Access to Affordable Medication in the Developing World: Social Responsibility vs. Profit

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David B. Resnik

NIEHS/NIH

Introduction

Access to affordable medications is one the most challenging moral, political, and economic issues facing the developing world today (Benatar 2000). Most people in the developing world cannot afford medications used to treat or prevent infectious diseases, such as HIV/AIDS, malaria, tuberculosis, cholera, and dysentery, and half the people in the developing world do not have access to even basic medications (Reich, 2000). Many people blame the pharmaceutical industry for this problem. According critics of the industry, pharmaceutical companies are charge exorbitantly high prices on medications and have no sense of social responsibility (Angell 2004). Drug prices, according to this view, are based solely on greed not on fairness (Chetley, 1990; Angell, 2000, 2004). If pharmaceutical companies had a greater commitment to social responsibility, then they would help people in the developing world obtain access to affordable medications.

The facts tend to support this view. The pharmaceutical industry is one of the most profitable businesses in the world. In 1999, the top ten companies in this industry had an average profit margin of 30%, and overall industry average return on revenues was 18.6% (Gerth and Stolberg, 2000). Drug companies continue to raise their prices higher than the rate of inflation, and the high price of prescription drugs plays a large role in the rising costs of health care in the United States (US) and other countries (Angell, 2004; Gerth and Stolberg, 2000). Critics also claim that the high prices of drugs cannot be justified as a way of making a return on R & D investments, since the industry spends too much money on marketing (Angell, 2004). The amount of money that the industry spends on marketing vs. R & D is difficult to determine. According to industry estimates, most companies spend twice as much on R & D as they do on marketing, but, according to other sources, most companies spend more money on marketing than on R & D (PHRMA, 2004; Angell, 2004). Finally, critics also point out that the industry tends to fund R & D that addresses problems of the developed world, not the developing one. 90% of the money spent of health R & D focuses on medical conditions responsible for only 10% of the world's burden of disease (Benatar, 2000).

Even though one can make a strong case for blaming the pharmaceutical industry for the access problem, the complete story is not so simple. First, pharmaceutical companies have sponsored R & D on many of the medications used to treat diseases with a high impact on the developing world. Most of the new HIV/AIDS drugs were developed by private companies. About 60% of all biomedical R & D is industry funded (Shamoo and Resnik, 2003). Even R & D devoted to solving a developed world problem, such as sexual dysfunction, can have an impact on the developing world. Moreover, developing nations cannot afford to develop their own drugs, since it costs $500, on average, to develop a new drug that will be sold in the US (Goldhammer, 2001).

Second, there would still be problems with access to affordable medications even if pharmaceutical companies drastically lowered their prices or gave away their medications, due to the inadequacies of the developing world's health care infrastructure. An HIV patient cannot receive a necessary medication if he has does not have access to doctors, nurses, pharmacies, hospitals, or clinics. Third, many developing nations have a high degree of social, economic, and political instability. It is difficult to provide access to any type of health care in the middle of civil wars, ethnic conflicts, and so on.

Even though the pharmaceutical industry is not the only reason why developing nations are having difficulties with accessibility to health care, it has become a convenient target as many governments in developing nations have taken steps to combat the industry. Some governments, such as India, Bangladesh, Thailand, and Brazil do not honor patents pharmaceutical manufacturing processes but not patents on pharmaceutical products. This strategy allows generic companies operating in these countries to manufacture patented drugs without paying any royalties to the patent holders, as long as they use a manufacturing process that has not been patented (McNeil, 2000a). Not surprisingly, the prices of drugs are much cheaper in these countries. For example, the wholesale price of fluconazole is $6.38 per pill in South Africa, but $0.41 per pill in Bangladesh, because Madawa Pharmaceuticals manufactures the drug in Bangladesh and pays no royalties to Pfizer (McNeil, 2000b). Most of the large companies have abandoned efforts to obtain or enforce patents in India (McNeil, 2000b). Countries that honor patents on pharmaceutical products can take advantage of the lower prices on drugs manufactured in countries that do not honor these patents. Kenya’s parliament debated a law that would allow the health minister to declare a public health crisis and would allow the minister to allow importation of cheaper, generic drugs, even when the patent on drug in Kenya had not expired (McNeil, 2000a).

Some countries have also considered compulsory licensing as a strategy for lowering drug costs. In compulsory licensing, a government forces the holder of a patent to license its invention to other businesses at a reasonable price. This strategy increases the supply of the drug, which lowers the cost. The Trade Related Aspects of Intellectual Properties (TRIPS), a global trade treaty signed in 1994, allows countries to use compulsory licensing to deal with a public health crisis. South Africa has considered compulsory licensing as a way of making drugs more affordable for its citizens (McNeil, 2000a).

Thus, drug development for developing world is an economic and moral dilemma for both pharmaceutical companies and for the governments of developing nations. Pharmaceutical companies must decide 1) whether and how to invest money R & D for medications designed to treat disease epidemics that plague the developing world, and 2) how to address the problems of affordability and accessibility of medications for the developing world. Developing nations, on the other hand, must decide how best to respond to pharmaceutical companies and whether to use any of the tactics described above. In this article, I will argue that large, global pharmaceutical companies have a moral obligation to develop affordable drugs for the developing world and to make these drugs accessible, and that developing nations should cooperate with these companies in achieving these goals. Although pharmaceutical companies and developing nations are often in conflict, I will argue that they must work together to develop drugs for the developing world.

In making this argument, I would like to stress that one should not underestimate the importance of other parties, such as the governments of developed nations, the United Nations, and non-governmental organizations (NGOs), such as private charities, in helping to address these problems (Daniels, 2001). Ideally, the solution to the accessibility problem will involve cooperative efforts on many different fronts, since the problem is too large to be solved by industry, government, or NGOs. Even though I recognize that governments and NGOs should play a large part in addressing this problem, I will focus on industry's responsibilities.

The Pharmaceutical Industry and Social Responsibility

Let's consider the pharmaceutical industry's obligations to developing nations. One popular conception of private businesses is that they are either immoral or amoral, operating outside the bounds of morality and barely within scope of the law (DeGeorge, 1995). During the 20th century, many business professors and economists provided a theoretical basis for this idea by arguing that companies have one primary obligation, to make profit. By pursuing profit, companies manage their resources effectively and produce goods and services that benefit society. Laws can be useful in regulating corporate conduct, but corporations have no moral obligations over and above the requirement to comply with law (Friedman, 1970). I suspect that many people regard pharmaceutical companies in the same light: pharmaceutical companies are moral pariahs.

Although many, if not most, companies frequently ignore moral standards, there are solid arguments for holding that businesses have moral responsibilities beyond merely obeying the law. All businesses are shaped by and depend upon social values, such as honesty, integrity, fidelity, diligence, and fairness. These values provide a social infrastructure for contractual arrangements, employer-employee relations, marketing, investing, trading, and so on. Values play a key role in creating a climate within and among companies for conducting business. Without these values in place, corruption, theft, fraud, disloyalty, and other ethical problems would make it impossible to do business. Thus, most businesses today recognize the importance of ethical conduct in business and many adopt and enforce codes of conduct (Murphy, 1998).

Many people would accept the idea that moral values play an important role within business, but they might argue that they play no role in the interaction between businesses and society at large. A business could adopt and enforce a code of ethics that applies to its dealings with employees, customers, stockholders, and associates yet show absolutely no respect for other social values not directly related to business. Although it is also probably the case that many businesses ignore these other values, many writers argue that business have social responsibilities. Businesses have these responsibilities because they exist within societies where people care about the environment, public health and safety, and other values.

There are at least two reasons why businesses have social responsibilities. First, businesses that ignore their social responsibilities may face the public's wrath. A company that wantonly pollutes, for example, will one day have do deal with additional pollution regulations. Companies that make unsafe products may have to deal with expensive lawsuits. Thus, social responsibility makes good business sense (DeGeorge, 1995). Second, corporations are like moral agents in that they make decisions that have important effects on human beings. In making these decisions, corporations can decide to either accept or ignore social values. Although corporations do not have a mind that makes conscious choices, they can be held legally and morally responsible for their decisions and actions. If corporations are like moral agents, then they have some of the same duties that apply to other moral agents. In particular, corporations have obligations to avoid causing harm and to promote social welfare and justice (DeGeorge, 1995).

Since pharmaceutical companies are corporations, they also have social responsibilities. At least two types of responsibilities apply to pharmaceutical companies:

1. <u>Beneficence</u>. Pharmaceutical companies should promote the greatest balance of benefits/harms for society. They should avoid doing harm and try to do good.
2. <u>Justice</u>. Pharmaceutical companies should distribute benefits and burdens equitably.

The rationale for a duty of beneficence is fairly straightforward and uncontroversial. Indeed, most countries have a variety of laws designed to regulate drug testing, manufacturing, and sales in order to prevent harms to the public and promote the development of effective drugs. In the US, the Food and Drug Administration (FDA) regulates drug testing, manufacturing, and sales (Brody, 1995). Although this duty is fairly obvious, its application is usually complex and controversial, as societies must consider benefits, harms, justice and basic liberties in deciding questions about approving the sale of new drugs (Schüklenk, 1998).

Many writers have argued that pharmaceutical companies should promote access to medications as a way of promoting justice. According to Brody (1996), pharmaceutical prices should not be so high that they make important medications inaccessible. Spinello (1992) applies egalitarian principles to pharmaceutical pricing and argues that medication prices should promote social justice. Both authors acknowledge that the duty of justice must be balanced against the practical need to make a reasonable return on investment. A “reasonable price” is a price that allows the company to earn its money but also promotes accessibility and equity (Brody, 1996).

Other writers have argued that companies should distribute the benefits and burdens of research participation equitably. For example, if a company sponsors a study using a specific population, then members of the population that participate in the study should derive some benefits from their participation. In particular, the drug should be made available to members of the population at a reasonable price. It is not fair to place members of the population at risk without a reasonable expectation of a benefit to that population. Research protocols that recruit subjects from a population without a reasonable expectation of some benefit to that population are exploitative (Crouch and Annas, 1998; Resnik, 2003).

How do the above considerations apply to developing drugs for the developing world? In general, these considerations imply that pharmaceutical companies have moral responsibilities to develop drugs that benefit society and to make those drugs available to participant populations at a reasonable price. Some pharmaceutical companies, such as Bayer Corporation, have adopted ethics and values statements that mention responsibilities to the community, customers, and the environment. Ciba-Geigy, a chemical company that merged with Sandoz (a pharmaceutical company) in 1997, adopted a vision and values statement that includes responsibilities to the environment and society (Murphy, 1998). However, merely recognizing that pharmaceutical companies should be socially responsible provides little guidance in determining how companies should exercise that responsibility. It does not provide specific guidance as to what a company should do, how much is should do, how many resources it should devote to a project, or even where it should focus its attention.

To get some insight into these questions consider how an individual might decide how to act socially responsible. Most major moral theories, including Kantianism, utilitarianism, and virtue ethics, hold that individuals have duties relating to beneficence and justice. However, there is also strong theoretical support for that many moral duties, including the duty of beneficence are not absolute: there are morally acceptable and desirable limits on the amount of good one may do for others. Although we should all do our part for society, we are not required to be moral saints. Since most individuals cannot completely sacrifice themselves for the good of society, they must weigh and consider other moral obligations and commitments in light of their circumstances and conditions in order to decide how to be socially responsible. Social responsibilities, such as the duty of beneficence, are Kantian imperfect duties (Pojman, 1995).

These points apply to social responsibility at the corporate level. Companies, like individuals, have obligations to be socially responsible, but these obligations are not absolute. Companies should not act like moral scoundrels, but they do not need to act like moral saints. To meet their social responsibilities, corporations must weigh and consider many factors, such as their talents, abilities, resources, interests, commitments, and obligations. As far as pharmaceutical companies are concerned, the goals of developing medications for populations and promoting access to those medications would seem to be a natural fit, given their interests, talents, and so on. But this still leaves open the question of how far a company should go in meeting this responsibility. Corporations, like individuals, must consider their resources, such as time and money, as well as other obligations and commitments, when deciding how to act responsibly. Most pharmaceutical companies will have little trouble fulfilling some minimal responsibilities if they develop drugs that benefit people and make those drugs accessible. But the harder question to answer is how far companies should go in exercising this responsibility. Companies also have commitments to their stockholders and employees. They have obligations to make a profit and to use their economic resources effectively. For example, Bayer's values statement also mentions duties to capital investment and resource allocation. Ciba-Geigy's statement mentions commitments to financial performance and improved market shares (Murphy, 1998). If one agrees that profit should play a key role in business decisions, then it is morally legitimate (and perhaps even morally responsible) for a company to weigh and consider financial factors when making a decision to be socially responsible (DeGeorge, 1995).

Money is not the only factor in deciding how to exercise social responsibility. Companies may also consider social, economic, legal, or political conditions, since these factors may impact the effectiveness of a particular program aimed at meeting social responsibilities. These factors may provide significant barriers to implementing social responsibility. For example, a company might decide that it is not worth the effort to supply free medications to a country if that country is in such political turmoil that distribution is futile or impossible. A company might also decide that it is not worth selling a medication at a discounted price in a country if that country does not honor the company's pharmaceutical patents. On the other hand, a company might decide to initiate a research program aimed at developing a vaccine for an infectious disease, if the company obtains financial and political support from a country that would like to have such a vaccine.

Finally, companies also need to consider geography in deciding how to exercise their social responsibility. I think there are several reasons why pharmaceutical companies have social responsibilities to the developing world. First, if a company conducts business in a country, then it has duties to act responsibly in that country. This is type of social responsibility can be justified in terms of reciprocity and should not be especially controversial: if you make money in a country, you have an obligation to give something back to that country over and above taxes, and good and services. But companies can avoid this responsibility by simply not doing business in developing nations. A pharmaceutical company could market its products in the developed world in order to avoid the economic, social, political, and legal challenges of conducting business in the developing world. This brings us to a second, perhaps more important reason why pharmaceutical companies have social obligations to the developing world: companies should promote the welfare of humankind. This implies duties of beneficence and justice to all people, not just to people living in the US or Europe. Obviously, it may be difficult for small, local corporations to promote the welfare of humankind, but large, global corporations, such as Merck, Glaxo-Wellcome, or Pfizer, should be concerned with the welfare of humankind and they should therefore conduct business in developing nations and attempt to meet social responsibilities to developing nations (Simpson, 1982). However, even global companies may decide to avoid doing business in some countries in the developing world due to adverse financial, political, legal, or other conditions.

Many pharmaceutical companies have taken important steps to act on their social responsibilities to the developing world. First, companies are now sponsoring research on diseases that affect people in the developing world, such as tuberculosis, HIV/AIDS, and malaria. Second, some companies have decided to provide free medications to people in developing nations. For example, Merck and the Gates Foundation have pledged to give $100 million worth of medicine and money to Botswana. Bristol-Myers Squibb has is providing $100 million over five years to trains doctors and develop community outreach programs in sub-Saharan Africa (Sternberg, 2000). Pfizer recently agreed to donate $50 million worth of fluconazole to be distributed in South Africa, a nation where 20% of adults are infected with HIV (Swarns, 2000). Although these offers have been met with a degree of skepticism and cynicism, they do represent a step on the path of social responsibility.

Thus, one can conclude that global, pharmaceutical companies have social responsibilities to developing nations. How much should they do to help? These are complex issues that depend, in part, on how developing nations respond to pharmaceutical companies. If we think of exercising social responsibility as attempt to make a gift to a society (or societies), and we understand giving as a relationship (or agreement) between the giver and recipient, then we need to say a bit more about the recipient of the gift. Exercising social responsibility in the developing world depends, in part, on social, economic, political, and legal conditions in the developing world, since these conditions can either assist or impede a company's attempt to exercise social responsibility or its business practices. Most companies, I believe, will resist doing business in the developing world if (1) they have no guarantee of a reasonable profit; (2)

they must overcome an unproductive business climate. But what is a reasonable profit and what is an unproductive business climate? We need to address these issues before returning to the topic of social responsibility.

Reasonable Profits, Drug Prices, and Patents

Determining what counts as “reasonable” profit is a complex issue in business ethics. According to some commentators, there should be no limits on profit other than the free market. If a company can make a 30% profit, then this is “fair” in the market sense of “fairness.” Moreover, profits are morally justifiable in that they contribute to the overall social welfare. Businesses that make profits can use those funds to compensate employees or stockholders or make investments in new equipment, buildings, or other resources (Jacobsen, 1991). Furthermore, according to this argument, attempts to control or regulate profit margins could have drastic economic consequences for businesses that would restrict their ability to contribute to society. First, investors might avoid an industry where the government regulates profits. Second, companies will have a more difficult time with financial planning and resource allocation if they are some legal limits on profits. Third, since profits depend, in part on prices, profit regulation must involve some form of price regulation which could lead to market inefficiencies because prices need to change quickly in response to market demands but government agencies often act slowly. Fourth, if companies face limitations on profits or prices, they may cut back on their investments in R & D and focus more on marketing.

For these as well as many other reasons, government regulation of profits under normal, free market conditions is morally and economically questionable. However, when free markets cannot set fair prices due to monopolies, exclusive dealing, price discrimination, or collusion, then the government may regulate or scrutinize prices in order to buffer or counteract these restrictions on trade. For example, there are good reasons to regulate the prices charged by public utilities and other corporations that have a monopoly. There may also be good reasons to investigate pricing practices when one suspects that different companies have adopted agreements designed to inflate prices (Ferrell and Frederick, 1991).

One might accept the thrust of this argument yet maintain that companies that make healthy profits have strong moral obligations to return more of those profits to society because they are better equipped to meet obligations of beneficence and justice. Consider the analogy with an individual. A person making a high salary, one might argue, has an obligation to give more money to charity than a person making a low salary because he can afford to give more to charity. There is nothing inherently wrong with being wealthy (or having a high profit margin) but greater wealth implies greater responsibility.

Now there are many ways that a profitable company could return some wealth to society. The company could offer price discounts, it could give away some of its products, it could invest funds in developing drugs to treat orphan diseases, or it could invest in other social programs. In any case, all decisions concerning the exercise of social responsibilities have an affect on profit margins because these choices incur additional costs or expenses. Thus, a morally reasonable profit (the profit a company should be allowed to realize) might be lower than an economically reasonable profit (the profit a company can realize). If a company decides to return some wealth to society through pricing practices, then its “morally reasonable” prices (the prices it ought to charge) could be lower than its “economically reasonable” prices (the prices it can charge).

How does all of this apply to the pharmaceutical industry? The argument implies that companies with high profit margins should consider taking additional steps to be socially responsible, such as discounts on prices, product giveaways, etc. If a company decides to fulfill its social responsibilities through pricing policies, then the company should be willing to lower its drug prices (and therefore perhaps lower its profits) in order to make those drugs more accessible. Since it is probably not very efficient to lower the prices of all drugs in all markets, a company should probably be selective in its socially responsible pricing policies, focusing its discounts on specific drugs in specific markets. If we focus our attention on the developing world, this argument implies that global companies with high profit margins, such as Pfizer, Merck, and Glaxo-Wellcome, should be willing to forego some profits in the developing world order to fulfill social responsibilities to the developing world. They can accomplish this task through many different ways, including price discounts or drug giveaways.

But how much money should a pharmaceutical company devote toward socially responsible projects? The answer to this question depends, in part on the company’s current and projected profits. Global pharmaceutical companies can (and should) be able to devote hundreds of millions of dollars toward projects designed to benefit developing nations without losing a great deal of profit. However, their ability to continuing realizing these profits depends on strong patent protection. Patents play a key role in profitability in the pharmaceutical industry since patents allows companies to obtain returns on their R & D investments (Goldhammer, 2001). Without this protection, companies would not make these risky investments. Pharmaceutical R & D investing is a high-risk proposition for several reasons. First, the new drug may not prove to be safe and effective and the company may decide to abandon the drug in the middle of clinical testing. Second, if the company completes its clinical trials, there is no guarantee that the FDA (or other relevant agency) will approve the new drug. Third, if the agency approves the new drug, it may not have a strong market due to competition from other drugs or lack of consumer demand. Fourth, once the drug is on the market, the agency could take it off the market to protect public health and safety. Finally, there is always the possibility that the company will face lawsuits from consumers that are harmed by the drug. Without adequate patent protection, a company might take these risks and develop its product only to have a competing company manufacture the product at a lower price. According to the pharmaceutical industry, only 30% of new drugs are profitable (Goldhammer, 2001).

Although patents offer pharmaceutical companies control over their inventions, this control is not absolute. First, in the US (and most other countries), a patent lasts 20 years from the time of the application, which gives a drug company an approximately 10-year window to make a return on its R & D investment (Goldhammer, 2001). Once the patent expires, a generic drug company can make the drug without infringing the patent. Second, most patent laws allow for some degree of "copycat" inventions. A copycat invention is an invention that is very similar to a previous invention but it represents a useful innovation or improvement. In the United States, companies can patent new, "copy cat" drugs by making slight changes to the original patented drugs. The possibility of copycat drugs creates a potential limit on a company's ability to control the market for a drug. For example, the company could invent a new blood pressure medication and dominate the market for this product until other companies develop copycat versions of the medication (Goldhammer, 2001). However, it is important to realize that the US Patent and Trade Office (PTO) does not accept all copycat drugs; it only accept those drugs that are useful improvements (Miller and Davis, 2000).

We should also note that patents only provide legal protection in the country in which they are issued: a US patent provides no legal protection in Britain. Thus, when a drug company develops a new drug, it usually applies for patent protection in the countries where it plans to sell the drug. If a country does not provide the company with patent protection, then it may lose business in that country and perhaps others. If we think of the whole world as a potential market, a company that invents a new drug and patents it in many countries may still lose a significant portion of its potential market volume if several countries do not honor the patent and export the drug around the world. This is why the pharmaceutical companies find India's patent policies so troubling: the companies lose out on the market in India as well as markets in other countries that import drugs from India. Drug companies can still make a profit when their patents are not honored around the world, but they have to make their profits in countries that honor those patents. It is hard to say exactly how much money pharmaceutical companies lose as a result of the failure to recognize patents globally. Industry representatives claim that they lose as much as 10% of their profits this way, and it likely that drug prices would be lower if the companies could take advantage of a larger market (Reich, 2000)

So what does pharmaceutical patenting have to do with reasonable profits, prices, and social responsibility? A great deal, I think. Briefly, companies can afford to do business in a country and exercise social responsibility insofar as they have a guarantee of reasonable profits. But obtaining these profits depends, in large part, on patent laws. When companies have strong patent protection, they can expect to profit from their R & D investments, and they can afford to devote more resources to socially responsible programs. If they fail to realize profits, they have less money to devote to programs designed to enhance social welfare. Thus, developing nations that fail to honor pharmaceutical patents may actually be harming themselves in the long run. In the short run, a developing country might obtain some benefit by not honoring pharmaceutical patents because it could acquire inexpensive drugs or attract generic drug companies or distributors. This strategy could backfire in the long run, however, since larger, global pharmaceutical companies may decide to not do business in countries that do not honor their patents and they may decide to not invest money in R & D for developing drugs for the developing world. Why invest several billion dollars in developing a malaria vaccine if generic drug companies will reverse engineer the vaccine and sell it at a very low price? If companies lack sufficient patent protection in the developing world, many patients in the developing world will remain therapeutic orphans.

One might attempt to undercut this argument by pointing out that pharmaceutical companies make very little money from sales to the developing world, and that over 95% of their sales revenues come from the developed world (Sterckx 2004). Even so, this economic reality is not a good reason for nullifying patent protection in the developing world. Pharmaceutical markets are global in scale and scope. A drug invented and tested in the U.S. may be manufactured in India, imported to Canada or Mexico, and then imported to the U.S. If companies lose control of their patent rights in any nation, there is a chance that the global pharmaceutical trade could undermine the profits that they make in the developed world. Pharmaceutical companies vigorously defend their patent rights around the world to maintain maximum control of these different markets.

Productive Business Environment

This section will address briefly another important factor in conducting business in the developing world and exercising social responsibility, the business environment. There are many different social, economic, political, and legal characteristics that contribute to a good business environment. A few of these are (Samuelson, 1980):

(1) A coherent and effective legal system.

(2) Ethical business practices.

(3) A stable currency.

(4) A reliable banking system.

(5) Free and open markets.

(6) A well-educated public.

(7) A middle class or consumer class.

(8) A physical and social infrastructure.

(9) Democratic institutions.

These characteristics played a key role in the rise of capitalism, and they can be found, to a great degree, in the developed nations, such as the US, Germany, and Britain. Very often, developing nations lack the characteristics that define a good business environment. Moreover, it may take many years for developing nations to develop some of these characteristics, such as a well-educated public, a physical and social infrastructure, or democratic institutions. It simply takes time to build bridge, roads, power lines, telephone networks, acquire education, develop a middle class, establish democracy, and so on. A company that refused to do business in the developing world because its business environment is less than ideal would be acting foolishly and unfairly: in order to expand their markets and their influence, companies need to take some risks and conduct business in undeveloped nations.

However, there are some acceptable limits on what a company should be willing to do to expand into a developing nation. Some business environments can be so adverse that doing business in that country is impossible or highly inefficient. Consider the difficulties involved in selling products in a society that uses the barter system, investing funds in a society where the banks do not insure savings or checking accounts, hiring employees in a society where employee theft is common, or signing contracts in a society where bribery is expected. In order to do business in the developing world and exercise their social responsibility, companies need to have a reasonable expectation that those nations are taking steps to promote the rule of law, ethical business practices, a stable currency and banking system, free and open markets, etc. Doing business in a country with an extremely poor business climate is going above and beyond the call of corporate duty. Developing nations can attract businesses by demonstrating that they are making progress toward developing a good business environment.

Conclusion: Reciprocity

Let's retrace the steps of my argument. In Section 2, I argued that large, global pharmaceutical companies have social responsibilities (or duties of beneficence and justice) to the developing world. There are a variety of ways that companies can exercise these responsibilities, including investing in R & D related to diseases that affect developing nations, offering discounts on drug prices, and initiating drug giveaways. However, I also argued that these social responsibilities are not absolute requirements and may be balanced against other obligations and commitments in light of economic, social, legal, and other conditions. In Sections 3 and 4, I argued that the degree to which a company may exercise social responsibility in a society depends on two major factors, (1) the prospects for a reasonable profit and (2) the prospects for a good business environment. Developing nations can either help or hinder the pharmaceutical industry's efforts to exercise social responsibility through various policies and practices. To insure that companies can make a reasonable profit, developing nations should honor pharmaceutical patents. If they do not honor those patents, this will lower the industry's profits and take away money that could be devoted to projects designed to promote access to medications. To insure the companies have a good business environment, developing nations should try to promote the rule of law, ethical business practices, stable currencies, reliable banking systems, free and open markets, democracy, and other social, economic, legal, and political conditions conducive to business.

Pharmaceutical companies and developing nations need to work together ro develop affordable medications for the developing world. Companies can do their part by investing in R & D for the developing world's diseases, offering drug discounts, or establishing drug giveaway programs. In return, developing nations should also take steps to promote a sound legal, ethical, financial, and social environment for business. Developing nations should provide strong patent protection and to take steps to establish productive business environments. Developing nations should adhere to international agreements on intellectual property, such as the TRIPS agreement. The TRIPS agreement sets minimum standards for patent protection and requires signatory countries to not undermine each other's intellectual property rights. TRIPS allows nations to engage in compulsory licensing and importation to address public safety or public health crises.

I do not oppose measures consistent with the TRIPS agreement that governments may use to respond to public health emergencies, such as the HIV/AIDS pandemic. It is very important for nations, especially developing nations, to have the ability to override intellectual property rights (IPRs) to deal with national emergencies. Overriding intellectual property rights should be regarded as a last resort, however. A country should take this drastic measure only after negotiating in good faith with the party who holds the IPRs. In some countries, such as the U.S., constitutional due process rules also require that governments compensate IPR-holders for their losses when they override these rights (Resnik and De Ville 2002). To prevent nations from abusing their authority to override IPRs under the TRIPS agreement, it is also important to clearly define the concept of a national emergency. There has been a great deal of dispute about what counts as a "national emergency." For a public health crisis to count as a national emergency it would have to be so severe that it interferes with basic functions of government, society, or the economy. For example, HIV/AIDS in sub-Saharan Africa may fit this definition of a national emergency, but HIV/AIDS in North America does not fit this definition.

In pursuing this cooperative approach, developing nations may use a variety of other strategies to encourage pharmaceutical companies to act responsibility. For example, a nation could help reduce the cost of R & D and marketing by subsidizing R &

D funding and by providing a company with a guaranteed market. If developing nations lower these costs to the company, the company will be able to develop a drug, sell it at a low price, and still make a reasonable profit. A developing nation could also help a drug company design research protocols and help the company with recruitment of subjects, informed consent, data monitoring, and other important aspects of humans subjects research. A nation could also help a company develop a drug giveaway program by providing an efficient, reliable, and fair system for distributing these medications. Finally, developing nations can also buy drugs in large quantities directly from pharmaceutical companies in order to take advantage of bulk buying. Nations could sell these drugs at a discounted price or give them away. Many countries have already pursued some of these strategies and there are many more constructive solutions than those mentioned in this essay (Reich, 2000).

Although I believe strongly in the importance of reciprocal arrangements between pharmaceutical companies and developing nations, I also recognize that these agreements may not always work and that an atmosphere of animosity can easily develop. If a developing nation starts making concessions to the pharmaceutical industry and the industry does not respond through socially responsible policies and programs, then it would be reasonable for that nation to take retaliatory measures, such as compulsory licensing or importing drugs from countries that do not honor pharmaceutical patents. On the other hand, if a pharmaceutical company offers to aid a developing nation and that nation does not respond in kind, then that company would also have reasons to not make good on its commitment to that nation. I can foresee that these situations will arise and I would not admonish either side for retaliatory conduct. However, I would still strongly urge developing nations and pharmaceutical companies to work together in addressing the urgent economic and moral dilemma of developing drugs for the developing world.

In closing, I would like to make it clear that I am not a naïve defender of the pharmaceutical industry. I recognize that industry decisions are based on profit and greed, and that most companies engage in socially responsible activities only as a means of enhancing their public relations (PR) activities, which tend to have a positive impact on profits. While I remain firm in my conviction that pharmaceutical companies have social responsibilities, I recognize that many companies ignore these responsibilities or do not take them seriously. Elsewhere, I have discussed many different ethical problems related to pharmaceutical research, such as suppression of research results, bias, and conflicts of interest (Shamoo and Resnik 2003). My defense of intellectual property rights for pharmaceuticals stems from a pragmatic approach to the justification of intellectual property, not from an ideological commitment to big business (Resnik 2003b). It would be wonderful if knowledge could always be shared freely at no cost to anyone. But we do not live in such a world. Knowledge is power and often costs much money to produce. In this less than ideal world, intellectual property rights are a necessary evil.

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