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by James Carroll

The rapid rise of prescription drug costs in the United States has triggered heated debate at the federal and state levels about how to control costs and expand access for those in need. In part, the United States finds itself in this situation because, unlike most countries throughout the world, the federal government, thus far, has refused to exact federal price restrictions on pharmaceutical products. James Carroll argues that this has left each state in the difficult position of trying to leverage lower costs and expanded access for its citizens. In this article, Carroll provides an overview of these attempts, including the Maine Rx program and the more recent legislation passed by Maine's 121st legislature. He concludes with an analysis of how effective such programs are likely to be in the long run, particularly if the federal government continues to abdicate on its responsibility to address the issue in comprehensive fashion.

INTRODUCTION

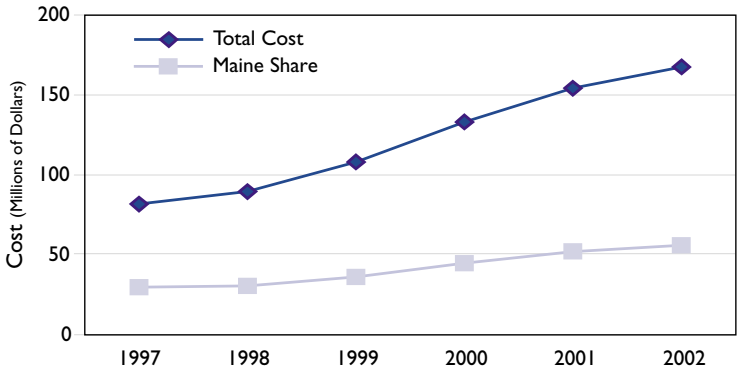
The explosive growth in both the use and costs of pharmaceutical products over the past 20 years is a major cause for public concern. The United States stands almost alone among countries in not having federal-level price restrictions on pharmaceuticals. Over time, the relationship between the pharmaceutical industry and government, at both the federal and state levels, has changed dramatically. In the past 30 years, the federal government's role has shifted from serving primarily as a regulatory body, providing guidance on what and how pharmaceutical products could be sold, toward acting as the largest purchaser of pharmaceutical products. Recently, the lack of meaningful federal price regulations is leading to a transformation in the relationship between state governments and the pharmaceutical industry, as states on their own increasingly attempt to do what the federal government has not—to control pharmaceutical costs and to expand consumer access.

Explanations for the greatly increased spending on pharmaceutical products since the 1980s are complex. The key reasons include: *cost-increase issues* (especially monopoly pricing for pharmaceuticals under patent, and increased costs for new products that have been developed), and *issues related to increased volume of usage of pharmaceutical products* (especially the change from treating acute diseases to chronic diseases and the transition of people from older products to newer ones). The trend toward increased spending for prescription drugs has combined with a movement to shift Medicaid costs toward state governments. This combination has heightened the focus on the financial burden states face for pharmaceutical products. For example, Figure 1 shows the increasing costs for prescription drug coverage under the state's MaineCare program. On the individual level, the costs of pharmaceutical products have become so prohibitive, they are not a viable option for most citizens without insurance plans that provide some coverage for prescription drugs.

Some spending-increase factors are largely beyond the scope of either federal or state governments to readily control. Others, however, are receiving attention by federal and state governments as they attempt to limit cost escalation and to improve citizens' access to prescription medications. The means by which the states and federal government are pursuing this agenda are somewhat varied, but clearly a number of states are acting as the policy laboratories. Maine is acknowledged as one of the leaders in seeking and developing new approaches to prescription drug policy questions.

This paper is designed to provide an overview and broad analysis of some of the policy ideas being proposed or implemented at the state level, both across the nation and in Maine, to deal with prescription drug costs. This paper also will provide a brief overview of the pharmaceutical industry and a discussion about some of the market forces that are being exploited for possible cost savings in the more recent legislation. Of particular interest is the emerging shift from a focus on direct cost reduction toward regulating the market in ways that change market behavior, and, as a result, lower costs.

FIGURE 1: **Change in Cost of Prescription Drugs in Maine, 1997-2002**



Source: Maine Department of Human Services, Bureau of Medical Services. "Annual Report to the State Legislature for MaineCare." (2002): 8

THE GROWING IMPORTANCE OF PHARMACEUTICAL PRODUCTS

In an earlier article in *Maine Policy Review,* Dora Anne Mills documented the transition from a focus on treating infectious diseases to the current focus on treating chronic disease (2000). That transition, which

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is discussed less frequently than the other causes for the high cost of prescription drugs, has substantially supported the explosive growth in pharmaceutical product use and costs.

During the 1980s and 1990s, the pharmaceutical industry developed and launched products that provide the ability to treat people with many symptoms associated with chronic diseases. For example, products known as beta-blockers and ace-inhibitors provided the first highly effective means to treat hypertension. There is substantial evidence that over the past 15 years, products such as these have contributed significantly to a higher quality of life for millions of people. However, taking medications for chronic disease for many people requires a lifelong consumption of these products to maintain that quality of life. For some products such as the ace-inhibitors, there are claims and some evidence that the cost of the medication is actually lower than the costs that would have been experienced without the medication, due to what would have been an increase in hospital use and critical care. However, such studies can be notoriously difficult to assess since they frequently discuss treatment costs as though end-of-life care and deaths were actually avoided, which is clearly not realistic. It is more accurate to note that the medications can delay the substantial costs related to end-of-life care and treatment.

Ultimately, the negative side of the dramatic growth in pharmaceutical use has been the increased costs for the payers: consumers, insurance companies, and the government. The positive side is two-fold: (1) millions of people have improved health and well-being, and (2) the pharmaceutical industry has been one of the most successful sectors of the United States economy over the past 20 years.

THE PHARMACEUTICAL INDUSTRY AND ITS RELATIONSHIP WITH GOVERNMENT

Slowing the rapid growth of prescription drug costs has become a crucial policy issue facing all sectors of the United States health care system, including insurance companies, providers, consumers, and state and federal governments. In order to evaluate and implement various policy alternatives, it is important to have some understanding both of the role of the federal government *vis à vis* the pharmaceutical industry and of the way the pharmaceutical industry itself operates.

Role of the Federal Government

Historically, the federal government was involved in regulating the pharmaceutical industry to ensure safety via the Food and Drug Administration (FDA). From the 1960s through the 1980s, the federal role in the overall health care system began to change, largely because of the creation of Medicare and Medicaid. The establishment of these programs led the federal government to become the single largest purchaser of health care in the United States. When Medicare was initially implemented, pharmaceutical costs were not substantial compared to the cost of hospitalization. There also were disagreements between industry lobbyists and lawmakers on the importance of including a pharmaceutical benefit in the program. Therefore, a prescription drug benefit was not included in Medicare. During this period, the government retained a role that was focused on regulation and encouragement of the growth of the pharmaceutical industry.

During the 1980s and early 1990s, the federal government began experiencing substantial costs for pharmaceutical products, through the Medicare hospital pharmaceutical benefit and the Medicaid and Veterans Administration programs in particular. It has reached the level where pharmaceutical costs are a substantial part of the government's health care costs. With the emergence of cost as an issue for the federal government, a change in the federal government's relationship to the pharmaceutical companies began to emerge in the 1990s. From being a pharmaceutical industry regulator, the federal government increasingly became a purchaser, similar to its role in relation to other health care providers.

Achieving a balance between managing spending and encouraging economic growth and public health continues to hamper the development of a Medicare prescription drug benefit. Trying to strike this balance seems to have essentially paralyzed the federal government in developing legislation that clearly delineates the pharmaceutical market and the role of the government as a purchaser. It is important to keep in mind that the federal government, because of its size as a purchaser and its simultaneous role as the key regulator of industry, has a unique leverage when setting policy in dealing with the pharmaceutical industry. However, unlike most countries throughout the world, the United States government has not used this leverage to exact price restrictions on pharmaceuticals.

State governments are not in a position to provide the kind of encompassing answer to the question of improved access and cost containment that the federal government could impose, nor do state governments have the leverage in imposing laws that the federal government has. However, with the lack of any direction emerging from the federal government to deal with the costs and access issues that have emerged, state governments have begun developing policies that try to manage costs in their own states. Because the vast majority of states do not feel any substantial economic benefit from the boom of the pharmaceutical industry, they have fewer incentives than the federal government to protect the industry, and thus are perhaps more willing to attempt policy alternatives the federal government has hesitated to propose.

The changing focus of federal policy for pharmaceuticals and the emergence of state-by-state legislation aimed at limiting pharmaceutical costs have huge implications with regard to regulating the behavior of pharmaceutical companies. As more market-based legislation is introduced at the state level, it is useful to understand how the pharmaceutical industry actually functions.

Overview of the Pharmaceutical Industry

The perception and reality of what pharmaceutical companies do has evolved substantially over the past 20 years. In the past, the large pharmaceutical companies focused on doing research to develop useful and occasionally dramatic new products. Indeed, this is the image that the trade association, PhRMA (Pharmaceutical Research and Manufacturers Association), continues to promote. However, marketing has now gained increased importance in the pharmaceutical industry. Indeed, consumer advocacy lobbying groups such as Families USA and Public Citizen expend a substantial effort to point out that the PhRMA companies spend more money marketing their products than they do on researching and developing new products.

The debate about how PhRMA companies divide their investments between marketing on the one hand or research and development on the other should be simple. However, the numbers that are used in the debate can be elusive. A substantial portion of all product development is now actually done outside of the PhRMA companies. Almost an entire industry exists of small research-based companies focused on the earliest phases of pharmaceutical product development. As an estimate, nearly 50% of all pharmaceutical research is now done outside of the PhRMA companies. However, the PhRMA companies, through a wide variety of investments, ultimately pay for much of the successful research. Because of this evolution in the way the industry operates, obtaining a simple number of how much the large companies invest in research can be difficult. This leads to the wide variations that can be seen in the numbers quoted by Families USA, which tries to minimize the amount that these companies spend on research, as opposed to the numbers quoted on the PhRMA Web site, which tries to maximize the amount that companies spend on research. Similarly, clearly identifying how much money is spent on marketing can be difficult, since a substantial portion of what Public Citizen would call "marketing," PhRMA might call "physician education."

It is clear that the importance of marketing for pharmaceutical products has grown dramatically over the past decade. Perhaps a simple way to observe this growth is to examine the number of people in the United States who now have a job "detailing" pharmaceutical products for prescribers. Detailing is essentially visiting prescribers, dropping off samples of various branded products, and seeking an opportunity to

explain the clinical benefits of the two or three products the detail representative is marketing. In the early 1990s, there were nearly 40,000 people detailing pharmaceutical products; today, there are over 100,000 people. It is safe to assume that the number of researchers within PhRMA companies has not witnessed a similar increase of at least 250% over the past decade.

Marketing pharmaceutical products is something that is done almost completely within the PhRMA companies. Large companies have shifted from an internal focus on research to an internal focus on marketing in support of combined internal and external research. This shift in strategy has had a huge impact on both the perception and the reality of these companies. It seems undeniable that the PhRMA companies are probably the most competent product-marketing group in the world, especially in regard to technical marketing. That knowledge and focus has coincided with PhRMA becoming recognized as the single most important and effective governmental lobbying body in the United States. As has been noted by Public Citizen and other groups, PhRMA retains more lobbyists than there are members of Congress.

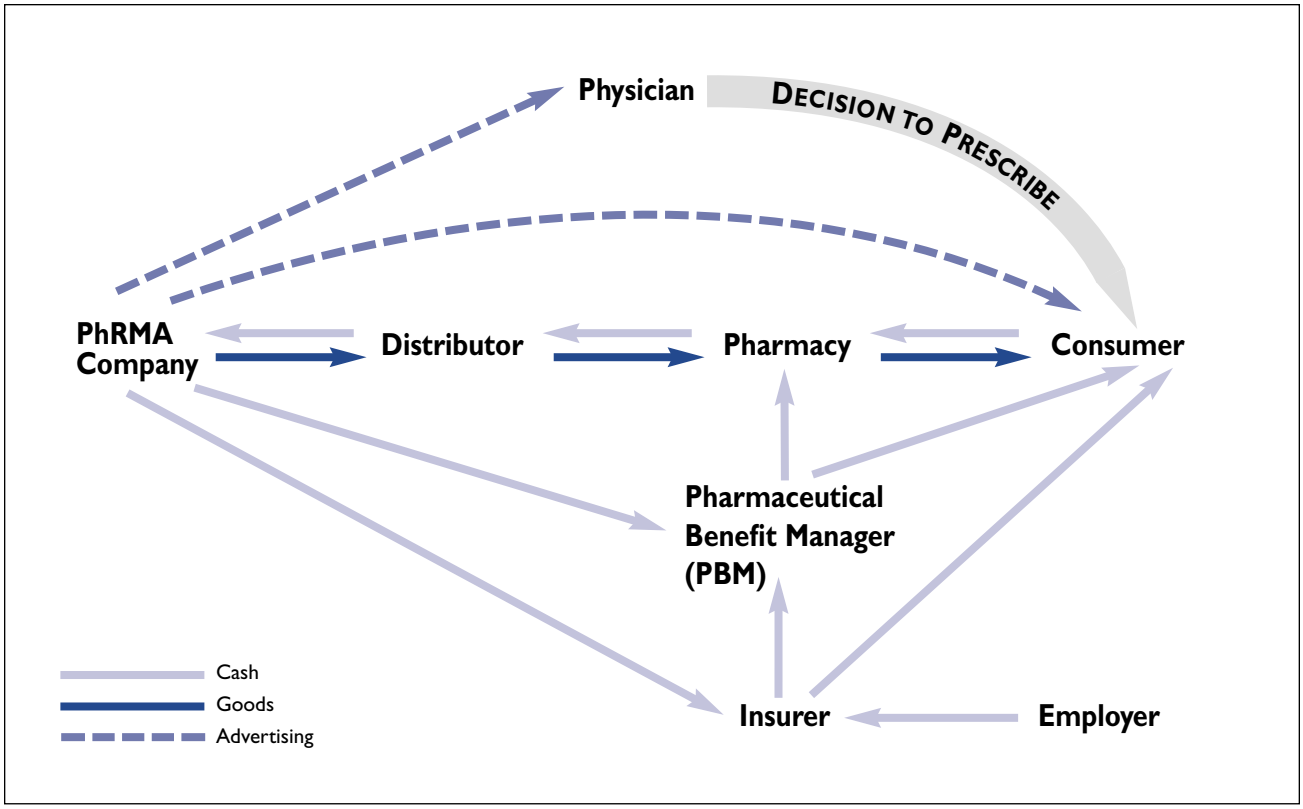
One area that has emerged as a substantial issue for PhRMA companies is understanding and managing the relationship between the industry and the federal government as the government has changed from regulator to purchaser of pharmaceutical products. While PhRMA's lobbying effort is highly successful, it has also needed to develop an optimal working relationship with the government as a customer. An example of the problems the customer/lobbying relationship has caused is Medicare's pricing of products. The federal government is supposed to be guaranteed a reduced rate relative to all other purchasers of pharmaceutical products in the United States. The separate federal programs, Veterans Administration, Medicare and Medicaid, each negotiate separately for pharmaceutical discounts. The mechanisms to ensure this, however, have some clear problems. The central problem is that it is very difficult to ascertain the exact price any one person or group is paying for a specific pharmaceutical product. The industry standard pricing, known as the *average wholesale price* (AWP), is readily acknowledged to be a poor standard since it does not include any discounts or rebates that specific purchasers, such as the government or any large purchaser, receive. Due to the failure to acknowledge those rebates in the pricing charged to the Medicare and Medicaid programs, the federal government filed charges of overcharging against essentially all major pharmaceutical companies in the late 1990s. To date, none of these suits has gone to court, but there have been some substantial out-of-court settlements, with payment from companies including Bayer and GlaxoSmithkline making restitution to the federal government.

The real problem that worries PhRMA companies in having the federal government as a key customer is that the government could impose true price controls, as opposed to the negotiated price discounts that currently exist. In almost every other country in the world, the federal government does in fact impose price restrictions for all products for which the government provides coverage. In the United States, the Medicare system has imposed price controls on reimbursement for other aspects of provider care. If a federal prescription coverage plan is implemented, PhRMA, probably reasonably, expects that over time, as prices increase, that the federal government would impose price restrictions. Because Americans pay the highest prescription drug prices in the world, the United States accounts for a wildly disproportionate amount of the worldwide revenue for pharmaceutical products, almost 40% of total revenue worldwide. Therefore, any kind of price controls, even if limited to federally funded programs such as Medicare, would severely impact on pharmaceutical company revenues and profits.

In trying to understand the pharmaceutical industry, the vast majority of effort is expended on considering marketing and research costs. An alternate way to think about the pharmaceutical industry is to try to understand the pharmaceutical marketplace, specifically the exchange of payment for goods received. Looking at this "flow" of goods and payments can suggest points at which policy efforts might be directed and help us to assess the feasibility of proposed policy alternatives.

Figure 2 shows the flow of goods going from the manufacturer to the consumer in dark blue, the flow of

FIGURE 2: **Flow of Goods, Cash, and Advertising for Pharmaceuticals**



money in light blue, and the marketing of pharmaceutical products in dashed blue. A key point is that the decision to prescribe a pharmaceutical product does not begin with the consumer, but rather comes from the physician. This explains why 90% of pharmaceutical marketing is directed toward physicians not consumers. A second key feature of Figure 2 is the difficulty in clearly tracking how the money for prescription drugs moves from the consumer or insurer to the pharmaceutical company. The disconnection between the flow of goods, cash, and marketing effort is at the heart of the complexity of the pharmaceutical marketplace.

Pharmaceutical Benefit Managers (PBMs) play an increasingly important role in the pharmaceutical cost "picture." As I shall discuss, a number of state-level policy initiatives relate to PBMs. Pharmaceutical Benefit Managers administer the prescription drug part of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and HMOs. These organizations negotiate with drug manufacturers to obtain rebates for a plan sponsor and with retail pharmacies to obtain discounts on prescription drug prices and dispensing fees for health plan enrollees. In exchange for these services, a PBM may receive a percentage of manufacturer rebates or a fee per prescription. Ideally, some part of the rebate is used to reduce the cost of the prescription drugs to consumers. A PBM typically tries to achieve high-quality care at the lowest possible cost by formulary development. (A *formulary* is a list of prescription drugs, grouped by therapeutic class, that are preferred by a health plan sponsor.) Drugs are included on a formulary, both for reasons of medical value and on the basis of price. Pharmaceutical Benefit Managers often will provide physicians and others with printed formularies that identify drugs according to their relative cost within a therapeutic class.

TABLE 1: **An Overview of Direct Cost-reduction Strategies**

PLAN (state examples)	MECHANISM FOR PROVIDING DISCOUNT	CONSUMER SAVINGS	FUNDING SOURCE
Discount for uninsured via Medicaid discount (e.g. ME, HI, VT)	Provide a pharmaceutical discount program for any state residents who meet some income eligibility level, where the discount is tied to the discount the state already receives for Medicaid prescriptions (e.g., Maine Rx)	Immediate	Pharmaceutical industry
Pharmacy discount (e.g., AZ, CA, IA)	Price is negotiated by the state; people have to meet eligibility requirements; most states require a specific up-front fee to join the program	Immediate	Pharmaceutical industry
Use assistance plans (e.g., MD, OR, TX)	Verify that all possible residents are taking advantage of pharmaceutical assistance plans (which sometimes offer free prescriptions) offered from various pharmaceutical companies	Immediate	Pharmaceutical industry
Aggregate purchasing plans (e.g., AR, OR, VT)	Join groups within the state, or combine with other states to increase negotiating leverage (e.g., Vermont, Michigan and Washington have combined as a group)	Immediate	Pharmaceutical industry
State-run Medicaid Rx plans (e.g., IL)	Provide a state-run and state-supported prescription drug benefit through the Medicaid program for those below an income threshold who are on Medicaid	Immediate	State
Rebates for people suffering specific illness (e.g. TX, NC)	Drug rebates for people suffering from specific illness (e.g., Texas has a program for drugs purchased by the Kidney Health Care program)	Immediate	State
Reimbursement	Reimburse some percentage of costs for people who meet eligibility and can document their costs (e.g., Indiana explored, and changed to direct benefit)	Delayed	State
Tax credit (e.g., MI, MO)	Reimburse some percentage of prescription costs via a state tax credit for prescription drug costs for people who meet eligibility criteria	Delayed	State

STATE-LEVEL POLICY DEVELOPMENTS

A number of proposals for prescription drug policies have been developed and implemented by various state legislatures.[1] In developing policy, most states have focused attention on three areas: (1) reducing costs to people who cannot afford the products, (2) managing the costs that states pay directly via Medicaid coverage (states are responsible for approximately 33% of the payments), and (3) increasing access to pharmaceutical products.

Direct Cost-reduction Strategies

Thirty-four states have proposed or enacted legislation in an effort to reduce consumer costs as a way to increase access to pharmaceuticals. These plans can be classified into eight relatively distinct strategies. These strategies have different implications in terms

TABLE 2: **Benefits and Challenges of Direct Cost-reduction Strategies**

PLAN	BENEFITS	CHALLENGES
Discount for uninsured via Medicaid discount	• Reduces costs for the most disadvantaged population • Requires relatively little state funding • Simple to implement	• Legality of the plan is in question
Pharmacy discount	• Provides immediate cost reduction for a large population	• Fairly complicated to explain • Could create cost demand from pharmacies rather than manufacturers
Use assistance plans	• Limited to zero cost for state • Tends to serve a high need population	• Criteria for acceptance in these plans can be quite limited • Inherent limits in the size and scope of these plans
Aggregate purchasing plans	• Provides a savings to the state and to consumers, so politically easy to sell	• Provides a savings only to people covered by state plans
State-run Medicaid Rx plans	• Provides broadest protection for state Medicaid recipients	• Highest cost exposure for the state of all plans
Rebates for people suffering specific illness	• Easy to implement • Limited cost exposure	• Very narrow population served
Reimbursement	• Conceptually simple • Clearly benefits those paying the most for pharmaceutical products • Allows uninsured to be protected	• Creates paperwork challenge for some people • Consumer has to pay money up front prior to reimbursement • Direct cost for state • Will be most difficult for most needy population
Tax Credit	• Conceptually simple • Clearly benefits those paying the most for pharmaceutical products • Allows uninsured to be protected	• Creates paperwork challenge for some people • Consumer has to pay money up front prior to reimbursement • Direct cost for state • Will be most difficult for most needy population

of their impacts on consumers and in terms of their funding sources. In terms of consumer impact, cost reductions may be immediate or delayed. Funding sources may be the state or the pharmaceutical industry.

Examining consumer impact and funding sources highlights some of the potential benefits of these plans as well as the potential difficulties. Benefits are more apparent when considered from the consumer's perspective; problems are more apparent when the funding source is considered. From the consumer's perspective, the benefit is obviously better if the cost saving is immediate. A delayed rebate will not facilitate obtaining access to a prescription if it is initially cost-prohibitive. Table 1 outlines the mechanisms involved in various cost-reduction strategies that have been implemented or proposed, and shows the impact on consumer savings, as well as the funding source for each type of plan. Several of the plans described here

TABLE 3: **The Maine Rx Program in Brief**

1. Any Maine resident may enroll in the Maine Rx program and receive a Maine Rx card. However, only those consumers who lack prescription drug insurance stand to benefit from the discounts provided by the program.
2. Persons who enroll in the program receive discounts for their prescription drugs if the state has negotiated a rebate with the manufacturer of that prescription drug.
3. Persons enrolled in the program pay the pharmacist the reduced price for the drug.
4. The pharmacist is paid by the state the amount of the discount plus an administrative fee. The state receives from the drug manufacturer the amount of the discount in the form of a rebate.
5. The program uses the market power of Maine's Medicaid program to bring prescription drug manufacturers to the table to negotiate rebates. If a manufacturer does not provide a rebate, that manufacturer's products may be placed on the Maine Medicaid program's list of drugs requiring prior authorization by Medicaid for payment.
6. The Maine Rx program requires the state to use its best efforts to obtain rebates from manufacturers equal to or greater than the rebates received by the Medicaid program.

are designed to improve access to pharmaceutical benefits for all eligible groups, including previously uncovered populations, as well as to reduce costs. Table 2 summarizes the plans in terms of their benefits and the challenges involved in implementing them.

The difficulties in implementing the plans are more apparent when the funding source is considered. Given the current, broad crisis in state funding, programs that require state funds to provide a consumer discount are facing enormous difficulties. At the same time, the pharmaceutical industry has worked to minimize the ability of states to enact legislation that forces pharmaceutical company discounts to be passed on to consumers.

After almost a decade of legislative attempts to provide direct cost reductions to consumers, there appear to be fewer new strategies being undertaken by state legislatures throughout the country. Rather, those states that were slow to initiate policies providing direct cost reduction are now trying to identify the strategies from the list in Table 2 with the best benefit/cost profile. Among these plans, the aggregate purchasing idea appears to be developing a broader appeal as a way to force pharmaceutical companies to negotiate larger discounts for states.

The Maine Rx-type program, in particular, has received broad attention as a novel means to lower costs for a large number of people. The Maine Rx program was developed as a way for Maine to use its leverage to negotiate lower prices to benefit uninsured people. The truly novel part of the Maine Rx program is its effort to lower prescription costs for people who do not directly receive any government-sponsored benefit. The pharmaceutical industry, through PhRMA, sued to halt implementation of the Maine Rx plan. A May 2003 ruling by the U.S. Supreme Court has now said that drug makers did not adequately show why Maine's plan should be blocked. Although further legal challenges are anticipated, Maine now intends to proceed with implementation. Even before the Supreme Court ruling on the constitutionality of the Maine Rx program, similar programs were enacted in Vermont and Hawaii, and these will presumably go forward now as well. Details of the Maine Rx program are shown in Table 3.[2]

Market-based State Legislation

States that have been pioneers in pursuing direct cost-reduction strategies now appear to be changing their focus to promote market-based reforms that could result in the lowering of costs by pharmaceutical companies for all consumers.[3] Market-based reforms include strategies such as counter-detailing and increased marketing disclosure. The idea supporting these approaches is that by creating a more competitive marketplace, costs can be decreased for consumers and the states. A basic tenet of a competitive marketplace is that good comparative information is readily available to consumers. However, for pharmaceuticals that is not usually the case. Even physicians, who are the true decisionmakers regarding prescriptions, do not have complete information regarding pharmaceuticals. A recent study noted that less than 50% of physicians are aware of the actual costs of pharmaceutical products (Korn et al. 2003). Therefore, it seems reasonable

that increasing the level and quality of information that physicians have would enable them to prescribe more cost-effective products.

For example, the core idea of counter-detailing is to make physicians aware of generic prescribing options in a similar fashion to the way brand-prescribing options are already communicated. If there were to be direct detailing of generic options, the hope is that physicians would prescribe generic products more frequently than they now do. This goes beyond the common and relatively simple measure ensuring that if a generic equivalent exists for a branded prescription then the prescription is filled with the generic medicine. Counter-detailing informs physicians of their prescribing options within a therapeutic category, including generic as well as branded products. This can be beneficial, since in some cases the same efficacy can be obtained with a generic product as would be expected from a more expensive branded alternative. Currently, the physician's own experience and study limit knowledge of generic prescribing options. As an example, physicians have over 90 products in nine drug classes that they could prescribe for hypertension. Most physicians would likely have identified their own preferred product in each of the nine classes, and some alternatives as combinations. It is not reasonable to assume that physicians can stay informed on all their options. This is not to suggest that physicians do not work to stay informed, but the sheer volume of information that exists about the over 6,000 pharmaceutical products is beyond any one person to manage. As noted earlier here, the pharmaceutical companies have found that it has been cost-effective to provide a 250% increase in the number of people telling physicians about new branded prescribing options. Similarly, counter-detailing could be cost-effective if a state could have a policy whereby physicians would be informed about the alternative generic prescribing options that exist. Indeed Merck-Medco, one of the country's largest pharmaceutical benefits managers (PBMs), has completed a three-year trial for counter-detailing and has decided to continue the program. (Merck-Medco, now known as Medco Health Solutions, is a subsidiary of the giant Merck pharmaceutical company.)

Another market-based policy approach would require pharmaceutical companies to release figures on their marketing costs. The hope is that by increasing public awareness of marketing practices, companies will be pressured to reduce their increase in marketing costs, thereby limiting their need to increase prices. This strategy seems unlikely to lead to actual cost reduction. However, obtaining information on marketing costs would allow states and consumer groups to more effectively counteract industry reports of the relative weighting of marketing versus research and development costs. This has been a central issue in many debates regarding pharmaceutical costs at the state and the federal level, and the lack of consensus on marketing costs undermines many efforts to accurately assess the pharmaceutical industry's claims about investment.

> …by creating a more competitive marketplace, costs can be decreased for consumers and the states.

Vermont's Approach

Probably the most comprehensive and novel single piece of legislation any state has enacted is Vermont Act 127 in 2002.[4] Because of its wide-ranging approach, it is worthwhile to examine Vermont's recent legislation in some detail. A summary of the bill is provided in Table 4. Act 127 includes two methods to try to provide direct cost reductions for consumers: pursuing a bulk purchasing strategy and enacting a program based on the Maine Rx program. However, the novel ideas are the market-based reforms intended to encourage cost reduction. The key specific plans include developing a preferred drug list for state-reimbursed prescriptions, counter-detailing, and marketing disclosure. These ideas offer new directions for state legislation to go.

The initial report on the results of the new Vermont legislation issued by the Department of Prevention, Assistance, Transition and Health Access

TABLE 4: **Act 127, Pharmacy Best Practices and Cost-Control Program for Vermont**

PLAN	METHOD OF DELIVERY
1. Aggregate purchasing plan	The state will join a broad coalition of states to form a large purchasing group for pharmaceutical products.
2. Maine Rx-based plan	The act creates an effort to increase access and lower costs directly, utilizing four of the strategies noted above. These include designing a prescription drug discount (similar to Maine Rx but distinct), coordinating utilization of pharmaceutical assistance programs from drug manufacturers, negotiating supplemental rebates from manufacturers based on reference pricing, and pursuing a bulk purchasing program.
3. Preferred drug list	The act requires the state to develop a preferred drug list based on efficacy and cost effectiveness, as decided by the state physician advisory board.
4. Counter-detailing and physician education	The state, through the Department of Prevention, Assistance, Transition, and Health Access (PATH), will begin creating a program to educate about the preferred drug lists that have been developed and will ultimately begin an effort to provide counter-detailing. A counter-detailing program would be designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists and other health care professionals authorized to prescribe and dispense prescription drugs.
5. Required marketing disclosure	The act requires all pharmaceutical companies to file an annual disclosure of gifts and cash payments to doctors. The companies shall disclose to the Vermont board of pharmacy the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in the state. Disclosure shall be made on a form and in a manner prescribed by the board. Initial disclosure shall be made on or before January 1, 2004 for the 12-month period ending June 30, 2003.

(PATH) in 2002 provides some support for the development of the preferred drug list, combined with an education program that is intended to grow into full counter-detailing.[5] Overall, the report notes that all programs utilized to control costs had resulted in savings of $6.7 million after allowing for the costs (~$2 million) of running the programs. Specifically, the preferred drug list and education effort had focused on three specific drug categories: gastric acid reducers, anti-inflammatories, and narcotic analgesics. From these three categories, PATH reported a pharmacy cost decrease of $3.8 million, comparing 2002 to 2001. The vast majority of these savings, over $3.1 million, was from the gastric acid reducers. The fact that one category was responsible for such a large savings raises a question regarding the broad applicability of this strategy. One question that should have been addressed was the impact of one specific product, Prilosec, becoming available as a generic in December 2002. Despite this question, a substantial savings was achieved merely by clearly defining preferred products, based on costs and efficacy, and then communicating the list of preferred products to physicians and pharmacists.

WHAT CAN MAINE DO?

Maine is in a difficult position in its attempt to increase prescription drug access in the midst of a budget crisis. New state-funded programs are unlikely to be created, and current programs relying on state funds are likely to be constrained. As a further challenge, a federal court ruling in December 2002

revoked the Medicaid waiver for Healthy Maine, the state's Medicaid prescription drug program. Healthy Maine, a distinct program from the Maine Rx program, provided a prescription drug benefit to Medicaid recipients. The federal government revoked the waiver on procedural grounds, claiming that Maine failed to secure the necessary signature from the secretary of the U.S. Department of Health and Human Services. The program has been placed on hold, meaning that over 100,000 people who had benefited from reduced costs for prescription drug products via Healthy Maine lost the savings and potentially the access to more affordable prescription drugs. Currently, Maine has revamped efforts to secure the necessary signature from Secretary Tommy Thompson, without success to date.

While Maine has been a leader in direct cost-reduction efforts, particularly with the Maine Rx program, it is now beginning to consider legislation similar to the more market-based reforms the Vermont Legislature passed in 2002. A number of specific bills dealing with prescription drug issues have been introduced in the 121st legislature's regular session and several have passed. These bills focus on three areas:

- Finding new avenues to directly reduce costs as a means to increase access;
- Regulating pharmacy benefit managers (PBMs);
- Requiring pharmaceutical companies to disclose marketing costs and to abide by their ethical guidelines for marketing their products to physicians.

The direct cost-reduction bills are variants on strategies discussed earlier. The pharmaceutical marketing disclosure bills are similar to the legislation enacted in Vermont. The PBM-focused legislation, which includes two distinct bills, is a new strategy that has not been enacted to date.

The PBM effort makes some sense, based on the flow of cash illustrated in Figure 2. The flow from pharmaceutical companies to PBMs would appear to be an avenue that could be tapped to offer a potentially low-cost method to try to manage consumer costs, primarily through passing on to consumers a greater share of the rebate money received by PBMs. A recent *New York Times* article stated that Merck-Medco, one of the nation's largest PBMs, has acknowledged receiving over $3.5 billion in rebates over three years (Freudenheim 2003). An unknown percentage of these rebates is passed on to customers. On the face of it, that seems like a substantial amount of money that should reasonably benefit consumers as opposed to the PBM.

One bill before the Maine Legislature would seek to make public the rebates that PBMs receive and ensure that the discounts go to consumers in the form of reduced prices. There are two key difficulties in implementing this kind of legislation: (1) ascertaining the actual price of a product, and (2) understanding how rebates are currently divided, which would need to be known before enacting the legislation.

The issue of understanding price is very similar to the problem discussed earlier regarding the charges companies make to Medicare/Medicaid based on their actual sales prices, as opposed to using the average wholesale price (AWP) when calculating these charges. Most PBMs would have a difficult time identifying the actual price for any products, since rebates and discounts change over time based on sales or other information.

Rebates could be difficult to legislate because they are not fully understood. One common rebate is a volume rebate, where a manufacturer will provide a rebate of a certain percent dependent on sales over a specific quarter. The percentage of the rebate increases as various sales thresholds are reached. Thus, the higher the sales are, the higher the rebate. This can be seen as an incentive for a PBM to encourage the use of a specific product, based on the rebate the PBM receives. At the same time, the PBM will reduce the cost of that product to pharmacies based on an estimate of the rebate they expect. Typically, that product would be the least-expensive brand alternative for the particular diagnosis involved. In the current system, the consumer is already a beneficiary of the PBM's ability to negotiate the rebate. A reasonable question remains about the scale of the consumer's benefit compared to the PBM's benefit based on the rebate. Legislation requiring the reporting of rebates might make a more reasonable first step, prior to legislating the specific

level of the rebate that the PBM must pass on to consumers. The other PBM-focused legislation seems to face similar challenges. Legislation requiring non-profit PBMs to be considered for state contracts inherently suggests that the marketplace is not providing the best benefit to customers, including the state. Again, increased transparency in how PBMs operate might offer a simpler step for the legislature to explore.

CONCLUSION

The frustration that both consumers and state legislatures are experiencing regarding the costs of pharmaceutical products is not likely to be solved in the immediate future by any of the ideas discussed here. Solutions, if they are to be found, need to be long-term ones. The advantage of the direct cost-reduction strategies that states have been employing, such as Maine Rx, is that the potential savings are immediate and readily apparent. The difficulty in actually implementing those programs, either because of legal delays or because of states' inability to afford them, has limited the benefit of these potential programs. Several of the market-based reforms being explored offer possible long-term solutions, but are unlikely to provide dramatic, immediate cost relief. Therefore, a combination of policies aimed at direct cost reduction and market-based reforms seem to provide the best opportunity to address both short- and long-term concerns over prescription drug costs and access.

The challenge that the United States is trying to solve is how we as a country can support the growth of the pharmaceutical industry while not allowing this one sector of the economy to grow out of proportion, to the detriment to the overall economy and health care of American consumers. As noted earlier, the United States is one of the only countries in the world that does not have some kind of price restrictions on pharmaceuticals. In choosing this course of action, we have so far been willing to take the risks involved in jeopardizing consumer access to pharmaceutical products. To make this a reasonable trade, it seems incumbent that the federal government provide for a more competitive marketplace as a way to provide some market-based controls on prices. This trade-off is easier to consider at the federal level as opposed to the state level, since the federal government is a beneficiary of the pharmaceutical industry and can try to balance industry growth with the needs of consumers and health care payers. However, this issue is hardly addressed in any of the discussion of prescription drug legislation. Instead, consumer demand for immediate decreases in prices is met by intensive lobbying from the pharmaceutical industry, which is trying to limit changes in the regulatory framework for its products. It seems apparent that the U.S. Congress and the executive branch of the federal government are unlikely to be able to reach any consensus to address the broad issue in the near future. Development of a federal Medicare prescription drug benefit, which does seem possible, would help to address some of the immediate access issues in individual states, but that will not likely impact the upward trend in pharmaceutical costs.

States are left on their own to try and develop market-based reforms that facilitate development of a more competitive, transparent pharmaceutical industry. In this situation, strategies that focus on increasing knowledge for consumers, physicians, and legislators all seem as though they provide a logical first step. Legislation that limits an industry and market that are not clearly understood is unlikely to be effective and could easily be counter-productive.

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ENDNOTES

1. A detailed listing and discussion of many of the state-level plans proposed and/or enacted to increase access and reduce costs can be found at the National Conference of State Legislatures Web site. I have drawn upon some of that information here. See: www.ncsl.org/programs/health/drugaid.htm and www.ncsl.org/programs/health/rxads.htm

2. The summary in Table 3 is provided by the Maine Citizen Leadership Fund from its Maine Rx Web site: www.rxmaine.com/home/index.cfm

3. Information listed on the National Conference of State Legislatures Web site, combined with information from Maine legislators about bills being introduced in this legislative session, identify some of the new policy strategies discussed in the section which follows.

4. See the Vermont State Legislature's Web site: www.leg.state.vt.us

5. The report can be found at www.path.state.vt.us/districts/ovha/ovha5.htm

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