Prescription Volume is the number of prescription claims processed by the PBM. Market Share is based on a total of 2.59 billion prescriptions dispensed in 1998.

source

National Association of Chain Drug Stores (NACDS), The Chain Pharmacy Industry Profile, 1999.

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Trends in Prescription Drug Expenditures

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two

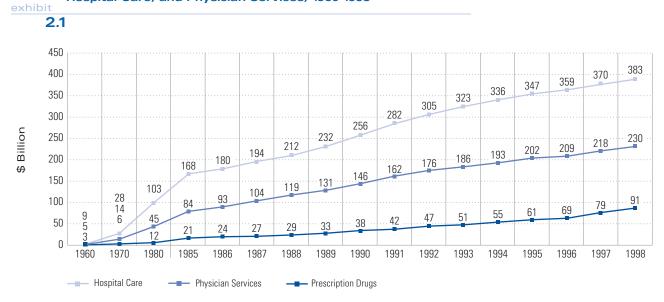
Trends in Prescription Drug Expenditures

Prescription expenditures have been one of the fastest-growing components of health care expenditures in the past decade. This growth has drawn attention to prescription drugs, even though they still represent a relatively small proportion (9%) of total personal health care expenditures.

National Health Expenditures for Prescription Drugs

- National health expenditures for prescription drugs totaled \$91 billion in 1998, and are projected to reach about \$243 billion in 2008.⁷ Although expenditures for all components of health care continue to increase, the trend for prescription drugs shows more rapid growth, especially in recent years (exhibit 2.1). The approximately \$10 billion annual increases for prescription drugs in 1995 through 1998 are similar to the dollar increases in physician services and hospital care, even though the total annual spending for these other services are more than double and triple, respectively, the total amounts for prescription expenditures.
- The annual percent increases in prescription expenditures have surpassed most other components of personal health care expenditures in the past decade, with percent increases exceeding 10% in all but 2 years (exhibit 2.2). In the last 5 years, the percent changes in prescription expenditures are 2 to 4 times the percent changes in major health care components. In 1998, for example, prescription expenditures increased 15% compared to 5% for physician services and 3% for hospital care. Between 1995 and 1998, prescription expenditures grew nearly 50%, while expenditures for physician services grew by 14% and expenditures for hospital care grew 10%.
- Despite the growth in expenditures, prescription drugs still comprise a small proportion of total personal health care expenditures (9%, compared to approximately 38% percent for hospital care and 23% for physician care) (exhibit 2.3). Although prescription drugs declined as a percent of overall personal health expenditures between 1960 and 1982, they have been rising steadily since then.

⁷ Smith, S. et al., "The Next Decade of Health Spending: A New Outlook," Health Affairs, July/August 1999, p. 94.



National Health Expenditures for Prescription Drugs, Hospital Care, and Physician Services, 1960–1998

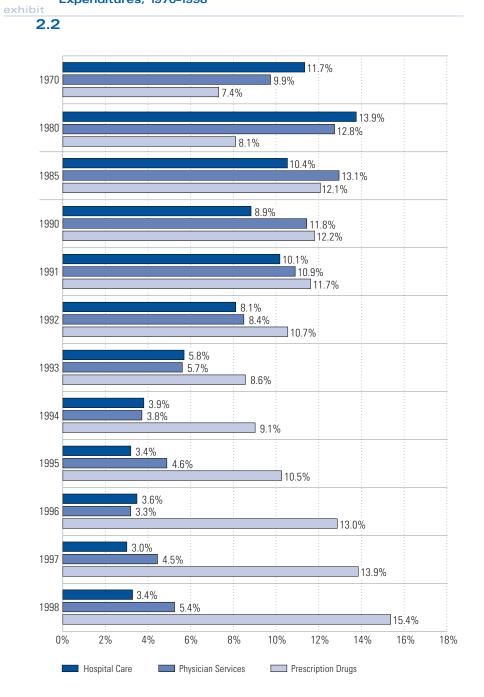
notes

Ten-year intervals from 1960–1980; 5-year interval from 1980–1985; 1-year intervals thereafter.

Expenditures for prescription drugs are limited to those purchased from retail outlets such as community or HMO pharmacies, grocery store pharmacies, mail order pharmacies, etc. The value of prescription drugs provided to patients by hospitals as part of a hospital stay, by nursing homes as part of care in a nursing home, or provided by physicians in their offices are not included in prescription drugs but are included in those respective expenditure categories. Consequently, the expenditures for prescription drugs shown here are underestimated and may differ from other estimates (e.g., prescription drug sales by manufacturers estimated by market research firms).

source

Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, HCFA web site: www.hcfa.gov, last updated January 10, 2000.



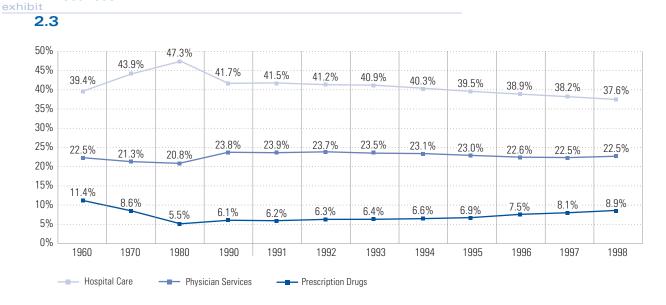
Annual Percentage Change in Selected National Health Expenditures, 1970–1998

note

Percent calculated as average annual percent change over 10-year period from 1970–1980; over 5-year periods from 1980–1990; and over 1-year intervals thereafter.

source

Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, HCFA web site: www.hcfa.gov, last updated January 10, 2000.



Prescription Drugs, Hospital Care, and Physician Services as a Percent of Total Personal Health Care Expenditures, 1960–1998

notes

Ten-year intervals from 1960-1990; 1-year intervals thereafter.

Expenditures for prescription drugs are limited to those purchased from retail outlets such as community or HMO pharmacies, grocery store pharmacies, mail order pharmacies, etc. The value of prescription drugs provided to patients by hospitals as part of a hospital stay, by nursing homes as part of care in a nursing home, or provided by physicians in their offices are not included in prescription drugs but are included in those respective expenditure categories. Consequently, the expenditures for prescription drugs shown here are underestimated and may differ from other estimates (e.g., prescription drug sales by manufacturers estimated by market research firms).

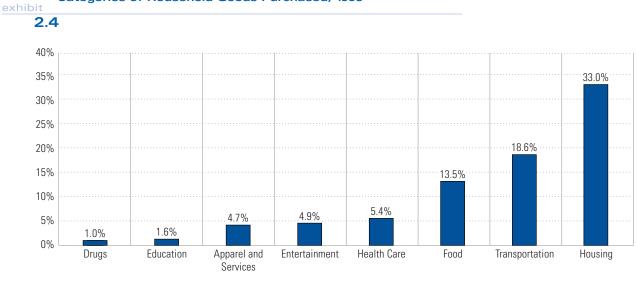
source

Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, HCFA web site: www.hcfa.gov, last updated January 10, 2000.

two

Consumer Expenditures

- Relative to expenditures for other household consumer goods and services, drugs (prescription and nonprescription) play a small role (about 1.0%) in average consumer outof-pocket spending each year (exhibit 2.4).
- However, older Americans spend more on prescriptions, both in dollar terms and as a proportion of total household budgets. The proportion of annual total household expenses that consumers aged 65 or older spent out-of-pocket on drugs (2.7%) was over twice as large as that for the next youngest age group (1.1% for those aged 55 to 64 years old) and almost 3 times as large as the average for all consumers (1.0%) (exhibit 2.5). Older Americans spend more out-of-pocket than the non-elderly on prescription drugs because they have more acute and chronic health conditions and use more prescription drugs to treat them, and they are less likely to have insurance coverage for prescriptions.



Percentage of Consumer Expenditures for Selected Categories of Household Goods Purchased, 1998

Percent of Total Household Consumer Expenditures

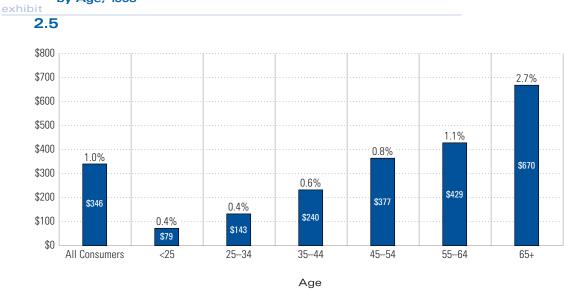
note

Expenditures consist of the transaction costs of goods and services acquired. Drugs include prescription and nonprescription drug out-of-pocket expenses, but exclude insurance premiums for drug coverage programs. Percents are based on total household expenditures (spending) for all goods and services.

source

Bureau of Labor Statistics (BLS), Consumer Expenditure Surveys 1998, BLS web site: www.bls.gov, last updated February 9, 2000.

two



Average Annual Consumer Expenditures for Drugs in Dollars and as a Percent of Total Household Expenditures, by Age, 1998

note

Expenditures consist of the transaction costs of goods and services acquired. Includes prescription and nonprescription drug out-of-pocket expenses (i.e, excluding payments by insurers), but excludes insurance premiums for drug coverage programs. Percents are based on total household expenditures (spending) for all goods and services.

source

Bureau of Labor Statistics (BLS), Consumer Expenditure Surveys 1998, BLS web site: www.bls.gov, last updated February 9, 2000.

International Expenditures

- Worldwide, the U.S. represents the largest market for prescription drugs, with its size and wealth contributing to this top ranking (exhibit 2.6). The U.S. prescription drug market in 1997 was more than twice as large as the next highest spending country, Japan.
- However, on either a per capita or a percentage of gross domestic product (GDP) basis, U.S. spending on pharmaceuticals is more on a par with other industrialized countries. Although countries such as Canada (\$251) and the U.K. (\$251) spend less per capita on pharmaceuticals than the U.S. (\$408), they are comparable in their percent of GDP spent on pharmaceuticals (1.3%, 1.2%, 1.4%, respectively) because of the higher relative wealth in the U.S. (exhibit 2.6). Most other countries control drug prices (which may lead to lower spending), but, on the other hand, they have significantly higher rates of health insurance coverage than the U.S. (which may lead to higher spending).

International Comparisons of Pharmaceutical Expenditures, 1997

exhibit 2.6

Rank	Country	Prescription Drug Market Size (\$ Billion)	Per Capita Expenditures on Pharmaceuticals (\$)	Percent of GDP on Pharmaceuticals (%)	Percent of GDP on Health (%)	
1	U.S.	101.4	408	1.4	13.9	
2	Japan	46.9	552*	1.5*	7.2*	
3	Germany	18.2	337	1.3	10.7	
4	France	17.1	393	1.7	9.6	
5	Italy	10.2	293	1.5	7.6	
6	U.K.	9.4	251	1.2	6.8	
7	Brazil	9.0	N/A	N/A	N/A	
8	Spain	5.7	207	1.5	7.4	
9	China	5.0	N/A	N/A	N/A	
10	Canada	4.7	251	1.3	9.2	

notes

*1996 data shown (1997 data not available for Japan).

N/A = not available.

"Pharmaceuticals" = prescription drugs and nonprescription drugs.

"Market Size" = sales of prescription drugs to retail pharmacies by wholesalers and manufacturers.

"GDP" (Gross Domestic Product) = a measure of the money value of the sum of all the products of the various industries of a nation; it represents the national income of a country.

sources

Market Size & Rank from IMS Health, Inc., *The Pharmaceutical Market World Review* 1998, IMS Health web site: www.ims-global.com, November 1999. Per Capita Expenditures and Percents of GDP from Organisation for Economic Co-Operation and Development (OECD), OECD *Health Data 1999, a Comparative Analysis of 29 Countries*, July 1999.

Factors Driving Expenditures: Price, Utilization, and Types of Drugs

Price Trends for Prescription Drugs 30	
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Utilization Trends for Prescription Drugs 38	
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Demographic Trends in Prescription Use	
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Growth in Number of Treatment Options Through	
Prescription Drugs	
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of New Drugs Available	

Explaining Increases in Drug Expenditures 61

Factors Driving Expenditures: Price, Utilization, and Types of Drugs

Increases in prescription drug expenditures are influenced by three primary factors: price increases, utilization increases (i.e., the growth in the number of prescriptions), and changes in the types of drugs used (particularly shifts from less expensive to newer, more expensive drugs).^s

Price Trends for Prescription Drugs

The price of a prescription for a given drug is influenced by the pricing behaviors of firms at all levels of the distribution channel for prescription drugs (from manufacturer to wholesaler to retailer). Increases in the prices of drugs charged by manufacturers, wholesalers, or pharmacies have had less of an effect on increased prescription spending than have changes in the types of drugs dispensed. Overall, the tendency for newer, more expensive drugs to be used along with or to replace lower cost drugs has contributed significantly to increases in the average prescription price.

How Drugs Are Priced

- Exhibit 3.1 shows pricing terminology and pricing methods at different levels in the "channel of distribution" for prescription drugs, which includes manufacturers (that produce drugs), wholesalers (that distribute drugs obtained from manufacturers), pharmacies (that dispense drugs to consumers), and, ultimately, consumers. Pricing behaviors of pharmaceutical manufacturers affect prices at all levels of distribution because the price a manufacturer sets for a prescription drug influences prices at the wholesale and retail levels as well.
- Exhibit 3.2 shows that when a pharmacy sells a prescription to a consumer, almost three-quarters (\$0.74) of each dollar from the price of the prescription goes to the manufacturer. Only a few cents (\$0.03) goes to the wholesaler for distributing the drugs from the various manufacturers to the pharmacies where they are dispensed; the pharmacy retains the remaining portion, about one-quarter (\$0.23) of each dollar of a prescription price.

^a Trends in the prescription drug market are monitored primarily by two market research firms, Scott-Levin and IMS Health, Inc. These firms analyze and produce data about prescription drug sales and utilization through audits of manufacturers, wholesalers, pharmacies, physicians, and hospitals. They also monitor promotional activities to both health care professionals (through audits of sales calls, meetings attended, and professional advertising in journals and professional publications) and consumers (through audits of advertising in magazines, newspapers, radio, and television media).

 Pharmaceutical manufacturers often negotiate rebates with insurers and health plans in exchange for the insurers' use of incentives for patients to use the manufacturer's drug. Although rebates do not affect prescription drug prices paid at the time of service, they do lower the insurer or health plan's overall costs.

Trends in Drug Prices

- Between 1991 and 1998, the average retail price of a prescription (which reflects both price increases for existing drugs by the prescription drug industry and changes in the types of drugs used) grew almost 60%, from \$23.68 to \$37.38 (exhibit 3.3). Over this time period, the average price of prescriptions for brand name drugs increased 80%, a much larger increase than the 55% increase for generic drugs.
- The average annual percent change in retail prescription prices from 1991 to 1998 was 6.7% overall, higher than the average annual increase of 2.6% in the Consumer Price Index (CPI) for all items and 4.6% in the CPI for medical care (exhibit 3.4). Prices of prescriptions for brand name drugs grew an average 8.8% per year, compared to 6.5% for generic drugs.
- Exhibit 3.5 shows the year-to-year price changes (inflation) by manufacturers for existing drugs, which are relatively small compared to, for example, the changes in national expenditures for prescription drugs (see exhibit 2.2) or average retail prices (see exhibit 3.4). Manufacturer price increases declined in the early to mid-1990s, but have risen in recent years, though they have been less than 4% every year since 1992. However, price increases by manufacturers for existing prescription drug products have not been the major factor in recent trends of prescription expenditure and price increases. These trends are more influenced by increased utilization of prescription drugs and shifts to the use of new, more expensive drugs on the market (see Section 3, Utilization Trends for Prescription Drugs, Trends in the Types of Prescription Drugs Used, and Explaining Increases in Drug Expenditures).

Comparing Prices for Alternative Treatment Approaches

- In general, the average retail price of prescriptions for brand name drugs has historically been about 3 times that of generic drugs (exhibit 3.3).
- The difference in cost between generic and brand name drugs can, in some cases, be dramatic. For example, exhibit 3.6 shows that for anti-ulcer drugs, the cost a pharmacy pays for the brand name drug Tagamet (the first histamine-2 receptor antagonist introduced, and at one time the most popular drug in that therapeutic category) is nearly 8 times more expensive than for the generic version (Cimetidine). Among drugs for depression, the brand name drug Elavil (also at one time a therapeutic category leader) is nearly 18 times more expensive than the generic version of the drug (Amitriptyline).
- New prescription approaches to treatment typically cost more than older ones.
 For example, exhibit 3.6 shows that in 1999 a day's therapy of Prilosec (the first proton pump inhibitor for ulcers, introduced in 1989) costs a pharmacy \$3.16, almost 15% more than Tagamet (introduced as an anti-ulcer drug in 1976). Among antidepressants, the newer approach to treatment, Prozac (a selective serotonin reuptake inhibitor, or SSRI), is almost 3 times as expensive as a previously popular treatment, Elavil (a tricyclic antidepressant).
- Pricing of new drugs by manufacturers may be influenced by a number of considerations, including: 1) the perceived advantages and incremental value of a therapeutic advancement, 2) recovering research and development costs, 3) funding ongoing research and innovation, 4) financing marketing efforts to stimulate sales, and 5) generating profits from drugs while they are under patent protection.

Channel of Distribution Levels and Price Terminology for Pharmaceuticals

3.1

exhibit

The levels of the "channel of distribution" for pharmaceuticals include manufacturers, wholesalers, retailers, and consumers.* Buying and selling occurs at each level in the channel of distribution, with specific terms applied to costs or prices at each level. In some cases, different terms used at different levels can refer to the same dollar amount.

Manufacturers

Manufacturers (both "major pharmaceutical firms," which emphasize research and brand name drugs, and "generic pharmaceutical firms," which focus on generic drugs) produce and market prescription and nonprescription drug products. They distribute their products predominantly through drug wholesalers, but also sell directly to individual pharmacies, pharmacy chains, hospitals, and others.

Their selling price (to wholesalers, primarily) = Average Manufacturer Price (AMP).** (Manufacturers also set the Average Wholesale Price (AWP) as a suggested list price for wholesalers to sell to pharmacies.)

Wholesalers

Wholesalers serve as the middlemen that distribute drug products from manufacturers to pharmacies.

Their cost to buy drugs (from manufacturers) = Wholesaler Acquisition Cost (WAC).

(A manufacturer's selling price (AMP) = Wholesaler Acquisition Cost (WAC).)

Their selling price (to pharmacies) is determined using either a "cost plus" or a "list less" approach. The resulting price might be very similar using either approach:

"Cost Plus" = Wholesale Acquisition Cost (WAC) plus a markup percent.

"List Less" = Average Wholesale Price (AWP) less a discount percent.

Retailers (Pharmacies)

Retailers (pharmacies) dispense prescriptions to consumers and provide professional pharmacist services.

Their cost to buy drugs (from wholesalers) = Actual Acquisition Cost (AAC). Sometimes pharmacies buy drugs directly from manufacturers; in that case, AAC = AMP.

Their selling price (to consumers):

- To Uninsured and Indemnity-Insured Consumers = The "Usual & Customary" (U&C) retail price which includes the cost of the drug plus the pharmacy's markup.
- To Other Insured Consumers ("Service Benefit" Insurance Coverage) = The insurer's payment formula, typically including its determination of the cost of the drug dispensed ("ingredient cost") plus what it allows for a professional dispensing fee. The pharmacy submits a claim to the insurer equal to the formula-based price less the consumer's cost-sharing amount (the copayment or coinsurance).

Consumer

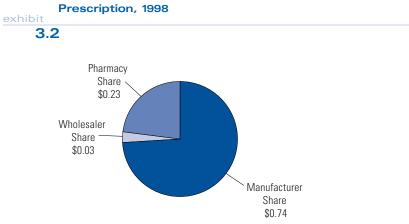
Their cost to buy drugs (from pharmacies):

If uninsured = U&C price. (Customers with indemnity insurance will pay U&C price and are reimbursed that amount less any cost sharing.) If insured = Copayment or coinsurance amount.

notes

* Insurers are not considered participants in the channel of distribution because they are not involved in the physical distribution of drugs, though they do affect channel participants through their payment and drug use policies.

** Pharmaceutical manufacturers negotiate rebates with insurers and health plans. These rebates ultimately lower the overall cost of drug program expenditures, but do not affect transaction prices (AMP). Rebates are "after market" arrangements that occur after and separately from the sales transaction.



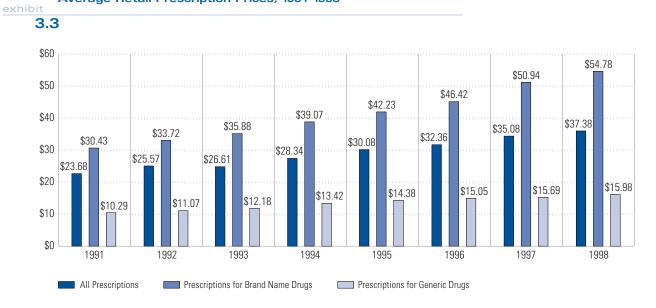
Distribution of a Dollar of Revenue from a Retail Prescription 1998

note

From each dollar of prescription sales, \$0.74 goes to the manufacturer for producing the drug, \$0.03 goes to the wholesaler for distributing the drug, and \$0.23 goes to the pharmacy for dispensing the drug.

source

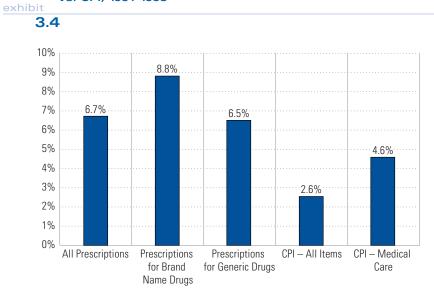
National Association of Chain Drug Stores (NACDS), based on data on file, December 1999.



Average Retail Prescription Prices, 1991-1998

source

Scott-Levin, Source Prescription Audit (SPA), December 1999.



Average Annual Percent Change in Retail Prescription Prices vs. CPI, 1991–1998

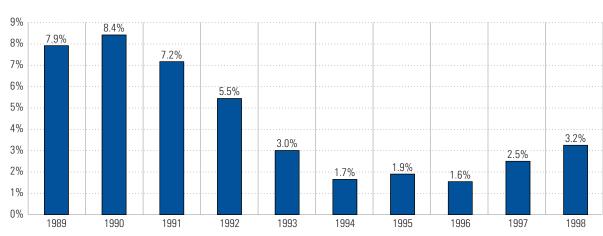
note

CPI = Consumer Price Index for all urban consumers.

sources

Sonderegger Research Center analysis, based on:

Average Prescription Prices from Scott-Levin, *Source Prescription Audit* (SPA), December 1999. CPIs from Bureau of Labor Statistics (BLS), BLS web site: www.bls.gov, December 1999.



Pharmaceutical Manufacturer Price Inflation for Existing Drugs, 1989–1998

Percent Change in Drug Prices from the Previous Year

note

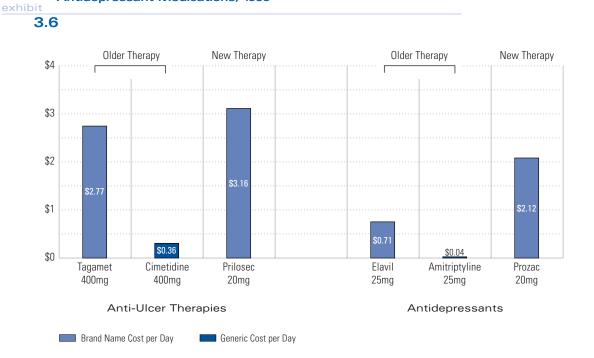
exhibit

3.5

These percents reflect manufacturer price increases for existing drugs from year to year.

source

IMS Health, Inc., *Pharmaceutical Pricing UPDATE*, March 1999, based on data from *Retail and Provider Perspective* (published in *Medical Marketing & Media*, May 1999). In the IMS data, prior to 1993, only retail pharmacies and nonfederal hospitals were included. From 1993 to 1998, data reflect sales by retail pharmacies, non-federal hospitals, staff-model HMOs, clinics, long-term care, and federal facilities.



Cost of Old and New Therapies, Anti-Ulcer and Antidepressant Medications, 1999

notes

This exhibit illustrates that newer, brand name drugs are typically more expensive than older brand name drugs and generic drugs. For anti-ulcer therapies, Tagamet is a histamine-2 receptor antagonist (H2RA), introduced in 1976 as the first in this drug class, and it became the most popular drug in this class. Cimetidine is the generic name of Tagamet. Prilosec is the first proton pump inhibitor drug for ulcers, introduced in 1989. It has become the most popular anti-ulcer drug, replacing H2RA drugs.

For antidepressants, Elavil is a tricyclic antidepressant, introduced in 1961. It was one of the first drugs in this class and became the most popular drug in this class. Amitriptyline is the generic name of Elavil. Prozac is the first selective serotonin reuptake inhibitor (SSRI) drug for depression, introduced in 1987. It has become the most popular drug for depression.

Cost per Day is based on the daily dosage for commonly dispensed product strengths and comparative therapeutic levels.

Cost amounts represent the net price a pharmacy pays for the drug.

sources

Sonderegger Research Center analysis, based on:

Brand Name drug cost estimated as Average Wholesale Price (AWP) listed in Drug Topics' *Red Book* price reference, less 18.3% (based on a DHHS Office of Inspector General report on pharmacy acquisition costs for drugs reimbursed under Medicaid that found the difference between AWP and the prices retail pharmacies pay for brand name drugs was 18.3%, OIG report A-06-96-00030, April 1997).

Generic drug cost based on HCFA Medicaid payment amount (Federal Upper Limit) published on the HCFA web site, www.hcfa.gov, December 1999.

Product usage patterns from Top 200 listings published in Pharmacy Times, April issues, various years.

Utilization Trends for Prescription Drugs

Utilization, which can be measured as the overall number of prescriptions dispensed annually or on a per capita basis, is one of the primary factors contributing to drug expenditure increases. Factors that, in turn, drive the growth in prescription drug utilization include: population growth, the aging of the population, increased numbers of prescribers (e.g., physicians), and promotion of prescription drugs to stimulate demand.

Trends in Number of Prescriptions

- On average, Americans used about 10 prescriptions per year in 1998 (exhibit 3.7).
- Whether expressed as the total number of dispensed prescriptions or on a per capita basis, prescription drug utilization shows steady growth (exhibit 3.7). Between
 1992 and 1998, the total number of dispensed prescriptions increased by 37%, and the number of prescriptions per capita increased by 32%. Over this same time period, the total U.S. population grew by just 6%.

Demographic Trends in Prescription Use

- Both gender and age influence prescription use. Starting at age 15, women consistently use more prescriptions than men (exhibit 3.8). The population aged 45 or older is of particular interest, because at age 45 chronic conditions tend to surface and the potential for treatment with prescribed medications increases. Between the ages of 45 and 75, prescription use nearly triples (from an overall average of 4.3 to 11.4 prescriptions per person annually).
- The proportion of the U.S. population 45 years of age or older is growing (from 31% to 34% over the past 15 years), increasing the median age of the population to 35 in 1998 (exhibit 3.9).

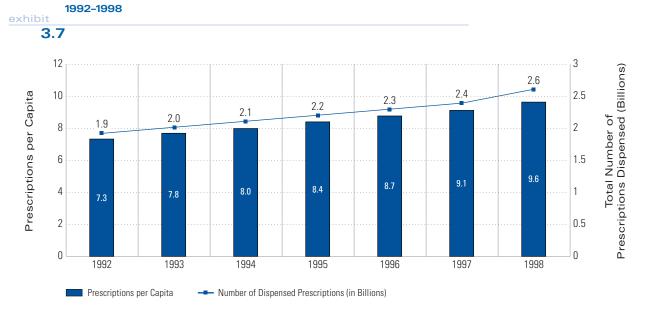
Trend in Number of Prescribers

 Access to prescription drugs is facilitated by an increased number of prescribers. The number of traditional "core" prescribers (Medical Doctors (MDs) or Doctors of Osteopathy (DOs)) per 1,000 population has increased steadily since 1985 (exhibit 3.10). As legal changes in various states allow prescribing by non-physicians such as nurse practitioners and physician assistants, access to prescribers increases, further increasing the potential for utilization.

Drug Product Promotion – A Factor in the Use of Drugs

 A factor affecting the use of prescriptions (particularly the use of new prescriptions) is the promotion of drug products by pharmaceutical manufacturers. Manufacturers promote prescription drugs in several ways, including "detailing" (sales calls by company representatives to physician offices and hospitals, including providing samples); journal advertising; displays and presentations at professional meetings and events; and, more recently, direct-to-consumer (DTC) advertising. Quantifying total promotion spending for prescription drugs can be a challenge. The promotional activities of pharmaceutical manufacturers and their impact are monitored primarily by two market research firms, IMS Health, Inc. and Scott-Levin. Since these two firms use different methods to identify promotion efforts and categorize promotion expenditures, examining both firms' data gives a more complete perspective on prescription drug promotion (exhibit 3.11). For example, their figures for DTC promotion are similar, but IMS Health's exclusion of the value of samples for "detailing" appears to omit a sizeable component of professional promotion.

- The largest (\$5.7 billion, or 69% of all promotional spending in 1998) and most traditional type of promotional spending continues to be "detailing," where a manufacturer's representative makes personal sales visits to prescribers in office practices or hospitals (exhibit 3.12).
- Although growth occurred in all promotional spending categories, spending for directto-consumer promotion more than tripled from 1995 to 1998 (from \$.4 billion to \$1.3 billion) and reached 16% of total promotional spending in 1998 (exhibit 3.12). This is, in part, due to revised guidelines for television advertising of prescription drugs issued by the U.S. Food and Drug Administration (FDA) in 1995 and later years.
- Exhibit 3.13 shows a breakdown of directto-consumer (DTC) advertising expenditures. Television advertising is experiencing considerable growth as pharmaceutical firms have begun to target individual consumers in addition to prescribers to stimulate demand for their products. Spending for television advertising (\$.7 billion, in 1998) was almost 20 times greater than in 1994, and had grown to represent half (50%) of DTC advertising (compared to 13% in 1994). In 1999, television advertising for prescription drugs totaled \$1.1 billion, representing 61% of DTC advertising for the year, and nearly a 70% increase over 1998 spending.³
- The highest spending on DTC advertising was for antihistamines, in particular, Claritin.
 Exhibit 3.14 identifies the specific drugs with the highest DTC spending amounts for 1998.
 Many of the highly advertised products (including Claritin, Prilosec, Zocor, and Prozac) are also among the top products by sales or by prescriptions dispensed (exhibits 3.15 and 3.16).



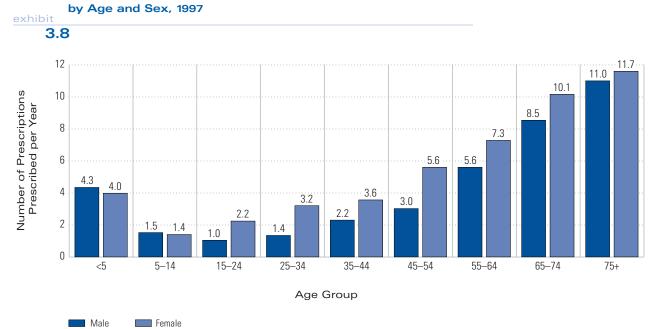
Total Prescriptions Dispensed and Prescriptions per Capita,

sources

Sonderegger Research Center analysis, based on:

Number of prescriptions data from IMS Health, Inc., National Prescription Audit, 1999.

U.S. population data from U.S. Census Bureau, Statistical Abstract of the United States, 1999.



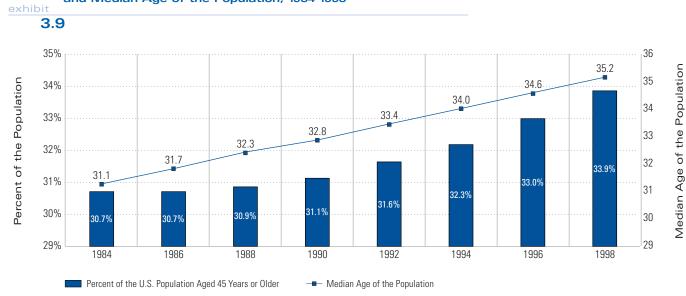
Average Number of Prescriptions Prescribed,

note

Prescriptions prescribed at outpatient physician offices in 1997.

source

National Association of Chain Drug Stores, The Chain Pharmacy Industry Profile, 1999; analysis based on data from the National Ambulatory Medical Care Survey, 1997.



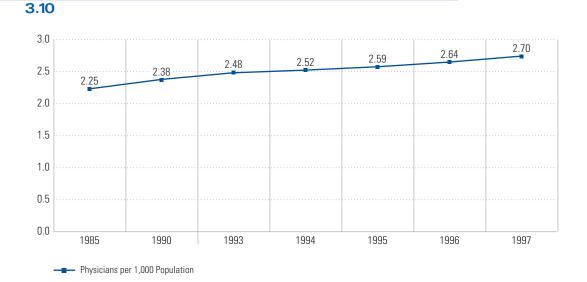
Percent of the U.S. Population Aged 45 Years or Older, and Median Age of the Population, 1984–1998

note

Age 45 can be considered the start of the "drug taking years." At age 45, ambulatory physician visits per year and percent of consumer expenditures for drugs begin to increase, signaling increased morbidity and drug use.

source

Sonderegger Research Center analysis, based on data from the U.S. Census Bureau, Statistical Abstract of the United States, 1999.



Physicians per 1,000 Population, 1985–1997 exhibit

notes

Five-year interval from 1985–1990; and 1-year intervals after 1993.

Includes traditional prescribers only (Physicians with Medical Doctor (MD) or Doctor of Osteopathy (DO) degrees) who are professionally active. Does not include Physician Assistants, Nurse Practitioners, Dentists, Optometrists, and other health professionals with prescriptive authority in various states.

source

Sonderegger Research Center analysis, based on data from the U.S. Census Bureau, Statistical Abstract of the United States, 1999.

Comparison of Major Pharmaceutical Manufacturer Promotional Spending, by Type of Promotion, 1998

3.11

exhibit

Description Trans	IMS Health Data	Scott-Levin Data
Promotion Type	(\$ in Millions)	(\$ in Millions)
Total Professional Promotion	4,554.7	7,004.2
"Detailing"	4,056.9	5,717.9
(Office Promotion)	(3,386.2)	—
(Hospital Promotion)	(670.7)	—
Journal Advertising	497.8	N/A*
Professional Meetings & Events	—	1,286.3
Total Direct-to-Consumer Promotion	1,316.7	1,345.5
Total Promotion	5,871.4	8,349.7

IMS Health Definitions

Total "Detailing" = sum of office and hospital promotion. Does not include the value of samples.

Office Promotion = sales activities for prescription products that are directed to office-based physicians. This includes sales calls as well as service visits. Does not include the value of samples.

Hospital Promotion = sales activities for prescription products that are directed to hospital-based physicians and directors of pharmacies. Does not include the value of samples.

Journal Advertising = advertising expenditures for prescription products appearing in medical journals.

Professional Meetings & Events = data not collected.

Direct-to-Consumer = magazine, newspaper, radio, and TV advertising in consumer media.

Scott-Levin Definitions

Detailing = competitive personal selling activity to office-based and hospital-based physicians. Includes providing samples during sales visits.

Professional Meetings & Events = small and large group meetings, symposia, third-party marketing events, and tele/video conferences.

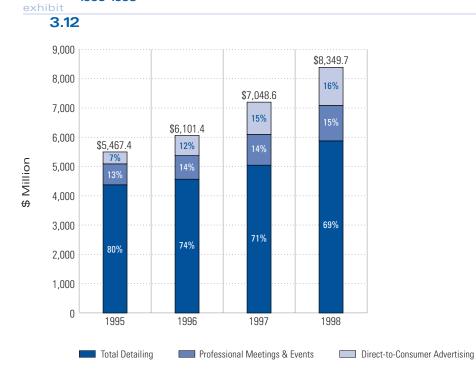
*Journal Advertising = advertising in professional medical journals and health care bulletins; auditing began in 1999, data not available for 1998.

Direct-to-Consumer = magazine, newspaper, radio, and TV advertising in consumer media.

sources

IMS Health, Inc., Integrated Promotional Services (Office Promotion Reports, Hospital Promotion Reports, National Journal Audit) and Integrated Share of Voice Report (with data from Competitive Media Reporting), November 1999.

Scott-Levin, Personal Selling Audit, Hospital Personal Selling Audit, Physician Meeting & Event Audit, DTC Advertising Audit, and Professional Journal Audit, December 1999.



Promotional Spending by Pharmaceutical Manufacturers, 1995–1998

Promotional Activity	Average Annual Percent Change 1995–1998
Total Detailing	9.4%
Professional Meetings & Events	20.6%
Direct-to-Consumer Advertising	53.4%
Total Promotion	15.2%

notes

% Within Bar = Percent of Total Promotional Activities.

Detailing = expenses for competitive personal selling activity (sales calls) to office-based and hospital-based physicians, including the value of samples.

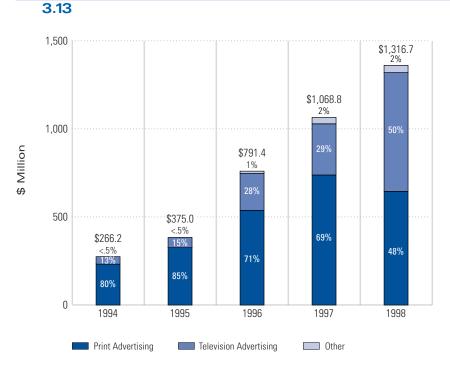
Professional Meetings & Events = expenses for sponsoring or conducting small and large group meetings, symposia, third-party marketing events, and tele/video conferences.

Direct-to-Consumer = expenditures for magazine, newspaper, radio, and TV advertising targeted toward consumers.

Professional Journal Advertising is not included because data were not collected until 1999. According to IMS Health, Inc., Professional Journal Advertising for 1995–1998 was \$357.0 million, \$458.6 million, \$510.3 million, and \$497.8 million, respectively (published in *Medical Marketing & Media*, May 1999, data from IMS Health, Inc., *Integrated Share of Voice Report*).

source

Scott-Levin, Personal Selling Audit (PSA), Hospital Personal Selling Audit (HPSA), Physician Meeting & Event Audit (PMEA), and DTC Advertising Audit (DTCA), December 1999.



Direct-to-Consumer Promotional Activity Spending by Pharmaceutical Manufacturers, 1994–1998 exhibit

% Within Bar = Percent of Total Direct-to-Consumer Promotional Activities

Direct-to-Consumer Promotional Activity	Average Annual Percent Change 1994–1998
Print Advertising	28.7%
Television Advertising	107.6%
Other	231.5%
Total Direct-to-Consumer	49.1%

notes

Print Advertising = prescription products advertised in magazines and newspapers.

Television Advertising = network, cable, and "barter syndication" television.

Other = radio and outdoor advertising for prescription products.

source

Sonderegger Research Center analysis, based on data from IMS Health, Inc., Integrated Share of Voice Report, and Competitive Media Reporting, November 1999.

Prescription Drugs with the Most Direct-to-Consumer Advertising, 1998

exhibit 3.14

Drug	Indication	Direct-to-Consumer Advertising (\$ Million)	Top 200 Ranking	
Claritin	antihistamine	\$150.2	11	
Propecia	hair loss	\$91.0	N/A	
Zyrtec	antihistamine	\$75.2	48	
Pravachol	cholesterol-lowering	\$59.6	29	
Zyban	smoking cessation	\$54.6	N/A	
Allegra	antihistamine	\$52.5	59	
Prilosec	anti-ulcer	\$49.7	5	
Zocor	cholesterol-lowering	\$41.6	15	
Evista	osteoporosis	\$38.9	N/A	
Prozac	anti-depressant	\$37.5	8	
Premarin	hormone replacement	\$37.0	1	
Imitrex	migraine	\$36.4	79	

notes

Top 200 ranking based on total prescriptions dispensed.

N/A = not among the Top 200 products.

sources

Direct-To-Consumer advertising amounts from *Competitive Media Reporting*, New York (published in *Med Ad News*, June 1999). Top 200 rankings from IMS Health, Inc., *National Prescription Audit*, November 1999.

Trends in the Types of Prescription Drugs Used

Changes in the types of prescription drugs used contribute to the increasing trend in prescription prices and expenditures. The types of prescriptions used are, in turn, a function of the products available on the market. Changes in therapy occur as research yields new ways of treating disease, and new drugs are developed where previously no treatments existed or where current drugs are less effective or tolerable. However, even when new ways of treating diseases are identified, old methods remain and continue with merit and often some popularity. Pharmaceutical manufacturers face considerable economic pressure to develop new products through research and development since markets for their existing products erode rapidly when product patents expire and lower-priced generic versions of drug products become available.

Importance of New Prescription Drugs

- Comparing the top prescription drugs ranked by dollar sales volume and number of prescriptions dispensed in 1998 reveals that there were more new drugs in the ranking by sales volume in dollar terms (exhibit 3.15), but older drugs continue to have market presence based on prescriptions dispensed (exhibit 3.16). Because newer drugs tend to be priced higher than older drugs, those on the market fewer than 10 years accounted for 75% of the Top 20 drugs by sales. However, drugs on the market fewer than 10 years comprised only 45% of the Top 20 drugs when ranked by number of prescriptions dispensed.
- Similarly, while no generic drugs were among the Top 20 in terms of dollar sales volume in 1998 (exhibit 3.15), a number of these less expensive generic versions of brand name drugs were among the Top 20 when ranked by number of prescriptions dispensed (exhibit 3.16).

- Exhibit 3.15 also shows that many drugs tend to experience considerable sales growth soon after first being marketed.
- Exhibit 3.17 illustrates how newer, more expensive drugs have overtaken older drugs within a particular therapeutic category – anti-ulcer drugs. By 1990, the more expensive Zantac had replaced Tagamet as the most prescribed anti-ulcer drug. By 1998, Zantac had been replaced by Prilosec which again cost more than its predecessor. Exhibit 3.17 also shows that older brand name drugs (Tagamet and Zantac) lose market share not only to newer, more expensive drugs but also, as their patents expire, to their generic drugs (Cimetidine and Ranitidine, respectively).
- · Replacement of older drugs with newer, more expensive drugs also is reflected in exhibit 3.18. As the patents on older drugs expire, more generic drugs can enter the market. Since 1991, the percent of prescriptions dispensed as generic drugs has increased from 33% to almost 45% of all prescriptions. However, the percent of total prescription sales in dollars attributed to generic drugs has declined since 1996, with generics accounting for less than 20% of prescription sales (or expenditures) in recent years. Sales of generic drugs, even of newly available generic versions of popular drugs with recent patent expirations, do not keep pace in the changing mix of drugs as newer brand name drugs carrying higher prices replace older drugs.
- Exhibit 3.19 shows that the annual increases in manufacturer price increases have been significantly lower (from 1 to 4 times lower) than the increases in average retail prescription drug prices. Average manufacturer price increases reflect inflationary changes

in prescription prices for existing drugs. The difference between manufacturer price increases and average prescription price changes at the retail level reflects the additional impact of newer, more expensive drugs.[®]

Growth in Number of Treatment Options Through Prescription Drugs

 The prescription drug arsenal available to prescribers for treating conditions has grown due to the number of new products brought to market by pharmaceutical manufacturers. An example is the increasing number of products for treating hypertension that have been popular enough to appear among the Top 200 products in the U.S. market, which nearly doubled from 1975 to 1998 (exhibit 3.20). Even though there are a number of new drugs with different mechanisms of action to treat hypertension, older drugs remain on the market and continue to be used. Newer drugs may reflect therapeutic enhancements (in effectiveness, safety, side effects, or quality of life aspects) and may be promoted for these advantages, but the older therapies still can have value in medical care and the market. This has contributed to an overall increase in the number of products on the market to treat different diseases.

Research and Development – A Factor in the Number of New Drugs Available

New products become available as the result of research by the "major pharmaceutical manufacturers" (those firms that emphasize research and brand name drugs). Domestic and foreign spending by pharmaceutical manufacturers for research and development (R&D) has risen from \$1.1 billion in 1975 to \$21 billion in 1998 (exhibit 3.21). Annual increases in R&D expenditures by U.S. pharmaceutical manufacturers have ranged from 6% to 19% over the past decade.

- Major pharmaceutical manufacturers are committing an increasing percentage of their sales revenues to R&D. As a percent of manufacturer prescription drug sales, R&D expenditures for prescription drugs have grown from 9.0% in 1975 to 16.9% in 1998, though spending has been flat in recent years (exhibit 3.22). However, among the top 10 major pharmaceutical manufacturers, R&D spending is less than half of net profit before taxes (exhibit 4.5)."
- The distribution of domestic R&D expenditures for prescription drugs by function for major pharmaceutical manufacturers is shown in exhibit 3.23. Although nearly a third (27%) of R&D spending by manufacturers is for what could be considered "basic" research to identify potential drugs (through synthesis, extraction, screening, and pharmacological testing), a larger portion is spent for applied research to develop those drugs into marketable products. Research by pharmaceutical manufacturers often builds on discoveries from basic research on the causes, diagnosis, prevention, and cure of diseases funded by the federal National Institutes of Health (NIH).
- One result of the R&D spending by manufacturers is the number of new products approved by the U.S. Food and Drug Administration (FDA) for sale. The average number of new drugs approved per year has doubled since the early 1980s, from 19 to 38 per year (exhibit 3.24).
- In addition, the time for FDA review and approval of new drug applications is less than half of what it was a decade ago, which helps new products reach the market more quickly, contributing to the recent growth in the number of new products approved (exhibit 3.25).

¹⁰ There is little evidence that wholesaler or retail pharmacy pricing contribute to increased prescription prices over and above manufacturer price increases.

¹¹ Reported R&D percents can vary because accounting practices vary across firms, and different categories of R&D efforts and sales may be used in the calculations (e.g., U.S.-only sales, total firm sales, etc.).

Top 20 Prescription Drugs Ranked by Dollar Sales Volume, 1998

exhibit

3.15

Rank	Product	Indication	1998 Sales (\$Million)	% Growth 1997–98 (+/-)	Brand or Generic?	Year First Marketed
1	Prilosec (Astra-Merck)	anti-ulcerant (PPI)	\$2,933	29	В	1989
2	Prozac (Dista/Lilly)	SSRI anti-depressant	\$2,181	12	В	1987
3	Lipitor (Parke-Davis/Warner Lambert)	cholesterol-lowering	\$1,544	165	В	1997
4	Zocor (Merck)	cholesterol-lowering	\$1,481	7	В	1992
5	Epogen (Amgen)	blood cell stimulating factor (for anemia)	\$1,455	21	В	1989
6	Zoloft (Roerig/Pfizer)	SSRI anti-depressant	\$1,392	16	В	1992
7	Prevacid (TAP/Abbott)	anti-ulcerant (PPI)	\$1,245	86	В	1995
8	Paxil (SmithKline Beecham)	SSRI anti-depressant	\$1,190	25	В	1993
9	Claritin (Schering)	antihistamine	\$1,150	27	В	1993
10	Norvasc (Pfizer)	calcium channel blocker (for hypertension)	\$1,086	19	В	1992
11	Zyprexa (Lilly)	anti-psychotic	\$1,054	83	В	1996
12	Augmentin (SmithKline Beecham)	antibiotic	\$926	15	B/G	1984
13	Pravachol (Bristol-Myers Squibb)	cholesterol-lowering	\$879	14	В	1991
14	Imitrex (Cernet/Glaxo)	migraine	\$857	8	В	1993
15	Premarin (Wyeth-Ayerst)	hormone replacement	\$854	6	B/G	1964
16	Neupogen (Amgen)	blood cell stimulating factor (for anemia)	\$784	92	В	1997
17	Cipro (Bayer)	antibiotic	\$779	10	В	1987
18	Vasotec (Merck)	calcium channel blocker (for hypertension)	\$770	-9	В	1986
19	Risperdal (Jannsen)	anti-psychotic	\$753	22	В	1994
20	Glucophage (Bristol-Myers Squibb)	anti-diabetic agent	\$727	43	В	1995

notes

B = Brand name (drug has remaining patent life; no generic versions available).

B/G = Brand name product but generics available.

$\mathsf{G}=\mathsf{Generic}.$

Sales represent pharmaceutical prescription purchases, in millions of dollars at pharmacy acquisition cost, by independent, chain, foodstore, non-federal and federal hospital, clinic, HMO, and long-term care pharmacies; does not include purchases by mail order pharmacies.

Growth is the percent change in sales from 1997 to 1998.

sources

Sonderegger Research Center analysis, based on:

Sales and Sales Growth data from IMS Health, Inc., *Retail Perspective* and *Provider Perspective*, published in *Medical Marketing & Media*, May 1999. Year First Marketed from Top 200 listing published in *Pharmacy Times*, April 1999.

Top 20 Prescription Drugs Ranked by Number of Dispensed Prescriptions, 1998

exhibit 3.16

Rank	Product	Indication	1998 Prescriptions Dispensed (Million)	Brand or Generic?	Year First Marketed
1	Premarin (Wyeth-Ayerst)	hormone replacement	46.8	B/G	1964
2	Synthroid (Knoll)	thyroid replacement	38.8	B/G	1963
3	Hydrocodone w/APAP (Watson)	narcotic analgesic	29.4	G	1977
4	Trimox (Apothecon)	antibiotic	28.5	G	1977
5	Prilosec (Astra-Merck)	anti-ulcerant (proton pump inhibitor – PPI)	26.7	В	1989
6	Albuterol (Warrick)	bronchodilator	26.0	G	1982
7	Lipitor (Parke-Davis/Warner Lambert)	cholesterol-lowering	24.9	В	1997
8	Prozac (Dista/Lilly)	SSRI anti-depressant	24.8	В	1987
9	Lanoxin (Allen & Hansbury)	cardiotonic (for heart failure)	24.2	B/G	1967
10	Norvasc (Pfizer)	calcium channel blocker (for hypertension)	23.4	В	1992
11	Claritin (Schering)	antihistamine	22.3	В	1993
12	Zoloft (Roerig/Pfizer)	SSRI anti-depressant	21.0	В	1992
13	Paxil (SmithKline Beecham)	SSRI anti-depressant	19.0	В	1993
14	Vasotec (Merck)	calcium channel blocker (for hypertension)	18.5	В	1986
15	Zocor (Merck)	cholesterol-lowering	18.5	В	1992
16	Prempro (Wyeth-Ayerst)	hormone replacement	18.3	В	1995
17	Coumadin Sodium (DuPont)	anti-coagulant	17.9	B/G	1954
18	Zestril (Zeneca)	ACE inhibitor (for hypertension)	17.5	В	1988
19	Glucophage (Bristol-Myers Squibb)	anti-diabetic agent	17.2	В	1995
20	Augmentin (SmithKline Beecham)	antibiotic	15.7	B/G	1984

notes

B = Brand name (has remaining patent life; no generic versions available).

B/G = Brand name product but generics available.

G = Generic.

Rankings and number of prescriptions represent total prescriptions dispensed through independent, chain, foodstore, long-term care, and mail order pharmacies.

sources

Sonderegger Research Center analysis, based on:

Prescriptions Dispensed from IMS Health, Inc., *National Prescription Audit (NPA) Plus*, published in *Medical Marketing & Media*, May 1999. Year First Marketed from Top 200 listing published in *Pharmacy Times*, April 1999.

Trends in Popularity and Price of Top Selling Anti-Ulcer Drugs, 1985–1998

3.17

exhibit

		Year First Marketed	Rank in Top 200 Listing	Average Wholesale Price/Dose	Average Wholesale Price/Day
1985	Tagamet 300mg	1977	7	\$0.34	\$1.36
	Zantac 150mg	1983	25	\$0.81	\$1.62
	Carafate 1gm	1975	174	\$0.33	\$1.32
1990	Zantac 150mg	1983	3	\$1.31	\$2.62
	Tagamet 300mg	1977	15	\$0.58	\$2.32
	Pepcid 20mg	1986	52	\$1.16	\$2.32
	Carafate 1gm	1975	54	\$0.51	\$2.04
1995	Zantac 150mg	1983	4	\$1.65	\$3.30
	Prilosec 20mg	1989	21	\$3.63	\$3.63
	Pepcid 20mg	1986	39	\$1.48	\$2.96
	Axid 150mg	1988	61	\$1.51	\$3.02
	Cimetidine 300mg (Mylan)	1994	105	\$0.57	\$2.28
	Carafate 1gm	1975	172	\$0.74	\$2.96
1998	Prilosec 20mg	1989	5	\$3.77	\$3.77
	Prevacid 20mg	1995	34	\$3.41	\$3.41
	Pepcid 20mg	1986	49	\$1.65	\$3.30
	Axid 150mg	1988	117	\$1.60	\$3.20
	Ranitidine 150mg (various mfrs)	1997	103*	\$1.48	\$2.96
	Zantac 150mg	1983	127	\$1.72	\$3.44

notes

* Three manufacturers' Ranitidine 150mg products were in the Top 200 for 1998, at ranks 103, 134, and 189.

This exhibit shows a tendency for newer, more expensive drugs to be more popular. Over time, new products replace older products in the Top rankings.

Rank in Top 200 Listing is by total number of prescriptions dispensed in the U.S. for all therapeutic categories for the given year.

Cimetidine is the generic name for Tagamet, Ranitidine is the generic name for Zantac. The introduction date of the generic drug is when the patent on the brand name drug expired. As patents expire, generic drugs can capture market share from the original brand name drug.

Average Wholesale Price is the manufacturer's suggested list price for wholesalers selling the drug to a pharmacy. According to recent DHHS Office of the Inspector General (OIG) reports (*A-96-06-00030*, April 1997, and *A-06-97-00011*, August 1997), pharmacies purchase brand name drugs from wholesalers at AWP less an 18.3% discount and generic drugs at AWP less a 42.5% discount.

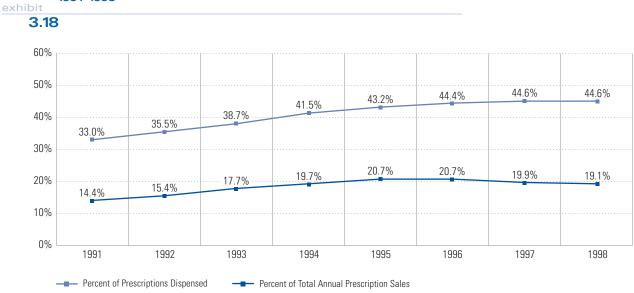
Per Day treatment prices based on recommended daily dosage.

sources

Sonderegger Research Center analysis, based on:

Top 200 listings published in Pharmacy Times, April issues, various years.

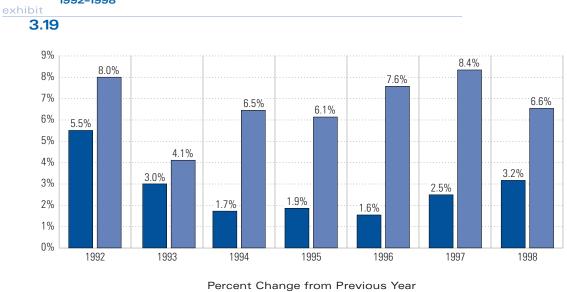
AWPs listed in Drug Topics' Red Book price reference, various years.



Generic Drugs as a Percent of Prescriptions Dispensed and Percent of Total Annual Prescription Sales in Dollars, 1991–1998

source

Scott-Levin, Source Prescription Audit (SPA), December 1999.



Retail Price Increases Reflecting the Use of Newer Drugs vs. Manufacturer Price Increases for Existing Drugs, 1992-1998

note

While the increases in retail prescription prices reflect the impact of shifts in use to newer, more expensive drugs, manufacturer price increases represent price increases only for existing drugs. There is little evidence that wholesaler or retail pharmacy pricing contribute to increased prescription prices over and above manufacturer price increases.

Average Retail Prescription Price Increase

sources

Sonderegger Research Center analysis, based on:

Inflation (Manufacturer Price Increase)

Manufacturer Price Increases from IMS Health, Inc., *Pharmaceutical Pricing UPDATE*, March 1999, based on data from *Retail and Provider Perspective* (published in *Medical Marketing & Media*, May 1999). In the IMS data, prior to 1993, only retail pharmacies and non-federal hospitals were included. From 1993 to 1998, data reflect sales by retail pharmacies, non-federal hospitals, staff-model HMOs, clinics, long-term care, and federal facilities.

Retail Prescription Prices from Scott-Levin, Source Prescription Audit (SPA), December 1999.

Trend in the Number of Top 200 Drugs for Treating Hypertension, 1975–1998

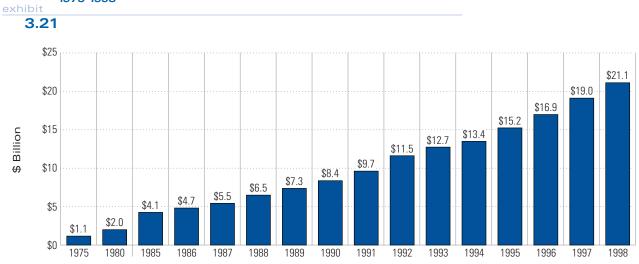
exhibit 3.20

	Number of Hypertension Drugs in the Top 200						
Drug Treatment Approach	1975	1980	1985	1990	1995	1998	
Diuretic	5	8	8	5	4	6	
Potassium-Sparing Diuretic	3	3	4	4	1	1	
Vasodilator	1	1	1	-	-	_	
Central-Acting AntiAdrenergic	2	3	3	1	-	_	
Peripherally-Acting AntiAdrenergic	7	5	1	3	2	2	
Beta Blocker	1	2	6	7	7	7	
Calcium Channel Blocker	-	-	3	6	8	9	
Angiotensin Converting Enzyme (ACE) Inhibitor	-	-	1	4	8	8	
Angiotensin II Antagonist	_	_	_	_	_	2	
Total, Top 200 Drugs for Hypertension	19	22	27	30	30	35	

three

source

Sonderegger Research Center analysis based on Top 200 listings of drugs ranked by number of prescriptions dispensed, as published in *Pharmacy Times*, April issues, various years.



Research & Development Expenditures by U.S. Pharmaceutical Manufacturers (Domestic & Foreign), 1975-1998

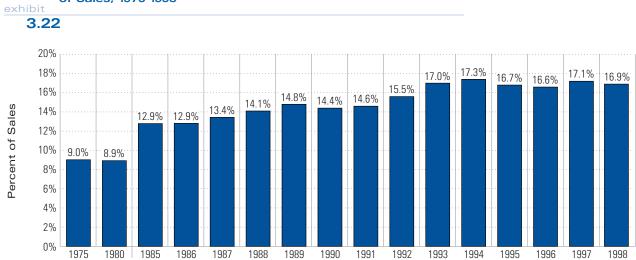
notes

Five-year intervals from 1975–1985; and 1-year intervals thereafter.

R&D expenditures for prescription pharmaceuticals only. Includes total expenditures (within the U.S. and abroad) by U.S.-owned research-based pharmaceutical companies ("major pharmaceutical firms"). Since 1990, foreign expenditures comprised approximately 19% of total R&D expenditures.

source

Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 2000, published on the PhRMA web site: www.phrma.org, May 1, 2000.



Research & Development Expenditures for Prescription Drugs by U.S. Pharmaceutical Manufacturers as a Percent of Sales, 1975–1998

notes

Five-year intervals from 1975–1985; and 1-year intervals thereafter.

Based on total domestic and foreign R&D expenditures and sales for prescription drugs only by U.S.-owned research-based pharmaceutical companies (major pharmaceutical firms).

source

Sonderegger Research Center analysis based on data from Pharmaceutical Research and Manufacturers of America, *PhRMA Annual Survey*, 2000, published on the PhRMA web site: www.pharma.org, 1 May 2000.

Domestic Pharmaceutical Research & Development (R&D) Spending by Function, 1998

exhibit 3.23

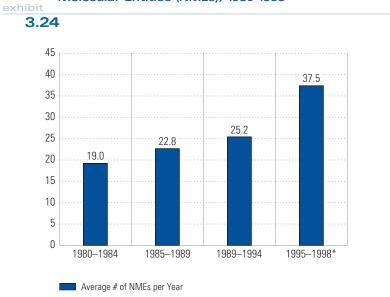
R&D Function	Amount (\$Million)	Percent of Total R&D Expenditures
Drug Synthesis & Extraction	\$2,066.7	12.0%
Biological Screening & Pharmacological Testing	\$2,600.5	15.1%
Toxicology & Safety Testing	\$895.5	5.2%
Pharmaceutical Dosage Formulation & Stability Testing	\$1,550.0	9.0%
Pre-Marketing Clinical Evaluation: Phases I, II, and III	\$4,873.9	28.3%
Post-Marketing Clinical Evaluation: Phase IV	\$998.9	5.8%
Process Development for Manufacturing & Quality Control	\$1,705.0	9.9%
Regulatory: IND and NDA (FDA Drug Approval)	\$757.7	4.4%
Bioavailability	\$413.4	2.4%
Other	\$1,360.5	7.9%
Total	\$17,222.1	100.0%

note

Amounts shown are for company-financed R&D activities in the U.S. by major U.S. pharmaceutical manufacturers for prescription drugs. The functions are listed in the approximate order of sequence in the drug discovery and drug product development process.

source

Pharmaceutical Research and Manufacturers of America, PhRMA Annual Survey, 2000, published on the PhRMA web site: www.phrma.org, May 1, 2000.



Average Annual Number of New Drug Approvals for New Molecular Entities (NMEs), 1980–1998

notes

*1995–1998 represents a 4-year period; the other groupings include 5 years.

A New Medical Entity (NME) is a unique new drug or drug compound that has not been previously approved. It includes entirely new chemicals; slightly different chemical forms of a drug derived from manipulating the molecular structure of existing, similar drugs ("me too" drugs); and also can include new mechanisms of drug release for an existing drug.

source

National Wholesale Druggists' Association, 1999 NWDA Industry Profile and Healthcare Factbook, based on U.S. Food & Drug Administration data.



Length of FDA New Drug Application Review and Approval Time, 1986–1998

note

Total time in months for a new drug application to be processed by the FDA.

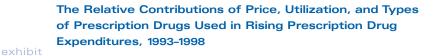
source

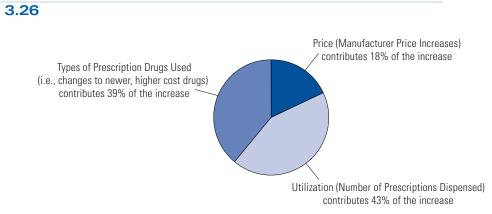
National Wholesale Druggists' Association, 1999 NWDA Industry Profile and Healthcare Factbook, based on U.S. Food & Drug Administration data.

Explaining Increases in Drug Expenditures

Exhibit 3.26 "decomposes" the growth in prescription drug expenditures to show the relative contributions of 1) price changes for existing drugs (inflation), 2) utilization, and 3) the types of prescription drugs used. Since there is no direct way of measuring the component for the types of prescription drugs used, it is estimated to be the residual from the growth in prescription expenditures after accounting for the percent changes in manufacturer prices for existing drugs and in the number of prescriptions dispensed. The component for the types of drugs used includes the impact of new drugs coming on the market that typically are priced higher than the older drugs and therapies they replace.

Price inflation, in the form of price changes by manufacturers for existing drugs (exhibit 3.5), has contributed a relatively modest portion (18%) of the increase in prescription drug expenditures since 1993. The balance of the increase in expenditures is due in approximately equal parts to increased utilization (43%) and changes in the types of drugs used to newer, higher cost drugs (39%). The introduction and use of more expensive drugs - often replacing older drugs in the same therapeutic category - is influencing the average prescription price faced by consumers and payers (health plans/insurers) more than year-to-year inflationary price changes made by manufacturers for their existing products.





Cumulative percent changes 1993–98 were: Price: 11.4% Utilization: 28.1% Types of Prescriptions Used: 25.4%

notes

Price = the annual increases in manufacturer prices, and is used to represent price increases at all levels of prescription drug distribution since there is little evidence that wholesaler or retail pharmacy prices are increasing faster than manufacturer price increases.

Utilization = the percent change in the total number of prescriptions dispensed in the U.S.

Types of Prescription Drugs Used = the residual after subtracting price and utilization changes from total prescription drug expenditure growth. It represents the shift from older, lower cost drugs to newer, higher cost drugs.

The cumulative percent changes are the compounded annual percent increases for each component from 1993–1998. Combined (multiplicatively), they comprise the total 79% increase in expenditures from 1993 to 1998.

sources

Sonderegger Research Center analysis, based on:

Number of Prescriptions from IMS Health, Inc., National Prescription Audit, published in Pharmacy Times, April issues, various years.

Manufacturer Price Increases from IMS Health, Inc., Pharmaceutical Pricing UPDATE, March 1999, based on data from Retail and Provider Perspective (published in Medical Marketing & Media, May 1999).

Prescription expenditure data from Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, HCFA web site: www.hcfa.gov, last updated January 10, 2000.

The Prescription Drug Industry: Manufacturers, Wholesalers, and Pharmacies

4
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The Prescription Drug Industry: Manufacturers, Wholesalers, and Pharmacies

The channel of distribution for prescription drugs has three primary types of firms: manufacturers (that produce drugs), wholesalers (that distribute drugs obtained from manufacturers), and pharmacies (that dispense drugs to patients). Exploring the different operations, costs, and markets of the firms at different levels in the channel of distribution is important in understanding prescription drug prices, utilization, and expenditures.

Pharmaceutical Manufacturers

Manufacturer Sales and Competition

- Pharmaceutical manufacturers can be categorized into two groups: "major pharmaceutical firms" with their emphasis on research and brand name drugs, and "generic pharmaceutical firms" that focus on producing drugs without patents. For major pharmaceutical manufacturers, the ranking by sales in exhibit 4.1 shows several firms in close contention for the top position, and gradually decreasing sales volumes for smaller firms. In contrast, sales volumes of the top generic firms fall off rapidly after the top several firms (exhibit 4.2). There was a 4-fold difference in sales between the 1st and the 20th ranked major pharmaceutical manufacturers (exhibit 4.1), compared to a 70-fold difference between the 1st and 20th ranked generic manufacturers (exhibit 4.2). (See exhibits 3.15 and 3.16 for the highest selling and most prescribed drugs from these manufacturers.)
- By sales, the generic drug industry is small relative to the major pharmaceutical manufacturers. The total sales of the top 20 generic manufacturers combined (\$7.0 billion) was only slightly more than the sales of the single top ranked major pharmaceutical manufacturer in 1998 (\$6.1 billion) (exhibits 4.1 and 4.2).

- Overall, major pharmaceutical manufacturers appear to be a relatively competitive industry, more so than generic pharmaceutical manufacturers (exhibit 4.3). One measure of industry competitiveness is the "concentration ratio," which indicates the percent of a market that is represented by a certain number of firms (in these examples, the percent of the market is based either on percent of prescriptions dispensed, or percent of sales, by the top 4 or the top 8 firms). The higher the concentration ratio, the larger the share of the market that is held by a few firms, and thus the less competitive the industry. The 4-firm concentration ratio (percent of the market represented by the top 4 firms) for major pharmaceutical manufacturers was 21.9%, compared to 30.1% for generic manufacturers. Expanding to the top 8 major pharmaceutical manufacturers (the 8-firm concentration ratio), only 38.7% of the market was represented by the top 8 firms, compared to 50.8% for generic manufacturers.
- However, within many therapeutic categories, a different picture of industry concentration emerges for major pharmaceutical manufacturers. The 4-firm concentration ratios for individual therapeutic categories often are relatively high, even approaching 100% for some categories, reflecting concentrated markets and potential for considerable market power by a few firms within those therapeutic categories (exhibit 4.4). As the recent trend of mergers and alliances between firms continues, therapeutic category concentration ratios may increase.

Manufacturer Financial Operations

 Based on financial operating information for the top 10 major and generic pharmaceutical manufacturers by sales, exhibit 4.5 shows how much of an average sales dollar they commit for various operating functions. Research and Development (R&D) is the smallest component of expense as a proportion of sales for both major pharmaceutical manufacturers (11%) and generic manufacturers (6%). However, for every dollar of sales, major manufacturers spend almost twice as much as generic manufacturers on R&D. Major manufacturers also commit more of each sales dollar to Marketing, General, and Administrative expenses (34% vs. 22%), but use a much smaller proportion of revenues for the raw materials and production costs (Cost of Sales) for manufacturing drug products (26% vs. 56%). Profits as a percent of sales for major manufacturers are approximately 1.5 times the profits for generic manufacturers (24% vs. 16%).

- Profits for the top ranked major pharmaceutical manufacturers have been relatively stable over the last 10 years (exhibit 4.6).
 Research and Development has also remained relatively constant, while Cost of Sales and Marketing, General and Administrative costs have declined.
- Pharmaceutical manufacturers historically have been the top ranking industry for profits as a percent of revenue (exhibit 4.7). In 1999, pharmaceutical manufacturers had a profit margin of 18.9%, compared to a median of 5.0% for all Fortune 500 firms.

Manufacturer Customer Mix

 Sales of prescription drugs to wholesalers continues to be the predominant mechanism of distribution for manufacturers' products (exhibit 4.8). Sales directly to retail pharmacies (including independent pharmacies, chain drugstores, and chain warehouse operations), hospitals, and other pharmacies and purchasers comprise only about one-fifth of all prescription sales since 1995.

Top 20 Major Pharmaceutical Manufacturers Ranked by Prescription Sales, 1997 and 1998

exhibit 4.1

Bank by Sales 1998 Company Sales (\$ Million) (% of Total Prescription Sales Market) 4 1 Pfizer, Inc. \$6,085 6.5 1 2 Merck & Company, Inc. \$6,076 6.5 3 3 Bristol-Myers Squibb Co. \$5,905 6.3 2 4 Glaxo-Wellcome, plc. \$5,376 5.7 6 5 Johnson & Johnson \$4,857 5.2 7 6 Eli Lilly and Company \$4,517 4.8 5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis A6 \$3,395 4.2 10 10 SmithKline Beecham, plc. \$3,618 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,261 2.4 15) only by (Calaa		1998 Prescription	Market Share (% of Total Prescription	Rank by Number of Prescriptions
1 2 Merck & Company, Inc. \$6,076 6.5 3 3 Bristol-Myers Squibb Co. \$5,905 6.3 2 4 Glaxo-Wellcome, plc. \$5,376 5.7 6 5 Johnson & Johnson \$4,857 5.2 7 6 Eli Lilly and Company \$4,517 4.8 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	'		Company			Dispensed, 1998
3 3 Bristol-Myers Squibb Co. \$5,905 6.3 2 4 Glaxo-Wellcome, plc. \$5,376 5.7 6 5 Johnson & Johnson \$4,857 5.2 7 6 Eli Lilly and Company \$4,517 4.8 5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn,	4	1	Pfizer, Inc.	\$6,085	6.5	5
2 4 Glaxo-Wellcome, plc. \$5,376 5.7 6 5 Johnson & Johnson \$4,857 5.2 7 6 Eli Lilly and Company \$4,517 4.8 5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Ro	1	2	Merck & Company, Inc.	\$6,076	6.5	8
6 5 Johnson & Johnson \$4,857 5.2 7 6 Eli Lilly and Company \$4,517 4.8 5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	3	3	Bristol-Myers Squibb Co.	\$5,905	6.3	2
7 6 Eli Lilly and Company \$4,517 4.8 5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	2	4	Glaxo-Wellcome, plc.	\$5,376	5.7	9
5 7 American Home Products Corp. \$4,334 4.6 8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	6	5	Johnson & Johnson	\$4,857	5.2	11
8 8 Schering-Plough Corp. \$4,270 4.5 9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	7	6	Eli Lilly and Company	\$4,517	4.8	20
9 9 Novartis AG \$3,995 4.2 10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	5	7	American Home Products Corp.	\$4,334	4.6	1
10 10 SmithKline Beecham, plc. \$3,815 4.1 14 11 Warner-Lambert Co. \$3,568 3.8 11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	8	8	Schering-Plough Corp.	\$4,270	4.5	6
1411Warner-Lambert Co.\$3,5683.81112Abbott Laboratories\$3,1113.31213Astra Merck, Inc.\$3,0763.31314Hoffman-La Roche, Ltd.\$2,2912.41515Amgen, Inc.\$2,2612.41916TAP Pharmaceuticals\$1,9452.11817Zeneca Pharmaceuticals\$1,8792.01718Pharmacia & Upjohn, Inc.\$1,8201.91619Hoechst Marion Roussel\$1,8061.9	9	9	Novartis AG	\$3,995	4.2	3
11 12 Abbott Laboratories \$3,111 3.3 12 13 Astra Merck, Inc. \$3,076 3.3 13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	0	10	SmithKline Beecham, plc.	\$3,815	4.1	14
1213Astra Merck, Inc.\$3,0763.31314Hoffman-La Roche, Ltd.\$2,2912.41515Amgen, Inc.\$2,2612.41916TAP Pharmaceuticals\$1,9452.11817Zeneca Pharmaceuticals\$1,8792.01718Pharmacia & Upjohn, Inc.\$1,8201.91619Hoechst Marion Roussel\$1,8061.9	4	11	Warner-Lambert Co.	\$3,568	3.8	13
13 14 Hoffman-La Roche, Ltd. \$2,291 2.4 15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	1	12	Abbott Laboratories	\$3,111	3.3	19
15 15 Amgen, Inc. \$2,261 2.4 19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	2	13	Astra Merck, Inc.	\$3,076	3.3	NR
19 16 TAP Pharmaceuticals \$1,945 2.1 18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	13	14	Hoffman-La Roche, Ltd.	\$2,291	2.4	NR
18 17 Zeneca Pharmaceuticals \$1,879 2.0 17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	15	15	Amgen, Inc.	\$2,261	2.4	NR
17 18 Pharmacia & Upjohn, Inc. \$1,820 1.9 16 19 Hoechst Marion Roussel \$1,806 1.9	19	16	TAP Pharmaceuticals	\$1,945	2.1	NR
1619Hoechst Marion Roussel\$1,8061.9	8	17	Zeneca Pharmaceuticals	\$1,879	2.0	NR
•••••••••••••••••••••••••••••••••••••••	17	18	Pharmacia & Upjohn, Inc.	\$1,820	1.9	15
20 20 Bayer AG \$1,489 1.6	16	19	Hoechst Marion Roussel	\$1,806	1.9	10
	20	20	Bayer AG	\$1,489	1.6	NR
Total for Top 20 Firms \$72,476 77.1			Total for Top 20 Firms	\$72,476	77.1	

notes

NR = not in top 20 firms ranked by number of total prescriptions dispensed in the U.S. in 1998.

Sales Rank and Market Share represent prescription purchases, in millions of dollars, at pharmacy acquisition cost by independent, chain, foodstore, non-federal and federal hospital, clinic, HMO, and long-term care pharmacies. Sales data do not include mail order data.

Rank by Number of Prescriptions Dispensed represents total prescriptions dispensed through independent, chain, foodstore, long-term care, and mail order pharmacies.

sources

Sales and Market Share from IMS Health, Inc., *Retail Perspective and Provider Perspective* published in *Medical Marketing & Media*, May 1999. Rank by Number of Prescriptions Dispensed from IMS Health, Inc., *NPA Plus*, published in *Medical Marketing & Media*, May 1999.

Top 20 Generic Drug Manufacturers Ranked by Total Sales, 1998

exhibit 4.2

Rank by Total Sales 1998	Company	Sales (\$ Million)	Market Share* (% of Total Market)
1	Teva Pharmaceutical Industries, Ltd.	\$1,115.9	10.0%
2	Perrigo, Co.	\$877.6	7.9%
3	Mylan Laboratories, Inc.	\$721.1	6.5%
4	Ivax Corp.	\$637.9	5.7%
5	Forest Laboratories, Inc.	\$624.0	5.6%
6	Allpharma, Inc.	\$604.6	5.4%
7	Watson Pharmaceuticals, Inc.	\$556.1	5.0%
8	Schein Pharmaceutical Inc.	\$523.2	4.7%
9	Barr Laboratories, Inc.	\$444.0	4.0%
10	Ranbaxy Laboratories, Inc.	\$257.3	2.3%
11	Copley Pharmaceuticals, Inc.	\$133.5	1.2%
12	Jones Pharma, Inc.	\$103.4	0.9%
13	Taro Pharmaceutical Industries, Ltd.	\$66.7	0.6%
14	Warner Chilcott, Plc.	\$64.9	0.6%
15	Pharmaceutical Formulations, Inc.	\$60.4	0.5%
16	Akorn, Inc.	\$56.7	0.5%
17	Duramed Pharmaceuticals, Inc.	\$49.8	0.4%
18	DynaGen, Inc.	\$25.0	0.2%
19	Hi-Tech Pharmacal Company, Inc.	\$23.3	0.2%
20	Bradley Pharmaceuticals, Inc.	\$15.9	0.1%
	Total for Top 20 Firms	\$6,961.3	62.4%

note

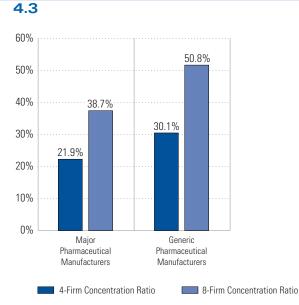
*Market Share based on \$11,150 million total U.S. market of sales for all generic drugs sold in the U.S. The companies listed are not subsidiaries and derive more than 50% of their business from generic prescription drug product sales.

source

"Generics: Best Years to Come," Med Ad News, October 1999.

Market Concentration Among Major Pharmaceutical Manufacturers and Generic Pharmaceutical Manufacturers, 1998

exhibit



notes

The 4-firm and 8-firm concentration ratios are the percentages of the market that the top 4 firms and the top 8 firms represent.

For the Major Pharmaceutical Manufacturers, the concentration ratios are based on total U.S. prescriptions by firm.

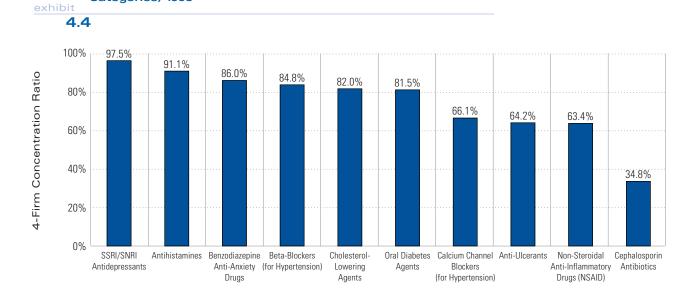
For the Generic Pharmaceutical Manufacturers, the concentration ratios are based on the total sales of generic drugs in the U.S.

sources

Sonderegger Research Center analysis, based on:

Total prescriptions by firm for major pharmaceutical manufacturers and total U.S. prescriptions from IMS Health, Inc., National Prescription Audit (NPA) Plus, published in Medical Marketing & Media, May 1999.

Top firms' sales figures and total sales in 1998 for generic pharmaceutical manufacturers published in "Generics: Best Years to Come," Med Ad News, October 1999.



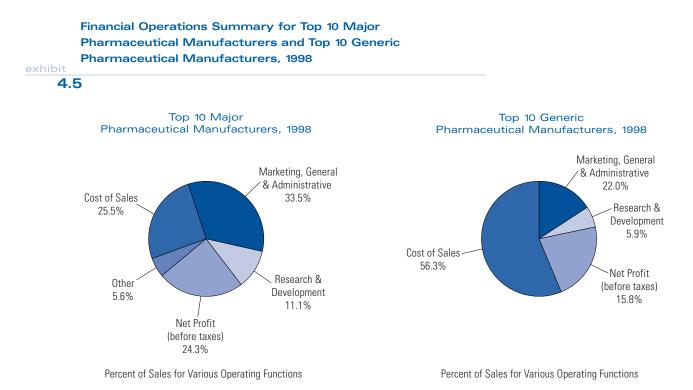
Market Concentration in the Top Therapeutic Categories, 1998

note

Includes all the top therapeutic categories, ranked by number of dispensed prescriptions, except for non-injectable Codeine & Codeine Combinations, and ACE Inhibitors. The 4-firm concentration ratio is the percentage of all prescriptions dispensed in that therapeutic category that are sold by the top 4 firms.

source

Sonderegger Research Center analysis based on U.S. prescription activity data from Scott-Levin, Source Prescription Audit (SPA) for selected products, December 1999.



notes

Top 10 rankings based on prescription sales.

Percents shown are the averages across firms, based on the amounts for all the firms' activities or expenses as a percent of total firm sales. The expenses and sales figures used in the calculations include prescription drugs and other products the firms manufacture.

Cost of Sales = cost of raw materials and production costs for manufacturing the finished goods to be sold.

Marketing, General & Administrative = costs of promoting and selling the goods, plus general business expenses.

Research & Development = costs of identifying new drugs and products, and developing them for market, including testing and approval.

Other = other costs, special charges, unusual items, restructuring charges, etc.

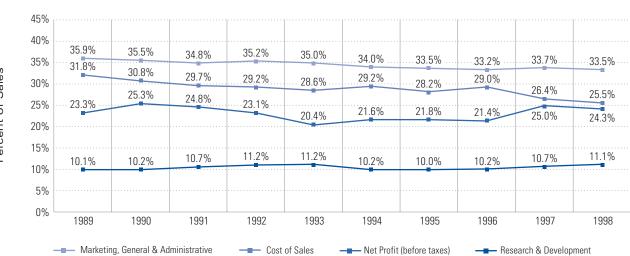
Net Profit (before taxes) = the residual from sales after deducting all expenses (i.e, Cost of Sales; Marketing, General & Administrative; R&D; and Other).

sources

Sonderegger Research Center analysis, based on:

Top 10 pharmaceutical manufacturers' consolidated financial statements in their Annual Reports for 1998 (from the firms' web sites). Firms included are American Home Products, Bristol-Myers Squibb, Glaxo Wellcome, Johnson & Johnson, Lilly, Novartis, Pfizer, Schering-Plough, SmithKline Beecham, and Warner-Lambert. Merck is not included to avoid the confounding influence from pharmacy operations of the Merck Medco mail order pharmacy subsidiary on the consolidated Merck financial statements.

Top 10 generic pharmaceutical manufacturers' financial data from "Generics: Best Years to Come," Med Ad News, October 1999.



Trends in Financial Operations for Top 10 Major Pharmaceutical Manufacturers, 1989-1998

Percent of Sales

exhibit

4.6

notes

Data represent financial statements and overall operations for the Top 10 major pharmaceutical manufacturers, based on prescription sales. Percents shown are the averages across firms, based on the amounts from the firms' consolidated financial statements, including expenses and sales for prescription drugs and other products that the firms manufacture.

Cost of Sales = cost of raw materials and production costs for manufacturing the finished goods to be sold.

Marketing, General & Administrative = costs of promoting and selling the goods, plus general business expenses.

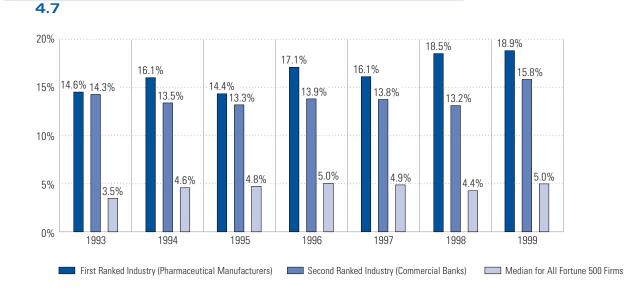
Net Profit (before taxes) = the residual from sales after deducting all expenses (i.e, Cost of Sales; Marketing, General & Administrative; R&D; and Other).

Research & Development = costs of identifying new drugs and products, and developing them for market, including testing and approval.

Other expenses (5.6% of sales in 1998, including other costs, special charges, unusual items, restructuring charges, etc.) are not shown.

source

Sonderegger Research Center analysis, based on financial statements of Top 10 ranked (by sales) major pharmaceutical manufacturers. Firms included are American Home Products, Bristol-Myers Squibb, Glaxo Wellcome, Johnson & Johnson, Lilly, Novartis, Pfizer, Schering-Plough, SmithKline Beecham, and Warner-Lambert. Novartis data are included only after 1995, when the company was formed by the merger of Sandoz and Ciba-Geigy. Includes only R&D and net profit data for Glaxo Wellcome. Merck is not included to avoid the confounding influence of pharmacy operations of the Merck Medco mail order pharmacy subsidiary on the consolidated Merck pharmaceutical manufacturing financial statements.



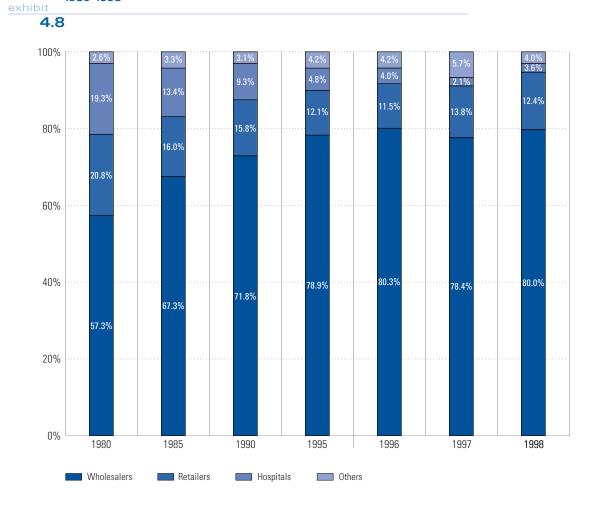
Profitability Among Pharmaceutical Manufacturers Compared to Other Industries, 1993-1999 exhibit

note

Percent shown is the median percent net profit after taxes as a percent of firm revenues for all firms in the industry. The second ranked industry each year was commercial banks.

source

Fortune 500 Industry Rankings, Fortune, April issues, various years.



The Customer Mix of Major Pharmaceutical Manufacturers, 1980–1998

notes

Five-year intervals from 1980–1995; and 1-year intervals thereafter.

Includes only major U.S. pharmaceutical manufacturers; does not include generic drug manufacturers.

source

Pharmaceutical Research and Manufacturers of America (PhRMA), 1980–1997 data from the PhRMA Annual Survey 1999, from the PhRMA web site: www.phrma.org, December 1999; 1998 data from PhRMA Annual Survey 2000, via www.phrma.org, May 2000.

Drug Wholesalers

Wholesaler Sales and Competition

The drug wholesaler industry is a very concentrated market, with the top 5 firms achieving nearly the entire industry's sales in 1998 (exhibit 4.9). Mergers and acquisitions within the drug wholesaler industry have contributed to this concentrated industry structure, with the proportion of sales among the top 8 firms growing to 95% by 1998 (exhibit 4.10).

Wholesaler Financial Operations

 Drug wholesalers have operated with declining Gross Margins (the difference between the prices they pay manufacturers for drugs and the prices at which they sell the drugs to pharmacies) and declining Net Profits (the Gross Margin minus Operating Expenses) as a percent of sales nearly every year since 1990 (exhibit 4.11).
 Wholesalers have grown increasingly efficient, with Operating Expenses declining over time.

Wholesaler Customer Mix

 The customer mix of drug wholesalers (exhibit 4.12) has shown consistent decline in sales to independent pharmacies, steady sales to chain pharmacies and mass merchandisers, but increasing sales to hospitals and other pharmacies (home health care, etc.). The increase in percentage of sales to hospital pharmacies has corresponded with a decreasing trend of sales directly to hospitals by manufacturers (exhibit 4.8). The decrease in sales to independent pharmacies is consistent with the decreasing number of independent retail pharmacies shown in exhibit 4.13.

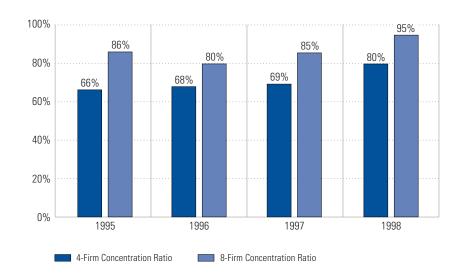
Top 10 Drug Wholesalers Ranked by Sales Activity, 1998

exhibit **4.9**

Rank	Drug Wholesaler	1998 Sales (\$ Million)	Market Share (% of Total Drug Wholesale Market)
1	McKesson HBOC Corp.	\$21,484	28%
2	Bergen Brunswig Drug Corp.	\$16,698	22%
3	Cardinal Health, Inc.	\$14,928	19%
4	AmeriSource Corp.	\$8,669	11%
5	Bindley Western Drug Co.	\$7,623	10%
6	Neuman Distributors, Inc.	\$1,668	2%
7	Kinray Inc.	\$905	1%
8	C.D. Smith Healthcare, Inc.	\$798	1%
9	D&K Healthcare Resources, Inc.	\$703	1%
10	Remo Drug Corp.	\$508	1%
	Total for Top 10 Firms	\$73,984	96%

source

National Wholesale Druggists' Association (NWDA) Industry Profile, 1999, based on data from NWDA surveys of member wholesalers.



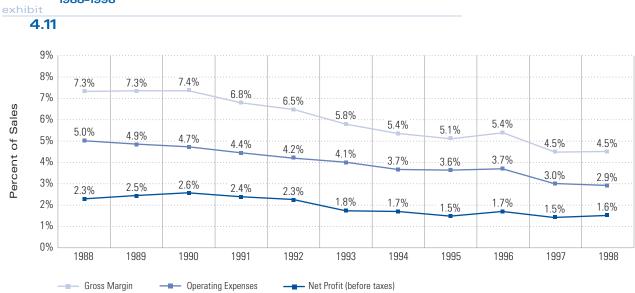
Market Concentration Among Drug Wholesalers, 1995–1998 exhibit 4.10

note

Concentration ratios are calculated as the percentage of total industry sales that the top 4 firms and the top 8 firms represent. (Totals may be different from exhibit 4.9 due to rounding.)

source

National Wholesale Druggists' Association (NWDA) Industry Profile, 1999, based on data from NWDA surveys of member wholesalers.



Trends in Financial Operations for Drug Wholesalers, 1988-1998

notes

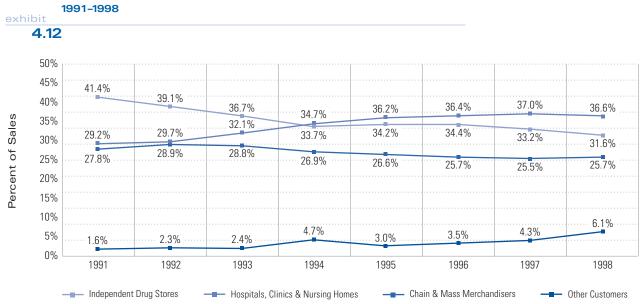
Gross Margin = the difference between the price paid by the wholesaler to obtain the drugs from a manufacturer and the price at which the wholesaler sells the drugs to pharmacies (i.e., Sales minus Cost of Goods Sold).

Operating Expenses = labor, rent, utilities, and all costs of operations other than the Cost of Goods Sold.

Net Profit (before taxes) = residual from Gross Margin after deducting Operating Expenses.

source

National Wholesale Druggists' Association (NWDA) Industry Profile, 1999, based on data from NWDA surveys of member wholesalers.



Percent of Drug Wholesaler Sales by Type of Customer,

note

Percent of sales shown is a composite of all wholesaler sales, including prescription drugs, nonprescription drugs, health and personal care items, general merchandise, and durable medical equipment/home health care. Prescription drugs comprised 79.2% of wholesaler sales in 1991 and grew to 88.4% of sales in 1998.

source

National Wholesale Druggists' Association (NWDA) Industry Profile, 1999.

Pharmacies

Number and Types of Pharmacies

 The types of retail pharmacies include: Independent pharmacies: individual pharmacies or small chains of pharmacies (e.g., 10 or fewer stores) that are privately owned. They have a greater reliance on prescription sales (70% – 85%) than traditional chain pharmacies, but have more general merchandise sales than pharmacies such as the Medicine Shoppe franchises.

Traditional Chain drug stores: traditional chain drug stores (such as Walgreen, Eckerd, Rite Aid, American Drug Stores, Longs Drug Stores, CVS). Their percent of sales from prescriptions is about 50%. *Franchise pharmacies* are also considered chain pharmacies; for example, Medicine Shoppe pharmacies are independently owned franchises that operate as apothecary or clinic-type pharmacies, with little or no general merchandise sales.

Mass Merchandiser pharmacies (such as Wal-Mart, Kmart, Target) and Food Store pharmacies (such as Kroger, Safeway, Albertsons): generally they are outlets in multi-store chain organizations. Prescription sales are a small part (approximately 5% – 10%) of their total business.

In 1998, there were about 52,000 retail pharmacies in the U.S., down from about 59,000 in 1990 (exhibit 4.13). In addition to the approximately 12% decline in the total number of retail pharmacies in the past 8 years, the market has shifted away from independent pharmacy operations toward traditional chain drugstores, food stores, and mass merchandisers. Between 1990 and 1998, the percent of retail pharmacies that were independently owned decreased from about 54% to 40%.

- Although there are only about 300 mail order pharmacies (including mail order divisions of chain pharmacies), sales of prescriptions by mail order pharmacies grew from 6.7% of the market in 1990 to 13.0% in 1998 (exhibit 4.14).
- Consumer access to prescription drugs through the Internet has increased in recent years. In 1999, several new "Internet pharmacy" sites began operating. These "Internet pharmacies" mimic traditional retail pharmacies and compete with them (e.g., they buy a full range of prescription drugs from wholesalers and manufacturers for dispensing to consumers, and may offer professional services such as patient education and screening for drug interactions). Other Internet "prescription sites" have opened as contact points for a limited selection of drugs (e.g., "lifestyle" drugs, such as Viagra). These Internet "prescription sites" offer both prescription order writing and filling services. In addition, traditional retail pharmacies have developed their own Internet sites as an alternative way for consumers to access the pharmacy for refills and prescription orders. Because consumer access to prescription drugs through the Internet is relatively new, data are limited. One source indicated that total Internet prescription sales in 1999 were \$160 million, representing less than 0.2% of the U.S. market for prescriptions.12 Although Internet access to prescription drugs may offer convenience, lower prices, and easy availability, those benefits may, in some cases, be offset by concerns about lack of patient education or safeguards, poorly monitored prescription writing, and the quality of the drugs themselves, especially with Internet "prescription sites."

¹² Johannes, Laura, "Competing Online, Drugstore Chains Virtually Undersell Themselves," Wall Street Journal, January 10, 2000, pp. B1, B6.

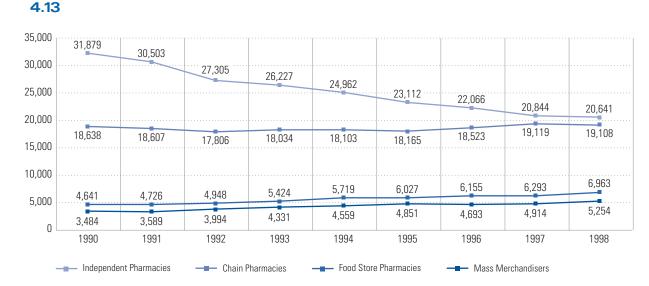
Pharmacy Sales and Competition

- Sales by the Top 5 selling drugstore chains account for nearly 80% of the Top 10 chains' prescription sales (exhibit 4.15). Several of the top chain drug stores have had sizeable increases in prescription sales volume since 1996 (exhibit 4.16). This growth reflects mergers and acquisitions (e.g., acquisitions by CVS and Rite Aid in 1996) plus new store openings.
- Exhibit 4.15 also shows varying contributions of prescription sales to total sales for the top drugstore chains. For traditional drugstore chains, about half of store sales are due to prescriptions, but for mass merchandiser and food store pharmacies, prescriptions are only a small part (about 5% - 10%) of the total store sales. For independent pharmacies, prescription sales generally account for a greater proportion of the total store sales (approximately 70% - 85%) than occurs in traditional drugstore chains.¹³
- The retail pharmacy industry (including all chain and independent pharmacies) appears to be a moderately competitive industry, based on the 4-firm and 8-firm concentration ratios for prescription sales nationwide (exhibit 4.17). In 1998, the Top 4 firms represented about one-third of the entire market, and the Top 8 firms represented slightly less than half of the market. Mergers and acquisitions among chain pharmacies have increased the concentration ratios since 1996.

Pharmacy Financial Operations

 Pharmacy Gross Margins as a percent of sales have decreased (exhibit 4.18), even though the average retail prescription price has increased (exhibit 3.3). With an increasing proportion of prescription expenditures paid by insurers (exhibit 1.3), pharmacies are affected by the payment approaches and cost containment efforts of insurers, which have reduced pharmacy payments (e.g., dispensing fees) and margins. Operating Expenses as a percent of sales also have decreased, yielding essentially unchanged Net Profits as a percent of sales over the last ten years.

¹³ NCPA–Searle Digest, 1999.



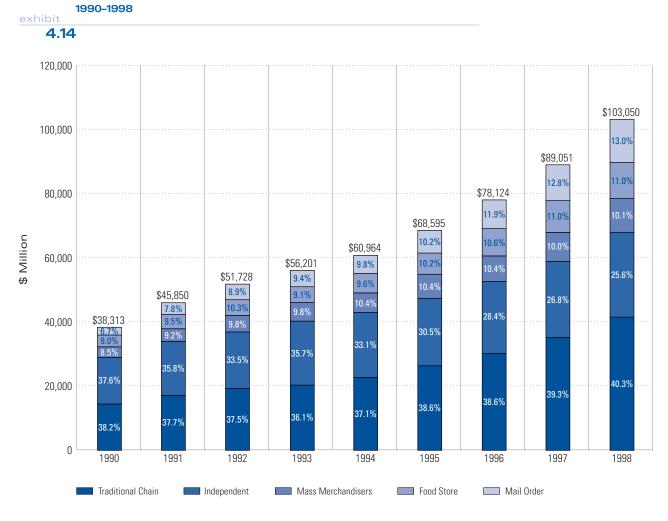
Trends in the Number of Retail Pharmacies, 1990–1998 exhibit

note

Does not include mail order pharmacies, numbering approximately 300 in 1998.

source

National Association of Chain Drug Stores (NACDS), The Chain Pharmacy Industry Profile, 1999, estimated based on data from IMS Health, Inc., National Council for Prescription Drug Programs (NCPDP), and American Business Information, Inc.



Percent of Retail Prescription Sales by Type of Pharmacy,

source

National Association of Chain Drug Stores (NACDS), The Chain Pharmacy Industry Profile, 1999.

Top 10 Drugstore Chains, 1998

4.15

Rank	Company	Prescription Sales \$ Million	Percent of Sales From Prescriptions
1	CVS Corp.	\$8,536	57%
2	Walgreen Co.	\$7,650	50%
3	Rite Aid Corp.	\$6,365	50%
4	Eckerd Corp.	\$6,665	64%
5	Wal-Mart Stores, Inc.	\$5,500	4%
6	American Drug Stores	\$2,900	44%
7	The Kroger Co.	\$1,800	6%
8	KMart	\$1,700	5%
9	Medicine Shoppe International, Inc.	\$1,294	95%
10	Longs Drug Stores, Inc.	\$1,210	37%
	Total for Top 10 Firms	\$43,620	

source

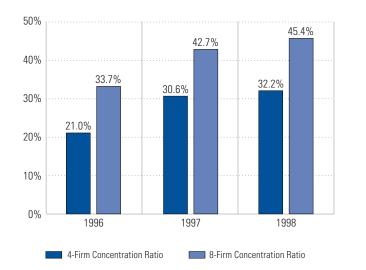
National Wholesale Druggists' Association (NWDA) Industry Profile and HealthCare Factbook, 1999, based on data from Drug Store News/Chain Store Guide, 1999.



Prescription Sales of the Top 5 Chain Drug Stores, 1996–1998 exhibit

source

National Wholesale Druggists' Association (NWDA) Industry Profile and HealthCare Fact Book, 1998 and 1999 (based on data from Drug Store News/Chain Store Guide, 1998 and 1999).



Market Concentration Among Retail Pharmacies, 1996-1998 exhibit

notes

4.17

The retail pharmacy industry includes all chain drug stores and independent pharmacies.

The 4-firm and 8-firm concentration ratios are the percentages of total retail pharmacy sales that the top 4 firms and the top 8 firms represent (the top 4 and 8 firms are all chain pharmacy corporations).

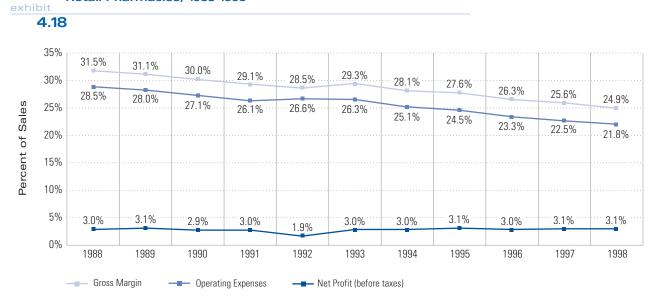
In calculating the concentration ratios, national prescription expenditures from the HCFA Office of Actuary were used as an estimate of total U.S. prescription sales for each year.

sources

Sonderegger Research Center analysis, based on:

Sales for chain drug stores from National Wholesale Druggists' Association (NWDA) Industry Profile and HealthCare Factbook, 1999.

National prescription expenditures from Health Care Financing Administration (HCFA), Office of the Actuary, National Health Statistics Group, from the HCFA web site: www.hcfa.gov, January 10, 2000.



Trends in Financial Operations for Independently Owned Retail Pharmacies, 1988-1998

notes

Gross Margin = the difference between the price paid by a pharmacy to obtain drugs from a wholesaler and the price at which the pharmacy sells the drugs to consumers (i.e., Sales minus Cost of Goods Sold).

Operating Expenses = labor, rent, utilities, and all costs of operations other than the Cost of Goods Sold.

Net Profit (before taxes) = the residual from Gross Margin after deducting Operating Expenses.

The data represent financial statements and overall operations for independently-owned pharmacies (where prescriptions were 82% of total sales in 1998). Similar results occur for traditional chain pharmacies. Analysis of annual reports from 5 of the top 10 traditional chain operations (including Walgreens, CVS, Eckerd, Rite Aid, and Longs Drug Stores) for 1996 and 1998, respectively, showed average Gross Margins of 26.0% and 25.6%, Operating Expenses of 21.6% and 21.5%, and Net Profits of 4.4% and 4.1% (Sonderegger Research Center analysis of top chain pharmacy annual reports).

source

NARD-Lilly Digest, NCPA-Searle Digest, various years.

glossary

Actual Acquisition Cost (AAC): the net cost at which the pharmacy acquires a drug. It varies with the size of container purchased (e.g., ten bottles of 100 tablets typically cost more than one bottle of 1,000 tablets) and the source of purchase (manufacturer or wholesaler).

Average Manufacturer Price (AMP): the price at which drugs are sold by the manufacturer to purchasers. For sales to wholesalers, AMP represents the Wholesaler Acquisition Cost (WAC) after all discounts; for sales directly to pharmacies, AMP represents the net "direct" price after discounts.

Average Wholesale Price (AWP): a national average of list prices charged by wholesalers to pharmacies. With few exceptions, the AWP is the manufacturer's suggested list price for a wholesaler to charge a pharmacy for a drug. It typically is higher than the pharmacy's actual acquisition cost (in 1997, the Office of Inspector General, Department of Health and Human Services, reported that pharmacies paid 18.3% less than AWP for brand name drugs and 42.5% less than AWP for generic drugs).

Brand Name Drug: generally, a drug product that is covered by a patent and thus is manufactured and sold exclusively by one firm. Cross licensing occasionally occurs, allowing an additional firm(s) to market the drug. After the patent expires, multiple firms can produce the drug product, but the brand name remains with the original manufacturer's product.

Cash Prescription: a prescription purchased in a retail pharmacy where the consumer pays the pharmacy's usual and customary (U&C) charge entirely out-of-pocket when the prescription is dispensed.

Chain Pharmacy: a corporate organization with multiple pharmacy store outlets under common ownership. Traditional chain pharmacies (such as Walgreen, Eckerd, Rite Aid, CVS) have approximately 50% of their sales as prescriptions and the remaining mix of sales in other merchandise. Mass Merchandiser chain pharmacies (such as Wal-Mart, KMart, ShopKo) and Food Store chain pharmacies (such as Kroger, Albertsons) have a small proportion (5 – 10%) of their total sales for prescriptions.

Channel of Distribution: all the groups and levels of firms involved in the process of getting products to end users, from producers of raw materials, to finished goods manufacturers, to middlemen distributors, to retailers, and ultimately to the consumer or end user. For pharmaceuticals, it includes producers of drugs in chemical form and manufacturers of drug products as finished goods, drug wholesalers, pharmacies, and consumers.

Concentration Ratio: a way of expressing how concentrated sales or production is within an industry (the higher the concentration ratio, the less competition among firms). Typically, 4-firm and 8firm concentration ratios are determined, with the ratios calculated as the percentage of total industry sales or production that the top 4 and 8 firms represent.

Coinsurance: a cost-sharing requirement under a health insurance policy that requires the patient to pay a percentage of costs for covered services/ prescriptions (e.g., 20% of the prescription price).

Copayment: a cost-sharing requirement under a health insurance policy that requires the patient to pay a specified dollar amount for each unit of service (e.g., \$10.00 for each prescription dispensed). Cost of Goods Sold: for retail or wholesale firms, the cost of merchandise that was acquired with the intent of re-sale to the firms' customers. For a drug wholesaler, the cost of goods sold is the net price paid to the manufacturer for the drugs the wholesaler subsequently sells to pharmacies (wholesale acquisition cost, WAC). For a pharmacy, the cost of goods sold is the net price paid to the wholesaler (or manufacturer, if purchasing directly from the manufacturer) for the drugs sold to consumers (actual acquisition cost, AAC).

Cost of Sales: within manufacturing industries, the cost of raw materials and production costs for manufacturing finished goods for sale. Cost of sales typically does not include the manufacturer's expenses involved in selling, distribution, research, or general administration. A parallel within wholesaling or retailing industries would be the cost of goods sold.

Customer Mix: the variety and proportions of different types of customers that a firm has, including, for example, those with different demographic characteristics or sources of prescription payment.

Detailing: personal selling activities by pharmaceutical manufacturer sales representatives. The representatives inform prescribers, pharmacists, and others about the specifics or details of their firms' products, thus the label "detailing." Sales representatives often leave samples of products for prescribers for trial use among their patients, to stimulate future prescribing.

Direct Pay Insured Prescription: a prescription covered under a service benefit drug coverage insurance plan (i.e., a private or public insured prescription program). Service benefit plans provide direct payment to the pharmacy for the prescription; consumers are required to pay only a copayment or coinsurance when obtaining each prescription.

Direct-to-Consumer Advertising/Promotion:

advertising for prescription drugs in print, radio, and television media targeted directly to consumers by pharmaceutical manufacturers. Consumers are the targeted audience, even though prescription drugs require a prescription order from a prescriber in order to be dispensed. Dispensing Fee: an amount added to the prescription ingredient cost by a pharmacy to determine a prescription price. The dispensing fee represents the charge for the professional services provided by the pharmacist when dispensing a prescription (including overhead expenses and profit). Most direct pay insured prescription programs use dispensing fees to establish pharmacy payment for prescriptions.

Drug: a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

Drug & Non-Durable Expenditures: spending for prescription drugs, over-the-counter medicines, and sundries purchased in retail outlets.

Drug Wholesaler: a firm involved in the logistics function (assembling, sorting, and redistributing) in the channel of distribution for pharmaceuticals. They purchase goods from manufacturers and redistribute them to pharmacies based on the needs and orders of the pharmacies.

Estimated Acquisition Cost (EAC): an estimate of the price at which most pharmacists can purchase a drug from a wholesaler or manufacturer. These estimates are developed by pharmacy benefit managers (PBMs) or prescription insurance program administrators in order to establish payment amounts to pharmacies for the drug costs of prescriptions dispensed (prescription ingredient costs) to covered individuals. An EAC is used in reimbursement for certain single source drugs (i.e., brand name drugs for which no generic equivalents exist). The size of the container or source of purchase are factors considered when determining the EAC.

Food Store/Supermarket Pharmacies: pharmacy departments within chain grocery store outlets. The prescription department generates a small proportion of total store sales, but is used to draw customers and build a "full service" image for the supermarket. Examples include Kroger, Albertsons, Sav-On/Tom Thumb, etc. Formulary: a listing of drug products that may be dispensed or reimbursed (positive formulary) or that may not be dispensed or reimbursed (negative formulary). A government body, third-party insurer or health plan, or an institution may compile a formulary. Some institutions or health plans develop closed (i.e, restricted) formularies where only those drug products listed can be dispensed in that institution or reimbursed by the health plan. Other formularies may have no restrictions (open formulary) or may have certain restrictions such as higher patient cost-sharing requirements for offformulary drugs.

Franchise Pharmacies: pharmacies that are independently owned, but organized under a franchising umbrella organization that often provides management, marketing, and purchasing support. These pharmacies share many similarities with independent pharmacies, but have a common name and identifying logo. The majority of store sales are prescriptions. Examples include Medicine Shoppe International, etc.

Generic Drug: a drug product that is no longer covered by patent protection and thus may be produced and/or distributed by many firms.

Gross Margin: the amount remaining from the sale of an item after paying for the cost of acquiring the item. It can refer to an individual sale, or the aggregate of combined sales over a period of time. For a prescription, it is the difference between the price a pharmacy charges for the prescription (retail price) and what the pharmacy had to pay to purchase the drug (Actual Acquisition Cost) that was dispensed in the prescription. It can be expressed as an amount or as a percent of the selling price (or of sales, if based on aggregated sales). For a drug wholesaler, it is the difference between the price at which the wholesaler sells the drug to a pharmacy and the price the wholesaler paid the manufacturer to acquire the drug (Wholesale Acquisition Cost or Average Manufacturer Price).

HCFA Federal Upper Limit (HCFA FUL): amount established by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services as a target amount of payment for a drug in a State Medicaid Program. States establish their own Estimated Acquisition Cost (EAC) and Maximum Allowable Cost (MAC) payment levels, but a State's total drug program payments cannot exceed what would be determined as the State's aggregate drug payments if the FUL amounts were used for payment. A State may pay above the HCFA FUL for some individual products as long as the aggregated payments are within the total amount determined using the FULs (e.g., the State may establish lower MACs than the FUL amounts to balance higher EACs for brand name drugs).

Indemnity Prescription Coverage: an insurance plan where the insured pays for the covered prescription and then is reimbursed or indemnified by the plan. Often these plans first require the insured to pay a deductible and then the insurer covers a percent (e.g., 80%) of the cost of prescriptions used by the insured. The insured pays the full retail price (Usual & Customary charge) when obtaining the prescription. Only a small proportion of consumers (5 – 10%) has this kind of insurance for prescriptions; most insured consumers have service benefit coverage for prescriptions.

Independent Pharmacy: an independent entrepreneur or small chain (< 10 units under one ownership) pharmacies, often viewed as the traditional "corner drug store." These pharmacies range from prescription-dominated clinic and apothecary pharmacies to pharmacies with the traditional mix of prescriptions, over-the-counter drugs, sundries, and general merchandise. For most independent pharmacies, prescriptions are the dominant share of total store sales (typically, 70% to 80% of sales or more).

Inflation: a measure of price changes over time. "Pure" or "isolated" price inflation is determined using a fixed market basket of goods so that the measure reflects the changes in prices for a consistent set of products. Generally, inflation measures are adjusted to reflect a changing basket of consumption that is a more realistic reflection of consumption expenditures, particularly consumer inflation measures. The Consumer Price Index (CPI) attempts to reflect changes in the goods consumed so that the market basket of goods matches actual consumer spending. Ingredient Cost: the cost of the drug product that is dispensed in a prescription. This can refer to the actual acquisition cost (AAC) or cost of goods sold for a pharmacy, or to the amount that an insurer would use in determining payment to a pharmacy for the drug dispensed in a covered prescription (i.e., Estimated Acquisition Cost (EAC) or Maximum Allowable Cost (MAC)).

Internet/Online Pharmacy: a pharmacy that dispenses prescriptions to consumers that contact the pharmacy via an Internet web site. Internet pharmacies are a relatively new phenomenon, first established in 1998 and starting sales in 1999. Although information about these pharmacies is sparse, due to their newness, they represent a small proportion of all prescriptions dispensed. Unlike traditional pharmacies, the pharmacies can serve more than the local market where the pharmacy is located. Since there typically is at least a short delay between ordering and receiving prescriptions, these pharmacies generally serve patients on long-term drug therapies and those without immediate drug needs.

Mail Order Pharmacy: a pharmacy that dispenses prescriptions to consumers who contact the pharmacy by mailing or faxing their prescription orders and then the prescription is mailed to the consumer. This can be an advantage for homebound patients or other patients without ready access to traditional community pharmacies. Unlike traditional pharmacies, the pharmacies can serve more than the local market where the pharmacy is located. Since there typically is at least a short delay between ordering and receiving prescriptions, these pharmacies generally serve patients on long-term drug therapies and those without immediate drug needs. The average size of prescriptions (number of capsules or tablets) dispensed in mail order pharmacies is larger than in local community pharmacies. Consequently, although mail order pharmacies represent less than 5% of all prescriptions dispensed, they comprise approximately 13% of total retail prescription sales.

Market Share: the proportion of the total market that a firm or a product represents.

Mass Merchandiser Chain Drug Store: pharmacy departments within mass merchandising department stores. The prescription department generates a small proportion of total store sales, but is used to draw customers into the store. Examples include Wal-Mart, KMart, ShopKo, etc.

Maximum Allowable Cost (MAC): the upper limit of ingredient cost for which a third-party payer will reimburse a pharmacy for dispensing certain multiple source drugs (i.e., drugs for which generic equivalents exist). MACs are used by public programs such as Medicaid and by private prescription insurance plans. Although there is no standard list of MAC drugs, often lists for different insurers or prescription programs include many of the same drugs and similar payment limits.

"Me Too" Drug: a drug closely related to another drug on the market, in terms of its chemical structure. Such drugs are designed to enhance or at least mimic the effects of an existing drug in a therapeutic category, in an effort to achieve market share.

National Health Expenditures (NHE): amounts of spending for health care in the U.S. by type of service delivered and source of funding for those services. The Health Care Financing Administration (HCFA) collects and publishes NHE data annually. The following are definitions used by HCFA in determining expenditures:

Prescription Drugs: includes spending for prescription drugs purchased in retail outlets. The value of prescription drugs used or provided by hospitals, nursing homes, or health professional is not included in prescription drugs, but is included in spending for these providers' services. Research and development expenditures of drug companies are included in the prescription drug category and not in the overall Research category (they are integral to the price manufacturers charge for their goods, and thus are incorporated into sales to and by pharmacies). *Drugs & Non-Durables:* includes spending for prescription drugs, over-the-counter medicines, and sundries purchased in retail outlets.

Physician Services: includes revenues/receipts in physician offices. NHE category includes both taxable and tax-exempt physicians (medical doctors and doctors of osteopathy), as well as employer and non-employer physicians.

Hospital Care: includes hospital revenues from inpatient and outpatient services rendered.

Personal Health Care: includes spending for hospital care, physician services, dental services, other professional services, home health care, drugs and other medical non-durables, vision products and other medical durables, nursing home care, and other personal health care. Does not include program administration and net cost of private health insurance, government and public health activities, or research and construction.

New Drug Approval: the process required by the Food and Drug Administration (FDA) before a drug can be marketed in the U.S. Approval for marketing is based on information submitted by the manufacturer about the drug's safety and efficacy based on the manufacturer's research and clinical trials (e.g., in an application for an Investigational New Drug, IND, or New Drug Application, NDA). FDA approval also is required for generic versions of drugs already marketed, but the emphasis is on the generic drug's equivalency with the originator's version of the drug; safety and efficacy is determined primarily by relying on the first approval.

New Molecular Entity: a unique new drug or drug compound that has not been previously approved by the Food and Drug Administration (FDA).

Nonprescription Drug: a drug product that can be purchased without a prescription order.

Over-the-Counter (OTC) Drug: a nonprescription drug.

Patent/Patent Life: a patent provides exclusivity in marketing a product. The patent life is the time during which a patent is in force and the product's manufacturer has exclusive marketing rights. The length of a patent for a drug is 20 years and is longer than for other products. The effective patent life for a drug may actually be shorter than 20 years depending on the time between discovery and market launch that is needed for safety and efficacy testing, clinical trials, and FDA approval for marketing.

Pharmaceutical: a prescription or nonprescription drug. General references to pharmaceuticals (such as industry or firm sales figures) sometimes include diagnostic agents and sterile solutions.

Pharmaceutical Manufacturer: a firm that produces drug products as finished goods for human or animal use. They generally are divided into 2 broad categories of firms, major pharmaceutical manufacturers and generic pharmaceutical manufacturers, as described below:

Major Pharmaceutical Manufacturer: manufacturers that identify and develop new prescription and/or nonprescription drugs through their research efforts. Typically these firms are large manufacturing companies. Sometimes they are referred to as "innovator" pharmaceutical firms, "brand name" pharmaceutical manufacturers, research-based pharmaceutical manufacturers, or generally as the "pharmaceutical industry." These firms invest in new product research and development and support their products with extensive promotional efforts. Their trade associations include Pharmaceutical Research and Manufacturers' Association (PhRMA), the National Pharmaceutical Council (NPC), and the Consumer HealthCare Products Association (CHPA; formerly the NonPrescription Drug Manufacturers' Association, NDMA). Some major pharmaceutical manufacturers also have generic manufacturing divisions or generic pharmaceutical manufacturer subsidiaries.

Generic Pharmaceutical Manufacturer: a firm that produces and markets generic prescription and/or nonprescription drug products. Some generic firms both manufacture and distribute drug products while others only repackage or distribute products manufactured for them by contract manufacturing firms (sometimes even a major pharmaceutical firm). Although all drug products must have FDA approval for sale, independent clinical trials are not required for generic drugs; the innovator's evidence of safety and effectiveness are accepted. Generic firms must show that their products are bio-equivalent, often through laboratory studies and assurances. Since generic firms often produce identical drugs, they generally compete on price to establish or gain market share.

Pharmacy Benefit Manager (PBM): an organization that provides administrative services in processing and analyzing prescription claims for pharmacy benefit and coverage programs. Their services can include contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; and operating disease management programs. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies.

Preferred Drug: a drug is designated "preferred" if the manufacturer agrees to make the drug available to a private insurer, health plan, or public program at a reduced price compared to other drugs that are considered therapeutic alternates. Health plan enrollees may pay lower cost-sharing amounts for preferred drugs, and pharmacists may be encouraged to dispense the preferred drug through higher reimbursement amounts (dispensing fees).

Prescriber: a health care provider licensed to prescribe drugs. Primary prescribers are physicians, but others may have prescriptive authority, depending on states' statutes and laws. For example dentists, physician assistants, nurse practitioners, optometrists, and others may have authority to prescribe, typically within limits. Prescription Drug: a drug that is restricted to sale only after issuance of a prescription order by a licensed prescriber. Sometimes referred to as a "legend" drug because the label on the prescription package includes the legend, "Caution: Federal law prohibits dispensing without a prescription order."

Prior Authorization: the process of obtaining prior approval from a private or public third-party prescription insurer as to the appropriateness and coverage of a service or medication.

Private Insured Prescription: a prescription covered under a privately funded health insurance plan or program.

Publicly Insured Prescription: a prescription covered under a Federal, State, or local publicly funded health program. Medicaid prescriptions dominate this category. Federal programs include prescriptions covered by the Department of Defense and Veterans Administration health care programs. Medicare has limited drug coverage provisions for outpatient drugs, primarily for drugs that are not self-administered (e.g., home infusion) and for recipients enrolled in managed care programs. Some state and local public welfare programs also exist.

Promotion: communication, education, and persuasion efforts intended to foster increased use of a company's products. Promotion includes advertising, coupons, personal selling, sales promotions and incentives, samples, etc.

Rebate: an amount that the manufacturer of a drug pays to an insurer or health plan for each unit of drug dispensed. Rebate arrangements exist between manufacturers and Medicaid agencies, HMOs, and other insurers or drug plans, and generally bypass the pharmacy. Rebates are referred to as "after market" arrangements because they do not affect the prices paid at the time of service, but are implemented later, ultimately reducing the payer's expenditures or program costs. The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) requires pharmaceutical firms to give a rebate to the Health Care Financing Administration (HCFA) for distribution to the States for all drugs covered under State Medicaid drug programs. Within the private insurance market, rebates often are associated with preferred drugs, and the rebate or level of rebate is contingent upon achieving market share goals.

Retail Prescription Price: the price charged by a pharmacy for prescriptions and related services provided. For cash (self-pay), uninsured patrons (and usually for those with indemnity insurance), it also is referred to as the "Usual and Customary (U&C)" charge, and is determined by the pricing policies of the pharmacy. For insured patients, it is the thirdparty payment or reimbursement amount determined by the insurance plan's payment formula and agreed to in the contract with the pharmacy. Third-party payment usually is established as an amount for the prescription ingredient (cost of drug dispensed) plus a professional dispensing fee (to cover dispensing and professional service costs of the pharmacist).

Service Benefit: insurance coverage where payment for services is made directly to the provider pharmacy via a claims process. The provider payment will be at a level or formula specified in the provider's contract, less any cost-sharing amounts required to be paid by the patient. Most consumers with prescription drug coverage are covered by service benefit plans.

Therapeutic Alternative/Equivalent: drugs that differ from one other, but are of the same pharmacological or therapeutic class and can be expected to have a similar ("equivalent") therapeutic effect when administered to patients in therapeutically equivalent dosages.

Third-Party Insurer: an entity (a public or private program, health plan, or insurer) that pays or reimburses the patient or pharmacy for all or part of the cost of services provided.

Third-Party Payment: payment or reimbursement amounts established by third-party drug programs for prescriptions and services dispensed to beneficiaries. Payment formulas typically specify an amount for the prescription ingredients to which is added a dispensing fee (e.g., EAC or MAC plus a dispensing fee) for calculating the total prescription "price" or payment from the third-party program. Third-Party Prescription: a prescription covered under public or private insurance drug program structured as a service benefit (the provider pharmacy submits a claim for services rendered and payment is made directly to the pharmacy, less any applicable copayment or coinsurance paid by the patient).

Top 200 Drug: a drug product ranked according to popularity among the top 200 drugs based on the number of prescriptions dispensed or among the top 200 drugs based on sales dollars. Top 200 drugs represent approximately half of all prescriptions dispensed.

Traditional Chain Drug Store: chain pharmacies usually are defined as having 10 or more units under the same ownership. Traditional chains are "freestanding" retail outlets with prescriptions, nonprescription drugs, sundries, and general merchandise departments. The prescription department usually contributes more to total store sales than the other merchandise departments (e.g., gifts, sundries, photo, magazines, etc.). Examples include Walgreen, Eckerd, CVS, Rite Aid, Longs, etc.

Usual and Customary (U&C) Charge: the amount a pharmacy or other provider charges self-pay (cash) patients. Some insurance programs dictate that a pharmacy's claim may not exceed its usual and customary charge for the prescription dispensed.

Wholesale Acquisition Cost (WAC): the price paid by the wholesaler for drugs purchased from the wholesaler's suppliers (manufacturers). On financial statements, the total of these amounts equals the wholesaler's cost of goods sold. Publicly disclosed or listed WAC amounts may not reflect all available discounts.

sources of information

The Chain Pharmacy Industry Profile, 1999

National Association of Chain Drug Stores (NACDS) 413 N. Lee Street PO Box 1417-D49 Alexandria, VA 22313-1480 phone (703) 549-3001 www.nacds.org

Express Scripts 1998, Drug Trend Report, June 1999 Express Scripts, Inc. 14000 Riverport Drive Maryland Heights, MO 63043 www.express-scripts.com

Generic Pharmaceutical Industry Association (GPIA) 1620 I Street, NW, Suite 800 Washington, DC 20006 phone (202) 833-9070 www.gpia.org

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Poisal, J.A. and G.S. Chulis, "Medicare Beneficiaries and Drug Coverage," pp. 248-256

IMS Health, Incorporated

660 West Germantown Pike Plymouth Meeting, PA 19462 phone (610) 834-5000 www.imshealth.com

The Henry J. Kaiser Family Foundation (reports are available at www.kff.org or by calling 1-800-656-4533):

Kaiser Family Foundation/Health Research and Educational Trust 1999 Annual Employer Health Benefits Survey, 1999

Medicare and Prescription Drugs, A Factsheet, March 2000

Retiree Health Coverage; Recent Trends and Employer Perspectives on Future Benefits, prepared by Hewitt Associates, October 1999

The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit, prepared by Mathematica Policy Research, Inc., January 2000

National Association of Boards of Pharmacy (NABP) 700 Busse Highway

Park Ridge, IL 60068 phone (847) 698-6227 www.nabp.net

NCPA-Searle Digest

National Community Pharmacists Association (NCPA) 205 Daingerfield Road Alexandria, VA 22314 phone (703) 683-8200 www.ncpanet.org

Novartis Pharmacy Benefit Report -

Trends and Forecasts

Novartis Pharmaceuticals Corp. 59 Route 10 East Hanover, NJ 07936-1080 www.novartis.com

The 1999 NWDA Industry Profile and

Healthcare Factbook

National Wholesale Druggists' Association (NWDA) 1821 Michael Faraday Drive, Suite 400 Reston, VA 20190-5348 phone (703) 787-0000 www.nwda.org

Pharmaceutical Benefits Under State Medical Assistance Programs

National Pharmaceutical Council 1894 Preston White Drive Reston, VA 20191-5433 phone (703) 620-6390 www.npcnow.org

Pharmaceutical Industry, Profile 2000

Pharmaceutical Research and Manufacturers of America (PhRMA) 1100 Fifteenth Street, NW Washington, DC 20005 www.phrma.org

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60 Blacksmith Road Newtown, PA 18940-1886 phone (215) 860-0440 www.scottlevin.com

U.S. Bureau of Labor Statistics,

Division of Information Services 2 Massachusetts Ave., NE Washington, DC 20212 phone (202) 691-5200 www.bls.gov

U.S. Department of Health and Human Services (www.hhs.gov):

Medical Expenditure Panel Survey: Agency for Healthcare Research and Quality, and the National Center for Health Statistics www.meps.ahcpr.gov

Medicare Current Beneficiary Survey: Health Care Financing Administration Office of Strategic Planning www.hcfa.gov/mcbs

National Health Expenditures: Health Care Financing Administration Office of the Actuary www.hcfa.gov/stats/nhe-oact

Prescription Drug Coverage, Spending, Utilization, and Prices; Report to the President, April 2000, Office of the Assistant Secretary for Planning and Evaluation http://aspe.hhs.gov

U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Rockville, MD 20857 www.fda.gov/cder



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