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Report to the Chairman, Special Committee on Aging, U.S. Senate

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PRESCRIPTION DRUGS

Spending Controls in Four European Countries

GAO/HEHS-94-30

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United States
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Health, Education, and
Human Services Division

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May 17, 1994

The Honorable David H. Pryor
Chairman, Special Committee on Aging
United States Senate

Dear Mr. Chairman:

This report, prepared at your request, examines how other countries regulate prescription drug prices, how those policies affect drug prices, and how they affect pharmaceutical research and development.

As arranged with your office, unless you publicly announce the contents of the report earlier, we plan no further distribution until 30 days from its issue date. At that time we will send copies of the report to interested congressional committees and other interested parties. We will also make copies available to others upon request.

This report was prepared under the direction of Jonathan Ratner, Assistant Director, Health Financing and Policy Issues. If you have any questions, please call Scott Smith, Assistant Director, who may be reached on (202) 512-7119. Major contributors to this report are listed in appendix VII.

Sincerely yours,

Sarah F. Jaggar
Director, Health Financing
and Policy Issues

Executive Summary

While the United States has traditionally let drug prices be determined by the free market, other countries use a variety of policies to control prescription drug costs.[1] However, the rising cost of health care, and increasing prescription drug prices in particular, has increased the financial burden on vulnerable segments of the U.S. population. In addition, widely reported disparities in prescription drug prices between the United States and other industrialized countries have heightened congressional interest in policies to control pharmaceutical prices.[2]

The Chairman of the Senate Special Committee on Aging asked GAO to study the range of policies to contain prescription drug costs in other industrialized countries. The Chairman was particularly interested in the pharmaceutical cost containment efforts of countries that—like the United States—are home to strong research-based pharmaceutical industries. In response to this request, GAO analyzed the effects of pharmaceutical policies in four European countries—France, Germany, Sweden, and the United Kingdom. Specifically, this report has three objectives: (1) to describe the strategies used in these countries to control prescription drug prices and limit pharmaceutical spending; (2) to review the effects of these policies on pharmaceutical prices and spending; and (3) to analyze the effects of these policies on pharmaceutical research and development (R&D).

Background

In the United States, some prescription drugs are purchased by consumers, some are financed by insurers, and some are paid for by government programs such as Medicaid. In contrast to the United States, prescription drugs in many other countries are financed entirely through a national health insurance system. Consequently, the financial viability of these national health insurance systems depends on restraining prescription drug costs. To control pharmaceutical spending and reduce the fiscal pressure on their national health insurance systems, governments in France, Germany, Sweden, and the United Kingdom have adopted a range of national pharmaceutical policies.

[1]The Omnibus Budget Reconciliation Act of 1990, which requires that drug manufacturers give Medicaid programs rebates for outpatient drugs based on the lowest prices available to any purchaser, is an exception to this rule. Prior to the passage of this bill, there were no government controls on drug prices in the United States.

[2]See, for example, Prescription Drugs: Companies Typically Charge More in the United States Than in Canada (GAO/HRD-92-110, Sept. 20, 1992); Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom (GAO/HEHS-94-29, Jan. 12, 1994); Association Belge des Consommateurs, Statement Prepared for the United States Senate Special Committee on Aging, (Nov. 16, 1989).

In each of these countries, however, this need for cost containment has been tempered by attention to how price restraint might affect pharmaceutical firms. Country officials must weigh the concerns of a strong, research-based pharmaceutical industry with the national interest in pharmaceutical spending restraint. In addition, national authorities remain concerned that their cost containment policies could diminish the development of new drug products. In the United States, this view has been expressed not only by the pharmaceutical industry but also by some consumer activists and independent analysts.

Results in Brief

To reduce the growth of pharmaceutical costs, the four countries we studied have employed a variety of national policies. These policies have largely—though not exclusively—targeted drug manufacturers. For example, France, and until 1993, Sweden, imposed product-by-product price controls.[3] Germany and Sweden have limited manufacturers' prices more indirectly, by imposing limits on insurer reimbursement levels, and the United Kingdom has imposed profit controls.[4] However, in recent years, these countries have extended pharmaceutical cost containment policies to other players in the market, like consumers and physicians. For example, governments in Germany and the United Kingdom have introduced incentives for physicians to prescribe more cost-effective medications.

As a group, these policies appear to have been effective at restraining drug prices, but they have been unable to prevent continued increases in drug spending. Despite modest increases in drug prices compared to the United States, between 1985 and 1991 these countries did not achieve the degree of pharmaceutical spending restraint sought by country officials. Instead, these countries experienced increases in pharmaceutical spending comparable to that in the United States. In these European countries, higher pharmaceutical spending has been driven largely by two factors—higher pharmaceutical consumption and the use of newer, more expensive drugs. Government policies have not controlled these forces entirely, although they have likely kept drug spending from rising even more rapidly.

Pressures to reduce this growth in prescription drug expenditures have spurred efforts to make patients and physicians more aware of drug prices

[3]In January 1993, Sweden changed its strategy from direct price controls to reimbursement controls.

[4]Other spending control policies used in these countries include consumer cost sharing and limits on which drugs are eligible for reimbursement.

and more financially responsible for drug spending. For example, in the last 5 years, consumers in all four countries have been asked to pay a greater share of prescription costs. In Germany and the United Kingdom, physicians have been given drug spending budgets or targets.[5] In addition, France, Germany, and the United Kingdom have stiffened regulation of manufacturers by implementing across-the-board price cuts. While it is generally too early to evaluate the success of these policies, country officials expect that they will help restrain spending by reducing consumption and over-prescribing.

In pursuit of pharmaceutical cost containment, each country—regardless of its specific policies—has encountered a tension between low drug prices and pharmaceutical research. Although the presence of pharmaceutical price regulation does not preclude the existence of an innovative industry, GAO's analysis supports the conclusion that higher drug prices strengthen the incentives for pharmaceutical R&D. However, the significance of this effect for public policy was difficult to evaluate, for two reasons. First, estimates of the size of the price-R&D relationship are imprecise. Moreover, the impact of declines in R&D spending for the production of new drugs, especially for the more significant innovations, is uncertain.

Although government regulation has restrained drug prices in the four countries we examined, the implications—and the desirability—of similar intervention in the U.S. pharmaceutical market are unclear. More specifically, determining the potential impact of a change in U.S. policy is complicated by existing institutional differences between the U.S. and other countries. In addition, the U.S. pharmaceutical market is appreciably larger than the market in any one of the other four countries. In any event, any gains from regulation of drug prices or spending must be weighed against the consequences of such regulations for pharmaceutical research and development.

[5]In January 1994, pharmaceutical industry representatives and government officials in France adopted an informal agreement that, among other things, would allow drug manufacturers greater flexibility in pricing within a target growth rate for pharmaceutical expenditures.

Principal Findings

Countries Control Payments Made to Manufacturers, Wholesalers, and Pharmacists

In all countries studied, the principal policy to control spending focuses on the price that manufacturers can charge. In France (and until 1993, in Sweden), the government sets prices paid to manufacturers. In Germany and in Sweden, manufacturers are largely free to set prices, but for many drugs there are limits on the amount insurers can pay. In the United Kingdom, the government limits the profits that manufacturers can earn from sales to the national health care system; manufacturers largely can set introductory prices within that constraint, but generally cannot increase drug prices. In addition to these policies, all four countries limit payments to drug wholesalers and pharmacists by setting wholesale and retail margins.[6]

Each country has imposed additional controls on consumers and physicians. All four countries have, to varying degrees, increased the consumers' share of drug costs. France, Germany, and the United Kingdom have also established drug lists that specify which drugs will not be reimbursed by the national insurance system. In addition, Germany has imposed drug budgets that make physicians financially responsible for over-prescribing. The United Kingdom has also placed more responsibility on physicians by giving each physician a drug spending target, and by providing physicians information on drug costs, efficacy, and prescribing patterns.

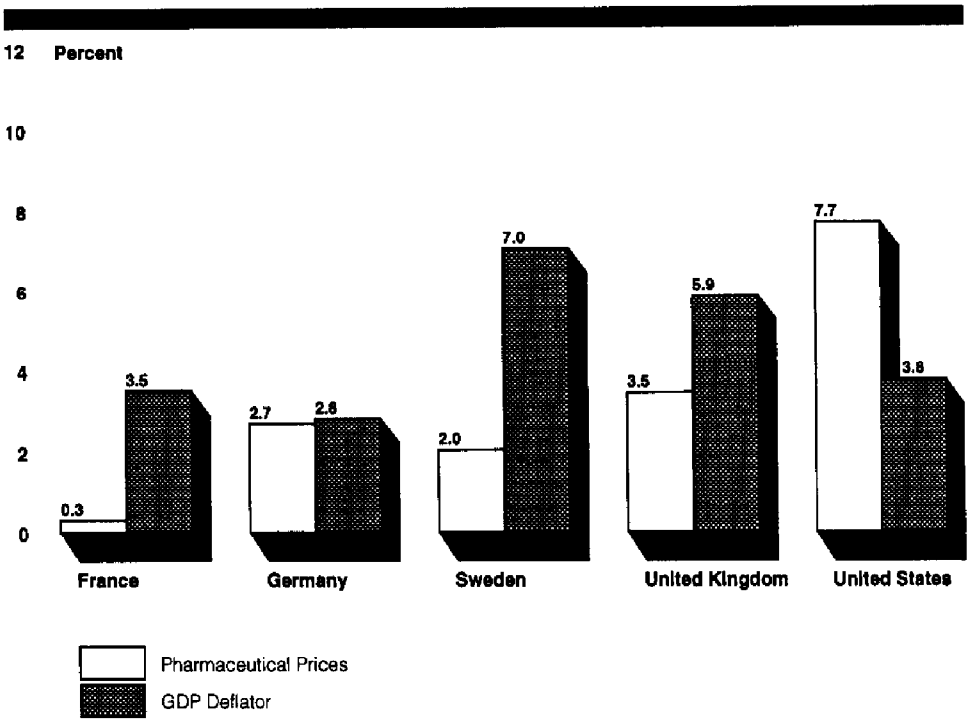
Policies Have Limited Drug Prices, but Drug Spending Has Continued to Increase

Generally, these policies seem to have been successful in achieving each country's pricing goals. Drug price increases between 1985 and 1991 were less than the overall inflation rate in all four countries we reviewed; by contrast, in the United States, drug prices rose at over twice the rate of inflation.[7] The lowest drug price increases were in France and Sweden, which had the tightest form of drug price controls. But even in the United Kingdom, which has the least restrictive form of pricing restraint, prices rose at only half the comparable U.S. rate. (See fig. 1.)

[6]The exception to this is in Sweden, where wholesaler fees are not subject to government regulation, but are negotiated between wholesalers and manufacturers.

[7]For each country, the inflation rate was measured by the growth in the gross domestic product (GDP) deflator.

Figure 1: Pharmaceutical Prices Have Risen Slower Than the Inflation Rate, 1985-91

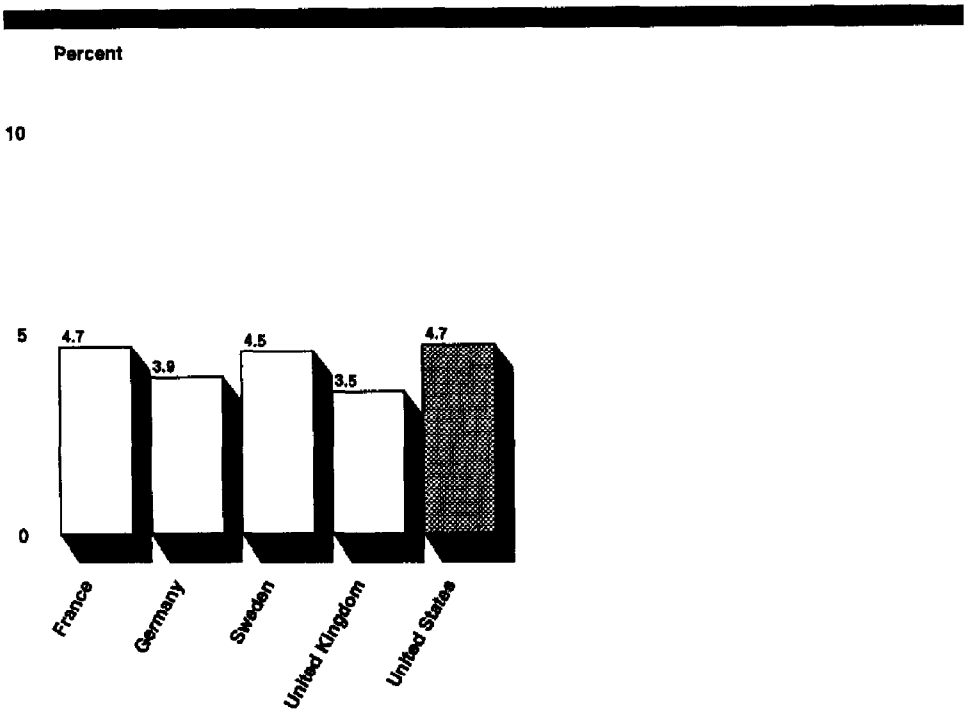


Note: Swedish data are for 1990.

Source: Organization for Economic Cooperation and Development.

However, while these countries' policies may have slowed the growth in drug prices, they have not completely contained the rise in drug spending. Even in countries with low prices, spending continues to rise because of increases in drug consumption, increases in the volume of prescriptions, and the higher relative prices of new drugs. Despite lower increases in drug prices, total drug spending in two of the four countries rose about as rapidly between 1985 and 1990 as did drug spending in the United States. (See fig. 2.)

Figure 2: Inflation-Adjusted Pharmaceutical Spending Growth, 1985-90



Note: United Kingdom data are for 1985-89.

Source: Organization for Economic Cooperation and Development.

Countries Are Adopting New Policies to Further Control Drug Spending

The menu of spending controls these countries have applied to manufacturers, wholesalers, and retailers has not achieved the degree of spending restraint sought by health financing officials. As a result, the governments in these countries are supplementing their existing policies in order to better control utilization and the mix between high- and low-priced drugs. These additional new policies are shifting the financial burden of drug spending from the government and insurance systems to consumers, physicians, and manufacturers.

For example, since 1993, all four countries have increased the patients' share of drug costs, and France, Germany, and the United Kingdom are limiting the types of drugs that will be reimbursed by the insurance system. France, Germany, and the United Kingdom have also imposed global cost reductions on pharmaceuticals. Germany has instituted a global budget for pharmaceutical spending, with the cost of budget

overruns to be borne by physicians.[8] France has also considered a global budget on pharmaceutical products which would give manufacturers more flexibility in setting drug prices but would make them accountable for drug budget overruns. In Sweden, the government implemented a system that will lower the amount that the insurance system will pay for many drugs.

Reductions in Drug Prices Lead to Lower R&D Expenditures

Transcending the specifics of each country's pharmaceutical policies is a tension between low drug prices and pharmaceutical research. GAO's analysis indicates that higher drug prices contribute to the development of new drugs by encouraging firms to devote more resources to R&D. However, the effect of prices on R&D is subject to several significant qualifications. First, the size of the effect is difficult to measure precisely. Second, the impact of an R&D spending decline on the production of new drugs is uncertain—both for breakthrough drugs and for more modest therapeutic improvements. Third, drug prices are only one of many factors that influence pharmaceutical R&D. Therefore, pharmaceutical spending control policies can coexist with a strong research-based industry, even though by themselves such policies would decrease R&D spending.

Recommendations

GAO is not making recommendations in this report.

Agency Comments

GAO obtained comments on this report from academic experts in the economics of the pharmaceutical industry and from selected officials in each country studied. Their suggested revisions were incorporated, as appropriate, into this report.

[8]Overruns during 1993 would have also been borne by drug manufacturers; however, the budget was not exceeded.

Contents

Tables

Figures

Abbreviations

AGI	annual gross income
AMM	Autorisation de mise sur le marché
DM	Deutsche Mark
EC	European Community
GDP	gross domestic product
GP	General Medical Practitioner
IPS	Indicative Prescribing Scheme
NHS	National Health Service
NSIB	National Social Insurance Board
OECD	Organization for Economic Cooperation and Development
PACT	Prescribing Analyses and Cost
PPRS	Pharmaceutical Price Regulation Scheme
R&D	research and development
RPS	reference price system

Introduction

Research efforts by the pharmaceutical industry worldwide, and in particular by companies based in the United States, have resulted in the development of many new drugs to treat diseases and prolong or save lives—benefits often viewed as priceless. Nonetheless, prescription drugs do have a price. Throughout the industrialized world, but especially in the United States, that price is considered by many citizens to be too high.

The increasing burden of paying for prescription drugs has led some members of Congress to propose federal regulations limiting prescription drug prices. However, critics of such regulations, within and outside the industry, have asserted, among other things, that regulations that reduce drug prices would cripple U.S. pharmaceutical companies' ability to develop life-saving and life-improving drugs.

Because the United States has not regulated drug prices in the past, our country's experience does not provide the evidence necessary to resolve this debate. European countries, however, have employed policies for several decades to control pharmaceutical prices and, indirectly, expenditures. The nature of the choices facing the United States can be illuminated by studying the European experience with these policies.

This report undertakes such a study, directed at analyzing both the ability of these policies to control costs and the potential tension between pharmaceutical innovation and cost containment. The report focuses on the pharmaceutical prices and spending control policies that have been adopted by four of these countries: France, Germany, Sweden, and the United Kingdom.

Rising Drug Prices Create Financial Burden for Many Consumers

Continuing increases in prescription drug spending have placed increasing financial burdens on those Americans who depend on prescription drugs to maintain good health. Total outpatient expenditures on prescription drugs in the United States nearly doubled between 1980 and 1991 (from $15.8 billion to $29.2 billion), even after adjusting for inflation.[1] Much of

[1]Some portion of this increase may be attributable to a general movement of treatment from inpatient to outpatient settings over this period.

this increase was driven by increases in prescription drug prices, which rose by more than twice the rate of inflation between 1980 and 1991.[2]

Health care consumers, in general, are particularly sensitive to these increases because of the high proportion of drug expenditures that are not covered by health insurance. While outpatient prescription drugs are a relatively small amount of total health care costs—less than 5 percent in 1991—over half of this amount is paid out of pocket (compared to 18.1 percent of spending for physician services and 3.4 percent for hospital care). The greatest burden of these out-of-pocket costs is likely to fall on the elderly, who as a group both use more drugs and are less likely to have insurance coverage for those drugs, because the federal Medicare program does not offer outpatient prescription drug coverage.

Pharmaceutical Industry Fears Price Regulation Would Hinder Drug Development

Recent developments by the pharmaceutical industry have led to important advances in medical treatment. Drugs that were not available prior to the 1980s are now commonly used to treat ulcers, cardiac disease, high blood pressure, Acquired Immune Deficiency Syndrome (AIDS), and many other ailments. Ongoing research, including the development of biotech drugs, may offer promising improvements in the types of medicines available both to prolong life and to improve the quality of life for people suffering from chronic illnesses.

Many such new drugs have been developed by pharmaceutical firms based in the United States. Among the world's top 15 companies in the innovative drug industry in 1991, 8 were U.S.-based; these companies had combined 1991 revenues of $36 billion. U.S.-based pharmaceutical firms developed over 40 percent of the new major global drugs discovered between 1970 and May 1992.[3]

[2]Price indexes provide some indication of the rate of prescription drug price increases as compared with price inflation in the general economy. But some research indicates that prescription drug indexes may over-sample medium-aged drugs that undergo above-average price increases, and under-sample younger products that experience less-than-average price increases, thereby overstating annual average drug price inflation. (See Ernst R. Berndt and others, "Auditing the Producer Price Index: Micro Evidence From Prescription Pharmaceutical Preparations," Working Paper No. 4009, National Bureau of Economic Research (Washington, D.C.: Mar. 1992). Alternatively, indexes may understate annual changes in average drug prices because they generally do not measure the impact of new drugs, many of which enter the market at relatively high prices.

[3]Heinz Redwood, Price Regulation and Pharmaceutical Research: The Limits of Co-Existence (Suffolk, England: Oldwicks Press Limited, 1993). Redwood defines major global drugs as those drugs that have been marketed or reached the post-clinical stage in at least six of the world's seven leading pharmaceutical markets—the United States, Japan, Germany, France, Italy, the United Kingdom, and Spain.

According to pharmaceutical industry representatives, as well as some independent observers, the threat of drug price regulation in the United States could threaten the continuation of this record of innovation. They contend that drug price regulation would severely decrease the rate of new drug development. They maintain that high profits are required to support the high costs associated with new drug development, estimated to be between $140 million and $194 million (in 1990 dollars) for each new chemical entity.[4]

Drug Prices, Research and Development, and Affordability in Other Countries

While the United States is a leader in new drug development, it is also a leader in drug prices. As several recent studies show, prescription drug prices in other countries are generally lower than in the United States.[5] Some of these countries have relatively little drug research and development, but others have relatively strong innovative drug industries. For example, France, Germany, Sweden, and the United Kingdom are home to firms that developed over 25 percent of new drug entities between 1970 and May 1992.[6]

Affordability of drugs to individual consumers is not as much of a problem in these other industrialized countries as it is in the United States. In this regard, many of these countries have universal health insurance systems that provide pharmaceutical drug coverage at little or no out-of-pocket cost to consumers.[7]

Universal drug coverage, however, has shifted the burden of paying for drugs from the individual to the insurance system, thereby creating an incentive for the government to restrain spending growth and to maintain

[4]This figure is net of tax preferences given to pharmaceutical R&D. See U.S. Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, OTA-H-522 (Feb. 1993), pp. 67-69.

[5]See, for example, Prescription Drugs: Companies Typically Charge More in the United States Than in Canada (GAO/HRD-92-110, Sept. 30, 1992); Prescription Drugs: Companies Typically Charge More in the United States Than in the United Kingdom (GAO/HEHS-94-29, Jan. 12, 1994); Association Belge des Consommateurs, Statement Prepared For the United States Senate Special Committee on Aging, (Nov. 16, 1989); and W. Duncan Reekie, "Drug Prices in the UK, USA, Europe, and Australia," Australian Economic Papers (June 1984), pp. 71-78.

[6]See Heinz Redwood, Price Regulation and Pharmaceutical Research: The Limits of Co-Existence (Suffolk, England: Oldwicks Press Limited, 1993), p. 22.

[7]There are also fewer networks for buying prescription drugs in other countries than in the United States. For example, in the countries we studied, consumers generally purchase their pharmaceuticals from retail pharmacists. By contrast, while most Americans buy their pharmaceuticals at retail pharmacies, many purchase through mail order houses and managed care organizations. See Stephen W. Schondelmeyer and Joseph Thomas III, "Trends in Retail Prescription Expenditures," Health Affairs 9:3 (Fall 1990), pp. 131-145.

the fiscal stability of the health insurance system. In addition, the relatively high level of drug spending in several European countries has increased the importance to government officials of restraining drug spending growth. For example, while pharmaceutical spending in 1990 composed about 8 percent of total health spending in the United States (as well as in Sweden), it accounted for almost 11 percent of health care costs in the United Kingdom, about 17 percent in France, and over 21 percent in Germany.

In response to the chronic pressure of rising health costs in general, and drug spending in particular, on their health insurance systems, these four countries (among others) have employed a variety of policies designed to restrain the growth in drug prices and spending. In implementing these policies, each country confronts two conflicting goals: the reduction of the costs of pharmaceuticals to the national health insurance system; and the maintenance of incentives to encourage pharmaceutical manufacturers to continue developing new drug products and attract industrial investment from the international pharmaceutical industry.

Objectives, Scope, and Methodology

The Chairman of the Senate Special Committee on Aging asked our office to report on how other countries regulate prescription drug prices, how those policies affect drug prices, and how they affect pharmaceutical R&D. Our first report on this subject examined Canada's approach to drug price regulation.[8] In this second report, we focus on countries that, unlike Canada but like the United States, have strong innovative drug industries.

Specifically, the objectives of this study were to

- describe the methods used in France, Germany, Sweden, and the United Kingdom to control prices of outpatient prescription drugs and to limit pharmaceutical spending;
- review the effects of these measures on pharmaceutical prices and spending; and
- analyze the effect of pharmaceutical prices and price regulations on R&D.

We reviewed the pharmaceutical price and spending control measures used by France, Germany, Sweden, and the United Kingdom (see apps. I-IV). We selected these industrialized democracies for their variety in the policies used to influence prescription drug prices and because they are

[8]Prescription Drug Prices: Analysis of Canada's Patented Medicine Prices Review Board (GAO/HRD-93-51, Feb. 17, 1993).

home to companies engaging in pharmaceutical R&D. Moreover, the governments in all study countries, like that of the United States, seek to contain rising health care costs and to reform elements of their health care systems.

In the course of our review, we collected and reviewed technical literature and government documents that describe pharmaceutical price control measures used in these countries and analyzed the effects of these measures. We interviewed officials in each study country representing the national government and the pharmaceutical industry. We also interviewed other officials, such as representatives of consumer groups, academia, and the health insurance systems about these issues. In addition, we developed a multivariate statistical model to estimate the effects of various factors on pharmaceutical R&D in European countries and in the United States (see app. V).

Our review was conducted from March 1992 through January 1994.[9] Because this report describes prescription drug spending controls in foreign countries, we did not obtain comments from the Department of Health and Human Services on this report. However, pertinent portions of this report were reviewed by academic experts in the economics of the pharmaceutical industry and by selected officials in each country. Based on the comments received, we made technical revisions to this report as appropriate.

[9]Although this report contains information through January 1994 on the price and spending control measures employed by the study countries, changes in these measures are frequent and ongoing.

Drug Cost Controls Have Mixed Success at Restraining Pharmaceutical Prices and Spending

As part of their national health insurance systems, France, Germany, Sweden, and the United Kingdom each covers prescription drugs, and all face a continuing challenge to restrain national spending on pharmaceuticals. In this persistent struggle, each country has developed spending control strategies consistent with two premises: first, that drug manufacturers can, if left unchecked by regulation, charge prices substantially above their costs, because patents and marketing efforts protect them from competitors; and second, that insurance coverage and physician responsibility for prescribing discourages comparison shopping by consumers, who lack incentives to seek out the most cost-effective drugs and have limited knowledge about alternative medications. In designing approaches to dampen pharmaceutical spending, governments have tended to rely more on regulations and sanctions than on policies to strengthen competition and incentives.

Currently, the scope of pharmaceutical cost containment strategies is diverse, targeting not only price but other determinants of drug spending. At least until the late 1980s, however, efforts to restrain drug prices had focused largely on controls at the point of sale—that is, at the prices charged, for example, by drug manufacturers to drug wholesalers, or by pharmacists to consumers. These traditional policies seem to have restrained prices, but increases in drug utilization and higher prices for new drugs have pushed up drug spending. Faced with this further stress on their national health care budgets, government officials in the countries we studied have concluded that, as a tool for restraining pharmaceutical spending, controls on prices alone are not sufficient.

As a result, each country has introduced or is developing a distinctive set of policies. They are designed to reduce the growth in prescriptions written, encourage the use of drugs that are more cost-effective, and shift some of the burden of higher drug spending from the national health insurance system to consumers, physicians, and drug manufacturers.

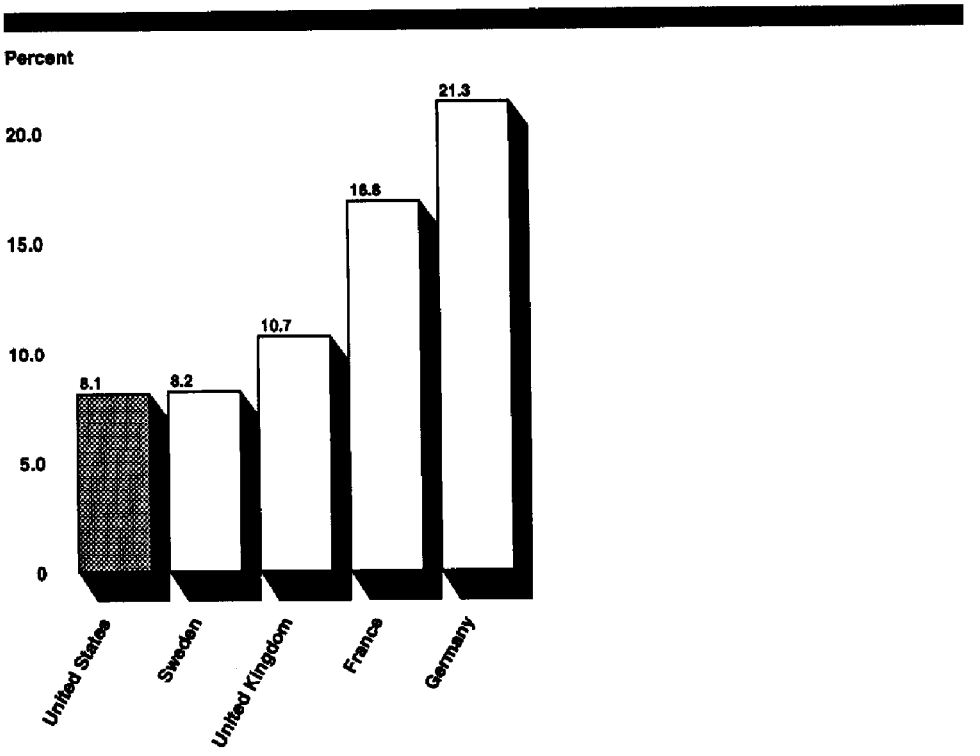
Fiscal Pressures on Health Insurance Systems Underlie Government Efforts to Control Drug Spending

Each of the four countries we reviewed has a national health insurance system that offers universal access to health care, including prescription drug products.[1] These systems pay for most or all of the costs of prescription drugs. Consequently, the insurance systems bear the financial burden of prescriptions most heavily and directly, while consumers pay relatively little.

In these countries, pharmaceutical outlays are a significant part of health care spending. In the period 1989 through 1990, the last years for which comparative data are available, pharmaceutical expenditures ranged from 8.2 percent of total health spending in Sweden to over 20 percent in Germany (see fig. 2.1). Given the fiscal weight of the pharmaceutical sector, each of these countries has looked to this sector for a significant contribution to the national effort at slowing the growth of overall health care spending.

[1]The particular type of health insurance system varies by country. Sweden and the United Kingdom have single payer systems in which the government provides health insurance for the entire population. Germany and France have multiple payer insurance systems, where workplace-based insurers provide coverage for most or all of the population. For a further description of these systems, see apps. I-IV; also, see Health Care Spending Control: The Experience of France, Germany, and Japan (GAO/HRD-92-9 Nov. 15, 1991) and Marilynn M. Rosenthal and Marcel Frenkel, eds., Health Care Systems and Their Patients: An International Perspective (Boulder, CO: Westview Press, 1992).

Figure 2.1: Pharmaceutical Expenditures as a Share of Total Health Spending, 1990



Note: United Kingdom data are for 1989.

Source: Organization for Economic Cooperation and Development.

Each Country Limits Drug Sellers' Ability to Set Prices Freely

Each country we reviewed has sought, as part of its efforts to manage its health care budget, to contain pharmaceutical spending with several different types of policies. These have included consumer cost sharing and restrictions on which drugs will be reimbursed, but the most prominent policies have been ones that limit drug manufacturers' ability to set their prices freely. That is, these countries have, until recent years, centered their pharmaceutical cost containment on regulations that limit drug prices directly or, by limiting insurance reimbursement, do so indirectly. These regulations are found at various points in the distribution chain for pharmaceuticals: the sale from manufacturer to wholesaler, from wholesaler to pharmacy, and from pharmacy to consumer.

Regulations targeted at drug manufacturers' prices in the four countries we studied embody one of three mechanisms:

- product-by-product price controls,
- limits on insurers' reimbursement levels, or
- profit controls.

Prices are also regulated at subsequent links in the distribution chain. The fees charged by wholesalers and pharmacists typically are not allowed to exceed a set ceiling.[2] These fees can be calculated as a fixed amount per prescription or as a percentage of price. (See table 2.1.)

Table 2.1: Wholesaler and Pharmacist Fees

Country	Payment Policy
France	Wholesale margin is set by law at 10.74 percent of the manufacturer price (exclusive of value- added tax). Pharmacist margin is calculated according to a sliding scale that decreases in proportion to the drug's price.
Germany	Allowable wholesale markups range between 12.0 to 21.0 percent of the manufacturer price, depending on the price of the product. Allowable pharmacy markups range from 30.0 to 68.0 percent of the wholesale price (exclusive of the value-added tax), depending on the price of the product.
Sweden	Wholesaler markups are negotiated between wholesalers and manufacturers, and average 4.2 percent of the manufacturer price (this is equivalent to 2.8 percent of the retail price). Pharmacies, which are run by an agency that is two-thirds owned by the government, add 41 percent to the wholesale price (this margin is equivalent to 29 percent of the retail price).
United Kingdom	Wholesale and pharmacist margin together cannot exceed 12.5 percent of the retail list price. Pharmacists also receive a dispensing fee of £1.512 per prescription for the first 1,500 prescriptions per month, and £0.715 for each prescription thereafter. In May 1992, this fee averaged £1.08 per prescription. Pharmacist fees are reduced by a rate intended to capture discounts they receive from wholesalers.

Regulations on Manufacturer Prices Differ in Degree of Pricing Freedom

Each country has regulations that are designed to limit—either directly or indirectly—the price that drug manufacturers charge to wholesalers (or to retailers that buy directly from the manufacturer). As described below, these policies differ in the extent that manufacturers are free to set launch

[2]The exception to this is in Sweden, where wholesaler fees are not subject to government regulation, but are negotiated between wholesalers and manufacturers.

prices for new products as well as to increase prices on existing products. (Apps. I-IV describe these policies in greater detail.)

Product-by-product price controls are the most direct form of price regulation, in that they largely bar manufacturers from selling their drug products at prices above those approved by the government (or other paying authority). In the two countries we studied where product-by-product price controls have been used for outpatient prescription drugs—France and, until 1993, Sweden—both new product prices and price increases were regulated by the government. New product prices emerge from negotiations between the government and each drug manufacturer. The criteria for setting these prices include the therapeutic value of the drug and the price of comparable treatments.[3] Price increases in both countries are allowed only with prior government approval.[4]

Limits on insurer reimbursement prices set an upper limit—or reference price—on the amount the insurer can pay for groups of identical or equivalent drugs. Drug manufacturers are free to set any launch price or price increase that they choose, but consumers must pay the difference between that price and the reference price. Manufacturers' ability to charge a price that is higher than the reference price is limited by consumers' willingness to incur out-of-pocket costs for pharmaceuticals.

Germany and Sweden illustrate different ways that reimbursement prices can be calculated. In Germany, a drug's reference price is computed essentially as the average of the prices of that drug and similar products.[5] In Sweden, the reference price for a drug is set at 10 percent above the price of the least expensive generic equivalent. In Germany, drugs are not covered under the reference price system (RPS) if they do not have a sufficient number of comparable products, while in Sweden, only one

[3]In France, as in Sweden, the allowable price may also be influenced by the contribution of the drug's sales to the national economy. In addition, Sweden based its allowable price on the price charged for the drug in other countries, and in particular, on the price in the manufacturer's home country.

[4]In France, the government prohibits price increases for drugs that have been on the market less than 2-1/2 years. After that time, prices can only be increased through a global pricing directive, which raises or lowers the prices of all drugs on the market by a set percentage. In Sweden, the government tries to keep drug price increases within the rate of inflation.

[5]Three different categories are used to define sets of similar drugs: (1) drugs with the same active ingredients (for example, brand name drugs and their generic equivalents); (2) drugs with therapeutically comparable active ingredients (for example, beta-blockers or H-2 antagonists); and (3) drugs with therapeutically comparable effects (for example, different aspirin combinations). The reference price for a particular drug is adjusted for variations from the average product's strength and package size.

generic equivalent is needed to set a reference price. In Germany, the statutory health insurers (known as sickness funds) pay the price that manufacturers set for drugs without a reference price (less the required patient copayment of Deutsche Mark (DM) 3 to DM 7).[6] By contrast, in Sweden the government negotiates with manufacturers the prices that can be charged for these drugs.[7]

Profit controls, used in the United Kingdom, are a more indirect form of drug spending control. A manufacturer that introduces a drug product into the U.K. market may freely set its launch price at any level, as long as company profits do not exceed a negotiated target. More precisely, the National Health Service (NHS), which in effect is the national health insurer, negotiates a profit ceiling with most drug manufacturers.[8] Through this process, the government relates each manufacturer's profits and hence, indirectly, their prices, to the level of investment in pharmaceutical production and R&D in the country for the purpose of supplying drugs to NHS.[9] However, even under this profit control scheme, drug manufacturers are still subject to drug price regulations. While manufacturers freely set prices when introducing new drugs—so long as profits do not exceed the target level—they cannot increase drug prices without prior government approval.

[6]In Germany, many single source products that lack comparable products cannot be assigned reference prices. Furthermore, other products do not yet have reference prices because of the technical difficulties in ascertaining which products have comparable therapeutic ingredients or actions. As of July 1993, about half of pharmaceutical products in Germany had reference prices. In 1993, the German government simplified the way that drugs are put into comparable groups. The government hopes that this simplification will allow for the eventual inclusion of 70 percent of drugs into the reference price system.

[7]These negotiations are performed for patented drugs that do not have generic substitutes and for over-the-counter drugs that the manufacturer wants included under the reimbursement system. Factors going into the negotiations include the basis of the drug's therapeutic value, the price of comparable products in other countries, the price of the drug in other countries, and the extent to which the drug's usage substituted for more expensive treatments. No negotiations take place for nonreimbursable drugs (for example, drugs sold in hospitals); instead, manufacturers are able to price these drugs freely.

[8]The United Kingdom's profit control scheme applies to all firms with sales to NHS of over £0.5 million (or about $740,000) per year.

[9]Under the United Kingdom's profit control scheme, which excludes generic drugs, manufacturers' profits are regulated in two ways, depending on their capital investment in the country. Manufacturers with sizeable capital investment are permitted to price drugs in line with target profit levels, based on their return on capital—current profit levels on sales to the NHS are set at 17 to 21 percent of the capital invested in the country, and devoted to supplying brand-name (that is, nongeneric) prescription drugs to NHS. Other manufacturers selling in the U.K.'s drug market also have target profit levels, but these are based on their return on sales. Manufacturers can justify keeping additional profits (up to 25 percent over their target level) if the additional profits are attributable to new products or to increased operating efficiency. (See app. IV.)

Regulations Are More Effective at Limiting Drug Prices Than at Restraining Drug Spending

The drug spending controls applied in these four countries have had mixed success at restraining the level of pharmaceutical expenditures. On the one hand, drug prices in these countries have grown relatively slowly under the price and profit controls—less than the rate of general inflation.[10] But while price restraint probably has kept total drug spending lower than it would have been otherwise, total drug spending—which is affected by the quantity of drugs sold as well as their prices—has continued to rise faster than the countries' governments are willing to accept.

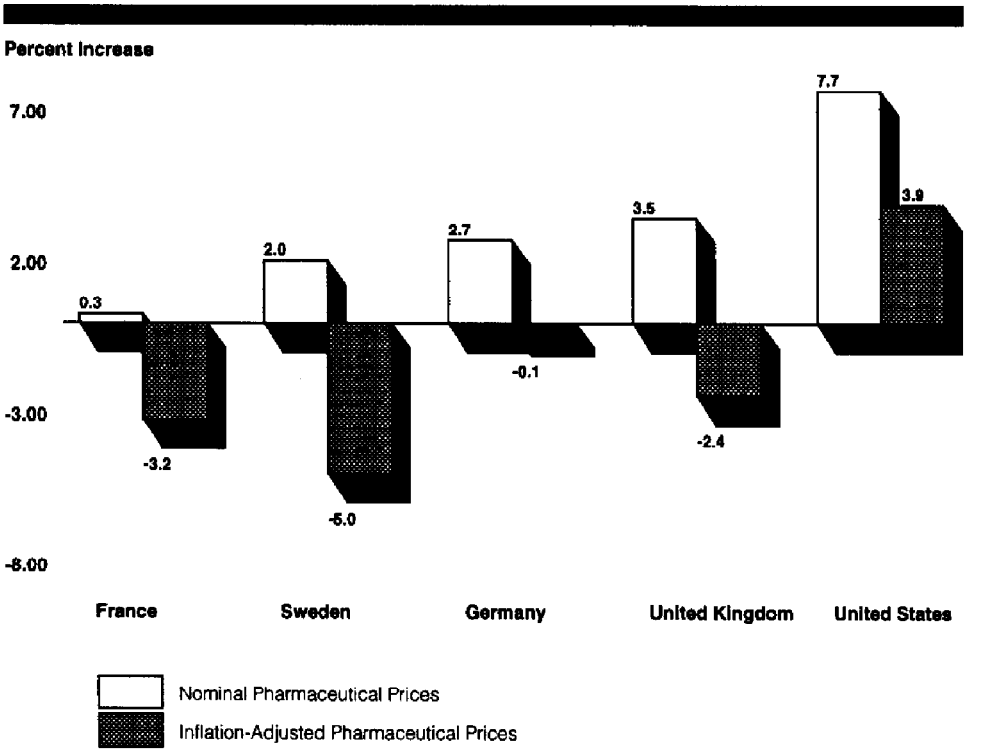
Between 1985 and 1991, the countries with the most direct types of price controls—France and Sweden—had the lowest average rates of increase in drug prices (see fig. 2.2).[11,12] In the United Kingdom, which has the most indirect type of price control, nominal drug price increases were the highest of the countries we reviewed; nonetheless, even U.K. drug prices rose relatively slowly—at about half the general rate of inflation. By contrast, during the same period (1985-91), pharmaceutical prices in the United States increased at an average annual rate that was over twice the general inflation rate.

[10]The general inflation rate is measured by the growth in the price deflator for Gross Domestic Product in each country.

[11]Swedish data are for the period 1985-90.

[12]Drug price inflation can occur even under regulatory regimes, such as those in France and the United Kingdom, which largely restrict drug price increases. This is because the pharmaceutical price index, on which drug price inflation is based, is composed of a market basket of drugs that changes over time. As new drugs become part of this market basket, the cost of this basket can increase if the price of those new drugs exceeds the average cost of the other drugs in the previous market basket.

Figure 2.2: Changes in Nominal and Inflation-Adjusted Pharmaceutical Prices, 1985-91



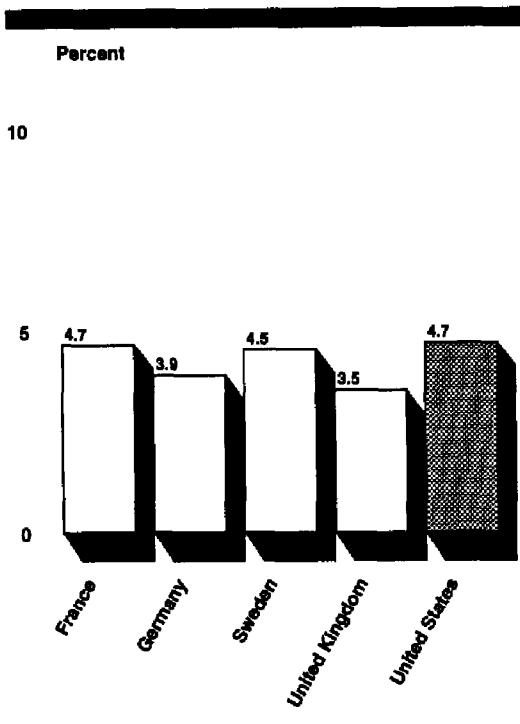
Notes: Inflation is measured by the growth in the GDP deflator. Swedish data are for 1985-90.

Source: GAO calculations, based on Organization for Economic Cooperation and Development data.

While the price restraint may have helped achieve some moderation in the growth of drug spending, the countries we examined had limited success in restraining the growth in total pharmaceutical expenditures during the same time period (see fig. 2.3). The relative increases in pharmaceutical spending were greater for countries with direct price controls than for those with more indirect approaches. In France and Sweden, the countries that employed direct price controls, the average annual growth in pharmaceutical spending between 1985 and 1990 was comparable to that in the United States. In Germany and in the United Kingdom, pharmaceutical spending grew at a slightly slower rate than in the United States. However, pharmaceutical spending in Germany and the United Kingdom grew more rapidly than overall inflation.[13]

[13]Data on pharmaceutical spending in the United Kingdom are for the period 1985 through 1989.

Figure 2.3: Pharmaceutical Spending Growth, 1985-90



Note: United Kingdom data are for 1985-89.

Source: Organization for Economic Cooperation and Development.

Spending Growth Is Largely Attributable to Factors Beyond the Reach of Drug Price and Profit Controls

The increase in pharmaceutical spending does not necessarily imply that the controls were ineffective at restraining drug spending. Indeed, these policies may have kept drug expenditures from rising higher than they would have otherwise.[14] However, the rise in drug spending suggests that factors outside the purview of these regulations outweighed any restraining impact that price and profit controls may have had on drug expenditures.

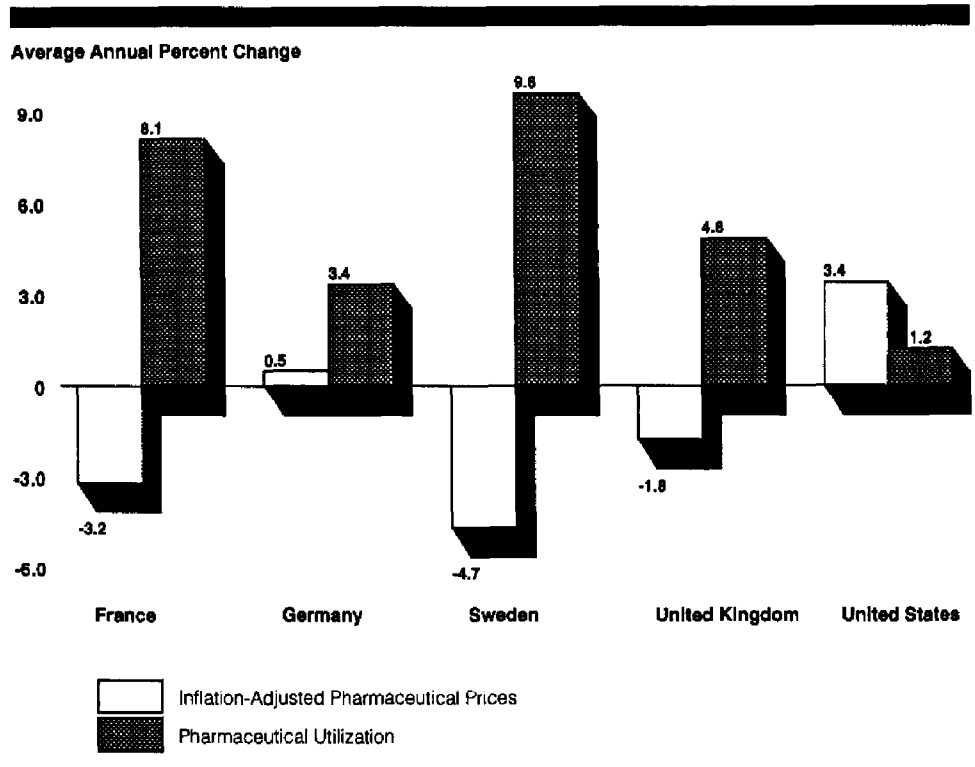
Increases in Drug Utilization

Increases in drug utilization likely provide one source of these spending increases. As figure 2.4 shows, drug utilization grew more rapidly than drug prices in the four countries we reviewed, suggesting that greater utilization accounted for a large amount of the growth in drug spending.

[14]Analyses of the effects of Germany's reference price system suggest that drug prices and spending were lower after the imposition of reference pricing than they would have been otherwise. We were not able to identify any formal studies on how the policies used in France, Sweden, or the United Kingdom affected drug spending, nor were there sufficient data for doing a before-and-after analysis on the policies' effects.

By contrast, in the United States drug utilization grew far less rapidly than drug prices, thereby suggesting a greater role for drug price increases in explaining spending growth. (See fig. 2.4.)

Figure 2.4: Growth in Inflation-Adjusted Pharmaceutical Prices and Utilization, 1985-90



Note: United Kingdom data are for 1985-89.

Source: Organization for Economic Cooperation and Development.

Increases in utilization can come from population growth and from increases in the elderly's share of the population—both of which occur independently of price and profit controls. The increases in the elderly can be of particular importance in explaining higher spending levels, since elderly people are likely to have higher per capita drug use than are the nonelderly. Each of the countries we reviewed has experienced increases in the elderly's share of the population, especially in persons over the age of 75. (See table 2.2.)

Table 2.2: Growth in the Share of the Elderly Population, 1985-91

Percent

Share of elderly in total population	France	Sweden	Germany	United Kingdom	United States
Age 65 and over					
1985	12.8%	17.4%	14.8%	15.1%	11.9%
1991	14.1	17.7	15.4	15.8	12.7
Age 75 and over					
1985	6.3	7.4	6.9	6.4	4.8
1991	7.0	8.1	7.2	7.0	5.2

Source: Organization for Economic Cooperation and Development.

Higher Prices for Newer Drugs

Increases in drug spending may also be caused by the use of newer, more expensive drugs. Despite the control mechanisms in place in these four countries, new drugs tend to have higher average prices than the drugs they replace, increasing the pressure on drug budgets even when consumption levels remain constant. These new products, which can range from innovative treatments to modest improvements over existing products, can strain drug budgets when they replace less expensive medications.[15] Higher new drug prices have been cited as a particular problem in the United Kingdom, where companies are free to set new drug prices so long as their profits remain within the target range.

The price and profit controls used in these countries generally do not provide patients and physicians with an incentive to choose products that are less expensive. Of the systems that we reviewed, only the reference price systems, used in Germany and Sweden, create incentives for consumers to choose lower-priced products. Under this system, a single reimbursement rate applies to drugs that are considered therapeutically equivalent or comparable to one another; if the price exceeds this level, then the consumer pays the remainder. By contrast, neither direct price controls nor profit controls create incentives for consumers or physicians to choose a less expensive medication.

[15]Even when use of these medications replaces more expensive nondrug treatments, they can increase the pharmaceutical budget. Consider the hypothetical example of a new medication that costs $1,000, but reduces the need for surgery that would cost $25,000. Each time that the medication is prescribed in lieu of surgery, hospital costs would be reduced by $25,000, but prescription drug spending—accounted for in another budget—would be increased by $1,000.

Increased Spending Has Spurred Adoption of Policies That Shift Costs and Encourage Cost-Effective Prescribing

The health financing systems in the countries we reviewed have been strained by the pattern of increases in pharmaceutical spending that approach or outstrip the growth of GDP. These strains have resulted in the adoption of major changes in the drug reimbursement policy in Germany and Sweden, proposals for major changes in such policy in France, and modifications in both Germany and the United Kingdom that are intended to make physicians more aware of drug costs. These new policies—sometimes working within the context of existing price and profit controls, and sometimes not—are designed to meet two objectives:

- first, to shift the burden of increased pharmaceutical spending from government to consumers, physicians, and drug manufacturers; and
- second, to stimulate price competition in the pharmaceutical sector by encouraging consumers and physicians to choose more cost-effective medications.[16]

Increases in Consumer Cost Sharing

One approach used to reduce drug spending is to increase consumers' financial responsibility for prescription drugs. From 1989 through 1993, all four countries have increased the patient's share of drug costs. (See table 2.3.)

[16]Sweden's recent payment reform was imposed, to some extent, for an additional reason—to respond to a European Community directive that requires member countries to publicly disclose the rules governing pricing of prescription drugs. The directive does not interfere with the right of countries to control prices or reimbursement by any method they choose, provided the method used is "transparent" and does not discriminate between foreign and domestic drug manufacturers. Sweden is not a European Community member, but has applied for membership.

Table 2.3: Patient's Share of Drug Costs Has Increased in France, Germany, Sweden, and the United Kingdom, 1989-93

Country	1989	1991	1993
France	Copayment of 0, 30, 60, or 100 percent of drug cost, depending on the particular drug.	Copayment of 0, 30, 60, or 100 percent of drug cost, depending on the particular drug.	Copayment of 0, 35, 65, or 100 percent of drug cost, depending on the particular drug (effective summer 1993).
Germany	Copayment of DM 3 per prescription. Starting June 1, drugs under the reference price system: Patients pay the amount by which retail price exceeds the reference price. Drugs not under the reference price system: DM 3 per prescription.	Drugs under the reference price system: Patients pay the amount by which the retail price exceeds the reference price. Drugs not under the reference price system: DM 3 per prescription	Copayment of DM 3-DM 7, depending on the price of the drug.[a] In addition, the consumer pays any amount by which the retail price exceeds the reference price.
Sweden	Flat copayment of SEK 90 for up to 10 drugs written on same prescription form.	Flat copayment of SEK 90 for up to 10 drugs written on same prescription form, for a maximum prescribing period of 90 days.	Copayment of SEK 120 for first prescription and SEK 10 for additional prescriptions obtained from the pharmacy at the same time, for a maximum prescribing period of 90 days. In addition, the consumer pays any amount by which the drug's price exceeds the reference price.
United Kingdom[b]	Flat copayment of £2.80 for drugs covered by NHS.[c]	Flat copayment of £3.40 for drugs covered by NHS.[c]	Flat copayment of £4.25 for drugs covered by NHS.[c]

[a]As of January 1994, the copayment in Germany is based on the size of the prescription rather than on the price of the drug.

[b]Table lists copayment levels as of April 1 of each year cited. In addition, patients in the United Kingdom receiving frequent prescriptions may buy a season ticket covering the costs of all prescriptions for either 4 months or 12 months. In April 1989, the 4-month season ticket cost £14.50, and the 12-month season ticket cost £40. By April 1993, these costs increased to £22 for the 4-month ticket and £60 for the 12-month ticket.

[c]Because of exemptions to cost sharing, about 80 percent of drugs dispensed in the United Kingdom have no consumer copayment.

The higher copayments may have the dual purpose of (1) shifting some of the financial burden of pharmaceuticals away from the national health insurance system and toward consumers, and (2) raising consumer cost-consciousness about their prescriptions, thereby reducing alleged overutilization of drugs.

Certain features of some copayment policies can be expected to limit their effectiveness at restraining drug spending. First, copayments that cover only certain drugs or certain segments of the population will reduce

spending less than would more comprehensive cost sharing. For example, until 1993, there were no copayments for German pharmaceuticals covered under the reference price system (so long as the drug's price did not exceed the reference price). Therefore, consumers had no incentive to reduce consumption of those items. In the United Kingdom, copayment exemptions for the elderly, the poor, children, and pregnant women (among others) eliminates all cost sharing for about 80 percent of prescriptions written.

Second, copayments that are the same amount for every prescription cannot affect the choice between more and less expensive medications. If the consumer's copayment is identical for an expensive drug and for a cheaper substitute, the consumer has no reason to choose the less expensive medication.

Third, the small size of the copayments may also limit their ability to reduce the number of prescriptions filled. However, raising the copayment could present a financial barrier to poor households or to people who need to use a high volume of pharmaceuticals.

Encouraging Physicians to Prescribe Less Expensive Medicines

To an increasing extent, pharmaceutical payment reforms in the countries we reviewed—particularly in the United Kingdom and Germany—are designed to encourage economical prescribing by physicians and to emphasize the use of less expensive drugs. These policies recognize the vital role of the physician as the primary decisionmaker regarding choice of pharmaceuticals and, to varying degrees, tie financial incentives for physicians to the prescribing choices that they make.

The United Kingdom uses a two-pronged strategy for encouraging physicians to be agents for lower pharmaceutical spending:

First, the government provides information to individual physicians about their prescribing habits (relative to those of their colleagues). Physicians receive a periodic report on the number and cost of the drugs they prescribed, compared to norms for physicians in their area. The government also provides physicians with information on the safety and cost-effectiveness of alternative drug products. This information is intended to allow the physicians to make more responsible choices about prescribing.

Second, physician spending targets are used to restrict pharmaceutical sales. Since 1991, physicians in the United Kingdom have been subject to the Indicative Prescribing Scheme (IPS), which sets financial targets for physician prescribing. Under IPS, doctors are given a financial benchmark, referred to as an indicative amount of prescribing. Physicians' indicative targets are based on several factors, including historical expenditures, demographic composition of their patients, and drug price inflation. These targets are not binding caps, although physicians who consistently prescribe more than their targeted amounts can be targeted for advice and detailed monitoring, and in a last resort, cases of gross over-prescribing can be penalized.[17,18]

Germany also instituted pharmaceutical budgets on physicians, but these controls—implemented in 1993 as part of a comprehensive health financing reform—place more stringent financial controls on physicians than do the United Kingdom's policies. As of January 1993, Germany has had a global budget for pharmaceuticals, which, if exceeded, will be offset by a reduction in the ambulatory care physician budget. In 1993, the total pharmaceutical budget for office-based physicians was set at about DM 24 billion, or about $15 billion. While 1993's spending did not exceed this level, any cost overrun up to DM 280 million (about $175 million) would have been offset by a reduction in the 1994 ambulatory care physician budget. (The cost overrun would also be borne by pharmaceutical manufacturers if it reached DM 280 million, up to another DM 280 million.) For most regions, the 1994 budget is set at the 1993 level, and all cost overruns will be borne by reductions in the ambulatory care physician budgets.[19]

The global budgets in Germany appear to have had an impact in the short time that they have been in effect.[20] Total prescription drug costs for sickness funds declined by about 20 percent in the first half of 1993, compared to the same period in 1992, and total 1993 drug spending was actually less than the budgeted amount and, therefore, less than 1991's

[17]The provisions requiring physicians to justify this prescribing behavior are separate from and predate IPS.

[18]Some physicians in the United Kingdom—25 percent as of April 1993—are subject to an alternative budgeting scheme, known as the GP fundholding scheme. Under this scheme, which is voluntary, physicians who are in relatively large group practices are given a practice budget, which is intended to cover all prescribing costs for patients as well as the cost of some hospital services, outpatient services, administrative services, and visiting and district nurse services.

[19]Most regional physicians' associations chose to accept the 1994 budget set at the 1993 level rather than negotiate a budget based on real 1993 expenditures.

[20]No systematic evidence exists on the effects of IPS in the United Kingdom.

total. In addition, in the first half of 1993, physician prescribing fell by about 17 percent below the 1992 level.

Several reasons have been suggested for the drop in drug spending in Germany. First, physicians substituted cheaper generic drugs for more expensive, brand-name drugs. As a result, sales of the cheapest generic drugs increased in some cases by as much as 250 percent. Second, many patients—especially those with long-term illnesses—obtained their prescriptions in December 1992 (before the law took effect) and thus did not need to acquire their drugs in the first few months of 1993. Third, physicians have been less willing to prescribe drugs with doubtful efficacy (e.g., anti-varicosis drugs) or drugs for conditions that can be treated in different ways (e.g., drugs for diets).[21]

Citizens and officials in both countries have been concerned about whether the budgets are reducing access to pharmaceuticals. In the United Kingdom, some observers believe that the budgets are constraining physicians' ability to prescribe the most effective drugs and respond to special patient needs, such as those of the elderly. However, government officials believe that the physician budgets could, instead, increase the quality and cost-effectiveness of prescribing, and so improve patient care. In Germany, some officials have expressed concern that the older drugs that physicians are prescribing in order to save costs may be less effective than newer, more innovative products. However, there is no firm evidence either to support or contradict this contention.

More Stringent Controls Being Applied to Drug Manufacturers

While many of the recent policy changes in the countries reviewed have applied to patient and physician practices, France, Germany, and the United Kingdom—to differing degrees—have also made efforts at reducing payments to manufacturers. These efforts have taken three forms: first, across-the-board price cuts; second, limits on total manufacturers' sales; and third, limits on the types of drugs eligible for reimbursement.

Across-the-Board Price Cuts

One method used to reduce pharmaceutical spending is across-the-board cuts in payments to drug manufacturers. France, Germany, and the United Kingdom have used this measure in recent years. France's most recent price reductions occurred in 1991, when the government ordered that

[21]There was a disproportionate decrease in the prescription of drugs that are considered to be therapeutically controversial and drugs that are considered to be therapeutically meaningful. For example, drugs in the former group include circulatory drugs and vitamins (which declined 29.9 percent and 29.1 percent, respectively). Drugs in the latter group include antibiotics and anti-diabetic drugs (which declined 5.2 percent and 0.7 percent, respectively).

pharmaceutical prices be cut by 2.5 percent. Germany implemented across-the-board price cuts in 1993, when the government ordered a 5-percent reduction in the price of drugs not covered by the reference price system, and a reduction in over-the-counter (nonprescription) drug prices to 2 percent below the May 1992 price level. The government also mandated a price freeze on these drugs that will be in effect through 1994. The United Kingdom also implemented global price cuts in 1993, ordering a 2.5-percent price cut on all products, which is to be followed by a 3-year price freeze.

Budgets

Of the countries we reviewed, only Germany has imposed budgets that apply to manufacturers. As described in the previous section, Germany's 1993 global budget sets total limits on annual pharmaceutical spending. While physicians were to bear part of the budget overrun—the first $175 million in 1993—subsequent overruns (up to $175 million) would have come from the pharmaceutical manufacturers. However, under the 1994 budget, manufacturers will not have to bear the financial burdens of overruns if physicians exceed the budget.

France may adopt drug budgets for manufacturers. In 1991, the French government proposed a drug payment system in which manufacturers would each have a budget for total drug sales to the social insurance system. Under this framework, manufacturers could have been able to set prices freely, as long as their total revenues from sales to the national health system did not exceed the budget. This proposal was never enacted, due to political opposition. However, in January 1994, representatives of the pharmaceutical industry and French government reached an informal agreement that, if implemented, would include many aspects of this 1991 proposal.

Limiting Drugs Eligible for Reimbursement

Governments can limit the drugs eligible for reimbursement through lists that explicitly identify specific drugs as ineligible for reimbursement. Drugs may be excluded from the payment system because they (1) offer questionable therapeutic value or (2) have prices that are high relative to alternative medications of similar or equal therapeutic value.[22]

Three of the countries we studied are either establishing or expanding negative drug lists in an attempt to limit prescription drug dispensing. In January 1994, France established a list of 24 drugs and procedures which will not be reimbursed. The United Kingdom is in the process of excluding

[22]In Germany, drugs will be excluded from reimbursement only if they have questionable therapeutic value; in France, Sweden, and the United Kingdom, reimbursement decisions take into account a drug's price as well as its therapeutic value.

additional drugs from its reimbursable lists. Germany currently has a nonreimbursable drug list, but after 1995 plans to replace this with a list of drugs that are eligible for reimbursement.

The Effect of Prescription Drug Prices on Pharmaceutical Research and Development Expenditures

As we described in chapter 2, France, Germany, Sweden, and the United Kingdom have employed a variety of policies to control pharmaceutical spending and prescription drug prices. Despite the differences in their specific policies, each country confronts a similar dilemma—preserving a strong domestic pharmaceutical industry while controlling national spending on pharmaceuticals. Specifically, the concern has centered on the potential trade-off between low drug prices and pharmaceutical firms' spending on R&D. Although other factors are also important, economic analysis confirms that higher drug prices strengthen the incentives for firms to invest in pharmaceutical R&D. Nonetheless, empirical estimates of the size of this price-R&D relationship are imprecise, and the significance of drug price decreases for the development of new drugs is uncertain.

Tension Between Low Drug Prices and R&D Incentives Transcends the Specifics of Each Country's Policies

France, Germany, Sweden, and the United Kingdom have adopted strikingly different price restraint mechanisms—from the product-by-product price controls in France to the United Kingdom's profit control scheme. Despite the differences in their specific policies, these countries' measures have had a common result—lower prescription drug prices.[1] In each of the countries we studied, the national authorities face a potential conflict between their interest in containing prescription drug costs and their concern that reductions in drug prices and spending may hurt the domestic pharmaceutical industry. In particular, this concern has focused on the potential depressing effect of lower drug prices on pharmaceutical R&D. Analysis of this relationship between drug prices and R&D reveals a tension that transcends the specifics of each country's pharmaceutical policies.

Although the specific form of pharmaceutical regulation will be important to pharmaceutical companies, these policies' impact on R&D stems primarily from their influence on prescription drug prices. A reduction in prescription drug prices can be expected to reduce companies' spending on pharmaceutical R&D, because firms will have less incentive to invest in R&D when they expect to receive lower prices for their products. Moreover, a reduction in drug prices can stem from any source—either a government regulation or other factors in the market. In this respect, the tension between drug prices and R&D transcends policy specifics.

The conflict between cost containment and R&D is not confined to countries like France, Germany, Sweden, and the United Kingdom—that

[1]These regulations reduce drug prices relative to their level without regulations. Even if regulated drug prices increase, as they often do, they usually rise less rapidly than in the absence of regulations.

is, countries that have adopted explicit pharmaceutical spending control policies—because the drug price-R&D connection does not rest on specific policies adopted in specific countries. Consequently, countries with less regulated pharmaceutical markets, like the United States, also contend with potential trade-offs between low drug prices and high spending on research. As a result, the general relationship between drug prices and R&D can be estimated by analyzing data from a wide range of countries, from the highly regulated to the more market-oriented.

Higher Drug Prices Strengthen the Incentive for R&D Spending, but Other Factors Also Matter

When prescription drug prices decline, pharmaceutical companies are faced with a potential loss of revenue—for both the drugs they currently produce and especially for their future product line. Pharmaceutical companies have less incentive to invest in costly R&D if the resulting products will bring in lower profits. However, a number of factors—including both government policies and market forces—influence firms' expectations of future profits, and are therefore important to firms' R&D decisions.

Regulations That Lower Drug Prices Reduce Incentives for R&D

As we described in chapter 2, governments in France, Germany, Sweden, and the United Kingdom have employed a range of strategies to control pharmaceutical prices and spending. In each country, these regulations have not only reduced the prices of today's pharmaceutical products, but also will undoubtedly put downward pressure on the prices of tomorrow's prescription drugs. For example, managers of pharmaceutical firms can expect French price controls to continue exerting downward pressure on drug prices in France. In addition, firms in the United Kingdom are restricted from increasing drug prices without government approval. In general, both current laws and prudent business judgment lead firms to expect that in the future, prescription drug prices will be lower with government regulation than they would have been otherwise.

These future prices are central to companies' R&D decisions. Firms invest in R&D today in order to discover new pharmaceutical products, which will earn profits in the future. According to the Office of Technology Assessment, a typical new drug is introduced to the market only after an average of 12 years of research and testing.[2] If firms foresee lower earnings potential for future products, R&D becomes less attractive.

[2]In this context, a "new drug" refers to a drug based on a new chemical entity or compound, rather than, for example, an extended-release form of an existing drug.

Countries With Higher Drug Prices Are Often Drug Innovators, but Exceptions Underline the Importance of Nonprice Factors

The pattern of world pharmaceutical R&D generally confirms that high drug prices create greater incentives for R&D. Among major industrialized countries, a pattern prevails—countries with higher drug prices tend to be associated with more pharmaceutical R&D. These countries (including the United States and Germany) have high prescription drug prices, high R&D, and many new drugs. Conversely, in low-price countries like Spain and Australia, R&D spending is low, and very few new drugs are developed.

However, despite this general link between drug prices and R&D, significant exceptions exist—a few low-price countries are pharmaceutical innovators, while several high-price countries lack strong industries. For example, in Sweden and the United Kingdom, an innovative industry coexists with price regulation, while in Canada, average or high prices have not resulted in significant R&D. France represents an intermediate case, neither fully conforming to the general pattern nor sharply deviating. France has been able to produce some innovative drugs, despite low domestic prices. However, with these low drug prices, France has experienced a decline in new drug development by French firms, and French products have not been widely adopted overseas.[3]

Countries with apparently weaker connections between drug prices and R&D—like the United Kingdom and Canada—reveal the importance of nonprice determinants of R&D. Although prescription drug prices can influence pharmaceutical R&D, drug prices are clearly not the only factor affecting research decisions, nor are they necessarily the most powerful. For example, while Canada has relatively high drug prices compared to many European countries, Canada's compulsory licensing policy and weakened patent protections appear to have limited the Canadian industry's research spending. Government policies, from tax credits to patent laws, can stimulate or deter pharmaceutical R&D investment. Likewise, market forces can encourage or discourage firms from spending more on research.

Government Policies Influence Pharmaceutical R&D

The government's impact on pharmaceutical research does not arise solely from drug price regulation, but also from other arenas such as patent policy and tax law. R&D decisions also hinge on these other government policies, which are described below:

[3]For example, in the period 1975 through 1989, France produced 12.2 percent of the world's new pharmaceutical products, but only 3.1 percent of "globalized" products—that is, those products available in six of the world's seven major pharmaceutical markets. (See P. Etienne Barral, Fifteen Years of Pharmaceutical Research Results Throughout the World (1991).)

- The effective patent life for new products is the period of time for which a firm has the exclusive right to market a new drug. The longer a firm is protected from competition, the greater the profits the firm can expect to earn from a new drug, and the greater incentive for R&D. However, firms must apply for patents as soon as a compound is discovered, before the drug is reviewed for safety and efficacy by the national authority. While the drug is being reviewed, some of the drug's patent term is "used up" before the product reaches the market. The longer the approval process takes, the shorter the firm's "effective" patent life is.
- Tax policy can create additional incentives for R&D. Some countries (including the United States) try to encourage firms' R&D efforts by giving firms special tax credits for each dollar they spend on R&D. These tax credits reduce the firm's R&D costs; therefore, tax credits may provide firms with an incentive to increase their R&D expenditures.
- Public funding (subsidies or outright grants for scientific research) may stimulate firms to do more applied research.
- Product liability law may deter firms from R&D projects (particularly in certain therapeutic categories) if pharmaceutical companies cannot protect themselves against the risk of costly suits related to new products.

Market Forces Also Affect Pharmaceutical R&D

Although the pharmaceutical market is heavily influenced by government policy, market forces also play an important role. The choices made by consumers and their physicians, together with government policy, create the market environment on which firms must base their R&D decisions. As described below, these market forces—which differ across countries—are also important factors in R&D decisions.

- The size of the market (both domestic and foreign) for a pharmaceutical product will influence the amount of revenue a firm can expect to receive for a product, and thereby affect its R&D. For example, countries with universal insurance coverage for prescription drugs may have higher consumption per capita, as consumers have access to pharmaceutical products regardless of their ability to pay. Lifestyle choice, cultural norms, and household incomes may also influence the use of prescription drugs.
- Wage and equipment costs form part of the out-of-pocket expenses involved in pharmaceutical R&D. An increase in these costs would make it more expensive for firms to conduct R&D.
- The "scientific infrastructure" of a region or country helps determine the pharmaceutical industry's access to qualified personnel. For example, a strong, nearby academic community may make it easier to hire qualified people and may enhance research output.

Reductions in Drug Prices Lead to Lower R&D Expenditures

In our statistical analysis, we found a positive relationship between drug prices and R&D, reinforcing the reasoning that higher drug prices strengthen the incentive for R&D. We estimated this relationship several different ways, and the size of the estimated R&D response to prices varied accordingly. According to a representative estimate, a 1-percent decline in drug prices leads to a 0.68-percent decline in R&D spending. However, while statistically distinguishable from zero, this estimate is statistically imprecise. The data are consistent with a response as high as 1.2 percent or as low as 0.1 percent. (See app. V for a more detailed discussion of these results.)

We obtained these estimates using a multiple regression model that relates changes in pharmaceutical R&D to changes in drug prices, controlling for the influence of other factors. The results pertain to data on the pharmaceutical R&D spending of 87 companies, for the years 1988 to 1991. This group of firms covers 12 countries, including France, Germany, Sweden, the United Kingdom, and the United States. We used the national index of drug prices to characterize the price levels facing a given company in a particular country.[4] Our results are consistent with previous economic analyses of the pharmaceutical industry, in which other measures of the incentive for R&D—for example, firms' profit rates and market shares—were positively related to R&D.[5]

Information Is Limited About Size and Significance of Potential R&D Reduction

Although our analysis reaches the general conclusion that higher drug prices encourage pharmaceutical R&D, we have more limited evidence about the effects of the specific policies adopted in specific countries. We urge a cautious interpretation of our results, for three major reasons: (1) we expect that the strength of the price-R&D relationship will differ across countries; (2) we do not know whether a decrease in R&D spending by firms would bear more on innovative or imitative drug products; and (3) these results suggest that drug prices are negatively related to R&D, but convey more limited information about the relationship between any specific policy of price regulation and R&D. A regulation's impact may depend not only on the resulting changes in prices but also on other factors, such as the size of the market on which these policies are

[4]This is a proxy for the company's expectation of the pricing environment that it will face when the results of its R&D—its new products in the future—reach the market.

[5]For example, see William S. Comanor, "The Political Economy of the Pharmaceutical Industry," Journal of Economic Literature, 24 (3) (Sept. 1986), pp. 1178-1217; and Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals, U.S. International Trade Commission, Report to the Committee on Finance, U.S. Senate. US ITC Pub. 2437 (Washington, D.C.: 1991).

imposed.[6] Therefore, the size of the effect of drug price regulation on new drug development remains an open question.

The Strength of the Price-R&D Relationship Is Expected to Vary Across Countries

Our statistical analysis estimates an average price-R&D linkage across national boundaries. However, we expect that the importance of domestic prices to R&D will differ from country to country. Economic theory suggests that two factors, which vary across countries, will affect the strength of the relationship between price regulation and R&D spending. First, the price-R&D connection can vary with the size of the pharmaceutical market in the manufacturer's home country. If a small country (such as Sweden) exhibited falling domestic prices, the impact on drug company revenues and R&D would be limited because this country's consumers account for only a small share of the global pharmaceutical market. By contrast, a loss of revenue in a larger market would likely have more far-reaching effects on domestic and foreign pharmaceutical firms. Second, domestic firms that are export-oriented will be less concerned with prices in the home country. For example, for firms in the United Kingdom, which earn much of their revenues and profits from exports, prices in the home market are less important. By contrast, when firms are more heavily oriented toward their domestic market, then domestic prices are likely to have a stronger impact on the R&D decision.

Regulation's Impact on the Production of New Innovations Is Uncertain

Although R&D spending undoubtedly leads to the discovery of new drugs, we cannot tell how a decrease in R&D spending would affect the distribution of new drug discoveries. Not all drugs are equally valuable to physicians and their patients. So-called "breakthrough" drugs are based on new compounds and represent a substantial improvement over existing therapies. These drugs are of considerable value in helping people get well. By contrast, "me-too" drugs represent little or no improvement over current treatments. Clinically, these "me-too" drugs are generally less valuable to patients than breakthrough products.[7] We cannot determine whether a reduction in R&D spending would manifest itself in "breakthrough" or "me-too" drug projects.

The effects of price regulation on the quality of R&D will depend on both the average price level for new drugs and the relationship between the

[6]In addition, price regulation could conceivably be implemented in conjunction with other policies—such as expanded insurance coverage for prescription drugs—that might be expected to encourage R&D.

[7]However, the clinical value of a new drug may not fully reflect that drug's value to society. For example, a "me-too" drug may, through price competition, lower the prices of competing therapies.

price of a new drug and its therapeutic value. For example, if regulators allow higher introductory prices for breakthrough drugs than for me-too drugs, this may create additional incentives for manufacturers to produce more innovative drugs. In addition, for drug manufacturers to have sufficient incentive to undertake high-risk projects, the firm must be able to pay the costs of the research projects that did not prove successful. In general, the lower the price given to new drugs, the less likely that the firm can bear the cost of failed R&D. Therefore, other things being equal, lower introductory prices can create a greater incentive for the firm to concentrate its R&D in projects with a higher probability of eventual success. Data are presently inadequate to estimate the extent to which these incentives may change the mix of breakthrough and me-too drugs.

Regulation's Impact on Quantity and Quality of R&D Will Depend on Regulatory Design and Implementation

While the major R&D impact of spending control strategies comes from their effect on prescription drug prices, the important though secondary effects of these policies may stem from their design. However, evidence of these potential effects is limited.

Controlling the Introductory Price or Controlling Only the Rate of Increase?

As described in chapter 2, the government in France controls both the price at which a drug is introduced to the market and any subsequent price increases. The United Kingdom, by contrast, allows manufacturers to freely set introductory prices (subject to the profit constraint) but largely controls future price increases. The United Kingdom's policy may create an incentive for new drug development, as companies can increase the average revenue of their product line only by putting new drugs on the market. The quality of new drugs, however, would not be assured. Companies may have an increased incentive to tinker with delivery mechanisms and dosages or produce imitative drugs in order to send "new" products to the market and command higher prices.

Are Firms Given Higher Prices to Reward R&D?

In addition to the United Kingdom, some countries may allow companies to charge higher introductory prices for innovative products than for less significant drugs. For example, in France, regulators will allow a higher price for a more innovative product. However, critics of the French system contend that this premium is not large enough to create sufficient incentive for innovation.

Are All Firms Treated Equally, or Do Some Firms Have an Advantage?

Some countries' price regulatory authorities may treat firms differently depending on their national origin. In the United Kingdom, for example, a

company's allowed profit is calculated on the basis of the capital it has invested in the United Kingdom; the more capital the firm invests in the United Kingdom, the higher the allowed profits. This policy gives an advantage to British firms and foreign firms that locate their European offices in Britain, and may encourage R&D in that country.

Conclusions and Policy Implications

While for decades many European countries have intervened in the pharmaceutical market to restrain prices and spending, the United States has allowed drug manufacturers to set prices freely. Recently, however, public dissatisfaction with the rising cost of prescription drugs has prompted new congressional proposals to restrict pharmaceutical prices. Indeed, as efforts at redesigning the U.S. health care system have accelerated, interest in drug price regulation has been heightened in both the legislative and executive branches. Lacking firsthand experience with pharmaceutical price and spending controls, the United States can learn from its European counterparts' attempts to contain drug prices and spending. The findings of this report suggest three lessons that should be considered:

1. Price controls for individual products are only one of a large number of pharmaceutical spending control policies, ranging from strict regulatory approaches to more market-based solutions.

Though price controls on prescription drugs have been prominent in Europe, they do not exhaust the variety of techniques and philosophical orientations that U.S. decision makers can consider. To control pharmaceutical expenditures, France, Germany, Sweden, and the United Kingdom each employs an array of policies, some regulatory and some market-based. The balance struck varies from country to country—ranging from controlling corporate and physician actions by legal and administrative sanctions to strengthening competition by reshaping incentives. For example, France has emphasized the regulatory approach by imposing stringent product-by-product price controls. By contrast, the United Kingdom has evolved a more eclectic strategy: profit controls—a relatively flexible regulatory approach that allows companies considerable pricing freedom—are coupled with policies to sharpen competition among drug companies by encouraging physicians to prescribe less expensive medicines.

A government's use of price or profit controls is sometimes confused with its preference for high or low drug prices. Though countries with unrestrained pricing tend to have high prices, the introduction in such countries of policies to strengthen competition might well reduce drug prices significantly. Likewise, though price controls tend to be found in countries (like France) with drug prices that are low, price controls and other types of price regulation could be used to achieve reductions in drug prices that are more modest. In short, it is important to distinguish the goals for drug prices from the means available to achieve those goals.

2. An effective approach to reducing pharmaceutical expenditures is likely to be multipronged, because policies exclusively aimed at drug prices are insufficient to control pharmaceutical spending.

Despite the existence in these countries of price and profit controls, total spending on pharmaceuticals has continued to rise. Contributing to this upward trend in spending is growth in both drug prices and the quantity of drugs sold. In turn, the quantity sold reflects the actions of drug companies as well as of consumers and their physicians. In line with this analysis, these countries have augmented their traditional controls, which primarily targeted the pharmaceutical industry, with additional strategies aimed at consumers and physicians. These policies—such as the increased use of cost-sharing and the adoption of physician drug budgets—are intended to encourage consumers and physicians to more carefully evaluate whether a prescription should be written, or whether a lower-priced drug could be substituted for a higher-priced product.

3. The presence of pharmaceutical price regulation does not preclude the existence of an innovative drug industry, but lower drug prices can discourage pharmaceutical research and development. However, it cannot yet be determined the extent to which less R&D translates into fewer new drugs that offer substantial therapeutic improvements.

In France, Germany, Sweden, and the United Kingdom, innovative industries coexist with drug price regulation. However, our analysis indicates that higher drug prices contribute to the development of new drugs by encouraging firms to devote more resources to R&D. Therefore, a decline in drug prices, from whatever cause—regulation, pro-competitive policy, or other market forces—can be expected to lead to a decline in firms' expenditures on R&D for new drugs.

The significance of less R&D is clouded by several factors. First, the extent of the response of R&D to lower drug prices has not been established precisely. Second, the significance to society of a reduction in R&D would be greater if only breakthrough drugs were affected, and much less if only the development of me-too drugs were slowed.

Although government regulation has restrained drug prices in the four countries we examined, the implications—and the desirability—of similar intervention in the U.S. pharmaceutical market are unclear. More specifically, the effects of a price reduction in any of these countries may differ from the effects of a similar price reduction in the United States,

because each country represents a relatively smaller share of the global pharmaceutical market. In addition, the particular price and spending control policies used in these countries may not be readily transferrable to the United States because of institutional differences across countries. In any case, any gains from regulation of drug prices or spending must be weighed against the consequences of such regulations for pharmaceutical research and development.

France's Drug Spending Control Policies

As a result of France's strategies to control pharmaceutical spending, drug prices in France are among the lowest in Europe. In conjunction with its regulation of the health insurance system, the French government has imposed a variety of controls on pharmaceutical prices that apply to participants throughout the pharmaceutical market: drug manufacturers, drug wholesalers and pharmacists, consumers, and physicians.

Although France's low prices have kept pharmaceutical expenditures from rising faster than they would have without its price controls, persistent rapid growth in spending has led the French government to consider supplementing price controls with significant new measures. France's low prices are viewed by some government officials and academic experts as encouraging over-consumption while discouraging drug companies from investing more in research and development. In 1991, the Socialist government then in power proposed a reform that called for two principal budgets: (1) a global budget for total pharmaceutical expenditures, composed of budgets for each manufacturer; and (2) budgets for certain innovative drugs. The reform was designed to mitigate the unwanted side effects of price controls by limiting increases in drug costs while encouraging expenditures on R&D; the government withdrew this plan from consideration after extensive debate. However, in January 1994, pharmaceutical industry representatives and government officials reached an agreement that adopts many aspects of this proposal.

Overview of the French Health Insurance System

The current French health care financing system, established in 1945, is part of the Social Security system (Sécurité Sociale). In keeping with a tradition dating back to 1893, when free medical assistance was first granted to the poor, it is designed to provide universal access to health care.

Three main national health insurance funds provide comprehensive health insurance to over 98 percent of the population. Most people—approximately 75 percent—belong to a single national "sickness fund"—in effect, a highly regulated nonprofit insurer; all other insured are covered by the other two national health insurance funds or one of 15 special (occupation-based) funds. Consumers do not pay deductibles for health care services, but copayments for physician and hospital services can reach 30 percent of the regulated fees. Most people (about 72 percent) also have complementary nonprofit and private insurance to pay the consumers' share of the costs not covered by their standard benefit package.

In 1991, health care represented 9.1 percent of the French Gross Domestic Product. The Social Security system financed about 73 percent of these expenditures. The government and local authorities contributed another 1.1 percent through earmarked taxes; private and nonprofit complementary insurance contributed 6.2 percent; and consumers paid the remainder out-of-pocket (about 19.7 percent).

Employers and employees both share in the cost of health insurance based on a government formula. The employers' and employees' contribution as a share of gross wages and salaries average about 12.8 and 6.8 percent, respectively. In 1991, total health care expenditures, which have slowly risen in real terms, were 498,130 million francs (or about $88.3 billion in 1991 dollars).

Pharmaceutical Coverage in the French Health Insurance System

The Social Security system is the principal purchaser of pharmaceuticals, which accounted for approximately 14 percent of the French health care budget in 1991. The system, together with French private and nonprofit insurance funds, provides nearly complete coverage for pharmaceutical products in France. Usually, consumers pay the full cost of the prescription and complete a form requesting reimbursement from the Social Security system or health insurer. However, consumers in France sometimes ask pharmacists to request the reimbursable amount directly from the Social Security system or the insurer and pay only the copayment amount.

About 4,200 different drug products are available on the French market. In contrast to other European countries, France has virtually no generic drug market.[1] The small size of the generic drug market is attributed to (1) low prices for brand name drugs and (2) French laws prohibiting pharmacists from substituting a generic drug for a brand-name drug.[2]

Spending Control Strategies Aimed at Drug Manufacturers

France uses a three-step process to set drug prices and closely monitors the increase in prices of new and existing drugs. Recently, government officials and pharmaceutical industry representatives supplemented the existing price setting process with an informal agreement that, among

[1]In 1991, generic drugs comprised less than 5 percent of total drug sales.

[2]Parallel imports—identical products imported from countries where drug prices are lower—are also discouraged for these reasons. However, because of France's low drug prices, it has benefited from "parallel exporting" and has been able to improve its pharmaceutical trade balance by acting as a form of drug discount warehouse to other countries.

other things, provides drug companies with greater flexibility in setting drug prices.

The Price Setting Process

In theory, drug manufacturers in France are free to set drug prices. In practice, France has price controls on most drug products, representing about 80 percent of the drugs sold in France.[3] Since Social Security is the largest payer of pharmaceuticals, the government is able to induce manufacturers to offer most products at the government-set level.

Introductory drug prices are determined in a three-step process.[4] First, the AMM (Autorisation de mise sur le marché) Commission, similar to the U.S. Food and Drug Administration, reviews each drug for quality, safety, and efficacy to determine whether to issue a marketing license.

Second, the Transparency Commission, composed in part of representatives from industry, medical universities, the national sickness funds, and the Ministries of Health and Social Affairs, reviews each drug to determine whether, compared to the existing drug for the same indication, it will be more cost-effective and produce better clinical results or fewer side effects. The Transparency Commission recommends a "technical price," based in part on whether the drug represents a major or minor advance in therapy and on the number of drugs in the same therapeutic class. If no other drugs are in the class, the Commission evaluates the new drug by comparing it to the average cost of treating the disease without this drug. If the Commission finds that the new drug offers additional therapeutic value relative to currently available drugs or treatments, a higher price is granted to the drug.

Third, the Economic Committee, primarily composed of representatives from four government ministries (the Ministries of Finance, Economics, Health, and Social Affairs), reviews the Transparency Commission's recommended technical price and the manufacturer's suggested price. Following this review, the Economic Committee proposes to the manufacturer an "economic price" for the drug. This economic price may be higher than the technical price if the new drug is expected to offer benefits to the national economy, such as increased exports, job creation, increased investments, or more R&D.

[3]About 11 percent are sold in hospitals, which negotiate drug prices on their own. The remaining 9 percent are sold privately, without any price constraints.

[4]During this three-step process, the government also sets the reimbursement rate of outpatient prescription drugs paid for by the Social Security system.

The economic price becomes the basis of negotiations between representatives of the Economic Committee and the manufacturer over the launch price of the drug and, in effect, becomes the drug price after the negotiations are completed. The negotiations between the Economic Committee and the manufacturer may last 6 to 12 months. A manufacturer can accept or reject the proposed economic price, which is fixed for a period of 2-1/2 years.[5] However, most manufacturers eventually agree with the Committee's proposed price because sales volumes would otherwise be drastically reduced.[6]

Drugs not reimbursed by the Social Security system are subject to review by the AMM Commission, but not subject to reviews by the Transparency Commission or Economic Committee. Manufacturers of these drugs, which account for about 10 percent of the drug market, can set prices freely.[7]

Determination of Drug Price Increases

For drugs marketed longer than 2-1/2 years, price increases are strictly controlled. The government limits the price changes for these drugs through blanket pricing directives, which raise or lower the price of all drugs on the market by a set percentage.[8] The most recent directive, issued in 1991, mandated a price decrease of 2.5 percent on all drugs. The term "blanket pricing directive" is somewhat misleading, because it does not apply uniformly to all drugs. Rather, the price change for individual drug products may exceed or fall short of the "blanket" price change, as the firm's average increase or decrease is equal to the mandated "blanket change."

Proposal Calling for Global and Individual Drug-Specific Budgets

A 1991 reform proposed by the government to the National Assembly would have provided manufacturers with incentives to increase research and capital expenditures, limited increases in drug prices, and promoted the more cost-effective use of drugs without reducing France's high level of social benefit coverage. The reform would also have limited the amount spent by manufacturers on advertising, which some believe is excessive.

[5]Price increases for new drugs—drugs on the market for less than 2-1/2 years—are seldom granted.

[6]There are no examples of important drugs that are not reimbursed by the government.

[7]These items are generally over-the-counter drugs. In some cases, they are products which are put on the market despite the lack of an agreed upon price between the manufacturer and the government. Examples of this latter group of products include third-generation contraceptives and nicotine patches.

[8]One industry official told us that the government has increasingly opted to reexamine and lower the prices of individual drugs marketed after 30 months, especially if the quantities sold are significant.

To discourage consumption, the government proposed setting a global limit on reimbursement for prescription drugs through the Social Security system. This global limit would have been subdivided into separate budgets that would apply to total sales, manufacturer by manufacturer. Within each manufacturer's sales budget, the manufacturer could freely set each drug's price. Innovative drugs would have been given separate drug-specific budgets for a period of 5 years as a means of encouraging investment. A manufacturer exceeding its budget would have been required to explain why and to refund most of all of the excess to the Social Security system. The proposal was controversial and was withdrawn on December 31, 1992.[9] However, in January 1994, pharmaceutical industry representatives and government officials supplemented the existing price setting process with an informal agreement that incorporates many aspects of the 1991 proposal. It would establish a target growth rate for pharmaceutical expenditures and provide greater flexibility to drug companies in setting prices. In addition, the agreement may result in a reduction in reimbursement rates for older products. Details of this agreement were not available at the end of January 1994.

Spending Control Strategies Aimed at Drug Wholesalers and Retailers

In France, the government regulates wholesale and retail margins to help control retail prices of prescription drugs.[10] These margins are regulated by decree and expressed as a percentage of the manufacturer's price.[11] According to a government official, modifying the value-added tax and pharmacists' and wholesalers' margins has produced substantial savings in pharmaceutical costs over the past 20 years. These modifications over the last two decades made it possible to lower the retail price of drugs by more than an estimated 25 percent; these reductions were accomplished without altering manufacturers' prices. In 1991, the numerous successive reductions of margins undertaken since 1967 resulted, according to a government estimate, in savings of nearly 20 billion francs (or about

[9]The government did, however, increase the tax on sales promotion costs from 7 percent to 9 percent. This increase, which took effect at the end of 1992, is viewed by the pharmaceutical industry as an indirect means of limiting expenditures on sales promotion.

[10]Wholesale and retail margins are not controlled by the government for nonreimbursable drugs; however, these margins are only slightly higher than the margins for reimbursable drugs.

[11]The normal wholesalers' margin is set at 10.74 percent of the manufacturer's price before tax. The pharmacist's before tax gross profit is calculated according to a sliding scale, which decreases in proportion to the price of the drug.

$3.55 billion in 1991 dollars)—roughly one-fifth of that year's pharmaceutical expenditures by the government.[12]

Spending Control Strategies Aimed at Consumers

In France, the consumer's share of drug costs represents the proportion of the drug cost not reimbursed by the Social Security system. Each drug's reimbursement rate is set at either 100, 65, 35, or 0 percent of the drug's cost, and the consumer pays the remainder.[13] The government sets the reimbursement rate of outpatient prescription drugs paid for by the Social Security system during the three-step price setting process described earlier.

Specifically, the Transparency Commission recommends one of three reimbursement rate categories. The reimbursement rate represents the proportion of the drug cost covered by the Social Security system. The reimbursement rate is set at 100 percent for 128 vital medicines and for all drugs used to treat patients with any one of over 30 diseases (defined as "long and costly"), such as Parkinson's disease and AIDS. The reimbursement rate declines to 35 percent for drugs used to treat disorders or ailments that are not normally severe (e.g., antiseptics and laxatives). Prescription drugs not reimbursed at 35 or 100 percent are reimbursed at 65 percent. The Economic Committee reviews the Transparency Commission's recommended reimbursement rate and determines a final reimbursement rate.

Certain groups of people are exempt from copayment. These include the chronically ill, the poor, the handicapped, and expectant mothers. Table I.1 shows that a large portion of the government's expenditure for prescription drugs is for drugs that do not require consumer copayment (i.e., drugs reimbursed at 100 percent).

Table I.1: Percentage of Prescription Drug Expenditures by Reimbursement Categories in 1991

Reimbursement categories[a]	Percent of expenditures	Percent of total market
100 percent	41.0 percent	1.0 percent
70 percent	48.0 percent	64.0 percent
40 percent	11.0 percent	21.0 percent

[a]Prior to July 1993, the reimbursement rates were set at 100, 70, 40, or 0 percent of drug costs.

Source: P. Etienne Barral.

[12]We did not obtain sufficient information to validate these government estimates.

[13]In actual practice, most patients have supplementary insurance for prescription drugs. This insurance picks up most, if not all, of the copayment cost.

Proposal to Limit Full Drug Reimbursement Cost

A 1987 plan reduced the number of drugs reimbursed at 100 percent by limiting it to specific drugs for specific illnesses, rather than all drugs for specific illnesses, but this plan was controversial and was rescinded after 1 year.

Spending Control Strategies Aimed at Physicians

In France, the government uses three measures aimed at providing physicians with prescribing information. The government also periodically reviews its drug reimbursement list and recently established a drug agency, which will focus on scientific and technical matters.

Provide Physicians With Prescribing Information

Pharmaceutical consumption in France is high compared to other European countries. As a result, the government has instituted three measures designed to reduce drug consumption. First, medical-social commissions examine each physician's prescribing pattern and ask physicians prescribing more than the average to limit their prescribing.

Second, the Ministry of Health distributes transparency sheets designed to provide summary information to physicians—for example, data on the costs of daily treatment, dosage forms, and drug interactions—which helps them select the appropriate drugs. As of December 1991, 30 transparency sheets had been issued; however, these have been criticized for being out-of-date, incomplete, and overly complex.

Third, the national convention of physicians tracks prescription drug costs in relation to the number of physicians' office and home consultations on a quarterly basis. These data are supposed to enable physicians to prescribe more cost-effectively by self-monitoring their prescribing patterns; however, this does not appear to be the case, as physicians frequently ignore such data.[14]

Periodic Review of the Reimbursable Drug List

France also uses a list to define all drugs eligible for reimbursement at the 100-percent, 65-percent, and 35-percent levels. The government periodically evaluates a drug's reimbursement status and sometimes lowers the reimbursement category for particular drugs (for example, from 65 percent to 35 percent).

In January 1994, the French government adopted a body of guidelines restricting 24 drugs or procedures. These guidelines, which are based on

[14]In December 1992, the National Assembly passed a law calling for tighter physician controls. One of the controls resulting from this law is described below.

an agreement between the insurance industry and the principal French physicians' unions, include restrictions on treatments for conditions such as pregnancy, hypertension, and hypoglycemia. Physicians consistently practicing outside the guidelines will be asked to explain their actions before a local committee of physicians and insurance representatives and can be assessed a financial penalty if they fail to provide a justifiable explanation for these practices.

Creation of New Drug Agency

In December 1992, the National Assembly approved the creation of a new drug agency. The new agency does not involve itself in pricing and reimbursement decisions; rather, it confines itself to scientific and technical issues and is similar in function to the U.S. Food and Drug Administration. The agency provides a stronger, more modern structure for the registration of drugs and for guaranteeing their quality, safety, and efficacy.

Germany's Drug Spending Control Policies

Pharmaceutical spending control strategies in Germany are designed to restrain the growth of drug expenditures without directly controlling drug prices. As part of its regulation of the health insurance system, the German government has imposed a variety of controls on pharmaceutical payment that apply to various participants in the pharmaceutical market: drug manufacturers, drug wholesalers and pharmacists, consumers, and physicians.

Increasing drug expenditures have led to several changes in the German regulations over the last 5 years. For instance, in 1989, the government adopted its first regulations limiting payments to drug manufacturers. The government also increased consumers' copayment levels at that time. Continuing increases in pharmaceutical spending led to further constraints in 1993 whereby the government mandated global budgets for pharmaceuticals, reduced prescription drug prices, increased consumers' copayment levels, and tightened controls over physicians' prescribing patterns.

Overview of the German Health Insurance System

The foundation of the modern German health care system was laid by Bismarck in 1883. Today, this system guarantees universal health care coverage to all German residents by requiring that working persons, regardless of income, have health insurance and by providing coverage for the unemployed. Germany has a multipayer system comprised of over 1,200 sickness funds. Approximately 90 percent of the total population is insured by statutory sickness funds and almost all of the remainder obtain private health insurance.

Health care, comprising about 8.5 percent of Germany's gross domestic product in 1992, is financed primarily through government-mandated contributions shared equally by workers and their employers. The required premium contribution operates much like a payroll tax—a fixed percentage of the employee's gross compensation is deducted from each paycheck and transferred directly to the private nonprofit sickness funds. The current contribution rate averages about 13.4 percent of wages up to the statutory income ceiling, with the employer and employee each paying half of this premium. The contribution rates for individual sickness funds, which are revised annually, range from 8.5 to 16 percent.

Under the sickness fund system, premiums reflect the incomes of the members as opposed to their actuarial risk. About 60 percent of health expenditures were derived from the sickness funds, about 21 percent from

general taxation, about 7 percent from private insurance, and about 11 percent from unreimbursed out-of-pocket expenditures. In 1992, total sickness fund expenditures were Deutsche Mark 167.29 billion (or about $107.24 billion in 1992 dollars).

Pharmaceutical Coverage in the German Health Insurance System

Sickness funds provide nearly complete coverage for pharmaceuticals. Consumers pay about $1.84 to $4.29 per drug prescribed, depending on the cost of the drug, and the sickness funds pay the difference.[1]

Almost 10,000 different drug products are available on the German market. These include both innovative drug products and generic drugs. Generic drugs are widely used in Germany, accounting for about 27 percent of prescriptions and about 18 percent of sales in 1992. In contrast to other European countries, there is little use in Germany of parallel imports—identical drug products imported from countries where drug prices are lower.[2]

Spending Control Strategies Aimed at Drug Manufacturers

Germany's principal spending control strategy aimed at drug manufacturers is the reference price system. This system does not set drug prices; rather, it sets the reimbursement levels at which sickness funds pay for each prescription drug (consumers pay the amount by which the product prices exceed the reimbursement levels). RPS has two primary functions: first, to lower the prices of drugs by inducing price competition, and second, to encourage greater use of generic drugs by making consumers pay a greater share of the cost of higher-priced, brand-name drugs.

In addition to RPS, Germany recently instituted two additional policies to restrict sickness funds' pharmaceutical expenditures: global drug budgets, and an order for manufacturers to lower their drug prices.

The Reference Price System

Reference prices for outpatient prescription drugs are determined in a two-step process. First, a commission comprised of physician and sickness fund representatives meets with scientists, manufacturers, and

[1]In addition, for drugs having a fixed reimbursable price, consumers also pay the difference between the drug's price and the fixed amount, if the drug exceeds that fixed amount.

[2]However, as of mid-1993, parallel imports must be sold when they are (1) legally on the market (i.e., importers have to obtain a marketing permit from the government) and (2) at least 10 percent and DM 1 cheaper than the drug produced in Germany.

pharmacists to group drugs into three classes. The three classes, established by the 1989 Health Care Reform Act, are the following:

- Class 1—drugs with the same active ingredients (that is, generic substitutes), which account for about 35 percent of Germany's total pharmaceutical market;
- Class 2—drugs with therapeutically comparable active ingredients (for example, different beta-blockers or H-2 antagonists); and
- Class 3—drugs with therapeutically comparable effects (e.g., aspirin combinations).[3]

The commission considers several specific factors when grouping drugs into classes. For example, differences in bioavailability of Class 1 drugs must be considered if they are relevant in the therapy.[4] Further, the grouping of drugs into Classes 2 and 3 must not restrict the availability of any medically necessary alternative therapy.

Second, representatives from the sickness funds propose a reference price for each grouping of drugs. A statistical methodology is used to calculate what is, in effect, an average price of drugs within a similar group; this average price varies with the strength and package size of a drug product, within each group of drugs. The reference price is set below the price of the most expensive drug in the group (typically the leading brand-name drug) and above the price of the least expensive drug (typically a generic drug). This price is finalized after conferring with drug manufacturers and pharmacists. The reference price is adjusted at least annually, taking into account inflation and other factors.

All prescription drugs available in Germany are covered by RPS, with the exception of (1) specified prescription drugs defined in the German Drug Act (e.g., vaccines), (2) pharmacy-made drugs, and (3) patented prescription drugs with a new active ingredient representing a therapeutic improvement or having fewer side effects than existing drugs.[5,6]

[3]Together, drugs in Classes 2 and 3 account for about 14 percent of Germany's pharmaceutical market.

[4]Bioavailability refers to the speed and extent to which a substance reaches the circulatory system.

[5]The 1993 reforms expanded the number of patented drugs exempt from RPS by clarifying what constitutes an innovative drug.

[6]In Germany, many single-source products that lack comparable products cannot be assigned reference prices. Furthermore, other products do not yet have reference prices because of the technical difficulties in ascertaining which products have comparable therapeutic ingredients or actions. In 1993, the German government simplified the way that drugs are put into comparable groups. The government hopes that this simplification will allow for the eventual inclusion of 70 percent of drugs into the reference price system.

Global Drug Budgets

As part of its 1993 health financing reforms, the German government established an annual budget for drug spending by the sickness funds. The 1993 budget set the pharmaceutical drug budget for office-based physicians at the 1991 expenditure level (approximately DM 24 billion, or about $14.7 billion in 1993 dollars). Expenditures above DM 24 million, up to DM 280 million (or about $175 million), would have been offset by a reduction in the 1994 ambulatory care physician budget. Additional overruns between DM 280 million and DM 560 million (or about $343.6 million) would have been paid for by the pharmaceutical industry through a reduction in drug prices. However, total drug spending for 1993 stayed within the budget.

For the 1994 budget, regional physicians' associations were given two options: (1) a 1994 global budget set at the 1993 level, but with cost overruns borne solely by reductions in the ambulatory care budget (rather than having the reductions capped at DM 280 million, as in 1993), or (2) negotiating a budget based on 1993 expenditures for the region. Most of the regional physicians' associations have chosen the first option.

The government does not consider global budgets to be an adequate long-term solution to structural health care problems. As such, the fixed budget for prescription drugs is considered to be only a temporary remedy for a period of 3 years to curb drug expenditures. It will remain in effect until the regional physicians' associations and the sickness funds agree on indicative prescribing amounts.

Mandated Reductions in Drug Prices

Also under the 1993 reforms, Germany undertook two new efforts aimed at drug manufacturers. First, it required manufacturers to reduce their non-RPS drug prices by 5 percent and reduce the prices of their over-the-counter products 2 percent below the May 1992 level. Second, the reform requires a price freeze for these drugs during 1993 and 1994. It was the first time that the German government had taken such steps.

Spending Control Strategies Aimed at Drug Wholesalers and Retailers

In Germany, the government sets allowable markups for drug wholesalers and retailers. These margins are in inverse proportion to drug prices; however, drug sellers have an incentive to increase their revenues by selling higher-priced drugs because they receive more revenues from selling a higher-priced drug than they do from selling a lower-priced drug.

Wholesale margins vary between 12 and 21 percent of the manufacturer's price, with the rate decreasing as the manufacturer's price increases.[7] Retail margins vary between 30 and 68 percent of the wholesale price (exclusive of the 15 percent value-added tax), with the rate decreasing as the wholesale price increases. In addition, German pharmacies are required by law to give the sickness funds a 5-percent discount off the drug's retail price. Table II.1 provides an example of the pricing structure for a drug, starting with the manufacturer's price and ending with its effective retail price.

Table II.1: A Typical Example of Pharmacy Pricing in Germany

Item/action		Amount
	Manufacturer's price	DM 15.00
+	Wholesaler's markup (18 percent)	DM 2.70
=	Wholesaler's selling price	DM 17.70
+	Pharmacy's markup (48 percent)	DM 8.50
=	Net pharmacy retail price	DM 26.20
+	Value-added tax (15 percent)	DM 3.93
=	Gross pharmacy retail price	DM 30.13
-	5-percent discount to sickness funds	DM 1.51
=	Effective retail price	DM 28.62

Source: Bundesvereinigung Deutscher Apothekerverbände (ABDA).

Spending Control Strategies Aimed at Consumers

The German government, at different times, instituted varying levels of consumer cost sharing. These policies have been implemented for several reasons: to shift some of the financial burden of pharmaceuticals from the sickness funds to consumers; to decrease utilization by making consumers aware of the costs of drugs; and to encourage consumers to choose less expensive drugs (such as generic substitutes) by having lower copayments on less expensive drugs.

The 1993 health reforms require consumers to make copayments on all drugs, regardless of whether the drugs have a reference price (previously, copayments were required only for drugs not under RPS or for drugs where the sales price exceeded the reference price). Since January 1994, copayment levels have been linked to the quantity of drugs purchased.[8]

[7]Wholesalers may reduce their margins to some extent; however, the savings must, by law, be passed on to pharmacists, not to consumers (that is, retail prices may not be reduced).

[8]In 1993, copayment levels were linked to the prices of drugs purchased.

Consumers are required to pay DM 3 (or about $1.84) for small quantities, DM 5 (or about $3.07) for medium quantities, and DM 7 (or about $4.29) for large quantities.[9] Upper limits on consumer cost sharing are based on gross income and family size.[10] Exemptions are given to drugs administered during pregnancy or directly related to pregnancy, children under 18 years old, and persons with low income. In addition, consumers pay the amount by which a product's price exceeds the reference price.

Spending Control Strategies Aimed at Physicians

In an effort to spread the burden of rising pharmaceutical costs, the government has tried to persuade physicians to prescribe more cost-effectively through the use of transparency lists and price lists; however, until recently, it had no direct means of persuading physicians to prescribe more cost-effectively. The 1993 reforms gave the government more leverage on affecting physician prescribing habits by instituting global drug budgets and through the future development of a streamlined list of drugs eligible for reimbursement.

Physician Drug Budgets and Increased Monitoring of Physicians' Prescribing Patterns

Office-based physicians in Germany bear financial responsibility for drug spending levels that exceed the annual budget. As discussed above, the 1993 pharmaceutical drug budget for office-based physicians was frozen at approximately DM 24 billion (or about $14.7 billion). Expenditures above DM 24 billion, up to DM 280 million (or about $175 million), would have been offset by a reduction in the ambulatory care physician budget; however, total drug spending for 1993 stayed within the budget. In 1994, physicians will bear sole financial responsibility for exceeding the 1994 drug budget.

As an additional measure to promote drug spending control, regional associations of office-based physicians and sickness funds are responsible for monitoring physicians' prescribing patterns and for establishing ceilings for the volume of drugs prescribed. Under the 1993 reforms, the regional associations of office-based physicians and sickness funds are now required to conduct an inquiry if physicians exceed standard

[9]The determination of what is a small, medium, or large quantity depends on the illness and the dosage. For example, for diabetic medications, a 20-tablet prescription is considered a small quantity, while for sedatives, a 20-tablet prescription is a medium prescription.

[10]The upper limit is based on the following formula: limit = (AGI - deduction) x percentage, where AGI is the annual gross income; deduction equals DM 0 for family of 1, DM 7,056 for family of 2, DM 4,700 for each additional family member; and percentage equals 2 percent for AGI below DM 68,400 or 4 percent for AGI above DM 68,400.

prescribing amounts for the region and their specialty by 15 percent and to seek redress if this amount is exceeded by 25 percent.[11]

Evidence suggests that these two actions have significantly affected physicians' prescribing patterns. In the first half of 1993, the number of drugs prescribed was about 17 percent below the 1992 level, and total sickness fund prescription drug expenditures declined by about 22 percent compared to the same period in 1992. There was a greater decrease in the use of drugs for which the therapeutic effect is less widely accepted than for more therapeutically meaningful drugs. For example, the prescriptions for vitamins, mineral preparations, and vein therapeutics fell by about 30 percent, while the decrease in prescriptions for antibiotics fell by about 5 percent, for beta-blockers by about 10 percent, and for anti-diabetes drugs by less than 1 percent.

Several reasons have been suggested for the drop in drug sales. First, physicians substituted cheaper generic drugs for more expensive, brand-name drugs. As a result, sales of the cheapest generic drugs have increased in some cases by as much as 250 percent. Second, physicians increasingly prescribed older products instead of newer, more innovative drugs. Third, patients—especially those with chronic illnesses (for example, diabetes)—obtained their prescriptions in December 1992 (just before the new regulations took effect) and thus did not need to acquire their drugs in the first few months of 1993. Fourth, physicians seem less willing to prescribe drugs with doubtful efficacy (such as anti-varicosis drugs) or for conditions that can be treated without drugs (such as diets for obesity). Finally, uncertainty and misinformation about how to manage within a drug budget caused physicians to curtail their prescribing more often than necessary.

Establishment of a Reimbursable Drug List

The 1993 reforms also call for increased use of drug lists to define eligibility for reimbursement by the sickness funds. The German government will establish a new Pharmaceutical Institute to develop a detailed list of the drugs for which the sickness funds will provide reimbursement after 1995. This list will replace the list of nonreimbursable drugs currently in use. This list covers medicines that have more than three active ingredients or those for which the effect of the active ingredients has not been therapeutically proven. Currently, about 2,200

[11]Until the beginning of 1993, these regional associations notified physicians surpassing their ceiling by more than 20 percent and those exceeding their ceiling by 40 percent were required to justify their actions. However, few physicians were penalized for over-prescribing, even though approximately 10 percent of the physicians surpassed their ceilings by more than 20 percent annually.

drugs are on the nonreimbursable list, accounting in 1992 for DM 140 million (or about $89 million in 1992 dollars) in sales.

Sweden's Drug Spending Control Policies

As a result of Sweden's pharmaceutical spending control strategies, drug prices in Sweden are at about the European average. Through its regulation over the health insurance system, the Swedish government has imposed a variety of controls on outpatient prescription drug prices that apply to various participants in the pharmaceutical market: drug manufacturers, drug wholesalers and pharmacists, consumers, and physicians.

In 1993, the Swedish government implemented important changes to the drug pricing regulations designed to reduce pharmaceutical costs, provide incentives for R&D, and comply with the European Community's directive on transparency of pharmaceutical pricing.[1] These reforms reassigned responsibility for negotiating the prices of reimbursable drugs, introduced RPS for reimbursing brand-name drugs where equivalent generic drugs exist, and increased the patient copayment level for outpatient prescription drugs. The reforms are expected to save the government up to SEK 1 billion (about $133.69 million): SEK 600 million (or about $80.21 million) from increasing the patient copayment and SEK 400 million (or about $53.48 million) from the introduction of RPS.[2]

Overview of the Swedish Health Insurance System

The fundamental principle of Sweden's social welfare system is that all citizens are entitled to good health and equal access to health care, regardless of where they live and their social and economic circumstances. In line with this principle, health care is seen as a public sector responsibility supported by a national health insurance system and by other social welfare services. In 1955, Sweden expanded social insurance benefits by establishing a comprehensive national health insurance system that provides health care, sickness, and maternity and parental benefits to Swedish citizens and alien residents. Today, health insurance pays for part of the cost of outpatient medical and dental care, and most of the cost of prescription drugs and hospital care, in addition to other services.

The National Social Insurance Board is the government agency that oversees these benefits in Sweden. It centrally administers and regulates

[1]The European Community's transparency directive requires its member countries to publicly disclose the rules governing pricing of prescription drugs. It does not interfere with the right of countries to control prices or reimbursement by any method they choose, provided the method used is based on objective and verifiable criteria and does not discriminate between foreign and domestic drug manufacturers. Although Sweden is not a European Community member, it is seeking membership.

[2]All dollar figures cited in this appendix were calculated using the average exchange rate for the first quarter of 1993.

the activities of 26 regional offices, which manage local social insurance programs.

In 1989, health care comprised about 8.6 percent of the gross domestic product. The system is primarily financed through employer contributions, with additional funding coming from state grants.

Pharmaceutical Coverage in the Swedish Health Insurance System

The national health insurance system provides nearly complete coverage for outpatient prescription drugs. NSIB sets the prices at which eligible drugs will be reimbursed. NSIB reimburses at these prices, less the patient copayment rate (if such rate applies). NSIB pays the balance of the cost directly to Apoteksbolaget (the National Corporation of Swedish Pharmacies), which reimburses the pharmacies.[3]

Over 3,000 different drug products are available on the Swedish market. Generic drugs are currently used in Sweden and the establishment of Sweden's reimbursement rate setting system is expected to further increase generic drugs' share of the market.[4] In contrast to other European countries, there is no use of parallel imports—identical products imported from other countries where drug prices are lower—because this practice is forbidden under Swedish law.[5]

Spending Control Strategies Aimed at Drug Manufacturers

Since January 1993, Sweden's principal strategy for controlling prescription drug prices has been through a reimbursement system that sets the prices that the national health insurance system will pay for prescription drugs.[6] The government determines the reimbursement level in one of two ways: (1) through RPS, which sets the reimbursement price

[3]Apoteksbolaget's legal foundation is based on an agreement with the government, which owns two-thirds of the shares.

[4]Currently, generic drugs account for about 13 percent of the pharmaceutical market in Sweden. Some officials expect that generic drugs' share of the market could increase to 25 percent under the reforms implemented in 1993 and that the government can save an additional SEK 800 million (or about $107 million) per year by using more generic drugs.

[5]Parallel imports and exports may be permitted after 1994, when an agreement between the European Community and the European Free Trade Association is ratified.

[6]Prior to implementation of RPS, Sweden directly set drug prices. The agency responsible for setting prices, Apoteksbolaget, negotiated with manufacturers the wholesale prices of all pharmaceutical drugs sold in Sweden—prescribed and over-the-counter—with the aim of setting Sweden's drug prices no more than 5 to 10 percent higher than the average of other European countries. These price negotiations were required prior to registering and approving drugs for marketing. When Sweden implemented RPS, it transferred the price setting responsibility from Apoteksbolaget to NSIB (for only those drugs subject to reimbursement by the government).

for brand-name drugs where equivalent generic drugs exist, or (2) by directly setting the reimbursement price for those drugs not under RPS.

The Reference Price System

Reference prices are set for nonpatented reimbursable drugs that have at least one generic competitor on the Swedish market.[7] Under RPS, the reimbursable rate for a prescription drug—known as the reference price—is set at the price of the lowest generic drug equivalent plus 10 percent. Manufacturers are free to set drug prices exceeding the reference price; however, the amount of this excess must be paid by consumers.

NSIB publishes its reference price list every 3 months. Manufacturers objecting to a reference price can appeal to the government for a price change, but these appeals must be filed within 3 weeks after the publication of the reference price.[8]

Reimbursement Price for Drugs Not Under the RPS

Manufacturers of drugs not under RPS—new and patent-protected brand-name drugs and over-the-counter products—must negotiate and agree on a price with NSIB if they want to be included under the reimbursement system; otherwise, the drug will not be eligible for reimbursement. Manufacturers choosing not to seek reimbursement for drugs can price these drugs freely.

NSIB conducts negotiations using the same criteria formerly used by Apoteksbolaget in setting prices for all reimbursable drugs.[9] NSIB emphasizes a drug's therapeutic value and its estimated contribution in reducing overall health care cost. It also considers (1) the price of similar products sold in other countries; (2) the price of the same product sold in

[7]To be included under RPS, drugs must meet several other criteria, including having at least 20 percent of the drug's sales for outpatient use and being on the market for more than 6 months.

[8]During 1993, only one appeal was filed. This appeal did not concern the reference price per se but whether a certain product should appear on the price list.

[9]Until April 1993, Apoteksbolaget acted as a consultant to NSIB on price negotiation matters. At that time, NSIB added personnel to perform the price negotiations. NSIB strives, as did Apoteksbolaget, to set a reasonable wholesale price for each drug.

other countries; and (3) the price of the product in its home market.[10,11] Finally, NSIB considers a drug's projected sales volumes, R&D costs, manufacturing costs, and the manufacturer's legal fees.

Spending Control Strategies Aimed at Drug Wholesalers and Retailers

In Sweden, retail margins are controlled by the government. Wholesale margins are not regulated but result from negotiations between manufacturers and wholesalers. The manufacturers' prices to the wholesalers account for 68.2 percent of the pharmacy selling price. Wholesalers add 4.2 percent to the manufacturers' prices (their share accounts for 2.8 percent of the pharmacy selling price). Pharmacies add 41 percent to their purchasing price, which gives them a margin of 29 percent.[12]

Spending Control Strategies Aimed at Consumers

In an effort to reduce health care costs to the government, patient copayment rules and levels for outpatient prescription drugs were changed. Effective July 1992, the copayment level rose to SEK 120 (or about $16.04) for the first drug on the prescription and SEK 10 (or about $1.34) for each additional drug.[13] Effective January 1993, the upper spending limit per 12-month period was raised from SEK 1,500 (or about $200) to SEK 1,600 (or about $214).[14] As under the previous system, patients only paid the actual drug price if drugs were less than the patient copayment.

For drugs included in RPS, which are priced below the copayment limit and at, below, or above the reference price, a patient's out-of-pocket expense equals the actual drug price. For drugs included in RPS, which are priced above the copayment limit and above the reference price, a patient's

[10]Apoteksbolaget used the same criteria to set drug prices for domestic and international firms, but ensured that foreign firms did not receive higher prices for products sold in Sweden than in the firms' home markets. Further, Apoteksbolaget ensured that Swedish firms selling outside the country received high prices for their drugs in Sweden.

[11]Apoteksbolaget obtained information on price differentials from 11 Western European countries—agreed upon by pharmaceutical manufacturers in Sweden as representing a fair set of comparisons—from agencies within those countries and through discussion with manufacturers in Sweden about drug prices in foreign markets. In addition, Apoteksbolaget determined mean and median price differentials between Sweden and these other countries and tracked price increases and decreases from year to year.

[12]The figures represent averages for the sale of outpatient, prescribed pharmaceuticals.

[13]Until July 1992, the patient copayment for prescription drugs (up to 10 drugs at a time) was set at SEK 90 (or about $12.03).

[14]Once patients reach their upper spending limit on medical treatments and/or prescription drugs, all subsequent treatments/drugs are provided free of charge.

out-of-pocket expense equals the difference between the price of the drug and the reference price plus the copayment limit. For reimbursable drugs not included in RPS, patients pay the actual drug price of drugs priced below the copayment limit and pay the copayment limit for drugs priced above the copayment limit. For nonreimbursable drugs, patients pay the full drug cost. For certain drugs, which treat 32 chronic illnesses or disorders (e.g., insulin for diabetics, drugs for epilepsy), there is no out-of-pocket expense for the patients.[15,16]

Spending Control Strategies Aimed at Physicians

Prior to January 1993, Sweden did not have in place any cost control strategies aimed at physicians. Now, by law, physicians must inform patients about lower-cost generic prescription drugs. Quarterly information sheets issued jointly by the Medical Products Agency and NSIB provide physicians with data on lower-cost generic alternatives. Prescribing doctors can choose not to substitute a generic drug for a brand-name drug for medical reasons; if so, the prescribing doctor must inform the patient and provide a written notice to the pharmacist to this effect.[17]

Use of Drug Lists

Except for six drugs, all prescription drugs available in Sweden can be subject to government reimbursement at a fixed retail price, less the patient copayment rate (if such rate applies). In addition, over-the-counter drugs can be subject to reimbursement if the drug has a generic competitor and if the manufacturer negotiates the price of the drug with NSIB.

A proposed reform would have changed the reimbursement rules so that only prescription drugs—and not any over-the-counter drugs—were covered under the reimbursement system; however, this proposal was dropped because of strong opposition from consumers. According to a government official, there are no plans to develop a negative list in the near future.

[15]Brand-name drugs having a lower-priced generic competitor cannot be provided free of charge. However, exceptions can be made for special patients on established therapies.

[16]The drugs treating the 32 chronic illnesses or disorders account for 20 percent of the total cost of prescription drugs in Sweden, reimbursable drugs account for 70 percent, and free aids (for example, testing kits for diabetics) and foods (for example, lactose-free dairy products) account for 10 percent.

[17]Substitution by the pharmacist is permitted in cases where the doctor is unavailable and a delay can be of serious detriment to the patient.

The United Kingdom's Drug Spending Control Policies

Pharmaceutical spending control strategies in the United Kingdom are designed to restrain the growth of drug expenditures within the U.K.'s health care system while encouraging pharmaceutical industry investment and promoting pharmaceutical R&D. This dual purpose has led to a policy that gives manufacturers considerable pricing freedom but ties allowable profits to a firm's capital in the United Kingdom, thereby awarding higher profits to firms with more investment in the country.[1] The U.K. government also places strong emphasis on policies aimed at physicians, with the intent of encouraging the rational prescribing of drugs. In addition to these strategies, the U.K. government has imposed a variety of additional controls that apply to various other participants in the pharmaceutical market, including drug wholesalers and pharmacists, and consumers.

The government periodically reevaluates these strategies in an attempt to ensure that the range of strategies adopted balance each other and produce a coherent overall system. Among the most recent changes, adopted in an effort to restrain rising drug expenditures, is a 2.5-percent price cut on all drug products, followed by a 3-year price freeze. In addition, the government has announced that it will further limit the number of drugs NHS can offer.[2]

Overview of the United Kingdom's Health Insurance System

NHS, which falls under the Department of Health, operates the United Kingdom's health care policy. NHS offers comprehensive medical services, including basic primary, hospital, and community care services to all residents of the United Kingdom, at little or no charge. NHS also reimburses the cost of most prescribed drugs. While some people have private insurance, over 95 percent of the patients treated in the United Kingdom receive their treatment from NHS.

Health care, roughly 6.6 percent of the gross domestic product in 1991, is largely financed from general tax revenues. Additional funds are derived from payroll and local taxes; charges for prescriptions and other services such as dental treatment; and payments by private patients in public hospitals. In 1991, total NHS expenditures, which have slowly risen in real terms, were 28.2 billion pounds (£) (or about $49.5 billion in 1991 dollars).[3]

[1]Specifically, allowable profits are tied to that portion of the firm's capital in the United Kingdom that is devoted to sales to the National Health Service.

[2]NHS' drug expenditures have risen about 12 percent per year during the last 2 years.

[3]Except where otherwise noted, all dollar figures cited in this appendix were calculated using the average exchange rate for the first quarter of 1993.

Of this, £18.1 billion (or about $31.8 billion) went for hospital and community care services and about £7.7 billion (or about $13.5 billion) for primary care (including about £3.5 billion (or about $6.1 billion) for pharmaceuticals covered by NHS).[4]

Pharmaceutical Coverage in the United Kingdom's Health Insurance System

NHS provides nearly complete coverage for prescription drugs in the United Kingdom. It is, in effect, the principal purchaser of pharmaceuticals because it buys more than 90 percent of all prescription drugs in the United Kingdom. Consumers simply pay a flat copayment of £4.25 (or about $6.25) to the pharmacist, regardless of the price of the drug, and the government pays the difference. However, many consumers are exempt from copayment, including the poor, the elderly, children under 16, expectant and nursing mothers, and people suffering from certain long-term illnesses. As a result of these exemptions, only about 20 percent of prescribed items were dispensed with a patient copayment in 1991.

Over 4,000 different drug products are available on the U.K. market.[5] These include both innovative drug products and generic drugs.[6] In recent years, the government has promoted generic prescribing, which has led to an increase in the proportion of generic drugs that were prescribed and dispensed. Between 1987 and 1989, the percentage of generic drugs dispensed increased from 29 to 37 percent of all prescriptions.

Spending Control Strategies Aimed at Drug Manufacturers

The principal strategy for controlling brand-name drug prices in the United Kingdom is a profit control measure known as the Pharmaceutical Price Regulation Scheme (PPRS). Aimed at drug manufacturers, PPRS is designed both to ensure reasonable drug prices and to promote a strong and profitable pharmaceutical industry. The U.K. government has a separate strategy for encouraging price competition among generic drug prices.

[4]U.K. pharmacies carry two types of pharmaceuticals: (1) prescription drugs and (2) over-the-counter drugs. This latter category also includes some drugs with "pharmacy only" status; that is, drugs that do not require a physician's prescription but require a pharmacist's permission to be purchased. The government provides reimbursement for both prescription-only drugs and over-the-counter drugs unless they have been specifically prohibited from NHS use under the Selected List Scheme (which limits NHS reimbursement to specific drugs).

[5]Currently, parallel imports—identical products imported from other countries where drug prices are lower—make up about 8 percent of the pharmaceutical market in the United Kingdom. However, U.K. pharmacists are moving toward greater use of these products, primarily because of the higher profits derived from this practice.

[6]There are over 40 generic manufacturers in the United Kingdom. However, one manufacturer has 50 percent of the market, and two others dominate the other half of the market.

The Evolution of PPRS

PPRS has evolved from a series of voluntary agreements between the Department of Health and the pharmaceutical industry.[7] The first agreement, dating back to 1957, was actually a price regulation scheme. By 1969, it had emerged as a scheme focusing on overall profits rather than individual drug prices.[8] Subsequent versions essentially retained the scheme established in the 1969 agreement.[9] The most recent PPRS agreement took effect in October 1993, replacing the 1986 agreement.

PPRS Regulations on Profits and Price Increases

PPRS is an indirect means of controlling brand-name drug prices by regulating the overall profitability of manufacturers from their pharmaceutical sales to NHS.[10] Under PPRS, manufacturers are free to set prices for new drugs, taking into account the impact of their pricing decisions on their overall profit targets, but are required to obtain government approval before increasing prices of existing drugs.

Most pharmaceutical manufacturers are subject to profit controls through PPRS.[11] A majority of these manufacturers' profits are limited to 17 to 21 percent of capital invested in the United Kingdom devoted to sales to NHS, with the exact rate negotiated between the manufacturer and NHS. Other manufacturers—those with relatively low levels of capital invested in the United Kingdom—have allowable profits set at 4.5 percent of their total sales to NHS.[12] In addition, manufacturers may be allowed to keep additional profits—up to 25 percent over their target level—if, for example, these higher profits are attributable to new products or

[7]PPRS is not governed by specific law. Rather, the agreement provides flexibility so that arrangements with individual manufacturers reflect the varying commercial practices within the industry.

[8]In the 1969 version, individual manufacturers' profits and costs became the focus of the price regulatory arrangements. This version required manufacturers to produce an annual financial return showing sales and their associated costs.

[9]The 1978 version renamed the scheme "Pharmaceutical Price Regulation Scheme." In 1986, generic drugs were removed from the scheme, leaving only brand-name drugs under PPRS.

[10]PPRS regulations apply to all firms with sales to NHS of over £0.5 million (or about $740,000) per year.

[11]As of October 1993, only manufacturers with sales of £20 million (about $29 million) or more are required to provide detailed financial information. There are currently about 43 such manufacturers. Under the previous version of the PPRS agreement, manufacturers with sales of £4 million (about $6.9 million) or more were required to provide detailed financial information. Less detailed controls apply to the 46 manufacturers with annual sales between £1 million (about $1.5 million) and £20.0 million.

[12]A firm's allowable profit is based on sales, rather than on capital invested in the United Kingdom, if its annual sales are greater than 3.75 times its U.K. capital investment. Of the 43 manufacturers with sales exceeding £20 million, 7 are assessed on a return-on-sales basis.

increased efficiencies.[13] Manufacturers exceeding their approved targets (including the permitted excess) must repay the government or agree to lower the prices of their existing drugs.

A three-step process is used to enforce PPRS. First, each manufacturer is required to provide NHS with sales, investment, and cost data, which allow the government to determine the manufacturer's profits.[14] Second, the government conducts an assessment of the manufacturer's capital investments in the country.[15] Third, the government assesses the manufacturer's costs, including the cost of goods, distribution, promotion, and R&D.[16]

Even under the profit control scheme, drug manufacturers are still subject to drug pricing regulations. While manufacturers freely set prices when first introducing new drugs—so long as total profits do not exceed the target level—they cannot increase drug prices without prior government approval. Only manufacturers not achieving their basic target profits may apply for price increases. In any one year, the government receives applications from between 15 to 20 companies for price increases. Increases granted in accordance with PPRS are generally below the rate of inflation and only enough to bring manufacturers up to their targets. In recent years, the drug price increases have increased the drug bill by less than 2 percent.

The most recent PPRS agreement imposed even tighter price controls on manufacturers than had been in place previously. This agreement required

[13]Prior to the current version of the PPRS agreement, manufacturers were allowed to keep additional profits—up to 50 percent over the target level. On an annual basis, about 30 manufacturers were required to justify having profits that exceed their target by up to 50 percent. Under the current version, there is no longer any requirement to justify retaining the additional profit (i.e., profits up to 25 percent over their target level).

[14]Manufacturers are expected to submit these reports within 6 months after the end of the manufacturer's financial year.

[15]This is calculated by taking the fixed assets (land, buildings, and manufacturing plants), adding the current assets (cash, debt, and stock), and deducting the current liabilities (creditors and current taxation). If fixed assets are used to produce drugs that are both sold to NHS and exported, the proportion of those assets that is taken into account in determining a manufacturer's profit is based on the ratio of NHS sales to export sales. (Under the current version of the PPRS agreement, the government will change its PPRS calculation method, effective October 1996. It will recognize all fixed costs associated with manufacturing in the United Kingdom, to avoid any disincentive to exports.) Borrowings that are part of a manufacturer's normal annual trading activities are included in the calculations, while borrowings of a long-term or structural nature are excluded.

[16]The maximum allowable amount for promotion is based on a mixture of a flat rate allowance for all manufacturers, a percentage of sales, and the number of significant drugs the company has on the market. The limit for the industry as a whole is about 8.2 percent of sales, although smaller manufacturers are allowed to deduct up to 18 percent of sales as marketing expenses.

firms to reduce prices on all products by 2.5 percent, and ordered a 3-year price freeze as of October 1, 1993.[17] It also established a threshold for price increases after that time, requiring company profits to fall to less than 75 percent of the company's target level before price increases could be granted.

Reimbursement Price for Generic Drugs

As with brand-name drugs, manufacturers freely set generic drug prices; however, the government sets out the level at which pharmacists are reimbursed for the cost of generic drugs sold to customers.[18] This price is calculated in one of three ways. Where there is considerable competition in the market, an average weighted amount is assessed on the basis of the list prices of the main manufacturers. Where there is limited competition in the market, an average weighted amount is assessed on the basis of the prices offered by the main wholesalers. Where there is effectively one product, that price becomes the tariff price. Therefore, the price listed in the Drug Tariff reflects the level of prices set competitively in the market.

Spending Control Strategies Aimed at Drug Wholesalers and Retailers

Wholesale margins in the United Kingdom are regulated by the government. These margins are set at 12.5 percent of the retail (or list) price, which is the same in all pharmacies.[19]

In practice, there is no fixed retail margin in the United Kingdom for drugs dispensed under NHS. Retail margins vary according to what wholesalers are prepared to offer pharmacists in particular circumstances from within their 12.5-percent margins. In addition to the retail margin, pharmacists also receive a dispensing fee for each prescription.[20]

[17]Companies are offered two alternatives in lieu of the global price cut. The first alternative allows a company to decrease prices by different amounts for different products (that is, cutting prices on some products by more than 2.5 percent, and others less than 2.5 percent), so long as the overall effect on receipts is the same as it would be under the global price reduction. The second option is to leave prices unaltered but to make cash payments to the government in lieu of the price reduction. NHS expects most companies to institute a global price cut rather than take any of these alternatives.

[18]In a monthly government publication called the "Drug Tariff," the government lists the prices at which it will reimburse pharmacists for drugs dispensed.

[19]The wholesaler margin consists of a 10-percent discount off the retail price of the drug plus an additional 2.5 percent from the manufacturer for prompt payment.

[20]The dispensing fee is negotiated annually and is unrelated to the price of the prescribed drug. Currently, pharmacists receive £1.512 (or about $2.23) for each of the first 1,500 prescriptions dispensed each month, and £0.715 (or about $1.06) for each prescription dispensed thereafter for the rest of the month, averaging £1.08 (or about $1.59) in May 1992. Prior to April 1993, pharmacists also received a payment of 2.5 percent of the cost of the drug dispensed.

Pharmacists are also subject to a reduction in their total payment. The basis for the reduction is a government attempt to recapture volume discounts that it believes many pharmacists receive from wholesalers and parallel importers. The reduction is also meant to ensure that the amounts pharmacists are reimbursed by the government reflect the discounts given in the market and to encourage pharmacists to seek these discounts. The reduction is applied at the same rate to all pharmacists, being linked to the value of the prescriptions dispensed each month rather than to the actual discounts received. The amount of these reductions is determined in periodic surveys conducted by the government.

Spending Control Strategies Aimed at Consumers

Patient cost sharing is the primary spending control strategy aimed at consumers, but a large fraction of the population is exempt. Among those exempt from copayment are children under 16 (under 19 if they are full-time students); the elderly; poor people; expectant and nursing mothers; people with certain long-term illnesses; and war or service pensioners who require prescription drugs for the accepted disablement. Together, these groups account for about 80 percent of the prescription drugs dispensed in the United Kingdom in 1991.

Consumers who are not otherwise exempt are required to make a copayment of £4.25 (or about $6.25) for each prescription drug.[21] Patients requiring a great deal of medication, but not exempt from copayment, can purchase a "season ticket," paying £60.00 (or about $88.00) per year for an unlimited number of prescribed items, rather than £4.25 for each item.[22]

Spending Control Strategies Aimed at Physicians

Over the last several years, the United Kingdom has implemented various spending control strategies aimed at physicians in an attempt to influence their prescribing patterns. The government first introduced the Selected List Scheme, which limits NHS reimbursement to specific drugs. It then introduced the Prescribing Analyses and Cost (PACT) system, which provides physicians with information on their prescribing patterns, followed by the Indicative Prescribing Scheme, which sets prescribing targets for physicians. Most recently, the government introduced the General Medical Practitioner Fundholding Scheme, which provides physicians with a financial incentive to prescribe effectively. In addition,

[21]Copayments have increased gradually over the last several years, from £0.45 (or about $0.66) in 1979 to the current £4.25.

[22]Where the price of the drug is less than the copayment, patients still pay the £4.25 copayment. Approximately 53 percent of the prescribed items dispensed cost less than the copayment.

the government has implemented several educational measures to further improve the quality and cost-effectiveness of prescribing.

Selected List Scheme

The Selected List Scheme was introduced in 1985 to control NHS drug expenditures and to promote the use of generic drugs. The list limits the number of drugs NHS can offer in certain categories, including analgesics for mild to moderate pain, indigestion remedies, laxatives, vitamins, cough and cold remedies, and benzodiazepine sedatives and tranquilizers. According to NHS officials, in 1986, the Scheme saved £75 million (or about $110.3 million in 1986 dollars).[23]

To help control rising expenditures on drugs, the government is planning to expand the Selected List Scheme into 10 additional therapeutic categories: anti-diarrheals, allergic disorders, hypnotic and anxiolytics, appetite suppressants, vaginal and vulval conditions, contraceptives, anemia, topical antirheumatics, ear and nose conditions, and skin conditions. The government has not said that NHS will not reimburse all products in these categories. Rather, an independent committee of experts will review all products in these categories to determine which ones are cost-effective and meet genuine patient needs. Final decisions on the individual products in all 10 categories will probably be made before mid-1994.

The Prescribing Analyses and Cost System

PACT, introduced in August 1988, enables physicians to compare their prescribing patterns against the patterns of other physicians. PACT provides physicians with information about their prescribing patterns within their practices. It also allows physicians to compare their prescribing patterns with local and national averages, and with the average for six major therapeutic groups in the country. Further, PACT provides additional information if physicians exceed the national averages by a set percentage. Government officials told us that in 1989, PACT is believed to have saved about £80 million (or about $131.2 million in 1989 dollars).

Indicative Prescribing Scheme

IPS, introduced in 1991, is an attempt to improve the quality and cost-effectiveness of prescribing by setting prescribing targets on pharmaceutical expenditures. A target is set at the regional level and broken down to the district and individual physician level.[24] The use of

[23]Savings figures are only available for the first year the scheme was in effect.

[24]In this report, the term "district" refers to the Family Health Service Authorities.

indicative monetary targets for prescribing is intended to make physicians more aware of the monetary implications of their prescribing choices, and to encourage them to use less expensive medications when feasible.

Indicative budget targets are reflective of the individual circumstances of each individual physician, depending on the demographics of his or her caseload. All physicians have an opportunity to discuss their indicative amounts with their district health authority. Prior to 1993, indicative amounts were set according to historical expenditures for the practices and were adjusted for comparable averages and special factors (e.g., the number of high-cost patients, and general increases to allow for the rise in drug costs). Since 1993, indicative amounts have also reflected regional expenditure patterns, projected requirements, and projected expenditures. Local factors to be considered in constructing these projected expenditures include the relative incidence of expensive patients in a practice; the incidence of specific local illnesses (e.g., industrial diseases); and the relative local morbidity as assessed by district health authorities.

While IPS does not place binding cash limits on physicians, it sets targets against which performance can be monitored. There are separate provisions that require physicians to justify their prescribing behavior where there is clear evidence of over-prescribing.[25]

GP Fundholding Scheme

The GP Fundholding Scheme is a modified version of IPS that is used for physicians who are in group practices.[26] Under this scheme, which was expected to cover 25 percent of the physicians by April 1993, GPs in large group practices (of at least 7,000 patients) are awarded a budget that meets the cost of some hospital services, administrative office costs, and visiting and district nurse services; and all prescribing for their patients. Physicians can use their funds for any of these services as they see fit. For example, they can also apply savings in any one year over the next 4 years either to improve their facilities or to buy more prescription drugs for patients.

[25]These provisions are separate from and predate IPS. There is no direct relationship between these provisions and the indicative budget targets, and exceeding the indicative amount would not in itself be sufficient to trigger these provisions.

[26]The GP Fundholding Scheme is voluntary and NHS can refuse applications to join it. The main criterion for eligibility is the size of the practice.

Educational Measures Aimed at Improving Quality and the Cost-Effectiveness of Prescribing

Other educational measures used to improve the quality of physicians' prescribing practices include (1) the Medicines Resource Center, which issues monthly bulletins on prescribing issues to all physicians; (2) the Prescribing Research Unit, which researches variations in prescribing practices and provides NHS with information about the normal range of prescribing practices for certain types of drugs; and (3) the Medical Advisers' Support Center, which trains and educates medical advisers who, in turn, work with physicians to improve prescribing practices.

A Statistical Analysis of the Effect of Drug Prices on Pharmaceutical Research and Development Expenditures

Pharmaceutical firms' R&D decisions are influenced both by market forces and government policies. Governments in many countries, including France, Germany, Sweden, and the United Kingdom, have imposed pharmaceutical price and spending control regulations. By lowering drug prices in these countries, such regulations can affect firms' R&D spending by changing the return the firm receives from its R&D investment.

We use statistical analysis to examine the impact of changes in drug prices on pharmaceutical R&D. Our results support the hypothesis that decreases in the average level of drug prices tend to reduce pharmaceutical firms' R&D spending; conversely, increases in average drug prices tend to increase pharmaceutical R&D expenditures. These results must be interpreted cautiously, as our estimates of the magnitude of this effect on R&D are imprecise and are also sensitive to statistical modeling choices. In addition, our information does not extend to how price changes affect the mix of innovative versus imitative new drugs.

Previous Studies Helpful, But Additional Research Is Needed

Previous studies have not directly examined the relationship between pharmaceutical prices and R&D expenditures. Some authors suggest that drug prices and profits are positively related to pharmaceutical R&D, but they do not test this proposition empirically.[1] An International Trade Commission report presents an analysis suggesting that R&D is positively related to companies' global market shares.[2] An older study of the pharmaceutical industry found that firms with relatively high profits in one time period tended to spend more on R&D in subsequent years.[3] More recent research has estimated the average costs of new drug development—for example, the Office of Technology Assessment has estimated that the average after-tax cost of developing a new chemical

[1]See Henry G. Grabowski, "An Analysis of U.S. International Competitiveness in Pharmaceuticals," Managerial and Decision Economics, 27, Special Issue (1989); and L.G. Thomas, "Industrial Policy and International Competitiveness in the Pharmaceutical Industry," presented at the American Enterprise Institute (Oct. 1993).

[2]See U.S. International Trade Commission, Global Competitiveness of U.S. Advanced-Technology Industries: Pharmaceuticals, USITC Publication 2437 (Sept. 1991).

[3]Henry G. Grabowski and John M. Vernon, "The Determinants of Research and Development Expenditures in the Pharmaceutical Industry," in Robert B. Helms, editor, Drugs and Health: Issues and Policy Objectives (Washington, D.C.: American Enterprise Institute, 1981).

entity lies between $140 million and $194 million 1990 dollars.[4,5] OTA estimated that even after accounting for the risk of failure in new drug development, the average revenues received from these new drugs exceeded their high development costs.[6]

Even on a theoretical level, however, considerable uncertainty remains as to the appropriate level of pharmaceutical R&D. By advancing the state of scientific and medical knowledge, R&D can create benefits to society above and beyond the payments the firm receives for its discovery. This line of reasoning suggests that private companies will likely invest too little in R&D. However, some private R&D spending may be wasteful. Multiple firms may "race" each other to create a viable product using the same basic chemical substances. While not all R&D spending in these races is wasteful to society as a whole, the effort of the "losing" firm may not produce much additional technological advance. In practice as well as in theory, little agreement exists on the desired amount of pharmaceutical R&D, nor has consensus been reached on what (if any) policy should be used to reach this desired level.

A Decrease in Drug Prices Will Lower the Firm's Payoff to R&D

Pharmaceutical firms, whose primary concern must be to maximize profits, fund R&D in order to discover new products. Their reward for discovering a new drug is the profit they can earn from selling this new drug in the marketplace. That higher drug prices provide an incentive for firms to undertake R&D may seem obvious, but nonetheless this has been challenged.

To maximize its profits, a firm must make its R&D choices by comparing expected costs and benefits of each particular R&D project. If the expected

[4]For example, see U.S. Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks, and Rewards, OTA-H-522, (Washington, D.C.: U.S. Government Printing Office, Feb. 1993); J.A. DiMasi, et al., "The Cost of Innovation in the Pharmaceutical Industry," Journal of Health Economics, 10, 107-142, 1991; Steven Wiggins, The Cost of Developing a New Drug (Washington, D.C.: Pharmaceutical Manufacturers' Association, 1987); and R. Hansen, "The Pharmaceutical Development Process: Estimates of Development Costs and Times and the Effect of Proposed Regulatory Changes," Issues in Pharmaceutical Economics, 1979.

[5]These figures include, as they should, expenses for failed R&D projects as well as successful ones. These figures estimate the average cost of new drug development, not the marginal cost of new drugs. While the average cost of a new drug would equal the total R&D spending across firms divided by the number of drugs, the marginal cost of a new drug would equal the change in R&D spending necessary to produce one more new drug. Therefore, it would be inappropriate to use these average cost figures to describe how new drug development would respond to a change in R&D expenditures.

[6]For a more comprehensive review of the economic literature on the pharmaceutical industry, see William Comanor, "The Political Economy of the Pharmaceutical Industry," Journal of Economic Literature, Vol. XXIV (Sept. 1986), pp. 1178-1217, and U.S. International Trade Commission, Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals, USITC Publication 2437 (Sept. 1991).

benefit of a new project—the revenues expected from the resulting product—exceeds the cost of research funding, the firm will increase its overall expected profit by funding the project. If the expected cost of the project is greater than the profit a firm can reasonably expect for its efforts, the firm will be better off not to fund the project.

Price regulation will have a direct impact on the expected benefit of an R&D project. A permanent and effective price regulation policy will reduce the revenues a firm will receive from tomorrow's prescription drugs. The firm's reward for spending money on R&D—the revenue the firm will receive from its future products—will decline with price regulation, compared to what revenue would have been in an unregulated market. With a reduction in the expected benefit from a successful R&D project, the firm has less incentive to invest in R&D.

Profits, Marketing Expenses Are Unlikely to Fully Cushion the Impact of Drug Prices on R&D

Recently, the profitability-R&D nexus has been explored from a different perspective. Attention has been directed to the question of whether the pharmaceutical industry has been earning "excess profits." Pharmaceutical industry critics have claimed that pharmaceutical firms' high profits imply that prescription drug prices could be lowered without a sacrifice in R&D. Similarly, some have suggested that pharmaceutical firms' marketing expenses could be reduced, instead of R&D, in the event of a decline in drug prices.

Economic theory suggests that the presence of significant industry profits or marketing expenses would be insufficient to break the link between drug prices and pharmaceutical R&D, for several reasons. First, drug companies, like other private corporations, generally seek to earn high returns; company profits provide the incentive for these firms to pursue pharmaceutical R&D. If the profits from selling new drugs are reduced, firms have less reason to commit to costly long-term R&D projects. A firm's high profit level may encourage other firms, who hope for similar results, to invest additional resources in R&D. Pharmaceutical firms must market the products generated by their R&D in order to realize the profit potential in their new drugs.

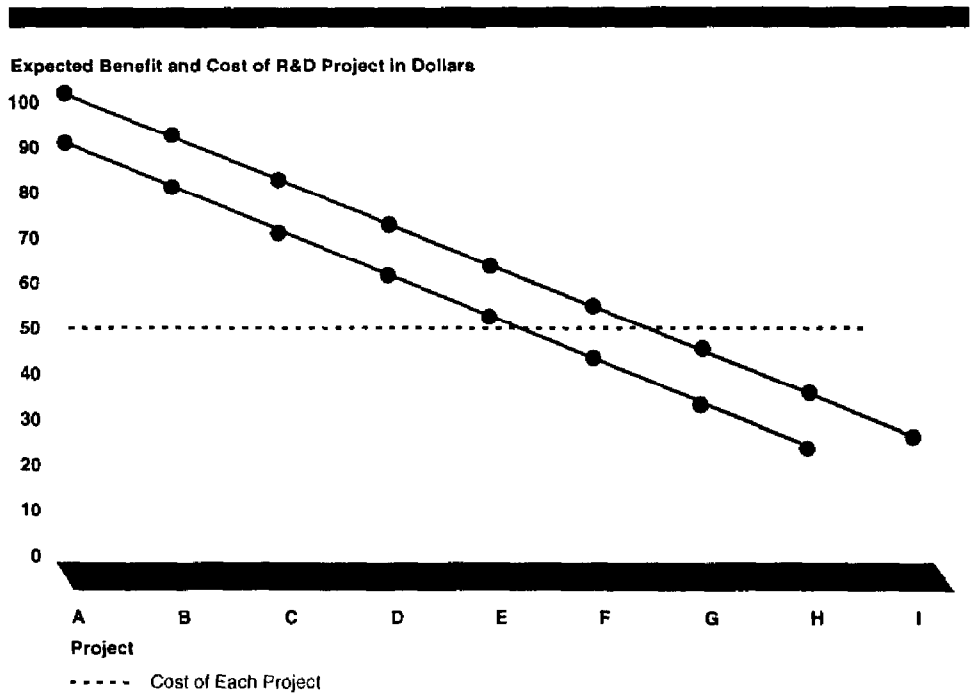
Second, because considerable uncertainty surrounds the payoffs to R&D, observed profits may not be an accurate indicator of the compensation necessary to induce R&D investment. R&D dollars must be committed long before the outcomes are known. Therefore, the stream of profits observed after the product is marketed will differ from the stream of profits the firm

expected to earn from the product when the initial R&D decision was made. Under these circumstances, firms' errors in forecasting future revenues would be indistinguishable from excess profits.

In addition, although there may well be "excess profits" on average over a group of drugs, R&D decisions are made for each individual drug. That is, the firm makes its R&D decisions by comparing the expected benefits and costs of each individual R&D project, not by looking at overall benefits and costs for a large number of projects taken together. For example, suppose that the firm has the choice of funding any or all of 10 research projects. The firm can rank these projects according to their expected payoff, as in figure V.1—if funded, project A can be expected to bring in about $100 million, project B has an expected value of $90 million, and so on.[7] If each project cost $50 million, the firm would maximize its profits by funding projects A through F. On average, the firm could expect to earn $150 million in profits from this set of drugs.

[7]These figures would take into account the uncertainty surrounding the success of each project. For example, if project A had a 25-percent chance of producing a $400 million product, its expected value would be $100 million.

Figure V.1: Relationship Between Drug Prices and R&D in the Presence of "Excess Profits"



If drug prices were decreased, lowering the expected benefit of each drug by 10 percent, then the benefits of funding projects A through E would still exceed their costs. However, project F would be unprofitable. The firm would maximize its profits by funding only projects A through E, earning a profit of $100 million. Despite the presence of high industry profits, a reduction in price would nonetheless result in a decline in R&D.

A Decrease in Drug Prices May Increase the Cost of Financing R&D

In addition to the role of drug prices in creating incentives for investment in R&D, drug prices may influence the cost of financing R&D. Industry representatives point out that pharmaceutical companies finance their R&D expenditures largely from current profits. From this fact, industry representatives conclude that if profits were reduced, firms would be unable to undertake R&D.

This argument is partially—but only partially—correct. A reduction in profits may force pharmaceutical firms to obtain more of their R&D financing from external sources. If it is cheaper for firms to finance R&D from current profits, then by limiting these profits, price regulation could

increase the cost of financing R&D projects. However, although pharmaceutical firms may choose to finance R&D through their current corporate profits, these firms do have other options.[8] Therefore, industry profits may facilitate R&D spending, but it would be incorrect to say that R&D would not be possible without high industry profits.

Other Government Policies Can Also Influence R&D

In each of the countries we studied, as well as in the United States, the government plays a crucial role in the pharmaceutical market—as regulator of drug prices and product approval; as granter of patents and tax credits; as creator and enforcer of product liability laws; as the provider of public funding for pharmaceutical and biomedical R&D; and (in the countries we studied) as sole or dominant purchaser of pharmaceuticals under the national health insurance system. In each of these roles, the government exercises considerable influence over pharmaceutical firms' R&D decisions.

For example, government safety regulations can affect the incentives for new drug development. The cost of clinical trials contributes to the cost of bringing a new drug to market; the more extensive these requirements are, the higher the expected cost of R&D is. As granter of patents, the government sets the period of market exclusivity. The longer this period is, the more profitable are new drugs and hence, the more incentives for R&D. Tax credits and public funding can spur R&D by reducing a firm's R&D costs, while strict product liability can increase the risk-related costs of developing new drugs.

Government Influence Depends on the Size and Importance of the Domestic Pharmaceutical Market

We expect the strength of government influence on R&D expenditures to depend critically on the size and importance of the pharmaceutical market in the manufacturer's home country. For example, if a relatively small country (such as the Netherlands) were to see a fall in drug prices, the impact on drug company revenues and profits would be limited because this country's consumers account for a relatively small share of the

[8]These other options include debt financing and equity financing. If a firm chooses debt financing, the firm borrows money to pay for its current R&D costs, and repays the debt once the revenue from the project is received. If a firm chooses equity financing, the firm issues additional stock shares and uses the proceeds to pay for its current R&D costs. The firm will know, better than potential outside investors, the expected costs and benefits of the project. If it wants to obtain the funds at the cheapest possible cost, the firm has every incentive to exaggerate the potential benefits of the project and minimize its potential costs. Investors will need impartial information to make their decisions, and gathering such information is likely to be very costly, if not impossible. Given the high degree of risk in pharmaceutical R&D and this lack of information, outside investors will likely demand very high interest rates for debt financing and low prices for new stock issues. Therefore, it is probably cheaper for pharmaceutical firms to finance their R&D through retained earnings. Indeed, this is what most of the major pharmaceutical firms do most of the time.

market. However, a loss of revenue in a larger country (such as the United States) would be expected to have more significant effects on all firms—domestic and foreign. Similarly, firms that derive a larger portion of their sales from exports will be less affected by the policies of their home governments.

Market Forces and R&D Costs Can Also Affect Pharmaceutical R&D

Despite widespread government influence in the pharmaceutical market, market forces remain important. Without some demand for new pharmaceutical products from patients and physicians, R&D projects will not be profitable. Marketing practices, such as advertising to physicians or (where allowed) directly to consumers, can affect physician and consumer demand. Cultural factors, demographics, and local prescribing and practice patterns will affect the consumption of prescription drugs and the acceptance of new products.

The costs of conducting R&D will depend on market forces as well. Wages for scientists and other skilled workers can vary across local labor markets. In addition, a strong university system and easy access to the scientific community may encourage research and development.

Empirical Analysis of Drug Prices' Effect on R&D

Because so many factors combine to affect firms' R&D decisions, isolating the impact of any one variable is difficult. In addition, some of these variables are difficult to quantify or measure reliably. However, many of the variables that influence pharmaceutical R&D do not change over time, or change over time only very slowly. Patent and tax laws, for example, are not changed very frequently. By looking at changes in R&D across countries over time, we can control for the influence of some important confounding variables.

Data were insufficient to estimate a complete structural model for the pharmaceutical industry in each country. However, we were able to exploit the variation in drug price growth across countries to test the hypothesis that drug price levels affect R&D. In addition, we used a simulation model to explore how government policy and domestic market conditions may influence the strength of the price-R&D relationship.

Economic theory suggested several alternative specifications for modeling the price-R&D relationship. We varied the form of the regression models we used to see how sensitive the results were to the model specification. The regression results suggest that any policy—regulatory or

competition-enhancing—that reduces drug prices will decrease R&D spending. The effect was statistically significant and appeared consistently throughout the different empirical models, although the size of the estimated effect was sensitive to the changes in specification.

Regression Models

We obtained data on reported pharmaceutical R&D expenditures for 87 firms in 12 countries for 1988 and 1989 from the Scrip Pharmaceutical League Tables.[9,10] These figures represent only that portion of the company's total R&D expenditures devoted to pharmaceuticals. Figures for major foreign subsidiary companies were generally reported separately from the parent company.

For data on the average drug price level in each country, our measure was the Organization for Economic Cooperation and Development (OECD) pharmaceutical price index for each country; we used this index to compare the growth in drug prices over time across countries.[11,12] We also obtained international economic statistics, such as the GDP and the GDP deflator (a measure of the general inflation rate), from the OECD Health Data Base.

These data enabled us to use regression analysis to estimate how pharmaceutical prices affect R&D.[13] We hypothesize that the growth in the firm's R&D spending would be affected by changes in drug prices and in

[9]Many pharmaceutical firms also produce other products. We included in our sample only those firms that specifically reported pharmaceutical R&D, rather than total company R&D. These firms represented Belgium, Finland, France, Germany, Italy, Japan, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the United States.

[10]We obtained similar data for 1990 and 1991. However, most firms in Germany did not report data for 1990 and 1991. We estimated our models on the 1988-1989 data, and on a pooled data set that included all 4 years of data. The results in each case were qualitatively similar. In this appendix, we report results based only on the 1988-1989 data, which include the German pharmaceutical firms.

[11]The Organization for Economic Cooperation and Development (OECD) is an international organization of 24 industrialized countries in Europe, North America, and the Pacific.

[12]The problems with price indexes for pharmaceuticals are well known; see Fredrik Andersson and Peter McMenamin, "International Price Comparisons of Pharmaceuticals—A Review of Methodological Issues," Battelle Medical Technology and Policy Research Centre (Aug. 1992). However, we believe that these indexes provide the best currently available measurement of pharmaceutical price changes over time in each country.

[13]This technique allows us to examine the impact of each characteristic on R&D, holding other factors constant.

real GDP.[14] We measured these changes both in absolute terms and as growth rates. We estimated a linear and a nonlinear (including squared terms) version of each model.

A Model Specified in Levels

A straightforward way to estimate the effect of prices on R&D would be to regress the firm's pharmaceutical R&D expenditure on the home country pharmaceutical price level plus a set of control variables. This approach, relating the level of R&D to the level of each determinant of R&D, is captured by equation 1. The variables in equation 1 are defined in table V.1.

1.

$$R_{ijt} = \alpha_t + \beta_1 P_{jt} + \beta_2 G_{jt} + \beta_3 X_j + e_t$$

Table V.1: Definition of Variables in Equations 1 and 2

Variable	Description
R_{ijt}	Research and development expenditures for firm i in country j at time t
α_t	Intercept term specific to time t
P_{jt}	Pharmaceutical price level in country j at time t
G_{jt}	Measure of economic activity (GDP) in country j at time t
X_j	Vector of other variables (patent law, tax law, etc.) that influence R&D and are specific to country j
e_t	Random error term

This model has the virtue of, at least potentially, including the complex set of determinants affecting R&D. However, the particular features of the pharmaceutical market make this specification inappropriate. For example, variation across countries in the accounting definitions of R&D makes it difficult to compare R&D data from different countries. Also, the levels approach would require the researcher to account for firm size on the right-hand side of equation 1, but doing so poses statistical problems. Larger firms, naturally, tend to spend more on R&D. Most measures of firm size, including the number of employees and total sales, are endogenous; consequently, an instrumental variables or systems estimator would be required to estimate this model. We lacked the data to construct such an estimator.

Finally, we were unable to obtain data on a number of important control variables. Specific measures of marginal tax rates, for example, are

[14]As discussed in chapter 3, economic theory suggests many potential determinants of R&D. Specifying a model of R&D in levels demands, therefore, a rich data set. However, data on R&D determinants are patchy. This lack of data necessitates an alternative model that both is operational and accounts for the (missing) confounding variables.

difficult to obtain. It is very difficult to quantify variables like "access to scientific infrastructure." Our inability to account for these variables would subject the estimation to omitted variable bias. In particular, the estimated coefficient on the drug price variable would be biased.

An Alternative, Operational Model

To surmount these difficulties, we specified empirical models in differences and in growth rates. These models helped us minimize omitted variable bias because we are required to account for only those variables that change over time. Instead of estimating the effect of this year's pharmaceutical price level on this year's level of R&D expenditure (as in equation 1), we looked at how changes in the pharmaceutical price level lead to changes in R&D spending from one year to another. Most of the key variables in the R&D decision, including patent lives and the scientific infrastructure, are fixed from one year to the next. Therefore, such variables will influence the level of R&D at a point in time, but should not influence the growth in R&D over time. We assumed that the coefficients of these variables are also constant over time; therefore, the variables can be eliminated by first differencing.

For example, we lagged equation 1 and subtracted it from the original equation; the result is given below. (Regression results based on this specification are given in table V.4.)

2.

$$R_{ijt} - R_{ijt-1} = \theta_t + \beta_1[P_{jt}-P_{jt-1}] + \beta_2[G_{jt}-G_{jt-1}] + e_t - e_{t-1}$$

Another way to estimate the effect of price regulation on R&D in terms of changes in variables is to formulate a statistical model in terms of growth rates. We hypothesized that the growth rate in prices and GDP from one year to the next will influence the growth rate in R&D spending from one year to the next. This specification is given in the equation below. (Regression results based on this specification are given in table V.2.)

3.

$$\frac{R_{ijt}-R_{ijt-1}}{R_{ijt-1}} = \alpha_t + \beta_1 \frac{P_{jt}-P_{jt-1}}{P_{jt-1}} + \beta_2 \frac{G_{jt}-G_{jt-1}}{G_{jt-1}} + e_t$$

We also estimated a model based on equation 3, but including squared terms. This specification is given in the equation below. (Regression results based on this specification are given in table V.3).

4.

$$\frac{R_{ijt}-R_{ijt-1}}{R_{ijt-1}} = \alpha_t + \beta_1 \frac{P_{jt}-P_{jt-1}}{P_{jt-1}} + \beta_2 \frac{G_{jt}-G_{jt-1}}{G_{jt-1}} + \beta_3 \left[\frac{P_{jt}-P_{jt-1}}{P_{jt-1}}\right]^2 + \beta_4 \left[\frac{G_{jt}-G_{jt-1}}{G_{jt-1}}\right]^2 + e_t$$

The results of these various regression models are given in tables V.2 through V.4. (For the specification in terms of differences, we calculated the elasticity at the point of means.) The elasticity estimate in table V.3, for example, implies that a 1-percent decrease in the pharmaceutical price level would lead to a 0.68-percent decrease in the average firm's R&D expenditures. The model with the smallest estimate would imply that a 1-percent decrease in drug prices would cause a 0.3 percent drop in R&D spending, while the model with the largest estimate would imply that a 1-percent decrease in drug prices would cause a 0.7-percent drop in R&D spending.

Not surprisingly, we found heteroskedastic errors in several of these equations. Where heteroskedasticity was found, the standard errors presented are based on consistent estimates of the covariance matrix for each regression, using White's test.

In each regression, our right-hand side variables explain a portion of the cross-country variation in R&D, but we are not attempting to explain the considerable variation among individual firms within a single country. In addition, these regressions express R&D in terms of differences, rather than levels. Therefore, our regressions explain a relatively small portion of the cross-sectional sample variation.

Table V.2: Regression Results I

Variable	Coefficient/estimated elasticity (standard error)	t statistic
Constant	21.512 (0.556)	4.218[a]
Pharmaceutical price growth	0.556 (0.318)	1.80[b,c]
GDP growth	-4.347 (2.050)	-2.121[a]

$R^2 = 0.046$
n = 87

Dependent variable: Percentage growth rate in R&D expenditures in 1988-1989 for firm i, which is located in country j, corrected for inflation with the GDP deflator.

Independent variables: Percentage growth in pharmaceutical prices for 1988-1989 for country j, corrected for inflation with the consumption deflator; and percentage growth rate in GDP for 1988-1989 for country j, corrected for inflation with the GDP deflator.

[a]Significant at the 0.05 level (two-tailed test).

[b]Significant at the 0.10 level (two-tailed test).

[c]Significant at the 0.05 level (one-tailed test).

Table V.3: Regression Results II

Variable	Coefficient/estimated elasticity (standard error)	t Statistic
Constant	–8.162 (29.430)	–0.277
Pharmaceutical price growth	0.676 (0.353)	1.914[a,b]
Pharmaceutical price growth squared	–0.015 (0.055)	–0.267
GDP growth	21.373 (24.978)	0.856
GDP growth squared	–5.047 (4.873)	–1.036

$R^2 = 0.073$
n = 87

Dependent variable: Percentage growth rate in R&D expenditures in 1988-1989 for firm i, which is located in country j, corrected for inflation with the GDP deflator.

Independent variables: Percentage growth in pharmaceutical prices for 1988-1989 for country j, corrected for inflation with the consumption deflator; percentage growth rate in GDP for 1988-1989 for country j, corrected for inflation with the GDP deflator; real price growth squared; real GDP growth squared.

[a]Significant at the 0.10 level (two-tailed test).

[b]Significant at the 0.05 level (one-tailed test).

Table V.4: Regression Results III

Variable	Coefficient/estimated elasticity (standard error)	t Statistic
Constant	29.517 (34.465)	0.856
Pharmaceutical price difference	0.494/0.306 (0.173)	2.864[a]
GDP difference	71133.4/0.00455 (58270.0)	1.22

$R^2 = 0.126$
n = 87

Dependent variable: Difference (in millions of dollars) between R&D expenditures in 1988 and 1989 for firm i, which is located in country j, corrected for inflation with the GDP deflator.

Independent variables: Percentage growth in pharmaceutical prices for 1988-1989 for country j, corrected for inflation with the consumption deflator; percentage growth rate in GDP for 1988-1989 for country j, corrected for inflation with the GDP deflator.

[a]Significant at the 0.05 level (two-tailed test).

The estimated impact of GDP varies among the models specified. This inconsistency may suggest that current GDP is a poor proxy for the GDP that will prevail when new drugs are marketed. In addition, a rise in GDP may be correlated with a rise in interest rates in the home country, which may depress R&D if capital markets are imperfect. However, prices have a consistently positive impact on R&D in each of the models tested.

Results Should Be Interpreted Cautiously

Caution is required in interpreting these results, because the magnitude of the effect was difficult to estimate and is subject to a number of qualifications. First, our sample of firms was limited to those firms that reported figures, and therefore this group constitutes a nonrandom sample. This nonrandomness will affect the results only if the reporting firms were to differ systematically from the nonreporting firms; we have no evidence that this is likely.

The simplicity of our specification may be considered a drawback of the analysis. Current price and GDP trends are only proxies for the trends a firm expects as it makes its R&D decision. Although most of the other variables that we expect to impact R&D are generally time-invariant in the short run, we are unable to account for long-run variation in these variables. Even if data were available, the small number of countries with research-based pharmaceutical industries restricts the number of explanatory variables we could potentially include. In addition, to identify the empirical model, we assumed that the marginal benefit of additional R&D spending for firm i in country j depends on pharmaceutical prices in the home country j and on the "world" pharmaceutical price (which would be the same for all firms). In fact, firms may have differing marketing and distribution advantages in markets other than in their home country, and so the available "world" market may differ across firms. We lacked the data to give our model this degree of complexity. The simplicity of our model also prevented us from exploring other possible forces behind the link between drug prices and R&D. For example, authorities in countries with weak industries may have felt free to impose low rates of increase in drug prices because they did not have a major domestic industry to protect. Similarly, in countries with strong industries, country authorities may have felt constrained to impose more moderate pricing policies. Data were unavailable to test this hypothesis.

In addition, we do not know how changes in drug prices may affect the social value of pharmaceutical R&D. The negative effect of a decrease in drug prices may fall largely on either innovative or imitative drug

products. The loss of innovative "blockbuster" drugs would be a bigger blow to patients than the loss of line extensions or "me-too" products.

The size of the effect of prices on R&D was difficult to estimate precisely, and the magnitude of the estimate was sensitive to the empirical specification. The statistical significance of the effect was generally unaffected by the specification adopted, but the estimate of the size of the effect differed across specifications. For all these reasons, the size of the effect of drug prices on pharmaceutical R&D must remain an open question.

Size of R&D Effect May Be Influenced by Other Variables

Unfortunately, data considerations prevented us from estimating a complete structural model of the R&D decision for firms in each country. As the major pharmaceutical countries differ in the size of their domestic markets, we expect that the strength of the price-R&D relationship will vary across countries in ways our regression model cannot capture. To explore how government policy and market conditions might affect the relationship between regulated prices and R&D, we used a computer simulation model. This model is designed not to test whether drug prices affect R&D across countries in general, but to illuminate those factors that may determine the size of the potential R&D effect in a given country.

Simulation Model

Although different countries have established different policy regimes with respect to the pharmaceutical industry, their historical experience with pharmaceutical price regulation is too limited for us to make empirical conclusions about the effects of government policy on R&D. One way to gain some insight into these issues is by using a computer simulation model to combine theory and experience.

A simulation combines a theoretical equation with actual data and with reasonable conjectures about the size of parameters. In a simulation model, the researcher first derives a theoretical equation that can be solved for the desired effect. Then he or she substitutes plausible values, or values derived from data, for the other variables in the equation and solves it. By varying the values used in the equation, the researcher can see how sensitive the effect is to changes in these parameters.

Our simulation model analyzes hypothetical industry situations. However, the model was formulated to take into account several important features of R&D in the pharmaceutical industry. Firms invest in R&D to maximize their profits. The probability of success for each individual project is low,

but successful projects generate considerable returns. In the baseline case for the model, we incorporate parameters representative of current industry experience (with respect to the probability of success, the tax credit rate, interest rates, and so forth). This model is not nearly sophisticated enough to provide a planning or forecasting device.

This simulation model follows the work of Grabowski and Vernon.[15] Grabowski and Vernon used a simulation model to explore the potential effects of lengthening pharmaceutical patent lives on the rate of new drug discovery and the concentration of the pharmaceutical industry. We are examining a different dependent variable than Grabowski and Vernon did—while they were interested in the structure of the industry and the rate of new drug development, we are examining the elasticity of R&D spending with respect to regulated drug prices. However, the two simulation models share several common parameters—the probability of technical success and the R&D tax credit being the most important examples.

To develop the simulation, we used a simplified two-period model of R&D. The firm maximizes its profits with respect to R&D by investing in an R&D project if the marginal benefit of the project exceeds its marginal cost. At the equilibrium R&D choice, then, the net benefit of the marginal R&D project is equal to zero.

In period one, the firm sells product A in its home (H) and foreign (F) markets at the regulated prices P^{AH} and P^{AF}. The firm must pay production costs C^{AH} and C^{AF}, plus the capital, labor, and financing costs of the R&D project, less any tax credits. In period two, the firm succeeds in generating new product B with probability of success s^B, and fails to generate a new product with probability $[1 - s^B]$. If the firm's R&D is successful, the firm will sell product B in its home and foreign markets at the regulated prices P^{BH} and P^{BF} and pay production costs C^{BH} and C^{BF}.

We assume that information is asymmetric—that s^B is known to the firm only, and the firm cannot credibly reveal s^B to outside investors. Outside investors will therefore demand a higher rate of return than the firm's opportunity cost of retained earnings. The firm will spend its profits on R&D before it seeks to borrow funds from the outside market. Therefore, if the cost of the firm's R&D project exceeds its current profits, it will finance the project using current profits and borrow the remaining sum. If the cost

[15]See Henry Grabowski and John M. Vernon, "A Computer Simulation Model of Pharmaceutical Innovation," in Arne Ryde Symposium on Pharmaceutical Economics (1984), p. 165.

of the R&D project is less than current profits, the firm will finance R&D solely through retained earnings.

We consider the more general case in which the firm's internal funds are insufficient to completely finance the marginal R&D project. The first order condition sets the net benefit of the marginal R&D project at

5.

$$\Pi^B = S^B[\delta[\overline{P_H^B}\,Q_H^B\,(\overline{P_H^B}) + \overline{P_F^B}\,Q_F^B\,(\overline{P_F^B}) - C_H^B\,(Q_H^B) - C_F^B\,(Q_F^B)]]$$
$$-[1+r_1][[1-\gamma][wL+r_K K] - [\overline{P_H^A}Q_H^A(\overline{P_H^A}) + \overline{P_F^A}Q_F^A(\overline{P_F^A}) - C_H^A(Q_H^A) - C_F^A(Q$$
$$-[1+r_2][\overline{P_H^A}Q_H^A(\overline{P_H^A}) + \overline{P_F^A}Q_F^A(\overline{P_F^A}) - C_H^A(Q_H^A) - C_F^A(Q_F^A)] = 0$$

The variables in equation 5 are defined in table V.5.

Price regulation can affect pharmaceutical R&D in two ways—through current profits and through expected future profits. Price regulation will reduce expected future profits and thereby lessen the incentives for firms to conduct R&D. Under price regulation, the firm will achieve lower profit levels than it would receive if it were allowed to set prices freely. The more stringent the price regulation (that is, the lower the regulated price), the lower the expected benefits to conducting R&D.

Price regulation can also influence the firm's R&D decision through its current profits. Price regulation will reduce the profits on the firm's current product line. If borrowing and lending rates differ, a decline in current profits means that there has been a decline in the availability of funds to finance new R&D. The firm may need to borrow additional funds for the external capital market, which represents an increase in the cost of financing R&D. If borrowing and lending rates are equal, this financing effect drops out, and price regulation's impact is confined to its effect on future prices.

We will define the effect of price regulation on R&D expenditure as follows:

6.

$$\frac{\partial R+D}{\partial P.REG} = \frac{\partial R+D}{\partial \overline{P_H^B}} + \frac{\partial R+D}{\partial \overline{P_H^A}}$$

R&D expenditures are represented in this model by $wL + r_K K$. Solving the first order condition for R&D expenditures and taking the derivatives with respect to prices yields

7.

$$\frac{\partial [wL+r_K K]}{\partial \overline{P_H^B}} = \frac{S^B \delta}{[1+r_1][1-\gamma]} [Q_H^B [1+\varepsilon_B [1-\frac{\frac{\partial C_H^B}{\partial Q_H^B}}{\overline{P_H^B}}]]]$$

and

8.

$$\frac{\partial [wL+r_K K]}{\partial \overline{P_H^A}} = [Q_H^A [1+\varepsilon_A [1-\frac{\frac{\partial C_H^A}{\partial Q_H^A}}{\overline{P_H^A}}]]] \; [\frac{1}{1-\gamma}] \; [1-\frac{[1+r_1]}{[1+r_2]}]$$

where ϵ_i equals the price elasticity of marginal cost for product i.

Evaluating the elasticity of R&D with respect to price at the point of means yields

9.

$$\varepsilon_B^{R+D} = [\frac{S^B \delta}{[1+r_1][1-\gamma]}] \; [1+\varepsilon_B [1-\frac{\frac{\partial C_H^B}{\partial Q_H^B}}{\overline{P_H^B}}]] \; [Q_H^B \frac{\overline{P_H^B}}{R+D}]]$$

and

10.

$$\varepsilon_A^{R+D} = [1+\varepsilon_A [1-\frac{\frac{\partial C_H^A}{\partial Q_H^A}}{\overline{P_H^A}}]] \; [\frac{1}{1-\gamma}] \; [1-\frac{[1+r_1]}{[1+r_2]}] \; [Q_H^A \frac{\overline{P_H^A}}{R+D}]$$

A major issue in any simulation is how to "initialize" the model. For several of these parameters, plausible proxies were available. We used the prime lending rate as a proxy for the borrowing rate (r_2), and the 10-year T bill rate as a proxy for the opportunity cost of internal funds (r_1). As starting values, we used estimates reported by the Office of Technology Assessment for the tax savings rate γ and the probability of success s^B; we then varied these parameters to test for sensitivity.[16] We varied the discount rate from 0.1 to 0.25. For several other parameters, we used plausible conjectures to narrow the range of values we considered. For example, in the pharmaceutical industry, production costs are likely to be relatively small compared to the total cost of any drug. The monopoly power granted to pharmaceutical firms through patents and pharmaceutical companies' relatively high profit margins also point to a low ratio of marginal cost to price. We varied the marginal cost-to-price ratio between 0.01 and 0.20. To identify the equation, we used the average pharmaceutical sales/pharmaceutical R&D ratio of 87 firms in 1989.

The simulation model is detailed in tables V.5 and V.6. The parameters and their values are given in table V.5; the results of the simulation are given in table V.6. The simulation results in table V.6 confirm the belief that the sensitivity of R&D to changes in drug prices may depend on the firm's environment. For instance, the variable that made the most difference in determining the response of R&D to changes in regulated prices was the R&D tax credit. The larger this credit was, the more responsive the firm was to changes in the regulated price. When firms receive large R&D tax credits, their cost of R&D is reduced, making it easier for them to exploit new R&D projects in response to a price increase.

[16]See Pharmaceutical R&D: Costs, Risks and Rewards, U.S. Congress, Office of Technology Assessment, OTA-H-522 (Feb. 1933), p. 196.

Table V.5: Variables Used in Simulation Model

Variable	Definition	Value	Source of value
s^B	Probability of success of marginal R&D project in producing a new drug[a]	0.10 - 0.30	The Office of Technology Assessment reports success rates of between 12.5 percent and 23.0 percent. We used these estimates to construct our boundaries.
δ	Discount rate	0.05 - 0.25	Grabowski and Vernon varied their discount rate from 0.05 to 0.2.
γ	Rate of tax savings for every $1 the firm spends on R&D	0.4 - 0.8	The Office of Technology Assessment reports an estimate of 0.54. We varied γ around this estimate.
$[P^{BH} Q^{BH}]/R+D$	Ratio of revenues to R&D for product B in market H	6.4842	We computed the average revenues/R&D ratio for 87 firms in 1989.
$[\partial C^{BH}/\partial Q^{BH}]/P^{BH}$	Ratio of marginal cost to price for product B in market H	0.05 - 0.20	Industry officials indicated that production costs were a relatively small portion of total costs.
ϵ^B	Elasticity marginal cost with respect to price for product B	0.01 - 1.5	Marginal costs are thought to be small compared to price; however, without strong priors on the magnitude of the elasticity of marginal cost, we selected a wide range.
r_1	Borrowing rate for external funds	10.50 percent	Prime lending rate as of January 1989[b]
r_2	Opportunity cost of internal funds	9.09 percent	10-year T bill rate as of January 1989

[a]This probability is conditional on the R&D having reached a point where a go/no go decision could be made on a specific product.

[b]We used these interest rates because they belonged to the same period as our data on the sales/R&D ratios of pharmaceutical companies.

Table V.6: Results of Simulation Model

Parameter	Value or range of values for parameter	Range of values for estimate of elasticity of R&D with respect to drug prices
Elasticity of marginal cost with respect to price	0.1-1.5	0.2803-0.6231
Discount rate	0.1-0.25	0.5325-0.8918
Probability of success	0.1-0.3	0.2465-0.7082
Tax credit rate	0.1-0.8	0.1246-1.094

All parameters were initialized at the baseline rates, and then varied as noted in the table.

Baseline rates:

Discount rate = 0.1
Probability of success = 0.2
Tax credit rate = 0.54
Elasticity of marginal cost with respect to price = 1.0

In addition, firms that face more elastic marginal cost curves in their current and future product lines are more sensitive to the impact of price regulation. This conforms to our intuition; the more elastic marginal cost is, the more the firm can exploit an increase in the regulated price by raising output. This effect, like the effects of all the varied parameters, was large, indicating that the effect of price regulation on R&D is responsive to the firm's environment. The probability of success in an R&D project was also an important variable. Firms are more likely to respond to price increases by increasing R&D when success is surer. Again, the range of values was quite wide.

A simulation model can be helpful in developing a range of plausible values, but it is of limited value in testing whether the effect truly exists. A simulation model is, after all, based largely on plausible conjectures rather than actual experience. While our regression model supports the contention that drug prices influence pharmaceutical R&D, our simulation model illustrates that policy parameters may influence the size of this effect.

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