LIFE-SAVING DRUGS FOR DESPERATE PATIENTS AT A FAIR PRICE

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ABSTRACT

In recent years there has been a growing concern that pharmaceutical corporations have been profiteering at the expense of the public good. That industry is, after all, one of the most successful in the United States with an average profit margin of 15 percent. It has yielded investors an annual return of 25% over the last decade.' But is this level of corporate "success" consistent with our moral standards of "fairness" when drug prices are set so high that many desperately ill patients are either driven into poverty or denied treatment because they cannot afford to pay for their lifesaving drugs? The prices of three drugs of desperation currently marketed in the United States illustrates this point.

**CHART I**

<table>
<thead>
<tr>
<th>Company</th>
<th>Use</th>
<th>Initial Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT</td>
<td>Burroughs Welcome AIDS</td>
<td>$8,300 yr.</td>
</tr>
<tr>
<td>Clozaril</td>
<td>Sandoz Schizophrenia</td>
<td>$9,000 yr.</td>
</tr>
<tr>
<td>Zofran</td>
<td>Glaxo Anti-nauzea used with chemo</td>
<td>$1,800 6 months or $300 per dose</td>
</tr>
</tbody>
</table>

In the United States, the high cost of pharmaceutical products is fueled by two primary conditions. First, patients suffering from painful, debilitating and potentially fatal diseases are often willing to pay a high price for pharmaceutical products that promise, even a modicum of relief. Second, high prices are also sustained by imperfect competition in
pharmaceutical markets buoyed by third party payment systems, FDA regulations, patent laws, and other forms of governmental market manipulation. Together, these two broad factors have made the industry enormously successful, but also a frequent target of social and economic reform.

This essay will explain how desperation and imperfect competition in pharmaceutical markets frame public policy debates over the fairness of drug pricing policies. Philosophically, this will entail the analysis of the concepts of "desperation" "exploitation," and "fair price." Economically, this will involve an assessment of the nature of competition in pharmaceutical markets. In the end, we will argue that public policy must take into account both the moral and economic principles that govern relationships between pharmaceutical corporations and their most desperate customers.

DESPERATION

The health care industry, and particularly the pharmaceutical industry, can be distinguished by the fact that its primary customers are, at least to a certain degree desperate. This factor has had a profound impact on both the moral and economic relationships between consumers and providers. Therefore some account of the normative concept of desperation is essential to both kinds of relationships.

The concept of harm is an essential part of the philosophy of desperation. Feinberg has predicated harms to interests. "It is only in virtue of having interests that people can be harmed,
and that is the only way to harm any person is to invade his interests."² An interest, moreover, is "what is truly good for a person whether he desires it or not."³

"A person is harmed when someone invades (Blocks or thwarts) one of his interests. A person has an interest in Y when he has a stake in Y. A person's interest in the singular (his personal interest or self-interest) consists in the harmonious advancement of all his interests in the plural."

Unfortunately, it is not always possible to harmoniously advance all of our interests without suffering harm.

Rational persons generally seek to avoid harms. "Objective harms;" such as death, pain, disability, loss of pleasure, and loss of opportunity, are those harms which most rational people seek to avoid, unless they have a good reason not to.⁴ Of course we might also want to differentiate between physical, psychological, and economic harm. The greater the harm, to be avoided the more desperate a person may become. Because one must take into consideration both the severity of the harms involved and the probability of suffering them, four values can be discerned:

1. The magnitude of harm to be avoided.
2. The probability of suffering this harm.
3. The magnitude of the alternative harm.
4. The probability that suffering this alternative harm will, in fact, result in avoiding the greater harm.

Therefore, persons who seek to avoid high probability major harms
like death, pain, and disability are usually the most desperate and willing to risk proportionately greater harms as alternatives.

The most difficult and heart-wrenching **predicaments** involve the avoidance of high probability major objective harms. Predicaments are, by their very nature, "coercive." As Feinberg has noted, coerced behavior may result from either the actions of other persons ("personal coercion") or nature ("circumstantial coercion"). In the former case, "another person threatens" and the latter case "nature threatens." A threat, in either case, signals an impending harm. Persons suffering from diseases of desperation operate initially under a form of circumstantial coercion.

An **offer** expands the options of a desperate person. Obviously, some offers are better than others. The most **enticing** offers are the ones that threaten the least and promise, with a high degree of certainty, the greatest benefit. One might also argue, however, that even enticing offers made to desperate persons are also coercive in the sense that they are accepted in a context of a predicament with few options. So, although it is eminently rational to be willing to suffer great economic harm in order to escape from substantial physical harm (especially death, serious disability or excruciating pain) that decision may also be coercive to some degree. Unfortunately, the logic of desperation also leaves the door open to both exploitation and fraud by others.
THE ECONOMICS OF DESPERATION

Classical economic theory says that all economic relationships are based on the simple principle that buyers and sellers voluntarily form contracts to advance their own self-interest. Conversely, transactions that are "involuntary" or "coerced" are deemed unfair illegitimate. Two classic forms of involuntary economic transactions involve fraud and exploitation.

Contemporary moral and legal strictures against fraud and exploitation have evolved considerably since the nineteenth century, when the rugged individualism of "Caveat emptor" ["buyer beware"] gave legal sanction to many predatory business practices. The rise of "patent medicine" in nineteenth-century America, however, demonstrated how laissez faire economic policy can breed fraud and exploitation while diminishing the quality of pharmaceutical products.

The moral and legal offense known as fraud occurs when intentional deception results in harm to another person. "Fraud in the inducement" occurs when an apparently enticing offer makes false claims or deliberately fails to fully disclose the risk of causally related harms. Throughout most of the twentieth century, drug companies have been required by the FDA to test for both safety and efficacy and label the products they offer. This is because we make a moral distinction between "disclosed" threats, which are voluntary and "undisclosed" threats which are not. The legal principle Volenti non fit iniuria ("To one who has consented no wrong is done.") is frequently cited as a good rule
of thumb. Since the early twentieth century, the FDA has not allowed pharmaceutical products on the market that are known to be unsafe or ineffective.

EXPLOITATION

One does not have to be responsible for another person's predicament in order to commit a moral transgression. Pharmaceutical prices will be regarded as *exploitative* if a company merely takes advantage of another agent's forced compliance. "Exploiters discover opportunities rather than create them." There are, however, varying degrees of exploitation. The morally repugnant form, known as "price-gouging," occurs when a company's pricing policies inflict unfair or excessive economic harms upon its most desperate customers. Some desperate patients have greater financial resources and/or comprehensive health insurance, and therefore are able to pay top dollar for life-saving drugs. Others, however, others are faced with the choice of suffering great economic hardship or being denied access to life-saving drugs altogether.

Drug companies are aware of this moral problem and have begun to implement programs guaranteeing that patients are not denied treatment for the lack of resources. But these policies do not prevent desperate patients from impoverishing themselves before their treatments are given to them free.

So it is rational for desperate persons suffering from life-threatening diseases like schizophrenia, cancer and AIDS to deliberately risk substantial harms. Often these harms are
physical, in the form of pharmaceutical side-effects. Because of the coercive nature of desperation, patients are also willing to suffer great economic side-effects in order to avoid imminent death, pain, or disability. Therefore, it is not surprising that pharmaceutical companies are able to set very high prices for pharmaceutical offers for diseases that breed the greatest degrees of desperation. Exploitation by drug companies, however, requires not only desperate patients but also imperfect competition in pharmaceutical markets.

COMPETITION IN THE PHARMACEUTICAL INDUSTRY

It is widely acknowledged that there are two types of market structure: perfect competition and imperfect competition. On the supply side of a perfectly competitive market, a large number of individual sellers compete among themselves, without collusion, to provide an identical product. There must be no external legal, financial, or cost barriers to enter or exit the market. This is important because the fewer the competitors, the easier it is for competing sellers are to engage in collusion or price-fixing. On the demand side, perfect competition occurs when individual buyers compete, without collusion, in full knowledge of the offers made by the sellers. The price a seller receives for its goods or services is, therefore determined solely on the basis of what the buyers are willing to pay. Companies that offer the best product at the lowest price may be rewarded by earning a profit.

Profit is defined as the excess of total revenue over total
cost. Normal profits are what a company must earn in order to simply remain in a given market. Economic profits are anything beyond that margin. In the long run under perfect competition, most companies can expect normal profits and economic profits of zero. Although some successful companies may earn economic profits for a short time, the absence of entrance barriers to the perfectly competitive market guarantees that other firms will soon be attracted to that successful market. This competition eventually drives the selling price down and profits are pushed back to normal levels.

Imperfect competition (or monopoly) may appear on either the supply or demand side of a market. On the supply side, imperfect competition occurs when a few sellers or buyers, perhaps in collusion, are capable of unilaterally controlling supply and price. In pharmaceutical markets, competition has been largely confined to the period after patent protection lapses when "generics" and can legally appear on the market. On the demand side, imperfect competition occurs when a large group of purchasers (such as an HMO, or a group of HMOs) in collusion, are capable of dictating the price it pays pharmaceutical companies for their products. So, in a perfectly competitive market both buyers and sellers are free to enter or withdraw from the market at any time.

Monopoly, therefore occurs when either a single buyer or a single seller is capable of unilaterally controlling the quantity and price of a product that has no substitute. When
both trading partners are monopolies, (bi-lateral monopoly) market forces resemble perfect competition. Hence, as HMOs become more powerful bargaining partners, pharmaceutical corporations can anticipate lower profit levels.

In the absence of powerful private HMOs, many governments assume the role of a single-payer of health care services in order to maintain bi-lateral monopolies and bargain on behalf of citizens.

The moral problem with supply-side monopoly is that it generates inequality of bargaining power, which may lead to exploitation. This is most evident in relationships between desperate patients, pharmaceutical corporations, and HMO's. As desperate patients become increasingly subjected to exploitative pricing policies, political demand for governmental intervention is inevitable. Indeed, social contract theorists like John Rawls argue that the primary function of government is to protect the "least advantaged" members of society from the predatory instincts of the naturally advantaged, and that at least some "social goods" ought to be distributed equally.' We will discuss the main philosophical views on social obligations to the disadvantaged and the public policy options later in this essay.

Pharmaceutical companies compete in a market characterised by imperfect competition in the forms of oligopoly and even monopoly. There are three main reasons: third-party payment systems, high cost of research and development of pharmaceuticals, and governmental interference in pharmaceutical
1. **Third-party payment for pharmaceutical products**

Third-party payment systems, such as private health insurance and government subsidized health care programs (Medicare and Medicaid) play a vital role in preserving imperfect competition for pharmaceutical products. The effect on prices is felt through the demand curve. When prices rise in **price sensitive** price elastic markets, quantity demanded tends to decline as buyers choose to spend their resources on other goods. However, in pharmaceutical markets where third-parties pay for a patient's drug treatment, price sensitivity is greatly diminished because insured patients are largely insulated from the effects of price increases.

Managed care plans, however, are price sensitive and therefore have begun to adopt strategies that increase their bargaining power over pharmaceutical companies. Many HMOs, for example, have begun to limit prescription drug benefits to a restricted list of **approved drugs**, which has enabled them to negotiate volume discount prices for drugs included on the lists. While this policy may be good business for HMOs, it has at least two disadvantages for their desperate patients. First, managed care plans are likely to exclude from these lists many expensive **orphan drugs** that serve small numbers of the most desperate patients. Second, the policy also might discourage the development of so-called **me-too-drugs**, that, for at least some patients, may prove to be safer and/or more effective than the
well established drugs on the preferred lists. 12 Hence, in the long run, these lists may actually tend to reduce competition and therefore contribute to higher prices. Of course, even if preferred drug lists did, in fact, lower wholesale drug prices, it would not necessarily mean that these prices will be passed on to individual patients in the form of lower insurance premiums.

The availability of life-saving drugs to desperate patients is often the product of the interaction of competing monopolies, usually pharmaceutical corporations, HMOs, or government programs. We may, however, be a bit naive in our unbridled faith in beneficent monopolies. How far can we trust an HMO to advance the interests of its patients when it's primary economic goal is to turn a profit?13

While it is true that health insurance reduces the out-of-pocket costs of health care that patients receive, it also increases the amount of health care consumed, and therefore raises the cost of health care to society as a whole. The increased consumption of health care due to insurance coverage is the consequence of an economic phenomenon known as moral hazard. If insurance reduces the cost of a specific treatment to the patient, then the patient does not have any incentive to equate the marginal value of the treatment with the marginal cost of it. So when the out-of-pocket costs to the patient are eliminated or reduced, moral hazard predicts that the patient will demand and consume more health care services than he/she would if the full price were paid out-of-pocket.
In the case of pharmaceutical products, patients with unlimited coverage for drug treatment, demand more drug treatment than they would if they had to pay the full prescription price because of price insensitivity. In contrast, their uninsured, price-sensitive counterparts are not immune to the economic ramifications of higher prices.

For desperate patients, moral hazard comes into effect when expensive treatments of marginal utility are sought by insured, price-insensitive patients as a last resort. In order to restrain the economic effects of moral hazard, insurance companies or HMOs have assumed the role of "gatekeeper" by limiting its health care benefits and expenditures. This is often accomplished by limiting coverage to those treatments that are deemed "medically necessary."

Third-party payment systems also create the possibility for drug companies to practice price discrimination. This is done through market segmentation of its customers. Elasticity of demand occurs when different patient populations have varying degree of willingness and ability to pay the price for drugs. In the United States, the pharmaceutical market is split primarily between price insensitive patients who have third-party coverage and price sensitive patients who have no insurance. Profit maximizing drug companies, therefore can charge a higher price to the price insensitive segment of the market and a lower price to the price-sensitive segment.

However, as HMOs and other third-party purchasing entities
become price sensitive and enroll larger numbers of patients, their collective bargaining power increases, and they can demand price discounts from the pharmaceutical companies. Therefore, drug companies become guilty of unfair price discrimination when they charge lower prices to the insured population and charge higher prices to desperate, uninsured, price-sensitive patients who have less bargaining power. That is why we often find that many uninsured patients, especially the elderly on Medicare, cannot afford to take their medications at recommended doses.

International pharmaceutical corporations practice price discrimination on a worldwide basis. That is why European countries with nationalized health care systems, and a lot of bargaining power, enjoy significantly lower drug prices than we do in the United States.\textsuperscript{15}

2. The high cost of developing pharmaceutical products

Although the pharmaceutical industry has been enormously successful, only a few companies can afford to compete in that market because the process of developing, testing, manufacturing, and marketing new drugs is time-consuming, expensive, and risky. Development time for new drugs has increased substantially from 4-6 years in the 1960s. Currently it takes about 12 years to bring new drugs to market. Each new drug also requires up to $359 million in corporate investment.\textsuperscript{16} The return on any one investment is far from guaranteed. Indeed the vast majority of drugs that have come under the scrutiny of the FDA turn out to be
either ineffective or unsafe. "For every 10,000 new medicines created in the lab, a thousand make it into animal tests, ten end up being promising enough to test in human beings, and one or two will make it to market." Patents on most new products in the United States are only months old when they reach the market, however the average patent life of a prescription medicine is diminished by the time it takes to get FDA approval. Although the Drug Price Competition and Patent Term Restoration Act of 1984 allows corporations to recoup up to five years of patent time, this results in only a brief delay in the appearance of highly competitive generics. Under relatively competitive market conditions, if a pioneer drug like AZT enjoys a virtual monopoly and economic profits in a given market for a period of time, its success will eventually attract other "me too" competitors and "generics" that will put downward pressure on high prices. The problem is that most pharmaceutical markets are not competitive.

3. Governmental intervention in pharmaceutical markets

The United States government routinely tampers with the competitive workings of the pharmaceutical market which has created artificial monopolies. Of course the taxation of corporate profits and regulation of the industry are the most obvious means of governmental intervention. But other more subtle forms of intrusion include: granting patent licenses to pharmaceutical products, requiring the companies to conduct expensive clinical trials to prove safety and effectiveness, and
by serving as a third-party payer for drugs for large numbers of patients enrolled in government programs such as Medicare and Medicaid.

Two recent legislative efforts illustrate how government can foster artificial monopolies in the pharmaceutical market.

First, the Orphan Drug Act of 1983, was an attempt by the government to encourage drug companies to develop drugs for rare diseases that afflict so few patients that it is not economically feasible for them to otherwise enter these markets. Included among its provisions were a seven year exclusive right to sell an orphan drug before other competitors would be allowed to compete in that market and lucrative tax incentives. Initially, the act required drug companies to disclose their research and development costs and document projected sales before gaining the orphan designation. Drug companies successfully fought this provision that would have exposed to public scrutiny, the profitability of these new drugs. They were also able to revise the definition of an orphan drug to include any drug that treats fewer than 200,000 persons in the United States, which had the effect of deflecting regulation away from the disclosure of profitability. While the act did encourage companies to enter into markets that would not be otherwise profitable, the high price of drugs developed under this program has raised the question of government collusion in price gouging.

Secondly, the Office of Technology Assessment has been trying to develop policies whereby the government can more easily
share the fruits of its research with private companies in order to advance the public good. Through the development of CRADAS (Cooperative Research and Development Agreements) the federal government has handed over to pharmaceutical corporations valuable primary research on pioneer drugs such as AZT and Taxol. For participating drug companies, CRADAS have certainly reduced the cost of developing drugs and therefore lowered the risk that they must assume in order to enter into specific markets. Although, one would expect significantly lower retail prices for government subsidized drugs this has not been the case.

THE TAXOL CONTROVERSY

In December 1992, the FDA approved the drug Taxol as a treatment for refractory ovarian cancer. It was discovered and developed by the National Cancer Institute and transferred to Bristol-Meyers Squibb as a CRADA. The production price paid for experimental quantities of Taxol by the National Cancer Institute was between $.60 and $.90 per milligram. Bristol-Meyer Squibb priced it at $4.87 a milligram or about $986. per three week cycle. In 1993, Congressional Hearings investigated the OTA's policies for sharing government funded research and concluded that these policies tended to increase profits of drug companies without appreciably advancing the public interest.

Officials for the company argued that the high price was justified by the high level of risk associated with drug research and development. But the highest level of risk exposure to the company is during the pre-clinical research phase. This sunk
cannot be recovered if the drug never makes it to market. In the case of Taxol, critics argued that the National Cancer Institute had funded pre-clinical research costs. So the time the drug reached the clinical phase, the government had funded approximately 85% its development costs.\(^{21}\)

**WHAT IS A FAIR PRICE?**

In classical economics, the price a corporation charges its customers for a product is the total cost of investment plus normal profit. For pharmaceutical corporations, investment involves four main areas of concern: development of the drug, which takes into account expenses incurred in conducting primary research; testing, which involves the expense of conducting clinical trials required by the FDA to insure safety and effectiveness; manufacturing, which covers those costs associated with producing the drug, e.g. raw materials, production machinery, labor, etc; and marketing, which includes expenses incurred to inform physicians, pharmacists, and insurance executives about their drug.

Critics of the industry argue that the prices charged by pharmaceutical corporations are exploitative and unfair. The question of fairness, however, is rather complex. Philosophically, a theory of distributive justice "attempts to establish a connection between the properties or characteristics of persons and the morally correct distribution of benefits and burdens in society."\(^{22}\) There are two broad kinds of theories of justice patterned theories and unpatterned theories.\(^{21}\)
Patterned theories judge the fairness of a distribution procedure based on the distribution pattern evident in the end-state. Traditionally, material distributions based on utility, need, merit, and equality fall into this category. Today three patterned theories seem to dominate the literature: egalitarianism espouses an equal distribution of social goods in the end-state, or at least equal access to such goods; communitarianism, prefers procedures that advance communal interests over liberal political systems that emphasize individual welfare and rights; utilitarianism promotes procedures that maximize public and private interests in the end-state. Hence, the main difference between these "patterned" theories is reflected in the kinds of end-state patterns that are morally deemed preferable.

An unpatterned (or libertarian) theory, of justice rejects the notion that justice can be found in end-states and therefore focuses on the fairness of the procedures that produce the end-state. Hence, any end-state that is generated by a fair procedure is just or fair, regardless of how the benefits and burdens are distributed. Because libertarians see the liberty principle as fundamental, they prefer minimal governmental interference in the personal choices made by individuals and therefore they are also avid defenders of laissez faire economics. Government intervention in markets is justified only to the extent that it promotes perfect competition. So from a libertarian perspective, an unfair drug pricing policy is simply
the product of unfair competition. As long as the selling price of pharmaceutical products is determined by free market forces, the price and the resulting distribution of social goods in the end-state are deemed fair. Jan Narveson, writing in the libertarian tradition, argues that there is an important distinction between Natural Monopolies and Artificial Monopolies.

[Natural monopolies arise]... "where some private enterprise, by virtue of superior products, more efficient operation, fortuitous situation in relation to supply sources, or lassitude on the part of potential competitors, ends up with all the business, even though no one has been forcibly prevented from entering the market. [Artificial Monopolies, in contrast, arise] "where the sole provider of the services or goods is so because the government won't allow anyone else to provide them." 25

In contrast, to the libertarian agenda, egalitarians, communitarians, and utilitarians would all agree that the government must play more a substantial role in the regulation of pharmaceutical companies. As they examine the consequences of any given pricing policy, at least some end-state distributions are judged unfair and therefore would be inclined to use the apparatus of the state to intervene.

In sum, the concept of fairness only makes sense from a specific theoretical perspective. Therefore, public policy debate over the fairness of pharmaceutical prices often reflects
deep philosophical disagreement. In assessing their own pricing policies, pharmaceutical corporations naturally prefer unpatterned theories of justice.

The price that a company decides to charge for its product can be arrived at on the basis of at least three different sets of criteria. Libertarians prefer opportunity-based pricing or risk-based pricing, while the patterned theories seek cost-based pricing.

Libertarians are committed to opportunity-based pricing policies, which set the profit margin at the highest possible level buyers are willing to pay, without increasing production volume to the point where it diminishes total profit. Opportunity-based pricing is deemed unfair only under imperfect competition. Libertarians are also in favor of risk-based pricing, which primarily takes into account the financial and market risk that a company takes by exploiting an economic opportunity in a given market. The greater the risk taken by the company, the higher the expectation for profit. Conversely, the lower the risk, the lower the profit expectation. An unfair price violates the formal principle of justice when prices are set higher than the risk exposure can justify.

Defenders of patterned theories of justice argue that one cannot evaluate the fairness of a pricing policy apart from how it effects buyers in the end-state. From their perspective both opportunity-based and risk-based pricing are inherently unfair. So when pharmaceutical companies set the price of a drug relative
to *similarly situated* drugs already on the market, and if those prices are already opportunity-based and risk-based, then any price unfairness in the end state will be perpetuated. Patterned theorists prefer *Cost-based* pricing policies which take into account a company's total investment in development, testing, manufacturing, and marketing of the product. Then the profit margin is set at a certain "reasonable" percentage. Of course, much here depends on how one arrives at this percentage and how one construes a reasonable profit.

In summary, the main issue for price fairness is whether corporations are obligated to take into account how prices of pharmaceutical products effect their patients and society in general. Unpatterned theories like libertarianism generally seek *procedural justice* while the patterned theories look for justice in the *end-state* and therefore are more likely to regulate drug pricing policies.

CONCLUSIONS

The forging of principled public policy toward pharmaceutical pricing has major implications for the future of health care reform in the United States. Worldwide, there are two fundamental philosophical orientations that might serve to guide the government's relationship to pharmaceutical corporations: the *American unpatterned free market model* and the *European and Canadian patterned regulatory model*.

Traditionally, the United States government has taken the *unpatterned free market approach* to the pricing of pharmaceutical
products. Corporations have been permitted to set prices at their own discretion, regardless of how these prices impact patients. In this essay we have argued that, even from a libertarian perspective, this approach is inappropriate for pharmaceutical markets which are essentially artificial monopolies that have profitted from imperfect competition. Other Western industrialized countries, with national health care systems, have adopted the patterned regulatory approach which carefully controls both the price and profits of pharmaceutical corporations.

The following chart compares the cost of four basic drugs in Canada and the United States.  

<table>
<thead>
<tr>
<th>DRUG</th>
<th>USE</th>
<th>WHOLESALE PRICE</th>
<th>COMPANY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ceclor</td>
<td>Bacterial Infections</td>
<td>$134.18</td>
<td>$84.14</td>
</tr>
<tr>
<td>Tylenol With Codeine</td>
<td>Pain Relief</td>
<td>$19.38</td>
<td>$3.32</td>
</tr>
<tr>
<td>Zantac</td>
<td>Ulcers</td>
<td>$70.19</td>
<td>$53.82</td>
</tr>
<tr>
<td>Xanax</td>
<td>Anxiety and Nervous Tension</td>
<td>$47.81</td>
<td>$16.92</td>
</tr>
</tbody>
</table>

Although the price of pharmaceutical products is consistently lower in Canada, defenders of the free market are quick to point out that in United States governmentally managed monopolies such as veterans hospitals and the postal service are plagued with inefficient cost control, high prices, and poor
quality service. They conclude that in economic matters, at least in the U.S., the best government governs the least. However, even the libertarians must acknowledge that government has an obligation to not only sustain competition in our markets, but also a duty to protect and enhance public safety and health. Hence, even the most rigid libertarians must realize that some governmental manipulation of the free market might be necessary. Historically, this line of reasoning has formed the basis for the regulation of public utilities. Libertarians might, therefore argue that the availability of safe and effective drugs at a fair price would seem to be a matter of public good, at least on par with cable television. But even when libertarian regimes create artificial monopolies as instruments of public policy, they have a clear mandate to insure that the entities actually promote the public good.

When pharmaceutical corporations adopt pricing policies that are contrary to the public good, the government really has two choices. One option is that the government can remove itself entirely from the pharmaceutical markets and move the industry toward perfect competition. This would entail dissolving the FDA, withdrawing patent protection, and ending other market intrusive policies. Of course, even if this approach could be economically justified, it is not likely to take place. Or, the government could regulate pharmaceutical companies as artificial monopolies and demand that they operate more in tune with the public good. Pharmaceutical companies, of course, prefer the
current policy which has afforded them the best of both worlds: the relative freedom from competition inherent to governmentally protected artificial monopolies, while reaping the kinds of profits that only natural monopolies deserve.

Regardless of which policy direction we pursue, it is important that we acknowledge that the pricing policies of pharmaceutical corporations serve as a mechanism for rationing their products. Pharmaceutical corporations typically justify high drug prices by arguing that they are entitled to be rewarded for the economic risks they assume for investing in research and development. However, these companies have resisted pressure from interest groups and the government to reveal their actual costs. We do know, as was the case with Taxol, that pharmaceutical corporations have been especially adept at "mining the motherlode of knowledge created by government-sponsored biomedical research and training." Therefore, much of the economic risk associated with research and development that pharmaceutical companies claim is often tempered by government investment at government laboratories and at public universities.

But in the United States, where corporate records are regarded as private property, pharmaceutical products are essentially rationed by the private decisions made by corporate leadership. Therefore, the fundamental issue in regard to price fairness is whether pharmaceutical products should be distributed on the basis of these "invisible rationing mechanisms."

John Rawls, perhaps the leading proponent of egalitarian
rationing, has argued that when essential social goods must be rationed in a just society, the distribution system employed must be visible and public. Leonard M. Fleck has also made a convincing case in favor of visibility.

Invisible rationing mechanisms permit the use of rationing criteria that are capricious and/or unreasonable. That is, invisible rationing mechanisms permit the unfair to be effectively disguised as the merely unfortunate. If the public condition is to be met, then the use of such invisible mechanisms must be foreclosed. Put more positively, the publicity condition requires that a certain kind of public conversation provide the basis for just agreements. . . . To the extent, then, that invisible rationing mechanisms subvert the possibility of such conversations with respect to the allocation of health care resources, they are especially insidious, morally speaking.

Regulation of the pharmaceutical industry will surely involve a major restructuring of the traditional relationship between the United States government and the pharmaceutical companies. Most obviously it will entail ending the longstanding practice of allowing drug companies to hide their pricing policies behind the constitutionally protected wall of "proprietary information," as if they were a natural monopolies.

If it is true, as we have argued, that pharmaceutical
corporations are, in fact, artificial monopolies, supposedly created by the government to serve the public interest, then regulation of the industry is easily justified. If our government cannot gain access to the corporate records that justify the high drug prices that in effect ration their products, then the goal of securing lifesaving drugs for desperate patients at a fair price will be continue to elude the American public.\textsuperscript{31}
ENDNOTES


6. As Aristotle observed, here is a proportion between voluntariness and moral responsibility. The greater the voluntariness for an act, the more likely we are to assert praise or blame. Conversely, there is also an inverse proportion between the degree of voluntariness and a level of coercion. An action is totally involuntary when there is literally no choice is possible as when an individual is forced to act by either internal compulsion or external force. Since both other persons and nature conspire to limit virtually all of our alternatives, to one degree or another, it follows that no human acts are absolutely voluntary. Therefore when we assert that an action is either non voluntary or involuntary we are making a normative judgment stating that the level of voluntariness is sufficiently diminished as to lessen the agent's moral or legal responsibility.

7. We use the term "rationality" of human actions in the sense described by Bernard Gert. Gert argues that irrationality a more basic normative concept than rationality. Therefore, an act is irrational if it is not irrational. Says Gert, "An action is irrational in the basic sense if it is an intentional action of a person with sufficient knowledge and intelligence to know the foreseeable consequences of that action and these include significantly increased risk of his suffering death, pain, disability, loss of freedom, or loss of pleasure (including the frustration of those rational desires which he considers in a cool moment to be his more important) and the person does not have an adequate reason for the action." See: Bernard Gert, Morality: A new Justification of the Moral Rules (New York:


11. For a Rawlsian analysis of the high cost of pharmaceuticals see: Richard A. Spinello, "Ethics, Pricing and the Pharmaceutical Industry" *Journal of Business Ethics* 11 (1992) pp. 617-626. Spinello claims that health care is a "primary social good" and therefore its "distribution should not be contingent on one's abilities and standing in the community." p.625


14. For an analysis of how the principle of "medical necessity" might be applied to mental health coverage see: James E. Sabin and Normal Daniels, "Determining Medical Necessity\" in Mental Health Practice" *Hastings Center Report* 24 (November-December 1994) pp. 5-13.


16. Murray Weidenbaum, "Are drug prices too high?" *Public Interest*, 112(Summer 1993) p.86


19. Ibid, p.153


26. Chart II was put together based on price information found in: John Greenwald's article, "The Pain of Pricey Pills" *Time* (March 8, 1993) p. 55.

27. Larry Churchill has argued [in: *Rationing Health Care in America: Perceptions and Principles of Justice* (Notre Dame: University of Notre Dame Press, 1987) p. 14-15] that although rationing based on price is not the same as rationing performed by a central authority, it is still nevertheless a form of rationing. "It is the genius of laissez-faire health care that it orders priorities of care by not ordering them, that is, by letting the market forces decide who gets what. This enables us to say regarding the outcomes, that we are all innocent of ill will or prejudice against those who cannot compete. In the end, since no one is in charge, no person or sets of persons are really responsible. The standard line is that these inequities are unfortunate but not unfair."


31. If the arguments put forth in this essay in respect to the pharmaceutical industry have been at all convincing, then one might ask: "What about the rest of the health care industry as a whole?" After all, pharmaceuticals account for only 7% of the total cost of health care in the United States. If our arguments apply equally to other aspects of the industry such as the cost of hospital care or the salary of surgeons, then comprehensive health care reform is surely warranted.