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## Effects of Other Provisions

**I**n addition to universal coverage, the Medicare benefit, and the Advisory Council on Break-through Drugs, three other aspects of the Administration's proposal would affect the pharmaceutical market directly:

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

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### 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the rebates that pharmaceutical companies now pay to the government on all drugs purchased through Medicaid would be repealed.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.<sup>1</sup> 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 If the Medicaid rebates were repealed, average unit revenues of the pharmaceutical manufacturers could increase by at least 2 percent (10 percent to 15 percent of 15.7 percent).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.

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### 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

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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.<sup>2</sup> 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:

- o The health maintenance organizations prescribed more drugs, even when differences in age profile were adjusted for.<sup>3</sup>
- o Health maintenance organizations used more generic drugs.
- o 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.

- o 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.

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## 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.<sup>4</sup> 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.<sup>5</sup> 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

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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.

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.<sup>6</sup> 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.

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6. *Ibid.*, pp. 22-23.



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

**W**hen 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.<sup>1</sup> 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.

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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.

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## 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.<sup>2</sup> 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).<sup>3</sup> These cost estimates are based on a large

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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) <sup>a</sup>              | 210                  | 230                             |
| Average Research and Development Costs <sup>b</sup> | 188                  | 194                             |
| Excess Profits <sup>c</sup>                         | 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.<sup>4</sup> 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, mar-

keting, 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.<sup>5</sup> 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).<sup>6</sup> 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.<sup>7</sup> 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 pro-

jected 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.<sup>8</sup>

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 develop-

ment (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 <sup>a</sup><br>(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) <sup>b</sup> |   |
| 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. | <u>0</u>   | <u>-39</u>                                 | <u>-13</u>   |   |
|  |   |  | 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.<sup>9</sup> 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.

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

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

ditures for both the under- and over-65 populations.<sup>10</sup> 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.

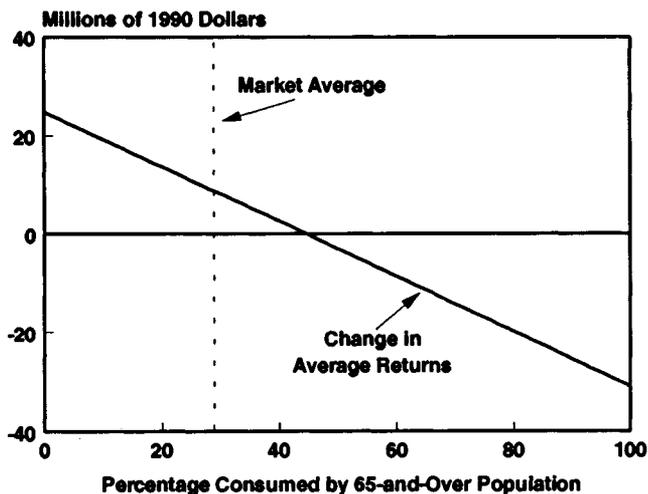
Although these changes in the over- and under-65 markets nearly balance out when returns are averaged among all drugs, they may affect the types of research projects that are undertaken. The returns from developing drugs primarily for those 65 and over would decline, whereas the returns from developing a drug for the under-65 market would rise. Although illnesses do not typically strike only the 65-and-over population, the prevalence 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.<sup>11</sup> 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:

- o 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;
- o 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;
- o The repeal of the Medicaid rebate would increase unit revenues on outpatient prescription drugs by 2 percent; and,
- o 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:<br>The Effect of<br>Universal Coverage <sup>a</sup> |                                 | Population Over 65:<br>The Effect of<br>Changes to Medicare |                                 | Market Average <sup>b</sup>                 |  |
|---------------------------|--|---------------------------------|---|---------------------------------|---|--|
|                           | Assumed<br>Change in<br>Demand <sup>c</sup><br>(Percent)                 | Effect on<br>Average<br>Profits | Assumed<br>Change in<br>Demand <sup>c</sup><br>(Percent)    | Effect on<br>Average<br>Profits | Assumed<br>Change in<br>Demand<br>(Percent) | Effect on<br>Average<br>Profits <sup>d</sup> |
| Base Case                 | 6  | 19                              | 3 <sup>e</sup>  | -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.<sup>12</sup> 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.<sup>13</sup>

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).

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

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

SOURCE: Congressional Budget Office.

- Universal coverage here refers to a universal entitlement to the standard benefit package proposed by the Administration. It includes a prescription drug benefit.
- 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 Varying Assumptions About Producer Price**

|                         | Percentage Change<br>in Producer Price <sup>a</sup> | Percentage Change<br>in Unit Revenue<br>When Combined<br>with the Rebate <sup>b</sup> | Change in Average Returns <sup>c</sup><br>(In millions of 1990 dollars) |  |
|-------------------------|---|---|---|--|
|                         |   |   | Assuming<br>Quantity Sold<br>Does Not Change                            | Assuming Quantity<br>Sold Changes <sup>d</sup> |
| 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).<sup>14</sup>

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.<sup>15</sup>

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.<sup>16</sup> 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.

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## Conclusions

If the changes proposed by the Administration were to increase the returns from drug development, in-

vestment 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.

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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).

