Pharmaceutical Expenditures in the Commonwealth of Virginia

A Report to the Governor and the Chairmen of the Senate Finance and House Appropriations Committees

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October 20, 2000

Acknowledgements

The Secretary of Finance wishes to thank the advisory group for their important assistance and contributions in developing this report. We would also like to recognize those members of the advisory group who offered presentations and other information to the group. Presentations and presenters are noted in the appendix.

The Secretary of Finance also gratefully acknowledges the valuable assistance provided by Ron Lyon from Trigon Blue Cross Blue Shield; Kay P. Anders, Barbara J. Dowd, and Mark C. Pugh from First Health Services Corporation; and John D. Tripodi and Kenneth W. Kolb from Heritage Information Systems, Inc.

Finally, the Secretary of Finance wants to recognize the assistance and cooperation provided by the Secretaries of Administration and Health and Human Resources and their staff. Assistance was also provided by staff from the Department of Medical Assistance Services; Department of Mental Health, Mental Retardation and Substance Abuse Services; Department of Health; Department of Corrections; Department of Juvenile Justice; and Department of Human Resource Management.

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Executive Summary

Like other states, Virginia has experienced rapid growth in expenditures on pharmaceuticals in recent years. The recent increases in government-funded pharmacy expenditures are of concern because they force a reallocation of tax revenues away from other possible uses. In response to this concern, Item 266C of the 2000 Appropriation Act directed the Secretary of Finance, in cooperation with the Secretaries of Administration and Health and Human Resources, to conduct a study that examines the trends in Virginia's pharmaceutical expenditures, the drivers of those trends, the impact of pharmaceutical utilization on the quality of health care, and budgetary impacts within government-funded health care programs. Consistent with the mandate, this study concentrates exclusively on government-funded pharmaceutical expenditures. The impact on consumers, while important, is beyond the scope of this study.

Pharmaceutical Expenditure Trends

In FY 2000, Virginia spent approximately $223 million, 2.2 percent of its total general fund budget, on prescription drugs. This is an increase of 86 percent from the $120 million spent in FY 1996. Total funds spent on pharmaceuticals in FY 2000 were approximately $441 million.[1]

The Department of Medical Assistance Services is the largest government purchaser of prescription drugs in the state, followed by the Department of Human Resource Management. Together, these two agencies accounted for over 90 percent of all government pharmaceutical expenditures over the past six years.

Increased utilization of prescription drugs has been a key factor in higher expenditures. In Virginia's Medicaid program, prescriptions per recipient have risen from an annual average of 18.5 in FY 1996 to 25.5 in FY 2000. In the state employee health

[1] These figures represent the estimated general fund portion of net pharmaceutical expenditures (exclusive of any indirect pharmaceutical expenditures paid for in managed care contracts) for the Department of Medical Assistance Services, Department of Mental Health, Mental Retardation and Substance Abuse Services, Department of Health, Department of Corrections, Department of Juvenile Justice, and Department of Human Resource Management. The total general fund budget in FY 1996 reflects total general fund expenditures and funds transferred out to higher education components from the Annual Report of the Comptroller to the Governor of Virginia. FY 2000 figure is preliminary estimate based on year-to-date expenditures and FY2000 appropriations to higher education components.

benefit plan, the average number of prescriptions per member rose from 8.9 to 10.3 in three years.[2]

Utilization Factors

- *Advancements in medical science*: The introduction of new therapies for previously untreatable diseases, improvements in rates of diagnosis and awareness of disease, and longer life spans all contribute to greater numbers of individuals receiving drug therapy treatment and remaining under treatment longer.
- *Demographics*: The increasing number of elderly individuals in the population have and will continue to be a significant factor in rising pharmaceutical expenditures for the foreseeable future. Older patients tend to have more chronic diseases or multiple conditions and, consequently, higher pharmaceutical use than other age groups in the population.
- *Changes in accepted medical practices*: Many new treatment protocols call for more pharmaceutically intensive treatment of diseases, such as drug-therapy intensive disease management programs.
- *Direct-to-consumer (DTC) advertising*: Advertising to consumers by pharmaceutical manufacturers has increased substantially in recent years. In 1999, prescription drug manufacturers spent $1.8 billion on DTC advertising, up 38.5 percent from the $1.3 billion spent in 1998 and 33 times the $55 million spent on DTC ads in 1991.3

Increased prices for prescription drugs have driven expenditure growth. The average net price per prescription (after rebates) in the state Medicaid program increased 53 percent in five years, from $22.40 in FY 1996 to $34.36 in FY 2000. In the state employee health benefit plan, the average net price per prescription (after rebates) increased 28 percent, from $33.84 to $43.38, in three years. The average price per prescription at the Department of Mental Health, Mental Retardation and Substance Abuse Services' aftercare pharmacy increased 168 percent, from $20.54 in FY 1997 to $55.03 in FY 2000.[4]

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[2] "Prescriptions per recipient" refers to the number of individual transactions, new or refill, per individual. The days supplied per prescription are variable. This information is not intended to make a comparison of utilization increases between agencies, as many factors, such as population mix, length of prescriptions, and co-payments may differ.

[3] National Institute for Health Care Management (NIHCM) Foundation. *Prescription Drugs and Mass Media Advertising.* September 2000.

[4] This information is not intended to make a comparison of cost increases between agencies, as many factors, such as population mix, length of prescriptions, and co-payments may differ. The data presented reflects the cost trend in each agency for years in which data is available.

Price Factors

- Increases in the prices of existing products and the introduction of new, higher priced, branded products both contribute to higher pharmaceutical expenditures.
- The average cost per prescription filled by DMHMRSAS's aftercare pharmacy increased 168 percent in four years. A significant factor in this increase is the use of new atypical anti-psychotic medications. In May 2000, the average price for an atypical drug was $184.87 compared to $24.02 for non-atypical drugs. Atypical medications accounted for approximately 22 percent of total prescriptions filled at the aftercare pharmacy in FY 2000. This represents an increase of 74 percent from the number of atypical prescriptions filled in FY 1999.
- In the Virginia Medicaid program, the average cost per claim (before rebates) in FY 2000 was $43.06. The average cost per claim for 36 of the more high profile new drugs was $121.61 that same year.[5]

The Pharmaceutical Market and Factors Driving Expenditures

To plan effectively for future expenditures and to ensure that these expenditures are managed to maximize the gain in health outcomes per dollar spent, it is critically important to understand the factors that give rise to the increased costs. The pharmaceutical market is driven by a variety of interrelated forces, including the large number of different decision makers and the complex set of relationships between these parties. Attempts to influence one component of this market, without the benefit of the larger market picture, have the potential to lead to unintended and, very possibly, undesirable outcomes that could outweigh any benefits achieved.

Supply of Pharmaceuticals

The long-run supply of new therapies is determined, in large part, by the amount of investment in research and development. The amount of investment in R&D is determined by the expected future revenue streams from sales of the developed product. Since investment in R&D has increased rapidly in the past two decades, it can be expected that a large number of new pharmaceuticals will be entering the market over the next decade. This trend is reinforced by the increased understanding of the human genome.

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[5] Department of Medical Assistance Services. These figures do not include drug rebates, as rebate data for individual drugs is not available.

The increased genetic information is expected to provide many new targets for innovative therapies.

By making much less expensive substitutes available for branded drugs, generic drugs add a significant element of price competition to the market. By providing close substitutes for branded drugs, generic drugs make the demand for the branded drug much more sensitive to price. It is interesting to note that the introduction of generic drugs does not necessarily result in reductions in the price of the branded version of the drug. However, for those buyers in the market who are sensitive to price, the approval of generic drugs represents an opportunity for significant savings.

Demand for Pharmaceuticals

The demand for prescribed medications is derived from the demand for medical care and good health. However, no medication can be demanded without a physician's prescription. The large number of different decision makers and the complex set of relationships between these parties complicate the demand for pharmaceuticals. A number of factors determine the demand for pharmaceuticals. The main factors include substitutability among therapies, demographics, advertising, and prices.

The substitutability among therapies, both actual and perceived, has an effect on how responsive demand for a prescription drug is to its price. The existence of close substitutes for a drug will tend to result in lower prices than would occur in markets without close substitutes. The aging of the population increases the demand for pharmaceuticals. The elderly population often has a greater need for medical care, and hence pharmaceuticals, than other age groups. The increase in advertising expenditures has resulted in more people seeking care for existing conditions and, in some cases, requesting specific therapies. Advertising is valuable because it alerts consumers to available therapies. However, advertising has the potential to shift prescription behavior away from the best or most cost effective therapy.

Firms charge different prices according to the sensitivity of a particular market to a change in price. As a market becomes more competitive, established firms and potential competitors must decide whether it is better to maintain a high price but accept a loss of market share, or charge a lower price to compete for market share. However, if pharmaceutical firms were only able to charge the much lower competitive price and were not able to earn the higher rate of return during the patent term, then the rate of return

on investment in pharmaceutical innovation would fall, and some investment projects, possibly many of them, would no longer appear profitable, at least in the near term. There is an inherent trade-off between receiving the most benefit from drugs already developed by charging low prices and encouraging a high rate of research and development by charging higher prices.

Effects of Pharmaceutical Utilization on Health Care

Expenditures on pharmaceuticals are often associated with significant benefits. The benefits of pharmaceutical spending may be in better health outcomes for those using the therapy, although the value of these benefits can be very difficult to measure. In addition, under certain circumstances, there is good evidence that the medically-appropriate use of specific drugs may be associated with reductions in non-pharmaceutical medical expenses such as emergency admissions, hospital days, nursing facility care, surgical costs, and physician office visits. However, the issue depends critically on the context in which the drug is used and the intervention with which it is compared.

In Virginia, over $18 million was allocated for the funding of new anti-psychotic medications in the 1998-2000 biennium. The expanded availability of these new medications allowed more individuals to remain at home with their families in their communities as opposed to spending time in an institution. Total admissions to state mental health facilities dropped 32 percent in those two years. Populations in Virginia's state mental health facilities also decreased during that time frame.

Results from the Virginia Health Outcomes Partnership program for Medicaid asthma patients projected direct savings to Medicaid of $3 to $4 for every incremental dollar spent providing disease management support to physician. The disease management program provided guideline information about recommended asthma drugs and new state-of-the-art medications for asthma. The dispensing of drugs recommended by the guidelines for asthma rose sharply during the study period for patients of physicians participating in the disease management training. The rate of emergency visit claims for patients of participating physicians who received feedback reports dropped an average of 41 percent from the same quarter a year earlier, compared to only an 18 percent drop for comparison community physicians.[6]

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[6] Rossiter, Louis F., and others. "The Impact of Disease Management on Outcomes and Cost of Care: A Study of Low-Income Asthma Patients." Inquiry 37 (Summer 2000): 188-202.

Chapter 1: Pharmaceutical Expenditure Trends

Introduction

Like other states, Virginia has experienced rapid growth in expenditures on pharmaceuticals in recent years. These high rates of expenditure growth have received a considerable amount of attention in the press, in academic studies, and at the federal and state levels of government. The recent increases in government pharmacy expenditures are of concern because they force a reallocation of tax revenues away from other possible uses.

In response to such concerns, Item 266C of the 2000 Appropriation Act directed the Secretary of Finance, in cooperation with the Secretaries of Administration and Health and Human Resources, to conduct a study of the rising costs of pharmaceuticals in government-funded health care programs. The study examines cost trends, the drivers of costs, the impact of increased pharmaceutical utilization on the quality of health care, and budgetary impacts within government-funded health care programs.

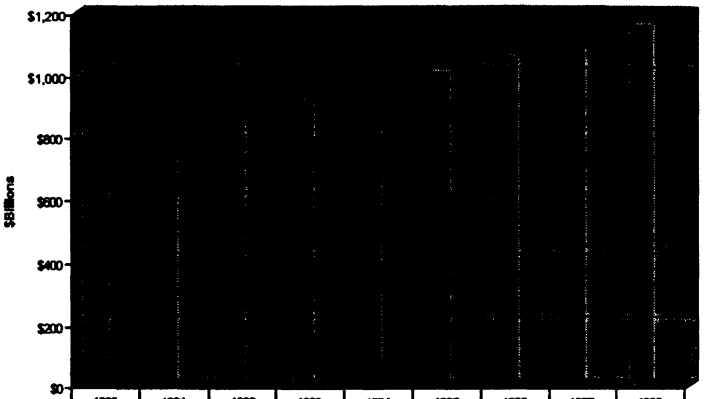
This chapter will first examine pharmaceutical expenditure trends nationally. Then, the pharmaceutical program in each of six major pharmaceutical purchasing agencies in the Commonwealth will be described. Additionally, when available, pharmaceutical expenditure, recipient and claim data will be provided for these agencies over the past five fiscal years.

National Pharmaceutical Spending

National spending for health care topped $1.1 trillion in 1998, up 5.6 percent from 1997. This marked the fifth consecutive year in which health care spending growth remained below six percent *(See Figure 1)*. Since 1993, economic growth has roughly matched health care spending growth, resulting in a relatively stable health care spending share of gross domestic product (GDP). The share of GDP devoted to health care in 1993 was 13.7 percent; by 1998 that share had fallen to 13.5 percent. Per capita health

spending has also grown relatively slowly, remaining under five percent since 1993. In 1998, United States spending on health care averaged $4,094 per person, a 4.7 percent increase from 1997.[7]

Figure 1: National Health Care Expenditures 1990-1998



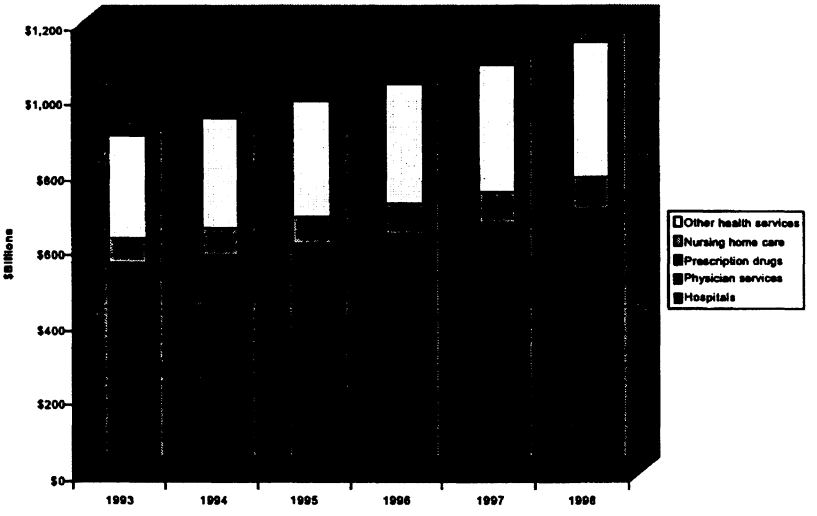
	1990	1991	1992	1993	1994	1995	1996	1997	1998
Total Expenditures (billions)	$699.4	$766.8	$836.5	$898.5	$947.7	$983.3	$1,039.4	$1,088.2	$1,149.1
% Change		9.6%	9.1%	7.4%	5.5%	4.8%	4.6%	4.7%	5.6%
% of GDP	12.2%	13.0%	13.4%	13.7%	13.6%	13.7%	13.6%	13.4%	13.5%

Source: Health Care Financing Administration, Office of the Actuary, 1998 National Health Expenditure Estimates

Spending on prescription drugs is a very different story. In relation to spending on other health care services, expenditures on prescription drugs are relatively small. However, they are growing faster than any other personal health category *(See Figures 2 and 3)*. From an increase of 8.6 percent in 1993, growth steadily accelerated to 15.4 percent in 1998. Drug expenditures rose from $51 billion in 1993 to $90.6 billion in 1998 *(See Figure 4)*. Per capita expenditures have followed much the same trend. In 1993, per capita prescription drug expenditures were $189 per person, an increase of 7.8 percent from the previous year. Since then, growth has steadily increased each year. In 1998, per capita expenditures grew 14 percent from the previous year to an average of $322 per person.

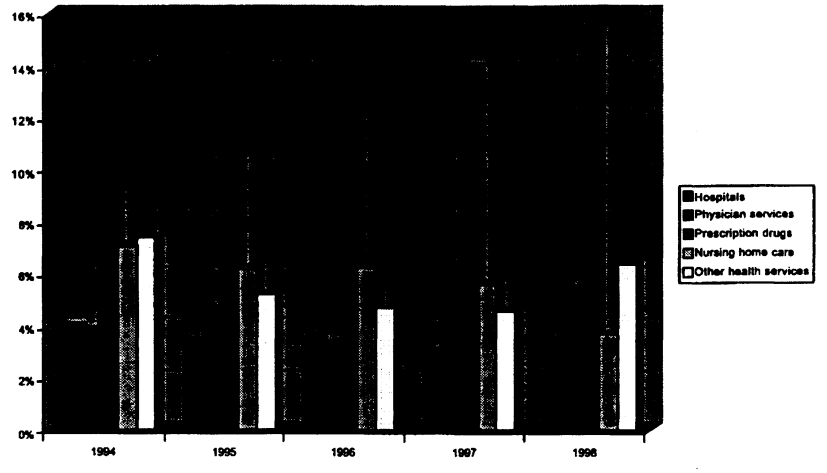
[7] Health Care Financing Administration, Office of the Actuary. *1998 National Health Expenditure Estimates*.

Figure 2: National Health Care Expenditures by Service Category 1993 - 1998



Source: Health Care Financing Administration, Office of the Actuary. *1998 National Health Expenditure Estimates*.

Figure 3: National Health Care Expenditure Growth Rates by Service Category

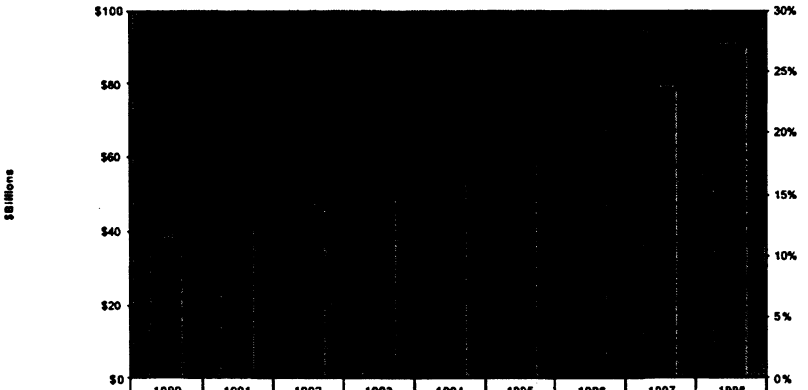


Source: Health Care Financing Administration, Office of the Actuary. *1998 National Health Expenditure Estimates*.

Consequently, prescription drugs are making up a larger and larger portion of total health care costs. The rapid growth in spending increased prescription drug costs from 5.4 percent of total health spending in 1990 to 7.9 percent in 1998. The percentage of health care expenditures being spent on hospital and physician services, which traditionally account for the majority of personal health care spending, has been declining. In 1990, hospital and physician services accounted for 58 percent of total health care spending. In 1998, that percentage declined to 53 percent.

The Health Care Financing Administration's (HCFA) 1999 national health care expenditure projections anticipate that prescription drug expenditures will increase approximately 10.6 percent annually and reach $243 billion by 2008.[8] Other researchers estimate that prescription drug expenditures may increase 11.2 to 18 percent annually over the next few years.[9] Price increases, higher utilization, and the use of newer, more expensive drugs all play a part in increasing pharmaceutical spending.

Figure 4: National Prescription Drug Spending and Growth Rates 1990-1998



	1990	1991	1992	1993	1994	1995	1996	1997	1998
Expenditures	$37.7	$42.1	$46.6	$50.6	$55.2	$61.0	$68.9	$78.5	$90.6
Growth Rate		11.7%	10.7%	8.6%	9.1%	10.5%	13.0%	13.9%	15.4%

Source: Health Care Financing Administration, Office of the Actuary. *1998 National Health Expenditure Estimates*.

[8] Health Care Financing Administration, *National Health Expenditures Projections: 1998-2008*, 1999.

[9] Mullins, C. Daniel, Francis Palumbo, and Bruce Stuart. "The Impact of Pipeline Drugs on Pharmaceutical Spending," presented at *Pipeline Pharmaceuticals: How they will Affect the Cost of Health Care*. Washington D.C., 13 April 2000. Mehl, Bernard. and John P. Santell. "Projecting future drug expenditures – 2000." *American Journal of Health-System Pharmacists* 57 (January 2000): 129-138.

Government-Funded Pharmaceutical Spending in Virginia

Only one part of state health care expenditures

Pharmacy expenditures are not the only expenditures that Virginia spends for health care, nor are they the largest. Along with prescription drugs, state agencies pay for physician services, hospital services, long-term residential care, transportation, medical equipment, home care, and a number of other services. The use of pharmaceuticals is closely related to the use of all of these other services. At the most basic level, a person requiring medical care will often require a number of different medical services in order to regain good health. Less obviously, and equally important to the subsequent discussion, these different medical services are often substitutes for one another.

The relationship between prescription drug costs and other medical costs is complex and will be discussed at greater length later in this report. Increased expenditures on pharmaceuticals will frequently displace costs in other areas and, in fact, may result in lower overall medical service expenditures for the Commonwealth. Therefore, rising drug costs do not necessarily imply rising medical expenditures. In addition, rising drug costs may also result in better health outcomes than were being achieved prior to the cost increase. Improved health outcomes is presumably the primary purpose of medical expenditures. Thus, it is important to inquire about the relative productivity of pharmaceuticals versus other medical services in achieving the desired outcome.

Why Virginia purchases pharmaceuticals

Expenditures on pharmaceuticals are essential components of a number of important functions of state government. In its role as a promoter of public health, in its role as a protector of the public safety, and in its role as an employer, Virginia spent approximately $223 million, 2.2 percent of its total general fund budget, on pharmaceuticals in FY 2000. This is an increase of 86 percent from the $120 million spent in FY 1996.[10] While the reasons for

[10] These figures represent the estimated general fund portion of net pharmaceutical expenditures (exclusive of any indirect pharmaceutical expenditures paid for in managed care contracts) for the Department of Medical Assistance Services, Department of Mental Health, Mental Retardation and Substance Abuse Services, Department of Health, Department of Corrections, Department of Juvenile Justice, and Department of Human Resource Management. The total general fund budget in FY 1996 reflects total general fund expenditures and funds transferred out to higher education components from the Annual Report of the Comptroller to the Governor of Virginia. FY 2000 figure is preliminary

the expenditures and the mix of drugs vary across programs, all programs with a pharmaceutical component have shown a similar pattern of increased expenditures in recent years.

Public Health

The **Department of Medical Assistance Services (DMAS)** administers the *Virginia State Plan for Medical Assistance*, which makes medical care available to indigent and medically needy Virginians under the federal Medicaid program. Prescription drugs are an optional service that Virginia has covered since the program's inception in 1969. A substantial proportion of the agency's pharmaceutical expenditures are direct payments for prescription drugs for clients eligible for fee-for-service coverage. An increasing proportion of DMAS clients are covered by health maintenance organization (HMO) plans, which include pharmaceutical coverage. These private HMOs receive a flat annual fee to provide all of the medical care, including prescription drugs, for each Medicaid enrollee.[11]

The Virginia Medicaid Program is both federally and state funded. The federal funding participation rate for medical expenditures has ranged from 51.05 percent in FY 1996 to 51.65 percent in FY 2000. Net pharmacy expenditures have increased an average of 13.8 percent annually over the past five years. The official Medicaid consensus forecast projects net pharmaceutical expenditures will increase an average of 11 percent per year over the next two years, reaching $366.9 million by FY 2002.[12]

Virginia's Medicaid program has an open drug formulary (i.e., any drug approved by the Food and Drug Administration with a rebate agreement under the Omnibus Budget Reconciliation Act of 1990 may be dispensed). However, the *State Plan* does require generic substitution for all multi-source brand-name products unless the prescriber specifically writes "brand necessary." Prior authorization is currently only required for weight loss drugs for treating morbid obesity. In FY 2000, mental health medications, which include antidepressants and new atypical drugs for treating psychosis, analgesics, and anti-ulcer medications, were the most

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estimate based on year-to-date expenditures and FY2000 appropriations to higher education components.

[11] Pharmacy data for managed care enrollees is maintained by the contracting HMO. The Medicaid recipient data presented and examined in this report only covers the fee-for-service population.

[12] 1999 Department of Planning and Budget and Department of Medical Assistance Services Consensus Medicaid Forecast.

commonly prescribed drugs and accounted for approximately 40 percent of net pharmaceutical expenditures.[13]

Table 1: Department of Medical Assistance Services, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$242,599,701	$276,394,192	$322,927,888	$373,858,267
Rebates[b]	$41,336,651	$54,358,385	$60,522,588	$75,477,394
Net Pharmacy Expenditures	$201,263,050	$222,035,807	$262,405,300	$298,380,873
Percent Growth from Previous Year Shown	*13.0%*	*10.3%*	*18.2%*	*13.7%*
Total Program Expenditures[c]	$2,253,817,240	$2,342,477,366	$2,461,612,625	$2,732,427,319
Net Pharmacy as a % of Total	8.9%	9.5%	10.7%	10.9%
Number of Recipients[d]	397,425	384,764	378,168	341,141
Net Pharmacy Expenditures per Recipient	$506.42	$577.07	$693.89	$874.66
Number of Claims[e]	8,054,152	8,252,400	8,548,251	8,683,145
Net Pharmacy Expenditures per Claim	$24.99	$26.91	$30.70	$34.36

Notes:
[a]Pharmacy expenditures reflect total funds (both GF and NGF) fee-for-service outpatient and nursing home spending on prescription drugs. Pharmacy expenditures during inpatient hospitalizations or for individuals in managed care programs or in mental health/mental retardation facilities are not included in these figures.
[b]Rebates from pharmaceutical manufacturers; listed in the year collected.
[c]Total medical assistance services expenditures (state subprograms 45607, 45608, 45609 and 45610)
[d]Annual unduplicated count of Medicaid pharmacy service recipients.
[e]Number of original pharmacy claims paid.

The implementation of managed care is a factor that must be explicitly considered when examining the Medicaid pharmacy data. The Medallion II program, implemented by the 1995 General Assembly, requires the mandatory enrollment of most Medicaid clients into HMOs. Medallion II is being implemented on a regional basis, and as of July 1, 1999, the program operated in 46 of the 137 Virginia localities with almost 150,000 beneficiaries enrolled.[14] The main exceptions from enrollment in managed care are long-term care recipients who are in institutions and those recipients enrolled in separate home and community-based care waiver programs targeted to the elderly and disabled.

[13] Department of Medical Assistance Services.
[14] Localities are defined by Federal Information Processing Standard (FIPS) codes. For Virginia they encompass counties and incorporated cities.

On average, the individuals exempt from managed care are more susceptible to severe illness and often have higher pharmaceutical utilization and use more costly medications than other individuals. As a result, some of the increase in utilization and average cost and overall pharmacy expenditures observed in the Medicaid program can be attributed to this change in the composition of the fee-for-service (FFS) population as healthier clients are moved into managed care programs. In FY 1997, the aged, blind and disabled individuals accounted for 37 percent of the total FFS population. That percentage had increased to 42 percent in FY 2000.

The **Virginia Department of Health (VDH)** provides public health, environmental, and medical services through 119 local health departments (LHDs). Based on the Code of Virginia, pharmaceuticals and biologics are provided at no charge for selected sexually transmitted diseases and for immunizations required for school entry. Most other pharmacy services are provided for eligible health department patients receiving treatment for tuberculosis, family planning, pediatric or maternity services, and in specialty primary care clinics. The most common types of pharmaceuticals dispensed by VDH clinics include vaccines, immunizations, oral and injectable contraceptives, medications and devices for diabetes, and antibiotics.

Table 2: Department of Health, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$9,133,159	$13,560,989	$15,065,593	$21,010,351
Rebates[b]	$0	$0	$0	$0
Net Pharmacy Expenditures	$9,133,159	$13,560,989	$15,065,593	$21,010,351
Percent Growth from Previous Year Shown	*30.0%*	*48.5%*	*11.1%*	*39.5%*
Total Program Expenditures[c]	$123,390,268	$131,055,159	$133,931,978	$138,894,897
Net Pharmacy as a % of Total	*7.4%*	*10.3%*	*11.2%*	*15.1%*

Notes:
[a]Expenditures on pharmaceuticals paid for with general fund dollars, local match funds, and earned revenues. The figures for FY 1999 and FY 2000 exclude any programs funded with 100% local funds. Prior to FY1999, VDH combined pharmaceutical drug expenditures with medical and dental supplies. Expenditures for FY1997-FY98 were estimated by applying the percent of total pharmacy, medical and dental supplies observed in FY1999 and FY2000.
[b]Not applicable to VDH pharmaceutical purchases.
[c]Total VDH clinical services. (Excludes administration, environmental and other non-medical programs)
*The number of total individuals served and the total number of prescriptions filled by VDH clinics is not available at the statewide level.

Ten health districts, typically those serving larger patient populations, have established their own pharmacies and employ

pharmacists. In these local health departments, prescriptions are filled on-site whenever possible to reduce barriers such as transportation difficulties or privacy concerns that some patients may have about certain diseases. VDH operates a central pharmacy, located in Richmond, which provides pharmacy services to local health departments that do not operate on-site pharmacies. Medical services, including prescription drugs, provided to VDH clients are paid for with a combination of funding that includes state general fund dollars, local match funds, revenues (from patient co-payments determined on a sliding income scale), and any additional local monies provided.

The **Department of Mental Health, Mental Retardation and Substance Abuse Services (DMHMRSAS)** operates 10 psychiatric facilities and five mental retardation training centers that provide in-patient treatment for persons suffering mental illness, mental retardation, and alcohol or other drug abuse problems. Clients access these state-operated facilities through Community Service Boards (CSBs). CSBs are local government agencies responsible for delivering mental health, mental retardation, and substance abuse services to citizens in their localities.

Payments from Medicaid, Medicare, federal benefit programs, commercial insurance, and patients pay for approximately 60 percent of services, including pharmaceuticals, provided in the state-operated facilities. State general fund dollars make up the remaining 40 percent of expenditures, which are usually made on behalf of indigent clients. In addition to providing pharmaceuticals for use in state mental health and mental retardation facilities, DMHMRSAS also operates an aftercare pharmacy that community service boards may use to purchase pharmaceuticals for their clients. These purchases are handled through the DMHMRSAS central office using general fund dollars appropriated to the CSBs. Anti-psychotic medications, including the new atypicals, and antidepressant medications account for the majority of DMHMRSAS's pharmaceutical expenditures.

Table 3: Department of Mental Health, Mental Retardation and Substance Abuse Services, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$12,022,726	$16,386,289	$20,635,043	$28,770,074
Rebates[b]	$0	$0	$0	$0
Net Pharmacy Expenditures	$12,022,726	$16,386,289	$20,635,043	$28,770,074
Percent Growth from Previous Year Shown	*6.9%*	*36.3%*	*25.9%*	*39.4%*
Total Program Expenditures[c]	$393,933,092	$433,893,393	$466,662,243	$504,063,629
Net Pharmacy as a % of Total	3.1%	3.8%	4.4%	5.7%
Net Pharmacy Expenditures per Claim[d]	$20.54	$28.40	$44.51	$55.03

Notes:

[a]Pharmacy expenditures for the 15 state-operated facilities and the central office. These figures include pharmaceuticals purchased by community service boards from the Hiram Davis aftercare pharmacy.
[b]DMHMRSAS does not receive drug rebates, but is a member of a multi-state drug consortium from which they receive a participation fee based on volume of drugs purchased, approximately $50,000 per year.
[c]Total facilities and central office expenditures. Excludes CSB expenditures except those pharmaceutical purchased from the Hiram Davis aftercare pharmacy.
[d]The average net cost per claim presented is based on data from the Hiram Davis aftercare pharmacy.
*The unduplicated number of patients served and total number of prescriptions filled is not available at the statewide level.

Public Safety

Virginia has an obligation to provide health care for inmates and confined juvenile offenders in state facilities. The **Department of Corrections (DOC)** manages the Commonwealth's prison system and the **Department of Juvenile Justice (DJJ)** operates the Commonwealth's juvenile correctional centers. DOC and DJJ are responsible for purchasing prescription drugs for the inmates and juvenile offenders in their custody. These agencies are funded primarily with by state general fund dollars. However, they also receive out-of-state revenues for housing out-of-state inmates and a small amount of federal and special funds.

At several of its institutions, DOC utilizes an outside medical contractor who agrees to accept a fixed fee for medical services (including prescription drugs) provided to inmates. DOC, however, does pay a separate fee (which is not part of the fixed medical service contract fee) for dialysis and for any Antiretroviral (HIV) and Hepatitis C medications taken by inmates at these institutions. Antiretrovirals and Hepatitis C drugs account for a significant portion of DOC's pharmaceutical expenditures.

Estimates indicate that just under two percent of the entire inmate population is being treated for HIV/AIDS or Hepatitis C.[15] Mental health drugs, including new atypical anti-psychotics and antidepressants, and cholesterol reducing medications also contribute significantly to DOC pharmaceutical expenditures.

Table 4: Department of Corrections, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$5,480,934	$7,278,421	$8,867,690	$11,928,720
Rebates[b]	$0	$0	$0	$0
Net Pharmacy Expenditures	$5,480,934	$7,278,421	$8,867,690	$11,928,720
Percent Growth from Previous Year Shown	*16.9%*	*32.8%*	*21.8%*	*34.5%*
Total Program Expenditures[c]	$507,674,895	$556,200,474	$656,343,865	$718,877,302
Net Pharmacy as a % of Total	*1.1%*	*1.3%*	*1.4%*	*1.7%*
Number of Recipients[d]	22,027	22,065	21,743	23,201
Net Pharmacy Expenditures per Recipient	$248.83	$329.86	$407.84	$514.15

Notes:
[a]Pharmacy expenditures reflect drugs purchased for inmates in institutions not under managed care contracts and Antiretroviral (HIV) and Hepatitis C drugs purchased for inmates at institutions under managed care contracts (these drugs are not included in the medical services provided under the contract).
[b]DOC contracts with Diamond Pharmacy for its formulary (pre-approved) drug purchases and with Trigon for its non-formulary (drugs that require prior-authorization) drug purchases. Any rebates are collected by Diamond or Trigon and reflected in the prices paid by DOC.
[c]Total DOC spending for Community Corrections and Divisions of Institutions. This figure does not include expenditures made by Virginia Correctional Enterprises (VCE).
[d]The number of inmates in institutions without managed care contracts.
*Prior to October 1999, DOC operated its own central pharmacy. Records were kept manually and the number of total prescriptions written is not available.

According to the most recent statistics, approximately 38 percent of the state's confined juvenile offender population receive medication. Psychotropic medications are used by an estimated 20 percent of that population. The most recently conducted review of patient information at DJJ revealed that 47 percent of youth committed to the Department have a history of being prescribed psychotropic medications prior to admission.

Part of the increase in expenditures in FY2000 is due to opening of the Culpeper Juvenile Correctional Center that year and that pharmaceutical expenditure data for the Oak Ridge Juvenile Correctional Center is not available prior to FY2000.

[15] These figures indicate only how many inmates are currently receiving treatment for these diseases and may differ from the number of inmates diagnosed with these diseases.

Table 5: Department of Juvenile Justice, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$168,166	$192,865	$257,605	$449,565
Rebates[b]	$0	$0	$0	$0
Net Pharmacy Expenditures	$168,166	$192,865	$257,605	$449,565
Percent Growth from Previous Year Shown	*24.8%*	*14.7%*	*33.6%*	*n/a**
Total Program Expenditures[c]	$38,122,960	$50,707,059	$60,262,252	$68,186,161
Net Pharmacy as a % of Total	*0.44%*	*0.38%*	*0.43%*	*0.66%*
Number of Recipients[d]	1,249	1,221	1,309	1,415
Net Pharmacy Expenditures per Recipient	$134.69	$157.96	$196.80	$317.71

Notes
[a]Pharmacy expenditures reflect drugs purchased by state Juvenile Correctional Centers. Data is not available for the Oak Ridge JCC prior to FY 2000. Note: Some of the increase in FY 2000 is due to the opening of the Culpeper JCC that year and that data for the Oak Ridge JCC is only available for FY2000.
[b]DJJ contracts with an outside vendor for its drug purchases. Any rebates are collected by the contractors and reflected in the prices paid by DJJ.
[c]Total Juvenile Correctional Center operating costs.
[d]Average number of confined juvenile offenders. FY1997-FY2000 excludes offenders in the Oak Ridge JCC since expenditure data is not available for that facility for those years.
*Prior to October 1999, DJJ obtained its pharmaceuticals from the DOC central pharmacy. Records there were kept manually and the number of total prescriptions written is not available.
*This figure is not reported since expenditure data for the Oak Ridge JCC is not included in the FY1999 figure and would indicate a higher percent increase than actually occurred.

Employee Compensation

Health insurance benefits for state employees are paid for by contributions from both the employer and the employee. Employer premiums are paid by each agency using varying combinations of general fund, nongeneral fund, special fund and earned revenue dollars. The cost and comprehensiveness of the plan is an important component of the benefits package that the state uses to recruit and retain an effective workforce. The **Department of Human Resource Management (DHRM)** administers the Commonwealth's health benefits program, which offers health insurance coverage to over 180,000 state employees, retirees, and their dependents.

Prior to 1989, prescription drugs were covered under major medical services and were subject to a multi-purpose $200 annual deductible[16] and 20 percent coinsurance payment. In 1989, a drug card plan was implemented with no annual deductible. Co-payments have risen over the years. Currently, the most popular

[16] This deductible applied toward all covered medical services.

plan (Key Advantage) charges a $13 co-payment for 34-day prescriptions filled at retail locations ($8 in 1989) and an $18 co-payment for 90-day prescriptions filled through the mail order pharmacy ($6 in 1989).

Prescriptions for central nervous system (CNS) agents, which include antidepressants, represented 22.4 percent of expenditures in FY 2000, followed by cardiovascular drugs (21.2 percent) and gastrointestinal drugs (13.3 percent).

Table 6: Department of Human Resource Management, Pharmacy Program Statistics

	FY1997	FY1998	FY1999	FY2000
Pharmacy Expenditures[a]	$46,784,527	$53,645,984	$65,330,030	$81,984,989
Rebates[b]	$1,696,564	$1,940,429	$1,637,705	$1,233,205
Net Pharmacy Expenditures	$45,087,963	$51,705,555	$63,692,325	$80,751,784
Percent Growth from Previous Year Shown	*21.7%*	*14.7%*	*23.2%*	*26.8%*
Total Program Expenditures[c]	$329,029,796	$317,715,133	$326,927,966	$360,986,615
Net Pharmacy as a % of Total	13.7%	16.3%	19.5%	22.4%
Number of Recipients[d]	174,404	172,541	173,644	180,305
Net Pharmacy Expenditures per Recipient	$258.53	$299.67	$366.80	$447.86
Number of Claims[e]	n/a	1,528,153	1,686,637	1,861,648
Net Pharmacy Expenditures per Claim	n/a	$33.84	$37.76	$43.38

Notes:

[a] Pharmacy expenditures reflect the grand total for all state programs with drug benefits, including active employees, COBRA beneficiaries, early retirees, and Medicare eligible retirees in the Option I, Advantage 65 or Drug only programs. Expenditures for the Local Choice program are not included in these figures.

[b] Rebates from pharmaceutical manufacturers; listed in the year collected.

[c] Total health care expenses for all state plans, including active employees, COBRA beneficiaries, early retirees, and Medicare eligible retirees in the Option I, Advantage 65 or Drug only programs. Expenditures for the Local Choice program are not included in these figures.

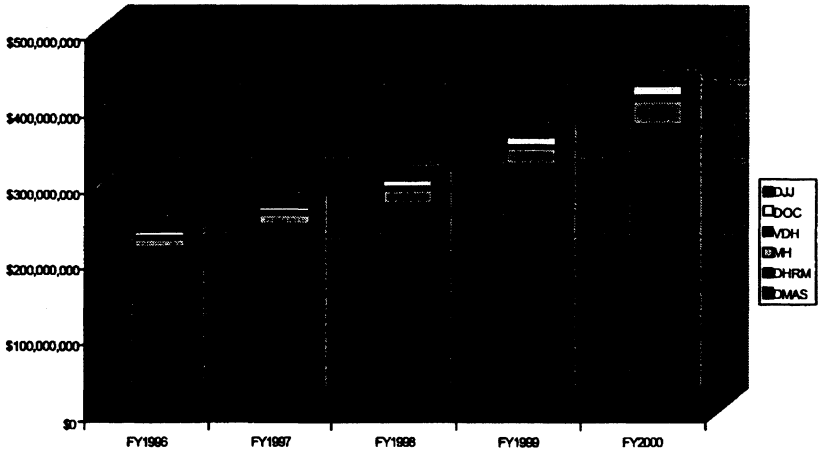
[d] Average number of members with drug benefit. Figures include employee, spouses, and eligible dependents.

[e] Number of claims for all programs with drug benefit.

Factors in Rising Pharmaceutical Expenditures

The Department of Medical Assistance Services is by far the largest government purchaser of prescription drugs in the state, responsible for 74 percent of pharmaceutical expenditures in FY 2000, followed by the Department of Human Resource Management, which was responsible for 16 percent. Together, these two agencies accounted for over 90 percent of all government pharmaceutical expenditures over the past six years *(See Figure 5)*.

Figure 5: Virginia Government Funded Net Pharmaceutical Expenditures - FY 1996 - FY 2000

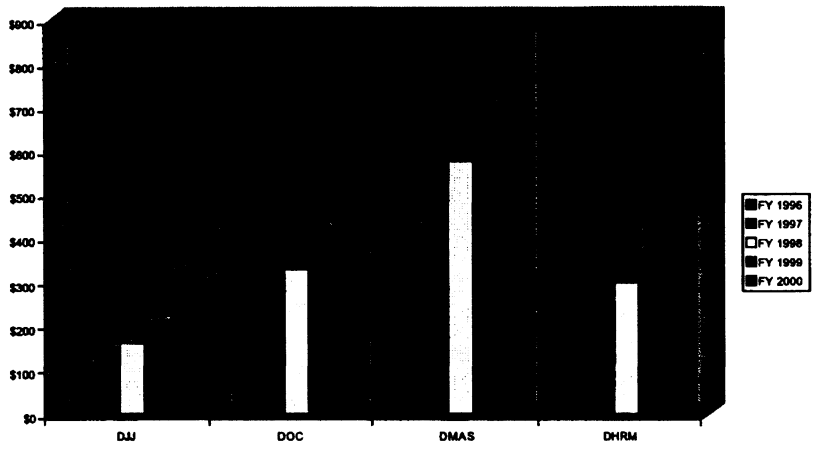


Source: Analysis by Department of Planning and Budget of data provided by agencies. These figures represent both general fund and nongeneral fund dollars and include any drug rebates received.

All of the agencies have experienced significant pharmaceutical expenditure growth in recent years. The average net (after rebates) pharmaceutical expenditure per recipient has increased between 20 and 30 percent each of the last five years for those agencies reviewed *(See Figure 6)*.[17] Not only are overall pharmaceutical expenditures increasing for these state agencies, but pharmaceuticals are taking up a larger proportion of their total program spending *(See Table 7)*.

[17] Annual unduplicated recipient data was unavailable for VDH and DMHMRSAS. Recipient data for DOC and DJJ refers to the average annual inmate population, excluding those in managed care programs. Recipient data for DMAS is annual unduplicated pharmacy service recipients. Recipient data for DHRM is average annual number of members with drug benefit.

Figure 6: Average Net Expenditures per Recipient



Source: Analysis by Department of Planning and Budget of data provided by agencies. This information is not intended to make a comparison of expenditures between agencies, as many factors, such as population mix, length of prescriptions, and co-payments may differ.

Table 7: Net Pharmacy Expenditures as a Percentage of Total Program Expenditures[18]

Net Pharmacy Expenditures as a percentage of Total Program Expenditures	VDH	DJJ	DOC	MH	DMAS	DHRM
FY1996	5.9%	0.30%	0.9%	2.8%	8.2%	11.9%
FY1997	7.4%	0.44%	1.1%	3.1%	8.9%	13.7%
FY1998	10.4%	0.38%	1.3%	3.8%	9.5%	16.3%
FY1999	11.3%	0.43%	1.4%	4.4%	10.7%	19.5%
FY2000	15.1%	0.66%	1.7%	5.7%	10.9%	22.4%

Source: Analysis by Department of Planning and Budget of data provided by agencies.

Nationally, researchers have found most of the growth in total drug expenditures has been concentrated in a few therapeutic categories. According to a study by the National Institute for Health Care Management, more than one-third (35.2 percent) of the entire 1993-98 increase in national prescription drug spending was attributable to just five categories of drugs: antidepressants, cholesterol reducers, antiulcer drugs, oral antihistamines, and

[18] Total program spending refers to total clinical program expenditures for VDH, total Juvenile Correctional Center operating costs for DJJ, total institution and community correction spending (excluding Virginia Correctional Enterprises) for DOC, total expenditures for facilities and the central office (excluding CSBs) for DMHMRSAS, total medical assistance services for DMAS, and total health care expenditures for DHRM.

antihypertension drugs.[19] A significant portion of the primary drugs used by each agency, as presented previously in the agency overviews, falls into one or more of these categories

Numerous studies and reports have examined the factors that have influenced the growth of prescription drug expenditures.[20] While the contribution attributed to each of these factors differs across studies, the explanations of the underlying causes of these increases all focus on the following: changes in the utilization of existing products in the market, increases in the prices of prescribed drugs. These factors differ widely depending on the therapeutic drug class or specific drug studied.

The remainder of this chapter will describe how utilization and prices affect Virginia's pharmaceutical expenditures. The next chapter addresses the various factors that affect utilization, prices, and the introduction of new products.

Utilization Factors

According to most researchers, utilization of prescription drugs is increasing and will continue to increase. Factors such as

- Improvements in the rates of diagnosis and awareness of disease, and increased life-spans (which result in a greater number of patients under treatment),
- Changes in accepted medical practices and treatment protocols (i.e., more drug intensive treatment of diseases),
- Introduction of new therapies for previously untreatable diseases,
- Direct-to-consumer advertising, and
- Demographic changes (i.e., aging of the population)

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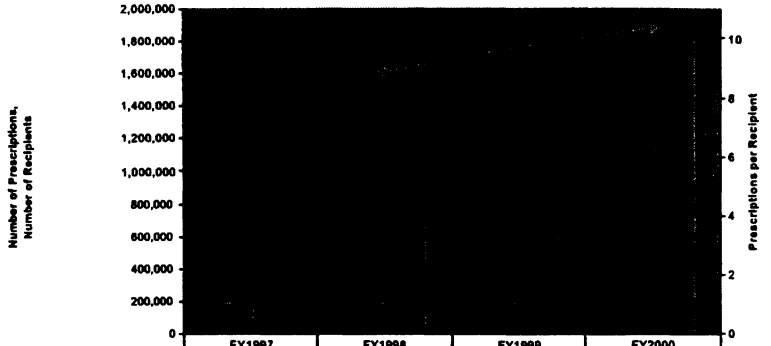
[19] National Institute for Health Care Management Foundation. *Factors Affecting the Growth of Prescription Drug Expenditures*. Prepared by Barents Group LLC. July 1999.
[20] National Institute for Health Care Management Foundation. *Factors Affecting the Growth of Prescription Drug Expenditures*. Prepared by Barents Group LLC. July 1999. Merck-Medco. *Managing Pharmacy Benefit Costs*. 1999. Teitelbaum, Fred, and others. *1998 Drug Trend Report*. Express Scripts, Inc. June 1999. Dubois, Richard, and others. "Explaining Drug Spending Trends: Does Perception Match Reality?" *Health Affairs* 19 (March/April 2000): 231-239 *Prescription Drugs: Cost and Coverage Trends*. Health Insurance Association of America (HIAA), September 1999. Copeland, Craig. *Prescription Drugs: Issues of Cost, Coverage, and Quality* Employee Benefit Research Institute (EBRI), April 1999. *Prescription Drug Coverage*. Summary of a Workshop and Audio Teleconference Series for State and Local Health Policymakers, January 10-12, 2000, User Liaison Program. Agency for Healthcare Research and Quality, Rockville, MD. National *States Face Increased Expenditures for Pharmaceuticals*. Governors' Association Center for Best Practices. February 2000. Wallack, Stanley S. *Factors Driving Prescription Drug Expenditure Increases*. Testimony before the U.S. Senate Committee on Health, Education, Labor and Pensions. 18 July 2000.

have all contributed to an increased demand for pharmaceuticals.[21] In Virginia, data from DMAS and DHRM shows that, in spite of slowly growing or even decreasing populations, the number of claims is steadily rising *(See Figures 7 and 8).*[22]

Figure 7: Pharmaceutical Utilization: Virginia's Employee Health Benefit Program



	FY1997	FY1998	FY1999	FY2000
Pharmacy Recipients	174,404	172,541	173,644	180,305
Number of Prescriptions	n/a	1,528,153	1,686,637	1,861,648
Prescriptions per Recipient	n/a	8.9	9.7	10.3

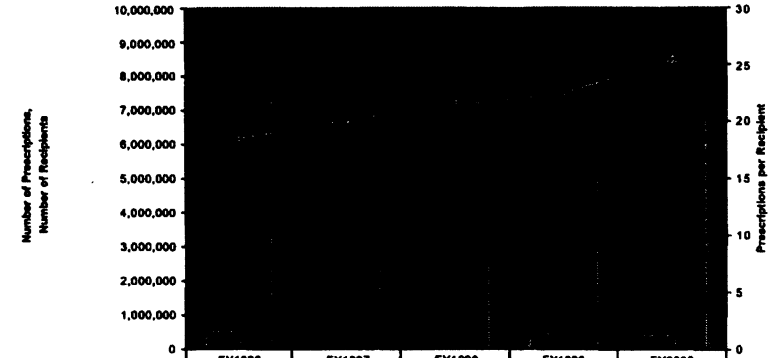
Source: Analysis by Department of Planning and Budget of data provided by DHRM. Recipients refers to the average number of members with drug benefits, including those individuals receiving and receiving prescribed drugs. "Prescriptions per recipient" refers to the number of individual transactions, new or refill, per member. The days supplied per prescription are variable.

The number of prescriptions per recipient in the fee-for-service Medicaid population has increased 38 percent in four years, from 18.5 in FY 1996 to 25.5 in FY 2000. "Prescriptions per recipient" refers to the number of individual transactions, new or refill, per individual. The days supplied per prescription vary. A significant factor in the Medicaid trend has been the change in the composition of the fee-for-service population as healthier clients have been moved into managed care programs.

[21] Ibid.

[22] This information is not intended to make a comparison of utilization increases between agencies (as many factors, such as population mix, length of prescriptions, and co-payments may differ). The data presented reflects the trend in each agency for years in which data is available

Figure 8: Pharmaceutical Utilization: Virginia Medicaid Program



	FY1996	FY1997	FY1998	FY1999	FY2000
Pharmacy Recipients	429,159	397,425	384,764	378,168	341,141
Number of Prescriptions	7,954,353	8,054,152	8,252,400	8,546,251	8,683,145
Prescriptions per Recipient	18.5	20.3	21.4	22.6	25.5

Source: Analysis by Department of Planning Budget of data provided by DMAS. Figures represent recipients in the fee-for-service population who received prescription drugs. "Prescriptions per recipient" refers to the number of individual transactions, new or refill, per individual. The days supplied per prescription are variable.

An examination of the increases in Medicaid pharmaceutical utilization by specific therapeutic class indicates that the psychostimulant-antidepressant class had the largest increase in number of prescriptions between FY 1997 and FY 2000, followed by hypotensives and antihistamines *(See Table 8).*[23]

Table 8: Increases in Medicaid Pharmaceutical Utilization FY 1997 – FY 2000

Therapeutic Class	FY 1997 Claims	FY 2000 Claims	FY97-FY00 Increase	FY97-FY00 %Increase
Psychostimulants-Antidepressants	366,113	473,675	107,562	29.38%
Hypotensives, Other	307,254	388,461	81,207	26.43%
Antihistamines	204,140	280,960	76,820	37.63%
Unclassified Drug Products	102,128	174,901	72,773	71.26%
Diabetic Therapy	242,670	310,232	67,562	27.84%
Anticonvulsants	239,381	306,871	67,490	28.19%
Lipotropics	78,865	142,904	64,039	81.20%
Analgesics, Narcotic	402,185	450,687	48,502	12.06%
Electrolytes & Miscellaneous Nutrients	159,529	202,763	43,234	27.10%
Anti-Ulcer/Other Gastrointestinal Preps	398,666	434,502	35,836	8.99%

Source: Department of Medical Assistance Services.

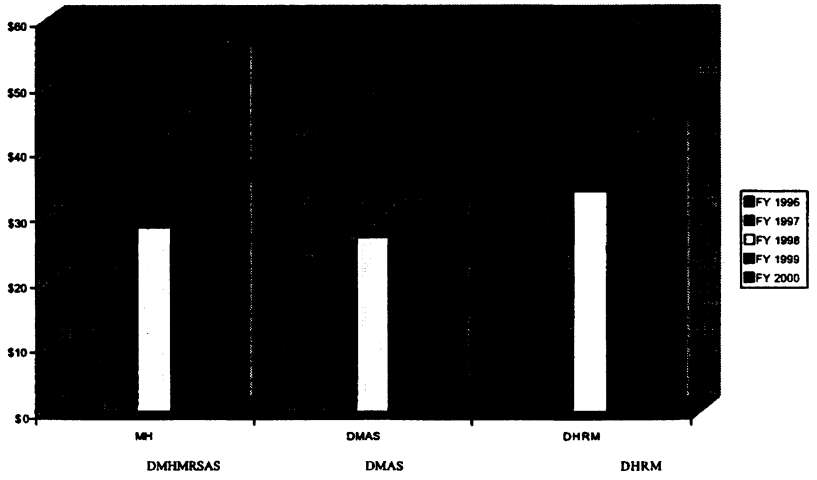
[23] Historic utilization information by specific therapeutic class was not available for other agencies.

Price Factors

Increases in the prices of existing products and the introduction of new products both contribute to higher pharmaceutical expenditures. These newer therapies are often more expensive than existing therapies. In Virginia, the average price per prescription paid by state agencies has increased steadily each year *(See Figure 9)*. The average cost per monthly prescription filled by DMHMRSAS's aftercare pharmacy increased 168 percent in three years, from $20.54 in FY 1997 to $55.03 in FY 2000. A significant factor in this increase is the use of new atypical anti-psychotic medications. In May 2000, the average price for an atypical drug was $184.87 compared to $24.02 for non-atypical drugs. Atypical medications accounted for approximately 22 percent of total prescriptions filled at the aftercare pharmacy in FY 2000. This represents an increase of 74 percent from the number of atypical prescriptions filled in FY 1999.

In the Virginia Medicaid program, the average cost per claim (before rebates) in FY 2000 was $43.06. The average cost per claim for 36 of the more high profile new drugs was $121.61 that same year.[24]

*Figure 9: Average Cost per Prescription**



Source: Analysis by Department of Planning and Budget data provided by agencies. Average prices reflect any rebates received.

*This graph is not intended to compare average cost across agencies (as many factors, such as population mix, length of prescriptions, and co-payments may differ) but to show the trend in average cost within the individual agency. The data presented reflects the cost trend in each agency for years in which data is available.

[24] Department of Medical Assistance Services. These figures do not include drug rebates, as rebate data for individual drugs is not available.

For the Medicaid program, an examination of the price increases in by specific therapeutic class indicates that there have been significant increases both in terms of absolute dollars and percentage increases. The cost of antiviral class drugs showed the greatest dollar increase per prescription between FY 1997 and FY 2000, followed by parasympathetic agents. Drugs in the anticoagulant class experienced the highest percentage increase, rising 615 percent during this period *(See Table 9).*[25]

Table 9: Increases in Medicaid Pharmaceutical Prices FY 1997 – FY 2000

Therapeutic Class	FY 1997 Cost per Claim	FY 2000 Cost per Claim	FY97-FY00 Increase	FY97-FY00 %Increase
Antivirals	$190	$287	$97	50.84%
Parasympathetic Agents	$46	$109	$62	134.07%
Anticoagulants	$7	$51	$44	614.79%
Antaractics-Tranquilizers	$33	$77	$43	129.42%
Dermatologicals, All other	$25	$56	$32	127.92%
Unclassified Drug Products	$136	$163	$27	19.51%
Antiarthritics	$26	$47	$21	80.94%
Antibacterials, Urinary	$29	$49	$20	69.51%
Psychostimulants-Antidepressants	$39	$56	$17	42.77%
Anticonvulsants	$45	$62	$17	37.28%

Source: Department of Medical Assistance Services.

Pharmaceutical expenditures for the agencies examined in this study have increased significantly over recent years. These expenditure increases have been brought about principally by increases in utilization and increases in prices. The following chapter examines the factors that drive utilization and prices.

[25] Historic cost information by specific therapeutic class was not available for other agencies.

Chapter 2: The Pharmaceutical Market & Factors Driving Expenditures

In order to better understand the various factors that are driving pharmaceutical expenditures, this section will provide a detailed overview of the pharmaceutical market and the incentive structures that drive changes in this market. In particular, the following topics are addressed:

- Increases in R&D expenditures
- Increases in new chemical entities approved by the FDA
- New drugs in the "pipeline"
- Generic and over-the-counter medications
- New uses for existing drugs and changes in the way existing drugs are used
- Therapeutic substitutions
- Aging population requiring more frequent and often expensive drugs
- Direct-to consumer advertising
- Prescription drug prices

A primary purpose of this report is to describe the pharmaceutical market and the various factors that influence pharmaceutical expenditures. The pharmaceutical market is a highly complex mechanism driven by a variety of interrelated forces. Attempts to influence one component of this market, without the benefit of the larger market picture, have the potential to lead to unintended, and very possibly, undesirable outcomes that could outweigh any benefits achieved. While it is beyond the scope of this study to evaluate specific policy options regarding the Commonwealth's purchase of pharmaceuticals, the evaluation of the pharmaceutical market provides the necessary framework for future decision making.

Pharmacy Expenditures: An Issue of Supply and Demand

While the pharmaceutical industry is heavily regulated in many ways, ultimately, pharmaceuticals are developed and made available through the auspices of the private market. Research and

development of new drugs, manufacturing, distribution, advertising, and sales are all handled primarily by private firms.

In the United States, government serves primarily as a regulator of safety and efficacy. All drugs must undergo an extensive testing process and receive Food and Drug Administration (FDA) approval before they may be marketed to the public. There are also significant restrictions on the marketing of pharmaceuticals. Other governmental regulatory activity in this market includes enforcing patent rights, contributing to the funding of both basic and applied research, and monitoring drugs for unintended health effects. Government is also involved in the market as a purchaser of pharmaceuticals. Some agencies such as the Veterans Administration are large direct purchasers of drugs for use in agency facilities. However, it is more common for government to be involved as the party paying for drugs used by individuals, as with the Medicaid program.

Understanding the structure of the pharmaceutical market is critical to understand both the policy and budget issues associated with rising pharmacy expenditures. Many discussions about rising pharmaceutical expenditures focus on pieces of the larger picture: drug prices, advertising, utilization, research and development, cost containment efforts, access and affordability, profitability, quality. This chapter attempts to arrange all of these pieces together in the larger and more complex picture that is the market for pharmaceuticals. Accordingly, the function of this chapter is 1) to facilitate an understanding of the key issues in the drug cost debate in the context of the relevant markets and 2) to attempt to indicate what we do and do not know about these markets. With this information in hand, it will be possible to make more informed choices relevant to the future of pharmaceutical expenditures made by state agencies in Virginia.

In the course of examining the market for pharmaceuticals, the discussion will be organized along the lines of seller and buyer behavior. Traditionally, economic analysis summarizes seller and buyer behavior in terms of a supply curve and a demand curve, respectively. First, this chapter will discuss the supply of pharmaceuticals. Then a discussion of the demand for pharmaceuticals will follow. Throughout, it will seek to clarify how the interplay of these two incentives generates the behavior we observe in this market.

The Supply of Pharmaceuticals

Suppliers of all products, including pharmaceutical products, seek to maximize the future financial rate of return to investors. Investors, in turn, have the option of moving their capital from firm to firm and industry to industry. Firms whose risk-adjusted expected rate of future return falls much below returns made elsewhere will lose value as investors move their capital elsewhere. The management of under-performing firms stands a substantial likelihood of being replaced. The opposite holds true for firms outperforming the market. They will generally experience an inflow of capital over time and will experience an increase in competition from new firms entering the market, unless some barrier to entering the market prevents the competition from materializing.

These fundamental concepts of firm behavior are useful for understanding the patterns of supply observed in the pharmaceutical market. The willingness and ability of a firm to supply a drug to the market depends on a dynamic process that unfolds over an extended period of time. This process may be usefully divided into three parts: 1) development of a new patentable chemical entity, 2) sale of a patented product, and 3) sale after the expiration of a patent. At each stage of the process, the firm is using the information available to answer the following question: "Given the current situation how can we maximize the expected future stream of revenue resulting from this activity?"

Responses to this question requires an estimate of all future events related to the possible profits to be earned from the development of a new drug, including the following:

- Clinical effectiveness of the treatment relative to other available treatments,
- Likelihood of FDA approval,
- Cost of producing the new drug,
- Size of the market,
- Likelihood of another firm getting there first,
- Likelihood of another firm developing a close alternative treatment,
- Length of post-approval patent protection, and
- Likelihood of generic entry after patent expiration.

At early stages of development, these factors will help determine if and when a drug will be supplied to the market. The new drug will be developed only if the firm believes that it can expect to earn at least a normal rate of return on its investment.

Once a new chemical entity is patented, the firm faces less uncertainty and must now, based on current information, answer the same question: "How can the firm maximize its expected future stream of earnings from the manufacture and sale of this product?" At this point, the cost and uncertainty of product development is no longer a concern. The price that the firm charges will depend primarily on demand for the product and to some degree on the costs of manufacturing and production.[26]

A prominent omission from the list of considerations that a firm uses in setting a drug's price is the cost of research and development required to bring the new drug to market. Although this may appear counter-intuitive, it would not be rational for a profit-maximizing firm to consider development costs when setting future prices. Suppose, for example, a firm develops a new product for a lower cost than it had originally planned. A profit maximizing firm would not set a low price based on the fact that the development costs had been lower than expected any more than a homeowner would choose not to accept a large capital gain on a house merely because its original cost was much lower than the current values in the neighborhood. If, on the other hand, development costs were high, a firm will not necessarily set a high price in a market full of substitutes. Even if it could not recover the full costs of development, the firm would still set its price to maximize the expected revenue stream from sales. Similarly, a homeowner needing to sell a home cannot expect to make money by pricing the house above what the current market will bear, regardless of the price paid for the house in the first place.

Once a drug loses its patent protection, or, if a close substitute is approved while the drug is still under patent, the firm must make a choice about whether to keep a high price and lose market share or to lower the price to retain a larger market. As previously stated, this decision will not depend on past performance or development

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[26] Production here is broadly defined to include such expenditures as packaging, shipping and advertising. The cost of actually manufacturing the product once a firm has received approval to market is quite low relative to the costs of research and development. The cost structure of the pharmaceutical industry is similar to that of the computer software and film industries. In all three of these industries, there are large up-front costs associated with developing the product. By the time the product goes to market, these costs are all "sunk" or "fixed." The additional cost of producing an additional unit of output, or marginal cost, is very low by comparison. For further discussion of this issue, see Schweitzer, *Pharmaceutical Economics and Policy*, 1997.

costs, only on what price will maximize future profits. Specific pricing strategies will be discussed later in this report. For now, it will suffice to say that the price charged depends on how responsive, or *elastic*, the demand for the drug is to price.[27]

New drugs

By nearly every measure, new drugs are responsible for a significant portion of the recent increases in pharmaceutical expenditures. Most of the attention in the discussion of drug costs focuses on new chemical entities approved by the FDA. However, other factors affecting pharmacy expenditures would include new uses approved for existing drugs and changes in the way existing drugs are used. Rather than focus exclusively on new chemical entities, it is probably more revealing to include all innovative new drug therapies.[28]

The effect of these newly approved drugs on the market will depend on how the therapy fits in the existing medical care market. New drugs' impacts on the market vary according to how innovative the therapy is relative to existing therapies. A new drug therapy for a condition formerly treated using non-pharmaceutical medical services will act to directly displace those other treatments. A new drug that treats conditions already addressed by other pharmaceuticals, but with different side-effects or effectiveness in various sub-populations, will act to divide the existing market. Alternatively, a new drug may treat a condition that formerly had no effective treatment.

Each new drug therapy will act partly to displace current treatments, partly to displace other drugs, and partly to expand the entire market for medical care rather than to replace care already being supplied by other means. Also, new chemical entities tend to be more expensive than older ones, leading to higher costs per prescription. The same is not necessarily true of new uses for existing drugs.[29]

R&D investment trends

The supply of new drug therapies arises from expenditures on research and development. Spending on R&D by research-based pharmaceutical companies has more than tripled in the past 10 years – from $8.4 billion in 1990 to $26.4 billion in 2000. The

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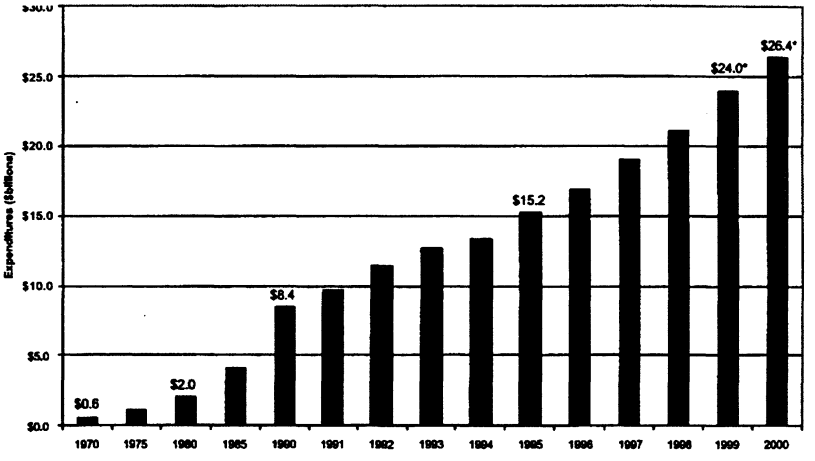
[27] See Schweitzer, Stuart O. *Pharmaceutical Economics and Policy.* New York: Oxford University Press, 1997.; and Folland, and others. *The Economics of Health and Health Care* 1993.

[28] An interesting recent example is the increased use of aspirin for use in preventing heart attacks and possibly even colon cancer.

[29] Again, the case of aspirin is a recent example.

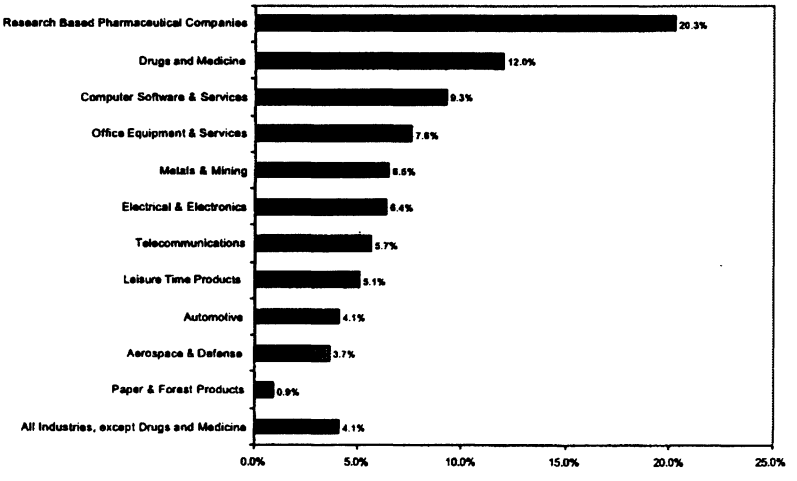
importance of R&D is reflected in the significant percentage of sales used for that purpose. In 2000, domestic R&D as a percent of sales for research-based pharmaceutical companies was 20.3 percent (*See Figures 10 and 11*).

Figure 10: Total R&D Spending by Research-Based Pharmaceutical Companies



Source: PhRMA Annual Survey, 2000
*Estimated figures.

Figure 11: R&D Spending as a Percent of Sales



Source: PhRMA Annual Survey, 2000.

The process of bringing a new drug to market has been much discussed and studied in recent years.[30] Bringing a new drug to market is a very time-consuming and expensive endeavor. It takes on average 12 to 15 years and $300 to $500 million for one new medicine to travel from a laboratory to U.S. patients.[31] In addition, the venture is extremely risky, with a large share of development projects ending in an unprofitable product. This occurs either because the project failed to result in a marketable product, or because revenues from the product did not add up to at least a "normal" rate of return on the product. Approximately only five in 5,000 compounds that enter pre-clinical testing make it to human testing, and only one of those five is ever approved for sale.[32]

Focus and direction of R&D

In spite of the risky and expensive nature of the development process, the pharmaceutical industry as a whole is, and has been for many years, a very profitable industry. The continued profitability of the industry makes it likely that research into pharmaceutical innovation will continue at an increasing rate for some time into the future. Should the expected future profitably of new pharmaceuticals fall appreciably, then it can be expected that some projects, which had appeared marginally profitable previously, would no longer be profitable to pursue.

There is a tradeoff between the pace of pharmaceutical R&D, which depends on future profitability, and the prices consumers pay for drugs, which helps determine future profitability. While economic theory does suggest ways of thinking about the appropriate tradeoff made between prices and profitability, there is ample room for disagreement about what constitutes the optimal level of R&D.

The discussion of R&D thus far has emphasized the *amount* of R&D effort. Another issue often raised in discussions of R&D is the issue of how the R&D is directed. Clearly, some research expenditures are duplicative. Two or more firms may race to be the first to patent a new chemical entity. Or several firms may undertake research for treating the same disease. The resulting therapies may be close substitutes for each other. In each of these

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[30] *Pharmaceutical R&D: Costs, Risks, and Rewards.* Office of Technology Assessment, February 1993. OTA-H-522.
[31] Mathieu, Mark P., ed. "Recent Estimates of the Cost of Developing New Drugs," *Pharmaceutical R&D Statistical Sourcebook 1999.* Waltham, *Massachusetts: Parexel Intl Corp, 2000.*
[32] Merck-Medco. *Managing Pharmacy Benefit Costs*. 1999; and Tufts Center for the Study of Drug Development, cited in PhRMA, *New Drug Approvals in 1999*, 2000.

cases, it may be argued that at least part of the research expenditures might better have been directed elsewhere.

Given the very long lead time from the initiation of R&D to the realization of an approved therapy, the risk of failure for a given research program, and the possibility that two parallel research programs may lead to distinct approaches to treating a given disease, the duplicativeness of the investment may be more apparent than real. Parallel research programs may help ensure that a path to the solution is found, although some of the efforts may fail. The race for the patent will also probably speed up the R&D cycle, bringing the therapies that do win approval to market sooner. Also, the existence of dual therapies for one disease may allow for a closer matching of therapies to the needs of a diverse population of patients. Finally, close substitute therapies can be expected to reduce the rate of growth in prices for the related therapies.

Patents

Current research and development expenditures are undertaken by private firms only because the firms expect to earn at least a normal rate of return on the investment. This is true of any privately provided R&D. To ensure that firms can earn a return on investments in inventive activity, the firms are granted a patent, which gives the firm a monopoly on supply of the invention for a period of time. This allows the firm to charge more for goods using the patented idea than it could if it did not have a monopoly on the use of the invention.

After the patent expires, anyone may make use of the innovation. The length of the patent period is an important instrument for encouraging investments in innovation. In general, the longer the patent's life, the higher the returns will be to the investment in innovation. Longer patent life also means that consumers face higher costs for using the invention. This reduces the net benefits from the inventive activity by reducing demand for the products that use the new invention. Choosing the length of time for patent life is an important public policy choice that involves a balance between the incentive to invest in innovation and the gains to the economy from the use of innovations that have already taken place.

Until 1995, patent protection extended for 17 years from the *date of issue* of the patent. This period was changed to 20 years from the *date of filing* of the application for the patent. In order to protect their investments in identifying new chemical entities, drug

companies must apply for a patent as soon as the chemical is created. Since creating a new chemical occurs very early in the research and development process, much of the life of the patent is used up by the time the new pharmaceutical comes to market. This gives pharmaceutical companies very strong incentive to bring patented chemicals to market as quickly as possible, but the shortened patent life reduces expected profits from developing new drugs. In 1993, the Office of Technology Assessment estimated average patent life for new chemical entities brought to market to be about 10 years.

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act) provided that patent protection for a drug can be extended for up to five years to compensate for regulatory delays provided that the patent term does not extend beyond 14 years after FDA approval. This change in patent terms was accompanied by provisions greatly reducing the regulatory requirements for approval of generic versions of previously patented drugs. The Congressional Budget Office has estimated that, on balance, the Hatch-Waxman Act reduced the expected return from new drug development by a small amount and that the effects of less costly and time-consuming generic development has been more significant than the effects of extended patent terms.[33]

Food and Drug Administration (FDA) review

The FDA must give its approval before a new chemical entity can be marketed or before an existing chemical can be used for a new therapy. FDA approval requires a lengthy and expensive testing regimen to ensure that a new drug is safe and effective in treating the target condition. The approval process represents a particular balance between providing the most rapid possible availability of a new therapy and the assurance that the drug will not cause undue harm and will do what the seller says it will. There is clearly a tradeoff to be made between the availability of treatments and the safety and efficacy of new treatments. Over the past decades, the FDA has been variously accused of erring too much on the side of approval and too much on the side of assurances of safety and efficacy.

Several regulatory changes have played an important role in speeding the flow of new pharmaceuticals to the marketplace. These changes include the *Prescription Drug User Fee Act of 1992* which authorized the FDA to collect fees from the industry to

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[33] *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry.* Congressional Budget Office (CBO). July 1998.

support the federal approval process in exchange for meeting rising annual performance targets, and the *FDA Modernization Act of 1997* which set more ambitions target for drug review and targets total development time not just regulatory review time.

In recent years, the FDA has approved more drugs and has done so at a quicker pace (*See Figure 12*). This change probably improves the profitability, on average, of developing a new drug. That does

Figure 12: FDA Approval of New Molecular Entities 1989-1999

	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Mean FDA Approval Time (months)	32.5	27.7	30.3	29.9	26.5	19.7	19.2	17.8	16.2	11.7	12.6
Number of Approvals Each Year	23	23	30	26	25	22	26	53	39	30	35

Source: U.S. Food and Drug Administration, 2000.

not necessarily mean that drug expenditures will fall or rise less rapidly than before. Higher profitability does increase the likelihood that other firms will enter with therapies of their own. But it also means that the given drug will arrive on the market sooner than before. If the new drug replaces an older drug or a generic, then speeding up FDA approval may actually increase pharmaceutical expenditures at a faster rate. This change produces benefits for patients receiving the new treatment. The impact of this change on overall medical care expenditures depends on the cost effectiveness of the new therapy and the extent to which it displaces other treatments or expands the market for care. These issues will be discussed in more detail under the discussion of demand for pharmaceuticals.

Changes in the nature of R&D

Enough is known about pharmaceutical R&D to draw some conclusions about what to expect in the coming years. One important change that has taken place in the nature of

pharmaceutical R&D in recent decades is that researchers are now able to automate important parts of the discovery process and are able to use computers to assist in the design of new proteins and enzymes for use in new drug therapies. This could compress some of the early stages of research and help firms bring new drugs to market more quickly than ever.

This pace of discovery and development may increase even more. Advances in the bio-chemical sciences in the 1970s and 1980s led to a quickening of the pace of discovery, as new discoveries provided researchers with many new genes or "targets" that new drugs could be designed to affect. With the completion of human genome mapping, the number of such targets is expected to rise dramatically, from around 500 to possible as many as 10,000.[34] The increase in the number of targets alone represents a dramatic increase in the potential for the development of new drugs.

The pharmaceutical pipeline

Given the combination of technological advancements, increased investment in R&D, and accelerated approvals by the FDA, one can expect that many new products will be approved for use in the coming decade. "Pipeline" pharmaceuticals are those drugs that currently are in the development and approval processes. Researchers at the Center on Drugs and Public Policy at the University of Maryland School of Pharmacy predict that 40 percent of future increases in pharmaceutical expenditures will be attributable to the cost of "pipeline" drugs.[35] Some of this increased spending will be for breakthrough drugs for conditions for which no current treatment exists, and some will be for drugs that will replace existing therapies. In general, drugs under development generally fall into the following categories:

- *Innovator or brand-name drug*: a drug that receives a patent on its chemical formulation or manufacturing process, obtains approval from the Food and Drug Administration (FDA) after extensive testing, and is sold under a brand name.

- *Generic drug*: a copy of an innovator drug, containing the same active ingredients, that the FDA judges to be

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[34] Pharmaceutical Research and Manufacturers of America (PhRMA). "The Human Genome Product – What's in it for Patients?" *New Medicines in Development: Biotechnology, 2000 Survey*. February 2000.

[35] Mullins, C. Daniel, Francis Palumbo, and Bruce Stuart. "The Impact of Pipeline Drugs on Pharmaceutical Spending," presented at *Pipeline Pharmaceuticals: How they will Affect the Cost of Health Care*. Washington D.C., 13 April 2000.

comparable in terms of such factors as strength, quality, and therapeutic effectiveness. Generic copies may be sold after the patent on a brand-name drug has expired. Generic drugs are generally sold under their chemical name rather than under a brand name.

- *Breakthrough drug*: the first brand-name drug to use a particular therapeutic mechanism -- that is, to use a particular method of treating a given disease.

- *Me-too drug*: a brand-name drug that uses the same therapeutic mechanism as a breakthrough drug and therefore competes with it directly.

According to several recent studies,[36] some of the classes of pipeline drugs that are most likely to contribute to increased spending include:

- Genetic therapies,
- Anti-hypertensives,
- Antidepressants,
- Cancer therapies,
- Oral diabetic agents,
- Anti-arthritic agents,
- Hormone replacement therapies,
- Erectile dysfunction therapies, and
- Cholesterol lowering agents.

Cost of Therapy Increases

Some drug categories may be expected to contribute significantly to future expenditures because the cost of the therapy itself is predicted to be very high (e.g. genetic therapies often cost more than $1,000 per patient per month). According to forecasts by Kaiser Permanente,[37] a not-for-profit national health plan with eight million members, certain classes of drugs are expected to

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[36] Forster, Carol. *The Future of Pharmacologic Treatment and Impact on Prescription Drug Costs. Presentation given to Virginia Task Force Studying Pharmaceuticals in Government-Funded Healthcare, Richmond*, Virginia, September 2000. Mullins, C. Daniel, Palumbo, Francis, and Bruce Stuart. "The Impact of Pipeline Drugs on Pharmaceutical Spending," presented at Pipeline Pharmaceuticals: How they will Affect the Cost of Health Care. Washington D.C., 13 April 2000; Merck-Medco. Managing Pharmacy Benefit Costs. 2000.

[37] Forster, Carol. *The Future of Pharmacologic Treatment and Impact on Prescription Drug Costs. Presentation given to Virginia Task Force Studying Pharmaceuticals in Government-Funded Healthcare*, Richmond, Virginia, September 2000.

experience significant growth in the cost of therapy. [38] A few examples are listed below.

- Antiviral agents used to treat Hepatitis C are projected to increase 30 percent in 2000 and 25 percent in 2001. One of these drugs, Interferon alfa 2a, costs approximately $6,500 per patient.
- Anti-rheumatic agents used to treat arthritis are projected to increase 50 percent. Disease-modifying anti-rheumatic drugs (DMARDs), such as lefunomide, etanercept, and anakinra, can cost around $11,000 to $12,000 per year per patient.
- AIDS drugs are projected to increase 10 to15 percent in 2001.

Volume Cost Drivers

In other cases, the size of the potential population drives the expected increase in expenditures (i.e., cardiac agents, antidepressants). It is important to note that pharmacy costs often represent only a small portion of the total economic costs of these diseases and disorders. For example, in 1990, the total economic cost of depressive disorders was $43.7 billion, while pharmacy costs made up only $1.17 billion of the total.[39] A few examples, drawn from Kaiser Permanente's forecast of specific volume drivers within these classes include:

- Expenditures on antidepressants are projected to increase ten percent due to expanded uses and the use of new agents being used as add-on therapies.
- Expenditures on atypical anti-psychotics are projected to increase 30 percent as more patients are expected to be treated. These drugs may be used for other diseases as well.
- Expenditures for asthma drugs are projected to increase 20 percent. These increases can be attributed to an increasing use of present therapy.
- Expenditures on cholesterol-lowering agents are projected to increase by approximately 20 percent, due to both higher utilization and higher cost of these drugs.

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[38] It is important to note that these projections by Kaiser Permanente are based on their population data. Increases in Virginia for these same drugs might actually be higher or lower than those projected by Kaiser Permanente for their population.

[39] Jurgensen, Michael. *Clinical Efficacy and Cost-Effectiveness of New Pharmaceuticals: A Review of Recent Literature*, presentation given to Virginia Task Force Studying Pharmaceuticals in Government-Funded Healthcare, August 2000.

A significant portion of the primary drugs purchased by the government of Virginia, as previously presented in the agency overviews, fall into several of these categories, specifically antidepressants, atypical anti-psychotics, and antiviral agents used to treat AIDS and Hepatitis C.

Generic drugs

Once a patent expires, another firm can produce the same chemical without paying royalties to the firm owning the patent. These copycat drugs are called generics. Because the actual cost of manufacturing is low and firms producing generic drugs do not need to undertake the initial R&D, the prices of generic drugs are usually much lower than the prices of the "branded" versions. Firms producing generics need only prove to the FDA that their copies of the branded drugs are "bio-equivalent" and "bio-available" to the original. This is a much quicker and cheaper hurdle than the initial approval process for the new therapy. In addition, the approval process for generics can begin before the patent on the branded drug has expired. This allows generics to come to market very soon after the expiration of the patent.[40]

According to a Congressional Budget Office study, within the first full calendar year after patent expiration of the brand-name drugs studied, those drugs lost an average of 44 percent of their market share to generic entries. This rapid growth in generic market share after patent expiration is a substantial change from the situation prior to the 1984 Hatch-Waxman Act, when there were very few producers of generic drugs. In 1983, for example, the generic market share averaged just 13 percent for all non-antibiotic drugs.[41]

By making much less expensive substitutes available for branded drugs, generics add a significant element of price competition to the market. By providing close substitutes for branded drugs, generic drugs make the demand for the branded drug much more sensitive to price. It is interesting to note that the introduction of generic drugs does not necessarily result in reductions in the price of the branded version of the drug. However, for those buyers in the market who are sensitive to price, the approval of generic drugs represents an opportunity for significant savings.[42]

The long-term impact of generic drugs on pharmacy expenditures is complicated by the possibility that continuing pharmaceutical

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[40] *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry.* Congressional Budget Office (CBO). July 1998.
[41] Ibid.
[42] Cantor, David J. *Prescription Drugs: Factors Influencing Their Pricing.* Washington D.C.: Congressional Research Service (CRS), February 1998. CRS 96-296 E.

research will result in a new, branded therapies that are superior to the older therapies now provided by generic drugs. A recent example of this process is the recent introduction of "COX2 inhibitors" which supplant a number of generic anti-inflammatories.

Over-the-counter medications

According to the Consumer Healthcare Products Association (CHPA), more than 700 products available over-the-counter (OTC) use ingredients or dosages that were available only by prescription at some point during the last 30 years. Eighty of these products have converted from prescription to OTC status since 1976. A pharmaceutical manufacturer can greatly expand the market for a drug by moving it off prescription. Estimates of the annual savings to consumers on products moved from prescription to OTC status range as high as $13 billion per year.[43]

Not only are OTC drugs generally cheaper than their prescription equivalents, the greater part of the savings may be in the elimination of physician visits for cases treatable by self-medication. There is obviously some risk in encouraging self-diagnosis and self-medication. However, those consumers who prefer not to take these risks may have the option of getting the advice of a health care professional before self-treating.

The Demand for Pharmaceuticals

The demand for prescribed medications is derived from the demand for medical care and good health. However, no medication can be demanded without a physician's prescription. The large number of different decision makers and the complex set of relationships between these parties complicate the demand for pharmaceuticals. For example, after a consumer makes the initial decision to enter the market for health care, a physician may decide that a particular drug is appropriate for the patient, an insurance company will pay for the prescription, and the consumer or a hospital or a physician may actually administer the drug to the ultimate user.

Because the decision about which medication to use is not made by the same person who pays for the medication, the prescribing physician and patient often do not have the usual incentives to economize on the purchase of the service. In addition, the

[43] Kline & Company, Inc. *The Economic Benefits of Self-Medication*, study for the Consumer Products Healthcare Association. 1997.

physician often knows whether the consumer will be paying for the product and may consider this when making prescription decisions. Much of the move toward capitated health services organizations is motivated by the savings that can accrue when the various stages of the process of consuming medical care are consolidated under one decision-maker's authority.

This web of incentives and relationships is further complicated by the dynamic nature of many drug therapies. Since many drug therapies affect health status much later in a person's life, decisions made now by one decision-maker will affect payments made by someone else altogether.

As the determinants of demand are discussed in the following section, care must be taken to account for the incentives faced by each of the parties involved.

A number of factors determine the demand for a pharmaceutical. The main factors include the existence of substitute therapies, demographics, the information and perceptions about various therapies, and the price of the product. Each of these factors will have different effects on demand depending on who is paying and who is making the decisions.

Substitutes

A given drug therapy may have any number of substitutes, including:

- Not seeking medical treatment,
- Non-drug therapies,
- Other branded therapies,
- Generic and OTC drugs, or
- Non-traditional therapies.

The substitutability of therapies will depend partly on the seriousness of the condition, on consumer preferences, on physician or pharmacist information about relative effectiveness, and on what is available to the consumer given his or her insurance coverage or lack of coverage.

The issue of substitution is important for two reasons. First, as common sense would suggest, the demand for a drug or any other commodity depends on the availability of alternatives. The closer the substitutes in the decision-maker's mind, the more responsive demand for the drug will be to changes in price. As more and closer substitutes for a drug become available, the demand curve

for that drug becomes more *elastic*, that is to say, the market for the drug becomes more responsive to price. In a market for a drug with many close substitutes, the prices for the substitute goods will all be close to each other, and any firm attempting to raise the price will lose revenues due to losing market share. This will have a significant impact on the price set for the drug in the marketplace. In general, the more substitutes, the closer price must be to the cost of production.

The second reason why the question of substitution is important is that the substitution of one therapy for another may result in some offsetting savings for a given increase in spending. If self-treatment or non-traditional therapies are viewed as close substitutes for a pharmaceutical, some health expenditures will fall as insurers generally do not cover these therapies. Also, new drugs may substitute for other expenditures such as hospital or nursing facility services, or, of course, other drugs.

An increased degree of substitutability, then, can work in favor of lower expenditures by driving prices lower and by offsetting other expenditures. The introduction of an innovative and effective new therapy will tend to replace earlier therapies used for the given condition, however, greatly reducing the degree of substitutability between therapies for that condition once the new, branded therapy becomes the standard. The new therapy may still offset other expenditures, but, at the same time, the new therapy will have a much lower elasticity of demand and will command a much higher price.

Decision makers view substitutability differently

Since substitutability depends on individual circumstances, individual preferences, and access to information, not all customers view the substitutability between two therapies in the same way. The market for a drug may be made up of different classes of customers who view the substitutability between two therapies quite differently. As a result, these different customers will have a different elasticity of demand for the drugs in question. This difference can be quite dramatic if the cost of obtaining accurate information about substitutes is high.

For example, an HMO with staff pharmacists may very readily move to generic versions of branded drugs as they become available or may find it worthwhile to develop information that allows the substitution of a cheaper branded drug for a more expensive one. Private insurance providers and government

agencies who find it profitable to purchase the information needed to know when substitutes are available will have elastic demand and should pay lower prices. Often this information is provided by pharmacy benefit services.

A physician, on the other hand, would probably not find it worthwhile to track the substitutes for a given therapy that closely because neither the physician nor the patient may have much of a stake in the potential savings from substitution. Physicians and individuals who do not have the incentive to gather and use information about substitutability will tend to subject third-party payers to higher prices due to inelastic demand.

Therapeutic Substitution

Unfortunately, information about substitutability is expensive. The clinical trials designed to prove safety and effectiveness to the FDA are not designed to answer questions about substitutability. Often, only actual experience can answer the questions about the relative cost-effectiveness of different therapies or about how different sub-populations respond to the different therapies. In addition, consumers may strongly prefer one therapy over another based on characteristics that are not strictly clinical in nature, such as dosage requirements, pill size or type (tablet, capsule), etc. These reactions are difficult to forecast accurately in advance and can only be measured after a therapy is on the market for a certain length of time.

It is probably easier to measure the degree of clinical substitutability between two therapeutically similar but chemically distinct treatments than it is to measure the substitutability between pharmaceutical and non-pharmaceutical treatments. However, in either case, much of the data needed to draw solid conclusions is in the hands of different firms or agencies and was collected for other reasons. The typical institutional arrangements for providing health care may involve contracts between a number of independent institutions such as hospitals, physicians, pharmacies, benefits management firms, and HMOs. In addition, many patients change health care providers as their circumstance change, adding yet another level of complication to the data collection and analysis problem. These problems present a very significant barrier to developing detailed information about the relative substitutability of different therapies for a given medical condition.[44]

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[44] Moran, Donald Will. "Prescription Drugs and Managed Care: Can 'Free-Market Détente' Hold?" *Health Affairs* 19 (March/April 2000): 63-77.

- Another problem is that purchasers may not have the appropriate economic incentives to use information at their disposal to analyze substitutability between drugs. Organizations or individuals may find it difficult to profit from developing information about therapeutic substitution if other groups can easily obtain, at low cost, the information that was generated at high cost by the original organization. This *public good* character of information about substitution may result in relatively low incentives to develop the information.

Once good information about clinical substitutability has been developed, the problem remains of how to make the information effective in modifying the behavior of the decision makers and consumers of pharmaceuticals. Even without competition from drug company detailing[45] and direct-to-consumer advertising, imparting information to physicians, pharmacists, and consumers in a way that will affect their choices is a difficult and expensive process. Private and state-run health insurance funds can supplement education with economic incentives such as cost sharing, where the consumer faces increased costs when choosing the more expensive of two equivalent therapies.

Demographics

Low-income populations

States face a substantial obligation to cover pharmaceutical expenses for low-income citizens. Low unemployment rates and welfare reform have decreased the overall Medicaid population. The average monthly number of individuals enrolled in the Virginia Medicaid program in FY 2000 was 488,744, an eight percent decrease from the 531,869 enrolled in 1995.[46] While Medicaid expenditures on pharmaceuticals in Virginia have grown substantially in the years since the 1995 welfare reform law took effect, the declining enrolled population has kept this rate of growth much lower than it would have been otherwise.

Elderly

The increasing number of elderly individuals in the population will push pharmacy expenditures higher for the foreseeable future. The elderly make much more intensive use of pharmaceuticals than other age groups in the population. Almost 14 million senior citizens, 38 percent of all Medicare beneficiaries, use more than $1,000 of prescription drugs annually.[47] It is estimated that the

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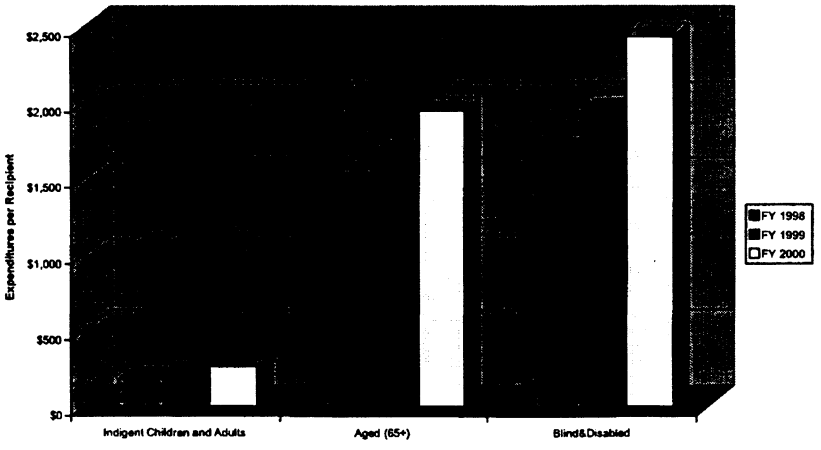
[45] Detailing is the name given to sales calls by pharmaceutical representatives on physicians, pharmacists, hospitals, and other health care providers.
[46] Average monthly eligibles as reported in MME370 Report Series, DMAS, October 2000.
[47] National Economic Council, Domestic Policy Council. *Disturbing Truths and Dangerous Trends: The Facts about Medicare Beneficiaries and Prescription Drug Coverage.* 1999.

elderly in the United States, who make up 12 percent of the population, use one-third of all prescription drugs.[48]

This group's high utilization of pharmaceuticals is due in part to a tendency for the elderly to have a greater need for medical care, on average, than other age groups. Another factor is the increased use of medications to treat chronic conditions. According to the National Institute on Aging, "as a group, older people tend to have more chronic illnesses -- such as arthritis, diabetes, high blood pressure, and heart disease -- than do younger people."[49] There are a host of other chronic diseases which disproportionately affect older Americans including depression and neurodegenerative diseases such as Alzheimer's disease, Lou Gehrig's disease, and Parkinson's disease.[50]

Data from the Virginia agencies examined in this report illustrate the large difference in average costs between recipient groups. In FY 2000, Medicaid pharmaceutical expenditures per person for aged recipients were almost 7.5 times larger than the expenditure per person for low-income children and adults *(See Figure 13).* Pharmaceutical care for Medicare-eligible retirees cost DHRM almost 2.5 times as much per person as for active/early retirees and their dependents *(See Figure 14).*

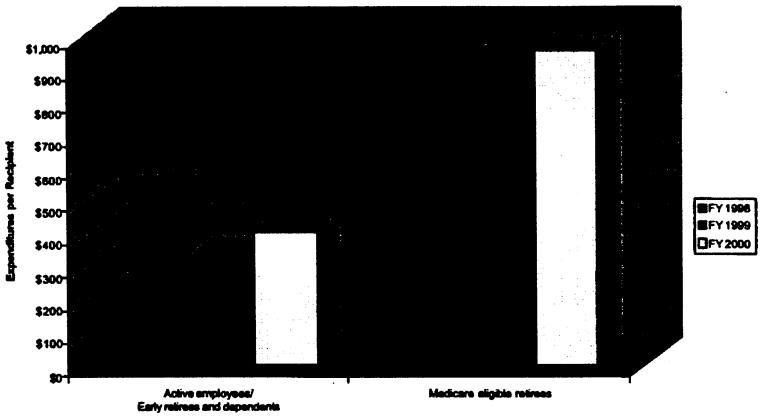
Figure 13: Medicaid Pharmaceutical Expenditures per Recipient by Eligibility Group



Source: Department of Medical Assistance Services.

[48] Senate Special Committee On Aging. *Developments in Aging: 1993*, 1994.
[49] National Institute on Aging. *NIA Age Page.* [Bethesda, MD]: National Institute on Aging, 1997.
[50] American Association of Retired Persons (AARP) Public Policy Institute and the Lewin Group. *Out of Pocket Health Spending By Medicare Beneficiaries Age 65 and Older: 1997 Projections.* December 1997.

Figure 14: DHRM Pharmaceutical Expenditures by Age Group



Source: Department of Human Resource Management.

The United States population continues to age dramatically. The elderly population aged 65 and older increased elevenfold between 1900 and 1994. During that same period, the under 65 population grew only threefold.[51] The aging of the "baby boom" cohort promises to continue to place upward pressure on pharmaceutical expenditures. Currently, those aged 65 and over represent 13 percent of the population. By 2015, they are expected to constitute 15 percent, and 20 percent by 2030. The fastest growing group among those 65 and over are those individuals aged 85 and older. Currently, that group makes up 1.5 percent of the population. By 2050, that group is expected to represent 4.6 percent.[52]

In Virginia, the population aged 65 and older currently accounts for 11.3 percent of the state's total population. By 2025, this same population is expected to make up almost 18 percent of the population of Virginia.

Table 10: Virginia State Population Projections: 1995-2025

	Total Population (thousands)	Population Aged 65+ (thousands)	Aged 65+ as % of Total Population
July 1, 1990	6,214	666	10.7%
July 1, 1995	6,618	737	11.1%
July 1, 2000*	6,997	788	11.3%
July 1, 2015*	7,921	1,109	14.0%
July 1, 2025*	8,466	1,515	17.9%

Source: U.S. Census Bureau, SERIES A Projections, 2000

[51] National Institute on Aging, *Aging America Poses Unprecedented Challenge Page.* [Bethesda, MD]: National Institute on Aging, May 1996.
[52] Senate Special Committee on Aging. *Developments in Aging: 1997 and 1998.* February 2000.

The proportion of prescriptions written for the elderly is also increasing. For example, in FY 1998, prescriptions for Medicare-eligible retirees accounted for 14 percent of the total number of prescriptions filled by the state health care plan. In FY 2000, the proportion had increased to 18 percent.[53]

Information and advertising

Economics of advertising

Advertising serves a number of functions for firms selling pharmaceuticals and takes many different forms. The primary economic function of advertising is to increase demand for a product, other things being equal. Effective advertising will differentiate a product from other products. This tends to make demand less elastic since the drug will no longer be perceived as having close substitutes. Effective advertising will expand the number of people aware that the product may help treat a condition that they would like to change. This will increase overall demand as more people see the drug as an appropriate alternative. Finally, effective advertising will develop brand familiarity and identity. This last function is intended to associate a name with a treatment so that those seeking or giving treatment for the indicated condition will think of the brand name instead of the generic chemical identity. This will help maintain demand once the patent expires and the treatment is sold as the generic chemical or when a similar treatment is offered by another firm.

These economic functions of advertising all involve a combination of information and persuasion. Setting aside for a moment the issue of whether the information contained in an ad is accurate or not, it is usually not possible to fully disentangle the information from the persuasion. Even advertisements that appear to be almost pure information will be presented in a way that gives the information the best chance of being noticed and believed. The most persuasive ads usually gain credibility by combining information with the persuasion.

The level of competitiveness in a market, and hence economic efficiency, can be hurt or helped by advertising. In markets where just a few firms compete, the first firm to reach the public's eye may gain significant advantages over other competitors. It is possible, in such circumstances, for advertising to reduce aggregate welfare.[54] Alternatively, advertising may be used by a potential competitor to enter a market already served by only a few firms.

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[53] Department of Human Resource Management.

[54] Leffler, Keith B. "Persuasion or Information? The Economics of Prescription Drug Advertising." *Journal of Law & Economics*, 24 (April 1981): 45-74.

This use of advertising may actually increase efficiency by increasing the level of competition in a given market.

By its very nature, advertising is "self-serving, one-sided, and incomplete"[55] because it is designed to alert decision makers about the benefits of consuming advertisers' products. Some observers have expressed the concern that drug advertisements contain "[e]xaggerated safety and efficacy claims, inadequate warnings of adverse effects, and promotion for inappropriate indications."[56] However, doctors, patients and other decision makers generally know that firms have incentive to give the best possible picture of the value of the firm's products.

Because information about the efficacy and value of pharmaceuticals is expensive to develop and disseminate, advertising can provide substantial economic benefits. Unfortunately, the decision makers considering which therapy to use may find it costly to evaluate the relative merits of therapies as presented by competing firms.

Increased information about the comparative effectiveness of treatment options can be used to reduce the probability that advertising will result in treatment decision makers making poor choices based on advertising. Such a strategy recognizes the benefits that may be conferred by advertising and supplements these benefits with the availability of additional comparative information. In fact, the rise of independent pharmacy benefits management services is a private response to this need for comparative effectiveness information. The information can be used to intervene in the prescription decision and provide additional data that will allow fully informed choices in the face of competing claims.

Advertising to medical professionals

Historically, most drug advertising has been directed at the medical decision-maker through advertising directed at the medical and pharmaceutical professions. Detailing is the name given to sales calls by pharmaceutical representatives on physicians, pharmacists, and hospitals. Detailing serves all of the economic functions of advertising listed earlier. Detailing directs both information and persuasion toward those expected to make the choice of therapeutic approach to the indicated medical condition.

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[55] Schweitzer, Stuart O. *Pharmaceutical Economics and Policy.* New York: Oxford University Press, 1997.
[56] Ibid.

Pharmaceutical firms invest an enormous amount of money and effort in detailing. According to the research firm IMS Health, spending on promotions directed toward physicians was approximately $4 billion in 1997.[57] In addition, pharmaceutical companies also provide a substantial amount of free samples to doctors' offices ($7.2 billion in 1999).[58] In recent years, detailing has also involved visits to HMOs, physician assistants, nurse practitioners, and other parties authorized to prescribe medications or likely to be making decisions about treatments.

In addition to detailing, pharmaceutical firms use print advertising, displays at professional meetings, and sponsorship of continuing medical education programs to raise awareness of their products among medical and pharmaceutical professionals.

Direct-to-consumer (DTC) advertising

Following a relaxation of very stringent rules on advertising pharmaceuticals directly to consumers, there has been a very substantial increase in *direct-to-consumer* (DTC) advertising in recent years. DTC ads in print and on radio and television have become a very important part of pharmaceutical firms' information and persuasion activities. Some DTC advertisements are directed at a disease in general while others promote a specific drug product. In 1999, prescription drug manufacturers spent $1.8 billion on DTC advertising, up 38.5 percent from the $1.3 billion spent in 1998 and 33 times the $55 million spent on DTC ads in1991.[59] However, DTC advertising accounted for only 27 percent of the total $6.6 billion spent promoting products to physicians and consumers in 1999.

Aside from developing brand awareness, these ads can act to inform people about the existence of treatable conditions, or that treatments exist for conditions previously not readily treated with pharmaceuticals, or that new treatments have fewer undesirable side-effects than older treatments. This function of DTC advertising serves to increase demand as new people seek treatment for the condition in question.

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[57] "National Survey of Consumer Reactions to Direct-to-Consumer Advertising." *Prevention Magazine*. 1998.
[58] National Institute for Health Care Management (NIHCM) Foundation. *Prescription Drugs and Mass Media Advertising*. September 2000.
[59] Ibid.

Table 11: Highly promoted prescription drugs

Drug	Manufacturer	Promotional Spending, 1999 (millions)	1999 Sales (millions)	Percentage Change in Sales, 1998-1999
Claritin	Schering-Plough	$136.8	$2,591	+21.1%
Prilosec	AstraZeneca	79.4	3,649	+23.9%
Xenical	Hoffman-La Roche	76.2	144	n/a*
Propecia	Merck	71.1	63	+56.7%
Zyrtec	Pfizer	57.1	551	+31.5%
Lipitor	Warner-Lambert	55.5	2,659	+55.7%
Zyban	Glaxo Wellcome	53.9	135	-26.4%
Flonase	Glaxo Wellcome	53.5	489	+37.9%
Viagra	Pfizer	53.0	616	+18.5%
Nasonex	Schering-Plough	52.3	264	+116.1%

Source: NIHCM Foundation: American Institutes for Research Analysis of Competitive Media Reporting data as presented in June, 2000 *MedAd News*.
*Xenical did not come on to the market until 1999.

In trying to develop demand among consumers for a given treatment, pharmaceutical firms are working to convince consumers to take a more direct involvement in the decision about treatment, a decision which was formerly considered to be uniquely the responsibility of health professionals. Insofar as this strategy is effective, the consumer is taking on some of the decision-making role formerly considered inappropriate for the consumer except in the case of over-the-counter drugs. According to *Prevention Magazine*, more than 53 million consumers talked to their physicians about medicine they saw advertised. A projected 21.2 million consumers talked to their doctor about a medical condition or illness they had never talked with their doctor about before seeing an advertisement. This has led to as many as 12.1 million consumers receiving a prescribed drug as a result of seeing a DTC advertisement.[60]

DTC advertising is widely believed to have a significant effect on the demand for new, more expensive, branded therapies.[61] According to a recent study by the National Institute for Health Care Management Foundation, the 25 top-selling drugs had an aggregate one-year sales growth in 1999 of 43.2 percent, while the growth in sales for all drugs was 13.3 percent. Likewise, the 25 top-selling drugs saw a 34.2 percent increase in the growth of overall prescriptions, while the growth in prescriptions for all other

[60] "National Survey of Consumer Reactions to Direct-to-Consumer Advertising." *Prevention Magazine*. 1998.
[61] Wilkes, Michael S., and others. "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications." *Health Affairs*, 19 (March/April 2000): 110-128.

drugs was 5.1 percent.[62] Concerns have been raised that many consumers may be demanding that their health care provider prescribe these drugs in response to the advertising and that physicians may be responding by prescribing the drugs even in cases where the therapy may not be indicated. According to the American Academy of Family Physicians, 71 percent of family physicians believe that advertising pressures doctors to use medications they would not otherwise use, because the drugs are requested and physicians want to keep their patients happy.[63]

Little research has been done to determine the overall effect of DTC advertising on health outcomes. What is known, however, is that seven of the ten most heavily advertised drugs fall into four therapeutic categories: oral antihistamines, antidepressants, cholesterol reducing drugs, and antiulcer medications. Between 1993 and 1998, spending on oral antihistamines increased by 612 percent, antidepressants by 240 percent, cholesterol-reducing drugs by 194 percent, and anti-ulcer medications by 71 percent.[64] These four heavily advertised therapeutic categories are also, not surprisingly, the therapeutic categories in the Virginia Medicaid program with greatest increases in utilization from 1997-2000.

According to Scott-Levin, a drug marketing research firm in Newtown, Pa., all office visits to doctors rose two percent during the first nine months of 1998, while visits for conditions targeted by ad campaigns rose much more drastically. Patient visits for smoking cessation rose 263 percent, for example, while visits to treat impotence jumped 113 percent, hair loss 30 percent, osteoporosis 22 percent, high cholesterol 19 percent and allergies 11 percent.[65]

Pharmaceutical prices

When viewed as a whole, the pharmaceutical industry has many firms competing for parts of the market. However, from the perspective of an individual therapy, there may only be few suppliers of therapies. In fact, a firm may have a patent, or legal monopoly, on the only available therapy. In this case, firms can increase their profits by charging different prices to different consumers according to their elasticity of demand. Firms will, when possible, charge more to those with a low elasticity of

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[62] National Institute for Health Care Management (NIHCM) Foundation. *Prescription Drugs and Mass Media Advertising.* September 2000.
[63] American Association of Family Practitioners (AAFP). "*Survey Asks FPs About Direct-to-Consumer Ads.*" *AAFP Directors' Newsletter*, February 1998.
[64] National Institute for Health Care Management (NIHCM) Foundation. *Factors Affecting the Growth of Prescription Drug Expenditures*. July 1999.
[65] Maguire, Phyllis. "How Direct-to-Consumer Advertising is Putting the Squeeze on Physicians." *ACP-ASIM Observer.* March 1999.

demand. Generally, these will be consumers who are the least willing to substitute other therapies for the one being supplied. Consumers with a high willingness to substitute therapies will be charged a lower price.

Because firms charge different prices according to elasticity of demand, any regulations which affect the ability of buyers to substitute therapies will tend to reduce demand elasticity and, hence, increase the price paid for pharmaceuticals. For example, any restrictions on an organization's ability to practice therapeutic substitution may have the unintended effect of causing an increase in the prices that the organization must pay for the drugs covered by the restrictions.

Prices in the domestic market

The existence of price differentials helps explain a paradox concerning the pricing of pharmaceuticals. It has been pointed out in a number of studies that the prices of branded pharmaceuticals often do not drop much when new competing therapies are introduced. In fact, a firm may even raise its price for a pharmaceutical once a competitor enters the market. A study by the Congressional Budget Office found that for 34 drugs that experienced generic competition for the first time after 1991, the average price increase between 1991 and 1994 was 22 percent. By comparison, average prices for brand-name drugs that faced no generic competition rose by 24.5 percent over that same period. In fact, in some cases, prices continued to rise at more than the rate of inflation after the introduction of a competing product.[66] A study by John Lu and William Comanor found that the average list price of brand-name drugs continued to rise after the introduction of a "me-too" competitor.[67]

As the market becomes more competitive, established firms and potential competitors must decide whether it is better to maintain a high price but accept a loss of market share, or charge a lower price to compete for market share. What a firm decides will depend on whether higher profits can be made by selling at a high price to the smaller segment of the market with low demand elasticity or selling at a lower price to the whole market which now has a much higher elasticity of demand. A firm attempting to enter the market will make a similar choice. A new therapy will generally be priced higher the more innovative it is relative to

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[66] *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry.* Congressional Budget Office (CBO). July 1998.
[67] Lu, Z. John, and William S. Comanor. "Strategic Pricing of New Pharmaceuticals. "*Review of Economics and Statistics*, 80 (February 1998): 108-118.

existing therapies in the market. The greater the improvement over existing therapies, the less existing therapies will be seen as close substitutes. For more marginal improvements or for generics, a low price is used to penetrate the existing market.

Studies have shown that even though the price of the initial product does not fall after the introduction of new products, the price paid by those willing to substitute new therapies for old ones does fall, and often dramatically.[68] By offering competition to existing therapies, "me-too" drugs and generics make the demand curve more elastic, thereby giving HMOs, health plans, and government agencies other, cheaper, alternatives. Whether these agencies can take advantage of the lower prices for competing products depends on whether they face legal restrictions on substitutability and on whether they have in place the administrative tools to ensure that substitution actually takes place.

Once an innovative therapy is developed, consumers would benefit most if the price charged were equal to the marginal cost of manufacturing and delivering the drug to market. Such a price would be much lower than the prices actually charged for most innovative therapies. However, if pharmaceutical firms were only able to charge the much lower competitive price and were not able to earn the higher rate of return during the patent term, then the rate of return on investment in pharmaceutical innovation would fall, and some investment projects, possibly many of them, would no longer appear profitable, at least in the near term. There is an inherent trade-off between receiving the most benefit from drugs already developed by charging low prices and encouraging a high rate of research and development by charging higher prices.[69]

International prices

Price differentials can also be observed in the international market. For example, the allergy drug Claritin cost almost $2 per pill in the United States, but only 41 cents per pill in Great Britain and 48 cents per pill in Australia. A daily dose of the AIDS drug PLC sells for $18 in the United States and $9 in Uganda.

As a result of the apparent differences in pharmaceutical prices across countries, there has been a substantial discussion recently about how properly to measure this differential and whether the

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[68] *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry.* Congressional Budget Office (CBO). July 1998; Cantor, David J. *Prescription Drugs: Factors Influencing Their Pricing.* Washington D.C.: Congressional Research Service (CRS), February 1998. CRS 96-296 E.

[69] Danzon, Patricia M. "Making Sense of Drug Prices." *Regulation* 23 (2000).

differential indicates that prices are too high in the United States. This cross-country comparison is complicated by the differing price regulations observed in different countries. Experience with price differentials of other products across countries indicate that it would be difficult to maintain very large differences because as differentials increased, so would efforts to circumvent restrictions on trading pharmaceuticals across national boundaries.

Efforts to force pharmaceutical firms to charge the same price in the U.S. as they do in other countries would not bring U.S. prices down to the levels in foreign countries. In fact, the equilibrium single world price would be in between the current prices, and, given the size of the U.S. market, would probably be much closer to U.S. prices than foreign prices. Sometimes forcing one price results in cutting off the small markets rather than lowering the price to the large market.[70] Forcing one price worldwide, assuming this were possible, involves a tradeoff between current prices, markets served, and the availability of new drugs in the future. A uniform world price would lower pharmaceutical firms' rates of return on investment and reduce the number of research and development projects undertaken by pharmaceutical firms.

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[70] Varian, Hal R. "Examining Differences in Drug Prices." *New York Times.* 21 September 2000.

Chapter 3: Impact of Pharmaceuticals on Health Care and Patient Care

Virginia's expenditures on pharmaceuticals have expanded rapidly over past several years and can be expected to continue to increase in the foreseeable future. These cost increases are often associated with significant benefits. The benefits of pharmaceutical spending may be in **better health outcomes** for those using the therapy, although the value of these benefits can be very difficult to measure. Another benefit is that increased use of medically appropriate pharmaceuticals may be associated with **reductions in other medical costs**. The reductions in other medical care costs are also difficult to measure, but it is known that in some cases they can be large enough to more than offset the cost of the new pharmaceutical therapy.

Ideally, all prescription drug use would have the intended effect of improving patient health at an efficient cost. However, the ultimate success of a drug at achieving this end is dependent on a variety of factors, including:

- The disease category,
- The use of an appropriate treatment protocol by the treating health care provider,
- Proper administration of the drug, and
- Various lifestyle factors on the part of the patient, such as compliance with treatment directives.

Depending on these factors, pharmaceutical-based treatment can range from being highly cost effective, to neutral if the medication is ineffective or has a very slight effect or, possibly, even harmful if an adverse drug reaction results in harm or injury. A treatment might also be harmful if it fails to provide a benefit while displacing an alternative treatment that could be beneficial.

It is important to remember that cost effectiveness does not necessarily imply cost savings. A pharmaceutical can be cost effective if it produces a significantly higher quality health outcome when compared with any other available treatment options, even if the overall costs have increased. The savings from some drugs may not even appear in the health care arena. For example, increased use of antipsychotics or other psychiatric drugs

may decrease the government spending on mental health, criminal justice, or welfare, but appear as net additions to medical spending.

Improved Health Outcomes

Enhanced health outcomes associated with pharmaceuticals include improved quality of life, reduced morbidity, increased life expectancy, and increased lifetime income. For example:

- According to a study conducted by researchers at Virginia Commonwealth University, an investigational new drug that helps insulin function more efficiently also appears to combat infertility, with no apparent side effects, in women with polycystic ovary syndrome, the most common cause of female infertility.[71]

- One HMO found that a new drug for migraines led to a 71 percent decrease in absenteeism, a 21 percent decrease in days worked with migraine symptoms, and an 85 percent increase in productivity on days worked with symptoms.[72]

- According to one study, ACE inhibitor drug treatment for congestive heart failure reduced deaths by 16 percent and hospitalizations by 26 percent over four years. Hypothetically, for every 1,000 patients with congestive heart failure, the new treatment would prevent about 50 premature deaths and 350 additional hospitalizations.[73]

- Approximately 285,000 children in the United States suffer from juvenile rheumatoid arthritis (JRA). Disease-modifying anti-rheumatic drugs (DMARDs), such as lefunomide, etanercept, and anakinra, which can cost around $11,000 to $12,000 per year per patient, are often prescribed. These drugs were originally invented to treat

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[71] Nestler, John E., and others. "Ovulatory and Metabolic Effects of d-Chiro-Inositol in the Polycystic Ovary Syndrome." *New England Journal of Medicine* 340, (29 April 1999); "New Drug May Help Women With Infertility Syndrome." *Doctors Guide to the Internet.* (Accessed October 1, 2000).

[72] Legg, Randall, and others. "Cost Benefit of Sumatriptan to an Employer." Journal of Occupational and Environmental Medicine 39 (January 1997): 652-657.

[73] SOLVD Investigators. "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure." *New England Journal of Medicine* 325 (July 1991): 293.

other diseases but were noted to have a positive effect on rheumatic diseases.[74]

One approach to managing health care costs is to compare the cost-effectiveness of different therapies in terms of the amount of money spent per unit of improved health outcomes. Properly implemented, cost-effectiveness analysis could allow direct comparisons of substitute therapies for the purpose of minimizing the cost of delivering a given set of health outcomes.

The use of cost-effectiveness analysis requires a standard measure of health outcomes. An example of a frequently used measure is the quality adjusted life year (QALY) which is intended to measure the relative value of different health outcomes.[75] Once agreement is reached on the QALY measure for a given therapy and the cost of providing the therapy, then the cost-effectiveness measure is determined by dividing the amount of money spent by the QALYs generated.

A number of problems arise in the use of cost-effectiveness measures. First and foremost is the setting of such measures for different health outcomes from different therapies. These measures are based on surveys or on observations of how people make choices about similar decisions that they face and extrapolating this to the health outcome in question. For example, one might study how much money people spend in order to protect against certain types of risk and then make an inference about the value people place on avoiding other, similar risks.

While cost-effective measures are highly subjective and highly individualistic, they are usually based on estimated average population values. Therefore, they can be used to make judgements about average cost-effectiveness of a treatment for a given population, but are more problematic for use in determining therapeutic measures in individual cases since individual values may diverge widely from population averages.

While cost-effectiveness analysis does have drawbacks, it serves an important function in examining health care expenditures. Resources used on health care are resources that cannot be used for other valuable social ends. Especially in the context of institutional and governmental decision-making, mechanisms are

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[74] "Juvenile Arthritis." *Arthritis Insight*, at: www.arthritisinsight.com (accessed 19 September 2000).

[75] Neumann, Peter J. and others. "Are Pharmaceuticals Cost Effective? A Review of the Evidence." *Health Affairs* 19 (March/April 2000): 92-109.

needed to make explicit the trade-offs implicit in every decision to spend resources for one purpose rather than another.

Reductions in Non-pharmaceutical Medical Costs

Earlier in this paper, it was shown that pharmaceutical costs statewide and nationally have been increasing as a percentage of total medical costs. It is worth asking whether the relative stability in overall medical costs is related to savings achieved through the use of more and more effective pharmaceuticals.

Under certain circumstances, there is good evidence that the use of specific drugs may be associated with reductions in non-pharmaceutical medical expenses such as emergency admissions, hospital days, nursing facility care, surgical costs, and physician office visits. However, the issue depends critically on the context in which the drug is used and the intervention with which it is compared. Some examples on appropriate and cost-effective drug utilization are:

- In Virginia, over $18 million was allocated for the funding of new anti-psychotic medications in the 1998-2000 biennium. The expanded availability of these new medications allowed more individuals to remain at home with their families in their communities as opposed to spending time in an institution. Total admissions to state mental health facilities dropped 32 percent in those two years, from 7,431 in FY 1998 to 5,069 in FY 2000. Populations in Virginia's state mental health facilities also decreased during that time frame. The average population in February 1997 was 2,082 patients compared to an average population of 1,747 patient in February 2000.

- Clozapine, a drug for schizophrenia, has enabled many patients to be treated outside the hospital, in less costly settings, according to a 1990 study.[76] The annual cost of the drug therapy was $4,500, compared to more than $73,000 a year for treatment in a state mental institution. Another, more recent, study by the Canadian Coordinating Office for Health Technology

[76] Terkelsen, Kenneth G., and Rene C. Grosser, "Estimating Clozapine's Cost to the Nation," *Hospital and Community Psychiatry* 41 (August 1990): 863-869.

Assessment (CCOHTA) estimated that the use of Clozapine was associated with .04 more quality-adjusted life years (QALYs) per year.[77]

- A study published by the *New England Journal of Medicine* showed that patients on ACE inhibitors for congestive heart failure avoided nearly $9,000 each in hospitalization costs over a four-year period.[78]

- The Center for Disease Control estimates that every $1 spent on the vaccine for measles-mumps-rubella (MMR) saves the health system $21, every $1 spend on the oral polio vaccine saves $6, and every $1 spend on the diphtheria-tetanus-pertussis vaccine saves $30.[79]

- A study released by the Agency for Health Care Policy and Research in September 1995 concluded that increased use of a blood-thinning drug would prevent 40,000 strokes a year, saving $600 million. The average annual cost of drug therapy and monitoring is $1,025.[80]

- Results from the Virginia Health Outcomes Partnership program for Medicaid asthma patients projected direct savings to Medicaid of $3 to $4 for every incremental dollar spent providing disease management support to physician. The disease management program included instruction on how to communicate more effectively with patients, especially asthma patients, and offered physicians guideline information about recommended asthma drugs and new state-of-the-art medications for asthma. The dispensing of drugs recommended by the guidelines for asthma rose sharply during the study period for patients of physicians participating in the disease management training. The increase was as much as 25 percent in some cases. The rate of emergency visit claims for patients of participating physicians who received feedback reports dropped an

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[77] Glennie, Judith L. "Pharmacoeconomic Evaluations of Clozapine in Treatment-Resistant Schizophrenia and Risperidone in Chronic Schizophrenia. *Technology Overview: Pharmaceuticals 7*, (July 1997).
[78] SOLVD Investigators. "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure." *New England Journal of Medicine* 325 (July 1991): 293.
[79] Boston Consulting Group. The Contribution of Pharmaceutical Companies: What's at Stake for America. September 1993.
[80] Agency for Health Care Policy and Research, Secondary and Tertiary Prevention of Stroke Patient Outcome Research Team: *9th Progress Report*, March 1996.

> average of 41 percent from the same quarter a year earlier, compared to only an 18 percent drop for comparison community physicians.[81]

There are also many new drugs that will not offset other medical costs, especially so-called lifestyle drugs that treat hair loss, sexual dysfunction or symptomatic illnesses such as allergies. Although these drugs certainly offer benefit to patients, their use increases health care spending without any corresponding reduction in other areas. In addition, as patients live longer as a result of improved medical care, short-term savings may equal net spending increases over the life of the patient.

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[81] Rossiter, Louis F., and others. "The Impact of Disease Management on Outcomes and Cost of Care: A Study of Low-Income Asthma Patients." *Inquiry* 37 (Summer 2000): 188-202.

Conclusion

Virginia's expenditures on pharmaceuticals have grown rapidly over the past several years and can be expected to continue to increase for the foreseeable future. Increased utilization due to changing demographics, direct-to-consumer advertising, price increases of existing products the availability of new therapies, especially the introduction of new, more costly therapies, will all contribute to this trend. To plan effectively for future expenditures and to ensure that these expenditures are managed to maximize the gain in health outcomes per dollar spent, it is critically important to understand the market forces that affect the suppliers and consumers in the market.

The market for pharmaceuticals is characterized by the division of the consumption decision and the payment responsibility. This can lead to cases where parties may not have the incentive to develop information necessary for optimal decisions. A number of effective management policies have been developed to reduce the impact of these incentive imperfections on overall medical care expenditures. Continued investment in information and in innovative management strategies may help generate the most cost-effective and high quality profile of pharmaceutical expenditures in the future.

Pharmaceutical Task Force Presentations

June 1, 2000

Trends in Health Services Spending
The Honorable Claude A. Allen
Secretary of Health and Human Resources
Therapeutic Substitution
Anne Waring, Communications Manager
Department of Human Resource Management

July 10, 2000

Trends in Virginia's Medicaid Pharmacy Expenditures
Dennis G. Smith, Director
Department of Medical Assistance Services
Cost Trends in Prescription Drugs: Employee Health Benefits
Anthony C. Graziano, Director, Health Benefits Program
Department of Human Resource Management
Explaining Drug Spending Trends: Does Perception Match Reality?
Karla Stricker Anderson, Senior Vice President
Sales and Marketing
Protocare

August 1, 2000

Clinical Efficacy and Cost-Effectiveness of New Pharmaceuticals
Michael Jurgensen
Medical Society of Virginia
Perspectives on Use and Benefits of Prescription Drugs and Pharmacy Services
John Coster
National Association of Chain Drug Stores
Successful Outcomes from Atypical Antipsychotic Medications
Thomas Peachey
Northwestern Community Services
Prescribing Solutions to Improve Quality and Reduce Costs
Dr. Kenneth W. Kolb, Vice President
Clinical Management Services
Heritage Information Systems, Inc.
Virginia Medicaid -- A Measure of Effectiveness
Dr. Robert R. Robinson
Robinson Associates

September 11, 2000

The Future of Pharmacologic Treatment and Impact on Prescription Drug Costs
Carol Forster, Executive Director
Pharmacy Management
Mid-Atlantic Permanente Medical Group

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Cantor, David J. *Prescription Drug Price Comparisons: The United States, Canada, and Mexico.* Washington D.C.: Congressional Research Service (CRS), January 1998. CRS 98-61 E. http://www.house.gov/berry/prescriptiondrugs/Resources/crscanmexdrugpricing.pdf

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