

The Economics of Price Regulation and Innovation

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In the pharmaceutical sector, research, manufacturing, and sales often are executed in geographically separate regions, with different sets of economic factors informing decisions about the physical and regulatory environment in which each activity is conducted. Research and development activities increasingly are being moved into the United States, often near universities. Meanwhile, the nature of pharmaceutical products — materials with high value relative to their bulk — allows companies to scatter manufacturing activities around the world, situating them wherever economic and regulatory factors are most favorable. From there, finished products easily can be shipped to their distribution channels and ultimately to consumers.

Defining the markets

Economists define various kinds of markets based on how each works. In a price searcher's market, a company has some latitude to search for the price that would maximize profits. In the real world, single pricing rarely is found outside agricultural commodities markets, in which sellers (price takers) must accept the price that is set by the market.

More commonly, sellers have an incentive to separate markets to maximize profits. The airline industry provides the classic example of market separation. Airlines can command higher prices from business customers — who often fly on short notice without paying the fare themselves — than from recreational customers, who have more time to shop for lower fares and are unwilling to pay high business prices. Rather than let seats go unfilled, airlines sell them at a discount. The marginal cost of flying an empty seat from one location to another, to the extent that it can be measured, ultimately serves as a floor to this type of pricing.

The keys to such multipart pricing (also known as multimarket or Ramsey pricing, and formerly, as price discrimination) are searching for prices within a market and keeping markets separate. In practice, multipart pricing is difficult to employ. First, the seller must identify each market. Second, entrepreneurial customers must be prevented from buying the product at the lower price and reselling it to the other market, thereby acquiring the profits that otherwise would go to the manufacturer.

In the United States, drug discounting is common, with manufacturers responding to the profit incentive by

giving discounts to the Veterans Administration, pharmacy benefit managers, and health plans. Compared with selling a drug at a single list price, a company can maximize its profits by selling at discounts to various buyers. State and federal regulation of the distribution of prescription drugs greatly facilitates the seller's ability to prevent reselling of its products from one market to another.

We often hear the argument that because most of the developed countries in Europe and Asia set prescription drug prices low, U.S. manufacturers must shift costs — by increasing prices charged to U.S. consumers — to pay for R&D.

From this premise, it follows that U.S. trade negotiators should induce other countries to raise their prices to promote continued R&D. A related argument is that if the government, via Medicaid, drives down drug prices in one market, then the price must be raised for everyone else.

Cost shifting is logically possible but highly unlikely. The incentive to set prices in one market has nothing to do with the price charged to customers in a different market; the price searcher sets prices in each market so as to maximize profits in that market. The flaw in these arguments is revealed by asking: If companies could have acquired greater profits by raising their prices in the unregulated market, why didn't they do so long ago?

The large unregulated U.S. market, within which numerous discounts are available, drives most of a company's decisions about which drugs to develop, and how fast. In smaller countries with national health systems, the question is whether the company should sell the product at the price demanded by the country's buying authority. The economics of the situation reveal that if the company can obtain a price that covers the marginal cost of producing and marketing the drug while satisfying regulatory policies, selling the drug in a given country makes more sense than not selling it. When markets are separate, a seller has a strong incentive to set prices



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so as to maximize profits from each market.

Cost-shifting and competition

This is not to say that sellers would not *like* to shift costs. In fact, many say that companies want to shift costs but that it usually does not work. Likewise, people who pay higher prices claim to be victims of cost-shifting. While cost-shifting arguments abound, they must be judged on their economic merits.

The U.S. pharmaceutical market dwarfs the Canadian market, with 2001 sales amounting to \$131 billion and \$3 billion, respectively. Reimportations from Canada were about \$1 billion in 2003. Obviously, U.S. companies will not continue to send products to Canada that can be sent back to the United States at a lower price, because doing so only undercuts their larger U.S. market.

Price is one way in which drug companies compete. They also compete to develop and market new drugs. Many large companies still conduct their own R&D, but the purchase or lease of products is an increasingly popular method for bringing new products to market. Companies also compete in managing the U.S. Food and Drug Administration approval process and in product promotion. Price competition gradually becomes more important in the later stages of a product's life cycle. The life cycle of a new chemical entity typically is 20 to 25 years, starting with the idea that leads to its development. A hypothetical product life cycle, based on empirical studies by Grabowski, Vernon, and DiMasi, is illustrated in Figure 1. Before the product reaches the market, the company's cash flow is negative, and the years of positive cash flow usually will be limited by entry into the therapeutic class of new branded or generic products. A financial analyst or a drug industry decision maker would look at this life cycle in terms of present value — discounting future revenue back to the present value. If the market rate of interest was 6 percent, the present value of a \$20 million investment in year 5 would be \$14.95 million — while the present value of \$20 million in positive cash flow in year 15 would be only

FIGURE 1 Up-front costs vs. delayed revenue

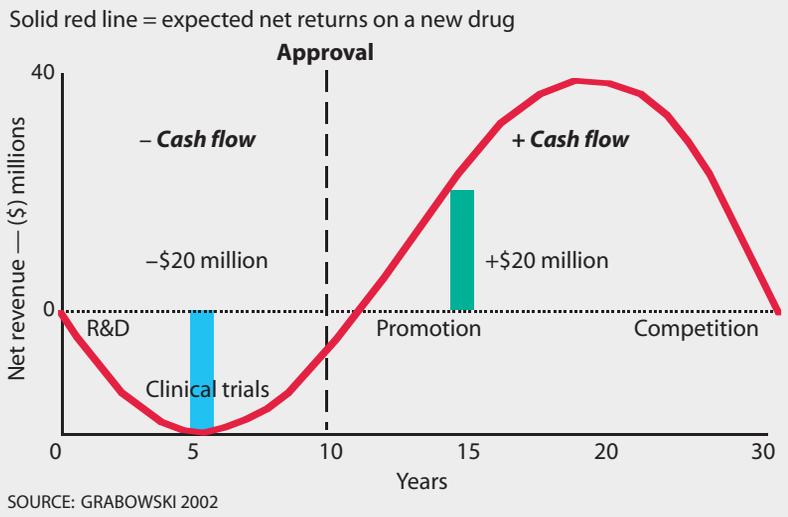
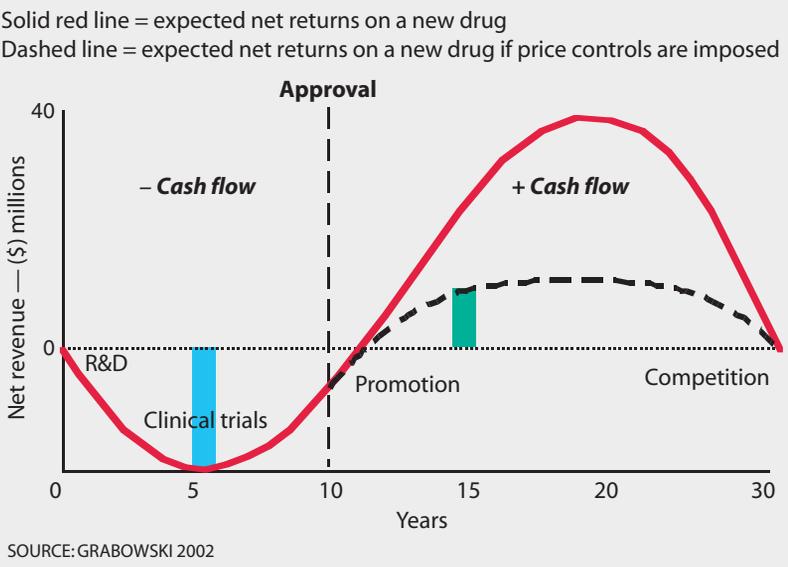


FIGURE 2 The effect of price controls



\$8.35 million.

The act of making decisions looking into the future is driven by expectations about future revenue and costs. The longer the expected development time, the lower the present value, because of the longer period of negative cash flow. Likewise, the smaller the expected market or the greater the risk of failure, the lower the present value (Grabowski 2002).

In the context of these economic considerations that affect R&D, how would a pharmaceutical company respond to price controls (i.e., the legalization of reimportation, which would be tantamount to importing the Canadian price controls)? This is clearly illustrated in Fig-

ure 2; the expected future revenue is assumed to be cut in half to only \$10 million in year 15. The present value also has been cut in half to only \$4.17 million, while nothing has happened to the present value of the investment that occurs prior to approval.

If a company expects to operate in an environment with price controls, standard economic theory predicts the company would reduce its R&D investment. Further, the company would concentrate on drugs with the largest markets instead of small-market products like vaccines. A company also would have an incentive to pursue short-term projects instead of longer-term projects. It is obvious that in a market that is expected to be limited, a company will reduce the risk profile of its projects.

Given the important role that the U.S. market plays in international markets, imposing price controls on the U.S. market would have a substantial effect on the expectations of R&D decision makers. This would not be the same as deciding to sell to a small country at a discounted price.

One historical example of how a research-intensive industry responded to price controls is given by the field market for natural gas. In the 1960s, when a Supreme Court decision led to much greater federal regulation of the natural gas production market, natural gas producers responded by cutting back on the search for new gas fields and by diverting gas into the unregulated intrastate market. The natural gas industry is analogous to the pharmaceutical industry in that investors are willing to incur high risk and up-front expenditures, provided there is the possibility of a large discovery and future revenues. The difference is that natural gas is a well-known product with well-defined characteristics, while new chemical entities are surrounded by uncertainty regarding safety and medical effectiveness. This provides an extra level of risk when compared to the search for new gas deposits.

As the pharmaceutical sector changes domestically and internationally, a major debate is occurring among securities analysts and economists regarding the viability of the blockbuster drug as the major motivating factor, and whether drug companies will reduce the risks they are willing to take in the face of smaller markets and lessened expectations. But there is no doubt that price controls in the United States would have a detrimental effect on what has been, up to now, an extremely productive industry.

Reference

Grabowski H, Vernon J, DiMasi JA. Returns on research and development for 1990s new drug introductions. *Pharmacoeconomics*. 2002;20(suppl 3):11–29.

Additional reading

- Calfee JE. *Prices, Markets, and the Pharmaceutical Revolution*. Washington, D.C.: The American Enterprise Institute Press. 2002.
- Danzon PM. *Price Comparisons for Pharmaceuticals: A Review of U.S. and Cross-National Studies*. Washington, D.C.: The American Enterprise Institute Press. 1999.
- Helms RB. *Natural Gas Regulation: An Evaluation of FPC Price Controls*. Washington, D.C.: The American Enterprise Institute Press. 1974.
- Morrisey MA. *Cost Shifting in Health Care: Separating Evidence From Rhetoric*. Washington, D. C.: The American Enterprise Institute Press. 1994.

Question-and-Answer Session

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QUESTION: Dr. Palumbo, if reimported medications are allowed to be dispensed through in-state pharmacies, or if personal importation is allowed to persist in some manner, will there be any attempt to regulate the Canadian pharmacies that are exporting drugs?

FRANCIS B. PALUMBO, PHD, JD: If pharmacists are allowed to act as importers of drugs, it will have an impact on the state pharmacy practice acts. The acts will have to be rewritten to accommodate the fact that pharmacists would be doing more than dispensing medications and providing information and counsel to patients, but are actually involved in importing. The states may end up changing their regulations on registration of importers, wholesalers, and distributors and require pharmacists to register as such in addition to being licensed as a pharmacist. This is all speculation on my part, however.

With regard to Canadian pharmacies, they're outside the reach of the states. A state's board of pharmacy has no jurisdiction over any Canadian pharmacy or any Canadian pharmacist, or anybody outside that state. And the federal government, because it doesn't license pharmacists or pharmacies, is not in that business at all.

QUESTION: Dr. Helms showed that a higher rate of return would promote research and new discoveries. Am I correct in assuming that consumers would benefit indirectly from that additional competition coming forth because of the higher rates of return?