

POLICY BRIEF

***Controlling Costs and Increasing
Access to Prescription Drugs:
State and Federal Solutions***

***Michael Sullivan and
Rebecca Kavoussi***



Economic Opportunity Institute

4738 11th Avenue NE
Seattle, WA 98105

Phone: (206) 633-6580
Email: info@EOIonline.org
Website: www.EOIonline.org

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About the authors:

Michael Sullivan was EOI's Health Policy Research Associate for the summers of 2000 and 2002. He has extensive research experience in health care economics, policy, and politics. Michael possesses a B.S. in Microbiology from the University of California, San Diego, and is a dual-degree candidate for a Master in Public Policy and Master in Public Health at the University of California, Berkeley.

Rebecca Kavoussi has expanded EOI's work on health care policy. She is a graduate of the University of Washington with a B.A. in Political Science. Before earning her Master in Public Policy at the University of California, Berkeley, she worked in Seattle conducting communications activities for two successful campaigns: the \$69 million City of Seattle Families and Education Levy and the statewide initiative-to-the-people to raise Washington's minimum wage.

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About the Economic Opportunity Institute:

The Economic Opportunity Institute is a nonpartisan, nonprofit, public policy institute focused on creating economic security for working Americans. The institute builds a bridge to economic security through research, policy, and public dialogue. The Economic Opportunity Institute is currently developing pragmatic policies in the following areas: Social Security, retirement security, early childhood education, health care, family leave, and workforce development.

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I. Executive Summary

Spending on health care in the United States continues to increase rapidly, consuming a greater share of the total economy each year. Over the past decade, prescription drug spending has been the fastest growing component of health care expenditures both nationwide and in Washington state. The federal government, state governments, individuals and employers all pay for prescription drugs, and everyone is affected by rising costs.

While it is true that overall drug *prices* have gone up, and in many cases at more than triple the rate of inflation, price increases alone do not account for the drastic increase in spending on pharmaceuticals. The three biggest cost drivers, in order, are:

- 1) the average person fills more prescriptions than ever before (increased utilization),
- 2) new classes of drugs arrive on the market in high demand and at high prices, and
- 3) pharmaceutical companies hike prices on existing drugs.

Double-digit increases in total prescription drug costs create two interrelated problems. First, higher prices mean less access for uninsured individuals, and often a difficult choice for the poor: to treat or eat? Second, increased drug spending forces state governments to face a similar choice: to continue funding drug coverage for seniors, the disabled and others at escalating prices and pay for it by cutting teacher salaries, raising taxes, and underfunding firehouses, or to roll back drug benefits and eligibility for already vulnerable groups?

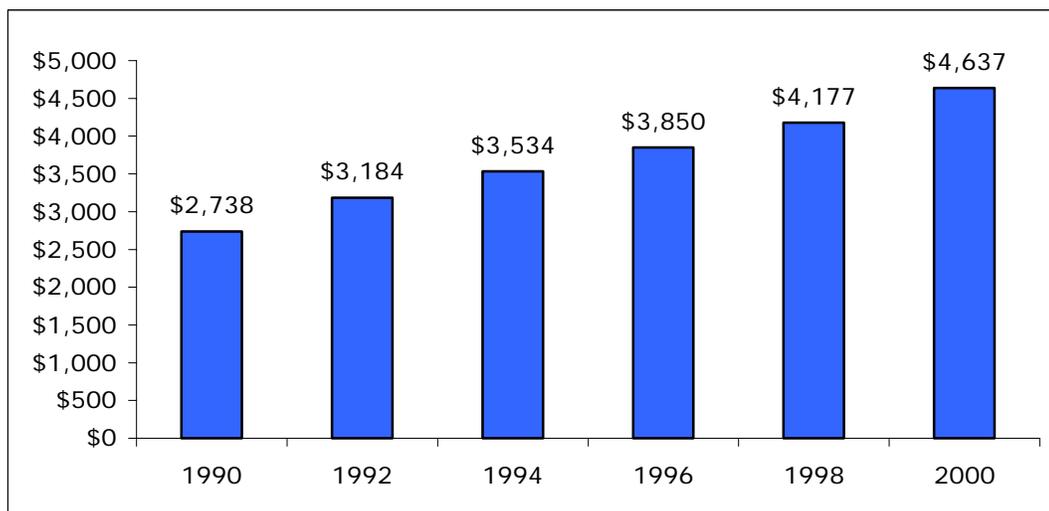
While Congress has thus far failed to pass Medicare prescription drug or generic drug legislation, and the executive branch has taken a hands-off approach, the states have taken the lead in designing innovative policies to reduce manufacturer prices and expand access to necessary drugs.

Legislation in Washington state, debated in 2002 and expected to be reintroduced in 2003, would allow the state to evaluate the benefits and costs of various and competing prescription drugs, negotiate price discounts for the best-value drugs, and pass the savings on to those who lack prescription drug coverage. Allowing the state to shop smarter is a sensible, near-term way for Washington to address the related problems of access and cost. Furthermore, an emerging consensus among states may drive more fundamental policy changes at the federal level.

II. Prescription Drug Spending is Driving Increases in Health Care Costs

Spending on health care in the United States continues to increase rapidly, consuming a greater share of the total economy each year.¹ Health care accounted for over 13% of gross domestic product (GDP) in 2000, making the U.S. health care system the most expensive in the world.² Since 1990, health care expenditures per capita have increased an average of almost 7% per year, for a total increase of 69% over the decade (see Figure 1)³. While this cost growth is driven by a variety of factors, the most marked factor over the past decade has been prescription drug spending.

FIGURE 1: Per capita national health expenditures, 1990-2000



Source: Henry J. Kaiser Family Foundation, Trends and Indicators in the Changing Health Marketplace, 2002, Figure 1.2. Numbers are in nominal dollars.

By every measure, drug costs are outpacing inflation and overall health care spending. While hospital and physician services dwarf prescription drugs in percentage of overall costs, drugs account for a disproportionate share of health spending growth in the last decade.⁴ Increases in nationwide drug spending averaged 12% per year over the past decade.⁵ Washington state, like all states, is realizing that it must balance the medical necessity of prescription drugs with the economic reality of shrinking revenues and dramatically rising costs.

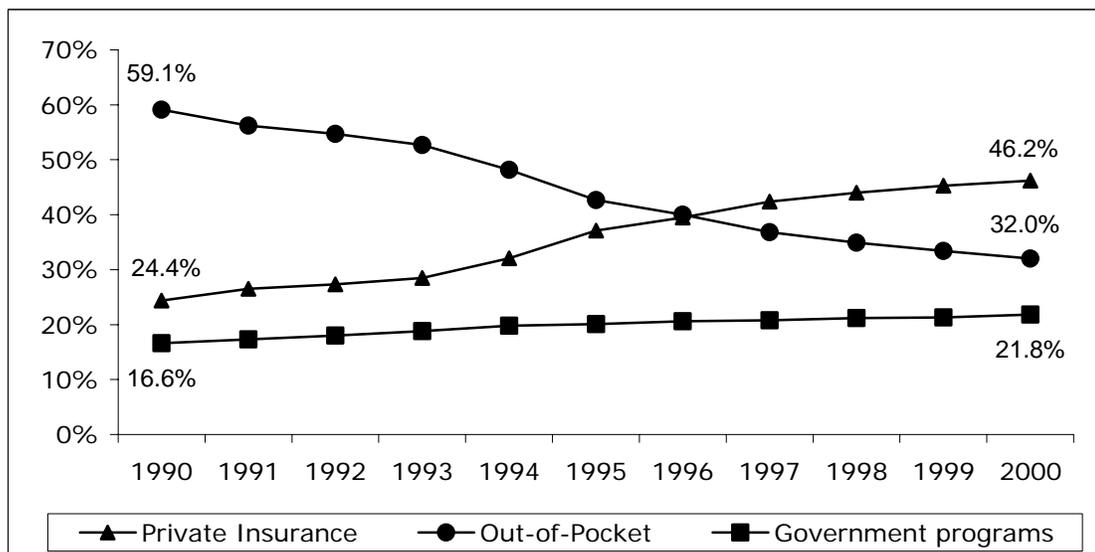
III. Who Pays?

The federal government, state governments, individuals and employers all pay for prescription drugs. Over the past decade, prescription drug spending has been the fastest growing component of health care expenditures both nationwide and in Washington state. Everyone is affected by rising health costs, either directly through out-of-pocket costs or indirectly through higher premium costs and compromised public services. These problems are even more acute in a sluggish economy.

Government

Government-administered programs paid for almost 22% of all prescription drugs sold in the United States in 2001 (see Figure 2), with Medicaid accounting for the lion's share.⁶ The states administer the Medicaid

FIGURE 2: National prescription drug coverage, distribution by payer, 1990-2000



Source: Henry J. Kaiser Family Foundation, Trends and Indicators in the Changing Health Marketplace, 2002.

programs that provide health care, including prescription drug coverage, to low-income, disabled and some elderly residents. (Although very low-income seniors and disabled persons are entitled to federal Medicare benefits, they often also receive services like nursing home care and prescription drug coverage through their state Medicaid program). The federal government regulates and provides partial funding for the Medicaid program, but states must spend their own money to draw the match. Nationwide, state spending on Medicaid jumped 13% in 2001, and now accounts for one-fifth of all state budgets.⁷ Prescription drug costs are driving much of this growth. Since the onset of the recession in 2001, state health budgets are being squeezed even more as the weak economy shrinks the labor force, curtails employer-sponsored health coverage, and boosts the number of uninsured.

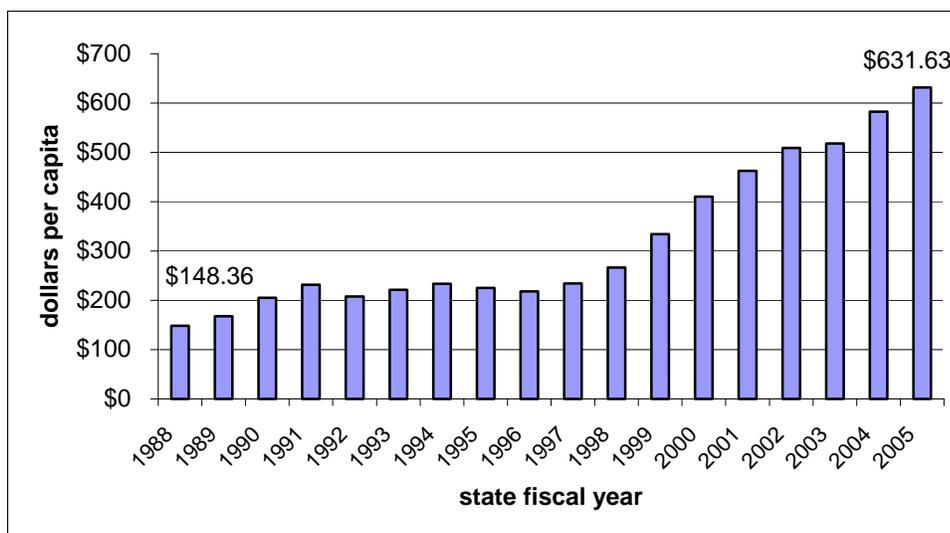
Washington state is no exception. Prescription drug spending per capita for Medicaid has grown at an average of 17% per year over the last 5 years, accounting for 20% of all medical assistance expenditures and drastically outpacing cost increases for any other factor.⁸ Washington's Medicaid program projects drug costs of nearly \$1 billion during the 2003-05 biennium, an amount equal to about one-half of Washington state's projected budget deficit over the same time period.⁹

State governments face a double bind during a recession: state tax revenues decline at the same time that more residents turn to the state for assistance with health care. State governments must either find new revenues, trim costs, or cut existing programs to balance their budgets.

Some states have saved on their drug bills by reducing payment rates to pharmacists. In many places this approach has become untenable, as pharmacists claim that additional payment cuts will force them to go out of business, or at least to drop all Medicaid patients. Indeed, when Washington state officials announced a reduction in the rate Medicaid would pay pharmacists in the summer of 2002, complaints about pharmacies closing their doors to Medicaid clients started making headlines.¹⁰

The growing portion of total spending consumed by health care puts a severe strain on the state's ability to provide other important services to residents. In Washington, the Medical Assistance Administration (MAA), a branch of the Department of Social and Human Services (DSHS), funds medical assistance programs for our state's low-income, elderly and disabled residents. These health programs now consume 41% of the DSHS budget, almost double what they consumed 15 years ago.¹¹ A 160% increase in per capita annual spending on prescription drugs since 1988 (see Figure 3) has led to a 600% increase in dollar costs, threatening to eat up not only health funding, but also funding for the broad range of services provided by DSHS, including

FIGURE 3: Washington state Medical Assistance Administration annual prescription drug spending per capita, 1988-2005



Costs for 2003-2005 are estimated. Source: Department of Social and Health Services, Medical Assistance Administration, Division of Business & Finance.

juvenile rehabilitation, child protective services, assistance for aging and disabled adults, cash and food assistance programs, and alcohol and substance abuse prevention and treatment.¹²

The Uninsured, Including the Elderly

The uninsured must pay for their prescription drugs themselves. While the percentage share of all drug spending that individuals pay out-of-pocket for prescription drugs has dropped steadily, replaced by a private insurance share that nearly doubled in the 1990s (see Figure 3), 32% of prescription drug spending is still out-of-pocket.¹³ Because Medicare, the universal federal health insurance program for the elderly and disabled people, does not include an outpatient prescription drug benefit, many elderly and disabled are counted among the ranks of the uninsured.¹⁴ The elderly are particularly central to the prescription drug debate because they use more prescriptions than any other group, and typically live on fixed incomes. Many seniors purchase drugs using supplemental insurance, but nationwide, almost 40% of the elderly lack any type of prescription drug coverage.¹⁵ Because of the rapid rise in overall drug expenditures, those buying out-of-pocket are paying more each year. Between 2000 and 2001 alone, retail prices for prescription drugs rose 10% or 5 times higher than the rate of inflation.¹⁶

Prescription drug manufacturers charge different buyers different prices for the same drug, which usually leaves the uninsured paying 100% of the retail price or more than any other payer. For example, if the typical retail cost of a 30-pill prescription for a particular drug in the U.S. is \$100:

- An uninsured Washington resident pays \$100 for that prescription;
- Medicaid and large HMOs pay \$65;
- Federally qualified health centers pay \$54;
- The federal government (largely the U.S. Department of Defense and the Veteran’s Administration) pays \$46 or less; and
- A Canadian resident pays \$60.¹⁷

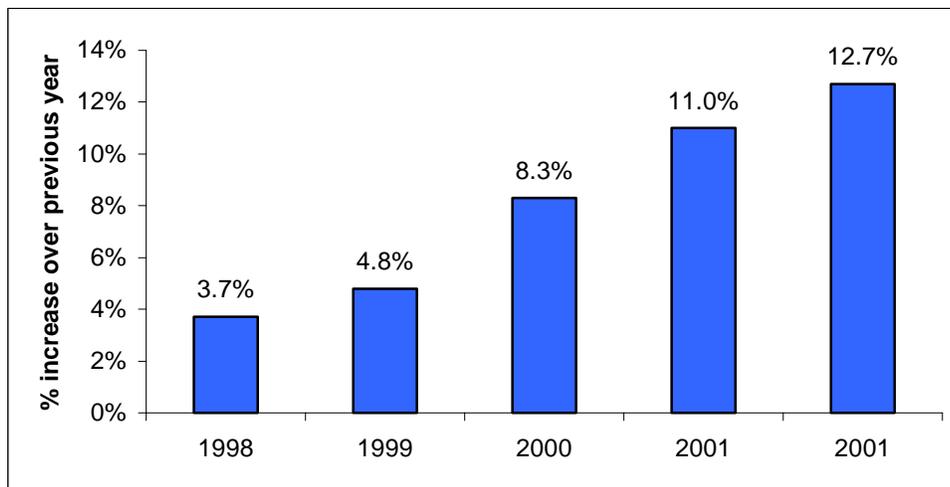
In Washington, there are 644,000 people under age 65 and an estimated 215,000 seniors who lack prescription drug coverage and are subject to the highest retail price for prescription drugs.¹⁸ As state spending on prescription drugs for covered groups goes up, revenue to expand coverage to uninsured residents dwindles.

Indeed, many administrators, advocates and policy makers are anticipating cutting people now eligible for public insurance programs from the rolls in order to balance the budget. For example, the account that funds Washington’s Basic Health Plan – a program for low-income working families living below 200% of the federal poverty level – is projected to run a deficit exceeding \$150 million during the 2001-03 biennium and will almost certainly have to reduce the number of people covered.¹⁹

Employers & Employees

Private insurance offered by both private sector and government employers accounted for 46% of nationwide prescription drug spending in 2001.²⁰ The cost of employer-based health premiums increased 12.7% nationally in 2002, continuing the steady increase over the past five years and marking the highest increase since 1990 (see Figure 4).²¹

FIGURE 4: Nationwide annual health insurance premium increases, all plan types

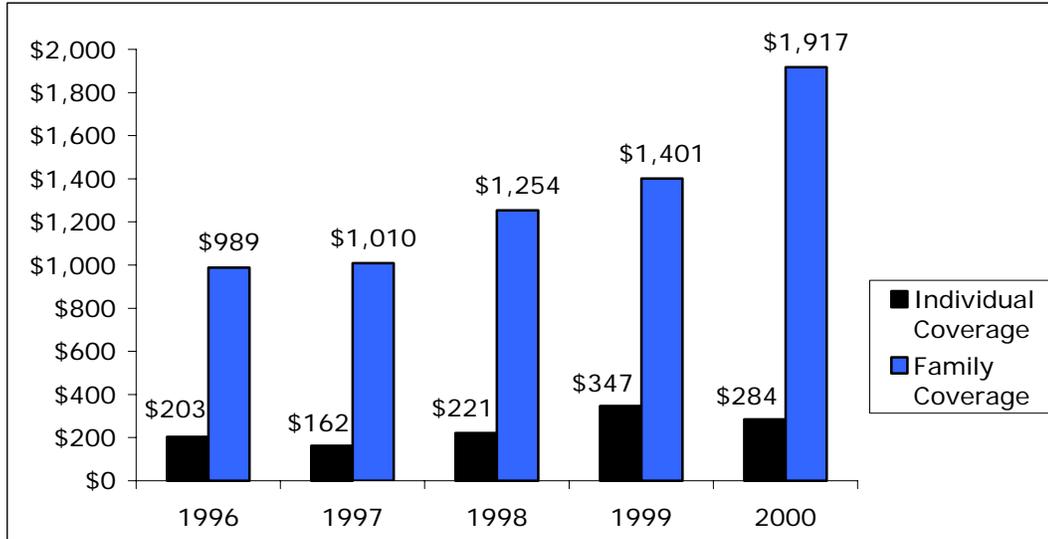


Source: Kaiser Family Foundation and Health Research and Educational Trust, 2002 Annual Employer Health Benefits Survey.

The rising cost of health insurance is leading some employers to discontinue coverage altogether and many more to pass on the increased costs to their employees. Between 1996 and 2000, employee insurance costs in Washington’s private sector have climbed an average of 40% for individual coverage and 94% for family coverage (see Figure 5).²² A recent study by Hewitt Associates estimates that in 2003 employee costs for health insurance will jump another 30%.²³ Cost increases of this magnitude gradually price individuals and

families out of the insurance market, and in the absence of other affordable options, lead to an increase in the number of uninsured.

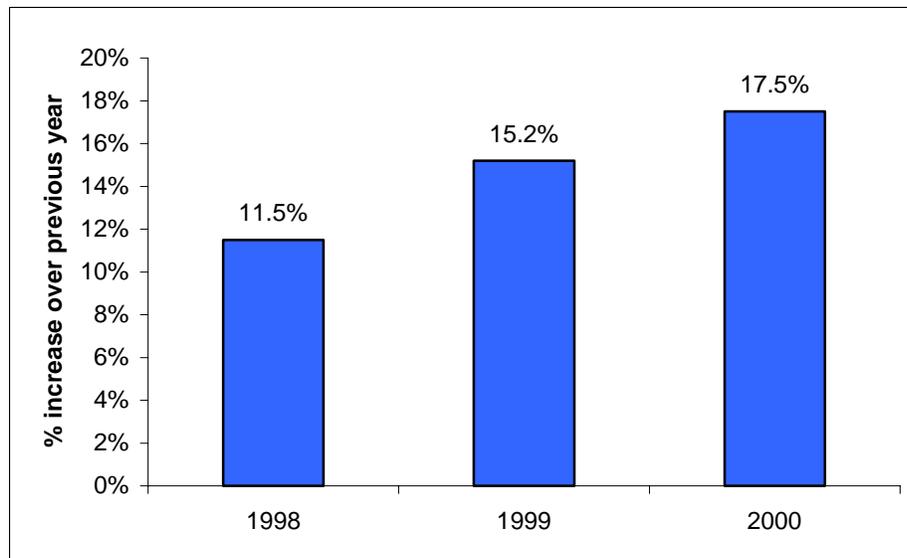
FIGURE 5: Average annual private sector employee contribution for health coverage in Washington, 1996-2000



Private sector employee costs are an average across all firm sizes and are in nominal dollars. Source: Agency for Health Care Research and Quality, Medical Expenditure Panel Survey, Insurance Component Index Tables, http://www.meps.ahrq.gov/Data_Pub/IC_Tables.htm, Tables II.C.2, II.D.2.

The prescription drug component of coverage has outpaced overall cost increases, soaring by 17.5% between 1999 and 2000, and by 44% between 1997 and 2000 (see Figure 6).²⁴

FIGURE 6: Nationwide annual cost increases for the prescription drug component of employer-based health insurance, 1998-2000



Nationwide data for all employers. Source: Patricia Lichiello, Mark Gardner, Amanda Sarata, "Trends in Employer-based Health Insurance in Washington State, University of Washington Health Policy Analysis Program, May 2002.

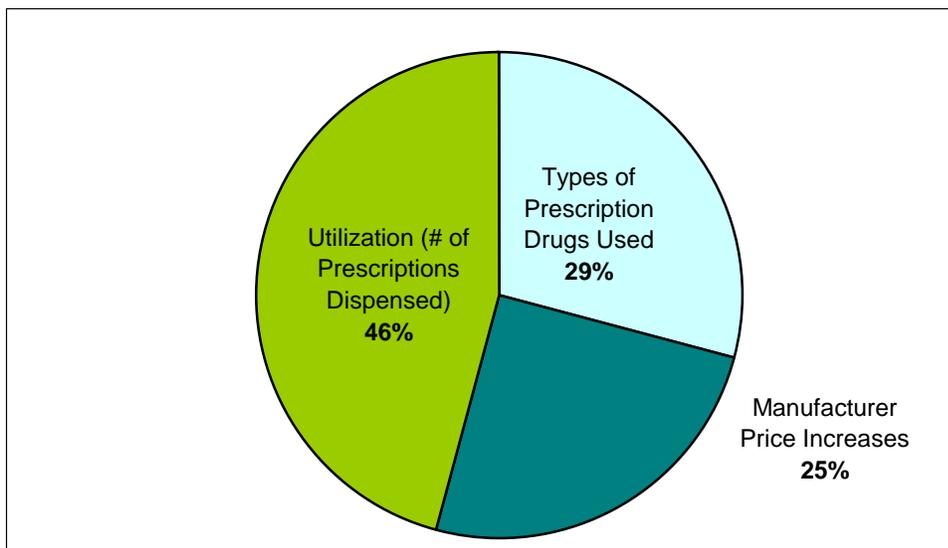
Health plans have increasingly enforced formularies, or restricted lists of drugs that will be covered, to help hold down costs. By 2002, 69% of employees were in a health insurance plan that used a formulary, up from 58% just one year earlier.²⁵ Employers have also raised premiums and instituted cost sharing in an attempt to transfer some of the financial responsibility for health care decisions to employees. By 2002, 56% of employers had instituted three-tier drug co-payments, with one for generic drugs (average co-pay \$9), another for name-brand drugs without a substitute (average co-pay \$17) and a third for name-brand drugs with a generic substitute (average co-pay \$26).²⁶ Both formularies and price-tiering are designed to encourage patients (and physicians, mindful of the patient’s ability to pay) to consider less costly, alternative medications.

IV. Why are we spending more on prescription drugs?

Although some would insist that the rise in prescription spending is due to “price gouging” by the pharmaceutical industry, the problem is more complex. Overall drug *prices* have gone up, and in many cases at more than triple the rate of inflation, but price increases alone do not account for the drastic increase in spending on pharmaceuticals. In fact, more of everything accounts for growth in drug costs: more people, more aging, more prescriptions, more new drugs (with new, high prices), more “diseases,” more advertising. The big three cost drivers, in order, are:

- 1) the average person fills more prescriptions than ever before (increased utilization),
- 2) new classes of drugs arrive on the market in high demand and at high prices, and
- 3) pharmaceutical companies hike prices on existing drugs.

FIGURE 7: Contributors to rising prescription drug spending, 1997-2000



Source: Henry J. Kaiser Family Foundation, Trends and Indicators in the Changing Health Marketplace, 2002.

Increased Utilization

From 1992 to 2000, the number of prescriptions per capita jumped from just over 7 per person to nearly 11,²⁷ with the total number of retail prescriptions topping 3 billion in 2001.²⁸ The boost in retail prescription drug use is consistent with an aging population, new effective drugs, the American appetite for technology in health care, and the ubiquitous advertisements for now-household-name drugs like Claritin, Prilosec, and Prozac.²⁹

Pharmaceutical industry spending on direct-to-consumer (DTC) advertising more than tripled between 1996 and 2000, and prescription rates for the most advertised drugs tracked their advertising budgets quite closely (see Table 1). For example, Prilosec was the second most heavily advertised prescription drug in 2000, at \$108 million, and topped the charts in sales, at over \$4.6 billion.³⁰

TABLE 1: Direct-to-consumer (DTC) advertising, 2000

DTC Spending Rank	Drug	Indication	DTC Advertising (in millions)	Rank in Dollar Sales	Rank in # of prescriptions dispensed
1	Vioxx	Anti-inflammatory	\$160.8	10	20
2	Prilosec	Anti-ulcerant	\$107.9	1	5
3	Claritin	Antihistamine	\$100.3	6	9
4	Paxil	Anti-depressant	\$92.1	8	14
5	Zocor	Cholesterol-lowering	\$91.2	5	17
6	Viagra	Erectile dysfunction	\$89.8	17	45
7	Celebrex	Anti-inflammatory	\$78.8	7	11
8	Flonase	Asthma	\$78.1	23	50
9	Allegra	Antihistamine	\$67.0	13	31
10	Meridia	Weight loss	\$65.0	NA	NA
Total DTC Spending			\$2,467.1		

Note: NA = rank not available. Source: Henry J. Kaiser Family Foundation, "Prescription Drugs: A Chartbook Update," November 2001 and National Institute for Health Care Management, "Prescription Drugs and Mass Media Advertising: 1999-2000," November 2001.

The pharmaceutical industry also markets heavily to physicians. The impact of this is evident in steep increases in the number of prescriptions per office visit. Between 1985 and 1999, physicians increased their prescription rate per 100 visits from 109 to 146.³¹

A significant (and disputed) portion of higher utilization represents a shift in consumer expectations and the way health care is delivered in the United States. The average patient knows and demands more in the doctor-patient relationship now that information about disease states and treatment options is easily located on the Internet. Health care consumers have high hopes about what medical technology and prescription drugs can do for their health and longevity. To some extent, these hopes are driven by major advances in medical technology and drugs. To another extent, these hopes are the outgrowth of more direct access to information through the Internet and a plethora of prescription drug advertising that suggests relief from a full range of natural emotions and experiences, from fear to anxiety to sadness, that are labeled as syndromes and disorders.

There are certainly cases where the use of prescription drugs has been clearly linked to lower future health costs.³² Most medical professionals can agree that prescription drugs hold great potential as a cornerstone of disease management programs. By targeting intensive users of medical services and providing them with evidence-based drug therapies and information to help them better manage their conditions, health care providers can help these patients maintain their health and avoid hospitalization.

However, in the absence of an intentional, well-coordinated system of disease management, there is little research to support the claim made by some that increased prescription drug use indicates smarter, more effective health care.³³ It is still unclear how or why providers are prescribing more drugs, and how prescription drugs impact eventual outcomes. Developing and promoting evidence-based data on cost-effective utilization is a key missing piece in the current debate.

New, High-Priced Drugs

Of the 20 top-selling prescription drugs in 2000, 15 came on the market after 1990 (See Table 2).³⁴ These 15 new arrivals alone accounted for 37% of the increase in prescription drug spending from 1999 to 2000. Four drugs introduced since 1995, Vioxx, Lipitor, Prevacid, and Celebrex, accounted for almost one-fifth of the entire increase in spending in 2000.

These drugs, and many other of the new, costly arrivals, represent medical advances and new treatments for old ailments. Lipitor is part of a new class of cholesterol-lowering drugs with fewer side-effects and greater efficacy for some patients; similarly Vioxx and Celebrex are part of a new generation of anti-inflammatories. But new does not necessarily translate into a good value. The question of medical and economic value is taken up below (See State Solutions section).

TABLE 2: Top-selling prescription drugs as a percent of the total market, and by the year first marketed

Product	Indication	% of Total Market Sales Growth 1999-2000	1999-2000 Sales Growth (in millions)	Sales Rank	Year First Marketed
Vioxx	Anti-inflammatory	5.7%	\$1,147	15	1999
Lipitor	Cholesterol-lowering	5.7%	\$1,145	2	1997
Prevacid	Anti-ulcerant	3.9%	\$790	3	1995
Celebrex	Anti-inflammatory	3.7%	\$745	6	1999
Procrit	Blood cell stimulating factor	3.3%	\$661	10	1991
Glucophage	Anti-diabetic	2.4%	\$492	12	1995
Zocor	Cholesterol-lowering	2.4%	\$484	4	1992
Prilosec	Anti-ulcerant	2.1%	\$433	1	1989
Zyprexa	Anti-psychotic	2.0%	\$410	9	1996
Paxil	Anti-depressant	1.6%	\$328	11	1993
Neurontin	Anti-epileptic	1.6%	\$323	20	1994
Risperdal	Anti-psychotic	1.3%	\$273	18	1994
Zoloft	Anti-depressant	1.2%	\$243	8	1992
Norvasc	Calcium channel blocker	1.1%	\$230	13	1992
Epogen	Blood cell stimulating factor	1.1%	\$219	7	1989
Augmentin	Antibiotic	1.0%	\$196	16	1984
Premarin	Hormone replacement	1.0%	\$193	19	1964
Claritin	Antihistamine	0.8%	\$153	14	1993
Pravachol	Cholesterol-lowering	0.6%	\$130	17	1991
Prozac	Anti-depressant	0.5%	\$94	5	1987

Source: Henry J. Kaiser Family Foundation, "Prescription Drugs: A Chartbook Update," November 2001.

Price Increases and the Pharmaceutical Industry

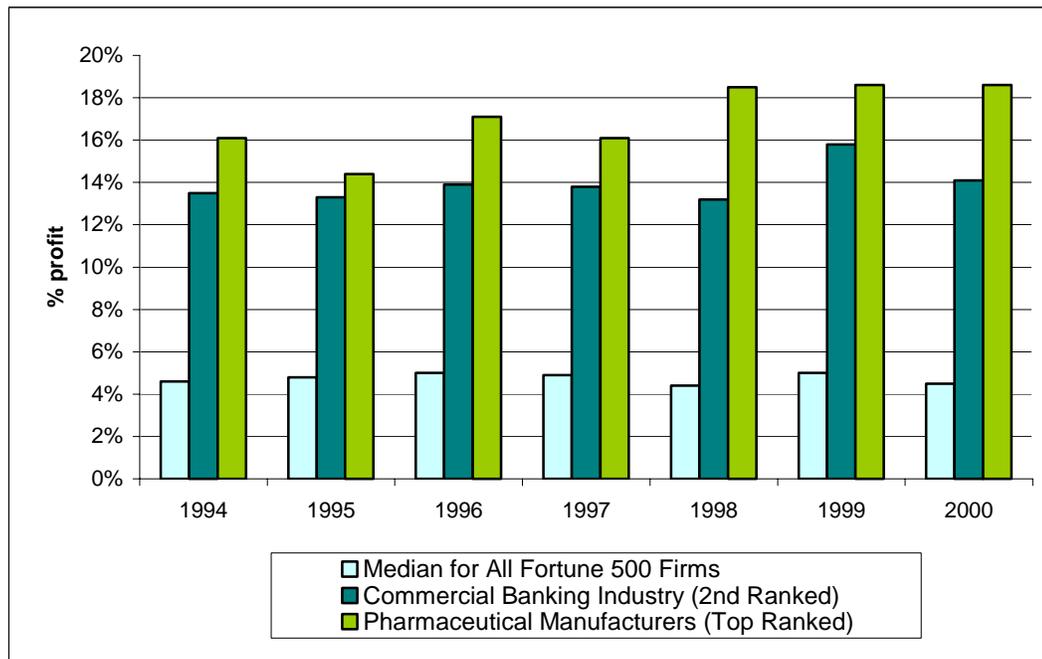
Of all new spending on prescription drugs between 1997 and 2000, over 75 cents of every dollar went to increased utilization and new, high-priced drugs. The remaining 23% of the overall increase was due to

inflation on *existing* drugs. In 2000, prices on existing drugs increased 3.9% while overall inflation was 3.4%, suggesting that price hikes on older drugs, overall, are not excessive.³⁵

However, in some specific cases, price increases do seem excessive, particularly in the case of those drugs where repeated price hikes come just in advance of the loss of patent protection and monopoly profits. For example, in the five years prior to patent expiration for the antihistamine Claritin, Schering-Plough raised its price 13 times, for an overall increase of 28%, over twice the rate of inflation in that five-year period.³⁶

As the most profitable industry in the world (see Figure 8), the pharmaceutical industry has a great stake in increasing drug utilization, developing new drugs, and raising prices on existing drugs. The pharmaceutical industry has argued that cutting the cost of prescription drugs will erode vital research funding, curtail

FIGURE 8: Pharmaceutical manufacturer profits as compared to other industries



Numbers are rounded to the nearest decimal. Source: Henry J. Kaiser Family Foundation, Trends and Indicators in the Changing Health Marketplace, 2002, Figure 4.11.

innovation and delay miracle cures. On the other side, advocates for greater prescription drug access argue that the industry could continue to afford research and development if it would cut spending on direct-to-consumer advertising or consider cutting into its handsome profit margin. The top 10 pharmaceutical companies in 2000 spent 250% more on sales, marketing, and general administration (34% of total revenue) than they did on research and development (13% of total revenue), and finished the year with net profits of 23.6%.³⁷

Furthermore, once a pharmaceutical company develops a blockbuster drug and covers its research, development, capital costs and marketing, it will continue to make an extremely healthy operating profit on the manufacture of drugs. Take the example of a single 500 mg tablet of the antibiotic Cipro, used to fight anthrax and other dangerous bacteria. According to researchers at Boston University, this pill costs the manufacturer, Bayer, between 10 and 20 cents to make.³⁸ Cipro costs an uninsured American almost \$5 per pill, or 25-50 times the production cost. Under the federal government's lowest price "340B" program, public health facilities buy the same drug for about 43 cents per pill, which still nets Bayer at least 100% profit over the production cost.

The basic assumptions in the prescription drug debate are that drugs work and that good health depends on access to affordable, effective pharmaceuticals. But it is crucial to recognize that each component – increased demand, the labeling of new conditions with drugs to match, and higher prices on existing drugs – are central to prescription drug costs and access, even though they may not fit easily or comfortably into policy discussions on the issue.

V. Federal Legislative Proposals

At the national level, Congress is full of sound and fury on the issue, but has failed to pass legislation; the executive branch has taken a hands-off approach, granting the states the flexibility to help themselves. As a result, the states are taking the lead for now in designing innovative policies to reduce manufacturer prices while also expanding access to necessary drugs. While both state and federal government have an important role to play, it is the judicial branch that will have the final say. Court battles will determine the extent of reforms and the viability of alternatives.

Preceding the 2002 midterm elections, Congress took up the issue of prescription drug cost relief for seniors over age 65 in the federal Medicare program. This made eminent political sense and some economic sense. Seniors do at least two things in greater numbers than any other demographic: they take prescription drugs and they vote.

Medicare

That Medicare does not yet pay for prescription drugs reflects three facts. First, at the inception of the Medicare program in 1965, prescription drugs did not play nearly as central a role as they do today. Second, the two parties have continually disagreed on the details of what a Medicare prescription drug benefit would look like. Third, a Medicare drug benefit would be expensive.

Competing federal proposals considered in 2002 differed significantly on two traditional issues: government role and cost. Should the federal government operate the program by contracting to private companies, as Medicare is today, or should private insurers administer it, in competition with one another, with the government's blessing and the government's money? The other issue is related: how much should the government be willing to pay?

The most modest proposal under consideration in the Senate during the summer of 2002 was a bill that would not necessarily help to pay for all drugs but instead would cap out-of-pocket expenses at about 20% of income for all seniors (known as means-tested catastrophic coverage). This reduced benefit would cost more than \$160 billion over seven years. The highest cost proposals, offered by House and Senate Democrats, included universal coverage and generous benefits, and would have cost \$600 billion over seven years.³⁹

The 2002 session closed without any action on prescription drug access for seniors. National priorities may be reflected in the following statistic: over the next decade, just half of the Bush Administration tax cut could have paid for generous prescription drug benefits for every Medicare beneficiary. Instead, all \$1.3 trillion is slated to go back to taxpayers, disproportionately those making over \$500,000 per year.⁴⁰

Generic Drug Legislation

Legislation to make it easier for generic drug alternatives to reach the market by limiting brand-name drug manufacturers' ability to extend their patents through litigation also picked up steam in 2002. While generic drugs have often been met with skepticism, the United States Food and Drug Administration (FDA) states

that a generic drug is “identical, or bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.”⁴¹

The average cost of a generic prescription is about one-third the cost of its brand-name equivalent.⁴² The FDA estimates that generic drugs save consumers using retail pharmacies between \$8 and \$10 billion per year.⁴³ While generic drugs currently make up over 40% of the drug market, they account for only 8% of dollar sales.⁴⁴ Both of these statistics suggest that great potential savings for state and federal government lie in increased use of generic alternatives.

Take the example of brand-name Cipro. While any buyer in the U.S. would pay between 75 cents and \$5 for one pill from the brand-name manufacturer, generic U.S. manufacturers offer prices as low as 43 cents per pill, and sellers abroad offer generic equivalents for as low as 5 cents per pill.⁴⁵ Furthermore, while brand-name drug prices increased at triple the rate of inflation between 2001 and 2002, generic drug prices rose less than inflation.⁴⁶

In order to rein in prescription drug spending and help bring generic drugs to the market sooner, Senators Charles Schumer and John McCain introduced the Greater Access to Affordable Pharmaceuticals Act (GAAP) of 2002 (S. 812). This bill sought to address loopholes in a hallmark piece of drug patent legislation, the Hatch-Waxman Act, which in 1984, extended brand-name drug patent life, made it more difficult for generic manufacturers to use brand-name ingredient data and created a streamlined FDA approval process for generic drugs.⁴⁷ Brand-name drug manufacturers have been exploiting loopholes in Hatch-Waxman to stall competition and keep generic competitors tied up in court. While the Schumer-McCain bill passed the Senate in July 2002, Republican leaders in the House did not bring it to a vote.

This piece of legislation was the main instance in 2002 where federal legislation attempted to address the actual manufacturer price of prescription drugs. Passing generic drug legislation before a Medicare drug benefit makes both political and policy sense to the extent that better generic drug competition lowers the overall cost of a Medicare prescription drug benefit and makes it more appealing to legislators worried about cost. Seniors would get relief from their prescription drug bills sooner with generic drug legislation, and states would also realize cost savings. Those savings could be reinvested in expanded access to necessary medicines for the uninsured.

VI. Solutions in Other States

Double-digit increases in prescription drug costs create two interrelated problems. First, higher prices mean less access for uninsured individuals, and often a difficult choice: to treat or eat? Second, increased drug spending forces governments to face a similar choice: to continue funding drug coverage for the elderly, disabled and others at escalating prices and pay for it by cutting teacher salaries, raising taxes, and underfunding firehouses, or to roll back drug benefits and eligibility for already vulnerable groups? Two problems, but, fortunately, one potential solution – smarter shopping.

The states, which are ultimately responsible for paying for medical services for their low-income, senior and disabled residents, have taken the lead in seeking innovative solutions to prescription drug spending and access. States have been asking: Is the *most expensive* drug medically necessary? Do we really have to pay *this much* for it? Are we getting our money’s worth? In seeking the answer, states are trying out several approaches.

State Pharmacy Assistance Programs

“State Pharmacy Assistance Programs” is a catchall phrase for any state-specific attempt to assist residents in the purchase of prescription drugs. While many programs have begun in the last few years, as states were forced to respond to increasing drug costs, several states have been helping people buy prescription drugs for decades. The flagship state pharmacy assistance program is Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly program (PACE). Long considered the gold standard for states to follow, PACE uses state lottery money to subsidize seniors’ purchase of pharmaceuticals. While PACE is an acknowledged leader, and serves 10,000 Pennsylvania residents, runaway drug costs are now strapping the program and exposing its limits. Flat lottery revenues and an aging population, combined with double-digit increases in drug spending, have left state officials concerned about the viability of the program and the robustness of the benefits it can continue to provide.⁴⁸

The majority of pharmacy assistance programs are not as ambitious as Pennsylvania’s PACE and have never claimed to be the solution for strapped seniors and others without drug coverage. Most efforts are limited to the very poor aged and feature restrictive formularies. The new Illinois drug assistance program, for example, covers a limited set of drug classes for about 365,000 low-income, elderly Medicare beneficiaries.

Direct benefit programs. At present, 34 states offer or intend to offer pharmacy assistance outside of Medicaid.⁴⁹ Most of these programs are *direct benefit* programs: the state pays the full price of the drug for residents who meet restrictive income and asset qualifications but a small co-payment is required from the consumer. Participation and benefits are limited.

Discounts. Some states make *discounts* available to qualified residents. These discounts reduce the price the customer pays, typically by 10-15%, but the state does not subsidize these purchases; either the pharmacies or the pharmaceutical companies make up the difference. States favor discounts because they offer some price relief to uninsured residents at no cost to the state.⁵⁰ While discount programs usually apply to a wider variety of drug classes and to a larger segment of the population than do direct-benefit programs, many low-income residents remain unable to afford even the discounted price.

Rebates resemble discounts: the customer pays a discounted price, courtesy of the pharmacy, but the state reimburses the pharmacy for that discount using rebates it collects from pharmaceutical manufacturers following the sale.

Medicaid

Unlike the Medicare program for seniors, Medicaid, the federal/state program for low-income people, includes a prescription drug benefit. Rebates are the key to this benefit. It is through Medicaid, primarily, that the states are attempting to ease increases in prescription drug expenditures and provide price relief to low-income residents. Federal law requires pharmaceutical companies to pay rebates to the states if they want their products to be covered by Medicaid. In return, the states agree to cover all drugs for which rebates have been negotiated.

Passed in 1990, the Omnibus Budget Reconciliation Act (OBRA) mandated that manufacturers sell to state Medicaid programs at the very best price available to *any purchaser*. Unfortunately, instead of lowering prices to Medicaid programs across the country to meet existing best prices, the pharmaceutical companies reacted by raising the lowest prices available to federal agencies like the Veterans’ Administration (VA). Two years later, Congress addressed this disincentive to lower prices by removing certain groups from the best price calculation; these ‘best price exemptions’ applied to the VA, the Department of Defense (DOD), the Coast Guard, and the Public Health Service at the federal level, and importantly, to state pharmacy assistance programs. These exemptions for the groups that previously enjoyed the lowest drug prices allowed

them to exercise their leverage independently of Medicaid programs, which freed the pharmaceutical industry to negotiate with Medicaid separately.

Currently, states receive approximately 15% off the retail price of prescription drugs in the form of after-sale rebates. Medicaid recipients pay much less than 85% of the retail price out-of-pocket; they either pay nothing or a small co-payment.⁵¹ The states make up the difference. In the last two years, several states have sought to manipulate this arrangement for two purposes: cost containment and increased access.

Illinois has extended its Medicaid prescription drug benefit to low-income seniors who otherwise would not qualify for state assistance and the Bush administration has endorsed the plan. Secretary of DHHS Tommy Thompson has approved a waiver, or rule change, that allows Illinois to use Medicaid money, including federal matching funds, to cover seniors with incomes up to 200% of the federal poverty level (FPL), which is \$17,720 in income per year for individuals and \$23,880 per year for couples. Given that eligibility for full Medicaid in Illinois is limited to residents living well under 100% of poverty, this represents a significant expansion.

Extending benefits to non-Medicaid seniors increases access, but does not necessarily save the state money. As a condition of the waiver, the federal government *will not provide any additional money* to cover the new beneficiaries. This condition, known as budget neutrality, requires the state to cover more people with the amount of money it would have spent in the absence of the waiver.

Illinois uses the following assumptions to meet this condition: Those seniors up to 200% of the FPL will, under the new program, be able to afford prescription drugs that will keep them well, keep them out of the hospital, and, ultimately, prevent them from spending so much on health care that they qualify for full Medicaid, which would cost the state far more per person than the additional prescription drug benefit alone.

Because the long-term cost savings resulting from preventive care are not necessarily quick to materialize, Illinois will be an experiment in determining if prescription drug coverage can result in enough immediate direct savings to the state to offset the additional costs. Illinois and the other states that receive this type of waiver are betting on immediate savings. If costs exceed projections, the financial burden will rest solely with the state.

Florida and Michigan have modified their Medicaid programs to reduce drug prices, with the primary goal of saving the state money. These two states, among many, are also applying for the Pharmacy Plus (Illinois) waiver to extend access to more low-income seniors, but their other efforts to reduce state spending on drugs have landed them in court.

As noted above, federal law requires state Medicaid programs to cover all drugs where the manufacturers have entered into rebate agreements with the federal government. Florida and Michigan created preferred drug lists to induce pharmaceutical companies to offer rebates beyond the standard Medicaid rebate. The preferred designation, conferred upon drugs with supplemental rebates, means that the drug may be prescribed by physicians without prior authorization by the state; non-preferred status requires prior authorization. The added step of obtaining authorization dissuades time-strapped physicians from prescribing non-preferred drugs, and the dissuasion works. Drugs that did not make the list in these states have seen market share drop significantly. For example, Merck's cholesterol drug Zocor did not make the list in Michigan, and subsequently lost over half its market share.⁵²

Maine passed a law in 2000 that required pharmaceutical companies to give rebates beyond the standard Medicaid rebate in exchange for having their products included on a preferred drug list. Under this new experiment, known as MaineRx, the state would use that additional rebate money to fund drug coverage for

all residents who lack drug coverage, not just seniors. If the industry did not negotiate sufficient rebates, in the eyes of the state, the law directed the Maine Medicaid commissioner to negotiate price ceilings.

The Pharmaceutical Research and Manufacturers of America (PhRMA), the powerful lobbying arm of the pharmaceutical industry, successfully sued the state of Maine in U.S. District Court, winning a preliminary injunction against the MaineRx program on constitutional grounds. The program, the judge concluded, was preempted by federal Medicaid law – the state could not force companies to grant rebates for the sole purpose of funding non-Medicaid drug benefits – and violated the Commerce clause of the U.S. Constitution. By seeking to control prices, the judge ruled, the state was unconstitutionally interfering with interstate commerce.

The decision was reversed on appeal, with the U.S. Circuit Court of Appeals concluding that providing drug benefits for needy residents was indeed consistent with the purpose of the federal Medicaid statutes, and that the benefit provided to Maine residents outweighed the minimal effects on interstate commerce. PhRMA appealed the reversal, and the U.S. Supreme Court will hear arguments sometime before spring 2003. The Court's decision will determine the latitude that states – including Washington – have in the regulation of drug prices and extending drug coverage to residents.

Oregon is banking on the theory that cooperation between physicians and state government will be more sustainable in lowering Medicaid costs than coercion through a strict drug list. Passed during the 2001 legislative session despite heavy pharmaceutical industry lobbying, Oregon's "Practitioner-Managed Prescription Drug Program" relies on voluntary compliance from healthcare providers to move market share from expensive drugs to more cost-effective equivalents, as opposed to imposing a prior authorization process or price ceilings.

Oregon is focusing on twelve classes of drugs which it has broken up into three phases for evaluation based on clinical effectiveness and cost.⁵³ The first phase of the evaluation has been completed and the results of the study have been made public. Drugs found to be the most cost-effective in the first four classes have been added to a preferred drug list. By early 2003 the list will encompass all twelve classes. Oregon hopes it can counter direct-to-consumer advertising with objective, evidence-based information that will be available to state residents and providers. Providers will have the final say in what to prescribe, but Oregon is hoping that armed with a sort of prescription drug "*Consumer's Report*," they will help doctors, patients, and the state shop smarter.⁵⁴

VII. Washington State Solutions

Just as in all states, prescription drug spending in Washington is compromising the sustainability of state health care programs at the same time that demand for these programs is growing. Washington has tested a variety of approaches to reduce costs over the past five years.

AWARDS Program

In September 2000, Governor Gary Locke issued an executive order to implement the AWARDS (Alliance to Reduce Prescription Drug Spending) Program. Under this program, Washington residents age 55 and up who joined a buyers club would be entitled to the same discounts as those already negotiated with almost 900 pharmacies for state employees. But in this case, the discount would have come from pharmacists, not manufacturers or through state subsidies. The program launched in January 2001 but dissolved not long after due to a state court decision that the program could not be implemented without legislative approval.

Therapeutic Consultation Service

The Therapeutic Consultation Service (TCS) was implemented by the Department of Social and Health Services in 2002 to educate doctors about cheaper alternatives to brand-name drugs. TCS identifies Medicaid patients who submit more than four brand-name drug prescriptions in one calendar month. At the pharmacy, the fifth monthly prescription for these patients is flagged and pharmacists are prompted to contact the prescribing physician. Physicians must then contact a pharmacy benefits manager who explains cheaper alternatives and drug interactions, and in the absence of agreement on alternatives, has the authority to grant authorization for brand-name requests. In an emergency, pharmacists are allowed to prescribe a 72-hour supply of the fifth brand-name drug, but since they are not guaranteed payment if the physician's prior authorization request is denied, there are anecdotal reports that pharmacists are hesitant to do this.

Washington's program is based on a similar, more established program in Florida where the lengthy approval process has changed doctors prescribing habits and resulted in first-year savings of \$252 million. According to the Pharmacy Benefits Manager of the Florida Medicaid program, 70% of physicians who receive a call from a pharmacist notifying them of the need to seek prior approval choose to prescribe a generic alternate. The other 30% choose to appeal and are almost without exception granted authorization for their brand-name request.⁵⁵

Prescription Drug Education and Utilization System

Most recently, Washington has followed the example of Oregon, Maine, Vermont, Florida and Michigan, in considering administrative, legislative, and market-based solutions to the drug spending problem. The most prominent effort in Washington tackles the dual issues of fiscal relief and patient access to medicines. Senate Bill (SB) 6368, proposed in the 2002 legislative session, would have created a comprehensive system for the state purchase of prescription drugs and reportedly relieved physicians of any prior authorization requirement. The bill garnered broad support from the advocacy, medical and pharmacy communities, and a similar measure will be reintroduced in 2003.

The key features of the system proposed in SB6368 were:

- Establishment of a Pharmacy and Therapeutics Committee. This committee would evaluate prescription drugs within each therapeutic class based on safety, efficacy and outcomes in all populations. Once "best in class" or reference drugs were identified, the committee would develop a preferred drug list comprising the drugs that show the best combination of medical efficacy and cost. Anti-psychotics, chemotherapy drugs, anti-retroviral drugs, immuno-suppressants, hypoglycemia rescue agents and drugs that are alone in their class were exempted from the 2002 legislation.
- Utilization of a Preferred Drug List. Providers who have agreements with any state-purchased health programs would be asked to endorse the preferred drug list. Those that did not endorse would simply remain subject to the current Therapeutic Consultation Service prior authorization process. Providers who endorsed would agree to use the preferred drug list, but would be given the authority to request that pharmacists "dispense as written" on non-preferred drug list prescriptions. There would be no prior authorization process for off-list drugs.
- Directive to Pharmacists. Pharmacists would be directed to automatically substitute reference drugs from the preferred list in any therapeutic category for brand-name drugs unless an endorsing provider has written "dispense as written".
- Establishment of a Purchasing Pool. Led by the Health Care Authority, the state agencies that buy drugs for Medicaid, the Basic Health Plan, UMP-PEBB (public employees), the Department of Corrections and L&I would streamline their purchasing to leverage buying power and increase efficiency. Within one year of the drug list's adoption, units of local government, private entities and

individuals who lack prescription drug coverage would be able to join the pool and access the same discounts at the pharmacy.

- Negotiation of Market Rebates. The Health Care Authority administrator would use the list to negotiate price discounts for this purchasing pool directly with drug manufacturers.
- Review of Utilization. To complement this program, an electronic tracking system would be developed that would identify those prescribers who write “prescribe as written” more frequently than most, and to ensure efficient, effective prescription drug usage. This system would be used to develop a strategy to educate providers about the preferred drug list and cost-effective therapeutic equivalents.

How much could Washington save?

The fiscal note for Senate Bill 6368 estimated 2004 savings of around \$30 million.⁵⁶ However, these estimates do not account for the savings that would accrue over time as more people gained access to necessary medicines or maintained their health insurance and sought preventive care that kept them out of the emergency room. Based on early reports from other states, actual near-term savings may be even higher.

Washington’s proposed program follows the standard practice of private insurers in steering prescriptions toward effective, lowest-cost drugs. It is similar to Maine’s in that it combines a drug list to leverage manufacturer discounts with a plan to increase access for the uninsured. However, it is in a crucial way more like Oregon’s practitioner-managed prescription drug program: it allows providers to prescribe off a preferred drug list without prior authorization. Time will tell which, if either, of these approaches is more successful and sustainable in containing costs.

Thus far, early financial returns on programs using prior authorization are impressive. Michigan merits its preferred drug list with \$800,000 in state savings per week, or an estimated \$50 million per year.⁵⁷ In just four months after Vermont instituted a list for three especially costly classes of drugs, the state saved \$1.7 million, or about 25% over the previous year.⁵⁸

It is unclear whether a program that hinges on voluntary compliance from providers can result in more savings. Early returns from one of the first drug classes evaluated under Oregon’s new drug program – proton pump inhibitors – show the number of prescriptions for non-preferred Prilosec and Nexium prescriptions down 37% and 28% respectively, while prescriptions for preferred drug Protonix are up 21%.⁵⁹ Actual dollar savings have not yet been calculated.

One difference between the two approaches has been highlighted by patients and their advocates. They are concerned that strict prior authorization rules are preventing effective medications from getting to the people who need them. Thus far, the evidence is mostly anecdotal and it is difficult to quantify in these early stages. But voluntary compliance programs, where provider decisions are given primacy over a preferred drug list, will likely prove more appealing to patients, their advocates and providers.

What’s ahead for Washington?

Each of the elements of Washington’s 2002 prescription drug-pricing proposal is in place in other states. Implementation of these reforms in Washington depends on at least two factors.

First, a new bill has to be introduced and passed by the legislature in 2003. Proponents of prescription drug pricing reform expect heavy opposition from the pharmaceutical industry in 2003. In 2002, the pharmaceutical industry argued that certain ethnic populations would lack access to name-brand drugs, compromising health, and that investor capital for Washington’s biotech companies would dry up in the face of fair-pricing negotiations.⁶⁰ However, these claims appear largely unfounded. PhRMA, the industry’s trade

association, hired a public relations firm to pose as a grassroots group that safeguards prescription drug consumers, following a practice in other states.⁶¹ The pharmaceutical industry has also worked the more traditional lobbying angle, spending \$1 million and deploying one lobbyist to Olympia for every five legislators in 2002.⁶²

Second, and perhaps more crucially for the prospects of long-run reform, the courts must affirm the constitutionality of these state efforts. By the spring of 2003, the United States Supreme Court and at least one federal district court will rule on the legality of preferred drug lists and the pricing negotiations for Medicaid predicated on those lists.

VIII. Conclusion

Prescription drug spending has outpaced all other health spending over the past decade, and has had a profound impact on the entire spectrum of health care purchasers, including uninsured individuals, employers, employees, and government. Increased spending by states, employers and individuals is driven by increased utilization, the continual advent of new, high-priced drugs, and price hikes on existing drugs. Mired in economic recession and faced with growing need for public assistance, states have been forced to look for ways to address prescription drug spending.

While the federal government has a crucial role to play in adding a prescription drug benefit to Medicare and easing the way for cheaper generic drugs, the states have taken the lead in bringing drug cost and access issues to the top of the public agenda. If legislation in 2003 is successful, Washington will join the growing ranks of states that are attempting to realize cost savings, and contribute to an emerging consensus that may drive policy changes at the federal level.

Providing Washington state government with the tools to become a smarter shopper is a sensible, near-term way for Washington to address the related problems of access and cost. Only by evaluating the benefits and costs of various and competing prescription drugs can Washington state ensure that taxpayers and patients are getting quality outcomes in return for each dollar. By demanding that better health *outcomes*, not new health *products*, are the focus, the state can insure more effective, cost-efficient care. State government has a responsibility to prioritize spending, strive for efficiency and protect the interests of Washington residents. By acknowledging that spending more efficiently and saving money are as important as raising new revenue, policy makers may build a more popular platform for state government's role in the provision of health care.

Developing this popular platform is more important than ever. A much larger crisis, of which prescription drug spending is just one component, looms before the states and the nation. Dramatically rising health care costs and the persistently high rate of uninsured children, individuals and families suggest that our current health care system may be heading for implosion. While shopping smarter for prescription drugs makes good fiscal and policy sense in the absence of a much more dramatic reorganization of our nation's health insurance system, states will still face large budget deficits, the number of uninsured will continue to rise, and taxpayers and health care purchasers will continue to face double-digit cost increases.

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⁵⁷ Gold and Hensley. See also, Michigan Department of Community Health Power Point presentation, “Michigan’s Pharmaceutical Best Practices Initiative,” October 2002, <http://www.oregonrx.org/OrgrxPDF/Governor's%20Conference%20presentations%20PDF/PharmacyInitiative-%20Oregon%20October%202002%20as%20of%2010.3.02.pdf>.

⁵⁸ Ron Winslow, Laurie McGinley and Chris Adams, “States, Insurers Find Prescriptions for High Drug Costs,” *Wall Street Journal*, September 11, 2002.

⁵⁹ Kitzhaber.

⁶⁰ To address racial disparity concerns, the pharmacy and therapeutics committee established under SB6368 would give “consideration to the needs and characteristics of populations, including racial and ethnic minorities, served by state purchased health care programs” [Sec 3 (e)] in their evaluation of the benefits, risks and potential outcomes for patients. At least one of the four physicians on the pharmacy and therapeutics committee “must have significant experience in serving racial and ethnic minorities” [Sec 5 (2a)]. For more information on the biotech issue, see Rebecca Kavoussi, “What’s Good for Washington: Fair Prescription Drug Pricing and the Biotechnology Industry,” December 2002, www.eoionline.org.

⁶¹ The industry is now facing an ethics investigation called for by the Maryland Citizen’s Health Initiative, a legitimate consumer advocacy organization. See Winthrop Quigley, “Drug Bill Foes Come Forward,” *Albuquerque Journal*, February 28, 2002, <http://www.abqjournal.com/news/xgr/612171news02-28-02.htm>; Center for Policy Alternatives newsletter, Spring 2002, <http://www.cfpa.org/alternatives/altbody2.cfm?volume=10.2&artnumber=4>.

⁶² Luke Timmerman, “Prescription plan becomes a racial issue,” *Seattle Times*, February 27, 2002, <http://archives.seattletimes.nwsourc.com/cgi-bin/taxis.cgi/web/vortex/display?slug=drughearing270&date=20020227>.