Trends in Payment for Prescription Drugs

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As soon as a new ethical pharmaceutical compound hits the market, revenues begin to flow to the drug manufacturer. These revenues depend on the decision of the physician to prescribe the drug and the decision of the patient to buy it, based on physicians' and patients' judgments of the drug's quality and price compared with those of other possible therapies.

The importance of price versus perceived quality depends on many factors, including the severity of the disease or condition for which the drug is intended, the availability of close substitutes, and the effectiveness of advertising and promotion in convincing doctors (and sometimes patients) that the drug is the right choice for the patient (86), Most important in tipping the balance between perceived quality and price, however, is health insurance.[1] When a medical service or product is covered under a patient's health insurance plan, the patient pays less and is less sensitive to price (5 16).

Like other medical services, pharmaceuticals are marketed in a world with a complex structure of health insurance. Health insurers offer different levels of insurance coverage for different kinds of services and products, Payment restrictions and regulations are as important as covered benefits in determining the demand for health care. As health care costs have increased, health insurers worldwide have adopted new methods to influence or control the use of health care products and services.

[1] Although ethical pharmaceuticals include some nonprescriptions items, health insurance coverage is typically limited only 10 prescription drugs. Consequently, the remainder of this chapter refers to prescription drugs.

This chapter documents recent trends in health insurance for prescription drugs beginning with a review of insurance coverage and payment controls for prescription drugs in the United States. The United States is not only the largest single national market for prescription drugs in the world, but it also has the world's most complex patchwork of insurance mechanisms. Americans are **almost alone in the** industrialized world in not having universal health insurance.

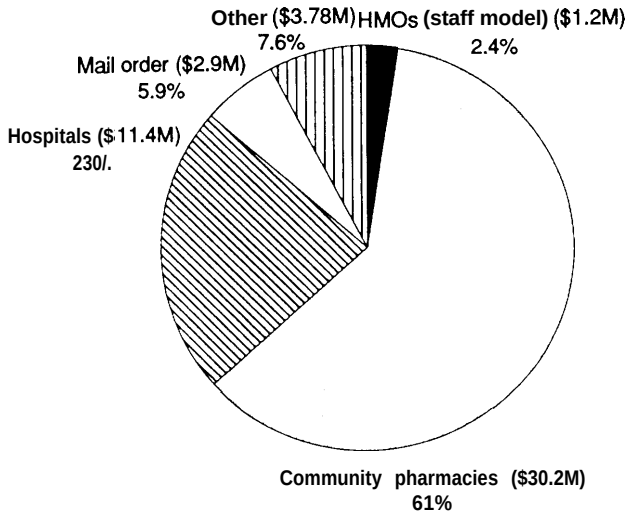
Virtually all other industrialized countries have national health insurance programs that include prescription drug benefits. Good examples, later in this chapter, are Australia, Canada, France, Japan, and the United Kingdom, which illustrate what other nations are currently doing to control expenditures for prescription drugs and what these controls mean for revenues from new drugs yet to be developed.

HEALTH INSURANCE FOR PRESCRIPTION DRUGS IN THE UNITED STATES

The Structure of Coverage

All public and private health insurers in the United States distinguish between inpatient, outpatient, and home health insurance benefits. So, whether or not an individual has insurance coverage for **a** prescription drug depends **not** only on whether he or she has health insurance but also on the setting in which the drug is prescribed and administered. *Inpatient benefits* cover services and products used in hospitals and sometimes in nursing homes. *Outpatient benefits are* for services or products obtained in clinics or offices of health professionals; *home health care benefits are* for services or products provided by certified personnel to patients at home.[2]

Figure 10-1—Pharmaceutical Sales in the United States by Trade Channel, 1991



SOURCE: IMS America, Inc., as cited in *F-D-C-Reports: Prescription and OTC Pharmaceuticals*, "Mail Order Grew 37% to $2.9 Bil. in 1991 IMS Survey; **Growth May Slow Soon," p. 11, Mar. 16, 1992.**

HOSPITAL COVERAGE

Most Americans-86 percent-have public or private health insurance, continuing **a** steady trend over the last decade (292). Virtually all health insurance plans cover hospital care, including drugs dispensed **to** hospitalized patients.

Sales to hospitals made up about 23 percent of total U.S. pharmaceutical sales in 1991 (128), a decline from about 29 percent in 1983 (291,320). (See figure 10-1 for a breakdown of pharmaceutical sales by type of buyer **at the** wholesale level.) A growing proportion of these sales represent drugs sold through hospital-based outpatient pharmacies,[3] so the inpatient hospital share of the pharmaceutical market today is actually below **23** percent.

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[2] Insurance for health services provided in the home generally does not affect prescription drugs, because most drugs administered at home would be covered under outpatient prescription drug benefits. Home health benefits sometimes cover the professional care and device costs associated with administering an intravenous drug to patients at home, thereby making administration of such drugs at home (rather than in a hospital or clinic) a viable option (454). Sometimes Medicare will extend coverage for certain intravenous drugs as part of its durable medical equipment benefit to patients in the home even though the program lacks outpatient prescription drug benefits. Other insurers may also occasionally permit such 'back door' coverage. Because such cases of extended coverage are relatively rare, however, they are not discussed in this report. See the Office of Technology Assessment's study of home intravenous drugs for more information (454).

[3] Virtually unheard of 10 years ago (369), this practice was carried on for profit by approximately 17 percent of U.S. hospitals in 1990 (120).

One reason for the decline in the inpatient hospital share of the overall pharmaceutical market is the major restructuring of hospital payment systems in the past decade. When Medicare adopted in 1983 a prospective payment system that pays by admission and not by specific service, Medicare created incentives for hospitals to reduce the services offered per stay and to reduce the length of stay for Medicare patients.[4] For drugs dispensed during the hospital stay in the 1980s, hospitals adopted stricter formularies,[5] aggressively used the cheapest generic drugs available, and closely scrutinized doctors' prescribing practices (41 1,412). Hospital use declined dramatically as well. Some of the shift from inpatient care to outpatient care means that medications that would have been prescribed on an inpatient basis are now prescribed to outpatients.

NURSING HOME COVERAGE

Pharmaceutical sales to nursing homes made up just 2.9 percent of total U.S. pharmaceutical sales in 1991 (128). Private insurance for nursing home care is very limited, but drugs dispensed to nursing home patients are typically covered under outpatient drug benefits if the patient has outpatient drug coverage. Medicare covers its beneficiaries for limited skilled care in a nursing home and covers drugs dispensed as part of a Medicare-covered stay as they would be in a hospital. If Medicare doesn't cover a patient's stay in a nursing home, Medicare would still pay for certain drugs that would be covered were the patient living at home (454).

Medicaid is a payer of last resort for nursing home residents whose personal funds are depleted, and virtually all State Medicaid agencies cover drugs as part of nursing home stays. Nursing home residents have a high probability (30 to 50 percent according to several studies) of becoming eligible for Medicaid while institutionalized, which then covers them for prescription drugs (137).

OUTPATIENT COVERAGE

Although fewer Americans have outpatient prescription drug coverage than hospital coverage, outpatient drug coverage grew in the 1980s. Most (67 percent) ethical pharmaceuticals in 1991 were dispensed through retail or mail-order pharmacies (128,324), so this growth in coverage has been an important stimulus to the demand for prescription drugs in the United States.

The proportion of outpatient prescription drug purchases paid for by insurance increased substantially, from 27 to 43 percent, between 1977 and 1987 (table 10-1).6 The average expenditure for prescription drugs by individuals with any prescription drug costs increased 135 percent between 1977 and 1987 (from $69 to $162 in 1987 dollars) (277). Although Medicare does not pay for most outpatient prescription drugs, these same trends hold among elderly Americans, for whom private insurance paid for 36 percent of outpatient prescription drug expenses in 1987 compared with only 23 percent in 197'?. People 65 and over are relatively heavy users of prescription drugs?

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[4] Medicare beneficiaries accounted for 45.2 percent of inpatient hospital days in 1989 and for 33 percent of the discharges (164).

[5] Formularies arc lists of drugs that either include or exclude drugs that may be prescribed by physicians without special exceptions. The number of hospital pharmacies adopting formularies has steadily increased. Studies conducted by the American Society of Hospital Pharmacists show the percent of hospitals adopting a well-controlled formulary system increased from 53.9 percent in 1985 to 58.4 percent in 1989 (101,412).

6 In 1977, and again in 1987, the Agency for Health Care Policy and Research (AHCPR), known until 1990 as the National Center for Health Services Research, collected data in a national survey of health care expenditures, payments, and insurance coverage. Both the 1977 study, called the National Medical Care Expenditure Survey (NMCES) and the 1987 study, referred to as the National Medical Expenditure Survey (NMES), included a household survey of expenditures and health care coverage for different types of health care products and services. Data on expenditures are available from both surveys. Data on coverage are not yet available from the 1987 NMES survey.

[7] In 1987, people 65 and over made up 12 percent of the U.S. population, but were responsible for 34 percent of the country's total expenditures on prescription drugs. Elderly Americans' per capita expenditure on prescription drugs in 1987 was $331, about twice that for the population as a whole (277).

Table 10-1—Sources of Payment for Prescribed Medicines in the United States

	Percent of expenditures 1977	1987
All prescribed medicines		
Family	73%	57%
Private insurance	14	28
Medicaid	8	10
Other sources[a]	6	6
Prescribed medicines for persons over 65 only		
Family	77	64
Private insurance	10	22
Medicaid	10	9
Other sources[a]	3	5

a Other sources include Workmen's Compensation, Medicare, other State and local programs, and any other source of payment.

SOURCE: Data from J.F. Moeller, Senior Project Director, U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, Rockville, MD, personal communication, Mar. 12, 1991; J.A. Kasper, Prescribed Medicines: Use, Expenditures, and Sources of Payment, Data Preview (Washington, DC: U.S. Department of Health and Human Services, National Center for Health Services Research, April 1982).

Insurance reimbursements alone do not reflect the full impact of outpatient insurance coverage on the use of prescription drugs. Coverage itself, though limited by deductible and copayment requirements, makes patients less sensitive to the cost of medical care than they would be without such coverage (294). Prescription drug costs frequently contribute to annual deductible amounts, and most privately insured people are protected from high expenditures by annual catastrophic limits on out-of-pocket costs.[8] Hence, people with health insurance, particularly those with chronic diseases or conditions requiring long-term medical treatment and medication, have relatively little incentive to minimize the cost of medical care, including drugs.

The Office of Technology Assessment (OTA) estimates private and public health insurance programs together provided at least some outpatient drug coverage for 67 to 69 percent of the total noninstitutionalized civilian population in 1979. By 1987, this figure had increased to between 70 and 74 percent (table 10-2). Among people 65 and older, the proportion with outpatient drug coverage increased more dramatically, from 36 percent in 1979 to between 43 and 46 percent in 1987.

Not only has insurance coverage for outpatient prescription drugs increased over the past decade, but these benefits have become more generous over time, as insurance plans have moved toward policies with flat copayments for prescription drugs (see below). On the other hand, all third-party payers have tried to contain the costs of prescription drugs.

Private Health Insurance Benefits for Outpatient Prescription Drugs

EXTENT OF OUTPATIENT COVERAGE

Very few private outpatient prescription drug benefit plans pay for 100 percent of the allowed cost of drugs. Table 10-3 shows that only about 3 percent of employed people with prescription drug coverage had full coverage throughout the 1980s. Full coverage is most common in health maintenance organizations (HMOs),[9] whose enrollment grew from 4 percent of the population in 1980 to 14 percent in 1990 (209). In 1989, 10 percent of employees of medium and large firms who were enrolled in HMOs had full coverage, compared with only 1 percent of those enrolled in fee-for-service plans (35).

Limitations of coverage vary across plans and include restrictions applying specifically to prescription drug expenditures (e.g., copayments for each prescription) and restrictions affecting overall health expenditures (e.g., a single annual deductible for all covered medical services in a "major medical" policy). Policies with specific copayments for prescriptions increased substan-

8 Most insurance plans (80 percent) have both an annual deductible and an annual maximum limit on out-of-pocket expenses (491).

9 Unlike traditional fee-for-service insurance plans, HMOs (sometimes referred to as 'prepaid health plans' collect a set premium for each member, but charge either nothing or a relatively small amount for each individual service. People enrolled in the HMO must receive their health care from providers designated by the HMO.

Table 10-2-Percent of U.S. Population With Outpatient Prescription Drug Coverage, 1979 and 1987[a]

I. ASSUMPTIONS

A. Total noninstitutionalized population

	Number of people (thousands)[b] 1979	1987
People under 65	**198,966**	**212,700**
People 65 and over	**24,194**	**28,487**
Total	**223,160**	**241,187**

B. Health insurance among people under age 65

	1979		1987	
	Number of people (thousands)[b]	Percent with prescription drug coverage	Number of people (thousands)[b]	Percent with prescription drug coverage
Group private health insurance	133,555	95'	140,909	95'
Other health insurance	**35,765**	**41-54**[d]	**41,071**	**53-75"**

C. Health insurance among people age 65 and over

	1979		1987	
	Number of people (thousands)	Percent with prescription drug coverage	Number of people (thousands)	Percent with prescription drug coverage
Medicare only (with no supplemental health insurance)	**4,645**[f]	0	**5,877**[g]	0
Group supplemental private health insurance	**1,706b**	**71**[h]	**8,830**[b]	**45-531**
Other supplemental private health insurance	**17,543b**	**43**[J]	**13,474'J**	**61-67**[k]

II. RESULTS

	1979	1987
Percent of total noninstitutionalized civilian population with outpatient prescription drug coverage		
People under 65	71-73	73-77
People 65 and over	36	43-46
Total	67-69%	70-74%

a A detailed memorandum describing OTA's **methods in preparing this table is available upon request.**

b **From th, Current population** Survey. C. **Nelson,** Census **Bureau,** U.S. Department **of Commerce,** Washington, DC, personal **communication, Mar. 26, 1991; K. Short, Census Bureau, U.S. Department of Commerce, Washington, DC, personal communication, Nov. 15, 1991.**

c From the U.S. Department of Labor, **Bureau** of Labor Statistics, surveys **of** employers; A. Blostin, U.S. **Department of Labor, Bureau Of Labor Statistics, Washington, DC, personal** communication, **Aug. 15, 1991.**

d Weighted averages **of percent of each type of "other health insurance"** with outpatient prescription drug coverage: Medicare—0%; Champus—100%; nongroup private health insurance—0-24% (maximum 240/. estimate from G.L. Cafferata, Private *Health Insurance of the* ***Medicare*** *Population,* **Data Preview 18, Publication No.** (PHS) **84-3362 (Washington, DC: U.S. Government Printing Office, 1984)); Medicaid-1** 00%.

e Weighted averages of following percents: Medicare—0%; Champus—100%; Medicaid-100%; nongroup private health insurance—0-53% (maximum 53% from Market Facts, Inc. *Consumer Awareness of* ***Medigap*** *Insurance: Findings* ***of a National Survey of Older*** *Americans* **(Washington, DC: American Associations of Retired Persons, 1990)).**

f Based on **estimates of Medicare only population in** Cafferata, **1964** (footnote d).

9 Based on estimates of Medicare only population **in J. O'Sullivan, and D.** Koitz, *Health Insurance* ***That Supplements Medicare:*** *Background* ***Materials and Data, 89-421*** EPW (Washington, DC: Congressional Research Service, 1989).

h From Cafferata, **1984** (footnote d).

i From Market Facts, **Inc., 1990.**

J **Weighted averages of percent of each t ype of "other health insurance" with prescription drug** coverage: Medicaid—1 OO°/~; Champus—1 OO°/.; State pharmaceutical assistance programs—IOO°/'; nongroup private health insurance-240/' (from Cafferata, 1984 (footnote d)).

k Weighted averages of **following** p$_{ercen}$**ts.** Champus—100%; State pharmaceutical assistance **programs—IOO°/o;** nongroup private **health** insurance—45-53% **(from Market Facts, Inc., 1990).**

SOURCE: Office of Technology Assessment, 1993.

Table 10-3-Limitations of Prescription Drug Benefits Among Nonelderly People With Private Health Insurance Covering Prescription Drugs

	1977[a]	1989/1990[b]
Full coverage	3%	3%
Separate limits (Copayments)[c]	9	30
Overall limits (major medical)[d]	88	61
Other limits[e]		7

a Results based on 1977 National Medical Care Expenditure Study Survey of employers and insurers of individuals under 65 years of age.
b Results based on U.S. Bureau of Labor Statistics 1989 and 1990 surveys of employers.
c "Separate limits" refers to restrictions applicable only to prescription drugs, such es a copayment for each prescription.
d "Overalllimits" refers to restrictions applicable to a broader set of medical services. For example, a major medical policy may carry a $100 deductible and 20-percent coinsurance rate that applies to all covered services, not just prescription drugs.
e Other limits include policies that combine fixed copayments with overall limits.

SOURCE: Office of Technology Assessment, 1993, based on data from P.J. Farley, *Private Health Insurance in the U.S. Data Preview #23*, DHHS Publication No. (PHS) 86-3406, 1986. U.S. Department of Health and Human Services, National Center for Health Services Research and Health Care Technology Assessment, September 1986; U.S. Department of Labor, Bureau of Labor Statistics, *Employee Benefits in Medium and Large Firms, 1989,* Bulletin 2363 (Washington, DC: U.S. Government Printing Office, June 1990); U.S. Department of Labor, Bureau of Labor Statistics, *Employee Benefits in Small Private Establishments, 1990,* Bulletin 2388 (Washington, DC: U.S. Government Printing Office, September 1991); U.S. Department of Labor, Bureau of Labor Statistics, *Employee Benefits in State andLoca/Governments,* 1990(Washington, DC: U.S. Government Printing Office, February 1992).

tially between 1977 and 1989, roughly from 9 to 30 percent of the insured population. Copayments have substituted for other types of restrictions, such as the inclusion of drugs within the deductible and coinsurance framework of the major medical policy.

The trend in the 1980s away from inclusion of prescription drug benefits in major medical policies toward separate limits on drug benefits themselves represents a move toward a richer benefit structure for prescription drugs. The vast majority (95 percent) of employees facing fixed copayments per prescription in 1989 had a copayment of $5 or less (35). For people whose overall medical expenses lie below the deductible, a flat copayment for prescriptions means lower out-of-pocket prescription drug expenses than do the major medical restrictions. Even after a beneficiary covered under a major medical plan meets the deductible, he or she may be responsible for a 20 percent or higher coinsurance payment. For example, a $30 prescription would cost the employee covered under a major medical policy with a 20-percent coinsurance rate $6, whereas the typical cost under a flat copayment would be only $5.

REIMBURSABLE AMOUNTS

For policies providing prescription drug benefits, the actual insurance benefit depends on the allowed reimbursement level. The reimbursable amount is not necessarily equal to the price charged by a pharmacy for the prescribed medication, although it is usually tied to the drug's price. In 1977, 76 percent of those with outpatient prescription drug coverage had policies that based reimbursement rates for a given drug on the amount usually charged by the dispensing pharmacy or by other pharmacies in the geographic area (130). More recent data are not yet available, but informal OTA discussions with insurance plan administrators suggest the reimbursement base may have shifted during the 1980s to average wholesale prices (AWP). In either case, if the drug is a ''single-source' drug,[10] the insurer essentially pays the manufacturer's price plus a retail markup.

REIMBURSABLE DRUGS

Private insurers generally cover all prescription drugs licensed for sale in the United States by the U.S. Food and Drug Administration (FDA) (35).[11] Thus, FDA approval is in essence a de *facto* coverage guideline for insurers. Indeed, pharmaceuticals are spared the additional insurance coverage hurdles that new medical devices must

10 A single-source drug is a molecular entity that is marketed under a single brand name. After the patent on a drug expires, generic copies may be approved by the FDA, and the compound becomes a multiple-source drug.

11 Most insurance plans d. not cover nonprescription drugs, vitamins, medical supplies, dietary supplements, diabetic supplies other than insulin, and non-oral contraceptives (35).

often clear.[12] For drug manufacturers, the relatively uniform coverage of pharmaceuticals reduces the company's uncertainty about the expected returns from a drug once it has been approved by the FDA.

There is at least one exception to predictable coverage that may become more important in the future. Although virtually every prescription drug that the FDA approves is covered by private insurers, a pharmaceutical may not be covered if a doctor prescribes it for a use other than the one the FDA has approved. Insurers are typically not contractually obligated to provide coverage in these instances (278). Although some of these prescriptions are clearly experimental, others are standard therapies. Pharmaceutical manufacturers often do not seek approval to sell a drug for additional indications once it is initially licensed, because the process can be costly and time consuming (238). The practice of prescribing for unapproved indications, known as off-label prescribing, occurs in many branches of medicine.

There is little published data to show how many claims for off-label prescriptions are denied, but cancer patients report they have found it increasingly difficult to get reimbursement for off-label prescriptions and their associated costs (e.g., hospital stay) as insurers have begun to examine the prescriptions, mainly to control costs (395). About 33 percent of cancer chemotherapy prescriptions are off-label and about 56 percent of all cancer patients receive at least one off-label prescription in their drug regimen (238). Insurers are generally willing to reimburse for off-label uses that have been documented as effective in one of three major medical compendia[13] or in multiple independent published studies. Physicians have complained that there are often long delays between proof of effectiveness and approval in the compendia or other literature (278).

RECENT COST-CONTAINMENT TRENDS

In the past 5 years, many private health insurance plans have begun cost-containment measures that either directly or indirectly control or influence the use of, and prices paid for, prescription drugs. Chief among such provisions are incentives to purchase generic drugs, drug utilization review programs, and mail-order pharmaceutical programs. These provisions may represent a ''second-tier barrier' to access to drugs beyond FDA licensing requirements (515). In addition, the rapid growth of HMOs over the past decade has added an indirect incentive to control the utilization of all services, including prescription drugs.

Incentives to Use Generic Drugs—The percent of enrollees in employer-based plans that encourage the use of generic drugs by reducing copayments when a generic is dispensed increased dramatically from 3 to 14 percent between 1985 and 1989 (35). The most common incentive is a lower copayment when a generic drug is purchased. In HMOs, where mandatory generic substitution can be enforced, the use of differential copayments appears to be just as effective as mandatory substitution in increasing the use of generics (515).

Formularies—A formulary restricts the doctor's choice of drugs to drugs on a list (or to those not on a list of excluded drugs) when more than one therapeutically similar compound is available to treat a condition, Except for HMOs, formularies do not exist in private health insurance plans. Recent surveys of HMOs indicate that between 28 and 55 percent of all plans have some type of formulary, but the nature and effectiveness of these restrictions have not been documented (515).

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12 Some private insurers subject medical devices and procedures to a rigorous review that can include Cost or COSt-effectiveness criteria in their coverage decisions. For example, the Blue Cross/Blue Shield Association of America has a Technology Management Program that undertakes such studies in order to make coverage recommendations to its individual insurance plans (12).

13 These sources include the American Hospital Formulary Service's *Drug Information*, the U.S. Pharmacopoeia's *Drug Information*, and the American Medical Association *Drug Evaluations*. None of these sources are published with the intent that they should be used as guides for insurance coverage; they are references for doctors and hospitals concerning drug options and activities (395).

Photo credit: U S FOOD AND DRUG ADMINISTRATION

The use of generic drugs is growing as health insurers give both patients and pharmacists incentives to substitute generic versions for brand-name versions of prescription drugs.

Drug Utilization Review (DUR)—DUR is the review of drugs prescribed or prescriptions filled to verify the drug's appropriateness, to identify potential interactions with other medications, or to identify alternative effective or cost-effective therapies for the patient (35,1 38,434,515).14

Data on the extent of DUR programs or their impact on the use of pharmaceuticals are limited. Among HMOs, about 70 percent report having a DUR program (5 15). OTA found no similar profile of DUR programs among fee-for-service insurance plans. A recent General Accounting Office (GAO) study described eight DUR programs, including some at retail chain pharmacies, one at a U.S. Department of Defense pharmacy, and one at a mail-order pharmacy (434). GAO found that the identification of potential adverse drug reactions or adverse interactions with other drugs that a patient is using are the most common features of DUR programs, but the report also stresses that these systems could be linked relatively easily to insurance claims systems. Thus, although there is little evidence DUR is currently a major tool in attempting to control the use of, or total expenditures for, prescription drugs, insurers or others concerned with costs may try to use DUR more extensively for such purposes in the future.

Mail-Order Pharmacies--Another way in which insurers try to constrain prescription drug costs is by contracting with a ''mail-order' pharmacy for drugs that patients need refilled on a regular basis. Unlike other cost-containment mechanisms, mail-order pharmacies do not necessarily restrict access to drugs or attempt to constrain use. These programs achieve cost savings through the economies of scale of a centralized mail-order operation and by providing incentives (usually through lower copayments) for patients to buy their medications in large quantities.

Mail-order pharmacy programs are also more effective than retail pharmacies in substituting less expensive generic versions of brand-name drugs when generic versions are available. One prescription drug insurance administrator with a large mail-order operation reported to OTA that between January and March, 1992, 44 percent of its mail-order sales of multisource drugs were for generic products. In contrast, only 31 percent of sales of maintenance multisource drugs purchased through the company's community pharmacy system were for generic products (255). Thus, the increasing use of mail-order pharmacies may appreciably reduce revenues for brand-name products that have lost patent protection.

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14 The now repealed Medicare Catastrophic Coverage Act (Public Law 100-360) included a mandated DUR program for the outpatient prescription drug benefit provided by that legislation. In 1990, the Congress required each State Medicaid program with a prescription drug benefit begin a DUR program by January 1, 1993 (Public Law 101-508). With the expectation that DUR may be a growing part of outpatient prescription drug dispensing, the Pharmaceutical Manufacturers Association (PMA), the American Pharmaceutical Association (APhA), and the American Medical Association recently adopted joint "principles" for DUR programs. This document stresses the importance of DUR m enhancing ''the quality of patient care, ' but docs not address its potential usc by health insurers to constrain prescription drug costs (138).

Mail-order pharmacy programs appear to be growing rapidly among employer-based health care benefit plans. In 1989, about 13 percent of U.S. employees had a mail-order drug benefit; by 1990, 20 percent of employees had such a plan (135).

HMOs—The rapid growth in HMO enrollment over the past decade, from 3 to 14 percent of the population, means that incentives to economize on medical services are increasing dramatically. But, many HMOs do not give their doctors incentives to economize in drug prescribing. A recent review of seven HMOs found the plans were structured so that the prescribing physician never bore financial risk for prescription drug costs (515).15 Rates of use of prescription drugs were actually higher in the seven HMOs studied than in traditional insurance plans (5 15). And, the enrollees in the HMOs used newly approved drugs at the same rate as did those in traditional fee-for-service plans.

Because HMOs are more suited than traditional fee-for-service plans to develop and enforce formularies, HMOs also are more able to negotiate discounts with makers of brand-name drugs, Some large HMOs have achieved substantial discounts on specific drugs for which close therapeutic alternatives exist.[16] Thus, the growth of HMOs has surely expanded price competition among single-source drugs and has reduced, though modestly overall so far, the returns to research and development (R&D).

Medicaid Prescription Drug Benefits

Medicaid, funded jointly by the States and the Federal Government, provides health insurance to people of limited financial means.[17] Coverage of outpatient prescriptions is an optional Medicaid benefit offered by 49 States and the District of Columbia. Medicaid enrollees get their prescribed medications from a retail pharmacy usually at little or no charge to them. The pharmacy, in turn, is reimbursed by the State Medicaid agency according to payment limits and established dispensing fees set by Federal Medicaid regulations. Medicaid is responsible for about 10 to 15 percent of the Nation's outpatient prescription drug expenditures.[18]

EXTENT OF OUTPATIENT COVERAGE

To get a prescribed medicine from a pharmacy, a Medicaid beneficiary usually presents a Medicaid card verifying his or her enrollment, along with the doctor's written prescription. A total of 22 States require Medicaid enrollees to pay apart of the cost of medications (287). In most States with this provision, the copayment ranges from $0.50 to $3.00 (287). Federal law prohibits States from requiring copayments from important groups of beneficiaries: children under 18, pregnant women, residents of long-term care and hospice institutions, some HMO enrollees, and

15 These HMOs were all Individual Practice Associations or Networks, These kinds of HMOs tend to have looser fiscal controls than staff model HMOs, where physicians are either employees or partners in the organization.

16 The magnitude of such discounts has declined since 1990, when the Medicaid Rebate Law (Public Law 1(31-508) made it costly for pharmaceutical firms to offer such discounts (431).

17 At a minimum, States must provide certain health services under Medicaid to the recipients of certain kinds of Federal financial assistance. In particular, recipients of Supplemental Security Income (SS1), Aid to Families of Dependent Children (AFDC), and several other groups of pregnant women and children meeting specific criteria are considered ' 'categorically' eligible for Medicaid. States may also decide to provide these services to other low-income individuals without health insurance (sometimes referred to as ''medically needy' individuals). States may also provide other services, including prescription drug coverage, to the categorically eligible only or to both the categorically and medically needy populations. In **1991, 17** States and the District of Columbia provided prescription drug coverage to the categorically needy only, while the rcmaining **34 States** provided drug benefits to both the categorically and medically needy, Of the *17* **States** having no prescription drug benefits for the "medically needy, " 16 offer Medicaid only to categorically eligible people (463).

18 As shown in table 10-1, the 1987 National Medical Expenditure Survey of noninstitutionalized Americans indicated Medicaid accounted for about 10 percent of expenditures for prescription drugs in 1987. The National Health Expenditures Series, which estimates national spending on health care based on a variety of data sources, estimates the Medicaid share of pharmaceutical expenditures was 15 percent in 1990 (464).

recipients of emergency and family planning services (287).

REIMBURSABLE AMOUNTS

State Medicaid programs reimburse the pharmacist after a drug is dispensed to a Medicaid enrollee (235). States pay a freed dispensing fee and an amount to cover the cost to the pharmacy of the prescribed drug. The median dispensing fee in 1990 was $4.10 (287).

Federal requirements for reimbursement of prescribed drug costs differ for single-source and multiple-source drugs. Until 1991, when a new Medicaid rebate law went into effect, State Medicaid agencies were required to pay no more for a single-source drug than either the pharmacy's estimated acquisition cost plus a reasonable dispensing fee, or the pharmacy's usual and customary charge to the general public (134). State Medicaid agencies generally discounted the published average wholesale price for the drug by a fixed percent (ranging from 5 to 11) to obtain the estimated acquisition cost (134). Since published wholesale prices are generally higher than the actual wholesale prices paid by retailers, Medicaid essentially paid the manufacturer's price plus a retail markup for single-source drugs.

Since the mid-1970s the Federal Government has tried to reap savings from price competition for multiple-source drugs by requiring that in the aggregate (i.e., across all multiple-source drugs) the State reimburse no more than 150 percent of the published price for the least costly product (134). States themselves have every incentive to pay as little as possible for multiple-source drugs. A big loophole in this regulation has been the exemption of any prescription from the upper limits if the physician has written by hand that a specific brand is medically necessary. When such an override occurs, the prescription is treated as a single-source drug even when generic competitors are available.[19]

REIMBURSABLE DRUGS

Until 1991, State Medicaid agencies had the authority to restrict the drugs that Medicaid covers. In 1990, about 22 States had restrictive formularies, which limited reimbursable drugs to a defined list. Another 28 States had ''open formularies," under which all drugs are reimbursable except for those explicitly identified as ineligible.

The use of restrictive formularies can add a measure of uncertainty and delay to the drug development process and could affect manufacturers' returns to R&D. In the past, there were reports of long delays in the adoption of new drugs into Medicaid formularies after FDA approval. A study of delays in Medicaid formulary approvals for new drugs introduced between 1975 and 1982 in six States with restrictive formularies found the average delays in approval time for drugs eventually accepted ranged from about 1 to 4 years after approval by the FDA (153). An update of that study, which examined nine States over the period 1979 to 1984, found similar delays (156).

OTA examined the status of three newly approved drugs in States with restrictive formularies. Two of the drugs, AZT and gancyclovir, were approved in 1987 and 1989 respectively for treating AIDS patients. The third drug, fluoxetine, the first compound in a new class of antidepressants, was approved in December 1987. By September 1990, virtually all States had approved the three drugs for Medicaid reimbursement, although it had taken almost 2 years for some States to approve AZT. In addition, several States required prior authorization to fill prescriptions for these drugs (503).

Many State Medicaid programs restrict payment for off-label uses of prescription drugs; however, the restrictions are applied only to a few very costly drugs. Therefore, the overall impact of such Medicaid restrictions is minor.

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[19] A study conducted in Florida in 1989 found almost 40 percent of prescriptions for multiple-source drugs were written with a physician's brand override and were filled with the originator's brand. In 1990, Florida issued a rule mandating the use of available generics and essentially refusing to pay for brand-name drugs regardless of the physician override when generic equivalents exist (517).

RECENT COST-CONTAINMENT EFFORTS: THE MEDICAID REBATE LAW

A new Federal Medicaid law enacted in 1990 rendered much of previous Medicaid prescription drug policy inoperative. The Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) required manufacturers selling prescription drugs to Medicaid patients to give States a rebate on their Medicaid purchases. In exchange, the law prohibited States from using formularies to restrict Medicaid patients' access to any FDA-approved drug in the manufacturer's product line. States *may* require doctors to get prior authorization for a drug but not for the first 6 months after FDA approval.

The required rebate on brand-name drugs[20] has two main components. The first is the Basic Rebate, which requires the manufacturer to effectively discount the price of each drug it sells to Medicaid by a specified amount. The second component is an Additional Rebate, which requires the manufacturer to pay money to Medicaid whenever the prices of its brand-name drugs increase more rapidly than price inflation. The Congressional Budget Office projected a total rebate for brand-name drugs (single-source and innovator multiple-source drugs) to the Federal Government of $637 million in fiscal year 1992 (431). Including the States' share brings this total to about $1.1 billion (317), or about 2 percent of total domestic manufacturer sales.

The Basic Rebate has two components—a flat discount off the average manufacturer's price[21] and a' 'best-price' discount that would equate the net Medicaid price with the lowest price offered by the company to any buyer. The required rebate is the higher of these two components. The flat discount increases over time as the law is phased in.[22]

The Additional Rebate operates one way until 1994, when it is slated to change in a manner that is potentially important for returns on new drugs. Through 1993, the average manufacturer's price of each brand-name drug product in any calendar quarter is compared with the price of the drug in the quarter ending October 1990. If the product's price has increased faster than inflation (as measured by the consumer price index (CPI)), then the manufacturer must give back to Medicaid the difference for each unit of the drug it sells to Medicaid. If a drug product is introduced after October 1990, then the price in the calendar quarter in which it was launched on the market becomes its baseline price.[23] Thus, while price increases to Medicaid are controlled, the launch price to Medicaid of a new drug is virtually unrestrained.

After 1993, the Additional Rebate for each drug is tied not to the pricing history of that drug alone but to the average manufacturer's price across the manufacturer's complete product line, weighted by the number of units of each product sold to Medicaid. The manufacturer's current weighted average price is compared with the manufacturer's weighted average price across its entire product line *as it existed in October 1990. If the* average price across drugs sold in a period after 1993 is higher than the average price as of October 1990, after accounting for general inflation, then the manufacturer must give back the

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20 Brand-name drugs are those available from only one manufacturer (i.e., single-source drugs) or, if generic competitors exist, the innovator company's brand-name product. The law also requires a rebate from generic manufacturers equal to 10 percent of the average manufacturer's price (increasing to 11 percent in 1994).

21 The Average Manufacturer's price (AMP) is the average price charged by wholesalers for products distributed to the m@ class of trade. The best price originally excluded depot prices and single-award contracts given any Federal agency. In subsequent legislation passed in 1992, prices paid by the Department of Veterans Affairs, the Department of Defense, Public Health Service Hospitals and other federally funded health providers, and certain hospitals that serve a disproportiomte share of poor people were also excluded from the best price (Public Law 102-585).

22 In the first 2 years, there are upper limits on the required rebate.

23 The law does not specifically indicate what should be done about drugs introduced after October 1990, but the law has been implemented so far in this way.

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Box 10-A–Medicaid's Additional Rebate After 1993: An Example

Suppose a company had two drugs on the market in 1990, with unit sales over the quarter ending October 30 and average manufacturer's prices as given below:

Drug	Price	Unit sales
X	10	100
Y	30	100

Suppose the consumer price index increased by a total of 10 percent between 1990 and 1995. Then, the inflation-adjusted baseline weighted average manufacturer's price in 1995 would be:

$$[(10(100) + 30(100)]/200] * 1.10 = \$22.00$$

Now, suppose in 1995 the firm introduces a new drug and its total sales now are as follows:

Drug	Price	Quantity
X	11	100
Y	33	100
z	25	100

The weighted average price in 1995 for this manufacturer is now $23.

For every unit of each product it sells, the manufacturer must give back to the Medicaid program $1, the difference between the current weighted average manufacturer's price and the inflation-adjusted baseline weighted average manufacturer's price. This manufacturer would owe Medicaid $300 in additional rebate.

Without the new drug, the manufacturer would have owed Medicaid nothing, so the new drug pays a penalty of $3 per unit to Medicaid for having been introduced at a relatively high price.

SOURCE: Office of Technology Assessment, 1993.

difference for every unit of each drug it sells to Medicaid.

The baseline average weighted manufacturer's price as of 1990 would not contain any drugs introduced after that period, so as the law is currently written new drugs introduced to the market at high prices relative to pre-existing drugs will face additional rebates. (See box 10-A for an example of how this works.) At the same time, the law states that the Secretary of Health and Human Services (HHS) may exclude from the calculation of today's weighted average price any new drug that effectively would lower the rebate manufacturers must give to Medicaid. (A new drug product entering the market at a very low price, for example, might be excluded from the calculation of the weighted average manufacturer's price, but the per unit rebate would still be payable for each unit of the new product sold to Medicaid.)

The law *does allow the* Secretary of HHS to exclude from the weighted average price calculation, new products that increase the rebate to Medicaid, but only if their inclusion would impose "undue hardship' upon the manufacturer. The law also gives the Secretary the power to impose an alternative mechanism for calculating the Additional Rebate. No such alternative approaches have been published to date.

In the short term, the Additional Rebate gives firms the incentive to introduce new products at high prices. While a company's price increases for existing products are controlled, launch prices are not. And, the prohibition of restrictive formularies for participating manufacturers increases

the potential for higher earnings in the early years after product launch.[24]

After 1993 the situation changes. If the Additional Rebate is implemented as designed, the effective launch price to Medicaid of a new drug will be constrained at or even below the inflation-adjusted weighted average price for 1990, Thus, new drug products launched at high prices will effectively face high Medicaid rebates, thus substantially reducing the revenues on this segment of the market.

The Post-1993 Additional Rebate as it is currently outlined in the law has implementation problems. Detailed data on the quantity of Medicaid drugs sold from June to October, 1990, necessary to compute the weighted average price of the manufacturer's products as of October 1990, do not exist in a usable form in most State Medicaid agencies. One technical solution to this problem would be to use a calendar quarter in late 1993 as the baseline date for quantity weights, because by that time Medicaid agencies would have better data on quantities of each drug product sold to their agency.

In the fall of 1992, technical amendments were introduced (but not passed) to change the post-1993 Additional Rebate (S.3274). Under the amendments, the baseline weighted average manufacturer's price would be calculated using the 1990 price for drugs already on the market in 1990 and the launch price of drugs introduced after that period. Importantly, it would weight those prices by unit sales in the current rebate period. This new rebate would not penalize firms when they introduce a new product at a relatively high price, although it would still control increases in prices to Medicaid after the introduction.[25] Thus, the effect on revenues obtained from newly introduced drugs would be less severe than under current law, which would effectively control the prices of new drugs to Medicaid.

State Pharmaceutical Assistance Programs

During the past 15 years, 10 States have established State Pharmaceutical Assistance Programs (SPAPs) that extend pharmaceutical benefits mainly to people 65 years of age and older who do not qualify for Medicaid but cannot afford to purchase private health insurance. Four of these SPAPs also cover the permanently disabled. Together these programs currently spend about $500 million annually on prescription drugs (34,38,181,191,237,246,252,256,259). Eligibility in a SPAP is limited by personal income ceilings that each State determines and that usually fall between one and two times the Federal poverty line. In 1977, the first year of the programs, 43,000 people participated. By 1991, this figure had grown to approximately 936,000 people representing about 3 percent of the population age 65 and older. Five of the programs cover nearly all FDA-approved prescription drugs; the other five limit the classes of prescription drugs for which they will pay.[26]

Virtually all of the State programs have policies encouraging the use of cheaper generic drugs. Five States require dispensing generics if they exist, unless the physician specifically specifies the brand-name drug. Two of these States have also adopted other incentives to promote the use of generics. In Pennsylvania, a pharmacist who convinces a physician to change a prescription

24 The Pharmaceutical Manufacturers Association (PMA) has complained that States are using the prior authorization rules as *de facto* formularies (37 la), thereby undercutting the positive aspects for the industry of the restriction on formularies. Such tactics are illegal for only the first 6 months of a product's life.

25 The technical amendments would also have removed the discretion of the Secretary of Health and Human Services to exclude new drugs from the weighted average price when such an action would lower the amount of the rebate. The Secretary also loses the discretionary power to change the overall approach.

26 For example, Illinois, Maine, Vermont, and Rhode Island cover pharmaceuticals only for the treatment of chronic conditions including heart disease, diabetes, hypertension, and arthritis, Rhode Island also covers cholesterol-lowering drugs as well as treatments for cancer, glaucoma, and Parkinson's disease. Since 1991, Maryland has limited the drugs its SPAP covers to chronic disease treatments, anti-infectives, and drugs for a limited number of other diagnoses. None of the programs cover over-the-counter drugs.

from brand-name to generic receives an extra dollar of reimbursement from the State, while in Maine the patient pays a higher copayment for a brand-name prescription if a generic is available. The five States without a generic substitution requirement do require higher copayments from beneficiaries for prescriptions filled with a brand-name drug.[27]

Medicare Prescription Drug Benefits

Although Medicare generally does not cover outpatient drugs,[28] it does cover drugs that only a doctor or someone under a doctor's supervision can administer. Many drugs given by injection or intravenous (IV) administration fall into this category. Ordinarily, Medicare leaves it to its carriers[29] to determine whether specific drugs will be covered under this provision. If the drug is usually self-injectable or self-administered, the carrier can deny coverage (88).

Biotechnology drugs are frequently large molecules that must be administered by IV or injection. Thus, these drugs are more likely to be covered under Medicare than are other drugs. Nevertheless, at least two recently approved biotechnology drugs, Actimmune™ and Protropin™, were denied Medicare coverage by certain carriers because they were classified as self-injectables (43).

When Medicare does pay for outpatient prescription drugs, the carriers determine pricing policies. There is no official Medicare cost control strategy pertaining to the few outpatient drugs covered by Medicare.

PRESCRIPTION DRUG BENEFITS IN OTHER COUNTRIES

The existence of universal health insurance in other industrialized countries means patient demand for such drugs is not much affected by prices. Nevertheless, insurers in universal health systems more strictly control the use of drugs and the prices paid. Although data on drug utilization and prices paid in other countries for drugs are not generally available,[30] special studies conducted in recent years suggest some European countries pay less for drugs than do consumers in the United States (457).

OTA reviewed recent trends in payment methods for prescription drugs in five countries: Australia, Canada, France, Japan, and the United Kingdom. To a greater or lesser extent in each of these countries, drug payment policy is governed by two potentially conflicting objectives: to minimize health insurance prescription drug costs and to help the country's domestic pharmaceutical industry. Payment policies represent a blend between these objectives.

Australia

Australia's domestic pharmaceutical industry is very small, and the country represents a small proportion of the world market for prescription drugs.[31] Consequently, Australia has not had a major economic stake in promoting pharmaceutical R&D. Instead, the main objective of Australia's pharmaceutical payment policies has been to minimize the cost of drugs, both to the government and to its citizens. Recently, though, the government has made efforts to promote the

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27 A recent in-house study conducted by New York's SPAP suggests this type of consumer-based price incentive may have only modest effects. The study found that in New York, the lower copayment for generics led to the dispensing of generics for only 27 percent of prescriptions filled compared with 24 percent for all prescriptions filled nationwide (34).

28 Medicare covers immunosuppressives after organ transplants, antigens, blood-dotting factors for hemophiliacs, and dialysis drugs such as erythropoeitin.

29 Medicare carriers are fiscal agents (typically Blue Shield/Blue Cross plans or other private insurance companies) under contract to the Health Care Financing Administration (under the Department of Health and Human Services) for administration of specific Medicare tasks. These tasks include determiningg reasonable costs for covered items and services, making payments, and guarding against unnecessary use of covered services.

30 The U.S. General Accounting Office is currently engaged in an examination of European prescription drug price mechanisms to determine their applicability to the United States.

31 Drugs subsidized by the Australian Government, which account for 75 percent of all prescriptions, were worth A$1.32 billion in 1990-91,

Australian domestic pharmaceutical industry through its pricing policies.

The Pharmaceutical Benefits Scheme (PBS) of Australia, adopted in 1950, originally made 139 life-saving and disease-preventing drugs available at no cost to patients. These drugs were supplied because the cost of treatment could be ''most burdensome' to people in life-threatening situations (308). However, as this program grew to cover hundreds of drugs and 105 million prescriptions annually (75 percent of all Australian prescriptions), the government began to consider options for cost control.

One primary approach to controlling the government's pharmaceutical bill has been to enact copayment requirements, determined annually according to the Australian consumer price index (125,178). In August 1992, the patient copayment per prescription was A$15.90 for general beneficiaries (to a maximum per year of A$30, then A$2.60 to a maximum of an additional A$51.60 that year), and A$2.60 for retirees[32] (up to a maximum per year of A$135.20) (178).

Since 1963, the government has negotiated prices with manufacturers for any new chemical entity to be reimbursed by the PBS. After a drug is approved for efficacy and safety it must be admitted onto the list of products covered by the PBS. Legislation passed in 1987 requires the Pharmaceutical Benefits Advisory Committee (PBAC), the body responsible for recommending whether anew chemical entity should be listed for federal reimbursement, to consider not only effectiveness but also cost.

Guidelines implementing this legislation were not drafted until 1990; since then the rules have been subject to extensive debate. Revised guidelines were released in August 1992 and will be followed for all major submissions to the PBAC as of January 1993. The guidelines recommend the use of final outcome measures, such as cost per year of life saved, cost per death prevented, or cost per quality-adjusted year of life, to evaluate a drug's cost-effectiveness compared with alternative therapies. Because these measurements are difficult to make in many cases, estimated cost-effectiveness analysis may be based on intermediate outcome indicators such as the number of patients achieving a target blood pressure for a new antihypertensive agent.

Once a new chemical entity is admitted to the PBS list, manufacturers undergo price negotiations with the Pharmaceutical Benefits Pricing Authority (PBPA) (formerly the Pharmaceutical Benefits Pricing Bureau) to determine the PBS price for the product. Price negotiations were originally applied to multiple-source as well as single-source drugs entering the market; however, since 1990, only drugs identified as being without generic equivalents must enter price negotiations (see below).

The PBPA presently considers the following factors in the pricing negotiations: the prices of drugs in the same therapeutic group, cost information supplied by the manufacturer or estimated by the Authority, prescription volumes, economies of scale, product stability, special manufacturing requirements, prices of the drug in other comparable countries, the level of activity being undertaken by the company in Australia (see below), other relevant factors presented by the company, and other directions by the Health Minister of the Authority.

In 1988, as part of an Industry Development Plan, the government declared it would consider "the level of activity being undertaken by the company in Australia including new investment, production, research and development" in determining a company price (308).[33] This provision, known as Factor-(f), granted further price increases ''where a company can demonstrate that it is making a significant contribution to internationally competitive production in Australia" (308).

To enter the Factor-(f) scheme, companies are expected to increase their Australian production

[32] This category includes those with unemployment benefits, war veterans, and war widows, as well as pensioners.

[33] This plan also increased the length of Australian patents for drugs by 4 years and gave the drug industry representation in the PBPA.

and R&D activities by 3 percent. The actual price increase is based on the increase in local value added for a company's manufacturing, exports, and R&D. Companies receiving a pricing dividend under the Factor-(f) provision can apply it to any drug in their product line. The government has confirmed its commitment to expanding the drug industry in Australia by announcing an extension of the Factor-(f) policy through the year 1999.

Until 1990, drugs with generic equivalent competitors on the market underwent the same pricing negotiations as new chemical entities. Since then, drugs with generic equivalents are no longer subjected to the PBPA pricing process. Today companies may set their own prices for any drug having a generic equivalent on the market, but the government sets a benchmark reimbursement rate for each chemical entity equal to the lowest priced generic alternative (178). When a consumer purchases a drug, the PBS reimburses the pharmacist only up to the benchmark rate; if the doctor prescribes a more expensive brand, the consumer must pay not only the copayment but also the difference between the price and the benchmark. Patients can ask the pharmacist to substitute the benchmark product for a more expensive prescribed brand, but the pharmacist must contact the prescribing physician for approval (178).

The current benchmark pricing scheme was adopted to give consumers incentives to economize on the use of prescription drugs for which generic equivalents are available (178,408) and to make the marketplace more price competitive. Drug prices were freed subject to the benchmark pricing scheme late in 1990. In early 1991,of651 brands subject to benchmark pricing, 131 (including the 65 most prescribed in Australia) have a price higher than the benchmark level (178). The government reports that market shares decreased slightly for drugs priced above the benchmark level, while there has been an increase in market share for benchmark priced drugs and an increase in generic prescribing (408). However, it is likely that manufacturers would not price their drug above the benchmark price if they do not expect total revenues from the sale of the drug to be higher than they would be with a benchmark price. Thus, the fleeing of prices means a potential shift of the burden of payment from the government to the consumer. Whether the consumer (or the physician) becomes more price conscious as the generic pricing system matures remains to be seen.

Canada

Like other countries OTA reviewed, Canada has sought a compromise between the two goals of pharmaceutical cost containment and development of a domestic pharmaceutical industry. Unlike other countries, Canada's national pharmaceutical cost control policy has used legislation that weakened the impact of patent protection on pharmaceutical sales in Canada.[34] This approach led to widespread penetration of generic products in the Canadian market, which in turn stimulated price competition among brand-name drugs in Canada. However, legislation passed in 1987 has restored a measure of patent protection to pharmaceutical products in exchange for the cooperation of multinational pharmaceutical companies in keeping pharmaceutical prices from increasing sharply and investing in R&D performed in Canada.

In the 1960s Canadian federal and provincial health programs did not yet include pharmaceutical benefits, so patients paid for nearly all drugs themselves. The early 1960s saw rapid increases in Canadian drug expenditures, which alarmed the public and created a national demand for price

[34] Canadian provinces operate independent programs to control the costs of pharmaceuticals. Control methods vary widely, using combinations of incentives for generics, restrictive drug lists, copayments, etc. Although this section focuses mainly on measures of the national government to control prescription drug expenditures, it should be recognized that provincial control over the prices of prescriptions sold through provincial drug plans (which make up 40 to 100 percent of drugs sold in individual provinces) gives Canada added leverage over market prices. One way most of the provinces exert downward pressure on prices is via a restricted benefits list; the manufacturers must negotiate prices with the provincial government to have a drug admitted to the list of those eligible for reimbursement in the province.

control. Three separate federal government studies conducted between 1963 and 1966 found drug companies had undue market power, allowing them to set unnecessarily high prices (90). The studies also concluded such market power would not exist if there were competition for many of the drugs protected by patents.

The legal right to bypass patent protection for pharmaceuticals has existed in Canada for quite some time. A statute enacted in 1923 permitted Canadian companies to apply for compulsory licenses to produce generic equivalents of drugs already protected by patents in Canada. This statute was not invoked often; since the Canadian market was small, it could not support a domestic manufacturing industry for generic drugs (244). However, in 1969, the Canadian Government extended the compulsory licensing provision to allow for import of generics from other countries.

In some Eastern European and South American countries, drug patent laws are either weak or nonexistent (90). Thus, when a company launches a new drug, manufacturers in these countries can reproduce the active ingredient and market the drug within about 2 years. The 1969 Canadian law allowed Canadian companies to apply for compulsory licenses to import and market these readily available generic products.

The government took other actions to support the growth of generic competition such as lowering the tariff on pharmaceutical imports, awarding large grants and loans to support domestic generic drug packagers and distributors, and setting up education programs for physicians (90).

By the early 1980s, generic drugs accounted for 10 percent of pharmaceutical sales. In 1968, the year before the law was enacted, Canadians paid, on average, 9 percent more than did Americans for 43 patented drugs. By 1976, Canadian prices for these drugs were, on average, 21 percent cheaper than in the United States (90). Imported generics generally entered the Canadian market at prices 10 to 20 percent below their patented counterparts and maintained this margin if the price of the patented versions were reduced in response (30). When multiple generic products were available to compete with a single brand-name drug, the generics were sold at prices as low as 40 percent below the brand-name price (244). In 1983, savings of $211 million in a $1.6-billion market were realized as a result of compulsory licensing (244).

As the provinces adopted their own pharmaceutical benefits plans, they took advantage of the savings that generics offered. By the middle of the 1980s, most of the provinces had enacted measures to ensure generics would be used more frequently. All 11 provincial or territorial governments now have provisions encouraging or requiring pharmacists to substitute generics on reimbursed prescriptions whenever possible (30), unless the physician states otherwise.

The pharmaceutical companies selling patented products in Canada claimed that cost-control via compulsory licensing put an unfair burden on the most innovative companies (90). Although the ratio of Canadian R&D to sales increased moderately from 3.6 percent in 1960 to about 5 percent in 1980, manufacturers claimed Canada was punishing innovation because it lacked patent protection. In 1985, the United States put additional pressure on Canada to restore patent protection for drugs as part of negotiations on free trade (244).

Canada responded in 1987 with Bill C-22, a law that gives 7 or 10 years of conditional protection from compulsory licensing after a drug is approved for marketing in Canada.[35] If a new drug is invented in Canada, the protection lasts for the full 20 years of the patent (309). In exchange for this lengthened period of exclusive marketing, the multinational companies publicly committed

[35] If the generic equivalent of a patented drug is produced in Canada, the period of market exclusivity extends 7 years from the time of approval. Generics imported into Canada must wait 10 years after approval (244).

themselves to increase the ratio of Canadian R&D to Canadian sales to 10 percent by 1996 (244).[36]

The new law also created an independent quasi-judicial body, the Patented Medicines Pricing Review Board (PMPRB), whose main charge is to ensure prices of patented medicines are not excessive. The PMPRB does not set or approve prices; it monitors manufacturers' prices, evaluates whether those prices are excessive, and negotiates with companies to lower prices when they are considered too high. The Board has authority across all the provinces; in its own words, it is "investigator, prosecutor, and judge" (309), with the power to remove the market exclusivity of every patented drug.

The Board developed its own guidelines to determine what constitutes excessive pricing. Patented medicines are broken down by the Board into two categories: existing drugs and new drugs. Existing drugs are those sold in Canada before Bill C-22 was enacted and those whose introductory prices have been approved by the Board since Bill C-22 was enacted. The PMPRB will assume an existing drug's price is excessive if its rate of price inflation exceeds the cumulative change in the Canadian consumer price index over the same period.

To review the prices of new drugs entering the market, the PMPRB categorizes them into three subgroups, each with its own criteria for excessive pricing. Category (IL), known as *line extension drugs,* includes product line extensions (such as new dosage forms). Line extension prices are judged excessive if the average price per kilogram does not bear a reasonable relationship to that of some other medicine or form of the same medicine with a comparable strength or dosage. Category (ii), *breakthrough drugs, are* deemed to have excessive prices if the price is greater than *both all* other Canadian drug products in the therapeutic class *and the* median price of the medicine in seven selected industrialized nations. Category (iii), *"other" drugs,* includes those that provide little improvement over their predecessors. Their prices will be judged excessive if they exceed the prices of other drugs in the same therapeutic class (309).

The Board has strong remedial powers at its command when a drug is found to have an excessive price. Although these powers have not been invoked since its inception, the PMPRB can order a drug's price lowered, or it can revoke the market exclusivity on both the drug in question and another of the manufacturer's patented drugs (the Board's choice) by granting compulsory licenses for the production of a generic equivalent of the patented medicine.

Both the price review measures and the efforts to stimulate R&D appear to have been successful in moderating price increases so far. From January 1987 to December 1991, patented drug prices increased at a rate of 2.9 percent annually, compared with an annual increase of 4.7 percent in the Canadian consumer price index.[37] The PMPRB reported that in its first 18 months of operation, compliance with the pricing limits was around 70 percent. Most of the cases where prices were deemed excessive were resolved, with a few exceptions where complicated circumstances delayed a solution. As of June 1992, the Board had not reported any incidents in which a patent was revoked in favor of compulsory licenses (31 1). The Board also reported that in the "existing drug" category, prices actually increased less rapidly than general inflation (309,310,31 1).

The PMPRB also monitors R&D conducted in Canada by firms selling drugs in Canada. The Board reported that by 1991 the ratio of R&D performed in Canada to sales in Canada had increased to 9.7 percent, up from around 5 percent in 1987 (311). Basic and applied research in-

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[36] In comparison, in 1989, Sweden, the United Kingdom, and the United States had domestic R&D per S&X ratios of 21.8,20.9, and 14.2 percent, respectively (71).

37 However, the 3.1 percent figure is for patented medicines only. When all Canadian pharmaceuticals are included, the annual rate of increase in pharmaceutical prices becomes 5.1 percent (244),

creased by 20 and 22 percent, respectively, from 1990 to 1991 (PMPRB 1992).

In January 1992, Canada proposed a bill to eliminate compulsory licensing as a punitive measure to further promote industrial growth as well as to maintain consistency with the draft text of a General Agreement on Tariffs and Trade released in December 1991.

Bill C-91, which was in the early stages of consideration by the Canadian legislature in the fall of 1992, proposes to amend the Patent Act to eliminate compulsory licensing during the entire course of a drug's standard 20-year patent life. The bill offsets the effects of this measure by enhancing the role of the PMPRB with extended judicial and punitive powers.

Under Bill C-91, PMPRB would have increased control over the introductory prices of new drugs entering the market. In the case of excessive pricing by manufacturers, the Board could essentially force manufacturers to roll back prices. If a manufacturer is found to be making a regular practice of continually pricing pharmaceuticals excessively, all frees and penalties could be doubled. Executives of pharmaceutical companies refusing to submit pricing and sales information or not willing to comply with the pricing orders of the Board would be subject to imprisonment for up to 1 year under the bill.

PMPRB has the authority to examine the prices of drugs being sold in all Canadian markets, public and private. The extended protection from compulsory licensing in Bill C-91 would essentially guarantee exclusivity for new drugs for a substantial period of time within a regime that monitors and, at least in principle, has the power to regulate excessive pricing of pharmaceuticals in all sectors of the market.

France

French Social Security Funds subsidize about 74 percent of the prescriptions filled in France (381). When a French patient buys a drug, he or she generally pays up front for the medicine and then applies for reimbursement to the national insurance fund that covers all but the required patient copayments.

There are three different levels of reimbursement to the patient for different classes of drugs: "mainstream drugs, " prescribed for common chronic and acute illnesses, are reimbursed at a rate of 70 percent. Medications 'intended for the treatment of troubles and diseases usually not serious' '[38] are generally reimbursed at a rate of 40 percent (386). The third category, single-source products for serious illnesses, is reimbursed at a rate of 100 percent.

Despite the seemingly high copayment requirements, the French have very low unreimbursed expenses. Numerous classes of people and chronic treatments are exempted from copayments. About 80 percent of the population belongs to supplementary insurance funds, or *mutuelles,* which pay for the bulk of the patient's drug costs, leaving only minimal copayments. Although 56 percent of prescriptions in France required some copayment in 1991 (381), most were very low. Thus, French consumers have little price sensitivity (67,174).

France boasts the highest per capita pharmaceutical consumption by volume in Europe (67) and the second highest per capita pharmaceutical expenditures among Organization for Economic Corporation and Development countries in 1990 (304). The high drug consumption rates at least partially explain why the French Government has found it necessary to regulate relatively strictly the price of pharmaceuticals. In 1990, the prices of medicines in France were the second lowest in the European Community (304). The government has focused its cost control measures on manufacturers' prices of the drugs that national insurance reimburses.[39] Although government efforts at

[38] Some examples are antinauseants, antipruritics, weight loss drugs, antispasmodic, antivaricose drugs, hormonotherapy drugs, laxatives, urological, and counter-irritants. There are a good number of other similar therapeutic categories included (386).

[39] The nationally reimbursed prescriptions make up 80 percent of drugs sold in France. About 11 percent are accounted for by hospitals, which negotiate prices on their own. The remaining 9 percent are sold privately, without any price constraints (386).

price control have been described as "piecemeal' and 'fragmented' (174), they have clearly been successful in keeping drug prices comparatively low.

Any drug to be sold and reimbursed by national health insurance must work its way through a maze of French ministries and commissions (174,386). To reach the French market, a manufacturer must see its drug through a three-step process. First, the drug must win the French equivalent of U.S. FDA approval. Second, the drug must be approved for addition to the list of reimbursable drugs. Third, it must go through price negotiations to determine what the reimbursement price for the drug will be and whether national insurance will pay 40, 70, or 100 percent of this price when a patient receives the drug.

Through each of these steps, the drug is evaluated for its efficacy, safety, and risk/benefit ratio (406). The French equivalent of the U.S. FDA reviews drugs for marketing approval. This process is completed relatively quickly; the government has 120 days to make a decision after an application for marketing authorization is filed, with a 90-day extension available (406).

Once a drug gains marketing authorization, the manufacturer seeks the approval of the Transparency Commission, which decides whether to admit the drug onto a list of drugs approved for reimbursement by the national insurance funds. Although a drug can be prescribed without approval of the Transparency Commission, physicians rarely do so (406). The Transparency Commission is empowered to compare the drug's cost with that of alternative existing treatments. The Transparency Commission tries to keep the market clear of too many ''me-too' drugs offering no real medical or economic advance (386).

Once a product is admitted to the list of drugs approved for reimbursement, its manufacturers must again document its benefits for a Pricing Committee, which negotiates both the price of the drug and its level of reimbursement (40, 70, or 100 percent). The Committee, made up of representatives from the Directorate of Pharmacy and Drugs, and the Ministries of Social Security, Industry, and Competition, enters into a two-step evaluation process. First, a "technical price" is set based on the effectiveness and economic efficiency of the drug. This price is set in relation to reimbursement rates for therapeutically similar drugs. "Me-too" drugs for which therapeutic equivalents are already on the market cannot receive a technical price higher than 90 percent of the price of existing therapeutic equivalents.[40] For breakthrough drugs with no close competitors, the price of the drug is compared with prices paid in other countries.

Second, the technical price is adjusted to an ''economic price, ' the ultimate selling price. A bonus is added if the raw materials used to make the drug were produced domestically. Similar additions are awarded if the drug provides a positive French trade balance or creates French jobs. Finally, if the drug is a result of French research efforts, it may also receive price increases. Because these kinds of national incentives are banned under the European Commission's Transparency Directive, they no longer officially exist.

The price increases available in the Committee's adjustment of the technical price to the economic price are incentives to promote an active French pharmaceutical industry. But the magnitude of such incentives may not be great enough to spur research, especially when there are countries nearby that offer greater financial re-

40 This rule also holds for generic equivalents of drugs already marketed. Manufacturers have actually used this 90 percent limit to slow the penetration of the French market by generics. When a brand-name manufacturer gets wind of a generic drug being developed for introduction into France, the manufacturer can quickly release a generic equivalent of its own. Multiple generic equivalents may be released by different subsidiaries of the company. With each generic accepted into the market, the price awarded decreases by another 10 percent. These generic copies are not marketed, but they ensure a competitor's generic entering the market will be granted a very low price, possibly not worth the trouble of importing or distributing. Low-priced generics may also be boycotted by pharmacists, whose profit margin is figured as a percentage of the drug's cost (174).

wards for R&D conducted within their borders. Between 1961 and 1970, France had the second highest rate of discovery of new chemical entities in the world; by 1981, France had slipped into fifth place (174). Although it is not at all clear what caused this decline, the French pharmaceutical industry blames the drop on 30 years of strict governmental price controls (174).

Japan

To be sold on the Japanese market, a drug must be approved by the Japanese Pharmaceutical Affairs Bureau (PAB), an equivalent of the U.S. FDA. Once the PAB approves a drug, the Japanese Health Insurance Bureau (HIB), a branch of Japan's Ministry of Health and Welfare (MI-W), must consider whether or not to add the drug to a national list of drugs that may be prescribed by Japanese doctors. Since the 1980s, the HIB has updated this list quarterly. Once a drug is admitted to the list, the HIB settles on the price that will be paid when the drug is prescribed.[41] Virtually the entire Japanese population is covered by some form of health insurance that adopts the HIB reimbursement rates, so these rates are applied to almost every prescription written throughout the country.

''Me-too drugs entering the market are generally granted a price similar to those already held by therapeutic equivalents, although there has been no explicit policy to mandate or formalize this procedure (527). "Me-too' drugs in Japan include generics as well as drugs chemically different from ones already on the market but not considered medical advances.

Drugs without any therapeutic equivalent or chemical predecessor (known in Japan as ''shining new drugs' are evaluated for their therapeutic usefulness and priced accordingly: drugs already on the market that are viewed as equally innovative may be used as guidelines for setting the reimbursement rate.

All changes in reimbursement rates go through the HIB, which revises them once every 2 years. Pharmaceutical companies that want to participate in Japan's $35-billion domestic drug market must accept the HIB reimbursement rate as the final price their product will fetch when a doctor prescribes it.

Despite their virtually universal control over prescription reimbursement rates, the Japanese ranked first and second in per-capita pharmaceutical spending in 1987 and 1988, respectively (139,361). This spending seems odd because Japanese drug prices were drastically cut by a total of 52 percent from 1981 to 1990. To explain such high pharmaceutical expenditures in the face of the price cuts of the 1980s, one must look at how drugs are delivered in Japan.

Most drugs are dispensed to patients directly by the physicians who prescribe them. In fact, only 10 percent (by value) of drugs in Japan were sold by independent pharmacists in 1985; the rest were purchased from independent doctors or hospital pharmacies.[42] Most drugs are sold by manufacturers to hospitals and clinics (139,163,344), usually through wholesalers, at a discount off the rate set by the HIB; wholesalers receive similar discounts from the manufacturers.[43] Therefore, when the doctor or hospital pharmacy is reimbursed for dispensing a drug at the HIB rate, he or she (or the hospital) makes a profit. Discounts vary widely but typically run from 10 to 30

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41 Insurance generally pays between 70 and 100 percent of this rate; the patient makes up any difference. HIB reimbursement decisions are guided by policies drafted by the Chu-Ikyo, or Central Social Insurance Medical Council, an independent governmental advisory board.

42 Doctors are found mainly in three settings in Japan. Private practices run by independent doctors are known as clinics as long as alley have 20 or fewer beds. Private hospitals have more than 30 beds, but are also owned and managed by the doctors who work at the facility. The remaining doctors work in hospitals run by universities or the government. Hospital-based physicians are salaried, while independent doctors are reimbursed on a fee-for-service basis, with fees determined by the government (163).

43 Wholesalers formerly were allowed to set their selling prices in collaboration with manufacturers, in exchange for price guarantees fTOm the manufacturers. This allowed wholesalers to adequately gauge what discount they could offer hospitals and doctors without risking discounting at rates higher than the manufacturers' rebates. However, the Japanese Fair Trade Commission has ruled wholesalers can no longer enter into these collaborative agreements with the manufacturers, and must set their prices independently.

percent of the reimbursement rate. In certain therapeutic categories, such as antibiotics where product competition is relatively strong, discounts have traditionally run even deeper.

In a medical system where the reimbursement rate is set above the actual cost of drugs while reimbursement rates for physicians' services, which are also set by the MHW, are set below cost (344), doctors and hospitals have depended on the sale of pharmaceuticals to make money. Profits from drug sales made up about 37 percent of the independent doctor's wages in 1987 (344). Since the Japanese health system offers few additional subsidies (outside the doctor's salaries or fees) to help clinics and private hospitals purchase equipment or maintain facilities, the sale of pharmaceuticals has become a primary source of revenue to ensure the normal functioning of nongovernmental medical facilities. With no formal method to keep track of physicians' prescription habits,[44] the incentive is strong for doctors to prescribe unnecessary and excessive medications (139, 163,344).

The Japanese Government has struggled to combat physician-income subsidization by high drug price margins. Although the government has shown some support for "bungyo," the separation of drug prescribing from dispensing duties, most cost reduction measures have used pricing policies to try to erode or eliminate the industry's ability to grant discounts to doctors. The drastic reimbursement rate reductions that took place in the 1980s were enacted partially for this purpose.

Products with the largest discounts had their prices cut the most. Ostensibly, these cuts would reduce the reimbursement rate of heavily discounted products to the point where manufacturers would no longer be willing to undercut the HIB price to grant doctors their margins. Despite these strong efforts, discounts were still reported as prevalent in 1991, with many pharmaceutical companies granting doctors margins of 20 percent or higher (163).

Just as doctors have seized upon the sale of discounted drugs as a way to gain some control over their own incomes, so too have pharmaceutical companies. In a market where manufacturers have little control over the reimbursement rate, discounts to physicians have become an important tool in the competition to get one's product to those who prescribe drugs. Since drugs with higher profit margins are often more heavily favored by doctors, the ability to offer a large discount remains a significant factor in determining use. Although the discounts may have diminished somewhat in magnitude, drug companies continue to view discounts as apart of the normal cost of doing business.

A new landmark pricing policy took effect in April 1992 to limit doctors' discounts. Rather than trying to eliminate pricing discounts and the overuse of drugs that may accompany them, the regulations aim to reduce the discounts to a ''reasonable level. This level, known in Japan as the "R-zone," would be effectively equal to 15 percent of the HIB price. When reimbursement rates are reviewed every 2 years, an average wholesale price of the drug over the past 2 years is calculated by dividing total sales for the drug by the number of units sold. The new reimbursement rate will be calculated by adding this AWP to 15 percent of the previous HIB rate for the drug.[45] This means that drug prices can be discounted at an average of 15 percent of the reimbursement

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[44] The Japanese Government has direct access to detailed information regarding each doctor's prescribing history. Doctors must file claim forms describing exactly what dosage of what drugs were prescribed in order to receive reimbursement for medications provided to patients. However, the government does not frequently review or rebuke doctors for their prescription habits or overuse of drugs. According to one observer (527), only about a half dozen doctors in Japan are censured each year because of their drug prescribing habits.

[45] Here is an example of how this works. A drug has a current reimbursement rate of 100 yen. However, the AWP of the drug is 80 yen, leaving a 20-yen margin for the doctors. When the HIB recalculates the new rate for this drug, it adds the AWP (80 yen) to 15 percent of the *old* HIB price (or 15 percent of 100 yen=15 yen), giving a new HIB rate of 80+15 or 95 yen.

Now suppose the AWP for the drug is 90 yen. The new rate would be the AWP, 90 yen, plus 15 percent of 100 yen, or 105 yen. The policy requires that the new HIB rate cannot be higher than the old HIB rate; thus in this instance, the new rate would remain at 100 yen.

rate without suffering further price reductions (417). If a manufacturer discounts less than 15 percent on average, the revised HIB rate will remain the same.

The HIB plans to gradually reduce the R-zone rate from 15 to 13, 11, and 10 percent over the next 6 years (319). The gradual reduction of the R-zone is intended to ease companies into a system in which doctors' margins are reduced to a certain (arbitrary) level.

The plan will probably benefit newer products that have relatively little history of discounting; older products, which tend to be more heavily discounted to compete with newer drugs, will probably suffer as they are either forced to reduce the amounts of their discounts or to have their prices continually lowered until it is no longer profitable for the manufacturer to market them. It is not clear how this change will affect prescribing habits or overall pharmaceutical spending (345). It is possible that reduced profit margins could lead to even more excessive drug dispensation as doctors try to compensate for income no longer received from larger discounts.

There are also stipulations in the new scheme that extend beyond the reduction of doctors' margins and overall costs. These rules establish a consistent policy for increasing the reimbursement rates of so-called innovative or ' 'shining new drugs' which are defined by the MHW as new chemical entities that are therapeutically as well as chemically innovative (2). In the rate revisions of "shining new drugs, " a 20 percent R-zone will be added to the AWP instead of the normal 15 percent. This percentage will not decrease over time, so by 1998 innovative drugs will be granted an R-zone rate twice that of generic and "me-too" drugs that show no improvement in side effects or effectiveness.

Orphan drugs and "me-too' drugs demonstrating an improvement in efficacy or side effects over their predecessors and deemed "relatively useful' will be given prices 3 percent above the normal rate. With competition through discounting as strong as it is, these additional rate increases translate into a significant advantage for the "shining new" new chemical entities entering the Japanese market. The pricing policies encourage R&D in Japan. Although innovative new chemical entities were often spared to some degree in the price cuts of the 1980s, the new approach marks the first definitive policy to extend benefits to these products (345).

It appears the main objective of Japanese pro-innovation policy is health-related: to increase treatments for the diseases that the growing elderly population will face in increasing numbers. The development of the Japanese pharmaceutical industry is a secondary goal.[46] A proposed measure increasing the R-zone for Japanese-originated drugs was dropped, apparently to facilitate the import of significant new drugs from other countries (417). However, some Japanese policymakers and industry representatives believe the new directives will indeed foster a strong Japanese industry steeped in innovative R&D (319).

United Kingdom

In the United Kingdom, the government controls the cost of pharmaceuticals not by limiting individual product prices, but by setting a cap on the profit that individual pharmaceutical companies can enjoy from their business with the National Health Service. Each company negotiates with the Secretariat of Pharmaceutical Price Regulation Scheme (PPRS) a total rate of return on the capital employed in generating its sales to the British National Health Service (NHS).

46 Historically, the Japanese pharmaceutical industry was not very active in developing drugs for the world market. Instead, Japanese drug firms grew mostly by serving a domestic market with generally high reimbursement rates for pharmaceuticals (508) and by the relative ease of government approval for marketing of domestically produced drugs (139,212). Between 1960 and 1980, only 10 Japanese drugs were approved as new chemical entities by the U.S. FDA (180). Only three 'breakthrough" drugs developed in Japan between 1960 and 1990 were licensed for marketing in the United States (180). Finally, out of 1,234 globally marketed new chemical entities developed between 1940 and 1977,46 (3.7 percent) were produced in Japan (332).

The PPRS is a nonstatutory arrangement in which confidential profit negotiations are held between individual companies and the PPRS Secretariat on behalf of the Ministry of Health. This plan, which has existed in various forms since 1957, was designed for two purposes: 1) to "ensure that safe and effective medicines are available to the NHS on reasonable terms' and 2) to ''ensure that the Department of Health and Social Security acts as a sponsor for the drug companies' to maintain the industry as one of the United Kingdom's healthiest and most profitable (84).

The U.K. pharmaceutical industry is the fourth largest exporter of drugs in the world and the third leading export industry in the United Kingdom (22). How much of this success is due to the PPRS is a matter of conjecture, but the results are at least consistent with the second goal of the scheme. Whether British drug prices have been controlled by the system is also unclear. The Association of the British Pharmaceutical Industry reports that the U.K. retail price index increased by 29 percent between 1984 and 1989, while the pharmaceutical price index increased by only 22 percent. However, the *Economist* reported that drug prices outpaced the national inflation rate by more than 4 percent for the same time period (1 17).

All pharmaceutical companies with NHS brand-name drug sales over £500,000 are included in the Scheme, but only firms with sales over £4 million must submit financial records for a yearly assessment of their allowable profit rates (44). These 65 or so companies provide audited annual financial reports that document their total sales to the NHS including expenses for manufacturing, distribution, promotion, and R&D associated with those sales, and the capital employed in generating the NHS sales. At most, 9 percent of a company's total NHS sales may be claimed for promotional expenses, but an additional allowance is made for informational activities (386). The PPRS attempts to pay for its share of R&D by allowing firms to apply their worldwide ratio of R&D expenses to sales to their sales in the United Kingdom.[47]

An annual rate of return as a percent of capital employed is compared with the actual sales of brand-name drugs to the NHS. If revenues do not exceed cost plus an allowed profit rate, the firm's prices are deemed acceptable to NHS.

The procedure is different for *multinational companies* with scarcely more than an importing or marketing subsidiary in the United Kingdom. The PPRS attempts to apply the same standards to these companies; however, much of the information regarding a multinational company's expenses would not be applicable to the United Kingdom, so an allowed rate of return on sales is used instead of a return on capital employed (44,84).

The allowed profit rate has generally hovered between 17 and 21 percent of the allowed capital employed (386), though this range is by no means freed. If a company exceeds the profit margin assigned by PPRS, it may attempt to justify the excess profits. Additional profits of up to 50 percent of the original rate can be awarded for expenses directed to innovation, new drug launches, improved drug efficiency, significant investment in the U.K. industry, and increased exports from the United Kingdom (44,84). Companies may attempt to justify profit rates outside of the limits on one or all of these grounds; they may also apply for future profit rate increases based on these criteria. These potential increases in profit rates are generally known as the ''Grey Zone' of PPRS pricing. The final allowed profit remains confidential.

Both critics and proponents of the Scheme claim the PPRS provides many other opportunities for increased profits (84,1 17,174). The fact that the government must rely completely on the pharmaceutical company's own information on capital employed allows the industry a great deal of latitude (174). For example, in the past, many companies mutually agreed to sell each other ingredients at artificially high prices to make it

[47] In addition, any investments in R&D facilities and equipment in the United Kingdom are added to the estimated capital employed.

appear as though manufacturing costs were much higher than they actually were (84). Although some observers have suggested the close ties between industry and government have made for a fairly open relationship between the two (84), others believe the PPRS has no real power to question or investigate the claims of the drug companies (1 17,174).

The profit targets that the PPRS approves may become more difficult to attain in a market currently experiencing increased price competition with parallel imports and generic equivalents. A *parallel import* a brand-name drug purchased by a middleman in a country where the price is relatively cheap and then is imported to other countries (possibly including the country of manufacture) where the drug's price is normally higher. The middleman sells the drug at a profit but undercuts the higher price. This practice is legal in Europe and is actually endorsed by the European Community. It is also growing in prevalence in Europe due to both wide variations in individual drug prices from country to country and the geographical proximity of the various markets (67). The United Kingdom is one of the largest targets for parallel imports, which currently hold about 8 percent of the British market (377). In addition, statistics for generics show they account for about 30 percent of British prescriptions and 9 percent of total sales (295).

Some experts claim the PPRS is responsible for the relatively successful containment of drug spending in the United Kingdom (17,376a). Low per capita spending (especially compared with countries such as Belgium, France, Germany, Italy, and the United States) is cited as an indicator that the PPRS is effectively managing pharmaceutical costs in the United Kingdom (304). However, data collected by Burstall indicate much of the cost reduction realized in the United Kingdom is due to the control of prescription volume, not prices (67). The per-person cost of drugs in the United Kingdom is the fifth highest in the European Community, 18 percent above the European Community average, and 170 percent higher than in France. Conversely, the consumption of drugs in the United Kingdom is quite low: two-thirds of the average European Community rate and one-third of the rate in France.

Because drugs bought through the NHS are paid for almost completely by the British Government, there has been almost no consumer-driven price competition in the U.K. market. Although there is a £3.75 copayment on each prescription a patient purchases through the NHS, so many classes of people are exempted from this charge that almost 80 percent of NHS ambulatory care prescriptions have this fee waived. Many of the poor in England are exempted from copayments; however, there is no formal method in existence to ascertain a patient's level of income. Tax records are confidential, and doctors have reportedly been unwilling to question patients on this matter (149). Thus, in practice, hardly anyone pays the prescription copayment. With no serious consumer interest in low market prices, pharmaceutical companies generally charge the NHS at least up to the limit of their allowed profits, assuring companies of the returns the PPRS has determined are acceptable (174).

Recently, new measures to influence prescribing and dispensing habits have been adopted as supplements to the PPRS. In 1988, the Department of Health formulated a list of drugs in therapeutic categories for which there are cheaper and/or more effective treatments. The NHS no longer pays for many of the most expensive brands. The therapeutic categories include antacids, cough and cold preparations, laxatives, vitamins, tranquilizers, sedatives, and analgesics. This effort may have saved as much as £70 million (117).

A more significant move was the exemption in 1985 of generics from the PPRS profit limits. Manufacturers were encouraged to promote generic drugs, since profits made from generics would no longer count toward a manufacturer's profit limit. To stimulate the prescription of generics by British practitioners, beginning in 1989 the NHS assigned each doctor an "indicative drug account' that monitors the cost of drugs

he or she prescribes. A suggested per capita limit is a guideline for further action. Doctors who surpass their limit must defend their practices to a locally employed medical advisor to the Family Health Service Authority. If the case is not resolved, the doctor must appear in front of a specially convened three-person council. Physicians who consistently exceed the limit without justification are penalized[48] (117). Doctors may begin to favor cheaper generic alternatives if they believe the penalties (or the inconvenience of justifying overspending) are worth avoiding. Although it is too early to judge how effective this plan will be in the long run, the aggressiveness with which per capita spending is monitored will probably determine the success of this initiative in reducing the cost of prescribed drugs.

The current version of the PPRS policy expired in October 1992. In late October 1992, negotiations were underway between the National Health Service and the Association of the British Pharmaceutical Industry to reformulate and reauthorize the PPRS. It is expected that the PPRS will be reauthorized without any major structural changes (45). However, the future direction of the program is still unclear in light of potential changes occurring in the European Community with the advent of Europe 1992 (377).

CONCLUSIONS

In the United States insurance coverage for prescription drugs broadened over the 1980s, with almost three-quarters of the U.S. population having some private or public insurance coverage for prescription drugs.[49] These benefits have improved substantially in quality throughout the 1980s, as plans requiring a flat copayment for drugs replaced plans covering drugs only after a deductible amount has been spent. Today, roughly 30 percent of people with private prescription drug insurance plans have freed copayments, compared with 9 percent in 1977.

The improvement in insurance coverage for prescription drugs in the United States has led to attempts to control prescription drug costs through a variety of mechanisms. Different kinds of payers have different avenues open for cost control. These mechanisms, which include incentives to use cheaper generic drugs as well as attempts to control utilization directly through formularies, are most common in hospitals, HMOs and the Medicaid program. Traditional private health insurance plans have also used incentives for generic drug prescribing, but they have little power to restrict the availability of FDA-approved drugs and generally must pay their share of the manufacturer's price for single-source drugs.

The most effective cost-control mechanisms are available to those private-sector plans that can control prescribing through formularies. Hospitals and staff-model HMOs have used this power to exact price discounts from manufacturers even when the manufacturers are single-source producers of a specific compound. Some HMOs not only have a measure of control over drug prescribing through formularies, but they also can encourage price competition by encouraging (or even requiring) physicians to consider costs as well as effectiveness in the prescribing decision.

The power of certain classes of purchasers to exact discounts was recognized by the framers of the 1990 Medicaid Rebate Law, which attempts to piggyback on the negotiating power of HMOs and large hospital groups to obtain the same discounts for Medicaid. The strategy may have backfired, however, because manufacturers become unwilling to give discounts to HMOs if, by so doing, they stand to lose the amount of the discount on 10 to 15 percent of the total market for

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48 Penalties may take the form of fines, or the doctor maybe asked to reduce his or her list of patients in order to reduce NHS expenses billed to that doctor.

49 Still, roughly 16 million people 65 years of age and older and 53 million people under 65 years of age lack any insurance for prescription drugs (see table 10-2). For these people, many of whom have chronic illnesses, prescriptions drug expenditures can be a severe economic burden. Several pharmaceutical companies have recently announced programs in which certain expensive drugs will be made available without charge to people unable to pay for them (296,327,458).

outpatient prescription drugs. A coalition of large pharmaceutical purchasing groups recently called for the repeal of 'best price' provisions because of the elimination of such discounts after the Medicaid rebate law went into effect (381a).

Trends in U.S. health insurance in the past decade have, on balance, provided an increasing potential market for prescription drugs, through more and richer third-party coverage, with modest downward pressure on the demand for such drugs or the price payers are willing to pay. The most comprehensive approach to prescription drug cost containment among third-party payers has been to encourage generic price competition for multiple-source drugs. Even there, the physician override provisions in both private and public insurance plans appear to have limited the loss of market share for originators. (See chapter 4 for recent trends in market shares for multiple-source, brand-name drugs.)

Under the universal health insurance found in other industrialized nations, the demand for drugs is not much affected by the price charged. Nevertheless, the utilization of specific drugs and the prices paid tend to be more strictly controlled by the insurers. To a greater or lesser extent, drug payment policy in other countries is governed by two potentially conflicting objectives: minimization of prescription drug costs and encouragement of the domestic pharmaceutical industry. National prescription drug payment policies are a blend of these objectives.

In the United States, there is no single coherent drug payment policy. To the extent cost-containment efforts exist, they are applied without regard to the country of manufacture or origin of a drug. Abroad, drug payment policy is generally developed with the two purposes mentioned above in mind.

Virtually all of the five foreign countries that OTA reviewed-Australia, Canada, France, Japan, and the United Kingdom-use some mechanism for controlling the price of single-source drugs as well as multiple-source drugs. Four of the five nations do so directly by setting payment rates for new drugs on the basis of the cost of existing therapeutic alternatives. The pricing policies in these countries do reward "breakthrough" drugs at a higher rate than 'me-too' drugs, though they accomplish this result in different ways. The resulting prices of breakthrough drugs may still be low compared with those in the United States.