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The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches

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Transportation and Industry Analysis Section
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Summary

The relatively high prices of prescription drugs was a major issue for the 106th Congress and will likely remain an issue during the 107th Congress. In particular, legislative discussion of the issue has focused on the uninsured elderly. High prescription drug prices can impose significant financial hardship on low-income seniors who do not have insurance coverage for prescription drugs. Medicare, which provides health insurance for most of the Nation's elderly, does not cover most outpatient prescription drugs.

Various factors play a role in prescription drug pricing, such as the policy of patenting innovative drugs and the degree to which therapeutically equivalent drugs are available. Discussions of prescription drug pricing tend to emphasize the ability of many third party buyers (e.g. health maintenance organizations, hospitals, and pharmacy benefit managers) to obtain discounted prices for pharmaceuticals. Other buyers (e.g. many retail pharmacies and uninsured consumers) do not tend to receive such discounts. The net effect of such discounts is that buyers such as retail pharmacies and uninsured consumers usually pay the highest prices for drugs while third-party buyers usually pay lower prices for drugs. Third-party buyers are able to receive discounts at both the manufacturing level and at the retail pharmacy level, although third-party payers who do not use a formulary to manage outpatient drug benefits also pay higher prices for drugs.

Economic analysis of the pharmaceutical market provides some insight into the reasons third-party buyers are able to obtain lower prices while other buyers are not. Third-party buyers negotiate prices and can exclude high-priced sellers (essentially manufacturers) from their portion of the pharmaceutical market. Conversely, other buyers (including uninsured consumers) do not negotiate over prices and are therefore unable to exclude sellers from the market. It is the ability to exclude sellers that tends to determine who pays the lowest prices for prescription drugs.

Critics of this differential pricing in the pharmaceutical market have raised a number of issues, including fairness, equity and access to drugs, and how to end the price discrimination that the elderly face when they must pay for their own prescription medicines. Congress has been exploring several options for easing the financial burden that high prescription drug prices can impose on the elderly. One approach would be to create a drug benefit for the Medicare population. Another approach is to require pharmaceutical manufacturers to offer discounts on drugs sold to the uninsured elderly. A third approach is to facilitate the importation of prescription drugs from countries where prices are lower. This report will be updated as warranted.

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The Cost of Prescription Drugs for the Uninsured Elderly and Legislative Approaches

Introduction

The relatively high prices of prescription drugs receive much attention from both the press and policymakers. High prices can impose significant financial burdens on those who do not have health insurance or whose health insurance does not cover prescription drugs. Although there are uninsured in most, if not all, segments of the population, particular emphasis has been placed on the effect of higher prices on the elderly. Most elderly receive their primary health insurance through the government's Medicare program, yet Medicare does not provide coverage for most outpatient prescription drugs. While approximately 65% of the elderly have prescription drug coverage through some sort of non-Medicare supplement, the remaining elderly receive no such benefit.¹ Even for those seniors who have some form of a prescription drug benefit, coverage may be insufficient or inadequate given their medical needs.² There is also evidence that the scope of their coverage may be eroding. The high prices of prescription drugs are considered to be particularly hard on the uninsured elderly because many of the Nation's elderly live on low, fixed incomes.

The purpose of this report is to explain why many of those who are least able to afford high drug costs are those who are most frequently charged the most. To do this, we examine the causes of pricing differences between the uninsured and third-party, or "preferred," buyers in order to better understand marketplace dynamics and the implications of the various alternatives that have been put forward to reduce such price differences. This report describes the basic economic theory underlying price differentiation and, in the context of the pharmaceutical market, analyzes the role and

¹Davis, Margaret, et al. "Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries. *Health Affairs*. January/February 1999.

²A study performed for the Henry J. Kaiser Family Foundation found that supplemental benefits offered by Medicare HMOs (including a prescription drug benefit) varied greatly in the level of coverage, with some offering very generous coverage while others offered very limited coverage. See The Henry J. Kaiser Family Foundation, *Analysis of Benefits Offered By Medicare HMOs, 1999: Complexities and Implications*. August 1999. Another study by the National Economic Council states that the only meaningful form of private prescription drug coverage is retiree drug coverage, and only 25% of the elderly have this type of coverage. See The White House, National Economic Council. *Disturbing Truths and Dangerous Trends: The Facts About Medicare Beneficiaries and Prescription Drug Coverage*. July 22, 1999.

behavior of pharmacy benefit managers (PBMs), pharmaceutical manufacturers, and retail pharmacies, respectively. It also looks at a number of the criticisms that have been made of the practice of differential pricing. Finally, this report discusses various policy approaches aimed at assisting the elderly to purchase prescription drugs.

Sources of Price Differentiation

Differential pricing has emerged as a major issue in the debate over the cost of drugs for the uninsured. In this section, the concept of differential pricing is discussed and its application to various groups of buyers of goods and services is described. The prescription drug market is characterized by differential pricing. In recent years, differential pricing has emerged as a major issue because of the dramatic increase in the segment of the market that is controlled by third-party buyers. The behavior of third-party buyers, manufacturers, and retail pharmacies all have an impact on uninsured consumers. These impacts are the subject of the various subsections that follow the discussion of price differentiation.

Price differentiation, or price discrimination, is a common business practice in markets with diverse buyer groups. Its effects can sometimes be beneficial in an economic sense, but F.M. Scherer and David Ross note:

“Price discrimination causes a redistribution of income toward the discriminator and away from its customers. In the absence of legal quirks, no firm with market power *has* to discriminate. It will do so only if a system of discriminatory prices yields higher expected profits than uniform pricing, *ceteris paribus*.”³

The charging of different prices to different consumers occurs in many industries in the U.S. economy.⁴ For example, airlines charge different fares to business travelers than to leisure travelers, as well as different fares within each group. Long distance telephone companies also charge different rates depending on the time of day that the phone call is made. Student discounts at movies and senior discounts at restaurants are also frequently cited cases in which lower prices are offered to groups that are relatively more price sensitive. Some magazines offer low introductory rates or free trial issues to new subscribers, while existing subscribers may have to pay full price for the same issue. Universities offer financial aid or academic scholarships to some students which effectively lowers the price of their education. In all of these situations, the good or service sold is identical and each consumer is purchasing the same amount, yet the prices vary by consumer or by time of purchase. Thus, such

³F.M. Scherer and David Ross, *Industrial Market Structure and Economic Performance*. 3rd ed., 1990. p. 494.

⁴Throughout this paper, “differential pricing” or “price differentiation” will be used to refer to what economists call price discrimination. Price discrimination refers to any non-cost based difference in pricing for different units of a good or service. The phrase “price discrimination” carries with it a negative connotation among the press and policymakers. However, it is very important to note that (unlike other forms of discrimination) price discrimination is an economic term and is neutral.

price differences are not related to differences in costs nor differences in the volume purchased; rather, the price differences are caused by some other factor, such as the sensitivity of readily identifiable groups of consumers to prices.⁵

Differential pricing is a characteristic of the prescription drug market. It is likely that, here too, the observed price differences may not be due to cost or volume differences. Instead, relatively lower prices are charged because manufacturers are able to differentiate among types of consumers. In this case, third party buyers are likely to go elsewhere (i.e., substituting therapeutic equivalents) or may be willing to forgo the purchase of prescription drugs altogether (i.e., not providing coverage for certain drugs) while the uninsured have a limited ability to go elsewhere and are much less likely to be willing to forgo the purchase of prescription drugs. Uninsured consumers are therefore likely to be charged relatively higher prices. This point can be restated as follows: Manufacturers and retailers of prescription drugs are able to differentiate with ease between third party buyers (who represent insured consumers) and uninsured consumers. The resulting price discrimination yields higher profits for any party with market power who is willing to establish a system that distinguishes among classes of customers. Scherer and Ross (1990) note that the type of price differentiation present in the pharmaceutical marketplace (third-degree price discrimination⁶) “redistributes income away from consumers in the low price elasticity groups, who normally pay a higher price than under simple monopoly, toward consumers in high-price elasticity groups, who pay lower prices.”⁷

Do conditions for price discrimination exist in the pharmaceutical market? The answer would appear to be unambiguously affirmative. Sellers of prescription drugs have control over prices, although the extent of this is difficult to measure and varies within and across the pharmaceutical market. Sellers in the pharmaceutical market can segment buyers and gauge how much various classes of buyers are willing to pay. Manufacturers differentiate between third-party buyers and retail pharmacies. Retail pharmacies differentiate between third-party buyers and uninsured consumers. In both segments of the market, sellers gauge how much third-party buyers are willing to pay through one-on-one negotiations with third-party buyers. Sellers charge separate (generally, non-discounted) prices to retail pharmacies and uninsured consumers.

⁵Two conditions must be present for non-cost based differential pricing. First, the seller must have some control over price. In perfectly competitive markets (which are extremely rare), price differentiation cannot take place. Second, the seller must be able to segment the demand for the product. That is, the seller must have some way of distinguishing which buyers are willing to pay a higher price and which buyers are willing to pay only a lower price. If the seller has no way of distinguishing among buyers, then he or she must set a single price for all buyers. For example, very hungry customers may be willing to pay more at a restaurant than less hungry customers, but because the restaurant cannot distinguish between the two types, it must charge a single price.

⁶According to Hal Varian, “Third degree price discrimination occurs when the monopolist sells different units of output to different people for different prices, but every unit of output sold to a given person sells for the same price.” Varian, Hal R. *Intermediate Microeconomics: A Modern Approach*. 4th Ed.. New York: W.W. Norton, 1996.

⁷Ibid.

Major Third-Party Buyers

The major third-party buyers in the pharmaceutical market are health maintenance organizations (HMOs) and pharmacy benefit managers (PBMs).⁸ These two groups have grown in importance over the last decade.⁹ In 1990, HMOs and PBMs handled approximately 25% of prescriptions; it is estimated that in 1999 these two groups will handle approximately 70% of prescriptions.¹⁰ Standard & Poor's has projected that third-party insurers will handle close to 90% of all pharmacy sales in 2000.¹¹

PBMs are contracted by employers and health plans to administer a prescription drug benefit. The objective of the PBM is to reduce the expenditures associated with operating a prescription drug benefit and to pass on those savings to the employer or health plan. It is estimated that PBMs contracted by health plans in the Federal Employees Health Benefits Program (FEHBP) saved those health plans 20%-27% on their drug benefit.¹²

One way that PBMs (as well as other third-party buyers) achieve such cost savings is through negotiated discounts with pharmaceutical manufacturers and retail pharmacies. An important cost-saving mechanism used by third-party buyers is the formulary. A formulary is a list of preferred drugs developed by PBMs, HMOs, and other third-party buyers. Drugs are added to formularies based on various criteria, such as efficacy, side effects, and price. Third-party buyers exercise market power through their ability to include or exclude prescription medicines from their formularies. As will be discussed, manufacturers place great importance on having their drugs included in formularies and often offer discounts to third-party buyers in exchange for inclusion in formularies.

Formularies can play an important role in the operations of PBMs and other third-party buyers. Health plans may encourage contracted physicians to prescribe formulary drugs over non-formulary drugs. If a health plan member is prescribed a non-formulary drug by a physician, then a health plan's PBM may contact the physician and have the prescription changed to a therapeutically equivalent drug that

⁸PBMs frequently negotiate on behalf of HMOs.

⁹Unless otherwise noted, third-party buyers in this paper exclude government buyers such as the Veterans Administration or the Department of Defense. Although they often negotiate in a manner similar to private third-party buyers, they are guaranteed a certain discount under the Veterans Health Care Act (P.L. 102-585).

¹⁰Robert Pear, "Tracking Just What the Doctor Ordered: Medicare Changes Would Bolster Prescription Management Services," *New York Times*, July 13, 1999.

¹¹Standard & Poor's. *Industry Surveys*. "Supermarkets and Drugstores." June 18, 1999. p. 8.

¹²U.S. General Accounting Office. *Pharmacy Benefit Managers: FEHBP Plans Satisfied With Savings and Services, but Retail Pharmacies Have Concerns*. GAO/HEHS-97-47, February 1999, p. 2.

is included in the formulary.¹³ Adding to complexity is the use of “open” and “closed” formularies. When a plan uses an open formulary, it covers all prescription drugs, regardless of whether they are included in the formulary. When a plan uses a closed formulary, it refuses to cover drugs that are not included in the formulary. Under a closed formulary, if a plan member is prescribed a non-formulary drug, then that plan member must either pay for the drug out-of-pocket or have his or her physician change the prescription to a therapeutically equivalent drug that is included in the formulary. Whether a plan uses an open or closed formulary could affect the level of savings that can be achieved.

In a study based on an examination of managed, fee-for-service plans using open formularies, the U.S. Congressional Budget Office (CBO) concluded “[m]uch of the savings that PBMs achieve appear to come from the lower prices paid to pharmacies rather than from the rebates offered by drug manufacturers.”¹⁴ The CBO findings were in turn based on a General Accounting Office (GAO) study which examined the cost savings achieved by three health plans participating in the Federal Employees Health Benefits Program (FEHBP).¹⁵ CBO notes that the GAO study found that 50% to 70% of the cost savings of the FEHBP plans resulted from paying less at the retail pharmacy level than what those plans would have paid without contracting with a PBM. CBO also notes that the GAO study found that 2% to 21% of the savings achieved by the FEHBP plans were the result of manufacturer rebates obtained by the PBM.

Some critics discount CBO’s findings on the grounds that the GAO study does not represent typical private health plans and that FEHBP fee-for-service plans are not comparable to HMO or other managed care plans that are more likely to use closed formularies. They argue that HMOs and plans that utilize a *closed formulary* will achieve a higher percentage of savings attributable to manufacturer rebates than is the case for FEHBP fee-for-service plans and that these rebates will exceed retail pharmacy discounts.

It is possible that the percentage of overall savings attributed to manufacturer rebates could exceed the percentage of savings attributed to pharmacy discounts. However, CRS is unable to determine whether manufacturer rebates exceed retail pharmacy discounts under a closed formulary or for other types of health plans because data on manufacturer rebates and pharmacy discounts for HMOs and other private health plans are proprietary (i.e., not available to the public). Nevertheless, it would appear that whether a plan uses an open or closed formulary, discounts come from either the manufacturer or the retailer, or from both.

¹³Therapeutic equivalents are drugs that perform the same function even though they may be different chemically. For example, the anti-depressant medications Prozac, Zoloft and Paxil belong to the same therapeutic class.

¹⁴U.S. Congressional Budget Office. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*. July 1998, p. 8.

¹⁵GAO, 1997.

Pharmaceutical Manufacturers

The structure of the pharmaceutical manufacturing industry creates conditions for industry control over prices and, consequently, price differentiation. The brand-name pharmaceutical manufacturing industry is characteristic of an oligopoly.¹⁶ First, there are relatively few firms that develop and manufacture pharmaceuticals. When one limits the pharmaceutical market to drugs that are therapeutically equivalent, there are even fewer firms. In some cases, there are no therapeutical equivalents for a brand-name drug; in such instances, the market resembles that of a monopoly.¹⁷ Firms with a virtual monopoly over a therapeutic class will probably not tend to offer discounts or rebates to any group of buyers. Second, there are certain barriers to entry that limit the extent to which new firms can enter the market and the extent to which existing firms can introduce competing products. One such barrier is the patent system, which protects the innovator of a drug from competition from identical products.¹⁸ Another barrier is the high fixed cost associated with developing and marketing new pharmaceuticals.

Pharmaceutical manufacturers generally differentiate their prices among chain and independent retail pharmacies, hospitals, managed care facilities, health plans, and PBMs. A Standard & Poor's *Industry Survey* describes manufacturers' pricing policies in the following way:

In general, drugs sold to wholesale distributors and pharmacy chains for the individual/physician market are priced at the high-end of the manufacturer's price scale. Hospital chains and other large institutional and managed care customers that buy directly from manufacturers pay prices well below the list price, as a result of heavy discounting and negotiated arrangements.¹⁹

Manufacturers are able to price differentiate because they have control over prices. The ability of manufacturers to set prices is constrained by the bargaining power exercised by HMOs, PBMs, and other preferred customers. When competition exists in a therapeutic class, manufacturers are frequently forced to extend discounts to those buyers with market power (third-party buyers). Third-party buyers tend to receive the lowest prices because they have the ability to exclude certain manufacturers from a significant portion of the market. Retail pharmacies, however,

¹⁶Scherer, F.M. *Industry Structure, Strategy, and Public Policy*. New York: Harper Collins, 1996, p. 5. In the spectrum of market structures, an oligopoly is the closest market structure to a monopoly. Oligopolies are characterized by relatively few firms (but more than one) and barriers to entry. Firms operating in an oligopolistic market have some control over prices, and thus have the ability to price differentiate.

¹⁷Ibid.

¹⁸It is important to note that although other producers cannot offer chemically identical products, they can introduce products that are therapeutically equivalent. Therapeutic equivalents often compete with one another. Thus, the patent does not necessarily protect the innovator from all competition.

¹⁹Standard and Poor's. *Industry Surveys*. "Supermarkets and Drugstores." September 14, 1998, p. 19.

must carry the widest possible range of inventory to meet the needs of their customers and have limited leverage in winning discounts from manufacturers.

Buyer Behavior at the Manufacturing Level. To obtain higher profits through price differentiation, a firm must be able to distinguish which consumers are willing to pay relatively high prices and which are willing to pay only relatively low prices for its products. Usually, this works through what is known as the “chargeback” system. Most buyers of pharmaceuticals obtain their products from wholesalers at the same price. However, preferred buyers receive negotiated rebates from the manufacturers. In the pharmaceutical market, this is achieved through negotiations with preferred customers, who generally pay lower effective prices than retail pharmacies. Some large retail pharmacy chains might also receive rebates, but they would tend to be less than those of the preferred buyers. In the case of some health plans or PBMs, the buyer does not actually take physical possession of the drugs. Rather, the health plan’s members obtain their drugs from a retail or mail-order pharmacy. However, the health plan or PBM may still receive a rebate directly from the manufacturer for certain drugs. Thus, the effective price, net of any rebates, still tends to be lower for preferred buyers than for retail pharmacies.

As mentioned earlier, HMOs, PBMs, and other third party buyers utilize formularies. Manufacturers place great value on being included in a formulary. This is particularly true when there is more than one drug in a therapeutic class. Inclusion in a formulary essentially means that a drug will be used more often than (or even exclusively over) competing drugs with the same therapeutic function. Moreover, if preliminary evidence is correct, particular drugs will be used more widely precisely because they are listed on a formulary.²⁰ Such inclusion is thought to promote the adoption of a drug by other formularies or by organizations that do not use a formulary at all.

Formularies provide preferred buyers with some degree of leverage and flexibility in response to price increases. A manufacturer could, for example, refuse to offer a rebate or offer a rebate that is less than that offered by a competing manufacturer for a therapeutically equivalent drug. However, the preferred buyer could refuse to include the lower-rebated (and hence higher-priced) product in the formulary and replace it with the therapeutically equivalent product of a manufacturer who would be willing to offer a larger rebate. The lower-rebated (higher priced) manufacturer would be denied the benefits of being included on a formulary. Thus, the ability of the formulary to potentially exclude a manufacturer from a significant portion of the market provides the manufacturer with an incentive to offer rebates to preferred buyers. The manufacturer may prefer not to offer lower prices (which might have taken the form of rebates), effectively charging a higher price. However, the forgone benefits of being included in the formulary could outweigh the revenue from higher prices.

²⁰See Berndt, Ernst R., Robert S. Pindyck, and Pierre Azoulay, “Network Effects and Diffusion in Pharmaceutical Markets: Antiulcer Drugs,” National Bureau of Economic Research, Working Paper 7024, March 1999.

Relative to third-party buyers, retail pharmacies have a more limited flexibility in their purchasing decisions. Unlike the third-party buyers, retail pharmacies do not have any exclusionary mechanisms such as a formulary, nor would such a mechanism be economically sensible. The determination of which drugs consumers will obtain from the retail pharmacy is made by the physician (or by the physician and the health plan in the case of an insured customer) and depends heavily on the preferences of that physician. For example, Physician A may prefer to prescribe Prozac for a patient with depression while Physician B may prefer to prescribe Paxil for another patient with similar symptoms. Both patients may choose to have their prescriptions filled at the same pharmacy. That pharmacy would either have to stock both drugs or have to turn down the patronage of one of the patients. Turning down customers would result in lost revenue. This is true for independent pharmacies and chain pharmacies alike. Although manufacturers have no incentive to provide drugstores with a preferred buyer discount, chain drugstores may obtain volume-based discounts for some prescription drugs. However, these volume-based discounts would likely be smaller than the rebates obtained by preferred third-party buyers.

Retail Pharmacies

Retail pharmacies may offer discounts and rebates to third-party buyers to gain access to their large memberships. Uninsured (cash paying) consumers are not offered similar discounts and, therefore, tend to pay relatively higher prices than those covered by plans using third-party buyers. The apparent willingness of retail pharmacies to offer discounts and rebates to these preferred customers indicates that retailers, in some instances, exercise some control over prices. Recent Standard and Poor's *Industry Surveys* suggest that the drugstore industry tends to be highly competitive.²¹ A number of forces have converged to squeeze pharmacy margins, including the rapid growth of managed care plans, competition with supermarket pharmacies, mail-order pharmacies, and other non-traditional suppliers of prescription drugs.

Third-party buyers generally are not willing to pay the same prices as other buyers for the use of retail pharmacy services. In their drive to control costs, health plans and other third-party buyers pay drug retailers a wholesale drug reimbursement rate (generally, the average wholesale price (AWP)) for the cost of the drugs, plus a fixed dispensing fee. As pharmacy sales have shifted from a cash basis to one in which an insurance plan covers some or all of its members' prescription drug costs, continuing efforts by insurers to cut costs have had a significant impact on pharmacies. According to one survey, drugstores' "gross margins on prescription sales have fallen significantly from what they once were."²² This survey goes on to note that reimbursement rates based on the AWP leave drug retailers with little if any profit.²³

²¹Standard and Poor's, 1998 and 1999.

²²Standard and Poor's. *Op.Cit.* p. 19.

²³Ibid.

Thus, pharmacies are placed in a situation not unlike that faced by pharmaceutical manufacturers: in order to gain access to a large customer base controlled by third-party buyers, pharmacies are forced to differentiate between those buyers who can demand discounts and those who cannot. Standard & Poor's *Industry Survey* explains in plain language the extent to which sellers (in this case, drugstores) exercise control over prices:

For much of this decade, the PBMs' rules were simple: they offered drugstore chains predetermined, take-it-or-leave-it rates to dispense third-party prescriptions under the programs that they administered. Pharmacies that didn't agree to these terms risked losing access to existing and potential customers who were members of that plan; those that acceded to the rate dictates risked losing money on each prescription.²⁴

One response of the retail pharmacy sector has been to purchase PBMs. Walgreen, CVS, Rite-Aid, Eckerd, and American Stores each operate PBMs that are able to deliver prescription drugs through their extensive networks of retail outlets. Drugstores have also retaliated against low margins by dropping unprofitable third-party contracts.²⁵

Buyer Behavior at the Retail Level. At the retail level, individual consumers appear to be the predominant buyer of prescription medicines. However, of the individuals who patronize retail pharmacies, some are cash-paying customers and others are clients of third-party buyers. As in the manufacturing segment of the pharmaceutical market, third-party buyers in the retail segment are not willing to pay the same prices as other buyers, namely uninsured consumers. Third-party buyers will, therefore, attempt to obtain the best price possible, and in some cases, they can refuse to reimburse members who use pharmacies that are outside of their plan.

Price is one important factor influencing an individual consumer's decision to patronize a pharmacy. In addition, consumers tend to purchase goods and services that are aligned with their individual tastes and preferences. For example, an individual consumer may prefer to patronize a pharmacy located a few blocks from his or her home over another pharmacy that is located farther away. Another preference that may lead a consumer to patronize a particular pharmacy is whether he or she knows the pharmacist personally.

Other consumers may have very different sets of preferences. For example, an uninsured elderly person on a fixed income may prefer to travel some distance to purchase a prescription drug, if that drug is offered at a substantially lower price. If the drug has to be taken on a regular basis, this may solidify the preference for traveling further to acquire the medicine at lower cost. It is difficult to generalize about the individual tastes and preferences of all uninsured consumers and, although economic theory suggests that the possibility that a consumer may prefer a store with higher prescription prices to one with lower prices if certain non-price or non-drug factors are important, there is little in the way of empirical evidence that demonstrates

²⁴Ibid.

²⁵Ibid., p. 20.

that uninsured consumers on fixed incomes allow non-price factors to predominate in their choice of which store or other prescription source to patronize.

Nevertheless, it is quite possible that some consumers will maintain long-standing relationships with higher-priced stores rather than switch to a store that offers less service or no personal relationship with a pharmacist. Indeed, one has only to observe that the choices and behavior of insured consumers are usually influenced primarily by the preferences of the insurer and not by their own preferences to understand that such preferences are not immutable. Given the rapidity with which third-party buying has become a commonplace in the United States, it is worth noting that preferences are subject, after all, to market forces.

There is little reason to believe that third-party buyers have non-price preferences—although their insured consumers (their members) may well have such preferences. Third-party buyers are not likely to be willing to pay higher prices in exchange for non-price benefits such as better service or closer location. A straightforward example of a type of pharmacy that offers little in the way of non-price benefits is the mail-order pharmacy. Members who use mail-order pharmacies must wait longer to receive their prescriptions than they would at a retail pharmacy. Members also do not come in direct contact with a pharmacist when they use a mail-order pharmacy, which may affect the perceived level of service that the member receives. That some health plans and PBMs aggressively encourage their members to use mail-order pharmacies suggests that the non-price benefits of purchasing from a local pharmacy are more important to many of the insured than the potential savings they might realize through use of mail-order prescriptions.

Many consumers (members of health plans as well as the uninsured) may purchase prescriptions at the same pharmacy. Health plan members will probably care about some of the non-price characteristics of the pharmacy—even if their insurer or third-party payer does not. One could speculate that location and relationship with a pharmacist might be as important to some insured consumers as to uninsured consumers.

What about uninsured individuals? Are they less likely to be responsive to the price of a good than to non-price characteristics (such as store location or quality of service)? If the uninsured were provided benefits similar to those available to consumers enrolled in insurance plans or HMOs, one might expect that the uninsured would behave in the same manner as insured individuals. However, not all consumers are alike. While preferences for non-price benefits lead some consumers to stay put, others may shop around; there will inevitably be *some* consumers who are very sensitive to prices. For these consumers, price will be the most important factor in choosing a pharmacy and, to the extent that they can, they will shop around until they find the lowest-priced pharmacy.

In the absence of detailed studies of the specific behavior and preferences of uninsured consumers, policymakers will have difficulty predicting their responses to various proposals to make prescriptions available to the uninsured. While consumer response may be difficult to predict with any certainty, economists and non-economists alike have sought to determine how proposed changes in policies on

prescription drugs and the uninsured might affect the ability of manufacturers, retailers, and insurers to participate in a system characterized by differential pricing.

Why is Differential Pricing a Problem?

A number of concerns have been raised with respect to price differentiation. One major concern is whether it is manufacturers or retail pharmacies which are chiefly responsible for charging significantly higher prices to the uninsured, including many seniors. A second concern has to do with allegations that manufacturers charge the elderly more than they otherwise might to compensate for discounts that they give to preferred buyers. A third concern is that price differentiation allows manufacturers to reap excessive profits. Fourth, critics argue that price differentiation is a form of anti-competitive pricing that harms competitors and consumers. Finally, price differentiation is considered by some critics to be a principal source of inequity in a system in which the poorest consumers pay the highest prices. Each of these issues will be briefly examined.

Manufacturers, retailers, and price differentiation

Price differentiation in the pharmaceutical industry has been heavily criticized by the press and by some policymakers. Pharmaceutical manufacturers are the target of much of the criticism of differential pricing, although retail pharmacies have not been entirely immune from criticism. Some observers believe that pharmaceutical manufacturers are responsible for most of the differential between prices paid by third-party buyers and those paid by uninsured consumers. This was the conclusion of two recent studies.²⁶ Using information found in a GAO study, however, the CBO determined that several fee-for-service federal health plans (FEHBP) achieved greater savings from pharmacy discounts than from manufacturer discounts.²⁷ Whether the GAO study is applicable to most private health plans is debatable. While evidence suggests that manufacturers and retail pharmacies have the ability to use price differentiation, it would be difficult to draw any definitive conclusions without further detailed studies that examine pharmaceutical pricing data that are not generally available to the public.

²⁶See the studies prepared by the minority staff of the House Committee on Government Reform and Oversight: "Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans," Updated October 20, 1998, and "Prescription Drug Pricing in the 29th Congressional District in California: Drug Companies Profit at the Expense of Older Americans," October 19, 1999. One of these reports covers a small sample of commonly used prescription medicines in selected locations around the United States; the other study examined pricing for the same drugs in California's 29th Congressional District, which includes parts of Los Angeles.

²⁷CBO, 1998, and GAO, 1997.

“Cost shifting”

Another criticism of price differentiation is that it leads to “cost shifting,” which purportedly occurs when sellers raise the prices they charge the uninsured in order to compensate for discounts given to third-party buyers. It is claimed that this occurs mostly at the manufacturing level, although at least one study claims that it occurs at the retail pharmacy level as well.²⁸

The concept of cost shifting (whether from third-party buyers to uninsured consumers, from HMOs to retail pharmacies, or from foreign buyers to U.S. consumers) is a hotly debated topic. Many economists reject the “cost shifting” idea. They maintain that sellers in the pharmaceutical market price differentiate by dividing buyers into separate markets based on the price sensitivity of buyers. Then sellers choose the optimal price in each market, and these optimal prices are unrelated to each other. If any firm raises the price of a good above its optimal level, it will sell fewer goods and, as a result, earn a lower profit.²⁹ Thus, if a seller in the pharmaceutical market charges a lower price to a third-party buyer, it does so because that buyer is part of a different market and has different demand sensitivity. In theory, the seller offers third-party buyers a lower price and charges a separately determined higher price to buyers in other markets. Each buyer is thus segmented into groups and pays the price dictated by his or her price sensitivity.³⁰

Studies have suggested that the high prices that the uninsured pay relative to the lower prices available to the customers of third-party buyers amount to cost-shifting.³¹

²⁸Serafini claims that cost shifting occurs at the manufacturing level. Marilyn Werber Serafini, “Bitter Pills,” *National Journal*, October 31, 1998; Kolassa, of the University of Mississippi, claims that cost shifting occurs at the retail pharmacy level. E.M. Kolassa, “Analysis of the Minority Report on Pharmaceutical Prices,” Mimeo, no date; Sager and Socolar claim that cost shifting from foreign countries to U.S. consumers occurs. Alan Sager and Deborah Socolar, “Affordable Medications for Americans (AMA): Problem, Causes, and Solutions.” Presented to the Prescription Drug Task Force, U.S. House of Representatives. July 27, 1999.

²⁹A well established economic principle, the law of demand, states that as price increases, quantity purchased decreases. Thus, as firms raise prices above the optimal level, the quantity decrease offsets the price increase.

³⁰CBO, 1998, p. 24. CBO’s conclusion is based on the analysis of price differentiation found in Jean Tirole, *The Theory of Industrial Organization*. Cambridge, MA: The MIT Press, 1988, pp. 137-139.

³¹U.S. Congress. Committee on Government Reform. “Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans.” Minority Staff Report Prepared for Rep. Henry A. Waxman. Updated Nov. 9, 1999; Schondelmeyer, Stephen W., “Competition and Pricing Issues in the Pharmaceutical Market,” PRIME Institute, University of Minnesota, August 1994. A critique of the 1998 update of the Government Reform Committee minority staff report was released by the Pharmaceutical Research and Manufacturers Association of America (Phrma) in April 1999: Danzon, Patricia. “Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross National Studies,” The Wharton School, University of Pennsylvania, April 1999. A link to this study

(continued...)

And while economists are in broad agreement that cost shifting could make the seller worse off, information and data concerning the private decisions of sellers in the pharmaceutical marketplace are unavailable. If we assume that economic theory is correct and cost shifting does not take place between segmented groups of buyers, the lack of information on how groups are segmented or prices set makes it difficult to know what specifically is determining the observed price differentials. An unexplainably wide price differential, without further information, is not dispositive of whether cost shifting is occurring.

Excessive Profits

Another criticism of price differentiation is that it sustains high profits for pharmaceutical manufacturers.³² According to economic theory, a firm will not price differentiate unless doing so maximizes its profits. Thus, because pharmaceutical manufacturers choose to price differentiate, one could infer that they earn higher profits than they would if they were to charge a uniform price.

Price differentiation may be a less successful profit-maximizing strategy for retail pharmacies. Some retail pharmacies reportedly are choosing to end price differentiation by refusing to deal with third-party buyers because of the relatively low reimbursement rates paid by some third-party buyers -- rates that sometimes fall below pharmacies' costs.³³ Thus, some pharmacies have chosen to stop segmenting groups of customers into the insured and the uninsured because some third-party buyers are unwilling to pay the full cost of the drug.

While price differentiation may be a profit-maximizing strategy, there is no established relationship between the absolute level of company profits and the use of price differentiation. High profitability is not necessarily related to price differentiation.

Anti-competitive pricing

Price differentiation has also been criticized on the grounds that it is anti-competitive. Indeed, the Robinson-Patman Act (15 U.S.C. §§13, 13a, 13b, 21a) outlaws unjustified price differentiation related to interstate commerce. However,

³¹(...continued)

may be found at <http://www.phrma.org/press/newsreleases//1999-04-19.40.phtml>. See also: Government Reform Committee Minority Staff, "A Response to Patricia Danzon, Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross National Studies," April 22, 1999.

³²Text of H.R. 664, the Prescription Drug Fairness for Seniors Act of 1999.

³³Low reimbursement rates by private third-party buyers are causing some independents to deal only with cash-paying customers (see Terry Pristin, "Rebelling Against Managed Care: A Small Pharmacy Stops Accepting Insurance Plans," *New York Times*, June 4, 1998). Low reimbursement by Medicaid is causing some large chains to quit filling Medicaid prescriptions in some areas (see Robert Berner, "Medicine Chess: Pharmacies Say Rates Paid By Rite Aid Unit Are Doing Them In," *Wall Street Journal*, June 30, 1999).

price differentiation does not violate the Robinson-Patman Act if the price differences are related to differences in cost or if the price differences are the result of a seller meeting the competition of another seller.³⁴ In 1994, a civil class action suit was filed by thousands of retail pharmacies against 25 pharmaceutical manufacturers, seven wholesalers, and one mail-order pharmacy. The retail pharmacies alleged that the industry's differential pricing practices were anti-competitive.³⁵ Most of the defendants settled the case. However, a directed verdict was entered in favor of those defendants that did not settle. The court found that price differentiation by manufacturers and wholesalers did not violate federal antitrust laws.³⁶

A 1999 staff report by the Federal Trade Commission (FTC) raised numerous concerns that price differentiation in pharmaceuticals has the potential to be anti-competitive.³⁷ The report "suggests that antitrust authorities need to apply the standard case-by-case approach to antitrust analyses of vertical and horizontal issues that arise in this industry."³⁸ Differential pricing potentially raises competitive concerns, but the authors of the report concede that careful evaluation of alternative efficiency explanations needs to be completed before challenging pricing or other strategies at issue.

Price differentiation is not necessarily inconsistent with competition; it may occur when the consumer can choose among four or five products, or in monopolistic markets, so long as entry is easy. The FTC report concludes that in order to assess whether pharmaceutical price differentiation harms competition, one must evaluate the extent to which firms can enter or expand in the market. Price differentiation is also criticized on the grounds that it harms consumers. The FTC report describes a number of scenarios that may give rise to anticompetitive behavior that is harmful to consumers, but it does not analyze the consequences of price differentiation at a level of detail adequate to reach firm conclusions.

Equity Considerations

Several other criticisms of price differentiation have been put forth. These criticisms, which are tied to notions of equity and public health, identify serious flaws in a system that would allow separate markets to be constructed in which those least able to afford expensive prescription medications are those who must pay the highest

³⁴For more information on the Robinson-Patman Act, see CRS Report 94-726 A, *Discriminatory Pricing and the Robinson-Patman Act: An Overview; Some Exceptions*, by Janice E. Rubin.

³⁵For an economic analysis of the case, see F.M. Scherer, "How US Antitrust Can Go Astray: The Brand Name Prescription Drug Litigation," *International Journal of the Economics of Business*, vol. 4, no. 3, 1997.

³⁶See *In re Brand Name Prescription Drugs Antitrust Litigation*, N.D. Ill., No. 94 C 897, 1/19/99.

³⁷Federal Trade Commission. Bureau of Economics. *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change*. Staff Report, March 1999. See: <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>

³⁸*Ibid.*, p. xii.

prices. Because of equity issues, legislation has been introduced in the 106th Congress that seeks to solve the problems faced by the uninsured elderly. Some have pointed to price differentiation as one of the major factors contributing to high drug prices for uninsured and under-insured seniors. Uninsured consumers, particularly the elderly, pay far higher prices than third-party buyers and often are the least able to afford the higher prices they are charged. For some, the decision to purchase medicine may reduce their ability to buy other necessities.

Policy Approaches

Several policy approaches have been under consideration to address the issue of prescription drug pricing. One approach is to create a prescription drug benefit for Medicare beneficiaries. Another approach would require manufacturers to grant discounts to individual consumers that are equivalent to those achieved by large, third-party buyers. A third, more limited approach, which was enacted by Congress and signed by President Clinton (P.L. 106-387) in October 2000, would attempt to lower prescription drug prices by facilitating the importation of pharmaceuticals from foreign countries.

Creating a Prescription Drug Benefit

The policy approach that has received the most attention among policymakers is the creation of an outpatient prescription drug benefit for Medicare beneficiaries. Currently, Medicare does not provide coverage for most outpatient prescription drugs. This approach would target the elderly, a segment of the population that tends to use the most drugs. All of the proposals put forth thus far would use private entities, likely pharmacy benefit managers (PBMs) to manage the benefit.³⁹ However, the proposals differ over whether the government or private entities would bear the risk of coverage (and thus pay for expenses incurred by beneficiaries). There is also debate about which seniors should be covered under such a benefit, what cost-sharing arrangements should be adopted, and the amount that should be covered.⁴⁰

Supporters of using private entities to manage a prescription drug benefit note several advantages. First, the government would have access to the same prices as large, third-party buyers without having to resort to administered prices. This would allow prices to be determined via market forces, much the way prices are determined between PBMs and sellers of prescription drugs in the private sector. Second, PBMs tend to adopt systems that track patients' medications. These systems can alert pharmacists to potential contraindications and allergies that the patient might

³⁹ For a discussion of pharmacy benefit managers, and their role under a prescription drug benefit for the elderly, see CRS Report RL30754 *Pharmacy Benefit Managers*, by Christopher J. Sroka.

⁴⁰ For a discussion of the major legislative proposals introduced in the 106th Congress, see CRS Report RL30584 *Medicare: Selected Prescription Drug Proposals in the 106th Congress*, by Jennifer O'Sullivan.

experience. Arguably, the tracking systems that PBMs implement could increase the quality of pharmaceutical care that seniors receive.

There are some challenges to using private entities to manage a prescription drug benefit for the Medicare population. The most cited challenge involves the way PBMs control costs. PBMs often restrict patient access to certain drugs and certain pharmacies in order to obtain savings. These practices, which already generate some controversy when used in the private sector, may lead to a public backlash if implemented under a public program. However, many elderly already receive health services from some sort of managed care organization, so they already have experience with the implementation of cost control mechanisms.

Manufacturer Discounts

Another approach to address prescription drug prices is to expand manufacturer discounts to the uninsured and elderly. Proposals using this approach have taken different forms. At the federal level, some have proposed mandating discounts equivalent to those already granted to “favored” buyers. In May 2000, Maine enacted a law that would allow the state to negotiate discounts on behalf of the uninsured; however, a federal court issued an injunction prohibiting the state from implementing the law.⁴¹ Vermont enacted a law that extends Medicaid drug discounts to seniors and low-income individuals who do not otherwise qualify for Medicaid drug coverage.⁴²

Supporters of plans to extend manufacturer discounts point out that this approach does not incur a cost to the government. They also believe that lower prescription drug prices would save taxpayers additional money because increased drug use would reduce the use of more expensive treatments, many of which would be paid by Medicare or Medicaid.

However, the pharmaceutical industry opposes plans to extend manufacturer discounts, and contends such proposals constitute price controls. The industry argues that extending discounts would reduce research and development (R&D), leading to the introduction of fewer new drugs. Supporters of manufacturer discounts argue that the industry, the most profitable by certain measures, can afford to offer discounts while still maintaining current levels of R&D spending.

⁴¹ The injunction is currently under appeal. The federal district court ruled that the Maine law was unconstitutional because it interfered with interstate commerce. See “Federal Judge Prohibits State From Enforcing New Drug Price Control Law,” *Health Care Policy Report*, BNA Inc., October 30, 2000.

⁴² This law is currently being challenged in federal court. In order for Vermont to extend those discounts, the state needed a waiver from the U.S. Department of Health and Human Services and the Health Care Financing Administration. The pharmaceutical industry, represented by the Pharmaceutical Research and Manufacturers of America (PhRMA) claims the waiver is illegal because Vermont’s program does not comply with federal Medicaid law. For more information, see Dana A. Elfin, “Drug Industry Sues to Block State From Implementing Discount Drug Plan,” *Daily Report for Executives*, BNA Inc., December 15, 2000.

Access to Drugs from Foreign Countries

It is generally accepted that prescription drug prices are lower in many foreign countries than in the United States. Several factors explain this phenomena: foreign governments often impose price controls on prescription drugs, income varies among countries, and liability laws differ among countries.⁴³ Recently, anecdotal accounts have appeared in the press describing seniors' trips to Canada or Mexico to buy prescription drugs at lower prices.

Until October 2000, however, federal law and Food and Drug Administration (FDA) policy made it difficult for large quantities of drugs to be imported into the United States. All drugs sold in the U.S., including imported drugs, must be manufactured in compliance with what FDA considers "good manufacturing practices." The FDA's policy was to assume that, unless the importer has proof to the contrary, imported drugs were not produced using good manufacturing practices.⁴⁴ Compliance with FDA's good manufacturing practices was seen as burdensome for importers because the foreign seller of the drug might not have accurate documentation proving that the drug was produced in an FDA-approved facility using FDA-approved methods. The restrictions on importation affected mostly trade in large quantities; for imports of a small quantity (limited to a 90-day supply), the policy generally was not strictly enforced.

As the policy debate over prescription drug prices intensified, many policymakers began to see large-scale drug importation as a way of lowering prescription drug prices. Under this approach, wholesalers and pharmacies would be allowed to import large quantities of drugs at lower, foreign prices. These entities would then distribute and sell these drugs to American consumers at reduced cost. This approach would not limit access solely to the elderly; all Americans would have access to imported drugs, although the elderly in particular could benefit since they consume a large portion of medications. The pharmaceutical industry opposes this approach, stating that it would expand foreign price controls to the U.S. market. Furthermore, the industry expresses concerns that drug importation could open up the possibility that unsafe or adulterated drugs could enter the country. Supporters of this approach, however, argue that sufficient precautions could be adopted to minimize the likelihood that unsafe or adulterated products could enter the country. Moreover, supporters of this approach argue that it is unfair that Americans pay the highest prices for prescription drugs. Americans, supporters claim, are subsidizing research and development for the rest of the world.

⁴³ One researcher found that differences in liability laws explain a significant amount of the price differences between the United States and Canada. Because it is easier for consumers in the United States to sue if a drug leads to harmful effects, U.S. drug prices are higher to compensate manufacturers for this risk. See Richard L. Manning, "Products Liability and Prescription Drug Prices in Canada and the United States," *The Journal of Law and Economics*, April 1997.

⁴⁴See "Information on Importation of Drugs," prepared by the Division of Import Operations and Policy, U.S. Food and Drug Administration. Available at <http://www.fda.gov/ora/import/pipinfo.htm>.

In October 2000, as part of the FY2001 Agricultural Appropriations bill (P.L. 106-387), an amendment to the Federal Food, Drug, and Cosmetic Act (FFDCA) was enacted to facilitate the importation and reimportation of prescription drugs.⁴⁵ Members of Congress who opposed the bill argued that its provisions could not be effectively implemented. Among other things, the legislation requires the Secretary of Health and Human Services (HHS) to promulgate regulations allowing pharmacists and wholesalers to import prescription drugs. The legislation allows the Secretary to adopt rules to ensure that the public health is protected. The legislation also requires importers to report certain information about the imported shipments, including information about their origin and destination. Under the legislation, manufacturers are prohibited from entering into explicit agreements or contracts with wholesalers that prevent importation. Several other provisions were included in the legislation, such as testing of shipments to determine if the imported drugs are safe. The legislation contained \$23 million in conditional funds to cover implementation costs in the first year. In order for the legislation to be implemented, the Secretary was required to demonstrate that the importation does not pose additional risks to the public and that importation would result in significant reduction in pharmaceutical costs.

However, it is not clear whether the amendment will be implemented. On December 26, 2000, Health and Human Services Secretary Donna E. Shalala announced that she would not issue rules to implement the legislation.⁴⁶ She stated that flaws and loopholes in the legislation make it impossible to demonstrate that the importation legislation would be safe or lower costs. Secretary Shalala characterized three provisions as such loopholes. First, the legislation allows manufacturers to deny importers access to FDA-approved labeling, which is required for all drugs sold in the United States.⁴⁷ Second, the law does not prevent manufacturers from indirectly interfering with importation, such as requiring foreign distributors to charge higher prices, limit supplies, or treat U.S. importers less favorably than foreign buyers. Third, the law is set to expire in five years, and this may discourage the private sector from investing in the necessary testing and distribution system. Moreover, according to Secretary Shalala, the taxpayer costs of implementing new safety monitoring would not offset savings from lower drug prices.

Observations

The issue of prescription drug pricing, which received much attention during the 106th Congress and in the 2000 congressional and presidential elections, is likely to

⁴⁵ For more information on P.L. 106-387, see CRS Report RS20750, *The Prescription Drug Import Provisions of the FY2001 Agriculture Appropriations Act, P.L. 106-387*, by Donna U. Vogt and Blanchard Randall IV.

⁴⁶ “HHS Secretary Declines to Implement New Pharmaceutical Reimportation Law,” *Health Law Reporter*, BNA, Inc., January 4, 2001.

⁴⁷ Many times, labeling on drugs sold in foreign countries does not meet FDA requirements for sale in the United States. To import drugs, importers would need the FDA-approved labeling that manufacturers place on the product when it is sold domestically.

continue to command attention during the 107th Congress. The complexities of ensuring access to affordable prescription drugs has so far prevented the emergence of a consensus. Many recent policy initiatives toward consumers with no prescription drug coverage have focused on the elderly.

Of the three policy initiatives outlined above, the creation of an outpatient prescription drug benefit under Medicare would potentially be the most far-reaching. While such a benefit would greatly reduce out-of-pocket expenditures for the elderly, there is a lack of agreement over whether government or private entities would bear the risk of coverage; which seniors should be covered; what cost-sharing arrangements would be adopted; and what level of expenditures would be covered.

The second approach, manufacturer rebates, would require that manufacturers provide discounts to pharmacies for prescriptions sold to seniors. Such discounts would be related to existing Medicaid discounts. Unlike the prescription drug plan for Medicare beneficiaries, the cost of the plan to government would not be an issue. However, pharmaceutical companies have opposed manufacturer rebates, arguing that lower revenues would lead to reduced revenues for research and development. Critics suggest that the level of research could be maintained if pharmaceutical firms spent less on advertising or accepted lower profits.

Finally, the 106th Congress passed a law allowing cheaper foreign drugs to be imported from foreign countries. The Clinton Administration refused to implement the law, arguing that the public could be exposed to additional risks, and that the cost of implementing the legislation would outweigh its benefits. As the 107th Congress considers these and other approaches, the debate will likely focus on how best to achieve affordable prices, safe products, new and innovative medicines, access to needed drugs, and an equitable distribution of the costs among the various parties (government, manufacturers, insurers, pharmacies, and consumers).