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Pharmaceutical Prices and Expenditures*

Stuart O. Schweitzer and William S. Comanor

INTRODUCTION

The press frequently reports on the difficulties people have in paying for prescription drugs. An article in the New York Times states, "Perhaps no issue touches as many lives as the cost of medication, which is why it is consuming the political landscape this year".¹ The author continues, "Prescription drugs are now the fastest-growing part of the nation's health care bill" (Ibid). An article in the Wall Street Journal noted substantial increases in pharmaceutical spending during 1997 and 1998, and stated that over the two year period, "insurers and health maintenance organizations spent 16.8 percent more on prescription drugs."²

These observations are hardly new. Pharmaceutical prices have been a matter of concern for nearly half a century. Our political leaders frequently comment on the increasing prices of new pharmaceuticals and deplore their consequences, particularly for elderly consumers who require large quantities of drugs and must often pay for them from their own resources. In 1961, the Kefauver Committee of the United States Senate produced a report on drug prices,³ that followed an extensive set of Hearings. Thirty years later, the same theme was repeated in 1993 Hearings before the Senate Special Committee on Aging. The Committee Chairman, David Pryor, stated: "Millions of older Americans go to bed at night wondering if they will be able to afford their medications...New drugs are selling in the United States at prices which are simply staggering. Unless I have read from the wrong economics textbook, this

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appears to be market failure at its worst...Where the market has not, will not, or cannot work, we must take prudent actions to assure that drugs are priced reasonably." 4

Despite major changes in the United States health care system since the 1950s, public discourse toward the pharmaceutical industry has remained fairly constant. The issue of pharmaceutical costs is long-standing. The purpose of this chapter is to discuss the issue's underlying causes and consider some possible solutions.

Unfortunately, part of the concern over drug expenditures is misplaced because of a failure to recognize that drugs are an integral component of the medical care process. In many cases drugs are a substitute for other medical care inputs, such as hospital stays and physician visits. H₂ Antagonists, like Tagamet and Zantac, for example, have practically eliminated the need for ulcer surgery, while anti-psychotic drugs have substantially reduced the need for mental hospital stays. For both of these drug classes, pharmaceutical expenditures rose after their introduction. Fortunately nobody expressed concern about the "problem of rising drug costs then," and the effect on overall medical care costs has been favorable.

However, not all drugs are cost-saving substitutes. Some, like the so-called "clot-busters" used in emergency rooms for heart-attack patients, are complements, making other services more efficient and improving outcomes. While these drugs have also lead to rising pharmaceutical expenditures, few would deny their value in increasing the quality of health outcomes. Thus, drugs can be both substitutes and complements to other healthcare inputs.

The concern over pharmaceutical costs is heightened by a lack of clarity of the nature of the problem. Spending on any good or service is a function

edition). San Francisco: Jossey-Bass Publishers, 2000 (in press).

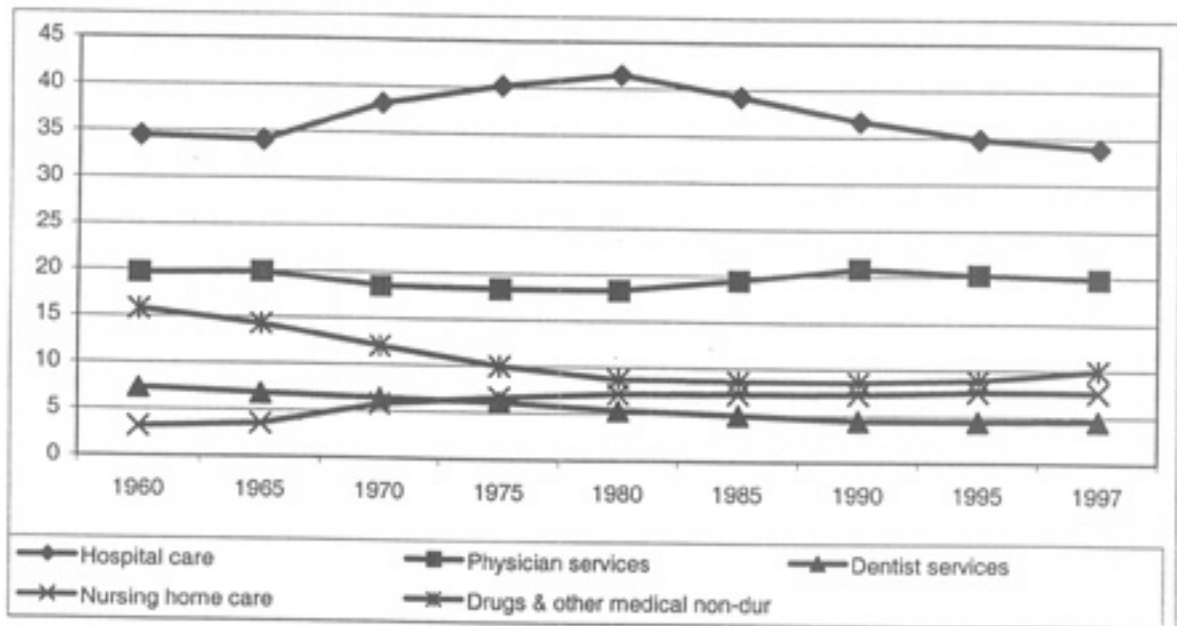
of both price and quantity. Is the problem of rising drug expenditures due to rising quantities of pharmaceuticals that are consumed? Or is it due to rising prices? The answers to these questions is complicated by the role played by rapid technological innovation in this industry, which leads to the frequent replacement of older products by newer ones. Often newer products are more expensive than the older ones, so that expenditures may rise because of displacement - even if prices of all drugs, new and old, and the number of prescriptions were to remain constant.

To understand rising drug costs, we first review trends in drug expenditures in the United States. Next we look at U.S. drug prices, considering first a series of issues that make the measurement of drug prices especially difficult. We then look at the evidence on whether U.S. drug prices are higher than those in other countries. We also examine the inter-temporal relationship between price increases and quality changes to determine whether pharmaceutical prices have increased after correcting for therapeutic improvements. Then, we describe the factors determining drug prices in the United States. Of particular importance are the roles of therapeutic advance and competition. Finally, we discuss a series of policy options for containing pharmaceutical expenditures. Some of these are directed at consumers, some at physicians, and still others at manufacturers. Current efforts to control pharmaceutical costs are a blend of all three approaches.

THE PROBLEM OF DRUG EXPENDITURES

The shares of pharmaceuticals and other components of the U.S. health care system from 1960 through 1997 are shown in Figure 1.

Figure 1 Share of National Health Expenditures by Type: 1960-1997



Source: Health United States 1999.

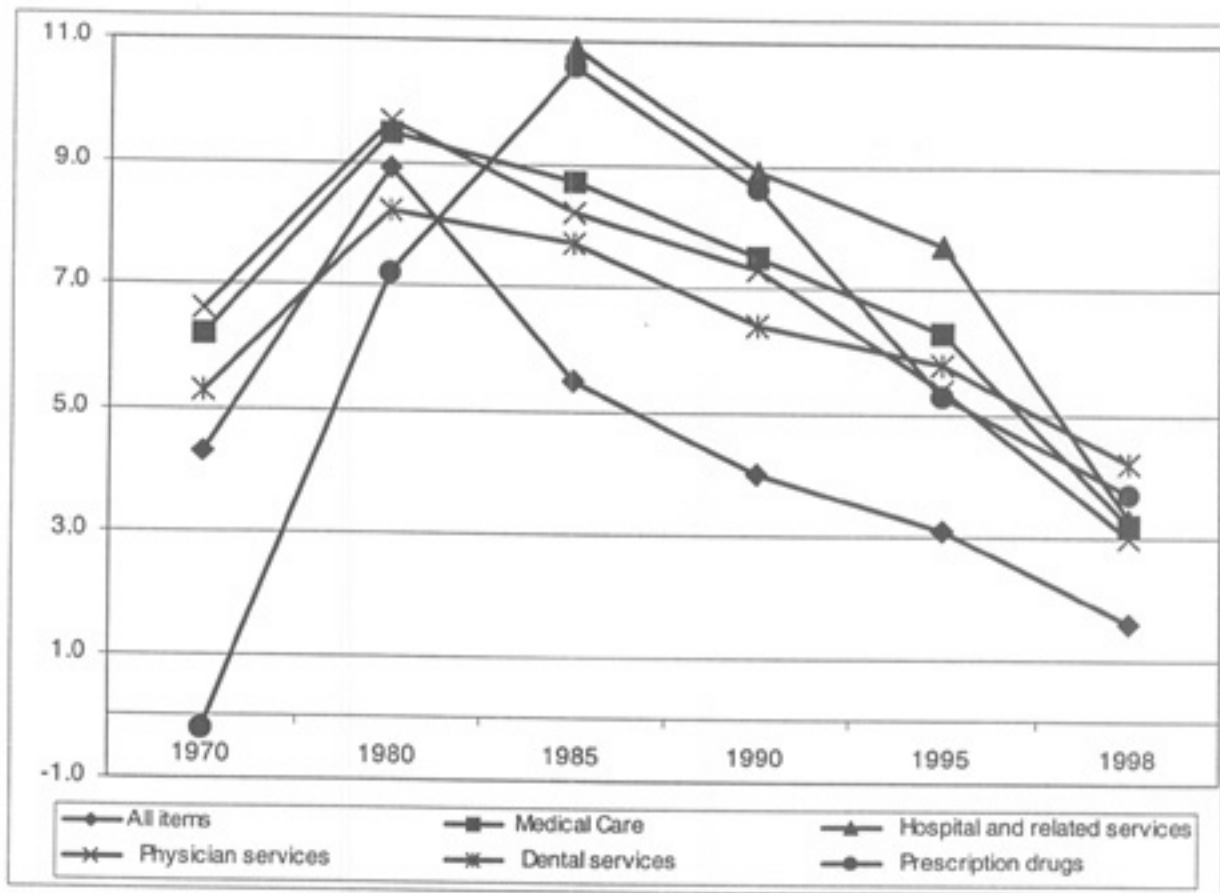
During this period of nearly forty years, the proportion of total health expenditures devoted to pharmaceuticals has actually declined. In 1997 its share was just under 10 percent, down by one-third from its 1960 share of over 15 percent.³ Of course the decline in pharmaceutical share was not due to falling drug expenditures, but resulted from a far larger rise in expenditures on other health services. While the pharmaceutical share is greater than that of nursing homes and dental services, the drug sector is clearly not a dominant source of health services expenditures.

We turn next to the question of price change of pharmaceuticals. Data on consumer prices, the Consumer Price Index (CPI), and its constituent parts, including pharmaceuticals and other health services are calculated and published by the Bureau of Labor Statistics. While there are various problems with these data, which are discussed below, it is still useful to review the reported trends in these statistics for they generally indicate maximum price

increases.

Figure 2 shows time series data on the rate of increase in the overall ("all-item") Consumer Price Index (CPI) figures, the overall medical care component of the CPI, and CPI trends for the hospital, physician, dentist, and drug components. The data shown are the annual rate of price change for the year prior to the date on the graph.

Figure 2 Consumer Price Trends for the Overall CPI and Health Components: 1970-1998



Source: Health United States 1999.

The data show that the rate of price increase of health care exceeded that of the overall CPI for the entire period, but that the rate of increase

of pharmaceuticals is similar to that of the other health care components. Prior to 1980, the rate of increase of drugs was below that of other components, but since, it has been above most of the components, although below the rate of change in hospital prices during the period for which data are available.⁶

If pharmaceuticals constitute only a small portion of overall health care expenditures, and if price increases have been relatively similar to other components for many years, what is the reason behind the continued public and Congressional concern over drug prices?

One answer to this query is that utilization has risen sharply, in part a result of the country's aging population. Furthermore, drugs can do more things today than in the past so they are prescribed more frequently. And Direct-to-Consumer advertising may also have led to increased consumption. As a result of all of these factors, we observe that the number of prescriptions filled per year has risen dramatically, from 1.9 billion in 1993 to 2.5 billion in 1998.⁷ Within some common therapeutic categories, the rise in quantity is even more dramatic. The number of antidepressant prescriptions filled increased by 111% during this period, and that for cholesterol-lowering drugs rose by 162 percent. For oral anti-histamines, the increase was fully 500 percent.⁸

Another response is that there is a fundamental difference between pharmaceuticals and other health service components: while most health care purchases are exclusively *services*, pharmaceuticals have both *service* and a *manufactured* components. The service role applies to the research and development behind all pharmaceutical products and also to the professional dispensing of the drug. But the drug itself is a manufactured product, and most drugs are manufactured on a very large scale, taking advantage of

economies of scale in the manufacturing process. The manufacturing costs of drugs constitute less than half of total costs.⁹ As the prices charged for pharmaceuticals are much higher than production costs, it would be possible to reduce prices substantially and still cover these costs.¹⁰ To be sure, high pharmaceutical margins cover high research and marketing costs that accompany the continued introduction of new drugs. At the same time, these are costs that generally have already been paid, and consumers may not see a link between the purchased product and what they are asked to pay. Further obscuring this linkage is the apparent willingness of most pharmaceutical companies to sell the same or similar drugs at very different prices, either through discounts to some health insurers or health plans, or to patients in other countries.

Still another reason for public concern with pharmaceutical prices lies in the fact that most insurance plans cover less than 100% of the patient charges for drugs. Although over four-fifths of health care costs in the United States are paid by government or private insurers, third-party coverage for pharmaceuticals has historically been lower than that of hospital and physician services.¹¹ At the time of the Kefauver hearings, there was virtually no insurance coverage for drugs. In 1961, private insurance paid for less than one half of one percent of pharmaceutical expenses. Consumers paid directly (as out-of-pocket payments) for 95.5 percent of drug costs.¹² By 1995, private health insurance covered nearly 40 percent of pharmaceutical expenditures, and the out-of-pocket share had fallen to 39.5 percent.¹³

Although insurance coverage for health care services has broadened in recent years, pharmaceutical coverage still lags behind the other segments of the medical care sector. In 1992, patients paid directly for 28 percent of their pharmaceutical expenses, but at the same time the out-of-pocket shares

of hospital and physician charges were only 5 and 18 percent respectively.¹⁴ The higher share of pharmaceutical expenditures paid directly implies that consumers are less sheltered from the burden of paying for drugs than for other services, making pharmaceutical prices more visible to consumers.

For the elderly the problem of substantial drug expenditures is more complicated. As noted above, the universal health insurer for the elderly is the Medicare program. But Medicare does not cover outpatient drugs. However approximately two-thirds of seniors either qualify for Medicaid coverage (which covers outpatient drugs) or have private health insurance as a supplement to Medicare coverage. Only about one-third of the elderly rely on Medicare alone and thus must pay fully out-of-pocket for their pharmaceuticals. Furthermore, cost-sharing is increasingly being implemented in Medicare supplemental policies. Co-insurance and/or deductibles are frequently linked to the type of drug used to fill a prescription. For example, a prescription filled with a generic product may require only a \$5 co-payment, while the co-payment for a brand product might be \$20.

It is striking that insurance coverage for drugs is far greater today than it was in the late 1950s, at the time of the Kefauver Hearings, and yet the public demand for government assistance is unchanged. One explanation may be that drugs have become both more costly and more essential over time. Another factor may be the disparity in coverage among segments of the population. Some people are covered relatively well by private insurance, while others find drug coverage to be meager, and still others have no insurance coverage for drugs at all.

INTERPRETING PHARMACEUTICAL PRICE DATA

Various reports, both public and private, have described rapidly rising drug prices. A 1992 report by the U.S. General Accounting Office observed

that "during the 1980s, prescription drug prices increased by almost three times the rate of general inflation and certain drugs increased in price by over 100 percent in five years."¹⁵ This report reviewed price data for a sample of widely used prescription drugs, and concluded: "Prices for nearly all 29 drug products increased more than the percentage changes for all three consumer price indexes for the six year period ending December 31, 1991. The maximum price increase for each product during this period generally exceeded 100 percent, with some prices increasing by 200 to 300 percent... During this same period, the CPI for all items increased by 26.2 percent, the CPI for medical care by 56.3 percent, and the CPI for prescription drugs by 67 percent."¹⁶

Unfortunately, these observations of the prices of pharmaceutical products are incomplete. Since the adoption of the 1984 law facilitating approval of generic drugs upon a drug's patent expiration, the importance of generics in pharmaceutical marketplaces has exploded. By 1998, fully 47 percent of pharmaceuticals dispensed, in terms of physical units, were for generic products, up from 40 percent as recently as 1993.¹⁷ Thus, nearly half of all drugs consumed in the United States are for products for which there is little suggestion that high prices are a problem.

The Effect Of Generic Products On Price

Not only are generic products priced substantially below their branded counterparts, but generic prices have declined over time. For most products, the share of total sales represented by generics for the particular molecule greatly expands following patent expiration. Griliches and Cockburn observe that within two years of a branded drug's patent expiration, its market share of product revenue generally falls by 50 percent.¹⁸ If this picture is even broadly correct, then the increasing role of generic products in

pharmaceutical markets has surely led to a declining average price for most products (including both the branded and generic versions) following patent expiration and the entry of generic producers. Our first question therefore is how the influence of generic entry, leading generally to price declines, relates to the claims that pharmaceutical prices have sharply increased.

To resolve this issue, one first needs to decide whether the generic version of a drug should be considered as the same "product" as its branded counterpart. Throughout most of the recent past, the Bureau of Labor Statistics (BLS) has assumed that branded products are inherently different from their generic versions.¹⁹ It notes that both patients and physicians frequently react differently to the two types of products despite their bio-equivalence. As a result, the BLS has treated these products as distinct entities and reported their price changes on an independent basis. Thus, it has not incorporated the increasing use of generic products into its reported price series.²⁰

In contrast, one could accept the implicit judgment of the Food and Drug Administration (FDA) that generic and branded versions of the same molecule are identical, and then produce a price series for the incumbent and entrants according to their relative output levels. When this procedure is carried out for individual products, we observe that average prices have typically declined.²¹

However, one cannot say that the FDA position is entirely correct and the BLS position is entirely wrong, because a substantial number of buyers do in fact treat these products as different. In their study of these issues, Griliches and Cockburn seek to account for these differences, and as might be expected, report price series which lie between the two more extreme assumptions.²² For the most part, their price series constructed for

individual drugs show some decline in price after the introduction of generics, although less than for the series based entirely on the assumption that branded and generic versions represent the same product.

Launch Prices And Drug Price Changes

In addition to the question of generic substitutability, there is also the effect of pricing strategies during the years following a product's introduction. Two strategies are used: "skimming" and "penetration." The former is setting a high introductory price and reducing it over time, while the latter is the reverse, where a low introductory price is set but prices rise over time. Clearly, prices set for the same pharmaceutical products will show a *declining* trend where "skimming" strategies are more commonly used, but an *increasing* trend where "penetration" strategies are more commonly employed.

There is evidence that both types of strategies are found in this industry. "Skimming" strategies are more typically applied to drugs representing a major therapeutic advance, while "penetration" strategies are more commonly used for more imitative products.²³ As a result, one is more likely to find rising drug prices when more imitative products are introduced, but declining prices when more innovative products are seen. Therefore, rising prices may be a consequence of low (penetration) launch prices, while more moderate price trends may result from *high* (skimming) launch prices.

Drug Prices And Quality Improvement

Not only do brand pharmaceutical products compete with their generic substitutes, but also they compete among themselves. Even though one drug may be therapeutically similar to the other drugs in its particular therapeutic category, it may differ in terms of side effects and adverse interaction profiles; and higher prices can frequently be explained by those types of improvements.²⁴ Thus, the price increases for new products reflect product

improvement, while prices for older products may actually decline.

To investigate this issue, Berndt and his colleagues estimated a series of hedonic regression equations in which several attributes were used as proxies for relative quality of various products. These measures largely reflected individual side effects. Through this technique, the authors were able to measure price trends while holding quality levels constant. For the years between 1980 and 1996, and dealing only with antidepressant drugs, they report average rates of price increase under three scenarios: price increases measured without accounting for generics or quality change, 7.11 percent; price increases including generics but without incorporating the improved quality of new products, 4.73 percent; and price increases incorporating both effects, 4.33 percent. Although the former correction was far more significant throughout the entire period that they studied, they observed that there were particular years where the quality change associated with new products was a more important factor than the increasing role of generics.²⁵

Measuring Drug Prices When New Drugs Replace Old Drugs

The BLS computes the overall Consumer Price Index (CPI) as well as its constituent parts as a "Laspeyres" index which compares the cost of a given bundle of goods (often referred to as the "market basket") purchased at current prices to the cost of that same quantity purchased at base-year prices.²⁶ This market basket, however, must be adjusted periodically to reflect current expenditure patterns, for otherwise the index will increasingly have little relationship with the actual goods purchased by consumers. With regard to health care, newer treatments for old problems, such as coronary artery disease or renal failure, have totally replaced techniques in use only a few years ago. And in many cases there are new therapies available for problems which were previously untreatable. If new

and improved drugs replace older ones, but at a higher price, the appropriate price index should account for quality improvement as well as price increases. When price statistics fail to account adequately for quality improvement, measures of price changes are biased upward.

The method used by the BLS for measuring price changes is designed to track prices for a fixed market basket, or one that changes slowly. When items in the market basket change through shifts in consumer demand, the BLS uses a "linking" technique through which the price index of a new market basket replaces the index for an older one. For example, when a new product, such as a more powerful anti-hypertensive drug, replaces an established but less expensive one, price indices with the old and the new product are each calculated, and the new index (with the higher priced product) is scaled downward to equal the older one. The index including the new item then replaces the prior index in future calculations. No attempt is made to assess whether an improved drug is more or less expensive than would be justified by the quality change represented by its introduction. The price index merely tracks the prices of all items comprising the market basket, and then recalculates the price index when a new product is included.

Failure to capture the effect of quality change is especially serious for pharmaceuticals, where the turnover of products is rapid and new products frequently are improved versions of older ones, with greater efficacy, fewer side-effects, or a more convenient regimen. The question of whether increases in drug prices exceed, fall behind, or accurately reflect quality changes is left unanswered.

Prices And Margins: The Difference Between Wholesale And Retail Prices

Before concluding this discussion of pharmaceutical price measurement, the important distinction between the prices set by pharmaceutical

manufacturers and those ultimately paid by consumers must be noted. The difference between these two prices is the distribution margin, which includes the costs and profits of both the dispensing pharmacy as well as the wholesaler, if one is involved in distributing the product. In many discussions of the cost of pharmaceuticals, there is the implicit assumption that distribution margins are constant across products so that whatever price is charged by the manufacturer is passed on to consumers, with merely a fixed amount added to cover distribution costs.

However, that picture is not generally accurate in the United States. Steiner, in particular, has pointed to "the inverse association between the margins of manufacturers and [those of] retailers."²⁷ His study provides empirical evidence on this relationship as well as the reasons for its presence. Salehi and Schweitzer²⁸ found that this relationship applies to pharmaceuticals. Branded pharmaceuticals, which typically embody a high manufacturing margin, have lower distribution margins, while generic products with lower margins at the manufacturing stage have much higher distribution margins. As a result, price differences between branded and generic products are greater at the manufacturing stage of production than at retail.

INTERNATIONAL PRICE COMPARISONS

International comparisons of drug prices have also contributed to public concern that drug prices are excessive in the United States. For example, the Congressional General Accounting Office (GAO) has published studies comparing U.S. drug prices with those in the United Kingdom and Canada.²⁹ These reports suggest that prices for the same branded products are generally higher in the United States than elsewhere. However, the GAO studies are subject to the same conceptual and methodological problems that were discussed above.

Most important, the GAO studies fail to account for generic substitution

in any comprehensive way. Thus, while their comparison of relative prices for a particular branded drug may be correct, they do not necessarily reflect differences in the actual prices facing consumers since generics are typically more important in the United States than elsewhere. As we noted above, the share of the market accounted for by generic drugs in the U.S. has grown substantially, and now comprises nearly one half of all drug units (doses) sold.³⁰ Therefore, merely comparing the prices of specific branded products, without including in the analysis the presence of generic products gives a misleading picture of the relative costs to consumers from filling their doctor's prescriptions.

For example, suppose that half of U.S. prescriptions for cimetidine are filled by the generic version, the price of which is \$104 per hundred, while the price of the branded product, Tagamet, is \$167. The average price is \$135.50. Suppose further that the price of Tagamet in Canada is \$150, and the generic price is \$100. But if the generic version's market share is only 20% in Canada, the average price there is \$140, which is higher than the average United States price, even though prices of both products are lower in Canada.

Another problem with the GAO approach is that it relies on wholesale prices, which do not account for the many discounts and rebates present in the United States. Even if these prices accurately described charges to pharmacies for cash customers, they will not in general reflect transaction prices to other classes of buyers, who in fact constitute the largest segment of demand. This factor is important to the extent that discounting is more widespread in the U.S. than in Britain or Canada.

Finally, the GAO studies failed to deal with different drug consumption patterns in the three countries studied. Not only are drugs used differently in each country, but even the same drugs are taken in different forms and

dosages.³¹ The GAO approach side-stepped the entire question and considered a narrower question: are wholesale prices higher in the U.S. than in Britain or Canada for the specific items that are major-selling American drugs? This approach may well compare prices of highly popular U.S. products with those of less commonly used products in other countries.

In response to the GAO reports, Danzon and Chao carried out a more complete analysis of international drug price comparisons.³² They included all drugs sold in each of nine countries, incorporating over-the-counter drugs, which substitute for prescribed drugs; and use data on average transaction prices at the manufacturer level. The authors found that price differences between countries depend greatly on the way in which the comparison is framed, particularly which country's quantity weights are used to construct the price index. Comparisons also differ depending on whether one compares prices per gram of active ingredient or prices per "standard unit," for example per capsule or milliliter of liquid. Although by most measures, average United States drug prices did exceed those in most other countries, this result did not always apply, and did not include the more significant role played by generic products in the United States.

THE DETERMINATION OF DRUG PRICES

We now turn to the causative factors that determine pharmaceutical prices. The research and development costs required to introduce a new drug are substantial - frequently in the hundreds of millions of dollars per drug. These costs include not only direct expenditures on research and testing, but also the time costs incurred resulting from the substantial differences between the times that the outlays are made and the revenues are received. Part of this lag is the time spent waiting for the FDA to approve a new product. Furthermore, these outlays are typically made before a single

prescription is filled. As a result, they represent a classic example of sunk costs, which do not vary with output. R&D costs, like those on fixed plant and equipment, have already been spent before the product is sold, so they cannot influence actual market prices. Whether these costs are high or low, the optimal prices charged by the pharmaceutical company is the same.

Similarly, most marketing costs are made in the early years of a product's life cycle and designed to introduce it to the medical community. Like research costs, they do not generally vary with output and therefore also represent sunk costs. The only variable costs in this industry therefore lie at the manufacturing stage. For large research-intensive companies, however, production costs are generally less than half of the value of the product.³³ Marginal costs for most drugs are quite low and thereby explain little about the prices that are charged.

Research and development, marketing, and manufacturing costs are all factors that reflect conditions on the supply side of the market. However, none of them has a major impact on pharmaceutical prices. Instead, prices depend predominantly on demand-side considerations. The prices charged for pharmaceuticals are determined largely by how valuable they are to consumers and what consumers are willing to pay for them. The critical factor is "willingness to pay" which in turn depends on various considerations. In this section, we consider the relevant factors and review some available evidence on their importance.

Therapeutic Advance

The demand-side factor most important in determining a pharmaceutical's price is its therapeutic advance as compared with products already on the market. Doctors and patients are willing to pay larger amounts for medically improved products as compared to those without a substantial therapeutic

advance. And with an increased willingness to pay, sellers can set higher prices without driving their customers away.

To explore the importance of this factor, Lu and Comanor examined the price premium for new products as compared to prices of their existing rivals.³⁴ The results are given in Table 1 for new products used for both acute and chronic conditions.

Table 1 Prices for New Pharmaceuticals Relative to those of Existing Drugs

FDA Designation of Therapeutic advance	Ratio of Median Prices of New Drugs to Existing Drugs	
	<u>Acute</u>	<u>Chronic</u>
Important Therapeutic Advance	2.97	2.29
Modest Therapeutic Advance	1.72	1.19
Little or No Therapeutic Advance	1.22	0.94

Source: Lu and Comanor, "Strategic Pricing of New Pharmaceuticals"

These data show that the launch prices of drugs which embody an important therapeutic gain are about two and one-half times greater than those of existing substitutes; drugs with moderate gains are priced about one and one-half times greater; while products with little or no therapeutic advance are generally priced at or about the same level as existing products.

Competitive forces

When a new product is introduced, whether it embodies a small or large therapeutic advance, there are typically existing products used for the same or similar indications. These alternate products are those which physicians would prescribe in the absence of the new product and are thereby the rival products with which a new one must compete. Note that this concept of

relevant market, resting on specific therapeutic indications, is far narrower than the conventional classification of a therapeutic category. Those classifications, such as antibiotics or hypertensives, are so broad that they include pharmaceuticals with very different indications, and hence products that do not actually compete with one another.

When there are alternative products available for the same or similar indications, prescribing physicians must select among rival drugs. They and their patients' willingness to pay for specific drugs are then influenced by any price differences that may exist. In this case, sellers can seek to increase sales by cutting prices, and the more rival products there are competing in a market, the more price cutting actually occurs. The Lu and Comanor study found that launch prices are substantially lower when there are more branded rivals in direct competition; and subsequent price changes are lower as well. Despite the common disdain of imitative products,³⁵ they play the essential role of promoting more competitive behavior and leading to lower final prices. New imitative products are an important competitive factor in the pharmaceutical marketplace.

Generic pharmaceuticals also have an important impact on market competition and price levels. Generic producers typically start production after the relevant patent has expired. They do so by gaining FDA approval of an Abbreviated New Drug Application (ANDA) which merely requires the demonstration of bio-equivalence to the original product. The prices set by generic producers are much lower than those charged by the original developer of the product as they compete largely by price. Moreover, the prices of generic products are also affected by the number of sellers. As their numbers increase, price competition becomes more vigorous, and prices decline below levels found when there is only a single entrant. A study of anti-infectives

found that the largest price effects occurred when the fourth and fifth generic firms entered. Average prices per prescription declined from nearly \$30 with two or three sellers to roughly \$17 with the presence of a fourth rival, and then to \$9.25 when a fifth firm entered.³⁶

These reported declines in average prices took place despite the fact that prices charged for the original branded products are typically increased but not reduced when entry occurs.³⁷ The original manufacturers do not typically compete on the basis of price with generic entrants but rather find it more profitable to concentrate on that segment of the market that includes brand-loyal customers. Such buyers are physicians and patients who know a particular brand and prefer it, so they continue to use it despite the presence of a lower priced substitute. When generic manufacturers enter production, the price differential expands as the prices charged for the original branded products increase.

Buyer Characteristics

Another major factor affecting consumers' willingness to pay for particular drugs is the mechanism by which payments are made. For uninsured patients who purchase pharmaceuticals much as they do other consumer goods, demand may be fairly price elastic. While the buyer is limited to the prescribed product, he or she can sometimes influence prescribing decisions by calling attention to the prices of alternate products. Where generic versions of the drug are available, patients may also ask the pharmacist to substitute it for the branded product. And the patient always has the option of not filling the prescription, which occurs in a large number of cases.³⁸ For all of these reasons, producers may encounter substantial price resistance if they set prices much above anticipated values.

On the other hand, this resistance is attenuated when buyers have

substantial insurance coverage. In that case, the out-of-pocket costs of prescribed pharmaceuticals may be minimal or quite low, and the economic reason to limit one's purchases is removed. Demand conditions thus depend on the conduct of managed-care organizations and other third-party payers, and also on the nature of the contractual agreements that govern their payments.

Where payers simply agree to cover the pharmaceutical costs of insured patients, perhaps with a deductible and co-insurance provision, demand becomes less price elastic. Judgments as to what products are prescribed are made exclusively by physicians whose decisions may depend on marketing and other idiosyncratic factors, and are not likely to be constrained by their patients' economic circumstances. And the more inelastic is consumer demand, the higher product prices will be. Increased insurance coverage of pharmaceuticals would then lead directly to higher prices.

However, there are other circumstances where expanded insurance coverage may lead to more elastic demand conditions so there is a shift "from patient-driven to payer-driven competition."³⁹ The central factor here is the conduct of third-party payers. When insurance companies and HMOs institute formularies, which are restrictive lists of approved products, and indicate to both doctors and patients that they will pay only for those drugs, they gain a direct influence on prescribing decisions. Furthermore, the drug's price can be a major determinant of whether or not it is included in the formulary. In these circumstances, pharmaceutical coverage will lead to more rather than less elastic demand. Of critical importance is whether third-party payers can influence prescribing decisions.

Where generic products are available in the market, the conduct of third-party payers can affect prices even without influencing prescribing decisions. That is because pharmacists can substitute generics for prescribed

branded drugs, and patients can be encouraged through various incentives to buy generics. In these circumstances, the price elasticity of demand for branded drugs will increase (in absolute value) and the affected producers will respond by setting lower prices. While there are few empirical studies that explore these factors, the structure of demand conditions for pharmaceuticals is clearly not a simple matter and depends on the complex relationships among patients, physicians, and third-party payers. Depending on the behavior of all of these parties, demand elasticities are determined, and so then are the prices that are set in the marketplace.

Before concluding this section, we note that insurance coverage for prescription drugs has increased over time, so there is an increasing difference between patient costs and market prices. Furthermore, there has been a general shift from overall deductibles to fixed co-payments, which means a richer insurance benefit structure for prescription drugs.⁴⁰ These factors suggest that demand conditions in pharmaceutical markets will increasingly depend on the conduct of managed care providers and other third-party payers. And the prices that are set will depend largely on what commitments are made by these payers to offer drugs to their subscribers.

Differential Pricing

Where prices depend on demand conditions, and also where there are clear distinctions among types of buyers, we expect to find different prices charged to different buyers. The economist's model of price discrimination provides a clear description of this process and indicates that prices will depend strongly on the relevant price elasticities of demand. Where these elasticities differ among classes of consumers, final prices will differ as well. There is considerable evidence that this pattern is pervasive throughout the pharmaceutical industry. While pharmaceutical companies

establish a list price for each drug, many (or most) sales are made by discounting that price, and these discounts can be substantial. A survey of drug prices in one area found that the average price charged for a selection of well known products sold to hospitals was only 19 percent of that charged to a local pharmacy.⁴¹ Since hospital demands for specific products are likely to be more elastic than those of individual pharmacies, who must stock a large number of products to fill individual prescriptions, hospital prices are expected to be much lower than those charged to pharmacies. Where prices are demand driven, differences in demand elasticities are reflected in differences in actual prices.

These discounts may also differ between individual and chain store pharmacies, and between hospitals and HMOs. A critical fact about the pharmaceutical industry is that there is no single price for an individual product even at a specific point in time; prices depend on the demand conditions presented by particular buyers.

When generic products enter the marketplace, they typically appeal more to some buyers than to others. In particular, HMOs and hospital pharmacies are more likely to use generic products as they have the knowledge and expertise required to evaluate them, in contrast to individual physicians. One expects therefore that generic rivals will make greater sales to some buyers than to others. That being so, producers of brand products will respond to generic competition more strongly in some market segments than in others. By setting much lower prices where generic competition exists, but keeping prices at their original levels or even higher where generic competition is less important, the sellers of many branded products have been able to maintain a large proportion of their original sales without depressing revenues excessively.

The evidence that major pharmaceutical firms have pursued this type of strategy is that they have generally maintained market shares following patent expiration and generic entry. By the sixth year after patent expiration, average market shares for 35 products between 1984 and 1987 were fully 62 percent in physical units and 85 percent in dollar sales as compared to their previous levels.⁴² The strategy of charging lower prices where firms face strenuous competition but setting higher prices where they do not has been used by many companies to maintain sales and market shares. Once again, buyers' willingness-to-pay is the critical factor that determines pharmaceutical prices.

APPROACHES FOR CONTAINING PHARMACEUTICAL COSTS

While pharmaceutical companies have sought to maintain or expand revenues, health care consumers, providers and insurers have looked for methods to limit drug expenditures. Here as elsewhere, buyers and sellers face opposing incentives. Some buyers have sought to reduce the quantity of drugs consumed but most have looked for means to lower the prices paid for specific products or to re-direct patients towards lower priced alternatives.

These methods can be divided into those focused on consumer behavior, physician prescribing patterns, and manufacturer actions. At this point, we review some measures that have been used.

Patient-focused Measures

Consumer behavior can be altered through economic incentives or education. Economic incentives typically mean cost-sharing through which patients bear more of the financial consequences of their actions by paying a larger share of drug costs. As the cost of drugs to consumers increases, the quantity purchased will decline, with patients either going without the prescribed drugs or shifting to less expensive alternatives such as generic

products or over-the-counter options.

Cost-sharing is sometimes criticized as being an overly "blunt instrument," because it may discourage the use of necessary, as well as unnecessary, therapies. The RAND Health Insurance Experiment studied the effect of cost-sharing on the consumption of prescribed drugs. Leibowitz and her colleagues reported that pharmaceutical expenditures by individuals without cost-sharing were as much as 60 percent higher than for those with cost-sharing.⁴³ The findings were similar for patients at a large HMO, although the differences were smaller.⁴⁴ A cost-sharing requirement of \$1.50 per prescription reduced the number of prescriptions filled by 10.7 percent, and doubling the co-payment led to an additional 10.6 percent reduction in the number of filled prescriptions. Furthermore, the authors found that consumers were more likely to reduce consumption of discretionary rather than essential drugs in response to increased cost-sharing. These findings are tempered, however, by the observation that the cost per prescription rose in response to higher cost-sharing. This change may have occurred because consumers purchased a greater quantity of drug per prescription, as their cost may have been related to the prescription rather than the quantity of product actually purchased.⁴⁵

An alternative to economic incentives in dealing with consumer behavior is patient education. An example of this type of program is informing patients that generic drugs are equivalent to brand products. Another is explaining to patients that the extensive use of certain drugs, such as antibiotics, is unnecessary and may even be harmful, thereby lowering the quantity purchased. While such programs can reduce consumer demand for specific products, they are unlikely to limit aggregate demand for pharmaceuticals to a substantial extent. Many patients still expect a

prescription at the conclusion of each physician visit, and physicians respond accordingly.

Provider-focused Measures

Despite the presence of consumer-oriented programs, most efforts at cost containment for pharmaceuticals are directed at those who make decisions on drug therapies: physicians, hospitals, and managed care providers. Because physicians, particularly those in private practice, have few incentives to limit pharmaceutical costs, physician-directed policies are not very different from those aimed at consumers. When financial constraints are removed from patients, they are also removed from their physicians.

However, physicians are also the subject of education programs that seek to improve the quality of prescribing and reduce overall drug expenditures. These programs are present especially in HMOs or other managed care programs, and have great potential because the pace of new drug introductions is rapid and physicians have difficulty keeping abreast of new therapeutic options. Without such programs, the primary means that physicians have to learn about new products is from pharmaceutical company marketing efforts, which are designed to increase rather than reduce spending on pharmaceuticals.

Even if physicians have few incentives to restrain costs, that is not so for organizations that actually pay for pharmaceuticals. Generic versions of drugs are generally favored, and newer, more expensive drugs often discouraged.⁴⁶ In addition, these payers may promote the shift of certain products to over-the-counter status. Not only can these drugs then be obtained without a visit to the physician's office but also such products are typically not reimbursed. More important, hospitals, HMOs, and government reimbursement plans have long adopted formularies designed explicitly to restrict the drug choices available to physicians in order to reduce costs.

These lists of approved drugs depend in principle on the relative cost and effectiveness of alternative products. While nearly all formulary programs permit exceptions, the burden of obtaining an exemption is often great enough to discourage a physician from doing so unless he or she feels that a non-listed drug is absolutely necessary.⁴⁷

Formularies, however, have the potential for increasing rather than decreasing health care costs if they are so restrictive that patients are prescribed less effective drugs. Even expensive drugs are generally less costly than physician visits or hospital episodes so that using sub-optimal drugs may be "penny wise but pound foolish." The question of whether or not a formulary lowers or raises drug or overall health care costs depends on the relative prices of the drugs included and excluded from the formulary, the number of patients who use the more expensive product when it is not necessary, and the treatment ramifications of patients who are switched to a less expensive drug when they need the more expensive one. Sloan and Gordon found that "limiting the number of drugs [through a formulary] appears to have been a very good idea for gastrointestinal disease patients and for those with asthma, but a bad one for coronary diseases patients."⁴⁸ In the latter case, total medical costs actually increased with the adoption of the formulary. Other studies have also shown that Medicaid formularies are not effective in either lowering drug expenditures or reducing overall health care costs.⁴⁹ Apparently, formularies have not been able to discourage consumption of expensive drugs whose use is unnecessary while allowing such use when appropriate.

Manufacturer-focused Measures

A more direct approach toward cost containment is the exercise of a payer's monopsony power to limit the prices charged by pharmaceutical

manufacturers for their products. These actions are frequently adopted by governments that provide coverage for pharmaceuticals in their national programs. Increasingly, foreign governments or insurance funds have sought to reduce drug prices as a means of cost control. In most countries, the question is not whether to fix prices, but how to do so, and in particular how to set prices without removing the incentive to develop new and improved pharmaceuticals. A typical response is to permit a product's use and reimburse its costs in accord with its relative therapeutic benefits. Note that, ideally, this objective leads to the same prices as those set in a competitive market. Regulatory objectives are thereby similar to those enforced by competitive markets.

Australia has progressed further than other countries in attempting to calculate the cost effectiveness of new drugs and setting reimbursement prices accordingly.⁵⁰ Canada uses this model at the national level as well. Britain, on the other hand, incorporates the profitability of the pharmaceutical company into its calculation of the National Health Service price for new products.

Similarly, managed care programs in the United States frequently determine the prices they pay for pharmaceuticals purchased on behalf of their patients in accordance with the perceived value of the products. For this reason, pharmaceutical manufacturers now provide managed care plans with studies of the cost effectiveness of new products. As a result of managed care purchasing power, these organizations typically pay less for pharmaceuticals than do individual patients.

Advertising is often suggested as a cause of rising pharmaceutical expenditures, and with the FDA's relaxation of prohibitions against Direct-to-Consumer (DTC) advertising, this particular marketing approach is more and

more visible to the general public. The criticism of DTC advertising is that it influences prescribing and consumption decisions adversely, that is, against patient interests. While the FDA monitors advertising carefully to guard against unsubstantiated claims, it has followed the guidance of the Federal Trade Commission in suggesting that advertising is inherently biased in favor of the sponsor's product (for any product or service) and one should not expect any different behavior on the part of advertisers. Firms are therefore permitted to present information that is favorable to their cause, and leave it to other producers to do the same for their competing products. If there is a need for unbiased information on competing products, that should be provided separately. In the field of pharmaceuticals, for example, there are already a number of independent newsletters, some directed to physicians, and others to patients, comparing alternative therapies. The potential of the world-wide web to increase this sort of information is also enormous.

The most serious question raised in any discussion of drug cost containment is whether success can be achieved without sacrificing the vitality and viability of the industry, whose hallmark is a large investment in R&D for new products. If cost containment is pursued too severely, will that effort diminish the returns from innovation to an extent that lower spending levels on research and development will ensue? Or are returns already sufficiently high that little will be lost? While it is obvious that some trade-off exists between cost containment and research spending, little is known about the terms of this trade-off and thereby little about how much reduced spending on pharmaceutical R&D might result from particular cost-reducing strategies. More research is needed before we can reach a firm conclusion on this matter.

CONCLUSIONS AND DIRECTIONS FOR FUTURE RESEARCH

Recent trends in pharmaceutical prices can be considered from various vantage points. That the prices of the most advanced drugs have increased over time is certainly correct, although this result turns largely on the increasing benefits of new products. Furthermore, this result is especially applicable if branded products are considered to be different and perhaps superior to their generic counterparts. On the other hand, prices for the same quality products have tended to decline over time. Since "inflation" represents price changes for the same or similar sets of products, one cannot conclude from recent experience that we have seen pharmaceutical price inflation. What instead has occurred, is that the prices of newer products, and especially their brand versions, have increased substantially, even while prices of competing products and generic alternatives have declined in price.

Our picture of drug price control is a mixed one. The share of health expenditures devoted to pharmaceuticals is relatively low, and there is a history of moderate price increases although with some acceleration in recent years. Furthermore, there have been rapid changes recently in the market for drugs, with increasing importance for provider-driven rather than patient-driven competition. These changes will have a growing impact on both average rates of price increase and patterns of price dispersion for pharmaceuticals. The increased segmentation of pharmaceutical markets on the basis of insurance coverage also means that average price levels convey less information about what is actually taking place. Not only are traditional measures of price changes inadequate and tend to inflate reported rates of increase but also international comparisons yield inconclusive results.

A critical policy issue for the cost of pharmaceuticals is whether uniform pharmaceutical prices should be mandated for different classes of

customers. If this type of proposal were enacted, either through legislation or judicial decisions, pricing practices would change sharply. Berndt has pointed out that under these conditions the vigor of competition in many pharmaceutical markets would diminish sharply and we could expect higher overall prices.⁵¹ That type of policy change would increase the cost of pharmaceuticals.

This overview of the major factors determining the cost of pharmaceuticals illustrates three important areas where additional information would assist policy analysts. The first is the need to understand better the relationship between drug prices and quality levels. Preliminary data show that prices are positively affected by a drug's therapeutic advance but the extent of this relationship is not well studied. This question is especially important because of our present inability to account for quality improvement in measures of pharmaceutical price increases.

Second, we know little about how quality levels of drugs are determined. Until recently, the FDA assigned a three-level quality improvement score to each drug for which marketing approval was sought. That designation was crude at best, and sometimes contradicted by the marketplace. However, the FDA currently does not provide even these designations, and there is no agreed-upon measure of the extent of therapeutic improvement in new drugs.

And third, we need a better understanding of the degree of competition in pharmaceutical markets. That factor is especially critical for we are now observing another wave of consolidation in this industry. A better understanding of the appropriate breadth of pharmaceutical markets is needed. How much rivalry is there within therapeutic categories or across therapeutic categories? An understanding of how pharmaceutical markets are structured and interact is essential to creating appropriate public policy for this industry.

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