BlueCross BlueShield of Tennessee

Rx for Pharmacy Costs in Tennessee

A White Paper Detail on Issues and Actions
to Address Double-Digit Drug Expense Increases

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Rx for Pharmacy Costs in Tennessee
White Paper Update - August, 2003

Since the *Rx for Pharmacy Costs in Tennessee* white paper was published by BlueCross BlueShield of Tennessee in 2001, there have been significant further increases in the costs related to prescription drugs:

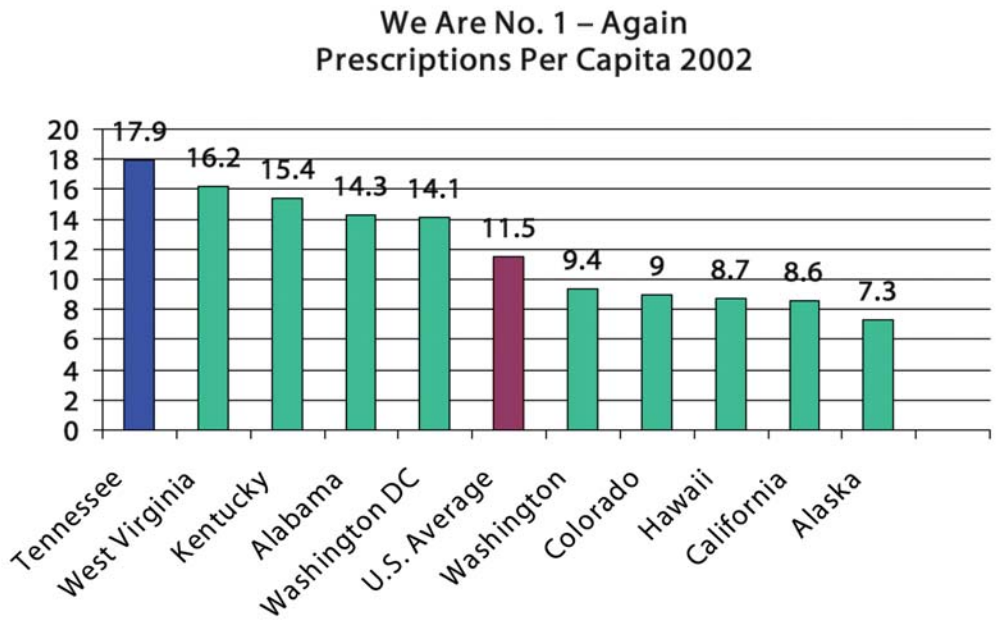
1. Direct-to-consumer advertising by pharmaceutical manufacturers has gone up by 50 percent.[1]

2. Prescription drug spending in Tennessee has more than doubled.

3. Health care costs have risen significantly; Tennesseans will spend about $34 billion on personal health care this year, about a 41 percent increase since 1999.[2]

This update describes the factors contributing to the greater increase in prescription drug spending in Tennessee.

Tennessee Still Leads the Nation in Prescriptions Per Capita



Source: Novartis

- Tennessee leads the nation again with 17.9 prescriptions for every man, woman and child in the state.[3]

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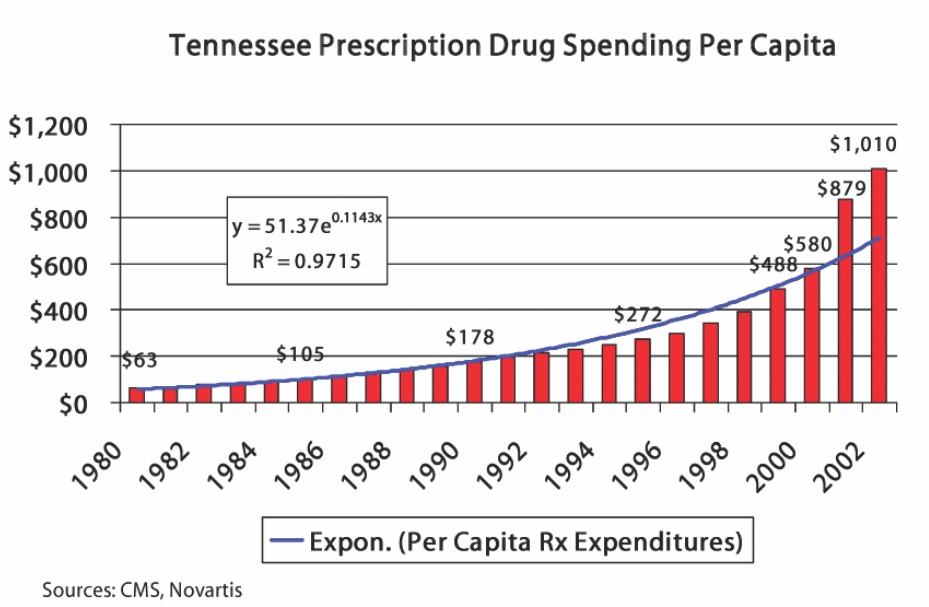
[1] *Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations*. General Accounting Office, October 2002.
[2] Internal BlueCross BlueShield of Tennessee estimate of personal health expenditures in Tennessee.
[3] *Pharmacy Benefits Report 2003*. Novartis.

- The Tennessee prescription use rate is over twice that of California and 28 percent higher than in 1999.[4]
- At 55 percent higher than the national prescription rate, the difference in prescription drug use between Tennessee and the nation is extreme.[5]

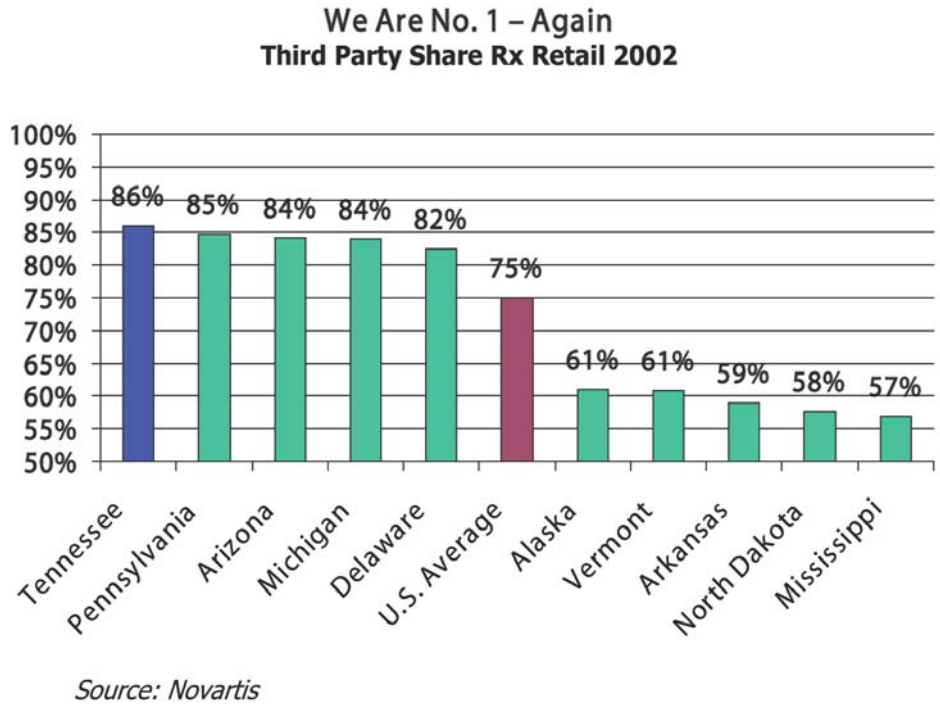
Prescription Spending in Tennessee Remains on the Rise



- Per capita drug spending in Tennessee is continuing to rise. Up to the year 2000 the increase in prescription spending in Tennessee was **only** exponential.
- Following 2000, prescription spending has taken an additional growth step that exceeds even the exponential curve, adding $300 per capita in 2001 and $131 in 2002; a 51 percent and 15 percent increase, respectively.
- The large increase for these two years is partially attributable to the Grier consent decree, an unusual modification of the benefits design for TennCare beneficiaries decreed by the District Court, M.D. of Tennessee, Nashville Division.

[4] Ibid.
[5] Ibid.

Tennessee's Third-Party Payers Continue To Bear The Highest Share

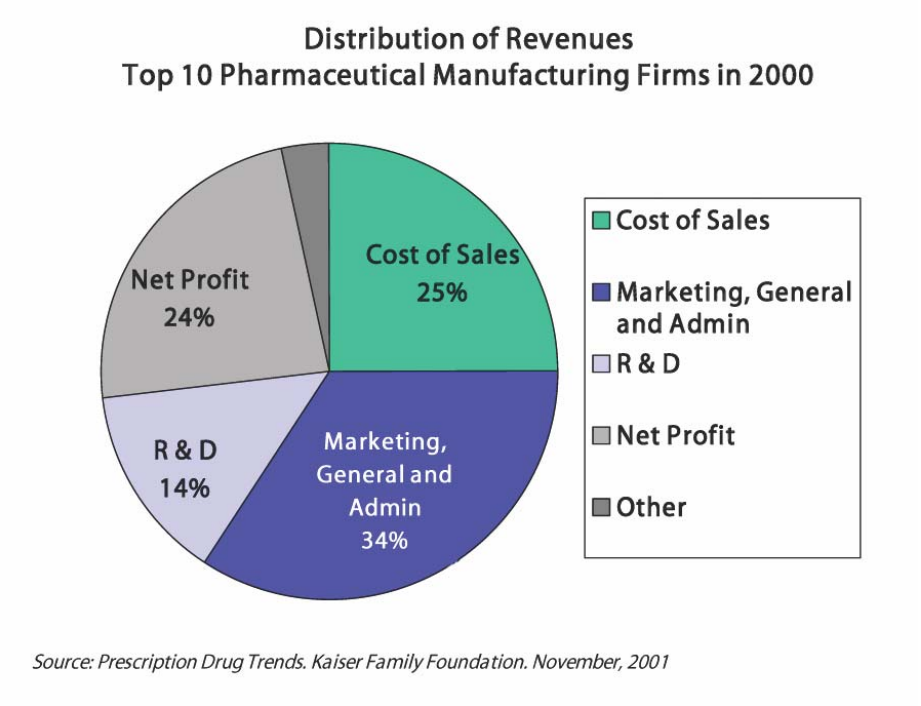


Source: Novartis

- Tennessee leads the nation in the portion of prescription costs paid for by third parties such as employers, insurers and TennCare.[6] Meaning that for a single prescription, the average consumer in Tennessee pays less than consumers in any other state. Because of this, Tennessee consumers are likely to be more susceptible to consumer prescription advertising. The high benefit levels in Tennessee are due to the effect of TennCare - commercial member cost sharing averages about 30% of total Rx cost, whereas, TennCare member cost sharing averages about 1.6% of total Rx cost.[7]
- Compared to somewhat comparable border states such as Arkansas and Mississippi, the benefit level in Tennessee is over 50 percent higher.[8]

[6] Ibid.
[7] Internal BlueCross BlueShield of Tennessee data.
[8] *Pharmacy Benefits Report 2003.* Novartis.

Pharmaceutical Firms Reap Revenue Rewards

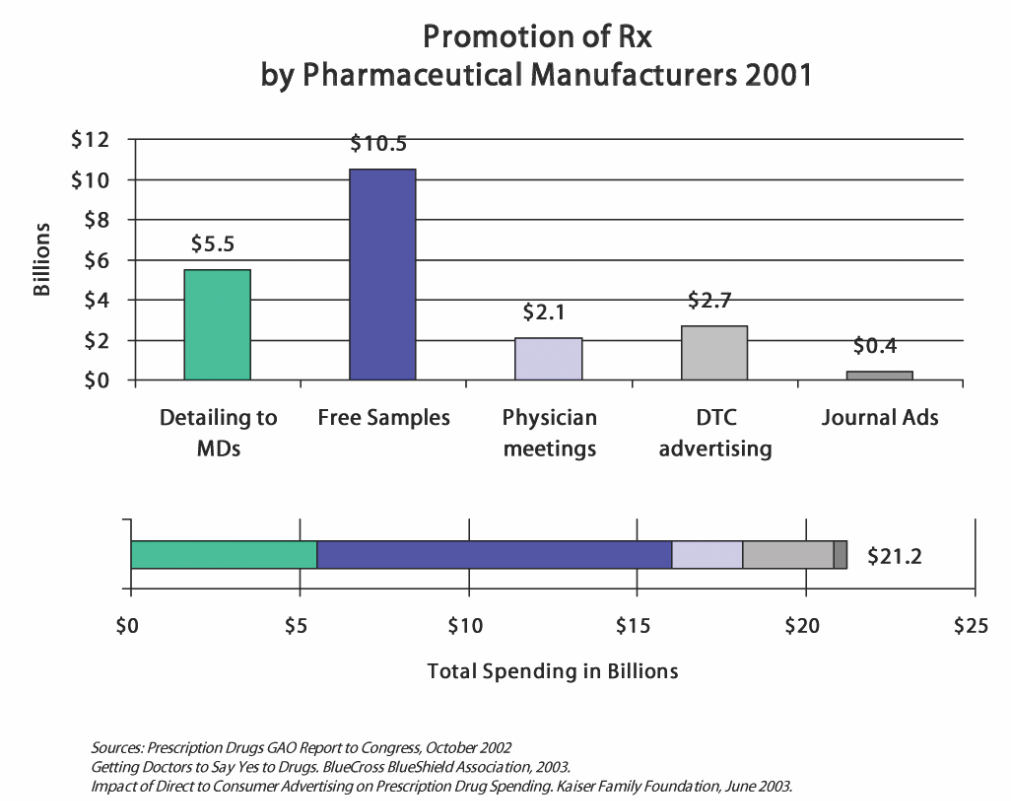


Source: Prescription Drug Trends. Kaiser Family Foundation. November, 2001

- Pharmaceutical manufacturing firms have millions of dollars to promote prescription drug use — with average, before tax, net profit levels that are nearly one-fourth of total revenue.
- Investment in marketing, general and administrative is over twice that spent on research and development.[9]

[9] *Prescription Drug Trends.* Kaiser Family Foundation. November, 2001.

Pharmaceutical Firms Spend Billions Promoting Drugs



Sources: Prescription Drugs GAO Report to Congress, October 2002
Getting Doctors to Say Yes to Drugs. BlueCross BlueShield Association, 2003.
Impact of Direct to Consumer Advertising on Prescription Drug Spending. Kaiser Family Foundation, June 2003.

- In 2001 over $21 billion was spent promoting the use of prescription drugs. Consumers pay for the drugs and pay for their promotion — nearly $75 for each U.S. citizen just for promotion.[10,11]
- Direct-to-consumer advertising spending totaled $2.7 billion in 2001, up from just $55 million in 1991.
- Most promotional spending — about $18.1 billion in 2001 — is directed at physicians.
- Consumer advertising is also effective; consumer advertising increased by $700,000,000 from 1999 to 2000 creating an additional $2.6 billion in spending.[12,13]

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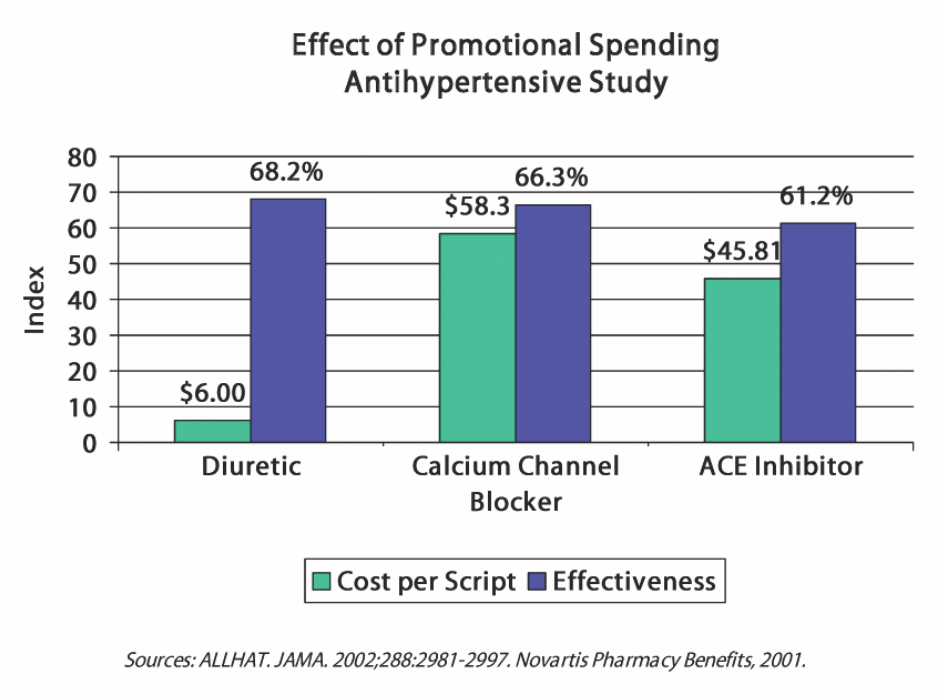
[10] See footnote 1.
[11] *Impact of Direct-to-Consumer Advertising on Prescription Drug Spending*. Kaiser Family Foundation. June, 2003.
[12] Ibid.
[13] Rosenthal, MB, and others. *Demand Effects of Recent Changes in Prescription Drug Promotion.* Frontiers in Health Policy Research, Vol. 6, edited by David M. Cutler and Alan M. Garber, MIT Press, June 2003.

Promotional Spending Has An Effect on Drug Utilization



Sources: ALLHAT. JAMA. 2002;288:2981-2997. Novartis Pharmacy Benefits, 2001.

- The ALLHAT study of antihypertensive prescription drug use showed that there is a high level of use of more costly less effective drugs to treat hypertension.[14] The high-cost drugs were heavily advertised in professional publications, while the more effective, lower-cost drugs were not as heavily advertised.
- Two high-cost, relatively less-effective drug classes were highly used: $10.3 billion was spent on calcium channel blockers and ACE inhibitors combined in 2001, both in the top 10 drugs. Diuretics, a drug at least equally effective, was not even in the top 30 drug classes by spending level.
- The effectiveness of promotional spending on the part of prescription drug companies is clearly illustrated in the ALLHAT study. Even though calcium channel blockers and ACE inhibitors are less effective when treating high blood pressure, and seven to nine times more expensive than diuretics, overall spending for them is much higher.
- Other cardiovascular drugs are also affected by promotional initiatives: For example in 2001 over 37 million prescriptions were written for angiotensin receptor blockers at an average cost of $57.14. Beta-blockers, which in many instances are used to achieve the same goals as angiotensin receptor blockers, are available in generic form at an approximate cost of $4.82 per prescription. Beta-blockers have the added advantage of being very effective at preventing repeat heart attacks.

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[14] ALLHAT. JAMA. 2002;288:2981-2997.

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Billions Are Being Spent on Prescription Drugs
And Tennessee is the Leader in Per Person Rates

The numbers alone are enough to make you reach for an aspirin bottle.

Collectively, in 1999, the United States spent $115 billion on prescription medication — the equivalent of 9.8 prescriptions per person per year, with a dollar cost equivalent of $412.48 per person. Within Tennessee, during that same time, $2.6 billion was spent on prescription medication — roughly the equivalent of 14 prescriptions per person, or $497.50 for every man, woman, and child. Tennessee led the nation in number of prescriptions per person per year.[1]

Prescription drug cost has the fastest rate of annual increase of any component of health care spending, rising at approximately 18 percent.[2] It is now very close to exceeding the cost of inpatient care.

Despite considerable slowing of the rate of increase of overall health care spending — which grew by "only" 28 percent from 1993 to 1998 — prescription drug spending increased by 79 percent during this same time.[3] Between 1995 and 1998, prescription drug spending grew faster than any other personal health category, accounting for 20 percent of the total increase in health spending in 1998 [alone]. A Brandeis University-sponsored study of a continuously enrolled insured population found that from 1996 to 99, the age-adjusted costs of prescription drugs rose 24.8 percent per year.[4] Drug expenses have roughly doubled as a percent of overall premium for private health insurers from 1993 to 1998, according to a study by the Health Care Financing Administration (HCFA).[5]

This paper presents reasons for this dramatic increase in prescription drug cost and utilization, both good and bad. The paper also addresses unique aspects of prescription drug use and cost in Tennessee, and concludes by raising several public policy questions for Tennessee. Though it is not the intent of this paper to focus on issues at the national level, some discussion of the national environment is necessary to help understand the current situation in the state.

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[1] Novartis, *Pharmacy Benefits Report, Facts and Figures*, 2000 Edition
[2] *ibid.*
[3] Hunt, *Prescription Drug Costs: Federal Regulation of the Industry*, ÓBCBSA Sept. 2000
[4] Wallach, Hodgkin, and Thomas, "Sources of Growth in Pharmaceutical Expenditures" May, 2000
[5] Levit, et. al. "Health Spending in 1998: Signals of Change*" Health Affairs*, Vol. 19, No. 1 (Jan-Feb 2000): 124-132

Six Key Drivers of Drug Cost Increases
And the Impact Each Has on Prescription Spending

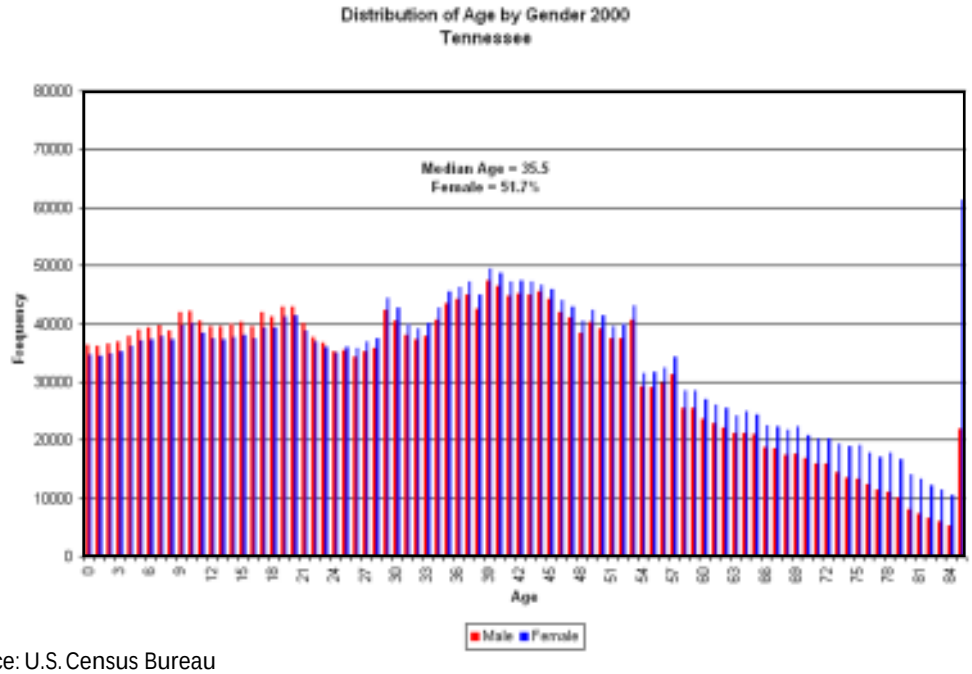
Not all of the drivers of increasing drug costs should be considered bad, or detrimental to the overall state of health care today. In fact, some of them are very good indicators of success. However, each has a dramatic impact on how and why prescription medication costs are rapidly escalating.

1. Aging Population

In 1920, the average life expectancy of a person born that year was 54 years.[6] By 2000, the average life expectancy was 78 years for a baby born with the new century. Still, many believe that to be a very conservative estimate, given some of the advances in genomics and other biomedical technology.

The 20th century brought many advances in public health, occupational safety, and medical care. As a result, there are more elderly people alive today than at any time in history. In Tennessee, in 2000, there were 82,000 people over the age of 85. *(Figure 1)*

Figure 1



Source: U.S. Census Bureau

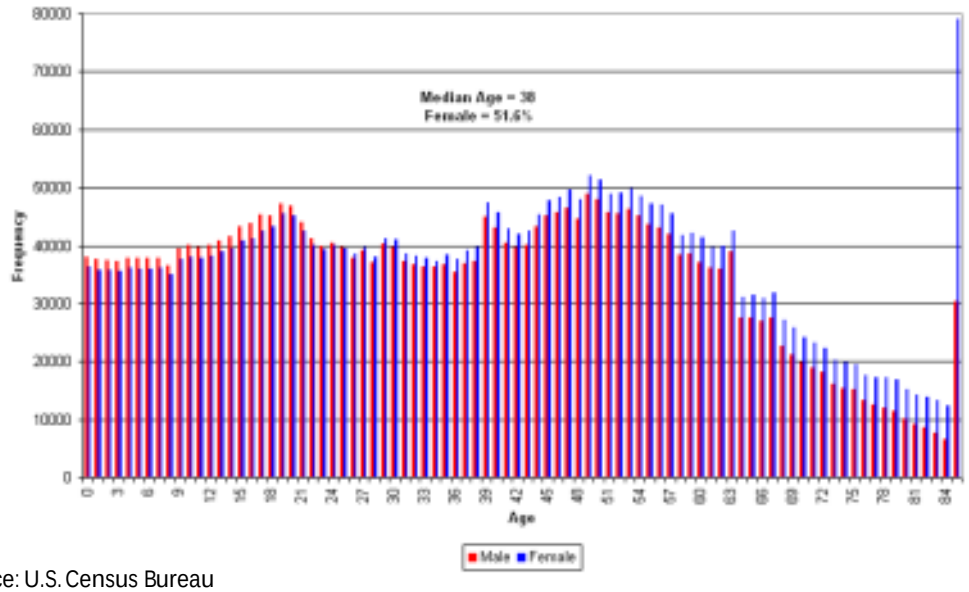
[6]. *ibid.*

By 2010, there will be 110,000 people over the age of 85. *(Figure 2)* The U.S. Census Bureau estimates that the 54 to 64 age group will expand by 59 percent between 1998 and 2010, and that 20 percent of the population will be over 65 by the year 2030.[7]

Current data from BlueCross BlueShield of Tennessee shows that persons over the age of 65 have drug costs approximately 2.3 times greater than those under 65.[8]

Simply put, the advancing age of our population — though clearly desirable as a social phenomenon — has serious implications from a prescription drug cost perspective.

Figure 2



Source: U.S. Census Bureau

2. More Aggressive Treatment Guidelines

As more is continually learned about the pathogenesis of disease, the causes and natural history of specific illnesses and disease, more and earlier opportunities are being found to intervene in an attempt to improve the quality of life and extend longevity. Again, this is fundamentally a good thing.

Yet, when the American Diabetes Association (ADA) redefined diabetes to include anyone with a fasting blood sugar of greater than 126 (it was previously greater than 140), it added 2 million people to that disease category. As there is clear

[7] U.S. Census Bureau Web site
[8] Internal BlueCross BlueShield of Tennessee data

evidence that good control of blood sugar prevents complications in diabetics, earlier identification of diabetics may therefore result in longer and better lives for those individuals, though this has not been as clearly demonstrated.[9,10]

In any case, an additional 2 million people became immediate candidates for oral hypoglycemics, a more aggressive use of ACE inhibitors for hypertension, and more likely to need lipid-lowering agents.

The Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III)[11] recently revised its recommendations as to who should receive lipid-lowering drugs. The numbers are staggering. Prior to ATP III, 12 million people were candidates for that drug therapy. Now 35 million people are.

At BlueCross BlueShield of Tennessee, we estimate this single guideline change could result in a 1.3 percent increase in *overall medical costs* (not just drugs) if fully implemented. Though the change in treatment guidelines is probably beneficial inasmuch as it will probably, again, improve and extend life, it is not, however, free. Nor is it guaranteed to result in an overall decrease in medical costs, as some claim. People who do not die from heart disease will die of another cause such as cancer, which is equally expensive to treat.

No one lives forever, and we all use the majority of health care resources in the final stages of our lives. The longer we live, the more we spend on health care and prescription medication. This is a good thing, not a bad thing. We should be glad to spend money that improves or extends quality life. But the decision to allocate resources to prescription drugs — as with any other medical technology or service — should be based on the expectation that such spending will result in improved quality of life or in additional life, and be measured by objective means.

3. More New Drugs, More Quickly to the Market

The dramatic increase in drug spending between the years 1993 and 1998 has already been cited. During that time, though, approximately two-thirds of the increase came from drugs approved by the Food and Drug Administration (FDA) since 1992. This is partly due to the pricing practices of the pharmaceutical manufacturers, which will be discussed shortly as one of the "bad" causes of increased drug spending. However, the spending increase for new drugs is due in large part to the fact that the FDA has dramatically reduced the time involved in its new drug approval process.

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[9] DCCT Research Group, "The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus" *NEJM* 1993 Sep 30;329(14):977-86

[10] Abraira, et. al. "Veterans Affairs Cooperative Study on glycemic control and complications in type II diabetes" : *Diabetes Care* 1995 Aug;18(8):1113-23

[11] *JAMA*, 285: No. 19 pp. 2486-97, May 16, 2001

In 1993, the average time required to approve a New Molecular Entity, or active ingredient that is new to the market, was 21 months. By 1999, that time had been reduced to 10 months.[12] This is further enhanced by the fact that through the use of combinatorial chemistry, high throughput, structure-based design, and other modern techniques, the average time to develop a drug for market has also been reduced by two years. [13] The net effect is that the number of new drugs reaching the market each year has almost tripled — from 14 in the 1960s, to 39 in 1996 to 1999.

Pharmaceutical companies have increased their financial commitment to research substantially over the last 20 years, from $2 billion in 1980 to $26.4 billion in 2000, according to Pharmaceutical Research and Manufacturers of America (PhRMA). At the same time, the National Institutes of Health (NIH) has seen its budget doubled to approximately $16 billion in 1999. This is important because the Stevenson-Wydler Technology Innovation Act (Public Law 96-480) requires transfer of any federally developed technology to the private sector. In 1995, the Clinton Administration, recipient of large contributions from the pharmaceutical industry, repealed the "reasonable pricing clause" entirely, enabling the virtually free transfer of research funded by public money to the private interests of the pharmaceutical companies.[14]

The net impact of all these factors is a significantly increased number of new drugs coming to market in record time. From the standpoint of patients who need these drugs, the stepped-up process is a desirable one. The costly and accelerated process does raise, however, some troubling issues from an economic public policy perspective.

4. More Drug Costs Shifted to Third-Party Payers

Out of their own pockets, individuals paid for 59.2 percent of the total cost of prescription drugs in 1991. By 1997, that rate had dropped to 29 percent.[15] *(Figure 3)*. The individual out-of-pocket cost level is very important because drugs behave exactly like any other consumer good with a predictable price/quantity relationship.[16] The more a person has to pay for something, the less of it he or she will purchase. The less a person has to pay, the more he or she will buy. *(Figure 4)* In Tennessee, according to Novartis, [17]insurance companies or TennCare℠ covered 78.2 percent of the cost of all prescriptions in 1999.

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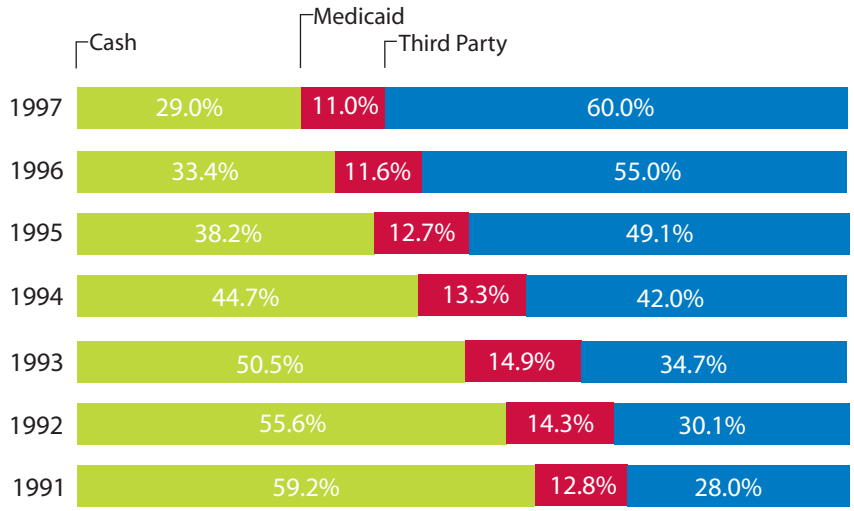
[12] Hunt
[13] Shulman, DiMasi, and Keitin, "Patent Term Restoration: The impact of the Waxman-Hatch Act on New Drugs and Biologics Approved 1984-1995" The Journal of BioLaw and Business, Vol. 2, No. 4, 1999:63-68
[14] Hunt, p. 33
[15] IMS Health, Plymouth Meeting, Pa.
[16] Coulter, S. "The Relationship between Prescription Volume and Customer Copayment" October 13, 1996, unpublished BCBSKC data.
[17] Novartis 2000

Figure 3

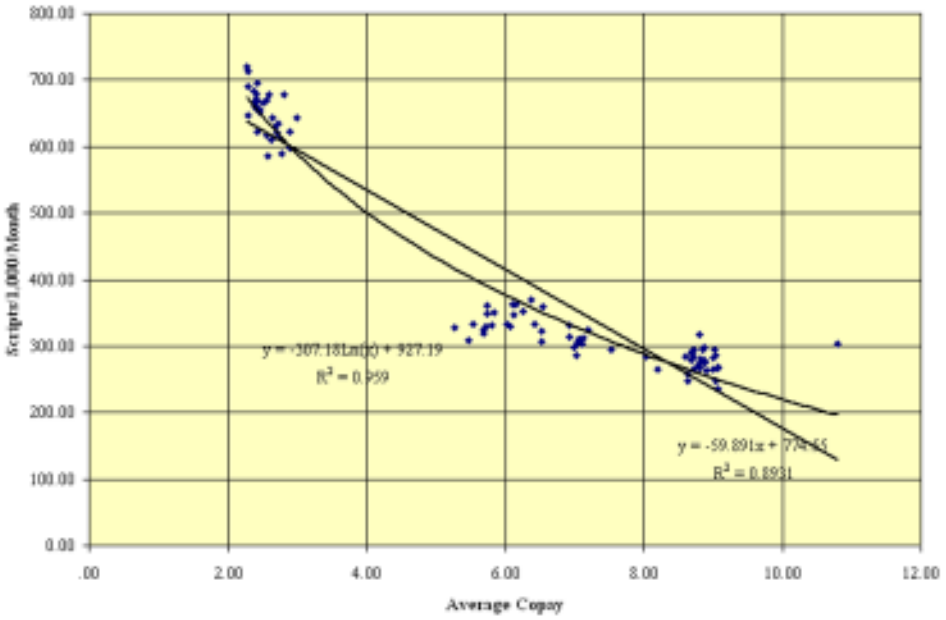
Percentage of Total Prescriptions



Percentages may not total 100 due to rounding.
Source: IMS Health, Plymouth Meeting, Pa.

Figure 4

Scripts as a Function of Copay-Brand



Source: BlueCross BlueShield of Kansas City Data

To this point, several of these drug cost drivers have had "good" characteristics in terms of their effect on health. Now, however, it's time to focus on some of the not-so-good reasons for drug cost increases.

5. Direct to Consumer (DTC) Advertising

The FDA was given formal authority over the advertising of prescription drugs in 1962, through the Kefauver-Harris Drug Amendments to the Federal Trade Commission Act of 1914. Prior to the mid-1980s, the marketing of drugs by pharmaceutical manufacturers was limited to direct marketing to physicians. In the early 1980s, several drug companies, under the rights granted by the First Amendment to the U.S. Constitution, began to directly market to consumers. The FDA managed to convince the companies to voluntarily refrain from this activity until it could issue its first set of regulations in 1985. Advertising was still quite limited by the restrictions contained in these regulations until August of 1997, when the rules were significantly liberalized, allowing, for the first time on a practical basis, the full use of television.

In 1996, television accounted for only 11.4 percent of total DTC spending. By 1999, that percentage had escalated to 61 percent. At the same time, total spending for prescription drug advertising zoomed from $55 million in 1991 to $1.8 billion in 1999.[18]

And just how effective is this advertising? *Prevention* magazine surveyed consumers in 1997, 1998 and 1999 to study the effectiveness of legend drug advertising. By 1999, 95 percent of adult consumers could recall seeing an advertisement for a legend drug. Thirty-one percent of those talked with their physicians about a specific drug, and 28 percent actually asked their doctor for a specific drug prescription. An astounding 84 percent of those who asked for a prescription for a specific drug, got the prescription. Dr. Rebecca Schwartz of the Harvard Medical School studied this phenomenon.[19] According to her study, physicians fundamentally are motivated by the same motives other businesspeople are — a desire to please and keep their customers. As long as the drug requested is not likely to actually harm the patient (at least as far as the physician knows), the physician is very likely to acquiesce to the desires of the patient.

Four classes of commonly used and advertised drugs accounted for 30.7 percent of the total increase in drug spend between 1993 and 1998.[20] Antidepressants (Prozac, Zoloft, and Paxil) accounted for 11.8 percent of the total, or $5 billion; non-sedat-

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[18] IMS Health, 2000

[19] Schwartz, et. al. , "Physician Motivations for Nonscientific Drug Prescribing*," Social Sciences and Medicine.* Vol. 28, No. 6 (1989) 577-582

[20] NIHCM Foundation Issue Brief, "*Factors Affecting the Growth of Prescription Drugs Expenditures*", July 1999

ing antihistamines (Claritin, Zyrtec, and Allegra) comprised 4.5 percent, or $1.9 billion; lipid lowering agents (Lipitor, Zocor, and Pravachol) were 8 percent, or $3.4 billion; and anti-heartburn medications (Prilosec, Prevacid, and Pepcid) represented 6.4 percent, or $2.7 billion.

There is another, more insidious aspect to this issue. While promoting new medications which are truly more effective than older ones may benefit the patient, at times the newer medications cost more — but are not as effective as the ones they replace.

A group of cardiologists set out in 1997 to determine why the standard guidelines for treatment of hypertension published by the Fifth Joint National Committee for the Detection, Evaluation and Treatment of High Blood Pressure (JNC V) were not being followed.[21] The standard recommendations were basically diuretics and beta-blockers, both of which are cheap and effective. Beta-blockers have the added benefit of helping prevent second heart attacks and various types of irregular heartbeats. The authors found that the drop in beta blocker and diuretic use was accompanied by an increase in calcium channel blocker use. Calcium channel blockers are three times as expensive, yet not as effective as the original recommended drugs.

What was the difference? Calcium channel blockers were the most heavily advertised drugs in the New England Journal of Medicine.[22] The twist in this scenario is that the advertising was focused on doctors, not patients.

A full discussion of pharmaceutical marketing strategy is beyond the scope of this paper. But suffice it to say that the drug companies are increasing their investment in DTC advertising at an exponential clip, and it is unlikely they would be doing so if it were not paying off handsomely.

6. Pricing practices

One of the downsides to the fact that a larger portion of the bill for prescription drugs is being borne by third-party payers is that consumers themselves have become relatively price-insensitive. Drug companies have capitalized on this rapidly. The price of new drugs introduced since 1995 is more than double the price of drugs introduced in the previous five years.[23] *(Figure 5)* Many of the drugs introduced in the last 18 months have very high price tags — such as Enbrel for rheumatoid arthritis which can run $947 per month.

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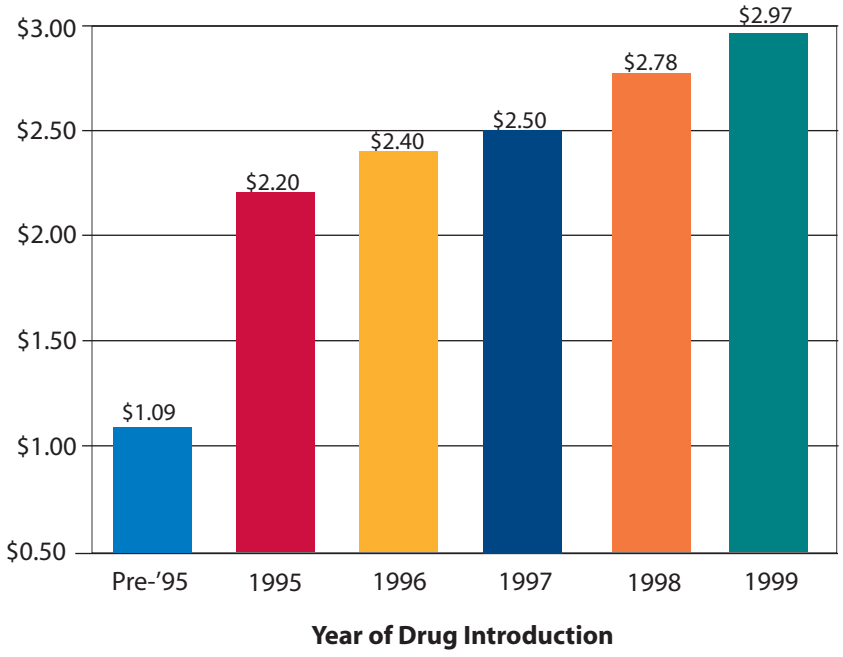
[21] Seigel and Lopez, "Trends in Antihypertensive Drug Use in the United States: Do the JNC V Recommendations Affect Prescribing?" *JAMA* Vol. 278, No. 21 (December 3,1997) 1745-1748

[22] Hunt

[23] NIHCM

Figure 5

The Average Cost Per Day and Rate of Increase of New Drugs is Significantly Higher Than Older Drugs



Source: Merck-Medco, 2000

There is also the widely reported disparity between the cost of prescription drugs in this country and the correlating cost of the same drugs in other countries. The same prescription for 30 Prozac 20 mg tablets costs $25.93 in Spain, $37.59 in Canada, and $72.16 in the U.S.[24] When asked about this disparity, pharmaceutical companies have responded that they need the profits to fund their research activities. However, they have offered no explanation why the U.S. has to bear the burden of research for the entire world.

[24] BlueCross BlueShield Association Fast Facts

Money Spent On Drugs
Does It Prevent Expenditures Elsewhere In The Healthcare System?

The pharmaceutical companies, in response to public discussion of their profit margins and the rapid increase in drug costs, have claimed that increasing expenses on drugs have led to lower medical costs for inpatient care. There are isolated examples of diseases such as asthma where increased use of medication leads to lower use of the Emergency Room and inpatient hospitalization. However, when considered at the aggregate level, overall medical costs continue to increase at rates greater than the Consumer Price Index - all items. Further, the predominant decrease in hospital days occurred in the first half of the 1990s, where the predominant increase in drug expenditures occurred in the latter half of the decade.

In Tennessee, from 1990 through 1995, inpatient hospital days per 1,000 declined from 1,033 to 756, a 26.8 percent decline. At the same time, per capita prescription drug costs increased 53 percent. Each additional dollar increase in per capita prescription drug costs during 1990 to 1995 is associated with a decline of 3.03 days per 1,000 (R squared = 0.989, p = 0.000029). At $1,200 per day, this translates into approximately a $.30 reduction in hospital costs for every $1 spent on drugs. However, it needs to be emphasized that this was the period in which the managed care industry was very focused on reducing hospital days. To attribute causality to what is probably at best only a coincidence would be difficult to establish.

From 1995 though 1999, inpatient days per 1,000 declined from 756 to 682, a 9.8 percent reduction, while per capita prescription drug costs increased from $272 to $498, an 83 percent increase. Each additional per capita prescription drug dollar spent in the latter half of the decade is associated with an insignificant reduction in days per 1,000 of -0.2. At this time, increasing drug expenditures do not appear to be correlated with any significant decrease in hospital expenses. This obviously does not take into account any possible improvement in health, but from a purely economic perspective, expenditures in excess of $300 per person per year appear to be unjustified. *(Figures 6 and 7)*

Figure 6

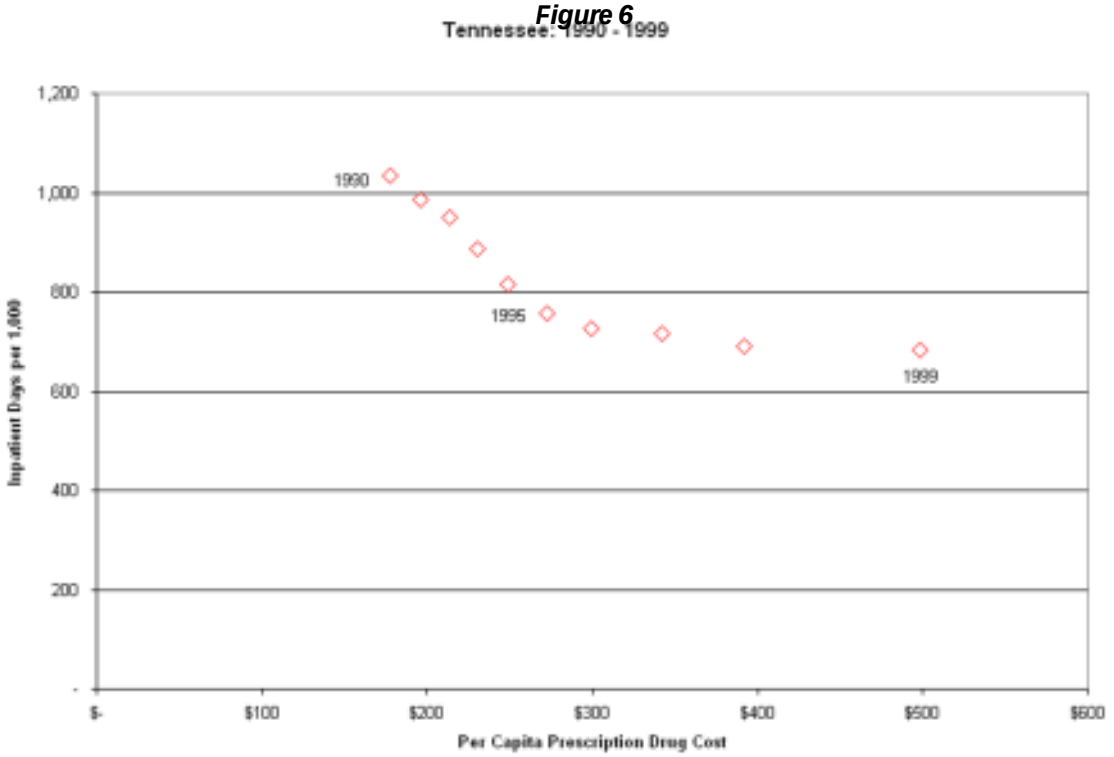
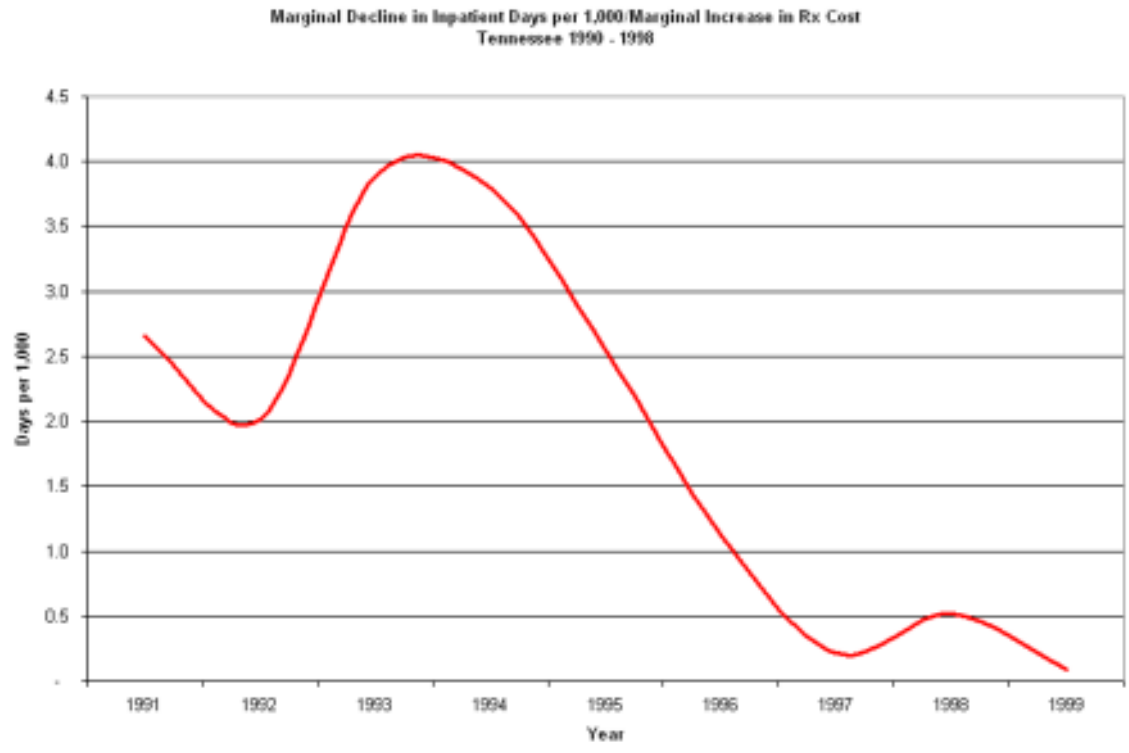


Figure 7



Drug Company Profits
Make No Mistake: Drug Companies Are Very Profitable.

In the fourth quarter of 2000, Pfizer reported a17.4 percent profit margin, Lilly reported 25.8 percent, and Bristol-Meyers-Squibb reported 22.3 percent. (The all-industry average for that same quarter was 4.6 percent.) As an industry, the pharmaceutical group made $23.759 billion in 2000. The consistent return over time of the established pharmaceutical companies is in the 19 to 24 percent range. In the same quarter, and by way of contrast, the automotive industry averaged 0.9 percent, aerospace and defense 4.3 percent, with tobacco and banks, respectively, at 11.2 and 10.2 percent. [25]

As an additional reference point, BlueCross BlueShield of Tennessee has an annual operating goal of generating 0.5 percent in excess revenue over expenses.

What does this mean in Tennessee?

In general, 75 percent of the retail price of drugs sold goes to the pharmaceutical manufacturers after the retail pharmacies and the wholesalers take their share.[26] TennCare spends roughly $1 billion per year on drugs, including the Medicare –Medicaid dual-eligibles and the long-term care recipients. If the average drug company profit margin is 20 percent, then simple mathematics tells us that the taxpayers of Tennessee are giving $150 million per year to the drug companies *as profit.* That amount would pay for 4,000 new teachers with an average annual salary of $37,500. In fact, to raise a more pointed question, why not consider how much of that money actually stays in Tennessee? Unlike money that goes to doctors and nurses, which is then taxed and spent largely within our state, drug company profits go to other states and other countries and don't directly do a whole lot to improve the standard of living of anyone in Tennessee.

Contrasting this with provider costs, it should be noted that in TennCare, most providers are discounting their services substantially compared to their commercial rates. In fact, most hospitals and some doctors are rendering services at actually less than the cost to deliver those services. Drugs are sold at the same (profitable) rate to TennCare recipients as to the commercially insured. That is, doctors and hospitals act as responsible community members and make contributions to the poor and underserved. Pharmaceutical companies have few programs in place to address such needs.

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[25] *Business Week*, February 26, 2001

[26] *Medicine and Health Perspectives* 4-17-01 reporting on Uwe Reinheardt's March 28th 2001 lecture to the Council on the Economic Impact of Health System Change

Intellectual Property Rights

The framers of the Constitution recognized the need to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." [27] There has always been a balance, however, between the need to encourage new discoveries and the need for those discoveries to receive widespread economical use.

In 1984, Congress passed the Waxman-Hatch Act in an attempt to address both of these legitimate societal needs. The act has provisions to allow drug companies to extend their useful patent lives on new drugs by up to five years, and even longer in some cases, while also lowering barriers to entry for generic drug companies. Though both ends were served by this act, some interesting and unpredictable consequences have ensued. For example, though there is a significant switch to generic product in the months following a patent expiration, the price of the branded drug is usually *raised.* The net effect of this is that the market share of branded products in dollars (as opposed to the more commonly reported volume in units) has risen from 88 percent in 1994 to 92 percent in 1997.[28]

The Orphan Drug Act was enacted in 1983 to encourage the development of medications for diseases that affect limited numbers of people, and therefore would not under normal circumstances represent enough market demand to justify the research and development expense involved with modern pharmaceuticals. Seven years of market exclusivity and tax credits for up to 50 percent of the clinical research costs are granted to companies that develop drugs for diseases that affect fewer than 200,000 people. This was very effective, resulting in a ten-fold increase in the number of drugs so designated between the decades 1973-83 and 83-93. The framers of the Act, however, did not address the pricing side of the equation, and many of these drugs have been introduced at exorbitant prices, such as zidovudine (AZT) for AIDS, which was introduced at approximately $10,000 per patient per year and has proven to be a multibillion dollar revenue source for its manufacturer.

It is beyond the scope of this paper to discuss the full implications of the intellectual property laws and their impact on drug costs. Further, it is the purview of the federal government to address these issues and this paper will attempt to focus the issue at the Tennessee level. However, it is illustrative to note the profound impact that public policy has on the behavior of pharmaceutical companies in their quest for profits.

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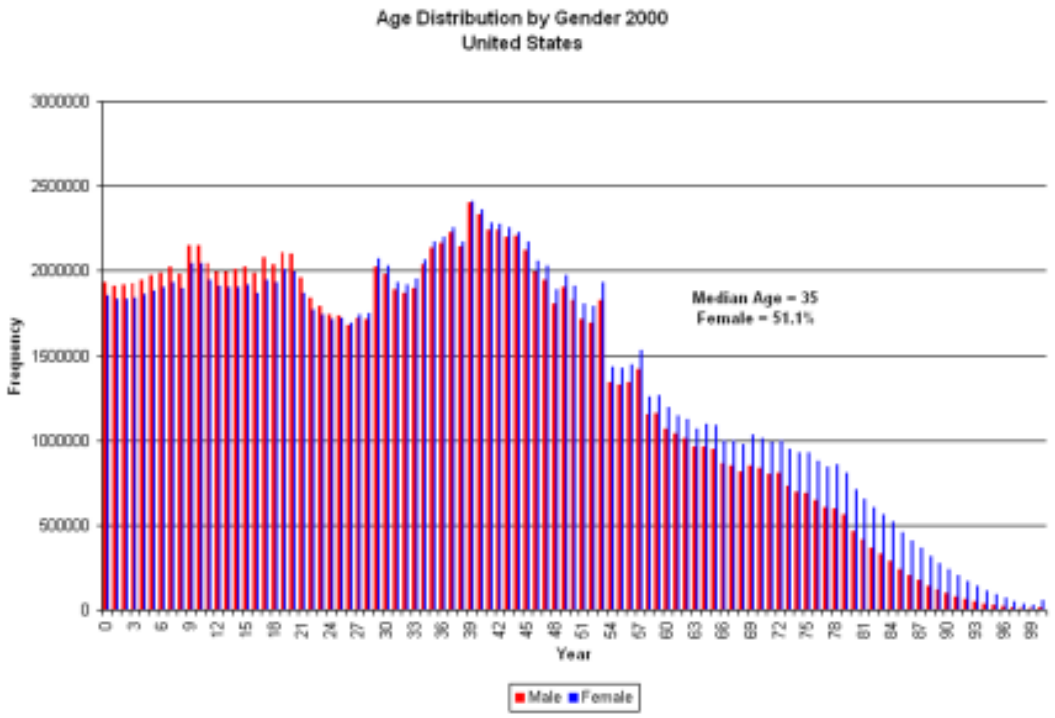
[27] Article 1 Section 8, The United States Constitution
[28] Hunt

Tennessee Drug Costs and Tennessee Health Status
So How Are We Different From Other States?

Demographics: We're older and getting comparatively more so

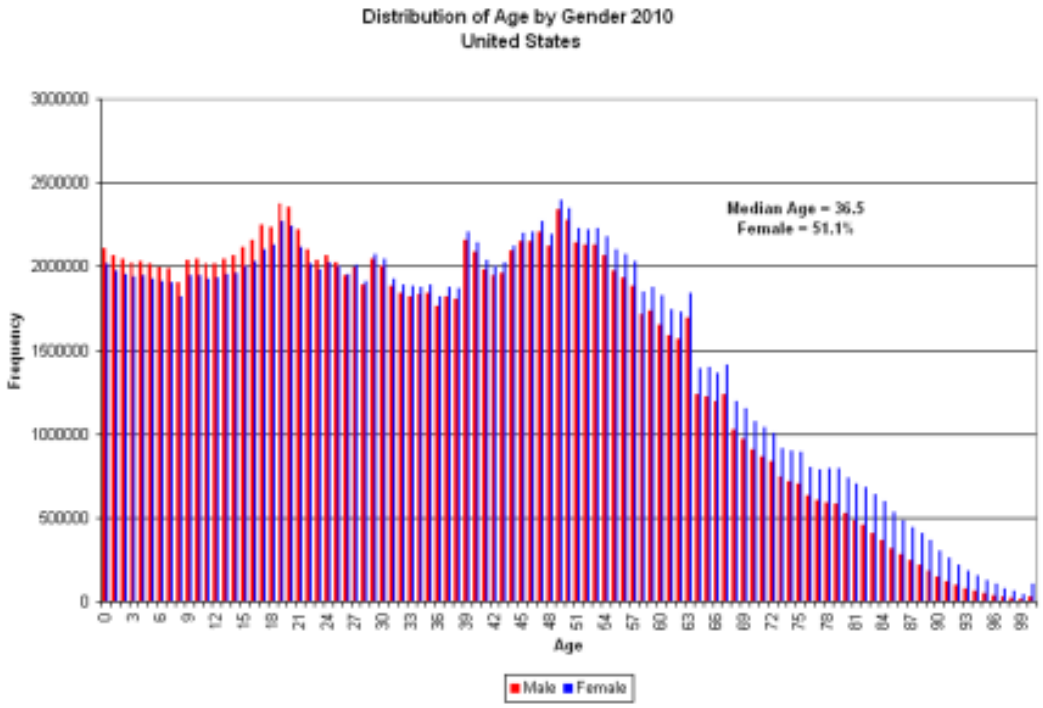
In 2000, the median age in Tennessee was 35.5 *(See Figure 1)* compared to the median age in the U.S of 35 *(Figure 8)*. By 2010, the U.S. Census Bureau estimates that the median age in Tennessee will be 38 *(See Figure 2)* compared to the U.S. median of 36.5 *(Figure 9)*. In other words, compared to the rest of the U.S., we are older and we're getting comparatively more so year by year.

Figure 8



Source: U.S. Census Bureau

Figure 9



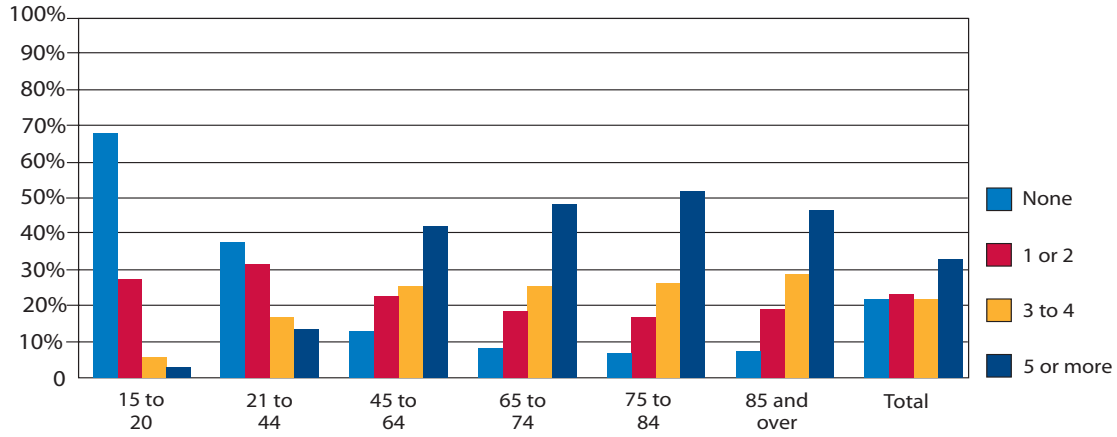
Source: U.S. Census Bureau

This has significant implications in terms of drug (and, for that matter, health care) utilization. *Figure 10* shows the distribution of pharmacy utilization by age group. You will note the profound difference in utilization patterns between the 21 to 44 year age group and the 45 to 64 age group. Where in the younger age group, one in 10 uses more than five prescriptions per day and four in 10 use none at all, in the older age group those figures are completely reversed. As the median age creeps up, the proportion of people in those two age groups changes for the worse. Each one-year change in the median age represents an additional 2.2 percent increase in overall health care costs. In a commercial population, the same change in age of that population results in a 4.8 percent increase in prescription drug costs.[29]

[29] Milliman and Robertson Guidelines

Figure 10

Pharmacy Utilization by Age Group



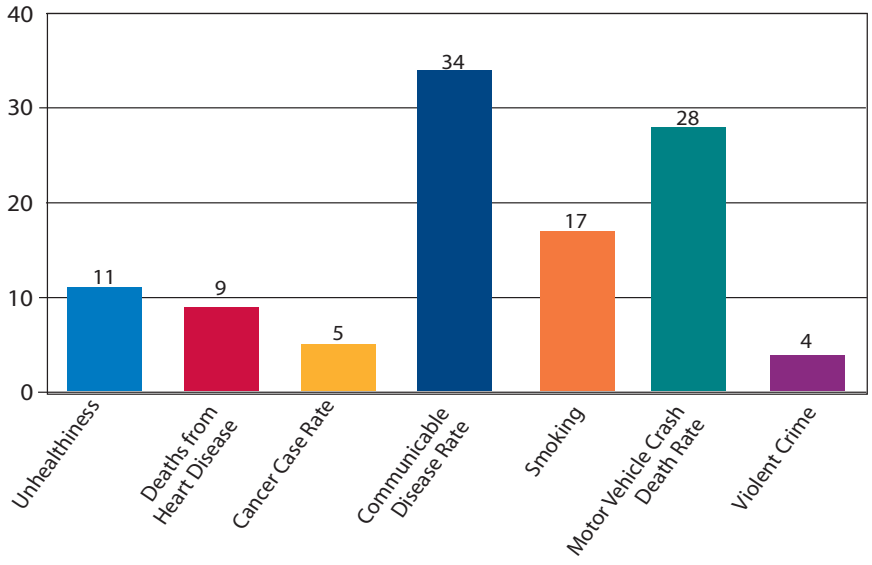
Source: Milliman and Robertson

Illness Burden: We're sicker and getting more so

In 1996, the Reliastar report[30] ranked Tennessee 42nd among the states in an overall "healthiness index," having fallen from 35th in 1990. This was 11 percent lower than the average for all states. We are in the top quintile of all states for communicable diseases, smoking, heart disease, cancer, and death from vehicular trauma. *(Figure 11)*

Figure 11

Tennessee: Percent Above National Average on Selected Health Measures



Source: ReliaStar Financial Corporation, 1996. Data 1994 or earlier.

[30] The ReliaStar Financial Corporation ranks states annually on an overall "healthiness index" which is a composite measure of 17 indicators such as mortality, morbidity, education, occupational safety, primary care access and others.

According to the American Cancer Society, Tennessee will have 4,060 new cases of lung cancer diagnosed in 2001, ninth-highest in the nation.[31] We were fifth in the nation in age-adjusted death rate from malignant neoplasms in 1998, and sixth in number of years lost by premature death from cancer.[32] We are ninth in total health care spending per capita. We were 12th in overall death rate in 1999 at 980.5 per 100,000 population.[33] In short, by virtually any measure, we have a greater than average illness burden compared to other states.

We are 42nd in the nation in child health, according to the Kids Count Data Book[34] which looks at such things as percentage of low birth weight babies, percentage of children in poverty, teen birth rate, child death rate and percentage of families with children headed by a single parent.

Physician Supply: We're about average

The American Medical Association (AMA) recommends that 145 to 185 physicians is optimal for each 100,000 persons, assuming appropriate geographic and specialty distribution. In Tennessee, we have 243 per 100,000.[36] That ranks Tennessee 19th in the U.S., very close to the average of 254 and slightly above the median of 234. On an ideal basis, we may have too many physicians. But on a relative basis we are in the middle of the pack.

Education: We're at the bottom

Data from the Community Health Status Indicators Project demonstrate that there is a strong correlation between health status and educational attainment. *Figure 12* shows the positive association between graduation from high school and good health. (In this graph, the higher the health status score, the poorer the self-reported health of the person.) We see the same type of correlation when reviewing death rate *(Figure 13)*, average unhealthy days in the last month *(Figure 14),* and life expectancy *(Figure 15)*. It is well known and widely discussed that Tennessee ranks at or near the bottom of the nation in most educational measures. Slightly less than half of the freshmen who entered high school in Hamilton County four years ago will graduate with their class in 2001. Tennessee ranks 48th in the nation in four year high school graduation rates. We are 49th in percentage of adults with a college degree, at 15.1 percent.[37] What is not as widely appreciated is the strong correlation between educational attainment and health status. Is there an opportunity here to reduce our medical costs by improving our educational status?

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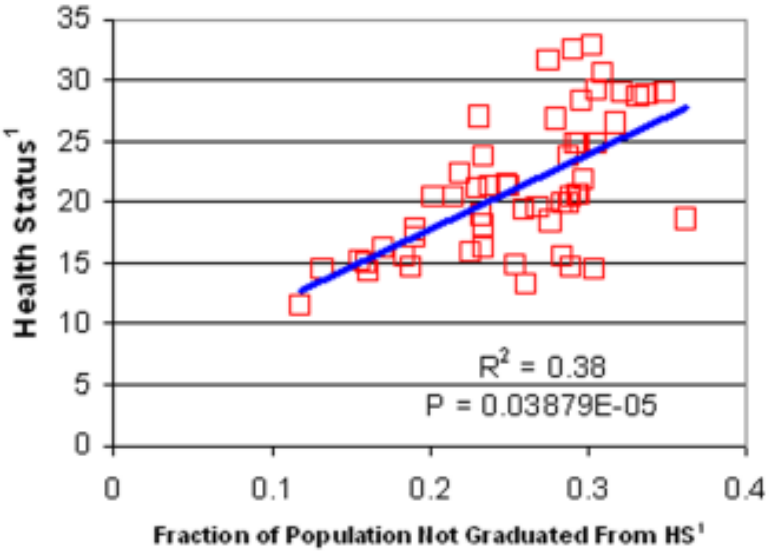
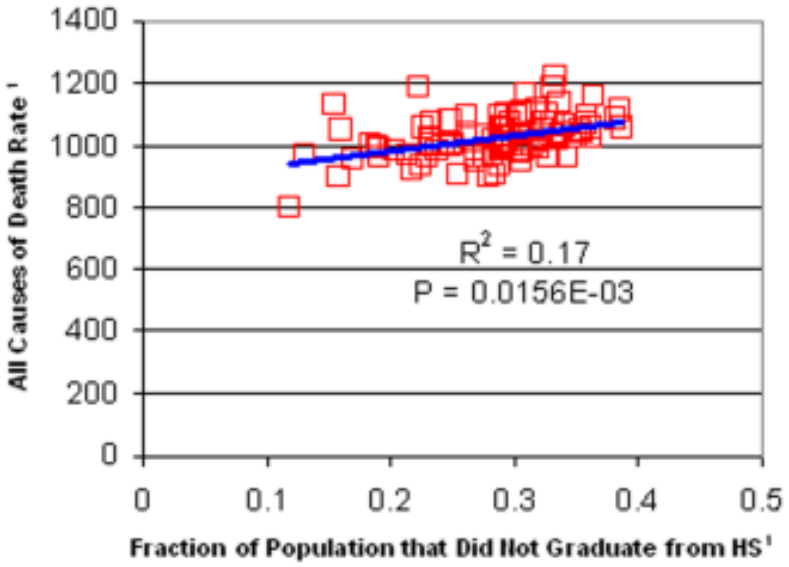
[31] Morgan and Morgan, *Health Care State Rankings, 2001*, p.367
[32] ibid. 153, 179
[33] ibid. p. 77
[34] Chattanooga Times Free Press, May 22, 2001
[35] Health Care State Rankings 2001, p. 19
[36] U.S. Census Bureau
[37] Chattanooga Times Free Press, May 25, 2001

Figure 12



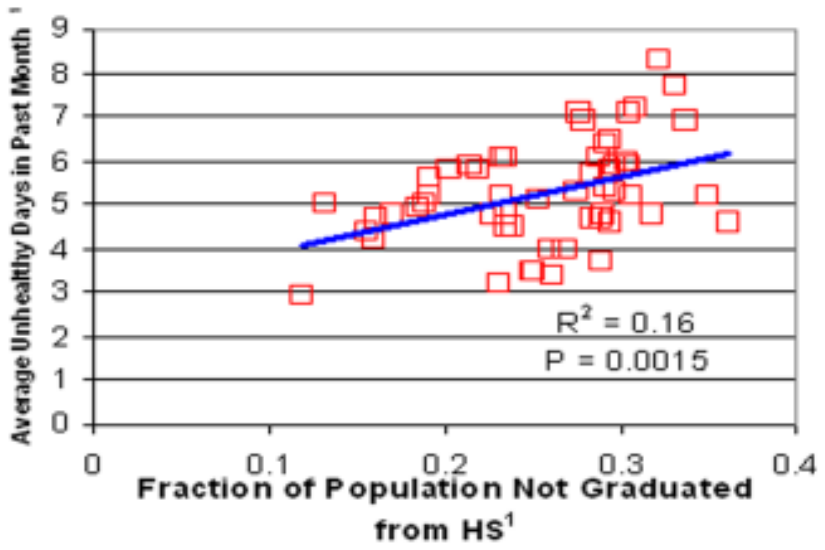
Source: Community Health Status Indicators Project

Figure 13



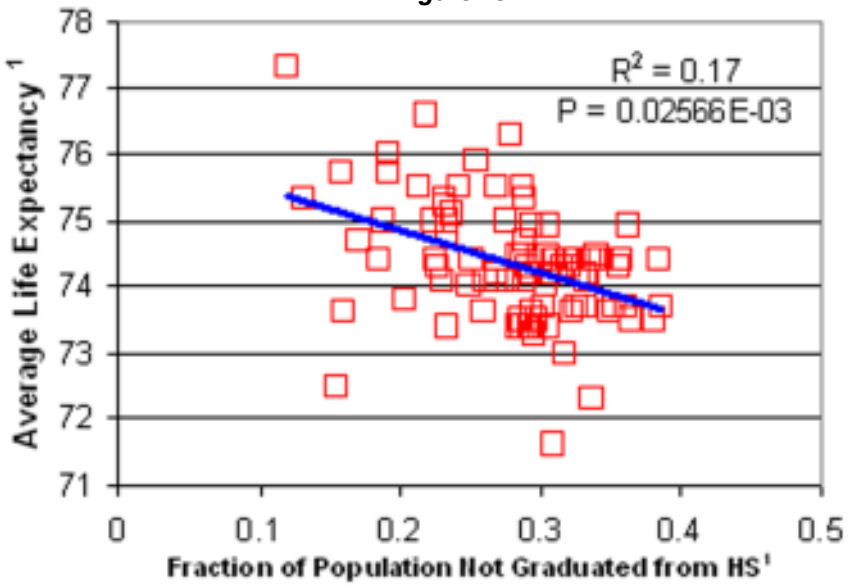
Source: Community Health Status Indicators Project

Figure 14



Source: Community Health Status Indicators Project

Figure 15



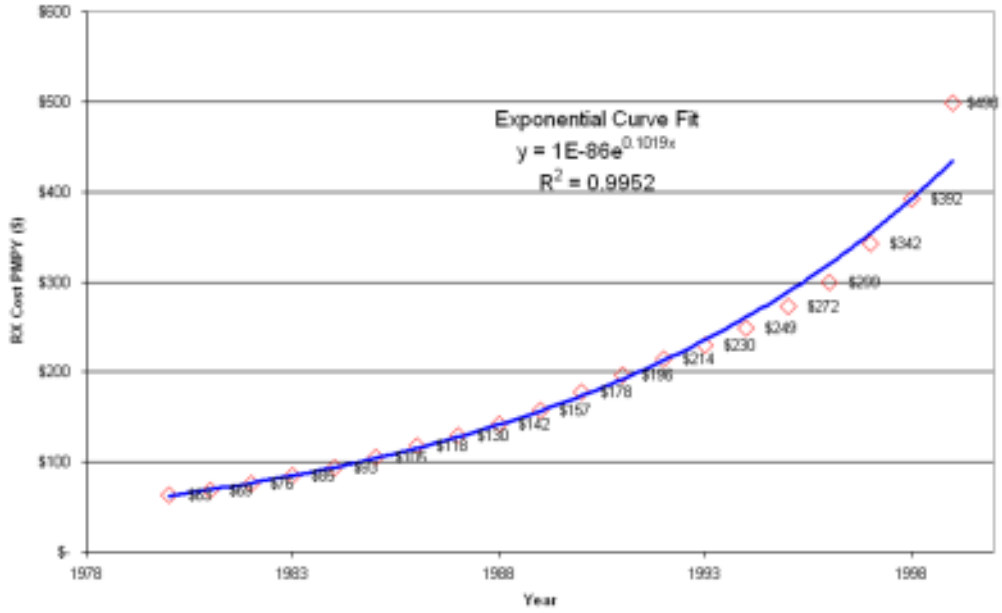
Source: Community Health Status Indicators Project

Drug Utilization: We're number one!

Tennessee has the distinction, as mentioned previously, of having the highest rate of prescription drug use per capita in the United States.[38] We have maintained that distinction for several years, predating the advent of TennCare. Compounding this, we have literally seen an exponential rise in the per capita cost of drugs over the last several years. *(Figure 16)*

Figure 16

Tennessee Prescription Drug Cost



Source: Health Care Financing Administration (HCFA)

There is a somewhat surprising lack of variability in prescribing habits by region within Tennessee. We see, for example, in the commercial PPO product at BlueCross BlueShield of Tennessee, which serves over a million people statewide, a generic prescription rate of 41percent in the northeastern region of the state, and 33.5 percent in the Memphis area, with the in-between regions falling in-between. We do not see a large degree of variability among the regions in terms of pure number of prescriptions, either, the highest only exceeding the lowest by 16 percent. When comparing our state to others, however, Tennessee at 14 prescriptions per person per year, is 43 percent higher than the national average of 9.8 and 86 percent higher than California. Whatever is driving this phenomenon seems to be impacting the entire state — and not just one area.

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[38] Novartis 2000

The Grier Impact

The *Grier v. Wadley Consent Decree* has profoundly impacted the way medications are prescribed and used in Tennessee among the 1.43 million TennCare enrollees. Tennessee's TennCare program provides coverage for Medicaid-eligible, uninsured, and uninsurable persons in the state. It is one of five states that have no drug cap, meaning that there is no limitation on the number of prescriptions that an enrollee can have. Prior to *Grier*, there was a closed formulary, which was heavily weighted toward generic drugs. Though the utilization is very high in this program (17 Rx per person per year), as one would expect in a program with no (or minimal in the case of some persons of means) co-payment, the costs were somewhat offset by the 68 percent generic utilization rate. (By way of comparison, open formulary programs typically have a generic rate of 40 percent.) *Grier* changed all that.

Under *Grier*, pharmacists are required to dispense a 14-day supply of any drug written by a physician, if the physician is not willing to use a formulary drug or cannot be contacted to request a change to a formulary drug. The pharmacist is also required to provide a form to inform each member of his/her appeal rights and the process to continue to receive the prescribed medication until his/her appeal is resolved. The new standard of medical necessity requires that the drug be allowed unless there is evidence in the medical record that would indicate that the drug would actually harm the patient. There is no requirement that there be evidence that the drug would actually help the patient.

As a practical matter, since BlueCross BlueShield of Tennessee receives roughly 700 to 800 of these prescription requests per day, it is impossible to send for, receive, and review all those medical records on the off chance that an absolute contraindication to the drug would be found in the record. Therefore, the net effect of Grier is to have opened the formulary.

The *Grier* consent decree is an example of how a court decree can have the effect of eliminating the last existing market counterbalance to supply in the TennCare system for prescription drugs.

Since *Grier* was implemented on November 1, 2000, the generic rate has fallen to 59 percent and is still dropping. The cost of drugs for just the BlueCare℠ membership has rocketed from $14 million to $20 million per month.

Pharmacy Assignment

BlueCross BlueShield of Tennessee implemented a pharmacy assignment program for the 500,000 members in the BlueCare program to improve the pharmaceutical care for high-utilizing members. A meta-analysis published in the *Journal of the American Medical Association (JAMA)* revealed the incidence of hospitalizations due to adverse drug events is 4.7 percent. An estimated 40 percent of patients receive drugs from multiple prescribers and/or multiple pharmacies. This places those patients at increased risk for adverse drug reactions since no single health care practitioner is aware of all medications a patient is taking. More than 26,500 members receiving more than five prescriptions per month over a six-month period were assigned to receive all of their prescriptions from a single pharmacy.

Claims data for the assigned population from the six months prior to pharmacy assignment was compared to data from six months after assignment. The pharmacy assignment program showed a decrease in the in ER visits (-10.05 percent), in-patient admissions (-12.23 percent) and the number of prescriptions per member per month (-5.05 percent). The Bureau of TennCare ordered the program to be suspended when questions were raised about assigning members based only on prescription utilization.

Table 1

Top Ten Most Prescribed Drugs in Tennessee

1. ***Hydrocodone***
2. ***Premarin***
3. ***Lipitor***
4. ***Zithromax***
5. ***Synthroid***
6. ***Prilosec***
7. ***Claritin***
8. ***Alprazolam (Xanax)***
9. ***Atenolol***
10. ***Cephalexin***

Source: BCBST data

Other BlueCross BlueShield of Tennessee Initiatives
Profiling, Therapeutic Switch, and Case Management

Most insurance companies and HMOs are actively seeking to counteract this escalating cost trend. The primary method used is to increase the proportion of cost borne by the patient. This is done through increasing co-pays, the addition of a "third tier," and most recently by a trend back toward co-insurance. A fixed copayment structure tends to shield the patient from the immediate impact of cost increases by the pharmaceutical companies. Of course, the employer paying the premiums sees this "hidden" increase at renewal time in the form of increased premiums. To illustrate this point, use a simple example of a drug with a typical market cost of $40 with a $20 copay. The patient pays $20 and the insurance pays $20. During the course of the year, the pharmaceutical company raises the cost of the drug to $44, an apparent 10 percent increase. However, the patient is still paying $20. The insurance company is paying $24, a *20 percent* increase.

Thus, a fixed copayment benefit structure has both the effect of shielding the consumer (to whom the drugs are being actively marketed) from the impact of price increases, while at the same time causing the insurance premium to rise at a much greater rate than the actual cost of the drug (this is what actuaries call the "leveraging" effect.) The net effect of this is that the drug companies are able to increase their prices (or accomplish the same thing by switching people to more expensive drugs) since people are rendered price insensitive by the blunting effect of the copay, while the insurance companies get the blame for the cost increases.

Profiling. At BlueCross BlueShield of Tennessee, the company has also been providing feedback to physicians regarding their prescribing habits through the use of profiles. These have not been as effective as we had hoped when simply provided to physicians. However, when accompanied by a personal visit from one of our regional pharmacy directors, these have proven highly effective in (temporarily) changing prescribing habits, reducing costs by as much as $5 per member per month (PMPM) for selected physician outliers. This is, however, highly labor intensive and only justified for those in the top quintile.

Therapeutic Switch. We have also initiated programs targeted at certain expensive drugs within a category of drug. For example, Claritin is a non-sedating antihistamine which costs about $72.36 for a month's supply. Allegra is a similar drug, which is more effective[39] and costs about $55.72 per month. Through a concerted program of communication with physicians and patients, supported by a three-tier benefit structure, we were able to shift the market share of Allegra for Tennessee insureds from 23 percent to 30 percent of this particular class. That small shift alone saved BCBST members over $500,000 in 2000. This program is being expanded to several other highly used drugs.

Case Management. We are also initiating case management programs for targeted individuals with high drug costs. It is too early to demonstrate results in that program, but we are very optimistic that it will both improve the quality of care our members receive by reducing drug interactions and inappropriate use, and also reduce costs within that 3 percent of the population that uses 27 percent of the resources.

However, these programs really only nibble at the edges of a huge problem.

Public Policy Issues to Consider

Why are we number one?

At the present time there is not a satisfactory answer to this basic question. BlueCross BlueShield of Tennessee believes that to properly address this issue, we need to approach it scientifically. "Diagnose first, then treat," is the medical axiom that would apply here. We propose a focused research initiative, undertaken under the oversight of a broad based advisory committee consisting of representatives from the academic, insurance, hospital, and medical communities. Once the cause is understood, it can be addressed appropriately.

Are we spending the money in the right place?

Should we continue to fund health care without regard to cost or demonstrable benefit, or should we fund education so that people can better care for themselves?

Both are important considerations in determining an action plan to address and cure the problem of escalating pharmacy costs, an overriding concern in health care in Tennessee today.

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[39] Medical Letter, April 30, 2001

"And nextly we'll drop in on young Dr. Ginns,
Our *A and S Man* who does Antrums and Shins,
And of course *he'll* refer us to Doctors McGrew,
McGuire and McPherson and Blinn and Ballew
And Timpkins and Tompkins and Diller and Drew,
Fitzsimmons, Fitzgerald, and Fitzpatrick, too,
All of whom will prescribe a prescription for you."

— Dr. Seuss
You're Only Old Once

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