

The Ethics of Pharma-Economics

An Examination of the Limit of Corporate Responsibility in the Pharmaceutical Industry

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Introduction

I remember making my first presentation about AIDS back in 1983, at the beginning of my senior year in high school. The disease was just beginning to cause public panic but was still considered a “gay problem.” My report was about the huge rush to start developing drugs and to discover the cure to the disease.

Flash forward 16 years: There is no AIDS cure and treatment has its limitations. A course of AIDS treatment costs between \$25,000-37,000 per year [11] and while the therapy has been effective at slowing the death rate, there has been a recent upswing of treatment resistant mutations [13]. There is clearly no easy cure and the research continues slowly and with uncertain outcome.

“Millions of children and adults are becoming infected, falling ill and dying without the barest essentials in medical treatment, counseling or social support.”

Kofi Annan, Secretary General of the United Nations addressing the 12th World AIDS conference

I began to wonder about the larger question of whether there was any ethical obligation of these pharmaceutical companies to develop, produce or supply medicinal products to markets that either cannot afford them or that are too small to bring a return on the investment. After all, few would argue that a computer company has a moral obligation to develop a product for a small unprofitable market, or provide computers at discount or no cost to markets that cannot afford them. Are pharmaceutical companies to be treated differently because of the product that they produce?

This is a timely question with eternal underpinnings. In this day and age, pharmaceutical companies are under tremendous pressure to escalate the rate and number of successful products that they bring to market. Because of the huge development expense, there is no way that a pharmaceutical company can be expected to spend precious research dollars on products that will not have the necessary financial returns, nor to squander the opportunity to earn returns on the product in the limited time left before patent protection expires.

Given these pressures on the pharmaceutical industry;

- Do they have any ethical obligation continue research into, for example, AIDS treatments if it may not be profitable?
- Do they have any ethical obligation to provide the drugs to the millions who cannot afford them, for example, in Africa?

Companies have to make decisions daily that are based on the financial implications to the company. In the case of pharmaceutical companies, this field is called pharma-economics. Underlying the corporate financial decisions for this industry is the eternal question: Ultimately, what is a life worth? And, do we have to pay for it?

This is not a paper about AIDS. AIDS and almost everything that is associated with it comes with its own set of moral and ethical issues. However, using this disease as a backdrop, this paper examines some of the ethical issues surrounding pharma-economics and the limit of corporate social behavior.

AIDS: The State of the Disease

It is estimated that by the year 2000, there will be 40 million cases of AIDS worldwide [10]. At an infection rate of one every five seconds, or 16,000 new cases a day, the plague is far from having run its course [10]. In the United States, AIDS death rates fell 47% between 1996 and 1997 due to drug treatment [13]. In Europe, where there is universal health care, the figure was 80%. Medicaid is the largest payer of HIV-related medical services in the United States [14] and the domestic market is estimated at \$5 billion [13].

Despite these magnificent results, however, over 90% of HIV-infected people are in the developing world. HIV is most severely affecting Africa, the Caribbean, Latin America and Southeast Asia; all the countries and continents not able to afford even the \$0.50 blood test for AIDS, let alone full drug treatment [11]. The majority of the pharmaceuticals consumed in these areas are imported because they do not have the manufacturing or R&D money or infrastructure to supply their own populations. Prices at world levels put even the most basic drugs out of reach of countries whose per capita incomes are 5-10% that of the US [15]. For example, in Indonesia, where per capita consumption of pharmaceuticals is \$2.50, or in Brazil where it is \$13, obtaining yearly AIDS medicines at \$25,000 is beyond possibility.

Clearly there is a gap in who gets treatment and who does not. AIDS treatment has become an issue of rich versus poor, rather than gay versus straight, but the problem of treatment disparity and access is broader than this particular disease. Additionally, the enormous cost of research, the slow and disappointing research progress, and the lack of return on investment has led to predictions that some companies will be forced into reducing or eliminating altogether AIDS related research [12,9].

Does the pharmaceutical industry have an obligation to continue developing drugs that may not recoup the cost of investment? Does the industry have an obligation to provide poor markets with pharmaceuticals? The answer, simply, is no. Outright donation of pharmaceutical products or the continued investment in financially unprofitable research is not in the best interest of the company, its shareholders or, ultimately, society.

Corporate Responsibility Versus Charity

The corporation has as its primary responsibility, action that best increases its shareholders wealth [1]. Management is charged with the responsibility to oversee the operations of the business and insure that actions taken benefit those who have vested financial interests in its performance. From the most basic financial perspective, this means that the company engages in projects whose returns exceed the amount invested to initiate the project. The more successful the company is in engaging in this behavior, the more financially successful the company is. Provided that the other operations of the company support money-making and cost control, the shareholders are ultimately benefited by the increased value of the company. The market responds to this increase in corporate value by increasing the share price; and the shareholder wealth is increased.

Corporations are legally obligated to act in a socially responsible manner and there are laws regulating every business practice from, for example, what can be produced and how it can be produced to where and when it can be sold. The set of laws were originally enacted to protect the consumer and society from the misdeeds of the corporation and some might argue that it is the only thing that keeps them from wantonly pursuing any mode of business to make a profit.

Not all business projects or behavior is strictly money making however. There are instances where the benefit of action is not readily measurable by strictly financial metrics. Take for instance the issue of corporate giving or charity. Over the past 20 years, corporate charitable contributions have been holding at approximately 1.9% of pre-tax income amounting to \$6 billion [2]. Altruistic corporate behavior, like charitable giving, sponsorship of community events, and donations of goods and services therefore must be driven by some powerful incentives. Why do corporations donate money, goods or service or support community activities? The answer is, simply, because it good business [3]. If you donate to charities, your company can generate quite a bit of good press coverage. Good media image has financial implications: it can increase goodwill and attract new investors or customers. It makes the company look friendly and more trustworthy. There are also significant tax incentives aimed at increasing corporate charitable donations. Good corporate citizenship is good for long term business.

Corporations are bound by law to act in a socially responsible manner [1], but there is no law that mandates corporate charity. Is the corporation morally or ethically obligated to support charities or community interests? Do corporations exhibit altruistic behavior?

Without either the financial incentives or the good publicity, corporate charity would not be a particularly good business practice since it would generate no financial returns that benefit the company. Continued engagement in this type of behavior, in fact, could be considered costly to the company and an abrogation of its primary responsibility to the shareholders. After all, no one invests in charities. Shareholders do invest in companies that maintain good community relations, but, not if it jeopardizes the value of the company or its ability to increase their wealth.

Merck: A Case of Corporate Altruism?

“We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they never failed to appear.”

George W. Merck, Chairman and CEO of Merck (1925-1950). [16]

Merck believes that there is an underlying corporate mandate to provide pharmaceutical products to society. They also are aware of the disparity between the access of the poor and rich to medicines. In the late 1980' s, Merck had received approval for a medicine to treat river blindness, a terrible parasite transmitted disease that affects 100 million people in Africa and Latin America. After having spent 10 years and millions of dollars in developing this treatment, it was discovered that despite the real need for the drug, no one was willing to pay for it. Merck tried to get governments and other agencies to pay for the treatment but was ultimately faced with the fact that there was no market. In this case, the company donated the drug to all who needed it [16].

Merck also produces AIDS medicines and the company has priced their newest, Crixivan, at 30% lower than its competitors. Unfortunately, the drug has to be taken with other drugs which still puts the total cost out of reach. Is Merck ethically obligated to donate Crixivan to AIDS patients?

“Giving our medicines away in general is an unsustainable and unrealistic answer because, at the end of the day, we must earn adequate return on our investment in order to fund future research.”

Raymond v. Gilmartin, Chairman, President and CEO, Merck & Co. Inc.

Merck donated the river blindness treatment in part because of corporate goodwill, but also because the product had already been developed, produced and had to be unloaded before expiration. The donation was altruistic, but also was good business as the resulting positive press increased the prestige and notoriety of the company. Had there been a viable market for the product, no donations would have taken place. Nor should they have. There is a responsibility of the company to the shareholders to promote corporate action that increases their wealth. Corporate charity on the grand scale would imperil the long-term ability to produce and sell other useful medicinal products as potential profits that would be slated for R&D, would be severely decreased. The question arises then, which population of patients should be served, and, how best to sustain the ability of the company to produce pharmaceuticals in the future. This is the question addressed by pharmaceutical economics.

Pharma-Economics and Drug Development

Pharmaceutical firms are facing greater challenges to increasing growth and shareholder value because of several factors including increasing competition, expiring patents and, most importantly, skyrocketing drug development costs.

It is estimated that it costs between \$350 to 500 million to take a chemical through screening and FDA approval to the market, and in 1999, drug companies will spend over \$21 billion on research and development [5,6]. “Over the past seven years, the R&D budgets of the 20 largest pharmaceutical companies have more than doubled in nominal terms. If this continues for the next seven years, annual R&D costs per company will rise from an average of \$1.2 billion to around \$2.5 billion by 2005” [7].

In order to meet shareholders expectations of 10% growth, it is estimated that pharmaceutical companies will have to bring 5 new products to market per year. Between 1990 and 1994, the top 20 pharmaceutical producers each averaged 0.45 new products per year, and, of those, only 8% achieved sales of \$350 million or more, the minimum considered to be successful [4].

Because of this enormous investment, drug companies are increasingly focussing on bigger market, developing only those chemicals that have the potential to become blockbuster products and devise better ways of increasing the return on investment. The enormous cost of research and development is forcing pharmaceutical companies to sharpen the initial screening process. “In the old days, a lab worker could produce perhaps 50 chemical compounds a year at a cost of over \$5000 each. Now, a worker using ‘combinatorial chemistry’ techniques can synthesize 1m molecules a year at a thousandth of the price” [8]. The screening process has been made much more efficient in terms of its selectivity and the volume of chemicals that can be screened, however, it has also set up the situation of how to choose the ones that go on to be developed.

One factor that weighs into this is an economic analysis of the market and a projection of the potential return on investment. Like any other industry, net present value projects are generally approved and NPV negative projects rejected. In this day and age, where there are many promising chemicals, but the pressure to recoup the enormous investment, many potentially promising chemicals do not make it through the screen.

“Five years ago, a \$100 million product would have been a good product. Now at a major pharmaceutical company, that doesn’t begin to make the screen” [6].

Therefore, some potential therapeutic products do not make it to market because the payback does not justify the investment. The obvious implication of this is that there are people who will not have the opportunity to have a cure or relief because the drug was not expected to be profitable enough. When you are on the consumer/patient end of this information, pharma-economics is a heartless judge.

In spite of the human cost, however, pharmaceutical companies cannot afford to develop drugs that are not going to provide the required returns on investment. This includes the drugs that look promising but may be directed toward too small a market--or would target an already saturated and therefore unproductive market. It also includes the continuation of drug research that has been ongoing but for which the market is drying up, or the research is too expensive and involved, and the potential for success very small. By devoting scarce resources to these sorts of projects, money is taken away from other drug products whose financial returns to the company can be invested in new research. In the end, society is best served by insuring that the pharmaceutical companies continue their research and development through the use of pharma-economics.

Who Is Responsible?

Social welfare and public health fall under the domain of government responsibility, not that of private industry. Governments are accountable for the baseline well-being of its citizens and, in Western countries at least, play an active role in health issues. The question is, if the government is responsible for the basic health of its citizens, and the pharmaceutical industry has the keys to cures or treatments, how is the government going to get the pharmaceutical companies to participate. Government already pays for many of the treatments but cooperation between these two sectors would be the ideal arrangement.

Government could certainly enact laws that force pharmaceutical companies to, say, develop therapeutic products that would ordinarily have been shelved or provide drugs at artificially low prices. This would be a highly dangerous proposition as interference with the ability to profit from one's labor or inventions would stifle innovation and productivity.

A more productive approach is to create incentives for pharmaceutical companies to increase charitable acts. Augmenting financial incentives or tax breaks for R&D might expand the number of products that can be affordably developed. If a pharmaceutical company determines that a particular chemical will not provide a reasonable financial return, perhaps the government could motivate them to donate the patent rights to the government for some tax break.

Conclusion

Pharma-economics underlies the decisions pharmaceutical companies make with regard to the development of their product lines. Because of the enormous financial resources that must be mobilized to take a product to market, pharmaceutical companies rely heavily on the analysis to insure returns on the investment. Given that the customer for these products is often in life and death situations, pharma-economics may appear to be a cynical approach to research and development. Pharmaceutical companies are not obligated to participate in charitable behavior, but, most I believe want to be both good corporate citizens and good shareholder investments. Part of that responsibility, however, means insuring the long-term survival of the company, and this often means making decisions that have ethical implications.

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