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The Ethics of Pricing and Access to Healthcare: A Social Justice Issue

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In most countries in the developed world, healthcare is considered a right, not a privilege. Access to appropriate medical services, including pharmaceuticals, is viewed as a natural part of the commitment of the government to its people. In the United States, though, the focus on pharmaceutical development has led to a kind of "free-for-all" in the industry, where each company strives to produce new products at an alarming rate, with the end goal of profitability and competitive advantage. Who pays for these medical advancements? Who pays for new drug research, development and distribution? Though pharmaceutical conglomerates produce thousands of new drug products every year and distribute them throughout the world, the United States pays the lion's share of the cost to bring these new products to the world's medicine cabinets.

With the prescription drug costs on the rise, many Americans living at or below the poverty level find themselves out of the loop of the necessary products needed to ensure their health. Because there is a disproportionate amount of illness among the nation's poor, these individuals are the hardest hit by pharmaceutical drug price increases. The question this raises, then, is whether pharmaceutical industry pricing and the impact that it has on access to healthcare reflects ethical business practices. From a social justice perspective, then, the application of ethical philosophies can be used to understand the overall problem of expansive pharmaceutical pricing and the social impacts for the nation's poor.

The Scope of the Problem

One of the most difficult problems in the modern health care environment is that even when effective treatments are available, not everyone can afford them. "Total outlays on healthcare products and services hit \$1.6 trillion in 2002--nearly 15% of the nation's total economic output." [1]. Many medical programs provide diagnostic services, testing and even support service, but do not cover expensive prescription drugs. Many patients, including the elderly, people at risk of repeated illness, and the socio-economically disadvantaged, often go without life-sustaining medications because of the issue If affordability.

Gokhale argues that there are populations of people that are especially hard-hit by increasing prescription drug costs, including retirees and single women [1]. Gokhale reports that financial pressures that are directly related to prescription drug costs have been reported. Estimates since 2000 suggest that retirees who are not in good health may spend upwards of 44 percent of their income on out of pocket prescription drug costs [2]. Another hard-hit population, low-income single mothers, has

also demonstrated problems in meeting their prescription drug needs; low-income single women not covered by Medicaid spent 52 percent of their income on health expenses [2].

One of the populations that get the most attention in regards to the issue of prescription drug costs is the elderly. Gokhale argues that the impact on seniors is less than expected [2]. Data collected in 2003 suggests that only 25 percent of people over the age of 65 who are no longer working are foregoing medications because of affordability [2]. "The most vulnerable categories of retirees on account of prescription drug expenses are those without any drug insurance (50 percent spending 4100 or more on prescription drugs), those in low-income groups (34 percent spending more than \$100 per month) and those with three or more chronic conditions (42 percent spending more than \$100 per month) [2].

Despite efforts in 2004 to introduce reform measures, healthcare coverage and prescription drug costs continue to remain a primary concern in the United States [2]. There are many misconceptions about the uninsured, underinsured and uninsurable in the United States. Many people who have insurance coverage through their employers, perceive this group as consisting of impoverished families, many of whom are eligible for Medicaid benefits anyway. The reality of the uninsured and uninsurable not represented by Medicaid in the United States is that this population generally consists of middle class families and children. In 1991, there were almost 36 million Americans without healthcare coverage [2]. Of this number, a surprising 51.3 percent were employed people under the age of 65 [2]. Almost 28 percent of the uninsured individuals were children, and only 16.8 percent were non-working adults. These figures present a surprisingly different perspective on the uninsured.

At the same time, researchers have also recognized that while there are large populations who receive insurance benefits, many of these people do not qualify for free or low-cost prescription drugs. As a result, many people have to choose between basic essentials (e.g. food, clothing, housing, heat) and payments for prescription drugs. This links the question of equity in the distribution of healthcare to the ability of the underinsured and underserved to also purchase their pharmaceuticals, which are increasing in cost every year.

Why Pharmaceuticals Cost So Much

The underlying reason pharmaceuticals cost so much is the same reason why business ethics seems to some to be an oxymoron: businesses are created to make money for their stockholders, so their ethical obligation is to the stockholder interest. Businesses that act in a manner that is considered socially ethical, meaning they provide goods and services that better society, often struggle with the bottom line view. Pharmaceutical companies, which provide lifesaving drugs, have one of the highest profit margins in the industrial sector and increasing drug pricing accounts for "44% of the total increase in healthcare costs" in the United States [3].

The explanations for the high cost of pharmaceuticals offered by companies in the industry differ significantly. The first argument that the industry uses to justify their high cost of drugs is that modern drugs have reduced the need for costly hospital stays, surgical procedures and longterm medical treatments as a result of costly chronic conditions. For example, hypertension medications have reduced the risk of heart attack and stroke in many populations, producing positive long-term health improvements. While there is truth to the statement that pharmaceutical companies have created medications that are beneficial to people, this does not support the ethics of price gauging [3]. This simply speaks to the argument regarding the impacts or rising medication costs on healthcare as a whole. In truth, while improved pharmacological interventions have reduced costly surgical procedures, including those for conditions like peptic ulcers and prostrate hyperplasia, long-term pharmacological use can be just as costly to the patient over time. For patients who are on Medicaid or who have health insurance that covers medical stays but not prescription drugs, the overall out of pocket expense for the individual is astronomically larger as a result of the need for pharmacological intervention. "(T)hat medicine may be keeping them from having to have a coronary bypass that may cost \$25,000. But under Medicare, they don't pay for the bypass surgery, so to them a coronary bypass is cheaper than a year's worth of hypertension medicine [3].

The second argument made by pharmaceutical companies to justify drug pricing is that "the industry needs to recoup the enormous overall cost of drug development where for one successful drug; the industry screens 5,000 compounds in the lab and 10 are subjected to expensive clinical trials [3]. While it is true that clinical trials are expensive and pharmaceutical companies pick up a large portion of the expense of new drug development, this does not account for the large profit margins demonstrated by these companies.

Antibiotics are one of the most common prescriptions that experience a fast spectrum of pricing, a situation that industry representatives say is due to the ongoing quest to create stronger and less resistant medication. We had a new antibiotic we put on the market, and the whole therapy [required] only six pills. Other comparable therapies took 30 pills. The cost of theirs with 30 pills was, say, \$30. We priced ours with six pills at \$35. But then the patient had stocker shock-six pills for \$35! - Although it was a better antibiotic, easier to give, etc. So we reduced the price by 25%, and it's one of the cheapest patented antibiotics on the market today, and it's growing like crazy. This is a very price sensitive market right now--thanks in large part to the HMOs [3].

The pharmaceutical industry is not blind to the ongoing clamor its pricing strategy has created for senior citizens, single mothers and low-income families; in order to address the issue many of the top companies have incorporated special marketing tactics to help appease the public. Merck & Co., one of the world's most recognizable pharmaceutical conglomerates, has already implemented one particularly innovative marketing strategy. In order to encourage consumer interest in the corporation's cholesterol-reducing drug Zocor, it instituted a money-back guarantee. This tactic, which is not a common marketing move for a company of such stature, is one of its most aggressive techniques in trying to maintain its competitive edge. Having lost the lead it once held in the cholesterol-lowering drug market, which is a multibillion-dollar business in and of itself it is scrambling to re-establish its position.

At the same time, many drug companies are supporting treatment paradigms in which patients are required to take multiple medications at one time. Poly-pharmacy, or the act in which an individual uses five or more medications at some time, is becoming an increasing problem [3]. Furthermore, when considered in the context of elderly patients, McCloskey (who is both a pharmacist and the manager of the Diabetes Center at the Baylor Medical Center) states that older people are "particularly at risk for adverse effects" of negative drug interactions and reactions [3]. There is an undeniable logic to such a statement since most elderly people have a number of health problems that will be treated by different specialists with different medications [3]. Obviously, the more medications a person takes, the greater the likelihood that there will be some sort of problem adverse reaction. Another issue is that: "They may also have sensory deficits resulting in non-adherence to their medication regimen because of confusion or other problems [3].

Pharmaceutical companies argue, then, that their costs are also related to the issue of poly-pharmacy and the increasing risk that this issue plays in their liability for adverse health reactions. McCloskey refers to work by Wilcox and others who reported in 1994 that, "inappropriate poly-pharmacy is a problem is elderly patients, up to 24 percent of whom receive inappropriate medications."[3] She then adds that this figure is particularly "worrisome" since, according to figures from the U.S. Census Bureau, "there may be 6.7 million Americans over the age of 85 by 2020." [3].

Bedell, at al, studied discrepancies that exist in the use of medications and what that means within the context of poly-pharmacy issues [3]. They worked from the premise that the misuse of medications is a major cause of morbidity and mortality but that few studies have examined the frequency of and factors associated with discrepancies between what doctors prescribe and what patients take in actual practice. They believed that such discrepancies would pose a serious health risk for the elderly. Pharmaceutical companies, then, have had to focus on methods to enhance the literature of each drug produced, including widespread testing of the interactions with other drugs. As a result, the cost of drugs has been related to the belief that adverse issues occur and drug literature must expand to incorporate knowledge of eventualities. Many companies have argued that their lack of competitive advantage is directly linked to the problem of adverse drug impacts.

The constant play in the industry has led many companies to pursue the stance that they are ethical organizations and that their costs are not primarily related to efforts to retain market prominence or market share. In fact, representatives from the pharmaceutical industry have argued that if price controls were introduced in any viable manner, the research and development of new drugs would slow to a crawl. Understanding their arguments in defense of maintaining inflated drug pricing is an important component of identifying the differing views of ethics in the industry.

The Arguments of the Industry

In recent years, the government has proposed the implementation of pharmaceutical price controls as a means of managing rising healthcare costs and creating greater equity in the distribution of healthcare. Pharmaceutical companies have challenged the introduction of price controls with varying support, maintained by the connection between business ethics and business motivations. Calfee, for example, argues that pharmaceutical research is defined and motivated by profitability and that the application of cost/benefit analyses are often utilized to determine whether a drug is economically feasible [4]. Because new drug development is a risk taking process for the pharmaceutical company, the possibility of large profits must be identified in order to support pharmaceutical development [4]. It is Calfee's contention, then, that after calculating for risk, the investment in pharmaceutical research and development limits industry profitability, which has not "persistently exceeded competitive levels [4].

In addition, it can also be maintained that pharmaceutical companies are challenged by the fact that there is no definitive measure of how well a drug will do until after it has been marketed. Research costs of varied drugs, then, are commonly shared by one company, which must assume research and marketing costs to promote the continued research of the next set of drugs. Subsequent marketing costs, including advertising, are seen as a means of addressing "information deficits of patients and doctors," a necessary part of product placement [5].

Calfee suggests that this will have a negative impact on the development of new drugs. If pharmaceutical industries are controlled in terms of their pricing, they will apply business models to determine how price controls will impact their payoffs [6]. If this occurs, drugs that result in a small level of profitability will not be pursued and continue to be produced. Calfee argues that price control has had a negative impact on the development of drugs for widespread problems like malaria, which hits Third World countries the hardest and where profitability is least likely [6].

Because the ethics of business decision-making places an obligation on the part of the pharmaceutical company to meet the expectations for the stockholders, price controls would result in a focus on entrenchment of vested interests and a protection of existing interests, which would result in a decline of new drug development. This has resulted in challenges to the development of generic drugs.

Generic drugs have been viewed as a means of increasing the availability of certain types of drugs for people on fixed incomes. Research suggests, though, that there is a high degree of competition among generic drub makers. The first generic on the market is the one that makes the most money. McLean observes that the first company to successfully wrangle its drug onto the marketplace "can usually sell its drug at 70% to 80% of the branded drug's price, but the price--and therefore the profit--plummet with full competition [7]. As more companies begin to manufacture the generic the price is driven down as the playing field becomes more densely populated.

Generic drug makers attempt to address patent issues and challenge the 20 year patents of larger drug companies based on the application of the Hatch-Waxman law. McLean clarifies that the Hatch-Waxman law allows a company to apply to the Food and Drug Administration to produce a drug even though it is protected by patent [7]. They do so by contending that their version is a distinct version to which the patent does not apply [7]. The Economist observes that generic companies are willing to challenge existing patents because "the potential prize is simply so large these days that the reward outweighs the risk of legal defeat [7]. The multibillion dollar sales of today's blockbuster drugs have invited greater legal scrutiny of patents and encouraged generics firms to find ways to innovate around them."

Pharmaceutical companies also argue that the development of drugs that impact Third World countries is an underlying reason that American pharmaceuticals are so costly. Essentially, the American consumers are paying the price for the development and distribution of low-cost pharmaceuticals in Third World nations. For many countries, the ability to import pharmaceuticals to address problems like HIV/AIDS is a matter of national health [7]. Though many of the countries of the Third World have focused their national attention towards the introduction and development of new pharmaceuticals, United States-based companies have passed on the expense of providing low-cost pharmaceuticals to Third World countries on to the American consumer. This has resulted in the questioning of the ethical decision-making in passing on cost to a population unable to continue to bear the burden.

The question raised by passing on the cost of pharmaceutical use in Third World countries to the American consumer raises the larger issue of the

ethics of rationing healthcare. The consistent difference in this matter is the nature of healthcare by physicians and the role of pharmaceutical companies, which operate within a business paradigm.

Ethics and Medicine

Satel and Stobel emphasis that the concept of "good" amounts to, according to medical ethicists, "encouraging doctors to give full consideration to certain key principles in resolving clinical dilemmas [7]. Among these principles is the traditional, if vague, obligation to act for their patients' benefit and to avoid harming them [7]. This argument is regularly presented within the context of establishing the rights of patients and assuring that "doctors are urged to respect the 'autonomy' of those who they care for [8]. While physicians take the Hippocratic Oath, a doctrine that asserts placing value on human life and causing no harm, pharmaceutical companies are not required to take such an oath. In fact, pharmaceutical companies conduct their business as a business solely, not as an entity with a responsibility or a social justice perspective.

This suggests a contradiction between the goals of using medications and the goals of producing them. Applying such thinking to the realities of the availability of healthcare for those who cannot afford it allows one to recognize that, once again, "act[ing] for their patients' benefit" is at the very core of the practice of medicine. To refuse care because of a potential patient has not proven that he or she can pay for it is, in and of itself, acting against the "patient's benefit [7].

Krizova and Simek argue that the issue of distribution of healthcare is imbedded in "... secretiveness and loss of public control over medical decisions and because of the fact that it simply leads to a false social illusion about universal right to healthcare [7]. Krizova and Simek add: "Assertive patients (better educated, rich, powerful, and motivated) may be preferred [7], and that this clearly shapes the way in which professionals address the needs of patients. The same professional standards applied to physicians are not applied to pharmaceutical companies, which can disregard the view of patient well-being because they lack an obligation to the individual consumer.

When statistics actually have faces associated with them, even the most self-righteous arguments supporting medical rationing or the effectiveness of public programs fall apart. Tauber makes note of the fact that we cannot help but be aware of the fact that: ". . . physician choices are influenced by economic forces that intervene between the healthcare provider and the patient. This highly complex social and economic structure is intimately linked to the public policy of healthcare, which in turn is grounded in both social philosophy and the ethics of medicine [7].

Tauber maintains that many "deeper philosophies" that are related to issues such as morality, justice, and equality are generally "left outside most discussions" [7] in the discussion of healthcare rationing and caring for all members of society. And yet, Tauber believes it is essential that those issues and concerns be addressed if society is to advance in ways that can be defined as "moral" [7]. Without looking at the "big picture" of why a society has chosen to allow entire groups of people to suffer, it is impossible, Tauber says, to make "an ethical commitment . . . towards establishing a national consensus about healthcare" [7].

Social Justice and Equity

The concept of equity is central to an understanding of social justice in relation to the impacts of pharmaceutical pricing on human healthcare. Equity in healthcare can be defined as the "absence of systematic disparities in health between groups with different levels of underlying social advantage/disadvantage" [7]. Specifically, equity relates to the ability of all people to achieve the same level of potential health related services, health systems, community health opportunities and pharmacological interventions. Bravemen and Gruskin recognized that

one of the systematic problems in the United States is that there is a large population of people who are underinsured or uninsured and cannot adequately access healthcare resources [7]. This same population is mostly heavily hit by increases in drug pricing. Social justice occurs when equity is derived within social constructs.

One of the significant arguments in regards to social justice and pharmaceutical pricing is that the pricing provides income that can be used to support further research and development. Assessments of the ethics of this view, then, relate to both the intent and the motive for the application of increased pharmaceutical pricing.

Pharmaceutical companies can apply a social justice model to the ethics of pharmaceutical pricing, as well as arguments against drug price limits. This is based on the ethical views outlined by theorists like Jeremy Bentham and John Stuart Mill. Mill argued that "while the rightness or wrongness of an action does not depend upon the agent's motive, it does depend 'entirely upon the intention'" [7]. "For a Utilitarian, the rightness of wrongness of an action is a direct function of its consequences. Either intentions or motives may have some influence on the consequences of an action, but there is no obvious reason to suppose that intentions, but not motives, are especially strongly connected to the consequence of actions."[7]

In the case of drug pricing as a means of supporting continued drug research, the motive of research may be economic for the pharmaceutical company, but the intent of the research is to provide benefits for those who take the medication. Researchers seek out methods to cure diseases and utilize research based on funding mechanisms and directives within the medical health field. While these motives may direct individual action, the intent of this research is to provide health benefits to humans. Pharmaceutical research has been viewed as a means of improving health and correcting health conditions ranging and though researchers have utilized increased pricing to fund their research, their intent in doing this was not to make medicines inaccessible to certain populations, but instead to improve the health of individuals through the introduction of new medications.

In his essay "On Liberty", Mill's main point is that "Over himself, over his own body and mind, the individual is sovereign" [7]. Mill felt "compelled" to make this declaration because of what he calls "the 'tyranny of the majority'; (a line from Alexis de Tocqueville's Democracy in America), wherein through control of etiquette and morality, society is an unleashed power than can do horrific things" [7]. Mill's championing of the individual's right to make decisions for himself also includes what we call the "Harm Principle," which states that "people can do anything they like as long as it does not harm others [7]. The problem here is that people do not always agree on "what exactly constitutes harm" [8].

Nehamas maintains that we have an imperfect understanding of nature" and that we tend to script our own experiences relative to what we need, rather than what is ethical [7]. Out of distinct efforts to keep full pockets and mete economic gain, the government has neglected the issue of the greatest god for the greatest number of people. Mill would argue that the use of pharmaceutical pricing to fund future research places existing drugs out of the ability of the average American to purchase and use. As a result, the research and development components of pharmaceutical companies do not reflect efforts at social justice or equity based on the desire to meet the needs of the greatest number of people.

The contradictions that exist in the pricing of pharmaceuticals so that they are cost-prohibitive for many Americans can be understood from a deontological perspective. From this view, if there is a substantial contradiction that can be noted in the rationale for an action, then this is enough evidence to suggest that the action is wrong. In terms of

pharmaceutical pricing, the contradiction exists in the role the business plays in creating pharmacological interventions that are designed for the betterment of society. If a company is driven by the need for money and then creates medications that are used by the socio-economically disadvantaged who have a greater propensity for illness, the cost-prohibitive nature of the medications precludes access.

Characteristic of a society where the rich get richer and the poor get poorer, the nation's elderly and impoverished citizens are often victims of a bureaucratic healthcare system that claims to help those who need it the most. Because society is fundamentally based upon performance and profit, it is not unusual to find that it is necessary to impart a sense of social responsibility with regard to pharmaceutical pricing. The ethical approaches of purpose, principle and consequence are integral components of business social performance; itemizing these contributions finds one incorporating the interests of ethics and morality within the healthcare structure, essential concepts that are often absent from a significant standpoint.

Conclusions

Ethics, healthcare and society must work in tandem or there is no purpose for any of its existence. Unethical pharmaceutical company practices, such as advanced pricing for new drugs and the use of competitive advantage to influence drug pricing, are what harbor ill will and create a climate of public contempt and distrust. There are myriad ethical considerations in the daily world of healthcare, and each one presents yet another moral dilemma: Should the decision be made for company or personal gain? How many will reap the benefit of drug pricing at the expense of all others? Is there a time when an individual's interests supersede those of the masses? These are ethical questions posed each and every day with regard to providing citizens without prescription drug coverage and in reference to advances in pharmaceutical pricing.

Endnotes

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