

PRICE COMPARISONS FOR PHARMACEUTICALS:  
A REVIEW OF U.S. AND CROSS-NATIONAL STUDIES

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EXECUTIVE SUMMARY

Several recent studies have been undertaken to determine whether pharmaceutical manufacturers are taking advantage of older Americans through price discrimination and, if so, whether this is part of the explanation for the high drug prices being paid by older Americans.<sup>1</sup> These studies attempt to measure price differentials for pharmaceuticals between different market segments within the US and between the US and Canada or Mexico. Specifically, these studies collected data on retail prices for the 10 brand name, prescription drugs with the highest annual sales to seniors in 1997 under the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE). The retail prices for the 10 drugs were collected from a sample of 75 pharmacies in seven congressional districts — 46 independent and 29 chain stores. In the domestic study, retail pharmacy prices to cash-paying customers for these 10 drugs were compared to Federal Supply Schedule (FSS) prices (hereafter, Minority Staff Domestic Report, 1998a).<sup>2</sup> The FSS prices are interpreted as prices to most favored customers, such as large insurance companies and HMOs. For the international comparison, prices for the same 10 drugs were compared in retail pharmacies in a particular congressional district in the US to retail prices in Canada and Mexico. The study for Maine (hereafter, Minority Staff International Report, 1998b) is illustrative of these cross-national comparisons.<sup>3</sup>

The Minority Staff Domestic Report reached the following conclusions:

- For these 10 drugs, the average differential between the retail price to cash-paying customers and the FSS price was 106 percent;
- The average price differential for other non-pharmaceutical consumer products was only 22 percent;
- These differentials were attributed primarily to manufacturer pricing policies, not to drugstores.

The Minority Staff International Report for Maine concluded that:

- Average prices in Maine to customers who buy their own drugs are 72 percent higher than the average prices in Canada and 102 percent higher than the average prices in Mexico.
- Discounts to preferred customers in the US and abroad result in cost shifting to US retail customers, including older Americans.

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<sup>1</sup> *Prescription Drug Pricing in the United States: Drug Companies Profit at the Expense of Older Americans*, Minority Staff Report, Committee on Government Reform and Oversight, US House of Representatives, September 25, 1998.

<sup>2</sup> *Ibid.*

<sup>3</sup> *Prescription Drug Pricing in the 1<sup>st</sup> Congressional District in Maine: An International Price Comparison*. Prepared for Rep. Thomas A. Allen, Minority Staff Report, Committee on Government Reform and Oversight, US House of Representatives, October 24, 1998.

After reviewing the methods and analysis in these two Reports, this study reaches the following conclusions:

- The Minority Staff Reports are based on a small, nonrepresentative sample of products and use seriously flawed methodology. That leads to exaggerated estimates of the magnitude of the price differences both between sectors in the US and between the US and Canada and Mexico. Moreover, the reasons for these differences are misinterpreted. These Reports therefore do not provide a sound basis for policy prescriptions.
- The Minority Staff Domestic Report is further flawed because it is apples-to-oranges, comparing prices at different levels of the distribution chain. It compares retail prices (prices charged by pharmacies) to cash paying customers with ex-manufacturer prices (prices charged by manufacturers) to federal customers. Retail prices reflect mark-ups charged by retail pharmacies and wholesalers, in addition to the manufacturer price, whereas the FSS price is a manufacturer-level price. Retail prices overstate ex-manufacturer prices for this sector by roughly 25.7 percent.
- Manufacturers are required by statute to give to the largest four federal customers a discount of 24 percent. This federal ceiling price (FCP) -- non-federal average manufacturer price minus 24 percent -- effectively becomes the ceiling for the FSS price. My estimate, based on the limited data available, is that these two factors alone — distribution margins and statutorily required FCP discount -- account for a retail-to-FSS differential of at least 65 percent.
- The median retail-to-FSS differential in the Minority Staff sample is 86.5 percent. Of this, three-fourths — or 65.4 percent -- can be explained solely by distribution markups and the statutorily mandated discounts. Adding an average discount to private customers of 10-15 percent would fully account for the median retail-to-FSS differential in the Minority Staff Reports of 86.5 percent.
- The Minority Staff Reports use a small, unrepresentative sample, confined to 10 branded prescription products with high sales volume, and excludes all generics. This sample is not representative of the range of drugs purchased by US consumers, including the elderly. Rather, the Reports appear to have sampled drugs which give atypically large discounts to nonfederal purchasers. These drugs will therefore have atypically low FSS prices and atypically high retail-to-FSS differentials, because manufacturers are required to give their best price to the FSS.
- The Minority Staff Reports base their conclusions on the simple average differential for these 10 drugs, whereas appropriate price comparisons use a representative sample and weight the products to reflect their relative importance in overall consumer budgets. An unweighted average of price ratios, as used by the Reports, violates standard principles of price comparisons and leads to results that are extremely sensitive to the sample used.
- GAO (1994) found that the median best price discount to private customers was 14-15 percent off the average manufacturer price, based on a study of the effects of the Medicaid best price provisions of the Omnibus Budget Reconciliation Act (OBRA 1990). Similarly, CBO (1996) found a weighted average best discount of 19 percent, based on a sample of roughly 800 brand name drugs. This is further evidence consistent with the conclusion here, that the Minority Staff Reports exaggerate typical best price discounts to private customers, hence *a fortiori* exaggerate

typical discounts to private customers.

- The smaller (22 percent) retail-to-FSS differential found for other consumer products is readily explained by several factors. First, manufacturers of innovator drugs are required by law to give the four largest federal purchasers a discount of at least 24 percent off their average price to private purchasers. No such mandatory discount applies to other consumer products on the FSS schedule. Second, manufacturers of other products are free to choose whether or not to list their products on the FSS, with no penalty for non-participation other than foregone opportunity for sales to federal purchasers who use the schedule. By contrast, pharmaceutical manufacturers are required to list their products on the FSS as a precondition for their products to be reimbursed under the Medicaid program. Third, retail pharmacy mark-ups are likely to be higher for drugs than for other consumer products that are subject to more competition from other retail outlets.
- The Minority Staff estimates that the average U.S.-Canada price differential is 72 percent. This estimate is also seriously upward biased, for similar reasons of biased sample and inappropriate methods. Our analysis of Canadian vs. US prices in 1992 (Danzon, 1996; Danzon and Kim, 1998) concluded that Canadian prices are between 13 percent lower and 3 percent higher than the US, depending on the price index used. Our estimates were based on the full sample of all matching compounds and use standard index number methods, hence are more robust than the Minority Staff estimates based on 10 drugs and unaccepted price index methods. The GAO (1992) study, which concluded that US prices were 32 percent higher than Canada and is cited by the Minority Staff Reports, similarly used a small and unrepresentative sample and inappropriate index methods.
- For Mexico, the only available more broad based evidence (NERA, 1998) suggests that prices are significantly lower in Mexico than in most European countries. This is not surprising, in view of Mexico's lower per capita income, weak patent protection before 1992 and even thereafter, and more price sensitive customers.
- Price discounting to managed care in return for increased volume is not limited to pharmaceutical manufacturers — it is common practice for hospitals, physicians, retail pharmacists, and other suppliers to managed care purchasers. Like these other suppliers, pharmaceutical manufacturers grant discounts to managed care and other customers who can move market share.
- Discounting to more price sensitive market segments is also common business practice in other industries, as evidenced by senior discounts for movie theatres, early bird discounts for restaurants, and advance purchase discounts on airlines. Such differential prices based on demand sensitivity can increase overall social welfare, particularly in the case of industries with significant joint fixed costs and low marginal costs, such as pharmaceuticals, airlines, restaurants and movie theatres (Danzon, 1998).
- Charging different prices to different market segments does not imply cost shifting, contrary to the assertion in these studies. Simply economics shows that a manufacturer who serves two separate markets rationally determines the price to charge in each of the two markets independently. If the markets are separate, giving a discount in one market does not affect the price charged in the other market.
- If pharmaceutical manufacturers are required by law to charge the same price in all sectors, these sectors are no longer independent. In this case, if a firm is required to give a best price discount to one sector equal to the lowest price given to the other sector, the result will be to increase prices in the sectors that previously received the largest discounts. Such a price increase occurred

after the enactment of OBRA 1990, which requires best price discounts for Medicaid. Between 1991 and 1993, the median best price discount given to HMOs declined from 24 percent to 14 percent, for group purchasing organizations (GPOs) the median best price discount declined from 28 percent to 15 percent (GAO, 1994). Similarly, CBO (1996) found that the weighted average best price discount declined from 36.7 percent in 1991 to 19.3 percent in 1994.

- Appropriate insurance coverage for the elderly is an important policy issue. The evidence here and from other sources suggests that coverage could best be provided through choice between competing private sector health care plans, as in Medicare+Choice or the Federal Employee Health Benefits Program. Many of these plans provide savings not only from discounts on manufacturer prices but also savings on distribution margins and use of mail order, in addition to quality controls. GAO (1997) found that, of the savings to the Federal Employee Health Benefit Program from use of a pharmacy benefit manager (PBM), roughly 50 percent of the estimated 20-27 percent savings resulted from discounts achieved on distribution costs and only 21 percent (of the 20-27 percent) was due to manufacturer discounts. Simply providing an indemnity benefit, through the traditional Medicare fee-for-service program, would exacerbate the problem of inelastic (price-insensitive) demand in the retail sector.
- The proposal in HR 664, to require sales to retail pharmacies at the lowest prices available to federal government purchasers, is likely to result in higher prices to managed care and other nonfederal buyers, as occurred following OBRA 1990. Moreover, since this approach does not increase the price-sensitivity of retail customers and does not require retail pharmacies to lower their prices, this approach does not assure that any reduction in ex-manufacturer prices accrues to customers as lower prices, rather than accruing to pharmacies as higher retail margins.

## **PRICE COMPARISONS FOR PHARMACEUTICALS: A REVIEW OF U.S. AND CROSS-NATIONAL STUDIES**

### **1. Introduction**

Several recent studies have been undertaken to determine whether pharmaceutical manufacturers are taking advantage of older Americans through price discrimination and, if so, whether this is part of the explanation for the high drug prices being paid by older Americans. These studies attempt to measure price differentials for pharmaceuticals between different market segments within the US and between the US and Canada or Mexico. Specifically, these studies collected data on retail prices for the 10 patented, nongeneric drugs with the highest annual sales to seniors in 1997 under the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE). In the domestic study, retail pharmacy prices to cash-paying customers for these 10 drugs were compared to Federal Supply Schedule (FSS) prices (Minority Staff Domestic Report, 1998a). The FSS is a price catalog for purchases by federal agencies. The FSS prices are interpreted as prices to most favored customers, such as large insurance companies and HMOs. The retail prices for the 10 drugs were collected from a sample of 75 pharmacies in seven congressional districts — 46 independent and 29 chain stores. For the international comparison, prices for the same 10 drugs were compared in retail pharmacies in a particular state in the US to retail prices in Canada and Mexico. The study for Maine is discussed here (Minority Staff International Report, 1998b).

The domestic Report concluded that for these 10 leading drugs, the average differential between the retail price to cash-paying customers and the FSS price was 106 percent. The average price differential for other, non-pharmaceutical items sold in pharmacies was only 22 percent. These differentials were attributed primarily to manufacturer pricing policies, not to drugstores.

The international Report concluded that average prices in Maine to customers who buy their own drugs are 72 percent higher than the average prices in Canada and 102 percent higher than the average prices in Mexico. Both the domestic and the international studies conclude that discounts to preferred customers in the US or abroad result in cost shifting to US retail customers, including older Americans.

The purpose of this study is to review two examples of these Minority Staff Reports, one Domestic and one International. All the Reports use similar methods and reach similar conclusions. Hence this study applies to them all. The main conclusion here is that the Minority Staff Reports are based on flawed methodology that leads to seriously upward biased estimates of the price differences between sectors in the US and between the US and Canada and Mexico. Both Reports are based on a small, unrepresentative sample of branded drugs; it also excludes generics. The Reports use methods that ignore standard principles of price indexes and lead to unreliable results. The domestic study is further biased by comparing prices at different stages of the distribution chain. It compares retail prices (prices charged by pharmacies) to cash paying customers with ex-manufacturer prices (prices charged by manufacturers) to federal customers. Retail prices reflect mark-ups charged by retail pharmacies and wholesalers, in addition to manufacturer prices, whereas the FSS price is a manufacturer-level price. The resulting estimates of the magnitude of the price differences both within the US and between the US and Canada and Mexico are seriously upward biased. The Reports ignore other evidence from two studies based on much larger samples — GAO (1994) and CBO (1996) — which show median best price discounts of 14-15 percent and weighted average best price discounts

of roughly 19 percent. Further, the Reports focus on pharmaceuticals, ignoring the fact that discounting is common for all medical services sold to managed care and is also common in other industries. The competitive benefits to consumers from discounting are also ignored.

In this paper, Section 2 summarizes standard principles for measuring price differences for pharmaceuticals. Section 3 reviews the domestic retail-to-FSS comparison (Minority Staff Report, 1998a). Section 4 reviews the comparison of US prices with prices in Canada and Mexico (Minority Staff Report, 1998b). Section 5 discusses the economic basis for discounting in health care in general and pharmaceuticals in particular, including the cost-shifting argument. Section 6 comments briefly on policy implications.

## **2. Measuring Price Differences for Pharmaceuticals: General Principles**

The Minority Staff Reports violate basic principles for performing price comparisons. The comparison of prices between different markets, different countries or different time periods poses methodological challenges that have been addressed in extensive economic literature on price indexes.<sup>4</sup> (certain widely accepted principles for price comparisons are applied by the US Bureau of Labor Statistics in its calculation of price indexes, and by the analogous statistical agencies in most other countries.)

### **2.1 Sample Selection**

In order to draw valid conclusions about the average price level for drugs to consumers in different markets, the sample must include a representative market basket of the drugs consumed. This can be achieved by taking a random sample or stratified random sample. Where the comparison is between two quite different markets — say, the US and Mexico -- the sample should be selected to be representative of both markets under comparison.

**Life Cycle.** In the case of pharmaceuticals, it is important to draw products from all stages of their product life, since prices can vary significantly over the life of a product and this life-cycle price profile differs across countries. For example, Berndt et al. (1993) found that the US producer price index (PPI) for drugs was significantly upward biased due to disproportionate representation of drugs in the middle years of their life cycle and under-representation of new products and generics. The sample should also be representative of the mix of dosage forms, strengths and packs for the products included, since the mix of forms and packs differs significantly across countries, reflecting regulatory, medical and cultural differences.

**Generics** A further requirement for a representative sample for pharmaceuticals is that it include generics as well as branded originator compounds. Generics accounted for 46 percent of scripts in the US in 1998, whereas generic penetration is lower in many other countries.<sup>5</sup> Since generics offer consumers a lower price alternative to branded products, the exclusion of generics biases upward the estimate of the average price level in a country with relatively high generic penetration and relatively low generic prices, such as the US. A similar logic argues for including over-the-counter (OTC) drugs, which do not require a doctor's prescription, where these offer a substitute for prescription products. Since both the market share and relative prices of generic and

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<sup>4</sup> See, for example, Diewert (1987) and references therein.

<sup>5</sup> The US figure is from IMS America. In particular, generic market share is negligibly small in countries with strict price regulation for branded products, such as France and Italy.

OTC products differ systematically across countries in ways that are related to the regulatory regime, valid conclusions about the effects of regulation on prices must be based on samples that include generics and OTCs.

Sample Selection Bias in the Minority Staff Reports The Minority Staff Reports are based on a sample comprised of the ten patented, nongeneric drugs with the largest annual sales to older Americans in 1997, as reported by the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program. PACE is a prescription drug assistance program for low-income seniors in Pennsylvania. PACE has a formulary of covered drugs, which are presumably selected based in part on the size of the rebate offered to PACE by manufacturers.

This sample selection violates principles of random selection and is likely to be systematically biased for several reasons. Third, since the selection criterion is products with the highest annual sales, by dollar value, not by number of prescriptions, the sample is biased towards products with relatively high prices, other things equal.

Second, the selection criterion admits only patented drugs, even though generics account for 46 percent of prescriptions countrywide. First, by focusing on leading products sold under a formulary such as PACE, the sample is likely to consist disproportionately of mature products that tend to give relatively large discounts. Simple economics predicts that manufacturers would give larger discounts to get on formulary for mature products that have several close competitors and are nearing the end of their patent life, than for newer products, particularly to a large formulary. CBO (1996) provides some evidence consistent with this. This conjecture, that this sample is biased towards products that give relatively large discounts, is supported by the evidence below. To the extent that this sample is biased towards products that give atypically large discounts, the estimates of retail-to-FSS price differentials for this sample overstate typical differentials, because large discounts to nonfederal purchasers such as PACE lead to lower FSS prices, as described below.

## 2.2. Matching drugs across markets

Ideally, prices should be compared for products that are identical in all relevant respects in the different markets -- same active ingredient, same manufacturer, same brand name, same dosage form, strength and packsize. In practice, a given compound is often produced by different manufacturers in different countries, due to licensing and generic entry; most products are available in several dosage forms, strengths and packsizes, which also differ across countries. Given this heterogeneity in the product range, applying strict matching criteria excludes many products from the comparison and hence makes it unrepresentative. Thus there is a trade-off. If strict comparability is required along all possible dimensions (chemical composition, manufacturer, dosage form, strength, pack-size) the sample of drugs that can be included in the comparison will be a very small and non-representative subset of the range of medicines that is available to consumers in each country. In particular, the requirement of matching manufacturer or brand is counterproductive, because it limits the comparison to compounds sold internationally by subsidiaries of multinational companies. It automatically excludes most generics and licensed products.

The preferred approach is therefore to compare the price of the molecule, computed as the volume-weighted average of prices charged by all manufacturers of the compound, including originator, licensees and generic manufacturers (Danzon and Kim, 1998). This implicitly assumes that generics are perfect substitutes for the innovator brand. Although this assumption may be too strong in some cases, it is less misleading than the assumption that generics are not substitutes, which is implied by omitting generics from the comparison, as the Minority Staff has done. Indeed, treating generics as perfect substitutes for brands is consistent with the reimbursement practices of most

managed pharmacy benefit programs and Medicaid in the US and with public payers in Canada, Germany and the UK.

### 2.3 Retail vs. Wholesale vs. Manufacturer Price

In principle, prices for pharmaceuticals can be measured at three points on the distribution chain: the ex-manufacturer price is the price at which the manufacturer sells to the wholesaler; the ex-wholesale price is the price at which the wholesaler sells to the retail pharmacy; and the retail price is the price at which the pharmacy sells to the consumer. Thus the retail price differs from the ex-manufacturer price due to the wholesale and retail distribution mark-ups. Value added taxes further widen the gap in some countries. In practice, true transactions prices may not be readily observable because of discounts related to volume, cash payment, etc., and because manufacturer prices, wholesale and retail markups may differ by class of customer, product and location.

In general, because retail prices include significant distribution markups that differ across markets and between products within some markets, comparisons of retail prices do not provide accurate measures of differences in ex-manufacturer prices. If comparisons are to be made at retail price levels, as the International Report purports to do, then information on the wholesale and retail margins is also required, if these retail price comparisons are to serve as a basis for valid inferences about differences in ex-manufacturer prices.

The Domestic Report is an apples-to-oranges comparison, because it compares retail prices to cash customers with the FSS price which is an ex-manufacturer price. This is discussed in detail in section 3.1 below.

### 2.4 Price and Volume Measures

There are several possible measures of quantity for pharmaceuticals, each with a corresponding measure of price — for example, price per pack, price per pill or dose, price per daily dose, price per course of therapy, or price per gram of active ingredient. Since countries differ in their range of dosage forms, pack sizes, strengths etc., comparisons are sensitive to the unit of measure used (see Danzon and Kim, 1998).

Moreover, a comparison that is based on price for a single strength/dosage form/pack size that is common in the US does not provide an accurate measure of price per course of therapy on average in the US or in the comparison countries, because price per pill and price per pack vary with pack size within and across countries. In particular, price per pill tends to decrease as pack size increases and price per gram tends to decrease with average strength. Some countries, including the US and Canada, permit distribution in very large packs to pharmacists who then split the packs for retail distribution. Other countries which do not permit pharmacists to split packs have much smaller average pack size, which tends to mean higher price per pill, since price per pill is typically lower in larger packs.

The Minority Staff Reports compare price for a single strength of a single form (tablets) and pack size that is supposedly typical for the US. The largest US packs, which have lowest price per pill, were apparently not used in these studies. For drugs that were included in the 1992 GAO comparison of prices in the US and Canada, the Reports use the same pack; for drugs not included in the 1992 GAO study, they used the dosage, form, and package size common in the years 1994 through 1997. No information is given about how a price was estimated for the comparison

countries if comparable packs were not available or were atypical. The 1992 GAO study used a larger pack size in Canada than in the US, which contributed to the upward biased estimates of US-Canada price differentials in that study. Similar bias probably applies to the Minority Staff Reports (1998a, b), but no information is given.

## 2.5 Standard Price Indexes: Weighting of products

Accurate comparison of the cost of medicines to consumers in different markets requires weighting the prices of different products in the market basket to reflect their relative importance in overall expenditures. When the relative importance of different medicines differs considerably across countries, there is no unique best weighting scheme. The analyst should choose the weights most appropriate to the context and question at issue.

The economic literature on price measurement has developed several standard price indexes, each of which reflects different assumptions and results in a different measures of cross-country price differences. In the context of a bilateral international price comparison between, say, Canada and the US as a base, the Laspeyres index weights each price by the volume of the US<sup>6</sup>. The Paasche index uses Canadian weights. The Fisher index is the geometric mean of the Laspeyres and Paasche indexes. If the current policy question is, What would be the cost of medicines to US consumers if they faced Canadian prices?, then a Laspeyres index that uses US consumption weights is appropriate. This implicitly assumes that US doctors and consumers would be unlikely to switch to Canadian consumption patterns, even if faced with Canadian prices, at least in the short run.

The Minority Staff Reports base their conclusions on the simple average of the price ratios, expressed as a percentage of the lower price, for the 10 products. There is no weighting for volume differences. This unweighted average is inconsistent with basic principles of index numbers (see Diewert, 1987). This simple average is extremely sensitive to the particular items in the sample. For example, in the 10 drug sample, if the two largest numbers are omitted, the average differential declines from 106 percent to 83 percent. Conversely, if the calculation includes two other drugs for which differentials of 1,407 percent and 584 percent are reported, the average differential increases from 106 percent to 254 percent! Clearly, the sample and methods used here do not provide a robust measure of average price differences.

## **3. The US Retail vs. FSS ( Best Price ) Comparison**

### 3.1 Retail vs. Ex-Manufacturer Prices

The Minority Staff Domestic Report (1998a) compares the retail pharmacy price, as a measure of price to cash-paying customers, including seniors, to the Federal Supply Schedule (FSS) price, as a measure of best price to large insurance companies and HMOs . This comparison is inappropriate because these prices are at different levels of the distribution chain. The price to cash customers is a retail price, hence it reflects wholesale and retail markups on top of the manufacturer price. By contrast, the FSS price is an ex-manufacturer price.<sup>7</sup> The Minority Staff Report (1998a) acknowledges but dismisses this issue, arguing that pharmacies appear to have relatively small

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<sup>6</sup> The volume weight corresponds to the measure of price. For example, if the price measure is price per gram, the weight is number of grams; if the price is price per dose, the weight is number of doses sold.

<sup>7</sup> The FSS prices are apparently reported net of a mandatory 0.5 percent Industrial Funding Fee that reimburses the VA for the costs of operating the Federal Supply Schedules Programs and recoups its operating costs from ordering activities (U.S. Code Section 552.238.77).

markups between the prices at which they buy prescription drugs and the prices at which they sell them (p. 7). The Report cites two pieces of evidence to support this conclusion: The average retail price for the ten most common drugs was only 4 percent higher than the published national Average Wholesale Price, and only 22 percent higher than the price available directly from one large wholesaler .

In fact, distribution markups are a significant contributor to the differences between retail and FSS prices. Contrary to the assertion in the Reports, the Average Wholesale Price (AWP) does not measure the average transactions price charged by wholesalers — the name is misleading. The AWP is a list price published by a pricing service. It serves as a benchmark from which pharmacy reimbursement and discounts are calculated, but actual average wholesale prices are significantly below the AWP. For example, a leading text on managed care states that managed care plans reimburse pharmacists at AWP minus 10-17 percent (Kongstvedt, 1996), which reflects the fact that pharmacists can acquire products at prices substantially below AWP. Similarly, 1997 HMO reimbursement rates to network pharmacies used an average discount off AWP of 14.2 percent, with a range of 10-20 percent (Emron, 1998 Managed Care Pharmacy Director CUE Program). Thus AWP significantly overstates the price at which pharmacies can purchase drugs.

A more plausible measure of the retail markup is obtained using the 22 percent markup over prices charged by the single wholesaler (McKesson) sampled in the Report. Differences in ex-wholesale prices charged by different wholesalers are probably small, since the wholesale sector is highly competitive. Thus a plausible assumption is that the 22 percent markup is representative of the average retail markup over the wholesale price. Consistent with this, a study of 5 leading drugs in Minnesota found that retail prices were 26 percent higher than pharmacies Wholesale Acquisition Cost. Thus the 22 percent retail markup used here may be conservative.

In addition, to obtain the ex-manufacturer price the wholesale margin must also be subtracted. This is typically roughly 2-4 percent of the average manufacturer s price (AMP).<sup>8</sup> Using these measures, if the average manufacturer s price (AMP) is 100, the ex-wholesale price is 103 and the retail price is 125.7 (100 x 1.03 x 1.22). Thus retail prices overstate the ex-manufacturer prices realized in the retail segment by roughly 25.7 percent.

### 3.2 The Federal Supply Schedule (FSS)

The federal supply schedule (FSS) for pharmaceuticals is a price catalog for purchases by federal agencies, including the Department of Veterans Affairs (VA), the Department of Defense, the Public Health Service, the Coast Guard and the Indian Health Service. The VA is the largest single purchaser, accounting for 71 percent of purchases from the pharmaceutical FSS in fiscal year 1996 (GAO, 1997). It is also responsible for negotiating the FSS prices with drug manufacturers. Under the Veterans Health Care Act of 1992 (P.L. 102-585-sec.603), manufacturers of innovator drugs — single and multiple source -- must make their products available on the FSS in order for their products to be eligible for reimbursement by Medicaid. Thus manufacturers face a significant economic penalty for failure to participate in the FSS. This in turn gives the VA leverage in negotiating FSS prices.

Under GSA procurement regulations, the VA in negotiating prices for the FSS must seek a price that represents the same discount off a drug s list price that the manufacturer offers its most-

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<sup>8</sup> The average manufacturer price AMP is typically roughly 2 percent below the manufacturer s list price, due to discounts routinely given to wholesalers.

avored nonfederal customer under comparable terms and conditions (GAO, 1997, p. 6, citing 48 C.F.R. sec. 538.270). To determine this best price, manufacturers are required to submit a commercial sales practices (CSP) form, which provides information on prices, terms and conditions, by product, charged to different customers. Whether a particular customer is considered comparable to the VA may be subject to negotiation and depends on various factors, including the terms and conditions of the commercial sale.

The Veterans Health Care Act also requires manufacturers of innovator drugs to sell these products to four agencies -- the VA, DOD, the Public Health Service and the Indian Health Service -- at a discount of at least 24 percent off their non-federal average manufacturer price (NFAMP). An excess inflation rebate is also required, equal to the percentage by which the price increase for this drug has exceeded the CPI in the prior period. Thus the federal ceiling price (FCP) is equal to  $NFAMP \times 0.76 \times (1 - p)$ , where  $p \geq 0$  is the excess inflation rebate. The NFAMP is a weighted average price for all non-federal classes of trade for each dosage form and strength paid by wholesalers, net of any cash discounts and chargebacks given to wholesalers. Thus discounts to all private customers are reflected in the NFAMP if these discounts are given directly to wholesalers. Omitted from the NFAMP are rebates that are given directly to final purchasers, such as a rebate given to a large HMO contingent on demonstrated market share performance. This mandatory federal ceiling price (FCP) discount applies to innovator products even after patent expiration. There is no FCP for generic products.

For innovator products, the FSS price may in theory be higher or lower than the FCP, depending on whether the best price to a comparable non-federal customer is less or greater than the mandated FCP discount. However, if the FSS price exceeds the FCP, the VA, DOD, PHS and Indian Health Service, which account for the great majority of FSS sales, would pay only the FCP. Thus the FCP tends to act as a ceiling on the FSS price. Thus, the FSS price tends to be the lower of: (1) the federal ceiling price, which is  $NFAMP \times 0.76 \times (1 - p)$ ; or (2) the lowest price given to a comparable nonfederal purchaser.

The evidence from a recent GAO report indicates that, for the majority of originator products, the FSS price is determined by the FCP mandated discount. In a review of FSS prices relative to FCP for Schedule Drugs as of September 30, 1996, GAO (1997) found that about 73 percent of products -- mostly generics -- were not subject to FCP. Although these FCP-exempt products account for a large fraction of products (a product is a single dosage form/pack), they account for only roughly 25 percent of sales to the VA. The remaining 27 percent of products, which account for about 75 percent of sales, are subject to FCP. These are the innovator products that are the subject of the Minority Staff Reports (1998a, b). Of these innovator products, 72 percent (or 19.3 percent of all products) had an FSS price at or above the FCP, implying that the best price to private customers was less than the mandated FCP.<sup>9</sup> Only 8 percent of products (28 percent of innovator products) had FSS price below FCP, hence had best prices to private customers that were lower than the mandated FCP, defined by a discount of 24 percent plus excess inflation off NFAMP. These products with FSS less than FCP were on average 52 percent below the NFAMP, as of Sept.30, 1996 (GAO, 1997, footnote 17).

Moreover, simple economics predicts that most private discounts are no greater than the minimum Medicaid-mandated discount of 15.1 percent off AMP, because any larger discount would

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<sup>9</sup> For most of these products with FSS above FCP (72 percent) the differential was less than 1 percent and probably due to the fee for the VA's administration of the FSS (GAO, 1997, p. 15 and footnote 17).

also have to be given to Medicaid. The Omnibus Budget Reconciliation Act of 1990 (OBRA) tried to reduce Medicaid's prescription drug costs by requiring that manufacturers give state Medicaid programs a discount equal to the greater of: (1) a fixed percentage (12.5 percent in 1991-2, 15.7 percent in 1993, 15.4 percent in 1994, 15.2 percent in 1995 and 15.1 percent thereafter) off the Average Manufacturer Price (AMP) to wholesalers for distribution to the retail class of trade; and (2) the best price given to any private customer. This matching requirement greatly increases the cost to manufacturers of giving discounts in excess of 15.1 percent to private customers. Giving a discount greater than 15.1 percent to a private customer would increase net revenue only if the additional private volume induced by the discount offset the lower price per unit on those private sales and the loss of revenue due to lower price per unit on sales to Medicaid. Since Medicaid accounts for 11 percent of sales on average, the Medicaid volume would usually be several times larger than any incremental private volume induced by the discount, making such discounting in excess of 15.1 percent off AMP rarely worthwhile.

The evidence from GAO (1994) and CBO (1996) is consistent with this prediction from simple economics, that requiring manufacturers to give their best price discount to Medicaid would reduce the discounts offered to private customers to the mandatory minimum discount of 15.1 percent. In a study of the effects of OBRA 1990, GAO (1994) found that, between 1991 and 1993, the median best price discount given to HMOs declined from 24.4 percent to 14.2 percent; for group purchasing organizations (GPOs) the median best price discount declined from 27.8 percent to 15.3 percent.<sup>10</sup> Thus by the first quarter of 1993, the median best price discount to private managed purchasers had fallen to about the minimum rebate required by OBRA of roughly 15 percent of AMP. Similarly, CBO (1996) found that the weighted average best price in a sample of roughly 800 brand name products declined from 36.7 percent in 1991 to 19.3 percent in 1994 (see Table 1). Although this evidence is from 1993 and 1994, it is likely to be still relevant today, since the Medicaid best price provisions are unchanged.

CBO (1996) notes that best price discounts on some products may still exceed 15.1 percent for several reasons. Larger discounts are more common for products with several competitors than for recently launched, single source products; for products with relatively small sales to Medicaid; and products to certain end users, such as academic medical centers.

The evidence that median best price discounts given to private customers are roughly 15 percent of the average manufacturer price to the retail sector, hence much smaller than the 106 percent average differential cited by the Minority Staff Reports, is further supported by estimates of savings achieved by pharmacy benefit management companies (PBMs). PBMs act on behalf of insurance companies, HMOs and self-insured employers to manage the pharmacy benefit. This includes negotiating discounts on drug prices with drug manufacturers and discounts on retail pharmacy margins with pharmacies who participate in the network. In a study of the effect of PBMs for the Federal Employee Health Benefit Program (FEHBP), GAO (1997a) estimated that PBMs reduced total pharmacy benefit costs by 20-27 percent, relative to what those costs would have been without the PBM. Of this total saving, the share attributed to manufacturer discounts was at most 21 percent, or 4-6 percent of total pharmacy benefit costs. A much larger share (52 percent of the saving, or 10-14 percent of total costs) was attributed to retail and mail order pharmacy discounts; maximum allowable cost (MAC) reimbursement for multisource compounds was the third largest

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<sup>10</sup> The median is the midpoint of a distribution, such that half the observations fall below and half above this point.

source of savings, yielding 14 percent of the total saving.<sup>11</sup> These figures for the FEHBP are similar to conventional wisdom on savings from PBMs. These quite modest savings are further evidence that the Minority Staff estimate of manufacturer discounts of 106 percent is grossly exaggerated as a measure of typical discounts.

These are several reasons why manufacturers may be willing, in some circumstances, to accept an FSS price that is low relative to much of their private business for several reasons. First, they are required by law to offer their products on the FSS, if they wish to receive reimbursement from Medicaid. Thus the choice is between foregoing all VA, DOD and Medicaid reimbursement or accepting the price offered for the FSS. Since Medicaid accounts for 11 percent of sales on average and the FSS sales are an additional 1-2 percent, refusing listing on the FSS would entail a potentially significant loss of sales for many products.<sup>12</sup>

Second, negotiating to resist a demand for a low FSS price is time consuming and costly, and may not be a good investment of resources, as long as the FSS accounts for only 1-2 percent of sales on average. If sales at FSS prices were a larger fraction of total sales, manufacturers would surely be more resistant to large discounts, as noted by several manufacturers during the debate over extending the FSS to state and local government purchasers (see GAO, 1997).

Third, many VA hospitals are affiliated with major medical centers and the VA is an important training ground for young physicians. Roughly 47 percent of medical residents rotate through the VA/DOD each year (U.S. Medicine Inc., 1998 Federal Market Facts). Manufacturers would rationally accept a relatively low price in such circumstances in order to assure widespread use of their drugs by these physicians in training, in the anticipation that these physicians would continue to use these products in their future careers. CBO (1996) argues that relatively large discounts may be given to medical schools for similar reasons.

A Minority Staff study of 5 leading drugs in Minnesota (Minority Staff, 1999) reports a 124 percent retail-to-federal price differential.<sup>13</sup> For the federal price, this study used the lowest federal price available. For 3 of the 5 drugs, this was the FSS price. For one drug the lowest price was the VA formulary price, and for another it was the VA's Blanket Pricing Agreement (BPA) price. Both the VA formulary and the BPA price are prices given in return for preferred status or volume performance. Not surprisingly, these are often lower than the FSS price.

### 3.3 Accounting for the Retail-to-FSS Differential

A simple calculation shows that the statutory 24 percent FCP discount and the retail and wholesale distribution margins account for a retail-to-FSS price differential of 65 percent. Adding in a discount to private customers of 15 percent raises the implied retail-to-FSS differential to 95 percent. To see this, recall that the calculation above showed that if AMP is 100, retail price is 125.7. Let us make the conservative assumptions that, because of minimal discounting to private customers, the NFAMP is equal to AMP and that the FSS price is equal to the FCP price, with the mandated minimum discount of 24 percent off NFAMP. Thus if NFAMP = AMP = 100, FSS is 76.

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<sup>11</sup> These figures are for the Blue Cross-Blue Shield Plan. The other two plans studied reported even smaller shares of savings attributable to manufacturer discounts and larger shares attributable to retail and mail order pharmacy discounts.

<sup>12</sup> GAO (1997) reports FSS sales at 1.5 percent of total pharmaceutical sales in the US, citing data from IMS.

<sup>13</sup> *Prescription drug pricing report: Minnesota's 6<sup>th</sup> Congressional District*. Minority Staff Report, Committee on Government Reform, US House of Representatives. April 5, 1999.

With these conservative estimates, the implied retail-to-FSS markup is 65.4 percent ( $1.257 / 0.76$ ). Thus the combination of distribution markups and statutorily required discounts together account for a 65.4 percent differential between retail and FSS price (see figure 2).

Alternatively, if we assume an average discount to private payers of 15 percent off AMP, then  $NFAMP = .85AMP$  and the implied retail-to-FSS markup is 94.6 percent ( $1.257 / (0.76 \times 0.85)$ ). If the average private discount is 10 percent, such that  $NFAMP = .9 AMP$ , then the implied retail-to-FSS markup is 84 percent ( $1.257 / (0.76 \times 0.9)$ ). To the extent that FCP includes an excess inflation rebate, such that the statutory discount off NFAMP exceeds 24 percent, the retail-to-FSS differential attributable to solely to distribution margins and legally mandated discounts would be larger. Thus of the median retail-to-FSS differential in the Minority Staff sample of 86.5 percent, three-fourths of this — or 65.4 percent -- can be explained solely by distribution markups and the statutorily mandated discounts. Adding an average discount to private customers of 10-15 percent would fully account for the median retail-to-FSS differential in the Minority Staff Reports (see figure 2).

In summary, for innovator products, manufacturers are required by law to give a federal ceiling price (FCP) equal to 24 percent off the NFAMP plus any excess inflation rebate, or the best price given to a comparable customer, whichever is lower. For the majority (72 percent in 1996) of innovator products, the FSS price is greater or equal to the mandated FCP, implying that best prices to most favored private customers are typically above or equal to the FCP. Distribution markups and the legally mandated 24 percent FCP discount alone imply at least a 65.4 percent retail-to-FSS differential, more if there is an excess inflation factor. Adding a 10 percent average discount to private buyers implies a 84 percent retail-to-FSS differential. Keeping discounts to private customers no more than 15 percent of AMP would usually be an economically rational strategy, given the Medicaid best price requirement. The evidence (GAO, 1994) confirms that the median best price discount fell to roughly 15 percent, following OBRA 1990 as predicted by theory.

To the extent that the drugs in the Minority Staff Report have retail-to-FSS differentials larger than the level that can be attributed, as shown above, to distribution markups, mandated discounts and private sector discounts of up to 15 percent, there are at least two possible explanations. First, actual retail margins in the sample pharmacies may exceed the average estimate of 22 percent used here. Second, the drugs in the sample may be drawn disproportionately from the 28 percent of products that have discounts in excess of the mandatory minimum 24 percent FCP discount. This would be consistent with the point made earlier, that by selecting the drugs that had the largest sales under the PACE program, the Minority Staff Reports sample disproportionately represents those drugs that give large discounts relative to other drugs. Thus this evidence tends to confirm that this is not a random sample. Rather, the study appears to have sampled drugs that give atypically large discounts, hence have atypically low FSS prices and atypically large retail-to-FSS differentials.

### 3.4 FSS prices for other commodities

The Minority Staff Report (1998a) compares the retail-to-FSS price differential for pharmaceuticals to the price differential on a selection of other consumer items. It concludes that the average differential for the other items is only 22 percent, compared to the estimated 106 percent for pharmaceuticals.

There are several problems with this comparison. First, as noted above, manufacturers of

originator drugs are required by law to give the four largest federal purchasers a discount of at least 24 percent off their average price to private purchasers. No such mandatory discount applies to other consumer products on the FSS schedule. Second, manufacturers of other products are free to choose whether or not to list their products on the FSS, with no penalty for non-participation other than foregone opportunity for sales to federal purchasers who use the schedule. By contrast, pharmaceutical manufacturers are required to list their products on the FSS as a precondition for their products to be reimbursed under the Medicaid program. Thus the penalty for not participating, at the mandatory minimum 24 percent discount, is loss of revenue not only from these federal purchasers but also from the Medicaid program, which accounts for a much larger fraction of sales.

Third, as noted above, the retail mark-ups are a significant fraction of the retail price for pharmaceuticals. Although I have no data on average retail markups for the other consumer products, I would expect them to be lower because there is greater competition between retail outlets in supplying other consumer products than in supplying drugs. Moreover, demand for drugs is likely to be more inelastic than demand for other consumer goods, due to insurance coverage of some cash-paying customers, the essential nature of some drugs, and the fact that prescribing decisions are made by physicians who are often uninformed or unconcerned about the relative prices of different drugs. Simple economics predicts that if demand for drugs is relatively inelastic, pharmacists would rationally charge higher markups on drugs than on other consumer items for which demand is more elastic.

Given the mandatory FCP discount, the greater penalty on pharmaceutical manufacturers for not participating in the FSS, and greater distribution markups on drugs, it is not surprising that the retail vs. FSS price differential is greater for pharmaceuticals than for other consumer products.

#### **4. Comparisons with Canada and Mexico**

The Minority Staff Report (1998b) compares prices for the same 10, brand name prescription drugs in the US to prices at a sample of 4 pharmacies in three provinces of Canada and three pharmacies in one town in Mexico. The Report finds that prices on average are 72 percent higher in Maine than in Canada, 102 percent higher than in Mexico. It concludes that drug manufacturers appear to be engaged in cost shifting. They charge low prices to consumers in Canada and Mexico and appear to make up the difference by charging far higher prices to senior citizens and other individual consumers in the United States.

There are several reasons why drug prices may be lower in Canada and Mexico. However, this study is based on severely flawed methodology and seriously overestimates the actual average differences.

##### **4.1 Canada**

Several factors may contribute to lower drug prices in Canada. First, there is lower exposure to product liability in Canada. Manning (1997) finds that this is a significant factor contributing to higher prices in the US than Canada. Second, Canada's federal government controls prices of new products and post-launch price increases are not permitted to exceed the rate of increase of the consumer price index (CPI). Third, until recently, these price controls operated under threat of compulsory licensing. If a manufacturer did not accept the government's price, the government could force the manufacturer of a patented product to license a generic producer to manufacture the product even though this nullified the patent protection. Under NAFTA this compulsory licensing is

no longer permitted. However, prices of products that were on the market under the compulsory licensing regime could still be affected because restrictions on price increases would prevent a catch-up price increase. Fourth, in addition to these federal government controls, some provincial governments in Canada operate other control mechanisms, such as the reference price system in British Columbia, which may constrain prices below the price permitted by the federal controls. Fifth, retail distribution markups may be lower in Canada than in the cash sector in the US. Precise comparisons are not possible because retail markups in Canada differ by province and by product.

Although these factors could lead to somewhat lower prices in Canada than in the US, the Minority Staff conclusion, that the average prices that senior citizens (in the US) must pay are 72 percent higher than the average prices that Canadian consumers must pay is exaggerated because of flawed methods. First, it is based on a sample of only ten products, all brand name products that are leaders by dollar volume of US sales, hence selected to be relatively high priced, other things equal. The sample excludes all generics, although generics account for over 46 percent of scripts in the US and generic prices are relatively low in the US. The sample also excludes OTC products.

Second, the study generally used the same single dosage, form and package size used by the 1992 GAO report comparing prices in the US and Canada, where available. For that study, if the US price is for the pack of 100 but that pack was not available in Canada, the GAO computed a Canadian price by linear imputation. For example, the price for a pack of 100 tablets was imputed by dividing the Ontario government's price for a 1,000 pack by 10. Since in fact price per tablet is typically lower in larger packs, this methodology results in systematic downward bias in estimates of Canadian prices relative to the U.S. No information is given on the selection of packsize for Mexico, but if the same linear imputation was used, then similar bias is likely. Moreover, the same linear imputations were apparently made for strength, which would further bias upward the estimates of US/Mexico differentials.

Third, the ten drugs are weighted equally, ignoring differences in market shares. As noted in section 2, these sample selection and weighting procedures are not robust and violate basic principles of price indexes that are accepted and used not only by academics but also by the Bureau of Labor Statistics and similar statistically agencies in other countries. For example, since the differentials for individual products range from 23 percent to 136 percent, the overall average is very sensitive to adding or deleting individual drugs from the sample.

The Minority Staff Report states that its finding, that retail prices are 72 percent higher in the US than in Canada, is broadly consistent with the findings of other analysis. In 1992, GAO looked at the prices that drug companies charge wholesalers for 121 prescription drugs and found that these prices were, on average, 32 percent higher in the US than in Canada. Since the 1992 study was of ex-manufacturer prices and the 1998 study was of retail prices, if both purport to describe the same market differentials as the Minority Staff Report, this would imply that retail pharmacy markups add an additional 40 percentage points in the US compared to Canada! The Report does not comment on this implication. It also does not comment on the fact that their 72 percent estimate of the differential is 125 percent higher than the GAO estimate of 32 percent, contrary to the claim that the findings are broadly consistent. In fact, the differences between these two estimates are not surprising. They further illustrate the sensitivity of comparisons to small and unrepresentative samples, particularly when the comparison is based on an unweighted average, as was used in both of the 1998 Minority Staff Report and the 1992 GAO report.<sup>14</sup>

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<sup>14</sup> GAO (1992) reported the average price for the market basket in the US to its average price in Canada. It also

In order to provide more reliable estimates of international price differences, we constructed price indexes using standard index number methods applied to a fully comprehensive data on all drugs available in the US, Canada and several other major markets in 1992. Using US consumption patterns as the weights, and comparing price per dose, our estimates of foreign prices relative to the US are as follows:<sup>15</sup> Canada +3.0 percent; Germany + 27.3 percent; France — 29.9 percent; Italy —9.3 percent; Japan —7.7 percent; Switzerland +44.4 percent; Sweden + 8.9 percent and the UK —23.9 percent (see Table 2). Note that these comparisons based on ex-manufacturer list prices do not reflect discounts to managed care, hospitals and government purchasers in the US. Thus these comparisons overstate average manufacturer prices in the US relative to the comparison countries.

A major conclusion of our analysis is that measures of international price differences for pharmaceuticals are very sensitive to the unit for measuring price, sample and weights used. We computed the comparisons using price per gram as well as price per dose, using different samples and different weighting schemes. For example, for Japan the estimates range from 28.2 percent higher than the US, using price per gram and US weights, to 55.2 percent lower than the US, using price per dose and Japanese consumption weights. There is no single right number. However, these estimates based on the full sample of products and packs, and using standard index number methods are clearly more accurate than the GAO estimate which was based on an unweighted average of prices for 121 drugs, using a single pack per drug and omitting all generics. It is noteworthy that using this distorted sample and inappropriate methods, GAO (1992) estimated the US as 32 percent higher than Canada (or Canada as 24 percent lower than the US), whereas using our fully representative sample, appropriate methods and US consumption weights indicated that Canada was 3 percent higher than the US based on price per dose, 13 percent lower based on price per gram (Danzon, 1996; Danzon and Kim, 1998. See also Table 2 below).

#### 4.2 Mexico

Mexico is not an appropriate benchmark for price comparisons with the US for several reasons. Mexico is at a less advanced stage of economic development, has lower real wages and per capita incomes, and lower prices for many goods and services. A recent study, *The Health Care System in Mexico* (NERA, 1998) reports Mexican average per capita GNP at US\$3,670 in 1996 using market exchange rates (US\$7,660 at PPP exchange rates, that take into account differences in price levels between countries). Per capita expenditure on health care is estimated at 4.7 percent of GDP in 1997, or less than half the percentage spent by the US (13.5) from its much higher per capita GDP (Anderson and Poulrier, 1999). Per capita spending on health care was \$391 in 1997 in Mexico, compared to \$3,925 in the U.S. Medicines accounted for 28-32 percent of total health care spending (Nera 1998), a higher percentage than in most OECD countries, although comparable to other less developed countries. By comparison, in 1995 the proportion of health expenditure devoted to pharmaceuticals was 8.5 percent in the US; 13.6 percent in Canada; 15.9 percent in the UK and 16.7 percent in France (NERA, 1998, p. 77).

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reported the median of the price ratios.

<sup>15</sup> These comparisons are based on IMS data for single molecule drugs. The product is defined by molecule and 4-digit anatomical therapeutic category (MOL/ATC), regardless of manufacturer or brand name. The price for a multi-source molecule is the weighted average price over all manufacturers of that compound for a particular 4-digit therapeutic category. The indexes compare price per IMS standard unit, averaging over all packs, strengths and dosage forms of products in the molecule. The IMS standard unit is one tablet, one capsule, 10ml. of a liquid, etc. and is a rough proxy for a dose. This avoids bias that occurs if comparison is limited to a single pack. For more detail, see Danzon (1996) and Danzon and Kim (1998).

The NERA study points out that the range of pharmaceuticals is very different in Mexico than the US and other developed countries. Anti-infectives ranked first by value in Mexico, whereas they are about the fourth group in most developed countries. Cardiovasculars, which in 1996 were the top selling group in developed countries, ranked only fifth in Mexico.

NERA reached the following conclusion on prices for pharmaceuticals in Mexico:

The construction of indices which allow accurate comparisons of pharmaceutical prices in different countries is a difficult task. However, it appears that prices in the private sector in Mexico are lower than in most OECD countries and some support for this view can be shown by a simple comparison of average pack prices in Mexico and other countries. Expressed in US\$, even in 1995, Mexican prices were less than half European prices in 1993, although the limits to the usefulness of such a calculation (e.g. it may be comparing the prices of different products or packages) should be acknowledged. (NERA, 1998, p. 84).

NERA correctly emphasizes that conclusions based on this price comparison are tentative because it does not standardize for product mix. Nevertheless, it does strongly suggest that Mexican prices are low relative to a broad average of European prices, not just relative to US prices.

I would expect several factors to contribute to these lower prices in Mexico. First, as noted above, average per capita income and average spending on health care are much lower in Mexico than in the US. Second, Mexico did not enact patent protection for pharmaceuticals until the Ley de Patentes of 1991. However, this law did not apply patent protection to originator products already on the market and did not provide for pipeline protection. Thus drugs registered prior to the legislation remain subject to competition from copy products. Copy products are products whose production could be prevented under the 1991 law, if this had been in effect. Copy products are thus distinct from generics, which are legal copies introduced after patent expiration. According to NERA: Copy products are mainly a threat for the private sector: it is estimated that 95 percent of the private market is made up of products that could potentially be copied. The potential or actual existence of cheap copy products, which do not incur the costs of R&D and information dissemination borne by originator products, makes demand for originator products more price elastic, which constrains the prices that originator firms would rationally charge.

Third, although in practice medicines are designated as either prescription or non-prescription (OTC) in Mexico, NERA reports that many prescription medicines are thought, in practice, to be widely available without prescription. If so, price-sensitive consumers can more directly influence the choice between drugs than in a system such as the US, where the choice between prescription products is made primarily by physicians who may not know or be concerned about product prices. To the extent that this direct consumer purchase of supposedly prescription products in Mexico is significant, this would be another factor making demand in the private market in Mexico more price elastic than in the cash-paying market in the US. Consistent with this, there is anecdotal evidence that retail pharmacists in Mexico compete by offering products at prices below the maximum government price that is stamped on the box.

Given the lower income, government use of monopsony power, weaker patent protection and more price-sensitive consumers in Mexico, it is not surprising that prices are lower. However, since the differentials range from 20 percent to 280 percent (or over 1,000 percent if one other product is included), this small, unrepresentative and unweighted sample does not provide a basis for conclusions on average US/Mexico price differentials.

## 5. The Growth of Price Discounting in Health Care

### 5.1 Discounting and Managed Care

In recent years, insurance coverage of medical care, including outpatient pharmaceuticals, has undergone major changes in response to the demand for control of costs. In pharmaceuticals, managed pharmaceutical benefits are replacing the old world of unmanaged prescribing by physicians, in which patient co-payments were the main constraint on spending. Indeed, the management of pharmacy benefits has spread more broadly than managed care for other health services, as the pharmacy benefit is often carved out and managed even within traditional fee-for-service health plans.

A managed pharmaceutical care strategy is an efficient response of competitive markets to the fundamental problem of health insurance. The purpose of insurance is to protect consumers from the financial burden of medical expense. But by insulating patients from costs, traditional insurance has the unfortunate effect of making consumers and providers insensitive to costs. Unrestricted insurance thus tends to encourage overuse of medical services, driving up health spending. The inevitable increase in insurance premiums is paid initially by employers and governments, but ultimately these costs must be passed on to employees, consumers and taxpayers.

In response to the demand from consumers and payers for control over rising health insurance premiums, insurers compete by developing strategies that control costs in ways that are least burdensome to patients. Under traditional indemnity insurance, patients and providers had virtually unlimited freedom of choice, while insurance passively paid the bill. The only constraint was patient co-payment, which is a useful but limited cost control strategy. Co-payments operate by reducing the patient's financial protection. But since financial protection is the reason why consumers buy insurance, co-payment reduces the value of the insurance product.

The key characteristic of managed care is the use of strategies other than co-payment to control costs. With managed care, insurance is no longer a passive payment mechanism. Managed care entities are actively involved in determining the type and terms of services eligible for reimbursement. Whereas traditional insurance targeted incentives to patients through co-payment requirements, managed care targets the incentives of providers. A fundamental managed care strategy is to contract with selected, cost-effective providers who agree to accept lower prices and other contractual terms. Patients are encouraged or required to use these contract providers. Although patients thus forego some freedom of choice, many find this less burdensome than achieving the same degree of cost restraint through co-payments.

The application of managed care principles to pharmacy benefits entails the use of strategies similar to those used in managing other health services. Based on negotiations with the payer, the benefit manager establishes a formulary of preferred drugs and a network of selected retail pharmacies. Through education, financial incentives and other strategies, physicians and patients are encouraged to use drugs on the formulary. HMOs, PBMs and other entities that manage pharmaceutical benefits are able to negotiate discounted prices from manufacturers of drugs that are listed on the formulary, because on-formulary drugs tend to gain market share relative to unlisted drugs.<sup>16</sup> Formularies can be used to encourage generic substitution (use of a low-cost source of multi-

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<sup>16</sup> The PBM is an intermediary that negotiates and manages the drug benefit, in return for a fee. In many cases the

source drugs) and therapeutic interchange (substitution of a low-cost source among therapeutically similar drugs, subject to permission from the prescribing physician). Similarly, patients are encouraged to use network pharmacies that agree to accept discounted margins. The patient thus gives up some freedom of choice in return for lower cost.

The great majority of managed pharmacy benefits use formularies and generic substitution programs. Although most generic substitution programs permit members to choose brand-name over generic drugs, the patient is typically required to pay the difference or a higher co-payment. Similarly, a higher co-payment may be required for an off-formulary product. Thus to compete with generics and with potential therapeutic substitutes, manufacturers of brand name drugs must offer discounts or rebates.<sup>17</sup>

Patients covered by managed care plans are encouraged or required to purchase their drugs from a network of contract pharmacies or through mail order. Network pharmacies agree to accept a discounted retail margin in return for being in the network. Network participants can expect some increase in volume that is greater, the more restrictive is the network. Network pharmacies are generally also required to have computer capability that permits on-line checking of the patient's insurance status, monitoring drug use to assure compliance and guard against incompatibilities, etc.

The strategies used for management of pharmacy benefits are thus similar to managed care strategies for medical services in general. Network pharmacy providers and drug manufacturers agree to accept lower prices in return for the higher volume that flows to preferred providers and suppliers.

The price discounts negotiated by the pharmacy benefit manager or HMO are ultimately passed on to consumers in the form of a lower overall insurance premium or lower co-payments, or more comprehensive coverage, improved convenience and service, such as on-line verification of insurance status and direct billing of the insurance plan. This pass-through of the value of discounts to consumers is sometimes questioned, and indeed it is hard to measure directly. However the most telling evidence is the rapid growth of the share of pharmacy benefits that are managed. The growing market share of these plans implies that consumers are willing to accept the restrictions on choice in return for the cost savings.<sup>18</sup> Far from being anti-competitive, price discounting is a competitive strategy that benefits consumers.

## 5.2 Common Business Reasons for Price Discounting

Charging different prices to different consumers is a common business practice for many goods and services, including hospital, physician, retail pharmacy and other medical services. There are several reasons for price discounts, including volume discounts to reflect economies of scale, and quality discounts, to reflect differences in service or convenience dimensions of a product or service. For example, restaurants offer early bird discounts to attract customers at a time of day that is less convenient for most customers and hence has lower opportunity cost to the restaurant owner.

Perhaps most common are price discounts that may be unrelated to the manufacturer's costs

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PBM does not directly buy drugs.

<sup>17</sup> For details of managed pharmacy benefit programs, see Novartis (1998).

<sup>18</sup> Nobel laureate George Stigler first suggested this "survivor" test for relative efficiency (Stigler, 1958). In any competitive market, firms whose product or service offers consumers greater value for money will tend to expand their market share, at the expense of firms whose products offer consumers a less desirable trade-off between cost, quality and convenience.

but are driven by differences in price-sensitivity of consumers. Offering a lower price to customers who are more price-sensitive is designed to increase sales to these customers, without reducing revenues from the less price-sensitive customers. For example, senior citizen discounts are commonly offered by movie-theaters, buses, restaurants and some retail pharmacies. Price discounting of pharmaceuticals and other medical services closely resembles the discounting to price-sensitive buyers that is widely accepted in so many other markets. It would therefore be anomalous to disallow differential pricing in pharmaceuticals while permitting it for innumerable other goods and services, including other medical services. Note that a class of customers receives a discount if it is more price sensitive than other customer classes. Age, student-status, time of day, etc. act as proxies for price sensitivity. Thus the business reason for the discounts is the same for pharmaceuticals and other services, even if the class of beneficiaries differ. Seniors are targeted as price sensitive customers for many services but not for drugs because it is the physicians, not the patient who typically makes the product choice for drugs.

The Reports ignore the important economic distinction between discounts based on *absolute* volume, which are typically based on scale economies, and discounts based on *incremental* volume, which are motivated by price elasticity. The rationale for discounts to managed care purchasers of pharmaceuticals (and other medical services) is *incremental* volume, not *absolute* volume. Manufacturers offer discounts to HMO and pharmacy benefit managers in order for their drugs to be favored in the formulary, since formulary drugs tend to gain in market share relative to competitors. Thus discounting is a strategy to gain *incremental* sales and market share for the discounted drug.

By contrast, if the manufacturer were to offer discounts to one or more independent pharmacies, this might shift market share among pharmacies, if the discount is passed on as a lower price to customers, which is not guaranteed. But the discount would have no effect on the manufacturer's total volume. Total volume sold of any drug depends largely on physicians' prescribing patterns, and these are minimally affected by discounted prices to pharmacists. Any increase in volume for the manufacturer would require that patients perceive the lower price at the pharmacy and ask their physicians to switch them to the discounted drug. But most patients have little information about the relative price of alternative drugs -- and may not care, if their co-payment is a fixed amount per prescription, regardless of the price of the drug. Thus if the same discount were offered by a manufacturer to retail pharmacies who sell to the cash sector, this would not have the same effect as the same discount given for incremental volume to a managed care purchaser who is thereby persuaded to give the product favored formulary status.

It has been suggested that pharmacists could influence physicians to shift their prescribing towards specific drugs, just as HMOs and other pharmacy benefit managers do. However, such switching would be less subject to monitoring to protect the interests of patients. A managed care formulary typically must be approved by the health plan and plan sponsor, following careful review by the pharmacy and therapeutics (P&T) committee. This review explicitly attempts to make appropriate trade-offs between lower cost to the plan and restricted choice for patients, taking into account consumer preferences as reflected in market choices among health plans. Thus the influence that managed care formularies have over prescribing patterns is exercised subject to market pressures to assure reasonable quality of medical care and pass-through of savings to consumers. By contrast, if a pharmacist were to induce a physician to switch to a specific drug, there is no objective review of the therapeutic merit of the switch and less assurance that the patient ultimately gets a lower price in return for switching.

### 5.3 Discounts Benefit Consumers

Permitting price discounting benefits consumers in two ways. Most obvious is the benefit of lower prices. Sherer (1998) suggests that permitting discounting encourages competition between drug manufacturers. Standard economic analysis of the welfare effects of price discounting concludes that consumers overall benefit if total sales volume increases, which is plausible in the case of pharmaceuticals. More generally, the managed care revolution depends on the ability of health plans to negotiate discounted rates in return for shifting market share to network providers and suppliers, thereby increasing their volume. Selective contracting in return for price discounts is fundamental to controlling costs for hospital and physician services, as well as for pharmaceuticals.

Second, in the case of pharmaceuticals that incur significant costs of R&D, charging different prices to different markets or countries is consistent with the most appropriate feasible (second best optimal) method of paying for the costs of R&D. R&D is a global joint cost that serves all consumers, in all countries of the world that use the product. This R&D expense cannot be attributed to any single group rather than another. There is no presumption that the best way to recoup this cost is for all consumers to pay equally. On the contrary, the theory of Ramsey pricing (Ramsey, 1927) concludes that in such contexts, charging different prices to different consumers based on demand elasticity is the most efficient way of covering the joint costs. The application of these principles to price differentials with the US and between different countries is discussed in detail in Danzon (1998).

#### 5.4 Discounting Does Not Imply Cost-Shifting

These studies make the argument, that discounting to some customers leads to higher prices for other customers. The source cited for this is a Standard and Poor s Report.<sup>19</sup> But this argument is inconsistent with rational self-interested behavior on the part of a firm. Simple economic theory shows that if a firm serves two separate customer groups, say A and B, that differ in their price sensitivity, the firm would maximize its overall net revenue by charging different prices in the two markets. It would charge a higher price in the market that is less price-sensitive, say market A, other things being equal. If demand in market B now becomes more price sensitive, the firm will lower its price in that market. But the price to the less price-sensitive market A is unaffected -- indeed, to raise price to group A would actually reduce net revenue, since by assumption it had already set the price to maximize net revenue in that market. By analogy, increased price-sensitivity in the managed care market has led suppliers to offer discounts in that market, but this does not affect prices to other customers.

If the manufacturer is required to charge the same price in both markets, then the single price will be within the range of prices that would have been charged, had markets been separable. The evidence from GAO (1994) and CBO (1996) confirms that for similar reasons, the OBRA 1990 requirement that manufacturers give a "best price" discount to Medicaid equal to the largest discount given to any other private purchaser, led to a reduction in discounts available to HMOs and other private purchasers (see Table 1 and Figure 2).

## 6. Policy Implications

Appropriate insurance coverage for the elderly is an important policy issue. Roughly two

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<sup>19</sup> Herman Saftlas, Standard and Poor s, *Health Care: Pharmaceuticals, Industry Surveys 19-20*. December 18, 1997.

thirds of seniors do have coverage, either through employer-sponsored or individually-purchased Medigap coverage; through Medicaid, which covers out-of-pocket expense for seniors with low incomes; or by choosing an HMO that offers drug benefits, under the Medicare Plus Choice program. A recent study (Health Affairs, 1999) reports that 35 percent of seniors do not have outpatient drug coverage.

A full analysis of the issue of appropriate outpatient drug coverage for seniors is beyond the scope of this paper. However, if coverage is provided, the evidence here and from other sources makes clear that this should not be simply indemnity coverage, which would make demand in this market segment even more inelastic and increase costs. A preferred approach is to give seniors the choice between competing private-sector health plans that offer a managed pharmacy benefit, as in many Medicare+Choice options or the Federal Employee Health Benefits Program. Compared to traditional indemnity coverage, a managed pharmacy benefit would yield savings not only from discounts on manufacturer prices but also savings on retail distribution markups and use of mail order, in addition to quality control. As noted above, GAO (1997a) found that of the savings to the Federal Employee Health Benefit Program from use of a PBM, roughly 50 percent resulted from discounts achieved on distribution costs.

There have been proposals that would extend to the Health Care Financing Administration (HCFA) the ability to contract directly with PBMs or to use other private sector best commercial practices to provide prescription drugs to Medicare beneficiaries as an add-on to traditional Medicare. Although this might seem logical, managed pharmacy benefits are more appropriately provided as part of an integrated benefit, as in many private sector health plans. If a pharmacy benefit is simply added to traditional Medicare, it is likely to become one component of traditional Medicare's current silo-budgeting approach to cost control. Each service component — hospitals, physicians, home-health, pharmacy etc. — would likely tend to be subject to separate budget controls, implemented by fee or price controls, which provides no incentive for providers to seek efficient integration and mix of medical services.

Another alternative, which has been proposed in HR 664, is to require sales to the retail segment at FSS prices. By increasing the volume of business at FSS prices but without increasing price responsiveness, this proposed approach is likely to result in higher prices to private managed care and to government customers who currently receive discounts, as occurred after enactment of the Medicaid best price provision. Note that this prediction is entirely consistent with the analysis in section 5.4. There it was argued, based on economic theory, that as long as the two market segments — the relatively price-inelastic retail sector and more price-elastic managed care/GPO sector — are separate, the prices in the two markets are set separately, so giving a discount to the managed care/GPO sector does not result in a price increase in the retail sector. By contrast, once the retail sector is required to get the same price as the FSS, which is already required to get at least the best price given to the managed care/GPO sector, the two markets are no longer separate. A price discount given to the managed care/GPO sector must be matched in the retail sector. A manufacturer would now rationally charge a price based on the weighted average price elasticity in the two sectors. This will be above the previous price to the managed care/GPO sector. Hence tying the retail sector to the FSS price will result in an increase in prices to managed care/GPO and federal and nonfederal purchasers. This effect is likely to be large, because of the size of the large size of the retail sector.

The effect of requiring manufacturers to charge the same price in all market segments was illustrated following the enactment of OBRA (1990), as discussed above. This law tried to reduce Medicaid's prescription drug costs by requiring that manufacturers give state Medicaid programs rebates based on the best price given to other purchasers. Between 1991 and 1993, the median best

price discount given to HMOs declined from 24.4 percent to 14.2 percent; for group purchasing organizations (GPOs) the median best price discount declined from 27.8 percent to 15.3 percent (GAO, 1994). Thus by the first quarter of 1993, the median best price discount to private managed purchasers had fallen to about the minimum 15 percent rebate required by OBRA, as predicted by simple economics (Figure 1).

Similarly, the losers from a requirement that retail customers be offered FSS prices would be managed care and other federal and nonfederal customers, who would face increased prices. The restrictions on discounts could also reduce best price rebates to Medicaid and hence increase taxpayer costs of financing the Medicaid program. Pharmaceutical manufacturers would also lose in the short run, due to the loss of flexibility to adapt to the more complex market conditions that include managed and unmanaged customers. In the long run this would adversely affect incentives for investment in innovative products.

Moreover, there is no guarantee that any price decrease to pharmacists would be passed on to retail customers. Since demand in the unmanaged retail market is determined largely by physicians, who typically are unaware of prices charged by retail pharmacists, competition puts little pressures on pharmacists to pass on reductions in acquisition prices to the unmanaged, cash-paying patients. Consistent with this, pharmacists' margins are often higher for generic drugs than for branded drugs, because they do not fully pass through the lower acquisition cost of generics. Thus a requirement that retail customers be offered FSS prices would result in a loss to managed care and GPO patients that would almost certainly exceed any gain from lower prices to unmanaged retail customers.

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**TABLE 1. AVERAGE BEST-PRICE DISCOUNTS, 1991-1994 (In percent)**

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Year	Quarter	All Drugs		Top 100 Drugs, Unweighted
		Weighted	Unweighted	
1991	1	36.7	42.1	35.1
	2	35.8	41.7	34.1
	3	35.4	41.1	33.6
	4	35.0	39.5	33.2
1992	1	27.8	37.7	27.8
	2	26.7	36.7	27.8
	3	28.2	36.9	27.8
	4	24.9	33.4	24.7
1993	1	20.2	29.2	18.8
	2	20.2	28.5	18.5
	3	19.8	26.3	18.5
	4	19.9	25.7	18.8
1994	1	18.5	25.0	18.8
	2	19.3	25.2	19.3

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SOURCE: CBO: How the Medicaid Rebate on Prescription Drugs Affects Pricing In The Pharmaceutical Industry, Jan. 1996.

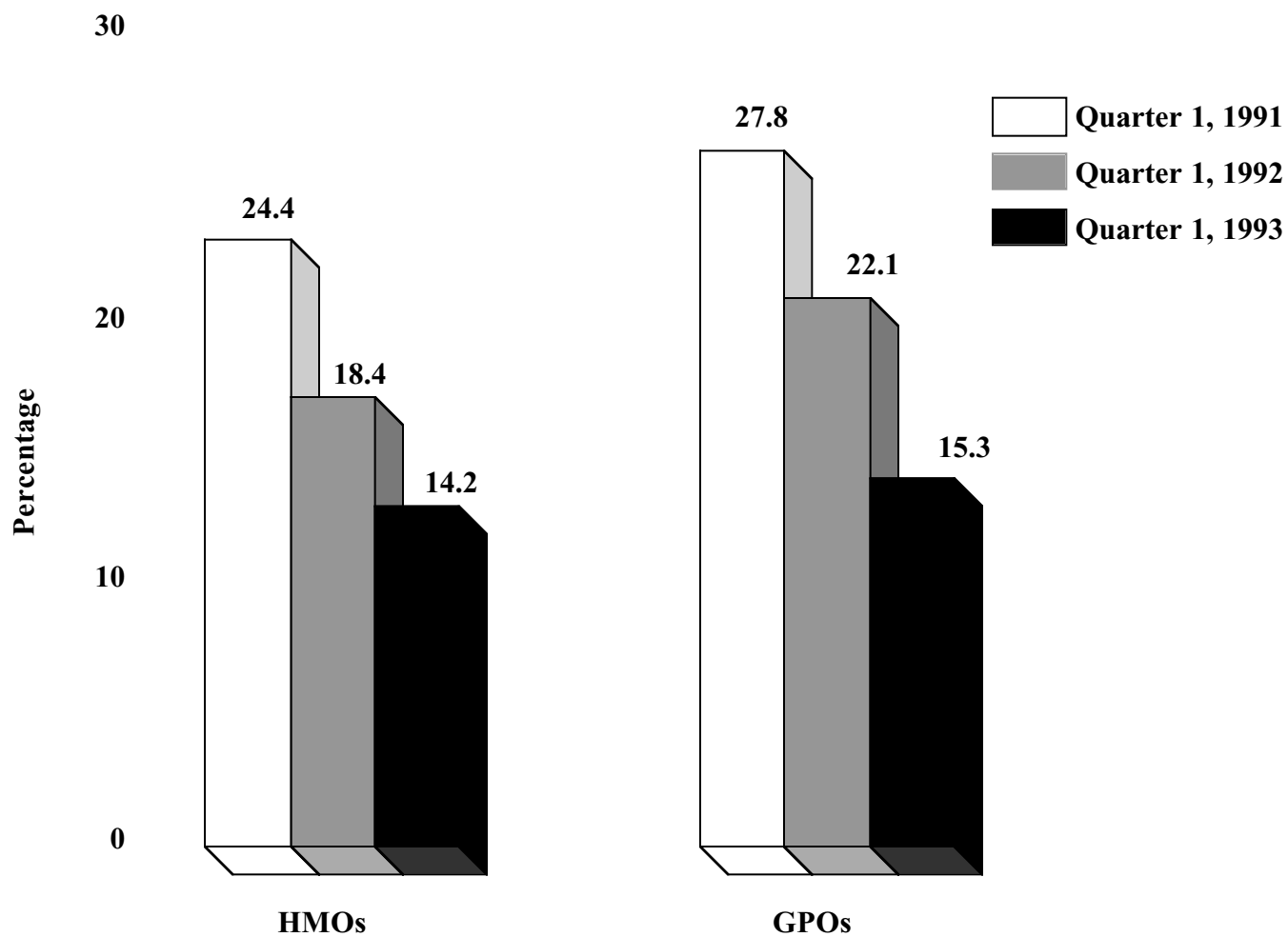
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**Table 2. Price Comparisons for All Matching Single-Molecule Drugs, 1992  
U.S. Weights**

	price/gram	price/dose	N
<b>Canada</b>	-13 .0	+3 .0	458
<b>Germany</b>	-2 .8	+27 .3	471
<b>France</b>	-43 .0	-29 .9	412
<b>Italy</b>	-26 .1	-9 .3	406
<b>Japan</b>	+28 .2	-7 .7	396
<b>Switzerland</b>	+4 .9	+44 .4	308
<b>Sweden</b>	-18 .9	+8 .9	261
<b>United Kingdom</b>	-32 .2	-23 .9	453

Source: Danzon, Patricia M. *The Uses and Abuses of International Price Comparisons.* In *Competitive Strategies in the Pharmaceutical Industry*, edited by Robert B. Helms. Washington, D.C.: AEI Press, 1996.

**Figure 1: Changes in Median Best Price Discounts for HMO and GPO Drugs, 1991 to 1993**



SOURCE: GAO: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals, Aug. 1994.

**Figure 2. How Distribution Margins and Mandated Discounts Contribute To Retail-to-FSS Ratio.**

