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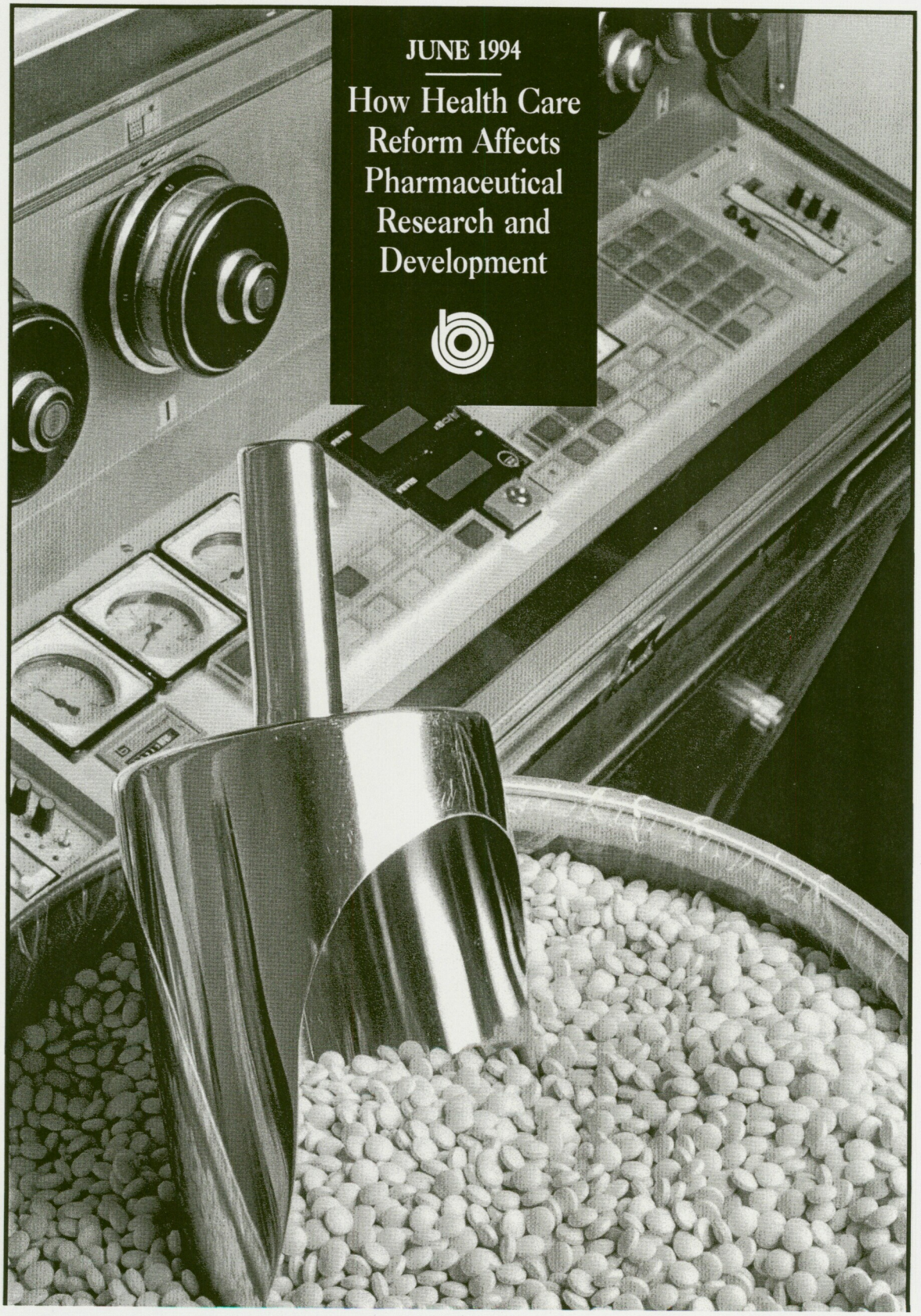

JUNE 1994

# How Health Care Reform Affects Pharmaceutical Research and Development

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#606

# S U M M A R Y

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## HOW HEALTH CARE REFORM AFFECTS PHARMACEUTICAL RESEARCH AND DEVELOPMENT

If the Congress were to enact it, the Administration's proposed health care legislation would not seriously affect the level of drug research and development (R&D) in the pharmaceutical industry.

In its study *How Health Care Reform Affects Pharmaceutical Research and Development*, the Congressional Budget Office (CBO) analyzes the economic impact of the Administration's proposed Health Security Act on the incentives for drug companies to develop pharmaceuticals. CBO concludes that the general effect of the proposal would be to increase the profitability of investments in drug R&D. But the change would be so small that manufacturers would be unlikely to spend much more on the development of new and better medicines. Although it focuses mainly on the Administration's proposal, the analysis can be extended to include other health care plans that contain similar provisions affecting drugs.

One of the knottiest problems of health care reform is how to contain costs while developing new and better medical technology. The Administration's proposal includes provisions that would expand drug coverage as well as hold down the cost of drugs. From the perspective of the drug companies, the two types of provisions balance out; the lost revenue from the cost containment provisions nearly washes out the sales added by the new benefits.

Within this average, however, the cost containment provisions of the Administration's proposal may reduce the incentives for pharmaceutical firms to develop new drugs for the elderly. The proposal would require drug companies to pay a rebate of 17 percent or more to the federal government on outpatient drugs purchased by Medicare beneficiaries. The rebate would reduce the profitability of investment in R&D for outpatient drugs aimed primarily at the 65-and-older population.

At the same time, the expansion of health care coverage would increase the profitability of developing drugs for people under 65. This could result in a small shift of R&D away from outpatient drugs aimed at the elderly and toward those developed for people under 65.

CBO estimates that the Administration's proposal would increase sales of prescription drugs by 4 percent to 6 percent. Most of this increase would result from providing benefits for drugs and physician's services to those who are currently uninsured. Adding outpatient prescription drug benefits to Medicare would increase drug consumption by 1 percent. CBO's estimates exclude those provisions that are surrounded with uncertainty and cannot be quantified, even imprecisely.

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# HOW HEALTH CARE REFORM AFFECTS PHARMACEUTICAL RESEARCH AND DEVELOPMENT

The Congress of the United States
Congressional Budget Office

## NOTES

Numbers in the text and tables may not add up to totals because of rounding.

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# Preface

The Congressional Budget Office (CBO) has prepared this report as part of its continuing analysis of the Administration's and other health care reform proposals. The report contains a general view of the provisions in the Administration's proposal that concern pharmaceutical benefits and costs. It also examines the effect of those provisions on the demand for drugs and on the incentives they offer pharmaceutical companies to invest in research and development. In keeping with CBO's mandate to provide nonpartisan analysis, the report includes no recommendations.

Anna Cook and Philip Webre of CBO's Natural Resources and Commerce Division wrote the study under the supervision of Jan Paul Acton and Elliot Schwartz. Linda Bilheimer of CBO's Health and Human Resources Division provided extensive aid and consultation. CBO analysts Leonard Burman, Sandra Christensen, Robert Dennis, Jon Hakken, Scott Harrison, Harriet Komisar, Charles Seagrave, Paul Van de Water, and Aaron Zeisler also provided valuable comments and assistance. Outside CBO, Sarah Glavin, Henry Grabowski, Gary Guenther, Robert Helms, Alison Keith, Janie Kinney, Joseph Newhouse, B. Randal, F. M. Scherer, Judith Wagner, and Joshua Weiner all provided useful reviews.

Sherwood Kohn edited the manuscript, and Christian Spoor provided editorial assistance. Angela McCollough and Donna Wood typed the many drafts. Kathryn Quattrone and Martina Wojak-Piotrow prepared the study for publication.

Robert D. Reischauer
Director

June 1994

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# Summary

In the fall of 1993, the Administration introduced a comprehensive proposal for health care reform. The Administration's proposal attempted to balance the desire for increased access to medical care with the need to control costs, both overall and in the specific case of pharmaceuticals. This report concentrates on how proposed changes in health care policy--primarily universal coverage and improved Medicare benefits--are likely to affect the size and composition of the pharmaceutical market and the incentives of drug companies to engage in research and development (R&D). The provisions in the Administration's proposal for health care reform that deal explicitly with pharmaceuticals focus mainly on outpatient prescription drugs. In general, the insurance status of inpatient and over-the-counter pharmaceuticals would not be changed directly, though the economic incentives facing those who produce and consume them are likely to change.

Although the study focuses on the Health Security Act, many of that plan's features are also included in other proposals for health care reform. Wherever those other proposals contain provisions similar to the ones examined here, the same analysis would apply.

## Industry R&D and Market Structure

Pharmaceutical expenditures have been rising both in real terms and as a share of national health expenditures. The share of prescription drug spending, excluding most over-the-counter drugs, accounted for 6.4 percent of total national health expenditures in 1991, up from 4.4 percent in 1981. As a share of gross domestic product (GDP), prescription drug spending rose during most of this period, reaching 0.8 percent of GDP in 1991. Outpatient prescription drugs account for three-quarters of all pharmaceutical sales. Other pharmaceuticals are administered in inpatient settings, such as hospitals. In 1993, U.S. prescription sales exceeded $55 billion, according to industry figures.

### Industry R&D

Research and development in the pharmaceutical industry (both foreign and domestic) has increased continuously for the last two decades, both in absolute terms and as a percentage of sales. According to industry figures, in 1993 domestic R&D funded by the industry reached $10.3 billion, or 18 percent of sales. The high level of R&D in this industry, together with relatively low production costs, has created a cost structure that encourages companies to seek ever-larger markets for their products, even if this requires substantial price discounts. The reason is that once a product is developed and approved for sale, it has already incurred R&D costs. Additional sales, even at deep discounts, serve to spread the R&D costs. The fact that pharmaceutical companies can offer some consumers price reductions that they do not offer to others also encourages discounting.

The high technical levels fostered by R&D, coupled with a favorable cost structure, have resulted in

a domestic industry that is very competitive internationally. U.S. firms developed almost half of the important new drugs--those that are sold in all major markets around the world--that were introduced between 1970 and 1992. According to the Department of Commerce, U.S. firms sold one-half (by value) of the world's pharmaceuticals that were consumed in 1991.

## The Changing U.S. Market

Seventy percent of prescriptions are for drugs that are manufactured by more than one company. Even the remaining 30 percent, however, often face competition by substitutes.

On a scale ranging between a perfect monopoly and perfect competition, the pharmaceutical industry can probably best be described as imperfectly competitive; firms have some power to raise prices and generate excess profits. Observers suggest, however, that recent events in the pharmaceutical market are undercutting this power somewhat and serving to move the industry in the direction of more competition.

The market is changing. On the supply side, sales of generic drugs are increasing. On the demand side, buyers exercise more market power to reduce the profits of the pharmaceutical companies. Demand-side changes include the spread of companies devoted to managing the pharmaceutical benefits for third-party payers, such as health insurance companies, and the expansion of the market share of managed health care providers. Both of these groups use a variety of techniques to reduce pharmaceutical costs, including aggressive negotiations with pharmaceutical companies, restrictive drug utilization lists, and widespread use of generic drugs. Although the use of these techniques is growing, only a small fraction of buyers currently employ them, and even then inconsistently. Still, as a share of total prescription sales, the volume of generic drugs has increased from 23 percent in 1980 to almost 40 percent. Furthermore, patents on many of the top-selling drugs will expire in the next few years, opening the door to even more competition among manufacturers of generic drugs.

# Provisions That Increase Demand for Prescription Drugs

The Congressional Budget Office (CBO) has analyzed two provisions of the Administration's proposal that are likely to increase demand for prescription drugs directly: a universal entitlement to a comprehensive package of health benefits, including reimbursement for prescription drugs (universal coverage), and the addition of a prescription drug benefit to Medicare, which is the primary source of health insurance coverage for the population that is 65 years old and older.

CBO's estimate of the change in demand for pharmaceuticals omits several provisions of the Administration's proposal, usually because these provisions proved impossible to quantify, even approximately. For example, CBO provides no estimate of the way in which shifts to managed care providers would affect the use of prescription drugs, although anecdotal evidence suggests that managed care providers use more prescription drugs than do fee-for-service providers. In addition, incentives facing providers would change under the Administration's proposal and might affect the use of drugs.

The proposed provision of universal coverage, including a drug benefit, would increase total prescription drug expenditures by 3 percent to 5 percent. Adding a drug benefit to Medicare would increase total prescription drug expenditures by 1 percent. CBO estimates that these provisions of the Administration's proposal would increase total expenditures on all prescription drugs by 4 percent to 6 percent.

## Effects of the Administration's Proposal for Universal Coverage on Drug Demand

The Administration's proposal would extend health insurance coverage to all legal residents of the United States. The under-65 population would be

covered by one of three basic types of plans, each of which would include coverage for hospitalization, physician visits, and outpatient prescription drugs. The drug benefit in the Administration's proposal for the high-cost-sharing option would pay 80 percent of the cost of prescription drugs after a $250 deductible had been met. If a person were to enroll in the low-cost-sharing option, he or she would pay $5 per prescription with no deductible. The combination plan would offer the low-cost-sharing benefits when a patient used a plan's network of health care providers. Otherwise, the high-cost-sharing benefits would apply. All three plans would place an annual limit of $1,500 per individual ($3,000 for families) on all out-of-pocket medical expenses.

Universal coverage under the Administration's proposal would have the greatest impact on demand for prescription drugs by extending benefits to the 37 million people under age 65 who are currently uninsured. Under the comprehensive benefits proposed, coverage would also improve for another 8 percent of the under-65 population who are insured. But most of the population under 65 already has hospital, physician, and drug coverage through an employer, similar to that included in the Administration's proposal. CBO estimates that universal coverage, including the proposed drug benefit, would increase demand by the under-65 population for all prescription drugs by 5 percent to 7 percent. It is primarily the demand for outpatient prescription drugs that would rise. The under-65 population currently accounts for two-thirds of all prescription drug sales. Thus, universal coverage would increase the total demand of the entire population for all prescription drugs by 3 percent to 5 percent.

## Effects of the Administration's Proposal for Expanded Medicare Benefits on Drug Demand

Under Medicare, everyone 65 and over and eligible for Social Security is automatically entitled to hospitalization benefits. So are certain disabled people under 65 and some people with severe renal disease. All people who are 65 and over, as well as other people who are eligible for Medicare's hospitalization benefits, may participate in Medicare's Supplementary Medical Insurance program, which covers physician, outpatient hospital, and independent laboratory services. Participants must pay a monthly premium. Supplementary Medical Insurance, to which the drug benefits would be added, covers 95 percent of the 65-and-over population.

Under the Administration's proposal, Medicare beneficiaries would for the first time have a prescription drug benefit as part of their basic coverage. That benefit would be approximately commensurate with the high-cost-sharing option available for the rest of the population under the Administration's proposal. The benefit would pay 80 percent of the cost of prescription drugs after a $250 deductible had been met. Once the recipient had paid $1,000 in out-of-pocket prescription drug expenses, Medicare would cover all pharmaceutical purchases for the year. The Medicare Supplementary Medical Insurance premium would be increased to pay for one-quarter of the cost of the new drug benefits. The new Medicare coverage would also encourage substitution of generic drugs unless otherwise requested by the physician.

By itself, adding the prescription benefit would not be likely to increase pharmaceutical purchases by the 65-and-over population dramatically. Just over half of the 65-and-over population already has supplemental coverage for prescription drugs, primarily through retirement plans. In addition to the basic benefits they get from Medicare, most 65-and-over Medicare beneficiaries also have supplemental coverage for physician services. Many analysts believe that access to physicians is a major factor determining prescription drug expenditures, perhaps more important than drug coverage itself. Consequently, CBO estimates that outpatient drug expenditures for the entire 65-and-over population would rise by only 4 percent if prescription drug coverage were extended to it as a basic benefit. Currently, this population accounts for one-third of all prescription drug purchases. The estimated increase in expenditures for outpatient drugs by Medicare beneficiaries corresponds to a 1 percent rise in the total prescription drug expenditures of the entire population.

# Provisions That Control Costs

The Administration's proposal attempts to control health costs, both directly and indirectly. Most important, it would control the rate of increase in the premiums that health plans could charge for the standard benefit package and would result in major changes in the structure of the health care marketplace. For prescription drugs, rebates and close inspection of introductory prices of new drugs may be the most important direct mechanisms. In addition, indirect effects on the medical care delivery system, such as through increased enrollment in health maintenance organizations that may substitute drugs for surgical or other medical procedures, could be substantial, but they cannot be measured without appreciable error and are not analyzed quantitatively in this study.

## Medicare Rebates

In order to reduce the impact of the expanded Medicare benefit on the taxpayer, the Administration's proposal includes a rebate of at least 17 percent that pharmaceutical manufacturers would have to agree to pay to the government on all brand-name (nongeneric) prescription drugs purchased on an outpatient basis by Medicare beneficiaries. (The rebate on drugs purchased by Medicaid enrollees would end.) The Medicare rebate would be based on the "average manufacturer retail price," which is defined as the price paid to pharmaceutical manufacturers for drugs that are sold through pharmacies and other retailers.

The rebate would increase if the difference between the average manufacturer retail price and the average price paid by institutional purchasers, such as hospitals, exceeded 17 percent. In that case, the rebate would equal the average discount given to institutional purchasers. If the amount of the drugs consumed by Medicare beneficiaries was sufficiently large in relation to the total demand for the drug, the manufacturer would be likely to keep the average discount rate afforded institutional purchasers at or below 17 percent.

This rebate would assure that the government paid no more on average for a drug purchased through Medicare than institutional purchasers do, and would sometimes pay less. The rebate would probably have a much greater effect on drug company profits than the price discount given to a typical institution. People who are 65 years old or older account for one-third of prescription drug sales, but each institution represents only a small fraction of the total market.

The rebate would also increase if the average manufacturer retail price of a drug rose faster than the rate of inflation as measured by the consumer price index. In addition, manufacturers would not be able to exclude a portion of their drugs that are already on the market from the rebate agreement. Either all of the manufacturer's existing drugs or none would be covered by Medicare.

Based on a sample of 100 patented drugs on which the Medicaid program currently spends the most money, CBO found that the median best discount given to institutional purchasers was 18 percent off the average manufacturer price (approximately the price paid by wholesalers and the Medicaid rebate equivalent of the "average manufacturer retail price"). Since the *average* discount given to institutional purchasers would be lower than the *best* discount given to any institutional purchaser, the average amount that brand-name drugs are discounted for institutional purchasers may often be below 17 percent.

Discounts are currently smaller than they might be in the absence of Medicaid rebates. The incentive to give institutional buyers discounts in excess of 17 percent on drugs purchased by people 65 and over would diminish, but perhaps no more so than it has already under the Medicaid rebate agreement.

## Medicare Rebates on New Drugs

For any prescription drug that was first marketed after June 1993, Medicare could negotiate a special rebate if the Secretary of Health and Human Services (HHS) believed the drug was priced excessively or if the drug was marketed abroad at a lower

price. The drug company and the Secretary would have six months from the date of the approval by the Food and Drug Administration (FDA) to negotiate a rebate agreement. If HHS and the company failed to negotiate such an agreement, the Secretary could refuse to reimburse purchases of the drug under the Medicare drug benefit. Without this provision, drug companies would be more likely to try offsetting the rebate by charging higher launch prices.

A special rebate could be negotiated if the price in one or more of almost two dozen foreign--mostly European--countries was significantly below the introductory price in the United States. Since it is unlikely that U.S. introductory prices of any given drug would be lower than the prices in all of these countries, all new drugs could be subject to special rebate negotiations.

Although much of the policy debate has been focused on breakthrough drugs, imitative ("me too") drugs also play a major role in the pharmaceutical market. By providing a therapeutic alternative, these drugs can make a market more competitive well before the patent on the original drug expires, thus limiting the ability of a breakthrough drug's manufacturer to sustain excessive prices. Under the Administration's proposal, only generic drugs would be exempt from the rebate on new drugs. If the Medicare rebate on new drugs is set too high, it could discourage competition and early entry. Given the uncertainty inherent in deciding on a reasonable price, the rebate provision increases the risk of launching new drugs. Similarly, if the rebate is extended to generic drugs, it might also discourage entry. These effects would not be felt immediately because drug companies would probably finish those projects that are nearing completion.

The actions of Medicare, sometimes in conjunction with the Advisory Council on Breakthrough Drugs, could give the federal government a major influence over the prices of many pharmaceuticals. Under the Administration's proposal, the Secretary of HHS would negotiate the initial rebate, based on the "reasonableness" of the launch price. After the launch period, the Medicare rebate would increase if a pharmaceutical company raised its prices above the rate of inflation. Consequently, the federal government would be sending strong signals to manufacturers on launch price and subsequent price increases. The combination of these policies would not have as much force as formal price controls, but would go against a longstanding trend of eliminating price and quantity controls and keeping health and quality regulations.

## Advisory Council on Breakthrough Drugs

Under the Administration's proposal, when any new drug that represents a significant therapeutic advance is approved by the FDA, the launch price would be subject to review by a 13-member Advisory Council on Breakthrough Drugs. This council, appointed by the Secretary of HHS, would be responsible for determining whether a launch price was "reasonable" or not, basing its judgment on related and foreign drug prices; manufacturer's costs, including R&D; various market forecasts; the cost effectiveness of the drug; and its potential contribution to the quality of life. The Secretary of HHS would publish the council's determination, together with minority opinions, in the *Federal Register*. Presumably, the Advisory Council's judgment would be a significant factor in the Medicare rebate negotiations and might affect private negotiations as well. Because the council would deal with all breakthrough drugs, its responsibilities would extend beyond Medicare.

Depending on how the proposed legislation is interpreted, however, the Advisory Council could play a role in just a very small number of drug introductions. Between 1975 and 1991, the FDA approved an average of 22 new drugs (containing new active ingredients, or "new molecular entities" in FDA parlance) per year. The breakthrough category, promising major new therapeutic potential, accounted for one-seventh of all new molecular entities, or about three drugs each year. Including drugs with only modest therapeutic improvement would increase this number to 11 per year.

Although only a few drugs can be classified as breakthroughs, many companies undertake their R&D with the intent of developing just such pharmaceuticals. Thus, even though the number of

drugs directly involved might be small, the inhibiting effect on pharmaceutical companies could be much greater.

## Effects on the Returns from Drug Development

Underlying the Administration's proposal are two conflicting effects: the extension of drug benefits to the entire population could increase the total demand for prescription drugs by 4 percent to 6 percent, boosting profits of pharmaceutical manufacturers; but rebates on drugs sold to Medicare patients and other cost controls could limit profits (or returns). The net effect on returns from drug development would be small and positive when averaged among all drugs, but would differ among drugs and could be negative for some.

Estimated profits from drug development, averaged among all drugs and outpatient markets, would

**Summary Table 1.**
**The Effect of the Administration's Proposal on the Present Value of Profits Generated Over the Lifetime of the Average Drug**

| Administration's Proposal | Description | Effect on the Presciption Drug Market | Change in Average Profits from Developing a Drug (In percent)[a] | | |
|---|---|---|---|---|---|
| | | | Drugs Purchased Only by People Under 65 | Drugs Purchased Only by People 65 and Over | Drugs Purchased Two-Thirds by People Under 65, One-Third by People 65 and Over (Market average)[b] |
| Universal Coverage | The proposal contains a universal entitlement to a standard benefit package that includes prescription drug coverage. Primarily affects the under-65 population. | Expenditures by the under-65 population on all pharmaceuticals would rise by 6 percent. | 8 | 0 | 6 |
| Medicaid Becomes Part of the Alliance System | Government would fully subsidize participation of most Medicaid recipients in the alliance system. | Medicaid rebates would be eliminated. Average unit revenues on outpatient sales would rise by 2 percent. | 3 | 3 | 3 |
| Drug Benefit Added to Medicare | Medicare would cover outpatient drugs. A rebate of at least 17 percent would be imposed on outpatient drugs purchased through Medicare. | Expenditures by the 65-and-over population on outpatient pharmaceuticals would rise by 4.5 percent. Unit revenues would decline by 17 percent. | 0 | -17 | -6 |
| | | Total | 11 | -14 | 3 |

SOURCE: Congressional Budget Office.

a. Change in the discounted value of the stream of profits generated by the worldwide sales of the average drug over its lifetime.

b. On average, people 65 and over account for 34 percent of prescription drug expenditures.

rise modestly--by less than 3 percent--under the Administration's proposal. Consequently, the level of industry R&D might not change appreciably, given the small changes in total returns from drug development. (See Summary Table 1.)

Behind this average, however, market segments would vary significantly. Profits would fall by an average of 14 percent on those drugs that are sold exclusively to the 65-and-over population and would rise by 11 percent on those drugs sold exclusively to the under-65 population. Although few drugs are marketed exclusively to either population, CBO's analysis found that under the Administration's proposal, once half of the market for a drug was made up of sales to the 65-and-over population, returns would decline slightly.

A decline in the profits from developing pharmaceuticals primarily for the 65-and-over market would reduce the incentives to produce such drugs. The difference in returns on the basis of age groups might cause some R&D to be shifted away from drugs targeted at those 65 and over toward drugs aimed primarily at those under 65.

These estimates should not be viewed as CBO's final analysis of the overall effects of the Administration's proposal. Rather, they are best viewed as illustrative estimates of the portion of the proposal that CBO was able to quantify. Although the factors omitted could serve to increase or decrease returns, CBO's sensitivity analysis showed that large variations in the assumptions about induced demand do not change the overall result--namely, that the proposal would affect average profits from drug development only slightly.

CBO's calculations assume that the manufacturers entirely absorb the cost of the 17 percent Medicare rebate. Such burdens, however, are usually shared between producers and consumers according to their relative sensitivity to changes in price. But because the Administration proposes to monitor launch prices and price increases, pharmaceutical companies might find it difficult to pass these rebates on to other consumers. Consequently, the drug companies would probably absorb a very large share of the rebate.

However, the more Medicare administrators are able to make pharmaceutical producers absorb the cost of the rebate, the less incentive these producers will have to invest in developing new drugs for the 65-and-over market. By contrast, the less Medicare administrators are able to make the pharmaceutical companies absorb the rebate, the more other drug consumers will pay for the Medicare benefits.

CBO's estimates assume that the federal government could enforce price restraints. But that is an open question. Many times in the past the federal government has tried to restrain price growth, usually with mixed results at best. The modern market is too complicated for a limited bureaucracy to track and control successfully. Prices in the drug market are especially complicated; drug prices vary in many dimensions (dosage, form, and packaging, to name only three), any one of which could be used to mask a price increase. Given the hundreds of drugs and manufacturers and the thousands of dosage and packaging forms, the federal agencies in charge of monitoring drug prices would have to rely on the basic compliance of the drug companies, as they do now for the Medicaid rebate. Such reliance often leads to incomplete compliance.

Chapter One

# Introduction

In many ways, the debate over the interaction between health care reform and the pharmaceutical industry represents a more general tension generated by changes in the health care system and the development of new medical technologies. On the one hand, U.S. medicine is the most technologically advanced in the world. The public appreciates this and generally endorses the continued development and provision of high-technology health care. On the other hand, many people feel that health care costs too much and that the rapid pace of technological development is a major contributing factor.

As proposals to restructure the health care system have proliferated, critics have expressed concern about the effects the proposed changes would have on research and development (R&D) and future access to new treatments, including pharmaceuticals and other medical technologies. The quandary facing health care reform efforts can be summed up as a public desire to save the goose that laid the golden eggs, but not to pay too much for the goose.

The desire for profits (or returns) is one of the basic reasons that investors fund the R&D needed to produce new pharmaceuticals and other medical technology. The higher the anticipated returns from technology development, the greater the incentive to invest in the necessary R&D. If changes in the health care system increase the profits from developing new medical technology, firms are likely to increase their investment in it. Conversely, decreases in the returns from developing new medical technology are likely to lower the level of R&D in this field. Thus, reducing costs must be balanced against affording sufficient incentive for drug companies and other providers of medical technology to continue investing in medical progress.

The Administration's proposal, the Health Security Act, could change the returns from pharmaceutical R&D.[1] Although this study analyzes the effect of the Administration's proposal on these returns, many of its conclusions apply to other plans that incorporate the same or similar features. Since other health care proposals are trying to accomplish similar goals, they face many of the same tensions and are likely to use many of the same mechanisms.

Most reform proposals contain three elements that would affect patterns of pharmaceutical use and spending:

- Expanding coverage in the form of new benefits and to new people,
- Shifting people into managed care, and
- Controlling costs.

What economists know about these elements is very spotty. Surveys are available to help quantify the effect of expanded coverage. Little information exists, however, to help predict the effects of a greater shift toward managed care plans or cost control mechanisms on pharmaceutical spending.

1. References to the Administration's proposal are to the Health Security Act, H.R. 3600 and S. 1757, 103rd Congress, 1st Session, 1993. For a more comprehensive analysis of that proposal, see Congressional Budget Office, *An Analysis of the Administration's Health Proposal* (February 1994).

For example, the comparison of the use of pharmaceuticals in fee-for-service health plans with their use in health maintenance organizations is based on one limited study. The dual nature of pharmaceutical consumption--the fact that drugs complement medical treatments as well as substitute for them--also complicates the analysis. Thus, cutting down health costs could lower pharmaceutical demand in one way, but increase it in another.

The Administration's proposal also contains provisions that may affect pharmaceutical demand and are likely to interact with each other as well as with the three elements above. A partial list includes:

- Outpatient prescription drug coverage for Medicare beneficiaries;
- Rebates on outpatient prescription drugs sold to Medicare beneficiaries;
- Special Medicare rebates on new drugs and an Advisory Council on Breakthrough Drugs to examine launch prices;
- An end to rebates on outpatient prescription drugs sold to Medicaid beneficiaries;
- Coverage of some services that are not well covered now by private health plans and have significant drug treatment components (examples include mental health and family planning services);
- Coverage of investigational treatments (such as some experimental drugs for human immunodeficiency virus--HIV--infection);
- Increased out-of-pocket costs for prescription drugs for many current Medicaid beneficiaries; and
- Constraints on the rate of growth of premiums for the standard benefit package.

The combined effect of these provisions on pharmaceutical demand and supply and on the future profitability of pharmaceutical R&D is highly uncertain. The Congressional Budget Office (CBO) cannot realistically provide a quantitative estimate of all the effects of the Administration's proposal on the pharmaceutical market. CBO's analysis examined the first four items on the list, in addition to expanded coverage. In cases where estimates of the quantitative effects could be made, CBO did so. In other instances, the range of uncertainty was too great and CBO made no estimate. Even when quantitative information is available, it must be applied with caution. In sum, the assessments discussed in this study are best considered illustrative and partial estimates of the effects of the Administration's proposal for health care reform on the profits from drug development.

Chapter Two

# Industry and Market Background

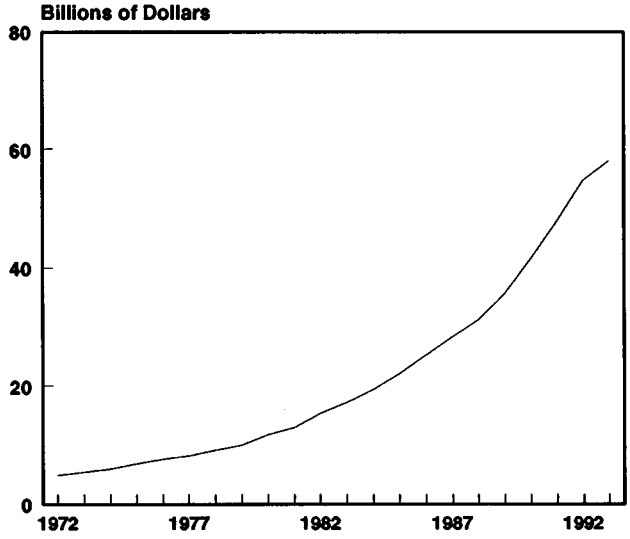
The U.S. prescription drug market has grown rapidly in recent years (see Figure 1). The industry estimates that domestic prescription drug sales, both institutional and outpatient, have almost doubled since 1988, reaching an estimated $58 billion in 1993.[1] Since 1980, U.S. spending for prescription drugs has grown at an average annual rate of 13 percent. (These estimates are not adjusted for inflation. Many economists are concerned about the accuracy of the Bureau of Labor Statistics' measures of price changes for pharmaceuticals (see Box 1). Instead of using them, this study presents pharmaceutical spending in relation to the economy and the rest of the health care sector.)

Although spending on prescription drugs has grown rapidly, it accounts for only a relatively small portion of national health expenditures (see Figure 2). Since 1972, prescription drug shipments have accounted for between 4.5 percent and 6.5 percent of total national health expenditures. Indeed, their share of national health expenditures has risen by almost half since 1981. These figures represent manufacturers' sales and do not reflect the final retail cost to consumers. The share of retail sales would be higher, but this estimate reflects the share of health expenditures that go to drug manufacturers.

Prescription drug spending has doubled its share of the gross domestic product (GDP) since 1972 (see Figure 3). In 1972, prescription drug shipments accounted for 0.4 percent of GDP. By 1993, this share had risen to 0.8 percent of GDP.

This estimate differs from other analyses in that it deals exclusively with prescription drugs. The national health accounts gather into one category

**Figure 1.**
**U.S. Prescription Drug Sales**




SOURCE: Congressional Budget Office based on Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 8.

NOTE: Includes institutional and outpatient prescriptions. Estimate for 1993 was revised by PMA in 1994 and adjusted by the Congressional Budget Office to reflect missing data.

1. This estimate excludes many over-the-counter drugs. Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 8. Data for 1993 were revised by PMA in February 1994 and adjusted to reflect missing data. The Congressional Budget Office obtained a similar estimate by adjusting data on industry shipments for over-the-counter drugs and net exports from the Census of Manufacturers.

**Box 1.**
**Measurement Issues in Pharmaceutical Price Increases**

By conventional measures, the pharmaceutical industry has consistently high inflation rates. But these conventional measures are not well suited to industries, such as the pharmaceutical business, that frequently introduce new products.[1] The measures may overstate the rate of increase in pharmaceutical prices. In essence, conventional inflation gauges fail to reckon with major forms of competition in the pharmaceutical industry and therefore may not be useful indicators of true inflation in the industry.

Measured by the producer price index (PPI), increases in pharmaceutical prices have been dramatic. The PPI for pharmaceuticals doubled between 1982 and 1993, while the PPI for all finished goods rose by only one-quarter. In other words, the average annual increase in pharmaceutical prices (6.5 percent) was more than triple that for all finished goods (2 percent).

Several economists have criticized the sample used by the Bureau of Labor Statistics (BLS) to measure pharmaceutical price increases in the PPI, saying:

- The sample is too narrow,
- It is biased toward older drugs,
- It improperly incorporates generic drugs, and
- The measure excludes changes in quality.[2]

These critics argue that the relatively small sample of drugs used by the BLS does not represent the movements of the larger universe of drugs. In one instance, the economists recalculated the degree of pharmaceutical inflation using a larger sample than that of the BLS and weighted the prices in a way that more appropriately reflected the increasing sales of new drugs. These two changes decreased the measured inflation for the 1988-1991 period from 8.4 percent as measured by the BLS to 6 percent with the corrected methodology and a larger sample.[3] (The PPI for all finished goods increased at an annual rate of 4.1 percent during this period.)

1. The number of drugs on the Department of Health and Human Services list of existing drugs increased by 50 percent between 1982 and 1987. See David Cleeton, Valy Goepfrich, and Burton Weisbrod, "What Does the Consumer Price Index for Prescription Drugs Really Measure?" *Health Care Financing Review* (Spring 1992), p. 45.

2. Although the studies analyzed the PPI in detail, similar comments apply to the consumer price index (CPI) with some modifications.

3. Ernst Berndt and Paul Greenberg, "Price Growth of Prescription Pharmaceutical Preparations: An Update and Explanation" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

(drugs and medical nondurables) both prescription drugs sold through retail outlets and other nondurable medical supplies, most notably over-the-counter drugs. Most estimates of prescription drug spending as a proportion of national health expenditures do not separate these out. Conversely, the national health accounts leave out of this category drugs that are consumed in hospitals, nursing homes, and doctors' offices.

After the Food and Drug Administration (FDA) approves a prescription drug, the drug's manufacturer often applies to have the product changed to over-the-counter status to take advantage of consumer brand loyalty, especially when the patent is nearing expiration.[2] How the Administration's proposal would alter the incentives to change a drug's status is beyond the scope of this study, which focuses on prescription drugs (see Figure 4 for a comparison of the U.S. over-the-counter and consumer outpatient prescription drug markets).

Although federal statistical sources tally prescription drugs according to where they were purchased, these categories do not necessarily correspond to the reimbursement categories used by Medicare, Medicaid, and private insurance compa-

2. "Self-Medication Boom," *Med Ad News* (February 1994), p. 44. See also "Switches Don't Come Easy," *Med Ad News* (January 1994), p. 21.

The BLS agreed with the first two criticisms and began to revise its pharmaceutical sampling methodology. The economists also argued that BLS methodology did not properly include generic drugs. When the BLS includes generic drugs, it usually classifies them as "new" drugs. Under most circumstances, the BLS does not link a name brand to its generic replacement. Only when the brand-name manufacturer of a particular drug also produces a generic version of that drug is the connection sometimes made.

This lack of connection between brand-name and generic versions of the same drug means that the BLS inflation measure usually misses the price decline caused by movement to a cheaper generic drug. For example, if a generic version costs 20 percent of what the brand-name version costs, shifting 40 percent of quantities purchased to the generic form would bring the average cost down by 32 percent.[4] If each drug is classified as different, however, the BLS will never measure a price drop. The BLS may catch future changes in the price of the generic drug, but a one-time shift to cheap sources would be missed. In the market for one drug, cephalexin, the conventional inflation measure showed a price rise of 14 percent during the April 1987-September 1990 period, while one that included generic versions showed a drop of 48 percent.[5]

The BLS price measures also have no way of incorporating the added benefit to consumers of better drugs; the prices of new drugs are not adjusted to reflect additional therapeutic value. Recently, one economist tried to make quality adjustments in one product class (ulcer medicine) to see how much prices had increased once the improvements were factored in. She found that nominal price measures had risen by 11 percent a year for the 1977-1989 period, but her quality-adjusted measure rose by only 6 percent a year for the same period.

Thus, two central policy goals for the pharmaceutical industry--controlling prices through new and generic drugs and encouraging the development of better drugs--are systematically mismeasured by both the consumer price index and the PPI.

4. Generic drug sales account for almost 40 percent of all drug sales.

5. Zvi Griliches and Iain Cockburn, *Generics and New Goods in Pharmaceutical Price Indexes* (Cambridge, Mass.: Harvard Institute of Economic Research, Harvard University, December 1993).

6. Valerie Suslov, "Are There Better Ways to Spell Relief? A Hedonic Pricing Analysis of Ulcer Drugs" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

nies.[3] Most important, drugs purchased in nursing homes are often classified as outpatient drugs for the purposes of private insurance and Medicaid reimbursement. Some drug purchases in certain skilled nursing facilities, however, are classified as inpatient for the purposes of reimbursement by Medicare, just as they would be in a hospital.

The Congressional Budget Office assumes that if outpatient prescription drug benefits are extended to Medicare enrollees, most nursing home drug expenditures not now covered by Medicare would be included. In 1991, nursing homes accounted for 3 percent of total U.S. pharmaceutical sales. Conversely, some drugs purchased in hospitals are for outpatient use. In 1991, hospitals accounted for 23 percent of total U.S. pharmaceutical sales. CBO assumes that these two sources of error in estimating the inpatient portion of the prescription drug market will largely offset each other and that the inpatient market is 23 percent of the total prescription drug market. CBO assumes the remainder is the outpatient market.

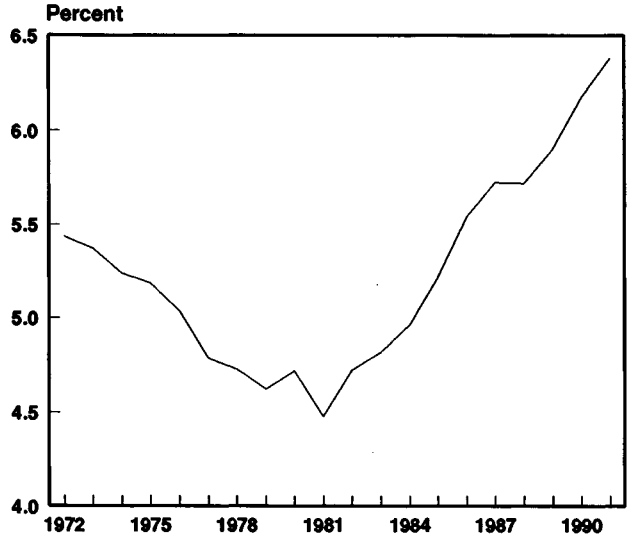
3. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993), pp. 238-240.

# Structure of the U.S. Pharmaceutical Industry

The U.S. pharmaceutical industry is internationally competitive and research-intensive. It produces medicines for both human and veterinary use. Within the human-use category, the industry includes companies that produce brand-name and sometimes generic drugs; those that manufacture brand-name drugs and products often related to other aspects of medical care; and makers of generic drugs, diagnostic substances, and bulk chemicals.

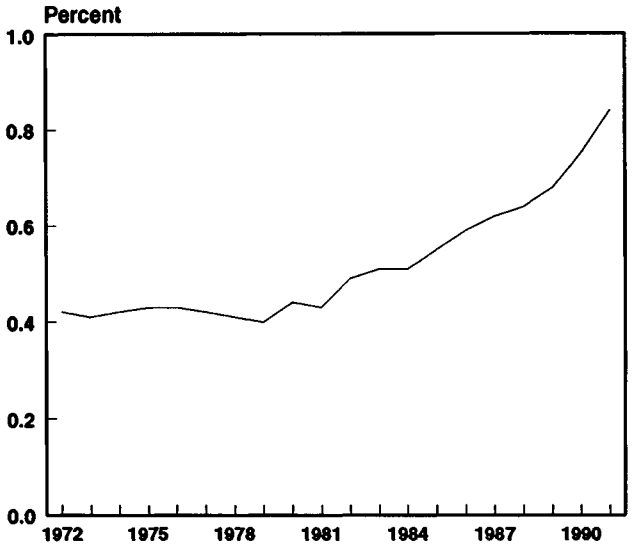
The industry is one of the most research-oriented in the United States. In 1991, it spent almost three times as much on research and development (as a percentage of sales) as the average for all U.S. manufacturers.[4]

**Figure 2.**
**Prescription Drug Spending as a Percentage of National Health Expenditures**




SOURCE: Congressional Budget Office based on Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 8, and data from the Health Care Financing Administration.

**Figure 3.**
**Prescription Drug Spending as a Percentage of Gross Domestic Product**




SOURCE: Congressional Budget Office based on data from the Bureau of Economic Analysis and Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 8.

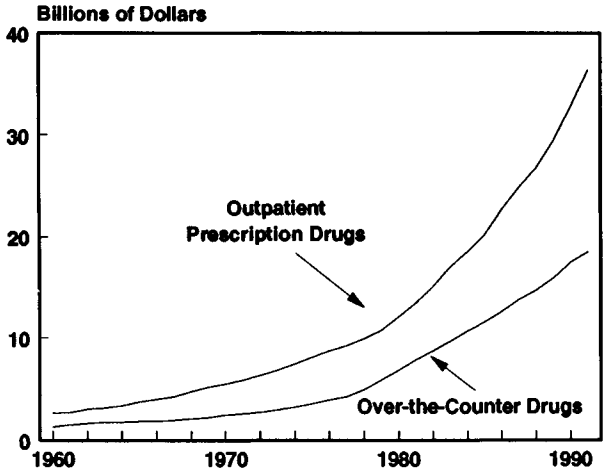
## Competition and Barriers to Entry in the Drug Industry

Manufacturers of the drugs that are most commonly prescribed do not enjoy a monopoly. Instead, they have competitors. In 1989, some 70 percent of prescriptions were written for multisource drugs, both brand-name and generic.[5] For the most part, these are drugs for which the patent has expired and that are now made by both generic and brand-name companies. Alternatively, the drug might still be under patent, but manufactured or marketed under license by more than one company. Only 30 percent of prescriptions were for single-source drugs.

4. National Science Foundation, *Selected Data on Research and Development in Industry: 1991* (1993), Table SD-9. Industry sources presented below differ.

5. Richard Caves, Michael Whinston, and Mark Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics, 1991* (1991), p. 6.

**Figure 4.**
**U.S. Consumer Spending on Pharmaceuticals**




SOURCE: Congressional Budget Office based on data from the Bureau of Economic Analysis and the Health Care Financing Administration.

Just because a drug is made by only one company does not mean that it has no competitors--often several different drugs will be available to treat the same medical condition.[6]

Although much of the policy debate has been focused on breakthrough drugs, the imitative drugs also play a major role in the pharmaceutical market. Imitative or "me-too" drugs use the same biological mechanism as breakthrough drugs and can therefore serve as alternative treatments. By providing therapeutic alternatives, these drugs can introduce competition into a market well before patents expire, thus limiting the ability of the breakthrough-drug manufacturers to sustain high prices. Me-too drugs are often competing single-source drugs.

When Prozac was introduced into the antidepressant market in 1988, for example, it offered a new treatment with fewer side effects than many of the older antidepressants.[7] The result was that Prozac became one of the five most widely prescribed drugs in the United States, enjoying worldwide sales of $1 billion in 1992.[8] Such a market was a tempting target for other companies. Within five years, three lower-priced drugs, all using some variant of the same treatment, were on the market in the United States. Four other drugs are being sold in Europe and await FDA approval for U.S. sale. Because there are several close rivals, manufacturers of antidepressant drugs are being forced to offer discounts, even though their patents last until after the year 2000, when generic versions will be permitted to enter the market.

One explanation for the rapid entry of rival drugs into the market is that all were exploiting a basic biomedical discovery and that the competing companies had products already in the approval process when Prozac was sanctioned for sale. In many instances, the first company to exploit a new biological discovery is merely the first among several to complete a race to market. In some cases, however, it is years before substitutes for truly innovative drugs are introduced, although this is probably correlated with the size of the market they serve.[9]

The Prozac experience is not unique. According to one recent study sponsored by the industry, in therapeutic areas where treatments already existed, new drugs introduced during 1991 and 1992 were launched with prices that averaged 14 percent below that of the market leader. New products in the most active therapeutic categories averaged 36 percent less.[10] Another recent study of 148 drugs introduced into the U.S. market between 1978 and 1987 indicated that more than half of those substances that provided the same benefits as existing drugs but offered no increase in therapeutic potential were

6. A drug is considered multisource if bioequivalent versions are available from more than one company. Other sources can be brand-name or generic. If a drug is single source, it may have close therapeutic substitutes, but not bioequivalent competitors. Imitators (or "me-too" drugs) use different molecules to accomplish the same treatment as a single-source drugs. A generic drug is certified by the FDA as being bioequivalent to the original drug that has lost its patent.

7. Milt Freudenheim, "The Drug Makers are Listening to Prozac," *New York Times*, Business Section, January 9, 1994, p. 7.

8. "100 Powerhouse Drugs," *Med Ad News Supplement* (May 1993), pp. S5, S7, and S14.

9. Z. John Lu and William S. Comanor, "Strategic Pricing of New Pharmaceuticals" (paper presented to the American Economics Association, Boston, Mass., January 1994).

10. Boston Consulting Group, *The Changing Environment for U.S. Pharmaceuticals* (New York: Boston Consulting Group, April 1993), pp. 8-9.

introduced at prices below the market leaders.[11] After drugs were launched at low prices, however, price increases for many of them were higher than average. (Drugs that provided new therapeutic capabilities were introduced at a premium.) But in general the authors found, "*both the introductory price and subsequent price increases are lower when there are more substitutes in the market.*"[12] [Authors' emphasis.]

In some instances, when there are only one or two imitators, competitive pressures may not be substantial. Often several drugs will be appropriate to treat a given condition, but will be imperfect substitutes. Each drug may have its particular strengths and weaknesses, and often side effects. Thus, a doctor may treat the same malady differently in different patients. Even when firms compete, they may primarily use nonprice factors to do so. A firm may, for example, increase its promotional efforts as a way of increasing market share. Price competition is more likely to occur after several rival manufacturers enter the scene. The fact that some drugs may not have identical substitutes gives the pharmaceutical companies some market power.

Although it is relatively easy to begin R&D in the pharmaceutical industry, it is difficult to initiate marketing. Some barriers are regulatory, such as the seven- to eight-year process of getting a drug approved by the FDA.[13] Others are legal, such as the monopoly provided by the patents on new medicines. Other barriers are economic, such as the large research infrastructure necessary to produce new and sophisticated chemicals that can compete in the world marketplace.

There are many small firms in the industry, but large firms play a disproportionate role in sales and R&D. During the 1980s, the largest 20 companies accounted for almost two-thirds of the pharmaceutical industry's total shipments.[14] But when only prescription drugs are counted, the top 20 firms account for more than 80 percent of the industry's sales.[15]

In recent years, biotechnology firms have entered the industry in large numbers, but they have yet to produce more than a handful of commercially successful products. If new technology reduces the cost of developing drugs, a substantial increase should take place in the number and role of these companies and their effect on prices and quantities of drugs sold in the U.S. market. This change would reduce some nonregulatory barriers to entry into the industry.

## Pharmaceutical Company Profits

High profits are commonly cited as proof of the lack of competition in the pharmaceutical industry. Although the industry does have high profit rates by conventional measures (even accounting for higher risk), such as the return on assets or return on equity, these gauges are not well suited to such industries as the pharmaceutical business, which invests heavily in intangible capital, such as marketing and R&D.[16] These measures of profitability may introduce a bias that results in an understatement of a firm's capital assets, which in turn produces an overstatement of its profit rate. In essence, conventional accounting measures of profit systematically

11. Lu and Comanor, "Strategic Pricing of New Pharmaceuticals."

12. Ibid., p. 26.

13. Joseph DiMasi and others, "Cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics* (1991), p. 123. See also Office of Technology Assessment, *Pharmaceutical R&D*, p. 151.

14. International Trade Commission, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals* (September 1991), p. 4-2. Shipments cover the received net selling values at the manufacturing plant of all product shipped.

15. Ernst Berndt and Paul Greenberg, "Price Growth of Prescription Pharmaceutical Preparations: An Update and Explanation" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

16. Most of the marketing expenses of the pharmaceutical industry are not in advertising, but in promotional visits to doctors, usually called detailing. In 1989, detailing accounted for three-quarters of marketing expenses. Almost a quarter was devoted to advertising in medical journals, with a small amount spent on direct mail advertising. Caves, Whinston, and Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," p. 12.

ignore major forms of investment by the pharmaceutical industry and may therefore not be the most appropriate measure by which to judge competition in this industry.[17] Economists have found that properly measured, pharmaceutical company profits are only slightly above the average for companies in all industries.

Conventional accounting rules permit firms to accumulate certain types of spending as capital assets, but require other types to be deducted from income in the year in which the expenditure is incurred. Expenditures for intangibles present special problems. Clearly, in the right circumstances, spending on marketing and R&D can benefit a company for years to come, just as it would benefit from money spent on a manufacturing plant. In a practical sense, such spending is an investment in company assets. But conventional accounting practice does not classify it as such. Instead, accounting practice treats it as a short-lived expense. Accounting measures of profitability are usually based on the level of a firm's assets; expenses are deducted from revenue to determine the profit level, which is measured in relation to company gross or net assets.

Because industries vary in their level of R&D and marketing, conventional accounting rules affect their measures of profit differently. Firms in industries in which high levels of both R&D and marketing are important, such as the pharmaceutical industry, may find their asset-based measures of profit systematically overstated. Conventional accounting more accurately measures assets and profits in such industries as heavy manufacturing in which neither R&D nor marketing has played an important role.

Recently, Kenneth Clarkson, an economist specializing in the field of intangible assets, analyzed the effects of conventional accounting rules on the stated profit rates of 113 firms in 14 industries, including the pharmaceutical industry.[18] He found that the rules distorted the measures of profitability in many industries, in different directions, and to different degrees.

First, Clarkson measured the importance of intangible assets in the pharmaceutical industry. Using income tax and census data, he found that among the 14 groups examined, the pharmaceutical industry was one of three that spent the greatest proportion, as a share of net sales, on marketing. Similarly, his measure of R&D showed the pharmaceutical industry to be third highest in spending share. He split R&D into its components, on the grounds that each would turn out marketable products at a different rate. Significantly, based on previous studies of the economic life of R&D, he argued that R&D in the pharmaceutical industry translates into products (accumulates) at between one-half and three-quarters of the rate of other high-R&D industries, partly because of lags in regulatory approval. Slower accumulation would mean that the R&D assets in the pharmaceutical industry are lower than their high share of sales would imply.

Next, Clarkson recalculated the rates of return on assets and equity (including the intangible assets) for the firms in these industries during the 1980-1989 period. He found that when he corrected for differing rates of investment in intangible assets, the average return on equity for all 113 firms fell slightly, from 14 percent to 11 percent. By contrast, the pharmaceutical industry's rate of return on equity fell from 21 percent to 13 percent. Although still higher than in most industries (it ranked third highest, after computer software and foods), the rate of return in the pharmaceutical industry was much closer to the mean--2 percentage points, not 7 percentage points, higher.

Clarkson's results are higher than, but generally consistent with, earlier studies that attempted similar adjustments. In general, the earlier studies found that (1) the measured pharmaceutical industry profit rate declined by between 2 percentage points and 6 percentage points when intangible capital was ad-

17. F. M. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry," *Journal of Economic Perspectives* (Summer 1993), p. 104.

18. Kenneth Clarkson, "Intangible Capital and Profitability Measures: Effects of Research and Promotion on Rates of Return" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

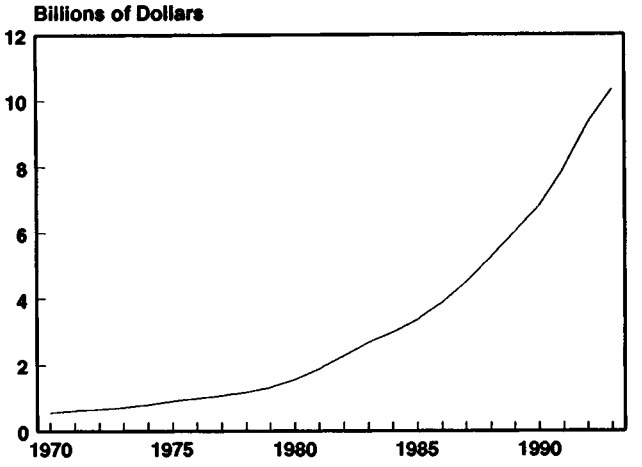
justed for and (2) despite this, the industry profit rate remained above the average by 3 percentage points. The Office of Technology Assessment (OTA) also sponsored an independent study of the pharmaceutical industry's profitability, using a different methodology. This study's conclusions are similar to Clarkson's.[19]

Thus, differing pictures of the pharmaceutical industry emerge, depending on the measures of profitability applied. The more conventional measures point to a very profitable industry in which monopoly profits generated by patents raise the industry return to very high levels. A more sophisticated look--one that more nearly matches the industry investment profile--shows a less but still quite profitable industry, but one in which R&D spending and patent rights generate imperfect competition rather than monopoly. This latter picture is consistent with the analysis presented later in this report, which shows that the average new drug produces a small amount of excess profits; that is, profits beyond those necessary to reward the investors after manufacturing and other costs have been paid. These excess profits also help explain why drug companies may have increased their R&D dramatically during the 1980s and why more firms are seeking to enter the market.

## The Role of R&D in the Pharmaceutical Industry

The U.S. pharmaceutical industry has always invested heavily in R&D. The process starts in the laboratory with the discovery of chemicals and molecules that have therapeutic potential, turns these substances into products, and culminates in testing on animals. Industry R&D then moves to clinical trials, where first safety, then efficacy, of the products are tested in three phases on ever-increasing numbers of people. Long-term animal trials typically continue during the human clinical trials. Drugs that fail one step typically do not proceed to the next.

**Figure 5.**
**Research and Development Spending by the U.S. Pharmaceutical Industry (In billions of dollars)**




SOURCE: Congressional Budget Office based on Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 6.

Industry research and development (both foreign and domestic) has increased continuously for the last two decades, both in absolute terms and as a percentage of sales (see Figures 5 and 6).[20] At least part of the increase in R&D is the result of rising costs of clinical trials.[21] Half of the industry R&D

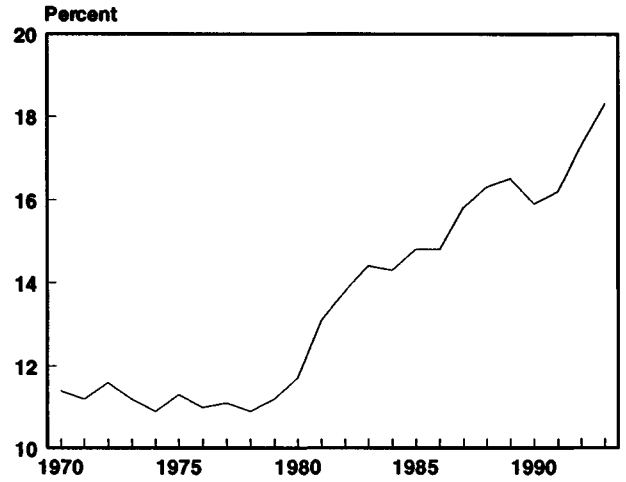
19. See Office of Technology Assessment, *Pharmaceutical R&D*, pp. 96-99. In fairness, Clarkson's sample of companies is the broadest, both within the pharmaceutical industry and generally, of any study reviewed by OTA. See William Baber and Sok-Hyon Kang, "Accounting-based Measures as Estimates of Economic Rates of Return: The Case of the U.S. Pharmaceutical Industry, 1976-1987" (paper produced under contract with the Office of Technology Assessment, July 1991).

Some people have argued that pharmaceutical companies have greater profits, but that they dissipate these profits in R&D races or by paying too much for the R&D they undertake. One study examined by CBO suggested that fears about R&D races were overstated. See Rebecca Henderson and Iain Cockburn, "Racing to Invest? The Dynamics of Competition in Ethical Drug Discovery" (Sloan School of Management, Massachusetts Institute of Technology, Cambridge, Mass., May 1993).

20. Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales & R&D*, pp. 4-8, and National Science Foundation, *Selected Data on Research and Development in Industry: 1991*. Both sources agree roughly on patterns and trends in R&D spending. There is a 15 percent discrepancy between the different sources. The industry and NSF also have different classifications for industry sales so their R&D-to-sales ratios differ.

21. Measured by number of clinical trials or patients per drug approval. Some analysts argue that these costs are rising because the pharmaceutical industry is now grappling with more long-term and complicated illnesses that do not lend themselves to straight-

**Figure 6.**
**Research and Development Spending by the U.S. Pharmaceutical Industry (As a percentage of sales)**




SOURCE: Congressional Budget Office based on Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales and R&D* (Washington, D.C.: PMA, October 1993), p. 7.

expenses occur once clinical trials have begun.[22] Furthermore, the share of trial-related expenses has been rising over the last decade.

Although the federal government spends heavily on biomedical research, it spends relatively little directly on drug development. Overall, federal agencies spent $750 million in clinical and preclinical pharmaceutical evaluations in 1990.[23] By comparison, the U.S. drug industry spent $10.8 billion worldwide on pharmaceutical R&D for human use in 1992.[24]

**R&D and the Industry Cost Structure.** It is well known that researchers in the pharmaceutical industry typically test thousands of chemicals in order to find one that passes all the clinical trials and is finally approved by the FDA. It is less well known that, on average, only 3 of 10 drugs approved by the FDA and brought to market sell sufficiently well to earn back the average investment in R&D for a new drug, which includes the cost of the pharmaceuticals that do not even make it to market.[25] Of these three, in the recent past, only one has been a principal source of industry income. Thus, a few very successful discoveries provide most of the income (see Figure 7).

As a share of sales price, pharmaceutical production costs are low; the Office of Technology Assessment estimates that the share is 25 percent.[26] One implication of this cost structure (high sunk costs, low production costs) is that a larger pharmaceutical market (in terms of quantity) permits lower prices because it allows the sunk costs, or money that has already been committed and spent for R&D costs, to be spread over a larger number of buyers. For drugs marketed during the early 1980s, these R&D costs, including funds spent during FDA clinical trials, averaged close to $200 million per drug.[27] Such costs are considered to be largely fixed, or constant, because the R&D is the same whether the company sells one or one billion pills.[28]

forward analysis. Boston Consulting Group, *The Changing Environment for U.S. Pharmaceuticals*, pp. 25-32. OTA also finds that the size of clinical trials is rising. Office of Technology Assessment, *Pharmaceutical R&D*, pp. 64-65.

22. Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales & R&D*, p. 29.

23. Office of Technology Assessment, *Pharmaceutical R&D*, pp. 214-215 and 311-315.

24. Pharmaceutical Manufacturers Association, *Trends in U.S. Pharmaceutical Sales & R&D*, p. 26.

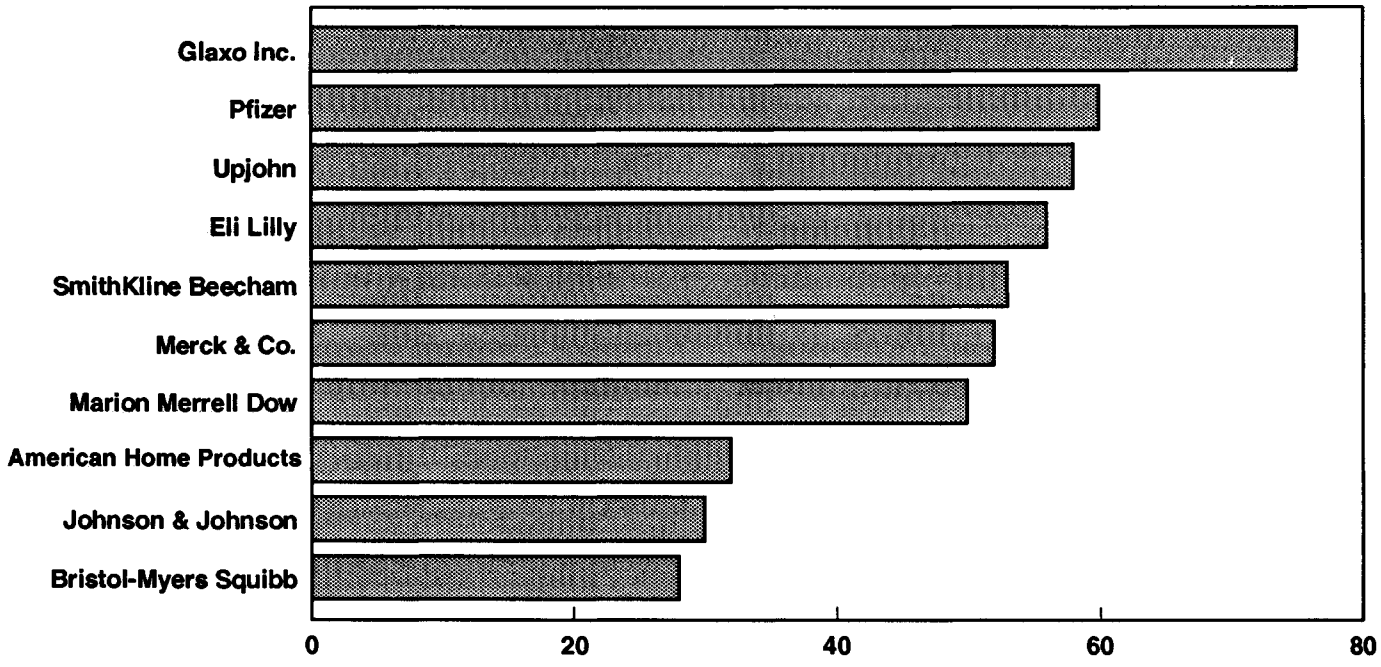
25. Henry Grabowski and John Vernon, "A New Look at the Risks and Returns to Pharmaceutical R&D," *Management Science* (July 1990), p. 816. Analysts lack published data on costs by project; only the average cost is available. Thus, a drug might still be profitable even if sales do not cover the average amount spent on R&D, but it is unlikely to be very profitable unless its R&D costs are also very low.

26. Office of Technology Assessment, *Pharmaceutical R&D*, p. 91. This 25 percent includes plant depreciation. Pure variable costs account for an estimated 17 percent to 21 percent of price. See the discussion of the rate of return calculations below.

27. These costs are capitalized--that is, they included the time value of money. Office of Technology Assessment, *Pharmaceutical R&D*, pp. 47-72.

28. There is some post-launch R&D--in enhancing production, for example--that can be varied, especially during the early years of the market. Obviously, there is R&D to sell improved versions of a product. But since the improved version also has to be approved by the FDA, this analysis is considering it as a new product. In addition, the marketing costs can largely be considered fixed.

**Figure 7.**
**Sales of Ten Companies' Top Three Drugs as a Percentage of Prescription Sales by Each Firm**




SOURCE: Congressional Budget Office based on Boston Consulting Group, *The Changing Environment for U.S. Pharmaceuticals* (New York: Boston Consulting Group, April 1993), p. 41.

Consequently, it is often profitable for pharmaceutical companies to sell drugs at deep discounts as long as the price is above the low cost of production. The high level of fixed costs also helps to explain why pharmaceutical companies try to market their drugs worldwide, even in countries that control prices; every foreign sale, even at a low price, helps to pay not only for the low production cost but also for the single large R&D investment. The fact that pharmaceutical companies can offer some consumers prices that they do not offer to others also encourages discounting.

**R&D and International Competition.** U.S. pharmaceutical companies are highly competitive in the international marketplace. The strength of the U.S. industry lies in its large R&D infrastructure and ability to produce new products of high quality. According to one recent survey, U.S. companies developed 113 of the 265 major globally prescribed drugs that were developed between January 1970 and May 1992.[29] U.S. companies develop a smaller share of all drugs, but produce almost half of all new drugs sold in all major markets. This technological success (and the R&D that precedes it) is not concentrated in a few therapeutic categories, such as anti-infective and cardiovascular drugs, but occurs in most major therapeutic categories.

In 1990, nine of the largest twenty pharmaceutical firms in the world were based in the United States.[30] According to the Department of Commerce, U.S. firms accounted for almost half of the world's pharmaceutical sales on a value basis. And the industry runs a positive balance of trade (that is, exports exceed imports). Most of the U.S. pharmaceutical exports went to Organisation for Economic Cooperation and Development (OECD) countries. Almost half of U.S. exports went to the European Community, which has several nations with strong pharmaceutical industries.[31]

29. Heinz Redwood, "New Drugs in the World Market," *The American Enterprise* (August 1993), pp. 72-80.

30. International Trade Commission, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, p. 4-2.

31. Department of Commerce, *U.S. Industrial Outlook 1994* (January 1994), p. 43-2.

The U.S. market accounts for one-third of world pharmaceutical sales.[32] Not all countries consume the same drugs, however. Many drugs are local, sold in protected or specialized markets. Global drugs are those that are sold in all or most major markets. The U.S. market for global drugs accounts for an even larger fraction of world sales for these drugs. Global drugs are usually considered more technologically advanced. Because the U.S. market possesses such a large fraction of the total sales of these drugs, U.S. health policy may have a disproportionate impact on the development of pharmaceuticals throughout the world. Alternatively, sales abroad represent more than half of the market for drugs patented in the United States and will therefore not be affected by health care reform.

# Competition in the U.S. Pharmaceutical Market

The U.S. pharmaceutical market has major structural features on both the supply and demand sides that impede the functioning of a perfectly competitive market. These factors have served partially to shelter firms in the industry from competition, as the profit figures discussed above suggest. But changes are taking place in the market, independent of proposed federal policy changes, that are lowering some of these impediments to competition.

## Consumers' Insensitivity to Cost

One factor that exacerbates the imperfect competition is the presence of doctors in the decisionmaking process. Doctors are relatively cost-insensitive in prescribing medicine, for which they do not pay. A doctor's objective is to treat the patient and not necessarily to provide the most cost-effective treatment.[33] Since prescription drugs typically constitute, in nonchronic cases, only a small fraction of the total cost of treating the patient, the doctor's incentive to examine drug costs declines even more. Moreover, because the consumer often cedes large parts of his or her decisionmaking power to a physician or other medical expert--and indeed is often not in a position to judge the medical cost-benefit tradeoffs--the usual cost-controlling mechanisms of the marketplace become less effective. The substitution of generic drugs, which is at the patient's choice in most states, is the major--and relatively recent--exception to the medical consumer's usual attitude toward costs.

Nor is judging the cost-effectiveness of treatment straightforward: different patients might value the same costs differently. Some patients might prefer more effective treatment at a higher cost, while others might be willing to incur some risk to save some money. Doctors, fearing malpractice suits or perhaps a negative reputation based on unsuccessful treatment, might also value the tradeoff between costs and risks differently.

Another element of the U.S. pharmaceutical market that serves to make demand less sensitive to price is the widespread coverage of pharmaceuticals by insurance and other third-party payers. Although only one-quarter of outpatient pharmaceutical expenditures were covered by insurance in 1977, by 1987 more than 40 percent of all outpatient prescription drug expenditures were covered by third-party payers.[34] Because patients are often reimbursed or because they only pay a small flat fee per prescription, they do not respond as much to costs as they would if they were bearing the full expense.

The presence of these cost-desensitizing factors, however, does not mean that consumers ignore price, just that they are less aware of it than they otherwise might be. Many consumers have large deductibles as well as coinsurance or copayments in their pharmaceutical coverage, making them more sensitive to cost. The result is that consumers bear a much higher share of the expenditures for prescription drugs than they do for physician or hospital services. In 1991, consumers paid out of pocket for 55 percent of prescription drug expenditures, 18 percent of physician services, and 3 percent of hos-

32. "Single Digit Growth for World Pharma [sic] Market," *Scrip Magazine* (January 1994), p. 32.

33. Doctors in managed health care provider groups may face different incentives.

34. Office of Technology Assessment, *Pharmaceutical R&D*, p. 239.

pital services.[35] And, as noted above, generic substitution is available in most states.

## Changing Factors in the Market

The behavior of consumers and third-party payers is changing. Third-party payers are increasing the share of total prescription costs that they pay, but also increasingly trying to rein in their costs. In addition, consumers are increasing their use of generic substitutes.

**Pharmaceutical Benefit Management.** The desire to control pharmaceutical costs has generated a growing number of companies devoted to managing pharmaceutical benefits for unions, insurance companies, and large corporations. The net effect of their efforts is to reduce pharmaceutical costs to the consumer through increased use of generic drugs and other techniques. (Managed care providers also perform many of these cost-reducing functions within their organizations.)

In a sense, these benefit-management companies act as agents of the pharmaceutical-purchasing public. They buy generic drugs where and when they can. When generic drugs are not available, they use buying power to get a good price, especially when imitative drugs are available. In economic terms, these techniques make demand for the products of any drug manufacturer more elastic--that is, more price sensitive--for whole segments of the population. This greater price sensitivity lowers the market power of a drug manufacturing firm by reducing its ability to price its products above the unit cost, which would be the price in a purely competitive industry.

In order to wield this buying power, a benefit-management firm has to press purchasing discipline on doctors and patients. It can negotiate a significantly better price with a drug company only if it can ensure that its members will only buy specific drugs. Among the tools at its disposal are approved drug lists (often called formularies) and even electronic point-of-sale technology, so that the pharmacist can intervene to persuade doctor and patient to use listed drugs. Similarly, organizations that manage prescription benefits can vary drug reimbursement for the patient according to the formulary: a high percentage for drugs on the formulary, a low percentage for drugs not on it. According to some industry estimates, the majority of people who have pharmaceutical benefits either have such restrictions on their benefits or will soon have them.

Even now, those companies that choose to can enforce their restrictions in order to get the discounts. Kaiser Permanente, the largest health maintenance organization in the United States, for instance, distributes its formulary to its doctors, tracks their prescribing behavior, restricts access to them by representatives of pharmaceutical companies, and provides information to them concerning the reasons that certain drugs are on the formulary. Consequently, as of May 1993, 96 percent of Kaiser's prescriptions were from the formulary and 75 percent of the prescriptions were for generic drugs.[36]

In general, however, it is difficult to estimate how much consumers and third-party payers truly have exercised buying power to reduce pharmaceutical costs. Although the trend seems to be definitely in the direction of managing pharmaceutical benefits, the actual carrying out of the demand management techniques may still be sparse and uneven. For example, a recent study in the *Journal of the American Medical Association* suggests that marketing by pharmaceutical companies can influence the inclusion of drugs on formularies, even when there is little, if any, therapeutic advantage.[37] The study showed that doctors are still able to choose the drugs they deem necessary for treating hospital patients, despite the attempts of hospital administrators to limit pharmaceutical spending through approved drug lists, and that doctors' decisions are substantially influenced by direct contact with pharmaceutical companies.

35. Congressional Budget Office, *Trends in Health Spending: An Update* (June 1993), pp. 56, 60, 66.

36. Sylvia Morrison, "Prescription Drug Prices: The Effect of Generics, Formularies and Other Market Changes" (Congressional Research Service, August 17, 1993).

37. About half of the doctors' requests for addition were for drugs with some therapeutic advantage. Mary-Margaret Chren and C. Seth Landefeld, "Physicians' Behavior and their Interactions with Drug Companies," *Journal of the American Medical Association* (March 2, 1994), pp. 684-689.

The definitions of managed care are also murky. Some traditional fee-for-service health plans have managed drug benefits. Even when drug benefits are managed, it does not necessarily mean that the plan is exercising substantial market power on behalf of consumers. For instance, although Merck recently reported that fully half of its sales come from managed care plans and that the company expects this share to rise, the firm's definition of a managed care plan is unclear.[38]

One factor limiting the further penetration of formularies is the lack of reliable studies of cost-effectiveness. The group with the largest individual incentive to undertake such studies, the pharmaceutical companies, is limited by FDA regulations that require its promotional claims to be backed by high-quality university studies, which are time-consuming and expensive.[39] The FDA must approve the claims, a process that also takes time. All users, including their agents in the health plans, may have sufficient economic incentive to explore the cost-effectiveness of medical procedures and drugs, but they cannot do it individually. Thus, such research, although growing rapidly, is still in its infancy.

**Increasing Use of Generic Drugs.** Another growing force in the U.S. pharmaceutical industry is the increasing penetration of the market by generic drugs. Under the Drug Price Competition and Patent Term Restoration Act of 1984, the Congress and the Reagan Administration chose to make generic drugs the principal cost containment vehicle in the pharmaceutical market by establishing a shorter process of regulatory approval for generic drugs. Consequently, the market share of generic drugs has been increasing. In 1980, generic drugs accounted for 23.3 percent (in units) of all pharmaceuticals sold in the United States.[40] By 1991, generic drugs accounted for a much higher share of the units sold --almost 40 percent, according to one estimate.[41] (In terms of value, generic drugs represented 13 percent of U.S. sales in 1989.)[42]

The existing group of generic drugs is large and should grow further over the next several years because many brand-name pharmaceuticals will be losing their patent protection. Drugs losing their patents between 1992 and 2000 include 54 of the 100 most popular drugs and account for an approximately equal share of such sales. Furthermore, only one of the 10 most widely used drugs will not lose its patent between now and 2000. That drug is Zantac, and although it is not losing its patent, its closest competitor, Tagamet, did this year.[43] Because of the number of important drugs that will lose their patents during the early 1990s, the revenue share filled by generic drugs is expected to rise to more than one-quarter of the market by the middle of this decade.[44]

The market-based movement towards generic drugs is likely to lower the profitability of investment in R&D less than regulatory or government-based attempts at cost containment. One reason is that generic versions of a pharmaceutical product come at the end of its patent life, which means that the present value of the lost sales is lower than if the generics could compete right away. By contrast, rebates, such as those currently given drugs paid for by Medicaid and proposed by the Administration for Medicare, are given from the date of introduction of a new drug and have a higher present value. Thus, an immediate rebate is likely to have a larger effect on the expected profitability of a drug than will its eventual displacement by generic equivalents. Similarly, other aspects of the Administration's proposal

38. Michael Waldholz, "Pharmaceutical Firms' Profits Rise Expected to be Slim," *The Wall Street Journal*, January 18, 1994, p. B12.

39. For one proposal, see John Calfee, "The Leverage Principle in FDA Regulation of Information" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

40. Alison Masson and Robert Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws* (Federal Trade Commission, 1985), p. 1113.

41. Morrison, "Prescription Drug Prices," p. 1.

42. International Trade Commission, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, pp. 4-3 and 4-4.

43. "100 Powerhouse Drugs," *Med Ad News Supplement* (May 1993), pp. S5 and S30. In addition, there is a lawsuit regarding the status of the patent on Zantac.

44. International Trade Commission, *Global Competitiveness of U.S. Advanced-Technology Manufacturing Industries: Pharmaceuticals*, pp. 4-3 and 4-4.

that have an immediate impact on a drug's price would be more likely to affect the profit on investment in R&D than would competition from a generic.

# Conclusions

In the continuum between a perfect monopoly and perfect competition, the pharmaceutical industry can probably best be described as imperfectly competitive: firms have some power to raise prices and generate excess profits. But events in the pharmaceutical market--including growth in generic drug use and more use of collective buying strength on the part of third-party payers--are beginning to undermine this power and make the industry more competitive.

Chapter Three

# How the Administration's Proposal Would Affect the Demand for Prescription Drugs

Of all the features of the Administration's proposed health care plan, universal coverage would have the greatest impact on the demand for prescription drugs. If it were enacted, this provision would extend a comprehensive package of health benefits, including coverage of prescription drugs, to the entire under-65 population, including 37 million people who are currently uninsured. The Administration's proposal for health care reform would also add a new drug benefit to Medicare, which is now the primary source of health insurance coverage for the 65-and-older population. Just under one-half of the 65-and-over population would receive drug coverage for the first time.

The Congressional Budget Office estimates that a universal entitlement to the standard benefit package in the Administration's proposal would increase spending on all prescription drugs by approximately 3 percent to 5 percent.[1] The proposed Medicare drug benefit would increase spending on all prescription drugs by an additional 1 percent. A high level of uncertainty underlies these estimates of what economists call induced demand.

CBO's estimates do not consider the effect that a greater shift to managed care plans might have on prescription drug expenditures. Prescription drug expenditures in managed care plans might be higher or lower than those in fee-for-service plans. Managed care plans might substitute prescription drugs for more expensive forms of treatment, thereby increasing prescription drug expenditures. But managed care plans might also exercise greater control over prescriptions, using generic drugs more intensively than fee-for-service plans, a policy that could lower prescription drug expenditures. CBO has not attempted to quantify these possible effects.

CBO's induced demand estimates are based on expenditures for outpatient prescription drugs reported in the 1987 National Medical Expenditure Survey.[2] These expenditures were not inflated to 1994 dollars because the induced demand estimates were based on the percentage of difference in average expenditures among groups. The estimates were calculated using the average percentage of difference in outpatient drug expenditures among people with different types of health coverage. These average expenditures have been adjusted for differences in population characteristics, specifically those according to health status, age, family income, sex, race and ethnicity, marital status, education, employment status, and region of residence. Underreporting is a problem in this survey, but does not affect CBO's analysis insofar as it is evenly spread among subgroups.

1. It is the combination of a universal entitlement with a generous benefit package (offering both comprehensive physician and drug coverage) that leads to CBO's estimate of induced demand. For the sake of brevity, this will be referred to as the universal coverage provision of the Administration's proposal.

2. This is a representative survey of the noninstitutionalized population in the United States. The tabulated results for prescription drug expenditures for 65-and-over Medicare enrollees were reported in the Congressional Budget Office study, *Updated Estimates of Medicare's Catastrophic Drug Insurance Program* (October 1989).

# The Administration's Proposal for Universal Coverage

The extension of health coverage to all U.S. residents primarily affects the under-65 population because Medicare already covers 98 percent of the 65-and-over population.[3] Almost all uninsured U.S. residents are under age 65. CBO projects that the universal coverage component of the Administration's proposal (which includes a drug benefit) would increase the expenditures for prescription drugs by the under-65 population by 5 percent to 7 percent. Most of the increase would result from extending coverage to those who are currently uninsured and only a small fraction from currently insured people who would be receiving better drug benefits under the proposed standard benefit package. The increase would occur mostly in outpatient rather than inpatient prescription drugs. The under-65 population accounts for about two-thirds of all prescription drug expenditures.[4] Universal coverage would therefore increase total prescription drug expenditures by an estimated 3 percent to 5 percent.

## Proposed Coverage

Under the Administration's proposal, the under-65 population would be covered by one of three basic plans, each of which would include coverage for both physician visits and outpatient prescription drugs. Much of the under-65 population already has employment-based physician and drug coverage that is similar to the coverage in the Administration's proposal.

The three basic types of plan included in the Administration's proposal are:

- A lower-cost-sharing plan that would employ a network of providers and require small copayments for most services;
- A higher-cost-sharing plan, under which patients would choose their providers, meet a deductible before coverage begins, and pay a coinsurance rate thereafter; and
- A combination plan under which patients would pay the lower-cost-sharing rates only if they use network providers, but would pay the higher-cost-sharing rates if they do not.

The lower-cost-sharing plan would require a $5 copayment for prescriptions and a $10 copayment for physician visits. The higher-cost-sharing plan would require that patients spend $300 on health services before physician coverage begins and $250 on prescription drugs before that coverage begins. A coinsurance rate of 20 percent would apply thereafter to most expenditures. One important advantage of the lower-cost-sharing plan would be that it has no deductibles. Each plan would limit annual out-of-pocket expenditures to $1,500 for individuals and $3,000 for families.

CBO did not determine which of the three kinds of plans would attract the most enrollees. The outcome would depend on how the public perceives differences in quality of care and how premiums vary among plan types (and within each regional alliance). CBO did not estimate how prescription drug expenditures would differ between the lower- and higher-cost-sharing plans. CBO's calculation of induced demand does not address the differences in coverage among the three kinds of plans.

Drug expenditures could be higher under the lower-cost-sharing plan for two reasons. First, the lower-cost-sharing plan would have no deductibles. In other words, coverage would begin with the enrollee's first physician visit and first prescription. Since the consumption of prescription drugs is closely associated with physician visits, this kind of coverage would tend to increase drug expenditures.[5]

3. Health Care Financing Administration, *Medicare and Medicaid Statistical Supplement* (1992), p. 14. Table 1 reports a lower number (96 percent) because it includes only those who obtain their primary coverage through Medicare.

4. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993), p. 239.

5. It is possible for those enrolled in fee-for-service plans to purchase supplemental coverage for cost sharing, in which case initial coverage would be as good as in the lower-cost-sharing plan.

Second, the lower-cost-sharing plan is likely to be a managed care plan such as a health maintenance organization (HMO), which may use prescription drugs more intensively. Nevertheless, drug expenditures in the lower-cost-sharing plan could be lower if it exercises greater control over prescription choice.

## Employment-Based Coverage

According to the 1990 Current Population Survey, two-thirds of the population under age 65 obtain their primary health insurance coverage through their employers. The Administration's proposal for comprehensive coverage is roughly equivalent to that of many employment-based plans. This similarity implies that the prescription drug expenditures of people who are insured through their employers would not increase because their coverage would not change appreciably.

Employees who are now insured through firms employing more than 100 workers have coverage that is, for the most part, at least as good as that proposed in the higher-cost-sharing plan. According to a recent Bureau of Labor Statistics (BLS) publication that examines the health insurance benefits in firms employing 100 or more workers, 83 percent of full-time employees are covered by health insurance. Of those covered, two-thirds are in fee-for-service plans, 16 percent are in preferred provider organizations, and 15 percent are in HMOs. The average deductible is $198 and only 6 percent of those insured have a deductible of $300 or more.[6] The most common coinsurance rate is 20 percent, and all but 12 percent of those insured through a large employer have a coinsurance rate of 20 percent or less. Only 4 percent of people insured by these firms do not have outpatient prescription drug coverage. The fee-for-service plans typically do not have a separate deductible for prescription drugs, which means that their drug coverage is usually slightly better than the proposal's higher-cost-sharing plan.[7] Apparently, deductible and copayment policies covering drugs and physician visits are slightly more generous under the employment-based plans than they would be under the higher-cost-sharing plan proposed by the Administration, but are not usually as generous as the lower-cost-sharing plan.

Coverage is similar for people who are insured through firms that employ fewer than 100 workers. According to another BLS survey, although a lower proportion of full-time workers in these establishments have coverage through their employers (69 percent), people who are covered often have benefits similar to those of employees in larger companies. The average deductible is $197 and coinsurance rates of 20 percent are common. All but 3 percent of those insured have prescription drug coverage.[8] People who are insured through their employers would therefore probably not increase their prescription drug expenditures because their current coverage is usually about as good as that proposed by the Administration.

## Outpatient Drug Demand and the Uninsured Under-65 Population

Increased demand for prescription drugs would result largely from extending coverage to the 17 percent of the population under age 65, or 37 million people, who have no health insurance (see Table 1). Those whose physician coverage would improve under the Administration's proposal or who currently do not have outpatient drug coverage would also increase their demand for prescription drugs. This outcome may apply to that portion of the population (7 percent) who are covered by policies that are privately purchased. The remaining three-quarters of the under-65 population already have physician and drug coverage through their employers or Medicaid that is for the most part as generous as that in the proposal's higher-cost-sharing plan. (The drug coverage currently provided by Medicaid typically has lower cost-sharing requirements than that proposed by the Administration.)

6. Bureau of Labor Statistics, *Employee Benefits in Medium and Large Private Establishments, 1991* (May 1993).

7. Cathy Baker and Natalie Kramer, "Employer-Sponsored Prescription Drug Benefits," *Monthly Labor Review* (February 1991), states that fee-for-service plans generally do not have a separate drug deductible, based on the Bureau of Labor Statistics results.

8. Bureau of Labor Statistics, *Employee Benefits in Small Private Establishments, 1990* (September 1991).

The amount by which prescription drug expenditures would rise if coverage were extended to the uninsured can be estimated using the outpatient prescription drug expenditures reported in the 1987 National Medical Expenditure Survey (NMES). According to this survey, average outpatient prescription drug expenditures for an uninsured person under 65 were about $35 in 1987. After adjusting for differences in population characteristics between the uninsured and those with employment-based coverage, CBO estimates that the uninsured under-65 population would have spent an average of about $62 per person (in 1987) if their coverage had been similar to that of those who had employment-based coverage.[9] This amount represents a 77 percent increase in outpatient prescription drug expenditures.

The comprehensive coverage proposed by the Administration is analogous to that of many employment-based plans. Logic would therefore suggest that the uninsured could increase their outpatient prescription drug consumption by approximately 77 percent under the Administration's proposal. Allowing for as much as a 25 percent error in this estimate indicates that the uninsured may increase their prescription drug expenditures by 58 percent to 96 percent under the Administration's proposal. This range is in line with other CBO estimates. Also based on the NMES, CBO has estimated that the uninsured would spend 57 percent more on all medical care if they were insured--a figure that is close to the lower end of the estimated range of increase.[10] Previous research by CBO and RAND indicates that prescription drug expenditures are closely tied to coverage of physician visits.[11] CBO has also estimated that the uninsured would spend 97 percent more on professional health services if they were insured. It might be reasonable to expect a similar increase in prescription drug expenditures.

Uninsured people constitute 17 percent of the under-65 population, but according to NMES they

**Table 1.**
**Primary Source of Health Insurance for the U.S. Noninstitutionalized Population, by Age, 1993**

| Source of Insurance | Total | Under 65 | 65 and Over |
|---|---|---|---|
| | **Population in Millions** | | |
| Employment-Based | 147.8 | 146.4 | 1.4 |
| Medicare | 32.5 | 3.6 | 28.9 |
| Medicaid | 20.5 | 20.5 | a |
| Department of Veterans Affairs[b] | 0.8 | 0.8 | a |
| Other Private | 15.1 | 15.0 | 0.1 |
| None | 37.4 | 37.1 | 0.4 |
| Total | 254.2 | 223.4 | 30.8 |
| | **Percentage of Age Group** | | |
| Employment-Based | 58 | 66 | 5 |
| Medicare | 13 | 2 | 94 |
| Medicaid | 8 | 9 | c |
| Department of Veterans Affairs[b] | c | c | c |
| Other Private | 6 | 7 | c |
| None | 15 | 17 | 1 |
| Total | 100 | 100 | 100 |

SOURCE: Congressional Budget Office tabulation of March 1993 Current Population Survey.

a. Less than 25,000.

b. Civilian Health and Medical Program for the Department of Veterans Affairs and the Civilian Health and Medical Program of the Uniformed Services.

c. Less than one-half of one percent.

9. The NMES expenditures were also adjusted upward by 10 percent to compensate for underreporting of drug expenses. The results of Marc Berk, Claudia Schur, and Penny Mohr, "Using Survey Data to Estimate Prescription Drug Costs," *Health Affairs* (Fall 1990), suggest that underreporting is larger as a percentage of average expenditures for those with low drug expenditures. This type of underreporting would tend to bias the induced demand calculation upward.

10. Congressional Budget Office, "Behavioral Assumptions for Estimating the Effects of Health Care Proposals," CBO Memorandum (November 1993). These estimates assume that the uninsured receive coverage similar to that currently provided by employment-based plans.

11. Congressional Budget Office, *Updated Estimates of Medicare's Catastrophic Drug Insurance Program.* The RAND studies include Willard Manning and others, "Health Insurance and the Demand for Medical Care," *American Economic Review*, vol. 77, no. 3 (1987), and Arleen Leibowitz, Willard Manning, and Joseph Newhouse, "The Demand for Prescription Drugs as a Function of Cost-Sharing," *Social Science and Medicine*, vol. 21, no. 10 (1985).

**Table 2.**
**Induced Demand for Prescription Drugs by the Under-65 Population Under the Administration's Proposal for Universal Coverage (In percent)**

| Insurance Status | Share of Under-65 Population | Assumed Increase in Outpatient Prescription Drug Expenditures | Estimated Increase in Expenditures of the Under-65 Population | |
|---|---|---|---|---|
| | | | For Outpatient Prescription Drugs | For All Prescription Drugs[a] |
| Uninsured | 17 | 58 to 96 | 4.5 to 7[b] | 4 to 6[c] |
| Employment-Based Insurance Without a Drug Benefit | 2 | 7.5 to 15 | 0.2 to 0.3 | 0.1 to 0.3 |
| Privately Purchased Health Coverage | 7 | 7.5 to 15 | 0.5 to 1 | 0.4 to 0.8 |
| Total | 26 | n.a. | 5 to 8 | 5 to 7 |

SOURCE: Congressional Budget Office.

NOTE: n.a. = not applicable.

a. Outpatient prescription drugs make up approximately three-quarters of the sales of all prescription drugs. Column 4 equals 77 percent of column 3.

b. This group accounts for only 8 percent of outpatient drug expenditures of the under-65 population. Calculation: (0.08)(58 to 96) = (4.5 to 7). The 8 percent is calculated by dividing the average expenditures of the uninsured by the average expenditures of all people under 65 (both according to the 1987 National Medical Expenditure Survey), then multiplying the result by the share of the population that is uninsured. Calculation: (35/76)(0.17) = 0.08.

c. Includes 0.6 percent from the increase in inpatient prescription drug expenditures.

account for only 8 percent of the outpatient prescription drug expenditures of this age group. If the uninsured were to increase their prescription drug expenditures by 58 percent to 96 percent, outpatient prescription drug expenditures of the entire under-65 population would increase by 4.5 percent to 7 percent (see Table 2).

## Outpatient Drug Demand and Improved Coverage

The Administration's proposal would improve the coverage of people who are currently insured through their employers but lack drug benefits. The Bureau of Labor Statistics estimates that 3 percent to 4 percent of those with employment-based plans had no prescription drug coverage in 1991.[12] This group constitutes approximately 2 percent of the under-65 population (3.5 percent of 66 percent). CBO assumes, based on the NMES data, that adding a drug benefit alone to a group that already has physician coverage would increase outpatient prescription drug expenditures by 7.5 percent to 15 percent.[13] Giving a drug benefit to the 2 per-

12. Bureau of Labor Statistics, *Employee Benefits in Medium and Large Private Establishments, 1991*. Four percent of those who have employment-based health coverage through firms employing fewer than 100 workers also had no prescription drug coverage. See BLS, *Employee Benefits in Small Private Establishments, 1990*.

13. See the discussion below on the increase in prescription drug expenditures for the 65-and-over population that currently has coverage only through Medicare.

cent of the population who have only physician coverage through their employers is likely to increase the total outpatient demand of the under-65 population for prescription drugs by less than 1 percent.

Both physician and drug coverage would generally improve for the portion of the population that has private insurance. Privately purchased health coverage is often not as extensive as employment-based coverage. Nonetheless, the effects on the demand of the under-65 population for drugs prescribed on an outpatient basis would be relatively small because the group constitutes only 7 percent of its age category. If many in this group were to receive better physician and drug coverage, the percentage of increase in prescription drug expenditures should be close to the 7.5 percent to 15 percent calculated for those who already have adequate physician but not drug coverage. CBO assumes that under the Administration's proposal those who have private coverage would also increase their outpatient prescription drug expenditures by 7.5 percent to 15 percent. If that took place, the result would be an increase in demand of about 1 percent for outpatient prescription drugs by the entire under-65 population.

## Inpatient Drug Demand

If the Administration's proposal for universal coverage were enacted, those who are currently uninsured would also expand their inpatient use of pharmaceuticals because they would tend to increase their use of hospital services. According to calculations based on the NMES, those who were not insured spent $330 a year in 1987 on hospital services (inpatient, outpatient, and emergency). If their coverage had been comparable to an employment-based plan, they would have spent $424 a year (adjusting for differences in population characteristics)--an increase of 28 percent. The uninsured account for about 10 percent of total hospital expenditures. Thus, a 28 percent increase in hospital expenditures by those who are currently uninsured implies that total hospital expenditures could rise by approximately 3 percent.[14] Assuming that inpatient prescription drug expenditures are a constant proportion of all hospital outlays, expenditures for inpatient prescription drugs could also rise by about 3 percent. Because the hospital market is roughly 23 percent of the total prescription drug market, the total prescription drug expenditures for the under-65 population would increase by less than 1 percent (0.6 percent).

## Total Increase in Demand for the Under-65 Population

Taken together, these calculations indicate that all prescription drug expenditures of the under-65 population might rise from 5 percent to 7 percent if the comprehensive coverage included in the Administration's proposal for health care reform were extended to this entire age group (see the last column of Table 2). The estimate does not take into account the effect that a large shift to managed care plans might have on the demand for prescription drugs. Nor does it account for a greater use of generic drugs. Because of the uncertainties involved in the induced demand calculations, Chapter 6 considers a broader range of changes.

# Medicare's New Drug Benefit

The Administration's proposal would add a new drug benefit to Medicare. Because this would give many Medicare enrollees drug coverage for the first time, the demand for pharmaceuticals would increase. CBO estimates that the demand for outpatient prescription drugs by the 65-and-over population would rise by about 4 percent as a result of expanded Medicare coverage. Because the outpatient market constitutes 77 percent of all prescription drug expenditures, and the 65-and-over population accounts for one-third of all spending on prescription drugs, the new Medicare drug benefit would increase total U.S. expenditures on prescrip-

14. The calculation: 10 percent of 28 percent is 2.8 percent (rounded to 3 percent). The 10 percent is calculated by dividing average expenditures for the uninsured on hospital services by average expenditures of the entire under-65 population on hospital services and multiplying that result by the proportion of the population uninsured in 1993, that is ($330/$551)*0.17 = 0.1.

tion drugs by 1 percent. About 1 percent of the under-65 population is also insured through Medicare. Therefore, this new drug benefit would also have a very small effect on the prescription drug expenditures of those who are under 65.

Under the Administration's proposal, the new prescription drug benefit would require a patient to meet a $250 deductible before prescription drug coverage begins and would apply a 20 percent coinsurance rate thereafter. The benefit would include an annual catastrophic cap of $1,000; once the patient had spent $1,000 on prescription drugs, all further expenditures on prescription drugs would be covered in full.

There are currently two types of Medicare coverage: Hospital Insurance (HI) and Supplementary Medical Insurance (SMI). Hospital Insurance is available to all Social Security beneficiaries and requires no premium. Those who are 65 and over and are not eligible for Social Security may buy HI at a monthly premium of $245. Hospital Insurance covers inpatient hospital services, some skilled nursing facility services, and hospice care. Enrollment in the SMI program is voluntary and requires a premium ($41.10 a month). Even people 65 and over who are not eligible for Social Security can buy SMI coverage at the regular premium. Supplementary Medical Insurance covers physician visits, outpatient hospital services, and laboratory services after a $100 deductible is met. SMI covers 96 percent of Medicare enrollees who are 65 and over.[15] The proposed drug benefit would be added to this second part of Medicare. The current SMI premium is set to cover one-fourth of the cost of the benefits and the federal government pays the rest. The SMI premium would be increased to cover one-fourth of the cost of this new drug benefit.[16]

The proposed Medicare drug benefit plan would encourage substitution of generic drugs. For multisource drugs, the reimbursement limit would be based on the wholesale price of the drug that falls in the middle of the group when drugs are ranked by price (the median price). A drug is classified as multisource if other bioequivalent substances are on the market, a situation that occurs either because the patent has been licensed so that more than one brand-name version exists, or because the patent has expired and there are generic substitutes. If there are more generic than brand-name forms of the drug, the reimbursement limit would be determined by a generic drug. In this instance, a Medicare patient would have to pay extra for choosing a brand-name drug. The reimbursement limit would also apply when calculating the amount spent to reach the $250 deductible. This lower reimbursement limit on multisource brand-name drugs, however, would not apply if the physician specifically prescribes the brand-name drug.

CBO did not take into account greater substitution of generic drugs in its induced demand calculations. The most important reason for excluding generic substitution from the induced demand estimates was not because it was difficult to gauge. Generic substitution begins to erode sales only after the brand-name drug's patent has expired (or the patent on one of its brand-name competitors has expired). During the first 7 to 12 years that a brand-name drug is on the market, it will not usually face competition from generic substitutes. If induced demand is estimated at 5 percent, a brand-name drug's sales should increase by an average of 5 percent in the years before generic competition is faced. When analyzing the changes in returns from drug development, CBO took into account increased substitution of generic drugs by examining greater sales erosion at the end of a brand-name drug's life, rather than by lowering the induced demand estimate.

## Calculating Induced Demand

Most Medicare enrollees (96 percent) participate in the SMI program. They must meet a $100 deductible before coverage begins. Thereafter, a 20 percent coinsurance rate applies. Thus, almost all Medicare enrollees are covered for physician visits and other basic health services, even if they do not carry supplemental coverage. In 1991, only 11 percent of 65-and-over Medicare enrollees had no coverage supplementing Medicare (see Table 3).

15. Health Care Financing Administration, *Medicare and Medicaid Statistical Supplement*, p. 14.

16. The increase would be larger for very high-income Medicare enrollees.

**Table 3.**
**Induced Demand for Outpatient Prescription Drugs by Medicare Enrollees 65 and Over**

| Insurance Status | Share of Total 65-and-Over Medicare Enrollees[a] (Percent) | Average Outpatient Drug Expenditures per Enrollee in 1987[b] (Dollars) | Assumed Increase in Outpatient Drug Expenditures (Percent) | Corresponding Increase in Total Outpatient Drug Expenditures of 65-and-Over Medicare Enrollees[c] (Percent) |
|---|---|---|---|---|
| Supplemental Coverage | | | | |
| Individually purchased (medigap) | 37 | 267 | 7.5 | 2.7 |
| Employment-based retirement plans | 38[d] | 287[e] | 0 | 0 |
| Medicaid: dual eligibles | 9 | 292 | 0 | 0 |
| Qualified Medicare beneficiaries | 3 | N.A. | 7.5 | 0.2 |
| Other | 2 | N.A. | 7.5 | 0.1 |
| No Supplemental Coverage | 11 | 179 | 7.5 to 15 | 0.7 to 1.3 |
| Total | 100 | n.a. | n.a. | 3.7 to 4.4 |

SOURCE: Congressional Budget Office. Column 1 is based on George S. Chulis and others, "Health Insurance and the Elderly," *Health Affairs* (Spring 1993).

NOTE: N.A. = not available; n.a. = not applicable.

a. Based on Round 1 of the 1991 Medicare Current Beneficiary Survey (from Chulis and others). Includes the institutionalized population.

b. Based on the 1987 National Medical Expenditure Survey. Adjusted to control for health status, age, family income, sex, race and ethnicity, marital status, education, employment status, and region of residence. Adjusted upward by 10 percent to account for underreporting. Underreporting will not affect the analysis insofar as it is evenly spread among subgroups.

c. Column 4 equals column 1 times column 3 times average expenditures of subgroup divided by average expenditures of all 65 and over Medicare enrollees. 2.7 equals (0.37)(7.5)(0.99) and 0.7 to 1.3 equals (0.11)(7.5 to 15)(0.77). Total has been rounded.

d. Includes 5 percent who have both employment-based and individually purchased supplemental coverage.

e. People with union-based retirement plans, which tend to have more generous benefits than employer-based retirement plans, are not included in this average.

Supplemental coverage picks up the coinsurance payments (and occasionally the $100 deductible) required by Medicare and may offer such additional benefits as drug coverage. Thirty-seven percent of 65-and-over Medicare enrollees had supplemental coverage through individually purchased plans (medigap) in 1991. Most of these plans do not offer a drug benefit.[17] If a drug benefit were added to Medicare, those people who do not have supplemental coverage and those who have only private medigap coverage would increase their demand for pharmaceuticals.

People who have employment-based retirement plans typically have both supplemental physician and drug coverage. The employment-based retirement plans generally do not have a separate deduct-

17. One estimate, based on the NMES, states that 19 percent of those people who have purchased medigap plans individually have prescription drug coverage. See Stephen H. Long, "Prescription Drugs and the Elderly: Issues and Options," *Health Affairs* (Spring 1994), p. 161. Currently, the only drug coverage that a private supplemental medigap plan may offer has a separate $250 deductible and a 50 percent coinsurance rate.

ible for prescription drugs and some require that beneficiaries pay only $1 to $4 per prescription.[18] Currently, 74 percent of people who work for firms employing 100 workers or more and who will obtain health benefits from their employers on retirement at age 65 will see little change in their coverage.[19] Such evidence suggests that the drug coverage offered by employment-based retirement plans is usually as generous as the proposed Medicare drug benefit. Therefore, no change in demand is predicted for this group.

**Private Supplemental Coverage (Medigap).** Retirees age 65 and over who have employment-based plans spend 7.5 percent more on outpatient prescription drugs than those who are insured through medigap plans (see Table 3). The increase is probably attributable to the addition of drug coverage; employment-based retirement plans typically offer a prescription drug benefit and most medigap plans do not. CBO therefore concludes that the expenditures for outpatient prescription drugs by 65-and-over Medicare enrollees who are insured through supplementary plans that do not frequently offer drug benefits would increase by 7.5 percent if the proposed prescription drug benefit were added to Medicare. Enrollees who have supplementary coverage that is equal to or better than the proposed drug benefit are not expected to change their spending on drugs.

**Those Eligible for Both Medicare and Medicaid.** Qualified Medicare beneficiaries (QMBs) constitute another group of people who have supplemental coverage but no drug benefits. These Medicare enrollees also qualify for assistance from Medicaid, but are not eligible for Medicaid's drug benefit. The income ceiling for QMBs was phased in at 85 percent of the poverty line in 1989 and reached 100 percent of the poverty line in 1992. It will rise to 120 percent of the poverty line in 1995. For those in this group who are at or below the poverty line, Medicaid picks up the premiums, coinsurance, and deductibles required by Medicare's Supplementary Medical Insurance program. Medicaid picks up only the Medicare premium for those with incomes above the poverty line (hence these QMBs have no Medicaid coverage supplementing Medicare's cost-sharing requirements). Because the QMB program did not exist in 1987, the increase in the number of Medicare enrollees who were also eligible for Medicaid between 1987 and 1991 can be viewed as a first approximation of the size of the QMB population. According to the 1987 NMES survey, 7.6 percent of Medicare enrollees were also eligible for Medicaid (these were all dual eligibles). According to the 1991 Medicare Current Beneficiary Survey, 11.9 percent of Medicare enrollees were also covered by Medicaid--an increase of 4 percentage points.

Since the number of dual eligibles did not increase much between 1987 and 1991, CBO viewed the 4 percentage point rise as indicative of the portion of the 65-and-over population who are QMBs with incomes at or below the poverty line. (All QMBs had incomes at or below the poverty line in 1991.) Some of this 4 percentage point increase, however, occurred because the institutionalized Medicare population was counted in the 1991 survey but not in 1987. The portion of this group that qualifies for Medicaid is greater than that of the entire 65-and-over population. Hence, the number of QMBs may have been lower than 4 percent of all 65-and-over Medicare beneficiaries in 1991.[20]

For the purpose of this induced demand calculation, CBO assumes that the number of QMBs at or below the poverty line is equal to 3 percent of all 65-and-over Medicare enrollees. Because this group, like most of those who have private supplemental insurance, has supplemental physician coverage but no drug coverage, CBO assumes that people in it would also increase their outpatient prescription drug expenditures by 7.5 percent if the proposed drug benefit were added to Medicare.

18. Congressional Budget Office, *Updated Estimates of Medicare's Catastrophic Drug Insurance Program*, p. 51.

19. Bureau of Labor Statistics, *Employee Benefits in Medium and Large Private Establishments, 1991*, Table 63.

20. Based on state-level data obtained from the Health Care Financing Administration, the Congressional Research Service reports that the number of QMBs was 1.3 million in 1992, or almost 4 percent of the Medicare population. See Congressional Research Service, *Medicaid Source Book: Background Data and Analysis* (January 1993). This number includes many people who not only qualified for Medicaid under the QMB standards but also were eligible for Medicaid's drug benefit. At the same time there were reporting problems that could make this estimate too low.

**Other Supplemental Coverage.** The induced demand estimate presumes that people who have some type of unspecified supplemental coverage would also increase their outpatient drug expenditures by 7.5 percent if the drug benefit were added to Medicare. The group is so small, however, that the effect on the induced demand estimate is slight.

**Those Without Any Supplemental Coverage.** It is assumed that people who have no supplemental coverage would increase their outpatient prescription drug expenditures by 7.5 percent to 15 percent under the Administration's proposed Medicare drug benefit. Medicare enrollees who are 65 years old and older, and who have supplemental coverage through employment-based retirement plans, spend an average of 60 percent more on prescription drugs than those who have no supplemental coverage (see Table 3). But a large part of this difference is attributable not to drug coverage but to the fact that many employment-based retirement plans offer supplemental coverage that picks up some of Medicare's cost-sharing requirements. The Administration's proposal affects drug coverage, but for the most part not Medicare's deductibles and copayments.[21] It is therefore necessary to determine the portion of this 60 percent difference that stems from drug coverage alone.

Medicare enrollees who are 65 and over and have employment-based retirement plans spend about 7.5 percent more on prescription drugs than those who have private supplemental coverage (medigap), which usually does not include drug coverage. Therefore, it is assumed that at least 7.5 percentage points of the 60 percent difference is attributable to drug coverage.[22] Another argument suggests that up to 10 percentage points of the 60 percent difference could be attributed to prescription drug coverage. Those who have no supplemental coverage would have to spend 50 percent more on prescription drugs to catch up with those who have medigap coverage, plus an additional 10 percent to catch up with those whose coverage is employment based (and who usually have a drug benefit). In addition, private medigap plans may pick up the coinsurance payments required by SMI more often than employment-based plans. Those who have medigap coverage may spend almost as much on prescription drugs as those who have employment-based plans, partly because they have better physician coverage. It follows that the amount of the 60 percent difference that is attributable to drug coverage could be greater than 10 percentage points.

According to CBO tabulations of NMES data, people who have no supplemental coverage purchased an average of 12 prescriptions a year, whereas retirees who have employment-based supplemental coverage bought an average of 16.6 prescriptions per year, an increase of 38 percent. Therefore, of the 60 percent difference in outpatient drug expenditures between those who have no supplemental coverage and retirees who have employment-based supplemental coverage, 38 percent is attributable to a greater quantity of drugs purchased and 16 percent is attributable to a higher price.[23] Drug coverage should increase both the quantity and the price of prescriptions purchased, whereas physician coverage should primarily affect the quantity of prescriptions purchased.[24]

Previous RAND and CBO studies indicate that most of the 60 percent difference should be attributed to increased physician coverage alone.[25] Attributing only the price increase to drug coverage implies a 16 percent increase in outpatient drug expenditures for those who have no supplemental coverage. On the basis of this calculation and the results of previous studies, if a prescription drug benefit was added to Medicare, the most that prescrip-

21. The proposal would introduce coinsurance payments on lab services.

22. Congressional Budget Office, "Behavioral Assumptions for Estimating the Effects of Health Care Proposals."

23. If the quantity purchased rises by 38 percent on average, then the price paid must rise by 16 percent on average to get a 60 percent increase in expenditures.

24. Congressional Budget Office, *Updated Estimates of Medicare's Catastrophic Drug Insurance Program*, pp. 47-50. These figures were adjusted to account for differences in population characteristics.

25. The RAND studies include Manning and others, "Health Insurance and the Demand for Medical Care," and Leibowitz, Manning, and Newhouse, "The Demand for Prescription Drugs as a Function of Cost-Sharing."

tion drug expenditures could increase for those who have no supplemental coverage is assumed to be 15 percent. Consequently, a range of 7.5 percent to 15 percent is used to reflect the probable response of this group, which now has no supplemental coverage.

**Total Demand Would Increase.** On the basis of these estimates, if the proposed prescription drug benefit were added to Medicare, the outpatient prescription drug expenditures of all 65-and-over Medicare enrollees would increase by about 4 percent (see Table 3). The amount that prescription drug coverage is estimated to increase for each group discussed above is weighted by the group's share of total prescription drug expenditures (by all 65-and-over Medicare enrollees). This weight takes into account the size of the group in relation to the entire Medicare population as well as the average prescription drug expenditures of each group.[26] Most of the increase in demand results from extending drug coverage to those currently covered by medigap plans and to the 11 percent of the elderly who currently have no supplemental coverage at all.

One percent of the 65-and-over population has no health insurance at all. Under the Administration's proposal, this group would be compelled to buy into either Medicare's SMI program or a comprehensive plan offered by a health alliance. The drug benefit that would be offered by Medicare is almost identical to that offered under the high-cost-sharing plan. Therefore, whether they get it through Medicare or an alliance plan, those who are 65 and over and uninsured will obtain coverage that includes a drug benefit. No survey numbers are available on which to base an induced demand estimate for this group. The estimate is therefore based on the 77 percent increase in expenditures projected for the uninsured people under 65. It follows, then, that if and when those who are not only 65 and over but uninsured as well receive coverage for the first time, the expenditures of all those 65 and over on outpatient prescription drugs would increase by no more than one-half of one percent.[27]

The Administration's proposal would increase the outpatient prescription drug expenditures of 65-and-over Medicare enrollees by about 4 percent. In 1990, 29.4 million U.S. residents 65 years old or older were enrolled in the SMI program. The total number of people in the United States 65 years old or older was 31.1 million. Therefore, approximately 95 percent of the 65-and-over population is covered by Medicare's SMI program.[28] Taking into account the small increase caused by extending drug coverage to the uninsured 65-and-over population, CBO estimates that the increase in outpatient prescription drug expenditures for all people 65 and over would also be about 4 percent.

Approximately 3.6 million Medicare enrollees are under age 65. They constitute less than 2 percent of the under-65 population (see Table 1). Because they are such a small portion of the under-65 population, their increase in outpatient drug expenditures under Medicare's new drug benefit would not alter the estimated 5 percent to 7 percent increase in prescription drug expenditures for the population that is under 65 years old.

# Conclusions

CBO calculates that universal coverage as proposed by the Administration could increase the under-65 population's demand for prescription drugs by approximately 5 percent to 7 percent. Because two-thirds of all prescription drugs are purchased by people under age 65, the resulting increase in demand would cause total prescription drug expenditures to rise by 3 percent to 5 percent. Most of the increase in demand would result from extending coverage to the 37 million uninsured (99 percent of

26. In constructing these weights, CBO assumes that the average expenditures of those with "other" coverage and those with Medicaid but no drug benefit are the same as the average expenditures of those with coverage through medigap, since these categories did not exist in the 1987 NMES.

27. As in the case of the uninsured under-65 population, it is assumed that this group's share in total drug expenditures is equal to just under half of its share of the total population.

28. Health Care Financing Administration, *Medicare and Medicaid Statistical Supplement*, pp. 14, 18-19, and Bureau of the Census, *Statistical Abstract of the U.S., 1993*.

whom are under age 65). The rest would be caused largely by those who have private insurance and would receive better health insurance coverage under the Administration's proposal.

Medicare's new drug benefit could increase the demand of the 65-and-over population for outpatient prescription drugs by about 4 percent. Since one-third of all prescription drug expenditures are made by people 65 and over, and 77 percent of prescription drug expenditures are outpatient, this increased demand would raise total prescription drug expenditures by approximately 1 percent. Many Medicare enrollees already have prescription drug coverage through retirement plans. Much of this increase would be caused by those who have only private medigap coverage, which usually does not include prescription drug insurance, and the 11 percent of Medicare enrollees who have no supplemental coverage at all.

Overall, CBO estimates that the universal coverage provision and the Medicare drug benefit proposed by the Administration would increase total prescription drug expenditures by approximately 4 percent to 6 percent.

Chapter Four

# The Rebate on Medicare Prescription Drugs and the Advisory Council on Breakthrough Drugs

Because its proposal would give all legal residents of the United States a pharmaceutical benefit that could create a windfall for the industry, the Administration hopes to ensure that the U.S. taxpayer would not be excessively penalized for providing new benefits to Medicare beneficiaries. At the same time, the Administration has reason to be skeptical of formal price controls. Consequently, it has devised new mechanisms for containing costs.

## The Medicare Drug Rebate Agreement

The proposal submitted by the Administration would require that a pharmaceutical manufacturer enter into a rebate agreement with the Secretary of Health and Human Services (HHS) if a drug is to be covered under Medicare's new drug benefit provision. Modeled after the existing Medicaid rebate, the proposal's agreement requires that pharmaceutical manufacturers pay a rebate to the federal government on all brand-name drugs purchased through Medicare. Generic drugs are exempt.

### Calculation of the Rebate

Under the Administration's proposal, the rebate would be no less than 17 percent of the "average manufacturer retail price," which is defined as the price paid to pharmaceutical manufacturers for drugs sold by pharmacies and other retailers.[1] Manufacturers usually charge institutional purchasers, such as health maintenance organizations and hospitals, a lower price than retail pharmacies charge for the same drug. The rebate would be larger if the difference between the average manufacturer retail price and the average price paid by institutional purchasers exceeds 17 percent. In that case, the rebate would equal the average discount given to institutional purchasers. Specifically, it would be equal to the amount by which the average manufacturer retail price exceeds the "average manufacturer nonretail price" (defined as the discounted price that institutional purchasers pay for the drug).[2]

This formula ensures that the government would pay no more for a drug purchased through Medicare than the average institutional purchaser. And the government would pay less than institutional purchasers when the average institutional discount is less than 17 percent. Although the discounts given to institutional purchasers can be partially justified on the grounds that bulk purchases lower distribution costs, this would not be true for drugs bought through Medicare.

1. Health Security Act (H.R. 3600 and S. 1757, 103rd Congress, 1st Session, 1993), Title II, Subtitle A, Sec. 2003(f)(1).

2. Health Security Act, Title II, Subtitle A, Sec. 2003(f)(2). The purchases of the Department of Defense and the Department of Veterans Affairs are included in the calculation of the average manufacturer nonretail price.

The rebate might be increased further if the average manufacturer retail price of a drug rose faster than the consumer price index. (The Medicaid rebate has a similar provision.) The rebate would be increased to offset any increase in the price of the drug above the inflation rate.

The Administration's proposal also includes a specific provision that requires the manufacturer to charge the same price to all wholesalers, retailers, and institutions that purchase drugs on the same terms. These terms include "prompt payment, cash payment, volume purchase, single-site delivery, the use of formularies by purchasers and any other terms effectively reducing the manufacturer's costs."[3] Many reasons therefore exist for differences in the terms of purchase. Buyers, such as retail pharmacies, that do not use formularies (lists of drugs that may be prescribed) could be charged a different price, even for the same quantity of drugs, than the institutional purchasers that do use them. In addition, formularies differ in their restrictiveness, a disparity that may constitute a difference in the terms of purchase. Apparently, this equal-pricing provision may not prevent manufacturers from granting greater discounts to hospitals and health maintenance organizations than to retail pharmacies.

The proposed Medicare rebate agreement would require that the pharmaceutical firms report to the Secretary of HHS the amount of their average manufacturer retail and nonretail prices on each drug covered by Medicare. In addition, the Secretary would be empowered to inspect the records of manufacturers and survey wholesalers, pharmacies, and institutional purchasers of drugs "as necessary" to verify reported prices.[4] Financial penalties of up to $100,000 could be imposed on manufacturers who refuse to comply.

The manufacturer could terminate the rebate agreement with the Secretary at any time. In that case, however, Medicare would not cover any of the manufacturer's drugs. Manufacturers would not be able to exclude some of their existing drugs from the rebate agreement. All of a manufacturer's drugs would be covered or none would be covered.

Drugs introduced after June 1993 would be an exception. The Secretary may negotiate a higher rebate than 17 percent on these drugs. If no agreement can be reached between the Secretary and the manufacturer on the rebate amount, that drug may be excluded from coverage and the remainder of the manufacturer's drugs would still be covered by Medicare.

## Problems with Reporting

In practice, isolating a price paid to the manufacturer for drugs sold at retail is difficult. Most retailers, primarily pharmacies, buy drugs through a wholesaler, but so do many institutional purchasers. About three-quarters of all drugs are distributed through independent wholesalers to both pharmacies and such institutional purchasers as hospitals. About 22 percent of the wholesalers' business consists of sales to hospitals.[5] It is therefore difficult to calculate the average manufacturer retail price on the basis of the price charged to wholesalers. This calculation is currently done, however, for the Medicaid rebates, based on prices reported by the pharmaceutical companies.

Under the Administration's proposal, the Secretary would report to the manufacturer the quantities of drugs purchased through Medicare on which a rebate must be paid. Rebates are likely to be requested on all drugs purchased by Medicare enrollees, even those that fall under the $250 deductible and are therefore not paid for by Medicare.[6] Underreporting could be a problem for Medicare enrollees whose drug purchases never exceed the $250 deductible. Medicare enrollees who spend less than $250 on drugs would have no incentive to report these expenditures, and neither would the pharma-

3. Health Security Act, Title II, Subtitle A, Sec. 2003(e).

4. Ibid., Title II, Subtitle A, Sec. 2003(b)(3)(C).

5. Mickey Smith, *Pharmaceutical Marketing, Strategy and Cases* (New York: Pharmaceutical Products Press, 1991), p. 50.

6. Health Security Act, Title II, Subtitle A, Sec. 2003(b)(1)(B).

cist.[7] According to Congressional Budget Office calculations, the prescription drug expenditures of the 65-and-over Medicare enrollees who spent just $300 or less constituted 10 percent of total outpatient prescription drug expenditures in 1987.[8] For this reason, somewhat less than 10 percent of drug expenditures by Medicare enrollees could go unreported. Therefore, no rebate would be paid on these sales.

# The Medicare Rebate for New Drugs

An additional rationale for examining drug launch prices is that in order to compensate themselves for the proposed Medicare rebate and in anticipation of not being able to raise prices later, pharmaceutical companies might be tempted to launch new drugs at high prices. The government would therefore want some way of controlling this effect.

The Administration's proposal would affect the prices of new drugs in two ways: through the Medicare rebate agreement and through the Advisory Council on Breakthrough Drugs. The Administration's proposal includes special rules for negotiating the Medicare rebate on new drugs. In addition, the Advisory Council on Breakthrough Drugs would examine the reasonableness of the prices of new drugs that bring significant new therapeutic potential to the marketplace.

For any drug that was first marketed after June 1993, Medicare could negotiate a special rebate if the Secretary of HHS believes the drug is priced excessively or finds that it is marketed abroad at a lower price.[9] If a rebate could not be negotiated, the Secretary could exclude the drug from reimbursement by Medicare. The company would have six months after marketing approval by the Food and Drug Administration to negotiate the rebate. Because Medicare beneficiaries represent more than one-third of the total pharmaceutical market, such a refusal is widely viewed as hurting the chances of commercial success of most drugs.

## Evaluating New Drug Prices

One aspect of this provision is that the Administration's proposal requires a determination of the potential for a special rebate on all new drugs, with the Advisory Council responsible only for breakthrough drugs. The Administration's proposal, however, presents no institutional mechanism, other than through the Secretary of HHS, by which the appropriateness of the prices of nonbreakthrough new drugs, which constitute the vast majority of new pharmaceuticals, is to be determined. As a result, the Secretary might have to expand the role of the Advisory Council.

If the price of a drug in any one of almost two dozen foreign (mostly European) countries specified in the Federal Food, Drug and Cosmetic Act (FFDCA) were significantly below its U.S. versions' average retail price, the Secretary could begin special rebate negotiations on new drugs reimbursed through Medicare.[10] Since the prices of drugs newly introduced into the United States are unlikely to be lower than the prices in all of the FFDCA-specified countries, all new drugs could be subject to special rebate negotiations. The Administration's proposal states that the new drug rebate can be no greater than the difference between the wholesale price in any one of the specified countries and the average retail price of drugs manufactured in the United States.

The proposal outlines various factors that the Secretary would use to deliberate on and negotiate with drug manufacturers, namely:

7. Unless the pharmacist bills Medicare, which then bills the Medicare enrollee for the drug. The current Secretary of Health and Human Services has granted a contract to GTE Government Systems Corp. to design a computerized billing system for Medicare; the enrollee will need only to present a card to the doctor and Medicare will bill the patient for what is not covered. Spencer Rich, "Medicare Billing to Join Electronic Superhighway," *The Washington Post*, January 20, 1994, p. A21. This system could be applied to pharmaceuticals, obviating the reporting problem.

8. Congressional Budget Office, *Updated Estimates of Medicare's Catastrophic Drug Insurance Program* (October 1989).

9. Health Security Act, Title II, Subtitle A, Sec. 2003(c).

10. Ibid., Title II, Subtitle A, Sec. 2003(c)(3)(A)(ii).

- o Prices of other drugs in the same therapeutic class;
- o Manufacturer's cost information;
- o Factors affecting costs, such as projected prescription volume, economies of scale, product stability, and special manufacturing requirements;
- o Foreign drug prices; and
- o Other relevant factors.

These criteria use guideposts that private actors in the market typically use to set prices, but adapt them to federal policy. If the criteria were applied mechanically or punitively, they could substantially reduce the return on new drugs (breakthrough or otherwise) purchased frequently by Medicare enrollees. If applied with judgment, some analysts argue, the criteria could protect the taxpayers' interest without harming the drug companies. Until the uncertainty concerning the ways in which they would be applied becomes clear, however, these provisions significantly increase the risk of developing new drugs.

The FDA has approved 90 nongeneric drugs a year, or an average of one every four days, during the last 20 years. Arriving at a clear judgment about an appropriate price (and rebate) for each of these may prove difficult. The very number of decisions suggests that mechanical interpretations of the law would be common.

**Prices of Similar Drugs.** Prices of other drugs in the same therapeutic categories (the first criterion) are certainly relevant in deciding how reasonably a new drug is priced. New drugs under review often offer benefits that other drugs in the category do not. (In most instances, unless they do offer new benefits, new drugs are priced at or below existing drugs.) What are these additional benefits worth? In some markets, great advances in performance are sometimes not highly valued because current technology is "good enough." In other instances, even a small improvement in therapy or convenience is valuable to consumers.

Thus far, because insurance has often insulated patients from the full costs of health care, or doctors have made decisions for them, patients have not had to make the types of cost-performance trade-offs faced by consumers in other markets. Consequently, it is exceptionally difficult to judge the value of product improvements in the pharmaceutical market. There is little data on how consumers really value new drugs. In the past, the concern was relatively unimportant because most of the evaluations by consumers were private. But under the Administration's proposal, the Secretary would represent the official position of the federal government (and the willingness of taxpayers to pay) as to the economic value of a particular drug in a given therapeutic category.

In their efforts to control overall health (not just drug) costs, doctors and other health providers have begun to consider not only the purchase price of medicines, but also their cost-effectiveness. The whole concept of deciding the economic value of pharmaceutical therapy (pharmacoeconomics) is relatively new and many questions regarding methodology and intangibles remain unanswered.[11]

**Manufacturers' Costs.** Most important, how would research and development and other fixed costs be accounted for in calculating the reasonableness of the introductory price? Although the Administration's proposal does not mention R&D and other fixed costs specifically, these factors dominate average drug costs.

Each commercially successful product must pay for its own R&D and for the R&D of products that fail technically and commercially. Obviously, not every successful product carries all of the costs of the unsuccessful ones. How would the Secretary determine what share of a firm's total R&D each product should be expected to pay? Using industry averages as guideposts makes it difficult to set individual prices because there are such wide devia-

11. William McGhan, "Pharmacoeconomics and the Evaluation of Drugs and Services," *Hospital Formulary* (April 1993), pp. 365-378; Stephen Coons and Robert Kaplan, "Quality-of-Life Assessment: Understanding Its Use as an Outcome Measure," *Hospital Formulary* (May 1993), pp. 486-498; and Tracy Skaer, "Applying Pharmacoeconomics and Quality-of-Life Measure to the Formulary Management Process," *Hospital Formulary* (June 1993), pp. 577-584.

tions among the industry averages. Pharmaceutical companies try to recover as much as possible through their successes, but are limited by market forces. Like the previous criterion--prices of similar drugs--this one uses guideposts that private actors in the market typically use independently of each other and turns them into federal policy for the entire market.

**Factors Affecting Costs.** The Secretary would obtain data on, or estimate, economies of scale, the expected size of the market, special manufacturing requirements, and product stability in order to determine the reasonableness of a drug's launch price. In some sense, the Secretary would be seeking data similar to that sought by public utility regulatory commissions when they set electrical or telephone rates. As with a regulatory commission, price levels could be set with relative ease, given some target rate of return.

There are substantial differences, however, between the pharmaceutical and utilities industries. The sales of a utility probably vary much less than those of a new drug. Utilities rarely sell a new product, while drug companies do so all the time. Forecasting the market size of any new product is notoriously difficult. Medicare officials could not be expected to know whether the drug companies should amortize the R&D and other fixed costs over 10 million pills or 100 million pills. Consequently, when the Secretary calculates the rate of return, he or she would be doing so with much poorer information than that available to a typical regulatory agency.

**Foreign Drug Prices.** Foreign prices, though often useful as a starting point for analysis, can be misleading if they are not put into an appropriate institutional context. For example, until 1993 Canada licensed drugs on a compulsory basis.[12] Companies had to allow other manufacturers to make and sell their drugs before the patent ran out. The result was competition among firms producing the same brand-name drugs and charging lower prices than in the United States.[13] Since the Canadian market is small, U.S. pharmaceutical companies have been willing to enter that market and license their products; they may not make large profits in Canada, but they can spread their fixed R&D costs further.

Another question facing federal authorities is how to determine which of the foreign prices are reliable indicators of recovery costs. Some prices are determined by foreign health authorities acting as buyers on behalf of their citizenry, using their market power equally against both domestic and foreign pharmaceutical makers. By contrast, other countries that would be used for comparison do not have a domestic pharmaceutical industry that performs world-class R&D and may be willing to negotiate low prices. Using the wrong set of foreign prices might result in prices fixed below the level of R&D cost recovery.

In other instances, exchange rate fluctuations could quickly drive a wedge between U.S. and some foreign prices, even if launch prices were similar. This could occur especially when a country was experiencing a drop in the value of its currency.

This criterion might also provide pharmaceutical companies with incentives to introduce their drugs first in high-price countries, so as to have only high foreign prices for purposes of domestic comparison. Such actions could reduce the availability of new drugs in countries with histories of low prices.

Some economists argue that for industries in which many costs are large and fixed, such as the airline or pharmaceutical industries, those consumers who are most willing to pay should bear those costs. In the airline industry, it is the business traveler who bears these fixed costs. Thus, if U.S. consumers are most willing to pay for new medical technology, they should bear a disproportionate share of the costs. Under these circumstances, international comparisons of prices would be misleading, especially when some U.S. customers pay a lower price because they have joined a health plan that manages the pharmacy benefit. Since the proposal uses average retail price, international com-

12. The debate over mandatory licensing of patents is much broader than drug pricing and will not be dealt with here.

13. General Accounting Office, *Prescription Drugs: Companies Typically Charge More in the United States Than in Canada* (September 1992).

parisons would overlook all those U.S. customers who are buying their drugs through such cost-saving plans. In this context, international comparisons would be between the least cost-sensitive U.S. consumer and the average foreign consumer.

**Other Relevant Factors.** The proposal's last set of criteria, designated as "other relevant factors," is undefined. But the Advisory Council's list of evaluative criteria does contain two additional entries that may serve as guidelines. These concern the cost-effectiveness of new drugs and their effects on the quality of life.

# The Advisory Council on Breakthrough Drugs

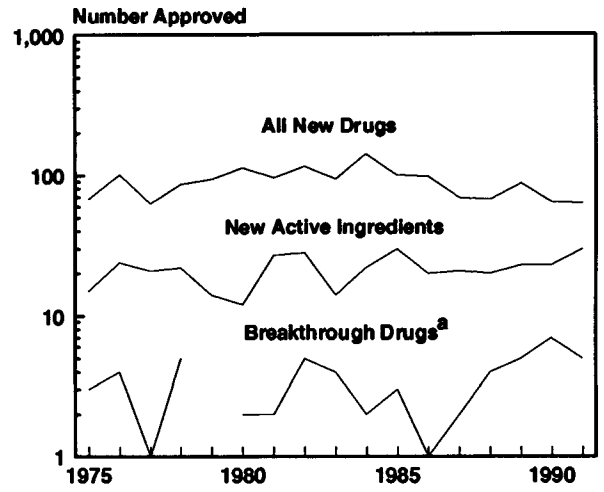
Under the Administration's proposal, when the FDA approves any new drug representing a significant therapeutic advance (or breakthrough), the launch price would be subject to review by an Advisory Council on Breakthrough Drugs.[14] The Advisory Council's findings, unlike the Medicare rebate negotiations, would be public and thus could have influence beyond the federal market. As the name implies, the Advisory Council has no direct legal power, but affects prices only through other economic actors--Medicare and other health plans--should they choose to listen to the council's opinion. Of course, the Advisory Council might help form public opinion, which has been quite powerful on occasion, but which is difficult to model or predict.

The 13 members of the Advisory Council, who would be appointed by the Secretary of HHS, would be responsible for determining whether or not the launch price of a breakthrough drug was "reasonable." The Secretary of HHS would publish the council's determination, together with minority opinions, in the *Federal Register*.

Depending on how the proposed legislation is interpreted, the Advisory Council might play a role in only a very small number of drug introductions. Although the Administration's proposal does not

14. Health Security Act, Title I, Subtitle F, Sec. 1572.

**Figure 8.**
**FDA Approval of New Drugs**
**(By therapeutic categories)**




SOURCE: Congressional Budget Office based on data provided by the Food and Drug Administration (FDA).

NOTE: Vertical scale is logarithmic.

a. In 1979, the FDA approved no breakthrough drugs.

define the term "significant advance over existing therapies," the FDA has used this classification for years and only recently switched to a new method of grouping. Between 1975 and 1991, the FDA approved an average of 22 new drugs (new active ingredients, which the FDA calls new molecular entities) each year (see Figure 8).[15] The breakthrough category, promising major new therapeutic potential, accounts for one-seventh of all new molecular entities, or about three drugs each year. (Including those new molecular entities that have only modest therapeutic potential would increase the

15. A new molecular entity is an active ingredient that has never been marketed before in this country. Other categories of FDA approval include derivatives of existing active ingredients and new formulations, combinations, uses, or manufacturers. These other categories could easily become commercially important without receiving regulatory priority. In total, the FDA averaged about 90 approvals a year for nongeneric drugs during the 1975-1991 period. For a description of FDA classification of drug approval applications, see Food and Drug Administration, *FDA Consumer Special Report; From Test Tube to Patient: New Drug Development in the United States* (January 1988), p. 30. All of these numbers exclude so-called biological preparations, such as blood products, which are handled differently by FDA and constitute about 5 percent of pharmaceutical sales.

total to about 11 drugs a year.) Thus, the Advisory Council could only consider a handful of cases each year if it were working on breakthrough drugs alone.

By contrast, if the proposal is interpreted to include new uses of existing drugs and other modifications of potential commercial (or medical) importance, the Advisory Council might play a more central role. The FDA's therapeutic classification system does not correspond to eventual commercial importance. (For example, Zantac, the world's best-selling drug, was not classified as a breakthrough drug by the FDA.) The classification system serves only to allocate FDA resources. Whether this system would be appropriate for another purpose is open to question.

Although very few drugs can be classified as breakthroughs, many companies undertake R&D fully intending to develop such a drug. Thus, even if the actual number of drugs directly involved is small, the effects on pharmaceutical companies can be much greater, especially because each company depends on a small number of drugs for a disproportionate share of its sales.

The Administration's proposal directs the Advisory Council to use many of the same evaluative criteria as the Secretary of HHS, although the Advisory Council would also explicitly consider research costs, which are not specifically included in the Medicare criteria. Many of the same observations about these criteria apply to the Advisory Council's findings. In addition, the Administration's proposal includes two other important evaluative standards:

- Cost-effectiveness, in relation to other pharmaceutical and nonpharmaceutical treatment; and
- Improvements in the quality of life, including the ability to work and live a normal existence.

Obviously, these additional criteria make the deliberations of the Advisory Council much more complete than those prescribed by the Administration's proposal for the Medicare rebate. But even these broader principles present problems. A new drug may be cost-effective in relation to its pharmaceutical predecessors and surgical alternatives, but still be more expensive than necessary to reward the investors and company for their expenses and risk.[16] Given the higher-than-normal profits for the industry, many breakthrough drugs may be in this position.

The Advisory Council might duplicate some of the work of the Agency for Health Care Policy and Research within the Public Health Service. The agency's missions encompass evaluating and reporting on the effects of new health care technology, including pharmaceutical therapy, with respect to health care costs, productivity, and market forces. (It also reports on safety, appropriateness, and efficacy, but that is less relevant here.) One division has a staff of more than 150 working in the area of health care costs, quality, and access. Another division focuses on outpatient pharmaceutical projects, including cost containment mechanisms. In addition, the agency regards the broadest dissemination of its research as part of its mission. In fiscal year 1994, the Congress appropriated $135 million for the agency. This organization might expand substantially under the Administration's proposal.

Unlike the Medicare rebate, which would exist ostensibly to protect the taxpayer, the Advisory Council would be created to judge prices for the public as a whole. It would not be the first time that the federal government has tried to determine the reasonableness of prices. In general, however, federal agencies have found it extremely difficult to determine what a reasonable price is, especially in a dynamic market like pharmaceuticals. The Supreme Court expressly disavowed imposing a "reasonableness" test in price-fixing cases because it was so difficult to determine and changed constantly.[17] What was "reasonable" in one year might not be a year later. In other areas, even those in which price regulation continues, federal and state regulators are moving toward mechanisms that would permit the market to have more influence in determining final prices.

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16. Statement of Judith Wagner, Office of Technology Assessment, before the Senate Special Committee on Aging, November 16, 1993.

17. F. M. Scherer and David Ross, *Industrial Market Structure and Economic Performance*, 3rd ed. (Boston: Houghton Mifflin Company, 1990), p. 336.

# Effects on the Pharmaceutical Market

Pharmaceutical manufacturers may attempt to raise prices in order to compensate for the proposed 17 percent rebate. In general, a manufacturer cannot charge the Medicare and non-Medicare populations different prices for the same drugs because most drugs are distributed through wholesalers and other intermediaries. Therefore, a manufacturer would have to try raising prices for all users of a drug.

Typically, economists assume that the costs of government actions, like the rebate, are shared by consumers and producers according to their relative sensitivities to changes in price. In this instance, however, not all sales of a drug would be subject to the rebate. Instead, only the purchases by Medicare beneficiaries would be affected. The purchases and profits of the drug companies for their sales to non-Medicare patients would not be affected.

Companies that raise the prices of their product typically lose market share. If the drug companies are already charging the prices that give them the highest profits, they cannot fully offset the rebate by raising prices.

The provision in the Administration's proposal that grants the Secretary of HHS the power to raise the Medicare rebate if the price of a drug rises faster than inflation is intended to make it more difficult for drug companies to raise prices to compensate for the rebate. The additional rebate could largely offset the benefits to the company from raising prices. The added rebate may prevent a drug company from raising its prices because the increase in the rebate would deprive it of additional revenues from Medicare sales. In addition, the higher price could decrease its share of the Medicare market. A price increase might also reduce market share (and possibly profit) for its non-Medicare sales.

If drug companies are not currently charging prices that guarantee them the highest profit, they might be able to circumvent at least part of the rebate through price increases. Firms that price their product to guarantee the maximum level of sales (or some other financial target), rather than profits, could be in this position and might be able to increase their profits in the non-Medicare market by raising prices.

## Effects on the Role of Government in the Pharmaceutical Market

As a result of Medicare's actions, sometimes in conjunction with the Advisory Council, the federal government might have substantial influence on the prices of many pharmaceuticals. Medicare would set the initial rebate based on the "reasonableness" of the launch price. After the launch period, the Medicare rebate would rise if a pharmaceutical company increased its prices above the rate of inflation. Consequently, the federal government would be sending strong signals to drug manufacturers about launch price and subsequent price increases. But the use of these policy mechanisms would oppose a 15-year trend in government policy toward regulated industries, which has been to eliminate price and quantity regulations while retaining quality and safety standards.[18]

Seen from another perspective, the Medicare rebates do not constitute price controls but serve the public purpose of limiting taxpayer costs. Before the 1990 Omnibus Budget Reconciliation Act established the Medicaid rebate and other cost containment provisions, Medicaid was paying some of the highest prices on the market. Without similar controls, some fear that Medicare could incur substantial costs. Furthermore, under the Administration's proposal, the Secretary of HHS must set the price that the federal government is willing to pay for new products, just as the operator of any other health plan does. Supporters of the proposal argue that the special rebate for new drugs, though imperfect, is adequate to ensure that the taxpayer is protected. The rebate agreement in no way legally limits prices charged to non-Medicare patients.

18. In 1977, 17 percent of U.S. gross national product was produced by regulated industries. By 1988, the regulated industries' share of GNP had been cut to 6.6 percent. Clifford Winston, "Economic Deregulation: Days of Reckoning for Microeconomists," *Journal of Economic Literature* (September 1993), pp. 1263-1289.

Furthermore, findings of the Advisory Council are not legally binding on any organization.

## Effects on Discounts to Institutional Buyers

As a result of the proposal's rebate agreement, institutional purchasers could pay a higher price for drugs. Based on interviews with representatives of drug companies, the Boston Consulting Group estimates that discounts given to institutional purchasers in 1992 averaged 16 percent less than list price.[19] Wholesalers commonly receive a discount from the list price. Therefore, the discount from the "average manufacturer retail price" would be lower.

The Medicaid rebate on a drug exceeds 15.7 percent if the best discount given to an institutional purchaser of the drug exceeds this amount. Based on a sample of 100 patented drugs for which the Medicaid program currently spends the most money, the Congressional Budget Office found that the median best discount given to institutional purchasers was 18 percent off the average manufacturer's price (approximately the price paid by wholesalers and the Medicaid rebate equivalent of the "average manufacturer retail price"). Since the *average* discount given to institutional purchasers would be lower than the *best* discount given to any institutional purchaser, the amount that brand-name drugs are discounted for institutional purchasers may often average below 17 percent.

Discounts for institutional purchasers are currently smaller than they might be without the Medicaid rebates. The incentive to give institutional purchasers discounts of more than 17 percent on drugs purchased by Medicare beneficiaries would diminish, but perhaps no more than it has already diminished under the Medicaid rebate agreement. If the amount of the drug consumed by Medicare beneficiaries is large enough in relation to the total demand for the drug, the manufacturer is likely to keep its average discount rate to institutional purchasers at or below 17 percent.

19. Boston Consulting Group, *The Changing Environment for U.S. Pharmaceuticals* (New York: Boston Consulting Group, April 1993), p. 10.

## Effects on Launch Prices

Part of the Medicare rebate could be recovered by setting a higher launch price. Since market share declines when price increases, it may not be possible for pharmaceutical firms to recover the rebate fully by raising prices. If manufacturers do not raise launch prices, they would be able to recoup part of the revenues lost to the rebate only by lowering negotiated discounts to institutional purchasers.

Drug manufactures could raise their launch prices and not necessarily incur a special rebate. The average new drug is currently launched at 14 percent below the price of the market leader. Pharmaceutical companies know that they would not be allowed to raise prices beyond the increase in the consumer price index without incurring an additional Medicare rebate. This knowledge would encourage them to increase their introductory prices on new drugs. Thus, instead of launching new drugs at an average of 14 percent below the market leader, pharmaceutical companies could introduce them at, say, 7 percent under the market leader. (Given the uncertainty surrounding all aspects of marketing a new drug, there may be a great deal of play in the current launch price.) Since the new drug prices would be less than the prices of existing drugs in the therapeutic category, pharmaceutical companies might not have an additional Medicare rebate beyond the 17 percent. But prices would be higher than they otherwise would have been. Furthermore, if launch prices are higher, the position of the market leader may be strengthened and the role of the imitator in restraining prices may be reduced.

## Effects on Competition

Some aspects of the drug market challenge popular notions about the ability of producers to keep prices high and the role of high prices in encouraging competition. As noted previously, generic drugs are not the only source of competition. Imitative brand-name drugs also play a role in bringing down prices, often before the patent expires. If the Medicare rebate on imitative drugs is set too high, the effect could be to discourage early entry and competition. If the rebate is extended to generic drugs,

as the Medicaid rebate currently is, competition in the industry would be discouraged even more.[20] Effects would not be felt immediately because drug companies are likely to finish projects that are already nearing completion.

## Effects on Biotechnology

Many biotechnology products would be subject to the rebate. An informal count of two dozen approved biotechnology products found that two-thirds could be used on an outpatient basis, either exclusively or in addition to inpatient use. Others are exclusively used on an inpatient basis and so would not be subject to the rebate. Several hundred biotechnology products now await approval or are in clinical trials. CBO has no breakdown of their inpatient or outpatient status. If a product is an outpatient drug and subject to the rebate, the discussion above regarding Medicare rebates would apply to it.

## Limits on the Ability of the Government to Hold Down Prices

The federal government has tried often in the past to restrain price growth, usually with mixed results. A limited bureaucracy cannot successfully keep track of and control the modern market. Prices in the drug market are also very complicated; they vary in many dimensions (dosage, form, and packaging, to name only three), any one of which could be used to mask a price increase.

Given the hundreds of drugs and manufacturers and the thousands of dosage and packaging forms in the market, the federal agencies in charge of monitoring drug prices would have to rely on the compliance of the drug companies, as they largely do now for the Medicaid rebate.

The Secretary of HHS may also operate under substantial political constraints. New drugs are typically introduced at prices higher than existing drugs only when the new drugs offer some therapeutic advance. Once a drug is on the market for six months--during negotiations--and has established itself as a treatment, it would be difficult for the Secretary to eliminate Medicare reimbursement and force patients to pay more or do without, especially if the drug in question does provide expanded therapeutic benefit. Without the threat of removing Medicare reimbursement, however, the government would have no leverage in negotiations.

# The Cost Containment Provisions in Perspective

The cost containment provisions of the Administration's proposal might be useful in reducing taxpayer costs for the new benefits in Medicare, but they would add administrative complexity, could have substantial side effects, and might not reduce overall pharmaceutical costs.

Spending on pharmaceuticals can be contained by slowing the growth of prices or quantities or both. The Administration's proposal focuses largely on containing costs on the price side. But part of the extraordinary increases in drug prices that have been reported over the last few years may be a statistical illusion, a result of the way drug prices are sampled and the price index is computed (see Box 1 in Chapter 2). Economists who have tried to correct the government price indexes for these effects have found that increases in brand-name drug prices, though above general inflation, were less than official price measures indicated. Most important, generic drugs, which in unit terms represent a large and increasing share of the prescription market, have experienced virtually no price increases and might actually be lowering average drug prices.

If price increases in pharmaceuticals have not been as large as reported, the need for cost control mechanisms may be less than previously thought. Still, there may be a few drugs every year that provide unique capabilities but are very expensive. And guaranteeing access to pharmaceuticals as part of every resident's basic health coverage merits concern over costs. Given the political constraints,

20. For an analysis of the effects of the current Medicaid rebates, see Institute for Pharmaceutical Economics, *The Impact of Medicaid Rebates on Gross Margins of Generic Pharmaceuticals* (Philadelphia: Philadelphia College of Pharmacy and Science, July 1992).

however, the proposed cost containment mechanisms might not be very effective at rolling back such prices.

The drugs that could force Medicare and other health plans to incur heavy expenses are those that are taken regularly, perhaps daily, by large numbers of people, but their price might not be high in absolute terms. It is difficult to determine in advance which new drugs--including those now in clinical trials--have the potential to impose higher costs on Medicare and other plans. If used by enough people, even a drug that has a reasonable launch price could be very expensive.

The increasing competition in the pharmaceutical market may also reduce taxpayer costs. Seventy percent of all prescriptions are written for drugs that are made by more than one company, and the percentage is expected to rise. The Administration's proposal includes some market-oriented steps: for example, the drug benefit in Medicare would increase competition by encouraging the use of generic drugs. Other fee-for-service benefit plans are already going beyond such measures by using techniques that involve increasing competition, such as employing companies that manage pharmacy benefits.

Chapter Five

# Effects of Other Provisions

In addition to universal coverage, the Medicare benefit, and the Advisory Council on Breakthrough Drugs, three other aspects of the Administration's proposal would affect the pharmaceutical market directly:

- Restructuring the Medicaid program and ending the rebate on Medicaid prescription drugs;
- Shifting more people to managed health care; and
- Limiting the rate of growth of health insurance premiums.

## Changes in Medicaid

Under the Administration's proposal, the rebates that pharmaceutical companies now pay to the government on all drugs purchased through Medicaid would be repealed. Medicaid provides health coverage for some people who have very low incomes. Under the Administration's proposal, direct Medicaid pharmaceutical benefits would be replaced with subsidies of the premiums for low-income people who obtained coverage through regional health alliances. Medicaid currently provides a generous package of health benefits. All states provide drug coverage but the generosity of the benefit varies. Pharmaceutical manufacturers would no longer have to pay the government a rebate on drugs purchased by those people who were formerly covered through Medicaid.

According to a recent Office of Technology Assessment report, Medicaid covers 10 percent to 15 percent of all outpatient pharmaceutical expenditures.[1] The Medicaid rebates are equal to 15.7 percent of the average manufacturer's price or to the best discount given by the manufacturer to an institutional purchaser, whichever is greater. The Medicaid rebates also increase if a drug's price rises faster than the inflation rate. The Congressional Budget Office found that 25 percent of the Medicaid rebate revenues in 1991 were paid on drugs for which the best discount exceeded 15.7 percent. If the Medicaid rebates were repealed, average unit revenues of the pharmaceutical manufacturers could increase by at least 2 percent (10 percent to 15 percent of 15.7 percent). This estimate does not account for the instances in which the Medicaid discount exceeds 15.7 percent; the estimate may understate the rise in unit revenues for this reason. However, if some of those who are now covered by Medicaid move into plans that manage their drug benefit (and therefore negotiate price discounts for drugs with pharmaceutical firms), the estimate could overstate the rise in average unit revenues. CBO assumes that these two effects offset each other and estimates that unit revenues on outpatient drugs would rise by 2 percent if the Medicaid rebates were repealed.

## Shifting Patients to Managed Care Providers

A managed care plan, such as a health maintenance organization, may tend to use drugs more intensively than fee-for-service providers. If people switch to managed care providers in large numbers and if such providers continue to use pharmaceuticals as they have in the past, the market for drugs

1. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993), p. 245.

could expand. CBO has not estimated how many people would switch from fee-for-service to managed care providers as a result of the Administration's proposal.

Anecdotal evidence suggests that managed care providers use more pharmaceuticals than the average fee-for-service provider, even when demographic and other differences between the enrollees are taken into consideration. Managed care providers, such as group or staff health maintenance organizations, which are at financial risk for the costs of their patients' care, have a strong economic incentive to provide cost-effective treatments.

Because the number of managed care providers has recently grown rapidly, there is little literature dealing with their prescribing behavior. Nevertheless, one limited study has provided evidence consistent with the anecdotal observations.[2] This study of one fee-for-service plan of a major corporation, which included a prescription benefit, and seven health maintenance organizations, which also included prescription benefits, revealed several differences in the behavior of the two types of plan toward pharmaceuticals, namely:

- The health maintenance organizations prescribed more drugs, even when differences in age profile were adjusted for.[3]
- Health maintenance organizations used more generic drugs.
- The total cost of prescription drugs--both to the plan and patient--was lower in health maintenance organizations than in fee-for-service groups because generic drugs were used more often. The health maintenance organizations' total prescription costs were about 9 percent less than the total prescription costs for fee-for-service groups for patients under 65.
- Health maintenance organizations began using new pharmaceuticals as rapidly as the fee-for-service providers. They reduced costs by substituting generics where possible, not by denying access to new drugs.

But these findings may have to be tempered because the fee-for-service plan may not have had typical benefits. In their review of the benefits, the authors did not mention a deductible, which most health plans have, although they did refer to a copayment, which most plans also have. The lack of a deductible might have increased pharmaceutical demand. Thus, the fact that these particular health maintenance organizations had a lower spending rate than this particular fee-for-service plan may have been caused by both factors and was not simply a result of managed pharmaceutical benefits.

The study suggests that the number of prescriptions would rise as more persons moved to managed care and that the primary beneficiaries of the increase would be manufacturers of generic drugs. Manufacturers of brand-name pharmaceuticals might benefit if they had a generic line of drugs, but their nongeneric lines might suffer. In fact, brand-name drug firms own many of the major generic drug companies, which produce the majority of generic drugs prescribed in this country.

Prescription drug use, however, is not the whole story. Health maintenance organizations also have lower rates of hospitalization than do fee-for-service plans. Since hospitals use a major quantity of pharmaceuticals, the lower rate of hospitalization experienced by health maintenance organizations might almost offset their greater use of outpatient prescription drugs. (These offsetting factors also serve to illustrate the uncertainty surrounding the demand estimates presented in the previous chapters.)

As managed care providers begin to occupy a larger fraction of the market, fee-for-service providers may have to change their prescribing patterns. Already the major health insurance plans encourage their members to join a preferred provider organization, a form that uses some of the control mechanisms currently found in health maintenance organizations. And many of the indemnity health plans have managed drug benefits.

2. Jonathan P. Weiner and others, "Impact of Managed Care on Prescription Drug Use," *Health Affairs* (Spring 1991), pp. 140-154.

3. Despite attempts to control for differences in population, substantial selection biases might occur in the two types of health plan.

# Constraining the Rate of Growth of Health Plan Premiums

The Administration's proposal would set up a National Health Board, which would, among its other duties, establish an initial target per capita premium for the standard benefit package in each regional health alliance.[4] The board would also limit the growth of the premiums. The weighted average premium would be constrained to meet the target. Each alliance would have a different target. CBO has made no explicit estimate of the effect of this provision on the pharmaceutical market.

Restraining the rate of growth of premiums would probably shift medical practice toward less expensive treatments, possibly including greater use of pharmaceuticals.[5] If a plan is limited in the growth of the premium that can be charged per person, the plan's sponsors would have every incentive to reduce the costs of treatment, which often means using drugs to substitute for more expensive forms of medical treatment. The managed health care example, discussed in the previous section, seems to point in this direction. Plans and providers would be unlikely to do so in excess, however, because of the development of practice guidelines.

Under the Administration's proposal, if the weighted average premium in a regional alliance was above the target, the National Health Board could require plans with excessive premiums (according to criteria specified in the proposal) to lower their premiums and their payments to providers.[6] The language is not clear about what would happen to payments for prescription benefits, although they have not been explicitly exempted from such cuts. Since pharmaceutical companies would not be considered "participating providers," the health plans would presumably not be able to reduce their incomes directly. The amount that the plan paid per prescription might be lowered for plans in which enrollees obtained their drugs from retail pharmacists. Plans that have their own pharmacies or managed drug benefits might try contracting with drug wholesalers in the same way that they would with participating providers; the contract could specify that if the plan's premium were forced down, wholesalers would have to accept a proportional reduction. Retailers and wholesalers, however, would in all likelihood attempt to pass back any reductions in income to pharmaceutical manufacturers.

4. For corporations that had opted out of the regional alliance system, the board would only control the rate of growth. Similarly, the board would also set per capita premium targets for states that set up alternatives to the alliance system. For a fuller discussion of the proposed National Health Board and the regional alliances, see Congressional Budget Office, *An Analysis of the Administration's Health Proposal* (February 1994), pp. 22-24.

5. Ibid., pp. 74-76.

6. Ibid., pp. 22-23.

Chapter Six

# The Effect of the Administration's Proposal on the Returns from Drug Development

When a firm considers investing in the development of new drugs, it weighs the costs it expects to incur in the research and approval process against the profits that the drugs are likely to generate throughout their time on the market. If the ventures are successful, the costs incurred in drug discovery and development are exceeded by the profits generated by those drugs that reach the market. If the changes proposed by the Administration increase the returns from developing new drugs, one would expect firms to invest more in drug development.

The Administration's proposal contains a universal entitlement to a standard benefit package that includes coverage for prescription drugs.[1] If enacted, this universal coverage provision, together with the changes in Medicare that the Administration proposes, would probably affect the average returns from drug development positively, but only slightly, when the average is taken of all types of drugs. The proposed changes would increase the returns on drugs that are marketed primarily to the under-65 population and decrease the returns on drugs that are marketed primarily to those who are 65 and over. When averaged over all drugs, the increase in returns is so small that it would probably not significantly affect the level of research and development undertaken in the pharmaceutical industry.

1. CBO's estimate of induced demand results from the combination of a universal entitlement and a generous benefit package (offering both comprehensive physician and drug coverage). For the sake of brevity, this combination will be referred to as the universal coverage provision of the Administration's proposal.

## What Previous Studies of the Returns from Drug Development Show

Two studies--by the Office of Technology Assessment and economists Henry Grabowski and John Vernon--have compared the returns from developing a new drug with the costs for drugs that were introduced in the United States in the early 1980s.[2] Both studies found that the profits generated by a new drug are generally more than sufficient to compensate for the cost of development, including the cost of capital. But the amount by which returns from developing a new drug exceed costs are modest, on average, and would be eliminated if the average price received for drugs sold worldwide were just 4.3 percent lower.

Both studies estimate that the average after-tax cost of developing a new drug, including the cost of capital, is about $190 million in 1990 dollars (see Table 4).[3] These cost estimates are based on a large

2. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993); Henry Grabowski and John Vernon, "Returns to R&D on New Drug Introductions in the 1980s" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington D.C., October 27-28, 1993).

3. Since research and development is treated for tax purposes as a current expense, spending $1 more on R&D costs a company just 65 cents when the marginal tax rate is 35 percent. Before accounting for this tax savings, Grabowski and Vernon estimated that it costs an average of $280 million to develop a new drug.

**Table 4.**
**The Cost of Drug Development Compared with Profits for the Average Drug (In millions of 1990 dollars)**

| | Estimates | |
|---|---|---|
| | Grabowski and Vernon | Office of Technology Assessment |
| Average Profits (Returns)[a] | 210 | 230 |
| Average Research and Development Costs[b] | 188 | 194 |
| Excess Profits[c] | 22 | 36 |

SOURCE: Congressional Budget Office based on Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, (February 1993), and Henry Grabowski and John Vernon, "Returns to R&D on New Drug Introductions in the 1980s" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

a. Present value of the profits generated from sales of the average drug over its product life.

b. Includes the cost of capital.

c. Equals average profits minus average research and development costs.

sample of drugs developed in the 1970s and marketed in the 1980s. They include investment in research and clinical tests to obtain Food and Drug Administration approval as well as the cost of failures--that is, investment in research for drugs that never made it to market.[4] The cost of capital alone constitutes approximately half of drug development costs (see Appendix A).

Returns from drug development consist of the present value of sales revenues less production, marketing, and administrative costs. The Office of Technology Assessment estimated that the present value of these profits would average $230 million; Grabowski and Vernon's estimate is lower: $210 million.

Both studies found that the returns from developing a new drug exceed the costs. Grabowski and Vernon calculated that the returns from developing a new drug exceed the costs by an average of $22 million; OTA found that the returns exceed costs by an average of $36 million in 1990 dollars (see Table 4). Although these estimates are relatively close, the assumptions made in each study differ in several important respects.[5] On average, developing a new drug yields returns greater than the amount required to compensate investors for their cost of capital. The excess profits, however, are modest. OTA found that they would disappear if prices fell by an average of just 4.3 percent worldwide (and the quantity sold did not change).[6] U.S. sales constitute at most one-half of the worldwide sales of drugs patented in the United States. Thus, a decline of at least 8.6 percent in the average price of prescription drugs in the United States would be necessary to eliminate these excess returns if prices elsewhere did not change.

Such estimates of excess returns are very sensitive to the cost of capital used to discount revenues and capitalize costs.[7] Increasing the cost of capital lowers the present value of returns and increases the present value of costs. Grabowski and Vernon point out that excess returns would be eliminated in both studies if the cost of capital were 1 percentage point higher. By the same token, excess profits would be higher--perhaps doubled--if the cost of capital were 1 percentage point lower.

4. Both studies base their cost estimates on the work of Joseph DiMasi and others, "Cost of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, vol. 10 (1991).

5. The cost of capital used in OTA's calculation of the cost of drug development is higher than that used by Grabowski. OTA uses a lower cost of capital than Grabowski in discounting profits. The differences offset each other. Grabowski also uses a higher cost for plant and machinery than does OTA.

6. Office of Technology Assessment, *Pharmaceutical R&D*, pp. 89-90.

7. Both studies based their cost of capital on an OTA-commissioned study that found the real cost of capital for this industry to be between 10 percent and 11 percent. An alternative estimate suggests that the cost of capital could be lower. (See Appendix A.)

# How the Returns from Drug Development Would Change

The Administration's proposal affects the returns from drug development by changing the quantity of drugs that a company can expect to sell and the revenue it can expect to receive on each unit of a drug. In analyzing the effect of the Administration's proposal on future returns from research and development, it is convenient to separate the pharmaceutical market into two parts: that serving the under-65 population and that serving the 65-and-over population. In the Administration's proposal, the alliance system covers almost all of those under 65, and Medicare covers almost all of those who are 65 and over. (The exceptions are that Medicare covers 1 percent of the under-65 population, and a small proportion of Medicare enrollees could choose to enroll in a health plan through the alliance system.)

The Administration's proposal for universal coverage would primarily affect the prescription drug expenditures of those people who are under 65. The addition of a drug benefit to Medicare would primarily affect those who are 65 and older. Manufacturers would be required to pay at least a 17 percent rebate to the federal government on outpatient pharmaceuticals purchased by Medicare enrollees. Since Medicare covers most of the 65-and-over population, the rebate would reduce the revenue received on drugs that are sold primarily to this group. The universal coverage provision would have its greatest effect on the demand for drugs by extending coverage to the uninsured, 99 percent of whom are under age 65. Most current Medicaid beneficiaries would obtain coverage through regional alliances, and the Medicaid drug rebates would no longer exist.

The Congressional Budget Office calculated the effect of these provisions on the returns from drug development using the sample of 67 drugs examined by Grabowski and Vernon. The drugs were introduced in the United States between 1980 and 1984. The sales data run through 1992; therefore, there were only 8 to 12 years of actual sales data for these drugs, depending on the year they were introduced on the market. Grabowski and Vernon projected sales after 1992 for each drug through its product life of 20 years.

The returns on a drug equal the present value of the profits it generates during its product life. When demand for pharmaceuticals rises, the change in profits is equal to the increase in sales less the cost of producing more units of the drug. The increase in returns on a drug equal the discounted value of this rise in profits in each year of the drug's product life.[8]

Almost all of the changes in the demand for prescription drugs, as well as those in the Medicare rebate, would apply only to outpatient prescription drugs, which constitute approximately 77 percent of all sales of prescription drugs in the United States. Also, these changes would affect only U.S. sales, which both Grabowski and OTA have assumed constitute one-half of all worldwide sales of the drugs in their samples. Evidence suggests that the U.S sales of patented drugs constitute somewhat less than one-half of worldwide sales (see Chapter 2). The sales of U.S. outpatient prescription drugs therefore constitute less than 40 percent of the total worldwide sales of drugs patented in the United States (77 percent of 50 percent).

CBO assumed that for the purpose of these calculations the cost of producing an extra unit of a drug is equal to 25 percent of the drug's price. This estimate of incremental costs is based on the OTA study, which found that production and distribution costs were equal to 25 percent of sales. The 25 percent included the depreciation costs of the manufacturing plant, which are not part of (variable) unit costs. The cost of producing another unit of a drug could therefore be below 25 percent of product price. If demand is permanently increased, however, pharmaceutical companies would be likely to increase their production capacity. Some adjustment should therefore be made for this new capacity. Using total plant depreciation clearly overstates the

8. The U.S. population is growing at a rate of about 1 percent a year. Investment in new R&D projects today puts the average drug on the market 12 years from now; however, the U.S. population will be larger then. As the pharmaceutical market grows, the returns from drug development will increase, all other factors being equal. CBO did not take this effect into account in these calculations.

cost of this incremental capacity. The overstatement might be justified, however, by arguing that some small adjustment can be made for producers' increases in administrative or marketing costs when responding to induced demand.

Other estimates of incremental (or marginal) cost range between 17 percent and 34 percent of product price (discussed further below). The results presented in this chapter are not very sensitive to variations of incremental cost within this range.

## The Under-65 Population

The quantity of prescription drugs sold to the under-65 market could increase by approximately 6 percent if the Administration's proposal for universal coverage were enacted. Because of the uncertainties involved in the induced demand calculations, CBO has considered a wider range of induced demand estimates in the sensitivity analysis section below.

For the base case, it is assumed that demand under the universal coverage provision of the Administration's proposal would increase expenditures for prescription drugs on the part of the under-65 population by 6 percent. The change in profits is equal to a 6 percent increase in U.S. sales, minus the cost of producing more units of the drug. An examination of the discounted value of this increase in profits over the product life of the drugs in the sample (20 years) shows that when demand increases by 6 percent, the profits from developing a new drug for the under-65 population could increase by an average of $19 million (see Appendix B). This amount constitutes an 8 percent increase in the average profits from developing a drug.

Absorbing Medicaid into the alliance system would eliminate the rebates that pharmaceutical manufacturers are required to pay to the government on all drugs purchased through Medicaid. A repeal of this rebate would raise the average revenue per unit of the drug sold on the outpatient market by 2 percent because Medicaid covers 10 percent to 15 percent of all outpatient pharmaceutical expenditures (see Chapter 5). A 2 percent increase in unit revenue on outpatient drugs would yield an average increase of $6 million in profits from drug development (see Appendix B). Thus, the repeal of the Medicaid rebate would further increase the present value of profits generated from marketing a drug by an average of $6 million.

Together, these two effects imply that the Administration's proposal would raise the profits from a drug developed exclusively for the under-65 population by an average of $26 million (see Table 5). This amount constitutes an 11 percent increase in the average present value of profits (returns) generated from marketing a drug. The increase is substantial, considering that it has been estimated that average returns exceed R&D costs by just $22 million to $36 million.

## The 65-and-Over Population

The proposal's new Medicare drug benefit could increase the quantity of outpatient prescription drugs sold to the 65-and-over population by approximately 4 percent (see Chapter 3). By itself, this change would increase the profits from developing a new drug for the 65-and-over population by an average of $10 million. But the proposal would also require that pharmaceutical manufacturers pay a 17 percent rebate to the government on all outpatient drugs purchased through Medicare. CBO estimates that a rebate of 17 percent on all outpatient drugs paid for by Medicare, together with the 4 percent increase in outpatient demand, would reduce the returns on drugs marketed to the 65-and-over population by an average of $39 million (see Appendix B). This would amount to a 17 percent decline in the average returns from developing a drug, assuming that the pharmaceutical manufacturers would not recover any of the rebate by raising prices. If manufacturers were able to offset some of this rebate by raising prices, the decline in returns would be smaller.

Under the Administration's proposal, people eligible for Medicare who are employed or married to an employed worker would obtain their primary coverage through an alliance rather than through Medicare. CBO has estimated that in 1998, when the Administration's proposal would become fully operational nationwide, this change in coverage would reduce the number of people who receive primary coverage through Medicare by 2.5 mil-

**Table 5.**
**The Effect of the Administration's Proposal on Average Profits from Developing a Drug: Base Case**

| Administration's Proposal | Description | Effect on the Prescription Drug Market (Base-Case Assumptions) | Change in Average Profits from Developing a Drug[a] (In millions of 1990 dollars) | | |
|---|---|---|---|---|---|
| | | | Drugs Purchased Only by People Under 65 | Drugs Purchased Only by People 65 and Over | Drugs Purchased Two-Thirds by People Under 65, One-Third by People 65 and Over (Market average)[b] |
| Universal Coverage | Coverage would be extended to the 37 million uninsured, almost all of whom are under 65. Coverage would improve for another 9 percent of the under-65 population. | Expenditures by the under-65 population on all pharmaceuticals would rise by 6.4 percent. | 19 | 0 | 13 |
| Medicaid Becomes Part of the Alliance System | Government would fully subsidize participation of most Medicaid recipients in the alliance system. | Medicaid rebates would be eliminated. Average unit revenues on outpatient sales would rise by 2 percent. | 6 | 6 | 6 |
| Drug Benefit Added to Medicare | Medicare would cover outpatient drugs. A rebate of at least 17 percent would be imposed on outpatient drugs purchased through Medicare. | Expenditures by the 65-and-over population on outpatient pharmaceuticals would rise by 4.5 percent. Unit revenues would decline by 17 percent. | 0 | -39 | -13 |
| | | Total | 26 | -33 | 6 |

SOURCE: Congressional Budget Office.

a. Equals the change in the present value of profits generated from worldwide sales of the average drug over its product life. The calculations involved in preparing this table are explained in Appendix B.

b. On average, 34 percent of prescription drug expenditures can be attributed to people 65 and over. This column equals 66 percent of column 3 plus 34 percent of column 4.

lion.[9] Since 0.7 million of these people would be disabled, by 1998 the number of 65-and-over Medicare enrollees would fall by about 1.8 million--an approximate 5 percent decline in the number of 65-and-over Medicare enrollees (below what it would have been without this provision). This decline in the proportion of the 65-and-over population that would be covered through Medicare was accounted for in the above calculation.

In 1987, Medicaid covered 9 percent to 10 percent of the outpatient prescription drug expen-

9. Congressional Budget Office, *An Analysis of the Administration's Health Proposal* (February 1994), p. 34.

ditures for both the under- and over-65 populations.[10] Thus, the repeal of the Medicaid rebate would affect the 65-and-over market much as it did the under-65 market. The returns from drugs developed primarily for those who are 65 and over should also increase by an average of $6 million. After accounting for the increase in average price, which would occur as the Medicaid rebates are repealed, returns from a drug developed for the 65-and-over population would fall by an average of $33 million (see Table 5). This net amount is a decline of 14 percent in the average returns from developing a drug. The decline would nearly eliminate excess returns as measured by OTA and would exceed excess returns as measured by Grabowski.

A decline in the returns from developing drugs for the 65-and-over population would reduce the manufacturers' incentive to develop them and could result in a decline in the level of research into drugs used primarily by the 65-and-over population. If that happened, research projects that were expected to be the least profitable would be dropped first. If the level of research into drugs aimed at the 65-and-over population were reduced, the projects that were undertaken would on average become more profitable. Most drugs that previously appeared profitable to develop for the 65-and-over population might still seem profitable.

## The Full Market--Over and Under 65

When averaged among all drugs, returns from R&D would rise slightly under the Administration's proposed changes. Returns from those drugs sold primarily to people 65 and over would fall, and those from drugs sold mostly to the under-65 population would rise. But few drugs are marketed exclusively to either population. The 65-and-over population consumes approximately one-third of all prescription drugs. When averaged among all drugs, the change in returns from drug development is equal to one-third of the change in returns calculated for the 65-and-over market, plus two-thirds of the change in returns calculated for the under-65 market. Thus, returns from drug development, averaged among all drugs, could rise by $6 million under the changes proposed by the Administration (see Table 5). The change is small--equal to less than 3 percent of total estimated returns from drug development.

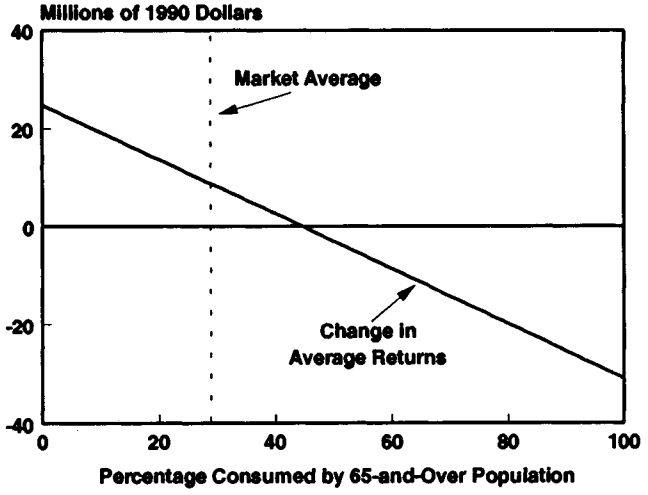
Although these changes in the over- and under-65 markets nearly balance out when returns are averaged among all drugs, they may affect the types of research projects that are undertaken. The returns from developing drugs primarily for those 65 and over would decline, whereas the returns from developing a drug for the under-65 market would rise. Although illnesses do not typically strike only the 65-and-over population, the prevalance of certain health problems is disproportionately high among this age group. People over 65 account for an extremely large share of the market for drugs to treat such disorders as prostate ailments, osteoporosis, and Alzheimer's disease. In other instances, they represent a large but not overwhelming share of the potential market; for example, doctors report that more than 55 percent of their prescriptions for cardiovascular drugs are written for people over 65.[11] Their larger than one-half share alone appears to be sufficient to change the Administration's proposal from a modestly positive net influence on returns to a negative one for these drugs (see Figure 9).

If two-thirds of a drug's potential market consists of people 65 and over, average returns would fall by $13 million. This decline would be eliminated if the Medicare rebate were reduced from 17 percent to 10 percent. Under the Administration's proposal, if half of the potential market for a drug consists of people over 65, average returns would drop by $4 million. This decrease is equal to less than 2 percent of the average returns from developing a drug.

10. Office of Technology Assessment, *Pharmaceutical R&D*, p. 240. The rate of expansion of under-65 Medicaid enrollees may have exceeded that of 65-and-over Medicaid enrollees since 1987.

11. Doctors' reports may differ from their actual prescriptions. The percentage represents the weighted average among several categories of coronary drugs. IMS America, *National Disease and Therapeutic Index, U.S. Drug Store and U.S. Hospital Audits* (Plymouth Meeting, Pa.: IMS America, Ltd., 1994).

**Figure 9.**
**How the Change in Average Returns from Developing a Drug Under the Administration's Proposal Varies as the Share Consumed by People 65 and Over Increases**




SOURCE: Congressional Budget Office.

NOTE: On average, people 65 and over consume 34 percent of prescription drugs.

If research can be sufficiently targeted, this difference in returns by age category could cause some shift in research away from outpatient drugs for the 65-and-over population toward drugs developed primarily for the under-65 population. The shift may be small, however, and is not estimated.

# Sensitivity of the Results to the Base-Case Assumptions

Given the uncertainties surrounding the estimates of induced demand and the effect of the Medicare rebate agreement on the price of new drugs, CBO changed the base-case assumptions to assess the degree to which these results could vary. The base case assumes that marginal cost would be equal to 25 percent of the unit price and that if the Administration's proposal were enacted:

- Universal coverage would increase all prescription drug expenditures of the under-65 population by 6 percent, and the Medicare drug benefit would increase all prescription drug expenditures of the 65-and-over population by 4 percent;
- The resulting Medicare rebate would effectively lower unit revenues (the per-unit manufacturer's price less the rebate) by 17 percent on drugs purchased by Medicare enrollees;
- The repeal of the Medicaid rebate would increase unit revenues on outpatient prescription drugs by 2 percent; and,
- There would be no further erosion of sales caused by generic competition after patent expiration.

## Changes in Demand

Based on the sales data of Grabowski and Vernon's sample of 67 drugs, every 1 percent increase in demand for pharmaceuticals in the United States would increase the net returns from the average drug by approximately $3 million after taxes (see Appendix B). The base-case estimates of induced demand are somewhat conservative; even so, the base case predicts a slight increase in returns from R&D under the Administration's proposal. If the assumptions were even more conservative, however, and demand growth were 50 percent below that assumed in the base case, the effect of the universal coverage provision and the Medicare drug benefit on average returns from drug development would still be small, lowering average returns by just $2 million (see Table 6). If the induced demand estimates were doubled, average returns would increase by $21 million, an 8 percent increase in the total returns from the average drug and a more than 50 percent increase in excess returns.

## Incremental Costs

The base case assumes that the marginal or incremental cost of producing one more unit is equal to

**Table 6.**
**The Effect of the Administration's Proposal on Average Profits from Developing a Drug Under Varying Assumptions About Induced Demand (In millions of 1990 dollars)**

| | Population Under 65: The Effect of Universal Coverage[a] | | Population Over 65: The Effect of Changes to Medicare | | Market Average[b] | |
|---|---|---|---|---|---|---|
| | Assumed Change in Demand[c] (Percent) | Effect on Average Profits | Assumed Change in Demand[c] (Percent) | Effect on Average Profits | Assumed Change in Demand (Percent) | Effect on Average Profits[d] |
| Base Case | 6 | 19 | 3[e] | -39 | 5 | 6 |
| Demand 50 Percent Higher | 10 | 29 | 5 | -35 | 8 | 13 |
| Demand 100 Percent Higher | 13 | 39 | 7 | -31 | 11 | 21 |
| Demand 50 Percent Lower | 3 | 10 | 2 | -43 | 3 | -2 |

SOURCE: Congressional Budget Office.

a. Universal coverage here refers to a universal entitlement to the standard benefit package proposed by the Administration. It includes a prescription drug benefit.

b. Averaged over all drugs, based on 34 percent of prescription drugs sold to those 65 and over and 66 percent of prescription drugs sold to those under 65.

c. The percentage increase in prescription drug expenditures (both inpatient and outpatient).

d. Equals 66 percent of column 2 plus 34 percent of column 4 plus $6 million (for repeal of the Medicaid rebates).

e. Outpatient drug expenditures are assumed to rise 4.5 percent in the base case for this group. Since outpatient drugs constitute 77 percent of prescription drug sales, total expenditures for this group would rise by 3.4 percent (77 percent of 4.5 percent).

25 percent of the product price. A lower estimate of incremental costs comes from the work of economists Richard Caves, Michael Whinston, and Mark Hurwitz, which shows that the price of generic drugs, after sufficient generic entry, amounts to 17 percent of the price of the brand-name drug against which they compete.[12] This ratio can be considered an estimate of marginal cost because the unit costs of producing a generic drug should be similar to those of producing a brand-name drug. By contrast, the Census of Manufactures reports that material and production-labor costs constituted 34 percent of the value of drug shipments in 1987. But this ratio probably overstates the share of incremental costs, since the census includes over-the-counter drugs, which are likely to have lower markups.[13]

The base-case results are not very sensitive to the marginal cost assumption (see Table 7). The

12. Richard Caves, Michael Whinston, and Mark Hurwitz, "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics, 1991* (1991). The generic price is estimated to be 17 percent of the brand-name price before patent expiration and generic entry. In addition, Henry Grabowski and John Vernon estimated the marginal cost of a patented drug to be 21 percent of product price. See "Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Act," *Journal of Law and Economics* (October 1992).

13. Bureau of the Census, *1987 Census of Manufactures, Industry Series, Drugs* (April 1990), Table 1a-1.

results do not change substantially for incremental costs that range between 17 percent and 35 percent of prescription drug prices. Even if the marginal cost were equal to 40 percent of a drug's price, the returns from the average drug would still rise slightly under the Administration's proposal.

## Changes in New Drug Prices

If pharmaceutical companies, by raising the prices of new drugs, can offset some of the revenue they would lose because of the rebate, the returns from the development of a drug for the 65-and-over population would decline by less than $33 million. This offset could occur if manufacturers increased the launch prices of new drugs and the Secretary of Health and Human Services did not increase the Medicare rebate. It is not known, however, whether launch prices would be higher or lower as a result of the Medicare rebate agreement. The larger the proportion of a drug's market that belongs to Medicare enrollees, the greater is the Secretary's power to influence the drug's price. The base case as-

**Table 7.**
**The Effect of the Administration's Proposal on Average Profits from Developing a Drug Under Varying Assumptions About Marginal Cost (In millions of 1990 dollars)**

| | Marginal Cost as a Percentage of Product Price | Population Under 65: The Effect of Universal Coverage on Average Returns[a] | Population Over 65: The Effect of Changes to Medicare on Average Returns | Market Average Change in Profits[b] |
|---|---|---|---|---|
| Base Case | 25 | 19 | -39 | 6 |
| Marginal Cost 8 Percentage Points Lower | 17 | 21 | -38 | 7 |
| Marginal Cost 5 Percentage Points Lower | 20 | 21 | -38 | 7 |
| Marginal Cost 5 Percentage Points Higher | 30 | 18 | -40 | 4 |
| Marginal Cost 10 Percentage Points Higher | 35 | 17 | -41 | 3 |
| Marginal Cost 15 Percentage Points Higher | 40 | 16 | -41 | 2 |

SOURCE: Congressional Budget Office.

a. Universal coverage here refers to a universal entitlement to the standard benefit package proposed by the Administration. It includes a prescription drug benefit.

b. Averaged over all drugs, based on 34 percent of prescription drugs sold to those 65 and over and 66 percent of prescription drugs sold to those under 65. Change equals 66 percent of column 2 plus 34 percent of column 3 plus $6 million (for repeal of the Medicaid rebates).

**Table 8.**
**The Effect of the Administration's Proposal on Average Profits from Developing a Drug for the 65-and-Over Population Under Variying Assumptions About Producer Price**

| | Percentage Change in Producer Price[a] | Precentage Change in Unit Revenue When Combined with the Rebate[b] | Change in Average Returns[c] (In millions of 1990 dollars) | |
|---|---|---|---|---|
| | | | Assuming Quantity Sold Does Not Change | Assuming Quantity Sold Changes[d] |
| Base Case | 0 | -17 | -33 | -33 |
| Price 5 Percent Higher | 5 | -13 | -15 | -18 |
| Price 10 Percent Higher | 10 | -9 | 4 | -4 |
| Price 5 Percent Lower | -5 | -21 | -51 | -48 |
| Price 10 Percent Lower | -10 | -25 | -70 | -62 |

SOURCE: Congressional Budget Office.

a. This percentage change in producer price is assumed to hold throughout the product life of the drug.

b. Equals column 1 minus 17 percentage points minus 17 percent of column 1.

c. Includes $6 million for the repeal of the Medicaid rebates. The calculations are explained in Appendix C.

d. Assumes that for every 1 percent increase (or decrease) in price the quantity sold falls (or rises) by 0.3 percent.

sumes that pharmaceutical companies are not able to circumvent the rebates by raising prices. If negotiations over the size of the rebate did not prevent drug prices from rising, returns could fall by less than 14 percent on drugs developed for the 65-and-over population. If these negotiations were to result in lower drug prices, returns could fall even farther.

The base case assumes that the Medicare rebate agreement does not affect prescription drug prices. In the base case, the changes proposed in Medicare would lower the returns from drugs developed for the 65-and-older population by $33 million. If, in addition, the prices of these drugs were lowered by an average of 10 percent throughout their product lives (and the rebate remained at 17 percent), returns could fall by up to $62 million on drugs sold only to the 65-and-over population (see Table 8).[14] This fall would represent a 27 percent decline in average returns from drugs developed for the 65-and-over population. Conversely, if a drug's price were raised by 10 percent, and the rebate remained at 17 percent, the returns on drugs developed for the 65-and-over population could fall by just $4 million. The change in returns on drugs developed primarily for the 65-and-over population depends critically on the effect of the Medicare rebate agreement on the prices of new drugs used intensively by Medicare enrollees.

## Competition from Generic Drugs

The present discounted value of U.S. sales used in these calculations was obtained from Grabowski and Vernon's sample of 67 new drugs introduced between 1980 and 1984. Since the sales data run only through 1992, there were only 8 to 12 years of actual information about each drug. Most drugs in the sample have effective patent lives of 9 to 13 years. Grabowski and Vernon projected the U.S. sales of

14. For these calculations, CBO assumes that demand is relatively unresponsive to price changes (specifically, for a 1 percent increase in price the quantity purchased declines by just 0.3 percent). See Appendix B for an explanation of the calculations.

each drug through a 20-year product life. Based on their previous work, the authors assumed that sales declined by 30 percent in the first year after patent expiration, 21 percent in the second, and 20 percent during the final four years. In the remaining years after patent expiration, they assumed sales would erode at a rate of 10 percent to 12 percent.[15]

The Medicare drug benefit would provide incentives for enrollees to choose generic substitutes when available. The proposal might also encourage a higher rate of substitution of generic drugs by the under-65 population. In the U.S. sales data used in the base case obtained from Grabowski and Vernon, it is assumed that five years after patent expiration, sales of the name-brand drug have eroded to just 38 percent of the value they had in the year before expiration. Grabowski and Vernon have estimated that if the generic erosion rate were increased by 50 percent, average net returns would decline by $19 million.[16] An OTA-commissioned study of 35 drugs that lost patent protection between 1984 and 1987 found that three years after patent expiration, sales were still at 83 percent of the level they had attained before patent expiration. OTA found that an erosion rate of more than 30 percent a year in each year after patent expiration would be necessary before returns would fall by $36 million, eliminating the excess returns from drug development.

# Conclusions

If the changes proposed by the Administration were to increase the returns from drug development, investment in new drugs would most likely rise. When averaged among all drugs, returns would increase slightly under the Administration's proposal. Returns from drugs developed mostly for the 65-and-over population, however, would decline, and the returns from developing drugs primarily for those under 65 would increase.

Previous studies have found that the returns from developing a new drug exceed the cost of development by an average of $22 million to $36 million. The Administration's proposal for universal coverage (including a drug benefit), together with a repeal of the Medicaid rebates, could increase the returns from developing a drug for the under-65 population by $26 million. The returns from developing a drug for the 65-and-over population would be affected by Medicare's new drug benefit, the new 17 percent Medicare rebate, and the repeal of the Medicaid rebate. CBO estimates that together these provisions in the Administration's proposal could reduce the returns from developing a drug for the 65-and-over population by $33 million.

The general level of R&D in the pharmaceutical industry may not change much as a result of these provisions because the returns change little when averaged among all drugs. However, the difference in returns by age category could cause an increase in research into drugs aimed primarily at the under-65 market and a slight decline in research into drugs aimed primarily at the 65-and-over market.

It is not known whether the launch price of a new drug would be higher or lower as a result of the Medicare rebate agreement. The more frequently a drug is purchased by Medicare enrollees, the greater is the Secretary's power to influence the drug's price. If the Medicare rebate agreement results in lower prices of new drugs used intensively by the over-65 population, the returns from developing drugs primarily for this population could decline further.

15. Grabowski and Vernon, "Brand Loyalty, Entry and Price Competition in Pharmaceuticals after the 1984 Act."

16. Henry Grabowski and John Vernon, "Returns to R&D on New Drug Introductions in the 1980s" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

Chapter Seven

# Conclusions

A review of the major provisions for pharmaceutical coverage in the Administration's health care proposal indicates that, on average, the returns from drug company research and development would be unlikely to change; increases resulting from one provision would wash out the decreases resulting from another. The incentive system facing pharmaceutical companies would probably shift, however. Individual parts of the drug market would be affected in different ways and in different directions, perhaps inducing pharmaceutical companies to shift their resources. But all of these results would depend crucially on how the pharmaceutical companies responded to the Medicare rebate agreement.

Clearly, the major direct vehicle in the Administration's proposal for containing pharmaceutical prices and costs would be Medicare's rebate on prescription drugs. Although other provisions also attempt to control costs, their effects would be indirect or diffuse. Because drugs are such a small part of total health care spending, the limits on the rate of growth of insurance premiums would be unlikely to inhibit drug prices substantially, especially if providers increase their use of drugs to substitute medicinal treatments for surgical procedures. The effect of the Advisory Council on Breakthrough Drugs might be limited to only a few drugs each year. Moreover, aside from its potential influence on Medicare rebate negotiations, it would at best have the power to make recommendations and sway public opinion. Public opinion has brought some drug prices down, especially when it has already been mobilized--as in the case of some drugs used to treat human immunodeficiency virus infection--but has failed in other cases.

In view of increasing competition within the pharmaceutical market, drug prices could easily decrease regardless of the Administration's proposal. The forces already at work will serve to reduce, but probably not eliminate, whatever excess profits exist in the industry. Given the reduced potential for profitable investment, R&D may (and perhaps should) decrease. But if the practice of medicine is going to change toward an emphasis on more cost-effectiveness, the use of pharmaceuticals is likely to rise independently of other factors in the pharmaceutical market or the Administration's proposal.

The reader should be reminded of the uncertainty surrounding the work of the Congressional Budget Office in this instance. The tools that economists use work best with marginal changes, but the contemplated changes are not marginal. Consequently, although CBO has tested its conclusions to see if they are valid in several dimensions, substantial imprecision remains.

The tensions and trade-offs discussed here go beyond the Administration's proposal. Any health care reform proposal that provides a prescription drug benefit and expands the market will provide more incentives for pharmaceutical R&D. Proposals to contain the costs of drugs will reduce these incentives. CBO's estimate suggests that the Administration's proposal balances these two aspects almost exactly, but other plans may not do so.

## Incentives Provided by the Medicare Rebate

Viewed in isolation, the Medicare rebate would provide pharmaceutical companies with many incentives to reduce their R&D on prescription drugs for the 65-and-over segment of the market, insofar as such specialized drugs can be identified. The proposed rebate of at least 17 percent would reduce the

returns on new drugs that are aimed largely at the 65-and-over market. For example, the returns from some cardiovascular medicines could be lowered slightly by the rebates because of the large number of 65-and-over consumers. Furthermore, the returns from drugs developed for the under-65 population would increase. This difference in returns on the basis of age group may cause some R&D to be shifted away from drugs targeted at people who are 65 years old and older, toward those pharmaceuticals aimed at younger people.

Medicare would impose additional rebates if price increases rose above changes in the consumer price index. New drugs, breakthrough or not, could face a special rebate if their introductory or launch price was judged too high, further lowering the profit incentive. All of these additional provisions are designed to ensure that pharmaceutical producers would absorb most, if not all, of the rebate from their profits.

The Medicare rebate would probably provide a different set of incentives than the Medicaid rebate. Whereas Medicaid beneficiaries are distributed throughout the population--indeed, poverty is the only common denominator--Medicare beneficiaries are concentrated in older age groups. And they dominate numerically the age groups in which they are concentrated, making up 90 percent of the 65-and-over population. Moreover, the portion of the market affected by a Medicare rebate is twice the size of that currently affected by the Medicaid rebate.

The Medicare program, however, would not operate in a political or economic vacuum. Politically, it would be difficult for Medicare to deny coverage for a drug that treats a major illness successfully, regardless of the outcome of rebate negotiations with the manufacturer. Furthermore, the market for most drugs is not perfectly segregated by age; therefore, the rebate would affect only a portion of the sales of each drug. Manufacturers may be able to recover part of their rebate costs from other sales by raising their prices.

The well-known serendipity of the R&D process is also likely to operate in this context. Companies not looking for treatments for conditions that mainly affect persons 65 and older could discover such treatments while searching for others. This serendipity is less likely now, given the costs and complexity of drug development and clinical testing. Quite often, however, drugs developed to treat one illness become widely used for other purposes.

In the context of all of these mitigating factors, the analyses in previous chapters should not be interpreted as meaning that there would be few new drugs developed for the 65-and-over market. There are too many counteracting factors to support that strong a conclusion. But the more successful health authorities are in making pharmaceutical producers absorb the cost of the rebate, the less incentive producers would have to produce drugs for this market. By contrast, the less successful health authorities are in making the pharmaceutical companies absorb the rebate, the more other drug consumers would pay to support Medicare drug benefits.

# The Changing Pharmaceutical Market

The Administration's proposal takes advantage of favorable trends in the pharmaceutical market. The increased pressure on drug producers noted in previous chapters fits with the Administration's general theme of encouraging more competition among health care providers. Specific provisions of the Administration's proposal, such as encouraging greater use of generic drugs by Medicare beneficiaries, also incorporate some of the techniques that are being used by managed care providers to control costs. Although they take occasional advantage of the general trend in the pharmaceutical market towards increased competition, some provisions that reduce Medicare costs, such as special rebates on new drugs, may serve to discourage the development of rival drugs.

# Appendixes

Appendix A

# The Cost of Capital

The cost of capital is a large component of the total cost of introducing a new drug. It takes an average of 12 years to develop a drug and obtain Food and Drug Administration approval. Grabowski and Vernon capitalized research and development (R&D) investment at a real interest rate of 10.5 percent.[1] Since investment in drug development in its early stages is more risky than in its later stages, the Office of Technology Assessment (OTA) varied the discount rate over time, beginning at 14 percent and declining linearly to 10 percent as market introduction approaches.[2] The resulting discounted value of R&D costs was higher than if a constant discount rate of 10.5 percent had been used. If $10 million (valued in 1990 dollars) is invested in a drug during the first year, the cost of that investment, capitalized to the year of market introduction, is $33 million (in 1990 dollars) at a real interest rate of 10.5 percent. In both studies, the cost of capital alone accounts for about half of the total cost of developing a new drug (capitalizing costs to the year of market introduction).

OTA commissioned a study of the cost of capital for the pharmaceutical industry in 1990. The study found that the cost of equity capital for 17 of the largest pharmaceutical companies, adjusted for inflation, was between 10 percent and 11 percent.[3] This real cost of capital appears to be high because inflation has already been deducted. It is based on previous returns to equity investors, which depend on after-tax corporate profits. And it includes a risk premium associated with the nondiversifiable risk for equity investors in the pharmaceutical industry. Nondiversifiable risk includes both the risk arising from swings in the entire economy and the risk that a firm cannot eliminate by investing in many projects.

OTA's estimate of the cost of capital is based on the capital asset pricing model. According to this model, the cost of equity capital is the sum of a risk premium (based on the stock market risk premium for investors in corporate equities estimated at a nominal rate of 8.7 percent in 1990) plus a risk-free rate (6.8 percent in 1990, according to the study). The risk premium associated with the pharmaceutical stocks is estimated to be 98 percent of the stock market risk premium in 1990. After adjusting for inflation expectations in 1990, the real cost of equity capital for this industry was estimated at 10.4 percent. By contrast, if the risk premium calculated by G. Bennett Stewart were used, the cost of capital would be about 1 percent lower than that projected in the study OTA commissioned.[4]

1. Henry Grabowski and John Vernon, "Returns to R&D on New Drug Introductions in the 1980s" (paper presented at the American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, Washington, D.C., October 27-28, 1993).

2. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards* (February 1993).

3. Ibid., p. 278. Stewart C. Myers and Lakshmi Shyma-Sunder did the study.

4. G.B. Stewart, *The Quest for Value* (New York: Harper Collins Publishers, Inc., 1991), and Office of Technology Assessment, *Pharmaceutical R&D*, p. 281.

Appendix B

# Calculating the Change in Average Returns from Drug Development

This appendix presents the method of calculating the changes in average returns from drug development under the Administration's proposal. The results of the first three calculations are summarized in Table 5 in Chapter 6.

1. Universal coverage under the Administration's proposal would increase the average profits on drugs sold to the under-65 population by $19 million (in 1990 dollars). The change in average returns on drugs sold to the under-65 population is equal to the increase in prescription drug sales caused by the universal coverage provision, less the cost of producing more units of the drugs.

The calculation:

$19 = [0.064 - (0.064)(0.25)]($621)(0.65)

where:

0.064 = the percentage increase in prescription drug sales to the under-65 population under the universal coverage provision,

0.25 = unit variable cost as a percentage of product price,

$621 = the present discounted value of U.S. sales at a real interest rate of 10.5 percent, in millions of 1990 dollars, and

0.65 = (1 - the marginal tax rate of 35 percent).

2. Under the Administration's proposal, the Medicaid rebates would be repealed. The Medicaid rebate is equal to 15.7 percent of the average manufacturer price or the best discount given to institutional purchasers, whichever is greater (see Chapter 5). Given that the rebate covers 10 percent to 15 percent of the entire outpatient prescription drug market, outpatient unit revenues would increase by about 2 percent if this rebate is repealed.

The calculation:

0.016 = (0.157)(0.10) or 0.023 = (0.157)(0.15)

Assuming that the repeal of the Medicaid rebate would increase outpatient unit revenues by 2 percent, it follows that the profits from developing a drug would increase by $6 million on average.

The calculation:

$6 = (0.02)($621)(0.77)(0.65)

where:

0.02 = percentage increase in outpatient unit revenues when the Medicaid rebate is repealed;

0.77 = the proportion of prescription drug sales that are outpatient.

3. The Medicare rebate, combined with the proposed drug benefit, would reduce the returns on drugs sold to the 65-and-over population by $39 million. This change is equal to the increase in demand caused by Medicare's new drug benefit less the cost of producing the extra output, less the rebate of 17 percent paid on all drugs sold to 65-and-over Medicare enrollees.

The calculation:

-$39 = [0.043-(0.17)(0.95)-(0.17)(0.043)(0.95)-(0.25)(.043)]($621)(0.77)(0.65)(0.946)+[0.0041-(0.25)(0.0041)]($621)(0.77)(0.65)

where:

0.043 = estimated increase in outpatient prescription drug expenditures of 65-and-over Medicare enrollees due to the Medicare drug benefit;

0.17 = 17 percent rebate paid on all outpatient drugs purchased through Medicare;

0.95 = the percentage of the current Medicare population that will pay the 17 percent rebate. Under the Administration's proposal the Medicare population would decline by 5 percent when those with working spouses receive health coverage through their spouses rather than through Medicare. This does not affect the induced demand calculation since these people still receive a drug benefit. However, the Medicare rebate will apply to a smaller portion of the population that is 65 and over.

0.946 = the portion of the 65-and-over outpatient market that would be covered by Medicare's new drug benefit. According to the Health Care Financing Administration, there were 29.7 million enrollees in Medicare's Supplementary Medical Insurance (SMI) program in 1990 over age 65. This number includes some non-U.S. residents. There were 0.3 million non-U.S. residents enrolled in SMI in 1990. Thus, the total U.S. resident population of those who are 65 years old or older who enrolled in SMI in 1990 was about 29.4 million. Since there were 31.08 million U.S. residents 65 or older in 1990, it follows that approximately 94.6 percent of U.S. residents age 65 or older were enrolled in SMI.[1]

0.0041 = the increase in prescription drug expenditures of the 65-and-over population, caused by physician and drug coverage for the uninsured in this age group. It is assumed that the drug coverage would be received through the alliance system (thus, no rebate is paid on the 0.4 percent increase in expenditures). Actually, the uninsured in this age group could be covered either by the alliance system or by Medicare. However, since this group is so small, the assumption has little effect on the result.

The increase in outpatient prescription drug expenditures of the 65-and-over population that lies behind this calculation is 4.5 percent.

The calculation:

0.045 = (0.043)(0.946) + 0.0041

4. It is stated in Chapter 6 that for every 1 percent increase in the quantity of prescription drugs sold, the average profits from developing a drug would rise by $3 million (after taxes).

The calculation:

$3 = [0.01 - 0.25(0.01)]($621)(0.65)

The change in returns is equal to a 1 percent increase in sales less the cost of producing 1 percent more units of the drug (less the taxes on this extra revenue).

The average U.S. sales of a drug during its product life used in CBO's calculations appear to be similar to those used by the Office of Technology Assessment (OTA) in its study on total returns from research and development in the pharmaceutical industry. Based on OTA's calculations, a decline of 8.6 percent in the U.S. price of all prescription drugs would reduce average returns by $36 million (eliminating the excess returns from drug development, assuming that the quantity sold does not change). According to the U.S. sales data used in the above calculations, a decline of 8.8 percent in the U.S. price is required to reduce returns by $36 million. This difference of just 0.2 percent indicates that the present value of U.S. sales used here is close to that obtained by OTA.

1. Health Care Financing Administration, *Medicare and Medicaid Statistical Supplement* (1992), pp. 14, 18-19, and Bureau of the Census, *Statistical Abstract of the U.S., 1993*, p. 21.

Appendix C

# Sensitivity of Profit Calculations to Product Price Changes

This appendix explains how the returns from drugs developed for the 65-and-over population change when product price varies. The results are summarized in Table 8 in Chapter 6. It is assumed that the price change occurs throughout the drug's product life on both inpatient and outpatient sales. The Medicare rebate is only paid on outpatient drugs and is assumed to remain at 17 percent.

Equations (1) and (2) estimate the change in average returns to drugs developed for the over-65 population under the Administration's proposal when, as a result of the Medicare rebate agreement, pharmaceutical firms change drug prices. Equation (1) assumes that the quantity sold does not change when price changes, but equation (2) allows for some adjustment in the quantity sold for a given change in price.

1. No change in the quantity purchased (Column 3 of Table 8).

$\Delta p$ = the percentage change in product price

Change in returns =

$$-33 + \Delta p[(621)(0.65)(0.77)(1.045)] - \Delta p[(0.17)(0.946)(0.95)(0.77)(621)(0.65)\cdot(1.043)] + \Delta p[(621)(0.65)(0.23)]$$

The first term is the change in returns in the base case. The second term is the increase in revenues that occurs when a higher price is charged on the outpatient market. (See Appendix B for an explanation of each number.) The third term is the increase in the Medicare rebate when the price is raised. The fourth term is the increase in revenues when a higher price is charged on the inpatient market. This calculation makes the extreme assumption that the quantity purchased does not change when price changes. Usually, when price rises, the quantity purchased declines. It is not always profitable to raise price because the increase in profits from charging more for each unit may be less than the decline in profits that occurs when fewer units are sold as a result of the rise in price.

2. The calculations underlying Column 4 of Table 8 account for a quantity response to a price change. It is assumed that a 1 percent increase in price will cause the quantity sold to fall by 0.3 percent.

Change in returns =

$$-33 + \Delta p[(621)(0.65)(0.77)(1.045)] - \Delta p[(0.17)(0.946)(0.95)(0.77)(621)(0.65)\cdot(1.043)] + \Delta p[(621)(0.65)(0.23)] - \Delta p(0.3)[(1-0.25)(621)(0.65)]\cdot[1-(0.946)(0.95)(0.77)] - \Delta p(0.3)[(1-0.25-0.17)(621)(0.65)(0.946)\cdot(0.95)(0.77)]$$

The first four terms are the same as in Equation (1). The fifth term subtracts the decline in profits because fewer units are sold on the non-Medicare market when price rises. The final term subtracts the decline in profits because fewer units are sold on the Medicare market.

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