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# PHARMACEUTICALS:

Their Role in the Cost of Health Care

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## FOREWORD

At its planning session on September 3, 1998, the Pennsylvania Health Care Cost Containment Council (PHC4) asked staff, in working with the Education Committee, to identify key issues related to pharmaceutical costs. The request was based, in part, on the predicted rise in the cost of prescription drug plans. A new federal study by the Department of Health and Human Services has predicted that, for the next decade, the biggest cost increases in the health arena will be for prescription drugs, with spending rising by nearly ten percent each year. Employers report that pharmacy benefits costs are rising more than overall medical plan cost increases. A survey by benefits consultant William Mercer, Inc. found that pharmacy benefit costs increased an average of 11% in 1997, in comparison with a 4% rise in total health plan cost. One source has suggested that the cost of prescription drug plans is expected to increase 15%-20% in 1999.

The PHC4 staff has identified the following questions to be important in understanding drug costs:

- What factors contribute to increased pharmaceutical costs?
- Are prescription drugs cost effective?
- What changes have occurred in the pharmaceutical marketplace and how does this affect price and accessibility of prescription drugs?
- What role does managed care play in pharmaceutical cost containment?
- How do government programs affect the utilization of prescription drugs?

### Overview of the Pharmaceutical Industry

Prescription drug purchase, though a relatively small percentage of total health expenditures, is one of the fastest-growing sectors of the health care arena. National spending for health care in 1996 increased by 4.4%. Spending on prescription drugs, however, increased 9.2%. New products have contributed to industry growth since 1970. In 1970, sales amounted to \$6.6 billion. In 1998, sales by research based pharmaceutical companies are projected to reach \$124.6 billion.

Pharmaceutical manufacturers sell mainly to large drug wholesalers. Wholesalers sell to retail pharmacies, hospitals, HMOs, clinics, mail-order companies, and other organizations that fill prescriptions. In 1996, 80.3% of sales flowed through wholesalers, up from 57.3% in 1980.

In 1997, the retail and non-retail sector – including independent, chain, food store and mass-merchandizing pharmacies – dispensed more than 2.4 billion prescriptions. Retail channels account for over 60% of dispensed prescription sales in the United States. Hospital pharmacies account for 14%, mail-order pharmacies comprise 11%, clinics 6%, long-term care pharmacies 3%, staff-model HMOs 2%, and other 4%. More than 90% of HMOs contract with retail pharmacies to fill prescriptions.

## **Research and Development**

Total time needed to develop a drug has increased from an average of 8.1 years in the 1960s to 14.9 years for drugs approved in the 1990s. According to the Pharmaceutical Research and Manufacturers' Association (PHRMA), the average cost of developing a drug, from start to finish, including the cost of research failures, was \$500 million in 1990. The Pharmaceutical Research and Manufacturer's Association also reports that only three out of ten approved drugs recover their research and development costs. Companies rely on a small number of highly successful products to make a profit.

Dollars spent on research and development in 1998 are expected to increase to \$21.1 billion, an increase of 10.8% over 1997. Research and development expenditures have doubled since 1990. Currently, U.S. pharmaceutical research companies have more than 1,000 new medicines in development, including:

- 96 new drugs for heart disease and stroke.
- 316 anti-cancer medicines.
- 124 drugs to treat AIDS.
- 17 new treatments for Alzheimer's disease.
- 24 new drugs for rheumatoid arthritis.
- 21 new medicines for diabetes.
- 85 new medicines for mental disorders.

## **Pharmaceuticals Dominated by Five Product Classes**

In 1996, sales of prescription pharmaceuticals were dominated by five major product classes. These were:

- Pharmaceuticals acting on the central nervous system – 23.9%
- Pharmaceuticals acting on the cardiovascular system – 18.8%
- Pharmaceuticals affecting cancers, the endocrine system and metabolic diseases – 17.9%
- Anti-infective pharmaceuticals – 14.9%
- Pharmaceuticals acting on the digestive or genitourinary system – 14.2%
- Smaller product classes are: respiratory products – 7.4%; dermatological products – 2%; and vitamins – 1%.

## **Pharmacy Benefits Managers**

The increase of managed care has ushered in dramatic changes in the delivery of prescription drugs. The increasing trend toward managing drug benefits has spawned new companies called Pharmacy Benefits Managers (PBMs). PBMs now provide pharmacy benefits for approximately half the insured population in the United States. The greatest demand for PBM services is due to its provision of on-line claims processing. Enrollees are given magnetically coded cards that give the pharmacy access to eligibility and other data, as well as allowing the pharmacy to bill on-line. The benefit is a reduction in administrative costs by eliminating paper claims.

PBMs manage pharmaceutical care only, marketing their services to employers, insurance companies, managed care groups, and Medicaid. There are approximately 40 PBMs in the United States today, although the top five companies account for more than 75% of the market. Since 1993, the largest PBMs have merged, or formed alliances with major pharmaceutical companies.

The growth of PBMs has paralleled the decline of the neighborhood pharmacy. Between 1985 and 1997, the total number of independent pharmacies declined by 14,341, while the total number of chain pharmacies increased by about 18,229.

Consumer groups claim that pharmacists and doctors are being pressured by PBMs to switch patients from drugs preferred by the doctors to drugs preferred by the health insurer. These consumer groups also claim that PBMs are pressuring health professionals to switch prescriptions to drugs made by certain companies.

### **Pharmaceuticals: Predicted To Be A Growing Portion of the Health Care Dollar**

A Department of Health and Human Services study predicts that national health expenditure amounts will be climbing 8.2% annually by 2007. Furthermore, the study predicts that the biggest spending increases will be for prescription drugs, with spending rising by nearly 10% a year.

Over the past twenty years, drug costs (including outpatient prescription drugs, drugs used in an inpatient setting, and other medical nondurables) have constituted a fairly steady percentage of total health expenditures – 8.7% in 1980, 8.6% in 1990, 8.5% in 1992, 8.4% in 1994, and 8.8% in 1996. However, there is concern that this trend is reversing, as biotechnology drugs proliferate and increases in drug expenditures outpace the rest of health care.

The proportion of health expenditures allocated to *outpatient prescription drugs* actually started to rise in 1985, according to the Pharmaceutical Research and Manufacturers Association. In both 1980 and 1985, the percentage of national health expenditures allocated to outpatient prescription drugs was 4.9%. By 1990, the percentage had risen to 5.4%, and by 1996 to 6.0%.

### **Greater Use of Prescription Drugs**

The pharmaceuticals industry claims that much of the cost increase is due to an increase in the numbers of prescriptions written, the number of doses per prescription and to the availability of new and more expensive drugs. Though spending on prescription drugs increased 9.2% in 1996, the Consumer Price Index reports that *prices* of prescription drugs increased 3.4% while spending due to the *use* of prescription products increased by 5.8%.

## **Out-of-Pocket Expenditures for Prescription Drugs are Decreasing**

The pharmaceutical marketplace has undergone major changes over the past twenty years. In 1970, 82% of money paid for prescription drugs was out-of-pocket. By 1996, this percentage had decreased to 34%. One contributing factor is that more than 90% of people covered by HMOs receive prescription drug benefits. As the percentage of Americans covered by HMOs increases, so does the percentage of those with prescription drug coverage.

Some analysts claim that lower out-of-pocket costs for prescriptions are a contributing factor to increased utilization. The number of prescriptions used by HMO enrollees has been found to be higher than that used by indemnity enrollees because of a higher number of physician office visits per enrollee. Another important trend is that health plans are tending to place certain patients on expensive maintenance drug therapies instead of sending them to the hospital or to the doctor.

## **Increase in Cost of Existing Drugs**

According to a report by the Agency for Health Care Policy and Research, the Consumer Price Index for the years 1991 through 1997 indicates an average annual inflation rate for prescribed medicines of 3.5%. The overall increase in *existing* drug prices (i.e. drugs already on the market) in 1996 was 3.4%. Statistics show that the highest increase was for fungicides, at 10%. Industry sources estimate that prices of existing drugs are expected to continue to rise at a rate of 2-4% for 1998.

## **Increase in Cost of Generics**

In recent years, prices on generic drugs have dropped about 10% annually. In the early part of 1998, however, several generic drug makers began to raise prices substantially. An example is the generic version of Ativan, a popular anti-anxiety drug, which rose from \$1.50 per 100 tablets to \$31.99 per 100 tablets. Other wholesale drug prices were raised as much as 300%.

Generic makers claim that it is no longer possible to keep lowering prices. One manufacturer, Mylan Pharmaceuticals, claims that 41 out of 97 drugs it makes were losing money. They cite the cost of bulk chemicals and the cost of patent litigation with brand name makers as reasons for the rise in price. The literature suggests that those generic manufacturers who have not yet joined the trend in increasing prices can be expected to do so in the future.

Approximately 40 drugs with combined sales of \$16 billion per year will lose patent protection by the end of 2002. With generic drug makers raising prices, the amount of savings that might be expected to be realized by these drugs entering the generic market may be less than expected.

## **The Role of New Drugs**

In the 1980s, new drugs began to appear with prices much higher than had been seen before. A number of factors were responsible. Pharmaceutical prices began to reflect the higher costs of new technologies. Two drug categories drew media attention due to

their unprecedented price tags: tissue plasminogen activator (TPA), used to treat heart attack and stroke at \$2,000 per dose, and the drugs developed to treat AIDS.

### **The Role of Marketing**

The pharmaceutical industry is becoming more marketing-oriented. Marketing and promotion of drugs aimed at doctors and conducted in doctor's offices requires huge sales forces. This type of marketing is expensive, absorbing about 23% of revenue (see chart on page 10).

Some industry sources claim that at least a portion of increasing pharmacy prices can be attributed to a new marketing trend in direct-to-consumer advertising. Historically, the medical community has resisted direct advertisement of prescription medicines to consumers, because of fears that patients would use medicines improperly. This is one of the fastest growing categories of advertising. In 1990, 10 different medicines were advertised directly to consumers. By 1997, this number had risen to 79 different medicines. Television advertisements that are prominent are Claritin, an allergy medication, and Propecia, a medication to help hair loss.

Pharmaceutical companies claim that direct-to-consumer advertising fosters competition among products, which can lead to improved quality and lower prices. Furthermore, it is claimed that direct-to-consumer advertising can improve patients' health by starting a dialogue between patient and doctor.

Prevention magazine recently conducted a study, which found that consumers are positive about pharmaceutical advertising because it educates people about health issues and about available medications. Additionally, the study found that this type of advertising has another positive effect – patients are more likely to feel good about the medication they are taking and have a higher level of compliance in getting prescriptions filled.

Unanswered questions are how much the increase in direct-to-consumer advertising has increased the prices of individual drugs and whether it has resulted in inappropriate usage of prescription drugs.

### **The Role of the Aging of the Population**

The aging of the population will have a significant impact on the use of prescription drugs, as well as on the use of health services in general. Currently, those 65 and over comprise about 13% of the population and use 34% of health expenditures, and about one third of all prescription drugs. By 2010, those 65 and over will comprise 20% of the population.

### **Cost Effectiveness of Prescription Drugs**

Used correctly, prescription drugs can eliminate the need for expensive hospitalization, surgery or nursing home care.

- Treating ulcers with newer drug therapies has caused surgeries for ulcers to decrease from 97,000 in 1977 to 18,926 in 1987. The annual cost of drug therapy for ulcers is \$900, compared to \$28,000 for surgery.
- Asthma patients on maintenance drugs demonstrated an average 42% decline in the rate of emergency room and hospital urgent care visits.
- The development of a wide range of antidepressants has resulted in the aggregate price of treating acute major depression falling by 25% over the 1991-1995 time period.
- A recent study found that treating stroke patients promptly with a clot-busting drug (TPA) not only reduces disability, it also saves substantial health care costs. While use of the drug initially costs more, the expense is more than offset by reduced rehabilitation and nursing home costs. Use of TPA to treat stroke resulted in a net savings to the health system of more than \$4 million for every 1,000 patients treated.
- A study released by the Agency for Health Care Policy and Research concluded that increased use of a blood-thinning drug would prevent 40,000 strokes a year, saving \$600 million. In economic terms, the lifetime cost of a stroke exceeds \$100,000, while the average annual cost of drug therapy and monitoring is \$1,025.
- Estrogen replacement therapy, which protects against osteoporosis, costs approximately \$3,000 for 15 years of treatment, while a hip fracture caused by osteoporosis costs an estimated \$41,000.
- Combination drug therapy can enable AIDS patients to avoid hospitalization. The annual cost of the therapy is between \$10,000 and \$16,000. The cost of treating advanced AIDS in a hospital is \$100,000 per year.

The following table compares the costs of drug therapy versus other therapies in three common illnesses.

ILLNESS	COST PER YEAR
<i>Hypertension:</i>	
Drug Therapy .....	\$ 400
Stroke Rehabilitation .....	\$ 15,000
<i>Ulcer:</i>	
Drug Therapy .....	\$ 1,000
Surgery .....	\$ 25,000
<i>Gallstones:</i>	
Drug Therapy .....	\$ 2,000
Surgery .....	\$ 12,000

While the use of drugs can be effective, an article in *Hospital Practice* urges caution. The author notes that new drugs, which tend to be expensive because of patent protection and recent research and development costs, are often greeted with much anticipation and high expectations by the medical community. However, it is important

to ascertain whether the newer drug is actually more effective than an older, cheaper drug. Some drugs that perform well under the ideal conditions of the testing period are

less effective under “real life” conditions. The article suggests that development of large scale outcomes research will help determine the cost effectiveness of new drugs.

Steering patients to cheaper or generic prescription drugs may not be saving money in the long run. A 1996 study reported in the *American Journal of Managed Care* claims that restricting access to drugs and substituting cheaper drugs may result in more visits to doctors’ offices and more visits to the emergency room. The study concluded that limiting what drugs can be prescribed – intended to prevent the unnecessary use of expensive drugs – is having the unintended effect of raising medical costs.

A 1994 study reported in *The New England Journal of Medicine* found that capping the number of prescriptions that schizophrenic Medicaid patients could have saved an average of \$47 per year per patient, but added \$1,530 in other health-care services.

Though generics are chemically identical to name-brand drugs, generic drugs produced by different manufacturers can actually differ by 20-25% in their effectiveness. In addition, using a restrictive formulary may prevent the use of a drug that would be better suited in a particular case than the permitted, less expensive drug. When less effective drugs are used, the effect can be to prolong or worsen the condition, driving up costs by trying to save money on the original prescription.

### **The Role of Patient Compliance**

Other issues affecting the efficient use of prescription drugs are: 1) patient compliance with medication regimens and 2) prevention of adverse drug interactions. Unless patients take their medicines according to physicians’ instructions, and systems are in place to guard against adverse drug interactions, prescription drugs may not be used cost-effectively. At least 30% of all patients do not take medications correctly. This percentage is even higher among the elderly. The misuse may involve taking more or less than prescribed, or the patient may be confused about instructions. Another common misuse is taking a medication with food or with another medication that causes complications. Taking medications incorrectly:

- Accounts for 10% of all hospital admissions, 25% of hospital admissions among the elderly, and 23% of all nursing home admissions.
- Causes an estimated 125,000 deaths every year in the United States for hypertensive patients.
- Costs 20 million workdays and \$1.5 billion in earnings annually in the United States for heart and circulatory diseases alone.

Overall, non-compliance with medications costs \$76 billion annually. Drug related problems result in over 8 million hospital admissions, 3 million admissions to long-term care facilities, and 115 million physician visits.

Result of Drug Misuse	Patients Affected	Estimated Cost (billions/year)
Further prescription medication	42-49%	\$1.9
Revisit with a physician	15-23%	\$7.5
Emergency room visit	6-12%	\$5.3
Hospitalization	5-9%	\$47.5
Admission to long term care facility	<1%	\$14.4
Death	<1%	N/A
<b>Total Estimated Costs</b>		<b>\$76.6</b>

12-19% of the patients affected by a drug misuse experience some result other than those listed above.

### Managed Care Organizations and Pharmaceutical Cost Containment

Many HMOs raised their rates during 1997, but failed to improve their overall profit situation. They cite the high cost and increased use of prescription drugs as a major reason for the decline in profits. Pharmaceutical expenditures as a percentage of total HMO operating cost rose to 10.4% in 1996 from 9.4% in 1995. This percentage had not increased since 1993.

HMOs spent \$121.63 per member per year on pharmaceuticals in 1996, up 3.9% from \$117.07 in 1995. Individual pharmacy premium per member per month rose 4.6% in 1996, from \$12.30 to \$12.87.

Managed care organizations have developed a variety of cost-containment techniques aimed specifically at pharmaceuticals expenditures.

- **Formularies:** 90% of HMOs use formularies. A formulary is a list of prescription drugs approved for insurance coverage.
- **Generic Substitution:** 71% of HMOs require generic substitution, where a brand-name drug is replaced with a generic copy.
- **Therapeutic Interchange:** About 18% of HMOs use therapeutic interchange. This practice involves substituting a drug having a different chemical composition than the one prescribed, usually in the same therapeutic class.
- **Drug Utilization Review:** More than 80% of HMOs require Drug Utilization Review. Drug Utilization Review involves retroactive monitoring of physicians' prescribing patterns. Drug Utilization Review programs are designed to ensure appropriate and safe use of prescription drugs, as well as monitor costs.
- **Step-Care Therapy:** About 35% of HMOs utilize step-care therapy. Step-care therapy requires that a physician follow a sequence of treatment, usually starting with a low cost alternative, before progressing to higher cost treatment.

## **Government Programs Affect Patient Use of Pharmaceuticals**

The government, at both the state and federal levels, is a major purchaser of pharmaceuticals. Government programs that purchase pharmaceuticals include Medicaid, Medicare HMOs, AIDS drug assistance programs, state senior assistance programs such as PACE, and veterans' hospitals. The Medicaid program paid for almost 20% of all prescription drugs in 1994.

Prescription drug benefits are a featured attraction for Medicare HMOs and the primary reason many seniors choose Medicare HMOs. The number of Medicare beneficiaries enrolled in state-licensed HMOs rose 29.9% in 1996, from 3.6 million to 4.7 million nationally. Among HMOs with Medicare members, pharmacy costs as a percentage of total operating costs rose from 9.2% in 1995 to 13% in 1996.

Another issue that is emerging is the trend of Medicare HMOs to cut back on prescription benefits. Many seniors, who joined HMOs on the promise of generous drug benefits not available under regular Medicare coverage, are now being asked to pay substantial amounts for their brand-name medications, many of which do not have generic equivalents. Many medications for chronic conditions such as diabetes, high blood pressure and high cholesterol do not have generic equivalents. HMO executives say the hikes in medication co-payments are needed because pharmaceutical drug costs are increasing substantially and Medicare reimbursements are not keeping pace with the cost of providing care.

### **Summary**

In summary, higher drug costs appear to be the result of:

- Increase in prescription drug utilization, including the number of prescriptions and the number of doses per prescription
- Increase in the number of expensive new drugs reflecting the most advanced technologies
- Increases in the cost of research and development
- Increases in the cost of generic drugs
- Increased marketing efforts
- An aging population

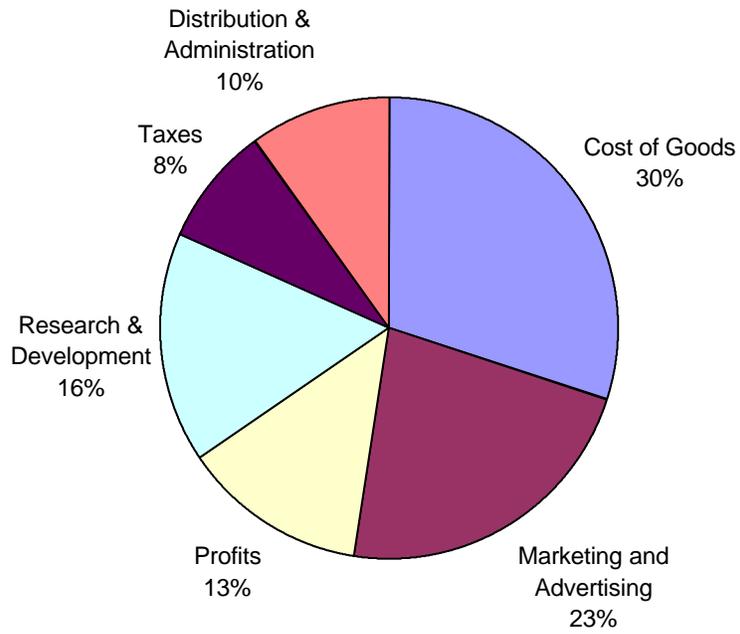
Other factors mentioned as contributing to greater expenditures on prescription drugs are lower out-of-pocket drug costs for consumers and increased litigation expenses between brand name and generic drug manufacturers.

### **Next Steps**

Given the issues discussed above, the following questions might be considered as next steps if the Council decides to pursue further action:

- What role can the Pennsylvania Health Care Cost Containment Council play?
- What specific information needs to be collected in order for the Council to fulfill this role?
- How can this data collection effort be implemented?

### Where the U.S. Prescription Dollar Goes (Manufacturers Component)



Source: Prime Institute, January 1993

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