



# The State as Drug Purchaser: Gaining Leverage in a Competitive Marketplace

Executive Summary

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## Introduction

On March 6, 2002, The New York Health Products Council hosted “The State as Drug Purchaser: Gaining Leverage in a Competitive Marketplace.” Presented by Francis B. Palumbo, Ph.D., JD, the discussion was part of a series of healthcare forums designed to provide information to those involved in the development of New York State’s healthcare system.

Dr. Palumbo is a Professor of Pharmacy Practice and Science at the University of Maryland School of Pharmacy. He is also Director of the University of Maryland Center on Drugs and Public Policy, which he co-founded in 1988. Dr. Palumbo received his BS in Pharmacy from Medical University of South Carolina, MS and Ph.D. in Health Care Administration from the University of Mississippi and JD from the University of Baltimore Law Center. He is a licensed pharmacist and member of the Maryland Bar.

Dr. Palumbo has been on the faculty of the University of Maryland since 1974. He and his colleagues conducted much of the early work on drug use review. He has been the principle investigator on major federal research grants examining the use of drugs by long-term care patients. In addition, Dr. Palumbo co-authored a book on containing costs in third party drug programs.

Because the issue of access to prescription drugs is real and consistent among our citizenry, a solution for more affordable access must be realized. Dr. Palumbo’s discussion on the role of the state as drug purchaser reinforced the fact that the issue is complex and that, to date, there is no clear answer on how best to handle this role.

In his discussion, he reviewed several examples of different approaches taken by states and examined the results and consequences achieved by these various programs. He identified the “vulnerable populations” that these programs are designed to help and looked at the myriad of ways states are trying to resolve the issue of access without bringing harm to the rest of the populations in terms of increased cost and lost employer benefits.



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## Why State Involvement

### A Brief History

Several actions by the federal government in the past decade have prompted states to take action on behalf of their citizens.

**1988/89** ~ Medicare Catastrophic Coverage Act was passed which added a drug benefit to Medicare. This was promptly repealed before benefits could start taking place due to financing issues.

**1990's** ~ President Clinton promised to devote a substantial effort to controlling the cost of pharmaceuticals in his Health Security Act. This act did not pass Congress but got a lot of people thinking about the issues of drug access and looking for ways to resolve the problem.

**2000** ~ President Bush proposed the Helping Hand Program that would make states responsible for drug coverage but this proposal was quickly rejected by states.

**2001** ~ Discount Card Program proposed by President Bush as a "stop gap" measure until Congress can determine what to do about incorporating a drug benefit into Medicare.

**2002** ~ President Bush proposes that \$190 billion be spent over the next ten years to establish a Medicare drug program. House Republicans estimate \$300 billion will be needed, and the AARP puts the number at over \$750 billion to develop an effective program for drug coverage.

At present, there is no definitive federal program in place to ensure access to prescription medicines for our citizens. A major shift in the federal government's attitude towards resource allocation to Medicare would need to take place before any type of program could be developed. With the current state of affairs in the world after September 11th, this is not likely to happen any time soon as additional funds are currently being allocated to defense purposes. This situation has resulted in the states trying to develop programs to deal with the issue of securing access to medicines for their citizens.

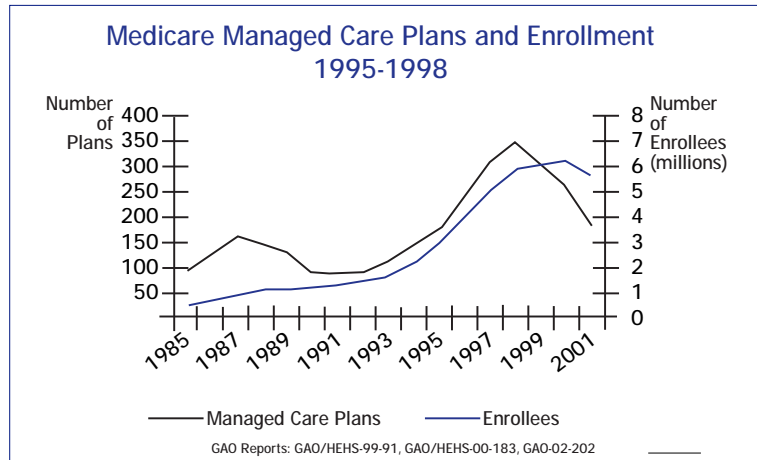
### The "Vulnerable Populations"

There are several "vulnerable populations" that need to be taken care of: the poor, the elderly and the "pharmaceutically indigent," people who do not fit into any existing plan for medical coverage. These indigent populations are caught in a "catch 22", they make too much money to qualify for any public programs, yet they do not make enough to afford very much in the way of private medical care if they have to pay for it out of their own pocket.

In regards to the elderly, studies indicate that about two-thirds of all seniors, including Medicaid recipients, have some type of drug coverage. That is not to say, however, that the drug coverage is comprehensive. As an example, the Medicare Plus Choice program drug benefit offered by the MCO's is actually very weak, limiting the drug benefit amount to between \$500 - \$1000 annually. In addition, the plans are not very cost efficient for the MCO's as they tend to attract elderly citizens not only in need of drugs, but in need of many other medical services as well. As a result, more and more plans are deciding to leave the program and fewer seniors are electing to join the plans that are left due to weak drug coverage.



*Pharmaceutically indigent patients make too much money to qualify for public programs, yet not enough to afford private medical care.*



The number of plans has decreased as well as the number of enrollees.

## The Cost of State Involvement

*It costs \$800 million to bring a drug from discovery to the market.*

*Drugs are expensive. Drugs are a serious issue. And the issue at the state level is access. How do we get drugs to the people that need them?*

**Fact:**  
*Annual drug expenditures increase at about 15%*  
*Price Increases 1/3*  
*Increased Utilization 1/3*  
*Pipeline Drugs 1/3*

The most recent figure released by Tufts University estimates that it costs \$800 million to bring a drug from discovery to the market. Some may disagree with the exact figure, but it is generally agreed that drugs are expensive to produce; drugs are a serious issue; and the issue at the state level is access. Which is why, how we get drugs to the people that need them is such a major topic of discussion.

### Drug Expenditures on the Rise?

Annual increase in drug expenditures in the US is estimated at approximately 15%, which is attributed to the combination of three factors:

- One-third due to an increase in price on existing drugs.
- One-third due to increased utilization of existing drugs.
- One-third due to the introduction of new drugs, or "pipeline drugs."

Studies indicate that, on average, one-third of existing drugs experience a price increase in a given year with two-thirds of drugs not increasing in price at all. As society continues to age and more new drugs are discovered and produced, the utilization of these drugs will continue to increase. Therefore, it is reasonable to assume that the 15% annual increase will remain fairly consistent for the foreseeable future.

### The Price of Drugs Across the Border

The cost of drugs in other countries has also come to the forefront of discussion in recent years. The perception that drugs are cheaper in other countries is one issue that is driving much of the activity at the state level, especially among border states like New York.

*When comparing drug prices purchasing parity and price controls must be considered.*

It's generally accepted that when compared, the cost of a medicine in the U.S. is usually slightly higher than in other countries. However, closer scrutiny of two factors is called for; purchasing parity and price controls.

**Purchasing Parity.** Comparing the percentage of income spent on prescription drugs, the cost difference between countries is greatly altered. For example, a drug may cost less in terms of purchasing dollars in Mexico, however, when comparing the dollar amount to the relative income of people in Mexico, it may not be very different from the percentage of income spent by Americans when buying medicines in the U.S.

**Price Controls.** Some countries, like Canada, use price controls to establish the cost of medicines that will be marketed in their country. Pharmaceutical manufacturers must establish a price point, one that is comparable to a reference price set by a similar medicine, to gain access to the market. Pharmaceutical companies, wanting to market their drugs around the world, find themselves having to capitulate to these rules. As a result there is little investment in research and development in these countries. Research and development primarily takes in the U.S. where revenues are reinvested into research.

## State Efforts to Contain Cost and Expand Drug Coverage

As states grapple with ways to provide prescription drug access to their citizens, financing the programs is a major issue to be considered. Coalitions have formed, and are forming, to try and find solutions. The Northeast Legislative Association, the Tri-State coalition among VT, ME and NH, and the Council of State Governments located primarily in the mid-west are a few examples. While states are examining a number of fiduciary choices, the options appear to be characterized into three categories:

### Prescription Drug Pricing on Senior Drug Programs

Given Congress' lack of action covering seniors' prescription drugs, states are developing discount programs designed to try and close this gap. Collectively these programs are known as Pharmacy Assistance Programs. These plans typically target elderly individuals not covered by Medicaid but whose incomes are insufficient to afford prescription drugs, and do not have any prescription coverage.

Currently at least 26 states have some type of pharmaceutical assistance. Most target those over the age of 65 but one or two states have no age restrictions. Some states are very generous with income requirements and cover almost any medication, while other states are very stingy on income requirements and only cover medication for chronic illnesses.

When developing or expanding a rebate program to expand access to pharmaceuticals for seniors or other vulnerable populations, the state must consider the following pricing methodologies:

**Supplemental Rebates.** Under OBRA 90 a manufacturer is required to give a rebate to a Medicaid program of 15%, or their best price, whichever is lower.



*Major options for state financed drug programs:*

- *Rebates from manufacturers*
- *Discounts from pharmacists*
- *Aggregate Negotiations*



States are trying several ways to utilize supplemental rebates in order to contain drug spending. Michigan, for example, requires manufacturers to match its “best in class” price. Vermont and Illinois obtained waivers from HHS to bring more people into their Medicaid programs thereby passing the manufacturer’s rebates on to more consumers. Based on their different funding methods, however, Vermont’s program was halted while Illinois is still occurring.

**Prior Authorization.** Problems with this type of program involve patients getting bounced around from medication to medication with what is called “formulary burden.” A patient must first fail on all the medicines on a state’s formulary before receiving a drug requiring prior authorization. Florida’s formulary, for example, requires manufacturers to give an additional 10% rebate or the product has to go on “prior authorization”.

This program is currently being challenged in several states. In its purest form, prior authorization should be based on clinical issues first, then cost issues. Prior authorization may have a place in state programs when used appropriately, and MCO’s and states are currently trying to come up with guidelines to develop these programs successfully.



**Pharmacy Discounts.** Some states, for example Florida and California, have begun programs requiring pharmacies to give a discount, usually 10%, to all Medicare eligible patients if the pharmacy wants to stay on the Medicaid program.

Other states, Washington and Iowa for example, have begun experimenting with discount card programs utilizing PBM’s. Residents, generally the elderly, pay an annual fee to join a “buyers club” through which they receive a discount on their prescription drugs. In Washington’s case, the enrollment fee goes directly to the PBM and the pharmacists are expected to absorb the discounts.

On their faces, these discount programs appear to benefit two constituencies: patients and PBM’s. The two entities in the production/distribution chain that are key to effective drug therapy – manufacturers and pharmacists – are expected to bear the financial burden. Washington State did its own economic impact analysis on their program after it was enacted and determined that it would cost their pharmacies almost \$24k in lost revenue annually. This is a no win situation for the state and the pharmacists.

*These discount programs may lower cost but aren’t necessarily going to ensure **access** to prescription drugs.*

The fact is these state and federal discounts may make prescription drugs a bit less expensive but they do not necessarily ensure better access to prescription drugs. A mandated 10% discount is not significant, and in many cases this type of discount already exists at large chain pharmacies in many states.

**Aggregate Negotiations.** States are very large purchasers of prescription medicines. However, these purchases seem to be segmented. For example, states enter into rebate agreements with manufacturers for their Medicaid programs. They enter into rebate agreements for the pharmacy assistance programs. States also act as a purchaser of prescription drugs for prisons, state employees and retirees, mental health institutions and chronic hospitals. When combined with the Medicaid and pharmacy assistance programs, this collective group represents a substantial expenditure of dollars at the state level. In order to deal successfully with aggregate negotiations a state needs to coordinate these programs.

All of the states purchasing entities, taken separately, are already receiving some sort of discount and/or rebate from manufactures based on individual contracts. Combining these entities will not increase the total market share for drug purchases so receiving higher discounts or rebates is questionable.

In implementing this type of program, states may address the needs of some of the patients but disenfranchise others in the process. Lowering the price for a large group of purchasers would most likely raise the price for others. Which groups of citizens would benefit most from this type of program? Does this system provide drug access to those who are not covered by any program, the so-called "vulnerable population," or merely provide more affordable pricing to those already receiving a discount?

## The State's Role in Drug Purchasing

The question remains as to whether it is feasible for the state, or group of states, to act as a direct purchaser of prescription drugs. Issues have to be dealt with in a manner acceptable to all parties for the system to work. These issues include whether products are to be placed on consignment with wholesalers and pharmacies, or placed in state established warehousing facilities; establishment of a distribution system and purchasing infrastructure; as well as obtaining the personnel and physical facilities necessary to operate such a program.

If one assumes that a bulk purchaser could obtain drugs at the FSS price, which is generally assumed to be 24%, the administrative costs described needed for activities would need to be deducted, leaving substantially less than a 24% discount available to consumers. In addition, it might be unrealistic for states to expect rebates above and beyond the already negotiated prices without a shift in market share.

*It may be unrealistic for states to expect rebates above and beyond the already negotiated prices without a shift in market share.*

## Impact of State Programs on Pharmaceutical Industry

*The negative impact on R&D will be manifested in many ways by the deep discounts that are expected without a shift in the marketplace.*

### On R&D

The federal government sponsors about 3% of the new drug development, and they do not have the money to take a new drug all the way to market. Ninety-seven percent of new drug discoveries come from within the pharmaceutical industry. The deep discounts states expect to receive will reduce the revenue pharmaceutical companies will have to invest in research and development.

### On Pharmacists

Approximately 3 billion outpatient prescriptions are dispensed in the US every year. By 2005 that figure is estimated to rise to 4 billion. If discounts are the answer, will pharmacists be expected to bear the burden of lost revenue? If so many pharmacies will be forced out of business, creating a new access problem. And if prices continue to go down for people in the covered sector, will the people paying for a prescription out of their own pocket pay more and end up subsidizing members of the protected sector through their purchases?

### On Private Sector Employees

Until recently the best way to gain access to insurance programs was through employer-sponsored programs. It is an expensive, but important, benefit for employers to offer. If state-sponsored programs are not carefully constructed it is likely that many employers will discontinue the benefit, knowing employees have alternative sources for coverage. The loss of private sector coverage would increase the number of people dependent upon the state programs, adding to the "vulnerable populations" that already exist.

## What the Drug Companies Are Doing

*Virtually every manufacturer has a free or discount drug program in place.*

Manufacturers have a number of programs to help ensure patients' access to medicines. In addition to the requirements under OBRA 90, many voluntarily participate in pharmacy assistance programs, and virtually every manufacturer has a free or discount drug program in place. An industry wide discount card is also being discussed among several manufacturers.

Pharmaceutical companies individually and as an industry are committed to ensuring access to medicines and appropriate use of their products and discussions of how to achieve these goals for all citizens in a cost effective manner are ongoing.



## Conclusion

The impact of state purchasing programs has yet to completely manifest itself. Currently many states are trying a variety of different approaches in order to bring access to prescription drugs to their citizens. It is too early to evaluate the results of these programs and to know the long-term impact they will have on patient access. However, because the issue of affordable drug access will continue to exist, the decision-makers in the states need to continue looking for viable solutions.

The states' motive in establishing a program is not suspect. The state desires to assist residents in obtaining healthcare and prescription drugs at an affordable rate. However, state budgets involve many factors. A state's actions may have severe repercussions for the healthcare system, as well as for other citizens currently insured under the private sector, so each program must be evaluated very carefully for long-term effects.

The key question that needs to be answered is, how to do we benefit the vulnerable populations, those needing the help of the state, without harming other populations? One way to find the answer might be through the formation of a "blue ribbon" panel to look at all the options and devise a set of principles to which states would have to adhere when developing programs. Another approach might be to simply sit back and observe the current programs and see what happens. If one is successful, then try and duplicate it in other states.

Either way, a solution will need to be found for the continuing challenge of access to prescription drugs. As stated, drug expenditures will continue to rise and drugs will continue to be expensive. Until a viable, long-term solution is found, these programs and other stopgap measures may help provide a short-term respite from the drug vs. food question for some vulnerable populations. The question then is, what will be the long-term effects on the healthcare system as a whole, and how do we resolve those issues in order to develop a successful program benefiting all citizens?

*The opinions expressed are of the presenters, and do not necessarily reflect the opinions of any institutions with which they are affiliated with, or of the sponsor.*



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The New York Health Products Council is a non-profit organization whose main concern is to provide the public with information about research-oriented pharmaceutical companies doing business in New York State. The companies' dedication to long-range, extremely costly drug research contributes to the health of millions of people in this state and to the economy as well.

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