

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

**B**ecause 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.

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## 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.<sup>1</sup> 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).<sup>2</sup>

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.

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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."<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> Under-reporting 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-

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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.<sup>7</sup> 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.<sup>8</sup> 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.

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## 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.<sup>9</sup> 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. version's average retail price, the Secretary could begin special rebate negotiations on new drugs reimbursed through Medicare.<sup>10</sup> 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:

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

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

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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).

- 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.<sup>11</sup>

**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.<sup>12</sup> 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.<sup>13</sup> 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.

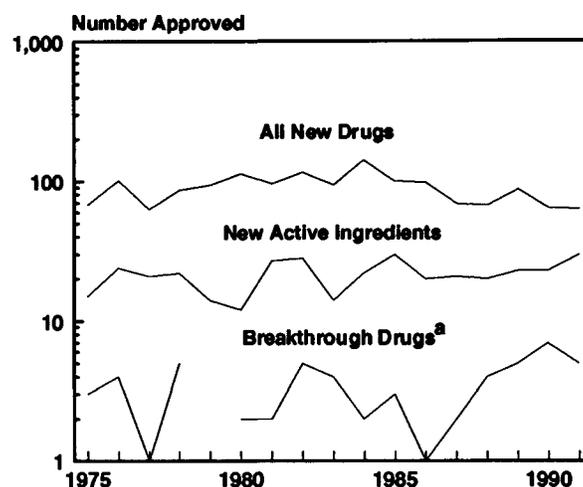
## The Advisory Council on Breakthrough Drugs

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.<sup>14</sup> 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

**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).<sup>15</sup> 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.

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

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:

- o Cost-effectiveness, in relation to other pharmaceutical and nonpharmaceutical treatment; and
- o 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.<sup>16</sup> 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.<sup>17</sup> 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.

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.

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## 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.<sup>18</sup>

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.

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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.<sup>19</sup> 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.

### 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,

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

as the Medicaid rebate currently is, competition in the industry would be discouraged even more.<sup>20</sup> 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.

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## 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,

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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.

