CAN DRUG PRICING BE MADE FAIR?

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Introduction

American consumer groups claim that drug prices are inherently unjust and exploitative and many advocate price regulation. Pharmaceutical firms say that regulation would harm innovation and that society as a whole would be the loser. This paper examines drug pricing among global pharmaceutical companies and whether, given the benefits society derives from new medications, drug resources are fairly allocated through the price mechanism. The economics of drug pricing and the structure of the pharmaceutical industry are considered.

Drug Market Economics

According to drug manufacturers the cost of pharmaceuticals is driven by the long and risky process of research and development ("How Much" 10). In the course of product development, drug companies synthesize and test thousands of drug compounds. The vast majority of these compounds will fail to provide therapeutic benefit and will be abandoned.

Drugs that do make it through the first part of the research process must also pass three phases of clinical trials on human subjects. This is the most expensive part of the process. In all, a fifteen year product development cycle is common and this cost must be recaptured, say the manufacturers. According to Ewe Reinhardt, a health care industry expert at Princeton University, the cost of developing a successful drug is several hundred million dollars, and only three out of ten drugs that go to market will recover this investment ("Other Drug War"). He compares the expense of drug development to that of oil exploration, where the cost of "dry holes" must be factored into the price.

While few deny the enormous expense of producing new drugs, critics point out that pharmaceutical companies are the most profitable in the world. On average, the 12 major American drug manufacturers earned before-tax profits of 18% in 2002, compared with only 3.5% for Fortune 500 companies as a whole. Such high profit margins are possible for several reasons:

Patent protection allows drug companies to set the price without regard to competitive pressures. Competion does occur in many drug categories, for example, Prozac was the first Selective Serotonin Reuptake Inhibitor (SSRI) for depression, but now there are seven SSRI's on the market. However, the large manufacturers tend to operate as an oligopoly and do not compete on price, thus protecting their margins. In his classic book, *Competitive Advantage*, the Harvard Business School's Michael Porter describes such markets as "well-behaved." It is only when a

drug goes off-patent that true price competition occurs. That is when generic drug makers may legally introduce identical products and sell them at a lower price.

In addition, once a drug is successfully introduced, the actual cost of production is typically low, perhaps only pennies per pill for a drug that may sell for five dollars. Thus, when a product has high fixed expenses but low marginal production costs, it is said to have "operating leverage," and large profits will flow to successful product introductions.

Companies often sell the same product at different prices in different national markets, a practice known ad "differential pricing." Selling the same product at different price points is a common business practice and is in fact accepted wisdom at American business schools, regardless of industry. Such pricing is a function of "marginal analysis," which seeks to determine the marginal, or "extra," cost of producing one more pill, shirt or automobile. So long as the price exceeds this cost, then the company will make money. To maximize profits, drug companies sell as many pills as they can at a high price, but must then find other buyers for the remainder. What distinguishes the pharmaceutical business from other industries are its peculiar market dynamics: patent protection; controlled distribution; the fact that the end customer is partially shielded from the true cost by insurance intermediaries; and the discipline of companies not to engage in price competition. From a purely business point of view, it is probably accurate to say that all companies in all industries would behave the same way, if only their markets would let them.

Criticisms

Consumer groups, especially those representing seniors who depend on medications, have been particularly vocal about drug prices. In addition, health insurers and HMO's have been pointing fingers at drug companies as a primary reason for insurance premium increases. And recently politicians have become more vocal about pricing in response to the rising tide of constituent complaints as well as the increased cost of providing benefits to public workers and retirees.

Dr. Marcia Angel, an MD and Harvard economist, questions industry claims that profits reflect as much risk as drug companies claim ("Other Drug War"). She describes the industry as "stunningly profitable." It is, in fact, the world's most profitable industry.

Other critics point out that a good deal of basic research costs are actually born by taxpayers through government-funded grants to universities, thus weakening manufacturers' claims of high up-front investment. These critics argue that companies should not be allowed to set the market price for products developed from public investments.

In addition, there is widespread criticism that companies invest heavily to develop "me-too" drugs that mimic existing solutions, rather than invest in new medications for under-treated diseases and conditions. For example, there are a multitude of acid reflux drugs and anti-depressants, for which there are millions of customers in developed countries. But there's very little investment in, say, "Lou Gehrig's" Disease (amyotrophic lateral sclerosis), a debilitating and terminal condition but one that affects only about 40 thousand people. The bottom line is that companies are not as interested in diseases that afflict relatively small populations.

Free Market Defenders

While the industry has no shortage of critics, it also has its share of defenders. Advocates such as the libertarian Cato Institute are enthusiastic supporters of a free market approach to drug development and marketing ("Making Sense"). In general, the industry and its supporters make the following arguments:

- Return on investment reflects the high risk of drug development and, given the benefits of new medications, it does not make sense to discourage innovation. In France, formerly number two in pharmaceuticals after the U.S., total investment in drug development has declined significantly due government price controls, according to a Cato Institute policy paper. They believe that similar efforts in the U.S. will discourage innovation.
- Comparisons of cross-national drug prices made by "liberal" consumer groups is flawed because they do not take into account the availability of generic substitutes, which comprise half of the U.S. market.
- Cross-national comparisons reveal that actual price differences are small when properly weighted for pack size. A study by Wharton professor of health care economics Patricia Danzon says that to the extent price differences do exist, they reflect nations' relative wealth and ability to pay ("Prices and Availability" W3-537). Without cross-national price differentials, many nations such as Mexico could not afford medications, the study concludes.
- Claims of health insurers that drug prices cause rising insurance costs are greatly exaggerated. PhRMA, the drug industry's association and chief lobbyist, claims that its data shows that drug prices accounted for less that one fifth of the total price increases in insurance costs since 1995.

Summary and Conclusions

Prescription medication pricing raises issues of resource allocation and presents touchy public policy concerns. Drug makers do take enormous risks with their R&D investment and there is no promise of a return if the wrong bet is made. The wisdom of capital markets suggests that investors will not accept this risk without an expectation of high returns, and without investment, fewer drugs can be funded. Manufacturers may be even further incented to focus only on blockbuster opportunities rather than much-needed solutions that serve smaller markets.

However, prescription medications are not the same as soft drinks, toothpaste or fashion apparel. Drug makers have a special obligation to serve society, and with market power concentrated in such a small number of companies, the lives of many millions rest on the decisions of a few.

While they make business decisions that will have enormous social impact, they also spend tremendous time, energy and resources on lobbying and political influence aimed at retaining their unique market advantage. Patent protection, high barriers to entry for new market entrants, a favorable regulatory environment, control of distribution, relative protection from price pressure owing to the price-insensitivity of prescribing physicians, oligopolistic industry behavior and operating leverage all insulate pharmaceuticals from normal market and competitive forces.

Given the social impact of their decisions and business practices, it would seem that society has a reasonable expectation that medications, partially paid for by public investment, will be affordable for the maximum number of people. Is regulation the answer? Certainly organizations like the Cato Institute would argue that competition and free markets are a better mechanism for real innovation, and that true price controls would be counterproductive. But, as has been documented, these companies don't really operate in a normal market. They behave the way the do because they can, and only if they were subjected to the same competitive forces as, say, the consumer electronics business, would prices be driven lower.

If a public policy could be fashioned to make the drug market truly competitive, pharmaceutical manufacturers would be unshielded from the unique structural protections they now enjoy, and society would reap the benefits of new medications at a much lower cost.

Sources

Danzon, Patricia. "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries." Health Affairs. October 29, 2003.

---. "Making Sense of Drug Prices." Regulation [Cato Institute] 56 Volume 23, No. 1. Mar 20, 2000.

"How Much Do Managed Care Companies Spend on Prescription Medicines?" Pharmaceutical Research and Manufacturers Association. Spring 2003.

The Other Drug War. Narr. Will Lyman. Writ. Jon Palfreman. Prod. Jon Palfreman and Barbara Moran. PBS. WGBH, Boston. June 19, 2003.

Porter, Michael. *Competitive Advantage*. New York: The Free Press, 1985.