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Prescription Drugs: Coverage, Costs, and Quality

Highlights

- ◆ Since 1965, prescription drugs have declined as a proportion of total health spending and currently represent less than 5 percent of national health expenditures. Although total expenditures for prescription drugs have increased more slowly than those for other medical services, the prices of these drugs have risen at a greater rate: 10 percent between 1989 and 1990.
- ◆ The majority of prescription drug expenditures (72.4 percent) are paid out of pocket. However, third parties are increasing their share of prescription drug outlays and have experienced higher than average growth in their prescription drug expenditures, which rose from 21.9 percent in 1980 to 28 percent in 1989.
- ◆ The distribution of prescription drug expenditures is an important policy concern. Whereas third parties pay for most other acute medical care needs, consumers pay most prescription drug costs directly. Individuals have reason to focus on drugs. More than 60 percent of all physician office visits recorded in a recent survey resulted in a recommendation for drug use. The price of some “high-tech” drugs can readily produce “sticker shock.”
- ◆ When employers provide health insurance coverage, the plans for full-time workers almost always cover prescription drugs. This benefit accounts for about 10 percent of plan costs for active employees and as much as 40 percent for plans covering Medicare eligible retirees.
- ◆ Most employers cover prescription drugs under the same insurance plan that covers other medical expenses, although some cover these drugs through a separate carrier that administers insurance for prescription drugs and pays the claims. To contain costs, employees may be encouraged to obtain prescription drugs through mail order pharmacies or purchase generic drugs.
- ◆ Lacking technical skills or knowledge of pharmacology, typical consumers may have difficulty assessing a drug’s value and to a large degree rely on physicians to choose a product. The prescription drug industry consists of many competing pharmaceutical manufacturers, the largest of which has about 9.3 percent of the U.S. prescription drug market.
- ◆ Public policy activity is focusing on government regulation of prescription prices, an issue that is likely to generate continued interest as policymakers look for ways to reduce health care costs. Pharmaceutical manufacturers perceive their markets as risky and set prices to obtain returns that they consider commensurate with their risks.

◆ Introduction

Rapidly growing health care expenses have led public and private payers to closely examine each component of their health care spending. Expenditures on prescription drugs,¹ like other health care service components, have been rising. In 1990, the nation spent \$32.3 billion for prescription drugs used outside hospitals. Prescription drug expenditures increased 8 percent between 1989 and 1990, but expenditures on other medical care sectors grew even more rapidly. Hospital care expenditures increased 10 percent, physicians' services increased nearly 11 percent, and total health expenditures grew 10.5 percent between 1989 and 1990 to total \$666 billion (U.S. Department of Health and Human Services, n.d.; and Lazenby and Letsch, 1990). **Since 1965, prescription drugs have declined as a proportion of total health spending and currently represent less than 5 percent of national health expenditures.**

While total expenditures for prescription drugs have increased less rapidly than those for other medical services, the prices of these drugs have risen at a greater rate. Prescription drug prices, as reflected in the Consumer Price Index (CPI),² increased 10 percent between 1989 and 1990. Over the past several years, price inflation for prescription drugs has exceeded the inflation rate for both medical care services and all items purchased by consumers (chart 1). Among medical items, only the price of hospital care grew faster than prescription drug prices during this period.

¹By federal law, prescription drugs cannot be purchased by individuals without a prescription from a licensed health provider and must bear a label attesting to that fact.

²The CPI attempts to measure the effects of price changes on a market basket of selected goods that are typically purchased by urban consumers. The Producer Price Index (PPI) measures prescription drug prices charged by manufacturers. It samples goods that represent a large portion of producers' sales, regardless of whether they are sold to consumers or to other producers. How well these indexes reflect the prices of goods such as drugs and other high technology items that are frequently replaced by improved products is controversial (Berndt, et al., 1990).

In addition to the absolute level of prescription drug spending and prescription drug prices, the distribution of prescription drug expenditures is an important policy concern. Whereas third parties pay for most other acute medical care needs, consumers pay most prescription drug costs directly. Thus, individual consumers may be more aware of prescription drug expenses than of other types of health care expenses. People aged 65 and over may be particularly sensitive to the cost of prescription drugs. The elderly are more likely than younger people to use prescription drugs, and Medicare, the federal health insurance program for the elderly and disabled, does not cover the cost of these drugs when they are administered outside the hospital.³ Supplemental private insurance (including employer-provided health insurance for retirees) provides outpatient prescription drug coverage for some of the elderly, but others may remain vulnerable to large prescription drug expenditures.



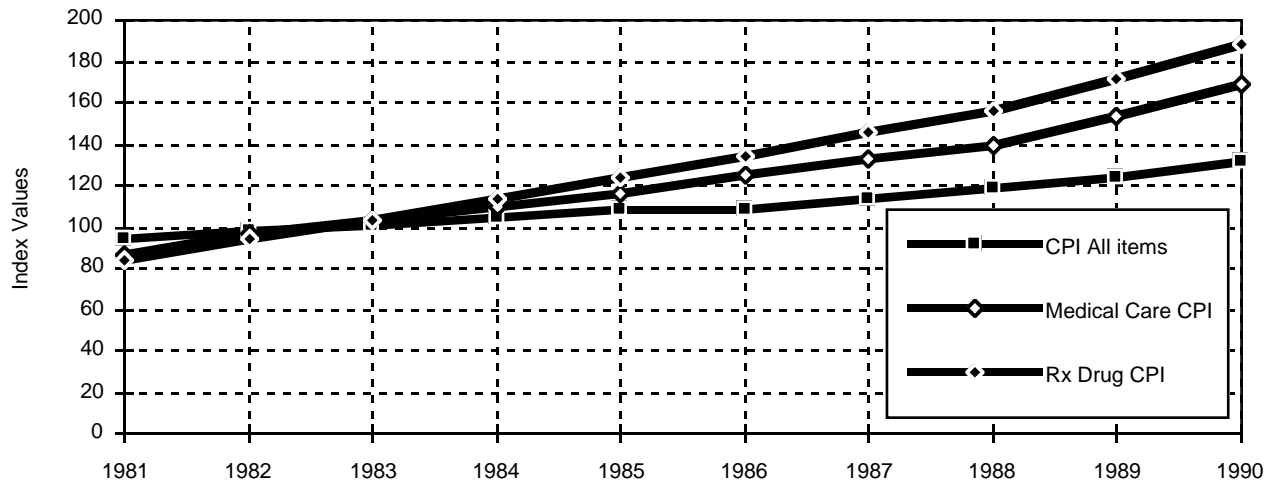
Third party payers' share of prescription drug expenditures rose from 21.9 percent in 1980 to 28 percent in 1989.



Although they are not the largest source of spending on prescription drugs, **third party payers' share of prescription drug expenditures rose from 21.9 percent in 1980 to 28 percent in 1989.** Insuring prescription drug benefits reduces out-of-pocket costs and encourages beneficiaries to comply with medical therapy.

³Medicare generally does not cover outpatient prescription drugs taken by a beneficiary. Drugs are covered when delivered in a hospital or administered during an outpatient physician visit or under a few other special provisions. Before its repeal, the Medicare Catastrophic Coverage Act of 1988 added coverage of outpatient prescription drugs. Concern about financing the cost of additional benefits led to the repeal of this act before Medicare prescription drug coverage was implemented.

Chart 1
Consumer Price Index for Prescription Drugs, Compared with Medical Care CPI and CPI for All Items, 1981–1990



Source: U.S. Department of Labor, Bureau of Labor Statistics, monthly CPI reports, various years.

Coverage of outpatient prescription drugs is a common feature of employer-sponsored health insurance plans. State Medicaid programs, which provide health insurance for certain people with low incomes, also cover outpatient prescription drugs.

Third party payers are increasingly concerned about obtaining adequate value for their expenditures on prescription drugs, just as they are concerned about obtaining value in health care as a whole. **Because third parties are increasing their share of prescription drug outlays, they have experienced higher than average growth in their prescription drug expenditures.** To control plan expenses and discourage overuse, public and private insurers sometimes place limits on the amount of reimbursable prescriptions they cover or require a copayment or deductible. They have also sought lower prescription drug prices through negotiation and group purchasing and are beginning to evaluate drugs for cost effectiveness.

This *Issue Brief* examines spending on prescription drugs and how use of prescription drugs varies among

demographic groups. It considers how fundamental characteristics of the prescription drug market affect the prices of pharmaceuticals. Prescription drug prices partly reflect return to risks in drug development but also produce higher profits than are typical in most industries. However, these returns are reinvested in new products as well as distributed to shareholders.

Finally, this *Issue Brief* considers how prescription drug cost containment activities can influence the quality of health care and the amount of expenditures. As is the case with many other health services, purchasers are moving to negotiate prescription prices and evaluate the therapeutic effectiveness of prescription drugs. However, recent changes in public insurance plans may restrict private payers' ability to negotiate prices. Some policymakers and advocacy groups have looked to government regulation of prescription drug prices as a way to resolve these conflicts. The outcome of public and private payers' competing activities may have unpredictable consequences for new drug development and market competition.

Table 1
**Physician Office Visits, Office Visits in Which Drugs Were Prescribed,
 and Number of Drugs Prescribed,^a by Age and Gender, 1985**

	Total Office Visits		Visits Resulting in One or More Drugs Prescribed as a Percentage of Total Office Visits	Drugs Prescribed	
	Number (thousands)	Percentage distribution		Number (thousands)	Percentage distribution
All Patients	636,386	100.0%	61.2%	693,355	100.0%
Patient Age					
Under 15 years	118,768	18.7	62.0	107,018	15.4
15–24	73,964	11.6	56.4	60,288	8.7
25–44	175,724	27.6	55.7	156,234	22.5
45–64	137,391	21.6	63.4	171,234	24.7
65 and over	130,538	20.5	68.2	198,582	28.6
Patient Gender					
Men	248,905	39.1	60.2	266,702	38.5
Women	387,481	60.9	61.5	426,653	61.8

Source: Hugo Koch and Dee A. Knapp, "Highlights of Drug Utilization in Office Practice: National Ambulatory Medical Care Survey, 1985," *Advance Data from Vital and Health Statistics* (May 19, 1987).

^aIncludes prescriptions for over-the-counter medications (e.g., aspirin) not requiring a physician's prescription (and not generally reimbursable by insurance) and drugs administered during the visit by the provider (injections, etc.). Only includes drugs intended for the principal diagnosis during the visit. Prescriptions associated with any other diagnosis or used for any other reason are not counted.

◆ Prescription Drug Use

Nationally representative data on who uses prescription drugs and how much they spend are incomplete.⁴ A 1985 survey of office visits to physicians' indicated differences in prescription drug use among population groups (table 1). **More than 60 percent of all physician office visits recorded in the survey resulted in a recommendation for drug use, including drugs available over the**

⁴Population-based surveys ask respondents to report their use and expenditures on medical care services, including prescription drugs, but respondents sometimes have difficulty recalling prescription drug use accurately (Berk, et al., 1990). Surveys of providers prescribing drugs also have a high potential for error (although errors can be reduced if physicians record data at the time of an encounter with the patient). Furthermore, provider surveys do not measure whether drugs prescribed were actually purchased and used by patients. Insurer claims data can be used to estimate the use of drugs by insured people. However, these data only represent people with insurance, and they do not measure prescriptions for which a claim was not submitted. Data collected from pharmacists at the point of sale are potentially most accurate for collecting data about drugs purchased, but truly comprehensive pharmacy surveys would be expensive to conduct and would present problems in obtaining accurate data about patients.

counter and those available only by prescription or administered during the visit. The elderly have drugs recommended more frequently than younger patients in addition to having higher rates of medical visits. Twenty-nine percent of all the drugs prescribed were for patients 65 and over, who represent about 12 percent of the total population. The survey data also suggest women are more frequent users of prescribed drugs than men, accounting for 62 percent of prescriptions. The greater use of drugs by women is consistent with their more frequent medical visits.⁵

The price of some "high-tech" drugs can readily produce "sticker-shock." Among Medicare beneficiaries

⁵How much of the gender difference in drug use results from drugs that are used only by women (e.g., contraceptives) cannot be determined by these data. However, a study of Detroit area residents in 1978 found greater use of legal drugs among women even after excluding such products (Verbrugge, 1982). This study found that most of the gender differences in drug use could be explained by differences in health status and in the prevalence of various socioeconomic factors among men and women. Residual variation might be explained by differing attitudes toward medical care and drug use or differences in physicians' treatment patterns.

living outside institutions, about 82 percent used at least one prescription drug during 1987, according to the National Medical Expenditure Survey (NMES). Elderly beneficiaries reported an average of 14.7 prescriptions and an average annual expenditure of \$248 on prescription drugs in 1987, amounting to total expenditures of \$7 billion (Moeller and Mathiowitz, 1989).⁶ Prescription drug use and expenditures among elderly Medicare beneficiaries generally increased with age, after adjusting for increased likelihood of older people dropping out of the survey due to death or institutionalization (table 2). Between 1980, when a similar survey was conducted, and 1987, average annual expenditures and average charge per prescription for the elderly more than doubled, while the average number of prescriptions per beneficiary grew from

12.1 to 14.7, or about 22 percent (Moeller and Mathiowitz, 1989).

◆ Spending on Prescription Drugs

The National Health Accounts, tabulated by the Health Care Financing Administration (HCFA), includes only spending on outpatient prescription drugs.⁷ After declining during the 1960s and 1970s, spending on prescription drugs has remained nearly constant as a share of national health expenditures since 1979 (chart 2). Growth rates of prescription drug expenditures are similar to growth in expenditures for other medical services. However, different payers experience different rates of expenditure increases. **Out-of-pocket expenditures for prescription drugs have grown more slowly than expenditures by private health insurance, which may indicate growing third party coverage for prescription drugs, increasingly generous reimbursement among individuals with such coverage, or greater demand for prescription drugs among individuals with third party coverage (table 3).**

Prescription drug prices can also vary widely. Although average wholesale prices (AWP) are published, most pharmacists pay less than the published AWP, and large volume purchasers can obtain deep discounts from AWP (U.S. Congress, 1989). Public and private insurance plans that formerly reimbursed prescription drug expenditures at AWP are beginning to include a fixed discount from AWP in their reimbursement rates. Other insurers have begun to audit actual purchase costs before reimbursement (Kirking, et al., 1990).

Coverage Sources

Prescribed drugs delivered during an inpatient hospital stay are usually included in the hospital's charges and

⁶NMES data have been criticized by other researchers for tolerating substantial misreporting. After conducting a separate survey that verified reported expenditures with pharmacy claims data, researchers developed a technique to adjust the 1987 NMES data for underreporting. They estimated that total expenditures of the elderly on prescription drugs were closer to \$10.6 billion in 1987, or an average annual expenditure of \$385 (Berk, et al., 1990).

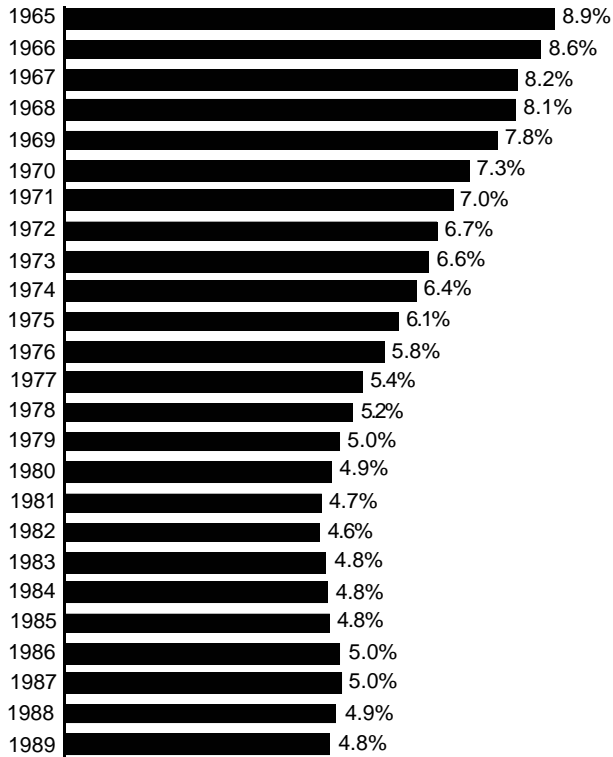
Table 2
**Prescribed Medicines Obtained by
Noninstitutionalized Medicare Beneficiaries,
by Age, 1987**

	Total Medicare Bene- ficiaries (thousands)	Percentage with at Least One Prescribed Medicine	Mean Prescribed Medicines per Beneficiary	Mean Expen- diture per Beneficiary
Total	31,801	82.0%	15.3	\$262
Age Under 65	4,381	77.5	17.1	317
Age 65-69	9,345	78.4	13.2	229
Age 70-74	7,459	82.5	15.5	264
Age 75-79	5,171	85.5	15.7	264
Age 80-84	3,265	88.4	17.9	295
Age 85 or over	2,181	87.4	14.7	226

Source: Moeller, J., and N. Mathiowitz, "Prescribed Medicines: A Summary of Use and Expenditures by Medicare Beneficiaries," *National Medical Expenditure Survey Research Findings* (Rockville, MD: National Center for Health Services Research and Health Care Technology Assessment, 1989).

⁷Expenditures on prescription drugs used by hospital inpatients are subsumed under expenditures for hospital care. Formerly, prescription drug expenditures were included with over-the-counter medications and medical sundries such as bandages and dressings. HCFA has only recently become able to provide separate estimates of the costs of prescription drugs.

Chart 2
**Prescription Drugs as a Percentage
of National Health Expenditures**



Source: U.S. Department of Health and Human Services, Health Care Financing Administration, Office of the Actuary, unpublished data.

are reimbursed under most health insurers' provisions for hospital coverage. Drugs that must be administered by a medical professional during an outpatient visit (e.g., injectable antibiotics or chemotherapy agents) are also often covered in the payment for the visit. Prescription drug coverage generally pertains to insurance payment for outpatient prescription drugs administered by the patient.

Employment-Based Coverage

Firm size, industry, and full- or part-time work affect whether employees have access to health insurance

coverage. When health insurance is provided, health insurance plans for full-time workers almost always cover prescription drugs (table 4). Prescription drug coverage may be perceived as a relatively inexpensive enhancement to health benefits that encourages employees and their dependents to comply with drug therapy. Typically, less than 10 percent of employer health plan costs for active employees is attributable to prescription drugs, according to one estimate, although prescription drug costs for plans that cover Medicare eligible retirees may amount to as much as 40 percent (McDevitt, 1990). Prescription drug coverage could be cost effective if it reduces payers' costs by avoiding hospitalization and other medical expenditures and

Table 3
**Prescription Drug Expenditures
by Source of Payment, 1965–1989**

	Total	Out-of-Pocket Payments	Private Health Insurance	Medicaid	Other Third Parties ^a
	\$ Billions				
1965	\$3.7	\$3.5	\$0.1	\$0.0	\$0.1
1966	4.0	3.6	0.1	0.1	0.1
1967	4.2	3.7	0.2	0.2	0.1
1968	4.7	4.2	0.2	0.2	0.1
1969	5.1	4.5	0.3	0.3	0.1
1970	5.5	4.7	0.3	0.4	0.1
1971	5.9	4.9	0.4	0.5	0.1
1972	6.3	5.2	0.4	0.6	0.1
1973	6.8	5.5	0.5	0.6	0.1
1974	7.4	5.9	0.7	0.7	0.1
1975	8.1	6.2	0.8	0.9	0.1
1976	8.7	6.6	1.0	1.0	0.1
1977	9.2	6.8	1.2	1.0	0.2
1978	9.9	7.1	1.5	1.1	0.2
1979	10.7	7.4	1.9	1.2	0.2
1980	12.0	7.9	2.5	1.4	0.3
1981	13.4	8.5	3.0	1.6	0.3
1982	15.0	9.5	3.6	1.6	0.3
1983	17.0	10.6	4.2	1.8	0.4
1984	18.5	11.3	4.7	2.1	0.5
1985	20.2	12.0	5.2	2.5	0.6
1986	22.6	13.4	5.5	2.9	0.8
1987	24.8	14.6	6.0	3.3	0.9
1988	26.8	15.6	6.5	3.6	1.0
1989	29.0	16.7	7.0	4.1	1.2

(continued)

prevents losses in productivity from illness and absenteeism.

Among full-time employees of private establishments with 100 or more employees in 1989, 97 percent of those enrolled in fee-for-service (indemnity) insurance plans and 90 percent of those enrolled in health maintenance organizations (HMOs) were covered for prescription drug costs. Lower prescription drug coverage rates among HMO covered employees may occur because prescription drug benefits are often offered separately as a rider to the HMO's basic health

benefits, and plan sponsors may be more likely to decline this coverage (Baker and Kramer, 1991). Health insurance plans for other employee groups have similar coverage rates. State and local governments covered prescription drug costs for 92 percent of full-time employees participating in health insurance in 1990 (U.S. Department of Labor, 1991a). Among smaller establishments surveyed in 1990, 96 percent of full-time employees participated in health insurance policies that cover prescription drugs (table 4) (U.S. Department of Labor, 1991).

Most employers cover prescription drugs under the same insurance plan that covers other medical expenses. Thus, prescription drug costs for employees covered under fee-for-service plans are often subject to the same deductibles and coinsurance provisions as medical services. According to a 1989 survey of medium and large private establishments, 74 percent of participants in fee-for-service insurance plans had prescription drug coverage that was subject to the same cost-sharing provisions as the overall plan (U.S. Department of Labor, 1990). Other fee-for-service insurance plans (covering about 22 percent of full-time employees of medium and large establishments) apply different cost-sharing provisions to prescription drugs (Baker and Kramer, 1991). Usually cost sharing consists of a copayment per prescription (specified in dollars), but occasionally a separate deductible is applied to prescription drugs. Because prescription drug benefits in HMOs are usually added separately as a rider, they are more likely to be covered under separate cost-sharing provisions (Gold, et al., 1989). Employees covered by prescription drug benefits with separate cost sharing (both under indemnity insurance and HMOs) on average paid \$5 or less in copayments per prescription, and one-half had copayments of \$3 or less per prescription (Baker and Kramer, 1991).

Prescription Card Plans—Other employers cover prescription drugs through a separate carrier that administers insurance for prescription drugs and pays the claims. These carriers provide enrollees a plastic identity card, similar to a credit card, that is presented



Table 3 (continued)

	Total	Out-of-Pocket Payments	Private Health Insurance	Medicaid	Other Third Parties ^a
	Percentage Distribution				
1965	100.0%	93.2%	2.9%	0.0%	3.9%
1966	100.0	91.4	3.4	2.6	2.7
1967	100.0	88.2	5.2	4.8	1.7
1968	100.0	88.8	4.8	4.6	1.8
1969	100.0	86.9	5.6	5.8	1.7
1970	100.0	85.0	6.2	7.6	1.2
1971	100.0	83.2	7.1	8.4	1.2
1972	100.0	82.7	7.1	8.9	1.3
1973	100.0	81.2	8.0	9.4	1.3
1974	100.0	79.8	8.8	10.0	1.4
1975	100.0	77.2	10.4	10.8	1.6
1976	100.0	75.3	12.0	11.1	1.6
1977	100.0	73.5	13.5	11.3	1.7
1978	100.0	71.6	15.5	11.2	1.7
1979	100.0	68.6	17.8	11.5	2.1
1980	100.0	65.5	20.7	11.6	2.2
1981	100.0	63.4	22.6	11.7	2.2
1982	100.0	63.2	24.1	10.8	2.0
1983	100.0	62.3	24.6	10.8	2.3
1984	100.0	60.9	25.4	11.3	2.5
1985	100.0	59.4	25.5	12.2	2.8
1986	100.0	59.3	24.4	12.9	3.5
1987	100.0	58.9	24.0	13.4	3.8
1988	100.0	58.4	24.1	13.5	3.9
1989	100.0	57.7	24.1	14.2	4.0

Source: Unpublished estimates from the U.S. Department of Health and Human Services, Health Care Financing Administration, Office of the Actuary.

^aIncludes workers' compensation, state general assistance programs, Department of Veterans' Affairs, Department of Defense, maternal and child health programs, and Indian Health Service programs.

Table 4
Percentage of Full-Time Employees with Health Insurance Coverage and of Covered Employees with Prescription Drug Coverage, by Type of Employer, Selected Years

	Percentage of Full-Time Employees Covered by Health Insurance	Percentage of Insured Employees with Prescription Drug Coverage
Employees of State and Local Governments (1990)	93%	92%
Employees of Larger Private Establishments (100 or more employees) (1989)	92	95
Employees of Small Establishments (fewer than 100 employees) (1990)	69	96

Source: U.S. Department of Labor, Bureau of Labor Statistics, *Employee Benefits in State and Local Governments, 1990*; *Employee Benefits in Medium and Large Firms, 1989*; and *Employee Benefits in Small Private Establishments, 1990* (Washington, DC: U.S. Government Printing Office, 1991, 1990, and 1991).

at the time of purchase. The cards are recognized by participating pharmacists, who then submit a claim for payment from the carrier. If a copayment is required, enrollees pay at the time of purchase. **Twenty-four percent of employers in one survey offered a prescription card plan in 1990, up from 20 percent in 1989** (A. Foster Higgins & Company, Inc., 1990).

Prescription drug card plans can be more convenient for enrollees, who may then be more likely to comply with the prescribed therapy. In addition, employers can benefit from lower reimbursement rates. Proponents of prescription card plans also argue that their payment systems are more accurate and may be better able to screen out fraudulent or abusive claims.

Prescription drug cards may raise payers' expenditures, because they create a claim for reimbursement at the point of sale. Under traditional insurance, many people accumulate several inexpensive prescriptions before submitting one larger claim. However, many such bills are never submitted, a phenomenon insurers call the shoebox effect (Rubinstein, 1991).

Mail Order Drug Plans—To contain prescription drug costs, employees may be encouraged to obtain prescription drugs through mail order pharmacies. Prices charged by mail order pharmacies may be lower because these pharmacies can negotiate lower prices from drug manufacturers and can more economically prepare larger prescriptions. The Bureau of

Labor Statistics found that 10 percent of full-time employees of medium and large private establishments participating in health plans had coverage for mail order prescription drugs in 1989 (Baker and Kramer, 1991). To encourage employees to use this option, insurance plans may charge a lower copayment for mail order prescriptions.



Employer health plans are also increasingly likely to offer incentives for enrollees to purchase generic drugs when they are available as alternatives to name brand prescription drugs.



Overall, mail order plans had about 6 percent of the prescription drug market, with sales of about \$1.5 billion, in 1989 (Horgan, et al., 1990). Since filling prescriptions by mail is impractical for acute conditions, plan sponsors usually provide a traditional prescription drug benefit concurrently with a mail order plan. Generally, only prescription drugs that are needed for a long term, where it is sensible to provide a 90- to 180-day supply, are dispensed through the mail. Nevertheless, because an estimated 65 percent to 75 percent of prescription drugs are used to treat chronic condi-

tions (Kirking, et al., 1990), the market share of mail order prescription drug plans is expected to grow.

Mail-order plans have more costs than community pharmacies. Because mail order prescriptions are larger, payers are more likely to pay for drugs that may be thrown away if therapy is ended or changed. Mail order plan charges must cover postage, packaging, and patient information materials. If cost sharing is reduced to encourage purchase of mail order drugs, payers' costs may rise. One study that estimates the contribution of each of these factors gives mail order pharmacies a modest cost advantage over community pharmacies, although no conclusive assessment has been made (Kirking, et al., 1990).

Generic Drug Coverage—Employer health plans are also increasingly likely to offer incentives for enrollees to purchase generic drugs when they are available as alternatives to name brand prescription drugs. Generic drugs are often less expensive than name brand drugs because they incur lower costs for marketing and research.

Pharmacists are allowed to substitute a generic drug for a name brand unless a physician specifies that no substitution is allowed. Some states allow "therapeutic substitution," where a pharmacist can offer an entirely different drug from the one the physician ordered if it has the same therapeutic effect. Consumers may prefer less expensive substitutes, either a generic equivalent to a name brand drug or a therapeutic substitute, espe-



Payments for prescription drugs were the third largest category of Medicaid expenditures after nursing home and inpatient hospital care and exceeded Medicaid spending for physicians' services in 1989.



cially if they are paying for prescription drugs out of pocket or face a large deductible before being reimbursed. Employer health care plans offered explicit incentives to purchase generic alternatives, such as lower copayments, to 14 percent of employees in medium and large establishments in 1989 (Baker and Kramer, 1991).

◆ Insurance Coverage

Insurance for prescription drugs is more widespread in the public sector than it is in the private sector.

Public Insurance Plans

Among all classes of payers for prescription drugs, expenditures have grown most rapidly in public programs, particularly Medicaid. Medicaid is the largest single public source of coverage for prescription drugs. Medicaid expenditures for prescription drugs rose from \$3.3 billion in 1988 to \$3.7 billion in 1989, an increase of 12 percent.

Medicaid programs are administered by each state. Each program must meet certain criteria to obtain a federal contribution, which covers at least 50 percent of program costs and can rise to 83 percent depending on the state's per capita income. The shared federal and state responsibility for financing Medicaid has made prescription drug costs a subject of both congressional and state government activity.

Payments for prescription drugs were the third largest category of Medicaid expenditures after nursing home and inpatient hospital care and exceeded Medicaid spending for physicians' services in 1989. In that year, Medicaid spent \$22.2 billion (41 percent of its provider payments) on nursing homes, \$13.4 billion (25 percent) on hospitals, and \$3.7 billion (7 percent) on prescription drugs. Medicaid physician expenditures totaled \$3.4 billion (6 percent), reflecting payment rates that are sometimes criticized as being too low to assure that physicians will treat Medicaid patients (Reilly, et al., 1990).

One-third of Medicaid prescription drug spending is attributable to elderly beneficiaries and nearly 42 percent to disabled beneficiaries, reflecting high prescription drug use among these groups. Adults and children in low-income families, who make up two-thirds of all Medicaid recipients, account for about one-fourth of Medicaid prescription drug expenditures (Reilly, et al., 1990).

To control program costs, many states limit the kinds or amounts of drugs dispensed under Medicaid and charge copayments to beneficiaries. However, federal law forbids Medicaid to charge copayments to beneficiaries who are children, are using Medicaid services related to pregnancy, or are institutionalized and applying their incomes to nursing home care. **In 22 states, Medicaid charges copayments to nonexempt beneficiaries, ranging from \$0.50 to \$3.00 for each prescription. States may also place limits on the number of prescriptions reimbursed per month or on the amount of a drug that will be supplied.** Some states reimburse for certain over-the-counter drugs to encourage low-income people to use less costly alternatives to prescription drugs (National Pharmaceutical Council, 1990). Congress has recently enacted limits on the prices Medicaid pays for prescription drugs and mandated state plans to establish systems to assure quality in drug prescription. These changes are discussed in more detail below.

Medicare generally does not cover the elderly's outpatient prescription drug expenses. Nine states (Connecticut, Delaware, Illinois, Maine, Maryland, New Jersey, New York, Pennsylvania, and Rhode Island) have programs to subsidize prescription drug costs for low-income elderly, apart from their Medicaid plans. Eligibility is limited to older people whose incomes are under specified levels but exceed the Medicaid eligibility level.

The Department of Veterans' Affairs administers health benefits for veterans with service connected disabilities and other veterans with incomes below certain levels. Since 1946 it has sponsored a mail order prescription

plan, which currently dispenses one-third of all mail order prescriptions (Horgan, et al., 1990).

Out-of-Pocket Spending

While third party payments for prescription drugs are growing, the majority of prescription drug expenditures (72.4 percent) are still paid out of pocket. By comparison, only about 5 percent of hospital expenditures and 19 percent of physician expenditures were paid out of pocket in 1989 (Lazenby and Letsch, 1990).

Out-of-pocket spending on prescription drugs remains large despite the prevalence of third party coverage for several reasons. One factor is the relatively low incidence of insurance for prescription drugs among the elderly. Cost sharing among insured groups also contributes to out-of-pocket spending.⁸ Because most health insurance covering prescription drugs requires cost sharing similar to that associated with major medical care, people may accumulate several prescriptions before meeting deductibles or other limits on cost sharing. Unsubmitted claims for prescription drugs covered by insurance also contribute to out-of-pocket expenditures. Third parties directly paid for 41.5 percent of prescriptions dispensed at retail pharmacies in 1989 (Schondelmeyer and Thomas, 1990). The remainder included prescriptions that could be submitted for later reimbursement by insurance or that were not covered by insurance.

◆ What Affects Drug Prices?

As in other areas of health care, the price of prescription drugs is influenced by unequal information be-

⁸Out-of-pocket expenses can be reduced by flexible spending accounts and section 125 salary reduction plans, which allow employees to set aside a portion of their salaries before taxes to pay uninsured medical and cost sharing expenses. See Jill Foley, "Flexible Benefits Plans and Changing Demographics," *EBRI Issue Brief* no. 113 (Employee Benefit Research Institute, April 1991).

tween consumers and providers. **Lacking technical skills or knowledge of pharmacology, typical consumers may have difficulty assessing a drug's value and to a large degree rely on physicians to choose a product.** Recognizing this, prescription drug marketing is primarily directed to physicians. Drug companies advertise in professional publications and employ sales personnel to persuade physicians individually to prescribe their company's product.

This does not imply that consumers have no influence on the purchase of prescription drugs. Advertisements for prescription drugs are increasingly being aimed at consumers (Festervand and Tucker, 1990). Although a physician must authorize access to prescription drugs, consumers may shop for a provider willing to provide a prescription they want. Patients' preferences for a prescription drug may change because of a higher price (or higher levels of cost sharing). If there are alternative products, health care consumers might prefer the least expensive. Furthermore, consumers may shop for a prescription drug vendor that offers the lowest price.

While demand for prescription drugs can be affected by consumer tastes and preferences, prescription drug use generally derives from a medical need. Groups that use more medical services generally use more prescription drugs (Koch and Knapp, 1987). When facing a medical need, consumers may tend to be relatively insensitive to drug prices, forgoing other more discretionary purchases. However, changes in consumer behavior could also be reflected in a choice between taking and not taking a prescription. Some studies suggest that prescription drug cost sharing slightly reduces the number of prescriptions (Soumerai and Ross-Degnan, 1990). Data from the Rand Health Insurance Experiment suggest that reducing the number of medical encounters through cost sharing for medical care decreases prescription drug use (Leibowitz, 1985).

Competition in the drug industry also influences the prescription drug market. **The prescription drug industry consists of many competing firms, the largest of which has about 9.3 percent of the U.S. prescrip-**

tion drug market (Vagelos, 1991). But the prescription drug market could be considered to be segmented into separate markets for products that address distinct diseases or that act on particular physiological systems. Within these classes, fewer companies may have competing products (Schwartzman, 1976). However, classes of drugs with relatively few competing firms face potential competition from products under development, so any advantages in market share are perceived as insecure.

Because drugs are so critical to health, they are heavily regulated. New products must be approved by the U.S. Department of Health and Human Services' Food and Drug Administration (FDA). Three stages of studies must be completed, requiring collecting data in a clinical environment on the drug's safety and efficacy in treating a specified illness. Winning approval requires enrolling hundreds or thousands of patients who meet clinical criteria, randomly assigning them into treated and nontreated groups, and using a "double-blind" experimental technique in which neither the patients nor the clinicians administering the drugs know which patients are receiving a real treatment and which are receiving a placebo.

These stringent studies are intended to assure safety and efficacy, but they are time consuming.⁹ Before a company can apply for FDA approval, it may spend several years collecting clinical data. When clinical trials are complete, the FDA takes an average of 30 months to

⁹Drugs are the only class of medical services that must provide evidence of efficacy before they can be used. New drugs do not have to prove that they are *more* effective than existing therapies, but studies meeting defined standards of statistical validity and significance must be performed to prove that the outcome from taking the drug is better than no treatment at all. Other types of medical innovations, such as new surgical procedures, can be introduced into medical practice without evidence that they improve patient outcomes. However, once a drug is approved for a particular condition, physicians can legally can prescribe it for any condition for which they consider it useful without a rigorous assessment of its efficacy for that condition.

review the evidence and approve the application. The Pharmaceutical Manufacturers Association (PMA) reports that bringing a new product to market requires an average of 10–12 years of research and development and an investment of \$231 million. Such requirements delay the entry of competitive new products.

Patents are intended to encourage innovation and research by granting a temporary monopoly on a product. To protect their future rights to market a new drug exclusively, drug companies generally apply for a patent on a new drug before they know whether it will be approved. The lengthy approval process may effectively reduce the companies' period of patent protection. At the same time, patented products face potential competition from new products that use a different chemical or an alternative approach to the disease process. Patents can also be viewed as impeding competition by forbidding other firms from entering into the market with the same product.

When patents expire, other companies may enter the market. Although numerous pharmaceutical companies produce generic versions of drugs whose patent has expired, so-called generic drug companies specialize in producing such drugs. Because these companies generally do little research leading to new drugs and have lower costs for marketing and advertising, they can sell their products profitably at lower prices than the original patent holder.

The original manufacturers may seek to differentiate their product from generic competitors. Innovations in packaging or in the mechanism that delivers the drug to the patient, such as a different dosage or a formula that is easier to swallow, are typical types of product differentiation. The generic competitor can compete by marketing the drug compound, but new packaging or delivery might make the name brand drug more suitable for certain purposes. Regardless of these innovations, name brand drugs are generally more expensive than their generic competitors (Grabowski and Vernon, 1990b).

To reconcile its desire to encourage innovation through patent protection and also to encourage price competition among drug companies, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984. The act provided that makers of new drugs could apply to extend patents for up to 5 years beyond the usual 17-year patent if approval was delayed. The law also contains provisions to facilitate FDA approval of generic drug equivalents when patents expire.

To remain in business, pharmaceutical companies must earn enough through sales to recover their research and development, advertising and promotion, and compensation costs and to achieve a return to investors. PMA reports its member firms spent 16.7 percent of revenue, or \$7.3 billion, on research and development in 1989 (Pharmaceutical Manufacturers Association, 1990). Investments in product promotion are rewarded when consumers and physicians develop brand preferences, and some estimates suggest that 20 percent to 30 percent of sales are spent on promotion and advertising (Hurwitz and Caves, 1988). Because drug research takes time and yields uncertain outcomes, drug companies probably set prices of successful drugs to achieve a certain rate of return on their investment in overall research and development, including the cost of unsuccessful research (Vagelos, 1991). One study estimated that only the 30 best-selling new drugs out of 100 introduced between 1970 and 1979 earned revenues greater than drug companies' capital costs (Grabowski and Vernon, 1990a). The possibility that competitors may enter the market with similar products and limit the time available to recover these costs increases a product's riskiness. Companies have an incentive to set prices to maximize revenues while they have exclusive rights to the market.

The drug industry has historically returned greater profits than the average among manufacturing industries (table 5). Drug industry profits as a percentage of sales were estimated at 16 percent in 1988, compared with an average of 6 percent among all manu-

Table 5
Corporate Profits as a Percentage of Sales, by Selected Industries, Selected Years, 1980–1988

	1980	1984	1985	1986	1987	1988
All Manufacturing Corporations	4.9%	4.6%	3.8%	3.8%	4.9%	6.0%
Durable goods industries	4.0	4.4	3.4	2.9	4.5	5.2
Nondurable goods industries	5.6	4.8	4.1	4.6	5.2	6.7
drugs	13.2	13.3	9.8	14.6	10.4	16.0

Source: U.S. Department of Commerce, Bureau of the Census, *Statistical Abstract of the United States, 1988* and *Statistical Abstract of the United States, 1990* (Washington, DC: U.S. Government Printing Office, 1988, 1990).

facturing corporations (U.S. Department of Commerce, 1990). Among the *Fortune* 500 leading industrial companies, the median rate of return to shareholder equity for pharmaceutical corporations was 26 percent in 1990, twice the median for all *Fortune* 500 companies, and this rate has exceeded the median rate for these companies since 1960 (O'Reilly, 1991).

Whether the rate of return implicit in drug prices is a fair return to risk cannot be determined. Rates of return that exceed the average, even over a long period, are not sufficient evidence that drug companies are benefiting from their market power. Higher risk investments lead investors to expect higher rates of return, and differences in returns among industries can reflect differences in risk. Drug industry profits may be reasonable given the expenditures on research and development required to retain a firm's market share.

On the other hand, some have charged that drug company research is largely directed at developing products that imitate competitors' products, and that true innovations are rare. The FDA categorizes drugs on the basis of their contribution to medical therapy. The Senate Aging Committee tabulated the FDA ratings of the 348 drugs introduced by the 25 largest U.S. pharmaceutical manufacturers between 1981 and 1988. The FDA rated 12 of these drugs (3 percent) as having important therapeutic potential, 44 (13 percent) as having modest potential, and the remainder as having little or no potential for therapeutic gain (U.S. Congress, 1989). However, drugs that do not make

major contributions to medical therapy compete for market share with innovative drugs. Whether this competition occurs on the basis of price or on other factors may depend on the characteristics of the market for a particular class of therapeutic drugs.

◆ **How Prescription Drug Cost Containment Influences Quality of Health Care**

Payers are becoming more attentive to the quality of medical care as they seek to restrain health care expenditures and justify expenditures in terms of improved outcomes. **Cost containment efforts directed at prescription drug costs can enhance health care quality to the extent that they discourage inappropriate use and prescription of drugs.**

Quality assurance in the purchase and use of prescription drugs involves a drug's appropriateness for a particular medical problem, physicians' prescription practices, and factors that influence patients' compliance with prescriptions. Utilization review programs for prescription drugs retrospectively analyze physicians' practice patterns for significant deviations from community norms (Rubenstein, 1991). Properly implemented, utilization review can identify cases in which drugs are prescribed inappropriately, in insufficient amounts, or excessively.

Other implications for quality of care involve the use of generic drugs and mail order pharmacies to contain

prescription drug costs. **Generic drugs have become generally accepted as substitutes for name brand drugs; however, although these drugs contain the same active ingredients as name brand drugs, they may contain a number of inactive ingredients that affect how rapidly they dissolve and are processed by the body.** Under policies implemented by the Drug Price Competition and Patent Term Restoration Act of 1984, generic drugs are not required to undergo the series of clinical tests to prove therapeutic efficacy that are required for new drugs. To obtain FDA approval, a generic drug is tested to determine whether, when consumed and absorbed by the body, it supplies the active ingredient to the site of action in sufficient quantities to produce the desired response (Strom, 1987).

Questions have been raised about whether the tests required for generic drugs assure that they are equally efficacious as their name brand counterparts. Some have called for generic drugs to undergo the same clinical tests for efficacy as new drugs. If this were required, some of the cost advantages of generic drugs would probably be reduced (Strom, 1987).

Testing and regulation of generic drugs were called into question when some generic drug companies were shown to have submitted false data and others to have bribed FDA employees in order to obtain approval. The FDA staff who were found guilty of accepting illegal gratuities resigned, and FDA Commissioner Dr. Frank Young stepped down in 1989, although he was not directly accused of wrongdoing. The scandal drew attention to FDA's difficulty in enforcing and reviewing generic drugs because of shortages of staff and other resources (Weiner, 1989). The commissioner who replaced Young, Dr. David Kessler, pledged to strengthen FDA oversight of generic drugs.

Some insurance plans, Medicaid programs, and HMOs require the use of generic drugs when they are available. These insurance plans and pharmacists will provide a name brand drug if a physician specifies that no substitution is allowed for a particular patient. Some of these

plans strictly control their expenditures for name brands by specifically asking physicians to confirm that the name brand is clinically necessary.

Quality issues in mail-order prescription drug plans reflect concern about patients' understanding of the drugs they order. Problems can arise because the pharmacists who fill mail order drug prescriptions may be unaware of other drugs the customer is taking and unable to warn against harmful drug interactions. To guard against this occurrence, mail order plans generally provide pamphlets discussing product use and contraindications, and they also maintain toll-free telephone lines for patient questions. Studies demonstrating how the use of mail order drug plans affect health care quality have not been performed (Kirking, et al., 1990).

There is no assurance that patients would be better protected from these risks in a community pharmacy, where they can talk directly with a pharmacist. However, **community-based pharmacists argue that patients should receive face-to-face counseling rather than educating themselves** (Miller, 1990). Increasing numbers of pharmacists and pharmacy chains also maintain computerized patient records that can cross-check with other prescriptions that might interact with the one being sought.¹⁰ If patients use one of these pharmacies regularly, they may reduce their risk of using prescription drugs inappropriately.

Physicians have a responsibility to assure that their patients understand the use of prescription drugs and

¹⁰The Medicare Catastrophic Coverage Act, before its repeal, called for a computerized claims system with terminals in all pharmacies to keep track of beneficiaries' drug expenditures, notify the pharmacist of eligibility for benefits when the patient's expenditures exceeded the deductible for the year, and provide information to pharmacists about how other drugs used by the beneficiary might interact with the prescriptions that they were being asked to fill. Merely implementing the claims system would have been an unprecedented undertaking, given the number of retail drug outlets and the number of transactions that would have needed to be cross-checked.

avoid harmful interactions, but they do not have pharmacists' day-to-day breath of experience. In practice, many physicians may not always adequately inform their patients about prescription use. If a patient is seeing several doctors for different conditions, one physician may not know which drugs the others have prescribed. This risk is particularly acute for elderly patients with multiple chronic conditions. In this case, the use of pharmacists and drug utilization review systems that collect information about the drugs used by beneficiaries may help flag potential unnecessary use and harmful interactions. However, changing physician prescribing practices may require face-to-face educational efforts (Soumerai, et al., 1989). Recent changes in the Medicaid program require states to embark on a program to educate physicians.

Public and Private Responses

Numerous approaches are being tried to manage prescription drug expenditures. Some payers seek to contain expenditures by negotiating prices. Drug companies sometimes offer substantial discounts from the AWP of prescription drugs, including name brand drugs still under patent. Volume discounts are usually available to hospitals or managed care providers such as HMOs with a defined patient population who may not have an alternative source of prescription drugs. Mail order prescription drug firms also obtain discounts. A few larger employers and unions have established in-house pharmacies to centralize their prescription benefits and negotiate discounts. Some community pharmacies and pharmacy chains have tried to form buying groups, sometimes in cooperation with employers. However, in some cases, drug companies have reportedly refused to negotiate with such groups (U.S. Congress, 1989).

Another approach, sometimes combined with price negotiations, is to develop a prescription drug formulary.¹¹ *Positive* formularies list prescription drugs

¹¹A formulary is a list of pharmaceutical substances.

that are reimbursable by an insurer or other payer, and *negative* formularies list drugs that are not reimbursable.

In developing a formulary, a purchaser may evaluate the costs and effectiveness of competing drug products and choose the product that offers the best ratio of costs to benefits. Used in this way, a formulary can consolidate information for physicians who may not keep track of all available information on competing drug therapies. Purchasers sometimes develop formularies on the basis of the lowest price available, not including more expensive drugs that also brings specific therapeutic benefits. Ideally, a formulary program would incorporate a means for a physician to obtain an exception to the formulary rule for a patient who needs access to an unlisted drug.



Medicaid programs reportedly had difficulty obtaining discounted prices from drug companies and may have used restrictive formularies to accomplish their cost containment goals instead.



Drug formularies are also used by bulk purchasers of drugs such as hospitals and HMOs, but their most controversial use has been by state Medicaid programs. Only 4 of the 48 state Medicaid programs that covered prescription drugs in 1988 did not limit the types of prescription drugs that were reimbursable. In general, these plans did not undertake evaluations of cost effectiveness when implementing the restrictions on Medicaid reimbursement (Soumerai and Ross-Degnan, 1990).

Medicaid programs reportedly had difficulty obtaining discounted prices from drug companies and may have used restrictive formularies to accomplish their cost

containment goals instead (U.S. Congress, 1989). In 1990, Senator David Pryor (D-AR), chairman of the Senate Special Committee on Aging, introduced a proposal to establish a committee of physicians, pharmacists, and clinical pharmacologists to evaluate prescription drugs' effectiveness and develop a national Medicaid drug formulary.



The regulation of prescription drug prices is the focus of current public policy activity.



The pharmaceutical industry opposed a mandatory national formulary, and a compromise was enacted under the Omnibus Budget Reconciliation Act of 1990 (OBRA '90). States are now prohibited from excluding a drug product from their formularies provided that the manufacturer agrees to give state Medicaid programs at least a 12.5 percent rebate from their published AWP and to increase the rebate to 15 percent in 1993. Manufacturers must also disclose their best price for the drug (the lowest price offered to bulk purchasers) and, in phases, will be required to grant the best price to state Medicaid plans. Beginning in 1991, manufacturers had to provide a rebate of 25 percent of the difference between the AWP and the best price if it is greater than the mandatory discount, increasing the rebate to 50 percent in 1992, and rebating the full difference between the AWP and the best price in 1993. Somewhat different discounts apply to generic drugs, for which it was assumed that competition already served to restrain prices. To allay criticism that states delay the inclusion of new drugs in their Medicaid formularies,¹² the act also requires that drugs newly

¹²Evidence to support this allegation is found in a study of approval rates for new drugs introduced between 1974–1982 by Medicaid formularies in six states (Grabowski, 1988). About one-half of

approved by the FDA be covered for at least six months.

Pharmaceutical companies now have an incentive to limit discounts from AWP to other payers in order to increase their best price to Medicaid. As a result, other payers who rely on discounted providers such as mail-order drug companies or HMO and hospital formularies to contain their drug costs might find that they are paying higher prices. Under the 1992 appropriations bill for the Departments of Veterans Affairs (VA) and Housing and Urban Development (H.R. 2519), which was signed into law October 29, 1991, discounts granted to VA hospitals are exempt from pharmaceutical manufacturers' best price. Thus, VA hospitals can continue to receive substantial discounts from manufacturers. However, this provision was enacted as a temporary measure. It is set to expire on enactment of authorizing legislation specifically dealing with pharmaceutical prices paid by VA hospitals or on June 30, 1992, whichever comes first.¹³ At any rate, revenues lost to Medicaid and VA discounts may translate into higher prices to other payers.

◆ **Current Public Policy Activity**

The regulation of prescription drug prices is the focus of current public policy activity. A report released in September 1991 by the staff of Senate Special Committee on Aging sharply criticizes the drug manufacturing industry.¹⁴ The staff report attacks the industry for

new drugs approved by the FDA were not included in these states' formularies, and those that were approved were delayed an average of between one and four years from the time they were first marketed. Drugs that were included or rejected varied greatly from state to state, and drugs rated as therapeutically important were also among those rejected.

¹³Legislation (H.R. 2890) introduced July 15 by Rep. G.V. Montgomery (D-MS), chairman of the House Committee on Veterans Affairs, would establish limits on the price of drugs procured by the Department of Veterans Affairs.

¹⁴According to the report, the document was printed for informational purposes. It does not represent either findings or recommendations formally adopted by the Senate Special Committee on Aging.

“excessive” price increases, “unmatched” profits, high-cost marketing campaigns, and large research and development tax credits. The staff report claims that since the enactment of the Medicaid Prudent Pharmaceutical Purchasing provisions of OBRA '90, some pharmaceutical manufacturers have “increased prices to other buyers of pharmaceuticals with which they have traditionally negotiated reduced prices or discounts.”

The Aging Committee staff report particularly criticizes the pharmaceutical industry for reaping the benefits of a windfall tax credit called the Possessions Tax Credit under the Internal Revenue Code. The credit provides an income tax exemption for business income earned in Puerto Rico and other U.S. territorial possessions. According to the report, 19 pharmaceutical firms accounted for almost one-half of all the section 936 tax credits claimed by all U.S. manufacturing companies between 1983–1987, resulting in tax savings of more than \$5 billion to the drug industry. The staff report concludes by offering a number of policy recommendations relating to pharmaceutical access and cost containment mechanisms.

Senate Aging Committee Chairman David Pryor introduced legislation November 21 incorporating several of the staff's recommendations. The Prescription Drug Cost Containment Act of 1991 (S. 2000) would reduce the section 936 tax credits for those pharmaceutical manufacturers that increase prices faster than the CPI. Revenue raised from this change would be directed to a new Federal Prescription Drug Trust Fund, which would be used to establish a Medicare Outpatient Prescription Drug Demonstration Project.

The bill would also establish a Prescription Drug Policy Review Commission to analyze trends in national and international prescription drug prices and make recommendations on providing or improving coverage, reimbursement, and financing for prescription drugs under federal health care programs such as Medicare and Medicaid. The commission, which would be composed of health care and pharmaceutical economists, physicians, pharmacists, and consumer represen-

tatives, would also study the feasibility of establishing a pharmaceutical price review board in the United States similar to Canada's. Finally, the legislation calls on the secretary of the Department of Health and Human Services, in consultation with the secretary of the Department of Treasury, to conduct a study of the “value of all the federal tax grants, subsidies, and write-offs given to the pharmaceutical industry.”

In response to the Aging Committee's staff report, PMA said that, compared with all other U.S. industries, the pharmaceutical industry devotes a higher percentage of sales revenue to research and development (16.5 percent in 1990 for all PMA member companies). According to PMA, this represents more than four times the average of all industries. Moreover, PMA maintains that “investments in high-risk ventures—such as new drug development, where fewer than 1 in 5,000 chemicals or biologicals actually tested is ever marketed—appropriately require a rate of return considerably higher than could be obtained from placing the same money in an average company” (Pharmaceutical Manufacturers Association, 1991).

PMA said the staff report's examples of “abusive marketing and promotional practices” are not reflective of today's market. According to PMA, the pharmaceutical industry's promotional practices conform to guidelines adopted by the American Medical Association on December 4, 1990. These guidelines forbid the practices cited in the report. Thus, legislative remedies are unnecessary, according to PMA. Moreover, PMA claims that several studies show that promotion by pharmaceutical companies enhances rather than inhibits competition.

With regard to the possessions tax credit, PMA asserts that the report “ignores the intent of Congress in enacting section 936: to create job opportunities and stimulate economic development in U.S. territories, particularly Puerto Rico.” PMA warns that the staff recommendations would have a damaging effect on both health care and U.S. international competitiveness. PMA criticizes Pryor's legislation for singling out

the pharmaceutical industry, saying it violates U.S. tax policy. PMA suggests three policy options to reduce the costs of prescription drugs: streamlining the drug approval process, reducing patent piracy, and cutting product liability costs.

Nevertheless, policymakers continue to offer proposals aimed at reducing drug prices. Sen. Edward Kennedy (D-MA) and Rep. Ron Wyden (D-OR) introduced **the Public Health Clinic Prudent Pharmaceutical Purchasing Act (S. 1729, H.R. 3405) in September 1991. The bill would require drug manufacturers to provide price rebates for drugs purchased by certain entities (e.g., migrant health centers, community health centers, AIDS clinics) funded under the Public Health Service Act.** Legislation (H.R. 3823) to disallow the research credit for duplicative medications and “excessively priced” new therapeutic medications was introduced November 19 by Rep. Pete Stark (D-CA).



Government regulation of prescription drug prices is not a new idea and is likely to generate continued interest as policymakers look for ways to reduce health care costs.



Another bill (H.R. 3551) introduced October 10 by Stark would impose a windfall profit tax on orphan drug companies. Under the Orphan Drug Act, companies are granted seven years of exclusive marketing rights to drugs they develop for rare diseases. In addition to allowing companies to recover their research and development costs, Stark’s bill would allow a company to earn up to a 25 percent annual profit from its orphan drug. The bill would tax any additional orphan drug profits at a rate of 75 percent for the remainder of the drug’s seven-year market exclusivity.

Government regulation of prescription drug prices is not a new idea and is likely to generate continued interest as policymakers look for ways to reduce health care costs. The American Association of Retired Persons recommended in debates over the Medicare Catastrophic Coverage Act of 1988 that prices for single source (patented) drugs be set by a governmental body that would account for production and development costs and assure a reasonable rate of return on investment—a policy similar to those followed in other countries (Guildroy, 1987). Countries that regulate drug prices tend to have lower prices (U.S. Congress, 1990). Pharmaceutical manufacturers argue that most pharmaceutical research is carried out in countries with relatively unregulated prices (Vagelos, 1991). It may be that drug companies in countries that do not interfere with their pricing decisions are more likely to be profitable and can thus afford more research. Other things being equal, it is likely that policies that restrict prescription drug prices will reduce drug industry profitability. Whether such policies would lead to reduced investment in future products is an unanswered question.

◆ Conclusion

Payers are concerned about rising prescription drug expenditures even though these expenditures are increasing less rapidly than those for other health care components. Consumers may be more aware of prescription drug costs than other health care expenditures because they are one of the more common medical services and are less likely than others to be paid by third parties. Consumers (especially the elderly, who use a disproportionate share of prescription drugs) may therefore be more likely to exert pressure for changes in drug pricing and reimbursement policy than for changes in other health services.

Prescription drug markets differ from most markets but are like the markets for other types of medical care in that consumers without medical training do not know which products they need. Physicians serve as their patients’ agents and when prescribing drugs consider

their patients' welfare and tend not to use price as a criterion. Therefore, drug price increases are likely to reduce the number of units sold less rapidly than increases in the prices of other goods and services.

Furthermore, because of patents, drug safety and efficacy approval, and the high cost of research, suppliers have relatively few competitors for certain classes of drugs. However, drug companies see these market advantages as temporary and unstable because competitors may introduce alternative products. Pharmaceutical manufacturers perceive their markets as risky and may set their prices to obtain returns that they consider commensurate with these risks.

Relatively inflexible consumer demand and barriers to new market entrants attenuate competitive market forces. On the other hand, alternative sources of prescription drugs such as generic drug manufacturers and bulk purchasers such as mail order pharmacies may limit the prices that firms charge. The prescription drug market, perhaps inevitably, is also characterized by a high degree of government intervention. Public policy plays a role in the market as states and the Congress strive to constrain Medicaid expenditures for prescription drugs. Recent changes in Medicaid reimbursement seem likely to result in higher prices for private payers. **Health care quality may be enhanced by public and private utilization review and other activities to improve the way physicians prescribe drugs.** Further efforts are being made to evaluate drugs' effectiveness in replacing medical care and to determine whether certain pharmaceuticals are more cost effective than others in treating particular conditions. It is unlikely the characteristics of the prescription drug market that reduce price competition can be eliminated. Payers interested in restraining their prescription drug expen-

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ditures increasingly will use research, selective purchasing under drug formularies, price negotiation, and, in the case of government payers, mandatory discounts or regulated prices.

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