



888 16th Street, NW
Washington, DC 20006
202.974.8222
www.retiredamericans.org

Dear Reader:

Our purpose in producing this report is to make the public aware of how price gouging by the pharmaceutical industry is allowing industry profits to soar at the expense of every American citizen and every American company with health benefits. Even the health plans covering younger and working citizens are being squeezed because of hyperinflation of prescription drug prices.

Unfortunately, those ages 65 and older and persons with disabilities suffer the most because they take more medications than other segments of the population. More than 40 percent of all prescriptions written are for retired Americans, who make up 13 percent of the U.S. population. While more than 13 million older Americans and people with disabilities have no prescription drug coverage at all, the coverage other Medicare beneficiaries have is often very expensive (some policies cost more than \$3,000 a year), inadequate and unreliable. Almost half of Medicare beneficiaries lack coverage for at least part of each year. In addition, health maintenance organizations (HMOs) have dropped more than a million Medicare beneficiaries, and employer-provided health and prescription drug insurance is declining.

The Alliance for Retired Americans believes the time has come for the federal government to act decisively to resolve the crisis. There is overwhelming support for the government to provide prescription drug coverage for the elderly and persons with disabilities and to confront drug prices. That support must be translated into political action.

The more than 2 million members of the Alliance for Retired Americans, organized this year and growing rapidly, are making the fight for prescription drug coverage for all Medicare beneficiaries their No. 1 legislative priority in the 107th Congress. Including pharmaceuticals as a basic, defined Medicare benefit would equip the Health Care Financing Administration, the agency of the U.S. Department of Health and Human Services that administers Medicare, to use its national purchasing power to

bring outrageously high prescription drug prices under control and set national standards for reasonable prices. Medicare drug coverage also would provide current workers with the peace of mind of knowing they will be able to get the medicines they need when they retire. Even such corporate giants as General Motors are calling for the addition of a universal prescription drug component to Medicare. Other approaches to use government authority to control and moderate drug prices also must be explored and adopted.

The Alliance believes that drug benefits, like other Medicare benefits, should be available to all Medicare beneficiaries with no income test; all medically necessary and approved treatments should be covered; enrollment must be voluntary so people who now have plans can keep them; provision should be made to encourage current employer retiree plans to maintain at least their current levels of benefits; premiums, deductibles and co-payments must be affordable; there must be reasonable limits on beneficiary out-of-pocket expenses; and lower-income beneficiaries should have all costs covered. Most importantly, to make the benefit affordable to taxpayers and beneficiaries, drug price cost controls are essential.

In the longer term, the Alliance believes the enactment of a universal health system that includes pharmaceutical treatments as a basic benefit is required to fully address the challenge of availability and reasonably priced drugs.

Our immediate challenge on behalf of older and retired Americans is to serve as a strong voice for the enactment of a drug benefit under Medicare, and for strengthening and improving Medicare and Social Security. For more information on the Alliance and to find out what you can do to help put an end to the outrageous price gouging by the pharmaceutical industry, we invite you to visit our website at www.retiredamericans.org.

Sincerely,



George J. Kourpias
President



Edward F. Coyle
Executive Director

Contents

Summary	1
Introduction	3
Principles for a Medicare Prescription Drug Benefit	4
Recent Trends in the Price of Prescription Drugs	6
Why Are the Prices Going Up So Rapidly?	7
Distribution Chain	9
Pricing Chain	10
Who Pays?	13
Illustration of Pricing Chains	14
The Money Chain: How Are Drug Revenues Spent?	16
Profits	16
Research and Development	17
Marketing	19
Lobbying	20
Why Not Have More Substitution of Generic Drugs?	21
Proposed Solutions	23
Conclusion	29
Glossary of Key Prescription Drug Pricing Terms	30
Endnotes	33

Summary

Prescription drug prices are rising rapidly and are projected to continue to do so through at least the next decade. This increase has the most adverse effect on the segments of the population without some type of insurance protection.

Drug spending overall is increasing largely because of three factors: utilization or volume increases; availability of new drugs for treating diseases; and rising prices for existing drugs. While a number of new drugs have extended and enhanced the quality of everyday life for many Americans, they remain too costly and out of the reach of millions.

The pricing chain for drugs is complex and difficult to trace because much of the information regarding prices is considered proprietary and hence is not publicly available.

The pharmaceutical market is unique in several ways. Manufacturers charge different prices for different customers and allow for discounts and rebates in order to maintain inclusion of their products on the formularies of large purchasers. It is the individual consumer without insurance coverage who pays the highest prices for prescription drugs.

Drug manufacturers also enjoy a lower tax rate than other industries. And although they maintain that high prices for new drugs are justified as their recovery for research and development expenses, most core research for drugs is funded by the federal government, primarily through the National Institutes of Health. Much of the companies' development of drugs actually is for derivatives of existing drugs rather than new drugs.

While the precise cost of drugs is difficult to pinpoint, the profit levels are not. In 2000, pharmaceutical companies had after-tax median profits of 18.6 percent, compared with 4.9 percent for all other Fortune 500 companies combined.

COVERAGE DOESN'T MEAN FULL COVERAGE

Ms. M of Suitland, Md., has congestive heart disease and is required to take 10 medications. Even though she is under a Medicare HMO, she pays full payments and co-payments of about \$300 per month. The HMO plan has a cap of \$1,000 per year for prescription drugs. When Ms. M surpasses that amount in June, she must assume the total costs of her prescriptions. She is ineligible for her state's drug assistance program because her income is just above the allowable level of 116 percent of poverty.

Drug manufacturers spend more of their revenues on profits than on research and development—and even more on marketing. They dedicate more than 18 percent of revenues to profits and 30 percent to marketing and administration, compared with 12 percent to research and development.

Promotional spending is directed toward doctors primarily through distribution of samples. Since 1997, direct-to-consumer (DTC) advertising has become a more significant part of marketing, accounting for \$1.3 billion in advertising outlays in the first half of 2000 alone. Drug companies also spend millions in contributions to political candidates and to lobby Congress.

Almost half of all prescription drugs sold in the United States are generic drugs—but this accounts only for about 10 percent of the costs of all pharmaceuticals. Generic drugs, which cost less than brand-name drugs, are able to enter the market only after the brand-name company's patent expires. These patents often are extended by various means, including deals with generic companies.

Since the enactment of Medicare 36 years ago, prescription drug treatment has become an essential component of medical treatment for older people and those with disabilities. For Medicare beneficiaries with serious chronic medical conditions, access to drugs is critical to survival and to the maintenance of an acceptable quality of life.

The most comprehensive approach to providing affordable prescription drugs for all Americans is to enact a universal, national health care system that includes a prescription drug benefit. Among Medicare beneficiaries, however, a crisis over both declining coverage and price escalation has been a top political and medical issue. National and state lawmakers are exploring a variety of interim approaches. This primer responds to the immediate need of Medicare beneficiaries and discusses a number of measures being pursued toward the goal of affordable, comprehensive drug coverage for such beneficiaries.

Introduction

The high costs of prescription drugs in the United States are not new but in recent years have made it to the front of the nation's radar screen. Prescription drug prices are rising rapidly, having the most adverse effect on the segments of the population without some type of insurance protection, including Medicare beneficiaries. As a policy issue, coverage of prescription drugs for Medicare beneficiaries became a major component in the 2000 presidential campaign and in many congressional races; it continues to be a major issue in the 107th Congress.

This report attempts to present the trends and reasons why prescription drug prices have increased so dramatically, where the money goes, examine proposals to address the issue and present recommendations from the Alliance for Retired Americans.

PRESCRIPTION DRUG COSTS LEAD TO IMPOVERISHMENT

Ms. FM of Rossville, Ga., is 73 and widowed. Her annual prescription drug costs are about \$4,200 (\$350 per month). Her income is \$608.50 a month—\$569 from Social Security and \$39.50 from her husband's pension. She has had both a heart attack and a hiatal hernia. She lost her insurance coverage and used her savings to pay for prescriptions, to the point where she doesn't have enough to pay her Medicare premiums. Fortunately, Family Services pays for her Medicare premiums now.

PRINCIPLES FOR A MEDICARE PRESCRIPTION DRUG BENEFIT

The Alliance for Retired Americans is committed to the enactment by Congress of a universal, comprehensive and affordable defined prescription drug benefit under Medicare.

The Medicare program is a vital and effective program on which more than 98 percent of older Americans and millions of persons with disabilities depend. However, Medicare lacks a core component of any comprehensive medical system—prescription drugs.

Prescription drug prices are rising rapidly, having the most adverse effect on the segments of the population without some type of drug coverage. Older Americans spend more out of pocket than the rest of the population because they have more acute and chronic illnesses, use more prescription drugs for treatment and are less likely to have insurance coverage.

Older Americans, 13 percent of the U.S. population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar spent on prescription drugs. Employer-provided health coverage for retirees is declining, and managed care plans are capping or dropping drug benefits and dropping out of the Medicare+Choice program.

The recent proposal to give block grants to the states to create prescription benefits for low-income seniors would be ineffective for the following reasons:

- It would leave millions of moderate-income older and disabled persons without protection;**
- It would take years to create;**
- It would give states wide latitude to restrict benefits;**
- It would delay the passage of a true universal and defined Medicare drug benefit; and**
- The record of states in enrolling persons in the QMB and SLMB programs gives little cause for optimism for expanded coverage.**

The Alliance for Retired Americans believes that a Medicare pharmaceutical benefit must incorporate the following principles:

- **Universal coverage for all who qualify for Medicare benefits;**
- **The benefit must be comprehensive and include the most current and effective treatments and quality controls;**
- **Enrollment in the benefit should be voluntary so that those who have superior benefits can remain in their employer's plan while assuring enrollment later for persons facing erosion or loss of current drug benefits;**
- **The benefit must have affordable premiums and co-pays and should protect all beneficiaries from high out-of-pocket expenses;**
- **The benefit must not be means-tested; however, low-income persons should have all costs covered;**
- **Dollar coverage of the benefit should be high enough to protect the out-of-pocket costs of average-to-higher pharmaceutical users and contain a reasonable cap on costs for those with catastrophic bills;**
- **Employers should be required and/or provided with incentives to maintain and expand the level of coverage of current, employer-provided prescription drug benefits; and**
- **Pharmaceutical prices for all consumers must be brought under some system of control, including, for example, enforcement of patent limits; negotiations on fair prices by the federal government where there is significant public investment in drug development; and provisions to achieve price discounts for Medicare beneficiaries based on the Federal Supply Schedule and comparable to prices charged to larger HMOs and hospital chains. Without action on the rising price of pharmaceuticals, the cost of a Medicare benefit will not be affordable and millions of Americans of all ages will be denied their right to first-class health services.**

LIMITED COVERAGE LOST WHEN HMO FAILS

Ms. D of Lebanon, Tenn., has annual prescription drug costs of \$2,900. In September 1998, Ms. D was forced to join an HMO or pay for all of her supplemental insurance, which she could not afford. She had a minimal prescription drug benefit, but the HMO folded in January 2001. Ms. D's pension is \$322.50 a month and her Social Security is \$538 a month. "It isn't always easy skimping and scraping to stay on top," she says.

Recent Trends in the Price of Prescription Drugs

- According to Bureau of Labor Statistics figures, drug prices rose 306 percent between 1981 and 1999, while the consumer price index (CPI) rose 99 percent during the same period.¹
- In 2000, total spending in the United States for prescription drugs was \$116 billion—more than twice the \$51 billion spent in 1993. And that amount is expected to more than triple to \$366 billion by 2010.²
- Older Americans and people with disabilities spend more out of pocket than the rest of the population because they have more acute and chronic illnesses, use more prescription drugs for treatment and are less likely to have insurance coverage. Older Americans, 13 percent of the U.S. population, account for 34 percent of all prescriptions dispensed and 42 cents of every dollar spent on prescription drugs.³ The average Medicare beneficiary fills 18 prescriptions a year.
- Annual spending per capita in the Medicare population for prescription drugs has jumped from \$674 in 1996 to \$1,539 in 2000 and is expected to climb to \$3,751 in 2010, an average rate of increase of 9.3 percent. Total prescription spending in the Medicare population will rise from \$61.2 billion in 2000 to \$174.4 billion in 2010, an average annual rate of increase of 11 percent.⁴ The Congressional Budget Office (CBO) estimates prescription drug spending for Medicare enrollees will total nearly \$1.5 trillion over the next decade.⁵
- Although nearly one-third (30 percent) of Medicare beneficiaries are expected to incur less than \$250 in drug expenses in 2001, more than four in 10 (43 percent) will have drug expenses greater than \$1,000—and 8 percent will have expenses of at least \$4,000.⁶

- Out-of-pocket spending for prescription drugs by Medicare beneficiaries in 2001 is estimated to average about \$686, with 20 percent expected to spend more than \$1,100.⁷
- Medicare beneficiaries without prescription drug coverage spend on average 83 percent more for their medicines than those with drug coverage. About half of Medicare beneficiaries without any form of prescription drug coverage have incomes less than 175 percent of poverty, which is \$15,000 in 2001.⁸
- As Social Security benefit increases are tied to the CPI and prescription drug prices are increasing much faster than the CPI, these trends make prescription drugs increasingly less affordable for Social Security beneficiaries.

Why Are the Prices Going Up So Rapidly?

Toward the end of the last century, changes were made in the way hospitals were compensated that prompted them to reduce the length of stay of patients. This “quicker and sicker” discharge from hospitals led physicians to increasingly rely on prescription drugs for treating patients. Drug interventions, in turn, forestall the hospitalization of many other older persons and help them to maintain lives outside of institutions. Consequently, the role prescription drugs play in the lives of older persons, in particular, has become much greater.

There is no doubt the introduction of many new drugs has extended and enhanced the quality of everyday life for millions of Americans. Technological advances in treating diseases include the utilization of new drugs that can arrest or cure many cancers, heart disease, high blood pressure, AIDS and other life-threatening conditions. Drugs have contributed to reducing costs of hospitalizations and surgeries, but new drugs are more expensive than older drugs, and three times more costly than generic drugs.

The spending increases for prescription drugs are attributed largely to three factors:

- Utilization increases;
- Availability of new drugs for treating diseases; and
- Rising prices for existing drugs.

The volume of drugs sold has increased dramatically. Between 1992 and 1998, the number of prescription drugs sold has increased 37 percent. The 3 billion prescriptions sold in 2000 are expected to rise to 4 billion by 2004.⁹

The increase in utilization or volume of drugs prescribed is greatly affected by promotional advertising by manufacturers.

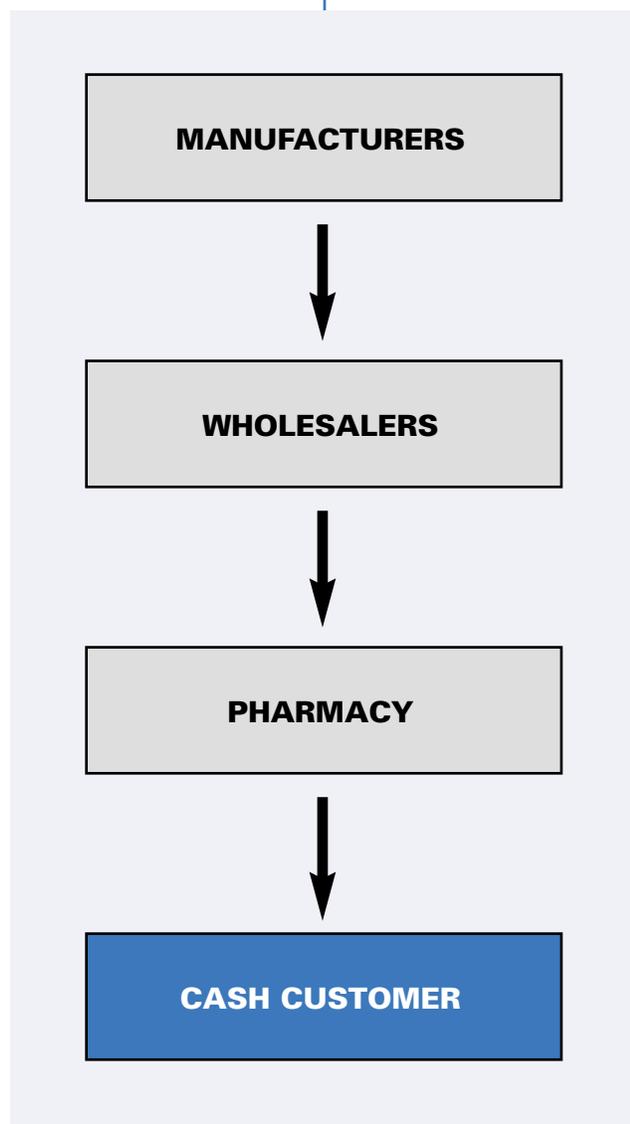
Manufacturers promote the use of new drug therapies in a number of ways. The most common practice is for thousands of drug company representatives to leave samples when visiting physicians and hospitals. Advertising directed at consumers is a relatively new practice that has grown considerably over the past 15 years. Promotional spending by drug companies reached \$13.9 billion in 1999, an 11 percent increase from 1998 levels. Of that total, direct-to-consumer (DTC) advertising accounted for \$1.8 billion, a 40 percent increase from 1998.¹⁰

The price of older drugs is increasing also, but at a rate of less than 4 percent per year. Additionally, in order to extend patents, drug manufacturers often will issue older drugs in new dosage forms or with other minor changes and charge higher prices. A Congressional Budget Office study found the average list price of brand-name drugs increases faster than inflation even after the entry of other therapeutically equivalent (“me too”) drugs on the market.¹¹

Distribution Chain

Generally, the chain of distribution begins with the manufacturer who distributes the drug by selling it to drug wholesalers, the middlemen between the manufacturer and the pharmacies. The wholesaler sells the drug to the retail pharmacy at the price of obtaining the drug plus a markup, usually between 2 percent and 4 percent. The pharmacist sells to the consumer at the acquisition price plus a markup of 20 percent to 25 percent. If the customer is insured, he or she will not pay the full amount, but rather a co-payment of differing amounts depending on the insurance plan. If the customer is uninsured, he or she will pay the full cost or highest price for the drug.¹²

For every dollar that a consumer pays for a prescription drug at the pharmacy, 74 cents goes to the drug manufacturer, 3 cents goes to the wholesale distributor and 23 cents to the pharmacy.¹³



Pricing Chain

It is extremely difficult to identify the actual cost of a drug because the pricing chains are more complex than the distribution chain. This table summarizes key pricing terms and the levels at which prices are and are not publicly accessible. Some prices are not publicly available, as they are considered to be manufacturers' proprietary information.

PRICE	DEFINITION
Retail price	<p>The price charged by retail pharmacies to individuals without insurance, known as “cash-paying” customers.</p>
Average wholesale price (AWP)	<p>The average list price that a manufacturer suggests wholesalers charge pharmacies. AWP typically is less than the retail price, which will include the pharmacy’s own price markup. AWP is referred to as a “sticker” price because it is not the actual price that large purchasers normally pay. For example, in a study of prices paid by retail pharmacies in 11 states, the average acquisition price was 18.3 percent below AWP. Discounts for HMOs and other large purchasers can be even greater. AWP information is available publicly.</p>
Average manufacturer price (AMP)	<p>The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. Federal Supply Schedule prices and prices associated with direct sales to HMOs and hospitals are excluded. AMP has a benchmark created by the Omnibus Budget Reconciliation Act (OBRA) in 1990 to use in determining Medicaid rebates and is not publicly available. The Congressional Budget Office (CBO) estimated AMP to be about 20 percent less than AWP for more than 200 drug products frequently purchased by Medicaid beneficiaries.</p>

DEFINITION	PRICE
<p>The average price paid to a manufacturer by wholesalers for drugs distributed to nonfederal purchasers. NFAMP is not available publicly.</p>	<p>Nonfederal average manufacturer price (NFAMP)</p>
<p>The price available to all federal purchasers for drugs listed on the Federal Supply Schedule. FSS prices are intended to equal or better the prices manufacturers charge their “most-favored” nonfederal customers under comparable terms and conditions. Because terms and conditions can vary by drug, the most-favored customer price may not be the lowest price in the market. FSS prices are available publicly.</p>	<p>Federal Supply Schedule (FSS)</p>
<p>The maximum price manufacturers can charge for FSS-listed brand-name drugs to the Veterans Administration, Department of Defense, Public Health Service and the Coast Guard, even if the FSS price is higher. FCP must be at least 24 percent of NFAMP. FCP is not available publicly.</p>	<p>Federal ceiling price (FCP)</p>
<p>The effective outpatient drug price after manufacturer rebates to state Medicaid programs. The basic rebate on brand-name drugs is the greater of 15.1 percent of the AMP or the difference between AMP and the lowest or “best” price the manufacturer charges any purchaser other than Medicaid. Rebates for generic drugs are 11 percent of the AMP. Rebates are larger for brand-name drugs whose AMP increases exceed inflation in the consumer price index. Information on rebate amounts is available publicly; AMP and best price are not available publicly.</p>	<p>Medicaid rebate net price</p>
<p>The price the VA has obtained through competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Contract prices are available publicly.</p>	<p>VA national contract price</p>

Source: GAO, *Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes*, August 2000



HEALTH PLAN COVERAGE NOT ENOUGH

Mr. and Ms. R of Lansing, Ill., have annual prescription drug costs of more than \$4,000. They do not have prescription drug coverage because it would cost about \$2,000 to \$3,000, while the policy would only pay about \$1,600.

Variations in the price can take place because of the power the drug companies have in their market and also because purchasers can be separated into groups that vary by their price sensitivity. This practice is known as price discrimination. Price-sensitive group health maintenance organizations (HMOs, see glossary), for example, would decrease the amount of a particular drug they purchase if the price of that drug increased, particularly if there are equivalent substitutions available. Doctors who prescribe medications and consumers with insurance coverage that covers most of the costs of drugs are considered to be price insensitive. An individual consumer without coverage and without bargaining power would be “price sensitive” to costs and more willing or forced either to use a substitute or decrease use.

Consequently, drug manufacturers charge different prices to different purchasers for the same drug. Agencies of the federal government, state Medicaid programs and many nonfederal public health entities have access to substantially lower prices through the Federal Supply Schedule (FSS) for pharmaceuticals.

Under the Omnibus Budget Reconciliation Act of 1990 (OBRA), drug manufacturers must provide rebates to state Medicaid programs for their outpatient drugs in exchange for Medicaid coverage. The minimum rebate for a brand-name drug is 15.1 percent of the average manufacturer price (AMP). Medicaid pays the pharmacy its acquisition price plus a dispensing fee and gets an average cash rebate of 19 percent to 21 percent from the manufacturer. Favored private purchasers with their own outpatient pharmacies, such as HMOs and hospitals, may deal directly with the manufacturers and consequently pay a price lower than that offered to wholesalers.

Insurers and pharmacy benefit managers (PBMs, see glossary) obtain both a retail discount and a rebate from the manufacturer wielding their bargaining power through the use of formularies, i.e. lists of drugs approved for use and

reimbursement. It is of significant economic importance to manufacturers to have their drugs included in the formularies of large purchasers. The amount of rebates can vary considerably by type of arrangement and by drug. Thus, together with co-pays from covered beneficiaries, discounts and rebates, an insurer and PBM likely would pay between \$30 and \$44 for a drug for which the uninsured cash customer would pay \$52. With rebates, Medicaid would pay about \$34 for the same drug.

Most retail pharmacies, however, do not have the bargaining power for discounts that other favored purchasers have, as they must stock a full range of drugs, not just those in specified formularies, in order to fill all prescriptions presented to them. At the bottom of the chain, it is the noninsured consumer who pays the most for a prescription drug.¹⁴

Who Pays?

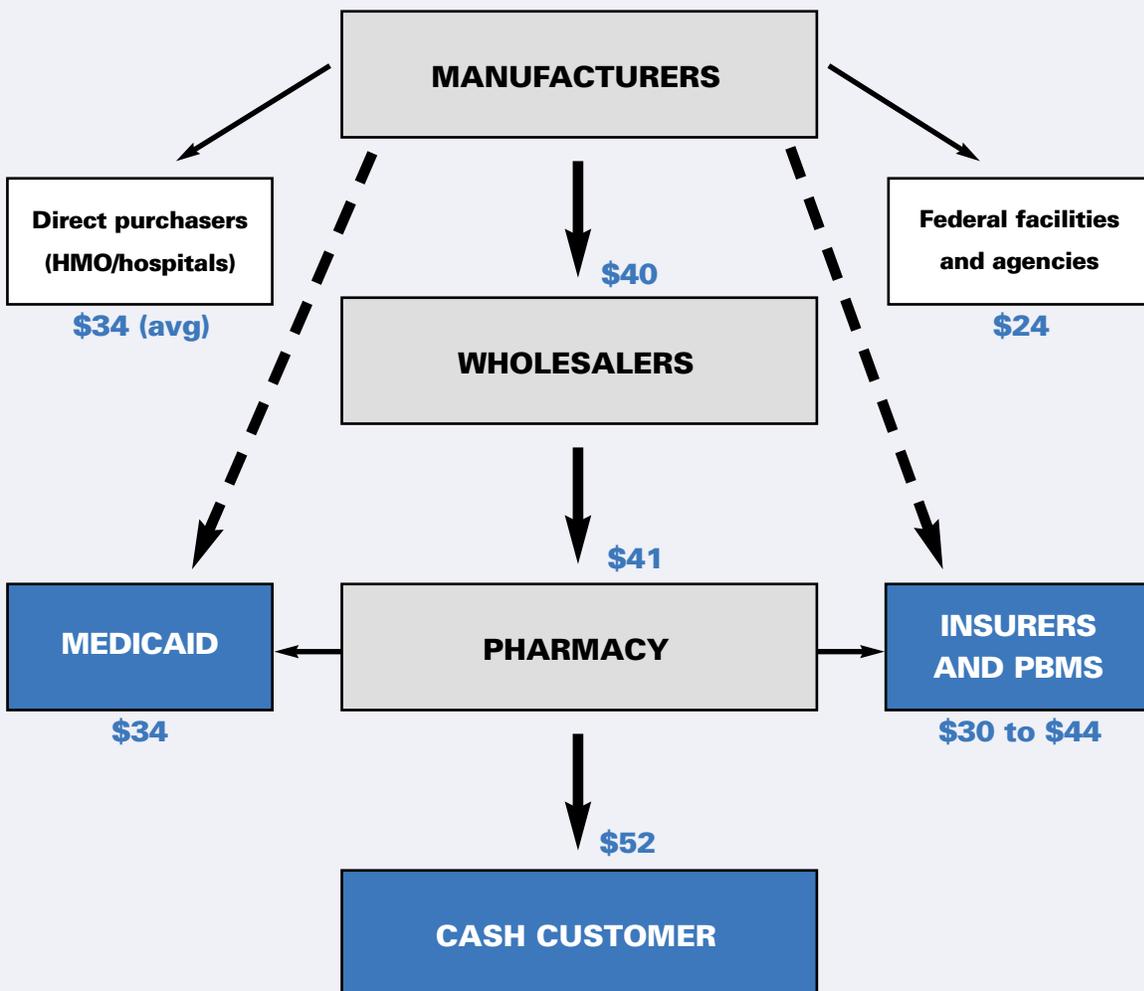
On average, Americans use about 10 prescriptions a year, but most do not pay full price for them. Slightly more than three in four (77 percent) of the non-Medicare population have prescription drug coverage. Sixty-one percent have coverage from their employer; 11 percent have coverage under Medicaid and 5 percent have private coverage. Nearly one-fourth of the non-Medicare population has no drug coverage, primarily because they do not have health insurance.

Since Medicare does not have an outpatient prescription drug benefit, at least one in three people in the Medicare population—approximately 13 million—have no drug coverage at all in the course of a year; nearly half have no coverage for at least part of an entire year. Employers cover prescription drugs for 24 percent of the Medicare population. Seventeen percent are covered by Medicare HMOs. Others rely on Medicaid (12 percent) and other sources (5 percent) for coverage.¹⁵ Another 8 percent purchase Medigap plans, but they must pay for the coverage and are subject to high administrative costs and high premiums as well as adverse selection.

The prescription drug benefit has been a major reason many Medicare beneficiaries are attracted to Medicare HMO plans. However, many of them are losing their prescription drug benefit either because of the withdrawal of HMOs from Medicare or a decline in the number of plans covering the benefit. Many rural counties now have either no carriers or only one noncompetitive plan. At the end of 2000, more than 900,000 Medicare beneficiaries were dropped from

ILLUSTRATION OF PRICING CHAINS

Illustrating a typical prescription dosage with an average wholesale price of \$50



Source: Adapted from Jack Hoadley, Ph.D., Office of the Assistant Secretary for Planning and Evaluation (ASPE), DHHS. Presentation to ASPE Conference on Pharmaceutical Pricing, Utilization and Costs, Washington, D.C., Aug. 8-9, 2000.

their HMOs; they encountered more difficulty finding an alternative HMO than the 700,000 who were dropped in 1998 and 1999. Of 237 HMOs once in the Medicare program, only 90 continue.¹⁶ A study of benefits under Medicare+Choice plans during the 1999–2000 period shows there was a decline in the number of contracts covering prescription drugs from 73 percent to 68 percent.¹⁷

There also is evidence of decline in either the generosity of the benefit or an increase in cost-sharing. Seventy percent of plans have an annual \$1,000 or less limit on drugs and 32 percent have caps of \$500 or less per enrollee.¹⁸ A survey of enrollees in Medicare HMOs found that 72 percent of them saw their annual HMO premiums increase by at least \$500 within one year.¹⁹

Similarly, employer coverage for retirees and the scope of their benefits has been declining in the past decade because of rising costs. Among employers with more than 200 workers offering retiree health benefits, 67 percent offered them to Medicare-eligible retirees in 2000, down from 80 percent in 1999, a 16 percent decline. Sixty-seven percent of firms of all sizes report that higher spending for drugs contributed “a lot” to increases in health insurance premiums in 2000.²⁰ Another survey of employers reports that drug costs represented 40 percent to 60 percent of employers’ retiree plan costs. Large employers (1,000+ employees) are most likely to offer retiree health plans. However, 40 percent of them are seriously considering cutting back on drug benefits for their retirees in the next three to five years and 30 percent would consider terminating coverage prospectively for retirees ages 65 and older.²¹

Consequently, the number of Medicare beneficiaries without prescription drug coverage can be expected to grow considerably, leaving millions more to pay the highest prices for their prescriptions.

The Money Chain: How Are Drug Revenues Spent?

Drug manufacturers devote more of their revenues to profits and marketing than to research and development (R&D). The 12 drug companies with the highest revenues spent three times as much on marketing as on R&D in 2000. More than 18 percent of revenues are dedicated to profits, compared with 12 percent spent on R&D and 30 percent on marketing and administration.²²

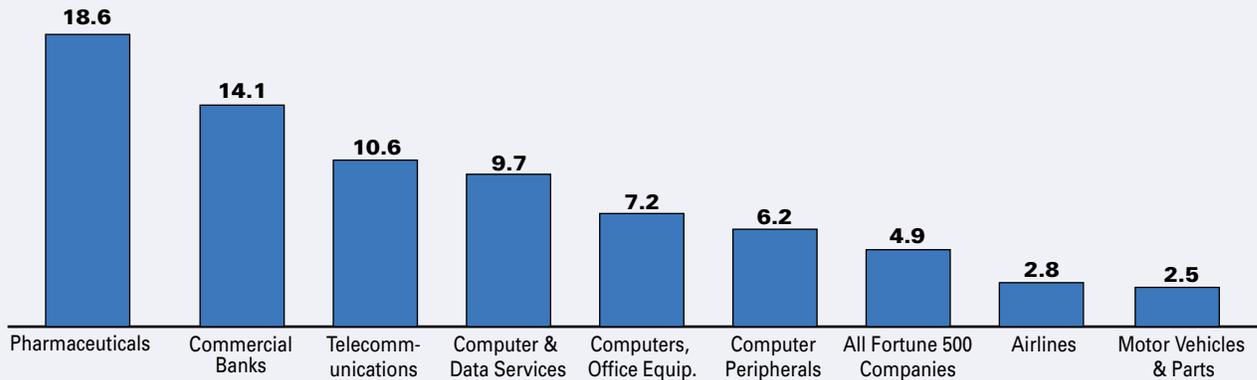
Profits

The pharmaceutical market differs from other markets in a number of ways:

- There is a ready demand for the old as well as the higher-priced new therapeutic products, so marketing is intense;
- There is insurance coverage and subsidization for the product;
- Government pays for a substantial share of research that leads to drug development;
- There is government compliance in supporting drug monopolies through allowing market exclusivity under a patent and the extension of patents; and
- There are hidden prices, discounts and rebates.²³

The pharmaceutical market differs also in the profits the industry makes compared with others. As can be seen in the following chart, data from the list of Fortune 500 companies show that in 2000, the after-tax median profits of pharmaceutical companies was 18.6 percent, higher than any other industry and considerably higher than the median after-tax profit level of 4.9 percent for the other Fortune 500 companies combined. This translates into \$192 billion in revenues and \$28 billion in profits in 2000 for drug companies. In fact, *Fortune* magazine places the pharmaceutical companies at the top in two of three categories—returns on revenues and returns on assets—and second in returns on shareholders' equity.²⁴

PROFITS AS A PERCENTAGE OF REVENUES, 2000



Source: *Fortune* magazine

Not only are pharmaceutical companies more profitable than other industries, they also have a lower tax rate. There are five federal tax provisions that result in greater tax savings for the drug companies than other major industrial categories. A Congressional Research Service report found that while the average tax rate for all industries was 27.3 percent between 1993 and 1996, the rate for drug companies was only 16.2 percent.²⁵

Research and Development

Although pharmaceutical companies claim the prices of new drugs are necessary to fund ongoing research and development, it is the federal government, primarily through the National Institutes of Health (NIH), that pays for the majority of the initial drug research in the United States.

A congressional committee found that of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques originating in federally funded research.²⁶ A team of journalists from *The Boston Globe* looked at 50 top-selling drugs approved by the FDA over a five-year period. Thirty-five were new bestseller drugs that the FDA considered most important or most unique, and 15 were so-called “orphan” drugs that treat rare diseases. Thirty-three of the 35 new drugs and

SOME MUST RELY ON SAMPLES

Ms. N of Los Angeles is 87 and widowed. She pays \$135.99 for an antibiotic and \$59.69 for prescription eyedrops. She is only able to take two other prescriptions her doctor has recommended by getting free samples.

12 of the 15 orphan drugs received money from NIH or the FDA to help in discovery, development or testing.²⁷

Drug manufacturers also maintain that the most expensive aspect of their research is in the clinical trials²⁸, yet NIH and other federal agencies are sponsoring 60 percent of current clinical trials and the industry is sponsoring just 11 percent.²⁹

During the 1980s and early 1990s, NIH required drug companies to charge a “fair and reasonable” price for drugs originally developed by taxpayer-funded research and development. This requirement was dropped by NIH in 1995. Reinstatement of this requirement is part of a proposal now in Congress, but it may not have sufficient support in the face of intensive industry lobbying.

In addition, a review of the government’s invention reporting system shows NIH does not keep track of the drugs invented with taxpayer monies; NIH tracks its spending by disease, not by drug.^{30, 31}

Much of drug manufacturers’ development of drugs is not for new drugs but rather copies of existing drugs. This is particularly important to them, as a number of patents are expiring between 2000 and 2004.

Until 1992, the FDA classified every new drug it approved according to its significance for human health. One classification was 1C, meaning little or no therapeutic gain, since a drug so ranked was a duplicate of products already available. During the period from 1982–1991, more than half of newly approved drugs (53 percent) were 1C or copycat drugs, indicating that much of drug manufacturers’ so-called research and development of drugs is actually of the “me too” variety—therapeutically equivalent drugs. Thirty-one percent of the approved drugs were classified as modest therapeutic gain, such as a change in formulation, so the drug could be taken less frequently. Only 16 percent were ranked as important therapeutic gain or a breakthrough drug.

Because of industry pressure, the Bush administration eliminated these rankings in 1992.³²

In the 1990s, the FDA approved 857 new drug applications. More than one-third (311) were new molecular entities (NMEs), compounds that have never been sold on the U.S. market. Nearly half (426) were “new formulations” or “new combinations” of compounds already approved. New formulations consist of active ingredients already on the market that have been modified; new combinations contain two or more previously approved active ingredients in a new single medicine.³³

Marketing

Pharmaceutical companies’ promotional spending directed toward doctors and consumers topped \$8 billion in the first six months of 2000, up 14.3 percent for the same period in 1999. The industry employs one of the largest sales forces among all manufacturing sectors. Distribution of prescription samples to doctors accounted for nearly 50 percent of promotional spending. Nearly half of the samples (45.1 percent) were given to patients over the age of 60.³⁴

Changes to FDA policy in 1997 have allowed drug manufacturers to expand advertising via mass media to consumers. Direct-to-consumer (DTC) advertising, primarily through television ads, totaled \$1.3 billion for the first half of 2000 only, compared with \$1.3 billion for all of 1998 and \$1.8 billion for 1999.³⁵

The direct-to-consumer advertising and dispensing of free brand samples by physicians generate market demand whereby consumers are introduced to and encouraged to request the brand-name drugs from their physicians. In a telephone poll conducted in 2000, 91 percent of Americans said they had seen or heard an advertisement for prescription drugs in the past year; 34 percent said they had talked with their doctor about a specific medicine they saw or heard advertised; and 7 percent said they asked their doctor

to prescribe a medicine they saw advertised.³⁶ DTC ads can produce significant returns. In the first 10 months of 2000, pharmaceutical companies Merck and Pfizer together spent \$206 million combined on advertising for their arthritis drugs, Vioxx and Celebrex respectively, resulting in combined sales of \$3.7 billion.³⁷

Lobbying

The drug industry spends a considerable amount on lobbying efforts to protect their interests. Overall, the industry spent \$278.5 million from 1997 to mid-2000 lobbying the Clinton administration and members of Congress on both sides of the aisle. During this period, nearly 300 lobbyists, many former members of Congress or former congressional/administration staffers, were hired to fight bills that would control their prices and limit their profits.³⁸ During the 2000 election cycle, pharmaceutical companies contributed \$26 million to congressional and presidential campaigns, about 30 percent to Democratic candidates and 70 percent to Republican candidates.³⁹

In addition, drug companies are financial backers of such front groups as “Citizens for Better Medicare.” In 2000, CBM waged a \$50 million ad campaign against a prescription drug benefit under the Medicare program.⁴⁰ Also, at least \$20 million was funneled through the U.S. Chamber of Commerce during the 2000 election cycle for ads defending candidates who oppose governmental solutions to the high costs of drugs and attacking members of Congress who favored a universal Medicare benefit and systems designed to moderate drug prices.⁴¹

Why Not Have More Substitution of Generic Drugs?

During the 1950s and 1960s, drug manufacturers persuaded doctors to prescribe brand-name drugs and state legislatures to prevent pharmacists from substituting generic drugs. Those laws were repealed during the 1970s and the drug companies then turned their attention to protecting their interests by obtaining patent extensions and using loopholes to stall the introduction of generic drugs.⁴² For example, many patents on drugs can be extended beyond the 17 years of a patent by altering dosages or shapes of the drugs for the sole purpose of obtaining another patent on essentially the same drug. Companies also are able to acquire 30-month extensions on brand patents when they obtain FDA approval to switch the patented prescription drug to an over-the-counter drug. During the extension periods, generic drug makers thereby are prevented from introducing their products.

In 1984, Congress attempted to keep drug prices down through the Drug Price Competition and Patent Term Restoration Act—also called the Hatch-Waxman Act. The intent of this legislation was to speed up the entry of generic drugs and encourage competition between companies producing generic and brand-name drugs. When the first generic is allowed to enter the market after expiration of a patent, it has six months' exclusivity and its price is 75 percent to 80 percent of the brand. After other generics are allowed to enter the market, within a 12- to 18-month period, the average generic drug price will be one-third the price of the brand-name drug price.⁴³ As part of a legislative compromise, the Act allows for brand patent extensions based on time spent in the FDA review process.

Today, more than 40 percent of all prescription drugs sold in the United States are off-patent generic drugs, but the dollar share of the market is less than 10 percent, indicating how far less costly generic drugs are.⁴⁴ However, a Congressional Budget Office study shows that increased competition from

DOSAGE DECREASES, BUT PRICES STAY THE SAME

Mr. S of Yarmouthport, Mass., is 87 and married. His annual prescription drug costs are about \$4,500. Originally, Mr. S's doctor prescribed 10 mg. of one of the drugs, which cost \$251.99. The dosage was later decreased to 5 mg., but the cost remained \$251.99 for the prescription.

generics has not reduced the profitability of the prescription drug industry.⁴⁵

In recent years, the intent and benefits of the Hatch-Waxman law have been undermined by generic as well as brand companies. Through federal investigations or lawsuits, several cases have come to light in which brand companies have made agreements with generic companies. Typically, the generic company agrees not to produce the generic drug in return for substantial compensation from the brand-name company.^{46, 47}

In applying for approval from the FDA, generic drug firms are hampered by having to address nearly every aspect of a brand-name patent in the FDA's registry, including patents on such nonessential features as color, size, shape and types of containers. Another obstacle is the practice by brand-name companies of filing "citizens petitions" that require FDA investigation of issues raised in the petition. Citizens petitions originally were created to allow individuals to voice concerns to the FDA about the safety or efficacy of a generic drug. However, the drug firms abuse this provision by filing petitions for the purpose of delaying entry of generic competition.

Currently, drug patents in force prior to June 8, 1995, have a term of either 17 years from date of issuance of the patent award or 20 years from the date of filing an application for a patent, whichever is longer, plus allowance for up to a five-year extension under the Waxman-Hatch Act. Under the Uruguay Round Agreements Act (URAA) of 1994, patents issued after June 8, 1995, have a term of 20 years from date of filing plus allowance for a five-year extension for court appeals, interference actions and certain other delays. The effective patent life, the portion of patent term remaining after clinical testing and FDA review, generally is less. Nevertheless, the average effective patent life of many drugs has increased by 50 percent over the past two decades. The Hatch-Waxman Act, URAA and other laws could add 4.4 to 5.9 years to effective patent lives of some new drugs, for a total of 13.9 to 15.4 years.⁴⁸

Proposed Solutions

Aside from plans that would expand or provide an affordable prescription drug benefit for seniors, a number of proposals have been made to alleviate the high cost of prescription drugs and check the growth in prices. A partial list includes:

- Allow the re-importation of drugs by pharmacies and health plans;
- Require drug companies to give local pharmacies the “best” price they give their most favored customers, or the average foreign price;
- Enact state initiatives to control prices;
- Close loopholes in the Hatch-Waxman Act that allow brand-name drug companies to obstruct entry of generic competitors;
- Elevate cost-consciousness of doctors and patients;
- Reinstate requirement for “reasonable pricing” on products that were researched and developed using taxpayer monies via NIH;
- Authorize the federal government to buy drugs in bulk and at discount for Medicare beneficiaries;
- Open the market to more competition by shortening the length of patents and/or eliminating the practice of patent extensions;
- Enact compulsory licensing; and
- Authorize the NIH to develop a yardstick for comparing prices.

PRESCRIPTION DRUG COSTS WIPE OUT LIFE SAVINGS

Ms. H of Springfield, Ill., has prescription drug costs of \$4,000 per year. Over a decade, this has amounted to \$40,000, depleting most of her life savings.

Allow the re-importation of drugs by pharmacies and health plans.

In the past, only drug manufacturers were allowed to re-import drugs made in the United States from countries where the drugs are available at lower prices.

A provision allowing the re-importation of FDA-approved prescription drugs was included in the FDA and Agriculture Department appropriations bill (H.R. 4461) passed by Congress and signed by President Clinton Oct. 28, 2000. It included \$23 million in funding for FDA implementation in the first year. However, Health and Human Services Secretary Donna Shalala did not request the monies to begin the program because of “flaws and loopholes.” Some members of the 107th Congress have asked President Bush to proceed with implementation.

Many in Congress and others have opposed the measure on the basis of the “loopholes” rather than the concept. That is, drug companies can refuse to allow re-importers to use the FDA-approved labels on their products, effectively blocking re-importation. The measure also does not prevent drug companies from imposing restrictive contract terms on foreign distributors, and a sunset stipulation ending the re-importation system after five years is seen as a disincentive for public and private investment in the program. There is also concern that the benefits of the Prescription Drug Marketing Act (PDMA) of 1987 are undermined. PDMA protects consumers from foreign counterfeits and improper storage in foreign countries. Legislation (H.R. 1512) has been proposed in the 107th Congress to close most of the loopholes.

Require drug companies to give local pharmacies the “best” price they give their most favored customers, or the average foreign price.

Legislation introduced in the 107th Congress (S. 125, H.R. 1512) would make it possible for pharmacies to purchase drugs for seniors and disabled persons on Medicare at the

lowest price pharmaceutical manufacturers give to such federal agencies as the Veterans Administration and military treatment facilities. A report from the federal General Accounting Office concluded that enactment of this proposal would not necessarily control the increase in drug prices overall, because drug companies likely would raise their prices to the federal agencies to offset losses in the reduction of prices to Medicare beneficiaries.⁴⁹ However, an increase in the volume of drugs sold would be sufficient to compensate the drug firms for the reduced prices. One analysis of a similar bill estimates that after adjusting for increased utilization, the net drop in total pharmaceutical industry revenues would be just 3.3 percent.⁵⁰ A variation on this proposal, also introduced in the 107th Congress (S. 699, H.R. 1400), would allow pharmacies to purchase the drugs at the average price at which the drugs are sold in other developed nations.

Enact state initiatives to control prices.

A number of states have taken on the problem of high prescription drug costs, largely because of inertia on the national level.

The state of Maine enacted the “Maine Rx Program” in 2000, which would have allowed the state to negotiate lower drug prices with drug manufacturers for Maine residents who lack prescription drug coverage. Drug companies found guilty of overcharging for drugs or restricting supplies would have incurred fines. The Pharmaceutical Research and Manufacturers of America (PhRMA) filed a lawsuit challenging the constitutionality of the law. A federal court ruled in favor of the drug makers and has blocked implementation of the Maine program. That decision now is under appeal.⁵¹

Legislation has been introduced in a number of other states focusing on lowering pharmaceutical costs by various means. Proposed approaches include pooling state residents without drug coverage to negotiate lower prices; removing

FOOD COMES LAST

Ms. H of Monroe, Ga., is 83 and widowed. Her annual prescription drug costs are about \$3,400 (\$283 per month). Ms. H’s monthly income is \$691 from Social Security. Her daughter, who was born with cerebral palsy, lives with her. After paying for utilities (about \$250 a month) and her prescriptions, Ms. H has only \$158 for food and other necessities.

restrictions on pharmacists that prohibit them from substituting generic drugs for protected brand-name drugs; requiring greater discounts from pharmacies; and prohibiting drug companies from selling drugs in the state at prices higher than those in Mexico or Canada.

Additionally, some states have formed bulk purchasing alliances, such as the Northeast Legislative Association on Drug Prices, to negotiate lower prices for segments of their populations, such as Medicaid recipients. Other states bordering Canada have begun to investigate joint ventures with Canadian pharmacies.⁵² And attorneys general in several states are considering legal action to require drug companies to lower prescription drug prices.⁵³

Close loopholes in the Hatch-Waxman Act that allow brand-name drug companies to obstruct entry of generic competitors.

Legislation introduced in the 107th Congress (S. 812) would streamline the approval process for generic drugs from the FDA. If a brand-name firm pays a generic firm to stay off the market, that company's 180-day market exclusivity as first generic would roll over to the next generic applicant. The measure also addresses abuse of "citizens petitions."

Elevate cost-consciousness of doctors and patients.

Survey data indicate that current Medicare beneficiaries rely on their physicians for guidance regarding selection of drugs. Furthermore, generic companies do not promote their products to doctors as brand-name companies do.

To enhance doctor and patient decision making and to ensure patient safety, Rx Health Value, a coalition of insurers, unions, private employers, academics and consumer and senior advocacy groups, recommends independent research to provide usable, reliable data for practitioners and consumers in deciding on the use of new drugs and

how to evaluate relative merits of different drugs within the same class.⁵⁴ Another recommendation is to publicly fund an independent organization as a reliable source of information on the quality of generic drugs and the equivalence across brand-name drugs in the same drug categories.⁵⁵ Presumably, doctor and consumer education also will lead to increased price sensitivity without coercion.

Reinstate requirement for “reasonable pricing” on products that were researched and developed using taxpayer monies via NIH.

In effect, this would eliminate the subsidy supplied to the drug makers. An amendment to that effect was passed in the House in the 106th Congress by a vote of 313–109. It is included in other drug cost-containment legislation (H.R. 1512) introduced in the 107th Congress. However, reinstatement of the requirement may not allow for retroactivity, meaning it would not apply to products already on the market. Additionally, NIH’s reporting system needs to be shored up considerably for this requirement to be effective.

Authorize the federal government to buy drugs in bulk and at discount for Medicare beneficiaries.

The Health Care Financing Administration (HCFA), which administers the Medicare program, could be given the authority to negotiate price reductions with pharmaceutical companies much as it does with such providers as hospitals, doctors and nursing homes. HCFA also could be authorized to use the prescription drug fee schedule the Veterans Affairs Department and other federal agencies have negotiated with the drug makers.⁵⁶

Open the market to more competition by shortening the length of patents and/or eliminating the practice of patent extensions.

This approach actually might produce greater technological breakthroughs because, without the 17 to 20 years of

exclusivity on patents, the drug manufacturers would have greater incentive to develop the next money-making drug. Patents spur innovation, but so do their expiration. Once a drug manufacturer has a blockbuster drug, it is inclined to protect the patent on that drug as long as possible, including making copycat drugs, in order to continue reaping substantial profits. Closing loopholes on patent extensions could shift attention to new research.⁵⁷

Enact compulsory licensing.

This option is discussed most recently in regard to measures African countries and Brazil are taking to obtain drugs for treating citizens with AIDS and HIV. A 1994 international trade agreement protecting intellectual property grants 20-year patents to drug manufacturers. However, compulsory licensing allows a government in a national emergency to license local or other manufacturers to produce cheaper versions of drugs whose patents are held by multinational companies. Compulsory licensing in the United States could take the form of allowing the originator of the drug to have a monopoly for a few years with no extensions, then compelling that company to license the drug to other manufacturers in return for a royalty payment.

Authorize the NIH to develop a yardstick for comparing prices.

The NIH could be designated the federal agency for developing, testing and producing new medicines. Using this experience to measure costs of research and development, NIH would be in a position to gauge whether prices charged by manufacturers are reasonable or excessive. Federal and state agencies then would contract only with manufacturers whose prices were reasonable.⁵⁸

A variation on this would be to endow a private, nonprofit institute as an independent source of research to verify whether drugs are new or just variations of old drugs.⁵⁹

Conclusion

Whatever solution or solutions are devised and implemented, the excessive rise in prices indicates that immediate action is necessary.

All developed countries that have lower drug prices than the United States also have some form of universal health insurance coverage. While the presence of insurance coverage increases utilization and expenditures for prescription drugs, it also provides the means and incentives for governments to control expenditures. For Medicare beneficiaries, the urgent need for such coverage is self-evident, as is the need for mechanisms to assure the affordability of such a benefit.

Ultimately, the best and most comprehensive approach to providing affordable prescription drugs for all the American people is to enact a universal, national health system based on a single-payer financing model.

RETURNING TO WORK ONLY WAY TO PAY FOR PRESCRIPTION DRUGS

Mr. S of Medford, Ore., is 71. His prescription drug costs per year are \$2,760 (\$230 per month). Social Security benefits cover the cost of rent, utilities and food, but not prescriptions. He has diabetes, high blood pressure and high cholesterol, all of which require medication. His savings were depleted by treatments for his wife's ovarian cancer. To pay for the drugs they need, Mr. S has gone back to work. "Our budget would be in serious trouble if this old 71-year-old man couldn't put on his boots and overalls and go to work every day," he says.

Glossary of Key Prescription Drug Pricing Terms

Average manufacturer's price (AMP). Average price paid by wholesalers to manufacturer. Established by manufacturers as a suggested list price for wholesalers selling to pharmacies. Also called the wholesaler acquisition cost (WAC).

Average wholesale price (AWP). Published wholesale price ("list price") suggested by the drug manufacturer. It is comparable to a sticker price on an automobile.

Cost-sharing. Consumers pay a portion or percentage of the price. Co-payments are consumer payments of a fixed cost per prescription (for example, \$5); co-insurance is payment of a proportion of costs (perhaps 20 percent). (See Tiers below.)

Discount. The price lower than the base price paid by certain purchasers to the retail pharmacy; amount is negotiated.

Formulary. List of drugs approved for use or payment—in other words, covered or reimbursable drugs. An open formulary includes all drugs; a restricted or closed formulary covers only the listed drugs. A partially closed formulary specifies drugs covered but allows exceptions with prior approval and/or with increased co-payments.

Generic drug. A generic drug is one that is chemically identical and bioequivalent to the brand-name drug. FDA approval requires that a generic drug must be absorbed into the body at essentially the same rate and to the same extent as the brand-name drug.

Health maintenance organization (HMO). A structure for providing managed care resulting in lower costs. HMOs under the Medicare+Choice program are paid a fixed monthly amount adjusted for beneficiary's age, gender, institutional status and Medicaid enrollment. They

typically yield lower costs and provide benefits, such as prescription drugs, not covered under Medicare for enrolled participants.

Indemnity coverage. As it pertains to prescription drugs, the insured pays for the prescription and then is reimbursed or indemnified by the insurance plan.

Launch price. The price of a new drug as established by a manufacturer when the drug is introduced on the market.

Market power. The degree to which a company exercises influence over the price and output in a particular market. Market power is related to the availability of substitute products. A drug manufacturer with a patent on an unrivaled drug has great market power.

Monopoly. A market in which there is only one supplier. A drug manufacturer with a drug patent has a monopoly on that drug. The patent protects the manufacturer from competition of chemically identical (but not therapeutically equivalent) drugs and allows it to set the market price.

Oligopoly. A market in which relatively few firms have significant influence over the price of a product in the market, such as when two or three drugs dominate a therapeutic category.

Patent. A patent on a drug protects it from replication competition for a number of years. The effective patent life is the portion of the patent term remaining after safety and efficacy testing, clinical trials and FDA approval for marketing.

Pharmacy benefit managers (PBMs). Private companies that contract with health plans to arrange discounts from retail pharmacies and manage distribution of drugs. They may also perform such functions as paying claims and negotiating price discounts via rebates.

PhRMA. Pharmaceutical Research and Manufacturers of America, an association of prescription drug manufacturers.

Price discrimination. The selling of the same product to different purchasers at different prices.

Price sensitivity. Refers to the extent to which a purchaser would change the amount of a product it would buy if the price of that product should rise or fall.

Rebate. Money that is returned to the purchaser by the seller after the purchase has taken place. Usually a percent of the value of the drug dispensed.

Retail price. The price charged by retail pharmacies to individuals without insurance, known as “cash-paying” customers.

Therapeutically equivalent drugs. Drugs that perform the same function as another drug even though they may be different chemically. Therapeutically equivalent drugs can be in competition with each other for listing on formularies.

Tiers of co-payments. Refers to the co-payment amount health plans may require for purchasing drugs from a formulary with the purpose of encouraging the use of generic drugs. The first tier co-payment would be for generic drugs and require the lowest co-payment, for example \$1; the second tier would be for brand-name drugs listed on the formulary with a co-payment of \$10, for example; the highest co-payment would be for drugs not listed on the formulary, perhaps \$20.

Endnotes

- 1 Bureau of National Affairs. Special Health Care Policy Report: Drug Prices. Vol. 8, No. 19. (May 8, 2000)
- 2 Health Care Financing Administration. National Health Care Expenditures Projections: 2000–2010. (March 2001) [www.hcfa.gov]
- 3 Families USA. Cost Overdose: Growth in Drug Spending for the Elderly, 1992–2010. (July 2000) [www.familiesusa.org]
- 4 Congressional Research Service. Medicare Prescription Drug Coverage for Beneficiaries: Background and Issues. (Jan. 26, 2001)
- 5 Congressional Budget Office. Laying the Groundwork for a Medicare Prescription Drug Benefit. Statement of Daniel L. Crippen, Director, before Subcommittee on Health of the House Ways and Means Committee. (March 27, 2001)
- 6 Kaiser Family Foundation. The Medicare Program: Medicare and Prescription Drugs. Fact Sheet. (February 2001)
- 7 Ibid.
- 8 Ibid.
- 9 Bureau of National Affairs. Special Health Care Policy Report: Drug Prices. Vol. 8, No. 19. (May 8, 2000)
- 10 Noonan, David. Why Drugs Cost So Much. *Newsweek*. (Sept. 25, 2000)
- 11 Congressional Budget Office. How Increased Competition from Generic Drugs Has Affected Returns in the Pharmaceutical Industry. (July 1998) [www.cbo.gov]
- 12 U.S. Department of Health and Human Services. Prescription Drug Coverage, Spending, Utilization, and Prices. Report to the President (April 2000). [aspe.hhs.gov/health/report/drugstudy]
- 13 Kaiser Family Foundation. Prescription Drug Trends: A Chartbook by Kreling DH, Mott DA, Widerhold JB, Lundy J, Levitt L. (July 2000) [www.kff.org]
- 14 U.S. Department of Health and Human Services. Prescription Drug Coverage, Spending, Utilization, and Prices. Report to the President. (April 2000) [aspe.hhs.gov/health/report/drugstudy/exec.htm]
- 15 Public Citizen. D.C. Area Consumers Pay More for Prescription Drugs While Pharmaceutical Profits Soar. (Oct. 24, 2000)
- 16 Weiss Ratings. Few Options Available for the Nearly One Million Seniors To Be Dropped from HMOs by Year-End. [www.weissratings.com]
- 17 Cassidy, Amanda, Gold, Marsha. Medicare+Choice in 2000: Will Enrollees Spend More and Receive Less? Commonwealth Fund. (August 2000) [www.cmf.org]
- 18 U.S. Department of Health and Human Services. Prescription Drug Coverage, Spending, Utilization, and Prices. Report to the President. (April 2000) [aspe.hhs.gov/health/report/drugstudy/exec.htm]
- 19 Medicare Rights Center. Trying to Fill the Medicare Gaps. (Winter 2000) [www.medicarerights.org]

- 20 Kaiser Family Foundation and Health Research and Educational Trust. Employer Health Benefits 2000 Annual Survey.
- 21 Hewitt Associates. Retiree Health Coverage: Recent Trends and Employer Perspectives on Future Benefits. Report prepared for Henry J. Kaiser Family Foundation. (October 1999)
- 22 Public Citizen. Drug Industry Most Profitable Again: New Fortune 500 Report Confirms “Druggernaut” Tops Other Industries in Profitability Last Year, 2001.
- 23 Schondelmeyer, Stephen. Role of Price Transparency in the Pharmaceutical Market. Presentation to ASPE Conference on Pharmaceutical Pricing, Utilization, and Costs, Washington, D.C., Aug. 8–9, 2000.
- 24 *Fortune* magazine. [www.fortune.com]
- 25 Congressional Research Service. Federal Taxation of the Drug Industry from 1990 to 1996, Memorandum to Joint Economic Committee. (Dec. 13, 1999)
- 27 *The Boston Globe*. Public Handouts Enrich Drug Makers, Scientists. (April 5, 1998)
- 28 PhRMA, Pharmaceutical Industry Profile 2000. [www.phrma.org/publications]
- 29 National Institutes of Health. Linking Patients to Research. [clinicaltrials.gov]
- 30 *The Boston Globe*. Public Handouts Enrich Drug Makers, Scientists. (April 5, 1998)
- 31 U.S. General Accounting Office. Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revisions. (August 1999)
- 32 Public Citizen. Why the Pharmaceutical Industry’s “R&D Scare Card” Does Not Justify High and Rapidly Increasing U.S. Drug Prices. (Jan. 26, 2000)
- 33 National Institute for Health Care Management. Prescription Drugs and Intellectual Property Protection. (August 2000)
- 34 IMS HEALTH, U.S. Pharmaceutical Promotional Spending Topped \$8 Billion in First-Half 2000 and, Pharmaceutical Direct-To-Consumer Ad Investment in U.S. Reaches \$1.3 Billion in First-Half 2000. (October 2000) [www.imshealth.com]
- 35 National Institute for Health Care Management. Prescription Drugs & Mass Media Advertising. (September 2000)
- 36 Congressional Joint Economic Committee Report. The Benefits of Medical Research and the Role of the NIH. (May 2000)
- 36 “The NewsHour” with Jim Lehrer/Kaiser Family Foundation/Harvard School of Public Health. National Survey on Prescription Drugs. (September 2000)
- 37 IMS HEALTH, U.S. Pharmaceutical Promotional Spending Topped \$8 Billion in First-Half 2000 and, Pharmaceutical Direct-To-Consumer Ad Investment in U.S. Reaches \$1.3 Billion in First-Half 2000. (October 2000) [www.imshealth.com]

- 38 Public Citizen. Addicting Congress: Drug Companies' Campaign Cash & Lobbying Expenses. (July 2000) [www.citizen.org]
- 39 Center for Responsive Politics. Pharmaceuticals/Health Products: Top Contributors, and, Long-Term Contribution Trends. [www.opensecrets.org/industries]
- 40 *The New York Times*. With Quiet, Unseen Ties, Drug Makers Sway Debate. (Oct. 5, 2000)
- 41 *The Wall Street Journal*. Drug Firms Underwrite U.S. Chamber's TV Ads. (Oct. 6, 2000)
- 42 Surowiecki, James. Big Pharma's Drug Problem. *The New Yorker*. (Oct. 16 and 23, 2000)
- 43 Schondelmeyer, Stephen. Prescription Drugs: Demystifying the Industry. Presentation to Health Action 2001 National Grassroots meeting. (Jan. 27, 2001)
- 44 National Institute for Health Care Management. Prescription Drugs and Intellectual Property Protection. (August 2000)
- 45 Congressional Budget Office. How Increased Competition from Generic Drugs Has Affected Returns in the Pharmaceutical Industry. (July 1998) [www.cbo.gov]
- 46 *The New York Times*. Medicine Merchants Holding Down the Competition: How Companies Stall Generics and Keep Themselves Healthy. (July 23, 2000)
- 47 Federal Trade Commission. Health Care Antitrust Report...Health Care Services and Products. [www.ftc.gov/bc/hcindex/conduct.htm]
- 48 National Institute for Health Care Management. Prescription Drugs and Intellectual Property Protection. (August 2000)
- 49 Merrill Lynch. A Medicare Drug Benefit: May Not Be So Bad. (June 23, 1999)
- 50 U.S. General Accounting Office. Prescription Drugs: Expanding Access to Federal Prices Could Cause Other Price Changes. (August 2000)
- 51 Wheatley, Ben, et al. State of the States 2001. State Coverage Initiatives. (January 2001) [www.statecoverage.net]
- 52 Ibid.
- 53 Stateline.org. Special Report: States Mull Suit Against Drug Companies. (April 2, 2001)
- 54 Rx Health Value: The Independent Information Center. [RxHealthValue@aol.com]
- 55 Moon, Marilyn. Prescription Drugs as a Starting Point for Medicare Reform. Testimony before the Senate Budget Committee. (Feb. 15, 2001)
- 56 Public Citizen. D.C. Area Consumers Pay More for Prescription Drugs While Pharmaceutical Profits Soar. (Oct. 24, 2000)
- 57 Surowiecki, James. Big Pharma's Drug Problem. *The New Yorker*. (Oct. 16 and 23, 2000)
- 58 Mintz, Morton. Still Hard to Swallow. *The Washington Post*. (Feb. 10, 2001)
- 59 Reinhardt, Uwe. How to Lower the Cost of Drugs, *The New York Times*. (Jan. 2, 2001)

About the Alliance for Retired Americans

The Alliance for Retired Americans is a new senior advocacy organization that was created in January 2001 by national and local affiliates of the AFL-CIO, together with community-based organizations, to provide a voice for the rapidly growing numbers of union retirees and older Americans.

The mission of the Alliance for Retired Americans is to ensure social and economic justice and full civil rights for all citizens so they may enjoy lives of dignity, personal and family fulfillment and security. The Alliance believes that all older and retired persons have a responsibility to strive to create a society that incorporates these goals and rights; and that retirement provides them with opportunities to pursue new and expanded activities with their unions, civic organizations and their communities. The Alliance's public policy and legislative goals will be achieved through mobilization of members in an extensive grassroots network in every region, state and district in the country.

Permission to reproduce all or part of this report is given with the provision that the following credit line be used:

Reprinted [or excerpted] from *The Profit in Pills: A Primer on Prescription Drug Prices* with permission of the Alliance for Retired Americans.