Trends in Prescription Drug Coverage and Expenditures for Senior Citizens



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EXECUTIVE SUMMARY

This report discusses trends in insurance coverage and expenditures for prescription drugs for older Ohioans. A mandate in Am. Sub. S.B. 192 of the 123rd General Assembly required the Legislative Service Commission to research these trends, particularly as they relate to low-income elderly Ohioans suffering from tobacco-related illnesses. This report is in response to that mandate.

Almost a third of all Medicare beneficiaries have no insurance coverage for outpatient prescription drugs, and nearly half were uninsured for at least part of the year. Of those with coverage, employer-sponsored coverage is the most common source, followed by Medicaid, individually purchased plans (Medigap), Medicare+Choice plans (Medicare HMOs) and other sources. Employer-sponsored coverage is the most stable source of coverage, but many employers have limited, or are considering future limitations on, prescription drug coverage for retirees. Few Medigap policies offer prescription drug coverage, and those that do are significantly more expensive than policies without drug coverage. Many Medicare HMOs have withdrawn entirely from the program in recent years, and some of the remaining HMO plans do not offer drug coverage as a basic benefit.

National prescription drug expenditures, \$99.6 billion in 1999, are expected to reach \$366 billion by 2010. Prescription drug spending for the Medicare population is estimated at \$56 billion for this year. Expenditures for prescription drugs comprise a small but rising percentage of personal health expenditures, and drug spending has been one of the fastest growing components of health care spending in the past decade.

Rapidly escalating drug spending can be attributed to two factors: rising drug prices and increased utilization. The average cost per prescription for senior citizens grew by over 48% between 1992 and 2000. Prices for brand-name drugs have risen much more rapidly than prices for generic drugs. Manufacturer price increases are responsible for about a fifth of the increase in drug spending, but nearly 40% of the increase is caused by a shift to the use of newer drugs.

Scientific research and shortened regulatory review have resulted in the introduction of many new drugs to treat conditions that were previously untreatable, as well as of drugs that replace other medical interventions like surgery or provide better outcomes with less significant side effects. These new drugs are significantly more expensive than older drugs. Even the rise in the number of generic drugs prescribed has not slowed escalating drug prices, because consumers are often shifted to newer drugs when a brand-name drug's patent expires.

Increased use of prescription drugs is responsible for nearly half of recent increases in prescription drug spending. The average number of prescriptions per senior citizen has grown from 19.6 to 28.5 since 1992 and is expected to reach 38.5 by 2010. Several factors drive rising utilization of prescription drugs. The aging of the U.S. population means that a greater number of people suffer from chronic and acute conditions that are treatable with medication. The rise in the number of people enrolled in managed care has resulted in a shift in the share of drug expenses paid for by private insurance. Increased access to primary care and low co-payments for prescription drugs mean that more prescriptions are prescribed and filled. Finally, dramatic escalation in direct-to-consumer advertising, particularly on television, has resulted in greater consumer demand for medications consumers have seen or heard advertised.

Insurance coverage has a major impact on drug spending and utilization. Both are significantly higher for Medicare beneficiaries who have coverage for prescription drugs. Nonetheless, despite using fewer prescriptions, out-of-pocket expenses for those without coverage are nearly double the expenses of those with coverage.

Prescription drug therapy may be particularly important in helping to reduce smoking-related diseases. Smoking is responsible for one in every five deaths and is a major preventable risk factor for cancer, heart disease, stroke, and respiratory disease. It results in more than \$50 billion in medical expenditures per year. Recent research by the federal government indicates that when drug therapy is used in combination with a doctor's help, smoking cessation rates increase by two to four times as much as counseling alone. Stopping smoking at any age substantially reduces the risk of death and disease.

More than half of the states have established a pharmaceutical assistance program to assist low-income senior citizens in paying for prescription drugs, although Ohio has not. In general, these programs are funded with general revenue funds, although some have received Medicaid waivers and several are using tobacco settlement funds. Most of the programs involve direct subsidies to seniors. A number of states are considering legislation to create similar programs or to expand existing ones.

I. INTRODUCTION

The 123rd General Assembly, in Am. Sub. S.B. 192, required the Legislative Service Commission to studv issues concerning availability of prescription drugs for low-income elderly Ohioans who suffer from tobacco-related illnesses. The General Assembly required that the report discuss the methods used to obtain prescription drugs, drug costs, and research utilization. development. The report is to present information regarding (1) average annual drug costs per person, (2) average annual drug costs per prescription. (3) drugs with highest volume usage, and (4) drugs with the highest cost. The General Assembly directed that the report examine how managed care and physician practices affect prescription drug cost and availability. It must also discuss other states' efforts concerning prescription drug for senior citizens. The report is not to include legislative recommendations.

This report first discusses in Part rates and sources II prescription drug coverage for the elderly. Part III examines major trends prescription in drug expenditures and analyzes the primary contributing factors to the

dramatic increase in drug spending: price and utilization. After reviewing causes of recent increases in drug prices utilization, the report analyzes the impact of drug coverage on spending and utilization. Part IV discusses the impact of smoking on medical expenditures and mortality rates and examines the role of prescription drugs in smoking cessation. Finally, report describes pharmaceutical assistance programs in ten states. In researching this report, the authors consulted a variety of sources, including state and federal law. legislation, and legislative materials; newspaper articles; and publications of the following entities: state and federal agencies, Association the American Retired Persons. the National Conference of State Legislatures. the Pharmaceutical Research and Manufacturers Association America, Families USA, the National Association of Chain Drug Stores, The Henry J. Kaiser Family Foundation, Project HOPE. pharmaceutical consulting firms, and the American Medical Association.

II. INSURANCE COVERAGE OF PRESCRIPTION DRUGS FOR THE ELDERLY

Prescription drug use increases with age, along with the prevalence of chronic and acute conditions, but the elderly are less likely than the general population to prescription drug coverage. Just over three-quarters (77%) of the non-Medicare population had coverage for prescription drugs in 1996, while almost a third (31%) of Medicare beneficiaries had no drug coverage.¹ Although nearly all persons age 65 or older are eligible for Medicare, the Medicare program does not generally cover prescription drugs on an outpatient basis. Medicare is a federal that provides program hospital insurance, known as Part A coverage, and supplementary medical insurance, Part B coverage. Part B covers primarily physician outpatient services. An elderly person who is eligible for coverage under Part A may receive Part B coverage by paying monthly premiums. But Medicare only covers prescription drugs thev if administered in institutional settings or if they belong to limited drug categories, such immunosuppresives, erythropoiten, oral anti-cancer drugs, hemophilia clotting factors, and some vaccines. In 1998, for example, Medicare paid only one per cent of the total national prescription drug expenditures.²

The Medicare population is particularly vulnerable to escalating costs for prescription drugs because

many elderly individuals live on fixed, limited incomes. Fourteen per cent of elderly Ohioans have incomes of less than 100% of the federal poverty guidelines, compared with 9.9% of non-elderly adults.³ Lack of prescription drug coverage is not a problem limited to the low-income elderly population, however. near-poor, those with incomes between 100 and 150 percent of the federal poverty guidelines, have the lowest rate of coverage (40%) among the elderly, in part because some of the poorest elderly receive coverage under Medicaid. Lack of prescription drug coverage is also a problem for 40% the over of Medicare beneficiaries who have incomes below 200% of the federal poverty guidelines.⁴ (See Appendix Figure 1.) Most of these beneficiaries rely on Social Security as their main source of income.⁵ (See Appendix Figure 2.) Additionally, one in four elderly persons with higher income (greater than 400% of the federal guidelines) has poverty prescription drug coverage.⁶ Recent surveys revealed that 16% of elderly individuals have failed to fill a prescription because of cost, 21% have had to give up things to buy prescription drugs, and 9% have had to give up basic necessities, such as food, to pay for medicine. (See Appendix Figure 3.)

There are a number of sources of prescription drug coverage for

Medicare beneficiaries. By far, the largest source of coverage employers (31%),followed by Medicaid (11%), Medigap (10%), Medicare HMOs (8%), and other sources (9%).8 (See Appendix Figures 4 and 5.) Sources of coverage for Medicare beneficiaries vary significantly by income. (See Appendix Figure 6.) There are other ways that seniors obtain medications as well, such as through a drug manufacturer, physician, discount card program, or purchase outside this country. While not technically prescription drug coverage, these sources do provide needed medications either for a discount or free.

Even for those who have prescription drug coverage, stability of that coverage is an issue. number of Medicare beneficiaries finding, losing, or switching coverage during the year is almost as large as the number with stable coverage.9 Only slightly more than half (53%) of Medicare beneficiaries had drug year. 10 entire coverage for an Medicare beneficiaries who are near poor, very old, and living in rural areas are most likely to be without drug coverage. Simple geography can boost the probability of drug coverage by 300%, with the western United States having the highest rates of coverage, while the Midwest has the lowest. Residence in a state that operates a pharmacy assistance program increases the probability of coverage by 60%. Residence in an urban versus a rural area increases the

probability of coverage by 90%.¹¹ Those who are 85 years of age or older are more likely to lack drug coverage than those between the ages of 65 and 74 (38% vs. 29%).¹² (*See Appendix Figure 7.*)

Employer-sponsored coverage

At 31%, employers are by far the largest source of prescription drug coverage for Medicare beneficiaries. It is estimated that employers spent billion on retiree nearly \$15 prescription drug benefits in 2000.¹³ Employer coverage is a relatively stable source of coverage and the benefits are usually more generous than those available under Medigap or a Medicare HMO. In general, Medicare beneficiaries with higher incomes who have prescription drug coverage are covered by an employer. Half of Medicare beneficiaries with incomes above 200% of the federal poverty guidelines in 1996 had employer-sponsored supplemental coverage, compared to only a quarter of the near-poor and 8% of the poor.

Despite the significance of employer coverage as a source of prescription drug coverage, there has been a steady erosion of retiree health benefits during the 1990s. The number of large employers offering health benefits to their elderly retirees declined from 80% in 1991 to 66% in 1999. The statistics are even bleaker with respect to smaller firms. Only 22% of firms with 500-1000 employees offered retiree health benefits in 1999, and only 8% of

firms with less than 200 employees offered retiree health benefits in 1998.15 Some drug coverage is provided in 80% of retiree health benefit plans. 16 In addition, a recent employer survey revealed that over 40% of employers are considering cutting back on prescription drug Medicare-eligible coverage for retirees in the next 3-5 years. (See Appendix Figure 8.) The impact of the decrease in employer coverage has, to a great extent, not yet been felt, because most firms that have dropped coverage have done so for the employees planning to retire in the future, not current retirees.

The decline in employer coverage has been attributed to two developments in the healthcare delivery system: (1) the widespread use of managed care plans, such as health maintenance organizations (HMOs) and preferred provider organizations, which offer a distinct drug benefit that requires only a copayment rather than a deductible and coinsurance percentage, and (2) the growth in the use of pharmacy benefits managers. An estimated 78% of people with non-Medicaid prescription drug coverage are in plans managed by a pharmacy benefits manager, while the rest are in plans managing their own benefits or in unmanaged plans. 18

Many employers that have retained prescription drug coverage for retirees have tightened eligibility rules by, for example, requiring employees 55 and older to have between 10 and 15 years' employment to qualify for benefits (30% in 1991, 49% in 1998)¹⁹ or requiring Medicare-eligible retirees to pay the full cost of their benefits (28% in 1995, 40% in 1999).²⁰

Medicaid

Eleven per cent of Medicare beneficiaries in 1996 received prescription drug coverage through Medicaid. Medicaid is an entitlement program for low-income people financed by federal and state funds and administered by the states federal according to guidelines. Coverage for outpatient prescription drugs is an optional Medicaid benefit. but all Medicaid programs currently offer prescription drug coverage. Pharmaceuticals are a rapidly growing part of total Medicaid spending. Medicaid spending for prescription drugs tripled between 1990 and 1998. In 1998 alone, an average of \$893 was spent for each elderly Medicaid beneficiary for prescription drugs.²¹

Medicaid coverage is generally available only to those with very low incomes. In 1996, half of the Medicare beneficiaries with incomes below the federal poverty guidelines were covered by Medicaid; the other half did not qualify. Medicare beneficiaries who also qualify for Medicaid are known as "dual eligibles."

In general, Medicaid must cover all prescription drugs manufactured by a company that has

signed a drug rebate agreement. For a state to receive federal Medicaid matching funds, the manufacturer must agree to rebate a portion of drug payments back to the government in return for Medicaid covering the drug products manufactured bv company. Additionally, federal law allows states to establish a formulary to limit coverage of specific drugs. Drugs not included in the formulary must be available with authorization, which requires that physicians or pharmacists obtain official permission before dispensing a particular drug.

There is considerable variation in Medicaid drug benefits from state to state. Most Medicaid programs enroll at least some currently beneficiaries in managed-care organizations. In 1992, only 12% of Medicaid beneficiaries were enrolled in managed care. That number had increased to 54% by 1998, but many states that use Medicaid managed care have excluded prescription drugs from the contract.²³ As managed care an increasing share grows, Medicaid expenditures for drugs shifts from fee-for-service payments to prepaid arrangements. Most states place limits on the number, quantity, and refills of all prescriptions. Thirtytwo states require co-payments for prescription drugs ranging from 50¢ to \$3 per prescription for certain beneficiaries.²⁴

Medigap policies

Medicare beneficiaries may individual Medicare buy supplemental policies, known as from private Medigap, insurers. Medigap policies provided prescription drug benefits for about 10% of Medicare beneficiaries in 1996. By 1999, of the six million beneficiaries with standard Medigap policies, only 9% had drug coverage. Medigap is not as stable a source of coverage for Medicare beneficiaries as employer-sponsored coverage, because 48% of those who have drug coverage from this source have it for only part of the year.²⁵

By federal law, an insurer selling Medigap must offer one or more of ten standardized policies. known as Plans A-J.²⁶ Although the plans are established by federal law, states regulate how the plans are priced and offered to the public. Of the ten plans, only three, Plans H-J, cover some drug costs. Plans H and I have a \$250 deductible and cover 50% of drug costs up to \$2,500. Plan J covers 50% of drug costs up to \$6,000.²⁷ Many carriers do not offer the plans with drug coverage and those that do may refuse to cover applicants perceived to be high risk. Insurers must accept an elderly beneficiary during a limited open enrollment period that ends six months after the beneficiary first qualifies for Medicare, as well as a beneficiary who lost supplemental coverage as a result of

termination of a Medicare HMO contract.

There is wide variation in premiums for Medigap policies, which have risen an average of 20.2% between 1998 and 2000 alone.²⁸ Annual premiums range from about \$1,400 to as much as \$4,700 depending on where beneficiary lives, the type of coverage the plan offers, and the beneficiary's age.²⁹ Premiums for plans with prescription drug coverage are much higher than for other Medigap plans, both because of the drug benefit itself and because the drug benefit attracts beneficiaries who incur higher medical expenses. For example, premiums individuals aged 65 averaged \$1,000 higher for Plan J than Plan F, the plan that is most similar to Plan J but does not have a drug benefit. The gap between premiums for Plans F and J widens for plans that use attained-age rating. which means that premiums increase as policyholders age.30 Attained-age rating is prohibited in twelve states.

A recent study found that individuals pay an average of 37% more for Medigap policies with drug coverage than they did three years ago, compared with a 15.5% increase in premiums for policies without drug coverage. The same study found that the average annual cost nationally for Medigap policies with drug coverage ranged from \$2,347 to \$3,065 based on quotes for a 65-year-old male.³¹ In some cases, the increased premium

for purchasing a Medigap policy with drug coverage was greater than the maximum value of the drug benefit.³²

Some Medigap plans have begun to use pharmacy benefits managers to negotiate lower drug prices for H, I, and J policyholders at preferred pharmacies and offer pointof-sale co-payments. But most Medigap plans are traditional indemnity plans that reimburse participants for their drug expenditures after the fact and do not manage the benefit.

<u>Medicare+Choice Plans</u>

Medicare+Choice plans, also referred to as M+C plans or Medicare risk HMOs, are a growing source of prescription drug coverage Medicare beneficiaries, assisting 8% of them in 1996 and as many as 12% in $2000.^{33}$ When a Medicare beneficiary chooses to enroll in an M+C plan offered by an HMO, the HMO receives a fixed monthly payment from Medicare to furnish all Medicare covered services to the individual. If the HMO projects that it can provide those services at a cost less than the Medicare payment, it must share the savings with its enrollees by providing supplemental benefits. That is how Medicare HMOs have been able to offer drug coverage in recent years. Medicare HMOs provide drug coverage at a much lower premium than enrollees would have had to pay for an equivalent Medigap plan and, unlike Medigap, M+C plans generally must

accept all applicants regardless of health status or age. In Ohio, the median annual M+C premium is \$432.96.³⁴ Consequently, M+C plans are attractive for beneficiaries willing to accept the accompanying restrictions on provider choice. Nearly one-third (29%) of those who have drug coverage through an M+C plan, however, have coverage for only part of the year.

It is unclear whether M+C plans will continue to be a reliable source of drug coverage for Medicare beneficiaries. The number of plans participating in the program has declined in recent years. In Ohio, for example, several Medicare HMOs discontinued or restricted their operations as of January 2001, action that the Ohio Department Insurance expected to result in more 70,000 Ohioans losing than coverage.35 According to Department, for the year 2001, there are no M+C HMO plans available in 39 of Ohio's 88 counties. The share of M+C enrollees with drug coverage as a basic benefit declined from 84% in 1999 to 78% in 2000.³⁶ Appendix Figure 9.) Eleven states did not have access to any plan offering drug coverage in 2000.³⁷ In Ohio, 15 of the 22 plans participating in the M+C program offer a drug benefit as part of their basic option.³⁸

Plans that continue to offer prescription benefits are starting to restrict them by capping benefits and increasing co-payments.³⁹ In 2000, 11% of Medicare beneficiaries

enrolled in an M+C plan were in plans with no annual prescription benefits cap, 24% were subject to a cap of \$1500 or less, and another 25% had a cap of \$750 or less per enrollee.⁴⁰ (See Appendix Figure 10.) Although one million people lived in areas in 1999 where M+C plans offered no co-payments prescription drugs, all beneficiaries were subject to co-payments in 2000.⁴¹ Additionally, the number of beneficiaries living in areas where co-payments on brand-name drugs averaged at least \$25 has more than tripled, affecting one million people in 2000.⁴²

Other sources

State senior pharmacy assistance programs

senior State pharmacy assistance programs provide some assistance to low-income Medicare beneficiaries who are not eligible for Medicaid. According to the National Conference of State Legislatures, as February 2001. 26 states have authorized some type pharmaceutical assistance program, 22 by legislative enactment and four by executive action. Twenty-four of the programs are in operation. The programs vary widely in terms of structure, eligibility, and benefits. While most provide a direct subsidy low-income seniors. other approaches include discounts, tax credits, and private insurance models. Specifics regarding ten of these programs will be discussed in Part V of this report.

<u>Miscellaneous federal and</u> <u>state programs</u>

citizens' Some senior prescription drugs are covered through the federal Department of Veterans Affairs (VA). Eligibility for services functions as the equivalent of insurance but only for prescriptions written by a VA physician. When a VA physician prescribes a drug, a veteran may fill the prescription at a VA pharmacy or through a VA mail-order program, usually with only a small copayment. Under the Veterans Health Care Act of 1992, drug manufacturers must make their brand-name drugs available to federal agencies at the federal supply schedule price in order to participate in the Medicaid program. The act requires that the federal supply schedule price for the VA be at least 24% below the price that the manufacturers charge the wholesalers. Although most federal prescription drug purchases are made at federal supply schedule prices, in some cases, federal agencies are able to purchase drugs at even lower prices. For example, the VA has used national contracts awarded on a competitive basis for specific drugs considered therapeutically interchangeable that allow the VA to get larger discounts by channeling volume certain greater to pharmaceutical products.⁴³

A very small number of Medicare beneficiaries are assisted in drug purchases by the Civilian Health and Medical Program of Uniformed Services (CHAMPUS) or workers' compensation programs.

Other individually purchased coverage

Some Medicare beneficiaries purchase individual supplemental coverage that is not a Medigap policy, such as private long-term insurance or a drug-only policy. There is no reliable information on the number of these policies or value of the benefits they provide.

Industry programs

Some Medicare beneficiaries without prescription drug coverage may receive certain drugs for free. manufacturers operate Many programs that make certain drugs available to uninsured people meeting specified eligibility criteria. The Pharmaceutical Research and Manufacturers of America, an association that represents drug manufacturers, estimates that the programs for which they have data filled 2.7 million prescriptions for nearly 1.5 million people in 1998. But these drug programs are not widely publicized and often require both the patient and physician to file extensive paperwork, which differs from program to program.

Manufacturers commonly distribute samples to be dispensed by physicians and clinics. IMS Health reported that from September 1998 to September 1999, companies gave drug samples with a retail value of about \$7 billion to office-based physicians. Physicians often distribute these samples to their patients to defray prescription costs.

Miscellaneous

Other individuals without coverage may purchase discount cards from insurers or groups such as the American Association for Retired Persons that enable them to receive a percentage discount for prescriptions purchased participating at pharmacies. Many pharmacies also offer discounts to seniors, either on their own, or through programs such as Ohio's Golden Buckeye Card program. There is no centralized data on the number of people taking advantage of these discounts or the value of the discounts they receive.⁴⁴

There is also highly publicized anecdotal evidence concerning senior citizens who travel to Canada to obtain less expensive prescription drugs. Although buying foreign drugs is not new, recently several lawmakers from states like Maine, Michigan, Minnesota, North Dakota,

and Vermont, as well as advocacy organizations, have sponsored organized bus runs of senior citizens to the Canadian border, where they visit a physician and then can purchase up to a six-months supply of prescription drugs.

In Vermont, a network of physicians called the United Health Alliance assists doctors in obtaining drugs from Canada for patients. The Alliance has published a form on its website that a doctor can fax to an Ontario pharmacy with the patient's credit card number. The pharmacy ships the drugs to the doctor's office, and the patients retrieve the unopened package from their doctor. The practice circumvents federal regulations that prohibit the reimportation of drugs because the Canadian pharmacy is merely filling a physician's supply order, and the physician is simply passing on a package, not dispensing drugs. The program started last summer, but there is no information on how many physicians have participated. There is anecdotal evidence that some Medicare beneficiaries share medication, split pills, or skip doses of medication to save money, but data exists reliable again, no concerning the prevalence of these methods of saving on out-of-pocket prescription drug costs.

III. TRENDS IN PRESCRIPTION DRUG EXPENDITURES

In 1980, expenditures in the United States for prescription drugs totaled \$12 billion. By 1990, prescription drug expenditures had risen to \$38 billion. 45 The Office of the Actuary in the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services recently released its figures for National Health Expenditures for 1999. In that year, growth in spending prescription drugs continued to outpace spending growth for other health services, with total spending reaching \$99.6 billion. The largest increase in spending was for antidepressants. followed bv cholesterol reducers, anti-ulcerants, antihistamines, oral and hypertensive drugs.⁴⁶ HCFA projects that prescription drug spending will rise at an average rate of 12.6% every year until 2010, estimating that expenditures will reach \$116.9 billion in 2000, \$135.7 billion in 2001, and \$366 billion in 2010.⁴⁷

National prescription drug spending for the Medicare population is increasing rapidly, from about \$30 billion in 1996 to an estimated \$56 billion in 2001.⁴⁸ From 1990 to 1998. Medicaid spending for prescription drugs for elderly doubled.49 enrollees more than Prescription drug expenditures for the elderly are projected to reach \$113.6 billion by 2010.⁵⁰ The Congressional Budget Office recently estimated that

seniors will spend \$1.5 trillion on drugs in the next ten years, 30% more than it projected just last spring.⁵¹

Expenditures for prescription still comprise drugs small a percentage (9.4%) of personal health care expenditures, but prescription drug spending was one of the fastest growing components of health care in past spending the increasing 16.9% from 1998 to 1999, compared to a 5% increase for all spending.⁵² personal health care Between 1995 and 1998, example, prescription expenditures grew nearly 50%, compared with physician services (14%) and hospital services (10%). (See Appendix Figure 11.) HCFA projects that prescription drug spending will rise to 16% of total personal health care expenditures by 2010, tripling its share of total expenditures since 1980.⁵³

Between 1992 and 1996, the total spending on prescription drugs per Medicare beneficiary increased at an annual rate of 9%.⁵⁴ The average annual per capita drug expenses for the Medicare population increased from \$559 in 1992 to an estimated \$1,205 in 2000 and are projected to reach \$2,810 by 2010.⁵⁵

In 1996, prescription drugs represented 18% of Medicare beneficiaries' total out-of-pocket health care spending, and the average Medicare beneficiary paid 47% of all prescription drug costs out of pocket. Levels of spending vary from state to state based on the state's level of Medicare payments to Medicare+Choice plans in the state, the state's Medicaid eligibility levels, the existence of a state pharmacy assistance program, and insurance regulations. In Ohio, 14% of all out-of-pocket health care costs for Medicare beneficiaries were for prescription drugs. and Ohio beneficiaries paid 52% of their drug costs out of pocket.⁵⁶ Relative to expenditures for other household consumer goods services. and however. prescription and nonprescription drugs play a very small role, constituting only 2.7% of out-of-pocket consumer spending.⁵⁷

The annual average out-ofpocket expense for prescription drugs for the Medicare population increased from \$390 in 1996 to an estimated \$686 in 2001.⁵⁸ Nearly a third of Medicare beneficiaries are expected to incur less than \$250 in out-ofpocket expenses, while 8% will have drug expenses of at least \$4,000. These 8% account for over a third of drug spending for all Medicare beneficiaries. Twenty per cent of beneficiaries are expected to spend more than \$1,100 out of pocket.⁵⁹ (See Appendix Figure 12.)

The impact of escalating drug spending is felt not only by consumers, but also by private third-party payers, like employers and health plans. Prescription drugs alone accounted for 37.6% of the

entire growth in benefit outlays by private third parties between 1993 and 1998, and drugs rose from 7.6% to 13.8% as a percentage of private third-party benefit payments. During that same period, drug spending by private third parties grew 130%, while consumer out-of-pocket spending grew only 17%.

The reasons for the dramatic rise in prescription drug spending are varied. but can basically categorized as increases attributable to pricing and increases attributable to utilization. Among the causes of escalating prescription drug prices are (1) price increases for existing drugs and (2) the prevalence of new drugs in the marketplace that either replace older drugs in the same therapeutic category or represent innovations in drug therapy. Factors resulting in increased utilization of prescription drugs (1) demographic changes in society as the population ages and more aged people with chronic conditions live longer, requiring long-term drug therapy, (2) an increasing number of persons enrolled in managed care plans that provide drug coverage for a minimal co-payment, and (3) a change in federal policy in 1997 enabled pharmaceutical that manufacturers to advertise directly to consumers through mass media. One report by The Henry Kaiser Family Foundation attributes 57% of the increase in prescription drug spending since 1993 to pricing-related factors and 43% to increased utilization. 61 (See Appendix Figure 13.)

Escalating prices of prescription drugs

From 1992 through 2000, the average cost per prescription for senior citizens grew from \$28.50 to \$42.30, an increase of over 48%. The average cost per prescription is projected to reach \$72.94 by 2010.⁶² The average annual increase in the retail price of a prescription was 6.7% from 1991 to 1998, exceeding both general inflation (2.6%) and inflation medical care (4.6%), according to the Consumer Price Index. Retail prescription drug price increases differ from manufacturer price increases because the retail price reflects not only manufacturer price increases for existing drugs but also shifts in use from older, cheaper drugs to newer, more expensive drugs. Prices of prescriptions for brand-name drugs increased more rapidly (8.8% per year) than for generic drugs (6.5% per year). (See Appendix Figure 14.) Brand-name drugs representing new alternatives for disease treatment typically cost more than their precursors, and a prescription for a brand-name drug is on average triple the price of a generic drug. 63 For example, in 1998, according to the National Association of Chain Drug Stores, the average brand-name price \$61.33, while the average generic price was \$18.41.

It is important to note that there is no one price for a specific drug product. Research-based drug companies have considerable latitude in setting prices for their various products. In the prescription drug market, there are multiple customers, distribution channels. multiple multiple prescription drug reimbursement systems, multiple purchasing arrangements, multiple methodologies, multiple pricing marketing techniques, and multiple cost control tools. For example, the average price differential between the price that would be paid by a senior citizen and the price that would be paid by the drug company's most favored customers is 134% for the five drugs with highest sales to seniors 64

Rising prices of prescription drugs are caused by two primary factors: (1) price inflation, and (2) the entrance of new, higher priced drugs on the market. Recent price increases are related more to changes in the type of drugs dispensed than to manufacturer price increases for existing drugs. Approximately 18% of the increase in drug spending is attributable to price increases for older drugs, while 39% of the increase is caused by the use of newer, more expensive drugs.

<u>Increases in prices of existing</u> <u>drugs</u>

Price inflation refers to price increases for existing drugs. Manufacturers have increased the

price of existing prescriptions at an average rate of 4.2% annually for drugs introduced in 1991 or earlier.⁶⁷ From January 1994 through January 2000, the prices of the 50 drugs most widely prescribed for seniors increased by twice the rate of inflation. 68 Attached as Appendix Figure 15 is a chart describing the five most expensive drugs of those most commonly used by senior citizens that includes the cumulative price changes from 1994-2000. Increases in the price of existing drugs have not been a major factor in recent trends in drug expenditures and price increases. The shift to newer, more expensive drugs and increased utilization have been far more significant.

Shift to use of newer, more expensive drugs

In recent years there has been an explosion of scientific knowledge, resulting in a significant increase in new medicines that prevent and treat disease and improve quality of life. Advances in scientific knowledge and technology have enabled researchers to target more complex diseases, providing treatments for conditions that could never before be treated. As the biotechnology revolution advances. our understanding disease and therapy is undergoing a profound shift. Before completion of the Human Genome Project, there were 500 known targets for drug innovation; now that number has increased to at least 3,000.⁶⁹ The study of genetics has revolutionized

the way pharmaceuticals are being developed. Proteins, not chemicals, are the building blocks of the new generation of drugs.

In some instances, new drugs have replaced other health care interventions. For example, new medications for the treatment of ulcers have virtually eliminated the need for some surgical treatments. Other new drugs provide better outcomes or fewer side effects than earlier medicines. As a result of these innovations, the importance of drugs as part of health care has grown.

The Pharmaceutical Research and Manufacturers Association of America (PhRMA) estimates that manufacturers spent \$26.4 billion on research and development in 2000, more than three times the \$8.4 billion that the industry spent in 1990. (See Appendix Figure 16.) Every year since 1980. pharmaceutical companies have increased research spending bv double digits, except in 1994 and 1995. PhRMA attributes the flattened spending for those two years to the price controls proposed as part of the Clinton health care reform plan. In addition to industry spending, the National Institutes of Health, part of the United States Department of Health and Human Services, spent \$17.8 billion on research and development in 2000. President Bush's FY 2002 budget allocates over \$23 billion to the National Institutes of Health. 71

According to an industry survey conducted by PhRMA, nearly 700 new medicines are development for seniors, including 350 for cancer, 122 for heart disease and stroke, 28 for respiratory and lung disease, 26 for Alzheimer's disease, 26 for depression, 25 for diabetes, 16 for Parkinson's disease, osteoporosis, 14 for 11 for rheumatoid arthritis. 11 for gastrointestinal disorders, and 9 for prostate disease. One hundred new drugs were approved for marketing in 1997 and 1998. Some breakthrough treatments, while others are incremental improvements over existing therapies, often referred to in the industry as "me too," drugs.

Newer drugs contribute significantly to the increase in prescription drug expenditures, because thev are much more expensive than older drugs. In 1998, the average price per prescription for new drugs (those introduced in 1992 or later) was \$71.49, while the price for previously existing drugs was \$30.47.⁷² Moreover, there is no real evidence that the use of these drugs decreases other medical costs, even though it may replace more expensive medical treatment, because since patients live longer, short-term savings may not equal the long-term spending increase over the life of the It is possible that some patient. savings realized by the use of these newer drugs may not show up in health care expenditures, because, for example, anti-psychotics and other psychiatric drugs could impact corrections, mental health, and welfare spending more than health care spending.⁷³

Drug Patents. On average, it costs \$500 million and takes 12 to 15 years to bring a new drug to market.⁷⁴ Despite those costs. Fortune magazine has ranked the pharmaceutical industry as the most profitable in the United States. (See Appendix Figure 17.) Companies that are successful in discovering drugs obtain patents. Patents are granted by the United States Patent and Trademark Office and give the owner the right to exclude others from making, using, or selling an invention for 20 years from the date of application. Patents do not grant complete monopoly power in the pharmaceutical industry, because other companies may introduce therapeutic alternatives. The first drug using a new mechanism to treat an illness (often referred to as a "breakthrough drug") usually has between one and six years before a therapeutically similar patented drug (a "me too" drug) is introduced. Research-intensive manufacturers try to price their products so that the bulk of their research and development recovered before costs are competitors enter the market.

According to HCFA, nearly \$27 billion in brand-name drugs with annual revenues of \$200 million or more are likely to lose patent protection during 2004-2005, which compares with \$15 billion in brand-name drugs likely to lose patent

protection in 2000-2003.⁷⁵ Some of the top-selling drugs facing upcoming patent expirations include Prozac, Pepcid, Augmentin, Claritin, and Prilosec.⁷⁶ HCFA projects that the likely appearance of generic equivalents of these drugs will depress spending growth slightly in the coming years.

Regulatory review. The effective life of a manufacturer's 20year patent is reduced by the time it takes to obtain approval of the drug from the federal Food and Drug Administration (FDA). manufacturer is required to conduct extensive clinical trials of a new drug over a period of years to determine that the product is both safe and effective for its intended therapeutic application. After the clinical phase of research and development is concluded, the manufacturer can submit a new drug application to the FDA for regulatory review. average number of new approved by the FDA per year has increased from 19 in the early 1980s to 38 in the late 1990s, and the length of time for FDA approval of new drugs has decreased from an average of 33 months in 1986 to 12 months in 1988. Accelerated review has generated some criticism in recent years due to several highly publicized drug recalls.

Despite shortened FDA review times, the time it takes to develop a drug has lengthened in recent years, primarily due to (1) larger clinical trials, (2) the

increased use of pharmacoeconomic studies, (3) patient recruitment/retention issues, and (4) a focus on chronic and complex conditions. The average effective life of a patent for new molecular entities approved in the late 1990s was 9.5 years. With patent extensions, the total estimated patent life may reach 13.9 to 15.4 years.⁷⁷

Generic Drugs. When the patent on a drug expires, generic drugs can enter the market. generic equivalent is essentially a drug that is chemically identical to brand name and is also bioequivalent.⁷⁸ Due to several factors, the number of generic drugs sold has increased dramatically in recent years. First, the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act) made it easier and less costly for manufacturers to enter the generic market. The Hatch-Waxman Act permits generic drugs to come to market as soon as a drug patent expires, rather than requiring clinical trials.

Many states have passed drug substitution laws that allow pharmacists to dispense a generic drug even when the prescription calls for a brand-name drug. Moreover, government and private health plans actively promote generic substitution. Although these efforts have increased the volume of generic drugs sold, concerns there remain that manufacturers attempt to forestall the

introduction of generics. As recently as April 2001, the Federal Trade Commission announced that it is investigating allegations that certain major pharmaceutical companies have paid smaller rivals to delay generic competition.

Although almost 45% of all prescriptions dispensed are generic drugs, they account for less than 20% of prescription sales in dollars because they are expensive. (See Appendix Figure 18.) Brand-name drugs are, on average, three times more expensive than generic drugs, and researchbased companies do not immediately lower the price of brand-name drugs in reaction to the introduction of generics. Sales of generic drugs have not kept pace with sales of brandname drugs as innovative drugs carrying higher prices replace older drugs. Physicians and consumers who attach great importance to brand names may be willing to demand and pay more for a research-based drug than others. Additionally, as the period of patent protection nears expiration, manufacturers move the market share to newer drugs. example. for treatment of gastrointestinal diseases, the indirect inhibitor Zantac went off patent in 1997. Within one year, its market share fell to about 15% and to 10% within two years.⁸⁰ But Zantac's loss of market share was not primarily due to the introduction of a generic equivalent. Rather, the new branded proton pump inhibitors Prilosec and Prevacid have largely replaced

Zantac and its generic equivalent, ranitidine, with the two new branded drugs attaining a 63% market share in 1998.⁸¹

Increased utilization of prescription drugs

Utilization. which can measured as the overall number of prescriptions dispensed annually or on a per capita basis, is responsible the increase in for 43% of prescription drug spending in recent vears.⁸² Utilization of prescription has accelerated rapidly. Between 1992 and 1998, the number of prescriptions dispensed increased by 37%, compared to 6% growth in the U.S. population.⁸³ The National Association of Chain Drug Stores (NACDS) projects that the total prescription sales volume for 2000 was 3.15 billion, up 5.5% from 2.97 billion in 1999, which was 9.1% more than the 2.73 billion prescriptions dispensed in 1998. NACDS estimates that the number will increase to 4 billion in 2005.84

On average, each American used about ten prescriptions in 1998. But the average number of prescriptions per elderly person has grown from 19.6 in 1992 to 28.5 in 2000 and is expected to reach 38.5 by 2010. According to HCFA, nearly nine out of ten Medicare beneficiaries report using prescription drugs on a regular basis. Utilization rates for women are consistently higher than those for men. Overmedication among the elderly population is a

concern. Research released in April 2001 by the National Institute on Drug Abuse, part of the National Institutes of Health, estimates that 17% of people age 60 and older misuse or abuse prescription drugs. 88

There are several factors driving increased utilization ofprescription drugs, including the aging of the U.S. population, increased third-party payment for drugs under managed care, the advent drug-intensive of disease management programs, an increased number of available prescribers resulting from legislation granting authority prescriptive to physicians such as nurse-practitioners and physician assistants. and advertising targeted directly at consumers.

<u>Demographic factors resulting</u> in rising drug use

The U.S. population is aging. According to a recent profile conducted by the AARP, there were 33.9 million Americans age 65 or older in 1996.89 The federal that government estimated number would rise to 34.4 million by 2000 and then increase rapidly as the "baby boomers" reach age 65, more than doubling 1996's numbers by 2030. (See Appendix Figure 19.) In 2000, 12% of the U.S. population was 65 or older. That number is projected to reach 19.6% by 2030.90 (See *Appendix* Figure Additionally, the senior population itself is getting older. In 1996, a person reaching age 65 had an average life expectancy of 82.7 years. 91

People age 65 and older use a disproportionate amount of medication as compared with the general population, consuming 34% of all prescription drugs. They also account for 42 cents of every dollar drugs.⁹² on prescription Prescription use triples between the ages of 45 and 75, in part due to the increased incidence of acute and chronic conditions in older adults. According to a 1998 survey by the Ohio Department of Health, more than 57% of Ohio's senior citizens report that they have at least one condition. 93 chronic This considerably better than the national average, in which nearly seven in ten Medicare beneficiaries report having two or more chronic conditions. including arthritis (56%),hypertension (53%),and heart disease (36%).⁹⁴ (See Appendix Figure 21.) In many cases, outpatient drug therapy has come to substitute for inpatient hospital care to manage chronic conditions. Attached as Appendix Figure 22 is a list of the 30 prescription drugs most commonly used by senior citizens as of January 31, 2000.

<u>Managed care cost shifting</u> <u>and low co-payments increase</u> <u>prescription volume</u>

Expenditure increases for prescription drugs have been affected by a profound shift in the share of

prescription expenditures paid for by private insurance. In 1965, private insurance covered only 3.5% of prescription drug spending. This increased to 20.1% by 1980 and by 1998 had reached 52.7%. State the same time, out-of-pocket spending has declined dramatically from 92.6% in 1965, to 66% in 1980, and 26.6% in 1998.

In addition, managed care has transformed the pharmaceutical market. In the past, insured individuals purchased drugs at retail pharmacies at retail prices and then sought reimbursement from their insurer. Under managed care, thirdparties influence which drug is purchased, how much is paid for it, and where it is purchased. conventional insurance plans, also known as indemnity or fee-forservice plans, enrollees can receive care from any physician or hospital they choose, but must pay some initial amount of health care spending (the deductible) and an additional percentage of costs beyond that (coinsurance). Providers are paid on a fee-for-service basis. In contrast, managed care plans encourage beneficiaries to use a limited network of health care providers and often reimburse physicians a fixed monthly amount per enrollee. Enrollees pay a amount (co-payment) fixed services. It is estimated that 26% of full-time workers with health insurance were enrolled in managed care plans in 1988. By 1995, that number had increased to 61%. The number of Medicare beneficiaries

enrolled in managed care is smaller, but rising.

The impact of managed care on prescription drug spending has been mixed. On the one hand, many health plans hold down costs by managing their drug benefits through negotiated discounts and formularies, but on the other hand, low copayments may lead to greater use of drugs and their policies may favor drug use as an alternative to costlier treatments. 96

Many employers, managed care organizations, and other insurers use a pharmacy benefits manager to their drug benefits. manage Pharmacy benefits managers currently manage an estimated 71% of the volume of prescription drugs dispensed though retail pharmacies that are covered by private third-party pavers. 97 Pharmacy benefits managers provide a number of services, including negotiating rebate contracts with drug manufacturers, developing and maintaining formularies, implementing programs to promote the use of generic drugs, managing drug utilization bv requiring prior authorization in certain circumstances, profiling physician prescribing practices to encourage the use of best practices, negotiating pharmacy network offering contracts, health management programs, and operating mail service pharmacies. (See Appendix Figure 23.)

Pharmacy benefits managers often negotiate rebates with drug manufacturers in exchange for their use of incentives for patients to use the manufacturers' drugs. Rebates do not affect the price of the drug, but they do lower the health plan's overall costs. Information about the prevalence, relative size. characteristics of rebate agreements is limited because they are confidential, contracts between private manufacturers and pharmacy benefits managers, but rebates are estimated to range from 2% to 35%, depending on the contract and type of drug. 98

A formulary is a common price control technique used by managed care organizations. It is a list of drugs grouped by therapeutic class and may be open, closed, or tiered. Under an open formulary, consumers suffer no penalty if physicians prescribe a non-preferred Closed formularies, which drug. provide reimbursement only for preferred drugs. generated have consumer dissatisfaction. example, the TennCare Program, which replaced Tennessee's Medicaid program in 1994, provides medical care including prescription services to enrollees through 12 managed care organizations that use restrictive formularies. A 1996 survey of physicians participating in TennCare found that 98% said they have been unable to prescribe their drug of choice because it was not covered by formulary, 95% had been advised to a patient's prescription because it was not covered by the

formulary, and two-thirds of physicians that were required to switch a patient's prescription reported that patients suffered problems such as worsening health or side effects as a result of the switch. 99

The fastest growing trend is the use of a formulary that covers all drugs but varies beneficiary costsharing for different drugs. As of August 2000, Scott-Levin Inc., a pharmaceutical consulting firm. reported that 80% of HMOs and pharmacy benefits managers have adopted a three-tiered co-payment structure, requiring different copayments for generic drugs, brandname drugs included in the formulary, and brand-name drugs that are not included in the formulary. Reduced co-payments have also been used to encourage consumers using maintenance drugs for chronic conditions to obtain them from particular suppliers, such as a mailorder pharmacy. 100 Some managed care organizations even encourage patients to split higher level doses of medications in half by offering lower co-payments.

To encourage people to enroll and accept a limited network of providers, managed care plans charge lower co-payments than traditional fee-for-service plans. The resulting transfer of responsibility for payment to third parties tends to increase the use of physician services, which in turn increases the demand for drugs. It is estimated that 60% of physician visits result in a prescription. In a

study of elderly individuals in Pennsylvania, prescription coverage increased drug use by approximately 3% for every 10% reduction in outof-pocket cost to consumers. 101 Managed care plans also generally have more extensive drug coverage than most fee-for-service plans. Therefore, although some managed care techniques put downward pressure on drug spending by lowering the prices paid for drugs and promoting the use of generic drugs, others, such as lower co-payments, tend to increase drug use and spending. 102

<u>Direct-to-consumer advertising</u> <u>increases consumer demand for</u> <u>specific medications</u>

As mentioned previously, it costs nearly \$500 million to develop a new drug from the laboratory through the FDA approval process. Once a drug has been approved for marketing, the manufacturer may spend an equal amount promoting the drug to medical professionals and consumers. The explosion of directto-consumer advertising contributed significantly to increased utilization of prescription drugs in recent years. For example, the ten drugs most heavily advertised directly to consumers in 1998 accounted for 22% of total increase in drug spending between 1993 and $1998.^{103}$ Compared to 1996, when drug companies spent \$220 million on direct-to-consumer advertising, \$1.13 billion was spent in 1999, and

spending is projected to exceed \$2 billion for 2000. 104

To stimulate the use prescription drugs, manufacturers promote them in several ways. the largest share promotional spending (52%) is for the distribution of free drug samples to physicians and hospitals, followed by "detailing" (31%), in which a representative makes personal selling visits to physicians, and advertising in medical journals (4%).¹⁰⁵ Pharmaceutical companies also have played a growing role in sponsoring continuing medical education and in contributing to medical literature by ghostwriting articles and paying doctors to submit them to medical journals. 106

In 1983, the FDA issued a moratorium on direct-to-consumer advertising while studies were conducted to assess its potential impact. The ban was lifted in 1985, and companies were allowed to directly advertise their products to consumers, provided that the ads did not make false or misleading claims and included balanced a representation of the benefits and limitations of the product. Direct-toconsumer advertising remained a small share of overall verv promotional expenditures until 1997. when the FDA issued new guidance regarding broadcast advertising that dramatically increased direct-toconsumer advertising, particularly on television. Today, this type of advertising constitutes 13% of total

promotional spending and is rising rapidly. In 1999 alone, direct-to-consumer advertising grew 40%. 107

Many of the products with the direct-to-consumer highest advertising expenditures are also among the top prescription drugs by sales and number of prescriptions dispensed. 108 Mass media advertising heavily concentrated among relatively few drugs. (See Appendix Figure 24.) Six new medicines first sold in 1999, for example, drove the burst in direct-to-consumer advertising in early 2000--Vioxx. Celebrex, Xenical, Tamiflu, Paxil, and Flovent. 109 Celebrex, an antiarthritic, was the most successful drug launch in history contributed to the rise in overall spending more than any other drug during that time period. 110 A number of the drugs targeted for direct-toconsumer advertising are so-called "lifestyle drugs," which include allergy medications like Claritin, Allegra, and Zyrtec, as well as other medications like Viagra and Propecia. 111

The benefits and drawbacks of direct-to-consumer advertising are the subject of much debate. Proponents claim that it increases patient education and awareness of treatments, particularly in the era of managed care when patients have a less personal relationship with their physicians. They assert that this advertising is an industry response to availability the mass misinformation the on Internet.

Critics argue that direct-to-consumer advertising interferes with the physician/patient relationship by encouraging consumers to demand vastly more expensive drugs than they need or drugs they do not need at all.

The impact of direct-toconsumer advertising on consumers is significant. A recent survey found that 91% of those questioned had seen or heard an advertisement for prescription drugs in the past year, 34% talked to their doctor after seeing or hearing an ad, and 7% asked a doctor to prescribe a specific drug they saw advertised. 112 Appendix Figure 25.) Partly in response to this demand. the Medical American Association's House of Delegates recently adopted a series of recommendations aimed at balancing efforts to curtail drug prices with patient needs, including supporting FDA funding so that the agency can monitor the industry's adherence to the Association's guidelines for direct-to-consumer advertising and advising physicians to self-monitor prescribing patterns that may contribute to spending growth. 113

Although the FDA's 1997 guidance became final in 1999, the future of direct-to-consumer advertising in the broadcast media remains questionable. In March 2001, the FDA announced that it is conducting a review of its guidance concerning television advertising to determine whether drug ads confuse

consumers and adversely impact the relationship between patients and their health care providers. The review will include a survey of doctors and patients.¹¹⁴

Impact of insurance coverage on prescription drug spending and utilization

The presence or absence of insurance coverage makes a major difference in the amount of drugs people obtain and how much they spend on them. Drug spending and utilization are significantly higher for Medicare beneficiaries who have coverage for prescription drugs than for those who do not. Even for the one in five beneficiaries who had coverage only for part of the year, drug spending and utilization were well below the levels of those who had coverage the entire year. 115 But despite using fewer drugs, out of pocket expenses for those without coverage are nearly double the expenses of those with coverage.

<u>Senior citizens without</u> <u>prescription drug coverage have</u> higher out-of-pocket costs

The AARP estimates that Medicare beneficiaries with some drug coverage in 1999 spent 3% of their income on out of pocket drug purchases, compared to 6% for beneficiaries without coverage. Poor beneficiaries spent 9% of their income on prescription drugs, and poor beneficiaries who are not eligible for drug coverage through Medicaid spent 13% of their income

on drugs.¹¹⁷ Beneficiaries with incomes between 175% and 250% of the federal poverty guidelines spend the most out of pocket on prescription drugs.¹¹⁸

In 1998, beneficiaries without drug coverage spent an average of \$546 out of pocket (\$33 per prescription), compared with \$325 for beneficiaries with coverage (\$13 per prescription). Among those in poor health, disparities in out-ofpocket spending were even greater (\$820 vs. \$490). (See Appendix Figure 26.) Out-of-pocket expenses for those without coverage were nearly the same as in 1997 expenses, but expenses increased 18% for those with coverage. The most significant increases in out-of-pocket expenses affected those who obtained coverage through Medicare HMO Medigap plan, with 33% and 21% increases respectively. 119 As a result, beneficiaries Medicare paid average of 33% of their total drug costs in 1998, compared to 31% in 1997. (See Appendix Figure 27.)

The disparity in out of pocket expense between Medicare beneficiaries with drug coverage and those without not only results from non-covered beneficiaries paying the total cost of the drug out of pocket, but also because beneficiaries with prescription drug coverage are often shielded from the full effect of drug costs by discounts negotiated by their insurer. The gap between drug prices for people with direct pay third-party coverage and those without nearly

doubled between 1996 and 1999, from 8% to 15%. One recent study found that, for the 20 drugs most commonly used by Medicare beneficiaries, cash payers (including beneficiaries with indemnity coverage) paid higher prices for 19. 122

<u>Senior</u> <u>citizens</u> <u>with</u> <u>prescription drug coverage use more</u> medications

The higher out-of-pocket costs for Medicare beneficiaries who lack prescription drug coverage do not result from greater utilization by those without coverage. In fact, the opposite is true. 123 In 1998. beneficiaries without drug coverage averaged eight fewer prescriptions per vear than those with coverage. Medicare enrollees without prescription drug coverage filled 16.7 prescriptions in 1998, a 2.4% decline from 1997, while those with coverage purchased just over 24 prescriptions per person, an increase of 9% from 1997. Among those in poor health, beneficiaries who lacked coverage averaged almost 15 fewer prescriptions than their insured counterparts. (See Appendix Figure 28.) Minorities without drug coverage use fewer prescriptions than non-minorities, but for those with coverage, the trend is reversed. 124 Consumers with indemnity coverage may also be sensitive to the number and types of drugs they obtain, because they must pay for their drugs pocket of and then reimbursed. 125

<u>Drug spending is higher for senior</u> <u>citizens with drug coverage</u>

Because more prescriptions are filled for those with drug coverage than for those without, drug spending is higher for insured individuals. In 1998, prescription drug spending was \$453 higher for Medicare beneficiaries with drug coverage than for those without coverage (up from \$330 in 1997). (*See Appendix Figure 29.*) For those in poor health, the disparity was \$910, an increase of 30% in the gap since 1997. 126

Despite negotiated discounts available for insured individuals, the average per prescription price is also higher for covered individuals than those without insurance. In 1996, the average retail price per prescription for covered Medicare beneficiaries was \$36.38, while the average for those without coverage was \$28.92.¹²⁷ This may be because the relatively small difference in out-ofpocket costs between brand-name and generic drugs gives insured individuals little financial incentive to choose generic drugs. There is also some indication that physicians themselves may consider insurance recommending coverage in appropriate treatment and may prescribe different medications to patients with and without drug coverage. 128

There is virtually no research on the nexus between insurance coverage and appropriate or

inappropriate drug use. The presumption is that lack of drug coverage is a barrier to appropriate drug therapy and impacts access to medications. According to one survey, one in ten Medicare beneficiaries without drug coverage reported that not getting needed prescription medicine in the last 12 months. because of the compared to only 2% of those with coverage. 129 **Systematic** underutilization of prescribed medications potentially increases other costs to the health care system in terms of emergency room and hospital admissions, physician visits, and nursing home stays.

Increased utilization of prescription drugs by individuals with drug coverage may also result from self-selection, meaning that Medicare beneficiaries who anticipate large drug expenditures may be more likely to purchase a policy with drug coverage than a beneficiary who does not anticipate those expenditures. It is also possible that lack of coverage reduces exposure to inappropriate drug use and thereby reduces the incidence of adverse drug events or addiction. because covered individuals may be more likely to request drug therapies and, as a result. be prescribed medicine inappropriately.

IV. NEXUS BETWEEN TOBACCO-RELATED ILLNESS AND PRESCRIPTION DRUG EXPENDITURES

An estimated 48 million adults in the United States smoke cigarettes, even though this behavior will result in death or disability for half of all regular users. 130 At 27.6%, Ohio has the third highest adult smoking prevalence in the United States, although cigarette smoking declined by 7.4% between 1984 and 1999.¹³¹ (See Appendix Figure 30.) Nearly 12% of Ohio's seniors were smokers in 1999. 132 Nationally, daily cigarette constitute 15.1% smokers Medicare managed care enrollees between the ages of 65-74, 9.1% of those age 75-84, and 4.5% of those 85 or older.¹³³ The prevalence of smoking in the Medicare population is declining, but the actual number of smokers is expected to increase as the baby boomers age.

Smoking-related disease is the most preventable cause of death and disability in the United States. Nationally, tobacco use is responsible for more than 430,000 deaths each year, or one in every five deaths. 134 In Ohio, the average annual number of deaths related to smoking is $19,527.^{135}$ Smoking is a major preventable risk factor for cancer, heart disease, stroke, and respiratory In 1998 alone, cigarette disease. smoking in Ohio was attributable to an estimated 31% of cancer deaths, 20% of cardiovascular disease deaths, and 47% of respiratory disease deaths. 136

Smoking-related disease in the United States has an enormous economic impact, costing more than \$50 billion in medical expenditures every year. 137 HCFA projects that Medicare will spend \$800 billion treating smoking-related illnesses between 1995 and 2015. Smoking is responsible for approximately 7% of total health care costs, and federal and state funds pay more than 43% of smoking-attributable expenses (89 cents per pack sold). In 1993, the most recent year for which statistics are available, prescription drugs accounted for 4% of all smoking-related medical costs for a total of two billion dollars. 139 smoking-related medical expenses totaled nearly two and a half billion dollars. Of that amount, nearly \$600 million were Medicaid expenditures. and nearly \$130 million were prescription drug expenditures. 140

Smoking cessation, even late in life, reduces mortality and can result in improved quality of life. A report on women and smoking released by the Surgeon General in March 2001 found that women who stopped smoking substantially reduced of their risk heart disease, no matter at what age they stopped. Similarly, the risk for stroke began to reverse and, after ten to fifteen years, approached that of a smoked. 141 who never woman

Seventy per cent of smokers would like to quit. Of smokers who try, those who have the support of their health care provider are the most successful. 142 But only half of smokers who see a doctor are urged to quit. African Americans, and Hispanics, Asian Pacific islanders are less likely to receive advice to quit, as are smokers age 75 and older, and those with an annual income of less than \$10,000.143 Only 15% of smokers who saw a physician in the past year were offered assistance with quitting, and only 3% were given a follow-up appointment to address the problem. 144 This is unfortunate, because a physician's assistance can produce cessation rates of 5-10% per year. More intensive interventions, such as combining behavioral counseling and therapy can produce cessation rates of 20-25% per year. 145

A guideline issued by the United States Public Health Service in June 2000 concludes that tobacco dependence treatments are both clinically effective and cost effective. include urges insurers It to counseling and effective drug treatments as a covered benefit, and clinicians for providing to pay dependence treatment. 146 tobacco The guideline identified five first-line

medications (bupropion SR, nicotine gum, nicotine inhaler, nicotine nasal spray, and nicotine patch) and two second-line medications (clonidine and nortriptyline) for treating tobacco use. The first-line medications have been found to be safe and effective for treating tobacco dependence and have been approved by the FDA. The second-line drugs have shown evidence of efficacy for treating tobacco dependence, but they are not FDA approved and have potential The side effects. guideline specifically found that smoking interventions that are effective in general population are effective for older smokers as well. 147

HCFA announced in July 2000 that it beginning new demonstration project help Medicare beneficiaries stop smoking. 148 As part of Medicare's Healthy Aging Project, demonstration will last three years and test specific cessation strategies in various states, including Ohio. Smoking cessation therapy is not currently a Medicare benefit, but HCFA has indicated that it could be if the demonstration project proves successful in identifying the most effective ways to help beneficiaries smoking. 149 stop

V. OTHER STATES' SENIOR PHARMACEUTICAL ASSISTANCE PROGRAMS

Ohio does not have pharmacy assistance program for seniors. Am. Sub. S.B. 192 of the 123rd General Assembly appropriated tobacco settlement funds to help certain seniors with pharmacy costs. Under the act, five per cent of Ohio's Health Priorities Trust Fund is earmarked for a non-entitlement program that provides emergency assistance in the form of medication or oxygen to seniors whose annual household income does not exceed the federal poverty guidelines and whose health has been adversely affected by tobacco use. The act also provides that if federal funding becomes available to establish a prescription coverage program for seniors, and the proposed federal program requires a co-payment, the General Assembly may use the five per cent allocation to cover the copayments.

According to the National Conference of State Legislatures, as of February 2001, 26 states have authorized some type of senior pharmaceutical assistance program, 22 by legislative enactment and four by executive branch action. Twenty of the state programs provide a direct subsidy using state funds, one provides a year-end tax credit, and five have created discount programs. Twenty-four of the programs are currently in operation. As of March 25, 2001, NCSL's Health Policy

Tracking Service reported that there were over 290 individual bills pending to create, expand, or alter senior pharmaceutical assistance programs, including legislation to establish programs in at least 14 states. But existing overruns in many states' Medicaid programs and current economic conditions may derail many of these efforts. A description of the programs offered by ten states follows.

Florida

The Pharmaceutical Expense Assistance Program (PEAP) was 2000^{-150} created in June Florida's Agency for Health Administration Care received appropriations from the state general revenue fund of \$15 million to the program, develop plus additional \$250,000 per year to administer it. PEAP was scheduled to have started January 1, 2001, but been delayed. Once has implemented, the program will automatically enroll eligible Florida residents. Those who prefer not to participate may opt-out. To be eligible, enrollees must be at least 65 years of age, eligible for both Medicaid and Medicare, not enrolled in a Medicare HMO, and have an annual household income between 90% and 120% of the federal poverty guidelines. PEAP will cover up to \$80 of prescription drug expenses per

participant, per month. Enrollees are to be charged coinsurance of 10% for each prescription purchased through the program. Any medication prescribed by a physician or other licensed practitioner authorized to prescribe medications and lawfully dispensed will be covered by the program.

Illinois

The Pharmaceutical Assistance Program (PAP) was created in 1985 to give low-income seniors access to essential prescription medications and is Illinois administered bv the Department of Revenue. PAP is funded by appropriations from the state's general revenue fund and from the Tobacco Settlement Fund. 151 Each participant receives Pharmaceutical Assistance card that validates participation in the program and shows the effective dates of coverage. To participate in PAP, applicants must be at least 65, or, if widowed, 63. Singles must have an annual income of no more than \$21,218, and couples, no more than \$28,480. PAP will cover up to \$2,000 annually for prescription medications used to treat heart disease. diabetes. arthritis. Alzheimer's disease. Parkinson's disease, lung disease, glaucoma, and smoking-related illnesses.

Participants who earn less than 100% of the federal poverty guidelines must pay an annual \$5 premium, but are not charged co-

payments. Those who earn more than 100% of the guidelines must pay an annual \$25 premium and a \$3 copayment per prescription received through the program. Once any participant, regardless of income level. has received \$2,000 coverage, the participant must pay 20% in coinsurance per prescription. Those who earn more than 100% of the guidelines also continue to pay the \$3 co-payment per prescription.

<u>Indiana</u>

In March 2000, the Indiana General Assembly earmarked \$20 million from the state's Tobacco Settlement Fund to establish the Indiana Prescription Drug Fund, known as Hoosier Rx. 152 Hoosier Rx, administered by the State Budget Agency and promoted by the Agency on Aging, the Office of Family and Children, and the Office of Social Security, compensates eligible seniors on a quarterly basis for up to \$1,000 per year in prescription drug expenses. The first quarter covered was October to December 2000. Most FDA-approved medications, including insulin, are covered.

To participate, Indiana residents 65 or older, or 55 or older if they receive Social Security disability payments, whose annual income is less than 135% of the federal poverty guidelines must apply annually by mail to the State Budget Agency. Coverage through other prescription or discount programs does not affect an individual's eligibility. If an

individual is eligible, the Agency will mail that fiscal year's quarterly refund certificates to the participant. At the end of each quarter, the participant is responsible for obtaining a pharmacy printout detailing all the prescription drugs the participant has purchased during that quarter and sending it corresponding refund with the certificate back to the State Budget Agency. Certificates and printouts must be sent no later than the last day of the following quarter. The State Budget Agency processes the claims and awards refunds on a sliding income scale.

Participants whose incomes fall between 120% and 135% of the federal poverty guidelines are reimbursed for 50% of their prescription drug expenses for up to \$500 annually. Participants whose incomes fall between 100% and 120% of the guidelines are reimbursed for 50% of their prescription drug expenses for up to \$750 annually. Participants with incomes of 100% of the guidelines or less are reimbursed for 50% of their prescription drug expenses for up to \$1,000 annually.

Maine

Established in 1975, the Low Cost Drugs for the Elderly Program provides low-income seniors and disabled persons with financial relief from high prescription drug expenses. The program is financed by appropriations from the state's general revenue fund and

administered by the Bureau of Revenue Services. The Department of Human Services is required to oversee promotional and outreach services for the program through the local offices of the Bureau of Elder and Adult Services and the Agency on Aging. 154

Any Maine resident who is age 62 or older, who is not receiving state supplemental income Medicaid pharmacy benefits, and whose annual household income is either (1) less than 185% of the federal poverty guidelines or (2) less than 210% of the guidelines if the household spends 40% or more of its annual income on prescription drugs, may apply to the Bureau of Revenue Services for assistance from the program. Medications covered include those used to treat diabetes, heart disease, hypertension, chronic disease, arthritis, high incontinence. cholesterol. thyroid disease. osteoporosis, Parkinson's disease, glaucoma, multiple sclerosis, and Lou Gehrig's disease, as well as anticoagulants, insulin, syringes, and needles. Generic drugs must be purchased when available, unless the prescribing physician otherwise directs.

Under the program, the state pays up to \$1,000 annually of a participant's prescription drug expenses. Drug cards issued to each participant are linked to the state's computer system and electronically monitor the amount that the individual spends on prescription

medications. For prescriptions purchased beyond the \$1,000 coverage limit, participants must pay the greater of 20% coinsurance or a \$2 co-payment. Participants must reapply to the program annually.

<u>Massachusetts</u>

Massachusetts Prescription Advantage was created by House Bill 5300 in July 2000 and is funded by a \$30 million allocation from the state's funds. 155 settlement tobacco Developed and administered by the Executive Office of Elder Affairs, Prescription Advantage replaces Massachusetts' existing prescription benefits programs: the drug Pharmacy Program and the Pharmacy Program. Prescription Advantage was implemented on April 1. 2001. The Executive Office of Elder Affairs established a formulary that includes most prescription drugs, insulin, and disposable syringes.

All Massachusetts residents aged 65 or older who are not eligible for or receiving Medicaid benefits enroll Prescription mav in Advantage. The program is unique, in that it is available to seniors of all incomes, although premiums, coand deductibles payments. according to income. The program does not charge a premium or deductible to those whose annual income is less than 188% of the federal poverty guidelines. For those who earn more than 188% of the guidelines, deductibles ranging from \$100 to \$500 are charged according to a sliding income scale. Premiums are also determined by a sliding income scale, ranging from \$15 to \$82 for single persons, and from \$12 to \$66 for married persons. Prescription Advantage subsidizes all participants' out-of-pocket prescription expenses that exceed the lesser of \$2,000 or 10% of the participant's annual income.

Prescription Advantage participants pay co-payments. Those whose annual incomes fall below 200% of the federal poverty guidelines pay a \$5 co-payment for a month's supply of a generic drug and \$12 for a month's supply of a brandname drug that has no generic equivalent. Those whose annual incomes are above 200% of the guidelines pay a \$10 co-payment for a generic drug and \$25 for branddrugs without generic equivalents. A participant who fills a prescription for a brand-name drug that is not on the formulary must pay the greater of \$25 or 50% of the drug's cost.

Prescription Advantage also includes a co-payment schedule for participants who purchase mail-order prescriptions. Those with an annual income of less than 200% of the federal poverty guidelines pay \$10 for a three-month supply of a generic medication and \$25 for a three-month supply of a brand-name drug without a generic equivalent. Those whose annual incomes exceed 200% of the guidelines pay \$20 for a three-month supply of a generic medication and

\$50 for a three-month supply of a brand-name drug with no generic equivalent. A participant, regardless of annual income, who requests a brand-name medication in place of one that appears on the formulary must pay the greater of \$50 or 50% of the medication's cost.

Michigan

Michigan currently provides seniors with financial assistance in buving prescription medications through two programs, the Michigan Emergency Pharmaceutical Program for Seniors (MEPPS) and the State Medical Program (SMP). MEPPS is a voucher program, established in 1988 and funded by appropriations from the state's general revenue fund. Administered by the Office of Services to the Aging and local offices of the Agency on Aging, MEPPS issues vouchers to eligible seniors as short-term financial assistance in purchasing necessary prescription medications. vouchers cover a three-month supply of any medication also covered by Medicaid, but generic equivalents must be dispensed unless specifically directed otherwise by the prescribing physician. While the vouchers have no fixed dollar value, medications that cost more than \$300 for a 30-day supply require special authorization from the Office. There is no limit to the number of individual prescriptions that may be purchased, but recipients are limited to threemonths' worth of each prescription and may receive MEPPS assistance

no more than twice annually. qualify for assistance, a senior must be at least 65, have an annual income of less than 150% of the federal poverty guidelines, and have had documented prescription drug costs that represented at least 10% of a single or widowed person's monthly income, or at least 8% of a married person's household income. Participants are not charged a premium or deductible, and a copayment of 25¢ per prescription is voluntary.

The SMP, also established in 1988 and financed by general revenue fund appropriations, provides pharmacy drug cost relief in the form of tax credits. Seniors citizens whose income is less than 150% of the federal poverty guidelines, and whose prescription drug costs exceed 5% of their annual household income may apply for tax credits of up to \$600 per year.

Legislation enacted in June 2000 creates the Elder Prescription Insurance Coverage (EPIC) program to replace the MEPPS and SMP programs. EPIC, established by a \$33 million appropriation from the state's Tobacco Settlement Fund, will funded by general revenue appropriations freed bv the elimination of the MEPPS and SMP programs. The activation date for EPIC was rescheduled from January 1, 2001 to October 1, 2001, pending the implementation of an automated pharmacy claims, adjudication, and prospective drug utilization review system. The MEPPS and SMP programs will remain operational until EPIC is activated, and EPIC will include a component similar to MEPPS vouchers to aid seniors with short-term needs.

EPIC is not an entitlement program; benefits are limited to levels supported by the funding explicitly appropriated to program. A drug coverage formulary has not yet been finalized but will be similar to that of the Medicaid program and include insulin and syringes. Any Michigan resident who is at least 65 years old, has an annual income at or below 200% of the federal poverty guidelines, and is not covered by or eligible for Medicaid, may apply for EPIC. Premiums are based on annual household income. Singles couples whose incomes fall at or below 100% of the federal poverty guidelines pay no premium. others, the premium increases as household income increases, up to. but not exceeding, 5% of household income.

New York

York's New Elderly Pharmaceutical Insurance Coverage (EPIC) program, created by executive order in 1987, is a cost-sharing program funded by allocations from the state's Tobacco Settlement Fund and general revenue fund. EPIC covers most prescription medications, both brand-name and generic. including insulin, syringes, and

needles. EPIC limits dispensation of medications to 30-day or 100-pill increments. Any New York resident age 65 or older who is not enrolled in Medicaid or another pharmacy benefits plan and whose annual household income is \$35,000 or less if single, or \$50,000 or less if married, may enroll in EPIC. EPIC participants are grouped according to their annual household income into one of two plans: the fee plan or deductible plan. Prescription cards issued to each participant are linked to a state computer system that electronically monitors the participant's fee or deductible payments.

Single residents who earn less than \$20,000 annually and married residents who earn less than \$26,000 annually are eligible for the fee plan. receive benefits. fee plan participants must pay an annual enrollment fee, which may be divided quarterly payments. amounts are determined by a sliding income scale, ranging from \$8 to \$230 for single persons and from \$8 to \$300 for married persons. Fee plan participants pay a co-payment to purchase medications.

Single persons who earn between \$20,001 and \$35,000 annually and married persons who earn between \$26,001 and \$50,000 annually may enroll in the deductible program. These participants pay full price for their prescriptions until they meet an annual deductible, which is based on a sliding income scale. The

deductible amounts range from \$530 to \$1,230 for single persons and from \$650 to \$1,715 for married persons. After meeting the deductible, participants pay only a co-payment for medications.

The co-payment for medications that cost less than \$15 is \$3. For medications that cost \$15.01 to \$35, the co-payment is \$7. For medications that cost \$35.01 to \$55, the co-payment is \$15. The co-payment for medications costing over \$55 is \$20.

Pennsylvania

Pennsylvania established the Pharmaceutical Assistance Contract for the Elderly (PACE) in 1984.¹⁵⁷ PACE is funded entirely by state lottery revenues and is administered by the Department of Pennsylvania residents age 65 or whose annual household income falls below 150% of the federal poverty guidelines may enroll in PACE. Enrollees must pay a \$6 co-payment per prescription, but are charged no deductible or premium. Once enrolled, participants receive a prescription card linked electronically to the state's prescription claims processing system.

While PACE covers most prescription drugs, including insulin, syringes, and needles, it does not cover experimental drugs, over-the-counter medications, or medications used to treat baldness or wrinkles. For maintenance medications, participants receive the lesser of a 30-

day supply or 100 units For medications that prescription. treat acute conditions, participants may receive up to a 15-day supply. The program requires that generic medications equivalents of dispensed whenever possible. participant who insists on receiving a brand-name medication when a generic equivalent is available must pay 70% of the average wholesale price of the drug in addition to the copayment. PACE had an annual budget of \$296.1 million in 1999, with an additional \$8.8 million in administrative costs.

In 1996, the PACE program was expanded to provide financial relief to additional seniors. PACENET. the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier, extends PACE benefits to seniors whose annual household income falls between 150% and 170% of the guidelines. federal poverty PACENET participants first pay a \$500 deductible, and then pay copayments of generic \$8 for medications and \$15 for brand-name medications. PACENET had an annual budget of \$12.9 million in 1999, with an additional \$0.8 million in administrative costs.

Vermont

VScript, Vermont's pharmacy assistance program for low-income seniors without drug coverage, is administered under the Vermont Health Access Program and funded by allocations from the state general revenue fund and by a Medicaid waiver under section 1115 of the Social Security Act. 158 Any Vermont resident age 65 and older whose annual household income is less than 225% of the federal poverty guidelines may enroll in VScript. The program provides three tiers of benefits according to participants' annual household incomes.

Those who earn less than 150% of the federal poverty guidelines receive coverage for all medications covered by Medicaid. The co-payment for prescriptions costing less than \$30 is \$1, for prescriptions costing over \$30, \$2. VScript charges no deductible. Those who earn between 150% and 225% of the federal poverty guidelines receive coverage under VScript and VScript Expanded for maintenance medications, meaning medications that are used to regulate chronic condition. such hypertension or diabetes. The copayment for participants who earn between 150% and 175% of the federal poverty guidelines is \$1 for prescriptions costing less than \$30, and \$2 for prescriptions costing more than \$30 with no deductible. those earning between 175% and 225% of the federal poverty guidelines, VScript pays 50% of the prescription cost.

An amendment to Vermont's existing waiver that significantly expands that state's pharmacy assistance programs for seniors has

been approved by HCFA, and the new program was implemented January 1, 2001, despite a pending legal challenge. Under the Pharmacy Discount Program. seniors with incomes between 150% and 225% of the federal poverty guidelines can now receive acute medications for a reduced rate, in addition to the maintenance medications they are eligible for under VScript VScript Expanded. For a \$3 per prescription fee, up to \$24 calendar year, Vermont seniors can purchase acute care drugs at the Medicaid rate reduced in anticipation of rebates from drug manufacturers (estimated to be a discount of 30%). Vermont seniors without coverage whose incomes exceed 225% of the guidelines also receive all Medicaid covered drugs at the same reduced rate for the \$3 fee. 159

Washington

A Washington Alliance to Reduce Prescription-Drug Spending, AWARDS, was created executive order in August 2000, and, despite a pending lawsuit, implemented in March 2001.¹⁶⁰ popularly AWARDS. termed a "buyer's club," is a state-sponsored cost-sharing cooperative. AWARDS to purchase allows participants prescription medications for 12% to 30% less than retail prices by merging their individual prescriptions with the state's buying power through its Uniform Health Plan. The state individual compiles these prescriptions, then purchases the

medications in bulk. AWARDS covers all prescription medications, but to receive the discounted rates, participants must purchase their prescriptions from participating pharmacies. AWARDS has no

income restrictions. Any Washington resident 55 or older may enroll. Participants pay an annual enrollment fee of \$15 for single persons and \$25 for families.

ADDENDUM

On May 8, 2001, the National Institute for Health Care Management Research and Educational Foundation (NIHCM) released a new publication, "Prescription Drug Expenditures in 2000: The Upward Trend Continues." That publication confirms that the trends described in this report persisted in 2000. Prescription drug spending increased 18.8% last year, reaching nearly \$132 billion. majority of that increase was due to higher expenditures among relatively small number of drugs. The contributing ten drugs most 1999-2000 significantly to the increase were Vioxx, Lipitor, Prevacid, Celebrex, Avandia, Actos, Oxycontin, Glucophage, Prilosec, and Zocor. The top ten drugs in terms of year 2000 retail sales were Prilosec, Lipitor, Prevacid, Prozac, Zocor, Celebrex, Zoloft, Paxil, Claritin, and Glucophage.

Retail pharmacies dispensed 7.5% more prescriptions in 2000 than in 1999. Additionally, the average price per prescription rose 10.5% to \$45.27. Among the top 50 best-selling medicines, the average prescription price was \$67.15, while the average price for all other drugs in 2000 was \$36.01.

The industry is beginning to respond to anticipated upcoming patent expirations. For example, the leading antidepressant, Prozac, is scheduled to go off patent in August 2001. Its manufacturer was recently granted FDA approval to market a once-weekly version of the drug, which has its own patent because the drug is coated differently. The manufacturer also separately markets Prozac as Serafem to treat mood associated with imbalances premenstrual syndrome and for the next six years has the sole right to market it for that use. Prilosec's manufacturer is promoting Nexium, antiulcerant. and Glucophage's manufacturer is heavily promoting a successor drug, Glocovance. The patents for both Prilosec and Glucophage are due to expire later this year.

The NIHCM report concludes by describing increased competition among brand-name drugs. At this point, competition occurs primarily at the marketing level, with each company claiming that its drugs are better than other drugs, rather than competing by price.

GLOSSARY

Average manufacturer's price (AMP) – Developed by the drafters of the Omnibus Reconciliation Act of 1990 and used to describe the average price received by a manufacturer after discounts for products sold to the retail class of trade. AMP is used for computing the rebates paid to state Medicaid programs.

Average wholesale price (AWP) – Neither an average price nor a price charged by wholesalers, AWP is the price that manufacturers suggest that wholesalers charge retail pharmacies. Few if any wholesalers even consider AWP today when pricing their prescription products. AWP is commonly used by retailers and others who dispense medications as the basis for many pricing decisions, and it is used as a surrogate for actual prices when studying prescription drug trends.

Brand-name drug – A drug generally covered by a patent and therefore sold by only one firm.

Cash prescription – A prescription purchased in a retail pharmacy where the consumer pays the pharmacy's usual and customary charge entirely out of pocket when the prescription is dispensed. This includes customers with no insurance coverage and those with indemnity coverage that requires consumers to pay the full charge and, after meeting a deductible, reimburses them for some portion of the expenditures.

Chronic condition – A health condition diagnosed by a doctor or other health professional that has lasted or is expected to last 12 or more months, such as high blood pressure; other heart disease and circulatory problems, arthritis, conditions of the nervous, endocrine, metabolic, blood and blood forming systems, diabetes, and back problems.

Coinsurance – A cost-sharing requirement under a health insurance policy that requires the patient to pay a percentage of costs for covered prescriptions.

Co-payment – A cost-sharing requirement under a health insurance policy that requires the patient to pay a specified dollar amount for each prescription.

Detailing – Personal selling activities by a pharmaceutical manufacturer sales representative that inform prescribers, pharmacists, and others about the details of the product.

Direct to consumer promotion – Advertising by manufacturers that is directly targeted at consumers.

Direct pay insured prescription – A prescription covered under an insurance plan that provides direct payment to the pharmacy for the prescription. Consumers pay only a co-payment or coinsurance at the point of service.

Federal poverty guidelines or federal poverty level – Guidelines issued by the United States Department of Health and Human Services and updated annually to reflect an increase in the previous year's Consumer Price Index. For FY 2001, the federal poverty guideline is \$8,590 for one person and \$11,610 for two persons in the same family unit.

Fee-for-service payments – Fee for service, as opposed to pre-payment or capitation, means that payment is made for services as they are rendered.

Formulary – A listing of drug products that may be dispensed (positive) or that may not be dispensed (negative) or reimbursed. Formularies may be open, closed, or tiered.

Generic drug – A drug that is not covered by patent protection and may be produced and distributed by many firms.

Indemnity prescription coverage – An insurance plan where the insured pays for the covered prescription and, after a deductible is met, is reimbursed by the plan for a percentage of the expense.

Patent/patent life – A patent provides exclusivity in marketing a product. The duration of a patent for a drug is 20 years, which is longer than for many other products. Effective patent life may be shorter than 20 years depending on the time between discovery and market launch that is needed for testing and FDA approval.

Pharmacy benefits manager – An organization that provides administrative services in processing and analyzing prescription claims for pharmacy benefit and coverage programs. Services provided can include contracting with a network of pharmacies; establishing payment levels for provider pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; and operating disease management programs.

Preferred drug – A drug that a manufacturer agrees to make available to an insurer, health plan, or public program at a reduced price compared to other drugs that are considered therapeutic alternatives. Enrollees in an insurance plan may pay lower cost-sharing for preferred drugs, and pharmacists may be encouraged to dispense them through higher dispensing fees.

Rebate – An amount a manufacturer pays an insurer or health plan for each unit of a drug dispensed. Rebates are referred to as "after market" because they do not affect the drug's price but reduce the payer's expenditures or program costs.

Retail prescription price – The price charged by a pharmacy for prescriptions and related services provided. For consumers who pay in cash, it is also referred to as the usual and customary charge and is determined by the pharmacy's pricing policies. For insured consumers, it is the third-party payment or reimbursement amount determined by the insurance plan's payment formula and agreed to in a contract with the pharmacy.

Therapeutic alternative/equivalent – Drugs that differ from one another but are of the same therapeutic class and can be expected to have a similar therapeutic effect when administered in therapeutically equivalent dosages.

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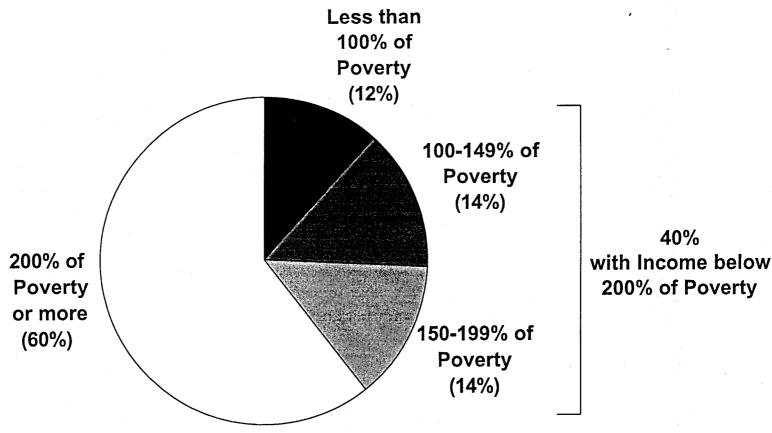
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- 152 Indiana Senate Bill 108, §6, signed by the Governor 3/13/00, effective 9/1/00.
- ¹⁵³ 36 Maine Rev. Stat. Ann. § 6161-6166.
- ¹⁵⁴ 22 Maine Rev. Stat. Ann. §254-A.
- 155 Mass. H.B. 5300, §46, 7-28-00.
- ¹⁵⁶ New York Executive Order 19-K §547, 1987.
- ¹⁵⁷ 72 Pa. Cons. Stat. Ann. 3761-506 to 709.
- ¹⁵⁸ Vt. Stat. Ann. Tit. 33, §§ 1991-1994, as expanded by 1999 Vt. Acts and Resolves 62, §§ 122-123.
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- ¹⁶⁰ Washington Exec. Order 00-04 WAC 246-30, 8-29-00.

Figure 1

Four in ten Medicare beneficiaries have incomes below 200% of poverty



Total = 36 Million Medicare Beneficiaries

Source: Urban Institute estimates based on 2000 Current Population Survey.

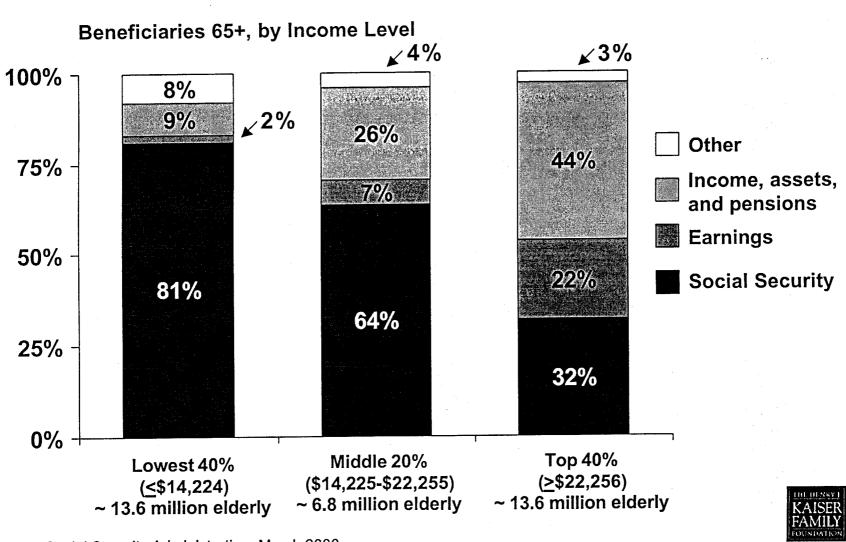
Note: Reflects income from all household family members. If income from household family members other than spouse were excluded, 17% would have incomes below poverty. 1999 federal poverty was \$8,240 for individuals; \$11,060 for couples.



(Poverty = Federal Poverty Guidelines)

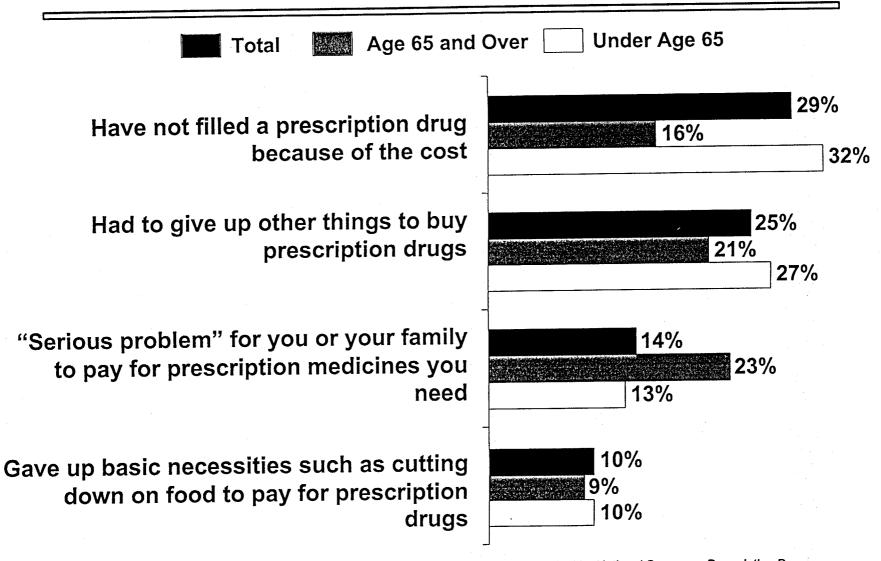
Figure 2

Most seniors rely on Social Security for the majority of their income



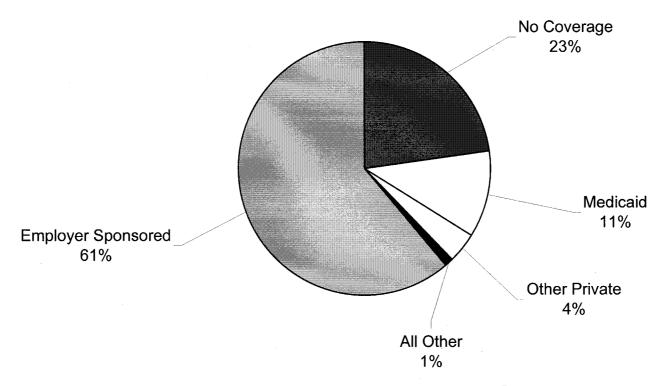
Source: Social Security Administration, March 2000.

Problems Paying for Prescription Drugs



Source: The NewsHour with Jim Lehrer / Kaiser Family Foundation / Harvard School of Public Health National Survey on Prescription Drugs, September 2000 (conducted July - Sept. 2000)

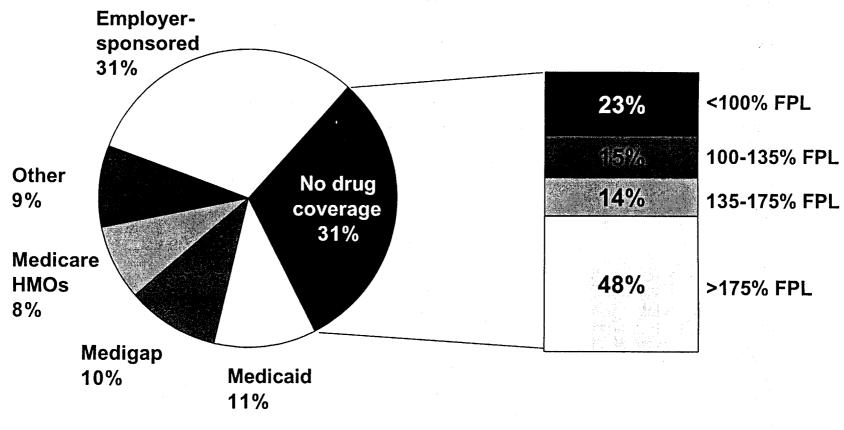
Figure 4
Insurance Coverage for Prescription Drugs,
Non-Medicare Population



Source: U.S. Department of Health and Human Services, *Prescription Drug Coverage*, *Spending*, *Utilization*, *and Prices*, April 2000.

Figure 5

Nearly a third of all Medicare beneficiaries lack drug coverage, about half of whom are low-income



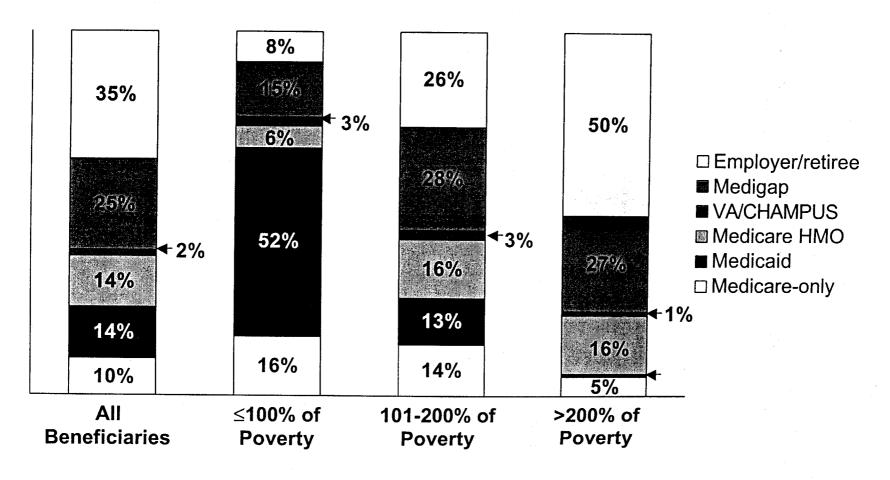
Total = 37.2 million beneficiaries

Total = 11.6 million beneficiaries without drug coverage

Source: Poisal, J.A., and G.S. Chulis, *Health Affairs*, March/April 2000. Note: Data are based on the noninstitutionalized population.



Supplemental insurance varies by income

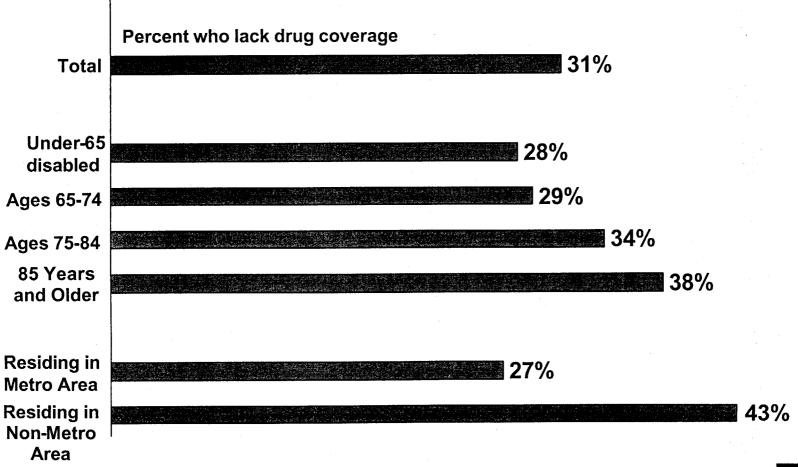




Note: Columns may not sum to 100%; other sources of public coverage not shown. Source: Urban Institute analysis of 1997 Medicare Current Beneficiary Survey.

Figure 7

The oldest-old and those living in rural areas are most likely to lack prescription drug coverage





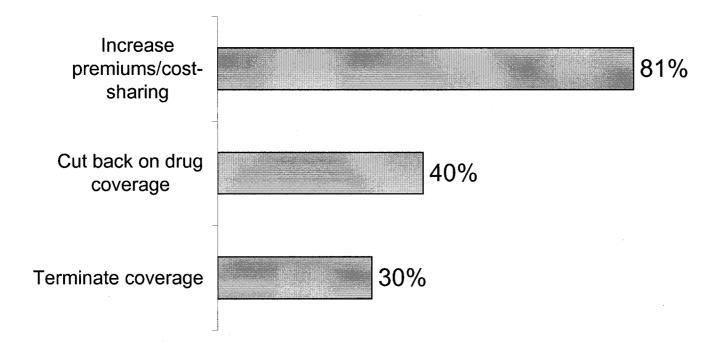
SOURCE: Poisal, J.A., and G.S. Chulis. Health Affairs, March/April 2000.

Figure 8

Percent of Large Employers Who Would "Seriously Consider"

Changing Their Retiree Benefits Over

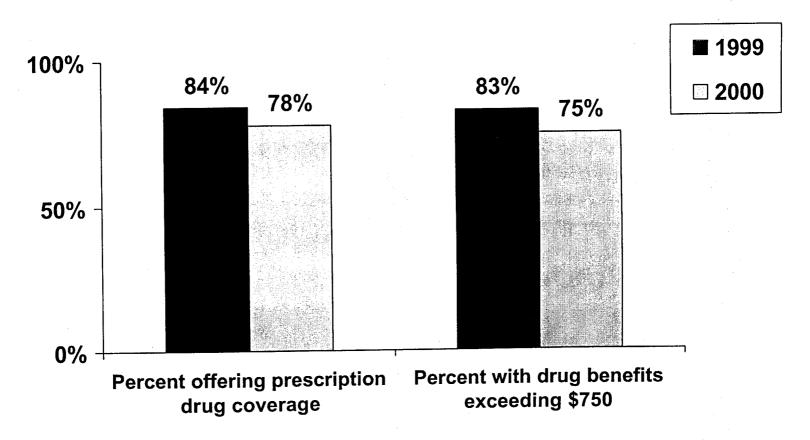
the Next Three to Five Years



Source: "The Implications of Medicare Prescription Drug Proposals for Employers and Retirees." Report prepared by Hewitt Associates for The Henry J. Kaiser Family Foundation, July 2000.

Figure 9

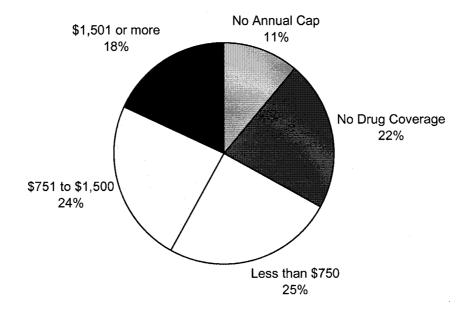
Prescription drug benefits offered by Medicare+Choice plans declined between 1999-2000





SOURCE: Mathematica Policy Research, Inc., analysis of Medicare Compare database 2000 for The Commonwealth Fund. (Benefit caps apply to prescription drug benefits in basic plans.)

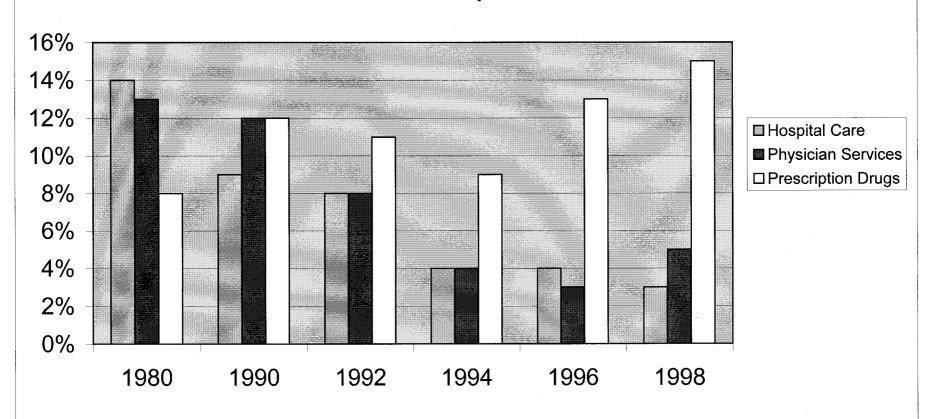
Figure 10 Many Medicare HMO Enrollees Have Limited Prescription Drug Benefits



Total = 6.2 million Medicare HMO Enrollees, 2000

Source: Cassidy, A., and M. Gold, *Medicare + Choice in 2000: Enrollees Spend More and Receive Less?* Report prepared for the Commonwealth Fund; HCFA 2000.

Figure 11
Annual Percent Change from Prior Year in
Selected National Health Expenditures, 1980 to 1998

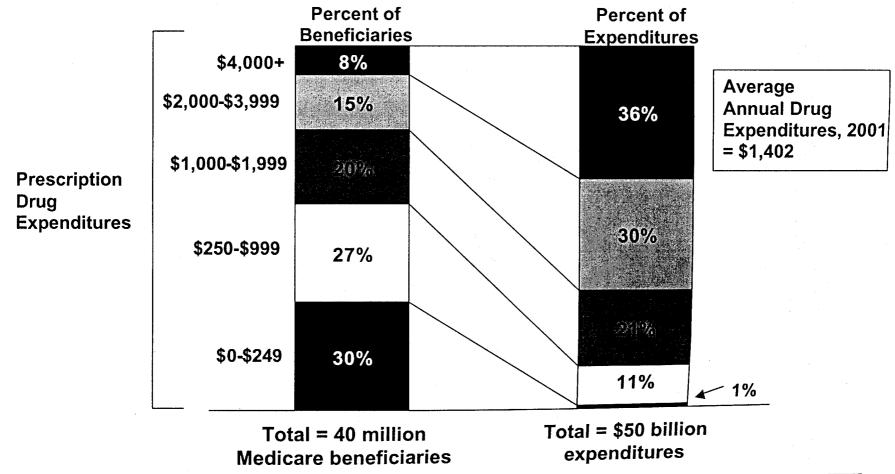


Source: Prescription Drug Trends: A Chart Book, The Henry J. Kaiser Family Foundation, July 2000.

Figure 12

Medicare prescription drug spending is skewed

Nearly a quarter of beneficiaries have drug expenses of more than \$2,000 per year

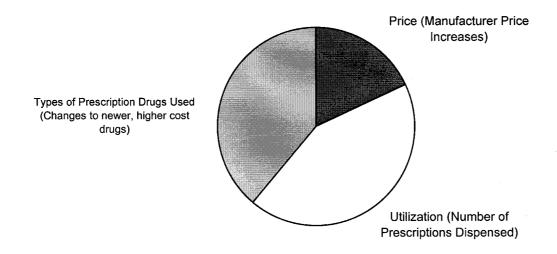


SOURCE: Actuarial Research Corporation, January 2001.

Note: Based on '95 and '96 MCBS, adjusted for under-reporting and the exclusion of the institutionalized population, and projected based on CBO baselines. Numbers may not add to 100% due to rounding.



Figure 13 Relative Contributions of Price, Utilization, and Types of Prescription Drugs Used in Rising Prescription Drug Expenditures, 1993-1998



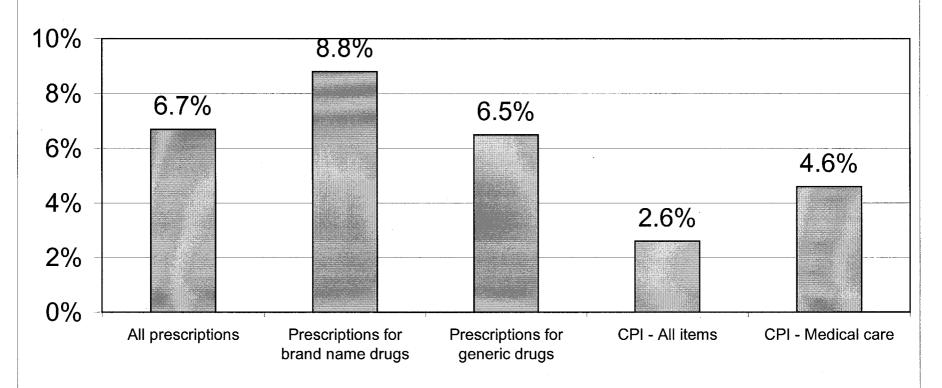
Sources: Sonderegger Research Center Analysis, based on:

Number of prescriptions from IMS Health, Inc., National Prescription Audit, published in Pharmacy Times, April issues various years.

Manufacturer price increases from IMS Health, Inc., Pharmaceutical Pricing UPDATE, March 1999, based on data from Retail and Provider Prespective (published in Medical Marketing & Media, May 1999).

Prescription expenditure data from HCFA, Office of the Actuary, National Health Statisitics Group.

Figure 14
Average Annual Percent Change in Retail Prescription Prices vs.
Consumer Price Index (CPI), 1991-1998



Sources: *Prescription Drug Trends: A Chartbook*, The Henry J. Kaiser Family Foundation, July 2000. CPIs from Bureau of Labor Statistics, December 1999.

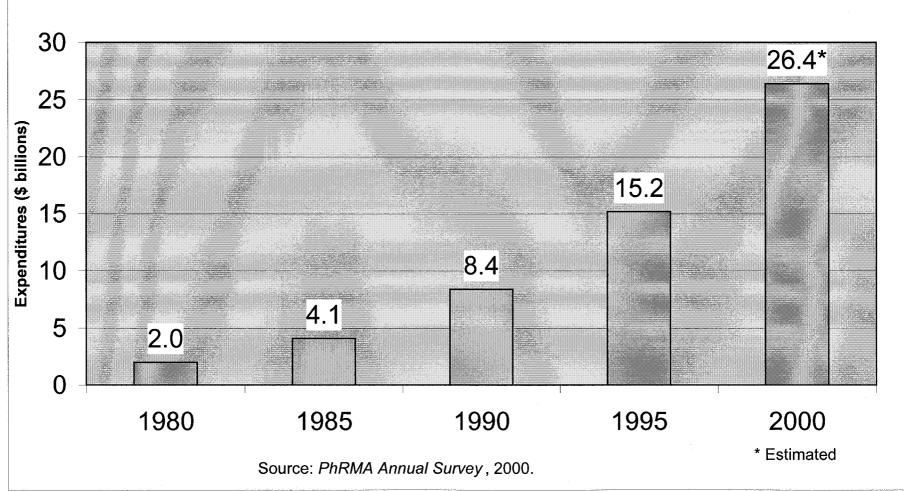
Figure 15

Five Most Expensive Drugs of the 50 Most Commonly Used by Senior Citizens as of January 31, 2000

Name of Drug	Rank	Class of Drug	Annual Wholesale Cost of Drug	Cumulative Price Change 1994-2000
Prilosec	2	Gastrointestinal agent	\$1,455	7.5%
Zocor, 20 mg	28	Lipid lowering agent	\$1,389	21.2%
Propulsid	44	Gastrointestinal agent	\$1,180	34.7%
Ultram	40	Anti inflammatory/analgesic	\$1,131	Not marketed during entire period
Procardia XL, 60 mg	32	Calcium channel blocker	\$901	20.4%

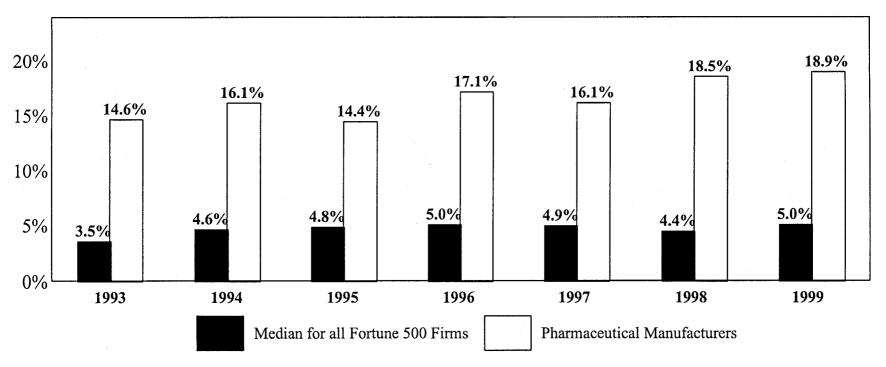
Source: McCloskey, A., Still Rising: Drug Price Increases for Seniors, 1999-2000, Families USA Publication 00-103, April 2000.

Figure 16
R&D Investments by Research-Based
Pharmaceutical Companies



Pharmaceutical manufacturers have ranked first in profitability among all industries.

Median percent net profit after taxes as a percent of firm revenues for all firms in the industry.

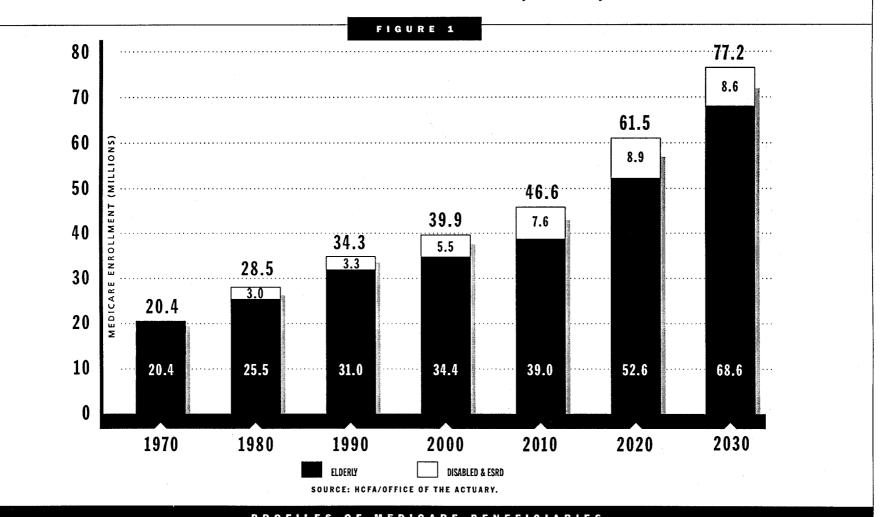


Source: Prescription Drug Trends: A Chartbook, The Henry J. Kaiser Family Foundation, July 2000.

Figure 18 Generic Drugs as a Percent of Prescriptions Dispensed and Percent of Total Annual Prescription Sales in Dollars, 1991-1998 50% **-**43.2%⁻ 40% **►**38.7% 35.5% **→**33.0% 30% 20% **14.4%** 10% 0% 1991 1992 1993 1994 1995 1996 1997 1998 → Percent of Prescriptions Dispensed - Percent of Total Annual Prescription Sales Source: Scott-Levin, Source Prescription Audit, December 1999.

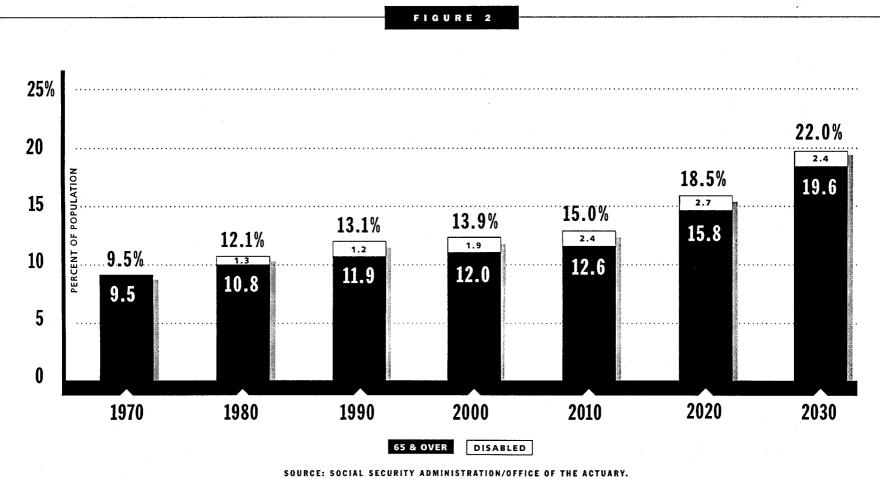
Number of Medicare Beneficiaries, CY 1970-2030

The number of Medicare beneficiaries will nearly double by 2030.



The Aging of the U.S. Population, 1970 - 2030

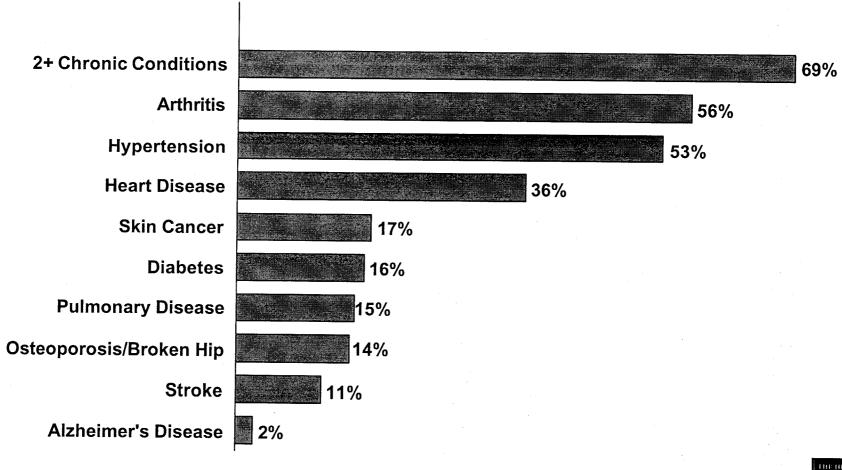
The U.S. population will age rapidly through 2030, when 22 percent of the population will be eligible for Medicare.



PROFILES OF MEDICARE BENEFICIARIES

Figure 21

The Medicare population has substantial health needs



SOURCE: 1997 Medicare Current Beneficiary Survey. Note: Data are for beneficiaries living in the community.

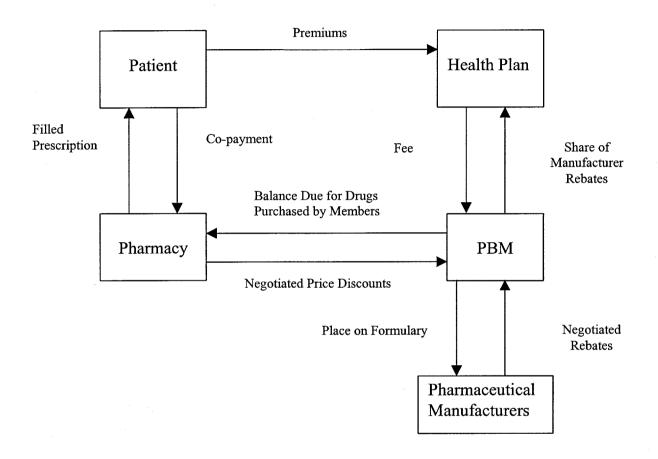


Figure 22
Top 30 Drugs (by Number of Claims) Used by the Elderly as of January 31, 2000

Rank by # of Claims	Brand-name of Drug	Therapeutic Category
1	Lanoxin (.13 mg)	Cardiac Glycoside
2	Prilosec	Gastrointestinal Agents
3	Norvasc (5 mg)	Calcium Channel Blocker
4	K-Dur 20	Potassium Replacement
5	Pepcid	Gastrointestinal Agents
6	Lanoxin (.25 mg)	Cardiac Glycoside
7	Imdur	Vasodilator
8	Synthroid (.1 mg)	Synthetic Thyroid Agent
9	Vasotec (5 mg)	ACE Inhibitor
10	Procardia XL (30 mg)	Calcium Channel Blocker
11	Glucophage	Oral Antidiabetic Agent
12	Lipitor	Lipid-lowering Agent
13	Fosamax	Osteoporosis Treatment
14	Synthroid (.05 mg)	Synthetic Thyroid Agent
15	Zoloft	Antidepressant
16	Vasotec (10 mg)	ACE Inhibitor
17	Xalantan	Glaucoma Treatment
18	Premarin	Estrogen Replacement
19	Cardizem CD (240mg/24 hr)	Calcium Channel Blocker
20	Humulin N	Insulin Anti-diabetic Agent
21	APAP/propoxyphene	Opiate Agonist
22	Cozaar	Angiotensin II Inhibitor
23	Cardizem CD (180 mg/24 hr)	Calcium Channel Blocker
24	Norvasc (10 mg)	Calcium Channel Blocker
25	albuterol	Respiratory Agent
26	Coumadin	Anticoagulant
27	Zocor (10 mg)	Lipid-lowering agent
28	Zocor (20 mg)	Lipid-lowering agent
29	Synthroid (.08 mg)	Synthetic Thyroid Agent
30	Imdur (30 mg)	Vasodilator

Source: McCloskey, Amanda, "Still Rising: Drug Price Increases for Seniors 1999-2000," Families USA Publication 00-103, April 2000.

Figure 23
How PBMs Fit into the Payment System for Prescription
Drugs



Source: Congressional Budget Office, based in part on General Accounting Office, *Pharmacy Benefit Managers: Early Results on Ventures with Drug Manufacturers*, GAO/HEHS-96-45 (November 1995).

Note: PBM = pharmacy benefit manager

Figure 24

DTC Advertising Expenditures: Top 5 Classes, January - September 2000

Class	DTC Expenditures
Antihistimines (capsules and tablets)	\$197,219,000
COX-2-inhibitors	\$192,858,000
Cholesterol reducers	\$130,350,000
Proton pump inhibitors	\$124,248,000
Inhaled nasal steroids	\$117,146,000

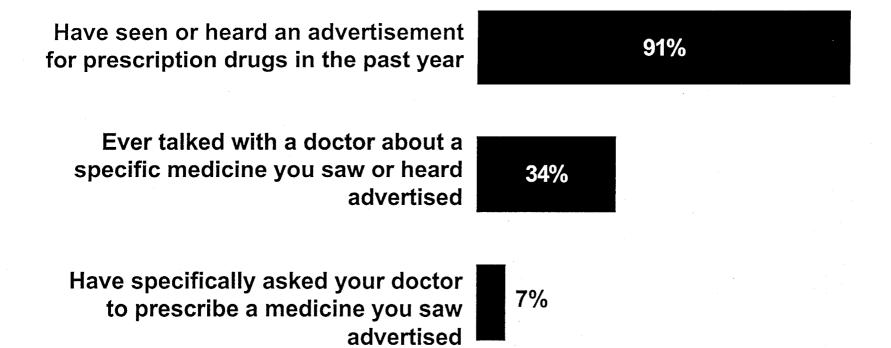
Top 5 DTC Advertised Products, January – September 2000

<u>Product</u>	DTC Expenditures
Vioxx	\$138,330,000
Prilosec	\$99,748,000
Claritin	\$84,934,000
Paxil	\$73,541,000
Viagra	\$67,721,000

Source: Scott-Levin, Direct-to-Consumer Advertising Audit, January - September 2000.

Figure 25
Direct-To-Consumer Advertising

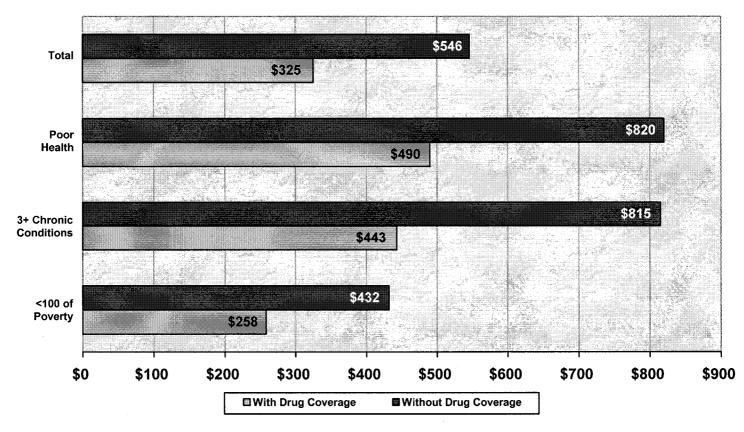
Percent who...



Source: The NewsHour with Jim Lehrer / Kaiser Family Foundation / Harvard School of Public Health National Survey on Prescription Drugs, September 2000 (conducted July - Sept. 2000)

Figure 26
Medicare beneficiaries without drug coverage face higher out-of-pocket drug costs

Average out-of-pocket spending, 1998



Source: Poisal, J.A., and L. Murray, Health Affairs, March/April 2001.

Figure 27
Out-of-pocket prescription drug costs vary
by source of supplemental coverage

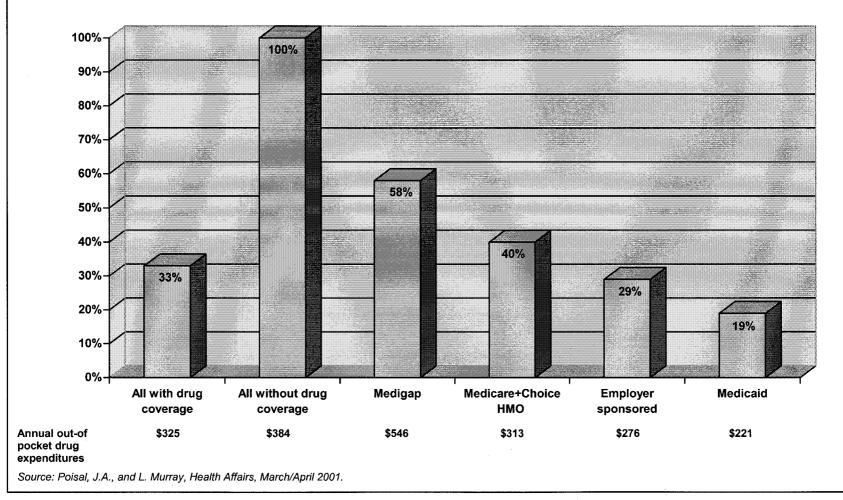


Figure 28
Medicare beneficiaries without drug coverage fill fewer prescriptions

Average number of prescriptions filled, 1998

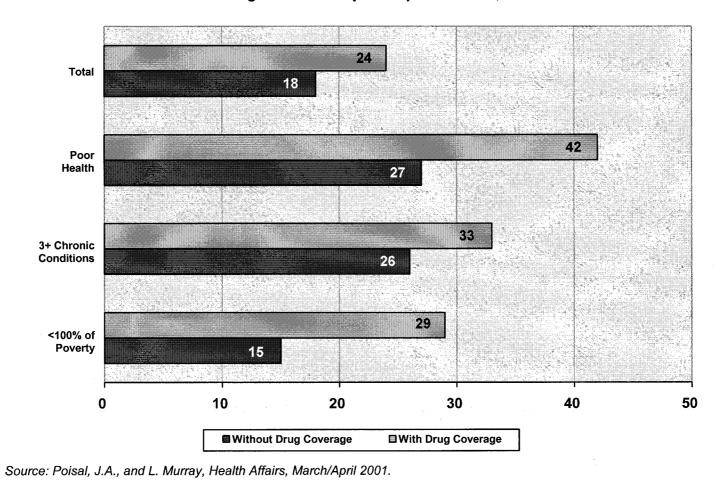
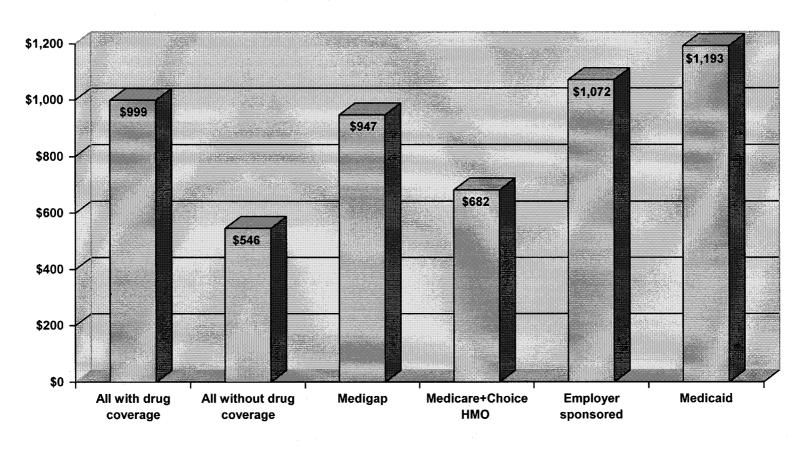


Figure 29
Medicare Beneficiaries' Average Prescription Drug Spending
by Drug Coverage Status, 1998

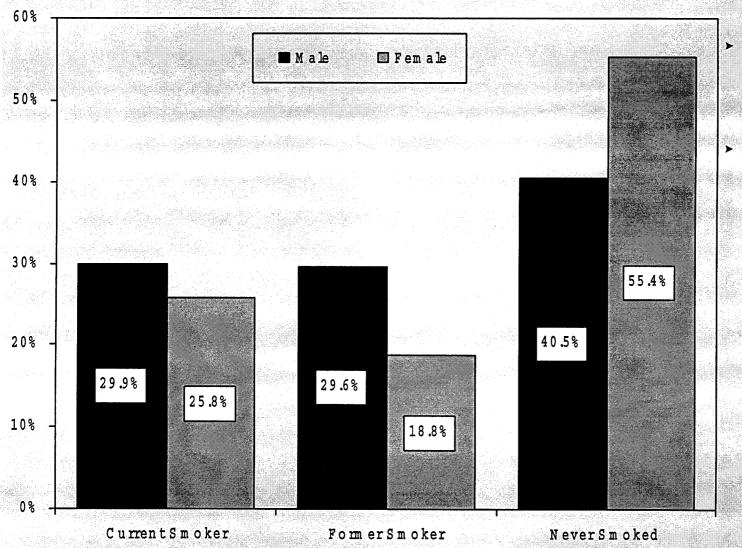


Source: Poisal, J.A., and L. Murray, Health Affairs, March/April 2001.



Smoking Status of Adult Ohioans by Gender, 1998





- A majority (55.4%) of adult female Ohioans have never smoked.
- Adult males were more likely to have smoked at some time than adult females (59.5% vs. 44.6%).