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Review Article

Impact of Drug Prices & Drug Price Discrepancies Between Some Countries

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ABSTRACT

Pharmaceutical prices are substantial and are rising faster mainly due to increasing population and increasing cost of new developing pharmaceutical technologies. Drug prices are correlated to income levels. Generic drug manufacturers are able to offer products at lower cost than the branded drugs. Branded drugs are sold at significantly lower prices in least developing countries. Development of innovative pharmaceutical products ensures the continued gains. To encourage the continued development of new drugs, economical incentives are essential. These incentives are provided by the direct or indirect funding of the government. Intellectual property rights and other policies favor innovations. It says that benefit designs, reference pricing and group purchasing will reduce the financial barriers and it keeps down the spending on pharmaceuticals. This article provides empirical evidence on the impact of drug price and drug price discrepancies in some countries.

Keywords: Generic drugs, branded drugs, Intellectual property rights.

INTRODUCTION

The impact of patents on drug prices has emerged as controversial issue in public health crises. Activists blame patents for keeping prices out of those who badly need new drugs for letting generics compete with original brand products protected by patents in developing countries. Patents play an important role to encourage research and development of new medicines and vaccine. After introduction of generics, prices of brand name products might even increase. Introduction of pharmaceutical product patent rights may increase the prices of the pharmaceuticals. Companies may be encouraged to set drug prices close to the marginal cost in least developed countries with a successive procurement of prices from high to low incoming countries. Pharmaceutical companies would set prices according to their income [(1)].

DISCUSSION

Supplier would charge in each country according to what the market can bear in order to maximize the profits in a particular country. Prices are proportional to the average economical capacity. It is not necessary in all cases because companies target only on a small share of wealthy people in poor countries. Although drug prices are regulated in the most of the countries and each country local regulatory has power in their home markets and joint costs are global.

In developing countries 70-90% of drugs are paid out of pocket as a share of drug expenditures. In low and middle income countries more than 40% of drugs are paid out of pocket as a share of drug expenditures. Public spending on medicines accounts for not less than 2% per person. They pay on average more for medicines through out of pocket expenditures. This is usual in developing countries than the consumers in the developed world. One third of inhabitant's lacks reliable access to essential drugs.

Consumer prices in developing countries are often charged higher than in developed countries, even though manufacturer prices may not follow the same path. Taking strategic prices of pharmaceutical companies and the fact is that the major R&D based pharmaceutical industry is worldwide in its structure and ownership, it is necessary to improve the affordability at a countrywide level. Also more spotlights must be put on intermediate sector, which plays a vital role in consumer price determination process. Pricing pattern where public of poor countries pay less for same drugs than in developed countries would ensure affordability. Affordability does not need to be concerning by political pressure. Affordability can be in concern of multinational pharmaceutical companies. If they can effectively limit their sales to particular country and set prices according to price elasticity's of demand. Pharmaceutical drug prices in developing countries are related to international level [(1-3)].

Annual data from 2014 on thirty essential drugs for ten low income representative countries like Armenia, Brazil, Cameroon, Ghana, India, Kenya, Philippines, Peru, South Africa and Sri Lanka revealed that the leading variable in drug pricing is the ratio of local median prices to international median prices both expressed in US $ at current exchange rates.

Prescription drug accessibility and affordability in Abroad

Low income Australians was the only income group to report financial barriers more frequently than higher income Americans. This reflects gaps in cover - age and higher cost sharing even insured Americans frequently

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experience. Low income Americans were at high risk of cost related non adherence. In Figure:1 More than 34% of low income Americans reported not filling prescriptions during past 12 months. Because of cost, below average and above average income groups are going without medications.

Adult ages like 30 to 49 and 50 to 65 are more likely to use at least one prescription than similar aged people in other countries though in the former of these two groupings there is little difference between Americans and Australians. Americans with chronic illness or none were more likely to fill one or more prescriptions than persons of similar health status in other countries except Netherlands. Doctors in the USA have greater propensity to prescribe drugs for relatively healthy people than do doctors in other countries. Perhaps it is notable that the USA and New Zealand are the only countries that permit to consumer advertising of prescription drugs and the intensity of practice is greater in the USA resulting patients are requested for prescriptions. Researchers in many countries have documented a positive relationship between income and health status [4-7].

Drug price regulations in some countries

Governments use a variety of strategies to control prices related to pharmaceuticals. These include direct or indirect price controls, reference pricing, profit controls, physician budget constraints and marketing approvals and limits on promotion, among by many others. These strategies have a tendency to have the most considerable impact on the newest and most inventive medicines, because the controls usually focus on when drugs first enter the national health care systems.

The control strategies can be intended either at the supply or demand of pharmaceuticals. The purpose of these measures is to limit government and private expenditures on pharmaceuticals. These interventions can produce a variety of unenthusiastic consequences for the national health systems and decrease social welfare by depressing the number of new drugs added to the global pharmacopoeia. Such controls can also delay the availability of some innovative medicines in foreign countries with the effect of limiting competition and requiring national health systems to give up the benefits of those innovations in reducing health care costs.

Price controls

Drug price regulatory systems of 11 OECD countries rely on some form of price controls to restrictions spending on pharmaceuticals. Government barriers are approval delays, reference pricing and procedural barriers, restrictions on prescribing and dispensing and reimbursement. These methods avoid companies from charging a market based price for their products. They also tend to be non transparent, as the rationale criteria for certain reimbursement amounts or pharmaceutical prices are not fully disclosed even to the pharmaceutical companies seeking to market their drugs.

Control prices are to set the sales price and make sales at any other prices illegal. Governments frequently are the dominant market observer and may negotiate favorable prices with manufacturers by leveraging this monopolistic power. Such negotiations normally result in prices lower than they would be in a market. Another method government uses are to set the reimbursement price of new drug is well below the market price.

Reference pricing

Reference pricing determines sales prices based on the existing therapies in same country or prices in other countries. Since reference pricing controls are the refund level and not the manufacturer's price, government frequently views this method as less restrictive than price controls. Many countries that moved from a liberal approach to a regulated pharmaceutical market employ several form of reference pricing.

International reference pricing

It's a common approach to establish reference pricing based on different prices from other countries. The comparison prices are frequently taken from a range of "peer" countries. Such comparisons are blemished by the many difficulties inherent in cross-national pharmaceutical price comparison, lack of standardization regarding name, form, strength, and presentation. Such comparisons also not succeed to adjust for differences in per capita income between countries or other factors that would account for price differences. By taking comparison prices from other countries, the regulation of drug prices in one country can straightly affect prices and revenues in another country.

Therapeutic reference pricing

Therapeutic reference pricing enhances the reimbursement to the price of the average or lowest price of other drugs in its therapeutic class. This comes close to the argument that it is proposed to allow physicians, patients and insurance companies to choose between similar products without concern for price.

Other pharmaceutical companies particularly research based pharmaceutical companies, raise concern that the process frequently undervalues additional therapeutic benefits of new drugs and assumes that all medicines within a category are suitable for any patient with a specific illness. If innovative drugs and generics are grouped in the same therapeutic categories, this method of reference pricing forces prices for new drugs toward the level of existing generics discouraging innovation by failing to adequately reward it [8-12].

Limitations on volume

Governments may also impose the limitations on volume to control the quantity of new drug that may be sold. Variation of the volume control is price volume agreement. This links new drugs compensation price to a volume threshold. If the threshold is exceeding, the manufacturer must provide compensation through cash payment or price reduction to the government or take out the product from the market.

Eg: Australia and France both countries impose price volume agreements on manufactures of new medicines.

Profit controls

Government may also impose on price controls & some countries impose profit controls on pharmaceutical manufacturers. The controls limit the sum of profit a company may earn per product or within a specified period of time. If the limit is exceeded, the company may require

to either compensating the government for accepting a price cut.

Price floors

Many countries require price floors for pharmaceuticals patent expiration in order to support the domestic generic manufacturing industry. Price floors are in general based on a percentage of the patented drug price. Maintaining high generic prices may lead to increase in the conservation of branded drugs. However countries keep relatively fixed pharmaceutical budgets and are imposed to pay related to off-patented medicines. They may be left with a smaller amount to pay for new, innovative drugs. The final impact of these floors on revenues to inventive firms is indistinguishable. Consumers are actually left with a smaller amount to pay for new, innovative drugs because they are compulsory to pay relatively more off-patented medicines [13-17].

Marketing endorsement

Marketing endorsement is required for sale of pharmaceuticals, apart from of whether they are over the counter or prescription drugs. While this necessity is designed to guarantee the safety and effectiveness of medicines, marketing endorsement can be extremely difficult to attain due to delays in time, approval costs, nature of regulations and approval criteria. In many countries the endorsement process suffers from non transparency, lack of standardization, unnecessary complexity. The process typically involves multiple stages of approval and multiple government and regulatory bodies, as a result technical delays tend to the standard. The regulation compelled manufacturers to submit significant quantities of proprietary manufacturing data to the food and drug as part of the drug approval process.

Cost effectiveness reviews, called the fourth hurdle requirements by industry, are defined as government concern of factors other than safety, efficacy, and quality in approving new drugs for marketing. Determination that new medicine is medicinally necessary or not cost effective can work much like price controls because the analysis can be perform in a way that makes understandable that price decline will make the drug acceptable. The reality is that approval criteria and procedures frequently lack transparency, combined with a near prohibition on post approval price increases, can cause cost effectiveness requirements to create registration delays and increased costs for manufacturers.

Pricing approval decision

Pricing approval decision suffers from many difficulties as the marketing approval decision. Manufacturers are typically required to submit scientific dossiers and economic reports & price data from other countries. Frequently the data required for reimbursement or pricing decisions is the same as the data required for marketing approval. The pricing decision may also delayed by extensive negotiations, multiple decision making stages, waiting periods and lengthy bureaucratic delays. But some member states that not yet succeeded in meeting this authorization. The consequent postponement in bringing innovative drugs to tolerate on health problems has been documented by academic experts [18-20].

Barriers to prescribing and dispensing

Restrictive formularies

A formulary is a choice of preferred drugs within a therapeutic class. A government body, hospital, health plans and third party insurer determine the list. Some health plans impose closed formularies, which prohibit the dispensing of drugs not listed in the formularies. Typically outside the formulary drugs are used only in specific, rare circumstances and prior approval from the authority is required. Other formularies may have certain restrictions or no restrictions, such as higher patent cost sharing requirements for off formulary drugs.

The category and choice of formularies are available at restrict manufacturers access to pharmaceutical market. In some countries which impose a single, closed, national formulary a particular drug must be listed on the formulary in order to be prescribed. If off-formulary drugs can be legally prescribed, fact is that they are not reimbursed is a sufficient disincentive to effectively prevent limit prescription in given current prohibition on manufacturer's communications to patients about the benefits of higher priced brands. In countries which have open formularies the access to the market depends on the range of formularies available and reimbursement rate.

International price comparisons

Innovative drug manufacturers fund most private R&D expenditure to develop new pharmaceuticals, any effort to analyze the effects of foreign drug price regulations on R&D requires an understanding of the effect of price regulation on revenue of such firms. Because their revenue depends mainly on patented drugs, study uses a set of the best selling drugs with patented active ingredients to serve as the basis for price comparisons and the implications for revenue and R&D spending.

Patented data set was also difficult by the fact that patent expiration dates vary across the nations and the patent expiration date itself can be unpredictable indicator when generic competition begins. In United States admission of generics into the market place and this makes the patent expiration date a good proxy for when generic drug competition starts.

International trade administration

In United States cholesterol reducing drug is known as Lipitor but in France and Germany the same drug sells under the brand names of Sortis and Tahor respectively. Proper comparisons are required a definition of product that matches across countries. The challenges are focused on appropriate basis for comparison of prices which would address the fundamental questions posted by the report. This led to a review of the principal classification criteria for pharmaceutical data. Those criteria's include brand name, molecular name therapeutic use, dosage form like (tablets, capsules and injections), strength & package size. Most of the studies are classified products at the molecular level, which is the broadcast of a product. However each countries pharmaceutical market is different, this approach produces comparisons of products that differ by dosage form, strength & package size. Matching products are based on identical classification criteria yields most accurate level of comparison.

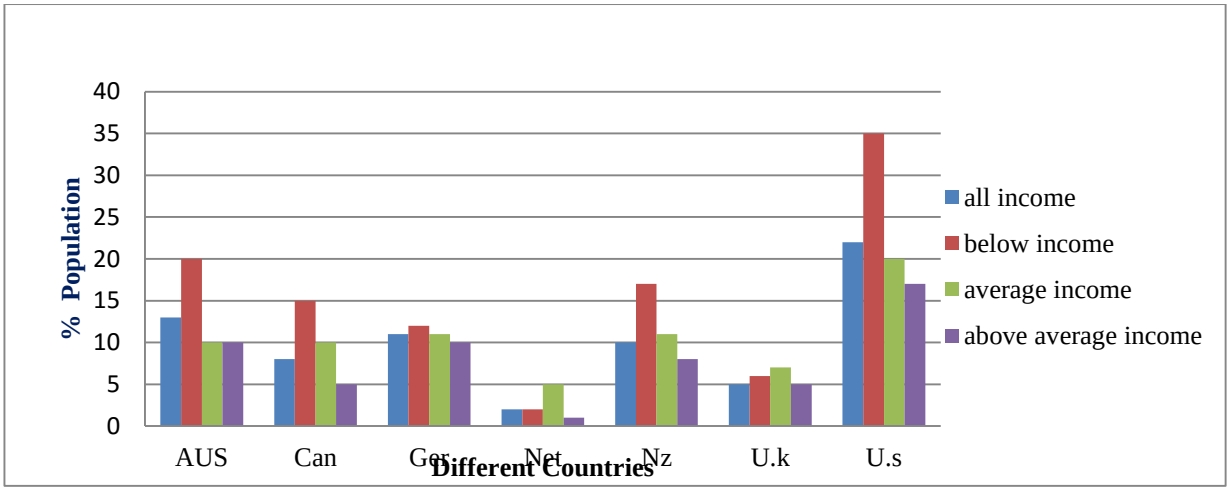

Figure1: Percentage of population report not filling a prescription or skipping dose because of cost during previous 12 months

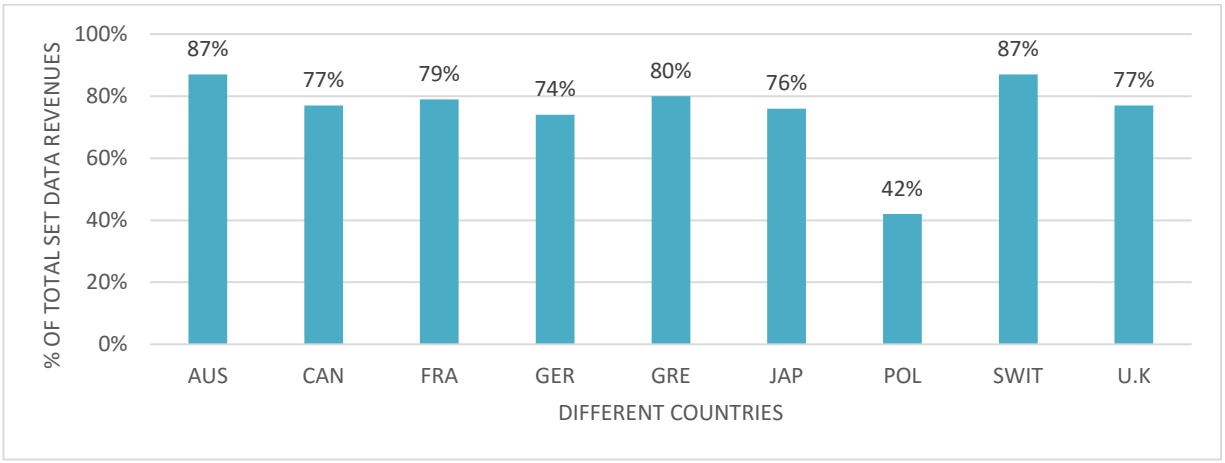

Figure 2: Revenue from Patented Drugs as a % of Total set Data revenues in 2014

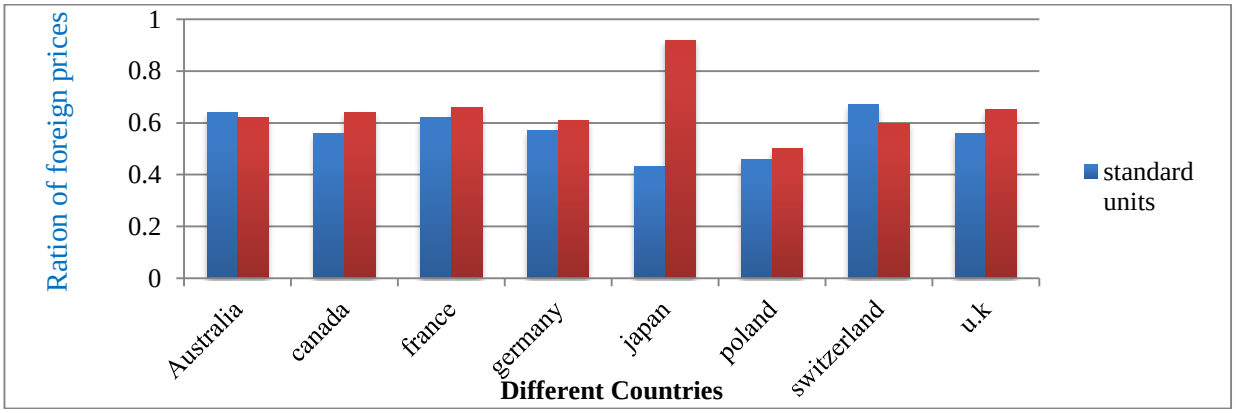

Figure 3: Patented drug data set prices in 2014

A product is defined as a bilateral match between the partner countries and United States at the molecular level. Data is provided based on 60 prescription products in the United States measured by 2013 sales. The molecular composition of each one was determined & combination of products containing multiple molecules was removed from the set data narrowing data was set to 54 molecules. The data set was then extended to all single molecule products made from these molecules. As a result the set data includes on and off for generics, patent brand name products produced by licensees and offers as sound as possible a basis for price comparisons, variation between national markets. 54 molecules sales data represents 26% of total drug sales in 2014 across 10 countries including United States. In figures 1 & 2 covers the total and patented data sets resulting from the molecule- level production. From the statistics in Figure:1 it appears that the effective patent life of molecules in most of the countries are shorter

than the United States. Analysis of the effective patent life for 46 out of 54 molecules included in the set data shows that effective patent life in the United States is 2 to 2½ years longer than in UK, Switzerland, Germany, France and in Poland and Greece it is 4 to 5 years. IMS health data set is based on an analysis completed by the Food and drug administration. Only 46 molecules out of 54 molecules in the set data were analyzed because 8 molecules were missing to calculate the period of effective patent life included the molecules launch date, expiration date, sales per year and volume per year.

Pharmaceutical prices in the absence of price controls

Market forces rather than government regulatory process would set pharmaceutical prices in the absence of price controls. The market for inventive pharmaceuticals is defined by several unique characteristics that must be considered when estimating prices in the absence of price controls. The high cost of developing and testing a new drug is no profit maximizing firm would make the investment needed to bring innovative and new medicines to the market in the absence of patent protection. To overcome this problem countries offer patent protection as a reward for innovation by conferring the right to use of the resulting chemical compound for a precise period of time. Such patent protection affords innovative pharmaceutical manufacturers considerable pricing power. Trade in pharmaceuticals generally cannot take place apart from authorized channels. Because direct manufacturing costs represent a relatively small percentage overall costs, prices can vary significantly. As a result pharmaceutical firms can be estimated to charge different profit maximizing prices in different markets. Low cost of production and absence of trade, the profit maximizing price will differ across countries because the patent holder will charge a price that reflects the demand factors in market.

A variety of factors that affect demand for different drugs in different countries, one consistent factor influencing demand is income. It is assumed for this study that pharmaceutical prices are the benchmark for relative levels of income and unregulated prices determine variances in prices among developed countries. However the variances in prices for each molecule are determined solely by income levels, only aggregate prices would vary based on relative income levels.

Revenues estimation in the absence of price controls

After adjusting the prices new foreign revenues are computed by multiplying in sync prices and volume measures. This study makes to simplify the assumption that consumption patterns would not alter in the absence of price controls. Imposing floors and ceilings on particular molecules of course imposes artificial constraint on the extent to which markets would respond.

Impact of deregulating prices on innovation, research & development, and consumers

The prior section examined the difference between prices in the United States and regulated prices surrounded by selected countries, and estimated the effect of deregulating prices in 11 of those countries on pharmaceutical revenues. Here, the study estimates the impact of deregulating prices in 11 countries on the propensity of innovative firms to investment additional R&D on new therapies, how changes in R&D spending will actually affect innovation delivered to the market and at last, the impact on consumers in the United States, both in terms of the effect on prices and the ultimate impact of greater opposition from generic manufacturers and new and innovative therapies.

Deregulating foreign prices would increase the flow of new molecular entities (NMEs) by 3 to 4 per year. It would increase access to new therapies by foreign consumers, potentially improving their health. By giving consumers greater choice among drugs, price deregulation would also provide health benefits to drug buyers. It would range from $5.9 billion to $8.5 billion annually [21-24].

Effects of Eliminating Foreign Drug Price Controls on Research and Development

The long-term effects of higher prices on consumers are tied closely to the effects on R&D and innovation. Both empirical evidence and economic theory indicate a close correlation between R&D expenditures on one hand and revenues, cash flow, and profit margins on the other. Academic experts present data showing an even closer relationship between R&D and cash flow during the years 1962-1996. In general, the trend in R&D is less subject to annual fluctuations than in cash flow.

Impact of Higher Research and Development on Innovation

The higher level of research and development spending attributable to the deregulation of prices and is translating the effects of price deregulation into greater innovation and higher consumer welfare. It addresses innovation and next consumer welfare. From increased innovation benefits would flow, competition in the market place from new innovative medicines and finally to the consumer in the form of low costs, better value or both.

The impact of higher R&D spending on innovation may vary substantially with the nature of the spending for new molecular entities. Only two-thirds of total out of pocket R&D spending is associated with the development of new medicines and approximately one third is spent on post approval for long term safety and efficacy studies in specific patient groups and for the development of new innovations or new formulations.

Increased spending on R&D will be split between new active substances and other purposes in the same proportions as the current spending on R&D with approximately two- thirds. Thus elimination of foreign price controls in eight countries could increase R&D spending on new drugs. A rough estimation of the effect of addition R&D on innovation could flow from costs of developing new drugs. Various studies have been made regarding the cost of developing new drugs [25-28].

Benefits of deregulating prices for consumer welfare

Deregulating prices will help residents of countries where prices are higher by bringing them faster access to more innovative medicines. It will also benefit residents of developed nations by increasing the flow of new therapies and treatments.

Deregulating prices will provide greater access to new drugs

Deregulating prices abroad may significantly increase patient's access to new medicines in some countries. This conclusion follows from systematic drug launches and from a comprehensive count of recently drugs available in different countries.

Earlier it was noted that latest research has suggested that foreign government's price controls have delayed the launch of drugs in different markets. There by adversely affecting patient's access to new medicines. Delays frequently are caused by the additional time it takes for companies and government to agree on the prices at which a drug will be sold or reimbursed [28-32].

Managing pharmaceutical costs

In providing by the coverage of universe, countries also manage expenditures on medicines by two mechanisms

The process and criteria used to determine the which medicines will be covered and cost of sharing

Pricing policies and negotiations concerning the price of the medicines.

Formularies and related price negotiations are common place in the U. S where major private insurances and some public buyers buying power on behalf of population subgroups. Different formularies may apply to dissimilar patients depending upon their insurer. Countries they have universal coverage and a commitment by contract and commitment to their base that cost sharing and coverage on best saving on best available evidence.

In most countries information about the comparative clinical and effectiveness of medicines in systematically assessed to determine which medicines should subsidized and which medicines should not subsidized and what level of exposure. In U.K the system is governed by a negative formulary. In other countries every medicine is appraised to determine at what rate it should be subsidized.

Using the available data we find some evidence of less strict pricing strategies for life saving drugs and the appearance of more affordable generic drugs. Affordability problem in developing countries together with assessment of the firms incentives for the investment in development of cheaper drugs that would suit well the needs of poor patients [32-36].

CONCLUSION

This study found that drug prices vary considerably across the countries. There is a positive correlation between income and drug price index. Drug prices tend to be higher in higher income countries and lower in lower income countries. However some low income countries pay vary different prices for drugs than other countries with similar levels of income.

Several possibilities could account for these pricing patterns. For example some governments have enacted policies to regulate pharmaceutical pricing in order to control costs, but some low income countries lack the financial resources to exercise such controls. Price discrimination is likely to increase both production of existing products and development of new ones. This is generally the case whenever there are fixed production costs.

Regardless of these general principles, the political and economic environments have a large impact on pricing policies that can impact pharmaceutical manufacturer's revenues. Legalizing the re importation of drugs from one country to another is one policy change that would reduce or eliminate difference between prices paid by Americans and prices paid by foreigners. Many countries have already implemented price controls and policies regulating the way drugs are purchased for government sponsored coverage, in efforts to control costs. Consumers might even benefit from such policies in short run; as they would reduce the amount consumers have to pay. But the policies also have less desirable consequences reductions in the amount of funding available for research and development & thus in the number of new drugs In long run, price discrimination has the ability to improve the well being of society. Pharmaceutical company managers and government regulators should be aware of this when they consider international variation in drug prices.

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