

The Role of Bioethics in the International Prescription Drug Market: Economics and Global Justice

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Abstract

In terms of health care access, bioethics has an important role to inform and shape policy issues and develop interdisciplinary ideas and interventions. The rising price of prescription drugs presents one of the most looming barriers to health care access in the world today. Including both theoretical and practical features of the pharmaceutical industry's behavior is necessary to find ethical solutions towards increasing access. Bioethics can evaluate global justice by weighing human rights theory and future innovation at the macro level, and by addressing market forces and responsibilities at the micro level.

Inherent structural features of pharmaceuticals, such as its reliance on research and development, cause the industry to employ pricing strategies that seem counter-intuitive to conventional wisdom, but that result in producing a just allocation as defined by market forces. Parallel trade and drug exportation/reimportation threaten the saliency of the industry's differential pricing scheme; a case-study of a single "Euro-price" within the European Union illustrates how this will actually create harm to the most needy member states.

This complex situation requires solutions weighing arguments from human rights theory with those from economic theory to arrive at the most globally just allocation of prescription drugs in the global marketplace, as well as to ensure future innovation and scientific progress. Bioethicists as well as economists need to partake urgently in this discourse for the betterment of the global injustices in the international prescription drug market.

Health care access is a major problem confronting many around the world. In the context of access, bioethics has important role to inform and shape policy issues and develop interdisciplinary ideas and interventions. The rising costs of health care provide one of the most looming barriers to health care access in the world today; one of the driving forces being pharmaceutical prices. The

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price of prescription drugs has been growing faster than other elements of health care, which therefore directly affects health care access to products such as life-saving, life-prolonging, and life-enhancing medication (KFF, 2004, p. 1).¹ In dealing with the implications that arise from disparities in health care access through drugs, it is important to understand both theoretical and practical explanations of the pharmaceutical industry's behavior when looking for ethical solutions. Access to medication involves evaluating both social and private responsibilities (Ryan, 2005, p. 544). Bioethics must therefore weigh the elements found in global justice and future innovation at the macro level, while addressing market forces and responsibilities at the micro level.

Global Justice and Human Rights Theory

This analysis applies the principle of justice, as posited by Beauchamp and Childress (1994, p. 225), to the analysis of prescription drug access. Justice involves determining the proper allocation according to certain standards, and the two main philosophies guiding the principle of justice are comparative and distributive (Daniels, 1981, p. 147). Comparative justice assumes an inherently scarce environment with a finite amount of money and resources that can be spent on health care, which posits that health care should be allocated based on existing needs and conditions. Distributive justice focuses on the use of doctrines to decide what is just rather than turning to elements found in the current state of affairs. Using welfare and difference measures of justice, the starkest injustice in pharmaceuticals involves the poorest countries in the world. The two most pressing features of low-income individuals in the drug market are affordability of medication and research into diseases endemic to poor countries (Frank, 2001, p. 116). An analysis into the current allocation of pharmaceuticals on the global market involves an in-depth look at the role of justice in theory and practice.

Literature on human rights theory discusses health care both explicitly and implicitly. In the United Nations Declaration of Human Rights (1948, Article 25), the enumerated rights present a stark contrast between positive and negative rights; that is, those that must be actively provided versus passively allowed. Article 25.1 states,

¹ "National prescription spending increased 15% from 2001 to 2002, compared to an 8% increase for physician and clinical services and a 10% increase for hospital care [in the United States]."

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care, necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. (Emphasis added.)

While the doctrine discusses the right to a standard of living with some level of health care, it does not go so far as to demand positive intervention from a governmental body in order to provide care. Creating a minimum standard of health care might refer to creating a public health environment with proper water and sanitation, rather than an imperative to provide citizens access to all available health care and regimens. However, ambiguity arises in determining the burden of care that should apply to the pharmaceutical industry.

Pharmaceutical Industry Structure

Economic Theory

Economic theory is helpful to analyze the global pharmaceutical industry and the corresponding allocation of drugs. There are four main models used in microeconomic theory: perfect competition, monopoly, monopolistic competition, and oligarchy. These models differ based on assumptions such as the symmetry of information between the buyer and seller, and whether the firm is a price-maker or price-taker. Inherent features of the pharmaceutical industry exist that most resemble the assumptions in the monopolistic competition model (Danzon and Towse, 2003, p. 188). In normal commodity markets, i.e. the perfect competition model, consumers benefit from the presence of competition. Businesses target consumers by developing and advertising new products to attempt to find a niche. The result begets new brands and nuances within brands, with the ensuing competition helping to drive down the price of close substitutes. However, inherent structural differences exist in the pharmaceutical industry in which competition (and lower prices) does not benefit consumers in the same manner as most other normal commodity markets. Two prime examples of the structural differences are the existence of patents and the use of differential pricing.

Patents

The World Trade Organization, which is the international organization that regulates the rule of trade between 149 nations, established an international patent life of 20 years in its 1995 charter. Patents and other intellectual property rights, which are utilized for reasons such as encouraging innovation and regulating competition in the global market, are governed by the WTO's Trade Related Intellectual Property Rights (TRIPS) agreement (WTO,

2006). The TRIPS agreement affords pharmaceutical companies the right to hold exclusive access to its product for a set amount of time and provides a standardized mechanism to license its products in other countries. The justification behind patents is two-fold: to encourage innovation and to recover R&D costs (Sykes, 2002, p. 57). If the company were not afforded the promise of patent protection, no company with heavy R&D focus would enter the pharmaceutical business. (This analysis reflects the current scenario in which drug R&D and manufacturing are linked.) Although critics argue that the patent period is too long and allows drug companies to make high profits, there does not seem to be a way to privately develop pharmaceuticals without the patent system (Gilbert, 1990, p. 112). Difficulties arise in trying to estimate R&D costs and a time frame in which to recover these costs. The R&D costs to be recovered not only include those for the drug in question, but also for other drugs that were lost in different stages of development. In one analysis of 68 drugs that entered the US market between 1980 and 1999, three health economists concluded that the average pre-FDA-approval price to the company was \$802M (DiMasi et. al, 2003, p. 180). A high rate of attrition exists in potential products through the stages of laboratory, animal, and human trials, as well as trials needed for regulation (Barton and Emanuel, 2005, p. 2076). According to the DiMasi (2002, p. 298), only 21% of drugs that begin in human testing receive final approval. Due to the complexity of the estimation, pharmaceutical firms argue that it is better to err on the side of higher profits than lower in order to ensure future innovation.

Differential Pricing

Differential pricing, also known as price discrimination or market segmentation, occurs when a company charges different prices to different consumers for the same product. An intuitive interpretation would conclude that charging different prices to different individuals would be an indisputable injustice; that is, those paying a higher price would be more justly served by paying the low price. However, market segmentation in price-sensitive industries actually increases access and lowers prices to the poorest without raising the prices to the richest. An oft-cited example is the price of movie theatre tickets. Adults pay the regular price while students and senior citizens pay a discounted rate. The theory is that students and seniors are price-sensitive – students have less money to spend than adults, and seniors have a smaller percentage to devote to entertainment on a fixed budget – so each might not attend a cinema if they had to pay full price. Charging everyone full price would restrict access to the show as the price-sensitive audience would not attend. Conversely, charging all patrons a discounted rate would not allow the theatre, and by extension the movie industry, to pay back the high costs of production, which would lead to negative consequences

for the entire industry. The best situation then, and the one that is in fact practiced, is to charge different prices to different markets. Therefore, access is expanded while the costs of production are paid back to those who fronted the costs.

This example is analogous to the pharmaceutical industry, except that price-sensitivity is, in theory, segmented by country rather than by age. Countries with high incomes per capita are analogous to the adult in the movie theatre example – they have relatively more money than citizens of poor countries and therefore more money to potentially devote towards drug expenditures. The students and seniors are in the movie example represent the poorer states in the world. De George (2005, p. 563) argues that using global differential pricing is in fact an ethical obligation in that it increases access. According to one analysis, price discrimination increases access by a factor of 4-7 times, which illustrates the economic concept that pharmaceutical companies accomplish the goals of expanding affordability and access by implementing a system of differential pricing (Dumoulin, 2001, p. 322).

Differential pricing occurs only because markets can be properly segmented to assure that lower prices do not erode into the general marketplace. In the theatre example, this transpires by forcing seniors and students to show proof of age or affiliation when purchasing tickets. The industry wants proof that only students and seniors are using their discounted prices and not purchasing tickets for use by full-fare adults. Likewise, when poor countries receive price discounts, it becomes imperative that some mechanism protects these discounts from spilling over into other markets; markets made up of those who in fact have the money to pay the initial price.

The manner in which markets are be segmented affects access. For instance, poor and/or uninsured citizens living within a country with high income will be unable to access the drugs at relatively high prices assigned to the country; this is the case in the United States and India. The best situation in terms of access for these individuals as well as sales for the pharmaceutical industry is to segment the

markets even further, such as by income. The downside to price discrimination is that those facing higher prices may look for other opportunities to acquire medication, which can lead to an implosion of the differential pricing scheme.

Duty to Shareholders

By virtue of the market mechanism, companies have a duty to their shareholders to provide them with a reasonable return for assuming risk as well as a profit margin to entice more capital (Dukes, 2002, p. 1682). Industries that produce products with a long time lag between research and appearance on the market involve an extra cost that economists refer to as the “opportunity cost of capital.” Basically, if the investors had chosen a typical industry (i.e. shorter time lag), they would have seen a return much sooner, and this implies more opportunity for interest and investment. Therefore, to attract capital in the pharmaceutical industry, companies must be able to entice investors by offering the potential for larger returns. Contrary to popular belief, the pharmaceutical industry does not consistently churn out exorbitantly high profits, as Table provided below illustrates.

Many reports focus on the high percentages of sales dollars spent on marketing compared to research in the pharmaceutical industry. Experts argue that the market itself has created an imbalance between research and marketing dollars (Barton and Emanuel, 2005, p. 2077; Angell, 2004, p. 1452). They suggest that, by reinvesting the marketing money back into R&D, more new drugs can be created and/or prices can be lowered. While this logic is valid, it does not account for the possible increase in demand caused by the marketing, which could affect the volume of drugs sold. Marketing is an important mechanism in which to promote scientific advancements in medicine, but the magnitude of marketing dollars is in need of further research and dialogue. This leads to the conclusion that if, like critics contend, marketing money was redirected toward R&D, the problem becomes the opposite – without sales in the first place, there will be no

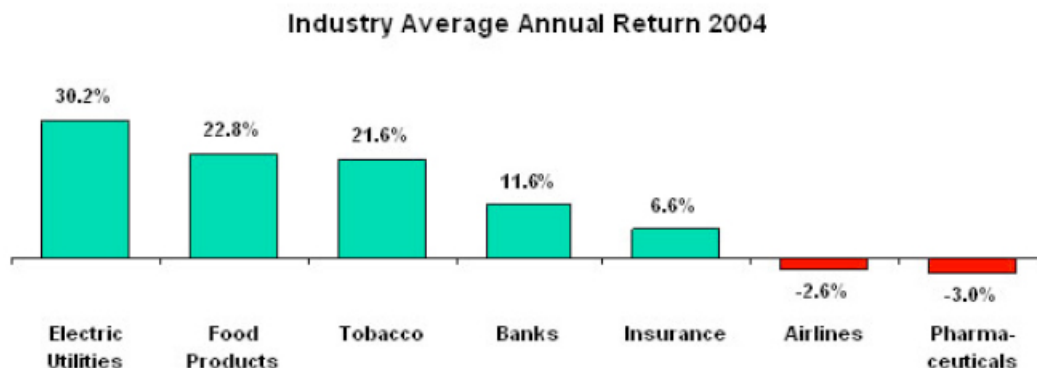


Chart Source: The Wall Street Journal Online, Shareholder Scoreboard, How Industry Groups Fared, Feb 28, 2005

money available to support R&D.

Research incentives

The structure of the pharmaceutical industry creates incentives only for drugs with potentially large markets in high-income countries. The market mechanism lacks incentives for R&D into pediatric cures, preventive interventions, vaccines, and rare diseases in developed countries, as well as ailments that affect persons predominantly in developing countries (Danzon and Towse, 2003, p. 184). Human rights theory necessitates the reconciliation of research priorities to resemble elements of justice, and the market mechanism fails in this regard. A flawed private market leaves the governments with some underlying notion to intervene and regulate to strive for a more just equilibrium.

Euro-Price

The “Euro-price” case study for pharmaceuticals is an example of how supranational governments can directly intervene in the market for prescription medications, but in this case causing more harm than good. The European Union, by virtue of free trade within the member states, has advocated for a single “Euro-price” to be charged to all states. This ideal of “parallel trade” can be achieved by importing drugs from those states with lower incomes and therefore paying lower prices than those charged by pharmaceutical companies. This appears to be an empowering solution to cut prices across EU countries. However, Ganslandt and Maskus (2004, p. 1036) discuss the theory behind parallel trade and why it does not produce positive outcomes specifically in the pharmaceutical industry, based on the differential pricing scheme discussed previously. When this pricing system is upset by parallel trade, i.e., when countries pay a lower price than originally mandated, manufacturers are left with the task to somehow cover their R&D costs (Towse, 1998, p. 273). Since addressing these cost deficits by raising prices on the rich countries is useless since they are already bypassing pharmaceutical pricing under a Euro-price, it forces the industry to increase the previously-discounted drugs, being those afforded to the poorest countries. A Euro-price, though a bargain for rich EU countries, ends up hurting the poorest members by raising prices of discounted drugs.

Possible solutions

Once short-comings of global pharmaceutical access are acknowledged, solutions and interventions need to be discussed and developed. Three areas in which interventions can be directed include drug prices and exportation/reimportation, industry structure, and development incentives (Barton and Emanuel, 2005, p. 2078). Although the global differential pricing scheme does provide discounts and access to lower-income countries, higher-income markets could increase access by further segmenting

the market by income. In this manner, the poor residing in rich countries can benefit from differential pricing and lower prices. The 2001 and 2003 conferences of the WTO confirmed the ability of countries to deny exports in order to prevent parallel trading (i.e. if a low-income country were being charged a low price, this discount would be assured by legal regulation that denies pharmaceutical exportation to richer countries that pay full-price) (Scherer and Watal, 2002, p. 939; WTO Doha, 2001, 01-5860). Parallel trade would force the pharmaceutical industry to intervene and raise prices to the poorest countries, but introducing stricter international regulations can be structured to address this problem sufficiently.

In terms of changing industry structure, one solution is the buy-out price system. In this model, the government pays a pharmaceutical company a lump sum payment equal to their R&D costs and a certain profit target. The idea is that the costs of R&D can be more evenly spread across the globe, and consequently the company will charge the world markets only the marginal cost of the pills. However, this creates a free-rider problem, whereas if a state does not donate to the buy-out, it will still reap the benefits of a pill or vaccine priced only at marginal cost.

The final solutions involve changing development incentives. In line with reconciling the research priorities justly, governments can change the incentive structure to create drugs to benefit developing nations or rare diseases in developed nations. Some examples include funding a prize for innovation or creating a pricing scheme based on social value rather than market demand (Barton and Emanuel, 2005, p. 2080). This would overhaul the current market-based pricing system, but the ramifications are beyond the scope of this paper.

The image of the pharmaceutical industry has been tarnished by recent examples of adverse effects in drugs, efforts to thwart the dissemination of negative results, abuses of patents, and conflicts of interest in the industry. Companies maintain they are only acting as economists and industry analysts would expect, i.e., as profit maximizing firms, and that they did not create the global economic injustices so should not have to change their practices in an attempt to correct them (Leisinger, 2005, p. 588).

In the end, all of these solutions pose the same conundrum: what must be the trade-off between current prices, future innovation, and global justice. Organizations or governments must intervene to determine a cut-off point at which the speed of new drugs entering the market no longer equals the societal costs of price increases. Government has a duty to correct market failures, ideally guided by bioethical theories reconciling notions of justice with access and affordability, as well as the economic theory governing market behavior. This complex situation requires interventions weighing arguments from human rights theory with those from economic theory to arrive at the most just

allocation of prescription drugs in the global marketplace, as well as ensuring future innovation and scientific progress. Bioethicists as well as economists need to partake urgently in this discourse for the betterment of the global injustices in the international prescription drug market. 🍌

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