Prescription Drug Study

A Report to the Minnesota Legislature on the Prescription Drug Market

April 1994

Health Economics Program
Division of Health Care Delivery Systems
Minnesota Department of Health

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PRESCRIPTION DRUG STUDY

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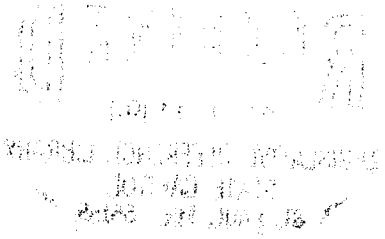


EXECUTIVE SUMMARY
PRESCRIPTION DRUG STUDY

INTRODUCTION

The State of Minnesota is in its third year of bipartisan effort of health care reform. The 1992 HealthRight Act (now known as the MinnesotaCare Act) addressed issues of access through the phase-in of a subsidized health insurance program for children, their parents, and eventually all uninsured Minnesotans. This legislation also created the Minnesota Health Care Commission, a 25-member commission of providers, payers, and consumers, to develop a detailed cost containment plan. This plan provided the framework for the cost containment provisions included in the 1993 MinnesotaCare Act. The goal of the plan is to reduce the rate of growth of health care expenditures by ten percent per year for the next five years.

Minnesota's approach to cost containment includes elements of both competition and regulation. The competitive approach is based on change in the service delivery system and focuses on Integrated Service Networks, prepaid health plans that will compete on price and quality. The regulatory component includes rate setting for payers outside of the ISN system and oversight authority based on expenditure limits for statewide health care spending.

Minnesota's health care reform legislation has moved the state closer to a seamless delivery system with universal access to affordable quality health care. The three key components of the reform plan include: 1) Integrated Service Networks (ISNs) that agree to provide a standard set of benefits for a fixed price; 2) Regulated All-Payer Option (RAPO) for providers that do not participate in ISNs; and 3) overall limits on the rate of growth in health care expenditures.

The 1993 MinnesotaCare Act also required the Minnesota Department of Health to study the state's prescription drug market and make recommendations to the Legislature on controlling its costs. In preparing this report, Health Department staff conducted an extensive literature review and met with close to 100 individuals representing retail and other pharmacists, drug manufacturers, consumers, hospitals, nursing homes, physicians, health maintenance organizations, other stakeholders and persons with relevant expertise and interest. Staff also consulted with the State of Minnesota Departments of Administration, Employee Relations, and Human Services, the Minnesota Health Care Commission, and with the University of Minnesota's PRIME Institute.

The purpose of the report is to describe the prescription drug market and the numerous factors that influence drug expenditures. As the report indicates, the pharmaceutical industry is multi-layered and extremely complex. *Any attempt to influence pricing mechanisms in one segment of the system may produce unintended and occasionally undesirable effects in another segment.* In addition, although the United States' drug market is one of the least regulated in the world, federal Medicaid policy has had a significant influence on the market over time. In many respects, federal Medicaid policy presents a significant limiting factor in reforming Minnesota's prescription drug market.

This Prescription Drug Study provides an overview of the total drug expenditures and trends at both the national and state level and a comprehensive description of the private market. Information is also

included to describe the different components of the system including drug manufacturers, wholesalers, pharmacies, consumers and third-party payers. The State of Minnesota also plays a unique role through its purchase of prescription drugs through the Department of Administration's state purchasing program, as a payer through the Department of Employee Relations' administration of the state employees health plan, and through the Department of Human Services' coverage of prescription drugs in the Medical Assistance, General Assistance Medical Care (GAMC) and MinnesotaCare programs.

A consistent theme throughout this report is the phenomenon of change - both in the prescription drug market and the health care systems in which it operates. Especially in Minnesota, the changing health care system has had a mostly positive impact on competition in the drug industry. The concept and implementation of managed care, for example, has increased the use of drug management tools that have reduced overall prescription drug costs for those patients in managed care systems. On the other hand, significant problems remain for those outside of such systems, particularly for retail pharmacists and the elderly and uninsured who pay for prescription drugs directly through out-of-pocket payments.

It should be noted that there is significant change anticipated at the national level as well. President Clinton's Health Security Act includes prescription drugs as a covered benefit under the Medicare program and it is likely that prescription drugs will be included as a covered benefit in any national health care legislation assuring universal access. It is unclear the direction national health reform will take, but prescription drugs are clearly on the agenda.

The following sections include a summary of key findings of Minnesota's Prescription Drug Study and recommendations regarding legislative options for change.

SUMMARY OF KEY FINDINGS

Drug Therapy and Pharmaceutical Care

- Appropriate use of pharmaceutical drugs saves the health care system millions of dollars annually by reducing reliance on more expensive surgeries, hospitalizations and admissions to nursing homes.

- Unintended adverse drug reactions increase the costs of the health care system through increased hospital admissions and additional medical expenses. Adverse drug reactions also decrease the outcomes and quality of patient care and accounted for 12,000 deaths in 1987.

- Pharmaceutical Care is the component of pharmacy practice that includes more direct intervention of the pharmacist with the patient for the purpose of caring for that patient's drug-related needs. The concept could have positive implications for improved patient outcomes and, in the long term, possibly decreased health care system costs if therapeutic outcomes improve and adverse drug reactions are reduced.

- Consumers should carry more responsibility for ensuring positive outcomes with drug therapy. This can be accomplished through more consumer education (particularly in understanding generic drugs and therapeutic equivalents) and greater involvement in decisions regarding treatment including the importance of better compliance with physician and pharmacist instructions regarding drug therapy for both prescription and over-the-counter drugs.

Expenditures and Trends

- Drugs and other medical nondurables accounted for approximately $60 billion, or 8%, of the estimated $750 billion spent on health care in the U.S. in 1991. Adding drugs dispensed in hospitals, nursing homes, and HMOs raises the estimate to $65 to $70 billion.

- Minnesota expenditures in 1991 for retail purchases of prescription drugs are estimated at $548 million. Adding expenditures for drugs dispensed in hospitals, nursing homes, HMOs and other non-retail pharmacies increases the total expenditures to approximately $1 billion.

- Nationally, prescription drug prices over the last decade have been increasing at an average annual rate of 9.4%, over twice as fast as the general rate of inflation. However, voluntary efforts on the part of drug manufacturers have brought the rate of inflation for prescription drugs in the last year in line with the general rate of inflation of 3%.

Third Party Coverage

- 55% of drug purchases in the U.S. are paid directly out-of-pocket by consumers. In Minnesota, 49% of drug purchases are paid out-of-pocket. The remainder are covered by a variety of third party payers.

- The elderly and the uninsured/underinsured represent the vast majority of consumers paying out-of-pocket for prescription drugs. Medicare does not include pharmaceutical drugs as a covered benefit. A 1988 survey of a sample of Minnesota seniors suggested that 24% of seniors have some type of Medicare supplemental coverage which includes a prescription drug benefit.

- National reform efforts are underway to include a prescription drug benefit under Medicare and in the new universal set of minimum benefits under universal coverage. President Clinton's Health Security Act addresses issues of both coverage and cost of prescription drugs.

- Nationally, Medicaid pays for approximately 13% of all outpatient prescriptions. In Minnesota, community pharmacies received approximately 13% of their prescription drug revenues from Medical Assistance (Medicaid) in 1991. As such, Medical Assistance is the largest single purchaser of outpatient prescriptions in Minnesota, which is the case in most other states as well.

- While Medical Assistance is the largest single payer of prescription drugs, its level of reimbursement to Minnesota pharmacies is set by both federal and state law. Consequently the State of Minnesota is severely limited in its capacity to formally manage drug expenditures beyond current state and federal provisions. Medical Assistance reimbursement for prescription drugs is significantly higher than the rates paid by other third party payers in the State of Minnesota.

Minnesota Pharmacies

- As of December 1992, there were 954 community pharmacies in Minnesota. In the last 10 years, there has been a net decline of 96 independents and a net gain of 131 chain drug stores, resulting in a statewide gain of 35 pharmacies.

- Each Minnesota county has at least one pharmacy. Almost two-thirds of all pharmacies in Minnesota are in urban areas and one-third are in rural areas. Almost 85% of rural pharmacies are independents, while 55% of urban pharmacies are independents.

Differential Pricing

- Manufacturers give different levels of discounted prices to different pharmacies and pharmacy purchasing groups. Hospital-based pharmacies, HMO pharmacies, mail order and government-run purchasing programs receive the largest discounts on the prescription drugs they purchase. Independent pharmacies typically receive little or no discounts.

- Differential pricing leads to cost shifting at two levels. First, manufacturers may charge independent pharmacies higher prices to partially offset the deep discounts given to other groups. Second, pharmacies may increase prices to cash paying customers, when possible, to make up for the losses due to low reimbursement from third party payers.

- Almost 20% of all community pharmacies in Minnesota operated at a net loss from pharmacy operations in 1991. Third party payers have significantly reduced their reimbursement rates to pharmacies and those pharmacies that rely more heavily on their pharmacy revenue to remain profitable (particularly rural pharmacies) are facing increasing financial difficulties.

Private Sector Initiatives

- A conservative estimate suggests that 75% of those with drug benefits included in their health coverage are currently involved in some type of drug management program intended to promote quality of care while reducing costs.

- Closed formularies, a key to most drug management companies' cost containment strategies, are becoming increasingly more important in the private sector; Minnesota wholesalers estimate that 60% - 70% of all prescription drugs sold in the State are under some closed formulary-based system.

- Aggressive drug management companies and managed care have effectively increased price competition among manufacturers through the use of formularies and other drug management tools. Competition has resulted in reducing some manufacturers' profits and has secured better prices for those that are able to negotiate with manufacturers through the use of formularies. Less competitive sectors, primarily independent retail pharmacies, do not see similar benefits.

CONCLUSIONS AND RECOMMENDATIONS

The legislative mandate authorizing this study also directed the Commissioner of Health to include recommendations on reducing the cost of prescription drugs for wholesale purchasers, consumers, retail pharmacies, and third-party payers. The Health Care Commission developed a set of guiding principles that were used to evaluate the various legislative options that have been proposed. The following provides a brief restatement of those principles. Reform and efforts to contain costs in the Minnesota prescription drug market should be consistent with the following guiding principles:

Partnership: Health care reform in the prescription drug market is very much a partnership venture between government and the private sector. This is primarily due to the fact that Medicaid represents the largest single payer of prescription drugs in the market and the federal legislation that establishes the "best price" policy for state Medicaid programs.

Shared Responsibility: It is unlikely the overall mission of health care reform in this area can be achieved without some investment or sacrifice by all of the stakeholders.

Incentives: Until proven inefficient or ineffective, incentives for the private sector shall be preferred over mandates from the government.

Role of Government: While virtually all of the interested parties realize that some level of governmental oversight is appropriate for the public good, private sector roles will be encouraged and facilitated while the role of government will be utilized only when necessary.

Balancing Competition and Regulation: There is near unanimous consensus that the ultimate goal of the health care system is to provide high quality health care at an affordable price. While competition generally is an effective force for achieving this goal and has some distinct advantages over regulatory approaches, it must also be recognized that competition is not always the most effective strategy and that regulation is appropriate in those circumstances where an uncontrolled competitive environment is not in the best interests of a majority of health care consumers.

Maintenance of Existing Programs and Policies: There is a clear recognition that policy in this area must not jeopardize the state Medical Assistance program's federal compliance. Through Federal Financial Participation (FFP) and manufacturers' rebates, Medical Assistance received approximately $55 million in 1993. In addition, the Department of Administration currently operates a successful drug purchasing program for state and local funded institutions. Any new initiatives must be designed and implemented in such a way as to not disrupt existing state and successful private-sector programs.

Flexibility: Any approach, especially one dealing with such rapid change as the prescription drug market, must be able to adapt easily. This includes flexibility to accommodate changes at both the state and national level related to overall health care reform and prescription drug benefits.

Regional Variation: An approach that works for urban markets may not necessarily be the most appropriate approach for rural markets. Different strategies may be appropriate for different regions of the state. Any approach recommended must be flexible enough to accommodate regional variations.

In addition, recommendations must be consistent with overall health care reform efforts. This includes the development of ISNs, the Regulated All-Payer Option and overall limits on the rate of growth of health care expenditures.

Finally, as a caveat, we point out that while this report is comprehensive, it does not and, of course, could not examine every issue. The complexity of the pharmaceutical industry and the specified legislative language authorizing this study limited its scope. For example, this report does not address the 2% provider tax imposed by the 1992 MinnesotaCare legislation. This issue was addressed in a study conducted by the Department of Revenue last year. While the tax certainly has implications for pharmacies in Minnesota, the issue of evaluating the provider tax as a means of funding MinnesotaCare is one which the Legislature and the Governor must ultimately address. In addition, there is limited discussion and analysis of federal policies, especially Medicare prescription drug coverage, over which Minnesota has very limited influence.

Consistent with the guiding principles and in light of the caveats described above, the following set of recommendations for reducing the cost of prescription drugs for wholesale purchasers, consumers, retail pharmacies and third-party payers.

Recommendations

1. Allow private sector initiatives, specifically ISNs and CISNs to develop in the State of Minnesota and build on the past success of managed care to moderate increases in pharmaceutical drug expenditures.

   Comment: Allowing private sector initiatives, specifically the development and implementation of managed care through ISNs and CISNs, may in fact be the most effective approach to further control drug prices in this state. It is clear that prices are moderating as we continue to move into a health reform climate at both the state and federal levels. The development of managed care to date has put Minnesota far ahead of the rest of the nation in terms of health care reform and in limiting the growth of health care expenditures. Accordingly, allowing the private sector to continue to seek market-driven solutions, even as it continues to work out the practical definitions, actual structures and public accountability of ISNs and CISNs, may be the most effective course of action the Legislature could take with respect to containing costs in the prescription drug market consistent with the broad goals of MinnesotaCare. We recommend that the current momentum of health reform be encouraged and allowed to develop.

   The Department recognizes the clear need for assistance for those who currently lack access to prescription drug coverage, primarily seniors and the uninsured and underinsured. However, any new assistance program to address these concerns will require a substantial financial base. We are reluctant to specifically recommend a prescription drug assistance program without a clear financing mechanism to support it. In addition, there is concern that the benefit associated with setting up an assistance program will not be realized if Congress passes legislation next year to include prescription drugs as a covered benefit under Medicare.

2. Establish a statewide formulary for the Regulated All-Payer Option (RAPO).

   Comment: All payers/providers who are not part of an ISN would be required to participate in such a statewide formulary and pay the same prices for prescription drugs. RAPO reimbursement rates would be determined by the State with public input and comment. Reimbursement would be set to cover pharmacy costs, would be phased in over time, and would include a component for pharmaceutical care services. The possibility of bidding out the administration of the statewide formulary to the private sector should be explored. Assurances would be required for the formulary to: 1) be used as a minimum with flexibility to purchase drugs outside the formulary for a higher copayment, 2) be used both as a dispensing function and as a price negotiation mechanism, and 3) be implemented statewide but include mechanisms to assure flexibility to meet the needs of providers and consumers by geographic area and populations with unique or special needs.

3. Incorporate the National Council of Prescription Drug Programs (NCPDP) standards for claims processing into subsequent MinnesotaCare uniform claims processing and billing requirements.

   Comment: The National Council of Prescription Drug Programs developed a standard format for the electronic submission of third party claims which are considered state of the art. These standards are being implemented by the State Medical Assistance program and are the standard across the country. The NCPDP standards fit with other uniform billing and claims processing initiatives and are very consistent with health reform efforts in Minnesota.

4. Require data reporting by payers on the amount of prescription drug rebates and use of those rebates in the management of their programs. This data should be included as a part of the information collected from payers on health care revenues and expenditures as required under MinnesotaCare.

   Comment: Currently, drug information obtained by the Commissioner of Health ignores the effect of rebates on the costs of drug expenditures. To ensure accurate cost containment guidelines, it is crucial to have true "net" costs of drug expenditures. This will require reporting of rebates received by Minnesota purchasers of pharmaceuticals.

5. Encourage community pharmacies (on an individual, joint or professional/ trade association basis) to explore the possibilities of establishing contractual networks with ISNs and CISNs to provide pharmaceutical services and to seek State exception from antitrust liability through the Department of Health's antitrust exception process.

   Comment: Community pharmacies face unique and serious problems in the current and future managed care dominated health care market. However, those pharmacies may be able to participate in a managed care network as Minnesota's health care system continues to define the identity and shape of the components that will make up ISNs and CISNs. The role that the community (retail) pharmacy will play in ISNs remains to be seen, but certainly among the possibilities are contracting with networks to provide pharmaceutical services, or perhaps even becoming an integrated component of an ISN or CISN. Retail pharmacies, either individually, or more likely jointly, through formal professional associations or informal regional alliances, should be encouraged to explore these possibilities in an atmosphere free of the fear of antitrust liability. If the ultimate result of such joint exploration is decreased prescription drug costs, increased access and/ or improved quality of care for Minnesota consumers, then antitrust exception is available through the Department of Health's antitrust exception process.

6. Examine the 1993 MinnesotaCare growth limit language to determine the plausibility of amending the law to address the unique concerns of retail pharmacies. The Minnesota Department of Health would work with pharmacy groups and other experts to come up with appropriate draft legislative language.

   Comment: Currently all payers and providers in the State are required to comply with interim limits on health revenues as provided under the 1993 MinnesotaCare Act. Independent retail pharmacies do not have control over acquisition costs and therefore should not be penalized for increases beyond their control.

7. Require the Department of Health to closely monitor the progress of federal health care reform, especially in the area of prescription drug benefits for Medicare beneficiaries, insuring that Minnesota's interests and priorities are effectively communicated to our national representatives.

   Comment: National reform efforts are underway to include a prescription drug benefit under Medicare as well as in the new universal set of minimum benefits under universal coverage. President Clinton's Health Security Act addresses both the coverage and cost of prescription drugs. The Commissioner will report to the Legislature on the progress (or lack of progress) of this national

health care reform effort, especially in the area of Medicare prescription drug benefits. Additionally, the Commissioner will develop specific recommendations related to seniors' access to prescription drugs based on the evolving status of national health care reform.

8. Support the concept of moving Medical Assistance and other State-funded programs into managed care.

   Comment: The Department supports moving Medical Assistance (MA), along with other State-funded programs, into managed care as quickly as possible. However, because of federal requirements and restrictions imposed on MA, the move into managed care is going to be difficult. The Department of Human Services should explore the development of additional mechanisms that could be incorporated into the current Medical Assistance program to facilitate the effective operation of the drug reimbursement program.

CHAPTER 1

NATIONAL AND STATE PRESCRIPTION DRUG EXPENDITURES AND TRENDS

NATIONAL AND STATE PRESCRIPTION DRUG EXPENDITURES AND TRENDS

INTRODUCTION

Although prescription drug expenditures were a rather small component (8%) of total health care spending in 1991, a decade of sharply increasing prices for pharmaceuticals has caused concern about the structure of the pharmaceutical marketplace. Prescription drug prices have increased faster than the general inflation rate for both the U.S. and the State of Minnesota over the last decade. Although recent voluntary efforts by large drug manufacturers have brought the rate of inflation for prescription drugs down to the general rate of inflation (the lowest rate in over two decades), the presence of competitive forces working to keep pharmaceutical prices and expenditures in check remains in question.

The following chapter provides an overview of the trends in prices and spending on pharmaceutical drugs in the U.S. and in Minnesota. The first section deals with the distribution of healthcare spending and how much drugs contribute to total health care spending. This is followed by a discussion of drug expenditure trends and the components of drug expenditures, namely, population, drug utilization or intensity, prescription prices, and administrative costs.

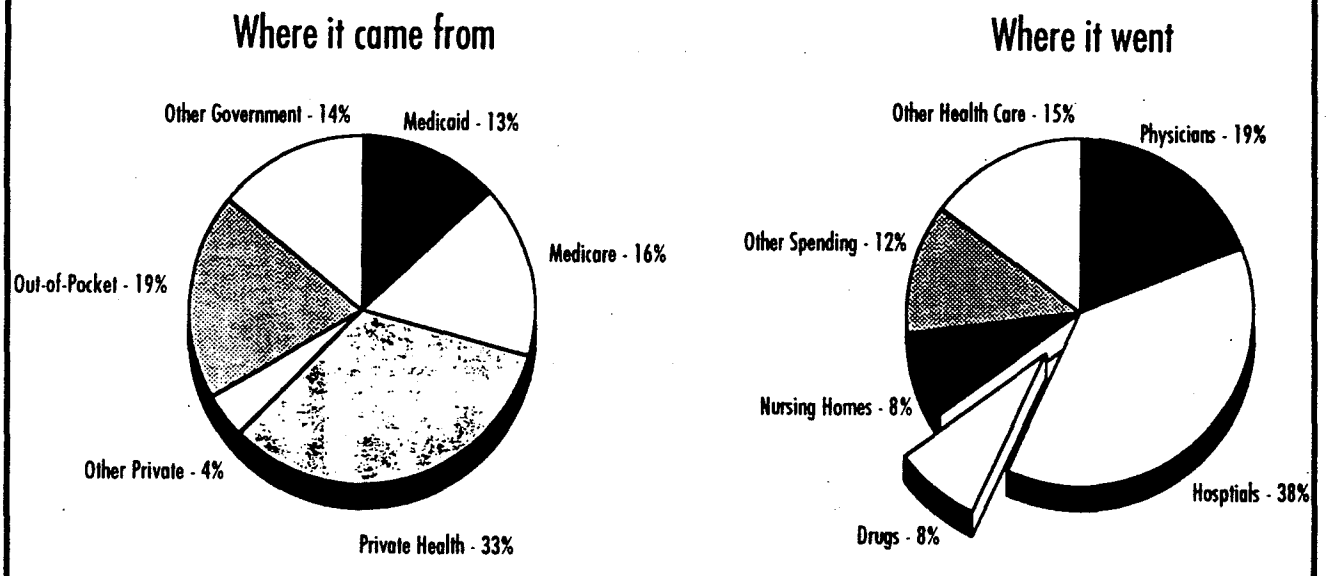
CURRENT DRUG EXPENDITURES AND FINANCING

Figure 1.1 depicts the distribution of U.S. health care spending by type of service for 1991. The estimate for national spending on pharmaceutical drugs was $60.7 billion or 8.0% of the $751.8 billion spent on health care in 1991.[1] This figure includes prescription drugs, over-the-counter (OTC) drugs, and medical sundries sold through retail outlets, but does not include drugs dispensed in hospitals, nursing homes, HMOs, and other nonretail settings. Accordingly, the figure underestimates total spending on pharmaceutical drugs. Prescription drugs comprise about 60% of these purchases ($36.4 billion) in 1991. The remaining $24.3 billion represent purchases for over-the-counter (OTC) drugs and other drug sundries such as contraceptive and first-aid products. In 1992, pharmaceutical drugs accounted for 15% of the increase in health care costs, while hospital costs and professional services accounted for 38% and 41% respectively.[2]

Estimates of expenditures for prescription drugs in Minnesota for 1991 was $548 million or less than 2% of total U.S. prescription drug expenditures. Again, these figures underestimate total purchases of prescription drugs as they exclude drugs dispensed in hospitals, nursing homes, HMOs, and other nonretail settings. Schondelmeyer estimates total Minnesota spending on outpatient prescription drugs at $816 million.[3] Between 1980 and 1991, current dollar expenditures for retail purchases of prescription drugs in Minnesota increased 287% from $191 to $548 million, compared to an increase in national drug expenditures of 302% over the same period. Minnesotans spend approximately 12% less per capita than the rest of the nation on prescription drugs.[4,5]

Nationally, over 50% of drug purchases are paid for directly out-of-pocket by consumers, primarily the elderly. The Medicare program does not provide coverage for prescription drugs and thus many consumers aged 65 years and older pay for prescription drugs directly. Third party payers accounted for

Figure 1.1
U.S. Health Care Spending, 1991



Source: Health Care Financing Administration

44.9% of all prescription drugs in 1991. Medicaid, the largest third party payer, paid for 13% of all prescription drugs and as such is the largest single purchaser of outpatient prescriptions in most states.[6] Prescription drug expenditures contrasts with services provided by physicians and hospitals, where 75% to 85% are covered by private and public third party payers.[7]

In Minnesota, independent and chain drug stores receive about 51% of their prescription drug payments from third party payers, including Medical Assistance (13%) and other third party payers (38%).[8] Medical Assistance is the largest single customer for prescription drugs in the state. Based on the dollar costs of prescriptions, rural independent pharmacies average over 22% of their receipts from Medical Assistance payments whereas urban chain stores average approximately 8%.[9]

Figure 1.2 shows that the share of prescription drugs paid by third parties in the U.S. has been increasing over the past 30 years.[10] Accompanying this increase in third party payments has been the emergence of active drug management programs and independent companies that contract with third party payers, HMOs and self-insured plans to manage drug expenditures. As third parties who provide drug coverage are ultimately responsible for covering the cost of prescriptions, they have a direct financial interest in actively managing the amount and rate of growth in prescription drug expenditures.

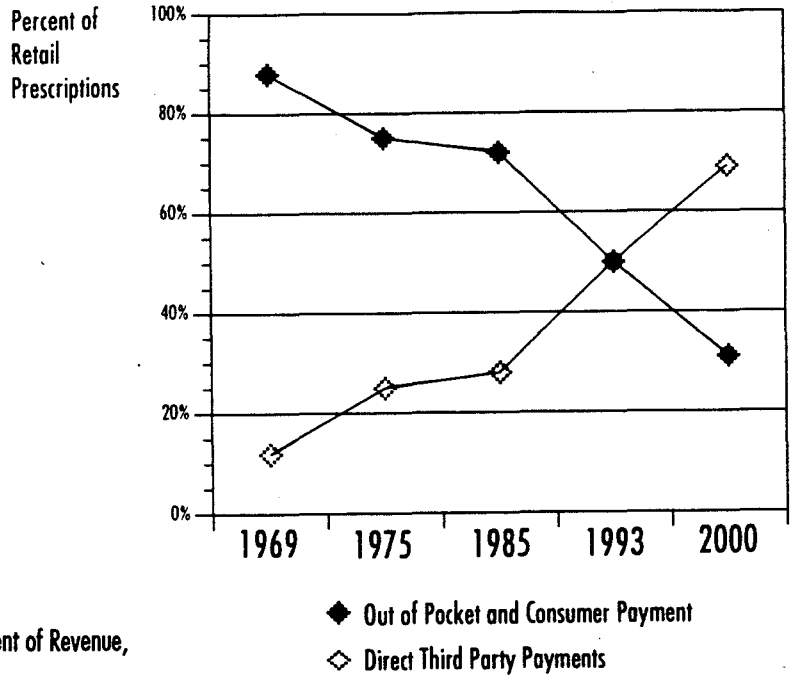
DRUG EXPENDITURE TRENDS

Figure 1.3 illustrates the percent annual change in retail purchases of prescription drugs in current dollars for the U.S. and Minnesota between 1981-91. The average annual growth rate for retail prescription drug expenditures in the United States was 10.6% compared to a 10.0% growth rate for

Figure 1.2

Change in Payment Source of Retail Prescriptions

1969-2000

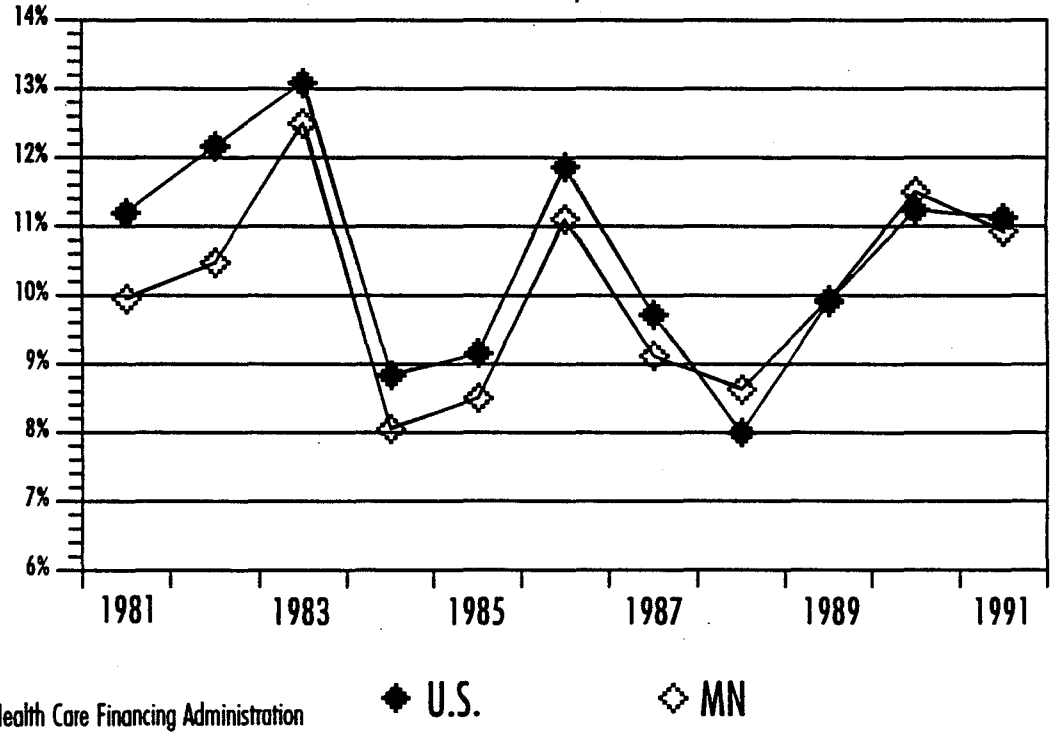


Source: Minnesota Department of Revenue, Tax Research Division, 1993

Figure 1.3

Retail Purchases of Prescription Drugs, Percent Annual Change

Current Dollars, 1981-91



Source: Health Care Financing Administration

While the CPI reflects what has been happening with prescription drug prices at the retail level, the producer price index (PPI-Rx) reflects prices charged for pharmaceuticals by manufacturers to all purchasers including hospitals, HMOs, mail order outlets, long term care facilities, physician offices, and other purchasers. Over the last five years, the PPI-Rx indicated that on a national basis, the rate of inflation for drug prices has been steadily declining. Drug price inflation fell from 9.5% in 1989 to 3% in 1993. The 1993 inflation rate is the lowest since 1981, the current index base year. At the same time, the overall PPI was also falling from 3.9% in 1989 to a low of 0.2% in 1993.

Schondelmeyer uses the 1991 PPI-Rx low of 7.1% and the CPI-Rx of 9.4% in 1991 to suggest that manufacturers have increased the price of drug products sold to retail pharmacies at a faster rate than the price of drug products sold to pharmacies in hospitals, HMOs, mail order and others.[19] The trend in prescription drug prices also varies by the type of product and whether it is a brand name or generic. In a recent analysis of rising prescription costs, the inflation rate for ingredient costs in 1991 was 15.9% for single source drugs (drugs available from only one company), 17.9% for multi-source brand name drugs, and 6.2% for multi-source generic drugs.[20]

Table 1.1 shows the average level of retail prescription prices for brand-name products, generics, and all prescriptions in 1992 for Minnesota and the U.S. Minnesotans used fewer brand-name products and more generics, paid higher prices for the brand-name products and lower prices for generics, yet in general, Minnesotans paid more for an average prescription ($26.39) than the average U.S. citizen ($26.04).[21]

Table 1.1

1992 Average Retail Prescription Price

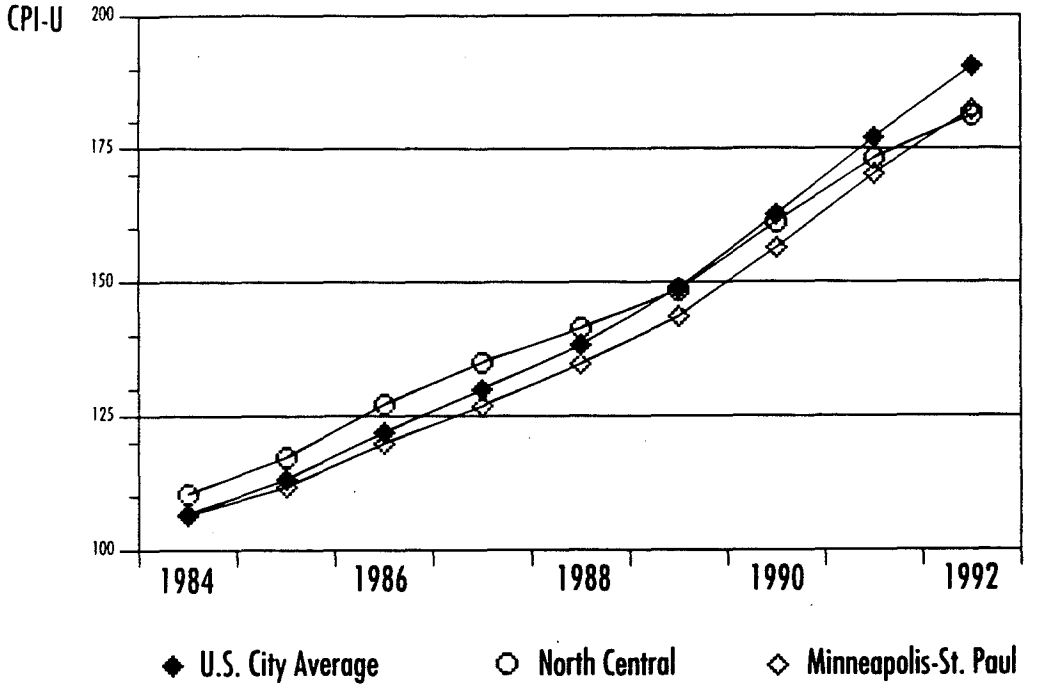
	National		Minnesota	
	Average Price	Percent of Rx's	Average Price	Percent of Rx's
Brand Name Rx's	$35.05	62%	$39.48	54%
Generic Rx's	$11.34	38%	$11.02	46%
All Rx's	$26.04	100%	$26.39	100%

Source: Minnesota Department of Revenue, Tax Research Division, 1993

Even though Schondelmeyer reports that Minnesotans paid more for an average prescription than the average U.S. citizen in 1992, since 1988, the average cost of overall medical care in Minneapolis-St. Paul has been consistently below the national average. Figure 1.6 shows the level of prices for medical care services using the CPI-U in the U.S., the North Central region[22], and Minneapolis-St. Paul.[23] The North Central region has experienced lower than average medical care prices since the mid 80s.

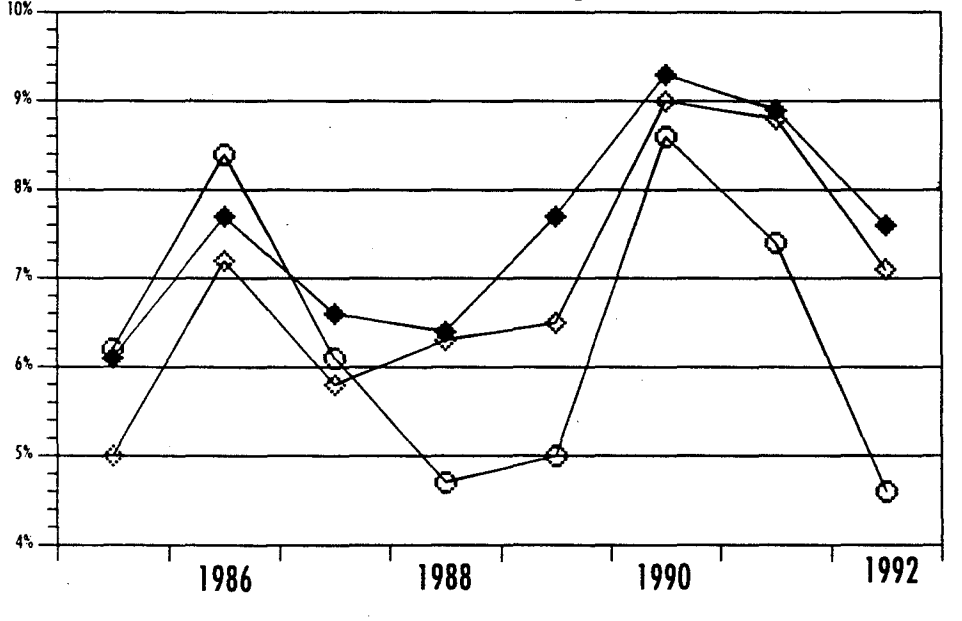
As the level of prices is important in realizing how much is spent on medical care, the rate of inflation indicates how fast prices are rising. Figure 1.7 illustrates the rate of inflation (the percent annual change in the CPI-U) for the price of medical care services in the U.S., the North Central region, and Minneapolis-St. Paul. Consistent with the trends in the level of prices, the rate of inflation for prices of medical care services in the North Central region was consistently lower than the national average. Just as prices in Minneapolis-St. Paul peaked in the mid 80s, the rate of inflation for prices of medical care services was also above national levels, but fell below both regional and national levels in recent years.

Figure 1.6
CPI-U Medical Care Services



Source: Bureau of Labor Statistics, Figures adjusted for base years 1982-1984.

Figure 1.7
CPI-U Medical Care Services
Percent Annual Change



Source: Bureau of Labor Statistics, Figures adjusted for base years 1982-1984.

Prescription Price Components

As indicated above, prescription drug prices are one component of pharmaceutical expenditures. In order to understand what has been driving the increase in prescription prices, the prescription price may be further broken down into three components:[24]

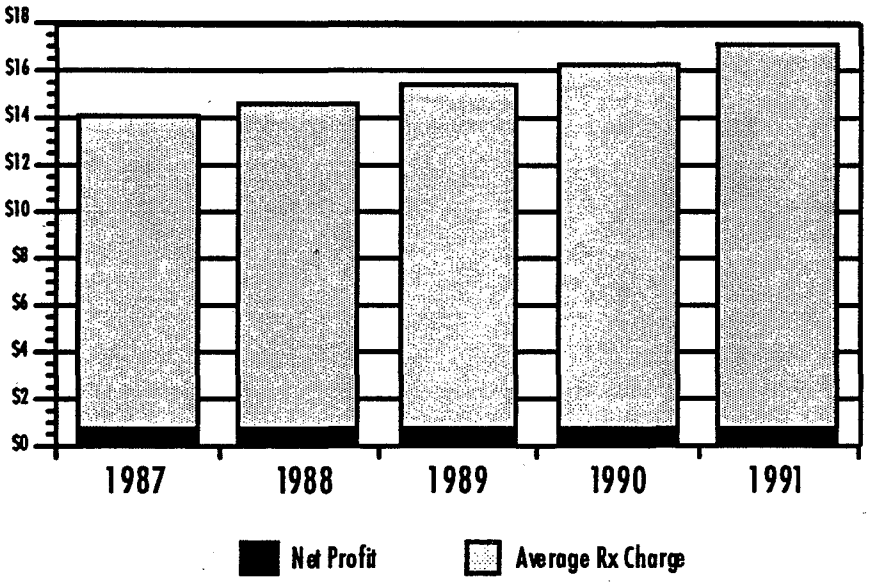
Prescription Price = Drug Product Cost + AWP Spread + Dispensing Fee
[----------Gross Margin----------]
[----------AWP Amount----------]

The drug product cost is the net cost paid by pharmacies to manufacturers or wholesalers for drug products or ingredients used when dispensing prescriptions. Pharmacies typically pay for the drug product at the Average Wholesale Price (AWP) set by drug manufacturers minus some percentage discount. Discounts earned through prudent purchasing practices, volume buying, and/or timely payments are known as the AWP spread.

The AWP spread and the dispensing fee compose the gross margin. After accounting for the drug product cost, the gross margin must cover operating expenses, rent, and profit. The AWP spread represents a variable rate contribution to a pharmacy's gross margin while the dispensing fee represents the fixed rate contribution to gross margin.

In Minnesota, 71.5% of the average prescription price in 1992 was attributed to product costs. The remaining 28.5% was attributed to wholesaler markups (1.7%) and to the retail pharmacists' services, including the dispensing fee (26.8%).[25]

Figure 1.8
Retail Prescription Components
Dollars Per Prescription



Source: Lilly Digest and Bureau of Labor Statistics, Figures adjusted for base years 1982-1984.

Figure 1.8 illustrates the trend in these components of retail prescription drug prices in constant 1982-84 dollars.[26] The average prescription price has been steadily increasing over time whereas net profits for retail pharmacies have been holding steady. Drug product costs, not increases in retail pharmacy margins, have been the major driving force behind prescription price increases and represent an estimated 80% to 85% of the prescription price increases.[27]

As an example, between 1982 and 1988, the cost of an average Medicaid prescription increased approximately 63%. Product costs increased about 87% whereas pharmacists' fees increased 15%. Given that the general rate of inflation between 1982 and 1988 was about 27%, pharmacists' fees actually decreased in real value while the drug product cost increased at more than three times the general rate of inflation.[28]

ENDNOTES

[1]Letsch, S., Lazenby, H., Levit, K., and Cowan, C. "National Health Expenditures, 1991." Health Care Financing Review Vol. 14, No. 2, Winter 1992, pp. 1-30. The value of drug therapy and pharmacy services in hospitals, nursing homes, physician offices, HMOs, government programs (such as the active military and the Veterans' Administration), and other nonretail settings are implicitly included in their respective spending sections of the nation's health care accounts and are therefore not included in the "drugs and other medical non-durables" section of the Health Care Financing Administration (HCFA) estimates.

[2]Moore, S. "Scapegoating the Pharmaceutical Industry." Healthcare Trends Report, Vol. 7, No. 3, March 1993, pp. 1, 15.

[3]Schondelmeyer, S. Pharmaceutical Care Expenditures in Minnesota, (Minneapolis: University of Minnesota, Prime Institute, 1993).

[4]Health Care Financing Administration, Office of the Actuary, Office of National Health Statistics. National, Regional and State Health Care Expenditures. HCFA, 1993.

[5]The value of drugs provided to patients by hospitals, nursing homes, HMOs, and health care practitioners in offices or clinics are not included under prescription drugs, but are implicit in the estimates of spending for those providers' services. The prescription drug expenditure estimates are based upon data from the Census of Retail Trade. Census data on prescription drug sales from mail order and direct selling establishments have not been used in the estimation of prescription drug expenditures by state, although these sales are included in the U.S. total.

[6]National Pharmaceutical Council. Pharmaceutical Benefits Under State Medical Assistance Programs. (Virginia: National Pharmaceutical Council, 1993), p. 101 and Letsch, S., Lazenby, H., Levit, K., and Cowan, C. "National Health Expenditures, 1991." Health Care Financing Review Vol. 14, No. 2, Winter 1992, pp. 1-30.

[7]Schondelmeyer, S. "Prescription for Growth of Retail Drug Chains in the 1990s." Luncheon Address to Salomon Brother's Retail Drug Seminar, New York City, Oct. 27, 1992, Prescription for Growth Retail Drug Seminar Review (New York: Salomon Brothers, 1992), p. 14.

[8]Minnesota Department of Revenue, Tax Research Division. MinnesotaCare Pharmaceutical Tax Study. (St. Paul: Minnesota Department of Revenue, 1993), p. 6.

[9]Minnesota Department of Revenue, Tax Research Division. MinnesotaCare, p. 7.

[10]Minnesota Department of Revenue, Tax Research Division. MinnesotaCare (Appendix), "Figure 5: Change in Payment Source of Retail Rx's: 1969-2000," and p. 17.

[11]Health Care Financing Administration, Office of the Actuary, Office of National Health Statistics. National, Regional and State Health Care Expenditures. HCFA, 1993.

[12]Schondelmeyer, S. Analysis of Prescription Expenditures at the Dalton Foundries, Inc.: 1989 VS. 1990. Unpublished report, p. 1.

[13]Days of therapy per person per year is a more precise description of intensity since a prescription for a 120 day supply has no more intensity than four prescriptions with a 30 day supply in each.

[14]Schondelmeyer, S. "Prescription for Growth of Retail Drug Chains in the 1990s." Luncheon Address to Salomon Brother's Retail Drug Seminar, New York City, Oct. 27, 1992, Prescription for Growth Retail Drug Seminar Review, (New York: Salomon Brothers, 1992), p. 24.

[15]Schondelmeyer, S. "Dynamics of Health Care Reform." Minnesota Pharmacist, Apr. 1992, p. 12.

[16]Gibbons, J. Memorandum to the Media. (Washington, D.C.; Pharmaceutical Manufacturers Association, June 18, 1993).

[17]FDC Reports Inc. "1993 Rx Drug Prices Increase 3% at Producer Level: Lowest Increase in 20 Years." FDC Reports Inc., 1994, p. 2.

[18]U.S. Congress, Congressional Budget Office. Projections of National Health Expenditures. (Washington, D.C.: Congressional Budget Office, Oct. 1992), pp. 29-30.

[19]Schondelmeyer, S. "Dynamics of Health Care Reform." Minnesota Pharmacist, Apr. 1992, p. 12.

[20]Schondelmeyer, S. "Dynamics of Health Care Reform," p. 12.

[21]Minnesota Department of Revenue, Tax Research Division. MinnesotaCare Pharmaceutical Tax Study. (St. Paul: Minnesota Department of Revenue, 1993), Table 1: 1992 Average Retail Prescription Price.

[22]The North Central region is one of 8 regions designated by the Bureau of Labor Statistics (BLS) and includes the 12 states: MN, ND, SD, NE, KS, MO, IA, WI, IL, IN, MI, and OH.

[23]The CPI for medical care services for Minneapolis-St. Paul is available for years 1984-92 only.

[24]Schondelmeyer, S. Analysis of Prescription Expenditures at the Dalton Foundries, Inc: 1989 VS. 1990. Unpublished report, p. 1.

[25]Schondelmeyer, S. Pharmaceutical Care Expenditures in Minnesota. (Minneapolis: University of Minnesota, PRIME Institute, 1993).

[26]Based on a survey of about 1,294 pharmacies, Lilly Digest, 1986-91. As prescription income for the pharmacies surveyed ranged from 66.5% in 1987 to 75.3% of total sales in 1991, the cost of goods sold, gross margin, and net profit figures are not reflective of the prescription department only, but rather reflect the pharmacies' overall business.

[27]Schondelmeyer, S. "Prescription for Growth of Retail Drug Chains in the 1990s." Luncheon Address to Salomon Brother's Retail Drug Seminar, New York City, Oct. 27, 1992, Prescription for Growth Retail Drug Seminar Review, (New York: Salomon Brothers, 1992), p. 21.

[28]Schondelmeyer, S. "Dynamics of Health Care Reform." Minnesota Pharmacist, Apr. 1992, p. 13.

CHAPTER 2

DESCRIPTION OF THE PRIVATE MARKET FOR PRESCRIPTION DRUGS

THE PRIVATE MARKET FOR PRESCRIPTION DRUGS

INTRODUCTION

The following chapter describes the private market for pharmaceutical drugs. The chapter is divided into six sections based on the key components of the market: manufacturers, wholesalers, pharmacists, third party payers, physicians and consumers. Each section includes a description of the key market component, its unique characteristics in the State of Minnesota, and a discussion of that components' impact on the pricing of pharmaceutical drugs.

MANUFACTURERS

Drug manufacturers research, develop, and market prescription and non-prescription drugs. Over $65 billion was spent in the prescription drug market in the U.S. in 1991[1] and an estimated $85 billion in 1993.[2] Minnesotans spent approximately $1 billion on pharmaceuticals in 1991.

There are two basic types of drug manufacturers: brand-name and generic. Brand-name companies invest heavily in the research and development of new drugs which are patented and cannot be produced by competitors. Generic firms develop pharmaceutical drugs that have the same active ingredient, route of administration, dosage form, and strength as a previously approved brand-name drug. The generic drug must be chemically and biologically equal to that of the approved brand-name drug[3] although the generic firms do not have to repeat the research that proved the innovator drug's safety and efficacy. Brand-name manufacturers have, in the past, and to a lesser extent, still do employ sales representatives who promote their products to doctors, nurse practitioners, nurses, and pharmacists in order to gain market share. Typically, sales representatives make one-on-one visits with these health professionals and try to influence the choice of drugs that are prescribed by physicians and that are stocked by pharmacists in the case of multi-sourced generic drugs. While brand-name companies have typically employed sales representatives to convince prescribers of the advantages of their drugs, generic manufacturers, on the other hand, have limited sales personnel, as these companies try to keep operating expenses to a minimum and keep their prices competitive. The one-on-one detail work with physicians is changing as managed care and other drug management programs increasingly influence physician prescribing practices.

These are tumultuous times for the pharmaceutical industry. There are increasingly more price-focused purchasers that demand both a good price and clinical value for the drugs purchased. In addition, increasing public pressure to reduce health care costs is being exerted in all health care sectors but especially for prescription drug prices. Other changes have increased the price competition among pharmaceutical manufacturers, including the increased presence of generic drugs, the growth of managed care organizations, large buying groups and drug management companies that aggressively monitor the type, use, and costs of prescription drugs.[4] Merck, a large national drug manufacturer estimates that managed care plans accounted for half of Merck's sales in 1993, up from 20% several years ago, with projections that managed care will comprise 75% of Merck sales by 1999.[5]

These pressures have resulted in changes, some radical, in the industry. Because of the increasing political pressure at the national level over soaring drug policy the pharmaceutical industry pursued a voluntary cost containment effort to limit the rate of increase in the price of the prescription drug

product. The consumer prescription drug prices rose 3.3% in 1993, nearly the same as the general rate of inflation. There has also been a recent flurry of mergers and acquisitions in the industry. For example, Merck, a large manufacturer, bought Medco, a drug management company, and brand-name companies have been purchasing generic drug firms. A recent article in The Wall Street Journal describes new "risk-sharing" agreements that some drug manufacturers are negotiating with managed-care and hospital buying groups. The underlying concept is that a drug company promises certain benefits in terms of drug costs and agrees to share in the risk of any costs over the targeted amount.[6] These arrangements are new and partly untested but promise new inroads into patient care management and the use of pharmaceutical drugs.

Research and Development (R&D)

Drug manufacturers invest heavily in R&D, the goal of which is to produce innovative breakthrough drugs as well as improvements on existing products (therapeutic equivalents). U.S. companies are considered leaders of the worldwide industry. Nearly half of all new drugs launched between 1975 and 1989 originated in the U.S., three times as many as any other nation.

Generic firms spend about 5% to 7% of sales on R&D while brand-name companies spend 16% to 18%.[7] Currently, there are an estimated 4,000 drugs in the R&D pipeline, reflecting a total investment of over $50 billion for the pharmaceutical industry. U.S. drug manufacturers spend approximately four times as much on R&D as the average manufacturing industry.[8]

Pharmaceutical R&D is a risk-filled activity. Since the commercial life of a typical brand-name product is only seven years, fewer than one-third of drugs launched have time to fully recover R&D investments before generic competition enters the market.[9] Nevertheless, there have been concerns raised that manufacturers earn more in profits than what they originally invested in research and development. Between 1981 and 1983, according to a congressional study by the Office of Technology Assessment (OTA), drug manufacturers earned at least $36 million more than needed to recoup R&D costs of each new drug introduced.[10] The Pharmaceutical Manufacturers Association (PMA) strongly objected to several of the economic assumptions made in the OTA study and argued that equally plausible alternative assumptions would have shown that R&D costs actually exceeded revenues for the new drug products included in the study.[11] Manufacturers also point out that spending on research and development is slowing down.[12]

Profits

Half of the industry profit margins from 1980 to 1993 was a result of increased prices on existing products, not from sales growth;[13] sales revenues more than tripled while the volume of drugs sold remained constant.[14] In 1992, manufacturers earned $2.31 in profits from the average prescription price of $26.04; retail pharmacists earned an average $.50 per prescription.[15] The same year, the pharmaceutical industry had the highest return on sales, assets, and stockholder equity of any industry in the Fortune 500. The 11.5% returns on sales was more than four times as high as the average Fortune 500 company and almost twice as high as the second most profitable industries. Eight of the top 25 companies with the highest absolute profits in the U.S. were drug manufacturers.[16] The OTA acknowledged in their congressional study that drug companies needed to earn more profits than other industries to attract necessary investment capital. The study revealed, however, that returns on R&D investments in new drugs introduced to the U.S. market between 1981 and 1983 were higher than was actually required to adequately reward investors for the time and risks incurred.[17]

The increasing pressures faced by drug manufactures in the marketplace are, however, changing the prospect for continued high earnings. Securities analysts predict fourth-quarter earnings for 1993 will rise on average only 3% to 6% compared to 15% to 20% in recent years. Drug companies that have innovative products where no equivalents are available (e.g. Merck, Pfizer) will probably continue to earn annual profits between 15% to 20% but analysts predict that for others (e.g. Eli Lilly, Marion Merrell Dow) the annual average profit growth will be closer to 5% to 10% through 1996.[18,19]

Industry analysts note that drug companies in the past had three ways to generate increased revenue: 1) introduce innovative, highly valued products, 2) launch "me-too" products (chemically different versions of patented drugs that treat the same condition effectively but at a lower cost) and 3) raise prices on all drugs. With the increasing pressures to keep prices down, one industry analyst claims that companies that simply increase prices will in fact lose market share.[20] Companies that succeed will be those that introduce breakthrough drugs and "me-too" products that can compete on price.

The Generic Industry

The generic industry boon began when Congress passed The Drug Price Competition and Patent Term Restoration Act of 1984. This legislation allowed generic drugs to receive Food and Drug Administration (FDA) approval in three years, approximately half the time that was previously needed. Since then generic drugs have achieved greater market share.

The FDA approved 229 new generic products in 1992, up almost 22% from 1991 and 186% from 1990.[21] The number of FDA generic drug approvals should increase further because brand-name products with combined annual sales of $18 billion will be going off patent in the next three years.[22] Included in this list is the non-sedating antihistamine, Seldane (Marion Merrell Dow) and the popular anti-ulcer drug, Zantac (Allen & Hansbury). By the year 2000, it is estimated that the patents for over 200 drugs will expire.[23]

Generics typically sell for half or less of the brand-name price of prescription drugs. For example, one brand-name antibiotic costs $110 for a month's supply compared to the generic product which costs $14.93 a month.[24] Brand-name volumes drop 50% to 60% the first year after patent expiration as a result of lower-priced generics entering the market.[25] Previously it took a generic counterpart almost 18 months to gain 50% market share; now it takes less than one year.[26]

Currently, over 300 firms contribute to the $9 billion generic industry, which constitutes 14% of U.S. sales of pharmaceuticals (prescription and non-prescription). In 1993, an estimated 30% to 40% of all prescriptions were filled with generics, up from 15% ten years earlier. By 1995 the Boston Consulting Group predicts that as more brand-name products lose their patent rights the generic industry may increase its annual sales to $21 billion, capturing 27% of the dollar volume and 50% of total prescriptions written.[27]

While the price of brand-name pharmaceuticals tends to increase annually, generic products typically decrease in price. This is because brand-name drugs compete with other brand- names on product differentiation such as side effect profiles, while generics compete primarily on price which is intense in the generic marketplace.

Other factors that account for the lower price of generic drugs are considerably less R&D expenditures and less marketing expense. Generic firms typically spend 5% to 7% of sales on R&D while brand-

name companies may spend as much as 16% to 18%.[28] The lower R&D expense is partly due to the fact that generic firms do not have to repeat the research that proved the innovator drug's safety and efficacy. The marketing expenses for generic firms are substantially lower because they do not employ nearly as many sale representatives as the brand-name companies.

The use of generics is pervasive in Minnesota. One large third party payer estimated that it saved an average of $20 every time a generic prescription was filled instead of using its brand-name counterpart. Currently 30% of all its prescriptions are filled with generic equivalents. If this payer increased its use of generics just by 1%, it estimated an annual savings of $400,000. This payer found generic substitution an especially good management tool for maintenance drugs (to treat chronic diseases), which comprise 70% of all prescriptions for which it pays.

Generic Drug Product Laws

The Drug Price Competition and Patent Term Restoration Act of 1984 amended the Food Drug and Cosmetic Act, permitting generic drug manufacturers to submit abbreviated New Drug Applications to the FDA. The result was that the generic formulation of a brand-name drug had only to produce a clinically equivalent outcome (bioequivalence) to the brand-name counterpart. Thus generic companies did not have to repeat the research that proved the innovator drug's safety and efficacy. Accordingly, soon after the patent expiration of the brand-name drug, a competitor's generic product could be on the market.

To facilitate the process of determining generic drug bioequivalence, the FDA set forth standardized testing procedures in Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as The Orange Book. A generic drug is considered to be bioequivalent if the rate and extent of its absorption is similar to the brand-name and it affects the patient's health to the same extent as the innovator drug. The bioequivalency comparison is rated "A" if there are no known problems and "B" if actual or potential problems exist. "B" rating indicates that the FDA does not consider the products bioequivalent. Products rated "AB" have demonstrated that any potential problems have been resolved based on laboratory and patient data. While pharmacists do assume a potential risk of liability with generic substitution, the risk appears minimal and more importantly, manageable. The risk is greater with therapeutic substitution. The Orange Book however, does not address the issue of therapeutic substitution.

Generic Substitution in Minnesota

The pharmacy Generic Substitution Law has been in effect in Minnesota since 1975. This law allows pharmacists to dispense a generically equivalent product for the brand-name when, in the professional judgment of the pharmacists, the two are therapeutically equivalent. The law also mandates that any difference in the actual acquisition cost between the generic and the brand-name be passed on to the consumer. The Board of Pharmacy believes that pharmacists are in compliance with the requirement to pass cost-savings on to consumers as they have not received a single complaint on this issue. However, some assert that consumers do not have enough information to determine whether cost savings have in fact been passed on or not.

Since January 1, 1994, generic substitution moved from a permissive to a mandatory statute (Minnesota Statutes 151.21, Subd. 3). The 1993 MinnesotaCare Act *requires* pharmacists to dispense a generic drug unless the purchaser objects or the physician has specifically indicated otherwise. Consumers must be informed if a generic is available and must be told that the generic will be dispensed even if the prescrip-

tion is written for a brand-name drug. Physicians may specifically direct that a brand-name be dispensed by writing "dispense as written" or "D.A.W." on the prescription, or by orally directing the pharmacist if the prescription is phoned in, pursuant to MS 151.21 (Subd. 2). Apparently, few physicians specify "dispense as written." Only about 1% of the prescriptions filled at Walgreens nationwide were specified as D.A.W.[29]

The Minnesota Board of Pharmacy estimates that as of December 1993, approximately 80% of all prescriptions with generic equivalents were actually filled with generics. This high rate of generic substitution is due in part to the intense price competition among retail pharmacies and mandated generic substitution required by third party payers through drug formularies. At best, the mandatory generic substitution law could affect the 20% of the prescriptions where substitution is in fact still possible. Thus, the Board of Pharmacy predicts the impact of the change from a permissive to a mandatory generic substitution statute will be minimal.

The 1993 generic substitution legislation specifically exempts eight drugs, Coumadin, Dilantin, Lanoxin, Phenobarbital, Premarin, Tegretol, Theophylline, and Synthoid, because they do not have a bioequivalent generic versions. Managed care formulary drugs are also exempt. Finally, pharmacists are not required to make a generic substitution that makes the prescription cost ineligible for third party reimbursement.

Reimbursement of Generics by Third Party Payers

Managed care, third party payers, and drug management companies have mandated generic substitution through the use of restricted formularies. A drug formulary is basically a restrictive list of approved drugs that payers agree to cover under their health plans. (See Chapter 6 for a more thorough discussion of formularies.) State-of-the-art computer technology allows pharmacists to check against the formulary at the point of sale.[30]

When third party payers instituted formulary policies that mandated generic substitution they also created a reimbursement formula whereby a pharmacist was paid a maximum allowable cost (MAC) for a generic prescription no matter what price the pharmacist actually paid to fill it. This encouraged pharmacists to buy products below the MAC, if possible, and created two levels of reimbursement: one for brand-name products (single source) and one for generic products (multi-source). Reimbursement for brand-name drugs is usually twice as high as the reimbursement for generics.

To address this issue, the Generic Pharmaceutical Industry Association (GPIA) has recommended a single-tier reimbursement system, based on median AWP for all multi-source drugs. "The higher brand-name reimbursement tier is essentially an artificial price support undercutting the competitive forces that would otherwise cause brand-name prices to fall close to generic price levels," says Association President Lewis Engman.[31] According to GPIA, by setting price reimbursement at the median AWP, generic manufacturers would be encouraged to price their products below the median to increase sales to pharmacists who want to purchase prudently and capture the difference between what they pay wholesalers and what they are reimbursed by third party payers. As this trend continues, the median AWP will decrease and competitive forces should decrease prices further.

Single-tiered reimbursement is being utilized by many third party payers, such as Medica in the Twin Cities. They do not prohibit the use of brand-name products, but only reimburse at a level that is comparable to generic products. This is sometimes referred to as a mandatory generic benefit.

Recent Trends in the Generic Industry

The threat of price controls and the intense competition from generic products has made the acquisition of generic companies very attractive. The trend is toward horizontal integration, that is, brand-name companies buying generic firms. Often times, favored generic companies are given exclusive rights by the brand-name company to manufacture the generic product *before* the patent expires. This way the brand-name company is able to flood the market before competitors, who must abide by patent laws, are allowed or able to market their product.

Some brand-name manufacturers actually produce the generic product and licenses its distribution to a generic firm that is already well entrenched in pharmacies. In September 1993, the Upjohn Company selected Geneva Pharmaceuticals, Inc. (a generic company owned by a different brand-name company, Ciba-Geigy Corp.) as the sole "distributor" of its two brand-name products, Xanax and Halcion, prior to patent expiration. Geneva's generic products are the same color, size, and shape as the branded product (with a different embossed logo) because UpJohn manufactures both products. Generic firms may manufacture their own products and/or distribute generic products manufactured by other companies.

Another recent example of the consolidation in this industry was last October's purchase by Hoechst Celenese Corp. (a brand-name company) of a controlling interest in Copley Pharmaceuticals Inc., one the nation's most profitable generic firms. That transaction was largely predicated on Hoechst selling Copley the ingredients to produce generic equivalents of its two brand-name drugs when they come off patent--Diabeta and Trental. That deal was preceded by a $275 million merger between Marion Merrell Dow, another large brand-name company, and Rugby-Darby Group, the nation's largest generic company.

Another marketing factor promoting generic firm acquisition is the ability to bundle generic products with other brand-name products made by the parent company when bidding for contracts with hospitals and third party payers. The manufacturer may offer only a moderately competitive price on its brand-name products, but a very low price on its generic line.

The significance of generics in the marketplace has been reinforced by the actions of the brand-name companies. Today, approximately 70% of the generic industry is owned by brand-name companies and the trend is increasing.[32] The following is a list of generic companies owned or controlled by brand-name manufacturers.[33]

OWNERSHIP OF GENERIC COMPANIES BY BRAND-NAME FIRMS

Brand-name company	Generic company
American Cyanamid	Lederle Standard Products
American Home Products	Elkins-Sinn, Inc.
Boehringer Ingelheim Pharmaceuticals Inc.	Roxane Laboratories,Inc.
Boots Pharmaceuticals, Inc.	Boots Laboratories
Bristol-Myers Squibb	Apothecon Products
Ciba-Geigy Corp.	Geneva Pharmaceuticals Inc.
Hoechst Celenase Corp.	Copley Pharmaceuticals Inc.
IVAX	Goldline Laboratories
Marion Merrell Dow	Rugby Laboratories Inc.

OWNERSHIP OF GENERIC COMPANIES BY BRAND-NAME FIRMS (continued)

Brand-name company	Generic company
Merck, Inc.	West Point Pharma
Monsanto	Schiapparelli Searle
Rhone-Poulenc Rorer Pharmaceutical Inc.	Arcola Laboratories
Sandoz Pharmaceuticals Corp.	Creighton
Schering Corp.	Warrick
Syntex	Hamilton Pharma
The Upjohn Co.	Greenstone
Warner-Lambert Co.	Warner Chilcott Laboratories
Wyeth-Ayerst Laboratories	ESI-Pharma
Zeneca Pharmaceutical Corp.	IPR Pharma

How Pharmaceutical Market Channels Affect Pricing

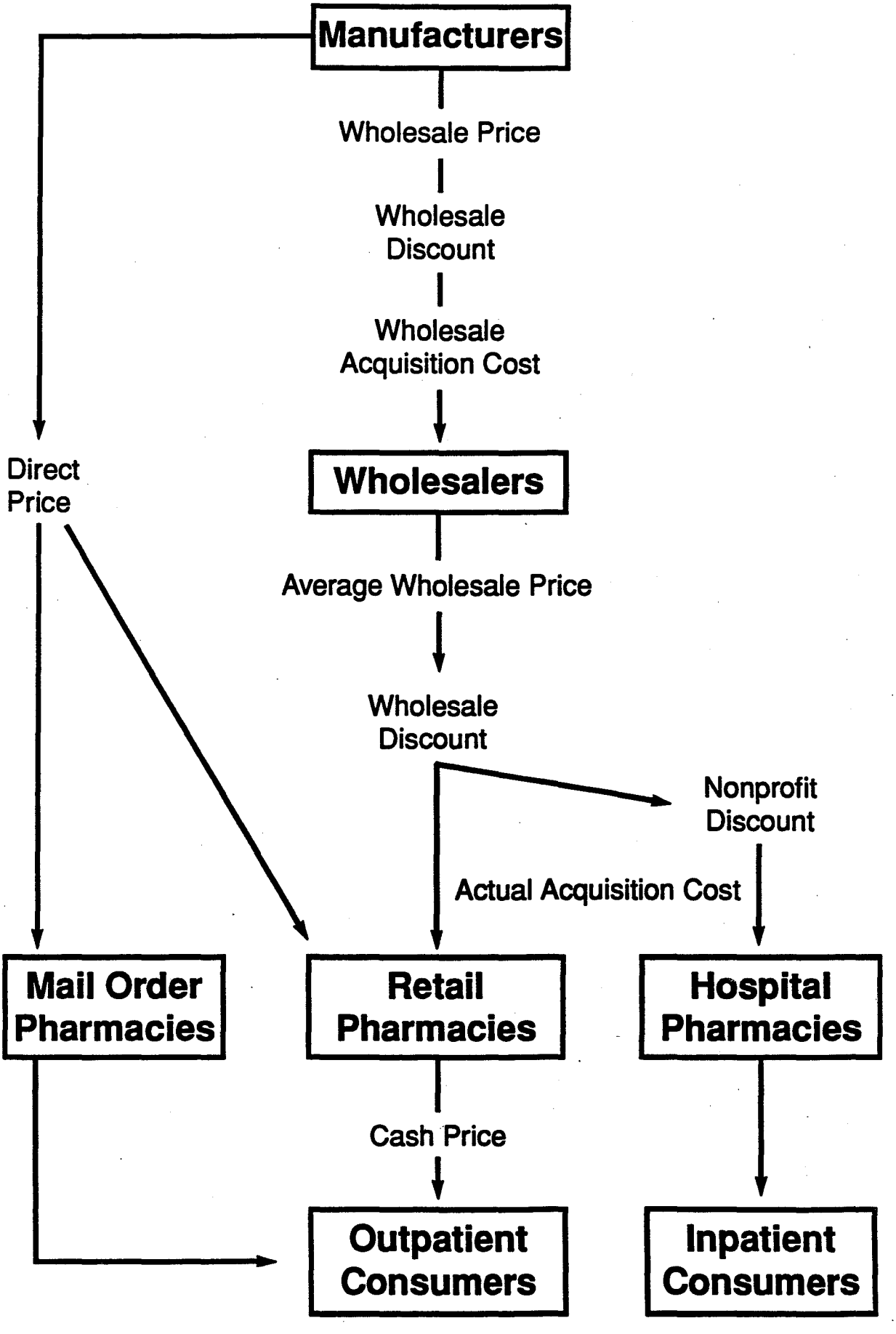
While pharmaceuticals are distributed through typical market channels--manufacturers to wholesalers to pharmacies to consumers, the pricing structure of pharmaceuticals is complex (See Figure 2.1). First, prices are based on the product's average wholesale price (AWP) which is set by the manufacturers. AWP is derived from an average of the manufacturer's list price to different wholesalers (some wholesalers are able to negotiate bigger discounts off the list price than others, but the differences are small). AWP is published annually in three sources: Master Drug Data Base, the Blue Book, and the Red Book.[34] The AWP is the starting point of all price negotiations.

Manufacturers set a product's list price and present it to wholesalers as a suggested price to sell to pharmacies. Wholesalers are generally given discounts off the suggested list price in order for wholesalers to generate profit margins. As with wholesalers, most, if not all, pharmacies negotiate for discounts off of the AWP. The actual amount the pharmacy ends up paying for a drug is called the actual acquisition cost.

What makes the pricing structure of pharmaceuticals seemingly complex is that manufacturers start at the end point, the suggested list price (or AWP) and work backward. For example, a manufacturer could sell to a wholesaler at AWP minus 15%, who could then turn around and sell to a pharmacy at AWP minus 12% to yield a 3% margin. Wholesalers claim that they actually sell on a "cost plus" basis, that is, at wholesale acquisition cost plus some charge for the value of the services they provide to the customer. Those services would include, for example, such items as deliveries, printing of price labels, special order processing and bar coded product identification stickers. This charge also includes a margin for profit. In essence, whether one uses the AWP minus X% approach, or the AWP cost-plus approach, the profit margin for the wholesaler is the same. Some larger chain drugstores (e.g. Walgreens, Wal-Mart) act as their own wholesaler and capture both a volume discount and the wholesaler margin in doing so.

Pharmacies usually do not pay the full AWP for a product; it is only a reference point from which to negotiate discounts. Thus, some industry analysts have labeled this system artificial. It is difficult to know the actual drug prices charged by manufacturers in this system because of the different discounts given to different purchasers.

Figure 2.1 Pricing In TheTraditional Pharmaceutical Marketplace



Rebates Complicate Pricing Structure

Rebates have further complicated the pricing structure in the pharmaceutical market. Figure 2.2 illustrates the complex pricing structure. Third party payers including managed care health plans that use restrictive formularies have been able to negotiate rebates from manufacturers in exchange for the inclusion of specific drugs on the payer's formulary. A formulary is basically a list of drugs that are approved by a committee of doctors and pharmacists (the Pharmacy & Therapeutics Committee) that decide which drug within a therapeutic class will be reimbursed by the payer. In addition, the Medical Assistance program receives rebates but these rebates are not associated with the use of formulary. Rather the rebates are used to assure that the state Medicaid programs receive the "best price" in the market (see Chapter 3 for discussion of Medicaid best price policy and manufacturer rebates).

Third party payers use formularies to negotiate rebates based on the guarantee of market share for drug manufacturers. For example, if the payer's formulary allows for only one ulcer medication, out of the four products on the market, then that one product has 100% market share for that particular payer. If a prescription was written for any of the other three products, the formulary product would be therapeutically substituted under guidelines established by the payer's Pharmacy & Therapeutics Committee.

Manufacturers provide rebates based on the exact usage of each product on the formulary. The pharmacist who fills a prescription for an insured patient sends the usage information (e.g., drug name, manufacturer, and quantity) to a third party payer via on-line claims processing. The payer's computer sends back a message to the pharmacy informing them of the reimbursement the pharmacy will receive and the amount to be paid by the patient (i.e., the copayment). The insurer takes the usage data from the pharmacy and uses it to collect manufacturer rebates based on the pre-negotiated contracts.

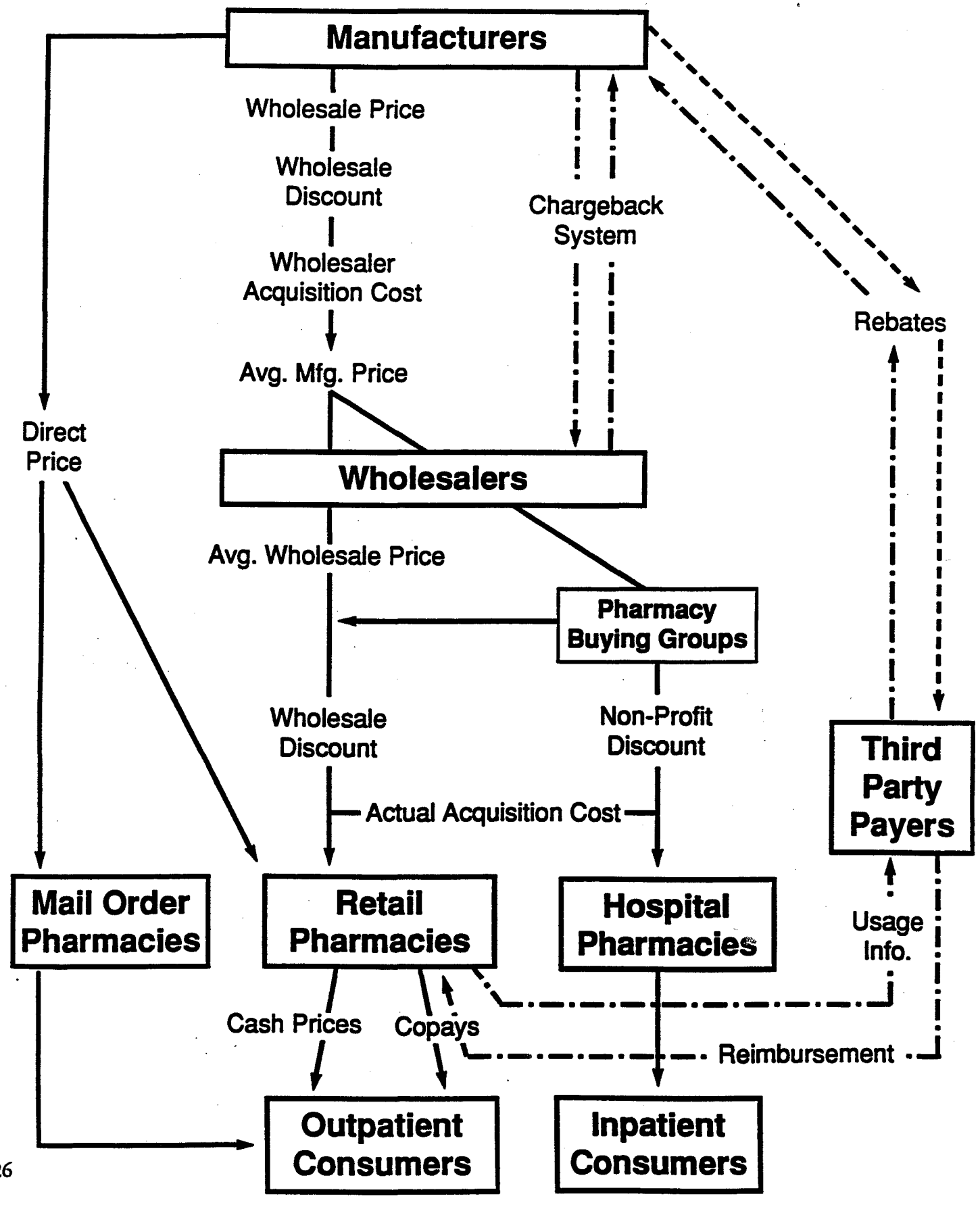
Medicaid and the Omnibus Budget Reconciliation Act of 1990 (OBRA 90)

Medicaid previously reimbursed pharmacists a discounted average wholesale price (AWP) plus a dispensing fee which provided a reasonable profit for most pharmacies. If pharmacy purchasers negotiate discounts off AWP with the wholesalers, they could be more competitive on the dispensing fee for Medicaid prescriptions. Pharmacist reimbursement had typically relied on lower than necessary dispensing fees because pharmacies were able to negotiate discounts off AWP. Now, state and federal legislation has set the Minnesota Medical Assistance reimbursement rate at AWP minus 7.6% plus a $4.10 dispensing fee for filling prescriptions. This compares to the average managed care or managed buying group payment of AWP minus 15% plus a $2 to $4 dispensing fee.

State Medicaid programs also receive rebates, based on the average manufacturer's price. OBRA 90 required drug manufacturers to pay rebates to state Medicaid programs, the largest single purchaser of outpatient prescriptions, to the level of the "most favored purchaser" in the marketplace. The "most favored purchaser" refers to the purchasers that receive the best national price for pharmaceutical products, typically hospitals and managed care entities. The rebates are based on pharmacy usage data and determined by a national formula applied across the country. Thus, Minnesota's Medical Assistance program pays no more than AMP minus 15% for brand-name drugs and often receives further discounts to match the best price offered by the manufacturer to any non-exempt purchaser.

The Medicaid rebates affect generic firms differently than brand-name firms. Federal policy sets Medical Assistance rebate for generics at AMP minus 11% as of January 1, 1994. While the rebate is smaller for generic products than brand-name, so are the net prices. Strong competitive pressures continue to keep generic prices down, too. In 1991, the impact of Medicaid rebates was more than four times

Figure 2.2 Pricing In Today's Pharmaceutical Marketplace



greater on the net income of generic firms, who experienced a 30.9% decline in net income, than on brand-name companies, who suffered just a 6.8% decline. As a result, the generic industry was impacted to a much greater degree than the brand-name manufacturers.[35]

Since generics are usually priced at a quarter to a half of their brand-name counterparts, gross and net margins for generic firms follow the same trend. While generic firms have gross profit margins (sales minus production costs) around 30%, brand-name companies have gross margins ranging from 64% to 80%, giving them two to three times as much room to absorb the cost of the Medicaid rebate. This means that brand firms have more than twice as much room as generic firms in their budgets to absorb Medicaid rebates.[36]

Because of the impact that generics have in lowering drug costs, the Generic Pharmaceutical Industry Association has advocated that generic products be excluded from any drug manufacturer rebate requirement programs MinnesotaCare may institute. They stress that the entry of generic firms into the market and the use of generic products should be encouraged.

WHOLESALERS

The basic function of the wholesale drug industry is to ensure the expedient, safe, and cost-efficient distribution of pharmaceuticals and other health care products to pharmacies across America. Wholesalers store products in closer proximity to their pharmacy customers than do manufacturers, which are based nationally. This enables wholesalers to deliver products to pharmacies "just in time" which helps pharmacies increase their turnover rate.

Wholesalers provide customers with economies of scale. To provide these economies, wholesalers perform a sorting function by concentrating goods, dispersing them in economic quantities, and then transporting these goods to the pharmacy. Wholesalers reduce the overall number of transactions required to supply pharmacies (61,000 nationwide) with product because wholesalers concentrate orders to manufacturers. The average wholesaler buys product from more than 600 manufacturers and delivers products daily to 500 customers. Wholesalers reduce the total number of transactions required each year by an estimated 90%. An average of 668 transactions or orders, containing 13 different products (invoice lines), are processed every day by wholesalers, costing just $2.04 to handle each invoice line.[37]

Wholesalers Doing Business in Minnesota

There are currently eight full-service wholesalers who provide most of the drug distribution to Minnesota pharmacies:

Alco Health Services Corporation, Eden Prairie, MN
Cardinal Whitmire Distribution Corporation, Eagan, MN
Fox Meyer Drug Company, LaCrosse, WI
Jewitt Drug Company, Aberdeen, SD
McKesson Drug Company, St. Paul, MN
Northern Drug Company, Duluth, MN
Northwestern Drug Company, Minneapolis, MN
Twin City Wholesale Drug Co, Minneapolis, MN

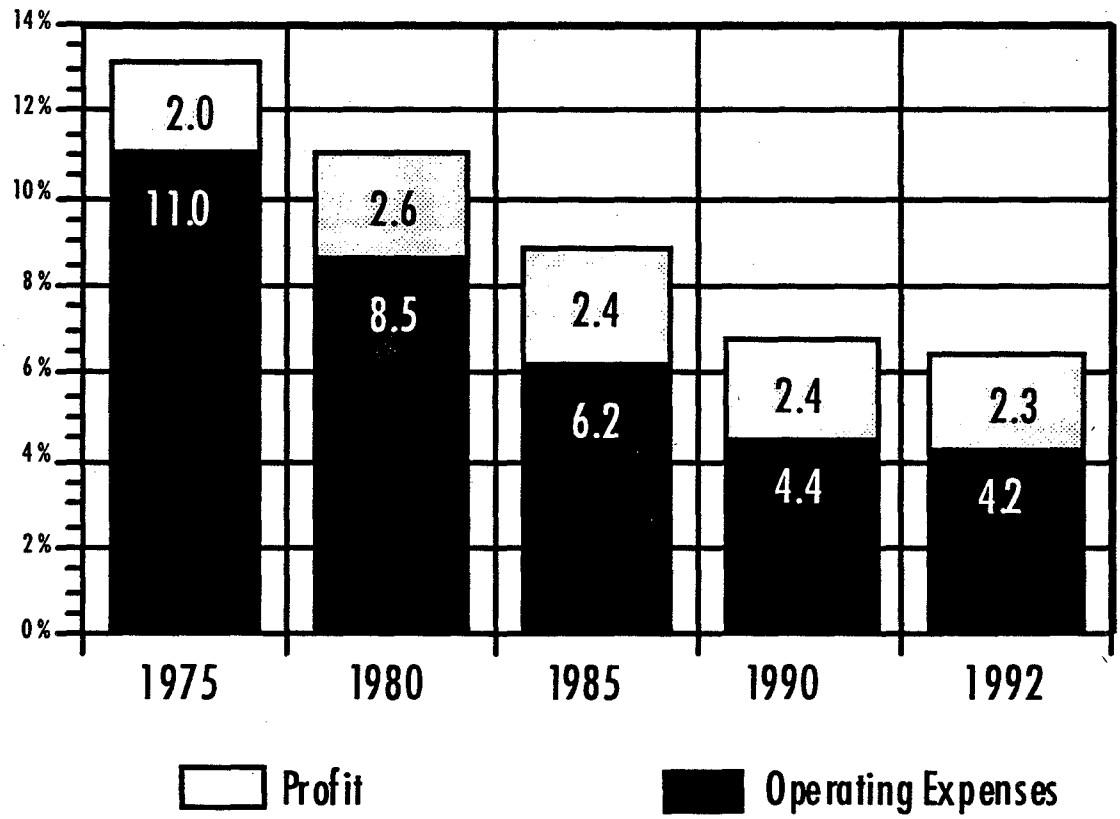
All of the companies listed above are national wholesalers except for Jewitt Drug which is locally owned

and operated. The Minnesota-based wholesalers employed over 425 Minnesotans and generated $640,725,000 in sales in 1992. This sales volume represents 1.5% of the total U.S. pharmaceutical sales through full-service drug wholesalers.[38] The Minnesota wholesaler industry operated on an average net profit after taxes of 1.28% in 1992.[39]

Efficiencies in the Wholesaler Industry

In 1992, the U.S. drug wholesale industry reduced its total operating expenses to 4.2% of sales through increased efficiencies. The industry has increased its ability to fill orders nearly error-free in 24 hours due to robotics and restructuring of workspace. Investments in computers and robotics, as well as value-added services (inventory management for pharmacies, co-op advertising programs, and coupon redemption services, etc.), brought more customers into the wholesaler distribution channel. Wholesalers *reduced* their gross margin to 6.5% and yet maintained a profit of just over 2%. The National Wholesale Druggist Association reports that several Minnesota wholesalers have cut operating expenses significantly lower than the industry average. The overall downward trend in gross margins is expected to continue due to the intense competitive forces in the marketplace, as depicted in Figure 2.3.

Figure 2.3
U.S. Wholesale Operating Expenses and Average Profits



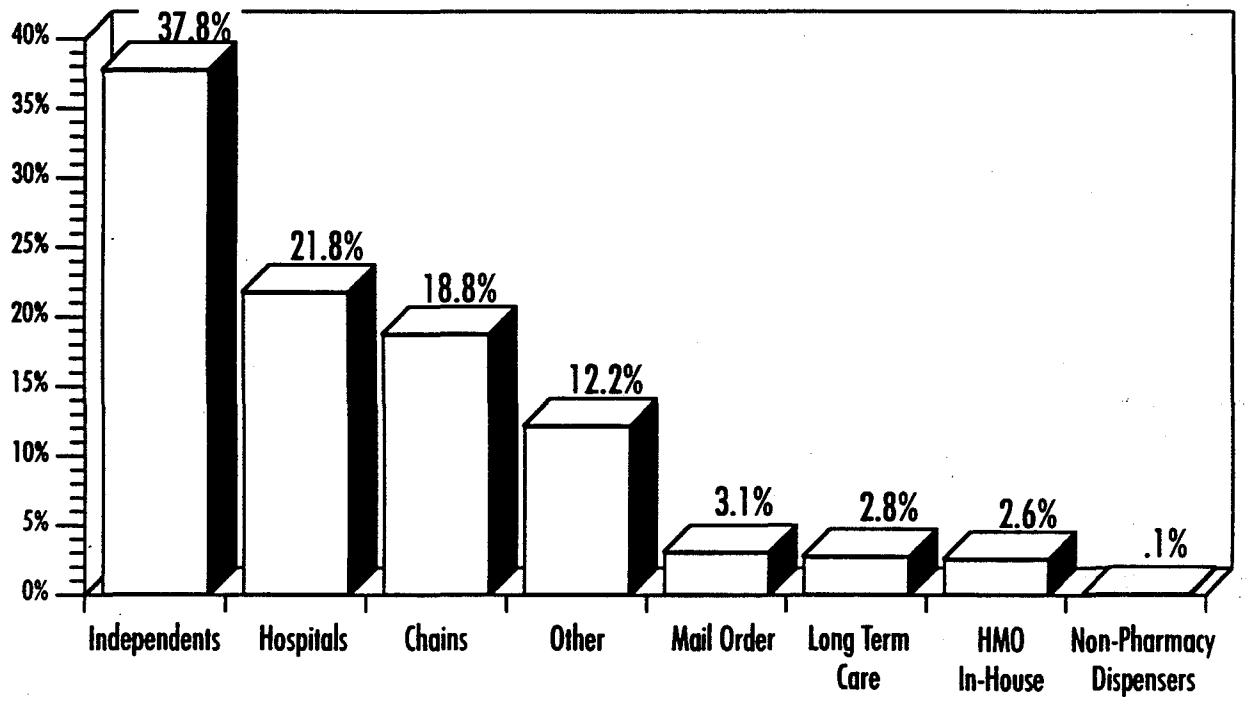
Note: Profit + Operating Expenses = Gross Margin
Source: National Wholesale Druggist Association

Wholesalers are Preferred Channel of Distribution

Wholesalers have become the preferred channel of distribution for pharmaceutical products. In 1976, 48.5% of all pharmaceuticals were distributed through full-service wholesalers; by 1990 that increased to approximately 75%.[40] Figure 2.4 shows the channels of distribution as a percent of Minnesota's wholesale drug revenue in 1991.[41] Over one-third of the wholesale business in Minnesota is with independent pharmacies, followed by hospitals (22%) and chain drug stores (19%).

Figure 2.4

Channels of Distribution as a Percent of Wholesale Drug Revenue in Minnesota, 1991



Source: Minnesota Department of Revenue, Tax Research Division, 1993

Wholesalers can offer pharmacies smaller minimum order requirements, easy return goods policies, and quicker service than direct purchasing from manufacturers. Several manufacturers, such as Lederle, Merck, the Upjohn Company and Wyeth-Ayerst, allow pharmacies to purchase products directly from the manufacturer, which saves pharmacists money by eliminating the wholesalers' markup. However, the amount of pharmaceuticals purchased directly from manufacturers is on the decline. Pharmaceutical products are also distributed through regional wholesalers and national chain drugstores such as Walgreens and Wal-Mart that warehouse their own supplies and distribute from a central location.

The federal government has tried a similar drug depot system. The Department of Veterans Affairs (VA) and the Department of Defense (DOD) determined that their own government-run depot systems were inefficient and turned to commercial wholesalers. A study conducted by the U.S. General Accounting Office (GAO) showed that the federal government, using its own wholesale network, spent nearly $11 in distribution costs for each $100 spent on pharmaceuticals in 1991 compared to $4.40 for each $100

spent by the average full-service private wholesaler.[42] The GAO study concluded that the private sector was far more efficient in distributing pharmaceuticals than the government. Additionally, the study found that purchasers themselves (such as the government) do not need to warehouse and distribute the product to be able to negotiate the best prices from manufacturers.

Like the VA, the DOD expects to save $75 million annually, and receive more reliable service, by switching from their government-run drug depot system to a private sector vendor system. Currently, McKesson is prime vendor for the DOD in four regions.

Competition in the Wholesale Drug Industry

The wholesale drug business is highly competitive and operates with decreasing margins because of the significant investments in technology that have been made in recent years. Over a 31 year period ending in 1991, wholesalers' average gross margins decreased from 17.3% to 6.8%. Wholesalers' contribution to pharmaceutical costs have been cut by nearly two-thirds over that period.[43]

To remain competitive, drug wholesalers have traditionally passed these savings to their customers. "This is especially true in Minnesota where competition has forced a reduction in the fees we charge our pharmacy customers of as much as 50% and more in the past few years," said one wholesaler interviewed for this study.

Volume Discounts

Wholesalers base their revenues on the cost of a drug plus a percent mark-up, a "cost-plus" formula. The mark-up is based on the dollar volume of purchases of a particular pharmacy buyer, and is relatively small compared to manufacturer mark-ups. Wholesaler's operating and delivery costs for large volume orders are a smaller percent of the value of the order and thus the mark-up for those purchasers is correspondingly smaller.

Wholesaler Participation in Chargebacks

While wholesalers for most other industries usually work to get the lowest prices for their customers, drug wholesalers typically do not negotiate prices on behalf of their pharmacy customers. As a result, drug wholesalers are often viewed by many pharmacists as more closely representing the interests of the manufacturer.

Wholesalers administer contracts for hospital buying groups who negotiate discount prices directly with pharmaceutical manufacturers. The wholesaler sells the product to their customer, the hospital, and invoices them at the negotiated discount price plus a small markup for warehouse and distribution costs. If that contract selling price is less than the wholesaler's acquisition cost for that same item from the manufacturer, as is often the case, the wholesaler issues a "chargeback" to the manufacturer for the difference between the contract selling price and the wholesaler's cost. The wholesaler generally administers the chargebacks as a service to the customer at no cost.

Wholesalers invoice buying groups at their net discounted price, and float the value of the chargeback to the manufacturers until the rebates are paid. For example, a wholesaler may charge one hospital pharmacy for the price of the drug plus 2%. If a wholesaler buys a particular product for $100 from the manufacturer (wholesaler acquisition cost) and sells it to a hospital which is a member of a hospital buying group which has (previously) negotiated a $50 discount from the manufacturer, the wholesaler will invoice this transaction at $50 plus 2%, not at $100 plus 2%. To recapture the $50 differential in

price, the wholesaler bills a $50 chargeback to the manufacturer along with the usage data of the hospital. With this information, manufacturers reimburse wholesalers $50 plus a service fee for processing the chargebacks.

In addition, many Minnesota wholesalers sponsor voluntary buying groups for pharmacy customers: Northwestern has Merritt; McKesson has Valu-Rite. These voluntary organizations have access, as a group, to products and services the wholesaler creates or negotiates for them such as advertising private label over-the-counter products and discount programs, including discounts off the wholesaler's regular price. As a group, these voluntary organizations can generally provide better access to programs and discounts from suppliers than each drug store could achieve on their own.

Looking Forward

In the short run, the gross margins of wholesalers will continue to be adversely affected by the voluntary slowdown in the rate of pharmaceutical price increases. Since wholesalers price pharmaceuticals at cost plus X%, any reduction in the base cost reduces their overall profit.

Another recent change for wholesalers was the 2% MinnesotaCare Tax effective January 1, 1994, on all gross receipts from prescription drug sales to pharmacy customers. Wholesalers try to collect this tax from their customers and must include any amount collected as part of their gross revenues. Since the tax liability in the state is based on revenues, the wholesale industry argues that this is a tax on a tax.

Wholesalers hope to make up for these decreased margins by improving operating efficiencies, restructuring wholesaler access by using regional distribution centers, and increasing the customer base, among other initiatives. Gross margins should continue to be influenced by increased sales to hospitals and chains, who have lower gross profit margins and lower associated operating costs.[44] Competition will remain a key factor in controlling prices in the wholesale drug industry.

THIRD PARTY PAYERS

Third party payers include health plans such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs), Blue Cross Blue Shield (BCBS), commercial insurers and government programs (e.g. Medical Assistance) that provide coverage for prescription drugs. Notably absent from this list is Medicare, which does *not* include prescription drugs as a covered benefit for the elderly and disabled. Prescription drugs account for 25% of all claims and nearly 8% of all charges of third party payers.[45] Coverage for prescription drugs generally includes reimbursement made directly to the pharmacy and a patient copayment. Reimbursement includes a payment for the cost of the product (average of AWP minus 12%-15%) and a dispensing fee ranging from $2 to $4.10.

In 1993, there were 12 licensed HMOs in Minnesota with a total of 1.2 million enrollees, nearly 27% of the state population.[46] Enrollment in HMOs is concentrated in the seven-county metro area of the Twin Cities where 44% of the population belongs to an HMO. In greater Minnesota, HMOs (mainly Blue Plus and Medica Choice) have enrolled about 7% of the population. Pockets of more intense HMO penetration occur around Duluth and St. Cloud.[47]

Blue Cross and Blue Shield of Minnesota (BCBSM) is the largest health insurer in Minnesota and pays for approximately 20% of all prescriptions filled in the State. BCBSM insures about 25% of the State's population under a variety of different health insurance plans. About 80% of BCBSM members are in

managed care plans including PPOs and 20% are in traditional indemnity plans. In addition, BCBSM serves as a fiscal intermediary for Medicare in Minnesota. Approximately 98% of Minnesota pharmacies participate in BCBSM's pharmacy network.

Given the heavy prevalence of managed care in Minnesota, it is not surprising to find that at least 75% of all Minnesotans enrolled in a health insurance plan that includes pharmacy benefits are involved in some type of a formal drug management program.[48] These programs, typically employ the use of formularies, drug utilization review, generic substitution, and prior authorization to manage drug expenditures. In addition, the drug management programs process rebates from manufacturers for third party payers' based on the usage of drugs included on the payer's formularies. The main types of managed drug benefit programs are those found in: 1) HMOs, 2) those provided by drug management companies that contract with HMOs, PPOs, commercial carriers and self-insured plans to manage drug expenditures, and 3) programs run by third party payers themselves. The larger drug management companies working with Minnesota payers include the following:

- Pharmacy Gold, Inc. is a subsidiary of BCBS and is organized as a separate, for-profit management company that provides managed care pharmacy services. Pharmacy Gold, Inc. purchases pharmaceuticals for over 9 million people across the country including BCBS enrollees in Minnesota.

- Diversified Pharmacy Services (DPS), a Bloomington-based for-profit subsidiary of United Health Care, manages the drug benefit programs for Medica, a Twin Cities HMO, and several PPOs, including Ethix, and self-insured plans. DPS manages drug expenditures for 12 to 13 million people.

- PCS Health Systems, Inc. is the largest pharmacy benefit management company in the country, managing drug benefits for approximately 45 million members with annual drug expenditures of over $6 billion. The clinical division, Clinical Pharmacy Advantage (CPA), is located in Minneapolis, Minnesota and provides the integrated formulary/drug utilization review programs as well as the clinical focus for client management and program development. McKesson Corporation, one of the nation's largest wholesalers, is the parent company of both PCS and CPA.

- Group Health (now HealthPartners) has its own internal drug management program and owns its own pharmacies and provides services to approximately 580,000 enrollees.

Combining pharmacy management tools--volume discounts, generics, drug utilization review, formularies, rebates, maintenance dispensing (100 day supply of chronic medications), and clinical management--maximizes the cost savings. PCS estimated that these tools enable them to save 25% to 30% off their projected drug budget. Drug management programs typically use the same general strategies to manage drug expenditures and process claims. The key strategies are listed in Table 2.1. The following sections describe in more detail the use of formularies and prior authorization as pharmaceutical cost containment strategies.

Table 2.1

Pharmaceutical Management Tools

Formulary
- Restricted List of drugs for prescription. Range from suggestions with cost flags to mandatory restricted lists
- Increasingly restrictive and widely used in group (70%) and staff model (88%) HMOs

Drug use review (DUR)
- Review of individual, or physician group, prescribing patterns, adherence to formulary, frequency of use, etc.
- Used to encourage compliance and identify high-cost users among physicians

Generic substitution
- Pharmacists allowed to substitute generic version for a brand-name drug prescription
- Widely used across all types of HMOs -- 40% of prescriptions are generics in HMOs

Copay option for patients
- HMO allows patient to choose brand-name drug over generic but patient pays some or all of the cost difference

Step therapy
- More expensive drugs only prescribed after low cost alternatives tried

Sources: Marion Merrell Dow; Boston Consulting Group analysis

<u>Formularies</u>

With the magnitude of the prescription drug market today--nearly 800 different drugs, (not counting all the generic versions of the same drug)--it is more difficult for physicians and pharmacists to keep up with the latest drug approvals. When taking into account all the different dosage forms of each drug--tablets, liquids, suppositories, and injectables--the typical pharmacy may stock as many as 7,000 different products.

To sift through the maze, most hospitals and third party payers have special committees of physicians and pharmacists who evaluate all products and give professional opinions about the relative value of different drugs. This committee is typically referred to as the Pharmacy and Therapeutic (P&T) committee. A formulary is derived from their collective medical opinions.

Formularies may be "open" or "closed" (restricted). An "open formulary is an oxymoron in that 'open' implies that all drug products are covered, while 'formulary' implies a selected list of drug products. An open formulary, as the term is used, is no more than a compilation of all drug products which are available for use in the target patient population. A "restricted" formulary is a 'restricted' list of drug products" based on specified criteria such as effectiveness, medical necessity, and cost.[49] Purchasers use this exclusivity to leverage better price from manufacturers, who want their drugs on the formulary because it trains physicians to choose certain brand-names when writing prescriptions.

How Formularies Provide Economy

A recent U.S. Department of Health and Human Services study concluded the Medicaid prescription drugs costs per recipient, in 1988, were 22% lower in the five largest states with restrictive formularies as compared with the five largest states with open formularies.[50] PCS Health Systems Inc. (a pharmacy benefit management company) and its clinical division (Clinical Pharmacy Advantage) report that formularies and manufacturer rebates save an average of 5% of their pharmacy budgets.

How Closed Formularies Save Money

Formularies channel physician prescriptions to approved drugs which concentrates pharmacy purchasing and provides for the ability to negotiate discounts from manufacturers. All types of pharmacies can move volume, but retail buying groups have little or no power to offer market share to manufacturers because they must stock drugs for several different third party payers, all with different formularies. Hospital buying groups and managed care formularies can provide market share to manufacturers and shift all non-formulary drugs to those on the formulary. Formularies are what distinguishes third party payer and hospital pharmacy bargaining positions from retail pharmacy buying groups.

Pharmacy & Therapeutic Committees (P&T)

The Food and Drug Administration (FDA) evaluates the safety and efficacy of new products before they are allowed to be marketed. Formularies were established to evaluate new products, particularly those in the same therapeutic class, in terms of efficacy, therapeutic need and cost. Third party payers and hospital pharmacists point out that only the safest, most effective, and least costly drugs are chosen to be on a closed formulary. Insurers believe formularies promote the use of the best therapeutic choices available because they trust their P&T Committee have employed rational thinking when they studied and selected the drugs. This type of group decision is thought to be more rational than a particular individual doctor's decision which could, for example, be biased by sales representatives. Prospective additions to the formulary are evaluated by a Pharmacy and Therapeutics (P&T) Committee that evaluates clinical drug studies and provide a "seal of approval." A hospital or a third party payer P&T Committee considers safety, efficacy (how well the drug works), and therapeutic need when evaluating a potential formulary drug. The final factor in considering a drug for inclusion in a formulary is cost.

How Formularies Offer Market Share

When designing their formularies, third party payers try to maintain a medically complete list of prescription drugs while avoiding duplication within therapeutic classes. For example, the Blue Cross Blue Shield of Minnesota's formulary lists six of nine available calcium channel blockers, that are prescribed to treat high blood pressure. This procedure gives choices to physicians while still containing pharmacy costs. Formularies use market-based influences to control pricing. With a formulary and therapeutic substitution in place, third party payers steer prescriptions and support certain manufacturers who give buyers discounted prices through rebates.

The percent market share a formulary can offer varies significantly between therapeutic categories of drugs. For example, it may be easier to therapeutically substitute antibiotics than pain medicine because it is easier to predict the patient response to infections than it is for arthritis symptoms.

Managed Care and Formularies

A closed, restrictive formulary is a pharmacy management tool employed by many third party payers/ drug management companies. Diversified Pharmaceutical Services (DPS), who provides pharmacy management services for Medica, has a formulary containing about 500 different medications represent-

ing all therapeutic classes of drugs. Most drug management companies see restrictive formularies as a means to improve the quality of care, not decrease it by hampering the ability of physicians to prescribe appropriate medications. In fact, one drug management company incorporates a clinical review of drugs to look specifically at quality and outcome data. Their finding was that restrictive formularies can actually promote the quality of care.

DPS has experienced few problems with the generic and therapeutic substitution policy in their formulary since they have a process by which physicians or patients can request an exception to the policy and receive a non-formulary drug. Formulary systems generally have mechanisms whereby patients who request exceptions to the formulary still have their prescriptions covered.

Minnesota wholesalers estimated that 60% to 70% of all prescription drugs are now under some closed formulary-based system.[51] Wholesalers have extensive experience with formulary management systems as many of the third parties payers and most of the contracts involving institutionalized care (hospitals and nursing homes) operate under a formulary drug management system.

Prior Authorization

A provision for prior authorization is included in many formularies in order to accommodate the needs of patients for a specific drug that is either not included in that formulary or is extremely expensive. Prior authorization establishes a hierarchy of drug therapy: it mandates that certain expensive drugs will be paid for only if lower-priced drugs or other non-drug therapy (diet, exercise, smoking cessation, etc.) were tried first and have not been successful. Third party payers find prior authorization be an effective addition to their formulary program because it promotes the best utilization of drugs.

Prior authorization is a point-of-service intervention that prevents dispensing payment of the prescription until certain criteria are met. The procedure poses certain logical questions to the physicians about prescription drugs.

Drugs requiring prior authorization for payment by third party payers are typically expensive, often as much or more than $1,500 per year. They include, for example, cancer chemotherapy, AIDS-related drugs, and biotechnology drugs.

Exclusions to the Formulary

Exclusions to formularies are often a result of benefit design. A benefit design describes what will be covered under the insurance plan; it defines what the enrollee is entitled to. Many feel that the first step of a managed care program begins with good benefit design. Most benefit designs exclude payment for non-prescription drugs and drugs primarily used for cosmetic purposes (e.g. Rogaine for hair growth). The benefit design may also mandate that enrollees accept generic substitution while providing such benefits as a 34 day supply of medicine for one copay. With more prescription products becoming available as over-the-counter (OTC) medications, third party payers are looking at mechanisms that encourage use of OTC medications. In a pharmacy benefit designed to exclude OTC medications, insurance companies could also stop paying for drugs similar to the OTC medication that still require prescriptions or refuse to pay without prior authorization (that is, until a demonstrated trial of OTC medications has proven not to be effective).

Physicians' Views on Formularies

Philosophically, physicians are sometimes opposed to formularies because they limit access to some of the pharmaceuticals on the market today. Including physicians in the decision-making process, however, helps to eliminate some of their concerns. Educating physicians on the value of formularies may increase their compliance with the rules. A 1992 national survey of physicians' attitudes about managed care formularies revealed that 30% approved of formularies, 48% expressed negative feelings, yet 69% usually complied with formularies.[52]

Drug Utilization Review

A formulary and prior authorization are two of the three pharmacy management tools that can provide quality care at lower prices. The other is utilization management or drug utilization review. Drug utilization management may be essential to managing drug expenditures. Legislation regarding formularies and prior authorization, as well as therapeutic substitution, address some of the issues of drug utilization management.

Restrictive formularies are an initial step to guide drug utilization. Formularies force rational, objective thinking about drug treatment and disease states. Most hospital pharmacists think a formulary system has enhanced the quality of prescribing, since it tends to give physicians a more balanced view than some manufacturers' promotional information. Formularies have evolved over time and are now used to set practice parameters for expensive drugs via prior authorization requirements. The use of formularies directly affects drug utilization patterns.

Third party payers have also begun to focus on the impact of medications on total health care expenditures. Managed care is in a unique position to measure patient drug therapy outcomes because it has access to both medical information and pharmacy information. Drug utilization management is consistent with the philosophy of managed care. Appropriate drug utilization can be enhanced by evaluating doctors' prescribing habits and patient compliance, and by pharmaceutical care. Most third party payers in Minnesota expect that pharmacists providing pharmaceutical care for patients will help eliminate inappropriate prescribing and further assist controlling drug expenditures.

Typical drug utilization programs being used in the private sector often contain the following aspects:

1. Individual employee evaluations are conducted to determine if a member is over- or under-utilizing a medication.

2. Drug-specific reviews are done to determine if certain drugs are used correctly and produce desired outcomes.

3. Physician and pharmacist evaluations are made to determine if prescribing guidelines for certain drugs are being followed.

4. Small Area Analysis is conducted to measure and compare the use of prescription drugs by geographical area.

5. On-line computer processing is utilized to capture information needed to evaluate drug utilization.

The State of Minnesota, for example, employs a drug utilization program for selected drugs under the Medical Assistance program. (Chapter 3 examines this in more detail).

Rebates and Third Party Payers

Rebates are provided to third party payers based on the usage information of each drug. The amount of rebate is negotiated up front and is typically 10% to 15% off the discounted price. Thus, a third party payer usually pays net-rebate approximating AWP minus 30%.

Third party payers have leveraged rebates from manufacturers through the use of formularies and therapeutic substitution. A manufacturer's aggressive rebate program may be the only way to get their "me too" drugs on restrictive formularies.

Because rebates are based on usage, third party payers must collect information on that usage from their network pharmacies in order to bill manufacturers for rebates owed. As a pharmacist fills a prescription, a computer claim is sent to the appropriate third party payer that includes the drug name, manufacturer, quantity dispensed and days supply. This data is compiled quarterly, and manufacturers are invoiced for the rebates owed. While many pharmacists would like to be able to get the rebates themselves instead of the third party payers, the administration of the rebate system is extremely complex. DPS, for example, currently employs the equivalent of eight full time staff to work solely on the processing of rebates.

Rebates to some third party payers become "off budget" dollars. This has a tendency to create a perverse incentive for buyers to include a drug on its formulary that gets the biggest rebate but may not necessarily be the most cost-effective drug. Rebates go to whomever pays for the prescriptions. The rebates DPS negotiates with manufacturers go to its third party payer customers and not to DPS itself.

PHARMACISTS

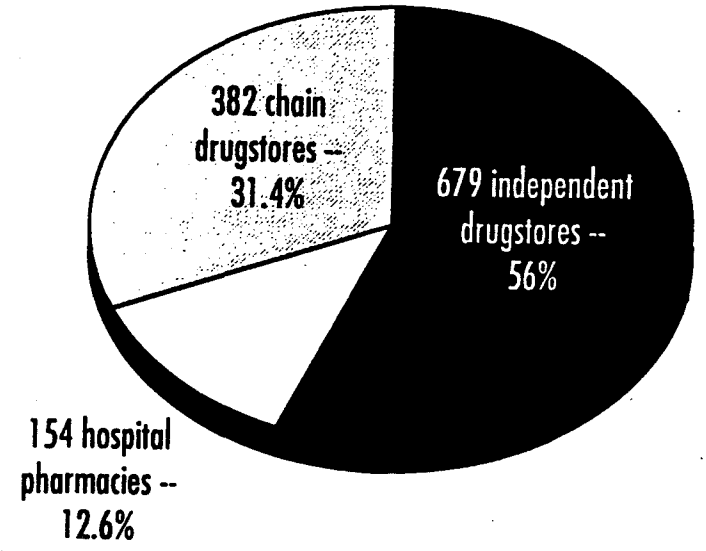
Pharmacists are the health professionals most often in direct contact with consumers and are responsible for filling prescriptions and counseling patients on prescription and non-prescription drugs. They also advise on the use of medical devices; for example, blood glucose machines used by diabetics. While filling a prescription, a pharmacist checks for proper dosage and directions and looks for interaction with other pharmaceuticals that would negatively affect the outcome of therapy. Pharmacists advise patients when to take their medicines, how to store them, what side effects to look for, and how to prevent or minimize these side effects.

Minnesota Pharmacies: Demographics and Access

The Board of Pharmacy regulates all Minnesota pharmacies through licensure and inspection. In 1993, the Minnesota Board of Pharmacy issued licenses to 1,215 pharmacies in the State. Figure 2.5 shows the distribution of pharmacies by ownership type. Over half of all pharmacies in the State of Minnesota are independent drugstores; 31% are chain drugstores and the remaining 13% are hospital-based pharmacies.

The Board also licenses approximately 5,000 pharmacists, of which 3,534 are actively practicing as pharmacists in the State (the 1,400 non-practicing pharmacists work in academia, industry, government, are retired, or live out-of-state). While only 13% of all pharmacies in Minnesota are in hospitals, 29% of all pharmacists practice in hospitals.

Figure 2.5
Distribution of Pharmacies by Ownership Type



Source: Minnesota Board of Pharmacy

Table 2.2 shows pretax net profits for Minnesota community pharmacies in 1991.[53] Independent pharmacies in Minnesota experienced a median net profit of 1.7% before taxes for their prescription departments in 1991 whereas chain pharmacies averaged a net profit of 2.7%. Chain pharmacies in rural areas experienced lower net profits than urban chain pharmacies (0.4% on average versus 3.1%

Table 2.2

Minnesota Community Pharmacy Pretax Net Profits, 1991

Pharmacy Type	% of Pharmacies	Average Net Profit	% Of Pharmacies w/ operating losses
Independent	66.5%	1.7%	
Rural	32.1%	1.9%	16.7%
Urban	34.4%	1.6%	10.0%
Chain	33.5%	2.7%	
Rural	5.9%	0.4%	44.4%
Urban	27.7%	3.1%	35.3%

Source: PRIME Institute, University of Minnesota, 1993.

respectively).[54] Approximately 16.7% of rural independents and 44% of rural chain stores operated at a net loss before taxes in 1991. This compares to 10% of urban independents and 35% of urban chain stores experiencing operating losses.[55] A survey of Minnesota pharmacies indicated that several pharmacies would be closing because of insufficient income.[56]

Rural Pharmacies

Rural independent pharmacies may face additional financial pressures because of higher transportation, shipping and other costs of doing business that make some rural pharmacies' costs higher than their urban counterparts. In addition, although HMOs are not as prevalent in rural areas as in the metro area, drug management benefit companies such as Pharmacy Clinical Advantage PCS/CPA, Diversified Pharmaceutical Services (DPS), and BCBS Pharmacy Gold, Inc. are prevalent and employ the same cost management strategies as HMOs for insured patients.

Almost two-thirds of pharmacies in Minnesota (62%) are in urban areas and one third (38%) are in rural areas.[57] Figure 2.6 shows the number of retail pharmacies along with the number of independent pharmacies in each county. The counties classified as urban are shaded. There is at least one independent pharmacy in every one of Minnesota's 87 counties.[58] Figure 2.7 provides a better idea of where those pharmacies are located within Minnesota. Each dot represents one or more pharmacies located in the same area.[59] Note that the northern and northeastern counties: (Kittson, Marshall, Lake of the Woods, Koochiching, Lake, and Cook) have very few pharmacies. However, the lack of pharmacies in these counties may be due to sparse populations, i.e. a lack of demand for pharmaceutical services. As Figure 2.8 shows, the number of retail pharmacies generally increases with population in Minnesota counties.

About one third of community pharmacies in Minnesota are chains and two-thirds are independents. Figure 2.9 shows that rural pharmacies are more likely to be independents.[60] About 85% of rural pharmacies are independents, compared to 55% of pharmacies in urban areas.[61] Some of the key evidence regarding the problems for rural independent pharmacies include the following:

- In general, rural pharmacies dispense fewer drugs than urban pharmacies. Urban pharmacies dispensed nearly 50% more and chains dispensed about 25% more prescriptions per pharmacy than rural independents.[62]

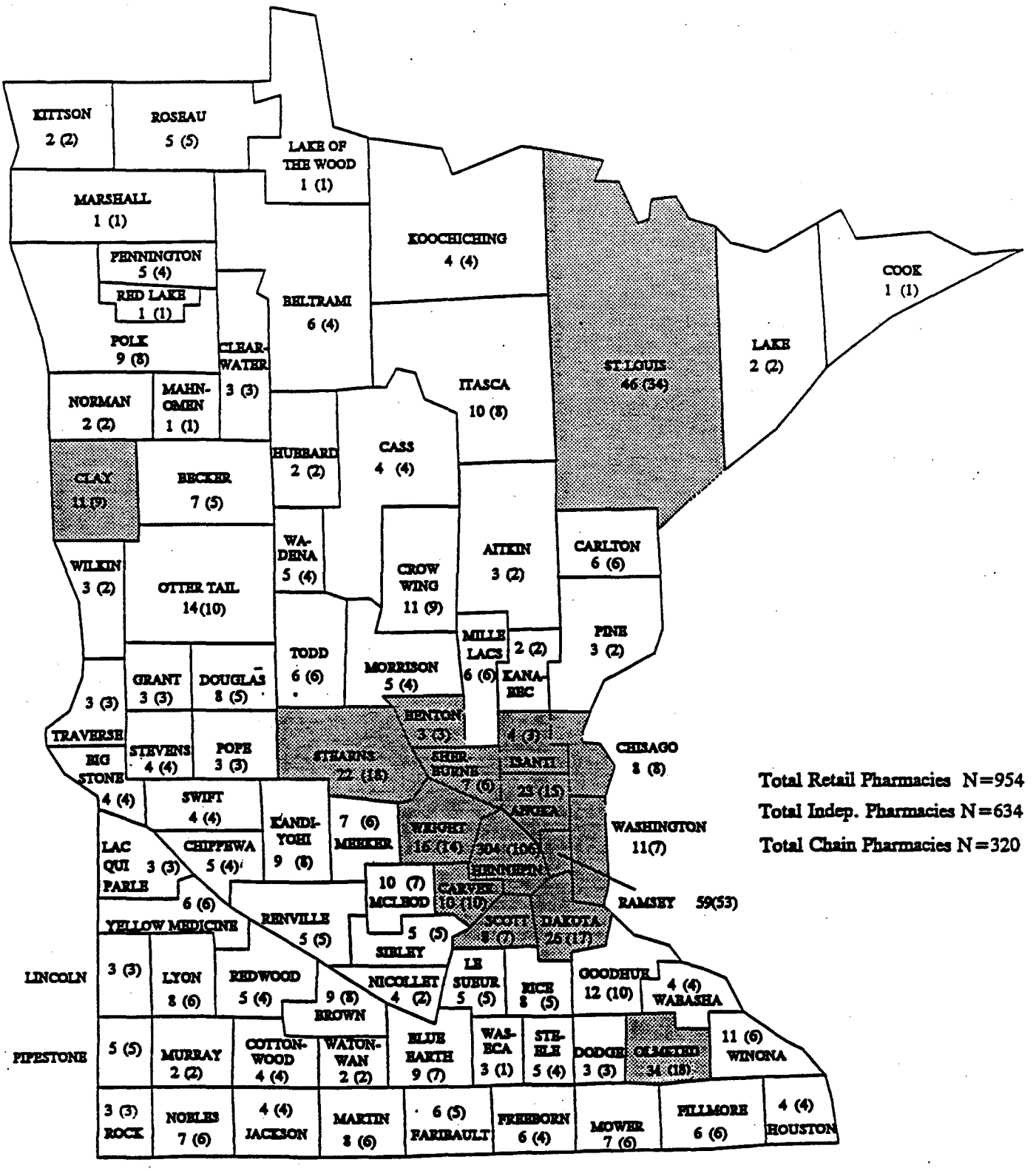
- Independent pharmacies rely more on the sale of drugs to meet the costs of doing business than do urban pharmacies. Prescription drugs comprised 70% of the sales for independent drug stores and 50% of the sales volume for chain drug stores.[63]

- Rural pharmacies rely more on revenue from Medical Assistance than urban pharmacies. Medicaid prescriptions accounted for as little as 7.6% of the average urban chain store's total prescription revenue and as high as 22.2% of the rural independent's total prescription revenue.[64]

- Average net profit before taxes has been steadily declining since 1970 for all community pharmacies. Independent pharmacies in Minnesota had a median net profit of 1.7% before taxes (for prescription drugs only) compared to 2.7% for chain pharmacies.[65]

Figure 2.6

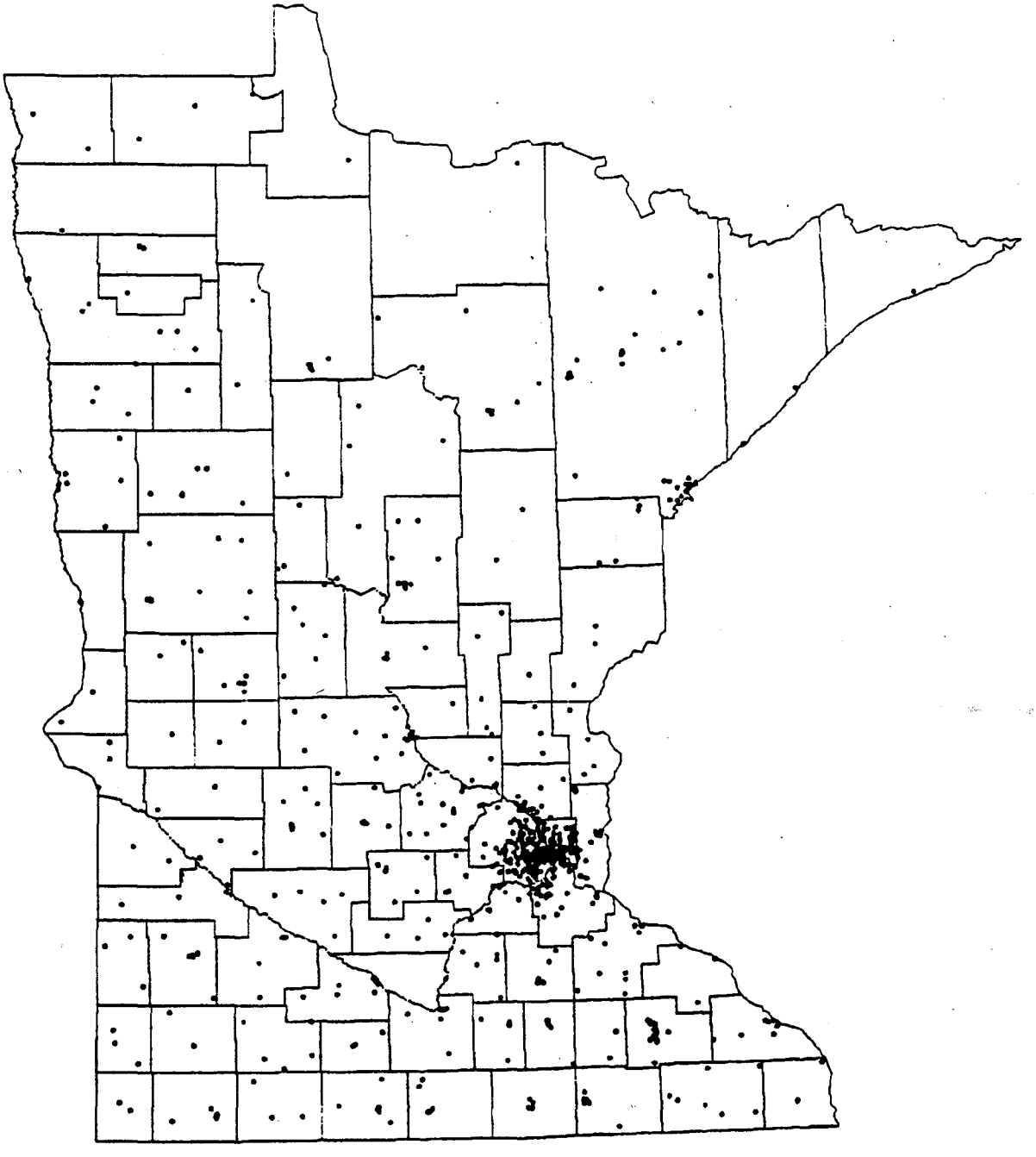
Retail Pharmacies in Minnesota Counties December 1992



Prepared by: PRIME Institute, College of Pharmacy, University of Minnesota

Figure 2.7

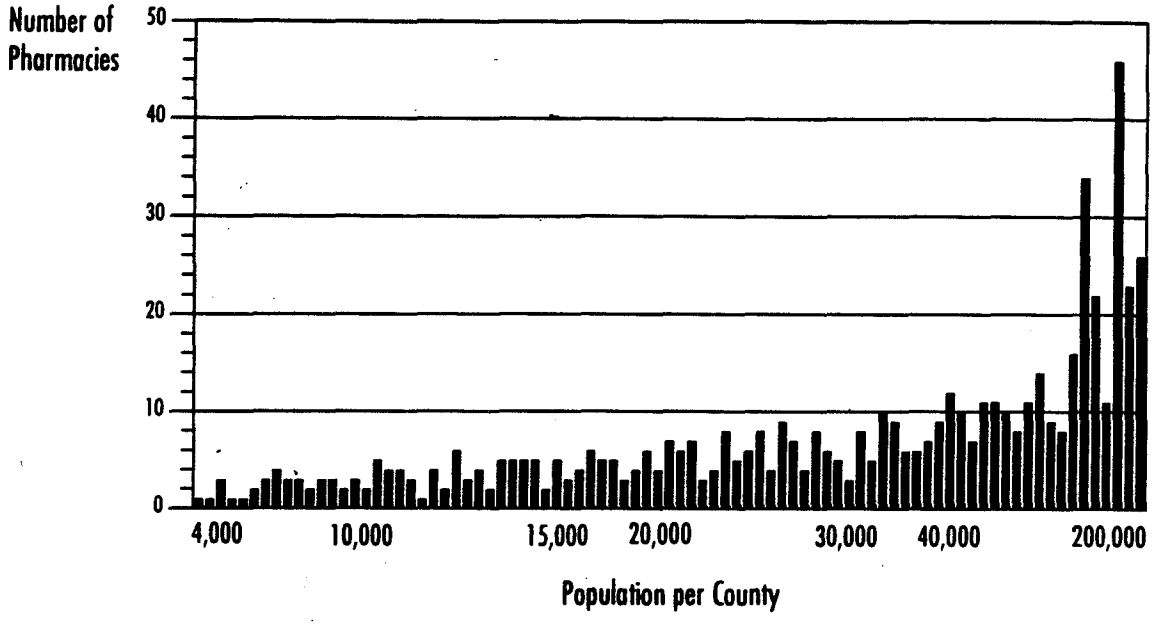
Minnesota Pharmacy Locations



Source: Diversified Pharmaceutical Services

Figure 2.8

Number of Retail Pharmacies per County by Population in Minnesota*

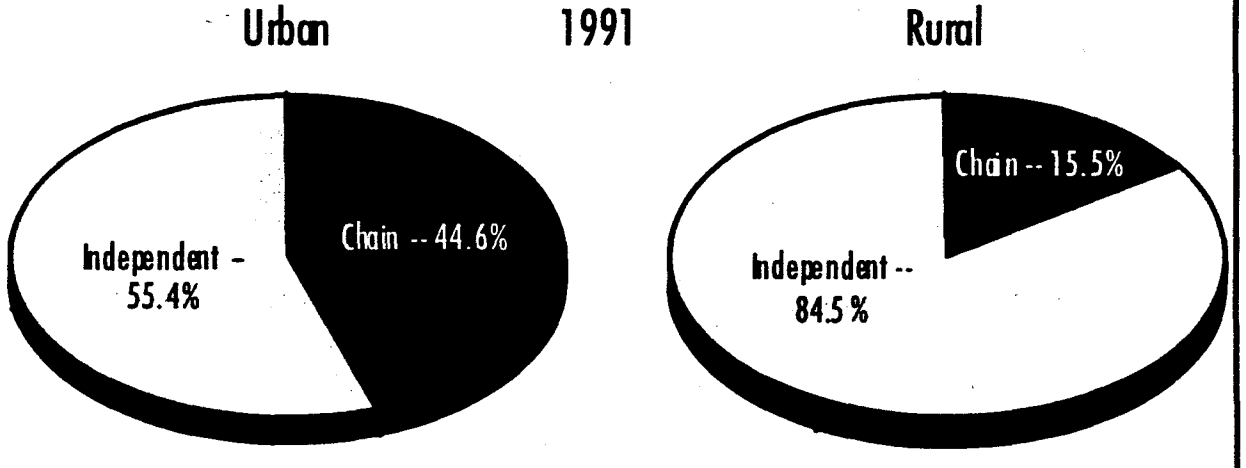


In Minnesota counties, the number of retail pharmacies generally increases with population. Hennepin and Ramsey counties are not shown. Hennepin County has 304 retail pharmacies and 1,032,431 people, while Ramsey County has 59 retail pharmacies and 485,765 people.

*Based on the 1990 Census and data from the PRIME Institute, University of Minnesota

Figure 2.9

Geographic Distribution of Community Pharmacies in Minnesota Urban vs. Rural



Source: Minnesota Department of Revenue, Tax Research Division, 1993

The Minnesota Board of Pharmacy reports that access to pharmacy services in rural areas has remained essentially unchanged. While a few rural pharmacies have closed, access to a pharmacy in the next town is generally only about 10 minutes away by car.[66] This level of access may not be significantly different from access in metropolitan areas. However, anecdotal evidence suggests that a number of rural pharmacies are closing.[67]

Over the past 10 years there has been a net decline of 96 independent pharmacies and a net increase of chain pharmacies of 131. Combining these figures produces a statewide gain of 35 pharmacies in the last 10 years. Predictably, the additional pharmacies have shown up in metro areas.[68]

Rural access to pharmacy services in Minnesota is not considered a problem by Diversified Pharmaceutical Services (DPS), a drug management company that provides services across the State. In those places where access is limited, DPS is willing to negotiate a different rate to secure the needed access. However, of the 750 drugstores in the Medica network that DPS manages, 80% are in the seven-county metro area.

Retail/Community Pharmacies

The term "retailer" in the broadest sense indicates a person who sells to the end user. "Retail" means something a bit more specific with respect to pharmacies, since it refers to a particular class of trade. Retail pharmacies are those found in the community that provide care for non-hospitalized patients. Included in this class of trade are independent drugstores (e.g. Sundberg Pharmacy in St. Paul) and chain drugstores (e.g. Snyder Drug Stores Inc., which has 83 stores across Minnesota, Wisconsin, Iowa, and Michigan). For the purpose of this report, retail pharmacies also includes specialty pharmacies, such as home health care and nursing homes because they purchase pharmaceuticals in a similar manner.

Prescription prices should theoretically cover the actual acquisition cost of a drug (approximately AWP minus 13% for retail pharmacy), the cost of dispensing the drug (the dispensing fee), and an amount for a reasonable profit. The dispensing fees are fixed and include salaries, supplies, utilities, rent, licensure, insurance, and billing charges when processing third party prescription claims. While pharmacists can set prescription prices for cash customers (primarily Medicare patients and the under/uninsured), third party payers set retail prices for insured customers. Problems arise when the contracted amount third party payers reimburse pharmacists is less than the amount it costs pharmacists to fill that prescription. It is estimated that this practice caused 20% of community (independent and chain) pharmacies to operate at a net *loss* in Minnesota in 1992.[69] As the number of Minnesotans insured by managed care companies increases, there is concern that many independent pharmacies will not be able to sustain such continued losses from their pharmaceutical operations.

Retail pharmacists provide the same service as other pharmacies but they do not have access to the discounted prices offered to hospital, managed care, and mail-order pharmacies. Retail pharmacists also point out that because most prescriptions are filled by retail pharmacists, they end up subsidizing manufacturers' discount prices to other groups. In practice, the HMOs and hospitals can leverage deep discounts in exchange for market share. That is, HMOs, hospital buying groups, and mail order pharmacies can assure a manufacturer that only its particular product will be sold to a particular market and no competitors will be covered. Market share is a function of volume and therapeutic substitution--by pre-selecting one drug in a therapeutic class it gives the buying group leverage in negotiation. In essence the buying group is changing physician prescribing practices through the use of a formulary.

Retail pharmacists have tried to develop their own buying groups but they have not been successful in negotiating discounts on brand-name drugs. This is partly due to the fact that pharmacists have limited influence over physician prescribing practices. The retail buying groups have been somewhat more successful in bargaining for generic products because of the competition among generic manufacturers.

Managed Care Pharmacies

Managed care pharmacy services can be fulfilled by either HMO-owned pharmacies or retail pharmacies. Group Health owns the pharmacies located on-site in many of its clinics. All other HMOs in Minnesota use the network of pharmacies in the community.

Independent retail pharmacies filling managed care prescriptions often find it difficult to make ends meet. Retail pharmacists purchase drugs at the highest prices in the market as they do not have the formulary leverage of in-house HMO pharmacies such as Group Health. Additionally, third party payers tend to set reimbursement rates for prescription drugs. In theory, the pharmacist can accept or reject the contracted price. In practice, however, few pharmacists are in a position to reject the offered price if they wish to retain their customer base.

In addition to the issue of reimbursement for product cost, some third party payers have relatively low dispensing fees. Some pharmacists contend that if dispensing fees paid by third-parties do not increase, many independent pharmacies may go out of business. Low dispensing fees do not have the same effect on the chain drug stores. The chains are able and in some cases, *willing*, to sustain a loss on their pharmaceutical business as long as the customer is in the store and purchasing other products.

Hospital Pharmacies

Most hospital pharmacies belong to national buying groups with like members. For example, the University of Minnesota Hospital and Clinics are in a national buying group composed mainly of teaching hospitals. Group purchasing by hospital pharmacists is successful because of the following factors:

- Volume purchased--Hospitalized patients tend to use more prescriptions than non-hospitalized patients. Therefore hospital pharmacies purchase greater volumes of drug product. Hospitalized patients also use more dosage forms (injectable, oral, suppositories) of the same drug than non-hospitalized patients, resulting in manufacturers bidding a lower price for a line of dosage forms.

- Uniqueness of members--Hospitals nationwide that have similar drug use need can join together to purchase needed drugs. For example, the University Hospital Consortium buys more chemotherapy than a community hospital would but probably not enough to secure leverage on its own. Therefore, it has joined a national buying group of teaching hospitals with similar needs.

- Commitment of members--There is commitment of buying group members to purchase all drugs through one particular buying group. This decreases the risk to the manufacturers as volume is predictable. Often the buying group will negotiate for multi-year agreements and offer only a third of their formulary products up for bid every year.

- Formularies and therapeutic substitution--Hospitals have traditionally used formularies and therapeutic substitution to manage drug expenditures. Hospitals are able to negotiate with manufacturers for a lower price in exchange for market share. This method has perhaps been the most effective at lowering drug costs as compared to various other initiatives.

- Bundling of drugs on formulary--Buying groups get better prices by linking the purchase of brand-name drugs with other products in the manufacturer's line. This bundling of different drugs from one manufacturer is an effective way to get competitive prices on single-sourced drugs. This could also be applied in the macro perspective and link pharmacy purchases with laboratory purchases.

Mail Order Pharmacies

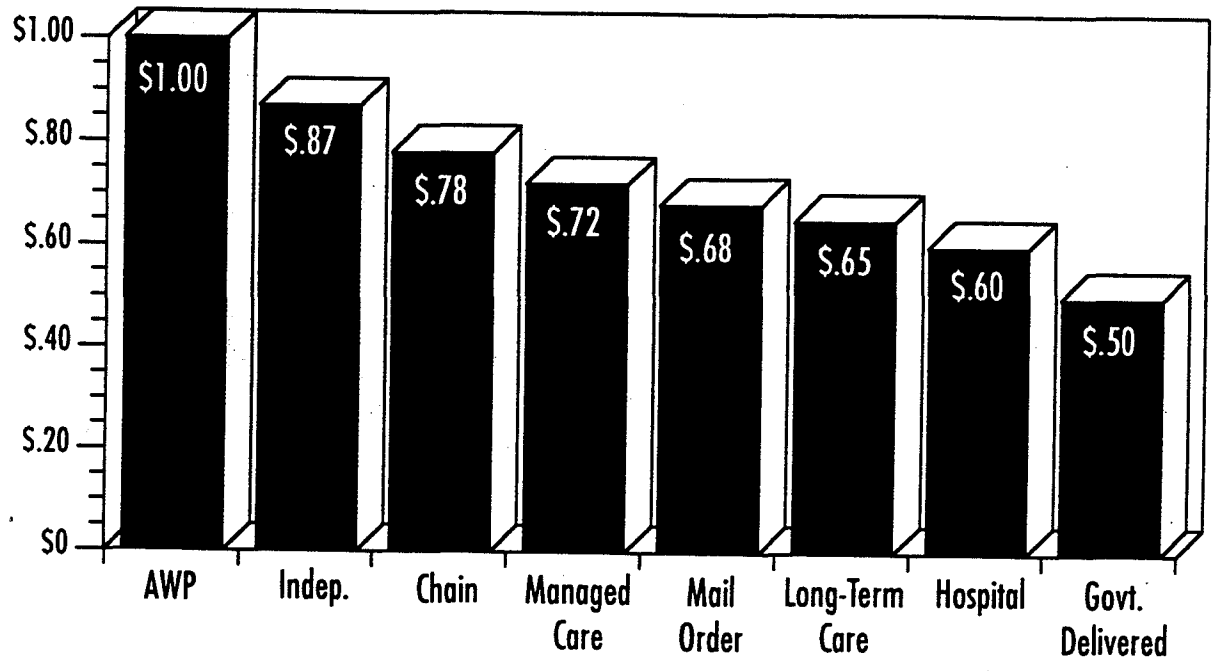
Mail order pharmacies distribute prescriptions directly to patients' homes and primarily compete with local retail pharmacies. Approximately 6% of all U.S. prescriptions are filled by mail-order pharmacies and are typically for the treatment of chronic conditions. One survey estimated that the two largest companies have more than two-thirds of all of the mail order business in terms of both dollar sales and number of prescriptions dispensed. The elderly account for over half (57%) of total sales for mail order pharmacies.[70] Since patients must plan ahead to get their prescriptions filled, acute care medicines such as antibiotics or pain medications are more often filled at local pharmacies. Mail order pharmacy service is utilized particularly in the rural areas, according to Minnesota seniors' groups and independent pharmacists.

Mail order pharmacies gain economies of scale by high volume purchasing, purchasing directly from the manufacturer, automation, generic substitution, and providing patients with large quantities (3 month supply or more) of medications at one time. There is only one mail-order pharmacy whose business is located in Minnesota but Minnesotans have access to the many mail order pharmacies located outside Minnesota. All mail order pharmacies that conduct business in Minnesota are registered with the State. Part of the registration process includes confirmation that mail order firms comply with their respective state's pharmacy laws, and that they agree to cooperate with the Minnesota Board of Pharmacy in the investigation of any complaints Minnesotans may lodge against them.

Discriminatory Pricing

There is a perception of discriminatory pricing practices by manufacturers to different classes of pharmacy trade. Hospital, HMO, and mail order pharmacies all receive substantial discounts from manufacturers but those same discounts are not shared with retail pharmacists. Figure 2.10, based on data compiled by the PRIME Institute, shows the estimated prices charged to various classes of prescription drug purchases in 1991. Discriminatory pricing is regulated by the Federal government under the Robinson-Patman Act. Hospitals and HMOs, as non-profit institutions, are exempt from the Robinson-Patman Act. In addition, hospital and retail pharmacies, by definition and law, do not compete for the same prescription customers. Hospital pharmacies fill prescriptions for a distinct population--hospitalized patients--and do not provide prescription drugs to patients who are not hospitalized. Thus, they do not directly compete with retail pharmacies. However, closed HMO pharmacies and mail order pharmacies do compete with retail pharmacies for outpatient prescriptions and therefore the possibility of discriminatory pricing exists. In response to that situation, retail pharmacists filed an antitrust lawsuit in October 1993, against manufacturers for just such alleged price discrimination. See Appendix D for more information.

Figure 2.10
Estimates of Prices to Various Classes of Prescription Drug Purchasers, 1991



Source: Compiled by PRIME Institute, University of Minnesota, 1991

Minnesota Statute §151.061 contains a provision relating to unfair price discrimination (see Appendix E). This law prohibits manufacturers or wholesalers doing business in Minnesota from discriminating between purchasers by selling prescription drugs at a lower price to one purchaser or buying group than another purchaser, after making allowances for quality, quantity, or shipping costs. It allows any person or entity injured by such unfair discrimination to bring a civil action and recover damages. This statute would seem to provide some protection for independent pharmacies competing with larger chain pharmacies. It does not, however, seem to provide any protection from alleged predatory pricing by mail order pharmacies located out-of-state, according to the Board of Pharmacy. Federal statutes, primarily the Robinson-Patman Act, would presumedly apply in those instances.

Pharmaceutical Care

Pharmaceutical care (PC) is an interactive process of pharmacists working directly with patients when they come in to get their prescriptions filled. A pharmacist explains the directions and precautions of a drug--either prescription or non-prescription--and the patient provides a brief history of diseases, drug allergies, and other medications the patient is taking. By improving the patient's understanding of drug therapy, PC is expected to improve therapeutic outcomes.

The concept of pharmaceutical care changes the way pharmacists currently practice by taking a more proactive patient-oriented approach as opposed to a product-oriented approach of dispensing drug products. The proposed goal of PC is to intervene where appropriate, ensuring patients know how and when to take their prescriptions, checking for drug interactions and side effects, and the duration of

appropriate drug therapy. In addition, pharmacists are expected to keep track of free samples dispensed to patients and over-the-counter drug products as well as prescriptions written by doctors in order to ensure proper patient care. In practice, tracking free samples may be very difficult.

With PC, important discussions with patients and physicians would be documented by pharmacists. PC builds on current State law that requires a pharmacy record, similar to a medical record, be kept for each patient. These records are on-line on the pharmacy's computer and are routinely reviewed by pharmacists when a patient comes in for more medication. The service will help ensure that patients are taking their medications correctly.

The Minnesota Pharmacists Association (MPhA) sees the patient as the key component to pharmacy benefits. Pharmacists are concerned that manufacturers want to increase utilization and price of drugs, while third party payers want to decrease both utilization and price, but neither looks at the patients' best interests. Patients would benefit from having someone oversee their entire drug regimen, including both prescription and non-prescription drugs, nutritional supplements, drug samples, and homeopathic medicine. Pharmaceutical care (PC) is MPhA's proposed solution. The Minnesota Board of Pharmacy supports the concept of pharmaceutical care, wherein pharmacists take more responsibility for promoting positive patient outcomes. The Board included a definition of pharmaceutical care in its most recent set of rules (Minnesota Rules 6800.0100 Subd. 7) in order to introduce the concept to pharmacists.

Proponents estimate that a typical PC patient counseling session would last approximately 1.5 to 2 minutes. The counseling must be face to face except for mail order pharmacies, which are required, according to the Board of Pharmacy, to provide toll-free phone lines to allow consumers to speak with pharmacists.

In the past, the Board of Pharmacy proposed that patient counseling and drug utilization review be required of pharmacists for all patients. However, OBRA 90 mandated these services only for Medical Assistance patients. Other states with drug review laws include all patients in such provisions. The Board's original proposal was rejected by an Administrative Law Judge, who ruled that the Board did not have the support of small business.[71]

A University of Minnesota study, under the direction of Dr. Linda Strand, Pharm.D., Ph.D. is conducting a three-year demonstration project (started in November 1992) on the implementation of pharmaceutical care in community practice settings. This project is a collaborative effort between the University of Minnesota College of Pharmacy, the Minnesota Pharmacists Association, the Minnesota Board of Pharmacy, representatives of the pharmaceutical industry, third party payers and drug management companies. The purpose of the project is to measure the impact of pharmaceutical care through outcomes research, cost-effectiveness, and payers' willingness to pay for pharmaceutical care services. The millions of dollars spent on health care and sick leave due to avoidable drug related illnesses represents the opportunity cost of not conducting pharmaceutical care and is one way to analyze the potential impact of pharmaceutical care on total health care expenditures. A reimbursement system for pharmaceutical care services will also be developed.[72]

Pharmaceutical Care may have an impact if pharmacists are focused on patient care and can increase efficiency in the dispensing area, according to the MPhA. The Board of Pharmacy has responded by increasing the ratio of pharmacy technicians to pharmacists (2:1) as of November 1, 1993 (Minnesota Rules 6800.3850). This increase only applies to pharmacies where pharmacists provide pharmaceutical

care to all patients, not just Medicaid patients as required by law. The Board sees this as a means to free pharmacists' time from dispensing functions to counseling and educational services.

Pharmaceutical Care - Another View

Not all components of the health care system are convinced of the utility or feasibility of the concept of pharmaceutical care (PC). Cost is one major concern. In the short run, at the very least, it would appear that implementing PC would increase rather than lower the cost of prescription drugs. This would be due in part to the increased ratio of pharmacy technicians to pharmacists to allow the latter to spend more time on counseling and education (cognitive) services and less on dispensing. Another cost factor, of course, is the PC fee itself. Still another major concern is privacy. Exactly where in the typical independent retail pharmacy the PC counseling sessions would take place is a significant issue as is the use of patients' medical records.

Concerns have also been raised by physician groups. While the Minnesota Medical Association (MMA) believes it is appropriate and necessary for pharmacists to be involved in explaining the directions and precautions involved in taking prescriptions, it strongly objects to expanding this scope to include taking patient histories and conducting related counseling. The MMA is highly skeptical that this could be done in 1.5 to 2 minutes, as PC proponents contend. The MMA strongly believes that the compilation of a patient's history of disease is a core function of the primary care physician in developing and managing a patient's treatment options. The MMA points out that it can sometimes be difficult for physicians to accomplish this activity in a 20-30 minute office visit and it is highly unlikely that a pharmacist would be able to do the same in a fraction of that time. The basic issue is professional role definition. The MMA, while recognizing the invaluable role that pharmacists play in the delivery of health care, contend that a pharmacist is not appropriately trained, nor should s/he be, to conduct health history reviews in the capacity of a primary care provider. Finally, the MMA doubts that the limited time investment is sufficient to generate any additional value to the patient.[73]

PHYSICIANS

Approximately 10,000 physicians currently practice in Minnesota. Many factors influence their prescribing decisions including medical appropriateness, familiarity with a particular drug (indications, dosage, side effects), interactions with other drugs or diseases, patient requests (taste, ease of administration, number of doses taken per day, side effects), predicted patient outcomes, previous treatments tried, and formulary regulations of third party payers or hospitals. With the tremendous number of drugs on the market since penicillin was first mass-produced during World War II, physicians have developed prescribing "habits" to simplify the scope.

The role of physicians is an important factor in managing drug expenditures. The therapeutic appropriateness of prescribing a given drug may be an answer to managing expenses. With drug utilization data, for example, physicians can compare their prescribing habits with their peers. They can compare their own prescribing behavior to the norm for both the disease (do most physicians use other drugs first?) and the drug (do most physicians use this drug for this condition?).

However, neither providers nor patients currently have much incentive to control costs when it comes to individual treatment plans. A physician often wants to prescribe the most beneficial drug, even though a modest improvement in benefits can triple the cost. A patient wants to receive the most state-of-the-art treatment, and often expects a prescription to cure everything that ails, even if it is medically unneces-

sary (e.g. an antibiotic for a cold). If insured, this patient often pays the same price for an expensive drug as for an inexpensive one. Even in situations where a higher copayment is paid to get the brand-name drug, the real cost of treatment is obscured at the patient level.

Drug Utilization Management

Drug utilization management may be the key to managing drug expenditures. Legislation regarding formularies and prior authorization, as well as therapeutic substitution, address some of the issues of drug utilization management. These activities require direct intervention with the physician and the physician's prescribing practices.

In the past, manufacturers spent a great deal of resources on sales representatives to work one-on-one with physicians to convince them of the benefits of their new drug product. With the increased use of drug management tools, there is more use of representatives of third party payers or drug management companies that use "counter-detailing." Counter-detailing is a one-on-one interaction with physicians to encourage doctors to prescribe drugs appropriately and to use the drugs on the payers formularies. Just as drug sales representatives encourage doctors to use a particular drug product manufactured by the company they represent, counter detailing attempts to remove the sales representatives' bias and employ universal logic or standard treatment protocols to ensure appropriate drug utilization.

CONSUMERS

Consumers experience the rising costs of prescription drugs in a variety of ways. For those with insurance coverage that includes a prescription drug benefit, it may mean increased copayments. However, this is a less severe circumstance than that faced by consumers who must pay the full price of the drugs purchased. Those without coverage for prescription drugs include the uninsured and those who often have some medical insurance but inadequate or no prescription drug benefit. The elderly are in the latter group because the Medicare program does not include prescription drugs as a part of its covered benefits. In Minnesota, 49% of the senior population pay directly out-of-pocket for their prescription drugs.[74] It is unknown, however, exactly how many of the seniors paying out-of-pocket for their prescription drugs were reimbursed through a supplemental policy. In a 1989 survey conducted by the Minnesota Center for Health Statistics, it was found that 66% of Minnesotans 65+ years old have an individual supplemental policy; 22% have supplemental coverage through a former employer; and 3% have supplemental coverage through a union.[75] However, there is no indication from this survey whether these supplemental policies covered prescription drug benefits. A 1988 survey, conducted by the University of Minnesota Division of Health Services Policy and Research, found that "24% of those seniors surveyed with Medicare supplements had prescription drug coverage. Of those with incomes below $10,000, 14.6% had a Medicare supplement that covered prescription drugs."[76] Clearly, many of the supplemental policies available to seniors do not carry prescription drug benefits. Where no drug benefit coverage is in effect, the cost of medications for chronic illnesses can be very difficult for seniors to manage as the costs are usually high and often continuous. If a person had to take medication for ulcers and chest pain (Pepcid and Vasotec), for example, it would cost approximately $800 per year.[77]

Impact of Medicare's Lack of Basic Prescription Drug Benefit

The elderly are particularly affected by rising prescription drug prices due to their extensive use of prescription drugs compared to other age groups. Persons over the age of 65 account for over 25% of the prescription drug sales even though they represent a much smaller proportion of the population.[78] One study found that 61% of people aged 65 to 84 years old living in the community (not a nursing

home or hospital) received three or more different prescription drugs in a year, 37% received five or more, and 19% received seven or more different drugs. Additionally, the average elderly outpatient uses two to four different prescriptions at any one time.[79]

These statistics are even more significant in light of the fact that people aged 65 and over are expected to reach 20% of the population within the next three decades.[80] Currently in Minnesota, 12.5% of the population is aged 65 or older, compared to 12.7% nationally.[81]

The elderly feel the impact of higher drug prices not only because of increased use of prescription drugs, but also because they often pay the entire cost of the prescriptions out-of-pocket. Among the concerns raised by elderly consumer groups were that U.S. drug prices are generally higher than in other countries. A recent study,[82] as well as testimony presented to the U.S. Special Committee on Aging,[83] showed that both Canada and Mexico have significantly lower drug prices than the United States. Identical prescription drugs purchased in the United States cost, on average, three times less in Mexico.[84]

The second factor is the concern over cost-shifting within the drug market which typically results in the cash-paying customers being charged the highest prices. The Special Committee on Aging described three tiers of cost shifting that impact seniors and others without prescription drug coverage. The first tier is the result of the United States subsidizing the lower prices paid in other countries where price controls exist.[85] The second tier is the result of multi-tiered pricing among classes of purchasers.[86] This occurs as HMOs and other large purchasers are able to negotiate deep discounts due to the large market share that they carry. Consequently, other purchasers such as small retail pharmacies pay more to offset the deep discounts to large purchasers. The final tier is the result of third party payers negotiating for lower drug prices, with the costs of those discounts passed on to the cash-paying customers. For example, discounts mandated by the federal government for the Medicaid program may be offset at the retail level by raising prices to the cash-paying customers. All of this tends to create the highest possible prices for seniors.

The third factor is that some seniors, in particular, tend not to buy generic drugs unless advised to do so by a physician. Apparently, those seniors assume that if the product were as good as the brand-name, then the physician would have prescribed it. Unfortunately, it is often the case that physicians do not make that recommendation. Those prescribing practices may be due to a lack of knowledge of generic options, a lack of knowledge of cost difference, or simply habit.[87]

Finally, seniors are particularly disadvantaged due to the fact that many are on a fixed income, making it difficult to pay for the costs of pharmaceutical drugs directly out-of-pocket. These four factors are critical determinants of whether seniors are able to purchase prescription drugs. In many cases, this inability to purchase prescription drugs results in even higher medical costs as conditions worsen and require hospital or nursing home admission.[88] Additionally, some seniors must make a choice each month between paying heating bills, buying food, or buying their prescriptions.[89]

Other issues involving seniors and prescription drug costs are inappropriate usage and adverse drug reactions. Noncompliance with prescription medications is a commonly-cited problem for all age groups. It is especially problematic for seniors because they are often on multiple medications. The possibilities for adverse drug reactions are thus increased. It has been estimated that $8.5 billion is spent annually on hospital admissions due solely to patients not taking their medications as prescribed. In addition, an estimated $7 billion annually is spent on drug related illnesses and deaths. Also adding to

the cost is the fact that nearly 25% of all nursing home admissions occurred because the people were unable to take their medications properly.[90]

Although other age groups generally require fewer prescriptions than the elderly, they may face the same financial difficulties in paying for prescriptions if they have a low income (for example, unemployed or part-time workers, migrant or seasonal workers).

Consumer Responsibility

There are some steps that consumers can take to decrease the cost of prescription drugs:

- Discuss the feasibility of the use of generic equivalents with your physician.
- Request a sample or prescription for a small quantity until it is determined that the medication is both effective and does not cause unacceptable side effects. Since prescription drugs are non-returnable, purchasing in small quantities when beginning a new prescription can prevent patients from paying for drugs that they may not be able to use.
- Make price comparisons before buying prescription drugs.
- Take medications exactly as directed by the physician to ensure best therapeutic outcome.

To make these steps more effective, some education must take place:

- Consumers must understand the differences and similarities between brand-name and generic drugs. For example, many consumers are not aware that generic drugs are therapeutically equivalent to brand-name drugs.[91]
- Consumers and physicians need access to comparative drug prices.[92] At the point of prescription, the information needs to be available about which drugs are the most cost effective. Even at the point of sale, it is already more difficult and costly to change the process as the pharmacist has to spend time typing to yet a new prescription approved by the physician.
- Consumers (and their physicians) need to be willing to try the older but effective drug therapies first, before more expensive and newer therapies are prescribed. For example, aspirin has been shown to be very effective in many cases in the treatment of pain involved with arthritis. That option should be explored before the new nonsteroidal anti-inflammatory drugs are prescribed. The outcome may be the same, but with much less cost.[93]
- Consumers must understand the directions for taking their medications. This includes information on how to take the drug (route, dose, etc.), expected results, anticipated side effects, and other relevant information.[94]

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[63]Minnesota Department of Revenue, Tax Research Division. MinnesotaCare Pharmaceutical, (Appendix) p. 24.

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[94]Hickler, R., pp. 35-36.

CHAPTER 3

DESCRIPTION OF STATE PROGRAMS FOR PRESCRIPTION DRUGS

DESCRIPTION OF STATE PROGRAMS FOR PRESCRIPTION DRUGS

INTRODUCTION

The State of Minnesota has three agencies that are involved in the purchase of pharmaceutical products. Those agencies are the Departments of Human Services, Employee Relations, and Administration. Each is unique in their role and population served. The focus of the Department of Human Services is on the State programs administered by that agency. The Department of Employee Relations focuses exclusively on coverage for State employees and certain other included groups. The Department of Administration acts as a group purchaser for agencies and institutions in Minnesota as well as 17 other states. The following sections discuss each agency in more detail.

DEPARTMENT OF HUMAN SERVICES

Background

The Department of Human Services' (DHS) role in the area of pharmaceutical products is both as a health care program and as a third party payer. In the Medical Assistance and General Assistance Medical Care programs, DHS is a third party payer. "Medical Assistance" (MA) is Minnesota's name for the national Medicaid program. The General Assistance Medical Care (GAMC) program is for individuals or families who do not meet a basis of eligibility under the MA guidelines, but who are determined to be medically needy. As health care programs, MinnesotaCare (and Children's Health Plan) provide health care coverage for certain groups of eligible uninsured persons upon monthly payment of a sliding-scale premium. The MinnesotaCare program is part of Minnesota's health care reform effort, with the goal of reaching targeted uninsured groups across the state.[1]

Health care is a major focus for DHS, contrary to popular opinion that "welfare" payments are the major expenditure. In fact, the fiscal year 1992 Health Care Budget for DHS was 66% ($2.41 billion) of the total appropriation ($3.65 billion). Prescription drugs for the state programs accounted for approximately 4% of the total Health Care Budget. In the past eleven years, both number of recipients and expenditures have continued to climb. Figure 3.1 shows the increasing numbers of recipients and insured groups. The increase includes additional recipients of MA and GAMC as well as the growing enrollment of families in the Children's Health Plan and MinnesotaCare. Figure 3.2 shows the increase in dollars spent for health care in these programs.

In fiscal year 1993, DHS spent approximately $111 million on prescription drugs for 389,711 recipients of Medical Assistance (MA), General Assistance Medical Care (GAMC), Children's Health Plan (CHP), and MinnesotaCare. MA accounted for 89% of the total prescription drug expenditures; GAMC for 9%; CHP for 2% and MinnesotaCare for >1%. (Total equals more than 100% due to rounding). Figure 3.3 shows the distribution of State drug expenditures by program.

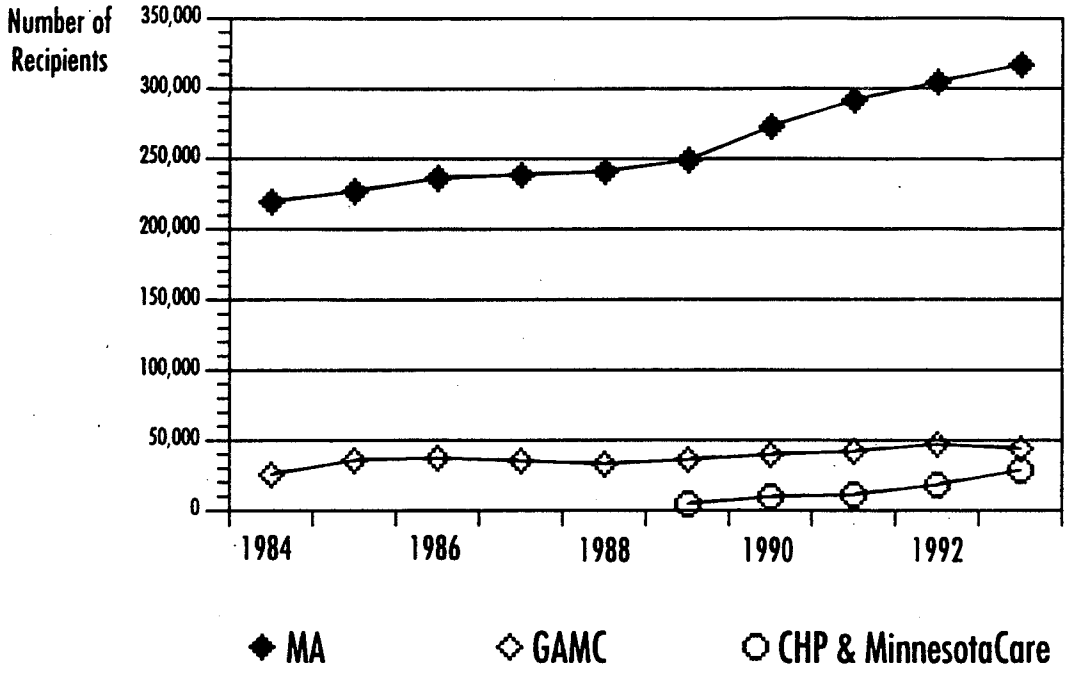
Medical Assistance

As indicated by the numbers above, drug expenditures by the MA program are overwhelmingly the most significant portion of the DHS drug budget (89%). DHS has been actively working on reducing expenditures in the MA program through increased efficiencies and streamlining. One of the ways in which DHS is trying to improve their management of the Medicaid program is through the implementation of an updated Medicaid Management Information System (MMIS II). MMIS II is a complex,

Figure 3.1

State Programs, Prescription Drug Recipients

Fiscal Year 1984 - 93

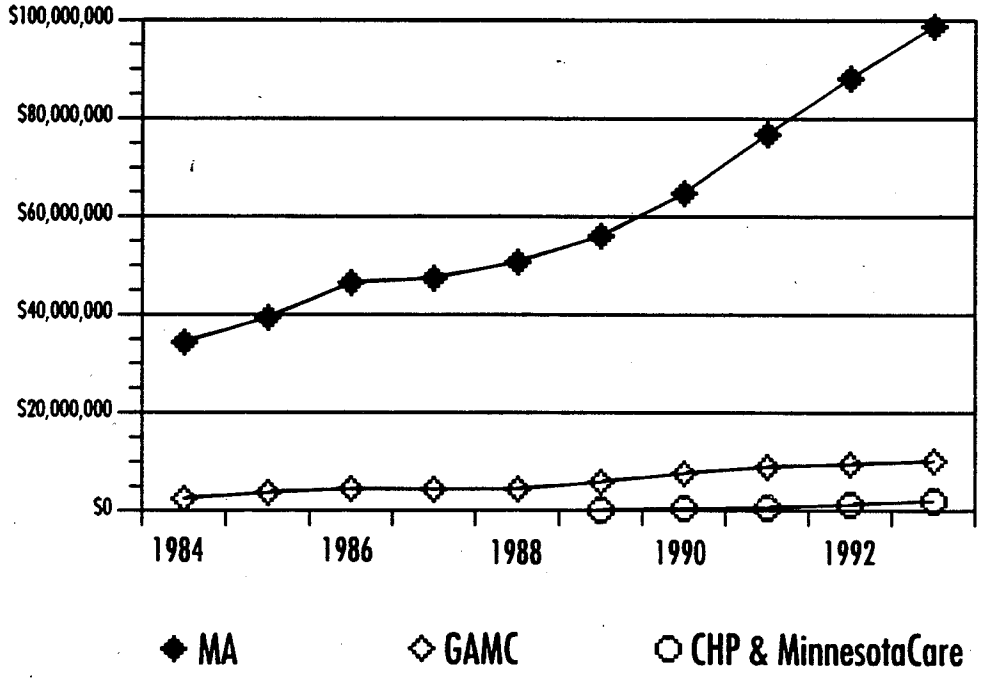


Source: Minnesota Department of Human Services

Figure 3.2

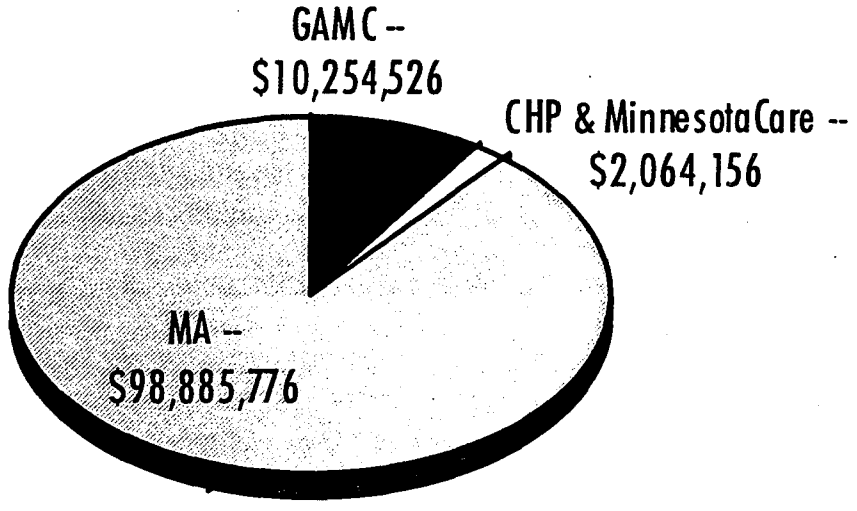
State Programs, Prescription Drug Expenditures

Fiscal Year 1984 - 93



Source: Minnesota Department of Human Services

Figure 3.3
Department of Human Services
Prescription Drug Expenditures
Fiscal Year 1993



Source: Minnesota Department of Human Services

highly integrated claims payment and information management and retrieval system. This system will not only provide efficient claims processing, but will also be used to identify trends, control health care expenditures, detect fraud and abuse, and implement specialized processes such as drug utilization review.[2]

MMIS II was implemented in "test mode" on January 31, 1994. Once the testing is complete, the system will be fully implemented in "production mode" including a point-of-sale pharmacy subsystem. Training sessions are being conducted for providers, county and state staff in an effort to ease the transition to a new system. Additionally, an MMIS II Helpline is available for questions with a local number for metro callers and a toll-free number for non-metro. The point-of-sale system operates in "real time" and will give providers online recipient eligibility information, DUR messaging, and claims processing. It will operate under the National Council for Prescription Drug Programs, Inc. (NCPDP) standards. These NCPDP standards are widely accepted as the industry standard and were requested by organized pharmacy in Minnesota. It is expected that more than 95% of the pharmacists statewide will choose to access MMIS II through this new system. The alternate billing methods and IVR system for recipient eligibility verification will still be available for those choosing not to participate in the point-of-sale system.

National Trends in Pharmacy Costs and Cost Containment Strategies

Between 1988 and 1992, Medicaid's national drug expenditures more than doubled from $3.29 billion to $6.79 billion.[3] A 1990 study by Schondelmeyer and Thomas found that inflation in the price per prescription was the largest contributing factor to increased expenditure in the Medicaid drug program. Further analysis showed that it was the cost of the drug, not the pharmacist's professional fee, that caused the greatest increase. Between 1982 and 1988, actual drug costs increased 86.5% compared to

15.1% for the pharmacist's professional fee. This is in comparison to the general rate of inflation (the CPI-all items) which showed an increase of 26.9% during the same time period. Thus, while drug costs were more than three times the rate of inflation, pharmacists' professional fees were slightly more than half that same rate of inflation.[4]

The Omnibus Budget Reconciliation Acts of 1990 (OBRA 90) and 1993 (OBRA 93)

OBRA 90 was passed in an effort to control the rising costs of pharmaceutical drugs in the Medicaid program. The primary focus was on establishing a rebate system, rather than formularies, to control costs. The rebate system was developed as a compromise between the drug manufacturers and Congress. It was designed to give Medicaid best price or a minimum rebate (15.7%) off the wholesale price of all their drugs. In exchange for the rebate, the Medicaid program was prohibited from establishing restrictive formularies. Medicaid also agreed to pay for any new drug a doctor prescribed for at least six months.[5] These rebates to the Medicaid program were guaranteed to give the "best price" available in the private sector. In other words, no other purchaser of pharmaceutical drugs in the private sector can be offered larger discounts than those offered to the Medicaid program, thereby assuring that Medicaid will pay less than anyone else in the private sector. This "best price" provision also states that in cases where discounts are larger to other purchasers (i.e. more than 15.7%), then the Medicaid program must also receive that larger discount--not just the 15.7%. In Minnesota, DHS pays pharmacies up front based on an established reimbursement formula (discussed in the section titled "DHS Reimbursement Policy") and gets a rebate from manufacturers for each unit of a drug reimbursed that results in net expenditure of "best price." These rebate requests are sent in quarterly to the drug manufacturer who then sends back the rebate or disputes it based on drug usage data.[6]

The general provisions of OBRA 90 regarding prescription drugs under the Medicaid program include the following key elements as outlined in a summary document prepared by Department of Human Services staff:[7]

- established the Medicaid Drug Rebate Program,
- limited federal financial participation to payments for drugs from rebating manufacturers,
- mandated coverage of all drugs from rebating manufacturers, except drugs in 10 therapeutic categories
- restricted the use of prior authorization programs,
- restricted the types of limitations on drug coverage and reimbursement,
- mandated coverage of new drugs for six months from FDA approval,
- prohibited reductions in pharmacy reimbursement,
- prohibited states from establishing additional state MA prices, and
- required the implementation of a Drug Use Review program.

Congress passed OBRA 93 which modified the Drug Rebate Program established by OBRA 90. The intent of these amendments to the Social Security Act was to generate additional program savings. The modifications in OBRA 93 include:

- revised rebate rate calculations,
- state discretion to require prior authorization for new drugs within first six-months from FDA approval, and
- limited state ability to establish formularies after 10-1-93.[8]

OBRA 90 and OBRA 93 have both received mixed reviews. While one-time savings have been secured, there is concern that rebates will not effectively alter the continued rate of growth of drug expenditures.[9] There is also concern that the establishment of the rebate will ultimately result in higher prices for most purchasers. This concern is not without merit. When OBRA 90 went into effect, the Department of Administration in Minnesota experienced an increase in the price of drugs they purchased. The discounts offered were revised based on the fact that the Department of Administration could no longer be offered a price lower than Medicaid. America's largest HMO, Kaiser Permanente, experienced a 10% increase (estimated at $50 million) in their costs for patented prescription drugs. They attributed it directly to the implementation of the Medicaid "best price" policy.[10]

Other concerns regarding OBRA 90 have surfaced. A 1993 General Accounting Office (GAO) report of the effects of the OBRA 90 rebate provisions on Medicaid drug expenditures found that although price changes experienced by health maintenance organizations (HMOs) and group purchasing organizations (GPOs) varied considerably, "price increases tended to be more common and more significant for outpatient drugs than for inpatient drugs..." The study also found that 80 percent of the drugs with large price increases were single-source drugs with no generic alternatives.[11] The report also cites concerns shared by HMO and GPO representatives regarding contract length and terms, and their ultimate impact on pricing. These concerns are summarized below:

- Since OBRA 90 has been in effect, contracts with the drug manufacturers are generally of considerably shorter duration than before OBRA 90. In the past, the contracts had commonly ranged from 1 to 5 years. Now, contracts of 1 year or less are very common. The major concern with shorter contract lengths is that there is the potential for drug manufacturers to raise prices more often.[12]

- Another trend concerning the GPOs and HMOs is that the drug manufacturers have changed their pricing structures. Until recently, manufacturers offered fixed prices for the duration of the contract. It is very common now for the manufacturer to offer a fixed percentage off a drug's wholesale price rather than a fixed price. In general, the newer contracts offer a maximum of 12.5% to 15% off of the list price (or AWP) charged wholesalers. As a result of this new pricing policy, prices are not stable even for the duration of the contract. The contract price will change every time the drugs' wholesale price changes. It is extremely difficult to estimate drug costs proactively because no one can predict how quickly or how much the price may change.[13]

DHS pharmacy program administrators believe that proper use of a DHS Health Care Program formulary may be more cost effective than the current rebate program. Before OBRA 90, the growth rate for DHS drug expenditures was approximately 11.7%. After OBRA 90 was implemented, the growth rate grew to 15.6%. This may be due to a number of factors, including the introduction of a number of new high-priced drugs on the market, drug price inflation, patient population growth, and the loss of a formulary. Although administrators believe that the use of a formulary would be more cost effective, DHS cannot do so without jeopardizing the 54% Federal Financial Participation (FFP) match. Under federal Medicaid law, Minnesota Medical Assistance can only fully implement a formulary as a demonstration project with a federal waiver of several Medicaid requirements. Without this waiver, Minnesota MA would lose approximately $55 million of FFP match and rebate annually. To date, HCFA has not granted any demonstration project waivers that would allow a state Medicaid pharmacy program to fully implement a formulary while maintaining FFP and rebate revenues. Federal formulary requirements in

OBRA 93 as well as current State law requirements make operation of a Medicaid formulary administratively difficult at best.

OBRA 90 also prohibited current pharmacy reimbursement rates from being reduced and from the establishment of any additional state "MAC" prices. "MAC" prices refer to "maximum allowable cost" for a specified drug. In addition to the Federal Upper Limits (FUL) imposed on prescription drugs at the federal level, Minnesota implemented a maximum reimbursement rate for certain drugs. OBRA 90 prohibited the state from implementing any new MAC prices. Additionally, OBRA 90 requires the implementation of a Drug Utilization Review program. The 12-member State DUR Board consists of 6 physicians, 5 pharmacists, and 1 public member. The program conducts both retrospective and prospective drug utilization reviews. The effects of this Board, with respect to cost containment in Minnesota, are unclear.

OBRA 90 also had an impact on DHS costs by requiring that all new drugs must be covered for the first six months after receiving FDA approval. Under the State formulary system, costly new drugs could be excluded immediately, or put on prior authorization (PA) status. Even though OBRA 90 allows states to have discretion on which drugs may be subject to the PA process, the drugs must still be covered. The effect in Minnesota of this is that very few drugs are put on PA status because DHS cannot handle the mandates regarding the PA process. Effective July 1, 1991, all PA requests were required to be handled within 24 hours. Thus, while PA could save some MA program dollars by preventing inappropriate utilization of expensive drugs, the cost of staff and systems funding is prohibitive. Currently, DHS requires prior authorization on 19 drugs.

Unfortunately, the result of OBRA 93 has not been exactly what was intended or anticipated. OBRA 93 modified the OBRA 90 provision excluding state formularies. However, the act still requires that drugs restricted from the formulary be available through the PA process. The cost of administering such a program, due to the requirement that PA requests must be approved/denied within 24 hours, is so prohibitive that DHS still cannot afford to implement a formulary. Only one state, California, has attempted to establish a restrictive state formulary under the modified OBRA rules. They have eliminated some drugs from the formulary, and have negotiated acceptable discounts from the manufacturers still on the formulary.

DHS' ability to effect cost containment within the MA program has been hampered by the inability to maintain a formulary. Mandates at the State level have also impacted DHS' ability to control prescription drug costs as discussed in the following section.

State Trends in Pharmacy Costs and Cost Containment Strategies

A March 1993 GAO study focused on Medicaid outpatient drug costs and reimbursements in two states (Maryland and Illinois). The report showed that the study pharmacies were paid by Medicaid on average 19% above what they actually paid for the drugs. Illinois pharmacies were paid 10% to 23% over their cost; Maryland pharmacies were paid 11% to 34% over their costs.[14]

This 19% difference in reimbursement may not, however, indicate excessive profits for these pharmacies. The reason for this is that both the Health Care Financing Administration (HCFA) and the state Medicaid officials were in agreement that excess Medicaid drug reimbursements must often be used to offset inadequate dispensing fees. However, due to the lack of current data, officials didn't know what an "adequate" fee should be.[15] This is compounded by the fact that under OBRA 90 there is a four-year

moratorium (until January 1, 1995) for HCFA and all states on reducing reimbursement limits for outpatient drugs or dispensing fees[16] Minnesota's MA dispensing fee is currently set at $4.10. HCFA felt that, due to the moratorium, it was inappropriate to reevaluate either dispensing fees or state reimbursement policies. Therefore, it will not be possible to determine what cost savings could be achieved until more current data is available.

Minnesota Drug Reimbursement History

The State has been concerned about the costs of pharmaceutical drugs over time and have implemented different strategies to address the problem. In 1984, a State Formulary was implemented to control costs of pharmaceutical products. The Formulary was a restricted, specific list of drugs that were eligible for reimbursement under the State Medical Assistance program. Drugs not on the list would not be reimbursed unless it was determined that there was a medical necessity for that specific drug. (For more information on formularies, see Chapter 2: "Formularies"). The use of such a formulary allowed the State to keep tight control over the use of brand-name drugs when generics or lower-priced therapeutic alternatives were available. The Drug Formulary Committee consisted of nine members: four physicians, three pharmacists, one nursing home representative, and one consumer representative. They developed the State Formulary and periodically conducted open meetings to obtain public comment and to hear requests for changes in the formulary. Under this system there were other drugs that were available only through prior authorization (PA). That means that the drug was eligible for reimbursement only if approval was granted before the prescription was dispensed. This allowed the State to determine if the use of very costly drugs was appropriate to the case, and also to monitor how often it was being used.

The provisions in OBRA 90 resulted in major changes to DHS payment policy and procedures. OBRA 90 required that, in order to receive manufacturer rebates, the state must offer the manufacturer's entire product line. This undermined the State's ability to maintain an MA formulary. Today the State Formulary Committee's responsibilities are limited to making recommendations for coverage within the 10 excluded therapeutic categories listed in OBRA 90 or for which drugs should be available only through prior authorization. They have developed criteria for the PA process which includes four cost factors as well as nine clinical factors. (This is different from the State Formulary criteria covering the 10 excluded therapeutics categories in which only clinical effectiveness is considered.)

OBRA 90 in effect abolished the State Formulary. DHS no longer had the ability to manage drug costs as effectively. Expanded coverage of rebating manufacturer's product lines was mandated. Federal reimbursement (called Federal Financial Participation, or "FFP") for drugs is limited to rebating manufacturers. In fiscal year 1993, with the Department of Human Services' drug budget in excess of $111 million, FFP[17] and rebates totalled an estimated $55 million.[18]

The most significant impact of OBRA 90 on cost containment in Minnesota is the manufacturer's rebate program. This rebate program has generated much controversy over its degree of effectiveness in holding down costs. The issues are complex and little generalizable data is available.

DHS Reimbursement Policy

Two factors influence the price that DHS pays for drug products. The first factor is the cost of the products. This consists of two parts: the acquisition cost of the drug, and a fixed dispensing fee. Both of these factors are set by the Minnesota Legislature and limited by OBRA 90. DHS reimburses on a fixed formula of estimated acquisition cost for the ingredient plus a fixed $4.10 dispensing fee. Acquisi-

tion cost is currently estimated at Average Wholesale Price (AWP) minus 7.6% (effective January 1, 1994). The pharmacy's profit depends on how large of a discount they receive from their wholesaler. In effect, each pharmacy's profit is equal to the difference between their discount and the 7.6% discount from AWP paid by DHS. Once the moratorium on reimbursement limits is lifted, it will be worthwhile to re-evaluate both dispensing fee payment levels and state reimbursement policies.

The second factor influencing price is expanded coverage. Under OBRA 90, in exchange for the drug rebate, all products in a rebating manufacturers' line are mandated to be covered, not just selected items. Consequently, cost and quality issues cannot be addressed resulting in the coverage of many products that would have been excluded under a formulary system. Additionally, state law has mandated coverage for some products within the OBRA 90 excluded categories (such as for over-the-counter vitamins) which even further reduces DHS' ability to control costs. The State of Minnesota's Medicaid coverage is much broader than in the majority of states.

The third factor influencing price is the number of Medical Assistance recipients in managed care plans. Drug reimbursement for pharmacy services is determined by the individual health plans. In these programs, DHS pays the health plan capitated payments for managed health care for enrolled recipients. The health plans then negotiate a reimbursement formula with their participating pharmacies. Pharmacy services provided by HMOs are excluded from the formulary prohibition, pharmacy reimbursement reduction moratorium, and rebate program requirements in OBRA 90.

DEPARTMENT OF EMPLOYEE RELATIONS

Background

The role of the Department of Employee Relations (DOER) is as a purchaser of drug benefits for both active and retired state employees, their dependents, and a few other small groups such as employees of the State Capital Credit Union. DOER also negotiates drug benefits for the State Health Plan. Through the State Employee Group Insurance Program (SEGIP), the agency provides a choice to employees (either active or retired) of five health maintenance organizations (HMOs) or the self-insured State Health Plan, administered by Blue Cross and Blue Shield of Minnesota. The HMOs offered are First Plan, Group Health, MedCenters, Medica Premier, and Medica Primary. These HMOs, along with the State Health Plan, provided coverage in 1992 to 143,980 persons (retirees, employees plus dependents). Although the exact numbers are not available at this time, there was a small increase in the number of enrollees for 1993. All plans provide coverage for prescription drugs, and DOER has found these costs in recent years to be increasing twice as fast as other costs. The annual premium volume was approximately $240 million in 1992.[19]

Health Maintenance Organizations

The HMOs vary only slightly in benefit levels, but a major difference is the organization type. There are several models to choose from: a staff-model, an independent practice association (IPA) or one of three network models.[20]

The HMOs are not restricted under SEGIP in how they manage their operation. Once the contract has been negotiated and signed, the HMOs carry the responsibility of cost containment, since they are then locked in to a set structure of copay and/or deductible amounts. The HMOs have responded in a variety of ways to control the growth of prescription drug costs. Some of them have a restrictive formulary designed to limit the use of brand-name drugs to those cases in which it is medically necessary.

Some require the substitution of generic drugs when available; but whatever method they choose is up to them. Overall, this has been a very satisfactory arrangement for SEGIP as they have seen only small increases in the 1993-1994 premium and drug copay levels. This has been in spite of the fact that prescription drug prices have increased at approximately twice the rate of other areas.

The HMOs are extremely competitive in their contracts. The incentive for this competition is to attain the status of "Low Cost Health Plan." Each county has a designated "Low Cost Health Plan" which is based not only on price, but also on their ability to meet other criteria (such as adequate provider capacity and ability to meet regulatory requirements). Approval of the state bargaining unions is also required. This highly-desired designation of "Low Cost Health Plan" means that for any employee choosing that health plan in that county, 100% of the cost of single coverage is paid for by the employer; also, 90% of the cost of dependent coverage is paid. This is a large incentive for people who are looking for the lowest premium payments possible while maintaining a comparable benefit level. If they choose a different plan, they must pay the difference between the "Low Cost Health Plan" and the one they choose. That difference (in 1991-92 biennium, with similar benefit levels) ranged from $5.79 to $42.48 per month depending on the plan chosen.[21]

In an environment where market share is so critical, this "Low Cost Health Plan" designation is an important means of gaining that edge. Since 1989, Group Health has consistently been designated the lowest-cost plan for the Twin Cities. This has resulted in its share of total group enrollment increasing from 19 percent to 35 percent.[22]

SEGIP staff believe that the marketplace works very well for them. Because of the great incentive to be rated as "Low Cost Health Plan" by the State, competition is intense and has resulted in reasonable premiums for a comprehensive benefit package. Besides wanting the "Low Cost" designation which may increase overall market share, competition is also encouraged by the fact that, for each of the HMOs, the State is already either their first or second largest contract. This benefits not only SEGIP, but also the enrollees by providing more options regarding premium price and type of HMO they want. That same competition is what helps to hold down the cost of prescription drugs within the HMO contracts.

State Health Plan

The State Health Plan (SHP) is administered by Blue Cross and Blue Shield of Minnesota (BCBSM). The SHP's prescription drug benefits are managed by BCBSM through a formulary. The formulary is generous in its coverage of some drugs (such as growth hormones) that generally are not available as prescription drugs. There is also a prior authorization process in place for a limited number of drugs. There is currently an $8.00 copay for prescription drugs under the SHP for formulary drugs or non-formulary in which the physician requests "dispense as written;" the copay is $14.00 for non-formulary drugs.[23]

The SHP provides coverage to approximately 60,000 persons. In many counties, the SHP is the "Low Cost Health Plan" by default because there are no HMOs that have an adequate network capacity. In fact, that's the main reason that the State developed its own self-insured plan. Because State employees (or others in the pool) are spread across the entire state, a plan was necessary that could ensure access to everyone. The SHP provides that access.

One separate group of persons being insured under the SHP is retirees. This group is different from others in that there is no employer contribution toward their coverage. Since the retired enrollees are,

by law, not subsidized for any portion of their insurance coverage, rising prescription drug costs are passed directly on to them in the form of higher premiums. In order to try to hold down these costs the creation of a special "Senior Formulary" is being considered. The development of this "Senior Formulary" would assist in stabilizing the costs of prescription drugs for this group, ultimately resulting in lower premiums. This specialized formulary would be developed through a collaborative effort of HMO and State Health Plan representatives along with State agency representatives..

DEPARTMENT OF ADMINISTRATION

Background

The Department of Administration's (DoA) role in the area of pharmaceutical products is as a group purchasing organization. The DoA purchases prescription drugs for state or local units of government in Minnesota, 16 other states and the city of Chicago. These units of government represent approximately 450 outlets. Five more states are interested in joining. Hospitals (including state institutions), correctional agencies, and county health facilities are the primary members of this group. The program is limited to purchasing for state and local agencies/institutions, and cannot by statute include private institutions or private citizens.

"Lead State Position" in Group Purchasing Organization

In 1993, the DoA purchased $65 million in prescription drugs. Out of that $65 million, $20 million (30.8%) was for Minnesota alone. Minnesota is in the "lead state position" and has joint powers agreements signed with the member states. The program is administered by 2 pharmacists and 1½ clerical staff plus an evaluation team comprised of pharmacists and purchase officials from each participating state. These positions are funded through an administrative fee paid by the participating drug manufacturers. This is not a rebate (as DHS receives on drugs covered under Medicaid), but it is similar in function as it is based on the number of drugs used. The administrative fee is 1.5% on generic drugs, and varies by brand-name company. (Other pharmaceutical purchasing groups range up to 5%.)

The DoA purchasing program has won both a state and a national award for their cooperative efforts and successes. The program negotiates discounts and buys through the manufacturer. The distribution is handled through wholesalers. Their "prime vendor contract" includes several drug management functions: inventory control, lot control, and recall control, warehousing and delivery, and management reports.

Additionally, there is a guarantee on the delivery commitments (same day within the metro area; one day in out-state areas) as well as a guarantee of 95% order fill rate. Because of these guarantees, members of the DoA were assured of having adequate access to pharmaceuticals without having to buy in large quantities. In the first 18 months of the contract, DoA's contracting members in Minnesota were able to collectively reduce their inventory by 58%.

Although DoA Materials Management Division is primarily charged with procurement and does not purport to be an expert in the heathcare business, they do exert pressure for containment and cost reduction in this program. The DoA does manage prescription drugs which results in a non-traditional formulary type approach or an umbrella formulary where separate, more restrictive formularies can function. There are sufficient multistate resources to support this program. This is accomplished by 1) Combining the needs of the participating multistate agencies; 2) These needs are then evaluated against availability of generic equivalents and therapeutic equivalents; 3) Then contracts are established for the

resulting generic equivalents and potential therapeutic equivalents by a combination of competitive bidding and negotiations; 4) Only one award for a generic equivalent is made; 5) Therapeutic equivalents may have one or more negotiated awards; 6) We do not contract for drugs the committee considers ineffective; 7) Drug items evaluated and added pursuant to the needs of members all year long.

The prices paid by the members are competitively bid and/or negotiated at the manufacturer level. A separate contract is negotiated with individual wholesalers serving various state regions for delivery, billing, etc. There is a charge back system between the manufacturer and the wholesaler for the difference between the contract price and the normal wholesale acquisition price. According to comparisons made by other states before joining Minnesota's program, their negotiated prices "compare favorably" or exceed similar purchasing programs across the country. Before OBRA 90, they were able to negotiate discounts of 40% to 60% as an overall discount Upon implementation of OBRA 90, state Medicaid programs were guaranteed "best price." As a result, prices over all purchasing programs increased due to the cost shifting in the industry. However, today DoA is still obtaining discounts for 15% on sole source drugs to 70% on generics.

Another factor affecting the program's prescription drug price is the availability of generic alternatives when a drug comes off patent protection. It will remain unclear whether this will be a positive or a negative influence until after the next contract negotiations in April 1994. On the one hand, there is an opportunity for negotiating a significantly lower price due to the availability of generic alternatives. On the other hand, there may be a decrease in the amount available for administering the program as the administrative fees are based on drug cost. Therefore, as much lower prices are negotiated either for the generic or for the name brand, the administrative fees will be significantly lower as well. It will be important to see if the contract lengths and terms change as dramatically in this market as in the Medicaid program.

The DoA is considering expanding pharmaceutical product negotiations to include durable medical equipment, and incontinency and hospital supplies. Currently, these products must be negotiated in separate contracts. Likewise, DoA is considering offering the program to other government entities.

ENDNOTES

[1]As of July 1, 1993 enrollees in the Children's Health Plan (CHP) were incorporated into MinnesotaCare (if they chose to) and the CHP as a separate program ceased to exist.

[2]Minnesota Department of Human Services. Minnesota Medical Management Information System User Manual. (Saint Paul: Minnesota Department of Human Services, 1994).

[3]National Pharmaceutical Council. Pharmaceutical Benefits Under State Medical Assistance Programs. (Virginia: National Pharmaceutical Council, 1993), p. 101.

[4]Schondelmeyer, S., and Thomas, III J. "Trends in Retail Prescription Expenditures." Health Affairs, Vol. 9, No. 3, Fall 1990, p. 140.

[5]Tully S. "The Plots to Keep Drug Prices High." Fortune, Dec. 1993, p. 121.

[6]As of June 30, 1993, 11% of rebates billed were in dispute amounting to $5.4 million. Other states, such as Maine, have also had a substantial number of billings disputed (Hearing Before the Special Committee on Aging, United States Senate, April 15, 1992).

[7]Minnesota Department of Human Services. Internal memorandum. Jan. 3, 1994.

[8]Minnesota Department of Human Services. Internal memorandum. Jan. 3, 1994.

[9]Schondelmeyer S., and Thomas, III J. "Trends in Retail Prescription Expenditures." Health Affairs, Vol. 9, No. 3, Fall 1990, p. 143.

[10]Tully, S. "The Plots to Keep Drug Prices High." Fortune, Dec. 1993, p. 122.

[11]U.S. General Accounting Office. Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions. (Washington, D.C.: U.S. General Accounting Office, Jan. 1993, pp. 17-18.

[12]U.S. General Accounting Office. Medicaid: Changes in Drug Prices, p. 22.

[13]U.S. General Accounting Office. Medicaid: Changes in Drug Prices, p. 23.

[14]U.S. General Accounting Office. Medicaid: Outpatient Drug Costs and Reimbursement for Selected Pharmacies in Illinois and Maryland. (Washington, D.C.: U.S. General Accounting Office, March 1993, pp. 4-5.

[15]U.S. General Accounting Office. Medicaid: Outpatient Drug Costs and, pp. 6-7.

[16]U.S. Congress. Omnibus Budget Reconciliation Act of 1990. (Washington, D.C.: U.S. Government Printing Office, 1990), p. 160.

[17]Federal Financial Participation accounts for an estimated 53% of the Medicaid budget.

[18]"Rebates" result in MA paying a net price equal to the lowest price available from the manufacturer. The prescriptions are reimbursed to the pharmacies up front. Quarterly billings are made to the manufacturers based on the amount of drug dispensed. Manufacturers then send back the rebate amount or dispute it based on usage data.

[19]Minnesota Department of Employee Relations. Biennial Report to the Legislative Commission on Employee Relations: Summary of the State Employees Group Insurance Program. 1991-1993. Unpublished report. 1993, pp. 2-12.

[20]Minnesota Department of Employee Relations. Biennial Report to the Legislative Commission on Employee Relations:, p. 7.

[21]Minnesota Department of Employee Relations. Biennial Report to the Legislative Commission on Employee Relations:, p. 33.

[22]Minnesota Department of Employee Relations. Biennial Report to the Legislative Commission on Employee Relations:, p. 33.

[23]Minnesota Department of Employee Relations, Minnesota State Employee Group Insurance Program. State Health Plan Certificate of Coverage 1994, Nov. 1993, pp. 21-22.

CHAPTER 4

PRESCRIPTION DRUG PROVISIONS OF PRESIDENT CLINTON'S HEALTH SECURITY ACT

PRESCRIPTION DRUG PROVISIONS OF PRESIDENT CLINTON'S HEALTH SECURITY ACT

INTRODUCTION

Prescription drugs are included in the Clinton health plan in two areas. First, pharmaceutical drugs are included as a covered benefit under the national Health Security Plan. Second, pharmaceutical drugs are added as a covered benefit under the Medicare program, the federal insurance program for persons aged 65 and older and the disabled.

HEALTH SECURITY PLAN

Prescription Drug Benefits

The drug benefit included under the universal plan includes coverage for both inpatient and outpatient use. Under the Health Security Plan, outpatient prescription drugs, biological products, and insulin will be part of the basic medical services covered for all enrollees. For outpatient services, there is no limitation on either the number of prescriptions dispensed or the frequency, other than reasonable rules, for amount to be dispensed per prescription and number of refills. Health plans may, if they choose, establish a formulary (including the use of generic substitution) or use mail order programs, or engage in drug utilization review.[1]

Cost Sharing Options

The basic benefit plan proposed under the mandatory health insurance program includes three cost sharing options: the Low Cost Sharing (HMO) option requires payment of smaller deductible and copayment amounts, but with higher premiums and no out-of-network coverage. The High Cost Sharing (Fee-for-service) option requires higher deductible and copayment amounts for some benefits, but offers lower premiums. The Combination Cost Sharing option offers the same benefits as Low Cost Sharing, but the option exists to go to an out-of-network provider. The out-of-network services may require significantly higher deductibles and copayments.[2] The cost sharing options are presented in Table 4.1.

In the Low Cost Sharing option, copayments for prescription drugs are set at $5 per prescription, with no annual deductible. The High Cost Sharing option requires a $250 annual deductible with a 20% copayment (subject to an out-of-pocket maximum of $1500 for individuals or $3000 per family). The Combination Cost Sharing option includes a $5 per prescription copay if the provider is a network provider; for out-of-network providers, the High Cost Sharing copayment and deductible levels apply.[3]

MEDICARE

Prescription Drug Benefits

Under the Health Security Act, Medicare beneficiaries will pay an annual $250 deductible. After meeting the deductible, beneficiaries pay 20% of the cost of each prescription. There is an annual limit on out-of-pocket expenditures of $1000. Subsidies for out-of-pocket costs will be provided for eligible low-income Medicare beneficiaries.

Table 4.1

Patient Cost Sharing

Consumers will choose among three types of plans:

- **HMO cost-sharing - Low**
  - No deductible
  - $10 copayments for most services
  - 20 percent coinsurance for out-of-network use
  - $1,500 out-of-pocket limit ($3,000 per family)
- **Fee-for-service - High**
  - $200 deductible ($400 per family)
  - 20 percent coinsurance
  - $1,500 out-of-pocket limit per person ($3,000 per family)
- **Combined**
  - Built on fee-for service cost-sharing
  - Reduced cost-sharing for in-network use
  - Increased cost-sharing for out-of network use
  - $1,500 out-of-pocket limit ($3,000 per family)

Source: Lewin-VHI, Inc.

The Medicare program will expand drug benefits to include all drugs, biological products and insulin approved by the Food and Drug Administration (FDA) for medically accepted indications for both inpatient and outpatient settings. These indications must be defined in one of several specified compendia identified by the Secretary of Health and Human Services. Medically accepted indications may also be determined by the carrier based on evidence presented in peer-reviewed medical literature.

Currently, under Section 1927(d) of the Social Security Act, the Secretary of Health and Human Services has the discretion not to cover certain pharmaceutical products for the Medicaid program. Examples of these discretionary areas are fertility drugs, medications used to treat anorexia or weight gain, and drugs used for cosmetic purposes. The Health Security Act (HSA) would extend this authority to the Medicare program as well. The Health Security Act currently proposes coverage for two of those discretionary areas: benzodiazepines and barbiturates.[4]

Home health care services under Medicare will be also be expanded to include prescribed home infusion therapy (IV drugs). These services can be utilized only if they will prevent the patient from being admitted to an inpatient setting (hospital, skilled nursing or rehabilitation center) for treatment of illness or injury. The need for continued therapy is re-evaluated every 60 days by the person who is primarily responsible for providing the home health care, with additional periods of therapy being covered only if the risk of hospitalization or institutionalization still exists.[5]

Cost Sharing Options

Medicare-eligible individuals may, upon approval of a waiver, be integrated into the state health alliances. However, they will not be subject to the cost sharing options (Low, High, or Combined) de-

scribed in the previous section. Medicare benefits and rates will be established separately from the benefits for the non-Medicare population. One of the conditions of integrating Medicare into the state health alliance is that beneficiaries must receive at a minimum, the same or better coverage as the standard Medicare benefit, with no additional cost over the established Medicare premium. Enhanced benefit packages may be made available with the consumer paying the difference between the Medicare reimbursement rate and the cost of the benefit package. Medicare-eligible individuals have the option to join one of the state health alliances (if it is offered in their state) or they may remain in the Medicare program.

If an individual is already in a health alliance when s/he turns 65, they may opt to stay in the health alliance and receive all benefits just as the non-Medicare population receives. However, the capitation rate will be calculated separately for Medicare enrollees, and they must pay any difference between the Medicare premium and the health alliance premium.

Cost Containment Strategies

Cost containment is integrated into all areas of both the national Health Security Plan and the new drug benefit under Medicare. Some of the strategies that will be employed are voluntary; most are incorporated as mandatory guidelines designed to restrain excessive growth in health care expenditures.

Upon introduction of the reform plan (as a transition measure), a voluntary program will be implemented urging all sectors of the health care system, hospitals, physicians, laboratories, drug manufacturers, and all others, to limit price and expenditure increases to a specified amount.[6]

Other efforts to implement cost containment will include the creation, under the authority of the National Health Board, of a "Breakthrough Drug Committee." The purpose of this committee is to encourage reasonable "launch" prices for "new drugs that represent a breakthrough or significant advance over existing therapies."[7] The Committee will only investigate drug prices for which evidence is already available suggesting that the price may be unreasonable. The Committee will have no authority to set or control drug prices, but it will issue a report to the National Health Board regarding the reasonableness of the drug price. The National Health Board will prepare an annual report for the President and Congress on their decisions and activities that would include the determinations of the Breakthrough Drug Committee. It is unclear at this time whether the Secretary of Health and Human Services would use this report in the decision that a drug is unreasonably priced and therefore subject to special pricing negotiations under Medicare provisions. If the manufacturer refuses to negotiate or the Secretary determines that the price is still excessive, the Secretary has the authority to exclude the drug from coverage under Medicare.[8]

As a condition of participation in either the Health Security Plan or Medicare program, drug manufacturers must enter into rebate agreements with the Secretary of Health and Human Services. The rebate guidelines are established in the Health Security Act and will apply to new drugs introduced into the market as well as existing products.

Other cost containment measures will be implemented for the Medicare program as well. In addition to excluding certain categories of drugs (such as those for cosmetic uses or for infertility), the Secretary may, in order to reduce waste, set maximum quantities per prescription and limit the number of refills. The proposal is designed to reduce costs by limiting the quantities dispensed. These waste reduction plans are designed to meet the changing needs of the patient and to closely monitor patient outcomes.

For example, if (for a specific patient) it is determined that a drug is not effective, negative side effects are too severe, the dosage needs modification, or there are other problems, the drug may be discontinued and the remaining portion of that prescription is wasted. Limiting refills ensures that patients return to the physician periodically to determine whether the drug is effective and being used at a proper dosage. The physician can also check for adverse side effects which may be undetectable to the patient.

Another measure included in the new Medicare drug benefit is to require prior authorization before prescribing or dispensing certain medications. Prior authorization status may be required if evidence exists that the drug is subject to clinical misuse or inappropriate use or is not cost effective as determined by the Secretary.

There are also incentives under the new Medicare drug benefit to encourage the use of generic drugs. Generic drugs are required to be dispensed unless the physician indicates that a brand name medication is necessary. This is referred to as "Dispense as Written" (DAW). Additionally, in an effort to reduce the number of brand-name prescriptions, the Secretary has the authority to require prior authorization for specific name-brand drugs for which a generic substitute is available. Under the Health Security Act, health plans are permitted to establish formularies. This will further encourage the use of generic drugs.

Medicare reimbursement amounts are set for both brand name and generic drugs covered under the Health Security Act. "For brand name drugs, reimbursement is the lower of the 90th percentile of actual charges in a previous period, or the estimated acquisition cost (EAC) plus a dispensing fee. For generic drugs, Medicare pays the lower of the pharmacists's actual charge or the median of all generic prices (times the number of units dispensed) plus a dispensing fee. For participating pharmacies, the dispensing fee is $5, indexed to the Consumer Price Index (CPI)." Participating pharmacies are required to accept assignment (the pre-determined limit for payment) on all prescriptions and cannot charge Medicare beneficiaries above this amount. For non-participating pharmacies, the dispensing fee will be reduced to $3 per prescription.[9]

A major change in the system under the Health Security Act will be that. "As a condition of participation under Medicare and Medicaid, manufacturers of prescription pharmaceutical products sold in interstate commerce would have to offer discounts to all purchasers of pharmaceuticals on equal terms."[10] Drug manufacturers could not offer differential discounts to purchasers except in return for differential economic advantages realized by the manufacturer, such as volume buying, prompt payment, prompt delivery, or other mechanisms that can influence physician prescribing behavior. This provision would specifically prohibit discounts which are based solely on class of trade. Sales to some federal health care programs that directly purchase pharmaceuticals would be exempt from these provisions.

<u>Commentary</u>

While increasing access to drug benefits is clearly a plus, there have been concerns raised. Among them are the following:

1) <u>Out-of-Pocket Costs Remain High</u>
   Concerns about the National Health Security Act have surfaced. For example, although it is agreed that expansion of drug benefits to the Medicare population is necessary, the seniors we talked to feel that the deductibles are too high and that drug prices will still continue to increase. They believe the Medicare benefit will simply not help many seniors.

2) Barriers to Access

Health care literature offers additional insight into potential problems that the Clinton Plan may face. One concern is access for low income persons to prescription drugs when a copay is in effect. Some studies have indicated that even with only a 50¢ copay, the number of prescriptions per patient has been reduced.[11] Consequently, patients must try to choose which medications are most important for them to take. This creates tremendous problems because patients generally are not qualified to distinguish which of their medications are medically necessary (such as hypertension medication or insulin) from those that are not. This appears to be especially true of elderly patients. There is concern that a $5.00 copay will reduce access. To the extent that a copay does in fact result in reduced access to medically necessary prescription drugs, an increase in institutionalization rates (acute care or nursing home) may be seen.[12]

3) Drug Price Competition

Concern has also been expressed regarding the single price policy. Some purchasers fear that competition will be stifled and all drug prices will rise as drug companies lose the incentive to discount to major purchasers. The ability of major purchasers, such as hospitals and HMOs, to negotiate for deep discounts based on market share works as an incentive to manufacturers to lower prices. If these purchasers can no longer negotiate these discounts, they will pay more. This has already been the case for some purchasers since the implementation of OBRA 90 and Medicaid "best price," resulting in millions of dollars of additional prescription drug expenditures.[13]

4) Research and Development Incentives

There is also a concern that price controls (such as the single price policy and growth limits) will reduce research and development of new "breakthrough" drugs--drugs for treatment of conditions in which treatment was previously unavailable. If drug company profits are reduced, it is feared that they will no longer engage in this type of expensive and financially risky research.[14]

ENDNOTES

[1]White House Domestic Policy Council. The President's Health Security Plan, (New York: Times Books, 1993), p. 27.

[2]White House Domestic Policy Council, pp. 37-43.

[3]White House Domestic Policy Council, pp. 37-43.

[4]White House Domestic Policy Council, p. 222.

[5]White House Domestic Policy Council, p. 26.

[6]White House Domestic Policy Council, p. 225.

[7]White House Domestic Policy Council, pp. 44-46.

[8]White House Domestic Policy Council, pp. 223-224.

[9]White House Domestic Policy Council, pp. 224-225.

[10]White House Domestic Policy Council, p. 226.

[11]Soumerai, S., and Ross-Degnan, D. "Experience of State Drug Benefit Programs." Health Affairs, Fall 1990, p. 43.

[12]Soumerai, S., Ross-Degnan, D., Fortess, E., and Abelson, J. "A Critical Analysis of Studies of State Drug Reimbursement Policies: Research in Need of Discipline." The Milbank Quarterly, Vol. 71, No. 2, 1993, p. 244.

[13]Tully S. "The Plots to Keep Drug Prices High." Fortune, December 1993, p. 122.

[14]Tully, S. "Why Drug Prices Will Go Lower." Fortune, May 1993, p. 58.

CHAPTER 5

INTERNATIONAL PERSPECTIVE

INTERNATIONAL PERSPECTIVE

INTRODUCTION

The U.S. pharmaceutical industry has maintained it's international competitiveness throughout the 80's and today, leading the world in market share, investment in research and development, and the creation of new patented drugs. Of several different pricing policies implemented in other countries, the U.S. policy is the most liberal. Keeping step with the social, political, and historical aspects of our free market economic system, the U.S. health care and prescription drug market is unique in its lack of regulation. In contrast, the drug pricing policies implemented around the world include product price controls, reference pricing, profit control, as well as the Canadian hybrid system of product price control and reference pricing. A description of these pricing policies as well as reimbursement systems, and how they influence a country's total pharmaceutical expenditures, is presented below.

INTERNATIONAL COMPETITIVENESS

The United States has a strong innovative drug industry relative to the rest of the world. In a study conducted by the U.S. General Accounting Office (GAO), of 11 high-tech industries in the United States, the pharmaceutical industry was the only *one* whose international competitiveness did not decline in the 1980's.[1] The U.S. pharmaceutical industry has the largest share of the world market, and it leads the world in investment in research and development (R&D) with a budget of $8 billion in 1990, more than double the 1990 Japanese budget of over $3 billion. U.S. pharmaceutical companies lead the world in creating and marketing new drug products, accounting for nearly half of the world-class drugs released between 1975 and 1989.[2] The U.S. pharmaceutical industry is also the number one creator of pharmaceutical patents. In 1991, the U.S. was more than twice as productive as Japan in patent registrations and more than 10 times as productive as Germany.[3]

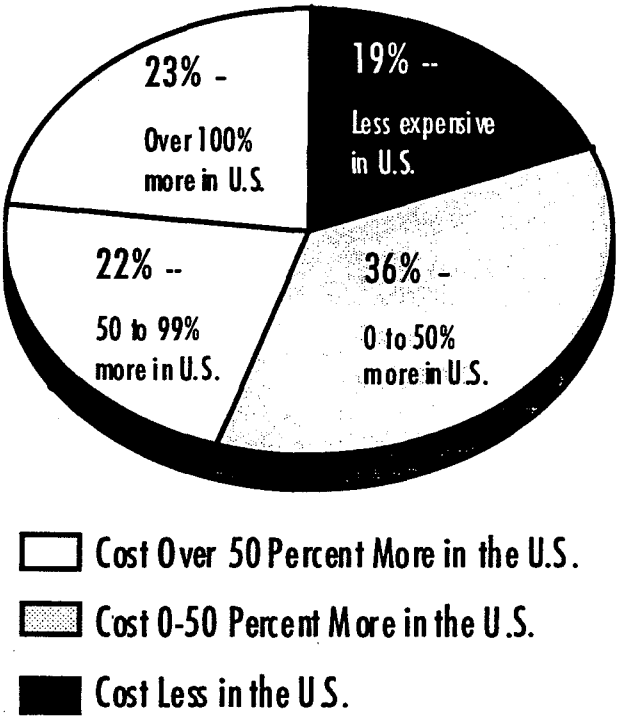
INTERNATIONAL PRICE COMPARISONS

According to a study done by the U.S. General Accounting Office (GAO) of 121 widely dispensed drugs sold in both countries, drug manufacturers typically charge wholesalers more in the U.S. than in Canada. This same basket of drugs purchased at factory prices would cost 32% more in the U.S. than in Canada in 1991.[4,5] U.S.-Canadian price differentials vary widely, ranging from 44% lower to 967% higher than Canadian prices. The median U.S.-Canadian price differential for the same drug purchased in each country was 43%. Of 121 drugs, over 80% were more expensive in the U.S., and almost half cost wholesalers over 50% more in the U.S. See Figure 5.1. Americans in the Southwest are routinely driving hundreds of miles to Mexico to purchase drugs at a fraction of the prices paid in the U.S.[6] Of course, as the pharmaceutical industry points out, just about everything in Mexico is priced below U.S. prices, related to the fact that the average hourly usage in the U.S. is many times higher than it is in Mexico. Other studies, however, have demonstrated similar comparisons where the U.S. has consistently charged higher prices than other western countries.[7] Europeans reportedly paid 40% less for prescriptions than the U.S. in 1991.[8] According to a study by the Department of Health and Human Services (DHHS), Americans pay 50-60% more than Canadians or Europeans for similar prescriptions.[9]

In a widely quoted 1991 survey, the investment firm Lehman Brothers International compared prices of 23 common prescription drugs in the U.S., United Kingdom, West Germany, Italy, France, and Japan.

Figure 5.1

Many Drugs Cost More in the United States than in Canada



Cost Over 50 Percent More in the U.S.

Cost 0-50 Percent More in the U.S.

Cost Less in the U.S.

Source: General Accounting Office

Although Germany most often had the highest price, U.S. prices were consistently first, second, or third. From their 1990 annual survey, the Italian Pharmaceutical Manufacturers Association put together an index using weighted average retail prices for brand-name drugs in 1989. See Table 5.1. Using Spain's prices as a base, the index shows that U.S. prices for brand-name drugs are over four times higher than those in Spain.[10]

In 1985, U.S. consumers spent almost 20% more on prescription drugs than predicted by their share of the population in the 23 industrialized nations comprising the Organization for Economic Cooperation and Development (OECD).[11] Since 1985, pharmaceutical prices have risen more rapidly in the U.S. than in other developed nations; thus the international price gap is probably wider today than it was in 1985. The 1985 figures indicate that prices are generally higher here than abroad, and that American consumers are indirectly subsidizing pharmaceutical sales in many other countries.[12] These comparisons, however, are at times a bit deceptive. A country's total pharmaceutical expenditures can be affected by international differences in prescribing patterns and many other factors besides simply the price of drugs. Although there are differences in the prescription status of drugs between countries, most products have equivalent classifications.

Table 5.1

Weighted Average Retail Prices for Brand Name Drugs, 1989

Spain	100
France	104
European Economic Community (EEC)	128
Italy	152
Belgium	159
United Kingdom	205
Germany	271
Netherlands	291
United States	427

Source: Italian Pharmaceutical Manufacturers Association

With a 13.6% return on sales in 1990, the U.S. pharmaceutical industry has a 9.5% margin over the average earned by other Fortune 500 companies in the U.S. In the same year, Japan's pharmaceutical industry earned a 5.7% return on sales, Italy's earned a 5.8% return, and the United Kingdom's pharmaceutical industry earned an 8% return.[13] The 1991 figures were almost identical: the average rate of return for a Fortune 500 company was 3.2%, while for pharmaceutical manufacturers it was 12.8%, a spread of 9.6%.[14]

Figure 5.2 illustrates the allocation of U.S. drug manufacturer costs in 1992. The average prescription price in the U.S. was $26.04, with $17.96 or 69% representing the manufacturer's component.[15] Of this manufacturer's component, over the lifetime of a drug product, marketing and advertising costs average 20% of sales, or $3.58 per prescription.[16] Only 15% went to cover research and development (R & D) expenses.[17] In Germany, drug manufacturers (who are free to set prices) spent 12.4% of sales on R&D and 14% on advertising and marketing.[18]

In the face of rising health care costs, the following section illustrates how other countries balance their concern for constraining pharmaceutical drug expenditures with the desire to maintain a strong research-based pharmaceutical industry. Drug expenditures are a function of price, consumption patterns, reimbursement policies, and social, economic, and political values. The types of pricing policies and regulations currently in use are described and illustrated for several representative countries. A discussion of reimbursement policies is presented in closing.

PRICING POLICIES

Pricing policies and regulations can be classified as one of four types.[19] These policy classifications and a sample of the countries implementing them include:

Product price control:	France, Italy, Portugal, Spain
Reference pricing:	Germany, Netherlands
Profit control:	United Kingdom (U.K.)
No control:	United States (U.S.)

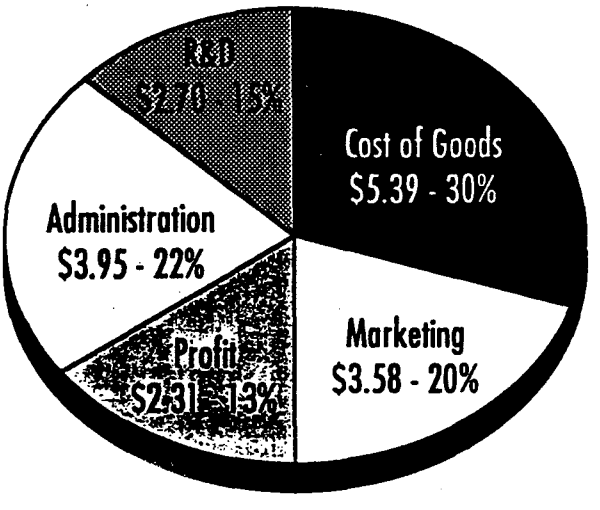
Canada uses a hybrid system of product price control and reference pricing. The producer sets prices within the guidelines established by the federal government's review board. Sweden, Norway, New Zealand, and Australia use drug pricing guidelines that are similar to Canada's.

Although there are substantial differences in pharmaceutical pricing policies, the most striking difference is that between the U.S. and other countries. All large industrialized countries except the U.S. impose some regulations on drug prices.

Product Price Control

Several European countries use product price controls to limit pharmaceutical expenditures and profits. Prescription drug benefits are provided directly by the government or by a government-sanctioned

Figure 5.2
Allocation of U.S. Drug Manufacturer Costs
(1992 Prescription Price = $26.04)



Source: PRIME Institute, University of Minnesota

organization. In price controlled countries, a product cannot be marketed until a price is established. Once a product receives marketing approval, the government agency or government-sanctioned body reviews a producer's price application. If the price is set lower than requested by the producer, the producer may appeal. Such appeals, however, delay access to the market.

There are two types of price-control systems: internal and external. Internal systems focus primarily on the producer's justification, while external systems base their decisions on prices charged for the same product in other countries.[20] Most countries use a mixture of the two. Both initial product prices and price increases are controlled. As controlled prices are rarely significantly increased from their initial level, producers need to market new products as a means of keeping profit margins up. Since innovation is not required for marketing approval, price control policies are regarded by some as removing research investment incentives.

The French people enjoy some of the lowest prescription drug prices in Europe. As practiced in Spain and Greece, prices of reimbursable drugs (90% of market) are negotiated and fixed by the Ministries of Health, Social Security and Economy in agreement with manufacturers. The French government requires product specific sales volume estimates so that the total pharmaceutical expenditures can be estimated. If sales are greater than estimated, the product's price will likely be reduced in an effort to control total expenditures. The focus on price regulations yielding lower prices is however, sometimes less than successful on a macro basis. While the French system of price controls yields some the lowest product prices in Europe, the country ranks second in *total* pharmaceutical expenditures.[21]

Reference Pricing

Germany and the Netherlands have implemented a pricing policy known as reference pricing. A reference price for a therapeutic class of drugs is established and consumers pay the difference or pay a copayment if a product is priced above the reference price. Since consumers will avoid products priced above the reference price, the reference price establishes a ceiling for most products in the category. In order to encourage pharmacists to dispense products below the reference price, the Dutch reference pricing system allows pharmacists to retain a percentage of the difference between the reference price and the price of the dispensed product.

In Germany, reference prices are set for therapeutically equivalent products. The combination of single-source (brand-name) and multi-source products (generics) allows huge potential savings as the average price is lowered by the generics. However, therapeutic advances are not rewarded by aggregating innovative brand-name products with generic therapeutically equivalent products. Research and development costs are not rewarded, and companies have no means of recouping their investments. The German pharmaceutical industry has warned that the emphasis on generics and generic-level price reimbursement limits set for thousands of brand-name products are forcing pharmaceutical companies to cut back on research.

Germany's supervised plan has succeeded in drastically cutting the amount spent on medications and prescriptions. In response to rising premiums and health care costs, the German government set a limit of $15 billion in 1993 on the total value of prescriptions doctors can order for their patients. These state-supervised "sickness funds" bargain with German doctors and hospital organizations for the "global" cost of health care just as "regional health alliances" would presumably do in the Clinton plan. If doctors had not succeeded in reducing the cost of prescriptions, ($16.5 billion in 1992) they would collectively have suffered reductions in the level of reimbursements "sickness funds" pay them for their

services. As a result, many doctors have begun prescribing generics whenever possible. The results were impressive. In the first six months of 1993, expenditures on retail prescriptions in Germany fell by more than 20% over 1992 levels. The 1,200 sickness funds ran a collective deficit of $5.7 billion for all of 1992; in the first six months of 1993, they had accumulated a $1.6 billion surplus.[22]

Profit Control

The United Kingdom (U.K.) is the only member of the European Economic Community (EEC) that utilizes regulations controlling profits. The cost-plus-profit concept used by the U.S. in regulating public utilities is the basic system used to control drug prices in Britain. The Pharmaceutical Price Regulation Scheme (PPRS), operated by the U.K. Department of Health, controls prices indirectly by limiting profits companies are permitted to make from selling prescription drugs to the National Health Service (NHS). Regulators reward innovative drugs with higher profit margins, while allowing much lower profits for copycat ("me-too") drugs. Companies subject to the PPRS may negotiate with the Department of Health regarding the level of profitability allowed. A target profit of 17% to 21% return on capital is usually agreed upon.

The British government also limits the amount a company can spend on advertising and promotion to 9% of sales income, while a maximum of 20% of sales income is allocated to research and development (R&D) for the industry as a whole.[23] Generic product producers are not subject to profit controls. Producers are permitted to set prices at any level as long as the company profitability on sales to NHS is limited. If a company goes over its sales threshold, the company must submit an annual financial sales report to NHS and provide a certificate of sales promotion costs.

Controlling profits is regarded by some as more likely to encourage research and innovation than a system that relies on product price controls. Innovation is rewarded through increased profits rather than rewarding new product introductions.[24] Along with Germany, the British system has produced pharmaceutical companies that are among the world's most powerful and innovative.

Canada's Hybrid System

Canada's pricing policies are a hybrid of product price control and reference pricing. Since R&D costs aren't allocated to specific products in the U.S. or Canada, the variation in U.S.-Canadian drug price differentials cannot be attributed to R&D. Furthermore, the costs of marketing, production, and distribution allocated to specific products do not significantly vary between the U.S. and Canada.[25] The variation in drug price differentials between the U.S. and Canada may be attributed to two factors. First, federal regulations restrain prices on patented drugs, and second, provincial drug benefit plans pay for drugs for a large segment of the population.

To ensure that prices on patented drugs (prescription and over-the-counter) are not excessive, the Patented Medicine Prices Review Board (PMPRB) was established in 1987 as part of a legislative package that included the extension of patent protection for makers of brand-name drugs. The PMPRB influences prices charged by manufacturers to wholesalers, but does not control pharmacists' dispensing fees or final retail prices. The maximum allowable price on a new drug is either tied to the costs of therapeutically comparable medicines or to the median price charged for the same product in seven other industrialized countries. Drug product price increases are limited to the rate of inflation, that is, the Canadian CPI.

Prior to 1987, the price of pharmaceuticals increased very rapidly. As a result of the requirement that drug price increases be limited to the rate of inflation, Canadian prices on patented drug products have risen slower than the Canadian CPI and prices on non-patented drugs since 1987. Thus, this mechanism is seen as an important method of controlling the price of pharmaceuticals in Canada.[26]

Prior to 1987, generic competitors could enter the Canadian market far more quickly than in the U.S. Canada's R&D levels were low relative to the U.S as Canadian patent laws may have made pharmaceutical firms reluctant to engage in R&D. Since the patent extensions, the ratio of drug R&D investment to sales in Canada nearly doubled from 1988 through 1991.[27]

The Canadian PMPRB can demand that any manufacturer whose price appears excessive appear for a hearing. If a satisfactory resolution is not reached, the board can reduce the company's exclusive right to market the drug, do the same to another one of the company's patented products, or order a price reduction. If the board takes away the company's patent, generic competitors are allowed to enter the market (recent changes in Canadian patent laws have altered these enforcement powers).

Provincial drug benefit plans cover a greater share of the population than any single payer in the United States. As large third party payers, provincial governments use their concentrated buying power to exert pressure on manufacturers to negotiate lower prices. For example, Ontario, Canada's most populous province, (accounting for 36% of Canada's population in 1988), pays for approximately 40% of the drugs sold in Ontario. The province's Drug Benefit Plan established a formulary - a list of drug products it will reimburse. Each product in the formulary has a maximum price a pharmacist is reimbursed - the best available price (BAP). The BAP represents the lowest amount a listed originator (non-generic) drug product can be purchased in Canada for wholesale or retail sale in Ontario. The price need only apply to the 40% of prescription drug sales covered by the provincial plan. The other 60% of prescription drug sales do not face any formal price restrictions in the private market.

Drug manufacturers submit updated BAPs for their products. If manufacturers and provincial officials can't reach an agreement on pricing, the manufacturer loses access to a share of the market. If a manufacturer lists its drugs on the formulary, it can in theory still charge a higher price to the private market. However, because prices are published in a formulary that is publicly available, the formulary provides a basis for prices throughout Canada. Private third party payers also use it to establish drug reimbursement rates.

Each of the twelve Canadian provinces or territories has its own drug benefit program. In nine of the provinces (including the two most populous, Ontario and Quebec), the drug programs pay only for drugs used by the elderly and low-income persons. In the remaining three (British Columbia, Manitoba, and Saskatchewan), the drug programs pay for drugs used by all residents. None of the provinces set product prices or limit company profitability at the federal level. PMPRB guidelines are used by provinces when negotiating prices with pharmaceutical firms; they may negotiate lower prices.

REIMBURSEMENT SYSTEMS

Drug expenditures are a function of price, consumption patterns, reimbursement policies, and social, economic, and political values. The combined effect of reimbursement and pricing policies influence total pharmaceutical expenditures. Various prescription reimbursement policies are used to control consumer and government expenditures for drugs. They establish how consumers, the government, or other agencies will pay for and share the cost of prescriptions.

The two most important aspects of reimbursement policies are the source of initial payment and consumer cost-sharing. European countries have similar initial payment methods. The predominant method is that the consumer receives a prescription without payment (except for cost-sharing), and the pharmacy provider submits a claim. In France, the consumer makes the payment first and subsequently submits a claim for reimbursement. The French system may be regarded either as a method of controlling unnecessary utilization and/or as an attempt to control expenditures by introducing a minor barrier. How successful the system is, however, can be debated, for as noted earlier. France rates second in Europe in total pharmaceutical expenditures.

Virtually every country uses consumer cost-sharing in the form of copayments (a fixed fee for each prescription regardless of price) or coinsurance (a percentage of price). The two methods are combined in Italy. Under U.S. Medicaid program rules, some states are authorized, but not mandated, to charge a prescription copayment.

Nearly every country using prescription cost-sharing places an upper limit on consumer out-of-pocket payments either for drugs or total health care expenditures. The combination of cost-sharing and out-of-pocket payment limits discourages unnecessary use, and ensures access by limiting financial burdens.

The limits on cost-sharing in some countries are modified to consider income. In the U.K. for example, entire groups (children, pregnant women, and the unemployed) are excluded from having to pay any copayments for prescriptions. In fact, over 80% of prescription purchases do not require copayments.[28]

Some countries set reimbursement rates based on therapeutic class or perceived usefulness. In France, three levels of cost sharing are defined: "life-saving" products are 100% reimbursed, most others are 70% reimbursed, while "trivial" products are reimbursed at 40%.

SUMMARY AND DISCUSSION

The U.S. prescription drug market (as well as the U.S. Health care system in general) is unique in its lack of regulation and is generally the most laissez faire in its pricing. No restrictions are placed on new products or price increases, and there is no government body that sets or approves drug product prices before a drug becomes available to consumers.

Although Medicaid establishes maximum allowable prices for certain products and a manufacturer rebate program is in place, the Medicaid market accounts for only about 19% of total U.S. prescription sales, leaving a substantial private market not found in Europe. While the policies implemented by other countries deserve consideration, it is important to keep in mind the unique social, political, historical, and economic aspects of the U.S. health care system and prescription drug market. The underlying economic and political systems of a country help explain the nature and degree of the success of policies implemented and enforced to control expenditures. The success of any policy implemented in the U.S. designed to control health care expenditures will depend in large part on whether the checks and balances implemented in the proposed system are consistent with this country's prevailing economic and political principals.

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CHAPTER 6

LEGISLATIVE REFORM OPTIONS

LEGISLATIVE OPTIONS

The following chapter describes each of the legislative options outlined in the legislation authorizing this report. Each option is described and the advantages and disadvantages of each proposal discussed. It should be noted that these options were not developed by the Department of Health, but that the Department was required, by law, to review these legislative options.

PURCHASING PROGRAMS IN THE PRIVATE SECTOR

References to drug purchasing programs in the private sector acknowledge the ability of pharmacy buying groups to negotiate deep discounts from drug manufacturers in exchange for market share. The major purchasers include hospitals, HMOs, and mail order pharmacies. The Department of Administration also administers a volume buying program for state and county sponsored institutions and agencies that includes sixteen other states and the city of Chicago.

Discounted pricing is a marketing strategy employed by the pharmaceutical companies. For example, much of the profit in pharmaceuticals comes from medications prescribed for chronic conditions. Pharmaceutical companies are willing, even eager, to lower the prices on drugs that they charge hospital buying groups because they assume that once a patient begins treatment on a specific medication, they may remain on that drug for decades. It becomes a short-term loss for a long-term gain for drug companies. Hospitals may pay the average wholesale price minus 40% to 50% whereas the best price the retail pharmacy down the street can get is the average wholesale price minus 12% to 15%. However, retail pharmacies have not been able to secure the same level of discounts, even when organized into buying groups, primarily because they have no control over physician prescribing practices or payer coverage policy.

In addition to the buying groups, payers have also been able to secure direct financial rebates in exchange for inclusion of the manufacturers products on the payer's accepted list of covered drugs (i.e. their formulary). These programs are administered by drug management companies that pay claims, process rebates, and manage drug expenditures for third party payers. They employ drug management tools such as restrictive formularies, prior authorization, and drug utilization review, and work directly with the manufacturers to manage the third party payer's rebate program. The drug management companies negotiate with manufacturers over the inclusion of drugs on their formularies in return for market share. Manufacturers then provide rebates to payers based on the actual use of their drug product by patients. The rebates are paid directly to the payer as incentive for including the manufacturer's product on its formulary.

A conservative estimate indicates that over 75% of insured Minnesotans with pharmacy benefits are involved in some type of drug management program.[1] Several pharmacy management companies are headquartered in Minnesota and do business nationwide. Diversified Pharmaceutical Services (DPS), a subsidiary of United HealthCare, is the HMO management company for the local Medica health plans. Blue Cross and Blue Shield enrollees have prescription benefits managed by Pharmacy Gold, Inc.; Aetna manages MedCenters; PCS/Clinical Pharmacy Advantage (CPA) also provides managed care capabilities, with CPA managing Preferred One in the metro area.

Advantages of Private Sector Initiatives

Many managed care advocates feel that the proliferation of private sector activities have dramatically changed the market for pharmaceutical drugs. There is intense price competition for those who can participate in one of the large buying groups and increased competition among manufacturers as they negotiate (through product and rebate incentives) to secure a place on payers' formularies. The increase in profits of some large manufacturers is slowing and there is a great amount of activity and competition in the market for the large buying groups and at the formulary level for payers.

The use of drug formularies and other drug management tools has led to educated buyers making informed choices about the use of drugs based on demonstrated efficacy and cost. These programs have forced manufacturers to bid competitively even on brand-name drugs and are one of the driving forces behind a changing industry.

Representatives of the drug management programs we talked with were convinced that quality of care had improved under aggressive drug management programs. More time and effort goes into the evaluation of new products for demonstrated improvements in patient treatment quality and outcomes. Pharmacists and physicians jointly participate in the Pharmacy and Therapeutics committees to evaluate and make decisions on adding new products to the payers' list of covered drugs based on quality.

Disadvantages of Private Sector Initiatives

There is little dispute that a large segment of the market is price competitive and that the large buying groups, namely hospitals, HMOs, and mail order pharmacies, are getting deep discounts from the manufacturers on drug product price. The result of this competitiveness is that some sectors are unable to compete as effectively as others. Retail pharmacists in particular are finding themselves in this position for a number of reasons. First, retail pharmacists do not have the leverage of formularies to negotiate discounts from manufacturers. Second, pharmacists and some consumer groups argue that manufacturers make up for the deep discount given to others through cost-shifting to the retail pharmacists by charging them higher prices. Third, many of the elderly, uninsured and underinsured that lack coverage for pharmaceuticals are not benefitted by drug management programs and must typically pay the full cost of the product directly out-of-pocket. Again, it is argued that cost-shifting is occurring, this time from the retail pharmacists that are paid low rates from third party payers to the cash paying customers in order to try to make up the difference.

Another concern expressed by the retail pharmacy industry is that there are too many different formularies in the market. This could be seen as a problem as it requires independent physicians that work with more than one payer to work with several different formularies. This can be time-consuming for the physician to understand the different programs. Consequently, they often rely on the retail pharmacists to intervene at the point of sale. Having several formularies also requires more work by pharmacists as they must contact physicians for new prescriptions each time a non-formulary product is prescribed (unless the patient agrees to pay cash). It also requires the retail pharmacists to stock different drugs for each of the formularies, which results in less than efficient inventory practices.

Specific Legislation

Given the success of managed care and drug management companies to moderate increases in pharmaceutical costs in Minnesota, one recommendation to consider in attempting to control prescription drug prices is that there be no intervention at this time. Allowing the unfettered development of the concept of managed care through ISNs may be the most effective private sector initiative to further control drug

prices in Minnesota. It is clear that prices are moderating as we continue to move into a health care reform climate at both the state and national levels. The development of managed care in Minnesota to date has undoubtedly put this state far ahead of the rest of the nation in terms of health care reform and the moderating of health care expenditures. Accordingly, allowing the private sector to seek market-driven solutions, even as it continues to flesh out the practical definitions and actual structures of ISNs, may be the most effective course the Legislature could take with respect to containing costs in the prescription drug market consistent with the broad goals of MinnesotaCare.

Until universal coverage is achieved, the needs of those without prescription drug coverage, particularly the Medicare population, may not be fully addressed by private sector initiatives. Yet it is unclear what, if any, role the State should play in this rapidly changing system. There is political pressure and interest to pass national legislation to include prescription drugs as a covered Medicare benefit. In addition, there is continuing debate about the need to move quickly toward universal care. In this context more seniors will be receiving their medical care through managed care systems and one may reasonably expect that this trend will lead to lower prescription drug prices for this segment of the market. In addition, there have been recent private sector initiatives to provide access for seniors to lower prescription drug prices including Medica's recent decision to include seniors in a rebate system, thereby reducing its senior members' prescription drug costs by up to 15%. Medica's approach is one example of allowing the creativity and competitive nature of the private sector to find solutions to current market inequities. It may be that only when universal coverage becomes a reality, including a prescription drug benefit, will the solution be found for the remainder of those currently disadvantaged under the present market system.

The current situation of the retail pharmacists is a difficult one, and not easy to address. There are, however, many potential possibilities as Minnesota's health care system continues to define the identity and shape of the components that will make up ISNs and CISNs. The role that independent retail pharmacy will play in ISNs remains to be seen, but certainly among the possibilities are contracting with ISNs (perhaps on a joint or association scale) to provide pharmaceutical services, or perhaps even becoming an integrated component of an ISN. It would appear that some consolidation is inevitable and retail pharmacies may choose to trade some of their independence for economic survival in a highly competitive managed care environment. Again, the most prudent answer may lie in allowing private sector initiatives to develop as opposed to legislative attempts to "fix" one component of the drug market at the expense of another more efficiently-operating segment.

MOST FAVORED PURCHASER/ANTI-PRICE DISCRIMINATION LEGISLATION

Most favored purchaser legislation refers to mandates that all purchasers receive the same discounts and prices offered to the "most favored purchaser" in the market. That is, the State would require that manufacturers offer the same price to all purchasers based on a given volume of drug product. Retail pharmacists would receive the same discounts as HMOs, hospital and mail order pharmacies, and government buying groups. This legislation is often referred to as "anti-discriminatory pricing" legislation or "single price policy;" it attempts to eliminate the perceived discriminatory pricing practices of manufacturers that offer different prices to different purchasers.

The Minnesota Pharmacists Association (MPhA) and retail pharmacists are in support of making the current practice of differential pricing for pharmaceuticals illegal, "The most fundamental action the Minnesota Department of Health could propose to the Minnesota Legislature to eliminate the high cost

of prescription drugs is the elimination of discriminatory pricing to retail community pharmacies through legislation to mandate that pharmaceutical manufacturers provide the best price to all Minnesota purchasers,"[2] claims MPhA. The contrary view is usually expressed by hospital pharmacies and other large managed care organizations. That view submits that if the new system of pricing does not also result in a decrease in the AWP (which is not controlled by the State) the prices to the consumers and their third party prescription providers will not be decreased. The only thing that will change is that the acquisition cost will go up for those parties that were previously benefitting from the preferred pricing system.

In 1976, Wisconsin passed anti-discriminatory pricing legislation that required that every pharmacy in the State be offered the same price as the most favored purchaser. That is, manufacturers could no longer give different levels of discounts to different pharmacy groups other than for discounts based on nonprofit status of the purchaser or functional differences among classes of trade. Likewise, Minnesota pharmacy law (Statutes 151.061, see Appendix E) makes it illegal to discriminate on the price of pharmaceuticals between purchasers for reasons other than freight costs and prompt payments. Both laws have small financial penalties associated with violation and neither have been actively enforced. The Wisconsin Pharmacists Association has proposed to increase the fine associated with violation of this statute from $250 to $10,000.[3]

The federal Robinson-Patman Act requires companies to sell products at the same price to competing customers in the same class of trade. Nonprofit institutions are exempt from Robinson-Patman and in Minnesota this includes HMOs and hospitals. There is much debate about whether there are distinct differences or classes of trade among different pharmacy groups. Information on a national lawsuit being brought by retail pharmacists, including several Minnesota pharmacies is presented in Appendix D. The case of Rite Aid Corporation, et. al., v. American Home Products Corporation, et. al, has been filed in U.S. District Court for the Middle District of Pennsylvania. The plaintiffs (owners and operators of drug stores) allege discriminatory pricing by defendants (pharmaceutical manufacturers and a mail order pharmacy) in violation of the Robinson-Patman Act. It remains to be seen whether the court will find in favor of the pharmacists or the manufacturers. Historically, according to those who enforce the antitrust laws, allegations of price discrimination based on the Robinson-Patman Act have not prevailed. Four of the six counts in the Rite Aid complaint are based on the Robinson-Patman Act.

A provision in OBRA 90 names State Medical programs as most favored purchaser. The legislation requires manufacturers to give state Medicaid programs rebates for outpatient drugs based on the lowest prices available to any purchaser.[4] The rebate amount must equal the greater of: 1) 15.7% of the average manufacture price (AMP) (which is approximately equal to average wholesale price [AWP] minus an estimated 17% [5]), or 2) the difference between the AMP and the net best price (less discounts and rebates) for a particular drug to any purchaser. Additional supplemental provisions allow state Medicaid programs to recapture increases in the AMP that exceed the rate of inflation through rebates received directly from the manufacturer.[6] These mandated rebates give state Medicaid programs the best price given to the most favored purchaser in the market.

Advantages of Most Favored Purchaser Legislation

The key advantage of this legislation is that it secures the best price for all purchasers and puts retail pharmacists on an equal footing with other pharmacies. In addition, it eliminates the concerns about differential pricing and the need for cost-shifting. Retail pharmacies who are not part of large purchasing groups would experience lower drug product prices and it is expected that these lower costs would translate to lower prices for retail customers.

Disadvantages of Most Favored Purchaser Legislation

The main concern with this legislative proposal is that it would essentially eliminate any private sector initiatives and market forces that have effectively brought product costs down for some segments of the market. In addition, assuring the best price for all purchasers may in fact increase prices for all. There would be little competition to keep prices down and there would need to be additional price control mechanisms to monitor the increases in prices, as well as to ensure that savings are passed on to consumers. Another possible consequence of such legislation could be to encourage consumers to purchase their prescription drugs from purchasers who can negotiate for various discounts, such as mail order pharmacies located outside of Minnesota.

Another concern is that this provision would eliminate the need for formularies which have been so effective in promoting competition among brand-name products and in promoting the development of cost effective products that produce the best patient outcomes. If all purchasers got the same price it would lessen the impact of formularies in getting the manufacturers to be price competitive.

MANDATORY DRUG CONTRACTING/PURCHASING PROGRAMS

Currently, the State of Minnesota, through the Materials Management Division of the Department of Administration (DoA), negotiates the purchase of $65 billion of pharmaceutical drugs for state and county funded institutions in Minnesota, 16 other states, and the city of Chicago. The DoA has been successful in negotiating with drug manufacturers to obtain discounts of 15% on sole-source drugs and up to 70% on some generics.

The DoA's drug contracting program is limited by law to include only state or county-funded agencies or institutions and participation is strictly voluntary. Proposals have been made to expand the DoA's role to provide state-wide volume drug purchasing for all pharmacies in Minnesota--both public and private organizations.

Under a mandatory drug contracting program, the State would assume the role of contractor for pharmaceutical products for all pharmacies in the State. After the State has completed its contracting process with the manufacturers, manufacturers would be required to offer the same negotiated price to all pharmacies.

A strict mandatory program would require all pharmacies in the State to participate. Private purchasing programs would be banned. Another option, more widely accepted, is to develop a mandatory option with exemptions for pharmacies that meet certain criteria. The criteria that have been proposed could include any or all of the following. Pharmacies would be exempt if they: 1) purchased drugs at a price lower than the state-negotiated price, 2) disclosed these prices to confirm that they have received a lower price, and 3) provided documentation that savings achieved from the lower prices were passed on to the consumer.

Advantages of Mandatory Purchasing Program

By requiring all pharmaceutical purchasers to participate in a single purchasing program all pharmacies would purchase drugs for the same price, eliminating the practice of selective discounting. In addition, the negotiating power of the DoA would be used to secure good prices for all pharmacies. The retail pharmacies who are currently not part of purchasing groups already would see a substantial decrease in the prices that they pay. It is expected that lower prices to retail pharmacies would translate to lower

prices to consumers, although no mechanism is currently in place to ensure that cost savings are passed on to consumers. Some estimates suggest that these lower prices may be up to 30% less than what cash customers currently pay for prescription drugs.

Another potential benefit of a mandatory program is that aggregate costs of administration across all pharmacies could be reduced by the consolidation of the negotiation and purchasing function in one central location. The administration of the current DoA program is funded entirely out of administrative fees paid by participating drug manufacturers.

Disadvantage of Mandatory Purchasing Program

A mandatory purchasing program would eliminate successful purchasing programs already well-established in Minnesota. This includes hospitals that participate in national or regional group purchasing organizations and managed care organizations that buy their own drug product. Exemptions could be granted to existing successful purchasing programs. The feasibility of documenting that the savings were in fact passed on to consumers is seriously questioned given the current market pricing complexities.

Replacing competing purchasing programs with one statewide program may force some purchasers to pay higher prices. Even with exemptions for hospitals and HMOs that already belong to successful purchasing programs, manufacturers may increase their prices to all purchasers to maintain their profit margins. When state Medicaid programs were guaranteed the "best price" under OBRA 90, prices to hospitals and managed care entities went up. In fact, some hospitals sustained "pharmaceutical price hikes as high as 14% to 20%.[7]

There are also some complicating factors involving the Department of Human Services (DHS). Currently manufacturers are required by law to offer DHS the "best price" in the market. DHS then collects rebates from manufacturers to assure that this price is received. In order to get the rebates, DHS must agree to offer the manufacturers entire drug product line. Under a statewide purchasing program, DHS would still need to purchase drugs outside of the system in order to obtain the rebates and secure federal financial participation (FFP) from the federal Medicaid program. Medicaid would need to be exempt from this program to maintain the federal payments (54%) for pharmacy reimbursement and rebates representing approximately $55 million in 1993. In order for any statewide program to work, the Medicaid "best price" policy must be preserved.

VOLUNTARY DRUG CONTRACTING/PURCHASING PROGRAM

Under a voluntary drug contracting program, the State would bid for drug price and then offer that price to all pharmacies within the state who choose to participate. All pharmacies would have the option to buy from the State or through other means. Thus, some agencies or organizations that might be adversely affected by purchasing at the State price could simply choose not to participate.

Advantages of Voluntary Purchasing Program

The key advantage of voluntary drug purchasing program is that pharmacies already participating in effective drug purchasing programs do not need to participate. The pharmacies most in need of a State-sponsored buying group can join but are not required to do so.

Disadvantages of Voluntary Purchasing Program

The key concern of pursuing a voluntary drug purchasing program is that the State cannot guarantee the volume of drugs that will be purchased. By allowing some purchasers to opt out, the leveraging impact of the statewide purchasing contract is diminished.

There may be additional administrative costs in implementing a voluntary program. The program must monitor membership in order to track pricing and rebates. These administrative costs will lessen the impact of the lowered prices, particularly if additional permanent staff are still required to manage the contracts and billing processes.

Under a voluntary program, cost-shifting would not be eliminated. Manufacturers may still shift costs between participators and non-participators.

MANDATORY STATEWIDE FORMULARY

Some consumers and retail pharmacists have proposed that the State establish a single statewide formulary that would cover both Integrated Service Networks (ISNs) and Regulated All-Payor Option (RAPO). This would assure the same price to all purchasers. Under such a system, health plans could decide how they want to administer the formularies within established boundaries. A statewide formulary does not mean that all existing managed care formularies or hospital formularies must be abandoned. Rather, the statewide formulary could be a consolidation of existing formularies. A vast majority of products are common to all formularies. These commonalities will provide the base for consolidation, thereby reducing the complexities of developing a statewide formulary. Any hospital or ISN could pick a unique subset of this umbrella formulary tailored to its particular patients. Other strategies such as the use of "preferred drugs" within a formulary are also possible. This allows a P&T Committee to establish a "best drug" within a group of sole source drug items. Health care systems using this strategy expect to achieve significant cost reductions while still maintaining or raising the quality of care and overall patient outcomes. Purchasers could get additional discounts on pharmaceuticals based on transportation costs or prompt payment.

The concept of combining formularies is not a new one. Mathematica, a national consulting research group, working with the Minnesota Health Care Commission and the Minnesota Department of Health to develop the Regulated All-Payer Option, proposed a state-wide formulary and single reimbursement schedule for drug benefits for all payers not included under an ISN. About ten years ago the Indian Health Service in Oklahoma City and western Kansas went through the process of combining multiple formularies. They eliminated redundancy and formed a single drug purchasing group that achieved substantial savings. Recently, HealthPartners began the process of combining the formularies of Group Health and MedCenters. If there is further consolidation in the health care market, movement to one formulary may not be much more difficult.

Advantages of Statewide Formulary

The key advantage of a statewide formulary is that it would substantially reduce or eliminate cost shifting. Under a statewide formulary based on contracted "best price," all purchasers would get the best price on drug products and this would secure the needed bargaining position for the independent pharmacies and, in theory, eliminate the need to cost-shift losses to cash paying customers. This would have a beneficial impact for seniors and the uninsured and underinsured.

Proponents also claim that such a system would promote quality, cost containment, and the use of practice guidelines by physicians. In addition, a statewide formulary would provide the state with additional leverage for negotiating drug prices given the large volume a statewide formulary would offer.

A statewide formulary would also provide continuity of patient care for patients that transfer from hospital to hospital, from hospital to home, or from one health plan to the next. Patients would not have to switch medications to accommodate the formulary requirements of the health plan or the hospital. It would also eliminate the many drug evaluations done by competing third party payers.

Another advantage would be the decreases in inventory of community pharmacists and local wholesalers who now have to stock many drug product to accommodate the different formularies.

Disadvantages of Statewide Formulary

One concern raised by some consumer groups and the manufacturers is concern over access to needed drugs that are not on the formulary and the potential of the formulary to interfere with doctor-patient relationship and privileges. Such a system could makes general decisions that may not apply to specific patients. The P&T Committee may choose a drug that causes less stomach upset, but more headaches, which is good for ulcer patients but not those who suffer from migraines.

There is the perception of loss of freedom of choice on the part of the physician to prescribe as necessary. There is also fear that with a statewide formulary, desirable drugs will not be included, and patient quality of care will be compromised. This fear may be exacerbated as new contracts are negotiated and drugs that have been available are suddenly replaced by a different product line. Even though the drugs are fully equivalent, it may appear to consumers to be inconsistent. This inconsistency could be interpreted again as compromising quality of care. And in some cases, that is true. For some reason, patients are at times unable to physically tolerate a change in drug, even though the new drug is an equivalent.

Any statewide formulary would need to include some provision for obtaining access to essential medication that is not on the formulary as well as a procedure for addressing concerns and complaints about quality of care. There is an additional concern about the liability of medical decisions regarding mandated formularies.

A statewide formulary would also decrease flexibility to provide different kinds of health care to members of different managed care plans. "One size fits all" may not work in a system that is based on competition. That is, one health plan may specialize in a particular type of care and may need drug products that are unique and not needed by other health plans.

Another concern raised is the ability of the State to administer and maintain such a large scale and complex program. One key concern in this regard is the ability of a State-run system to react in a timely matter to changes in medical information that would require modifications in the formulary. Many believe that the private sector is better able to react to a rapidly changing industry. There is also the issue of the cost of such a system.

Costs of administering a statewide formulary could be substantial. Options for financing such a system include the following: 1) Charge manufacturers a user fee, much like the FDA charges them for processing new drug applications, 2) Assess all players who benefit, like HMOs or manufacturers, a percentage based on the volume of drugs purchased in the market. Efficiencies in the system may help pay for the program in the long run.

Concerns have also been raised that a statewide formulary would reduce competition just as the multi-source (generic) industry is growing as a result of patent expiration on many of the leading drugs. Use of a statewide formulary may eliminate potential for new competitors who might provide lower prices in the marketplace. There is concern as well that a sole manufacturer may not be able to support the volume required; the increased demand could result in shortages or delays in delivery.

The Medical Assistance program would need to operate outside of any Statewide formulary. OBRA 90 currently prohibits State Medical Assistance programs from participating in a statewide program. In order for Medical Assistance to receive the "Best Price" on prescription drugs, they must offer the entire product line of all rebating manufacturers. Failure to offer all drug products places the MA program at risk for loss of federal financial participation and rebates totalling approximately $55 million per year.

LIMITING PRICE INCREASES

Price controls may be effective in holding down costs on a short-term basis. Currently, all providers (including pharmacists) are subject to the growth limits as outlined in the MinnesotaCare Act of 1993. MinnesotaCare has imposed limits on the growth rate of health care revenues and spending for health care payers and providers, including both pharmacists and physicians. Pharmacists have raised concerns about the application of growth limits, because the majority of the cost of the drugs they sell are set by manufacturers. Of the average prescription filled in 1992, manufacturer charges contributed 69% of the price.

Voluntary Price Controls

Seventeen research-based manufacturers voluntarily pledged to keep their average price increases to within the general inflation rate. These seventeen companies account for about two-thirds of the prescription drug market. In 1993, the rate of inflation for prescription drugs was the same (3.3%) as the general rate of inflation for all items. This represents the lowest rate of increase since 1981.[8]

There have been concerns raised over the actual impact of these voluntary pledges. The concern is that pledging increase limits based on averaging allows manufacturers to vary prices cross different classes of trade and across different products in their line. Senator Pryor (D-AR), chairman of the U.S. Senate Special Committee on Aging, investigated seven of the seventeen companies that took this price pledge and looked at the increases in the retail prices of the top 200 biggest-selling drugs. The study found that drug prices to retail pharmacies increased more than prices to hospital, mail-order, or managed care pharmacies. The report concluded that eight of the ten drugs that increased the fastest in price in 1992 were those that senior citizens often used.

To offset the concerns raised by increases based on an average, additional price pledges were given in 1993 by manufacturers. Merck, Inc., and Smith Kline Beecham vowed not to raise wholesale prices on any individual product by more than the inflation rate plus 1%.[9]

How Price Controls Could be Implemented

The closest example of price caps in place today occurs under OBRA 90 Medicaid Rebate Law (where the government gets the better of AMP-15% or lowest price offered to any purchaser). Since the increase in the AMP is tied to the general rate of inflation as measured by the consumer price index (CPI), the rate of growth is controlled although overall prices are not lowered.

A proposal has been made to tie price limits to a state-run drug contracting program operated by the Department of Administration. To set prices, it was suggested to use the Medicaid rebate price as the standard discounted price and tie the increases to the general rate of inflation.

Another option to implement price controls would be to use a cost-plus-profit model, similar to the model used to set the prices of public utilities. It is proposed that the state cap prescription rates to consumers like they do with utilities. For example, the pharmacy reimbursement rate could be AWP minus 10% plus a $5 dispensing fee. This would eliminate cost-shifting to cash paying customers. If adopted, price caps could be monitored by state audit via computer claims processing. In any program to limit prices, some type of monitoring would be necessary to ensure that consumers receive full benefit of the cap.

New products are more difficult to control, but other countries have found various degrees of success with price controls. See Chapter 5 for a discussion of these programs.

Advantages of Price Controls

The key advantage of price controls is that prices would be limited for all sectors of the market and thus eliminating any concerns about differential pricing. Price controls may provide the most benefit to those consumers who have had to pay for prescriptions out-of-pocket (primarily senior citizens and the uninsured). Price controls may, at least in the short-run, reduce prescription drug expenditures by allowing for more centralized control, although some evidence indicates prices controls are not as effective over an extended period of time.

Disadvantages of Price Controls

Several concerns have been voiced regarding the implementation of price controls. Gold, et.al., reported some of the problems and shortcomings of price controls.[10] First, limited price and payment controls are not as effective as the more far-reaching, broad-based controls that limit the ability of providers to increase volume or intensity of care to compensate for the controls. Second, setting price controls on individual institutional and non-institutional services can result in short-term savings, but if the controls are not maintained over time, rapid inflation may undercut any savings achieved when controls are removed. Third, voluntary price controls are effective only so long as the threat exists that mandatory controls will be implemented if the voluntary efforts are not effective. This threat is difficult to maintain over time, and thus probably should not be considered a means to long-range savings.[11]

Another concern raised about price controls is that it would eliminate price competition and stifle the development of new medicines by providing incentive for pharmaceutical research to introduce low-risk, low-benefit new products.[12]

Another possible problem is that some drugs may be difficult to obtain for some consumers. If the State implements price controls on products sold here, some companies may choose not to sell their entire product line in this state at the set price requiring consumers to travel out of state to purchase their drugs.

Finally, price controls would also require an elaborate process to set prices for new drugs. This would involve extensive information and technical expertise to determine these prices and the build up of government-run programs to manage these systems. There would be a substantial state cost associated with the administration of a price control mechanism.

THERAPEUTIC SUBSTITUTION

Therapeutic substitution is an agreed-upon medical decision to substitute one drug for another with the same effectiveness and safety but at a lower cost. Therapeutic substitution is not the same as generic substitution. With therapeutic substitution, a drug is dispensed that has different active ingredient, but is in the same therapeutic class.

Therapeutic class refers to a group of drugs intended to treat a particular medical condition or a group of related diseases. Within a therapeutic class, such as oral contraceptives, there are many different brand-name products. A formulary may have a partial listing: low estrogen pills, high estrogen pills, and tri-phasic pills that have three different levels of estrogens in the course of the month. Those brand-name products not on the formulary are replaced by others in the same therapeutic class.

Therapeutic substitution is a pharmacy management tool that allows formularies to become restrictive. Drug management companies and hospital pharmacies use therapeutic substitution as a means to get manufacturers to price brand-name drugs competitively. In order for a "me-too" drug to compete in a therapeutic class it must be priced an average of 14% lower than the market leader of that class. The competition is more intense with drugs taken for a lifetime to treat chronic diseases. In these cases, it takes a price discount of over 35% for a me-too drug to become established.[13]

Pharmacists are not allowed to make a therapeutic substitution without the consent of the prescribing physician; pharmacists are allowed to make generic substitutions without this consent. In addition to needing the consent of physicians, most pharmacists *want* the consent of physicians before they substitute therapeutically equivalent drugs. They do not want to accept the liability for making the decisions without physician advice.

Therapeutic substitution has been practiced to varying degrees by many hospital pharmacists for years. However, it is more accepted because it is easier to manage in this closed setting (a defined group of doctors, pharmacists and patients). Drugs in the hospital are routinely substituted with others under the direction of each hospital's Pharmacy & Therapeutic Committee, in situations where therapeutic substitution has been approved. Many hospitals target only a limited number of selected drugs for therapeutic substitution. If a physician inadvertently prescribes a non-formulary drug for a hospitalized patient, the pharmacist automatically has authority to substitute a therapeutic equivalent in this setting. "Prior consent" has already been established by the P&T Committee and practicing physicians have already agreed to abide by their decisions.

This practice saves money for both the hospital and the pharmacy. The hospital is assured that the most cost-effective drugs are prescribed, and the pharmacy saves money in inventory as manufacturers fight to lower prices of therapeutically equivalent ("me-too") drugs in order to be included on the formulary.

Currently, therapeutic substitution is not allowed in Minnesota without the prior consent of the prescribing physicians. Prescribers can be required to accept therapeutic substitution decision, but the Board of Pharmacy would have to make a statutory change to MS 151.21 (Subd. 1) which currently reads:

> "Except as provided in this section, it shall be unlawful for any pharmacist, assistant pharmacist, or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber."

This section of the pharmacy laws would need to be changed to allow the pharmacist to obtain the physician's consent prior to making a therapeutic substitution. It does not appear that the "prior consent" currently accepted in a hospital setting would be any differently defined in an HMO or statewide system basis according to the State Board of Pharmacy. Any system of therapeutic substitution, however, must be developed in such a way that the physician is informed that the drug prescribed for the patient is being replaced with a different drug of the same therapeutic class. Optimal patient care requires that the patient's medical record reflect the actual medication the patient is taking.

The Minnesota Pharmacists Association (MPhA) uses the term "formulary management" to describe a mechanism used to obtain prior agreement between the pharmacist and the physician. By authorizing pharmacists to develop a formulary management system for their patients, in agreement with physicians, pharmacists would be able to safely provide therapeutically equivalent medications for their patients. Proponents believe this will provide cost savings for patients and will be an educational tool for physicians. MPhA does not advocate that pharmacists have unilateral therapeutic substitution, which is opposed by pharmaceutical manufacturers, many physicians and a number of pharmacists. Rather, formulary management is a consensus among a specific pharmacist and a specific physician for a specific patient. The proposal is to develop a process whereby both health care professionals will exchange information in an effort to promote quality and cost effective management of patient care.

Advantages of Therapeutic Substitution

Therapeutic substitution encourages manufacturers to price brand-name drugs competitively with "me-too" drugs on the market. This mechanism may also serve to weed out drugs with more side effects or which are less effective. With appropriate prior consent of the physician, therapeutic substitution allows the pharmacist to participate more actively in the pharmaceutical care of the patient.

Disadvantages of Therapeutic Substitution

Concerns have been raised that therapeutic substitution ignores the subtle differences between drugs in the same class. For example, there may be small differences between drugs in terms of effectiveness, dose, rate and extent of absorption, metabolism pathways, and side effects. If sub-optimal therapy is chosen, it could result in an adverse outcome requiring more physician visits and possible hospitalization.[14]

The concept of "formulary management," which is to maintain communication between physicians and pharmacists for the benefit of the patient, describes the central component of the practice of pharmacy. However, the establishment of patient-specific arrangements for drug substitution would be a time-consuming and potentially costly proposal.

Currently, it is the responsibility and liability of physicians to prescribe drugs which are the most effective for a patient's particular needs. To delegate this responsibility could raise serious malpractice issues.

MANDATORY PRICE DISCLOSURES

The actual prices paid to manufacturers by different classes of pharmacy (retail, hospital, mail-order, etc.) remains somewhat of a mystery. Manufacturers do not currently disclose actual selling prices. The only published price is the average wholesale price (AWP), which is the average of the suggested list price, set by manufacturers, for wholesalers to sell to pharmacists.

Manufacturers refuse to disclose levels of discounts given to different classes of pharmacies or give explicit criteria for discounts. This is similar to the private insurance market in which insurers negotiate discounts off provider charges, but do not reveal the level of these discounts. Legislation requiring price disclosure would reveal the criteria manufacturers use in giving discounts. It would also reveal the magnitude of discounts.

Some attempts have been made to reveal the pricing structure for pharmaceuticals. The Pharmacy Freedom Fund, a group of independent pharmacists in Texas, collected and published some information on the prices paid by different pharmacy groups in 1990. Data compiled by the PRIME Institute illustrating estimated 1991 price comparisons are based on the AWP and include the following:[15]

Hospitals	AWP minus 40%
HMO pharmacies	AWP minus 28% (after rebates)
Chain Drugstores	AWP minus 22%
Independent	AWP minus 13%

However, using percentages off of AWP does not reveal absolute prices. The higher the base cost of a drug, the smaller the percentage it takes to make a big difference in how much the pharmacist actually pays.

One proposal we received linked a statewide drug contracting program with price disclosures. If the State were to administer a drug contracting program, the negotiated drug prices would be filed with the Department of Administration (DoA) and be publicly available. Manufacturer prices and DoA discounts would be revealed and pharmacists would be publicly accountable for their particular mark-ups on each prescription. These price disclosures could result in many independent pharmacies being unable to compete effectively for customers. Some groups have expressed their opinion that this is discriminatory. Other groups believe that free market competition *should* determine which pharmacies survive.

Advantages of Mandatory Price Disclosures

The main advantage to price disclosures is that it would inform all pharmacists about the true price, the level of discounts offered, and criteria used to determine who is offered best prices. This information may be used in negotiations with manufacturers or to inform consumers of the prices obtained. The consumer would be able to see the markup of individual drugs and may be more able to compare prices between pharmacies in an effort to obtain the best cash price. Proponents of mandatory price disclosure claim that revealing the true price of the product and the level of discounts given would be useful for negotiating purposes and for revealing the deep discounts given to some pharmacies and not others.

Disadvantages of Mandatory Price Disclosures

Price disclosures may destroy the competitive market for prescription drugs. The large buying groups we talked to did not think price disclosure would help them in their negotiations with the manufacturers. They felt they had enough information to leverage discounts. Revealing prices may have the unintended consequence of raising prices for everyone.

Another concern expressed to us is that requiring price disclosure will lower the status of the pharmacist from a professional to a vendor level. In other words, price disclosure may result in the price of prescription drugs becoming the sole factor considered in a consumer's choice rather than also considering the level and quality of professional services rendered by the pharmacist.

MARKETING AND PROMOTION

Pharmaceutical marketing involves the transfer of technical information from the manufacturers---regarding the actions and proper use of its products--to health care professionals, patients, and third party payers. All proposed labeling, advertising, and promotional materials used by manufacturers are scrutinized by the Food and Drug Administration. In 1992, the FDA objected to less than 2% of all promotional materials they reviewed.[16]

This information is most often relayed through sales representatives who make one-on-one calls to physicians at their offices. Studies and samples are brought directly to the physicians. Although this information is available from other sources, sales representatives are undoubtedly the most convenient method of teaching physicians about new drug products.

Manufacturers provide educational materials about their products and the conditions they treat to health care professionals. Physicians often use drug company materials to aid in patient communication and education. When the technology is new, sales representatives are often the primary source of information for physicians and pharmacists according to the National Pharmaceutical Council. Medical literature often lags behind; many clinical drug studies measure factors that require years of experience with the product once it is marketed.

As information goes out from manufacturers, it also comes in. Sales representatives in the field provide valuable market research information. Their assessment of patients' unmet needs can guide R&D efforts toward the development of improved versions of existing products or to delve into new areas of discovery.

By all available analyses, drug companies spend a significant amount on marketing. The study found an average drug manufacturer's revenues were allocated as follows: 16% on R&D, 22% on sales and marketing, 26% on manufacturing and distribution, 13% on administration, and 9% on taxes, which leaves 14% for profit.[17] Similarly, in 1992, Schondelmeyer estimated that 20% of an average manufacturer's budget is spent on marketing expenses.[18]

There is some movement among manufactures to reduce marketing expenses. For example, one chief executive officer with a large drug manufacturer estimated a reduction in marketing expenses from the current 20% to 30% down to 15% to 20%. He also estimated that after-tax profit margins will drop to half the current level of 20%.[19]

Drug Samples

If manufacturers spend their marketing money prudently, smaller expenditures in marketing could have the same impact on sales. Industry analysts estimate that 60% of the marketing budgets are used for sales representative salaries and the cost of samples.[20] Samples are intended to prime the pump for sales. According to Glaxo, Inc., 30 Zantac tablets are sold for each tablet sampled.[21]

Samples of one or two tablets are very expensive to package. However, if used judiciously, several patients could benefit from a sample drop-off by a sales representative; the reality is that one patient often leaves the doctor's office with all of the samples and no prescription. A potential problem exists if the sampled drug interacts with another product the patient is taking. Many patients and physicians alike rely on pharmacists to catch drug interactions, but the current sampling process leaves pharmacists out of the loop.

One proposed alternative would be for sales representatives to leave coupons for samples that would be dispensed for free by a pharmacist, who then redeems the coupon with the manufacturer. The American Pharmaceutical Association is creating a task force to look at alternative means of drug sampling.

Gifts to Physicians

While some physicians and consumers appreciate drug samples, other give-aways left by sales representatives may be unnecessary, and still contribute to marketing expenses. In 1988, Minnesota Attorney General Hubert Humphrey III, found that the pharmaceutical industry spent $54 million on reminder items and $24 million on other direct gifts to physicians. More recently, it was estimated that the industry spends over $2.5 billion annually on marketing. That equates to $5,000 for every physician in America.[22] The Attorney General recommended that the industry forego all give-away programs except drug samples. The 1993 MinnesotaCare legislation (see Appendix E) allows gifts to practitioners that have a combined value of no more than $50 annually. Exempted from the "gift" status are drug samples, honoraria for speaking engagements, compensation for research consultation, and publications or educational materials. Manufacturers feel they are in compliance with this regulation.

The Minnesota Attorney General proposed that "bona fide" educational and research funded by manufacturers be distinguished from those activities that are "simply disguised gifts." He proposed that manufacturers contribute an amount equal to that spent on educational and research grants paid to physicians to a State-sponsored drug utilization review program to support "academic detailing," a counter-advertising effort to give physicians unbiased information. He also proposed that physicians who receive research grants, scholarships, free travel, etc. must disclose the nature and value of the gifts to their patients before prescribing the company's products.[23]

Advantages of Limiting Marketing and Promotion

Consumer groups have advocated proposals to limit the marketing of prescription drugs as a way for manufacturers to slow the escalation of drug prices without sacrificing their research and development investments. Consumers and health professionals alike would rather see manufacturers reduce marketing and promotion budgets rather than R&D budgets to achieve cost-savings. Screening of drug sample educational material could increase physicians reliance on scientific, unbiased evaluations of drug therapy and not on showmanship of sales. "Since sales representatives do not have access to any important information that is not otherwise available, yet they have specific incentive to mask unfavorable information, they are clearly not the best way to get information," explained one doctor. Limiting gifts also decreases the gratitude physicians show sales representatives in exchange for drug samples, dinner, or other gifts. Many physicians feel that to compensate the sale representatives they must prescribe his/her line of drug products.

Many of the poor and uninsured receive free medication through the use of samples. Although there are problems with using samples to provide medications, it does provide the physician with the ability to properly treat a patient who might not otherwise follow through on a treatment protocol because of ability to pay.

Disadvantages of Limiting Marketing and Promotion

Limiting a manufacturer's budget for marketing and promotion may limit the amount of knowledge available to health professionals and consumers. Sales representatives who may be the most convenient way for physicians to become informed about new products may decline in number. In addition, drug companies may also decide to decrease support of their sponsorship of meetings and seminars that are used to educate physicians and scholarship donations to pharmacy students.

PREFERENTIAL TREATMENT FOR UNDERSERVED OR DISADVANTAGED RETAIL PURCHASERS

The underserved or disadvantaged retail purchasers consist primarily of the elderly and those persons who are underinsured or uninsured. The elderly often fall into this category because Medicare carries no prescription drug benefit, and many seniors cannot afford the optional coverage that includes drug benefits. Some consumer groups have advocated that preferential treatment be given to these underserved and disadvantaged groups in order to facilitate their receiving the necessary medications at a reasonable price.

National and State Efforts to Provide Access to Health Insurance Coverage

The Universal Coverage Report, released by the Minnesota Department of Health on February 1, 1994, states that "about 280,000 Minnesotans (6.5%) are uninsured at any given point in time and approximately 370,000 Minnesotans (8.6%) are uninsured at some time each year."[24] It is the goal of the State of Minnesota, under current MinnesotaCare health care reform efforts, to provide universal access to comprehensive, quality health care services by July, 1997.

National health care reform efforts are also focusing on universal coverage. President Clinton's National Health Security Act addresses the issue of access for all persons under the age of 65 by promoting the establishment of regional alliances. These alliances would provide continuous coverage for all persons under age 65 through a variety of mechanisms regardless of whether the person was currently employed or not.

The Health Security Act also addresses the issue of access for senior citizens through the inclusion of a prescription drug benefit in the standard Medicare coverage. Although controversial, the intent is to provide coverage for prescription drugs for all persons over age 65. The passage of these measures will impact the strategies Minnesota utilizes to assure coverage for its seniors.

Nationally, over 50% of drug purchases are paid for directly out-of-pocket by consumers, primarily the elderly. Minnesota is slightly lower than the national average with 49% of drug purchases being paid for out-of-pocket.[25] As mentioned above, senior citizens are a disproportionately large part of the population paying for drugs out-of-pocket. This situation is further exacerbated by the fact that independent retail pharmacies, where many of the elderly purchase their prescriptions, generally are not able to negotiate as competitively on drug prices as the managed care or chain drugstore pharmacies can. Also impacting independent retail pricing is the relatively low reimbursement rates contracted by some third party payers. As a result, the independent retail pharmacies must often charge the cash paying customers higher prices in order to compensate for their reduced profit (or actual loss) on drugs reimbursed by third party payers. Thus, the senior citizen or uninsured who are least able to afford prescription drugs, are often paying the highest prices.

One proposal suggests an expansion of the role of the Department of Administration (DoA) in purchasing prescription drugs to include underserved and disadvantaged populations by making the discounted prices available to independent retail pharmacies. Currently, the DoA negotiates the purchase of prescription drugs for state and county-funded agencies or institutions in Minnesota, 16 other states, and the city of Chicago. Although they have been successful in negotiating with drug manufacturers to obtain discounts of 15% on sole-source drugs and up to 70% on some generics, these discounts are not available to private citizens or businesses. (See pages 6-7 through 6-9 for a review of the advantages and disadvantages of a mandatory or voluntary purchasing program as proposed for the DoA.)

PENNSYLVANIA'S SOLUTION: A number of other states have addressed the problem of underserved or disadvantaged retail purchasers with specific assistance programs. Currently, ten states have programs designed to assist the elderly with their purchase of prescription drugs. Pennsylvania's Pharmaceutical Assistance Contract for the Elderly Program (PACE), by the largest and often considered the most successful, is now in its tenth year. A comprehensive assistance program, it provides for senior enrollees to purchase all needed prescription drugs for a copayment of $6.00 per prescription. Eligibility is based on age (65 and over), residency and income ($13,000 for an individual; $16,200 for a couple). Of the state's 1.3 million senior residents, PACE officials estimate 800,000 are potentially eligible for the program; current enrollment is 325,000, or about 40.6% of those estimated to be eligible. For the last year for which data are available, PACE processed 10 million prescription claims at a total cost of $240 million. Rebates from drug manufacturers reduced that cost by about $33 million, for a net claims cost of $207 million. The program is funded entirely from the net proceeds of the Pennsylvania State Lottery. From its start in the early 1970's, all net proceeds derived from the state lottery have been dedicated to programs to assist the elderly.

There are both advantages and disadvantages to such a program as PACE. Among the advantages are that for a relatively low copayment, seniors with low to moderate incomes can afford to purchase necessary prescription drugs. It is also a relatively easy program to administer and can be targeted to the segment of the population most in need of assistance. The cost of such program, however, is the major disadvantage. Additionally, the program, at least as established in Pennsylvania, does not address the problem of the working poor who are either uninsured or underinsured.

Advantages of Preferential Treatment for Underserved or Disadvantaged Retail Purchasers

The obvious advantage to implementing some type of preferential treatment is that access to prescription drugs is enhanced. The benefits of drug therapy are well-documented in research and are very cost-effective from a preventative standpoint. Both State and national efforts in health care acknowledge this and are moving toward implementing universal access.

It is also not clear that state and national reform will be comprehensive enough to assure universal coverage. Although the goals are stated clearly, the financing mechanism needed to achieve them are not yet in place. By waiting for something to happen at the state or national level will only perpetuate the existing access problems for those who currently lack prescription drug coverage.

Disadvantages of Preferential Treatment for Underserved or Disadvantaged Retail Purchasers

One disadvantage of implementing preferential treatment for underserved or disadvantaged consumers is that there may be a conflict in moving ahead at this time without first seeing how the national reform effort is to be implemented. Developing a new publicly supported program for those currently lacking prescription drug coverage will cost money and it is not clear from where the financing would. Although many acknowledge that access is a concern, it is not clear that the substantial expenditure of money needed to set up a program would be well spent if additional Medicare coverage of prescription drugs is imminent. Much time, money, and effort may be lost in a duplicated effort.

Implementing preferential treatment under the DoA proposal is problematic even apart from the issue of duplication of effort. There are some major costs involved in the expansion of this program to accommodate purchasing for the private pharmacy market. There is also some concern that the profit resulting from lower purchase prices on behalf of the retail pharmacies may in fact not be passed onto the consumer. Even if this were mandated, it would be extremely difficult to document that the savings

were actually passed on. Some groups feel that the role of government should not be expanded further in this area, but that the market should be free to operate without intervention

Finally, a probable result of offering preferential treatment to underserved or disadvantaged consumers is that prices for most, if not all, other purchasers may increase depending upon how the preferential treatment is implemented. Costs may be shifted to some other purchasers who have been more successful in price negotiations in the past.

ENDNOTES

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[2]Raines, G., Bond, W. Written comments submitted to the Minnesota Department of Health for the Prescription Drug Study. Minnesota Pharmacists Association (MPhA), Jan. 14, 1994.

[3]National Association of Retail Druggists. "States Begin to Topple the House of Cards." NARD Journal, Sept. 1993, p. 51.

[4]U.S. General Accounting Office. Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions. (Washington D.C.: U.S. General Accounting Office, Jan. 1993), p. 1.

[5]Average manufacturer price (AMP) refers to the average price manufacturers charge to wholesalers; average wholesale price (AWP) is the manufacturers suggested price that the wholesaler should charge the pharmacy.

[6]U.S. General Accounting Office. Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions. (Washington D.C.: U.S. General Accounting Office, Jan. 1993), p. 26.

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APPENDIX A

LEGISLATIVE LANGUAGE AUTHORIZING THE PRESCRIPTION DRUG STUDY

APPENDIX A

CONFERENCE COMMITTEE REPORT ON H.F. NO. 1178
CHAPTER 345, ARTICLE 5, SECTION 15
PRESCRIPTION DRUG STUDY

The commissioner of health shall prepare and submit to the legislature by February 15, 1994, a study of the manufacturing, wholesale, and retail prescription drug market in Minnesota. In conducting the study, the commissioner of health shall consult with the commissioners of administration, employee relations, and human services, the Minnesota health care commission, and the University of Minnesota pharmaceutical research, management, and economics programs. The commissioner shall also consult with representatives of retail and other pharmacists, drug manufacturers, consumers, senior citizen organizations, hospitals, nursing homes, physicians, health maintenance organizations, and other stakeholders and persons with relevant expertise.

The study shall examine

(1) how distinctions based on volume purchased or class of purchaser affect manufacturer, wholesale, and retail pricing;
(2) how manufacturer and wholesale pricing are affected by other industry practices, by federal and state law, and by other factors such as marketing, promotion, and research and development;
(3) how manufacturer and wholesale pricing affect retail pricing;
(4) other factors affecting retail pricing; and
(5) methods of reducing manufacturer, wholesale, and retail prices, including but not limited to:

(i) mandatory prescription drug contracting programs operated by the state;

(ii) voluntary prescription drug contracting programs operated by the state;

(iii) legislation to facilitate the development of manufacturer and wholesale purchasing programs in the private sector;

(iv) most favored purchaser legislation;

(v) legislation limiting manufacturer and wholesale price increases;

(vi) legislation providing for preferential treatment for underserved or disadvantaged retail purchasers;

(vii) legislation providing for the use of a state formulary or other formularies;

(viii) legislation requiring pharmacists to substitute for prescribed drugs a less expensive therapeutic alternative in appropriate circumstances.

(ix) legislation providing for price disclosure; and

(x) limitations on drug promotion and marketing.

The study must include recommendations and draft legislation for reducing the cost of prescription drugs for wholesale purchasers, consumers, retail pharmacies, and third-party payors. The recommendations must ensure that parties benefiting from price savings at the manufacturer or wholesale level pass these savings on to consumers. The recommendations must not reduce costs through methods that would adversely affect access to prescription drugs, reduce the quality of prescription drugs, or cause a significant increase in manufacturer, wholesale, or retail prices for certain market segments.

APPENDIX B

CONTACT LIST

APPENDIX B

MANUFACTURERS

Organization	Contact	Status
Pharmaceutical Manufacturers Association (PMA)	Randolph W. Morris Attorney at Law, Lobbyist McGrann Shea Franzen Carnival Straughn & Lamb Gary S. Persinger Deputy Vice President, Health Care Systems Paula A. Johnson, Ph.D. Senior Regional Director, State Government Affairs	I,W
The UpJohn Company	Patrick L. McKercher, R.Ph., Ph.D. Executive Director, Corporate Policy Initiatives Vaun C. Olhausen Manager, State Government Affairs Chair PMA Task Force	I
Marion Merrell Dow, Inc.	Sharon Kasel D'Agostino Regional Manager, Government Affairs Vice Chair PMA Task Force	I
Generic Pharmaceutical Industry Association	Lewis A. Engman President	W

I = Interviewed

W = Written Comments

WHOLESALERS

National Wholesale Druggist Association	David A. Kosar Director of State Affairs	I, W
Minnesota Wholesale Druggists Association	Randolph W. Morris Attorney at Law, Lobbyist McGrann, Shea, Franzen, Carnival, Straughn & Lamb	I, W
Twin City Wholesale Drug Company	Barry M. Krelitz President, Chief Executive Officer Michael Krelitz Director of Business Development	I
Northwestern Drug Company	Kent Olson President	I
Alco Health Services Corporation	Michael J. McNamara Regional Vice President	I
Northern Drug Company	Steven B. Goldfine President	I, W
Fox Meyer Drug Company	Lee Strozinsky Distribution Center Manager Gary Zuckweiler Distribution Center Manager	I
Fox Meyer / Snyder	Bill Vidmar Vice President	I
Whitmire Distribution Corporation	Jim Wusterbarth Distribution Center Manager	I
Jewett Drug Company	Jody Lindsey Vice President	I
McKesson Drug	Jay H. Chalgren Distribution Center Manager Sean McCollar Inventory Manager	I, W

RETAILERS/PHARMACISTS: Professional/Organizations

Minnesota Pharmacists Association	William Bond Executive Director Gary Raines President Herb Whittemore President Elect	I, W
Minnesota Board of Pharmacy	Dave Holmstrom Executive Director	W

RETAILERS/PHARMACISTS: Chains

National Association of Retail Druggists (NARD)	Charles West Executive Vice President	W
Snyders	Donald Beeler Chairman, President, Chief Executive Officer	W

RETAILERS/PHARMACISTS: Independents

Sundberg Pharmacy	Richard Sundberg Pharmacist	I
Borgstrom Pharmacy	Peter Amundson Pharmacist	I
Noble Snyders	Merle Mattson Pharmacist	I
Blomberg Pharmacy	Julie Johnson Pharmacist	I
Lake Elmo Pharmacy	Colleen Horiesh Pharmacist	I
Shoppers Pharmacy	Herman Windisch Pharmacist	I
A/M Corner Drug	Racha & Jay Adams Pharmacist	I
West Bank Pharmacy	Joel Albers Pharmacist	W, I
Pharmacy Freedom Fund	Bob Gude President, Pharmacist	I

RETAILERS/PHARMACISTS: Hospital

American Society of Hospital Pharmacists	Paul W. Abramowich, Pharm.D. Associate Professor and Director of Pharmaceutical Services The University of Minnesota Hospital and Clinic	I
Minnesota Society of Hospital Pharmacists	Charles E. Daniels, Ph.D. Associate Director, Pharmaceutical Services Assistant Professor of Pharmacy The University of Minnesota Hospital and Clinic Ronald Broekemeier, Pharmacist Director of Pharmaceutical Services Health One Mercy & Unity Hospitals, Fridley, Minnesota Darwin Zaske, Pharm.D. Director of Pharmaceutical Services St. Paul Ramsey Medical Center,	I, W
Minnesota HealthCare Partners	Jill Larsen	I

OVERVIEW

PRIME Institute University of Minnesota	Dr. Stephen Schondelmeyer M. Pub. Adm., Pharm.D., Ph.D. Professor Pharmaceutical Economics & Director Judy Johnson, MHSA Research Fellow	I

THIRD PARTY PAYERS/DRUG MANAGEMENT COMPANIES

Aetna	Jo Anne Hessen Pharmacist, Pharmacy Policy and Education Michael Sax, Pharm.D. Pharmacy Management	I
United HealthCare Corporation Diversified Pharmacy Services	Henry Blissenbach, Pharm.D. President Bruce Edgren, Pharm.D. Director, Clinical Services & Pharmacy Programs Lyla Aaland Pharmacist, Director of Pharmacy	I, W
BCBS	Debra Dullinger, Pharm.D. Vice President, Pharmacy Programs Rick Bruzek, Pharm.D. Vice-President, Marketing and Product Development	I
PCS/Clinical	Suzanne Blackburn Clinical Claims Processor Pam Bertrand Clinical Manager	I
InterStudy	Shawn D. Schwartz Assistant Director	I
Bravell Claims Management	Catherine S. Lamovec Marketing Representative	I

RETAILERS/PHARMACISTS: Managed Care

Group Health	Lynn Scott Pharmacy Administrator of Clinical and Financial Services	I

PHYSICIANS

Minnesota Medical Association	Janet Silversmith Health Policy Analyst	W
	Dr. Steven Hillson Internist, Ramsey Clinic Assistant Professor, School of Medicine and Center for Health Services Research	I, W

CONSUMERS

Minnesota Senior Federation*	Monta Childers President Alice Fradenburgh President, South Central Region Vic Rosenthal Staff Director	I, W
HealthCare Campaign of Minnesota (MN COACT)	Kip Sullivan Research Director Doris Calhoun Pharmacist	I

* Attending were 11 additional Minnesota Senior Federation Members

STATE AGENCIES

Department of Human Services (DHS)	Nancy McMorran Health Services Policy Supervisor for Pharmacy Services Gerald Drinane Pharmacist, Pharmacy Consultant Eric Anderson Pharmacy Reimbursement & Rates Consultant	I, W
Department of Administration	John Haggerty Director of Materials Management Division Donnalee Kuchera Pharmacist Manager of Contracts and Technical Services	I,W
Department of Employee Relations	Kathleen Burek Supervisor of Contracts & Networks Dennis Mackey Insurance Analyst Nanette Dahms Senior Research Analyst	I

APPENDIX C

INTERVIEW GUIDE/STUDY QUESTIONS

Minnesota Department of Health
121 East Seventh Place
P.O. Box 64975
St. Paul, MN 55164-0975

PRESCRIPTION DRUG STUDY
INTRODUCTION/STUDY QUESTIONS (General)
November 1993

The State of Minnesota is in the midst of health system reform. Bipartisan legislative efforts led to the development of a comprehensive plan to reduce the rate of growth of health care expenditures by ten percent per year over the next five years. The 1993 MinnesotaCare Act provides for the development and implementation of three key components of this reform: 1) Integrated Service Networks (ISNs), health plans that agree to provide consumers a range of benefits for a fixed price; 2) Regulated All-Payers' System (RAPS) for providers who do not participate in ISNs; and 3) overall limits of the growth in health care expenditures. We have enclosed a summary of the general reform efforts for your information.

The 1993 MinnesotaCare Act also requires the Minnesota Department of Health to study and make recommendations on managing drug expenditures in the State. This study will explain the influence of drug manufacturers, wholesalers, pharmacists, doctors, third-party payers, and consumers on the price of prescription drugs and make recommendations to the legislature on policies necessary to manage drug expenditures. The legislative language outlining the study is also enclosed.

A balanced report to the state legislature can be ensured by evaluating all points of view. We would like to hear your point of view which can be conveyed to us through personal meetings, written position statements giving specific details on how to implement your ideas, and/or additional background information. Tell us specifically what should be done to manage drug expenditures as well as what should not be done, and why. We are under a tight schedule and would like to receive your input by January 7, 1994.

After reading the enclosed legislation describing details of the study, please consider these key questions in your written comments and/or position statements:

1. What influences the price you charge for pharmaceuticals?
    a. cost of goods sold
    b. industry practices
    c. federal and state laws
    d. volume purchased
    e. class of purchaser
    f. profit
    g. competitive influences (formularies, bid purchasing)

2. Which of your customers get the best price now and why?

3. How can the State of Minnesota ensure that all citizens get a fair price on prescriptions? How can drug costs be balanced across all market segments? How do we resolve issues of cost shifting?

4. What specific approaches could the State of Minnesota take to manage drug expenditures?

5. What specific plans, if any, does your organization have to control its costs in the future?

6. What other strategies could be used to make the pharmaceutical marketplace become more cost-effective?

7. What will be the result of cost-management measures in the marketplace? Please identify the cost-management strategies that would have the most negative impact on the pharmaceutical market and those that would have the most positive impact and why.

We look forward to hearing your specific suggestions and methods of implementing cost management in the pharmaceutical marketplace. We would appreciate answers to any or all questions in writing. It is imperative we hear from you by January 7, 1994.

If you have questions, feel free to contact Lynn Blewett, Director of the Health Economics Program at (612) 282-6361 or Yvonne Jonk, Research Analyst at (612) 282-6326.

Enc: 1993 MinnesotaCare Summary
Legislative Language-Prescription Drug Study (Chapter 345, Article 5, Section 15)

Minnesota Department of Health
121 East Seventh Place
P.O. Box 64975
St. Paul, MN 55164-0975

PRESCRIPTION DRUG STUDY
INTRODUCTION/STUDY QUESTIONS (Consumers)
November 1993

The State of Minnesota is in the midst of health system reform. Bipartisan legislative efforts led to the development of a comprehensive plan to reduce the rate of growth of health care expenditures by ten percent per year over the next five years. The 1993 MinnesotaCare Act provides for the development and implementation of three key components of this reform: 1) Integrated Service Networks (ISNs), health plans that agree to provide consumers a range of benefits for a fixed price; 2) Regulated All-Payers' System (RAPS) for providers who do not participate in ISNs; and 3) overall limits of the growth in health care expenditures. We have enclosed a summary of the general reform efforts for your information.

The 1993 MinnesotaCare Act also requires the Minnesota Department of Health to study and make recommendations on managing drug expenditures in the State. This study will explain the influence of drug manufacturers, wholesalers, pharmacists, doctors, third-party payers, and consumers on the price of prescription drugs and make recommendations to the legislature on policies necessary to manage drug expenditures. The legislative language outlining the study is also enclosed.

A balanced report to the state legislature can be ensured by evaluating all points of view. We would like to hear your point of view which can be conveyed to us through personal meetings, written position statements giving specific details on how to implement your ideas, and/or additional background information. Tell us specifically what should be done to manage drug expenditures as well as what should not be done, and why. We are under a tight schedule and would like to receive your input by January 7, 1994.

After reading the enclosed legislation describing details of the study, please consider these key questions in your written comments and/or position statements:

1. Getting the best price on prescription drugs.
   a. Which customers are able to get the best price and why?
   b. Is comparison shopping cost-effective or does it fragment care when consumers use multiple pharmacies (i.e. are drug interactions missed)?
   c. Are consumers aware of price breaks available to those who buy in bulk? Are consumers willing to buy 3 month supplies to get discounts?

2. Do copayments eliminate consumers' concerns about drug prices? That is, if ISNs eventually cover 90% of Minnesotans, will the concern about the cost of pharmaceutical drugs diminish?

3. How important are independent pharmacists in the delivery of pharmaceutical care? What specific services do they provide? How do these services differ by pharmacy setting (chain stores vs independent)?

4. Do rural Minnesota pharmacies and consumers have special needs? How might these needs be addressed?

5. Mail order pharmacy.
   a. Do patients get enough drug information when purchasing pharmaceuticals through the mail?
   b. How quickly can they get new prescriptions filled?
   c. Do consumers feel that using mail-order to fill chronic medications and local pharmacies to fill prescriptions needed immediately fragments care?

6. Formularies.
   a. How can consumers be assured that price savings from drug contracting programs or formularies are passed on to consumers?
   b. Do formularies provide enough access to pharmaceutical drugs?
   c. Should certain non-prescription drugs be included in formularies (e.g. Monistat)?
   d. Should there be one statewide formulary? Should participation be mandatory or voluntary?

7. Does therapeutic substitution compromise quality of care?

8. Should there be limitations on drug promotion and marketing?
   a. Is television advertising effective?
   b. How valuable are drug samples?
   c. How valuable are patient education materials provided by drug companies?

9. What has been the effect of rebates on consumers?
   a. Are there alternative approaches that might be used in place of rebates to benefit consumers?

10. What is the appropriate role for the state to play in managing drug expenditures?

We look forward to hearing your specific suggestions and methods of implementing cost management in the pharmaceutical marketplace. We would appreciate answers to any or all questions in writing. It is imperative we hear from you by January 7, 1994.

If you have questions, feel free to contact Lynn Blewett, Director of the Health Economics Program at (612) 282-6361 or Yvonne Jonk, Research Analyst at (612) 282-6326.

Enc: 1993 MinnesotaCare Summary
Legislative Language-Prescription Drug Study (Chapter 345, Article 5, Section 15)

Minnesota Department of Health
121 East Seventh Place
P.O. Box 64975
St. Paul, MN 55164-0975

PRESCRIPTION DRUG STUDY
INTRODUCTION/STUDY QUESTIONS (Physicians)
November 1993

The State of Minnesota is in the midst of health system reform. Bipartisan legislative efforts led to the development of a comprehensive plan to reduce the rate of growth of health care expenditures by ten percent per year over the next five years. The 1993 MinnesotaCare Act provides for the development and implementation of three key components of this reform: 1) Integrated Service Networks (ISNs), health plans that agree to provide consumers a range of benefits for a fixed price; 2) Regulated All-Payers' System (RAPS) for providers who do not participate in ISNs; and 3) overall limits of the growth in health care expenditures. We have enclosed a summary of the general reform efforts for your information.

The 1993 MinnesotaCare Act also requires the Minnesota Department of Health to study and make recommendations on managing drug expenditures in the State. This study will explain the influence of drug manufacturers, wholesalers, pharmacists, doctors, third-party payers, and consumers on the price of prescription drugs and make recommendations to the legislature on policies necessary to manage drug expenditures. The legislative language outlining the study is also enclosed.

A balanced report to the state legislature can be ensured by evaluating all points of view. We would like to hear your point of view which can be conveyed to us through personal meetings, written position statements giving specific details on how to implement your ideas, and/or additional background information. Tell us specifically what should be done to manage drug expenditures as well as what should not be done, and why. We are under a tight schedule and would like to receive your input by January 7, 1994.

After reading the enclosed legislation describing details of the study, please consider these key questions in your written comments and/or position statements:

1. What role can physicians play in controlling drug costs?

2. How can doctors become better informed about relative drug prices?

3. What is the appropriate role for the state in controlling drug costs?

4. Formularies.
   a. Do formularies provide enough access to pharmaceutical drugs?
   b. Should certain non-prescription drugs be covered by formularies (e.g. Monistat)?
   c. Do formularies control costs?
   d. Should there be one statewide formulary? Should participation be voluntary or mandatory?

5. Therapeutic Substitution.
   a. Does therapeutic substitution compromise quality of care?
   b. Should pharmacists call for a new prescription or should pharmacy law be changed to allow therapeutic substitution (e.g. cephradine for cephalexin)?

6. Should there be limitations on drug promotion and marketing?
   a. Is television advertising an effective way to educate consumers?
   b. Are sales representatives the best way to get drug information? If not, what is?
   c. How valuable are samples? Do doctors get too many? Do they actually save patients money?

7. Should the state provide incentives to encourage collaborative purchasing programs in the private sector (similar to Medica and United HealthCare Corp.)? If yes, how?

We look forward to hearing your specific suggestions and methods of implementing cost management in the pharmaceutical marketplace. We would appreciate answers to any or all questions in writing. It is imperative we hear from you by January 7, 1994.

If you have questions, feel free to contact Lynn Blewett, Director of the Health Economics Program at (612) 282-6361 or Yvonne Jonk, Research Analyst at (612) 282-6326.

Enc: 1993 MinnesotaCare Summary
Legislative Language-Prescription Drug Study (Chapter 345, Article 5, Section 15)

Chapter 345, Article 5, Section 15
PRESCRIPTION DRUG STUDY.

The commissioner of health shall prepare and submit to the legislature by February 15, 1994, a study of the manufacturing, wholesale, and retail prescription drug market in Minnesota. In conducting the study, the commissioner of health shall consult with the commissioners of administration, employee relations, and human services, the Minnesota health care commission, and the University of Minnesota pharmaceutical research, management, and economics programs. The commissioner shall also consult with representatives of retail and other pharmacists, drug manufacturers, consumers, senior citizen organizations, hospitals, nursing homes, physicians, health maintenance organizations, and other stakeholders and persons with relevant expertise.

The study shall examine:

(1) how distinctions based on volume purchased or class of purchaser affect manufacturer, wholesale, and retail pricing;

(2) how manufacturer and wholesale pricing are affected by other industry practices, by federal and state law, and by other factors such as marketing, promotion, and research and development;

(3) how manufacturer and wholesale pricing affect retail pricing;

(4) other factors affecting retail pricing; and

(5) methods of reducing manufacturer, wholesale, and retail prices, including but not limited to:

(i) mandatory prescription drug contracting programs operated by the state;

(ii) voluntary prescription drug contracting programs operated by the state;

(iii) legislation to facilitate the development of manufacturer and wholesale purchasing programs in the private sector;

(iv) most favored purchaser legislation;

(v) legislation limiting manufacturer and wholesale price increases;

(vi) legislation providing for preferential treatment for underserved or disadvantaged retail purchasers;

(vii) legislation providing for the use of a state formulary or other formularies;

(viii) legislation requiring pharmacists to substitute for prescribed drugs a less expensive therapeutic alternative in appropriate circumstances.

(ix) legislation providing for price disclosure; and

(x) limitations on drug promotion and marketing.

The study must include recommendations and draft legislation for reducing the cost of prescription drugs for wholesale purchasers, consumers, retail pharmacies, and third-party payors. The recommendations must ensure that parties benefiting from price savings at the manufacturer or wholesale level pass these savings on to consumers. The recommendations must not reduce costs through methods that would adversely affect access to prescription drugs, reduce the quality of prescription drugs, or cause a significant increase in manufacturer, wholesale, or retail prices for certain market segments.

1993 MinnesotaCare Act

Summary Compiled by the Minnesota Department of Health · May 1993

1. Integrated Service Networks

Integrated Service Networks (ISNs) are responsible for arranging or delivering a full array of health care services, from routine primary and preventive care through acute inpatient hospital care, to a defined population for a fixed price from a purchaser. ISNs must charge the same rate for each individual in a group.

ISNs are accountable for keeping the total revenues within the limit of growth set by the Commissioner of Health. There must be separate accounting for each ISN. Competition is encouraged.

ISNs may be formed by health care providers, health maintenance organizations (HMOs), insurance companies, employers, or other organizations. ISNs may be organized as a separate nonprofit corporation or as a cooperative. Nonprofit health carriers may form an ISN without creating a separate entity if they meet certain conditions. Governmental subdivisions may form ISNs without creating a separate entity.

The Commissioner of Health, in consultation with the Minnesota Health Care Commission, will develop an implementation plan with proposed rules and legislation for the 1994 Legislature by January 15, 1994 to allow ISNs to begin forming July 1, 1994. The plan must:

- insure a wide range of choices for purchasers, consumers and providers;
- provide financial solvency, net worth and reserve requirements;
- address problems of provider recruitment and retention in rural areas;
- consider malpractice liability within ISN structures;
- consider how enrollees should be protected in the event of an insolvency;
- determine the possible relationships between providers and ISNs in a manner that both provides contractual arrangements and produces flexibility in such relationships.

ISNs are placed under the supervision of the Commissioner of Health. The Commissioner's rules will encourage and facilitate competition, flexibility, expansion of access and coverage, ability to bear financial risk, participation of providers, service to rural communities, limitation of growth, standard benefit set, and prevention of conflicts of interest. Rules will be established that may include:

- requirements for licensure
- quality standards
- availability and comprehensiveness of services
- requirements regarding the defined population to be served
- incentives for ISNs to accept enrollees with high risks and individuals or groups with special needs
- prohibitions against disenrolling individuals or groups with high risks or special needs
- requirements that enrollees receive specified information
- limits on copayments and deductibles
- mechanisms to prevent and remedy unfair competition
- maintenance and reporting of information on costs, prices, revenues, and other data
- provisions regarding liability for medical malpractice
- methods to ensure that ISNs and other health plans are subject to the same regulatory requirements
- provisions for appropriate risk adjusters to prevent or compensate for adverse selection
- standard ways for ISNs to describe and disclose prices, copayments, deductibles, out-of-pocket limits, enrollee satisfaction, and anticipated loss ratios

Covered Services: Enrollees must be provided "appropriate and necessary" health service. The benefit package controls costs without cost-shifting caused by reduced coverage, and achieves lower premiums through use of copayments, coinsurance, and deductibles rather than through reducing benefits.

The Commissioner of Health will adopt rules establishing not more than 5 standard ISN benefit sets, encompassing a range of cost sharing options.

As a condition of licensure, ISNs must participate in medical assistance, general assistance medical care, and MinnesotaCare.

The Commissioner of Health will monitor the effects of ISNs and the regulated all-payer system in communities where a substantial portion of health care provided to Minnesota residents is provided in states bordering Minnesota.

An ISN Technical Assistance Program will be established by the Commissioner of Health to give technical assistance to all parties interested in establishing an ISN in Minnesota. The Regional Coordinating Boards will also provide technical assistance related to ISNs.

Arrangements between an ISN and any of its participating entities should not be interpreted to violate the federal Medicare antikickback laws.

2. Regulated All-Payer System

The All-Payer System will govern services not provided through ISNs and will be phased-in over a two year period.

The All-Payer System will not be punitive, but will regulate and monitor fees, utilization, and quality to assure that growth limits are being met and quality is being maintained.

The Commissioner of Health and the Minnesota Health Care Commission will make recommendations for the design and implementation of an all-payer system by January 1, 1994. Phase-in of the all-payer system begins July 1, 1994, with full implementation by July 1, 1996.

3. Growth Limits

Growth limits for calendar years 1994 to 1998 will be based on the change in the regional consumer price index for urban consumers plus additional percentage points representing "medical inflation." The allowance for medical inflation will be reduced each year, so that the growth rate will come closer and closer to the inflation rate in the rest of the economy.

The annual limits on growth of health care costs are:

1994 – CPI + 6.5%
1995 – CPI + 5.3%
1996 – CPI + 4.3%
1997 – CPI + 3.4%
1998 – CPI + 2.6%

The Commissioner of Health will use the change in the health care financing administration's forecast for growth in national health expenditures instead, if this is lower than the specified rate of growth. Projected limits for each year will be published by April 15 of the preceding year.

The Commissioner may adjust growth limits to account for differences between the actual and projected consumer price index. The Commissioner is directed to:

- enforce statewide limits on growth in spending and revenue, allowing adjustments for artificial inflation or padding of costs
- impose and enforce growth limits for ISNs, and to reduce future premiums by the amount overspent
- regulate the all-payer system to hold costs within limits, allowing reductions in reimbursement rates to recover money overspent.

Regional Coordinating Boards will advise the Commissioner of Health on the allocation of regional limits on growth for providers in the all-payer system.

Transition Spending Limits

The Commissioner of Health will set expenditure targets for total expenditures by each health carrier and revenue limits for health care providers for calendar year 1994 and 1995.

Health carriers and providers will be monitored and regulated to ensure that savings resulting from the establishment of expenditure and revenue limits are passed on to consumers in the form of lower premiums and charges.

Lists of health carriers that exceed expenditure targets will be published in the State Register and made available to the public.

Health carriers and providers that exceed expenditure and revenue limits must repay the amount overspent through assessments.

4. Data Collection

The Data Analysis Unit in the Department of Health will provide information to assist group purchasers and consumers in making informed purchasing decisions. An information clearinghouse will provide information on health care costs and quality of care.

Health care providers will submit data for each calendar year by February 15 of the following year to the Commissioner of Health.

Specific public health goals will be established. Health care providers and ISNs will report information on changes in health outcomes related to these goals. Regional Coordinating Boards will adopt regional public health goals, taking into consideration local county board plans. The Commissioner of Health may increase regional spending limits if the public health goals for that region are achieved.

The Commissioner of Health will publish data on health care costs and spending, quality and outcomes, and utilization for health care organizations and provider groups, in order to provide information to purchasers and consumers.

A public/private data institute, governed by a 20-member board of directors, will be established to:

- direct and coordinate public and private sector data collection efforts
- establish a data system that promotes high-quality, cost-effective, and consumer-responsive care
- use and improve existing data sources to the greatest extent
- provide information in a useful format and timely manner
- protect individual privacy and minimize administrative costs

The Commissioner will monitor long-term care costs and cost-shifting related to government health care program reimbursement rates. The Data Analysis Unit will evaluate the streamlining and consolidation of administrative, payment, and data collection systems.

5. Technology Advisory Committee

The Health Technology Advisory Committee (formerly the Health Planning Advisory Committee) will:

- develop criteria for evaluating health care technology
- conduct evaluations of specific technology
- consider safety, improvement in health outcome, the degree to which technology is clinically effective and cost effective; and other factors
- submit preliminary technology evaluations to the Health Care Commission for public comment
- recommend methods to control the diffusion and the use of technology within the all-payer system

6. Prescription Drugs

The Commissioner will study the manufacturer, wholesale and retail prescription drug market in Minnesota and report to the Legislature by February 15, 1994. The study must examine methods for reducing manufacturer, wholesale, and retail pricing.

Pharmacists must dispense a generic drug if an equivalent less expensive drug is available, unless the prescriber specifically requires the prescription to be dispensed as written or unless the purchaser objects.

Manufacturers of wholesale drug distributors may not offer or give any gift of value to a health care practitioner.

7. MN Health Care Commission

The Minnesota Health Care Commission and the Regional Coordinating Boards will expire July 1, 1996 unless extended by the Legislature.

Commission responsibilities:

- Submit to the legislature and Governor by December 15, 1993, a plan that will lead to universal health coverage for all Minnesotans by January 1, 1997.
- Advise the Commissioner of Health on the implementation of the ISN regulatory system and the design of the all-payer system.
- Study and report on the requirement that ISNs be separate organizations except when specified conditions are satisfied.
- Advise the Commissioner of Health on methods of identifying costs of medical education and research, assessing and collecting costs from group purchasers, and allocating funds to providers.
- Report on the future of the Health Technology Advisory Committee
- Advise the Commissioner of Health relating to methods of improving the manufacturer, wholesale, and retail prescription drug pricing systems.

8. Antitrust Exceptions

A process is created by which health care providers or purchasers can apply to the Commissioner of Health for an exemption from antitrust law. This process will promote collaboration that improves health care cost, quality or access. Approval by the Commissioner will be an absolute defense against any action under state or federal antitrust laws.

9. Insurance Reform

Health plan premium increases will be reviewed for reasonableness by the Commissioners of Health and Commerce.

Premium changes in the individual and small employer market that are due to the 1992 HealthRight Act will be phased in over two years.

Loss ratios for the small employer market are increased by 1% a year beginning in 1994 until the ratio reaches 82% in the year 2000.

10. MinnesotaCare Program

The Departments of Health and Human Services will develop a plan, by February 1, 1994, to ensure that MinnesotaCare expenditures for the 1996-97 biennium do not exceed revenues.

Families with children potentially eligible for MA may enroll in MinnesotaCare for up to 60 days while their MA applications are being processed.

Children from families with incomes equal to or less than 150 percent of the federal poverty guidelines, who meet the Children's Health Plan eligibility criteria, may enroll in MinnesotaCare for a $48 annual premium.

Procedures will be established for the provision of MinnesotaCare services through managed care plans. Managed care plans must cooperate with local public health agencies to ensure childhood immunization.

The Commissioner of Human Services will seek a demonstration waiver to allow premiums to be charged for medical assistance recipients above 185% of federal poverty guidelines. A study will look at the impact of MinnesotaCare on Medical Assistance costs, and recommend changes in revenues or expenditures to ensure solvency for the next biennium.

11. Health Professional Education

A summer health intern program and an urban primary care physician loan forgiveness program for medical students and residents will be created.

A grant program will be established for colleges and schools of nursing that operate nurse practitioner programs to establish rural clinical sites for nurse practitioner education.

Urban areas will be included in initiatives to encourage newly graduated primary care physicians to establish practices in areas that are medically underserved.

12. Financing

The temporary provision that allowed hospitals to pass through to third-party payers the amount of the tax is made permanent. This authority is also extended to the health care provider and surgical center taxes.

Staff model health carrier is defined as a health carrier which employs one or more providers to deliver health care services to its enrollees. Other HMOs will not be subject to the tax. (The tax will be collected at the provider level rather than at the HMO level.)

Nonprofit and governmental hospitals will be allowed to deduct from gross revenues subject to the tax, revenues equal to expenditures for allowable research programs. The total amount of the deduction statewide is limited to $1.3 million per year beginning in 1995.

APPENDIX D

RETAIL DRUGSTORES' ANTITRUST ACTION AGAINST DRUG MANUFACTURERS

Rite Aid Corporation

• MAILING ADDRESS
P.O. Box 3165
Harrisburg, PA 17105

• GENERAL OFFICE
30 Hunter Lane
Camp Hill, PA 17011

• (717) 761-2633

FOR IMMEDIATE RELEASE
Thursday, October 14, 1993
11:00 A.M.

CONTACT: Michele de Milly or John Burke
Geto & de Milly, Inc.
212/686-4551
OR
Suzanne Mead
Rite Aid Corporation
717/975-5887

MAJOR DRUGSTORE OPERATORS FILE LAWSUIT CHARGING PRICE DISCRIMINATION AND PRICE-FIXING AMONG PHARMACEUTICAL MANUFACTURERS

-- Chains, Independents Seek "Sweeping Change" In Anti-competitive Practices of Brand Name Manufacturers To "Level Playing Field" and Benefit Consumers --

Companies representing over 5,000 retail pharmacies across the nation filed suit in federal court today (10/14/93) charging seven of the largest manufacturers of brand name drugs in the U.S. with wide-ranging violations of the federal antitrust laws, including price discrimination and illegal price-fixing. The suit seeks sweeping changes to eliminate long-standing anti-competitive practices among pharmaceutical manufacturers and to insure that all retailers have equal access to discounts, thus reducing the cost of prescriptions to consumers.

The manufacturers charged are Pfizer, Inc., SmithKline Beecham Pharmaceutical Co., Schering-Plough Corporation, Searle Corp., Ciba-Geigy Corporation, American Home Products Corp., parent company of Wyeth-Ayerst Laboratories and Glaxco, Inc., all of which conduct business nationwide. Also named as defendants are Medco Containment Services, Inc. and two Medco subsidiaries which operate a large mail order pharmacy business.

The action was brought by 10 chains and 10 independent pharmacies that operate approximately 10% of the retail drugstores nationwide and was announced today at a news conference in New York City by top executives of two of the plaintiffs, Rite Aid Corporation and Revco D.S., Inc.

(more)

Alex Grass, Chairman and CEO of Rite Aid Corporation, the drugstore chain with the largest number of retail outlets in America (2,600 stores), said: "These pharmaceutical manufacturers are charging higher prices to community pharmacies as compared with the prices charged to other non-drugstore retail outlets. Consequently, we and our millions of customers must pay as much as 1200% more for the same drugs. This preferential treatment is costing American consumers hundreds of millions of dollars annually."

Jack Staph, Senior Vice President of Revco D.S., Inc., an Ohio-based, 1,200-store chain added: "We simply want a level playing field with our competitors. Strict enforcement of the antitrust laws will result in vigorous competition to deliver the product to the consumer at the lowest possible price and with the best possible service."

Dan Seigel, President and CEO of Thrifty Corporation, a Los Angeles-based chain with 570 stores that is also a plaintiff, said, "We at Thrifty believe that our customers have been penalized for too long by this practice of discriminatory pricing in favor of mail-order pharmacies."

In addition to Rite Aid, Revco and Thrifty Corporation, the plaintiffs include these chains: Perry Drug Stores of Pontiac, Michigan; K&B Incorporated of New Orleans; Kerr Drug Stores of Raleigh, North Carolina; Snyder's Drug Stores and Thrifty Drug Stores, Inc. of Minnesota; the Bartell Drug Company of Seattle; and Taylor Drug Stores of Louisville.

The lawsuit, filed in the United States District Court for the Middle District of Pennsylvania (Harrisburg), is a private action brought under the Clayton Act, the Sherman Antitrust Act and the Robinson-Patman Act. The charges include these:

- The manufacturers have violated the Robinson-Patman Act by giving substantial discounts to mail-order pharmacies and HMOs without according the same discounts to retail drugstores. Such practices have deprived the retailers of the ability to compete and have disadvantaged their customers, comprising more than 60% of retail drug sales in the United States.

(more)

- The manufacturers have violated Section 1 of the Sherman Antitrust Act by entering into illegal vertical combinations with wholesalers to sell brand name drugs to certain favored purchasers -- including hospitals, nursing homes and HMOs -- at discounted prices, often as much as 50% below the prices paid by community retail pharmacies; and by entering into horizontal combinations which maintain higher costs to retail community pharmacies by requiring that certain discounts and rebates benefit only the "favored purchasers" and not the traditional drugstores.

Lead counsel for the retail drugstores will be Arlin M. Adams, former Judge of the United States Court of Appeals for the Third Circuit, of the firm of Schnader, Harrison, Segal & Lewis of Philadelphia.

BACKGROUND INFORMATION ON RETAIL DRUGSTORES' ANTITRUST ACTION AGAINST DRUG MANUFACTURERS

THE LAWSUIT: CAUSES OF ACTION

- Brought as a private civil action under the federal Clayton Act, which enables "any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws" to sue in federal district court and recover treble damages.

  The Clayton Act also enables "any person, firm, corporation or association" to sue for injunctive relief ". . . against threatened loss or damage by a violation of the antitrust laws . . . "

- The suit charges violations by the defendant drug manufacturers of Sections 2(a) and 2(d) of the Robinson-Patman Act and Section 1 of the Sherman Act. The pertinent sections of those statutes read as follows:

  Robinson-Patman Act, Section 2(a), 15 U.S.C. Sec. 13(a):

  > It shall be unlawful for any person engaged in commerce, in the course of such commerce, either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality, where either or any of the purchases involved in such discrimination are in commerce, where such commodities are sold for use, consumption, or resale within the United States . . .

  Robinson-Patman Act, Section 2(d), 15. U.S.C. Sec. 13(d):

  > It shall be unlawful for any person engaged in commerce to pay or contract for the payment of anything of value to or for the benefit of a customer of such person in the course of such

> commerce as compensation or in consideration for any services or facilities furnished by or through such customer in connection with the processing, handling, sale, or offering for sale of any products or commodities manufactured, sold, or offered for sale by such person, unless such payment or consideration is available on proportionally equal terms to all other customers competing in the distribution of such products or commodities.

Sherman Antitrust Act, Section 1, 15 U.S.C. Sec. 1:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal . . .

THE LAWSUIT: DAMAGES

- Under the antitrust laws, the plaintiffs can recover, and have sought in their complaint, an award of three-fold the damages sustained by them as a result of the unlawful conduct of the defendants plus the costs of the litigation, interest and reasonable attorneys fees.

  Because of the nature of the litigation, it is not possible for the plaintiffs to state the amount of damages at the outset.

NATURE AND IMPACT OF MANUFACTURERS' ILLEGAL CONDUCT

- The lawsuit alleges wide ranging price discrimination and other anti-competitive practices engaged in by drug manufacturers, which have the effect of keeping overall prices of prescription drugs higher than they should be.

- Drug manufacturers' profits are more than four times the average for all industries.

- The drug manufacturers wall off or segment one or more relatively small elements of the pharmacy marketplace and sell prescription drugs to those sectors at

artificially low prices. This may be done, for example, to ensure that one manufacturer's brand name drug is used in treating a chronic illness in preference over another manufacturer's drug. It may be part of an effort to build market share for a drug. It may be done to encourage physicians still in training to prescribe certain brand name drugs in the expectation that familiarity will lead them to continue to do so. Whenever drug manufacturers practice price discrimination favoring some sectors of the marketplace, other sectors are unfairly penalized.

- The most heavily penalized sector is that made up of the approximately 54,000 community retail pharmacies. This sector accounts for more than 60 percent of all sales of prescription drugs in America. Manufacturers can gain the benefits of selling at artificially low prices to other retail sectors and keep their extraordinarily high profit margins as long as they charge artificially high prices to the dominant sector, retail pharmacies. Community retail pharmacies must, of course, reflect the high prices they pay in higher costs to the consumer. Thus, the American public pays for the illegal antitrust activities of the drug manufacturers. Although a minority of consumers now pay low prices, most do not. Free and fair competition would result in overall lower prices for the consuming public.

- The drug manufacturers' price discrimination results in massive cost shifting -- with drugstores paying artificially higher prices to make up for the special lower prices provided to such retailers as mail order pharmacies and others. Ultimately, consumers and third-party insurers pay for this cost shift.

THE CLINTON HEALTH CARE REFORM PROPOSALS

- Price discrimination and cost shifting by drug manufacturers was identified as a major issue by the President's Task Force on Health Care Reform. As a result, the President's reform proposals include two measures to deal with the issue -- an "Equal Access for Purchasers to Pharmaceutical Products" proposal and a "Medicare Tax Rebate" proposal.

- Under the "Equal Access" proposal, price discrimination would be eliminated by requiring that prescription products be sold to all segments of the marketplace at the same prices, except for true economies of scale.

- The "Medicare Rebate Tax" is an effort to recoup partially the tremendous cost to the government of cost shifting expenses paid on behalf of Medicare beneficiaries for artificially high-priced prescriptions as a result of the manufacturers' discriminatory prices.

- The Pharmaceutical Manufacturers Association, the industry trade group, has opposed both measures, in a September 23, 1993 official position statement and earlier in an August 24, 1993 letter to Ira Magaziner, Senior Advisor to the President on health care reform.

END

10/14/93

THE PLAINTIFFS

- **The Bartell Drug Company (38 Pharmacies)**
  4727 Denver Avenue Sough
  Seattle, Washington 98134
  206/763-2626
  206/763-2062 (FAX)
  George H. Bartell, Jr., Chairman of the Board and CEO

- **K&B, Incorporated (171 Pharmacies)**
  K&B Plaza, Lee Circle
  New Orleans, Louisiana 70130
  504/586-1234
  504/585-4535 (FAX)
  Sydney Besthoff, III, Chairman of the Board and CEO

- **Kerr Drug Stores, Inc. (94 Pharmacies)**
  8380 Capital Boulevard
  Box 61000
  Raleigh, North Carolina 27661
  919/872-5710
  919/872-3442
  Banks D. Kerr, Chairman of the Board and CEO

- **Perry Drug Stores, Inc. (208 Pharmacies)**
  5400 Perry Drive
  P.O. Box 436021
  Pontiac, Michigan 48343
  313/334-1300
  313/674-7753 (FAX)
  Jack A. Robinson, Chairman of the Board and President
  Robert A. Berlow, Senior Vice President, General Counsel and Secretary

- **Revco D.S., Inc. (1,190 Pharmacies)**
  1925 Enterprise Parkway
  Twinsburg, Ohio 44087
  216/425-9811
  216/487-1679 (FAX)
  D. Dwayne Hoven, President and COO
  Jack Staph, Senior Vice President, Secretary and General Counsel

- **Rite Aid Corporation (2,583 Pharmacies)**
  P.O. Box 3165
  Harrisburg, Pennsylvania 17105
  30 Hunter Lane
  Camp Hill, Pennsylvania 17011
  717/975-5708
  717/975-5952 (FAX)
  Alex Grass, Chairman of the Board and CEO
  Franklin C. Brown, Executive Vice President and General Counsel

- **Snyder Drug Stores, Inc. (84 Pharmacies)**
  14525 Highway 7
  Minnetonka, Minnesota 55345
  612/935-5441
  612/936-2512 (FAX)
  Donald D. Beeler, Chairman, President and CEO

- **Taylor Drug Stores, Inc. (34 Pharmacies)**
  P.O. Box 1884
  4010 Crittenden Drive
  Louisville, Kentucky 40201
  502/368-6541
  502/368-6575 (FAX/Evening)
  502/368-6541, Extension 444 (FAX/Day)
  William H. Harrison, Jr., Chairman of the Board and CEO

- **Thrifty Corporation (570 Pharmacies)**
  P.O. Box 92333
  Los Angeles, California 90009
  3424 Wilshire Boulevard
  Los Angeles, California 90010
  213/251-6000
  213/251-6021 (FAX)
  Daniel A. Siegel, President and CEO
  James T. Haight, Senior Vice President, Secretary and Chief Corporate Counsel

- **Thrifty Drug Stores, Inc. (Thrifty White) (45 Pharmacies)**
  10700 Highway 55 West
  Minneapolis, Minnesota 55441
  612/545-2234
  612/545-3832 (FAX)
  Clifford G. Wallace, CEO

And the following independent drugstores in Minnesota:

- **Sheldon H. Bloom** doing business as (d/b/a) Danielson, Medical Arts Center
  Drug Express Pharmacies, Inc. d/b/a Otto Drug Express
- **Jay Harris** d/b/a Medicap
- **Michael Hart** d/b/a Hart Snyder Drug
- **Paul Iverson** d/b/a Iverson Corner Drug
- **David Kohler** d/b/a Hunt Silver Lake Drug
- **Lake City Drug, Inc.**
- **Richard C. Oftedahl** d/b/a Oftedahl Drug
- **Setzer Pharmacy, Inc.**
- **Richard C. Sundberg** d/b/a/ Sundberg Pharmacy

THE DEFENDANTS

- **American Home Products Corp.**
  685 Third Avenue
  New York, New York 10017
  212/878-5000

  - **Parent company of:**

    Wyeth-Ayerst Laboratories, Inc.
    555 East Lancaster Ave.
    St. Davids, Pennsylvania 19087
    215/971-5400

- **Ciba Geigy Corporation**
  444 Saw Mill River Road
  Ardsley, New York 10502
  914/479-5000

- **Glaxo, Inc.**
  5 Moore Drive
  Research Triangle Park, North Carolina 27709
  (near Raleigh & Durham)
  919/248-2100

- **Medco Containment Services, Inc.**
  100 Summit Avenue
  Montvale, New Jersey 07645
  201/358-5400

- **Pfizer Inc.**
  235 East 42nd Street
  New York, New York 10017
  212/573-2323

- **Schering-Plough Corporation**
  2000 Galloping Hill Road
  Kenilworth, New Jersey 07033
  908/298-4000

- **Searle Corp.**
  5200 Old Orchard Road
  Skokie, Illinois 60077
  708/982-7000

- **SmithKline Beecham Pharmaceutical Co.**
  1 Franklin Plaza
  P.O. Box 7929
  Philadelphia, Pennsylvania 19101-7929
  215/751-4000

APPENDIX E

OTHER RELEVANT MINNESOTA LEGISLATION

1992 Minnesota Statutes
Administrative Procedures, 14.115 (Subdivision 2)
Vol. 1, Pages 337-338

14.115 SMALL BUSINESS CONSIDERATIONS IN RULEMAKING.

Subdivision 1. **Definition.** For purposes of this section, "small business" means a business entity, including farming and other agricultural operations and its affiliates, that (a) is independently owned and operated; (b) is not dominant in its field; and (c) employs fewer than 50 full-time employees or has gross annual sales of less than $4,000,000. For purposes of a specific rule, an agency may define small business to include more employees if necessary to adapt the rule to the needs and problems of small businesses.

Subd. 2. **Impact on small business.** When an agency proposes a new rule, or an amendment to an existing rule, which may affect small businesses as defined by this section, the agency shall consider each of the following methods for reducing the impact of the rule on small businesses:

(a) the establishment of less stringent compliance or reporting requirements for small businesses;

(b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) the consolidation or simplification of compliance or reporting requirements for small businesses;

(d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and

(e) the exemption of small businesses from any or all requirements of the rule.

In its statement of need and reasonableness, the agency shall document how it has considered these methods and the results.

151.061 UNFAIR PRICE DISCRIMINATION.

Subdivision 1. Any person doing business in this state and engaged in the distribution (other than at retail) of any prescription drugs, who shall discriminate between purchasers by selling prescription drugs at a lower price or rate to one purchaser or association of purchasers than offered to another purchaser or association of purchasers within this state (other than at retail) after making allowance for the difference, if any, in the grade, quality, or quantity, and after equalizing the distance from the point of distribution and freight costs therefrom, shall be guilty of unfair discrimination. Unfair discrimination occurs when quantity discounts are not reasonably based on actual cost savings to all like purchasers. Unfair discrimination shall embrace any scheme of special rebates, collateral contracts, or any device of any nature which in substance violates the provisions of this subdivision. Nothing in this subdivision shall apply to purchases for their own use by schools, colleges, universities, public libraries, churches, hospitals or charitable institutions not operated for profit.

Subd. 2. Any person injured by unfair discrimination as defined in subdivision 1 may bring a civil action and recover damages, together with costs and disbursements, including reasonable attorney's fees, and receive other equitable relief as determined by the court. The remedies provided by this section are cumulative and shall not be construed as restricting any remedy which is otherwise available.

History: *1973 c 722 s 1*

6800.3850 SUPPORTIVE PERSONNEL.

Subpart 1. **Nonspecified tasks.** Supportive personnel may be used in performing pharmacy tasks not specifically reserved in these rules to a licensed pharmacist, assistant pharmacist, or pharmacist-intern under the immediate and personal supervision of a pharmacist.

Subp. 2. **Permissible duties.** Supportive personnel may perform functions which do not involve professional pharmaceutical judgment.

Subp. 3. **Certifying.** Pharmaceutical products prepared by supportive personnel must be certified for accuracy by a licensed pharmacist, as provided for in part 6800.3100, item F, prior to release for patient use.

Subp. 4. **Written procedures.** Written procedures for the use of supportive personnel shall be prepared by the pharmacist-in-charge, shall be submitted to the board, and a copy shall be kept on file in the pharmacy. These procedures must comply with the standards set forth in this rule and will be approved on that basis. Approval must be obtained prior to implementation of the procedures.

These procedures shall indicate in detail the tasks performed by the supportive person and the certification steps performed by the licensed pharmacist. New procedures or changes in procedures shall be submitted to the board for approval as specified above.

The submitted procedures shall be automatically approved 90 days after receipt by the board unless the pharmacist-in-charge is notified by the board of the specific reasons the procedures are unacceptable.

Subp. 5. **Supervision.** Supportive personnel shall be supervised by a licensed pharmacist stationed within the same work area who has the ability to control and is responsible for the action of the supportive person.

Subp. 6. **Ratios.** The basic ratio of supportive personnel allowed by this rule to work with one pharmacist shall be 1:1. Specific functions shall be excepted from the 1:1 ratio as follows:

A. intravenous admixture preparation (parts 6800.7510 to 6800.7530), 3:1;

B. unit dose dispensing (part 6800.3750), 3:1;

C. prepackaging (part 6800.3200), 3:1; and

D. bulk compounding (part 6800.3300), 3:1.

Subp. 7. **Persons not included.** Personnel used solely for clerical duties such as typing, looking up refills, filing prescriptions, record keeping, etc. need not be included in the ratios of the functions performed by supportive personnel.

A pharmacist-intern submitting hours toward completion of the 1,500-hour requirement is not considered a supportive person for the purpose of determining the number of supportive persons supervised by a licensed pharmacist.

Subp. 8. **Petition for different ratio.** A pharmacist-in-charge of any pharmacy may petition the board for use of supportive personnel in ratios in excess of those allowed under these rules or for functions not specified in these rules. This petition for the use of additional personnel must be based on evidence that patient care and safety is maintained. The burden of persuasion is on the pharmacist-in-charge. Such a petition shall be automatically approved 90 days after receipt by the board unless the board shall send to the pharmacist-in-charge notification of the specific reasons why the petition is unacceptable.

Subp. 9. **Penalty.** The use of supportive personnel in the performance of delegated tasks not included in approved written procedures may be considered to be unprofessional conduct on the part of the pharmacist supervising the supportive personnel and the pharmacist-in-charge.

Statutory Authority: *MS s 151.06 subd 1*

History: *9 SR 1656*

1993 Minnesota Statutes
1993 Supplement
Pharmacy: 151.21
Vol. 3, Pages 369-370

151.21 SUBSTITUTION.

Subdivision 1. Except as provided in this section, it shall be unlawful for any pharmacist, assistant pharmacist, or pharmacist intern who dispenses prescriptions, drugs, and medicines to substitute an article different from the one ordered, or deviate in any manner from the requirements of an order or prescription without the approval of the prescriber.

Subd. 2. MS 1992 [Renumbered subd 3]

Subd. 2. When a pharmacist receives a written prescription on which the prescriber has personally written in handwriting "dispense as written" or "D.A.W.," or an oral prescription in which the prescriber has expressly indicated that the prescription is to be dispensed as communicated, the pharmacist shall dispense the brand name legend drug as prescribed.

Subd. 3. MS 1992 [Renumbered subd 4]

Subd. 3. When a pharmacist receives a written prescription on which the prescriber has not personally written in handwriting "dispense as written" or "D.A.W.," or an oral prescription in which the prescriber has not expressly indicated that the prescription is to be dispensed as communicated, and there is available in the pharmacist's stock a less expensive generically equivalent drug that, in the pharmacist's professional judgment, is safely interchangeable with the prescribed drug, then the pharmacist shall, after disclosing the substitution to the purchaser, dispense the generic drug, unless the purchaser objects. A pharmacist may also substitute pursuant to the oral instructions of the prescriber. A pharmacist may not substitute a generically equivalent drug product unless, in the pharmacist's professional judgment, the substituted drug is therapeutically equivalent and interchangeable to the prescribed drug. A pharmacist shall notify the purchaser if the pharmacist is dispensing a drug other than the brand name drug prescribed.

Subd. 4. A pharmacist dispensing a drug under the provisions of subdivision 3 shall not dispense a drug of a higher retail price than that of the brand name drug prescribed. If more than one safely interchangeable generic drug is available in a pharmacist's stock, then the pharmacist shall dispense the least expensive alternative. Any difference between acquisition cost to the pharmacist of the drug dispensed and the brand name drug prescribed shall be passed on to the purchaser.

Subd. 5. Nothing in this section requires a pharmacist to substitute a generic drug if the substitution will make the transaction ineligible for third-party reimbursement.

Subd. 6. When a pharmacist dispenses a brand name legend drug and, at that time, a less expensive generically equivalent drug is also available in the pharmacist's stock, the pharmacist shall disclose to the purchaser that a generic drug is available.

Subd. 7. This section does not apply to prescription drugs dispensed to persons covered by a health plan that covers prescription drugs under a managed care formulary or similar practices.

Subd. 8. The following drugs are excluded from this section: coumadin, dilantin, lanoxin, premarin, theophylline, synthroid, tegretol, and phenobarbital.

History: *1993 c 345 art 5 s 10*

151.461 GIFTS TO PRACTITIONERS PROHIBITED.

It is unlawful for any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner. A medical device manufacturer that distributes drugs as an incidental part of its device business shall not be considered a manufacturer, a wholesale drug distributor, or agent under this section. As used in this section, "gift" does not include:

(1) professional samples of a drug provided to a prescriber for free distribution to patients;

(2) items with a total combined retail value, in any calendar year, of not more than $50;

(3) a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;

(4) reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;

(5) compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project;

(6) publications and educational materials; or

(7) salaries or other benefits paid to employees.

History: *1993 c 345 art 5 s 11*

ACRONYM LIST

PRESCRIPTION DRUG STUDY

ACRONYMS

AARP	American Association of Retired Persons
APhA	American Pharmaceutical Association
AMA	American Medical Association
AMP	Average Manufacturer's Price
AWP	Average Wholesale Price
BAP	Best Available Price
BCBSM	Blue Cross and Blue Shield of Minnesota
CBO	Congressional Budget Office
CHP	Children's Health Plan
CPA	Clinical Pharmacy Advantage
CPI	Consumer Price Index
DAW	Dispense As Written
DHHS	Department of Health and Human Services
DHS	Department of Human Services
DoA	Department of Administration
DOD	Department of Defense
DOER	Department of Employee Relations
DOR	Department of Revenue
DPCO	Drug Price Control Order
DPS	Diversified Pharmaceutical Services
DRG	Diagnostic Related Group
DUR	Drug Use Review
DVA	Department of Veterans Affairs
EAC	Estimated Acquisition Cost
ECM	Electronic Claims Management
EEC	European Economic Community
FDA	Food and Drug Administration
FFP	Federal Financial Participation
FUL	Federal Upper Limits
GAMC	General Assistance Medical Care
GAO	General Accounting Office
GPO	Group Purchasing Organization
HCFA	Health Care Financing Administration
HMO	Health Maintenance Organization
IPA	Independent Practice Association
ISN	Integrated Service Network
IV	Intravenous
IVR	Integrated Voice Response
MA	Medical Assistance
MAC	Maximum Allowable Cost
MMIS	Medicaid Management Information System

NACDS	National Association of Chain Drug Stores
NARD	National Association of Retail Druggists
NCPDP	National Council for Prescription Drug Programs, Inc.
NHS	National Health Service
NPA	National Prescription Audit
NWDA	National Wholesale Druggists Association
OBRA	Omnibus Budget Reconciliation Act
ODB	Ontario's Drug Benefit Plan
OECD	Organization for Economic Cooperation and Development
OTA	Office of Technology Assessment
OTC	Over-The-Counter Medications
P&T	Pharmacy and Therapeutic
PA	Prior Authorization
PACE	Pharmacy Assistance Contract for the Elderly
PC	Pharmaceutical Care
PMA	Pharmaceutical Manufacturers Association
PMPRB	Patented Medicine Prices Review Board
PPI	Producer Price Index
PPO	Preferred Provider Organizations
PPRS	Pharmaceutical Price Regulation Scheme (United Kingdom)
PRIME	Pharmacy Research Institute of Management and Economics, University of Minnesota
R & D	Research and development
USD	U.S. Pharmaceutical Market--Drugstores
SEGIP	State Employee Group Insurance Program
SHP	State Health Plan
SSI	Small-Scale Industrial Units

GLOSSARY

PRESCRIPTION DRUG STUDY

GLOSSARY OF TERMS

All-Payer System: A system under which the government and private insurance plans ("all payers") pay the same amount for the same service. For instance, federal-state Medicaid insurance programs would not be able to reimburse hospitals at a lower rate than Blue Cross, a private insurer. This would prohibit the health provider from shifting costs from one payer to another.

Average Manufacturer Price (AMP): The average price paid by wholesalers for products distributed to the retail class of trade.

Average Wholesale Price (AWP): The standardized cost of a pharmaceutical calculated by averaging the cost of an undiscounted pharmaceutical charged to a pharmacy provider by a large group of pharmaceutical wholesale suppliers.

Best Price: Lowest price paid by any purchaser (exclusive of depot prices and single-award contract prices defined by any federal agency) and includes products with special packaging, labeling or identifiers.

Brand-Name: The commercial name given to a drug product by an individual company for marketing and promotion purposes.

Breakthrough Drug: New drugs that represent a breakthrough or significant advance over existing therapies.

Buying Groups: Purchasing alliances that buy drugs on behalf of several plans.

Capitation: A payment method in which a health care provider is paid a fixed amount for each individual served for a specified time period. This payment does not vary with the amount of services provided.

Capitation Payment: A method of payment for health services in which an individual or institutional provider is paid a fixed amount for each person served in a set period of time, without regard to the actual number or nature of services provided to each person. This is the characteristic payment method in health maintenance organizations (HMOs). See fee-for-service.

Chain Pharmacies: Organizations consisting of 5 or more pharmaceutical retail outlets. Includes chain, supermarket, and mass merchandiser pharmacies.

Chargeback: Reimbursement to a wholesaler of an established manufacturer discount offered to a specific buying group (based on usage data). The reimbursement is paid to the wholesaler from the discounting manufacturer and includes a service fee.

Closed Access: A type of health plan in which covered persons are required to select a primary care physician from the plan's participating providers. The patient is required to see the selected primary care physician for care and referrals to other health care providers within the plan. Typically found in a staff, group or network model HMO. Also called closed panel or gatekeeper model.

Coinsurance: A cost-sharing requirement under a health insurance policy. It provides that the insured party will assume a portion or percentage of the costs of covered services. The health insurance policy provides that the insurer will reimburse a specified percentage (such as 80 percent) of all, or certain specified, covered medical expenses in excess of any deductible amounts payable by the insured. The insured is then liable for the remainder of the costs until the maximum liability, if any, under the insurance policy is reached. See also deductible.

Constant Dollars: Dollars expressed in terms of their purchasing power in a base year. Constant dollars adjust for changes in buying power due to inflation or deflation between the base year and the year of measurement.

Copayment: A cost-sharing arrangement in which a health plan member pays a specified charge for a specified service, such as $10 for an office visit. The member is usually responsible for payment at the time the health care is rendered. Typically, copayments are fixed or variable flat amounts for physician office visits, prescriptions or hospital services.
Some copayments are referred to as co-insurance with the distinguishing characteristics that copayments are flat or variable dollar amounts and co-insurance is a defined percentage of the charges for services rendered. Also called copay.

Cost Shifting: The practice of charging certain groups of consumers higher rates to offset lower rates negotiated or mandated by payers for other groups..

Current Dollars: The value of dollars spent or received at the time of the transaction, without adjusting for inflation or deflation since the transaction date.

Current (Gross) Margin: Net sales minus goods sold; the difference between sales revenues and manufacturing costs as an intermediate step in the computation of operating profits or net income.

Deductible: Under a health insurance policy, a dollar amount incurred by an insured individual for covered services -- either a specific amount of money (e.g., $200) or the value of specified services (e.g., 2 days or hospital care or one physician visit) -- that the insured individual must pay before an insurer will assume liability for all or part of the remaining covered services. Deductibles are usually tied to some reference period over which they must be incurred (e.g., $200 per calendar year, benefit period, or spell of illness). A deductible is a type of cost sharing. See also copayment.

Diagnosis Related Groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are the case-mix measure used in Medicare's prospective payment system.

Dispense As Written (DAW): Physicians indicate that the brand name (rather than a generic brand) should be dispensed by writing "dispense as written" or "D.A.W." on the prescription, or by orally directing the pharmacist if the prescription is phoned in to the pharmacy.

Dispensing Fee: Payment to a pharmacy for pharmacist services related to filling and dispensing a prescription drug. In Minnesota, the current dispensing fee is $4.10 under the Medicaid program. The dispensing varies by payer.

Disproportionate Share Adjustment: An "add on" payment to providers who serve a high percentage of low income and special needs populations.

Distributor: A pharmaceutical company that contracts with a manufacturer to make a product which is then sold under their own label. Many firms marketing non-originator multiple source products are technically distributors rather than manufacturers for some or all of their product line.

Drug Formulary: A list of prescription medications which are approved for use and/or coverage by the plan and which will be dispensed through participating pharmacies to a covered person. The list is subject to periodic review and modification. Also referred to as a "restrictive formulary."

Drug Utilization Review (DUR): An evaluation of prescribing patterns or targeted drug use to specifically determine the necessity, appropriateness, efficiency, and cost effectiveness of drug therapy. The two primary objectives of DUR systems are: 1) to improve quality of care; and 2) to assist in containing health care costs.

Federal Financial Participation (FFP): Federal reimbursement for health care costs for recipients of Medicaid. Minnesota FFP for Medical Assistance represents approximately 53% of the cost of care.

Fee-For-Service (FFS): Method of billing for health services under which a physician or other practitioner charges separately for each patient encounter or service rendered. Under a fee-for-service payment system, expenditures increase if the fees themselves increase, if more units of service are provided or if more expensive services are substituted for less expensive ones. This system contrasts with salary, per capita, or other prepayment systems, where the payment to the physician is not changed with the number of services actually used. See also capitation.

Formulary: See Drug Formulary.

Generic Drug: A chemically equivalent copy of a brand-name drug whose patent has expired. A generic is typically less expensive and sold under a common or "generic" name for that drug, not the brand (e.g., the brand name for one tranquilizer is "Valium," but it is also available under the generic name "diazepam"). Also called generic equivalents.

Generic Substitution: Substitution of a generic version of a branded off-patent pharmaceutical for the branded product when the latter is prescribed. Some HMOs and Medicaid programs mandate generic substitution.

Gross Margin: Net sales minus goods sold; the difference between sales revenues and manufacturing costs as an intermediate step in the computation of operating profits or net income.

Group Purchasing Organizations (GPOs): A buying group that represents hospitals for the purchase of pharmaceutical products.

Health Care Financing Administration (HCFA): An office in the U.S. Department of Health and Human Services that has primary responsibility at the federal level for administering the Medicare and Medicaid programs.

Health Alliance: As proposed in the Health Security Act, it is a purchasing pool responsible for negotiating health insurance arrangements with state-certified health plans and provider networks. By requiring each certified plan to charge essentially the same premium to all who enroll, the alliance can spread the risk and largely eliminate plan-to-plan variations in premium. Alliances will be responsible for enrollment, premium collection, data collection, and publication of performance measures comparing health plans. Also called "health purchasing alliance."

Health Maintenance Organization (HMO): An organization that, in return for prospective capitation payments, acts as both insurer and provider of comprehensive but specified health care services to an enrolled population.

Health Outcome: A measure of the effectiveness of preventive or treatment health services, typically in terms of patient health status. Attributing changes in outcomes to health services requires distinguishing the effects of the many other factors that influence patients' health.

Independent Pharmacies: Less than four commonly owned stores.

Indigent Care: Health services provided to the poor or those unable to pay. Since many indigent patients are not eligible for federal or state programs, the costs which are covered by Medicaid are generally recorded separately form indigent care costs.

Integrated Service Networks (ISNs): The health plan proposed under MinnesotaCare that will be accountable for the cost, quality, and accessibility of health care services provided to their members. Under the ISN system, providers and insurers will have incentives to prevent illness, improve quality, and control costs. Competitions among ISNs will be encouraged. While competition is expected to be effective in controlling costs, each ISN will be subject to an overall limit on the rate of increase in the ISN's expenditures.

Manufacturer: Drug companies engaged in the sale of finished prescription drug products to wholesalers, pharmacies, and practitioners. (Note: in the traditional market system a manufacturer sets at least four specific prices: the wholesale price; the direct price: the list price; and contract prices to special channels of distribution.)

Manufacturer Rebate: The Omnibus Budget Reconciliation Act of 1990 requires pharmaceutical manufacturers to enter into a rebate agreement with the federal government in order for their products to be eligible for reimbursement under Medicaid rules. The purpose of the rebate is to guarantee that the Medicaid program receives the best price available in the private sector for pharmaceutical products.

Me-Too Drug: A new chemical entity that is similar but not identical in molecular structure and mechanism of action to a pioneer new chemical entity.

Medicaid (Medical Assistance): A federally aided, state operated and administered program that provides medical benefits for some indigent or low-income persons in need of health and medical care. The

program, authorized by Title XIX of the Social Security Act, covers only those persons who meet specified eligibility criteria. Subject to broad federal guidelines, states determine the benefits covered, program eligibility, rates of payment for providers, and methods of administering the program.

Medicaid Management Information System (MMIS II): MMIS II is a complex, highly integrated claims payment and information and management and retrieval system designed to handle the needs of the Minnesota Medical Assistance (Medicaid) program.

Medicare: A uniform national health insurance program, authorized under Title XVIII, for 1) people aged 65 and over; 2) persons eligible for social security disability payments for two years or longer; and 3) certain workers and their dependents who need kidney transplantation or dialysis. Health insurance protection is available to insured persons without regard to income. It consists of two separate but coordinated programs: hospital insurance (Part A) and supplementary medical insurance (Part B). Prescription drugs are not currently included as a Medicare-covered service.

Medigap: These are private health insurance plans that augment Medicare by paying costs not covered by the federal government. Payments could include co-insurance, coverage of Medicare deductibles and services not covered by Medicare (including prescription drugs).

Most Favored Purchaser: Legislation mandating that all purchasers receive the same discounts and prices offered to the "most favored purchaser" in the market. That is, the state would require that manufacturers offer the same price to all purchasers based on a given volume of drug product. Also referred to as "anti-discriminatory pricing."

Multiple Source Drug: Any drug for which there were two or more drug products rated as therapeutically equivalent according to the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations." After the patent on a drug has expired, other manufacturers may apply for and receive FDA approval to market the drug. Once these manufacturers bring additional products to the market, the drug is generally referred to as a multiple-source drug.

Negative Formulary: A formulary listing that specifies which pharmaceutical products will NOT be covered rather than which ones WILL be covered.

Out-Of-Pocket: The portion of payments for health services paid by the enrollee, including copayments, coinsurance and deductibles.

Over-The-Counter (OTC) Drug: A drug product that does not, by federal or state law, require a prescription.

Patented Drugs: Brand-name drugs that are marketed by a pharmaceutical company under exclusive marketing rights.

Pharmaceutical Alternate: One of two types of therapeutic interchanges in which the question: "Is this prescribed medication available, as the same drug, in a less costly dosage form?" is asked. Thus a pharmaceutical alternate is a different dosage form for a specific drug.

Pharmaceutical Care: The concept of pharmacists working with patients and health professionals to design, implement, and monitor drug therapy plans to improve patients' quality of care. Drug counseling and patient evaluation are included.

Point-Of-Sale: Location at which prescription drugs are sold to the consumer, such as a retail or HMO pharmacy.

Preferred Provider Organization (PPO): An organization which selectively contracts with or arranges for a network of doctors, hospitals, and others to provide services at a discounted price schedule. Providers in a PPO network may be required to agree to utilization management. Patients are free to use providers outside of the network; however, they are given incentives, such as lower cost sharing requirements or coverage of extra benefits, to use a specified network of providers. PPOs can be established by health insurers, health care providers, and other organizations.

Prescription Drug: A drug which has been approved by the Food and drug Administration (FDA) and which can, under federal or state law, be dispensed only pursuant to a prescription order from a physician who is duly licensed to do so. Such products are also referred to as "legend" drugs and bear the legend: "Caution: federal law prohibits dispensing without prescription."

Price, Depot Price: The price(s) available to any depot of the federal government, for purchase of drugs from the manufacturer through the depot system of procurement.

Price, Direct Price (DP): The price a pharmacy pays the manufacturer when purchasing a drug product directly from the manufacturer. The direct price is usually not discounted except for timely payment of the invoice. (Note: Manufacturers selling direct to pharmacies usually require a minimum dollar value per order [e.g., $100 or $250] and in some cases a minimum quantity of purchased items [e.g., 6 bottles of 100 dosage units]. The pharmacy may, at times, have to pay shipping costs of the drug products in addition to the direct price.)

Price, List Price: The price set and published by each manufacturer. This is the manufacturer's suggested price for the wholesaler to charge a pharmacy for the drug product. [Note: wholesalers are free to set the actual price they charge a pharmacy based on competitive forces in their marketplace.]

Price, Wholesaler Price (WP): The initial transaction price listed on an invoice when a wholesaler purchases a drug product from a manufacturer. The net, or actual, wholesaler acquisition cost may include reductions to the invoiced price in the form of discounts, rebates, chargebacks, promotional allowances, or other allowances based on volume of the product purchased, total dollar volume of the business with the manufacturer, or other considerations.

Prime Vendor Contract: A drug wholesaler that has a contract, for a fee, with a purchasing group to warehouse, deliver, invoice, supply management reports, etc. for drugs under contract to manufacturers by that purchasing group. There is a chargeback system between the manufacturer and the wholesaler for the difference in the normal wholesalers' acquisition cost and the manufacturers' contracted price with the purchasing group which is expected to be lower.

Prior Authorization (PA): The process of obtaining prior approval for a specified service or medication. Without such prior authorization, the service or medication is not a covered service. Under Medicaid

rules, drugs on a restricted formulary must still be available through prior authorization. Additionally, new drugs or biological products are exempted from PA during the first six months after FDA approval and must be covered.

Real Dollars: See constant dollars.

Self-Insured: A form of private coverage in which an employer, rather than an insurance company, assumes the risk. Third-party administrators or insurers, however, may administer the plan.

Single-Payer System: A universal coverage plan under which the government collects insurance premiums and administers health car benefits for everyone in the country. It cuts out the role of insurance companies.

Single Price: Requirement that pharmaceutical manufacturers offer the same price to all purchasers of a given volume of a prescription drug product, regardless of market share or other considerations.

Single Source Drug: A drug that is marketed under one brand name usually by only one manufacturer or distributor. To encourage innovation, the Federal government grants exclusive marketing rights (patents) for a limited period of time (17 years) to companies for new chemical entities. During this period of exclusivity, when the drug is available only from one company, the drug is called a single source drug.

Therapeutic Alternatives: Drug products containing different therapeutic modalities, but which provide similar pharmacological action or chemical effect when administered to patients in therapeutically equivalent doses.

Therapeutic Class: A group of drugs intended to treat a particular disease or group of related diseases.

Therapeutic Equivalents: Drug products containing different therapeutic substances which, when administered in similar therapeutic doses, will provide the same clinical outcome or effect as measured by the control of a symptom or illness.

Third Party Payer: Any organization, public or private, that pays or insures health care services provided to beneficiaries or enrollees (the first party) by a health care provider (the second party). Blue Cross/Blue Shield, commercial insurance companies, Medicare, and Medicaid are examples of third party payers.

Wholesaler: The "middleman" in the pharmaceutical drug industry. Wholesalers' core function in the pharmaceutical market channel is the concentration-dispersion of pharmaceutical products. They concentrate the buying power of many retail pharmacies into a single purchase from a pharmaceutical manufacturer and disperse products to many pharmacies in their service area. Wholesalers provide: automated accounts receivables, customized price stickers, inventory control, electronic order entry, management information and product movement reports, third party claims processing, retail pricing guides, and pharmacy computer systems.

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