The Legal Costs of Prescription Drugs

An Honors Thesis (HONRS 499)

by

Nicholas G. Hermann

Thesis Advisor
Patricia Lang, Ph.D.

Ball State University
Muncie, Indiana

May 2001

Graduation Date: May 5, 2001
Acknowledgements

I would like to express my sincere gratitude to my advisor, Dr. Patricia Lang, who was instrumental in helping me to complete this project. The gifts of her advise, her time, and her encouragement are greatly appreciated.

I would like to thank all of the people who offered their input into this paper, including Dr. John Cranor of the Political Science Department and Dr. Kevin Fales of Eli Lilly and Company for their insights and suggestions.

Special thanks go to my family for their efforts during the process of completing this project. In particular, I would like to thank my grandmother for sending numerous articles, my fiancé for helping me stay organized, and my parents for their unwavering support and encouragement.
Abstract

The healthcare costs in the United States are growing at an alarming rate. With the costs expected to more than double in the next decade, the issue of what do about it has become a highly politicized topic. With many different constituencies offering their own solutions, focus has shifted away from the overall problem of healthcare costs and settled on the specific topic of the price of prescription drugs. This paper examines the increase in prescription drug expenditures, inspects why drugs cost as much as they do, reviews the patent laws concerning prescription drugs, and explores possible solutions to the problems caused by the inflated costs. This paper is not meant to provide an absolute answer to the problem of rising pharmaceutical expenditures, but it does propose a series of possible solutions which address not only the high costs of prescription drugs but also the difficulty of ensuring the uniformity of price reductions and the financial compensation required for the innovation of new drugs without sacrificing the quality of care that patients receive.
Costs of Drug Development

According to an article in *Newsweek*, drug expenditures in the United States have increased from $65 billion in 1995 to $125 billion in 1999, and the article estimates that prescription-drug spending will reach $243 billion by the year 2008. In order to discuss the effects of patent law on the price of prescription drugs, one must first investigate the costs associated with the discovery, development, and marketing of new drugs. Because patents do expire allowing generic drug competition and a consequential decrease in profits, pharmaceutical companies must compete by means of innovation. However, a company must first discover a new drug before it can introduce it to market.

Seeing drug discovery as a way to broaden markets, increase profits, and increase the price of a company’s stock, pharmaceutical companies in the United States have actively sought to increase the amount of money that they invest in discovery. The amount of money invested in research and development has risen from 11.9% of total sales or $1.5 billion in 1980 to 20.3% of sales or $22.5 billion in 2000. During this time period, companies have systematically accelerated the research process of discovering new drugs, and research teams used in the discovery process have changed. They have become larger and more academically diverse, allowing colleagues to put forth ideas from different academic disciplines to use and test numerous leads, and to systematically investigate numbers of related groups of compounds. Another advantage to increasing the size of research groups is that it allows for further modification of compounds. In other words, different chemical groups can be added or deleted from compounds in order to increase solubility, to pass toxicology tests, or simply to discover more potent analogs.
Pfizer’s Chairman and Chief Executive Officer William C. Steere, Jr. contributes Pfizer’s industry-leading growth rate to its currently marketed human pharmaceutical products and its promising research pipeline. In an address to financial analysts on December 11, 2000, he stated, “Pfizer’s strong, sustained performance is driven by our strategic focus on innovative research and a diverse product line that addresses major unmet medical needs.” His statement was later echoed by President and Chief Operating Officer Henry A. McKinnell, Ph.D. Dr. McKinnell attributes Pfizer’s continued growth to “a broad base of key products, a diverse new product pipeline, continuing profit margin expansion and investment for future growth.” Pfizer projects that the company will submit at least six new pharmaceutical candidates in the next two years for regulatory approval. These candidates include “innovative treatments for diabetes, neuropathic pain and epilepsy, and HIV/AIDS.” In addition, the company also reports “significant progress in its research and development programs covering compounds for treating smoking cessation, cancer, depression and cardiovascular disease.” The Vice Chairman and President of Pfizer Global Research and Development, John F. Niblack, Ph.D., asserts that Pfizer is now the largest pharmaceutical research and development operation in the world. According to Dr. Niblack, Pfizer’s research efforts include “approximately 12,000 employees, six discovery sites and an expected 2001 investment in total R & D of approximately $5 billion” that contain “19 research areas, covering just about every major disease.”

In 1999, Eli Lilly and Company was one of the pharmaceutical industry leaders in the area of research and development investment with respect to total sales. According to an informational booklet distributed by Eli Lilly and Company in 2000, the emphasis on
research and development dates back to the company's founder, Colonel Eli Lilly, who was, himself, a pharmaceutical chemist. The booklet states that Colonel Lilly "vowed to develop products based on the best science of the day." Under Colonel Lilly's leadership in the 1880's, "Lilly became one of the first companies to initiate a bona fide pharmaceutical research program." The company's emphasis on innovation did not stop there. Colonel Lilly's grandson, also named Eli, referred to research as "the heart of the business, the soul of the enterprise." Today, the company continues to invest large amounts of capital to improve and expand the capabilities of their research and development division. The company has committed itself to hiring hundreds of new scientists "to strengthen and deepen [their] expertise at all stages of research and development."

Investment in the research and discovery of new drugs is a vital component of the pharmaceutical industry. Pharmaceutical companies, like all other companies, exist to turn a profit. There are two ways of doing this. The first is simply to cut prices. After a drug has been discovered, it is covered under a patent granted by the government in order to allow a company to recoup the money invested in its discovery. However, the patent does expire. Following a patent expiration, other companies are allowed to make the product. After their product passes the stringent tests imposed by the Food and Drug Administration, it can be marketed. Multiple companies can essentially duplicate the compound and compete with the company that discovered the compound in the first place. When this happens, the companies compete for market shares. They compete through advertising campaigns and cutting prices. As long as the drugs are essentially the same, the only overriding factor is the cost.
While the price cutting strategy is simpler than discovering and developing new drugs, it is not a good way for a company to earn a profit. The lower the price is set, the lower a company’s profits from the sale of the drug. In order to obtain large sales and to dominate a portion of the pharmaceutical market, a company must offer a unique drug. It must introduce either a drug that treats previously incurable diseases or it must offer some benefit over previous used drugs. For example, a benefit could be an extra strength drug, a more specialized drug, or one that has to be taken less frequently. This strategy for increasing profits is much riskier than the price cutting strategy because the firm must always make a large investment in research and development in order to discover and develop a new product which may win large sales but also runs a risk of failure. This risk of failure drives up the already inflated costs of discovering new drugs.

As mentioned earlier, companies have made concerted efforts to hire new scientists and expand the size of their research groups. While this is important, it is not all that can be done to accelerate the research and development of new drugs. In order to accomplish this goal, companies must also invest in technology. They must buy new equipment, update older equipment, and utilize the latest technological discoveries. In addition, companies must also investigate biotechnology and other nontraditional fields in order to either discover new candidates or find quicker, more efficient ways to produce currently marketed pharmaceuticals. However, all these methods, combined with a lengthy approval process, and the previously mentioned failures of some compounds, have contributed to a dramatic increase in the cost of the research and development of new drugs.
The graph below shows the tremendous increase in the costs of the research and development per marketed drug. The costs have increased from $54 million in 1976, to $231 million in 1987, to $350 million in 1994, and to approximately $500 million in 2000.

The dramatic increase in the costs of research and development has magnified the risks associated with the development of new pharmaceuticals. According to estimates, for every 5,000 substances examined, only one is likely to prove safe and effective. In addition, once a drug is discovered, it takes an average of 12 years to bring it to market. When taking into consideration both the uncertainty of drug development as well as the time that it takes to bring a drug to market, it is easy to see why only 3 out of 10 Rx medicines recover that average cost.

While the costs of discovering new compounds continue to increase, companies are becoming more dependent on their financially successful products in order to cover the costs of research and development of other compounds. For example, a 1992 survey
of major American pharmaceutical companies found that seven out of ten large pharmaceutical companies derive at least 50 percent of their sales from their three largest products.\textsuperscript{12} It is important to realize that the financial benefits reaped by these companies for their top three products are not constant. After a patent expires for a particular compound, competition from generic drug makers begins, prices decrease, and the company that discovered the compound's market share decreases drastically. (The phenomenon of generic competition will be discussed in the next section of this paper.)

Once a drug has been discovered, developed, and approved by government regulatory agencies, it is ready to be marketed. However, new drugs are not automatically prescribed by doctors and bought by patients. First companies must promote their products. In fact, drug companies have a higher ratio of promotion expenditures to sales in pharmaceuticals than in other industries.\textsuperscript{13} In addition, doctors often complain about the excessive mailings that they receive as well as the personal visits from pharmaceutical salesmen.

Despite the costs of these promotions, pharmaceutical companies continue to aggressively promote their products. They do this not to persuade doctors to over prescribe medications, but instead to educate doctors. By educating doctors, drug companies can inform them of new uses for drugs, newly found side effects, and new products that may be superior to products currently being used. Doctors do not prescribe new drugs immediately after they are introduced, partly out of caution but also out of ignorance.\textsuperscript{14} Policies that are designed to limit the promotional expenses of drug companies run the risks of leaving doctors essentially unprepared to prescribe new medicines and to decrease the quality of therapy that they offer to their patients.
Research does not end just because a drug has been developed and brought to the market. Pharmaceutical companies continue to research their products to search for new uses, different doses, ways to decrease the frequency that patients have to take pills, and continue to test their drugs’ safety. Despite rigorous governmental testing, some drugs with potentially harmful side effects are marketed. The potential for harmful side effects leads to a potential for lawsuits. Major pharmaceutical companies have always been concerned with these product liability lawsuits. However, they are more concerned with product liability concerns in the United States as opposed to cases in Canada and Europe.

There are two reasons for this. The first is the evolution of strict liability lawsuits in the United States. These types of lawsuits allow for companies that produce products with manufacturing, design, or communications defects to be sued without the plaintiff establishing an injury or loss. Under these lawsuits, people can sue the companies for lack of information and/or warning labels.

Canadian and European courts have been less willing to hold manufacturers to the strict standards that the current United States legal system does. For example, market share liability, where a whole industry can be sued for lack of warning labels, is a unique characteristic of the American legal system. Additionally, United States courts have historically awarded much larger judgements than those of their foreign counterparts. One reason for this is that in the United States, litigants have the right to request jury trials in civil cases. Traditionally, juries are more willing than judges to favor plaintiffs at the expense of the deep pockets of a drug company.\textsuperscript{15} Judges in Canada and elsewhere are less likely to award large punitive and compensatory damages. In fact, damages that Canadian judges are able to award are often subject to statutory limits.\textsuperscript{16} Additionally,
Canadian litigants are limited in their rights of appeal. Legal costs are an expense for every pharmaceutical company. These costs are passed on to the consumers through increases in the price of the drugs. Legal costs are greater in the United States than in Canada or in the European Union. Therefore, the costs added to the price of drugs in the U.S. are greater, meaning that drugs are more expensive.
In order for pharmaceutical companies to continue to invest in research and development, they must continue to see a return on their investments. In other words, the company must make a profit off of the drugs that they do manufacture. In order for a drug to become profitable, the price obtained from the sale of the drug must not only cover the costs of manufacturing, marketing, testing, and distributing the drug, but it also must be sufficient in reimbursing the company for the money that it invested in research and development. Like all businesses, a pharmaceutical company shows a profit when its total income exceeds its total expenditures. When one considers that only one in 5,000 substances that are examined is proven both safe and effective and only thirty percent of all prescription drugs recover the average costs of development, as discussed in the previous section, it becomes evident that not all drugs are profitable. Therefore, for a company to be profitable, it must return a higher than average profit on the thirty percent of the drugs that are able to recover the costs of development in order to offset the losses that the company incurs from the drugs that are not.

In a free market system, however, it is next to impossible to recover these costs without governmental intervention. For in a free market society that is unimpeded by governmental intervention, it would be difficult to consistently return higher than average profits from the sale of any one product. If a company was able to sell a product at an inflated price, then competing companies would enter the market and sell their own version of the product for a price lower than the initial company’s price, and the initial company would essentially lose the money that it invested in the research and
development of the product. Therefore, for pharmaceutical companies to become profitable, they must rely on governmental intervention to help them to recover the excessive costs associated with the research and development of their products.

The means through which the United States government intervenes in the market is provided by Article 1 Section 8 of the Constitution. It states that “The Congress shall have the Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” 17 This article of the Constitution paved the way for the creation of the United States Patent and Trademark Office in 1802. 18 The patents that this office is authorized to grant prohibit others from making, using or selling the invention in the United States for a given period of time. 19

Monopolies

When a company first begins to market a new product, it is the sole supplier. Until competition is introduced into the market, the company can set the price as high as it likes. The consumer can either purchase the product from the supplier at the price set or not at all. This situation in which a single firm is the only supplier of a product or service for which buyers cannot easily find a substitute is known as a monopoly. 20 Monopolies of some form exist in every market and arise for a variety of reasons. The most common form of monopoly is when new products are introduced into markets. Initially, the company that first markets a new product is the beneficiary of a monopoly even if regulatory measures, such as patents and trademarks, are not available. The reason for this is that it takes time for competitors to produce and market competing products. Two other potential causes for monopolies deal with the market factors of supply and demand.
A monopoly may exist because the market for the product is only big enough to support one supplier. In this case, the most efficient supplier that is able to produce the product at the lowest cost can essentially run the competing suppliers out of the market therefore establishing a monopoly for itself. Another way that a company can hold a monopoly is if it is able to control the entire supply of raw materials that are needed to produce a certain product. Without access to these raw materials, competing companies cannot produce their own versions of the product.

In the pharmaceutical market, a monopoly is necessary to allow companies to recoup the money that they have invested in the research and development of their products. Patents and trademarks, granted by the government, create these monopolies for the companies. Some people argue that pharmaceutical patents are not necessary for two reasons. They argue that the lack of appropriate technology may prevent potential competitors from entering the market quickly. The assumption with this argument is that each drug is complex and that it is very difficult to acquire the technical knowledge that is required to produce it. The second argument is simply that pharmaceutical companies are innovative, and it does not take long for competition to arise, even if it is from a chemically different drug. In this instance, patent protection is essentially devalued by the prospect of another company being able to find a different way to treat a disease.

The flaw in the first argument is that it is, in fact, rather easy for competitors to duplicate products. Companies are required to report a drug’s chemical formula on its label. With the knowledge of the chemical formula, scientists at other companies can easily duplicate products. Due to the ease of replication, patents take on added
importance for pharmaceutical companies. The flaw of the second argument lies both in the flaw of the first as well as in the degree of speculation that is assumed by the argument. While some drugs that are under patent protection do lose their share of the market to newer drugs, one cannot assume that just because a drug is successful that a competing drug will enter the market, let alone steal a large share of it.

**General Agreement on Tariffs and Trade**

On December 8, 1994, as a part of the General Agreement on Tariffs and Trade, the United States patent law was changed in order to make it similar to the ones used in other countries. Before this modification, the law had provided protection of new products for seventeen years from the date of issuance. The General Agreement on Tariffs and Trade changed the law to provide patent protection for twenty years from the date of application. Despite the appearance that the length of patent protection in the United States was extended through this law, some experts argue that this may not necessarily be the case. Lewis A. Engman, the president of the Generic Pharmaceutical Industry Association, stated, “The change in the law ultimately will benefit generic manufacturers by eliminating situations in which delays in granting of patents and multiple patents extend the term of effective protection.” His argument is that, in the past, pharmaceutical companies have received patent protection for periods of time longer than twenty years through delays in the issuance of patents.

By definition, a patent gives the holder, or patentee, the right to exclude others from making, selling, or offering to sell the product or process claimed by the patentee for a specified period of time. According to United States law, the specified period of time is twenty years. However, the effective or actual amount of time that the
pharmaceutical company has to market a patented product may be considerably less. To obtain an estimate of the effective time that the company has to market the product under patent protection, one must first subtract the time that it takes for the patent office to approve the patent, since the law states that the twenty years begins with the date of application. An additional variable that must be taken into account is the amount of time that the FDA takes to approve the drug. While pharmaceutical companies typically apply for patents immediately after a compound has been synthesized and proven effective in animal tests, the company is not able to market the compound until after it has received approval from the FDA to do so.

**FDA Testing**

Before a drug can be tested on human subjects, a pharmaceutical company must first prove that is safe to test on people through preclinical laboratory and animal tests. Experts estimate that only five in 5000 pharmaceuticals that enter preclinical testing advance to human trials and of these five, only one will eventually be marketed as a new product.\(^{26}\) Once substantial evidence has been gathered to prove that a drug is safe for human trials, a company can apply for permission to conduct these clinical trials through submitting an Investigational New Drug (IND) application. If the FDA does not comment adversely within thirty days of the application, then clinical testing may begin.\(^{27}\)

Clinical trials provide pharmaceutical companies with the opportunity to gather information concerning the safety, effectiveness, and dosage of a drug through testing it on human subjects. Clinical trials are typically divided into three phases. Phase I generally involves a relatively small number of healthy subjects. This phase can last
several months and is used to determine any potential side effects of the drug. Assuming that everything goes well, the clinical trials are expanded from the twenty to one hundred patients tested in Phase I to several hundred patients in Phase II. As opposed to the healthy individuals used in Phase I, Phase II subjects actually have the condition the product is intended to treat. Phase II studies are usually performed through double-blind investigations, meaning that neither the patient nor the investigator knows whether the patient is receiving the drug or a placebo. These tests are conducted mainly to test the effectiveness of the drug, but they are also used to determine the optimal dosage levels of the drug and to monitor any short-term side effects. Phase II clinical trials typically last from several months to two years.

If a drug is permitted to move into Phase III clinical testing, it will be tested on a large number of subjects, often from several hundred to several thousand. These subjects are tested at different sites throughout the country and are involved in a second double-blind study. The purpose of these tests is to determine the drug's effectiveness in comparison to certain controls, to determine the proper dosage of the drug, and to look for any potential long-term side effects. Phase III testing can last from one to four years. Once the clinical trials have concluded, the company can then submit a New Drug Application (NDA) to the FDA for review. Upon approval from the FDA, a company may begin marketing a new drug. Phase IV testing then begins. Phase IV testing involves surveys, samplings, and continued testing to investigate adverse reactions that people have to the drug.

According to the United States Department of Health and Human Services, it takes an average of thirteen years eleven and a half months for a drug to go from the
initial synthesis, through the preclinical and clinical testing process and review by the FDA, to market. The pie graph below shows the average distribution of this time.\textsuperscript{29}

![New Drug Development Timeline](image)

Assuming that companies apply for patents near the start of clinical testing, the period of time that a drug is under patent, yet unmarketable, is on average approximately seven and a half years, leaving an average of only twelve and a half years for a company to market the drug while under patent protection. During these twelve and a half years, companies must price the drug high enough to recover the costs of its research and development, production, and marketing, while not pricing it too high and alienating the drug's market. As discussed earlier, a company must also work to cover the costs of other drugs that have not been able to recover the costs of their research and development. Any additional money that is made off of this drug is a profit for the company, which can choose to reinvest the money in further research.

**Patent Expiration**

Patent expiration occurs twenty years from the date of the initial application for a patent. After the patent has expired, the invention is public domain and can legally be reproduced and sold by anyone.\textsuperscript{30} When a patent expires, the government created
monopoly that once existed is no more. Other companies begin to enter a drug’s market almost immediately. And unlike the company that initially discovered the drug, subsequent companies’ costs for research and development are incredibly low in comparison. For example, the entry barriers for duplicates, unlike new chemical entities are virtually nonexistent. The Waxman-Hatch Act of 1984 encourages the entry of generic pharmaceutical companies into the market by allowing use of the research undertaken on behalf of the pioneer product to gain generic approval. In other words, the generic pharmaceutical company needs only to prove that their product contains the same active ingredient as the pioneering product. The company can rely upon the research of the pioneering company to provide information on the safety and efficacy of the drug.

In addition to a real lack of entry barriers, a generic drug company does not rely on a large marketing campaign in order to steal a large share of the market. Instead, it appeals by offering the drug at a much lower price than the pioneering company. The company can do this because in comparison to the pioneering company, its overhead costs are virtually nonexistent. It does not pay for extensive research and development of new drugs, a large marketing campaign, or any other indirect costs like failed research projects searching for other potential drug candidates. In fact, because a generic pharmaceutical company has such low costs to produce a drug, it can sell it for a relatively small profit and therefore undercut the price of the product offered by the initial company.
Cutting Costs

During the 2000 presidential campaign, the *Indianapolis Star* reported after examining the prescription drug plans offered by the major party presidential candidates show that there is no miracle cure. The article analyzed both the Bush and Gore plans for aiding senior citizens with the costs of prescription drugs. The two plans offered such initiatives as adding prescription drug benefits to Medicare, comprehensive Medicare reform, and block grants to give states the option to help low-income Medicare beneficiaries. The article concluded, however, that neither plan would be a “miracle cure.” It pointed out that seniors with an annual income between $11,000 and $16,000 a year, spend more on prescription drugs than any other group. Nonetheless, individuals in this income bracket are not poor enough to qualify for maximum assistance under either plan.

While the article pointed out that the combination of initiatives offered under either plan would make prescription drugs more affordable to lower income senior citizens, it also concluded that neither plan would be a comprehensive solution to the problems caused by high prescription drug prices. Seniors cannot rely solely on the federal government to assist them in affording prescription drugs. In order to make prescription drugs affordable to seniors, a combination of cost cutting initiatives must be utilized. This section examines both the benefits and liabilities of some of these initiatives.

**Pharmaceutical Companies Lower Their Prices**

The most obvious way to lower the price of prescription drugs is for pharmaceutical companies to simply lower their prices. However, this scenario is very
unlikely. A company would simply refuse to lower prices unless the discount was profitable to the company. For example, if a company reduced the cost of a certain drug by 15%, the move would only be profitable if the company's sales of that drug increased by more than 15% to cover the money lost through the discount as well as the increase in production costs for producing more drugs. A large increase in sales triggered by a discount in price is unlikely for two reasons. The first is that there is a limited customer base. There are only so many people that need the drug. A decrease in price would raise a company's market share, but would not have a dramatic increase in the sale of all of the drugs in the field. The end result would be that the company that discounted the drug would take business from other companies who would discount their prices to regain their respective market shares therefore rendering the discount unprofitable for the original company.

Pharmaceutical companies are not pressured to lower the costs of their drugs while they are under patent. Generally, any discounting that does take place occurs after a patent has expired unless a drug receives competition by a chemically different drug that treats the same disease. Once a patent does expire, competing pharmaceutical companies are free to enter generic drugs into the market. Generally, the emergence of small generic producers does not effect the price of the original drug because they make up a very small percentage of the market. When this occurs, it is unlikely that a company will cut prices because it is unlikely to recoup the revenue lost as a result of the price cut. Once major generic pharmaceutical firms enter the market, the price of the original drug is forced down. The larger firms have more money to market their drugs and promote
them in medical journals and through direct salesmen who persuade doctors to prescribe the generic substitutes to the drug in order to save their patient money.

For these reasons, a dramatic discount in the price of prescription drugs sold by pharmaceutical manufacturers is very unlikely. A company must be concerned with the profitability of its drugs. The loss of income incurred from a price cut is immediate, while the reduction in the quantity sold due to the entry of new products is gradual. Profits that may be attained in the future often take a backseat to an immediate decrease in profits. A pharmaceutical firm is reluctant to cut prices because the loss is immediate and the gain is merely speculative. The future is always less certain than the present, and an immediate cut in price is certain to reduce revenues.

**Formularies and Bulk Purchases**

Formularies are catalogues of pharmaceutical products and their prices. The function of these catalogues is to list the names of drugs, their generic equivalents, and the prices of each. They are intended to influence doctors and pharmacists to favor generic drugs. Some countries, such as Canada, have adopted the use of such formularies to determine the reimbursement of healthcare costs. When formularies are used exclusively to determine costs, the process is called mandatory price selection. When governments or insurance companies use mandatory price selection, it would seem that the winning bidder could potentially capture the entire reimbursement market.

There are some flaws to this system, however. The prices published in the formulary are not static, but the prices reported in the formulary are. Every six months, a new price for each drug is published in the formulary. The lowest submitted price is then designated as the reimbursement price for the drug. Once the formulary is published, a
pharmacist can expect to be reimbursed for the cost of the lowest available price in the formulary, but he is not bound to buy from that company. The pharmacist then buys the lowest priced drug he can. Thus, the companies enter into a second round of bidding for market shares. The result is that companies report a list price to the formulary of what they would charge if they held a monopoly on the product. If they are the only company listed in the formulary, then they can command that price. If other companies are reported in the formulary, the price is driven down, but only in the second round of bidding. The result of a formulary is that it truly does not drive prices down. Since drug companies cannot be bound to the published prices of the formulary, it is a mere formality. The true price pressures of the formulary rely on the market pressures in competing for the pharmacists’ prescription, which is dependent solely on the kickback that the pharmacist can receive from the difference in the reimbursement costs and the price he or she pays for the drug.

Another way that governments and large healthcare providers attempt to control the price of drugs is through buying drugs in bulk and engaging in aggressive price negotiations. In these negotiations, they use their large volume and cost-containment techniques to back up their negotiating stance. The largest purchasers in the United States are the federal and state governments through the prescription drug coverage extended to people on Medicaid. It is estimated that government purchases represent ten to fifteen percent of total sales. In 1990, the government not only mandated states to set up drug utilization review boards to monitor which pharmaceuticals are prescribed by physicians, but also set up mandatory rebate levels for Medicaid purchases. The rebate
formula, requires drug companies to reimburse the larger of 15.7 percent of the average manufacturer price (AMP) or the AMP minus the best price given on the market.  

Through the use of formularies and bulk buying, healthcare providers, insurance companies, and governments have “reduced industry revenues substantially.” Subsequently, the costs of these drugs have gone down, but there are some inherent flaws in these types of price controls. The first is that by decreasing the profits of major pharmaceutical companies, the money available for research of new drugs is diminished. The second flaw is that by limiting the profits that companies are able to make off of their drugs, the opportunities to recoup the money invested in the research and development of the drugs are decreased. There are only two ways that pharmaceutical companies can respond. They can refuse to develop certain drugs if they see the risk associated with recovering the money invested outweighs the potential economic benefits of the drug for the pharmaceutical company, or they can increase prices on those people who do not benefit from the formularies, rebates, and discounts offered to bulk buyers. An article in Newsweek points out that “just 26 percent of drugs in the United States will be sold at full price this year.” The article also states that the government, through negotiations and rebates can obtain prices of up to fifty percent off of the market price. Through aggressive price negotiations, HMO’s and insurers can obtain prices up to forty percent off. This undoubtedly leads to a price increase in the costs of drugs to the uninsured, who do not qualify for government programs and cannot afford insurance.

Governmental Regulation

The rising costs of prescription drugs have led many states to look for ways to contain Medicaid costs. In Indiana, where the Medicaid pharmacy costs have risen
steadily, lawmakers are looking into ways to impose managed-care techniques, higher co-payments, and approved lists of drugs to control the $3.5 billion Medicaid program’s fastest-growing expenditures. A graph of reported and projected spending on pharmaceuticals for Medicaid in Indiana is listed below.

Two ways in which lawmakers can lower the costs of statewide Medicaid is to eliminate services provided by Medicaid that are not required by the federal government and to impose a procedure of prior authorization for certain drugs. The first scenario is unlikely because there is virtually no chance that elected officials would vote to end drug benefits, toss people out of nursing homes or stop caring for the mentally disabled, which are the most costly optional services. The second scenario is strongly opposed by pharmaceutical companies that argue the latest drugs are safer and more effective than less-expensive ones. For example, Eli Lilly and Company “strongly opposes prior authorization because it could deny Medicaid patients effective drug therapies they could not afford on their own.”

One example of a way that a state can hold down the costs of prescription drugs is to simply cap them. In an attempt to control the costs of prescription drug benefits
afforded by state Medicaid programs, the state of New Hampshire set a cap of three prescriptions per month on each of the Medicaid recipients. This cap was initiated in 1981 and was projected to save the state $300,000 to $400,000 in annual drug costs. It was dropped after less than a year.\textsuperscript{40} During the time that the cap was in place, the utilization of prescription drugs by Medicaid patients fell by 35 percent. However, it was discovered that limiting the number of drug prescriptions placed frail, low-income, elderly patients at increased risk of institutionalization in nursing homes.\textsuperscript{40} Studies of the program reported that under the cap, the elderly population had more than a 50 percent greater chance of being admitted to nursing homes. It was found that the state incurred additional costs of increased hospital, physician, and nursing home use that far outweighed any projected savings of the program.
Solutions to the Problem

There are no quick, one step cures to the inflated costs of prescription drug prices. The previous section examined some methods used by governments and by large healthcare services to control the price of prescription drugs. While these methods are, in many cases, successful in holding down the cost of pharmaceuticals, they also contain unintended, sometimes hidden costs. The negative attributes of these programs include inferior treatment of patients, a decrease in pharmaceutical companies’ profits which could lead to a decrease in the rate of discovery and development of new drugs, and the costs of the research and development being shifted to other customers. While many efforts have been made to correct the problem of rising costs, all have failed in one way or another.

In order to find a solution, one must first identify the problem and set goals to correct it. When dealing with the rising costs of pharmaceuticals, there are no miracle cures. A solution must be long term and comprehensive. It must set broad, decisive goals that can be achieved through cooperation between the government, large healthcare providers, and the pharmaceutical companies to ultimately benefit the patients. There are two goals that must be set. The first is to lower the cost of prescription drugs to make them more affordable and therefore more available to patients. The second is to increase the quality of care given to them.

Lowering Costs

It is true that there has been a dramatic rise in pharmaceutical expenditures in recent years. According to an article in Consumer Research Magazine, "Outpatient expenditures on prescription drugs (with inflation taken into account) almost doubled
between 1990 and 1998.” The share of spending on pharmaceuticals has climbed from 4.9% of healthcare costs in 1985 to 7.2% in 1997.\textsuperscript{41} Despite these facts, price increases of pharmaceuticals cannot be blamed for this problem. The prices of pharmaceutical drugs have risen less than 4% annually, which is only slightly above the rate of inflation and far below the rate of increase in expenditures for prescription drugs since 1993.\textsuperscript{41} The article estimates that increases in the price of drugs can only account for up to one quarter of the increase in pharmaceutical expenditures. The other 75% is attributed to several other factors.

The first such factor is the aging baby boom generation. Individuals in this generation are approaching the age of fifty. Their increasing age is a major contributor to the increase in the volume of drugs prescribed because older patients tend to have more chronic and severe cases of disease or multiple conditions, each of which may require more treatment.\textsuperscript{42} The baby boom generation encompasses approximately 77 million United States citizens or roughly 30% of the U.S. population. As their generation continues to age, an increase in the volume of drugs prescribed will continue to rise. The demographic shift toward an older population in the United States provides evidence that the problem of rising healthcare costs will continue to get worse, unless something is done to correct it.

Nothing can be done to counteract the effects of an aging population except to cut costs in other ways. There are several other variables that account for the increase in costs of healthcare. Among others, they include the increase in diagnosis of diseases across the board, the high costs of advertising promotions, the need for pharmaceutical companies to make profits in order to fund additional research, and the piracy of patented
products. The increase in diagnosis stems both from an increase in ailments of an aging population as well as the use of better techniques to detect diseases. Once again, the increase in diagnosis is a contributing factor in the rising costs of healthcare, but there is nothing we can do to control it.

As discussed in the first section, the rising costs of the promotion of pharmaceuticals, about $6 billion in 1998, are a contributing factor in the price of the drugs. Pharmaceutical companies justify these costs by pointing to the need to educate doctors about new drugs and their uses. In order to help curb these costs, the federal government should institute an independent, nonpartisan review board to examine the performance of drugs during clinical testing. The board could then summarize the results of its research and report the uses, benefits, and side effects of drugs to doctors. In this way, the money that is currently being spent toward the promotion of drugs could be greatly reduced, and therefore lead to an across the board decrease in the price of pharmaceuticals.

The need for pharmaceutical companies to make a profit in order to recoup the large amounts of money spent on research and development, as outlined in the beginning of the second section, is an important consideration to take into account when looking for a way to cut pharmaceutical costs. Newsweek reports that in 1999, the pharmaceutical industry was the highest rated industry with respect to return on revenues, return on assets, and return on shareholders’ equity. During his bid for presidential office in 2000, Al Gore blasted drug companies for “gouging the consumer unfairly.” Merck public-policy executive Ian Spatz best echoes the industry’s response. In refuting the claim that drug company profits are excessive, he argued that Gore was not taking the
high risks associated with drug discovery into account. He argued, “If we are successful, if we develop great new medicines that have value, we should be profitable.” Without setting price controls and regulating the industry’s profit margins, there is little that the government can do with respect to the financial success of pharmaceutical companies.

The fact that pharmaceutical companies currently return better than average profits is not necessarily a bad thing. In fact, it benefits consumers of pharmaceuticals in several ways such as encouraging new companies to enter the market and providing money for research of other new drugs.

The piracy of patented products has to do with the lack of enforcement of patents in other countries. The Congressional Research Service estimates that U.S. companies lose approximately “one dollar to inadequate protection of intellectual property rights for every three dollars of revenue gained from exported products.” In other words, U.S. companies lose up to $80 billion dollars a year because of inadequately enforced intellectual property rights. These losses effect all companies that export goods and cause the companies to raise prices for other consumers to cover these losses. These losses are particularly prominent in the pharmaceutical industry due to the ease of duplication of the products.

In order to minimize the effects of weak intellectual property law enforcement in other countries, the United States government must actively lobby the governments of other countries to strengthen the framework of their intellectual property laws. The problems of patent piracy stem not just from the nonexistence of intellectual property laws but also from the lack of enforcement of existing laws. The United States government must lobby these governments through the use of treaties, trade agreements,
and diplomatic negotiations. Through working to limit the money lost overseas to the piracy of intellectual property rights, the government can play an active role in decreasing the price of prescription drugs in the United States across the board.

**Increasing the Quality of Care**

While the issue of the costs of prescription drugs is important in the respect that it affects the availability of the drugs to the public, the benefits of new drugs and pharmaceutical research far outweigh the costs. Prescription drugs are estimated to only represent seven percent of total health care expenditures, yet they have reduced mortality and morbidity rates more than any other scientific advances. The costs of prescription drugs can be quantitized, however the benefits cannot. The book, *Changing Environment for U.S. Pharmaceuticals* points out that “for many diseases, drug therapy obviates the need for more drastic and expensive forms of treatment such as hospitalization and surgery.”

In tallying the true benefits of drugs, one must tally up the costs of disease. Public opinion often focus on the monetary costs of prescription drugs, but no one ever gives the pharmaceutical companies credit for saving the consumers the monetary, physical, and emotional stresses of having a disease. Prescription drugs benefit society by shortening or eliminating the need for long hospital stays, saving people from potentially fatal diseases, enabling people to return to work sooner, and allowing people to live longer and healthier lives. For these reasons, it is important to allow pharmaceutical companies to continue to make large returns on their investments. This encourages new investments by the industry and by new companies entering the market. This leads to additional research to find new cures that will benefit society.
A simple example of how the discovery of a drug can benefit society is the introduction of \( \text{H}_2 \) antagonists in 1977. These drugs are used to help treat ulcers, and the result is the rate of surgical operations for ulcers has dropped from 155,000 to around 16,000 per year.\(^{50}\) Considering that an ulcer surgery costs approximately $25,000 and the drugs costs approximately $1,000, this implies a net cost savings of over $3 billion per year.\(^{51}\) However, this estimate only takes the costs of the surgery and the drugs into account. It ignores any savings resulting in shorter hospital stays, an earlier return to work for the patient, and less suffering for the patient.

The previous case points out how prescription drugs truly benefit society and why additional research should be done to discover new drugs. Research should not only be done to find cures for currently incurable diseases, but also to research current drugs to identify any additional uses they may have. An example of this is the current research of aspirin. Through this research, it has been discovered that an aspirin regiment reduces heart attacks, strokes, and angina through improving blood flow through the arteries by making it less sticky and less likely to clot.\(^{52}\) Other research should be done on other drugs to discover any other possible health benefits that they may have.

Additional research can be considered both a way to cut costs and a way to improve care. However, all of the research does not have to be done by the pharmaceutical company itself. For example, the government could research the FDA approval process in order to find ways to make it quicker, safer, and more efficient to approve drugs. Also, the government could take advantage of collegiate researchers to aid in the discovery of new drugs. Through offering more grants and possibly even tax breaks to companies who involve undergraduate and graduate researchers, the process of
discovery can be accelerated, and universities would be furnished with new sources of income to update equipment and to better educate their students through practical experiences.
Endnotes

11. Flint, 50-52.
15. Richard L. Manning, “Products Liability and Prescription Drug Prices in Canada and The United States,” (Brigham Young University, 1997), 208.
23. Lepree, 4.
24. Lepree, 5.
27. Schwartzman, 163.
28. Whitmore, 63.
29. Whitmore, 65.
31. Schwartzman, 255.
32. www.pfizer.com
34. Schwartzman, 259.
40. Boston Consulting Group, Inc., 46.
43. John E. Calfee, 10.
44. Noonan, 29.
45. PHRMA, Opportunities and Challenges for Pharmaceutical Innovation (1996), 3.
48. Schwartzman, 7.
51. S. Siegelman, Business & Health Supplement, January 1992, 8-14, Blue Cross/Blue Shield.