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A Conceptual Model for Pharmaceutical Pricing

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Economics of pharmaceutical pricing

According to economic theory, both demand and production costs play a role in determining the price of a drug. This applies to the pricing of both branded and generic drugs. The line that illustrates demand for a manufacturer's output (known as demand curve) slopes downward because people will buy more as the price declines (see Figure 1). For example, if the manufacturer's price decreases from p_1 to p_2, then the quantity that the company can sell increases from q_1 to q_2. It is profitable for the manufacturer to lower the price from p_1 to p_2 only if the increase in profits from the larger quantity sold (represented by shaded area B) more than compensates for the loss in profits from the lower price charged on the first q_1 units sold (represented by shaded area A). In this example, the manufacturer would continue to lower the price until it could no longer profit from doing so. Economists refer to this as the point at which incremental, or marginal, revenue from selling another unit of the drug is equal to the cost of producing another unit. To keep Figure 1 simple, the cost of producing another unit is assumed to be the same no matter how much is produced (therefore, unit production costs are represented by a horizontal line). The profit-maximizing, or equilibrium, price will exceed the cost of producing another unit of the drug, and the profits earned from selling at that price (represented by areas B plus C, if p_2 is the equilibrium price) provide the incentive for companies to invest in drug development [2, 19-20].

When a new drug is introduced, it usually has a patent protection and faces no competition. Since no alternative treatment of equal quality and effectiveness exists, demand for the drug is fairly insensitive to price. In other words, the drug has a much steeper demand curve, and a given percentage change in its price is associated with a smaller percentage change in the quantity sold. Over time, as the drug becomes more popular, demand increases allowing the manufacturer to sell more units. The demand curve shifts to the right. At that point, the quantity of the drug sold increases, and its equilibrium price usually rises. After patent expiry, when generics enter the market, demand for the breakthrough drug becomes more sensitive to price as close substitutes are now available and that too at relatively low prices. At that point, an increase in the price or persistence with the old price of the branded drug might prompt some purchasers to switch to the substitutes. Thus, branded drug prices usually see a substantial fall after patent expiry. Figure 2 is a graphic depiction of changes in the profit stream for a new drug [2, 20].

From the aforesaid note on general price trends and profitability, it is easy to discern the criticality of the initial launch price for a new drug. Branded drug makers aim to come up with a base price which will continue to churn in profits till the treatment becomes obsolete and the drug is no longer in demand. This price is such that it can be increased during the patent protection period and decreased adequately after the patent expires (P_B in Figure 3). Generic drug manufacturers

on the other hand aim to launch their product at a base price (P_G) which has the capacity to withstand the downward price pressure post patent expiry and still generate profits. Demand for a drug is the primary determinant of its appropriate base price. There are a number of factors that can affect demand. The strength of the drug (higher strength could mean less dosage which would directly impact the demand for different variations of the same drug), seasonality (common cold drugs are usually more in demand during season changes), therapeutic class (a new drug for the treatment of arthritis could be more in demand than a new drug for the treatment of blood pressure), and expected market penetration (local or global) could be some of the factors. Near accurate demand forecasting is a very difficult proposition for branded drug makers, specifically if the subject drug is a new innovation. Generic drug makers usually focus on blockbuster drugs and can acquire the sales data of these drugs to arrive at reasonable demand estimates.

If setting a base price is hard, arriving at an optimal price is even harder. Pharmaceutical pricing involves a number of key issues besides demand related concerns. These issues include the effect of continued cost containment, reimbursement regulations and the application of reference pricing. Other issues impacting pharmaceutical pricing include the use of pharmacoeconomics, and the impact of parallel imports. Key issues specific to branded drug pricing include the effects of price on generic substitution, niche market therapies, breakthrough blockbuster therapies, 'me-too' specialty therapies and 'me-too' blockbuster therapies. Issues specific to generic drug pricing involves a consideration for the number of key competitors [12, 19] [13, 1]. Since our focus has been only on 'the generic threat', we will not discuss the issues specific to branded and generic drug markets.

Cost Containment: Cost containment describes the action of pharmaceutical payers to limit and, in some cases, reduce the costs borne from the purchase of pharmaceuticals. As the available choice between different therapeutic options increases, pharmaceutical payers have been able to utilize their elevated purchasing power to limit their exposure to pharmaceutical costs. Managed Care Organizations (MCOs) and Pharmacy Benefit Managers (PBMs) look to contain cost through the negotiation of lower prices, while national healthcare reimbursement bodies are able to limit costs through approved prices, reference pricing, pharmacoeconomic evaluations and parallel importing [12, 20].

Reimbursement Regulations: Reimbursement describes the process of payment of part or all of the cost of a pharmaceutical product by a third party. This third party is usually a private or public health insurance organization, which in turn sets regulations for the reimbursement of different pharmaceutical products. In its simplest form, reimbursement is determined by the reimbursement price, the proportional level of reimbursement and the coverage of different patients or policyholders. However, a number of additional indirect cost containment measures can affect a product's reimbursement status. These include physician spending budgets, pharmacoeconomic-based prescribing protocols and parallel import substitution guidelines [12, 20].

Reference Pricing: Reference pricing is employed to ensure that drugs of similar therapeutic value receive similar prices, thereby preventing a company from achieving premium prices based on non-therapeutic attributes such as corporate brand value. For this reason, reference pricing usually results in lower prices for new products. This impacts a product's revenue potential and subsequently manufacturer profits. External reference pricing takes into account benchmark countries in making decisions regarding the price of new drugs. Governments attempt to ensure that they do not pay higher prices than the prevailing prices in other countries which are economically equivalent. This protects governments from exorbitant pharmaceutical costs. Internal reference pricing operates by grouping comparable products together to determine the

price of a new drug. It either involves direct comparison with a similar marketed product or identifying a maximum reimbursable amount based on a cluster of similar drugs grouped by drug class and therapeutic value [12, 21].

Pharmacoeconomics: Pharmacoeconomics describes the application of economic principles to the use of drug therapies. The aims and objectives of pharmacoeconomic evaluations are to improve public health provision through rational decision-making based on the relative values of alternative therapies. Pharmacoeconomics attempts to allocate a monetary value or qualitative measurement to alternative treatments and their outcomes in order to achieve the most efficient allocation of limited healthcare resources. Common qualitative parameters by which different treatments are assessed include life years gained, number of hospitalizations prevented or quality of life for patients and careers. Terms closely related to pharmacoeconomics include health economics and outcomes research. However, while health economics and outcomes research generally include the evaluation of a wide range of treatment options, including surgery or rehabilitation, pharmacoeconomics is a more defined discipline primarily assessing the impact of pharmacological interventions [12, 21].

Parallel importing: Parallel importing is defined as the transportation of a pharmaceutical product from its original market, where it was sold directly by its manufacturer or marketing partner, to a different market for resale by the importer. Parallel importing only occurs where there is sufficient difference in the price of the product in the two markets to cover the importer's costs and generate some profit and incentive to the importing company. In most industries where it occurs, parallel importing has led to the convergence of prices of the same product among different countries. However, since pharmaceutical prices are constrained by government control in almost all developed markets outside the U.S., manufacturers have remained widely exposed to parallel trade [12, 22].

An ideal pricing approach under such complexities is to first arrive at a base price using the demand model. This base price should then be adjusted against factors like cost containment and reimbursement regulations. The basic goal during the base price determination and optimization should be to ensure that all the costs associated with the new drug development (R&D, production, marketing etc) is recovered under the worst possible scenarios. A quick and easy way of arriving at a ballpark estimate for the base price range is by performing a 'Present Value' (Present Value of Investment = -Investment + Expected Return) analysis on expected returns. The worst case scenario can be obtained by setting the present value to zero.

A Simplified Pricing Model using the Present Value Approach

In arriving at a present value (PV) equation for drug pricing, it is necessary to identify the factors most likely to alter the actual returns from the drug. These factors include: (1) the period of accumulation of intangible capital expenditures before the drug becomes an asset and production begins, (2) the economic life of the drug after production begins, (3) the opportunity cost of the resources used in the drug development, and (4) the appropriabilty of returns from the drug. For decision-making purposes, these conditions can be summarized in the following equation [14, 106-107].

$$\text{Let Investment} = \sum_{t=0}^{i-1} \frac{K_t(P_t)}{(1+r)^t}, \qquad \text{Expected Returns} = \sum_{t+i}^{n} \frac{p(R_t - C_t)(P_t)}{(1+r)^t}(A_t)$$

We know: Present Value = - Investment + Expected Returns. Hence,

$$PV = -\sum_{t=0}^{i-1} \frac{K_t(P_t)}{(1+r)^t} + \sum_{t+i}^{n} \frac{p(R_t - C_t)(P_t)}{(1+r)^t}(A_t) \qquad (1)$$

Where

PV = present value

t = index to year

K_t = capital expenditures in year t

P_t = price index for year t

r = opportunity cost of capital

R_t = gross revenues in year t

C_t = manufacturing costs in year t

p = probability of favorable occurrence

A_t = appropriabilty of returns to enterprise in year t

i = number of years before sales begin

n = end of the economic life for the investment

Thus if the accumulated capital expenditures (corrected for the changes in the price level and adjusted for the opportunity cost of capital) is equal to the expected discounted net revenues (corrected for changes in the price level and for appropriabilty factors like retailer/distributor margins), the present value of the investment will be zero. The price P_t at which PV becomes zero will be the worst case base price for the drug. A spreadsheet tool can be used for the computations. Average inflation rate can be a criterion for generating the variable values over the time horizon specified [14, 108].

Equation 1 can be used as is by generic drug makers for rough price estimations. It takes into account the time lag before the beginning of sales. Besides, the reduction in revenues due to alternate generic entries can also be accounted for by the appropriabilty factor. However, the equation has to be modified for innovator drug price estimates. The expected returns of an innovator drug can be split into two components (Figure 2). The first would be the expected returns during the patent protection. The other would be the expected returns after patent expiry. Similarly, the investment component should be split up into two parts; R&D cost, and the costs of production and distribution. By the time production starts, manufacturers should have the exact R&D expense figures. Following is our modified version of equation 1.

$$PV = -\left[RD + \sum_{t=0}^{i-1} \frac{K_t(P_t)}{(1+r)^t}\right] + \left[\sum_{t+i}^{e} \frac{p(R_t - C_t)(P_t)}{(1+r)^t}(A_t) + \propto \sum_{e+1}^{n} \frac{p_1(R_t - C_t)(P_t)}{(1+r)^t}\right] \quad (2)$$

Where

RD = fixed research and development expenses

e = time to patent expiry

α = percent of market share

p_1 = probability of favorable occurrence of market share assumption

Note: Equation 2 has not been validated due to unavailability of data.

We had noted that predicting the demand for a new innovator drug is a difficult proposition. It is possible that companies overestimate the demand for a drug during the patent protection period. Under such circumstances, expecting returns after patent expiry would be risky. So we have come up with a third equation which is more likely to be used for ball park estimates.

$$PV = -\left[RD + \sum_{t=0}^{i-1} \frac{K_t(P_t)}{(1+r)^t}\right] + \sum_{t+i}^{e} \frac{p(R_t - C_t)(P_t)}{(1+r)^t}(A_t) \quad (3)$$

Equation 3 is a repeat of equation 1 with modifications. R&D expenses are included in the investment part of the equation. The summation factor in the expected returns portion of the equation is the patent duration rather than the economic life.

The PV approach discussed above is not accurate. However, it does provide a very good starting point for developing more complex pricing models. Each and every variable and component in the basic PV equation (equation 1 or 3) can be split into smaller fragments. Each of these smaller fragments can then accommodate the factors affecting it (like arriving at equation 2 from equation 1 by splitting up expected returns based on patent expiry).

Global Pricing Strategy

The most widely used pricing strategy in the pharmaceutical industry is that of reference pricing (comparing a new product price with the price of existing substitutes). The greatest advantage of reference pricing is that the manufacturers do not have to worry about getting the quoted price approved by reimbursement bodies. However, such a strategy is usually not applicable for innovative drugs as there are usually no benchmarks. This provides substantial leeway to branded drug manufactures in pricing the new product. Following are some of the key elements of a global pricing strategy for innovator drugs [12, 166-188].

Negotiating Power: Effective negotiation is the key to obtaining a high price within a reimbursement environment. Pharmaceutical companies use data from trials conducted during R&D to provide compelling evidence of the product's benefits and thereby justify a specific price [12, 166].

Marketing Prowess: A product's launch price is usually the best price it will receive during its lifecycle. In case the initial price was an underestimate, proper brand positioning and the economic value of the product can significantly increase the sales volume making up for the opportunity loss due to under pricing. Brand positioning depends on a product's attributes, unmet need, innovation, and perceived benefits, while its economic value is related to the cost-effectiveness, cost savings and affordability of the drug. Large pharmaceutical companies usually have a lot of experience in marketing [12, 166].

Brand Reputation: For certain products in some reimbursement and pricing environments, a target price is unlikely to be granted irrespective of the negotiations undertaken. In such cases, big pharmaceutical companies can launch the drug outside reimbursement and use its reputation to partner with patient support groups, physicians and hospitals [12, 166].

Impact of Pharmaceutical Pricing on Consumers

The increased competition from generics should have resulted in excess supply which should have driven down drug prices. On the contrary, drug prices have been increasing. From January 2000 through December 2004, retail prices for drugs frequently used by Medicare beneficiaries increased 24.0% - an average rate of 4.5% per year. During that same period, average price of branded drugs rose three times faster than the average price rise of generic drugs. Tracking prescription drug prices can be complicated by the different prices that different purchasers, such as consumers, insurers and other third-party payers, and wholesalers, pay for the same drug. Several price benchmarks represent these differing amounts paid by different purchasers. For example, individuals without prescription drug coverage, including Medicare beneficiaries who do not currently have drug coverage, may pay the full retail price at the pharmacy, known as the usual and customary (U&C) price. Insurers and other third-party payers, including state Medicaid programs, typically pay negotiated prices with retail pharmacies, often receiving discounts from the average wholesale price (AWP), commonly referred to as a list price. Retail pharmacies may obtain drugs directly from pharmaceutical manufacturers or through wholesalers. Wholesalers/Hospitals would almost always purchase drugs directly from manufacturers. In this mesh of buyers and suppliers, it is difficult to determine the exact points where drug prices may get inflated abnormally [15, 5-17].

Such increases cannot be justified on the basis of inflation alone. Surely the increased competition in the pharmaceutical industry has a role to play. Whatever the major reason for the increase in drug prices, one thing is certain; it is the end consumer who will have to bear the impact of rising prices. It is not easy to regulate or benchmark the price of an innovative drug. There can be no reference pricing and the demand is relatively inelastic. Besides, the drug is usually protected by a patent. Pharmaceutical companies can easily increase prices of such drugs and maintain their profit margins.

With branded drug prices increasing at a faster rate as compared to generic drug prices, private and public health organizations will continue to encourage the use of generic drugs when

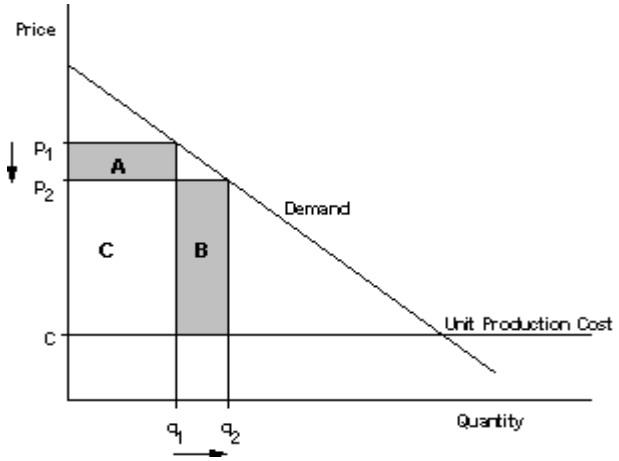
available. To counter the loss from increased generic usage, branded drug makers will continue to increase the prices of exclusive blockbuster products. And in this price war, consumers will continue to suffer. In our final section we will explore some of the strategies that branded drug manufacturers can employ in lieu of increasing prices.

Conclusion

In this paper we came up with simple present value pricing models to explain the difference in prices between an innovator drug and its generic substitute.

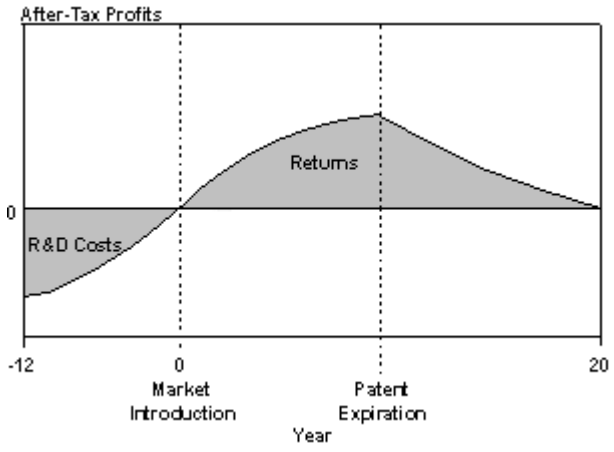
Generics have exploded in the last few decades and are poised for even bigger growth. However, the increased competition has not benefited the end consumer. Prices of all drugs in general and branded drugs in particular have increased in a manner which cannot be justified by economic fluctuations alone. The complexity of pricing an innovator drug and the inelasticity of demand for such a drug has allowed pharmaceutical companies to increase prices and maintain profits.

Figure 1: Choosing a Profit Maximizing Price for a Drug



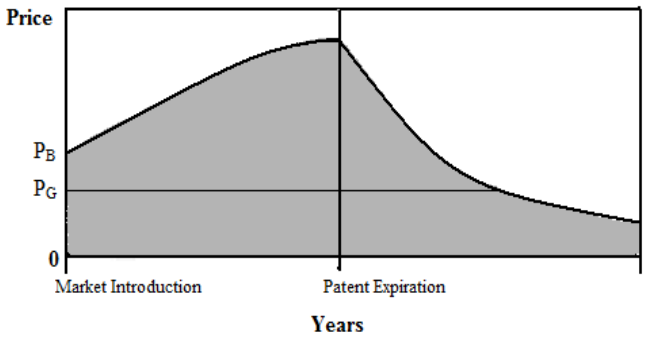
SOURCE: Congressional Budget Office [2, 19]

Figure 2: Changes in the Profit Stream for a New Drug



SOURCE: Congressional Budget Office [2, 16]

Figure 3: Setting a Base Price



SOURCE: Congressional Budget Office [2, 20]

References

1. Carly Z (July 2008), *Branded Pharmaceutical Companies Can Expect to See Sales Drops of up to 70 Percent after Patent Expiration from Generic Competition*. Advertising Industry Newswire

2. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*. Congressional Budget Office, Washington, DC, July 1998

3. Debra B. Feinberg (2007), *Pharmacy Law*. Published by McGraw-Hill Professional

4. *The Pharmaceutical Market*. Report by German Association of Research-Based Pharmaceutical Companies (vfa), 2009

5. *The History and Analysis of the Pharmaceutical Industry*. Case Study by Verbigena

6. *The Top 10 Generic Pharmaceutical Companies: Positioning, performance and SWOT analyses*. Business Insights, July 2008

7. Jacob Goldstein (October 2008), *Pfizer Goes Generic*. Wall Street Journal

8. Danzon, Epstein, and Nicholson (May 2004), *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries*. Wharton School

9. *Pfizer's acquisition of Wyeth brings scale but will fail to deliver sustainable sales growth*. Datamonitor staff writer, January 2009

10. Loden, D John,Liebman, Milton (March 2000), *High compression marketing superchanges drug revenues*. Medical Marketing and Media

11. *Shopper's Guide to Prescription Drugs - Number 2: Generic Drugs*. Consumer Report, Best Buy Drugs, 2006

12. Steven Seget (Feb 2003), *Pharmaceutical Pricing Strategies: Optimizing returns throughout R&D and marketing*. Business Insights

13. Reiffen and Ward, February 2002, *Generic Drug Industry Dynamics*.

14. Robert I. Chien (1979), *Issues in Pharmaceutical Economics*. Lexington Books

15. *Price Trends for Frequently Used Brand and Generic Drugs from 2000 through 2004*. United States Government Accountability Office, Washington DC, August 2005

16. *Generics Threats and Opportunities: Mounting an Effective Defense Strategy*. Publisher - Eularis, June 2008

17. *Patent litigation the most commonly used generic defense strategy among pharmaceutical companies*. Medical Patent News, November 2004

18. *Generics Defense Strategies: Effective Brand Protection through Patent, Formulation, OTC and DTC Strategies*. Business Insights, Jan 2005

19. Rupali Mukherjee, *Pharma M&A Wave Set to Reach India*. Times of India, March 2009