

Prescription Drug Costs in Tennessee

John G. Morgan
Comptroller of the Treasury
Office of Research
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STATE OF TENNESSEE
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November 27, 2002

The Honorable John S. Wilder
Speaker of the Senate
The Honorable Jimmy Naifeh
Speaker of the House of Representatives
And
Members of the General Assembly
State Capitol
Nashville, Tennessee 37243

Ladies and Gentlemen:

Transmitted herewith is a report prepared by the Office of Research concerning prescription drug costs in Tennessee. The report provides information and recommendations that may be useful to policymakers in considering ways to reduce prescription drug costs for both the state and its citizens.

Sincerely,

John G. Morgan
Comptroller of the Treasury

Prescription Drug Costs in Tennessee



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Comptroller of the Treasury

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Executive Summary

Prescription drug costs have risen rapidly in recent years, with retail sales of prescription drugs in Tennessee reaching almost \$4.4 billion in 2001.¹ These costs have produced a significant drain on state resources through TennCare, state employee health plans, and agency purchases and have strained the state's overall health care market. Rising prescription drug costs are not unique to Tennessee, and many states are pursuing actions meant to curb this growth. This report:

- examines underlying causes of rising drug costs;
- reviews steps private organizations and the federal government have taken to curb growth in pharmaceutical spending;
- evaluates methods Tennessee agencies and state employee health plans use to purchase prescription drugs;
- evaluates actions of other states to reduce prescription drug costs; and
- outlines further options for Tennessee to slow drug cost growth in state employee health plans, state wholesale purchases, and the state prescription drug market as a whole.

The Office of Research plans to release a report examining prescription drug costs in the TennCare program at a later date.

This report concludes:

Two national information sources recently found Tennessee has the nation's highest rate of prescription drug use, both in scripts per capita and spending per capita.² Several factors contribute to this, including:

- Tennessee's high proportion of senior citizens,
- Lower educational attainment and poor health status among Tennessee citizens,
- Tennessee's high rate of insurance, and
- Inappropriate use.

(See pages 30-34.)

Tennessee lacks a comprehensive approach to state wholesale pharmacy purchases. The state of Tennessee spent approximately \$16 million for wholesale prescription drug purchases in fiscal year 2002. The Department of General Services coordinates most wholesale prescription drug purchases for state entities through the Minnesota Multistate Contracting

¹ The Kaiser Family Foundation, "Total Retail Prescription Sales, 2001," <http://www.statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs+%282001%29&topic=Retail+Prescription+Sales>, (accessed September 5, 2002).

² The Kaiser Family Foundation, "State Health Facts Online: Number of Prescriptions per Capita, 2001," <http://statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs&topic=Prescriptions+Per+Capita>, (accessed July 12, 2002); Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed.

Alliance for Pharmacy (MMCAP). However, the Departments of Correction and Children's Services contract with a private company to provide pharmacy services. Both of these initiatives have produced significant savings over previous arrangements. However, the state has not conducted a comprehensive evaluation of wholesale pharmacy purchases to determine whether it could obtain prescription drugs more cost-effectively. (See pages 35-36.)

Many county jails do not purchase prescription drugs in a cost-effective manner. County jails purchase prescription drugs in a variety of ways, including contracting with private firms for all health care expenses, contracting with firms only for prescription medications, and purchasing drugs through local pharmacies. Many county jails have no doctor or nurse on site and must transfer inmates to local emergency rooms to receive prescriptions. Though a few county jails have formularies in place to control costs, those that obtain prescriptions through emergency rooms often have difficulty gaining physician compliance with the formulary. Finally, because county jails purchase drugs individually, they are unable to use their collective purchasing power to negotiate discounts from pharmacy service providers or pharmaceutical companies. In some cases, county jails are not able to provide the most effective treatment for mentally ill inmates because of the high cost of medication. (See page 36.)

Prescription drug costs have been the fastest growing component of state health plan costs in recent years. From 1997 to 2001, pharmacy costs for the state PPO plan grew 326 percent; overall costs in the PPO plan grew only 44 percent during that time. Pharmacy costs were responsible for over 75 percent of the net change in plan costs from 1997 to 2001. The POS and HMO plans also experienced high rates pharmacy cost growth. (See page 37.)

Premiums for state employee plans have risen significantly in recent years, increasing the risk of adverse selection. Adverse selection occurs when healthier members of an insurance pool choose to drop their coverage because they feel the coverage is not cost effective for them. As infrequent utilizers of services leave health plans, the average cost per enrollee increases, and premiums rise for those who remain.³ The Division of Insurance Administration lacks data necessary to determine if adverse selection is occurring in state employee health plans. (See pages 37-38.)

Tennessee's state employee health plans contain less extensive cost sharing provisions than those found in surrounding states. Research has shown significant three-tier copayments encourage plan members to use lower cost medications. Tennessee's health maintenance organization (HMO) and point-of-service (POS) plans use two-tier prescription drug copayments of \$5 and \$15. The state preferred provider option (PPO) plan uses three-tier copayments of \$5, \$15, and \$25. These copayments are significantly less than copayments for state employee plans in most surrounding states, shown in Appendix C. (See pages 39-40.)

State employee health plan members use some classes of prescription drugs more frequently than members of commercial groups. State employee plan contract partners have noticed differences between utilization patterns for the state employee health plans and their commercial populations. It is unclear if these utilization differences are attributable to

³ Mark Pauly and Sean Nicholson, "Adverse Consequences of Adverse Selection," *Journal of Health Politics, Policy, and Law*, October 1999.

demographic differences in patient populations. If not, the state may need to develop strategies to address them. (See pages 40-41.)

The Division of Insurance Administration has added many disease management programs to state employee plans in recent years, but the state lacks a focused strategy for the development of these programs. Disease management programs are designed to help patients with high cost conditions, such as asthma and diabetes, manage their own health better. The Division of Insurance Administration has coordinated the implementation of disease management programs for most state employee health plans. (See Appendix D.) However, the PPO plan, which includes about half of all plan members, includes no DM programs, and the state lacks a focused strategy for the development of disease management programs based on the state's identification of its needs and performance criteria to measure progress toward meeting those needs. As a result, the state may be purchasing programs that are not cost effective and/or failing to purchase programs that could produce significant benefits for the state and plan enrollees. (See pages 41-42.)

Many states have taken steps to modify prescription drug markets and lower costs. State governments have significant influence on prescription drug markets. As costs have increased, states have used this influence in a variety of ways, including:

- Legislation to promote the substitution of generic drugs for name-brand equivalents;
- Discount programs for specific populations, usually the poor and/or elderly;
- Discount programs open to any state resident;
- Controlled substance monitoring programs;
- Appropriate antibiotic use campaigns;
- Patient safety campaigns;
- Gift-disclosure laws requiring pharmaceutical companies to report to the state large gifts to doctors, pharmacists, and other providers;
- Litigation against pharmaceutical companies; and
- Patent-law reform efforts.

(See pages 42-50.)

Tennessee's generic substitution law promotes the use of generic medications less aggressively than other states' laws. All states except Oklahoma have laws authorizing pharmacists to substitute generic medications for equivalent brand drugs in some cases. Thirty-eight states, not including Tennessee, allow or require pharmacists to substitute generic medications for brand drugs unless the prescribing physician writes "brand necessary" or a similar message on the script. A 2001 University of Florida study estimated generic substitution laws like Tennessee's decreased the use of generic drugs and increased spending about 6.5 percent.⁴ (See pages 42-44.)

Tennessee has not pursued strategies to lower prescription drug costs through increased market share. As with most markets, larger market share in the prescription drug market generally allows purchasers to negotiate lower prices. Market share can offer benefits in

⁴ David Denslow, "The Two-Line Prescription Pad: Economic Impact on Florida's Health Payers," working paper, April 28, 2001.

negotiations with pharmacies, pharmacy benefit managers (PBMs), and pharmaceutical companies. Some states are exploring ways to combine Medicaid programs, state employee health plans, and/or wholesale purchases to negotiate discounts. Many more are seeking to join with other states to negotiate discounts on drug purchases. Most of these initiatives are still in planning stages or early stages of implementation. (See pages 51-53.)

The report contains recommendations beginning on page 54.

Legislative Recommendations

- The General Assembly may wish to revise TCA §53-10-203 to promote the use of lower-cost generic medications when possible.
- The General Assembly may wish to encourage the Tennessee congressional delegation to pass patent law revisions to promote the availability of generic prescription drugs.
- The General Assembly may wish to create an interagency committee to study state and local non-retail pharmacy purchasing practices and create a comprehensive approach to those purchases.

Administrative Recommendations

- The State Insurance Committee should:
 - consider implementing more aggressive cost-sharing provisions in the state employee pharmacy benefit;
 - explore whether or not mail-order services for maintenance drugs can reduce costs for the Tennessee state insurance plans; and
 - develop a focused strategy for the development of disease management programs in state employee health plans.
- The Department of Finance and Administration, in conjunction with the state's contract partners, should explore making more information as to the effects and costs of prescription drugs available to consumers online.
- The Department of Finance and Administration should study the feasibility of joining a multistate consortium or pursuing a joint contract with TennCare to reduce drug costs for the state health plans.
- The Department of Finance and Administration should analyze utilization trends for specific conditions and medications in the state employee plans.
- The Department of Commerce and Insurance and other affiliated groups should proceed with the current development process for the state controlled substance registry.
- The Department of Health should continue its efforts to curtail inappropriate use of prescription medications.

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Introduction

Prescription drug costs have risen rapidly in recent years, with retail sales of prescription drugs in Tennessee reaching almost \$4.4 billion in 2001.¹ These costs have produced a significant drain on state resources through TennCare, state employee health plans, and agency purchases and have strained the state's overall health care market. Rising prescription drug costs are not unique to Tennessee, and many states have taken or are considering actions meant to curb this growth. This report:

- examines underlying causes of rising drug costs in Tennessee and the nation as a whole;
- reviews steps private organizations and the federal government have taken to curb growth in pharmaceutical spending;
- evaluates methods Tennessee agencies and state employee health plans use to purchase prescription drugs;
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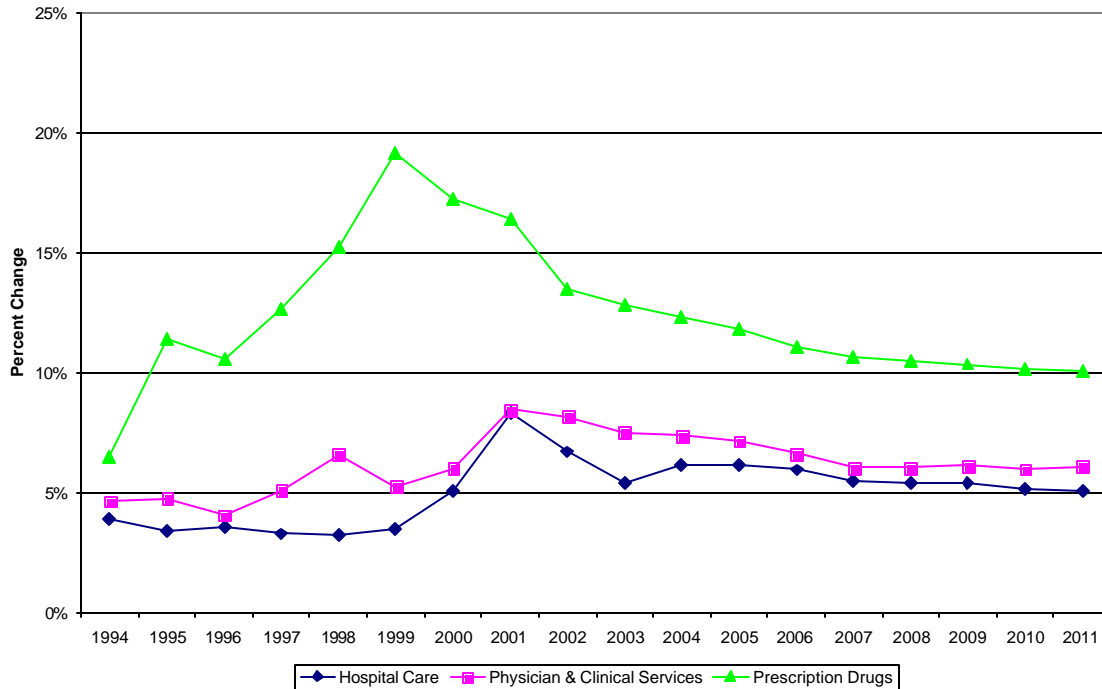
The Office of Research plans to release a report examining prescription drug costs in the TennCare program at a later date.

Background

According to the Center for Medicare and Medicaid Studies (CMS), U.S. spending on prescription drugs increased from \$51.3 billion in 1993 to \$121.8 billion in 2000, a 137 percent increase. In contrast, overall health care spending grew by only 48 percent. As seen in Exhibit 1, CMS projects growth in prescription drug spending to outpace increases in other areas of health care spending for at least the next decade.

¹ The Kaiser Family Foundation, "Total Retail Prescription Sales, 2001," <http://www.statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs+%282001%29&topic=Retail+Prescription+Sales>, (accessed September 5, 2002).

Exhibit 1: U.S. Annual Health Care Spending Growth



Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Table 2 (<http://www.hcfa.gov/stats/NHE-Proj/proj2001/tables/t2.htm>) and Table 9 (<http://www.hcfa.gov/stats/nhe-oact/tables/t9.htm>).

Third-party payers such as Medicaid or private insurance have borne the brunt of these spending increases. Exhibit 2 shows the average change in national prescription drug spending from 1994 to 2000, and Exhibit 3 shows spending on prescription drugs as a percent of all health care spending. Out-of-pocket spending includes deductibles and copayments but does not include insurance premiums. Increased prices, increased utilization, or a combination of the two always drives increased spending. Both factors have contributed to rising prescription drug spending.

Exhibit 2: U.S. Annual Change in Prescription Drug Spending

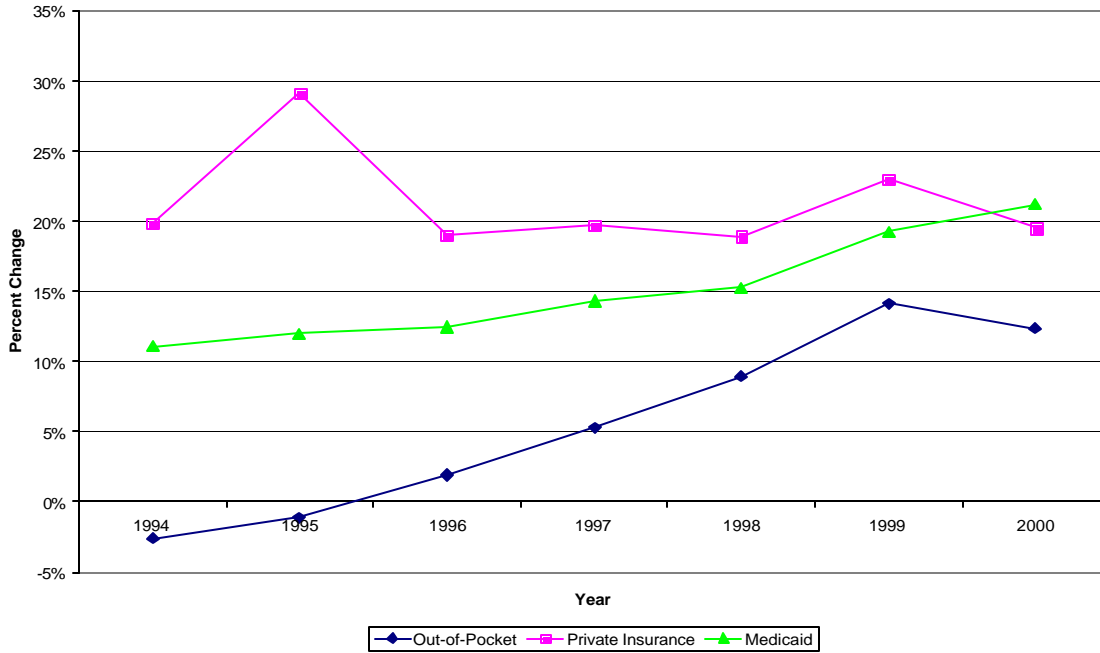
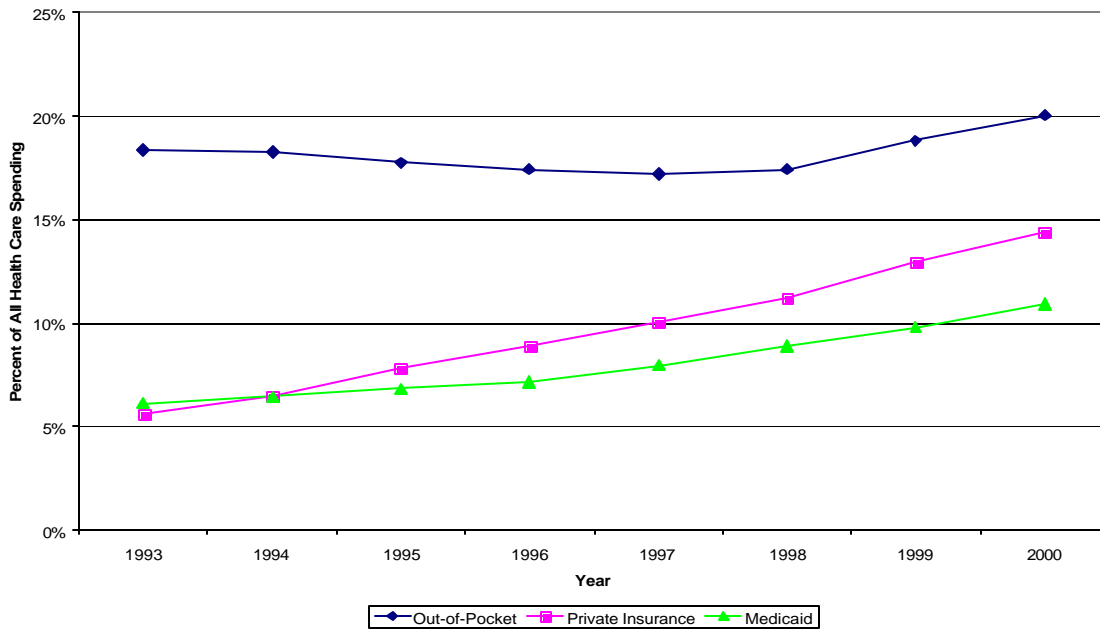


Exhibit 3: Prescription Drugs as a Share of all U.S. Health Care Spending

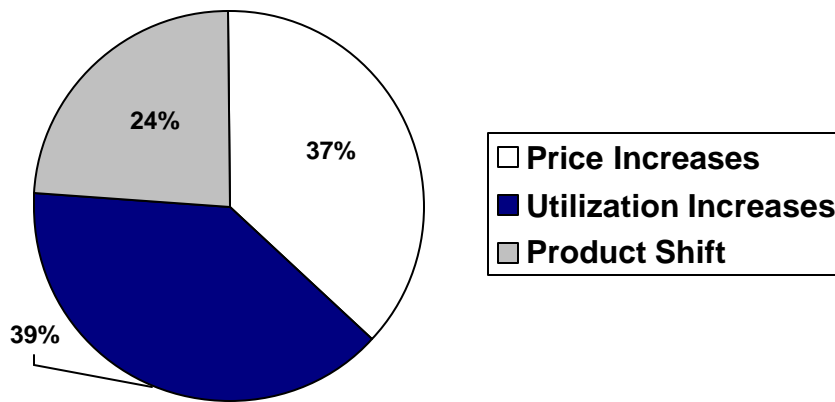


Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures, Table 9 (<http://www.hcfa.gov/stats/nhe-oact/tables/t9.htm>).

Recent National Trends

According to the National Institute for Health Care Management, drug spending grew 17.1 percent in 2001. Thirty-nine percent of this increase was attributable to an increase in the number of prescriptions. Product shift from lower-cost to higher-cost drugs accounted for 24 percent of the increase. The final 37 percent was caused by price increases for drugs already in use.²

Exhibit 4: Factors Driving Increased Prescription Drug Spending in 2001



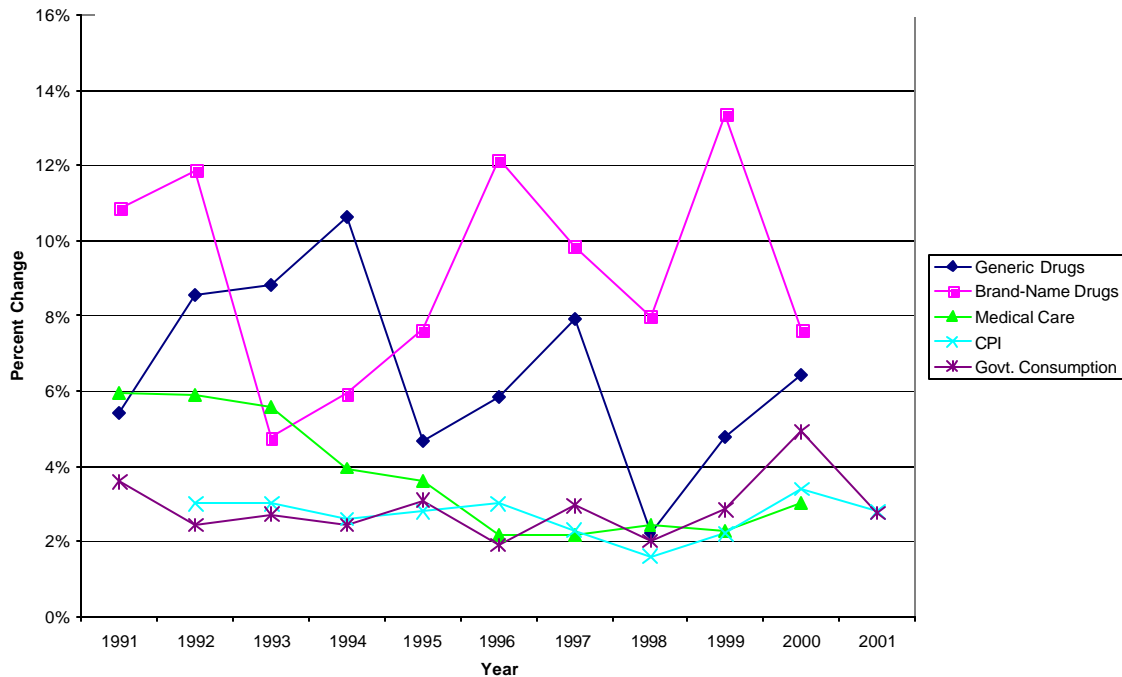
Source: National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002.

Price Increases

Prescription drug prices have increased much faster than prices for other goods and services over the past decade. Exhibit 5 shows five measures of annual price increases. The consumer price index (CPI) measures average prices faced by consumers, and the government consumption index measures average prices faced by governments. Both of these measures of inflation have remained low throughout the past decade. After moderately high inflation in the early 1990s, prices for most medical goods and services have grown at low rates for the past six years. In contrast, prices for both generic and brand-name drugs have grown rapidly.

² National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002, p. 6.

Exhibit 5: Annual Inflation Rates for Prescription Drugs, Health Care Purchases, and General Purchases



Sources: IMS Health, Inc. National Prescription Audit Plus, April 2001
 Bureau of Economic Analysis, National Income and Product Accounts Table 7.20
 Bureau of Labor Statistics, Consumer Price Index—All urban consumers
 UT Center for Business and Economic Research

These price increases have a number of sources. Greater spending on research and development and marketing have both contributed. Price increases have allowed pharmaceutical companies to maintain higher profit margins than those of any other industry. Finally, the structure of the pharmaceutical market, with stringent patent protections and high rates of third-party payment, allows drug companies to increase prices more easily than companies in other industries.

Research and Development

Drugs marketed in the United States must first undergo significant preclinical testing followed by three stages of clinical trials on humans. The length of this process varies considerably, but some pharmaceutical companies estimate it takes 12 years on average.³ From a typical set of 5,000 compounds examined by researchers, only five will reach Phase I clinical trials, and only one will eventually receive FDA approval for sale in the U.S.⁴ Over the past decade, drug development costs have increased at 2.5 times the rate

³ Dale Wierenga and Robert Eaton, “Phases of Product Development,” Pharmaceutical Manufacturers Association, Office of Research and Development, http://www.allp.com/drug_dev.htm (accessed May 8, 2002).
⁴ CME, Inc., “The Drug Development and Approval Process,” <http://www.mhsource.com/resource/process.html> (accessed May 6, 2002).

of inflation. Including all these costs, a drug company typically spends \$802 million in research and development to bring one new drug (new chemical entity) to market.⁵

Part of the reason for that increase is the changing nature of drug research. Scientists discovered many breakthrough drugs, including cholesterol medications Lipitor, Zocor, and Pravachol, through enzyme research. After decades of enzyme-based discoveries, drug companies have exhausted most opportunities for new drugs through that channel, and new gene-based research has yet to bear fruit.⁶ In the words of Robert Rubin, professor of health sciences and technology at Harvard University, “In some ways the easy drugs have been done.”⁷ Because of these trends, drug companies are spending ever greater sums to bring new drugs to market, and these drugs often offer little therapeutic benefit. Only 15 percent of new drug applications submitted to the FDA from 1989 to 2000 were new compounds that appeared to be significant improvements over existing therapies.⁸

Pharmaceutical companies seldom bear the full weight of research costs. Some drug development costs are tax deductible.⁹ Also, the 1980 Stevenson-Wydler Technology Innovation Act requires federal pharmaceutical research to be transferred to the private sector for marketing. The 1986 Federal Technology Transfer (FTT) Act authorized federal laboratories to enter into formal cooperative research and development agreements (CRADAs) with private companies. Under CRADAs, a public agency such as the National Institutes of Health (NIH) provides personnel, services, facilities, equipment, or resources to facilitate research and often agrees to grant licenses to the collaborating partner on any inventions resulting from the joint research. Thus, a pharmaceutical company can shift some research and development costs to the federal government through a CRADA but maintain revenues derived from that research.

In 1989, the NIH instituted a “reasonable pricing clause” for CRADAs, requiring that products created through joint research reflect a “reasonable relationship between the pricing of the licensed product, the public investment in the product, and the health and safety needs of the public.”¹⁰ The NIH removed this clause in 1995, citing concerns that the clause inhibited the development and marketing of new health care products.¹¹ The

⁵ Tufts Center for the Study of Drug Development, “Tufts Center for the Study of Drug Development Pegs Cost of New Prescription Medicine at \$802 Million,” <http://www.tufts.edu/med/csdd/images/NewsRelease113001pm.pdf> (accessed May 6, 2002).

⁶ Gardiner Harris, “Dose of Trouble: For Drug Makers, Good Times Yield to a New Profit Crunch,” *Wall Street Journal*, April 18, 2002, p. A1.

⁷ Andrew Pollack, “Despite Billions for Discoveries, Pipeline of Drugs is Far from Full,” *The New York Times*, April 19, 2002, p. 1.

⁸ Michie Hunt, *Changing Patterns of Pharmaceutical Innovation*, National Institute for Health Care Management, May 2002, p. 9.

⁹ Michael Gluck, *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals*, Georgetown University Institute for Health Care Research and Policy and the Kaiser Family Foundation, July 2002, p. 23-25.

¹⁰ Hunt, *Prescription Drug Costs: Federal Regulation of the Industry*, Blue Cross Blue Shield Association, September 2000, p. 33.

¹¹ Michael Gluck, *Federal Policies Affecting the Cost and Availability of New Pharmaceuticals*, Georgetown University Institute for Health Care Research and Policy and the Kaiser Family Foundation, July 2002, p. 22.

repeal of the reasonable pricing clause allows pharmaceutical companies to charge whatever prices they choose for drugs developed with the help of the federal government. The number of CRADAs executed by the NIH increased from about 35 per year in 1993 to 1995 to over 142 per year from 1997 to 1999, largely in response to the repeal of the reasonable pricing clause.¹²

Even with CRADAs, every new drug that comes to market in the U.S. is largely the product of the research investments of pharmaceutical firms. Pharmaceutical companies will not invest millions in large-scale clinical trials for drugs no longer under patent because they have no financial incentive to do so. Sepsis kills an estimated 215,000 Americans each year. Dr. Umberto Meduri at the UT Health Science Center has conducted a small-scale study that suggests doctors can use cheap, common steroids to treat the condition. However, the FDA will not approve steroids as a sepsis treatment unless large-scale clinical trials demonstrate conclusively that the drugs are effective. Because these drugs are no longer covered by patents, pharmaceutical firms have no incentive to sponsor the trials and few other groups have sufficient financial resources to fund them.¹³

Increased Marketing

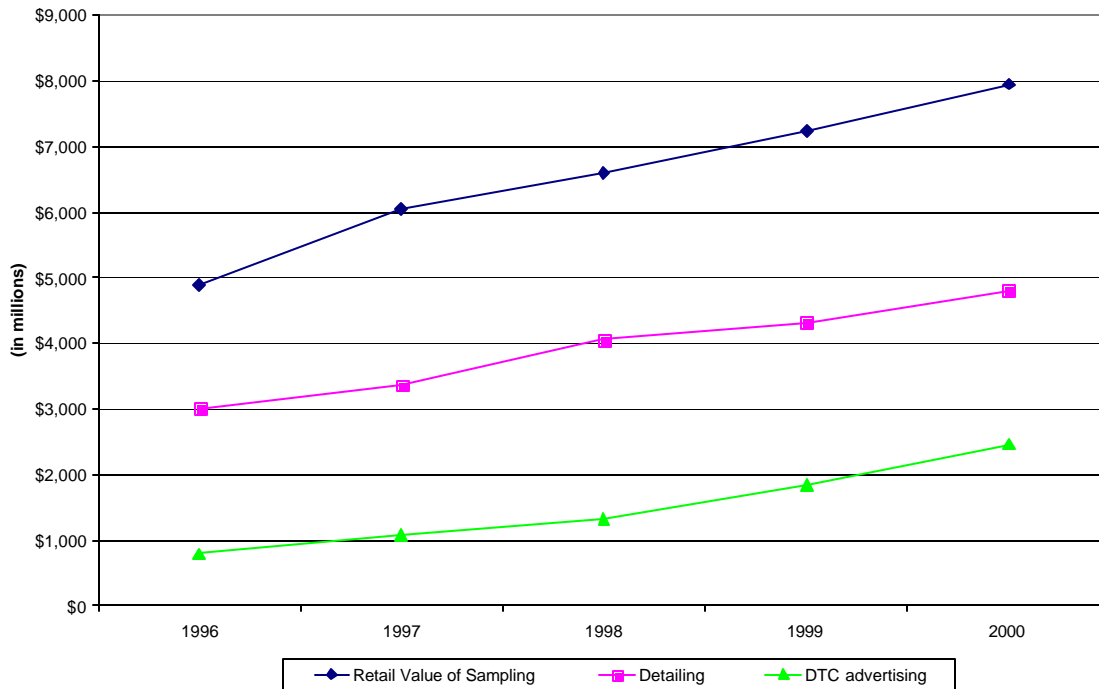
As prescription drug prices have increased, pharmaceutical companies have drawn widespread criticism for aggressive marketing campaigns that many believe drive prices even higher. In 2000, pharmaceutical companies spent over \$15.7 billion in marketing efforts.¹⁴ Sampling, detailing, and direct-to-consumer (DTC) advertising comprise the vast majority of pharmaceutical marketing budgets. Spending for all three areas has increased significantly in recent years. (See Exhibit 6.)

¹² Hunt, *Prescription Drug Costs: Federal Regulation of the Industry*, Blue Cross Blue Shield Association, September 2000, p. 33.

¹³ Thomas Burton, "Left on the Shelf: Why Cheap Drugs that Appear to Halt Fatal Sepsis Go Unused," *Wall Street Journal*, May 17, 2002, p. A1.

¹⁴ David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 31.

Exhibit 6: Pharmaceutical Promotional Spending



Source: David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 31.

Direct-to-Consumer Advertising

From 1996 to 2000, mass media spending by the pharmaceutical industry grew almost \$1.7 billion, an average annual increase of 32.9 percent. This makes mass media the fastest growing component of pharmaceutical marketing budgets in percentage terms, though sampling and detailing had higher dollar growth. Representatives of the pharmaceutical industry frequently claim mass media ads educate consumers on treatments available for their illnesses and encourage them to ask their doctors about available medications. Without the ads, they argue, many consumers would not be aware that drugs exist to treat their conditions and would simply endure them rather than receiving treatment. Critics of the ads charge that they are narrowly focused on promoting products with high profit margins without mentioning other available treatments that are more cost effective.

The largest contributor to the growth of mass media spending is television advertising. The FDA relaxed rules in 1997 that had prohibited most pharmaceutical television promotions.¹⁵ Spending on television advertising subsequently surged, growing from \$220 million in 1996 to almost \$1.6 billion in 2000, an annual increase of over 63

¹⁵ Paige Albiniak, "Is TV Too High on Drug Money?" *Broadcasting and Cable*, February 25, 2002, p. 5.

percent. In contrast, spending on magazine, newspaper, radio, and billboard ads increased an average of 12 percent per year during that time.¹⁶

Many pharmaceutical companies have begun to pursue less conventional avenues of direct-to-consumer advertising. Several health care companies have paid money or donated equipment to television shows to receive prominent product placements. Some drug companies have paid celebrities to appear on morning news programs and talk shows and discuss health conditions and company products. The regulations of television ads do not apply to such appearances.¹⁷ Pharmaceutical companies are also using drug stores to promote their products. Several have begun paying drug stores as much as \$1.50 per letter and \$3.50 per phone call to contact customers urging them to purchase company prescription drugs.¹⁸ After an investigation by the Florida Attorney General's Office, Eckerd Corporation agreed to stop using information gleaned from customer pick-up logs for direct mail marketing.¹⁹

Sampling

Sampling is the largest component of pharmaceutical promotional efforts. In 2000, the retail value of samples given to office-based physicians by pharmaceutical representatives was almost \$8 billion.²⁰ Pharmaceutical companies generally give away samples of their newest and most expensive products. If the drugs work, patients often purchase prescriptions of them after their samples run out even though less expensive therapies might be equally effective.

Pharmaceutical companies have recently begun targeting samples of their drugs directly to consumers. For example, in April the manufacturer of the weight-loss drug Xenical offered a six-month supply for the cost of a three-month supply, a savings of \$356. That same month Eli Lilly offered consumers a free month supply of Prozac (fluoxetine), a retail value of \$75. A month supply of generic fluoxetine cost only \$46 for a month supply at that time.²¹

Detailing

Detailing includes expenses for sales activity (other than sampling) of pharmaceutical representatives. Pharmaceutical spending on detailing in 2000 totaled over \$4.8 billion.²² According to Quintiles Informatics, a health care consulting firm, the pharmaceutical industry employed 81,600 sales representatives in 2001, a 45 percent increase from

¹⁶ David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 31-32.

¹⁷ Melody Petersen, "Heartfelt Advice, Hefty Fees," *The New York Times*, August 11, 2002, p. 1.

¹⁸ Ann Zimmerman and David Armstrong, "Swallow This: How Drug Makers Use Pharmacies to Push Pricey Pills," *Wall Street Journal*, May 1, 2002, p. A1.

¹⁹ Linda Kleindienst, "Eckerd Settles Customer Privacy Case," *South Florida Sun-Sentinel*, July 11, 2002.

²⁰ David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 31.

²¹ Tara Parker-Pope, "The Latest Craze in Coupon Clipping: Free Trial Offers for Prescription Drugs," *Wall Street Journal*, April 16, 2002, p. D1.

²² David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 31.

1998.²³ There were about 607,000 physicians and surgeons in the U.S. that year.²⁴ This would yield a ratio of 7.4 doctors for every drug representative, though the practical ratio would be even lower since the physicians and surgeons total includes doctors who focus primarily on teaching or research rather than clinical practice. Quintiles estimated drug companies held 370,300 meetings and events for doctors in 2001.²⁵

Market Structure

Patent protections and high rates of third-party payment allow pharmaceutical companies to raise prices without significantly reducing demand for their products. Three-fourths of Americans have some type of drug coverage.²⁶ These customers pay only a fraction of drug costs out of pocket in copayments, and most of those copayments are fixed. Thus, a patient may pay the same copayment for a drug that costs \$50 for a month supply as for a similar drug that costs \$120. Companies can charge especially high prices for drugs with few or no major competitors. Often, once a company establishes a drug as one of the dominant leaders in a particular product category, it can raise the price without significantly reducing sales.²⁷ Since price increases don't directly impact consumers, customers do not reduce consumption of drugs as they would with other products.

Patents initially shield brand-name drugs from generic competition. Pharmaceutical companies apply for patents for new drugs very early in the development process. Thus, a number of years of the patent are "wasted" because the company cannot market its patented drug until it receives FDA approval. The remaining period on a drug's patent after FDA approval is its "effective patent life." The 1984 Hatch-Waxman Act²⁸ extended the effective patent life of new drugs and streamlined the approval process for generic drugs, a compromise between the desire for pharmaceutical companies to receive a high return on their investment in research and consumers' need for affordable prescription drugs. Since 1984, the Hatch-Waxman Act and other federal legislation, along with new rules under the General Agreement on Tariffs and Trade, have extended the potential effective patent life of some new drugs from 8.1 years to almost 18 years.²⁹ However, research conducted for the Pharmaceutical Research and Manufacturers of America places average effective patent life between 11 and 12 years, in contrast to over 18.5 years for most other industries.³⁰ A drug's effective patent life depends on several factors

²³ Melody Petersen, "TV Ads Spur a Rise in Prescription Drug Sales," *The New York Times*, March 8, 2002, p. C13.

²⁴ U.S. Department of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook*, "Physicians and Surgeons," <http://www.bls.gov/oco/ocos074.htm> (accessed July 16, 2002); estimate represents 1.5 percent growth from 2000 estimate of 598,000.

²⁵ Melody Petersen, "TV Ads Spur a Rise in Prescription Drug Sales," *The New York Times*, March 8, 2002, p. C13.

²⁶ David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 15.

²⁷ Fred Gebhart, "Still Growing," *Drug Topics*, March 18, 2002, p. 25-30.

²⁸ The official title of the act is "The Drug Price Competition and Patent Term Restoration Act of 1984."

²⁹ National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection*, August 2000.

³⁰ Robin Strongin, "Hatch-Waxman, Generics, and Patents: Balancing Prescription Drug Innovation, Competition, and Affordability," National Health Policy Forum Background Paper, June 21, 2002, p. 5.

including research time before the drug reaches market, the duration of potential legal proceedings as a drug approaches the end of its patent life, and to what extent the drug may qualify for any of several patent extensions. These factors make it difficult to estimate the effective patent life of any individual drug. Federal law allows drugs that use a new chemical not previously approved by the FDA to apply for patent extensions of up to five years to cover lost patent time during the research process. For drugs qualifying for this extension, the total patent life after drug approval including the extension cannot exceed 14 years.³¹

While the Hatch-Waxman Act brought about rapid growth in the generic drug industry, many observers believe brand-name manufacturers have exploited provisions of the act to stifle generic competition. Among other things, the act allows brand manufacturers to sue generic manufacturers charging patent infringement. Current law requires the FDA to withhold generic approval for up to 30 months while a case is litigated whether or not the case has merit.³² Furthermore, through settlements in these suits brand manufacturers have essentially paid generic manufacturers not to bring their products to markets.³³

Brand manufacturers have tremendous financial incentives to take steps to avoid generic competition. Eli Lilly's patent on Prozac expired in 2001, and in only three months of competition generic fluoxetine garnered almost half of Prozac's market.³⁴ Because of generics' impact on company revenues, drug companies often alter their schedules for new drugs to mitigate the impact of patent expirations. For example, Schering-Plough has developed Chrinex, an allergy drug that offers no significant benefit over its existing drug Claritin. The company worked to get FDA approval for Clarinex in 2001 so that drug could capture Claritin's market share before it becomes available over the counter.³⁵

Industry analysts refer to drugs such as Chrinex as "me-too" drugs. Me-too drugs are chemically similar to drugs already available and offer little or no therapeutic advantage over those drugs. Another prime example of a me-too drug is AstraZeneca's heartburn medication Nexium. The company's main patent for its popular drug Prilosec expired in October 2001. However, the company has used a series of lawsuits and patent claims against 10 potential generic competitors to prevent them from entering the market.³⁶ If current Prilosec users begin using generic versions when they become available, AstraZeneca revenues will plummet. Against this backdrop the company launched its new heartburn medication Nexium in 2001. Company-sponsored tests have found that Nexium is only three percent better at treating one form of heartburn. In some tests, 40mg doses of Nexium performed no better than 20mg doses of Prilosec. David Campen, a physician and pharmacy executive with Kaiser Permanente, the nation's largest managed

³¹ Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998.

³² Business for Affordable Medicine, "Hatch/Waxman Reform Legislation," <http://www.bamcoalition.org/HWRReform.htm> (accessed May 1, 2002).

³³ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, pp. i-xi.

³⁴ Fred Gebhart, "Still Growing," *Drug Topics*, March 18, 2002, p. 25-30.

³⁵ Fred Gebhart, "Still Growing," *Drug Topics*, March 18, 2002, p. 25-30.

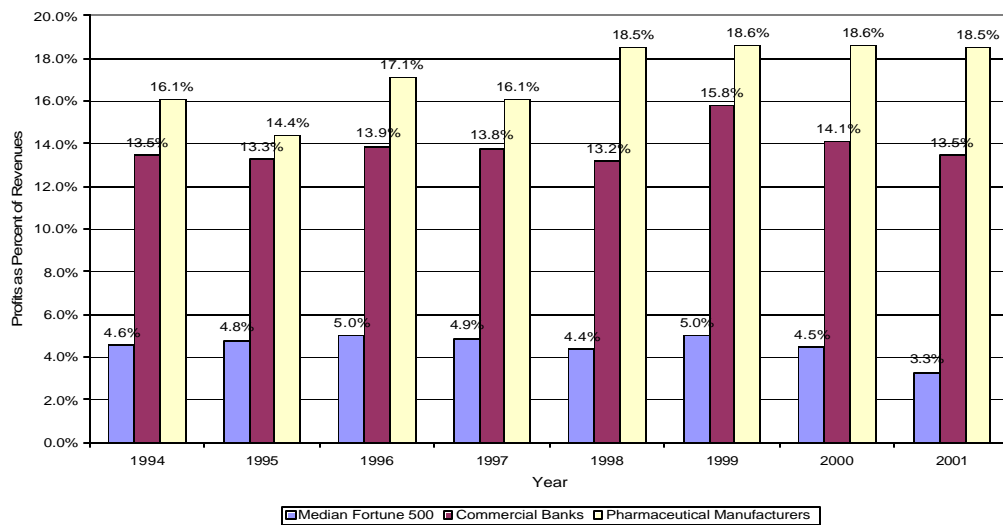
³⁶ Ronald White, "Key Drug Patent Ruling Nears," *The Los Angeles Times*, May 28, 2002, p. C1.

care provider, noted, “Nexium clearly is no value-added drug.”³⁷ Some interviewees have suggested that Nexium and Clarinex are actually less effective than their predecessor drugs. Still, AstraZeneca now encourages current Prilosec users to switch to Nexium, “the new purple pill” whose patent will extend well into the future.

Corporate Profits

Critics of the pharmaceutical industry long have argued company profit margins are excessive. The industry as a whole has been the nation’s most profitable for over 20 years.³⁸ Exhibit 7 shows the return on revenue for pharmaceutical manufacturers and the second ranked industry, commercial banks. This chart shows that pharmaceutical profit margins, already extremely high, increased during the late 1990s. The industry return in 2001 was more than five times the Fortune 500 median return.

Exhibit 7: Corporate Profitability



Source: Fortune 500 Industry Rankings, *Fortune*, April issues, various years.

Some analysts believe the pharmaceutical market is approaching a period of slowing or declining profits for the industry. While companies have exhausted most opportunities for enzyme-based drugs, new gene-based therapies are generally five to ten years from market. Thus, pharmaceutical companies will bring fewer new drugs to market in the near future than they have in recent years. Meanwhile, conversions of brand-name drugs to generics or over-the-counters will lower company revenues and consumer prices.³⁹

³⁷ Gardiner Harris, “Fast Relief: As a Patent Expires, Drug Firm Lines Up Pricey Alternative,” *Wall Street Journal*, June 6, 2002, p. A1.

³⁸ National Institute for Health Care Management, *Prescription Drugs and Intellectual Property Protection*, August 2000, p. 3.

³⁹ Gardiner Harris, “Dose of Trouble: For Drug Makers, Good Times Yield to a New Profit Crunch,” *Wall Street Journal*, April 18, 2002, p. A1.

Drug Utilization Increases and Product Shift

Utilization increases and shifts to more expensive products have been the primary drivers in prescription drug spending increases. The National Institute for Health Care Management found that 39 percent of increased drug spending in the United States in 2001 was attributable to an increase in the number of prescriptions and 24 percent to consumers shifting to higher cost drugs within a therapeutic category.⁴⁰ In 1992, the average American received 7.3 prescriptions. By 2000, that number had risen to 10.6.⁴¹ Many factors have driven this increase, including: demographic shifts, increases in product diversity and quality, changes in the structure of the overall health care market, and increased marketing by pharmaceutical companies. Improper use and abuse of prescription drugs also contribute to high utilization, though there is no clear evidence of an increase in recent years.

Demographics

It is no secret that the U.S. population is aging. From 1980 to 2000, the number of Americans over age 65 grew from 25.5 million to almost 34 million, an increase of 37 percent. During that time, the nonelderly population grew by less than 23 percent.⁴² As baby boomers age, elderly Americans will become an even greater share of the nation's population. By 2020, the U.S. elderly population will likely exceed 53 million.⁴³ The growth of the elderly population brings with it significant costs. In 2000, the average nonelderly, nondisabled adult consumed \$142 in prescription drugs. Per capita expenditures for the nondisabled aged were \$893, over six times as much.⁴⁴

In a sense, the American health care system has become a victim of its own success. Average life expectancy grew from 68.2 years in 1950 to 76.7 in 1999.⁴⁵ As advanced medical techniques have prolonged the lives of the sick and the elderly, they have greatly expanded the market for prescription drugs.⁴⁶ For example, new cholesterol medications are very effective, preventing heart attacks and strokes and extending lives. In the short run, this can reduce health care costs even though the drug itself is expensive. However,

⁴⁰ National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002, p. 6.

⁴¹ Based on prescription use from David Kreling, et al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 30 and population data from U.S. Census Bureau, <http://eire.census.gov/popest/data/counties/tables/CO-EST2001-12/CO-EST2001-12-00.php> (accessed April 23, 2002).

⁴² Christine Himes, "Elderly Americans," Population Reference Bureau, 2002, http://www.ameristat.org/Content/NavigationMenu/PRB/AboutPRB/Population_Bulletin2/Elderly_Americans.htm (accessed July 12, 2002).

⁴³ Ibid.

⁴⁴ Source: David Kreling, et al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 23.

⁴⁵ U.S. Centers for Disease Control and Prevention, National Center for Health Statistics, *National Vital Statistics Report*, Vol. 50, No. 6, March 21, 2002, p. 33.

⁴⁶ JD Kleinke, "The Price of Progress: Prescription Drugs in the Health Care Market," *Health Affairs*, September/October 2001, p. 43.

in the long run, costs increase as patients remain on the drug throughout their lives and incur additional health costs in other areas.

Product Diversity and Quality

The number of new drugs brought to market each year has risen modestly over the past two decades, but has begun to decline in recent years.⁴⁷ Even with that decline, the FDA approved 56 new drugs in 2001.⁴⁸ The growing repertoire of prescription drugs has increased the number of conditions treatable through medication. For example, Eli Lilly recently introduced Xigris, the first drug approved by the FDA to treat sepsis.⁴⁹ Drugs such as this drive up utilization rates as previously untreatable conditions become treatable. Also, some medications previously available only in a doctor's office are now available at retail, increasing retail prescription drug costs but reducing overall health care costs.

Some health professionals have argued that greater spending on prescription drugs reduces overall health care costs because the drugs enable patients to avoid more costly hospital visits and other treatments. Some research supports this conclusion in a general sense.⁵⁰ However, the impact of newer medications from class to class varies considerably, and is often difficult to determine both between classes and within classes. For example, ACE inhibitors are a widely accepted means of treating diabetes and hypertension. One study found that using the generic ACE inhibitor captopril can save \$32,500 in other medical expenses over the course of a lifetime for a patient with Type 1 diabetes and \$9,900 for a patient with Type 2 diabetes.⁵¹ Another study found no difference between newer and older ACE inhibitors in non-drug medical costs.⁵² Thus, in the case of ACE inhibitors, the creation of the class of drugs appears to have produced significant benefits while some innovations within the class have not. Other researchers compared the cost-effectiveness of inhalers and newer and more expensive oral medication in treating asthma. The study found no significant difference between the two treatments for medical costs incurred or for all asthma-related expenses including prescriptions.⁵³

⁴⁷ Andrew Pollack, "Despite billions for Discoveries, Pipeline of Drugs is Far from Full," *The New York Times*, April 19, 2002, p. 1.

⁴⁸ Fred Gebhart, "Still Growing," *Drug Topics*, March 18, 2002, p. 25-30.

⁴⁹ Interview with Butch Benson, Eli Lilly and Company, Account Manager, May 31, 2002.

⁵⁰ Alber Wertheimer, Richard Levy, and Thomas O'Connor, "Too Many Drugs? The Clinical and Economic Value of Incremental Innovations," *Investing in Health: The Social and Economic Benefits of Health Care Innovation*, v. 14, pp. 77-118; Frank Lichtenberg, "Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS," *Health Affairs*, September/October 2001, pp. 241-251.

⁵¹ Roger Rodby, Louise Firth, and Edmund Lewis, "An Economic Analysis of Captopril in the Treatment of Diabetic Nephropathy," *Diabetes Care*, October 1996, pp. 1051-1061.

⁵² Ralph Small, et. al., "Evaluation of the Total Cost of Treating Elderly Hypertensive Patients with ACE Inhibitors: A Comparison of Older and Newer Agents," *Pharmacotherapy*, November 5, 1997, p. 1015.

⁵³ Don Bukstein, Henry Henk, and Allan Luskin, "A Comparison of Asthma-Related Expenditures for Patients Started on Montelukast Versus Fluticasone Propionate as Monotherapy," *Clinical Therapeutics*, Vol. 23, No. 9, 2001.

The impact of prescription drugs on worker productivity is another important economic consideration. One study found that employees who took newer nonsedating antihistamines were much more productive than those who took older antihistamines. The researchers concluded it would be cost effective for the employer to pay for the drugs because productivity gains were worth more than the drug price.⁵⁴ Other studies have concluded that newer migraine medications result in fewer days missed from work and productivity increases offset the drugs' costs.⁵⁵

Although studies like these may provide insights, researchers will never compare all treatments for all medical conditions. Many health providers use a cost-effectiveness analysis (CEA) to determine optimal treatment for a condition.⁵⁶ However, CEAs often do not provide clear-cut answers. Multiple brand-name and generic drugs are available to treat most conditions, each with its own unique benefits and side effects. Most studies compare the effectiveness of drugs to placebos rather than other drugs in their class. These studies often fail to demonstrate whether drug A or drug B would be safer and/or more effective in a given situation.⁵⁷ Determining which specific therapy is generally the most cost-effective is difficult, if not impossible. Even for conditions with widely accepted standards for treatment, patients may have a variety of responses and reactions to the same drug therapy. This uncertainty further complicates treatment decisions. Some physicians have responded by automatically prescribing the newest drugs even though older, less costly treatments might be equally effective for many of their patients.

Market Changes

HMOs emerged as a means of controlling health care costs in the 1980s, and the share of physician office visits covered by HMO plans grew almost 200 percent from 1985 to 1999.⁵⁸ Many managed care plans include features to encourage prescription drug use because the appropriate use of medications can prevent the need for more costly procedures later on.⁵⁹ These include stricter adherence to treatment guidelines and greater prescription drug benefits. From 1988 to 1999, the number of insured workers with drug coverage grew from 91 percent to 99 percent.⁶⁰ As a result of these trends, out-of-pocket

⁵⁴ Iain Cockburn, et. al., "Loss of Work Productivity due to Illness and Medical Treatment," *Journal of Occupational and Environmental Medicine*, November 1999, pp. 948-953.

⁵⁵ Randall Legg, "Cost Benefit of Sumatriptan to an Employer," *Journal of Occupational and Environmental Medicine*, July 1997, pp. 652-657; Jennifer Lofland, "Cost-Effectiveness and Cost-Benefit of Sumatriptan in Patients with Migraine," *Mayo Clinic Proceedings*, November 2001, pp. 1093-1101.

⁵⁶ Louise Russell and Nancy Wolff, "The Impact of Drug Pricing Policies on the Health of the Elderly," *American Journal of Preventive Medicine*, Vol. 22, No. 3, 2002, p. 152.

⁵⁷ Michael Stein, Alastair Wood, and Theodore Pincus, "Implementation of Multiple Outpatient Formularies: Undesirable Effects," *Clinical Pharmacology and Therapeutics*, January 1997, p. 5.

⁵⁸ Catharine Burt, "National Trends in Use to Medications in Office-Based Practices, 1985-1999," *Health Affairs*, July/August 2002, p. 211.

⁵⁹ National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002, p. 3.

⁶⁰ Catharine Burt, "National Trends in Use to Medications in Office-Based Practices, 1985-1999," *Health Affairs*, July/August 2002, p. 211.

expenditures for prescription drugs actually declined in the mid 1990s.⁶¹ This decrease created an incentive for people to increase their prescription drug consumption.

Increased Marketing

More aggressive marketing by pharmaceutical companies has likely driven demand for their products. In 1997, the FDA relaxed rules that had prohibited most pharmaceutical television advertising.⁶² Since then, pharmaceutical industry spending on television advertising has soared. A 2001 survey found that 30 percent of Americans had spoken to their doctor about a prescription drug they saw advertised. Almost half of these received a prescription for that drug.⁶³ In 1999, Schering-Plough, Pfizer, and Aventis spent a combined \$237 million on direct-to-consumer advertising for their allergy drugs Claritin, Zyrtec, and Allegra. The combined increase in sales for these drugs in 1999 accounted for 4.4 percent of the overall increase in nationwide drug spending. Many of those sales are likely the result of patients requesting prescriptions from their doctors. Visits to doctors for allergy symptoms increased over 25 percent in 1999.⁶⁴ AstraZeneca's heartburn medication Prilosec became the nation's top-selling drug in 1999 with \$3.6 billion in sales. The company spent \$79.4 million touting "the little purple pill" that year in ads designed to maximize consumer product recognition.⁶⁵ The company now actively promotes Nexium, "the new little purple pill."

In addition to their use of mass media, some drug companies have recently begun giving away coupons and free samples for their products in hopes that consumers will continue to buy the products after their initial doses run out.⁶⁶ Pharmaceutical companies would not pursue these marketing strategies if they did not increase sales, but the actual sales increase is difficult to quantify.

Marketing practices may also influence physician behavior. In 1993, the Fifth Joint National Committee on the Detection, Evaluation, and Treatment of High Blood Pressure recommended physicians prescribe diuretics and beta-blockers to lower high blood pressure because those were the only treatments that had proven successful in long-term clinical trials. However, from 1992 to 1995, the number of prescriptions for these treatments declined while those for calcium channel blockers (calcium antagonists) increased.⁶⁷ During that time, calcium channel blockers, which are three times as expensive as the other treatments, were the most highly advertised drug class in the *New England Journal of Medicine*. Some industry analysts have speculated these

⁶¹ Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, National Health Expenditures Table 9, <http://www.hcfa.gov/stats/nhe-oact/tables/t9.htm> (accessed April 22, 2002).

⁶² Paige Albinak, "Is TV too High on Drug Money?" *Broadcasting and Cable*, February 25, 2002, p. 5.

⁶³ "Drug and Formulary Trends," *Formulary*, February 2002, p. 67.

⁶⁴ National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising*, September 2000, p. 3-4.

⁶⁵ National Institute for Health Care Management, *Prescription Drugs and Mass Media Advertising*, September 2000, p. 5.

⁶⁶ Tara Parker-Pope, "The Latest Craze in Coupon Clipping: Free Trial Offers for Prescription Drugs," *Wall Street Journal*, April 16, 2002, p. D1.

⁶⁷ David Siegel and Julio Lopez, "Trends in Antihypertensive Drug Use in the United States: Do the JNC V Recommendations Affect Prescribing?" *JAMA*, December 3, 1997, pp. 1745-1748.

advertisements drove higher prescription rates.⁶⁸ Many interviewees contend that detailing and sampling by pharmaceutical companies significantly alter physician prescribing habits.

Improper Use and Abuse

There are many types of improper drug use: using no drug or the wrong drug for a condition, using an improper dose, using unneeded drugs, or using drugs that interact with other treatments to produce an adverse reaction.⁶⁹ Some research suggests that the use of inappropriate medications is declining.⁷⁰ Nevertheless, improper use of prescription drugs is a major drain on national resources. One recent study estimated the cost of improper drug treatment to be \$177.4 billion nationwide.⁷¹ However, the researchers calculated this number by using pharmacist estimates as well as empirical data. Thus, the actual cost of improper drug treatment could be significantly higher or lower. Improper drug use appears to be a greater problem in the South. One recent study found 3.3 percent of elderly patients in the South used medications that should always be avoided by the elderly. The national average was 2.6 percent.⁷²

Abuse of pharmaceuticals has also become a significant national problem. The U.S. Drug Enforcement Administration (DEA) has become particularly concerned with the painkiller OxyContin. OxyContin contains large amounts of the pain reliever Oxycodone in a time-release formula. Abusers typically crush the pills and snort, swallow, or inject them for a more potent analgesic effect.⁷³ DEA's Drug Abuse Warning Network (DAWN) records emergency department episodes involving narcotics. DAWN episodes involving Oxycodone increased from less than 3,000 in 1996, the year OxyContin was introduced, to over 10,000 in 2000.⁷⁴ Purdue Pharma, the manufacturer of OxyContin, is developing a form of the drug that would be resistant to abuse. However, complete testing of the product will take four to five years.⁷⁵

Whole-Market Cost Containment Mechanisms

Rising drug costs have placed a tremendous strain on governments, private employers, and citizens. The federal government and private sector entities have taken a number of

⁶⁸ Steven Coulter, *Rx for Pharmacy Costs in Tennessee*, Blue Cross/Blue Shield of Tennessee, p. 8.

⁶⁹ Jeffrey Johnson and Lyle Bootman, "Drug-Related Morbidity and Mortality: A Cost-of-Illness Model," *Archives of Internal Medicine*, October 9, 1995, p. 1950.

⁷⁰ Chunliu Zhan, et. al., "Potentially Inappropriate Medication Use in the Community-Dwelling Elderly: Findings from the 1996 Medical Expenditure Panel Survey," *JAMA*, December 12, 2001, p. 2825.

⁷¹ Frank Ernst and Amy Grizzle, "Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model," *Journal of the American Pharmaceutical Association*, March/April 2001, p. 197.

⁷² Chunliu Zhan, et. al., "Potentially Inappropriate Medication Use in the Community-Dwelling Elderly: Findings from the 1996 Medical Expenditure Panel Survey," *JAMA*, December 12, 2001, p. 2827.

⁷³ U.S. Drug Enforcement Administration, "DEA Briefs and Background, Drugs and Drug Abuse, Drug Descriptions, Oxycodone," <http://www.usdoj.gov/dea/concern/oxycodone.html> (accessed June 25, 2002).

⁷⁴ Asa Hutchinson, Administrator, Drug Enforcement Administration, testimony before House Committee on Appropriations, Subcommittee on Commerce, Justice, State, and Judiciary, December 11, 2001, <http://www.usdoj.gov/dea/pubs/cngtest/ct121101.html> (accessed July 12, 2002).

⁷⁵ CNN.com, "Abuse-Resistant OxyContin Hits Development Snag," June 19, 2002, <http://www.cnn.com/2002/HEALTH/06/19/oxycotin.snag.ap/index.html> (accessed June 25, 2002).

steps to attempt to control drug costs. Most of these strategies are designed to lower the prices paid for drugs, reduce the number of prescriptions filled, or encourage consumers to use older, more cost-effective therapies.

Private Sector Insurance Plan Actions

Pharmacy Benefits Managers

In the 1990s, many insurance plans contracted with pharmacy benefits managers (PBMs) or created their own PBMs to rein in growing drug costs. PBMs usually carry significant market clout, allowing them to negotiate significant discounts with individual and chain pharmacies. Pharmacy payments from PBMs come in two forms: reimbursement rates and dispensing fees. Reimbursement rates theoretically cover the actual cost of drugs while dispensing fees cover the incidental costs involved in filling prescriptions. In practice, the line between how pharmacies use these two payment forms is not distinct. Reimbursement rates for brand-name drugs are usually based on average wholesale price (AWP). Commercial publishers of drug pricing data derive AWP from data that drug manufacturers report to them. AWP is not a true average, and it seldom reflects actual prices paid by wholesalers. Instead, AWP is roughly equivalent to the “sticker price” or “list price” in the automobile industry.⁷⁶ PBMs usually pay pharmacies a reimbursement rate of AWP minus some percent. For example, under the state employee health plan of West Virginia, Express Scripts pays pharmacies a reimbursement rate of AWP minus 15 percent.⁷⁷ PBMs use prices of generic products to establish maximum allowable cost (MAC) limits that determine the reimbursement rates for multisource drugs. The average MAC for the West Virginia state employee plan is AWP minus 63 percent.⁷⁸ PBMs also use their market clout to obtain lower dispensing fees from network pharmacists. Express Scripts pays pharmacies a dispensing fee of \$2.00 per brand script and \$2.50 per generic script in the West Virginia public employees plan.⁷⁹

Because PBMs are significant purchasers, they can negotiate discounts from pharmaceutical manufacturers as well, generally in the form of manufacturer rebates of product purchases. Rebate negotiations may be on a drug-by-drug basis, or a PBM may negotiate discounts for a company’s entire product line simultaneously. If a PBM is not satisfied with price concessions offered by a drug company, it will not place its drug on the formulary or preferred drug list. Depending on the structure of an insurance plan’s pharmacy benefit, patients will either have to pay a higher copayment or receive prior authorization from the PBM to receive nonformulary medications through the plan. Some pharmacists have concluded that the increased reliance on rebates have simply encouraged drug companies to raise the retail price of prescription drugs.⁸⁰ If this is the

⁷⁶ Dawn Gencarelli, “Average Wholesale Price for Prescription Drugs: Is there a More Appropriate Pricing Mechanism?” National Health Policy Forum, June 7, 2002, p. 3.

⁷⁷ Tom Susman, West Virginia Public Employees Insurance Agency, Director, testimony at RXIS States meeting, September 12, 2002.

⁷⁸ Ibid.

⁷⁹ Ibid.

⁸⁰ Herb Jackson, “Drug-Benefit Firms are Under Political Fire in New Jersey,” *The Hackensack Record*, August 9, 2002.

case, rebates do little to reduce the true market price for prescription drugs and may contribute to higher drug costs for those without insurance.

Finally, pharmacy benefit managers reduce costs by discouraging inappropriate use of medications. Almost all PBMs use an electronic link system with doctors and pharmacies to facilitate benefits management. This usually includes electronic edits to notify pharmacists of redundant prescriptions or prescriptions that are likely to cause an adverse reaction. PBMs also accumulate data on physician prescribing habits so they can identify doctors who issue prescriptions at higher rates or more frequently prescribe higher cost medications.

Though pharmacy benefit manager (PBM) contracts are theoretically designed to control drug costs, some create incentives for PBMs to *encourage* increases in costs. Insurance companies must pay an administrative fee to use a PBM. This fee can take a number of forms, the most common being a charge per script. Thus, a PBM would receive greater compensation if those enrolled in affiliated insurance plans used more prescription drugs. Many PBMs also receive a percentage of the rebates they negotiate with pharmaceutical manufacturers. In such cases, PBMs may have an incentive to channel patients toward drugs that bring greater rebates even if less expensive therapies are available. Furthermore, PBMs sell data and provide services to drug companies that help the companies promote their products.⁸¹ In a 2001 national survey, only 13 percent of firms felt PBMs were “very effective” in controlling prescription drug costs.⁸² Several interviewees contended that PBMs were ineffective in managing drug costs. One interviewee went so far as to call PBMs “glorified claims processors.” The U.S. Justice Department is investigating the practices of Medco Health (formerly Merck-Medco) and Advance PCS, two of the nation’s largest PBMs.⁸³ Aetna recently announced it will terminate its PBM contract and bring all PBM services in house.⁸⁴

Some forms of PBM reimbursement may reduce conflicts of interest. PBMs may guarantee a fixed reimbursement rate for their pharmacy networks. If they are able to negotiate lower rates, they retain the difference between the actual rate and the guaranteed rate.⁸⁵ Some PBMs maintain “pass through” contracts, where all savings accrue to the entity contracting with the PBM. This compensation method removes perverse incentives created by the above contractual features, but it undermines some incentives PBMs have to reduce costs. PBM contracts may also include cost trend lines. If costs remain below the lines, PBMs receive bonuses.⁸⁶

⁸¹ Barbara Martinez, “Letter to Medco Indicates Gravity of U.S. Inquiry,” *Wall Street Journal*, August 21, 2002, p. A2.

⁸² Kaiser Family Foundation, *Employer Health Benefits: 2001 Annual Survey*, p. 124.

⁸³ Barbara Martinez, “Letter to Medco Indicates Gravity of U.S. Inquiry,” *Wall Street Journal*, August 21, 2002, p. A2.

⁸⁴ Barbara Martinez, “Aetna to Handle Own Drug Business,” *Wall Street Journal*, October 23, 2002, p. A2.

⁸⁵ Anna Cook, “Strategies for Containing Drug Costs: Implications for a Medicare Benefit,” *Health Care Financing Review*, Spring 1999, p. 31; Patrick Renaud, “Control of Prescription Drug Costs—is it Possible?” *Employee Benefits Journal*, March 2002, p. 11; and various interviews.

⁸⁶ Correspondence from Rick Dillon, Express Scripts, Sales Director, July 11, 2002.

Drug Utilization Review

Drug utilization review (DUR) examines prescriptions filled under a health plan and produces information that can be used to reduce drug costs. There are two types of DUR: prospective and retrospective. Prospective DUR examines prescriptions before payment is authorized while retrospective DUR aggregates data for dispensed prescriptions. Retrospective DUR shows PBMs the medications doctors are prescribing so the PBM or insurer can contact doctors and encourage them to alter their prescribing habits.⁸⁷ Follow up with doctors often involves “counterdetailers,” insurance company or PBM employees who visit physicians who frequently prescribe nonformulary medications. Counterdetailers present clinical and cost information to doctors in an effort to persuade doctors to prescribe lower-cost drugs that may be just as effective.⁸⁸ Retrospective DUR can also reveal trends in individual pharmacies such as their generic dispensing rate or the doses and quantities of dispensed prescriptions. General Motors analyzed records through retrospective DUR and found that 92 percent of Prilosec prescriptions under company health plans were for people who had never tried drugs known as H-2 antagonists that are available as generics. After this discovery, GM began promoting these drugs in its “Generics First” campaign.⁸⁹

Prospective DUR attempts to change prescriptions before reimbursement is made. Pharmacists have always conducted prospective DUR, checking for potential reactions of prescribed drugs with other medications or patient allergies. However, computer systems now provide a more thorough check for potential drug interactions, allergies, and improper dosages.⁹⁰ Other forms of prospective DUR focus more explicitly on drug costs. The share of U.S. employers using prior authorization, one form of prospective DUR, grew from 43 percent in 1996 to 77 percent in 2000.⁹¹ Prior authorization requires the prescribing physician to provide additional information and justification to the insurer for certain drugs before the prescription can be filled.⁹² Benefits managers hope this process increases physician awareness of which drugs are most cost-effective. Another form of prospective DUR is step therapy or a “fail first” requirement, which requires physicians to prescribe older, less expensive drugs first. A patient may only receive the newer, costlier medication if those interventions fail.⁹³

⁸⁷ Miriam Basch Scott, “Effective Management of Prescription Drug Benefit is Crucial to Health Care Cost Containment,” *Employee Benefit Plan Review*, January 2001, p. 22.

⁸⁸ Marc Kaufman, “Doctors Hear Alternatives to Drug-Firm Sales Pitches,” *The Washington Post*, August 5, 2002, p. A01.

⁸⁹ Thomas Burton, “Pushing Pills: Reining In Drug Advertising,” *Wall Street Journal*, March 13, 2002, p. B1.

⁹⁰ Many insurance companies now categorize this system of checks as “concurrent DUR” rather than prospective DUR.

⁹¹ “Drug and Formulary Trends,” *Formulary*, April 2002, p. 176.

⁹² Miriam Basch Scott, “Formulary is Top Pharmacy Benefit Management Tool,” *Employee Benefit Plan Review*, January 2001, p. 35.

⁹³ Miriam Basch Scott, “Effective Management of Prescription Drug Benefit is Crucial to Health Care Cost Containment,” *Employee Benefit Plan Review*, January 2001, p. 22.

Formularies

A formulary is a list of drugs selected by an insurance company on the basis of their effectiveness and cost-effectiveness in treating medical conditions. Prices, discounts, and rebates offered by manufacturers influence drugs listed on formularies. Formularies come in three types: open, closed, and incentive. Open formularies suggest certain drugs to prescribing physicians but do not limit use of any particular drug. Companies with closed formularies cover only drugs listed on the formulary. However, patients can generally obtain drugs not included on the formulary through prior authorization programs. Incentive formularies allow enrollees access to any drug but require them to pay higher copays for drugs not on the formulary.⁹⁴ In 2000, 59 percent of U.S. employers used open formularies, 39 percent used incentives, and two percent used closed formularies. However, the use of incentive formularies grew from only 25 percent in 1999,⁹⁵ and many interviewees believe that number is well over 50 percent in 2002.

Formularies can have a tremendous impact on utilization of specific drugs. Eli Lilly's patent on Prozac expired in 2001, and in only three months of competition generic fluoxetine garnered almost half of Prozac's market.⁹⁶ A large part of this decline was due to rapid formulary adjustments. Before generic fluoxetine was available, 80 percent of formularies covered Prozac. Within months of its launch, 91 percent covered generic fluoxetine and only 41 percent covered Prozac.⁹⁷

Promotion of Generic Drugs

Generic drugs can offer significant savings over brand name products. In 2000, the average retail price for generic medications was \$19.33 compared to \$65.29 for brand name drugs.⁹⁸ Insurance companies use "maximum allowable cost" (MAC) lists for drugs available in generic form. For drugs on these lists, the insurance company will only reimburse the pharmacist for the cost of the generic. For example, a generic medication might cost \$.10 per pill while the brand-name drug costs \$.25 per pill. The pharmacist would require a patient who insists on using the brand-name drug to pay the difference in cost.⁹⁹ Insurers may use different methodologies for computing MAC prices. For drugs with several generic forms, the computation methodology can have a significant impact on reimbursement rates. The most aggressive MAC policies drive consumers to the lowest cost generic product available.

Pharmacy benefit manager (PBM) promotional efforts can also increase generic market penetration. In the weeks leading up to the launch of generic fluoxetine, Merck-Medco

⁹⁴ Miriam Basch Scott, "Formulary is Top Pharmacy Benefit Management Tool," *Employee Benefit Plan Review*, January 2001, p. 23.

⁹⁵ "Drug and Formulary Trends," *Formulary*, February 2002, p. 67.

⁹⁶ Fred Gebhart, "Still Growing," *Drug Topics*, March 18, 2002, p. 25-30.

⁹⁷ "Drug and Formulary Trends: SSRI Formulary Status before and after Generic Prozac," *Formulary*, March 2002, p. 126.

⁹⁸ David Kreling, et.al., *Prescription Drug Trends: A Chartbook Update*, The Kaiser Family Foundation, November 2001, p. 27.

⁹⁹ Grant Ritter, Cindy Thomas, and Stanley Wallack, *Greater Use of Generics: A Prescription for Drug Cost Savings*, Brandeis University, The Schneider Institute for Health Policy, January 2002, <http://www.gphaonline.org/pdf/brandeis-text.pdf> (accessed May 9, 2002).

(now Medco Health) phoned or faxed physicians who often wrote “dispense as written” on Prozac prescriptions, notifying them of generic availability and explaining the benefits of the generic version. The company also acquired an ample stock of generic fluoxetine for initial sales. As a result, the generic uptake rate for Merck-Medco exceeded the industry average.¹⁰⁰

Both of the above approaches are designed to encourage patients to use generic forms of prescribed drugs. However, some groups have instituted more aggressive strategies that encourage patients to use generic drugs rather than brand drugs that have no generic equivalent. General Motors’ pharmacy-benefits provider delivers free generic samples to doctors’ offices to compete with brand-name samples distributed by major pharmaceutical manufacturers in the company’s “Generics First” campaign. In the campaign’s first year, the share of generic drugs prescribed to members of GM health plans increased three percent, saving the company an estimated \$36 million. In another approach, Blue Cross/Blue Shield of Michigan distributes coupons for free samples of generic drugs.¹⁰¹

Trigon, Virginia’s Blue Cross/Blue Shield plan, requires prior authorization for Celebrex and Vioxx, two heavily prescribed treatments for arthritis and acute pain. The drugs, known as Cox-2 inhibitors, cost between \$604 and \$732 a year compared to \$32 to \$140 a year for older generic medications called NSAIDs. Studies have shown that Vioxx and Celebrex are no more effective in treating pain than the generics but are less likely to cause gastrointestinal bleeding and other stomach problems for some patients. Trigon doctors who wish to prescribe these drugs for their patients must demonstrate that the patients are at risk for these side effects.¹⁰²

Tiered Copayments

Most companies now require employees to pay higher copayments for higher cost drugs. A typical two-tier drug plan offers one copayment level for generic drugs and a higher level for brand-name drugs. Three-tier plans split the brand-name tier into preferred and elective (sometimes called formulary and non-formulary) drugs. For example, members of many Blue Cross/Blue Shield commercial plans in Tennessee may purchase generic allergy medications with a \$10 copay. They must pay a \$20 copayment for Allegra and Claritin, which are listed on the company’s preferred drug list. The copayment for the elective tier, which includes Zyrtec, is \$35.¹⁰³ The use of three-tier copayment structures has risen rapidly in recent years. In 2000, 35 percent of large employers contracting with Express Scripts, a national pharmacy benefit manager, used a three-tier copay. That number rose to 63 percent in 2002.¹⁰⁴ Some companies have added a fourth tier for

¹⁰⁰ “PBM Shares Strategy behind Prozac Switch Success,” *Formulary*, November 2001, p. 778.

¹⁰¹ Thomas Burton, “Pushing Pills: Reining In Drug Advertising,” *Wall Street Journal*, March 13, 2002, p. B1.

¹⁰² Robert Pear, “Virginia Blue Cross Plan Leads Shift to Lower-Cost Drugs,” *The New York Times*, August 18, 2002, p. 20.

¹⁰³ Blue Cross/Blue Shield of Tennessee, “2002 Preferred Drug List,” January 1, 2002, <http://www.bcbst.com/pharmacy/prefdrugs02.htm> (accessed May 14, 2002); correspondence with Terry Shea, pharmacy benefit director, Blue Cross/Blue Shield of Tennessee, May 15, 2002.

¹⁰⁴ Correspondence from Rick Dillon, Sales Director, Express Scripts, July 31, 2002.

“lifestyle” drugs.¹⁰⁵ Lifestyle drugs offer no direct health benefits and include fertility drugs, oral contraceptives, and Viagra.¹⁰⁶ Some drug plans base tiers on treatment-type rather than price: major-therapy (e.g., cholesterol control drugs), minor-therapy (e.g., cough and cold medication), and lifestyle drugs.¹⁰⁷

Most three-tier drug plans require flat copays for drugs (e.g., \$10 for generic drugs, \$20 for brand-name formulary drugs, and \$35 for nonformulary drugs). Some employers have chosen percentage copays in lieu of tiered copays. Under these plans, a customer might pay 10 percent of retail for all prescriptions. The most aggressive copay structure is a tiered percentage model. A three-tier percentage model might require customers to pay five percent for generics, 10 percent for formulary drugs, and 20 percent for nonformulary drugs. This model creates the greatest incentives for consumers to choose less costly drugs, and those incentives increase as drug prices rise.¹⁰⁸ However, many plan administrators have found that customers prefer to know exactly what a drug will cost them at the pharmacy and prefer flat copays to percentage copays.

Tiered copayments have become a popular cost control mechanism for several reasons. A recent study found that three-tier copayment plans encouraged the use of less expensive drugs and reduced overall prescription drug spending in the plans without increasing costs in other areas. Most importantly, after an initial drop in prescription costs, the three-tier plan also showed slower growth than a two-tier plan.¹⁰⁹ While closed formularies may be even more effective at controlling costs, they are unpopular because consumers are often unwilling to participate in plans that they perceive as limiting their choice of medication. Three-tier copayments offer customers their choice of almost all drugs and simultaneously impose some controls on plan costs.

Disease Management

In the early 1990s, HMO advocates predicted managed care would provide insurers with financial incentives to promote patients’ long-term health. In theory, relatively small expenditures on prescription drugs and preventive care in the short run would allow patients to avoid costly procedures and yield greater profits in the long run. Managed care companies would thus have an incentive to encourage the use of these services. Unfortunately, market practice has only partially followed this theory. One industry researcher noted, “With 20 percent annual enrollment turnover and quarterly financial targets, investments in the long-term health status of their [HMOs’] covered lives via more aggressive pharmaceutical care does not make business sense—especially in the

¹⁰⁵ “Prescription Drug Copayments,” *The Controller’s Report*, May 2002, p. 4.

¹⁰⁶ “Plan Design Crucial Element in Rx Benefit Cost,” *Employee Benefit Plan Review*, November 2001, p. 17.

¹⁰⁷ Michael Prince, “PBMs Still Effective in Reducing Employers’ Drug Costs,” *Business Insurance*, April 2, 2001, p. 14.

¹⁰⁸ Patrick Renaud, “Control of Prescription Costs—Is It Possible?” *Employee Benefits Journal*, March 2002, p. 11-14.

¹⁰⁹ Brenda Motheral and Kathleen Fairman, “Effect of a Three-Tier Prescription Copay on Pharmaceutical and Other Medical Utilization,” *Medical Care*, December 2001, p. 1293-1304.

absence of data regarding those investments.”¹¹⁰ Thus, recent increases in drug utilization do not necessarily indicate that insurers are encouraging drug utilization to reduce overall health costs.

Still, there are areas where theory has translated into practice. Over the past 10 years, disease management (DM) has become a significant component of many health plans. The Disease Management Association of America defines it as “a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant.”¹¹¹ That is, DM programs work to ensure that patients are taking necessary steps in the treatment of their conditions. They generally include strategies to promote healthy lifestyles such as proper diet, appropriate use of medication, and maintenance of a healthy home environment. These programs work best for high cost medical conditions such as asthma, diabetes, and congestive heart failure (CHF). Because one of the goals of DM programs is appropriate use of medication, they also increase prescription drug costs with the goals of improving patient health and reducing overall medical costs.

Firms specializing in disease management have grown rapidly over the past decade, and many employers and PBMs have their own disease management programs.¹¹² Only 14 percent of employers used disease management programs in 1994. By 2000, that number rose to 44 percent.¹¹³ DM programs are clearly growing in popularity, but research has yet to demonstrate conclusively that the programs consistently produce net savings. Numerous studies have shown that DM programs can improve health outcomes and produce savings in certain areas. However, the Advisory Board Company reviewed 100 articles published since 1995 with titles suggesting an analysis of the cost effectiveness of disease management programs and found only two documented actual return on investment (ROI) for participating insurance plans. The Advisory Board also noted that many studies meant to analyze the effectiveness of DM programs suffer from significant methodological flaws that cast doubt on their conclusions.¹¹⁴

Despite these concerns, several interviewees have concluded that DM programs can simultaneously improve patient care enough to produce measurable financial savings. Some disease management firms are willing to place 100 percent of their fees at risk in contracts that tie those fees to financial outcomes.¹¹⁵ Well-crafted DM programs targeting specific high-cost populations likely improve health status and produce meaningful

¹¹⁰ JD Kleinke, “The Price of Progress: Prescription Drugs in the Health Care Market,” *Health Affairs*, September/October 2001, p. 46.

¹¹¹ Disease Management Association of America, “Definition of DM,” <http://www.dmaa.org/definition.html> (accessed August 15, 2002).

¹¹² *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report*, Pharmacy Benefit Management Institute, 2001, p. 12-13.

¹¹³ *The Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report*, Pharmacy Benefit Management Institute, 2001, p. 11.

¹¹⁴ The Advisory Board Company, “Promise of Medical Management: Persistent Questions on Disease Management ROI,” *Rising Acute Care Demand: Implications and Strategy for Health Plans*, April 2002, pp. 62-63.

¹¹⁵ Interview with Peter McCann, American Healthways, Vice President for Development, June 25, 2002.

savings, but groups contracting for the programs should be careful in creating quantitative measures to assess the success of disease management.

Mail Order

Mail-order prescription drug sales reached \$20.7 billion in 2001, an increase of 27 percent over the previous year. Mail-order sales now account for over 12 percent of all prescription sales.¹¹⁶ Prices at mail-order distributors are below those at retail pharmacies and are particularly attractive to patients taking drugs for chronic conditions.¹¹⁷ Most mail-order prescriptions are for 90-day supplies rather than the 30-day supplies typical of retail pharmacies. Insurance companies benefit from sharply reduced reimbursement rates at mail-order pharmacies, and many charge members lower copayments if they use mail order. Some insurance plans require enrollees to obtain prescription refills through mail-order services.¹¹⁸ Many online retailers have also emerged, with sales totaling approximately \$1.1 billion in 2001.¹¹⁹ That year, 83 percent of commercial/group plans offered prescription mail service to enrollees, and 56 percent offered internet-based services.¹²⁰

Several interviewees noted filling 90-day scripts for maintenance drugs through mail order can reduce pharmacy costs by lowering reimbursement rates and dispensing fees. For example, brand-name retail scripts for the West Virginia state employees insurance plan cost AWP minus 15 percent plus a \$2 dispensing fee. Mail-order scripts cost only AWP minus 19.5 percent plus \$1.¹²¹ However, interviewees also noted that mail order can result in wasted drugs because a single script usually includes much more medication. Some plans have responded to this dynamic by requiring patients to receive at least one 30-day supply before purchasing a 90-day supply. Also, 90-day mail order prescriptions can result in increased pharmacy costs for employers depending on copayment arrangements. Most commercial plans require 90-day mail copayments that are twice 30-day retail copayments. This arrangement produces savings for plan members and the plan itself.

Internet Services

Many insurance companies have created expanded online services that reduce customer service costs and provide plan members more information on plan benefits. These services provide plan members user IDs and passwords that allow them to access benefits information, track bill payments, request replacement ID cards, and handle other matters that might ordinarily result in a call to customer service lines. Expanded online services often give patients more detailed information about drug side effects and provide drug

¹¹⁶ National Institute for Health Care Management, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, April 2002, p. 9.

¹¹⁷ Lisa Rapaport, "Mail-Order Prescription Sales Rising Sharply," *Knight-Ridder Tribune Business News*, March 30, 2002, p. 1.

¹¹⁸ "Plan Design Crucial Element in Rx Benefit Cost," *Employee Benefit Plan Review*, November 2001, p. 17.

¹¹⁹ Rafael Gerena-Morales, "Finding Reliable Online Pharmacies Getting Easier," *Knight-Ridder Tribune Business News*, February 4, 2002, p. 1.

¹²⁰ Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed., p. 15.

¹²¹ Tom Susman, West Virginia Public Employees Insurance Agency, Director, testimony at RXIS States meeting, September 12, 2002.

costs, both to the plan and the enrollee. To promote online services, Medical Mutual Insurance entered enrollees who registered for the services in a drawing for various prizes, including a Caribbean cruise.¹²² Many interviewees have commented that physicians have very little time to explain to patients the similarities and differences between highly marketed drugs and less expensive therapies that are often marketed less. Others have noted that doctors seldom know what drugs cost to plans or patients. By providing this information to patients, insurance companies give them information that can encourage more cost-effective utilization.

Other Private Sector Actions

Foreign Purchases

Recently, differences among drug prices in the United States and other countries have received widespread publicity. Canada's Patented Medicine Prices Review Board (PMPRB) prevents pharmaceutical companies from charging prices it determines are excessive. Provinces negotiate directly with pharmaceutical manufacturers to obtain even lower prices for government programs. These discounts influence prices in the Canadian private sector. As a result, drug prices in Canada are well below U.S. prices.¹²³ A January 2002 PMPRB study examined prices for dozens of popular drugs in Canada, European countries,¹²⁴ and the U.S. The study found regulated Canadian prices were 8 to 29 percent lower than U.S. average wholesale price (AWP) in all but one case. Furthermore, regulated prices for 66 of 80 drugs studied were equal to or lower than the U.S. federal supply schedule. That would place these prices lower than those available in the U.S. private sector or in state Medicaid programs. European prices were generally comparable to Canadian prices.¹²⁵

About 50 Canadian-based pharmacies allow patients to use the Internet to purchase prescription drugs from Canada,¹²⁶ but such purchases are technically illegal. U.S. law prohibits the importation of drugs from other countries outside the FDA approval process even if the drugs are identical to those already available domestically.¹²⁷ However, enforcement agencies are not eager to investigate and prosecute violators, many of whom are Medicare beneficiaries who lack prescription drug coverage.¹²⁸

Marketing Limits

Many industry observers have criticized pharmaceutical companies for aggressive marketing tactics. Several interviewees echoed this concern. Their criticisms include:

¹²² Cheryl Powell, "Some Health Insurers Begin to Offer More Services on Internet," *Akron Beacon Journal*, August 5, 2002, p. 1.

¹²³ Devidas Menon, "Pharmaceutical Cost Control in Canada: Does It Work?" *Health Affairs*, May/June 2001, p. 92-103.

¹²⁴ France, Germany, Italy, Sweden, Switzerland, and the United Kingdom.

¹²⁵ Patented Medicine Prices Review Board, *Verification of Foreign Patented Drug Prices (2000)*, January 2002, PMPRB Study Series S-0215.

¹²⁶ Joel Baglole, "Manitoba Fills Niche for Affordable Drugs," *Wall Street Journal*, October 10, 2002, B3.

¹²⁷ Rebecca Eisenberg, "The Shifting Functional Balance of Patents and Drug Regulation," *Health Affairs*, September/October 2001, p. 135.

¹²⁸ Thomas Burton and Sarah Lueck, "Insurer to Cover Drugs Bought Outside U.S.," *Wall Street Journal*, October 11, 2002, B1.

- **Television ads that offer very little therapeutic information.** No ads mention generic alternatives that could often work as well as the advertised products. Most egregiously, many of the ads do not even state what conditions the drugs are meant to treat.
- **The high number of pharmaceutical representatives.** Most pharmaceutical representatives have little or no clinical background and are narrowly focused on promoting a few core products with high profit margins. While the information they present to doctors is generally accurate, doctors do not receive comparable information on older, less expensive therapies. Interviewees generally felt this skewed the playing field in favor of newer medications. Nationwide, there is one pharmaceutical representative for every 7.4 physicians. (See pages 9-10.)
- **Advisory contracts with physicians.** Many pharmaceutical companies establish physician advisory committees to receive input from physicians. Several interviewees felt that these contracts were designed to promote company products to prominent physicians rather than to facilitate physician input. Some commented that these contracts may include lavish trips to resort locations that companies tailor to the interests of specific doctors.

Private sector groups have taken steps to curtail some of these activities. One Seattle clinic has begun charging pharmaceutical representatives \$30 an hour to enter the building. The clinic plans to ban all sales reps starting in 2003. Another firm in Kentucky contracts with a private company to schedule sales representative visits. The company charges \$105 per slot to meet with doctors.¹²⁹

In April, 2002, the Pharmaceutical Research and Manufacturers of America announced new voluntary guidelines prohibiting gifts to doctors ranging from lavish dinners to floral arrangements to sporting event tickets. The new guidelines went into effect July 1.¹³⁰ The guidelines also clarify and limit the employment of doctors by pharmaceutical companies as consultants. However, some industry observers feel the guidelines will encourage companies to expand their use of consultants and increase expenditures on direct-to-consumer advertising.¹³¹ One interviewee hypothesized that pharmaceutical companies are willing to impose such guidelines on themselves because they have determined expensive gifts given to doctors are less effective marketing tools than direct-to-consumer advertising.

Discount Cards

Over the past several years, insurers, retail pharmacies, pharmaceutical firms, and independent companies have begun marketing drug discount cards. Some target the elderly or low-income individuals while others are open to anyone, though the cards are

¹²⁹ "Some Doctors Attempt to Thwart Drug-Industry Sales Reps," *CNN.com*, June 14, 2002,

<http://www.cnn.com/2002/HEALTH/06/14/doctor.access.fees.ap/index.html> (accessed June 20, 2002).

¹³⁰ Bill Brubaker, "Drug Industry Adopts Guidelines on Giveaways to Doctors," *The Washington Post*, April 20, 2002, p. E03.

¹³¹ Scott Hensley, "Sorry, Doc, No Dinners 4o-Go—Drug Sales Reps Begin Building a New Marketing Playbook," *Wall Street Journal*, April 23, 2002, p. D4.

of no use to those with prescription drug insurance coverage. The array of cards has created confusion and red tape, and many cards fail to deliver substantial savings.¹³² These cards appear to shift drug costs to the privately insured but actual drug prices for cardholders may remain higher than for insurance companies since PBMs negotiate steep rebates with manufacturers. In April, seven drug companies joined to create the Together Rx Card, which offers low-income senior citizens a 20 to 40 percent discount on their medications.¹³³ Rising prices for prescription drugs may negate large portions of these savings. A single card should reduce confusion surrounding drug cards but is not likely to alter the market dynamics driving rising drug costs.

Federal Actions

Drug Reimportation

In July, 2002, the U.S. Senate approved a measure that would allow the importation of drugs from Canada, which has a regulatory regime similar to that of the United States. However, the Department of Health and Human Services announced that it does not intend to carry out provisions of the bill, citing concerns that Canada could serve as a conduit to the United States for unsafe products from other parts of the world.¹³⁴ Boston University researchers estimated U.S. consumers could save \$38 billion if they could easily purchase drugs at Canadian prices. Tennesseans paid an estimated \$2.4 billion for prescription drugs in 2001. The researchers concluded those purchases would only cost \$1.5 billion if Canadian prices were in place in Tennessee, a savings of \$900 million.¹³⁵ However, the study may underestimate the value of manufacturer rebates to PBMs, private insurance companies, and Medicaid programs. If so, actual savings would likely be somewhat lower. As of October 28, companion legislation was still pending in the house and appeared unlikely to pass this year.¹³⁶

Patent Law Revisions

In July, the Federal Trade Commission (FTC) released a report on the impact of federal laws on the availability of generic drugs. The report recommended the FDA permit only one automatic 30-month stay per drug product per generic application. The report also recommended brand-name drug companies and generic applicants file certain agreements with the FTC. The FTC found that from 1998 to 2000, 14 settlements had the potential to delay generic drug market entry. The FTC alleges that in at least three of those settlements, the brand manufacturer essentially paid the generic competitor not to enter the market.¹³⁷ On October 21, the Bush administration announced proposed federal

¹³² Bill Brubaker, "Is the Right Drug Price in the Cards?" *The Washington Post*, March 10, 2002, p. H01.

¹³³ Gardiner Harris and Sarah Lueck, "Drug Makers Unite on Discounts for Elderly to Ease Confusion," *Wall Street Journal*, April 10, 2002, p. A3.

¹³⁴ Robert Pear, "Plan to Import Drugs from Canada Passes in Senate," *The New York Times*, July 18, 2002.

¹³⁵ Alan Sager, "Americans would Save \$38 Billion in 2001 if We Paid Canadian Prices for Brand Name Prescription Drugs," testimony before the Senate Committee on Commerce, Science and Transportation Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, September 5, 2001.

¹³⁶ "Bill Summary and Status for 107th Congress—H.R.4614," <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR04614:@@X> (accessed October 28, 2002).

¹³⁷ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, July 2002, pp. i-xi.

regulations based on the recommendations of the Federal Trade Commission.¹³⁸ However, the administration will only implement these regulations after a lengthy comment period, and final regulations may differ significantly from those proposed.

Senators Charles Schumer of New York and John McCain of Arizona introduced legislation, S.812, to amend many provisions of the Hatch-Waxman Act and lower barriers to generic market entry.¹³⁹ On July 31, an amended version of the bill passed the U.S. Senate. The legislation as passed would allow only one automatic 30-month stay per brand drug and would require brand companies to list all relevant patents. As of October 28, the House version was still pending in the Subcommittee on Health of the Committee on Energy and Commerce,¹⁴⁰ and the legislation is unlikely to pass this year.¹⁴¹

On October 22, Pfizer received a “use patent” for Viagra. Unlike traditional patents, which protect the rights to a certain chemical, the use patent prevents other companies from marketing chemicals that, though different from Viagra, work in the same manner. The company immediately filed suits to prevent two competitor drugs from reaching market in the U.S. All three drugs treat erectile dysfunction by inhibiting the enzyme PDE-5.¹⁴² If successful, suits such as this could increase the monopoly power of pharmaceutical companies and dramatically increase prescription drug costs.

¹³⁸ Scott Lindlaw, “Bush Announces New Rules on Generic Drugs,” *The Washington Post*, October 21, 2002.

¹³⁹ “Bill Summary and Status for 107th Congress—S.812,” <http://thomas.loc.gov/cgi-bin/bdquery/D?d107:22:/temp/~bdpMnX:@@L&summ2=m&/bss/d107query.html> (accessed June 21, 2002).

¹⁴⁰ “Bill Summary and Status for 107th Congress—H.R.5311,” <http://thomas.loc.gov/cgi-bin/bdquery/z?d107:HR05311:@@X>, (accessed October 28, 2002).

¹⁴¹ Scott Lindlaw, “Bush Announces New Rules on Generic Drugs,” *The Washington Post*, October 21, 2002.

¹⁴² Scott Hensley, “Pfizer Sues to Block Viagra Rivals,” *Wall Street Journal*, October 23, 2002, p. A3; Matthew Herper, “Pfizer Must Lose This Battle,” *Forbes.com*, October 23, 2002.

Analysis and Conclusions

Tennessee Prescription Drug Utilization

Two national information sources recently found Tennessee has the nation's highest rate of prescription drug use, both in scripts per capita and spending per capita.¹⁴³

(See Exhibit 8.) Based on data from these sources, had Tennessee prescription drug spending mirrored the national average, total retail sales in the state would have been between \$1.2 billion and \$1.5 billion less.¹⁴⁴ According to Novartis data, Tennessee's utilization rates for all 32 drug classes studied were higher than the national average.

These drug types are listed in Appendix B. Age, health status, insurance coverage rates, and physician prescribing behavior have all contributed to Tennessee's high prescription rate.

Exhibit 8: Per-Capita Prescription Drug Use in 2001

Source	Measure	Tennessee Average	National Average
Kaiser Family Foundation	Scripts per person	15.3	10.3
Kaiser Family Foundation	Prescription drug spending per person	\$762.82	\$542.41
Novartis Pharmacy Benefit Report	Scripts per person	17.8	11.7
Novartis Pharmacy Benefit Report	Prescription drug spending per person	\$878.56	\$632.59

Sources: The Kaiser Family Foundation, "State Health Facts Online," <http://www.statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Costs+%26+Budgets&welcome=1> (accessed July 12, 2002); Novartis, "Pharmacy Benefit Report: Facts and Figures," 2002 ed., p. 21.

Tennessee's high proportion of senior citizens increases per capita drug utilization.

Demographics significantly impact drug utilization. As people age, they tend to use more drugs. Fifty-one percent of people ages 65 to 74 use two or more prescription drugs per month compared to only 21 percent of the nation as a whole.¹⁴⁵ In 2002, approximately 7.1 percent of Tennessee's population were in this age group compared to 6.8 percent

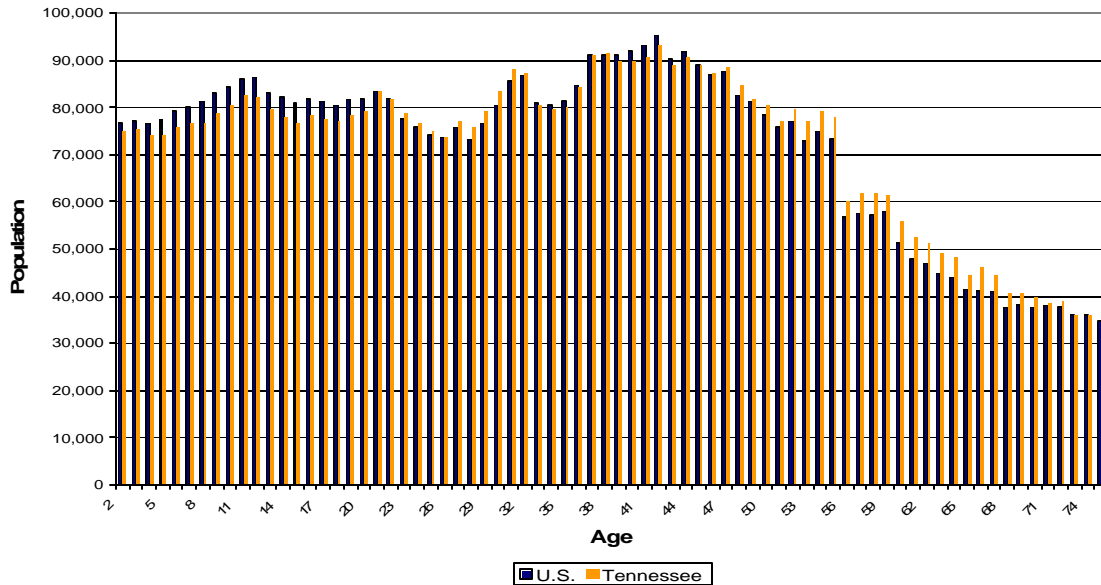
¹⁴³ The Kaiser Family Foundation, "State Health Facts Online: Number of Prescriptions per Capita, 2001," <http://statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Costs+%26+Budgets&subcategory=Prescription+Drugs&topic=Prescriptions+Per+Capita>, (accessed July 12, 2002); Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed.

¹⁴⁴ Office of Research analysis of 2001 Kaiser Family Foundation data and Novartis data.

¹⁴⁵ U.S. Department of Health and Human Services, Centers for Disease Control, National Center for Health Statistics, "Patterns of Prescription Drug Use in the United States, 1988-94," *National Health and Nutrition Examination Survey*, <http://www.cdc.gov/nchs/about/major/nhanes/databriefs/preuse.pdf> (accessed May 8, 2002).

nationally.¹⁴⁶ Furthermore, Tennessee, like the nation as a whole, faces much higher prescription drug spending as baby boomers approach old age. (See Exhibit 9.)

Exhibit 9: Age Distribution in Tennessee and the U.S.



Estimated 2002 Tennessee population based on 2000 census data. U.S. population is shown relative to Tennessee population, not in actual totals.

Lower educational attainment and poor health status appear to increase

Tennessee’s prescription drug utilization. Individuals who receive fewer years of formal education use more prescription drugs and have lower life expectancies.¹⁴⁷ Some researchers have found that education attainment is a better predictor of cardiovascular disease than either income or occupation.¹⁴⁸ In 2000, Tennessee ranked 45th nationally in the percent of its population over 25 with a high school diploma and 40th nationally in the percent with a college degree.¹⁴⁹

Tennessee’s population is also less healthy than the nation as a whole. In one survey, fewer than two-thirds of Tennesseans exercised in the prior month. (See Exhibit 10.) In a separate survey, 18.5 percent of Tennesseans reported their own health as fair or poor. (See Exhibit 11.) These factors likely increase Tennessee’s rate of prescription drug use.

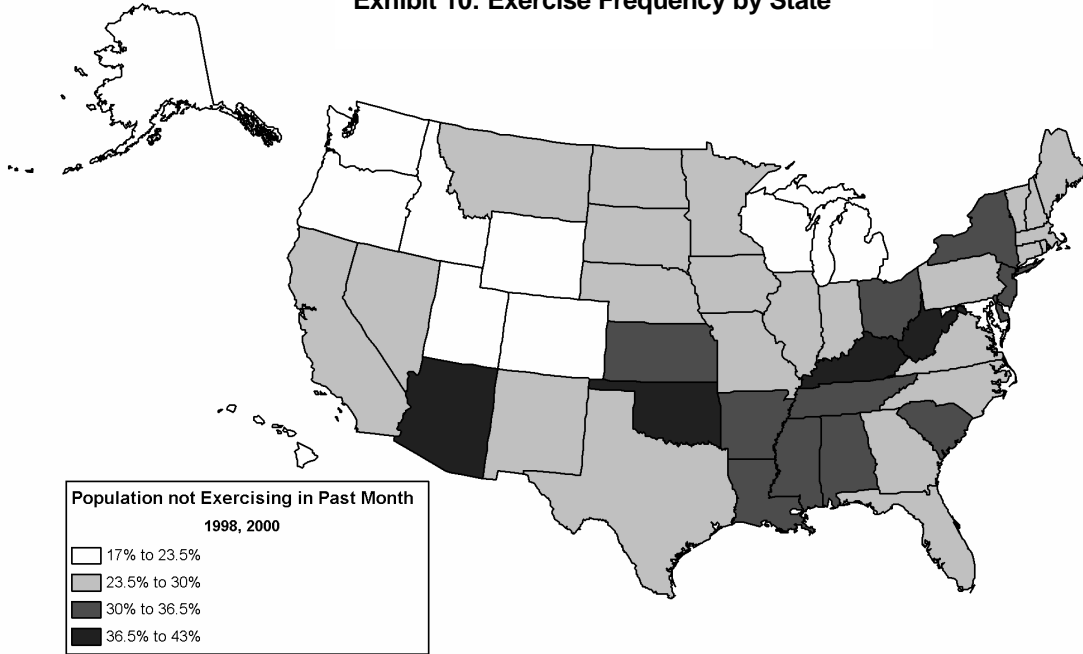
¹⁴⁶ Office of Research analysis of U.S. Census Bureau data.

¹⁴⁷ Office of Research analysis of utilization and educational attainment data.

¹⁴⁸ Nancy Adler and Katherine Newman, “Socioeconomic Disparities in Health: Pathways and Policies,” *Health Affairs*, March/April 2002, p. 62.

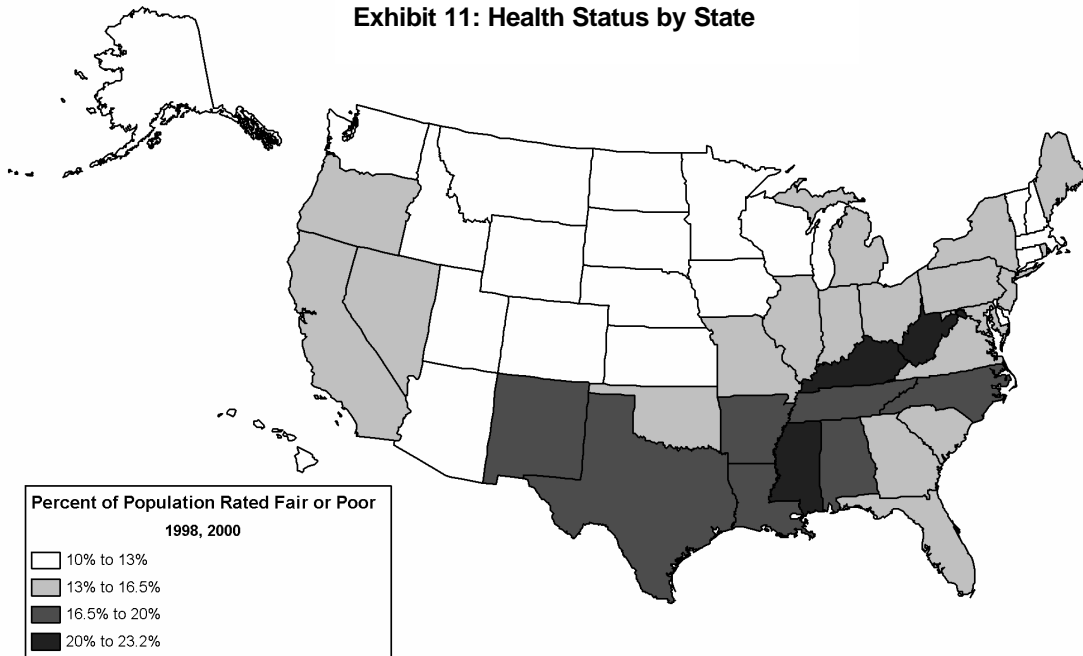
¹⁴⁹ National Center for Education Statistics, *Digest of Education Statistics 2001*, Chapter 1, Table 11, “Educational attainment of persons 18 years old and over, by state: 1990 to 2000,” April 2001, <http://nces.ed.gov/pubs2002/digest2001/tables/dt011.asp> (accessed August 5, 2002).

Exhibit 10: Exercise Frequency by State



Source: Centers for Disease Control, National Center for Health Statistics

Exhibit 11: Health Status by State



Source: Centers for Disease Control, National Center for Health Statistics

Tennessee's high rate of insurance appears to increase prescription drug utilization.

In 2000, 90 percent of Tennesseans had some kind of insurance compared to a national average of 86 percent.¹⁵⁰ Because out-of-pocket drug costs are lower for those with insurance, they are more likely to purchase prescription drugs. Third-party payers, usually private insurance and TennCare, accounted for 83.8 percent of pharmacy spending in Tennessee in 2001, the highest level in the nation. The national average was 73.8 percent.¹⁵¹

Several studies suggest that Tennessee's doctors may overprescribe certain drug classes. The above factors, taken as a whole, drive Tennessee's rate of prescription drug use above the national rate. However, they do not fully account for per-capita prescriptions almost 50 percent higher than the national average. This discrepancy suggests that Tennessee's doctors may overprescribe some drugs. For example, Tennessee has the highest rate of penicillin use in the nation.¹⁵² In 1997, the Centers for Disease Control and Prevention examined bacterial resistance to penicillin in eight states. The study found that 38.3 percent of *Streptococcus pneumoniae*¹⁵³ strains in Tennessee were not susceptible to penicillin, the highest rate of resistance in the studied group. In contrast, only 15.3 percent of strains were nonsusceptible in Maryland, the lowest level of resistance.¹⁵⁴ This likely indicates Tennessee physicians have overprescribed penicillin in past years, and drug-resistant bacterial strains have developed as a result.

Novartis data show that Tennessee also led the nation in spending for calcium channel blockers in 2001, a drug class frequently used to treat high blood pressure and congestive heart failure.¹⁵⁵ Research on the effectiveness of these drugs has produced mixed results, and several studies have concluded that the risks from these drugs outweigh their potential benefits.¹⁵⁶ Express Scripts, a nationwide pharmacy benefit manager, found that Southern states including Tennessee have higher prescription rates for analgesic painkillers than the nation as a whole.¹⁵⁷ According to the U.S. Drug Enforcement Administration, "The diversion and abuse of pharmaceuticals, especially OxyContin,

¹⁵⁰ The Kaiser Family Foundation, "State Health Facts Online: Population Distribution by Insurance Status, 1999-2000," <http://statehealthfacts.kff.org/cgi-bin/healthfacts.cgi?action=compare&category=Health+Coverage+%26+Uninsured&subcategory=Insurance+Status&topic=Distribution+by+Insurance+Status>, (accessed April 23, 2002).

¹⁵¹ Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed., p.19.

¹⁵² Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed., "State Facts at a Glance."

¹⁵³ *Streptococcus pneumoniae* is the most common cause of meningitis, bacterial pneumonia, and ear infections.

¹⁵⁴ L Gelling, et. al. "Geographic Variation in Penicillin Resistance in *Streptococcus pneumoniae*—Selected Sites, United States, 1997," *Morbidity and Mortality Weekly Report*, August 6, 1999, Table 1.

¹⁵⁵ Novartis *Pharmacy Benefit Report: Facts and Figures*, 2002 ed., "State Facts at a Glance."

¹⁵⁶ Steven Dosh, "The Treatment of Adults with Essential Hypertension," *The Journal of Family Practice*, January 2002, p. 74-80; Lori Dickerson and Peter Carek, "Are New Antihypertensive Agents Better than Old Hypertensive Agents in Preventing Cardiovascular Complications?" *The Journal of Family Practice*, January 2002, p. 9; Jo Leonardi-Bee, et. al. "Blood Pressure and Clinical Outcomes in the International Stroke Trial," *Stroke*, May 2002, p. 1315-1320.

¹⁵⁷ Brenda Motheral, et. al. *Prescription Drug Atlas*, Express Scripts, 2002.

represents a significant threat to Tennessee.”¹⁵⁸ Numerous interviewees have commented that Tennessee citizens use more pain-killers than the rest of the nation. While there are legitimate reasons why Tennessee might have higher use rates for these drug classes, utilization rates that lead the nation warrant further investigation.

State Pharmacy Purchases in Tennessee

State governments are among the largest purchasers of prescription drugs, and rapid cost increases in recent years have strained state budgets. Prescription drug costs impact state budgets in three general areas: Medicaid programs, state employee health plans, and direct institutional purchases for use in state facilities such as prisons and state health centers. Medicaid is the largest segment by far. In fiscal year 2002, TennCare pharmacy costs after rebates were approximately \$1.16 billion.¹⁵⁹ Tennessee’s Federal Financial Participation (FFP) percentage that year was 63.64 percent,¹⁶⁰ leaving approximately \$422 million in pharmacy costs with the state. Taking into account pharmaceutical rebates, the state health insurance plans paid approximately \$89 million in pharmacy claims in fiscal year 2002.¹⁶¹ Tennessee state agencies make most institutional purchases through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP). The state spent almost \$12 million through MMCAP in calendar year 2001. The Department of Children’s Services and the Department of Correction purchase prescription drugs through an outside contractor. These costs appear to be just below \$4 million annually, though firm data are unavailable because of the capitated payment structure.¹⁶² Finally, the state incurs indirect costs through BEP funding for local education health insurance premiums. State BEP funding of prescription drug costs in local education plans was an estimated \$34 million in fiscal year 2002.¹⁶³

¹⁵⁸ U.S. Drug Enforcement Administration, “DEA Briefs and Background, Drugs and Drug Abuse, State Factsheets, Tennessee,” <http://www.usdoj.gov/dea/pubs/states/tennessee.html> (accessed June 25, 2002).

¹⁵⁹ Memo from Martin Staehlin, Price Waterhouse Coopers, June 25, 2002.

¹⁶⁰ Federal Funds Information for States, “2003 FMAPs: A Trail of Broken Premises,” Issue Brief 01-53, September 25, 2001, Table 2.

¹⁶¹ Office of Research estimate based on Division of Insurance Administration paid claims data and pharmacy rebate data.

¹⁶² Office of Research estimate based on department interviews.

¹⁶³ Office of Research estimate derived from Tennessee Department of Finance and Administration, Division of Insurance Administration, *2001 State Group Insurance Program Annual Program and Financial Report*, p. 25 and the Department of Education 2001-2002 BEP model.

Exhibit 12: Tennessee Prescription Drug Spending in Fiscal Year 2002

Program	Amount
TennCare	Approximately \$422,000,000*
State Employee Health Plans	Approximately \$89,000,000*
Wholesale Purchases for Agency Use	Approximately \$16,000,000
BEP Funding of Local Education Plans	Approximately \$34,005,624

* Totals do not include copayments paid by plan members. Totals also do not include rebates paid to the state by pharmaceutical manufacturers.

Institutional Purchases

Tennessee lacks a comprehensive approach to wholesale pharmacy purchases.

Institutional providers of prescription drugs usually lack the buying power to negotiate lower prices and the resources and expertise to engage in such negotiations. In 1985, the Minnesota Department of Administration created the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) to address this problem.¹⁶⁴ The group pools the purchasing power of over 2,900 government facilities in 40 states to establish contracts with pharmaceutical manufacturers and other vendors. Its annual pharmaceutical sales volume is \$600 million.¹⁶⁵

Tennessee's Department of General Services joined MMCAP in 1999. The department estimated savings of over \$1.3 million (11.6 percent) in the first year of participation for the 179 most frequently used drugs.¹⁶⁶ Most Tennessee agencies receive their non-retail prescription drug purchases through MMCAP.

In February 2001, however, the Department of Correction contracted with Correctional Medical Services (CMS) to provide a range of medical services, including prescription medications. Prior to this time the department had participated in MMCAP, but had struggled to retain licensed pharmacists and pharmacy technicians. CMS contract costs are 8.8 percent lower than projected costs had the department retained control of medical services. This represents a savings of almost \$12 million over the five-year contract.¹⁶⁷ The contract includes incentives to manage prescription drug utilization, but because it is based on a capitated rate, the department does not maintain data that would indicate how pharmacy costs have changed.¹⁶⁸ The Department of Children's Services does not

¹⁶⁴ Samantha Ventimiglia, "Pharmaceutical Purchasing Pools," National Governors Association for Best Practices," October 24, 2001, p. 4.

¹⁶⁵ Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), <http://www.mmd.admin.state.mn.us/mmcapii.htm> (accessed July 17, 2002).

¹⁶⁶ Phil Campbell, Purchasing Agency Supervisor, memo to George Street, Director of Purchasing, Tennessee Department of General Services, Purchasing Division, October 9, 2000.

¹⁶⁷ Ray Register, Tennessee Department of Correction, Director of Contracts Administration, "Cost Comparison—Health Services Proposal 329.00-001."

¹⁶⁸ Correspondence from Ray Register, Director of Contract Administration, Tennessee Department of Correction, July 26, 2002; telephone interview with Fred Hix, Assistant Commissioner for Administration, Tennessee Department of Correction, July 25, 2002.

maintain a pharmacist on staff to distribute prescription drugs, and contracts with the Department of Correction to provide these services under the CMS contract.¹⁶⁹

Many county jails do not purchase prescription drugs in a cost-effective manner.

County jails purchase prescription drugs in a variety of ways. Some contract with private firms for all health care expenses, including pharmaceuticals. Others purchase drugs from private firms that provide only prescription medications. Still others purchase drugs through local pharmacies. Many county jails have no doctor or nurse on site and must transfer inmates to local emergency rooms to receive prescriptions. Though a few county jails have formularies in place to control costs, those that obtain prescriptions through emergency rooms often have difficulty gaining physician compliance with the formulary. Finally, because county jails purchase drugs individually, they are unable to use their collective purchasing power to negotiate discounts from pharmacy service providers or pharmaceutical companies.¹⁷⁰

According to a study completed in 1998 by a Sub-committee of TennCare Partners Roundtable, almost 19 percent of county jail inmates in Tennessee have a mental illness diagnosis.¹⁷¹ Due to the high cost of mental illness medications, some county jails are not able to provide the most effective treatment for this population. Ineffective treatment can increase hospital utilization at an even higher cost to the state.¹⁷²

Tennessee State Employee Health Insurance Plans

The Department of Finance and Administration contracts with private insurance companies to administer three state insurance options: preferred provider option (PPO), point of service (POS), and health maintenance organization (HMO). Each of the options is self-insured, meaning the state bears the responsibility for costs incurred by plan enrollees. However, all have risk features that reward contractors who keep costs below target levels and penalize contractors when costs rise above target levels.¹⁷³ The State Insurance Committee is responsible for overseeing these plans.¹⁷⁴ Employees pay 20 percent of PPO plan premiums, and the state pays the remaining 80 percent. In 2002, employee premium shares were 17.5 percent for state POS plans and between 16 and 16.5 percent for state HMO plans. These shares will increase to 20 percent by 2005.¹⁷⁵ Exhibit 13 compares employer premium shares in Tennessee to national averages.

¹⁶⁹ Correspondence from Phil Campbell, Department of General Services, Purchasing Supervisor, August 1, 2002.

¹⁷⁰ Telephone interview with Terry Hazard, University of Tennessee, County Technical Assistance Service, Criminal Justice Consultant, October 7, 2002.

¹⁷¹ *A Survey of County Jails in Tennessee*, The TennCare Partners Roundtable, October 1998, p. 5.

¹⁷² Correspondence from Liz Ledbetter, Department of Mental Health, Criminal Justice Mental Health Liaison, October 10, 2002.

¹⁷³ Interview with Richard Chapman, Department of Finance and Administration, Director of Insurance Administration, July 22, 2002.

¹⁷⁴ TCA §8-27-102.

¹⁷⁵ Richard Chapman, Department of Finance and Administration, Director of Insurance Administration, memorandum to members of the State, Local Education, and Local Government Insurance Committees, Agenda Item 2.c, August 7, 2002.

Exhibit 13: Employer Premium Shares

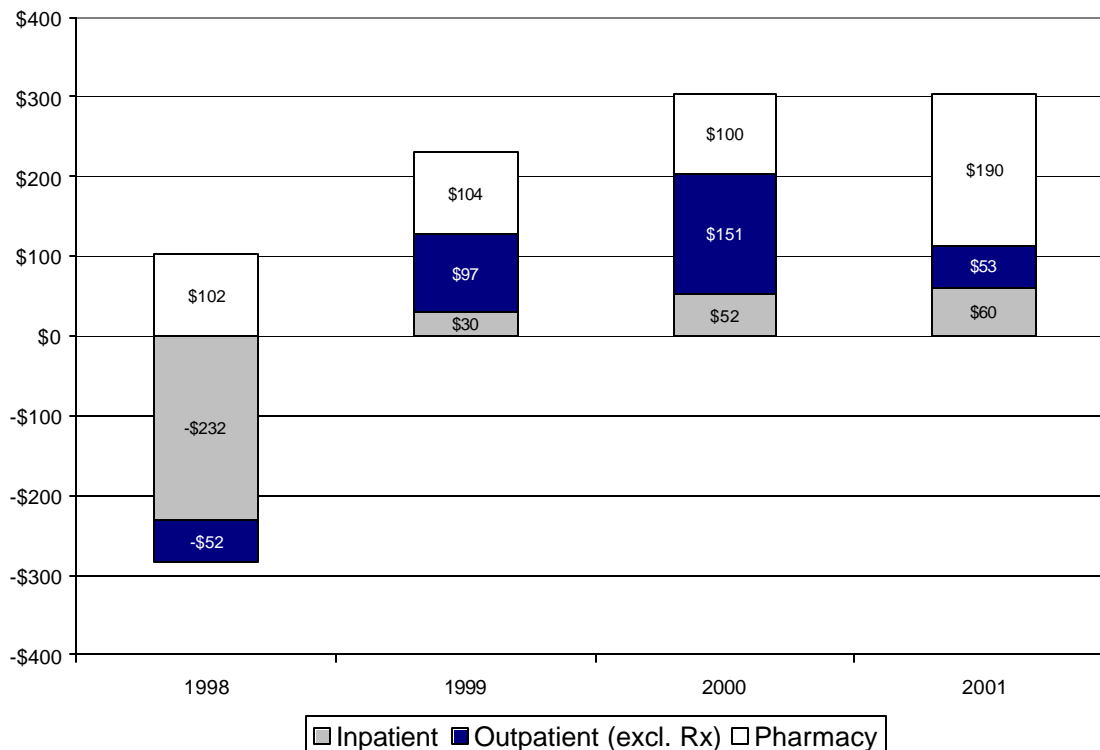
Health Plan	HMO		POS		PPO	
	Single	Family	Single	Family	Single	Family
Tennessee State Employees	84	84	82.5	82.5	80	80
National State/Local Govt.	89	84	93	75	91	74
National—All Industries	83	74	83	72	85	72

Source: Kaiser Family Foundation, *Employer Health Benefits 2002 Annual Survey*, p. 88.

Plan Cost Increases

Prescription drug costs have been the fastest growing component of state health plan costs in recent years. From 1997 to 2001, total per-capita costs in the state PPO plan grew from \$2,386 to \$3,431, an increase of 44 percent. During that time, pharmacy costs per-capita for the PPO plan grew from \$218 to \$712, an increase of 326 percent. The POS and HMO plans also experienced high rates pharmacy cost growth. Exhibit 14 shows the net change in per-capita costs for the PPO plan broken down by category. Pharmacy cost growth equaled over 75 percent of the net change in plan costs from 1997 to 2001.

Exhibit 14: Net Per-Capita Change in PPO Plan Costs from 1997 to 2001



Premium Increases and Adverse Selection

Premiums for state employee plans have risen significantly in recent years, increasing the risk of adverse selection. Rising plan costs have resulted in rising premiums. On August 9, 2002, the State Insurance Committee, after considering a

proposal that included premium increases and several changes to the benefits structure of all three options, approved premium increases for 2003 with no change in the benefits structure. Exhibit 15 shows premium increases for the years 2001, 2002, and 2003. Over these three years, premiums for state plans grew between 59 percent and 80 percent.

Exhibit 15: State Insurance Plans Premium Growth

Health Plan	2000	2001	2002	2003	4-Year Compound
Tennessee State PPO	0%	15%	25%	25%	80%
<i>PPO National Average</i>	9%	12%	13%		
Tennessee State POS	0%	15%	26%	16%	68%
<i>POS National Average</i>	8%	9%	12%		
Tennessee State HMOs					
Aetna-Nashville	0%	14%	32%	12%	69%
Aetna-Memphis	0%	13%	28%	10%	59%
Blue Cross/Blue Shield	0%	13%	27%	N/A*	N/A*
John Deere Health	0%	15%	32%	15%	75%
<i>HMO National Average</i>	8%	11%	13%		

*Blue Cross/Blue Shield will discontinue its HMO plan for West Tennessee at the end of 2002.

Source: Kaiser Family Foundation, *Employer Health Benefits: 2002 Annual Survey*, p. 14.

Adverse selection occurs when healthier members of an insurance pool choose to drop their coverage because they feel the coverage is not cost effective for them. As infrequent utilizers of services leave health plans, the average cost per enrollee increases, and premiums rise for those who remain.¹⁷⁶ In 2001, Milliman and Robertson, an actuarial consultant for the health insurance industry, forecasted increases in the health cost index of just over eight percent. Increases in this measurement represent medical inflation. The group also projected increases in costs to employers and insurance carriers of 10 percent or more. Adverse selection was responsible for the difference between the two estimates.¹⁷⁷

It is unclear to what extent adverse selection is occurring in the state employee health plans. The Division of Insurance Administration has not encountered any evidence that adverse selection is a significant problem, but long-term trends in insurance take-up rates, which the division lacks, would provide the only clear evidence. Approximately 40 percent of enrollees in state employee health plans use no services in those plans during a given year.¹⁷⁸ Because such a large percentage of plan members use no services, if premiums continue to increase at current rates, adverse selection could emerge in the future.

¹⁷⁶ Mark Pauly and Sean Nicholson, "Adverse Consequences of Adverse Selection," *Journal of Health Politics, Policy, and Law*, October 1999.

¹⁷⁷ John Cookson, "Outlook for Health Care Trends," Council on Health Care Economics and Policy, January 11, 2001, Current Issues.

¹⁷⁸ Richard Chapman, Department of Finance and Administration, Director of Insurance Administration, testimony before the State Insurance Committee, August 9, 2002.

Cost Sharing

Tennessee state employee health plans contain less extensive cost sharing provisions than those found in surrounding states. Per capita pharmacy costs in the state PPO plan grew from \$74.21 in 1994 to \$384.92 in 1999. In response to these rapidly rising costs, the State Insurance Committee implemented an incentive formulary with a three-tier copayment¹⁷⁹ structure for the plan and removed pharmacy copayments from the out-of-pocket limits and deductibles, setting a separate out-of-pocket limit for pharmacy costs.¹⁸⁰ State HMO and POS plans have a closed formulary with two-tier copayments¹⁷⁹ and no out-of-pocket limits.

Exhibit 16 shows copayments under Tennessee state employee plans in 2002. These copayment levels will remain in place for 2003. The percentage of workers nationwide under three-tier copayment plans grew from 36 percent in 2001 to 57 percent in 2002.¹⁸¹ Many interviewees believe that number will be significantly higher in 2003. Because pharmacy costs have risen rapidly in recent years but copayment levels have remained relatively stable for state employee plans, the portion of drug payments borne by employees has decreased and the portion borne by the plans has increased. (See Exhibits 17 and 18.) Interviewees have commented that copayments in Tennessee state employee plans are well below those found in commercial practice. Copayment levels for state employee plans in surrounding states are generally higher. Appendix C lists copayments for state employee plans in Tennessee's border states.

Exhibit 16: Insurance Plans Copayment Levels

2002/2003 State Employee Plans			
Tier	HMO	POS	PPO
First	\$5.00	\$5.00	\$5.00
Second	\$15.00	\$15.00	\$15.00
Third	N/A	N/A	\$25.00

¹⁷⁹ Two-tier copayment structures charge a lower copay for generic drugs than for brand products. In a closed formulary, a patient's physician must submit a prior authorization request to the insurance company for that patient to receive a brand product not on the preferred drug list. Under three-tier incentive formularies, the lowest copayment is for generic drugs, the middle copayment is for brand products on a preferred drug list, and the highest copayment is for nonpreferred brand drugs. Virtually all brand products are available without prior authorization. See page 22 for more information on tiered copayments.

¹⁸⁰ Richard Chapman, Department of Finance and Administration, Director of Insurance Administration, memorandum to members of the State, Local Education, and Local Government Insurance Committees, March 21, 2001.

¹⁸¹ Kaiser Family Foundation, *Employer Health Benefits: 2002 Annual Survey*, p. 120.

Exhibit 17: State POS Plan Per-Capita Drug Payments

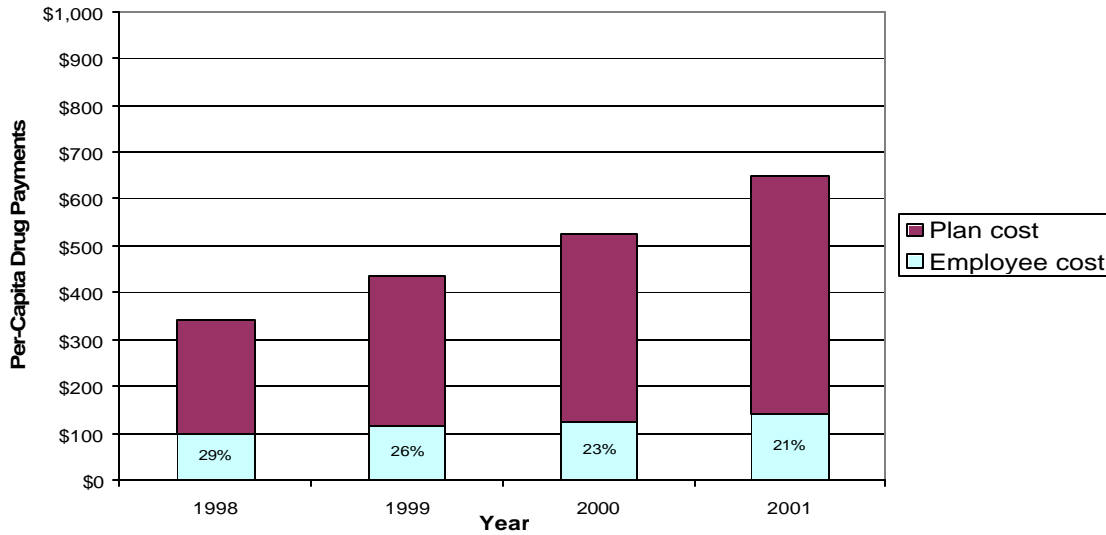
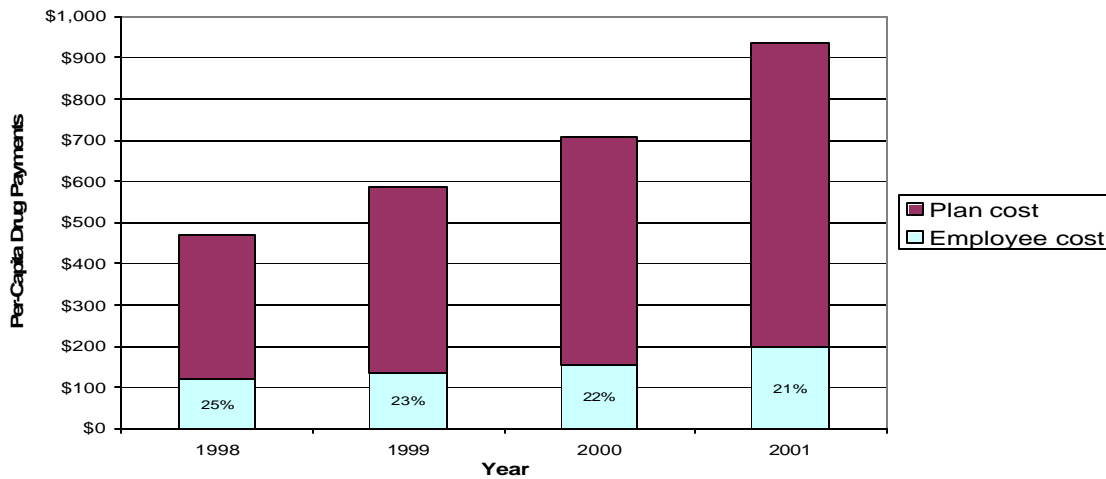


Exhibit 18: State PPO Plan Per-Capita Drug Payments



Utilization Differences

State employee health plan members use some classes of prescription drugs more frequently than members of commercial groups. State employee plan contract partners have noticed differences between utilization patterns for the state employee health plans and their commercial populations. For example, members of the Blue Cross/Blue Shield state employee plans more frequently use services for rheumatoid arthritis than do members of Blue Cross/Blue Shield’s commercial population. The average cost of

rheumatoid arthritis treatments for state employee plan members is also higher.¹⁸² In John Deere Health's experience, commercial populations covered by the State of Tennessee employee health benefit plan tend to exhibit somewhat higher rates of hydrocodone (a highly prescribed pain killer) utilization than most other John Deere Health commercial populations.¹⁸³ It is unclear if these utilization differences are due to demographic differences in patient populations. If not, the state may need to develop strategies to address them.

Disease Management

The Division of Insurance Administration has added many disease management programs to state employee plans in recent years, but the state lacks a focused strategy for the development of these programs. Disease management programs are “a system of coordinated healthcare interventions and communications for populations with conditions in which patient self-care efforts are significant.”¹⁸⁴ These programs exist for high-cost disease states like congestive heart failure (CHF) and asthma. They generally include strategies to promote healthy lifestyles such as proper diet, appropriate use of medication, and maintenance of a healthy home environment.

The Division of Insurance Administration has added disease management programs to most state employee health options in recent years. The RFP for current POS and HMO contracts required those options to offer disease management services. Each contract partner (Blue Cross/Blue Shield, Aetna, or John Deere Health Care) contracts with a separate disease management company to provide DM services. The Division of Insurance Administration will evaluate any potential DM programs added to existing plan options based on:

- The ability to incorporate the program within the existing insurance plan contract;
- Operational elements of the program;
- Prevalence and cost of the disease under focus;
- Gross savings produced by the program;
- The return on investment (ROI) for at least three years; and
- Fees for the program.¹⁸⁵

Appendix D lists disease management programs included in state employee health options for calendar year 2003.

The RFP for the state PPO plan did not require disease management services, and the PPO option, which contains half of all plan members, does not include any DM

¹⁸² Interview with Terry Shea, Blue Cross/Blue Shield of Tennessee, Director of Pharmacy Management, July 9, 2002.

¹⁸³ Telephone interview with Jim Utt and Bill Strozyk, John Deere Health, Regional Pharmacy Managers, May 23, 2002.

¹⁸⁴ Disease Management Association of America, “Definition of DM,” <http://www.dmaa.org/definition.html> (accessed August 15, 2002).

¹⁸⁵ Correspondence from John Anderson, Department of Finance and Administration, Assistant Director of Insurance Administration, October 15, 2002.

programs. The state lacks a focused strategy for the development of disease management programs based on the state's identification of its needs and performance criteria to measure progress toward meeting those needs. (See pages 23-25 for more information on disease management programs.)

Pharmacy Cost-Containment in Other States

Generic Substitution Laws

Tennessee's generic substitution law promotes the use of generic medications less aggressively than other states' laws. Generic substitution, the filling of a prescription with a generic form of a brand drug, is common commercial practice throughout the U.S. However, the practice is not universal. A University of Texas analysis of that state's Medicaid data found that seven percent of all prescriptions were for multi-source brand products, brand drugs that had generic alternatives.¹⁸⁶ Researchers projected the state could save \$257 million, 2.3 percent of total drug spending, in 2001 if those scripts were filled with generic drugs.¹⁸⁷

Tennessee allows pharmacists to substitute "A-rated" (chemically equivalent) generic drugs for brand products.¹⁸⁸ Tennessee state law requires prescription pads to have two lines for prescribing physician signatures, one if the physician wishes to allow the pharmacist to substitute a generic drug for the prescribed drug and another if the physician wants the patient to receive the brand-name product.¹⁸⁹ Exhibit 16 shows generic substitution laws in other states, both whether states use one-line or two-line script pads and whether states mandate that pharmacists substitute generic products or simply permit them to do so. Twelve states require two-line prescription pads, and four others permit them. Thirty-nine states allow generic substitutions if the doctor does not request a brand drug either by signing on a "dispense as written" side of a two-line pad or by a written request for the brand product on the script. Ten states require the pharmacist to substitute a generic in the absence of a physician brand request. Thirty-six states require patient consent for pharmacists to substitute generics for brand products. Oklahoma does not allow generic substitution.¹⁹⁰

¹⁸⁶ Michael Johnsrud, *Estimating the Economic Impact of Increasing Generic Substitution of Multi-Source Brand Name Prescription Products in Texas*, The University of Texas at Austin, The Center for Pharmacoeconomic Studies, May 2001, p. 3.

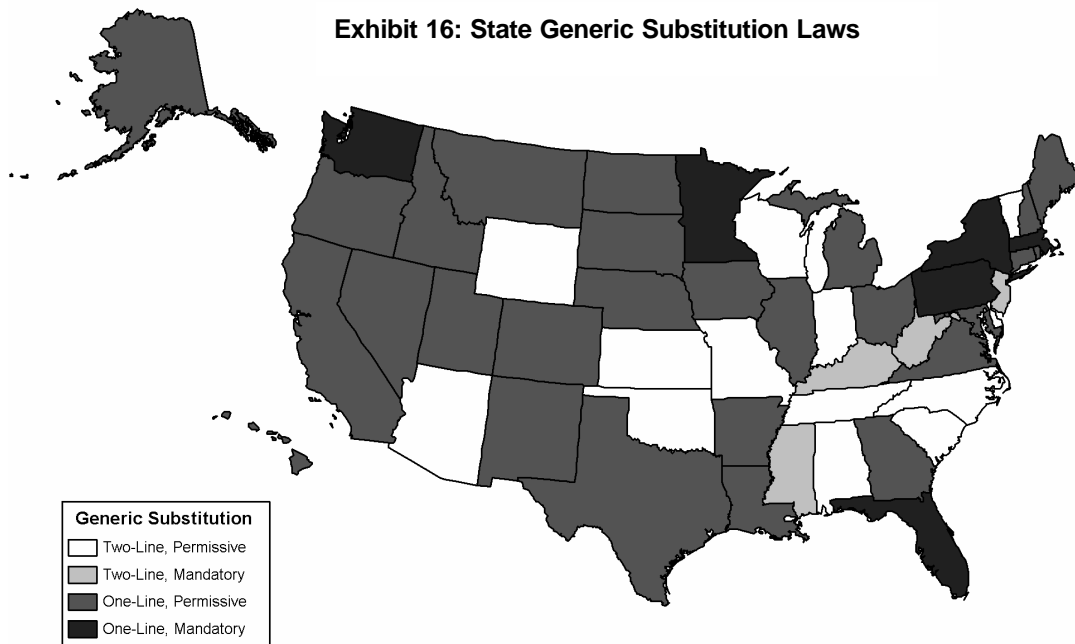
¹⁸⁷ University of Texas, Office of Public Affairs, "New Texas Generic Drug Law Could Save Patients Millions, Researchers at the University of Texas at Austin Say," June 28, 2002.

¹⁸⁸ TCA §53-10-204. Drugs approved by the FDA through a New Drug Application (NDA) are known as reference products. Generic manufacturers must submit an Abbreviated New Drug Application (ANDA) that shows their product is chemically equivalent to a reference product. Many brand drugs brought to market are actually different formulations from reference products, approved through an ANDA in the same way as generics. Drugs approved through an ANDA receive an A Rating.

¹⁸⁹ TCA §53-10-203(a).

¹⁹⁰ National Association of Boards of Pharmacy, *2001-2002 Survey of Pharmacy Law*, pp. 51-53.

Exhibit 16: State Generic Substitution Laws



*Oklahoma does not allow generic substitution. Kansas, Kentucky, North Carolina, and Utah permit but do not require two-line prescription pads.

Source: National Association of Boards of Pharmacy, *2001-2002 Survey of Pharmacy Law*, pp. 51-53.

Though Tennessee state law requires two-line script pads, pharmacies routinely receive one-line scripts. State law does not include any consequences for using one-line pads. Pharmacists have the legal authority to substitute a generic medication for a brand drug if they receive a script not in compliance with the law “unless the physician indicates ‘dispense as written.’”¹⁹¹ However, some one-line pads require physicians to check a box to allow substitution. In these cases, “dispense as written” is the default prescription unless the doctor indicates otherwise. Many pharmacists are reluctant to substitute equivalent generic medications when they receive such scripts.

Even if all script pads complied with state law, research has shown two-line prescription pads may encourage physicians to sign requesting brand drugs without intending to prevent generic substitution. Florida is one of 33 states that use one-line script pads and require physicians to write “brand necessary” or a similar message on the script to prevent generic substitution. A 2001 University of Florida study estimated moving to a two-line pad would significantly decrease the number of generics dispensed increasing the cost of drugs in the state by up to \$550 million a year, about 6.5 percent of total retail prescription drug spending.¹⁹² Texas had a two-line prescription system similar to Tennessee’s in place, but the state legislature passed legislation in 2001 replacing that

¹⁹¹ TCA §53-10-203(b).

¹⁹² David Denslow, “The Two-Line Prescription Pad: Economic Impact on Florida’s Health Payers,” working paper, April 28, 2001.

system to promote the use of generics. Now physicians must write “brand necessary” or “brand medically necessary.” If they do not, pharmacists, with patients’ permission, may substitute generic equivalents.¹⁹³

Some interviewees expressed concern that requiring physicians to write “dispense as written” or a similar message on prescriptions to prevent generic substitution would increase the “hassle factor” for physicians. Others indicated such a move could produce marginal or significant savings depending on how routinely physicians currently sign scripts on the “dispense as written” line without necessarily wanting to prevent generic substitution.

Discount Programs for Special Populations

Many states have created discount prescription drug plans for low-income individuals. As drug costs in the private market have escalated, many states have passed legislation designed to make prescription drugs more affordable for citizens, particularly the elderly and low-income groups. Most programs leverage federal funds through a Medicaid waiver and/or obtain lower prices through negotiated manufacturer rebates or legislatively-mandated discounts.¹⁹⁴ Wisconsin and Illinois have created state-funded prescription drug plans for senior citizens below 240 and 250 percent of the federal poverty level. Both states have applied for Medicaid waivers to draw down federal dollars to support the program, and the Center for Medicare and Medicaid Services (CMS) has approved Illinois’s waiver.¹⁹⁵ Populations in these programs are similar to TennCare’s “dual eligible” population in that state provide prescription drug benefits to them by using manufacturer rebates and federal funding in conjunction with state funding.

Maine’s Healthy Maine Prescriptions program allows residents with income up to 300 percent of poverty to purchase drugs at Medicaid prices, a discount of about 25 percent. In June 2001, the U.S. Court of Appeals struck down a similar program in Vermont, ruling that rebates from Medicaid best-price provisions are designed to accrue to federal and state governments, not to purchasers of prescription drugs. As a shield against a similar ruling, Maine subsidizes the program with about \$20 million state funds a year. PhRMA has filed suit, and the case is currently pending at the Court of Appeals level. In May, the court refused a request to halt the program until a decision is rendered.¹⁹⁶

¹⁹³ University of Texas, Office of Public Affairs, “New Texas Generic Drug Law Could Save Patients Millions, Researchers at the University of Texas at Austin Say,” June 28, 2002.

¹⁹⁴ National Conference of State Legislatures, “2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” May 9, 2002, <http://www.ncsl.org/programs/health/drugdisc01.htm> (accessed May 13, 2002); and National Conference of State Legislatures, “2002 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” May 9, 2002, <http://www.ncsl.org/programs/health/drugdisc02.htm> (accessed May 13, 2002);

¹⁹⁵ Richard Cauchi and Donna Folkemer, “Medicaid Prescription Drug Laws and Strategies, 2001-2002,” National Conference of State Legislatures, May 16, 2002, <http://www.ncsl.org/programs/health/medicaidrx.htm> (accessed May 17, 2002).

¹⁹⁶ Bart Jansen, “Federal Official Gives Maine Rx a Boost,” *Portland Press Herald*, June 1, 2002.

Maryland, New Hampshire, South Carolina, and Vermont have applied for federal waivers to create similar programs.¹⁹⁷

Open Discount Programs

Maine and Hawaii have created, but not implemented, prescription drug discount programs that would be open to all state citizens. In addition to its Healthy Maine Prescriptions program, Maine has also crafted another program open to all state residents. Public Chapter 786 of 2000 instituted many reforms in the prescription drug market, including creation of the Maine Rx program. Participants will receive discounts negotiated by the state Department of Human Services (DHS). If manufacturers choose not to offer large rebates to the Maine Rx program, DHS can choose to require prior authorization for their drugs in the state Medicaid program.¹⁹⁸ The law also authorizes the Commissioner of Human Services to establish maximum retail prices beginning in July 2003 if prices under the Maine Rx program are not “reasonably comparable to the lowest prices paid in the state.” In August and September of 2000 Smith-Kline Beecham, Bristol-Myers Squibb, and Astra-Zeneca announced they were pulling out of the Maine market as a response to Chapter 786.¹⁹⁹ PhRMA has filed suit against the state, and the U.S. District Court initially halted the program. Subsequently, the U.S. Circuit Court of Appeals overturned that ruling, but left the injunction in place pending action from the U.S. Supreme Court.²⁰⁰ In June, the Supreme Court agreed to hear the case, *Pharmaceutical Research v. Concannon*, later this year.²⁰¹ Many states have considered similar programs, and Hawaii’s governor signed Act 76 in May 2002, establishing a Hawaii Rx program similar to Maine’s program.²⁰²

Controlled Substance Monitoring Programs

Tennessee has begun development of a controlled substance monitoring program to decrease abuse of prescription drugs. As of May 2002, 15 states had controlled substance monitoring programs designed to control the illegal diversion of prescription drugs. These programs collect, review, and analyze prescription drug data from pharmacies and provide data and analyses to state law enforcement and regulatory agencies to assist in identifying and investigating illegal activities.²⁰³ The programs significantly reduce investigation time required for drug diversion cases. Kentucky saw investigation time for “doctor shoppers” decrease from 156 days to 16 days after the

¹⁹⁷ National Conference of State Legislatures, “Prescription Drug Laws in Maine,” April 18, 2002, <http://www.ncsl.org/programs/health/pharm-me.htm> (accessed May 17, 2002).

¹⁹⁸ Philip Lebowitz, “Pricing Pressures States Take Action,” *Pharmaceutical Executive*, March 2002, p. 77.

¹⁹⁹ National Conference of State Legislatures, “Prescription Drug Laws in Maine,” April 18, 2002, <http://www.ncsl.org/programs/health/pharm-me.htm> (accessed May 17, 2002).

²⁰⁰ Bart Jansen, “Federal Official Gives Maine Rx a Boost,” *Portland Press Herald*, June 1, 2002.

²⁰¹ Edward Walsh, “Court Agrees to Review State Regulation of Drug Pricing, HMOs,” *The Washington Post*, June 29, 2002, p. A08.

²⁰² National Conference of State Legislatures, “2002 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” August 23, 2002, <http://www.ncsl.org/programs/health/drugdisc02.htm> (accessed September 10, 2002).

²⁰³ U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, May 2002, GAO-02-634, p. 2.

implementation of its monitoring program; Nevada investigation times fell from 120 days to 20 days.²⁰⁴ Monitoring programs also appear to reduce the availability of abused drugs by allowing physicians to review prescription drug histories of their patients and alerting them to potential abusers.²⁰⁵

In June 2002, the General Assembly passed Public Chapter 840, the Controlled Substance Monitoring Act of 2002. The act directs the Department of Commerce and Insurance to create a controlled substance database. The database will include information on all prescriptions for schedule II, III, and IV controlled substances in Tennessee. The act also created a committee comprised of members of the state's health professions licensure boards to develop rules for the program.²⁰⁶ After rules are established, the department will issue an RFP for database services, award a contract, and begin to collect data for committee review. Department officials expect this process to take 18 to 24 months. Once complete, the database will provide information to department regulatory boards, which will then use it as the basis for interventions targeting individual patients and providers.²⁰⁷

Appropriate Antibiotic Use Campaigns

Thirty-three states, including Tennessee, are conducting campaigns to reduce the inappropriate use of antibiotics. Antibiotics are the primary method of treating many bacterial infections. Unfortunately, repeated use of antibiotics contributes to the rise of strains of bacteria that are resistant to the drugs. Multiple interviewees have noted that the United States in general and Tennessee in particular have a culture that encourages overuse of prescription drugs, especially antibiotics. Parents take their children to the doctor's office for minor conditions and often request antibiotics even though antibiotics are useless in treating viral infections. Many states have initiated programs designed to curtail the inappropriate use of antibiotics and thus slow the rise of resistant strains of bacteria. The Centers for Disease Control (CDC) sponsors programs in 19 states. Health Departments in 14 other states have appropriate use programs as well.²⁰⁸

In 2001, Tennessee had the highest per-capita use of penicillins and cephalosporins, two common groups of antibiotics, in the nation.²⁰⁹ A 1997 CDC study found Tennessee had the highest rate of penicillin resistance among eight studied states,²¹⁰ and in 2001 more than half of bacterial infections in Knox County could not be cured with penicillin.²¹¹ The

²⁰⁴ U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, May 2002, GAO-02-634, p. 15.

²⁰⁵ U.S. General Accounting Office, *Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion*, May 2002, GAO-02-634, pp. 15-16.

²⁰⁶ Tennessee Public Acts 2002, Public Chapter 840.

²⁰⁷ Interview with Kendall Lynch, Department of Commerce and Insurance, Director of the Tennessee Board of Pharmacy, July 30, 2002.

²⁰⁸ U.S. Centers for Disease Control and Prevention, "Appropriate Antibiotic Use Partners," June 11, 2002, <http://www.cdc.gov/drugresistance/community/partners.htm#suppcdc> (accessed August 15, 2002).

²⁰⁹ Novartis, *Pharmacy Benefit Report: Facts and Figures*, 2002 ed., "State Facts at a Glance."

²¹⁰ L. Gelling, et. al. "Geographic Variation in Penicillin Resistance in *Streptococcus pneumoniae*—Selected Sites, United States, 1997," *Morbidity and Mortality Weekly Report*, August 6, 1999, Table 1.

²¹¹ Active Bacterial Core Surveillance, Brenda Barnes, Project Manager, Vanderbilt University.

Knox County Health Department has taken steps to curtail the overuse of antibiotics. In 1997 the Knox County Health Department created the East Tennessee Drug Resistance Task Force, a coalition of public and private health organizations. From May 1997 to April 1998, the group conducted an educational campaign targeting health care providers, parents of young children, and the general public. The campaign resulted in an 11 percent drop in antibiotic prescription rates in Knox County.²¹²

Relying primarily on CDC funding, the Tennessee Department of Health is conducting a Tennessee Appropriate Antibiotic Use Campaign for the years 2002 and 2003. The department has created coalitions in Davidson and Knox Counties to develop methods of educating practitioners and parents of young children on appropriate antibiotic use. The coalitions include representatives from childcare centers, physician groups, TennCare MCOs, and other groups heavily involved in the use of antibiotics. In October, department staff will conduct seminars at daycares that outline appropriate practices regarding the use of antibiotics. They will also provide educational materials to physicians. The department is conducting a survey to gain information on people's knowledge, attitudes, and beliefs regarding antibiotic use.

Next year, the department plans to expand the effort statewide. It will provide materials to local health departments, who will oversee local efforts such as seminars in day care centers. The department also plans to air public service announcements crafted by the CDC to promote appropriate use of antibiotics. Department staff intend to analyze survey data and prescription utilization data to determine the effectiveness of these efforts.²¹³

Patient Safety Campaigns

The Department of Health has begun collecting detailed data on patient safety incidents in Tennessee health facilities and is coordinating efforts to promote patient safety. The 1999 Institute of Medicine report *To Err is Human: Building a Safer Health System* drew national attention to the problem of adverse events in hospitals. Extrapolating from earlier work, the report's authors estimated preventable inpatient medication errors cause about \$2 billion in hospital expenses each year.²¹⁴ A recent study of 36 health care facilities in Atlanta and Denver found administrative errors²¹⁵ for 10 percent of prescribed medications. A physician advisory panel for the study concluded 10 percent of these errors could result in patient discomfort or jeopardize the patient's health and safety.²¹⁶

The Department of Health is coordinating Tennessee Increasing Patient Safety (TIPS), a broad coalition dedicated to developing a statewide strategy for improving Tennessee's

²¹² Joseph Perz, et. al., "Changes in Antibiotic Prescribing for Children after a Community-wide Campaign," *JAMA*, June 19, 2002, pp. 3104, 3106.

²¹³ Interview with Katie Garman, Tennessee Department of Health, Appropriate Antibiotic Use Campaign Coordinator, August 15, 2002.

²¹⁴ Linda Kohn, Janet Corrigan, and Molla Donaldson, eds., *To Err is Human: Building a Safer Health System*, Washington, DC: National Academy Press, 2000, p. 2.

²¹⁵ Drug omitted, wrong dose given, or unauthorized drug given.

²¹⁶ Kenneth Barker, et. al., "Medication Errors Observed in 36 Health Care Facilities," *Archives of Internal Medicine*, September 9, 2002, pp. 1897-1903.

healthcare delivery system focusing on ways to reduce adverse events, including medication errors, in health facilities such as hospitals and nursing homes. The coalition, which began in July 2001, includes representatives from numerous health boards and associations, the TennCare Bureau and MCOs, consumers and corporate purchasers of health care services, state legislators, and state universities. On March 1, 2002, TIPS adopted a set of best practices to promote patient safety. The Board of Medical Examiners, Board of Nursing, Board of Pharmacy, Osteopathic Board, and the Board of Licensing Health Care Facilities have since adopted these standards as well. The department is collecting data on patient safety incidents for a report to the General Assembly in 2003.²¹⁷

Gift Disclosure Laws

Vermont now requires pharmaceutical companies to report to the state many gifts made to health care practitioners. In recent years, a number of state legislatures have debated measures designed to curtail excesses in product promotion. In June, Vermont became the first state to enact a gift disclosure law. The law requires pharmaceutical companies to disclose gifts worth over \$25 made to doctors, hospitals, pharmacists, and nursing homes. The state attorney general will annually publish a list of gifts greater than \$25 on the Internet. The law includes free travel or honoraria for speaking fees but does not include scholarships or free samples.²¹⁸ The state pharmacy board and attorney general's office will absorb expenses associated with the program. Language requiring drug representatives to pay fees to cover the costs was included in the original legislation but was removed from the final version. Representatives of the pharmaceutical industry argue that the guidelines will have very little impact given new voluntary industry guidelines that went into effect July 1, 2002.²¹⁹

Litigation

Many states, including Tennessee, may receive significant payments through litigation against pharmaceutical companies. In 2001, federal prosecutors won an \$885 million settlement from TAP Pharmaceutical products. The suit centered on TAP's failure to incorporate certain free samples of its prostate cancer drug Lupron when calculating average wholesale price (AWP) and "best price" for Medicaid programs.²²⁰ More than 35 states are exploring the possibility of collective suits against pharmaceutical manufacturers that they hope would mirror the success of the \$208 billion tobacco settlement. One avenue would, like the Lupron suit, focus on pricing structures that may have resulted in overcharges to state Medicaid programs. A ruling on these charges

²¹⁷ Interview with Judy Eads, Tennessee Department of Health, Assistant Commissioner for Bureau of Licensure and Regulation, August 22, 2002.

²¹⁸ Marc Kaufman, "Vermont Requires Firms to Report Gifts to Doctors," *The Washington Post*, June 14, 2002, p. A02; Laura Johannes, "Vermont to Require Drug Companies to Disclose Gifts," *Wall Street Journal*, June 14, 2002, p. B2.

²¹⁹ Andis Robeznieks, "Vermont Watches Drug Marketing Costs," *American Medical News*, July 1, 2002, pp. 9,12.

²²⁰ Charles Prouty, "State, Federal Fraud Probes Target Drug Firms' Sales Tactics, Pricing," *The Boston Globe*, August 8, 2002.

would have no direct impact on the broader drug market. However, states are also considering mounting suits against drug manufacturers they feel are unfairly extending patents on major drugs and preventing generic competition. Last December, 29 states sued Bristol Myers Squibb, alleging the company lied to federal regulators to protect the patent for its antianxiety drug Buspar.²²¹ Suits such as this could have major implications for the broader pharmaceutical market. The AARP has announced its intention to join these suits to promote generic availability.²²²

In January, the TennCare Bureau received \$102,488 as the result of the settlement against TAP Pharmaceutical Products. Several multistate suits are pending against pharmaceutical companies revolving around prices charged to state Medicaid programs and barriers to generic competition. Though Tennessee is not a named plaintiff in any of these suits, the attorney general's office may intervene at a later date. Furthermore, even if the state does not enter the suit, the defendants may choose to enter into a settlement with the state.²²³

Patent Law Reform Efforts

Eleven governors have taken an active role in encouraging Congress to revise patent laws covering prescription drugs. Some states have concluded that pharmaceutical companies legally exploit provisions of the Hatch-Waxman Act to stifle competition from generic drugs. A number of major companies have joined with state governors to create Business for Affordable Medicine (BAM), a coalition dedicated to eliminating what they believe are legal loopholes that allow drug companies to extend their patents unfairly.²²⁴ BAM seeks to change five features of federal law:

- Brand-name manufacturers can sue generic manufacturers for patent infringement. The FDA must withhold approval for the generic for up to 30 months while the case is litigated. Brand-name companies do not pay damages if their suits fail. Critics charge many of these lawsuits have no merit and are simply designed to forestall generic competition.
- The FDA's "Orange Book" lists all patents for FDA-approved drugs, and drugs with patents in the Orange Book are shielded from competition. Companies can submit "add-on" patents for products already listed in the Orange Book after development of generic competitors has begun, delaying the date those competitors can go to market.
- The first generic competitor to market receives 180 days of market exclusivity. That is, for six months, it faces no competition from other generic products. Brand-name manufacturers can file patent infringement suits against the initial generic manufacturer and then enter a settlement in which the brand-name

²²¹ Andrew Caffrey, Scott Hensley, and Russell Gold, "Drug Raids: States Go to Court in Bid to Rein in Price of Medicine," *Wall Street Journal*, May 21, 2002, p. A1.

²²² Robert Pear, "AARP Wants Bigger Role in Prescription Drug Cases," *The New York Times*, April 23, 2002.

²²³ Telephone interview with Michael Bassham, Tennessee Office of the Attorney General, Assistant Attorney General, July 25, 2002.

²²⁴ Thomas Burton, "Pushing Pills: Reining in Drug Advertising," *Wall Street Journal*, March 13, 2002, p. B1.

manufacturer essentially pays the generic manufacturer not to bring its product to market.

- Citizens may petition the FDA to review data concerning a new product's safety or efficacy prior to granting final approval. Brand manufacturers can file these petitions, delaying generic market dates.
- Current law does not allow generic versions of "biologic" pharmaceuticals. Unlike traditional drugs produced through chemical processes, biologics are made from living cells, blood factors, or genetically engineered proteins. When patents for these drugs expire, they do not face competition from generics.²²⁵

Governors of 11 states have joined the BAM coalition, and Governor Jeanne Shaheen of New Hampshire and Governor William Janklow of South Dakota have both testified before Congress advocating revisions to the Hatch-Waxman Act.²²⁶

State Pharmacy Purchases Cost Containment

States have three general areas of prescription drug costs: retail purchases through Medicaid programs, retail purchases through state employee health plans, and wholesale purchases for use by prisons, hospitals, and other state institutions. Many states have begun to explore ways to use market share to negotiate deeper discounts from pharmacies, pharmacy benefit managers, and especially prescription drug manufacturers. These efforts generally involve pooling buying power among different state programs within states, pooling buying power in similar programs across different states, or both. Most of these efforts are relatively new, and it is still too early to tell which approaches are most effective.

Institutional Purchases

Multistate cooperatives use various methods to lower non-retail prescription drug costs. The Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) pools the purchasing power of over 2,900 government facilities in 40 states to establish contracts with pharmaceutical manufacturers and other vendors. Its annual pharmaceutical sales volume is \$600 million.²²⁷ Most Tennessee agencies participate in MMCAP. Massachusetts and California participate in a similar program, the Massachusetts Alliance for State Pharmaceutical Buying (MASPB). Instead of using a competitive bidding process for drug purchases like MMCAP, MASPb uses a private pharmaceutical group purchasing organization to establish acquisition prices, allowing the program to respond more quickly to market shifts. This organization also provides data management tools and assists participating states in constructing a formulary that can further reduce costs.²²⁸ Both groups claim to offer meaningful savings over the other group.²²⁹

²²⁵ Business for Affordable Medicine, "Hatch/Waxman Reform Legislation," <http://www.bamcoalition.org/HWRReform.htm> (accessed May 1, 2002).

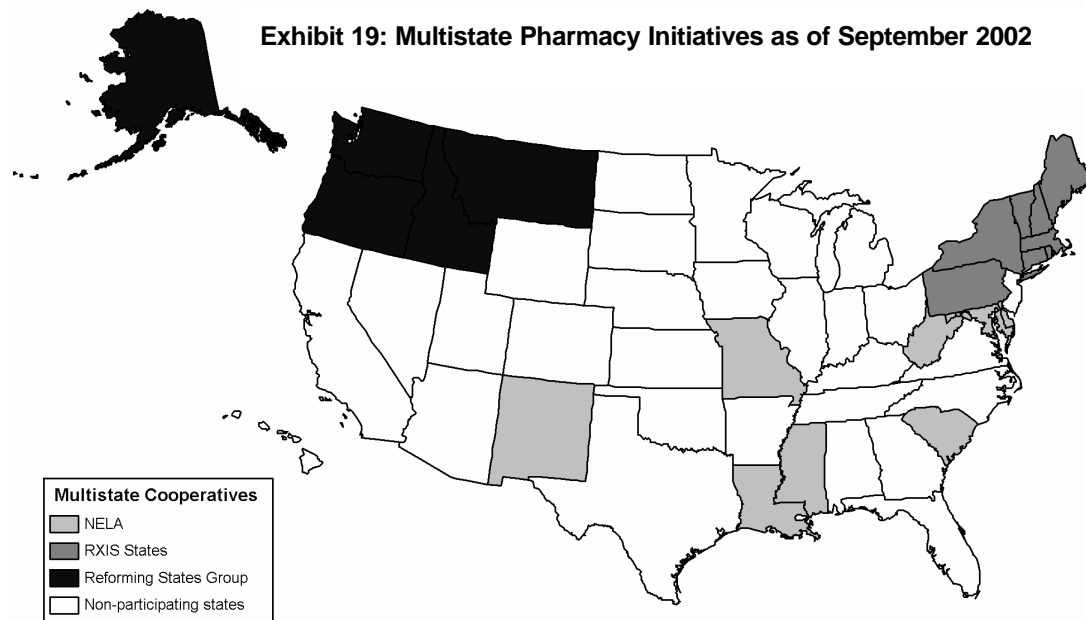
²²⁶ Business for Affordable Medicine, <http://www.bamcoalition.org/> (accessed June 21, 2002).

²²⁷ Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), <http://www.mmd.admin.state.mn.us/mmcapii.htm> (accessed July 17, 2002).

²²⁸ "MASPB Facts," The Commonwealth of Massachusetts Pharmaceutical Purchasing Program.

State Employee Health Plans

Tennessee is not among the 21 states participating in multistate initiatives to lower pharmacy costs for state employee plans. Many states are attempting to create cooperatives that combine the buying power of multiple states to leverage lower prices from pharmacy benefit managers and pharmaceutical companies. Exhibit 19 shows states participating in multistate cooperatives as of September 2002. Other states are formally or informally considering joining such groups. In March, the Alabama General Assembly passed legislation authorizing the state to participate in such consortiums. Iowa's General Assembly passed legislation creating a working group to study the feasibility of such programs.²³⁰



In 2001, eight northeastern states created the Northeast Legislative Association on Prescription Drug Prices (NELA) to study how collective action might reduce drug costs in state Medicaid programs and state employee health plans. The group has since renamed itself the National Legislative Association on Prescription Drug Prices and invites participation from any interested state. Earlier this year Vermont passed model legislation proposed by the group, and NELA directors, which include legislators from participating states, have requested a report on commonalities among state formularies to

²²⁹ "MASPB Facts," The Commonwealth of Massachusetts Pharmaceutical Purchasing Program; "Comparison of Prices/Costs between Massachusetts Alliance for State Pharmaceutical Buying (MASPB) and Minnesota Multistate Contracting Alliance for Pharmacy," Minnesota Multistate Contracting Alliance for Pharmacy, January 4, 2002.

²³⁰ National Conference of State Legislatures, "2002 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation," July 10, 2002, <http://www.ncsl.org/programs/health/drugdisc02.htm> (accessed July 17, 2002).

better understand the feasibility of creating a common formulary.²³¹ In October, the group announced a plan to create a nonprofit PBM. In tandem with this initiative, the group seeks to make it more convenient to import drugs from Canada at lower prices.²³²

Another multistate effort is the Pharmacy Working Group. Twenty-two states participated in group meetings which began in March 2001.²³³ Eight states, referred to as the RXIS states, participated in a pharmacy benefit manager (PBM) bid earlier this year. The West Virginia Public Employees Insurance Agency (PEIA) issued an RFP on behalf of the group. In March, PEIA announced that Express Scripts won the bid.²³⁴ Participating states may remain with existing vendors or switch to Express Scripts. PEIA expects to save \$7 million in fiscal year 2003 from savings in its pharmacy network and PBM contract.²³⁵ As of July 30, West Virginia, Missouri, and New Mexico had joined. All other RXIS states and two other states have indicated an interest in joining the group.²³⁶ The group hopes to craft a multistate preferred drug list and negotiate rebates with pharmaceutical companies. State officials believe this offers an opportunity for even greater savings than those realized in PBM and pharmacy network contracts.²³⁷

A third group, the Reforming States Group, has also begun to explore “the option of managing prescription drug prices through cooperative strategies with other Northwest states.” However, the group has not taken any formal collective actions.²³⁸ Tennessee has not joined any of these three groups. It is unclear whether participation in a multistate effort could produce savings for the state. The state uses three different contracting partners (Blue Cross, John Deere, and Aetna) to provide health benefits to state plan members. The bargaining leverage achieved by partnering with other states may or may not exceed the bargaining leverage achieved by combining with commercial participants in plans administered by those partners.

Combined Approaches

Consolidating all state pharmacy purchases to maximize bargaining power could produce savings but presents significant logistical challenges. Several states have

²³¹ Correspondence from Cheryl Rivers, National Legislative Association on Prescription Drug Prices, Executive Director, September 5, 2002.

²³² *Associated Press State and Local Wire*, “Prescription Association Trying to Set up Own Manager,” October 22, 2002; Karen Pallarito, “State Lawmakers’ Group Proposes Nonprofit PBM,” *Reuters Health Information* 2002, October 22, 2002.

²³³ National Conference of State Legislatures, “2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” June 27, 2002, <http://www.ncsl.org/programs/health/drugdisc01.htm> (accessed July 17, 2002).

²³⁴ *PEIA News*, “Express Scripts is New PBM,” Vol. 3, No. 5, May 2002, p. 1.

²³⁵ Telephone interview with Tom Susman, Director of West Virginia Public Employees Insurance Agency, July 11, 2002.

²³⁶ Correspondence from Tom Susman, Director of West Virginia Public Employees Insurance Agency, July 30, 2002.

²³⁷ Telephone interview with Tom Susman, Director of West Virginia Public Employees Insurance Agency, July 11, 2002.

²³⁸ National Conference of State Legislatures, “2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation,” June 27, 2002, <http://www.ncsl.org/programs/health/drugdisc01.htm> (accessed July 17, 2002).

examined the possibility of combining various pharmacy programs into a single bid, leveraging their buying power to negotiate lower prices for prescription drugs. Massachusetts has examined combining pharmacy benefits for its Medicaid and state employee plans. Federal “best price” provisions for Medicaid programs²³⁹ complicate such arrangements, and the initiative has stalled. The Massachusetts Division of Medical Assistance is attempting to craft a proposal to achieve savings by combining the programs without forfeiting federally mandated discounts for its Medicaid program.²⁴⁰

Texas has examined bulk purchasing to lower pharmacy costs for various state entities, but several factors have undermined this effort. Payments to pharmacies comprise 90 percent of state agencies’ pharmacy costs. A few agencies qualify for public health pricing, steeply discounted prices mandated by the federal government. As a result, the Texas Interagency Council on Pharmaceuticals Bulk Purchasing has adopted a set of guiding principles to govern agency behavior rather than implementing statewide bulk purchasing.²⁴¹

Georgia addressed logistical problems of consolidating health purchases by creating an entirely new state department, the Department of Community Health (DCH). The governor facilitated this process, making the creation of the agency an administration priority. The department oversees all state health programs including Medicaid/PeachCare, state employee health plans, rural health, and women’s health. DCH officials feel it has produced savings by placing contracting, budgeting, finance, and other aspects of health programs under one roof. Georgia also has a single statewide preferred drug list and contracts with a pharmacy benefit manager (PBM) to administer prescription drug programs for these groups and the state Board of Regents.²⁴²

²³⁹ 42 USC 1396r-8(c) requires pharmaceutical companies to give Medicaid programs their “best price” available in the private sector and most public purchases. This does not include prices paid by the Department of Veterans Affairs, state homes, the Public Health Service, or certain types of public clinics; prices charged under the Federal Supply Schedule; prices used by state pharmaceutical assistance programs; and depot prices and single award contract prices. As a result of best price provisions, of two similar drugs, one might be cheaper for Medicaid programs and another for state employee health plans.

²⁴⁰ Telephone interview with Jennifer Rubino, Fiscal Policy Analyst, Massachusetts Office of Finance and Administration, May 30, 2002.

²⁴¹ Correspondence from Bob Harris, Texas Health and Human Services Commission, August 3, 2002.

²⁴² Telephone interview with Lori Garner, Pharmacy Director, Georgia Department of Community Health, May 29, 2002.

Recommendations

Legislative Recommendations

The General Assembly may wish to revise TCA §53-10-203 to promote the use of lower-cost generic medications when possible. Current state law requires prescription pads to have two lines for prescribing physician signatures, one if the physician wishes to allow the pharmacist to substitute a generic drug for the prescribed drug and another if the physician wants the patient to receive the brand-name product.²⁴³ This may create situations where physicians sign requesting brand drugs without intending to prevent generic substitution. Furthermore, because there are no legal consequences for physicians who use script pads in violation of state law, pharmacists routinely receive scripts on one-line pads. Thirty-four states allow pharmacists, with patient permission, to substitute generic medications unless prescribing physicians write a message such as “brand necessary” on the script. Though most interviewees asserted that Tennessee physicians are generally conscientious in prescribing generic drugs when appropriate, several believed this requirement could increase Tennessee’s generic drug utilization rate. University of Florida research supports this conclusion.

The General Assembly may wish to encourage the Tennessee congressional delegation to pass patent law revisions to promote the availability of generic prescription drugs. Many features of existing federal law allow brand pharmaceutical companies to delay generic competition well beyond the patent expiration dates of their products. Changes to the Hatch-Waxman Act could potentially save Tennessee consumers and the state millions of dollars each year, but those changes can only be made at the federal level. As part of this effort, the General Assembly may wish to encourage the Governor to join the Business for Affordable Medicine Coalition.

The General Assembly may wish to create an interagency committee to study state and local non-retail pharmacy purchasing practices and create a comprehensive approach to those purchases. Tennessee agencies spent approximately \$16 million in fiscal year 2002 to purchase prescription drugs directly from wholesalers and vendors other than pharmacies. The state lacks a fully coordinated approach to these purchases. Furthermore, many county jails fail to purchase prescription drugs in a cost-effective manner. A committee including representatives from affected agencies and local governments could develop a more comprehensive and efficient framework for meeting the state’s prescription drug needs. This committee would need to address the following questions:

- What prices are state and local governments paying for drugs including both initial costs and subsequent rebates?
- How are these prices affected by bundling drug coverage with other medical service? Can state agencies and local governments carve out drugs from capitated arrangements, and, if so, should they?

²⁴³ TCA §53-10-203(a).

- Are there efficiencies in the private sector not found in state and local purchases? Could state agencies and local governments achieve savings by contracting with private companies or copying some of their practices?
- What advantages do the Massachusetts Alliance for State Pharmaceutical Buying (MASPB), Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), and other interstate cooperatives present?
- How quickly do state agencies and local governments respond to market changes such as price drops when new generics enter the market?
- Could state agencies and local governments use formularies and prior authorization procedures to reduce reliance on higher cost drugs and increase rebates from manufacturers?
- Are the current levels of drug utilization review in state and local pharmacy programs appropriate?

Administrative Recommendations

State Insurance Committee Recommendations

The State Insurance Committee should consider implementing more aggressive cost-sharing provisions in the state employee pharmacy benefit. Most commercial insurance plans use significant three-tier copayments to discourage use of the most expensive prescription drugs. Tennessee's HMO and POS plans still use two-tier copayments with a closed formulary. Copayments for all three health plans are generally below those found in surrounding states. Larger three-tier copays could reduce the overall use of prescription drugs and provide an incentive for members to use less expensive medications when possible while giving plan members greater access to all products.

The State Insurance Committee should explore whether or not mail-order services for maintenance drugs can reduce costs for the Tennessee state insurance plans. In 2001, 83 percent of commercial/group plans nationwide offered prescription mail service to enrollees. Many employee health plans in other states have reduced the cost of prescriptions for both enrollees and the plans themselves through mail-order pharmacies.

The State Insurance Committee should develop a focused strategy for the development of disease management programs in state employee health plans. Research suggests well crafted disease management programs can improve health outcomes and reduce costs in treating some conditions. On the other hand, many disease management programs are expensive, and critics have charged that much of the research body supporting DM programs is flawed. Tennessee state employee insurance plans already include a number of disease management programs, though the PPO plan, which includes about half of all state plan enrollees, has no DM programs. (See Appendix D.) The state lacks a focused strategy for the development of these programs. Such a strategy, drawing on analysis of plan member needs and specific performance and outcome criteria, should serve as the basis for determining whether or not to purchase specific disease management programs.

Agency Recommendations

The Department of Finance and Administration, in conjunction with the state's contract partners, should explore making more information the effects and costs of prescription drugs available to consumers online. Tiered copayments are most effective when plan members have a clear understanding of alternative treatments available to them. Expanded online services would allow some patients to view which prescription drugs they are taking, potential side effects of those drugs, and the prices of other products in those therapeutic categories. This information could reduce adverse reactions to drugs and encourage members to pursue less expensive medications.

The Department of Finance and Administration should study the feasibility of joining a multistate consortium or pursuing a joint contract with TennCare to reduce drug costs for the state health plans. Several states have pursued initiatives to pool buying power to reduce pharmacy costs for state employee health plans. These initiatives are designed to reduce costs in three areas: pharmacy networks, pharmacy benefit manager (PBM) contracts, and prices paid to pharmaceutical companies for prescription drugs. All multistate cooperatives remain in planning stages or have been implemented only recently. While preliminary evidence suggests that these initiatives can yield significant savings, it is too early to draw any firm conclusions. Another option would be to use a single PBM and preferred drug list for state employees and Medicaid recipients as Georgia has done. Both scenarios would necessitate a carve-out of pharmacy benefits under the state plans. Further study should reveal whether or not these strategies could produce savings for Tennessee state health plans.

The Department of Finance and Administration should analyze utilization trends for specific conditions and medications within the state employee plans. Some contractors with the state health plans have noticed utilization differences for certain conditions and medications between state health plan members and the rest of their commercial populations. Further study is necessary to determine whether or not these trends reflect underlying demographic differences in the populations. Such a study could yield a better understanding of utilization differences and lay the groundwork for targeted intervention strategies to address specific problems. The department may wish to take advantage of expertise at the University of Tennessee Health Science Center to conduct this study.

The Department of Commerce and Insurance and other affiliated groups should proceed with the current development process for the state controlled substance registry. In 2002, the General Assembly passed Public Chapter 840, directing the Department of Commerce and Insurance to create a controlled substance registry. Such programs have reduced the abuse of prescription drugs in other states. A committee created by the legislation will craft rules to govern the registry. After this process is complete, the department will issue an RFP for database services, award a contract, and begin to collect data for committee review. Department officials expect this process to take 18 to 24 months.

The Department of Health should continue its efforts to curtail inappropriate use of prescription medications. The Department of Health is using federal funds to conduct an Appropriate Antibiotic Use Campaign in Davidson and Knox Counties. The department plans to expand the program statewide in 2003. This program has the potential to reduce the inappropriate use of antibiotics in Tennessee. The department should continue this campaign and, if empirical evidence shows its strategies to be successful, consider expanding its efforts to include other drug classes.

The Department of Health is also coordinating efforts of Tennessee Improving Patient Safety (TIPS), a coalition dedicated to reducing adverse incidents in Tennessee's health facilities. The department's efforts include strategies to reduce medication errors. If the department successfully addresses these problems, it should examine the feasibility of programs to analyze the extent of overuse of medications in medical institutions.

Appendix A: Organizations/Persons Interviewed

AARP

Brian McGuire, Tennessee State Office Legislative Director

Affiliated Computer Services (ACS)

Jerry Dubberly, Director of Clinical Services

Jennifer Carpenter, Clinical Services Manager

American Healthways

Peter McCann, Vice President for Development

Aventis Pharmaceuticals

Walter Gose, Senior Regional Manager, State Government Relations

Blue Cross/Blue Shield of Tennessee

Steven Coulter, Senior Vice President and Chief Medical Officer

Dan Barnett, Senior Medical Director for Medical Risk Management

Terry Shea, Director of Pharmacy Management

Robert "Ned" Giles, Regional Pharmacy Director

David Locke, Director of Government Relations

Caremark

Jon Couch, Area Vice President for National Account Sales

Joseph West, Director of Clinical Services

Jack Gierat, Director of Government Accounts

Eckerd Pharmacy

Les Jones, full-time practicing pharmacist

Bruce McKinnon, full-time practicing pharmacist

Eli Lilly and Company

Butch Benson, Account Manager

Express Scripts

Emilio Tiele, Director of Government Programs, National Employer Division

Rick Dillon, Managed Care Division Sales Director

Florida Agency for Health Care Administration

Jerry Wells, Medicaid Pharmacy Program Manager

Georgia Department of Community Health

Lori Garner, Pharmacy Director

Idaho Division of Medicaid

Gayle Gray, Graduate Research Analyst

John Deere Health

James Utt, Regional Pharmacy Manager

Bill Strozyk, Regional Pharmacy Manager

Maine Bureau of Medical Services

Jude Walsh, Director of Quality Improvement

Managed Care Pharmacy Solutions

Sonya King, Pharmacy Benefit Specialist

Massachusetts Alliance for State Pharmaceutical Buying

Brian Putnam, Procurement Manager

Massachusetts Office of Finance and Administration, Fiscal Affairs Division

Jennifer Rubino, Fiscal Policy Analyst

Memphis Managed Care

Edna Willingham, Director of Medical Management

Jamie Patterson, Vice President for Medical Management

Mark Stephens, Pharmacy Director

Mercer Human Resources Consulting

Paul Berger, Principal

Dave Hollis, Principal

Merck and Company

Glen Belemjian, National Account Executive

National Association of Boards of Pharmacy

Melissa Madagan, Professional Affairs Director

National Institute for Health Care Management

Steve Findlay, Director of Research

National Legislative Association on Prescription Drug Prices

Cheryl Rivers, Executive Director

North Carolina Department of Health and Human Services, Division of Medical Assistance

Sharman Leinwand, Pharmacy Program Manager

Office of Vermont Health Access
Ann Rugg, Managed Care Senior Administrator

OmniCare Health Plan
Bruce Triebel, Pharmacy Administrator

Schaller Anderson of Tennessee
Deidra Dorsey, Executive Director
Bob Swiekhart, Associate Medical Director
Bob Atkins, Associate Medical Director
Joseph Howard, Director of Health Program Design
Kim Seay, Director of Medical Policy
Lori Hoenig, Director of Policy & Procedures/Change Management
Omari Winbush, Director of Regulatory Affairs
Steve Miller, Pharmacy Director
Michael Colangelo, Statistician

Scrip Solutions
Recie Bomar, President
Phonzie Brown, Vice President of Sales
Daniel Colucci, Director of Sales and Marketing Operations

TennCare Bureau
Leo Sullivan, Pharmacy Director
Jeff Stockard, Associate Pharmacy Director

TennCare Centers of Excellence
Terri Jerkins, Endocrine Steering Committee and full-time practicing physician

Tennessee Citizen Action
Eric Cole, Director

Tennessee Department of Commerce and Insurance
Scott White, Deputy Commissioner
Kendall Lynch, Director of the Tennessee Board of Pharmacy

Tennessee Department of Correction
Fred Hix, Assistant Commissioner for Administration

Tennessee Department of Finance and Administration, Division of Insurance
Administration
Richard Chapman, Director
John Anderson, Assistant Director
Keith Athow, Benefit Claims Analyst

Tennessee Department of General Services
Phil Campbell, Purchasing Supervisor

Tennessee Department of Health
Judy Eads, Assistant Commissioner, Bureau of Health Licensure and Regulation
Katie Garman, Appropriate Antibiotic Use Coordinator

Tennessee Department of Mental Health
Liz Ledbetter, Criminal Justice Mental Health Liaison

Tennessee General Assembly
Rep. Gene Caldwell, retired physician and chair of TennCare Oversight
Committee
Rep. David Shepard, pharmacist
Sen. Randy McNally, pharmacist

Tennessee Health Care Campaign
Tony Garr, Executive Director

Tennessee Justice Center
Gordon Bonnyman, Managing Attorney

Tennessee Medical Association
Richard Lane, Regional Vice President and full-time practicing physician
Fred Ralston, TennCare Reform Task Force Chairman and full-time practicing
physician

Tennessee Office of the Attorney General
Michael Bassham, Assistant Attorney General

Tennessee Pharmacists Association
Baeteena Black, Executive Director
Roger Davis, Associate Executive Director

Texas Health and Human Services Commission
Bob Harriss, Member and Consultant (former manager of the Texas Medicaid
Vendor Drug Program)

University of Memphis, Fogelman College of Business and Economics
Cyril Chang, Professor of Economics

University of Tennessee, County Technical Assistance Service
Terry Hazard, Criminal Justice Consultant

University of Tennessee, Health Science Center

David Mirvis, Director of the Center for Health Services Research

Teresa Waters, Associate Director for Research of the Center for Health Services Research

Dick Gourley, College of Pharmacy, Dean

Naseem Amarshi, College of Pharmacy, Director of the Drug Information Center

Walter Fitzgerald, College of Pharmacy, Professor of Pharmacy Practice and TennDUR Project Director

James Bailey, College of Medicine, Chief of the Division of General Internal Medicine and TennDUR Medical Review Officer

U.S. Food and Drug Administration

Gordon Johnson, Office of Generic Drugs, retired Deputy Director

West Virginia Public Employees Insurance Agency

Tom Susman, Director

Xantus Healthplan of Tennessee

John Gore, Chief of the Healthplan

Wendy Macleod, Medical Director

Appendix B: Tennessee Prescription Drug Utilization Data

Per-capita spending and per-capita scripts are shown as percents of national averages. Drug classes in which Tennessee's per-capita spending is at least 40 percent above national averages are in **bold**. Drug classes in which per-capita spending leads the nation are underlined.

Drug Class	Per-Capita Spending	Per-Capita Scripts
<u>ACE Inhibitors</u>	144%	154%
Alpha-Blockers	129%	134%
Alzheimer's Dementia Agents	106%	110%
Angiotensin II Receptor Blockers	133%	140%
<u>Anticonvulsants</u>	154%	161%
<u>Antidepressants</u>	151%	164%
Antidiabetic Agents	133%	136%
<u>Antifungals - Systemic</u>	131%	163%
<u>Antihistamines</u>	143%	164%
Antimigraine Agents	120%	135%
<u>Antipsychotics</u>	161%	160%
Beta-Antagonists	106%	118%
Beta-Blockers	114%	124%
<u>Calcium Channel Blockers</u>	144%	152%
<u>Cephalosporins</u>	159%	171%
Cholesterol Reducers	129%	134%
<u>COX-2 Inhibitors</u>	145%	155%
<u>Estrogen Products</u>	162%	169%
Fluoroquinolones	138%	137%
<u>H2-Antagonists</u>	228%	232%
Leukotriene Agents	133%	140%
Macrolides	132%	131%
<u>NSAIDs</u>	152%	153%
Oral Contraceptives	123%	131%
Osteoporosis Products	104%	111%
<u>Penicillins</u>	190%	163%
<u>Proton Pump Inhibitors</u>	151%	157%
<u>Sexual Dysfunction Products</u>	156%	148%
Steroids & Others - Bronchial	119%	125%
<u>Steroids & Others - Intranasal</u>	140%	143%
Trimethoprim	136%	176%
<u>Weight Loss Products</u>	145%	164%

Source: Novartis *Pharmacy Benefit Report: Facts and Figures*, 2002 ed.

Appendix C: State Employee Health Plan Copays for Tennessee's Border States

State	Alabama—2002	Arkansas—2002	Georgia—fiscal year 2003	Kentucky—2003
Plan	PPO	All plans	PPO and Indemnity	HMO, POS, and PPO
Tier-1	\$5	\$10	\$10	\$10
Tier-2	\$15	\$25	\$20	\$15
Tier-3	\$35	\$50	20% (\$35-\$75)	\$30
				EPO
				\$25
				\$35
				\$50
State	Mississippi—2002	Missouri—2003	North Carolina—2002	Tennessee—2003
Plan	All Plans	All Plans	All Plans	HMO and POS
Tier-1	\$10	\$10	\$10	\$5
Tier-2	\$25	\$25	\$25	\$15
Tier-3	\$35	\$40	\$40	N/A
				\$25
State	Virginia—fiscal year 2003			
Plan	Cost Alliance	Key Advantage	Piedmont	Kaiser
Tier-1	\$20	\$17	\$10	\$5 or \$15*
Tier-2	N/A	N/A	\$20	N/A
Tier-3	N/A	N/A	N/A	\$15
				\$30

Based on 30-day to 34-day supplies.

For three-tier plans: Tier-1 includes generic drugs; Tier-2 includes preferred brand drugs; Tier-3 includes non-preferred brands.

*Lower copayments are for Kaiser on-site pharmacies.

Appendix D: Disease Management Programs in Tennessee State Employee Plans

Preferred Provider Option (PPO)—Blue Cross/Blue Shield: Statewide

- No offerings

Point of Service (POS)—Blue Cross/Blue Shield: West and Middle Tennessee

- Coronary Heart Disease
- Congestive Heart Failure

Point of Service (POS)—John Deere: East Tennessee

- Heart Disease
- Asthma
- Diabetes

Health Maintenance Organization (HMO)—John Deere: East Tennessee

- Asthma
- Diabetes (beginning 2003)

Health Maintenance Organization (HMO)—Aetna: Memphis and Nashville

- Diabetes
- Maternity
- Asthma
- Heart Disease
- Back Injury
- Women's Health

Appendix E: Response from the Department of Commerce and Insurance



STATE OF TENNESSEE
DEPARTMENT OF COMMERCE AND INSURANCE
500 JAMES ROBERTSON PARKWAY
NASHVILLE, TENNESSEE 37243-5065
615-741-2241

DON SUNDQUIST
GOVERNOR

ANNE B. POPE
COMMISSIONER

MEMORANDUM

TO: Ethel Detch, Director
Office of Research
Comptroller of the Treasury

FR: Anne B. Pope *Anne B. Pope*
Commissioner

DA: November 18, 2002

RE: Prescription Drug Costs in Tennessee

This memorandum is in response to your letter to me dated October 30, 2002 concerning the Comptroller's draft report, *Prescription Drug Costs in Tennessee*. The following comments are based on a regulatory perspective as the Board of Pharmacy is the primary regulator of the practice of pharmacy in this state.

Tennessee Generic Substitution Law

We agree that amendments to current Tennessee Generic Substitution Laws could create cost savings. The Board of Pharmacy could philosophically support a revision to TCA 53-10-203 related to prescription forms as well as a revision to TCA 53-10-204 which presently limits the substitution of generic drugs to those that are A rated entities by the Federal Food and Drug Administration.

Controlled Substance Monitoring Act

We concur with the conclusions and recommendations of the report related to controlled substance monitoring programs, and we are optimistic that Public Chapter 840, the Controlled Substance Monitoring Act of 2002, will provide benefits similar to those found in other states with similar programs. Rulemaking for this project is currently under way, and we are hopeful that the program will be functioning earlier than our original 18 to 24 month estimate.

Ms. Ethel Detch
November 18, 2002
Page 2

Pharmacy Benefit Managers

We concur with the report's findings that Pharmacy Benefit Managers (PBMs) have the potential to effect cost savings if designed correctly. There is some concern from the state board of pharmacy, however, that some PBM's may be engaging in the practice of pharmacy. The National Association of Boards of Pharmacy (NABP) has indicated an interest in requiring the licensure of PBM's. Georgia is actually the first state in the nation to regulate PBM's by requiring them to hold a pharmacy license. Attached for your information is an internet article related to a West Virginia lawsuit against PBM Medco Health Solutions, Inc. by which the state alleges the state's prescription drug program costs have actually increased.

Other cost Containment Mechanisms

We concur that Internet and mail order pharmacies have the potential to reduce prescription drug costs; however, there is some concern that online pharmacies could also have the potential to become a haven for the drug addicted by allowing patients to obtain controlled substances too readily. Additionally, patients do not typically receive counseling when prescriptions are purchased online. The Board of Pharmacy further notes that all online and mail order pharmacies should be licensed in this state per TCA 63-10-410. *Although we are not specifically recommending it at this time, an additional consumer safeguard related to online pharmacies would be to require such pharmacies to obtain the Verified Internet Pharmacy Practice Site (VIPPS) seal from the NABP <http://nabp.net/>.* For your information, I have attached a copy of the September 2002 NABP Newsletter with information related to both Canadian drug imports and Internet pharmacies.

Thank you for the opportunity to respond to this report. Should you have questions or comments related to the response, please do not hesitate to contact Kendall Lynch, Director of the Board of Pharmacy at 741-1300.

Attachment

cc: D. Scott White
Kendall Lynch
Richard Gurley

df

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Director

◆ Ethel Detch

Assistant Director (Research)

◆ Douglas Wright

Assistant Director (Education Accountability)

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◆ indicates staff who assisted with this project