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).

Δp = 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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