

Does The Regulation Of Pharmaceutical Drug Prices Discourage Innovation?

I. INTRODUCTION

The price of pharmaceutical drugs in the United States is nearly double the price of prescription drugs in the United Kingdom, Japan, Canada, Germany, France and Italy (Danzon, 1997). This is an alarming figure to the consumers of these drugs, and is becoming more alarming as it appears the price of these drugs is not going down. Some argue that drug manufacturers are taking advantage of prescription drug users; whereas manufacturers say high drug prices can be attributed to the steep price of research and development.

Drug prices vary across countries, and these differences between countries can be partly explained by the varying government intervention. There are many different ways that these countries implement price regulation; however, the United States is, for the most part, not involved in the price regulation of pharmaceutical drugs. The majority of economists argue that the regulation of a market will discourage innovation because of research and development costs or other cost that are incurred in bringing a product to the market. Some of the other causes of the high prices are lack of competition due to twenty year patent rights acquired by the pharmaceutical manufacturing companies, and small share of generic drugs entry into the market.

This thesis examines whether price regulation will discourage innovation. One anti-price regulator said, “One day you will walk into a doctor's office to find that your doctor has no drugs newer than twenty years old to prescribe because the discovery of new drugs are not worth the cost of development to pharmaceutical companies” (Kreling, 2000). This is a bit of an exaggeration, but could become reality if companies were to find that they were not making up their research and development costs in the prices of drugs sold.

How much of the R&D cost of a drug is borne by the manufacturing company? The percent of drugs that come from public universities in the United States is 40% (AAU, 2002). United States pharmaceutical companies receive a 50% tax write off for their R&D expenses, and they only spend about 6% of annual revenues on R&D (Sulston). There are seven variables that I will model that might affect the number of new drug patents issued in a country. First I will look at the population of a country. The second factor in the number of new patents is the percent of Gross Domestic Product spent on Pharmaceuticals. The third factor will be the Analytical business expense research and development or ANBERD. The fourth factor is the amount of business expense research and development financed by the government or BERD financed by government in OECD reports, since government financing of drug company R&D reduces risk to a manufacturer. Fifth, I will look at the amount of research and development being done in higher educational institutions, which the OECD reports as HERD or Higher Educational Research and Development. Many universities do drug research and the successful innovations are then licensed out to the private industries. The amount of money that is spent acquiring new innovations is a principal cost that

pharmaceutical companies claim to be recovering in their pricing schemes. The number of new patents focused on in this paper will be Cardiovascular and Diabetes research patents, two of the top ten areas of research according to R&D Directions, a pharmaceutical industry magazine.

To test the effects of the seven variables on innovation, I will look into the number of patents granted in four different countries. The patent information will be coming from a company called NERAC that has access to databases from the United States Patent Office (USPTO), the European Patent offices and the Japanese patent office. The dependent variable is the number of patents and the independent variables are HERD, BERD financed by government, existence of government regulation, the pharmaceutical drug market size as a percentage of GDP, ANBERD, and the population. I will also look into the different types of government regulations in different countries and examine two similar studies on regulation's effect on innovation that have been done using different independent variables than those I have chosen.

In the next section, I will look into the background of the pharmaceutical industry, describing the process of bringing new drugs to a market to lay a base for where the manufacturers are saying that the price of the drugs comes from. In the third section I will look into the argument of regulation and the different countries that are regulating their drug prices. I will then briefly present the studies similar to my analysis and mention the differences. The penultimate section will discuss the findings and what they mean, and in conclusion I will tie the findings to the hypothesis and I will either reject or

fail to reject the effects of government regulation of the pharmaceutical market on innovation

II. BACKGROUND: The PHARMACEUTICAL INDUSTRY

The first pharmaceutical companies were chemical manufacturing plants. They had all the right equipment and ability to refine chemicals into pharmaceutical products. Since that time the industry has had exponential growth and become more complex, but a pharmaceutical manufacturer is sometimes only involved in the final production process.

In 2000, the cost of bringing a new drug to the market was \$800 million (DiMasi, 2000). Though the cost to bring a new drug to the market is high, it is not intuitive where all the cost comes from. There are five parts of the drug discovery process, beginning with discovery that can be done within the laboratories of a private firm, a government facility such as the Center for Disease Control, or at a research university. Much of the early discovery work may not turn into a drug innovation, as e.g., a new gene sequence may be tested thousands of times and found to be useless, or found to have enough value to move into a predevelopment stage. If the discovery is found by a research facility, it may be marketed and licensed to a firm that will take it through the rest of the stages.¹ The licensee will try to place a value on the innovation and then take 25% of that value for themselves, but this valuation process is extremely difficult since it is in such an early

¹ In a ranking of patentees by number of biotechnology patents and products the University of California ranks fourth with 131 patents in a group that consists of Merck and Co, Smith Kline and other pharmaceutical companies. The Imperial College in London established around one new company a month between 1997 and 2000. “The progenitors of many of the blockbusters of tomorrow are being investigated in academic laboratories worldwide” (Greener, 2001).

stage, and only 5% of discovery-stage drugs will get to the market, so there is still a lot of risk involved.(DiMasi, 2000).²

Now that the drug has been licensed it will begin the predevelopment stage, which involves refining the innovation to determine exactly how the discovery is to be used. It will then go into a preclinical stage using animal testing, and then start into the three clinical phases. After the clinical trials are done, the FDA will review all the data and either approve it, send it back for more tests or reject it. Any where along this path of development, it could be determined that the patent is not of value and the development discontinued. Though the project may be rejected, many times there is value in the rejected data that leads to different discoveries. Therefore, when a company states that the cost of bringing a drug to market is \$800 million, they are not only taking into account the cost of going through all those stages for that particular drug, but also adding in the lost costs that are incurred when the other licensed innovations ended–up being a dud innovation. When pricing a drug, a company not only tries to cover the specific cost of producing the one in 20 approved FDA drugs, but make up the cost for the other 19 drugs that didn't get through FDA approval or past the different phases.

Also in this expense estimation of bringing a new drug to the market is the cost of administration, marketing, and advertising a new drug to get the market share that it needs to become successful. As can be seen on television, the advertising of a new drug is becoming a big deal. About 16% of revenues are spent on administration, marketing,

² The most common licesning formula includes an upfront fee, maybe 10% of the licensee value of the drug, plus milestone payments, which are payments that are made after completing each stage in the

and advertising (Kreling, 2000). Even though a new drug might have a patent, once it comes to the market and is shown to be a success, other pharmaceutical companies may create a similar drug that might be of equal or better use, called “me-too” drugs. The countries that have large market are able to support more pharmaceutical companies and therefore will have more drugs coming into their markets. In 1994 the United States was the major producer and consumer of the drugs with Japan in second and closing the gap.

Table 2.2: Growth in sales in pharmaceutical products by country, 1990 to 1993

<i>Country</i>	<i>1990</i>	<i>1991</i>	<i>1992</i>	<i>1993</i>	<i>Av. annual change</i>
	<i>US\$ billion</i>	<i>US\$ billion</i>	<i>US\$ billion</i>	<i>US\$ billion^a</i>	<i>% pa</i>
US	40.4	46.4	54.2	60.0	14.4
Japan	27.6	30.1	33.1	42.0	14.5
Germany	11.8	12.5	15.8	12.0	2.9
France	11.2	11.3	13.6	13.5	7.7
Italy	11.0	11.8	11.3	9.0	-6.2
UK	5.1	5.4	6.0	6.0	6.1
Other	40.3	44.4	48.9	52.5	9.3
Total	147.4	161.8	182.9	195.1	10.1

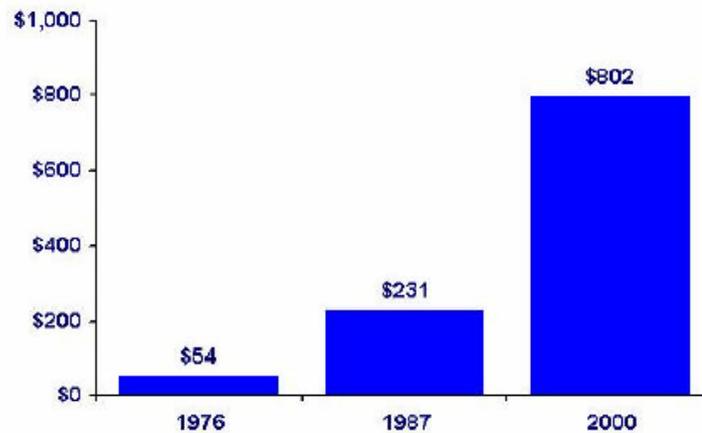
a Converted to US dollars using average end of month exchange rates for twelve months to March 1994.

Sources: JPMA 1994, p. 9; Glaxo 1994, p. 8

process and then to ask for royalties on the final products net sales.

Cost of Developing a New Drug Over Time

Cost of Development (Millions of Dollars)

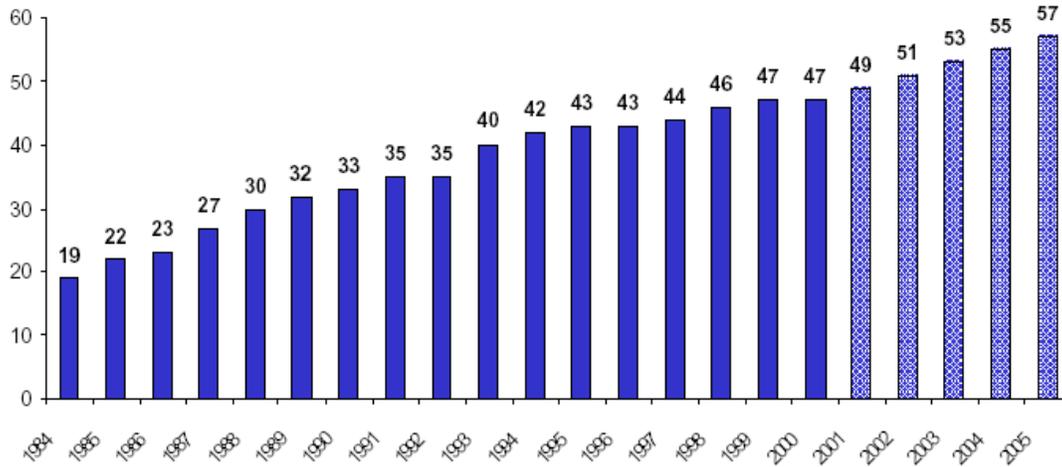


Sources: DiMasi et al., J. Health Econ 1991 10:107-42, and Tufts Center for the Study of Drug Development 2001.

Why has the cost of developing a new drug increased so much? In 1976 it cost \$54 million to develop a new drug; 1987 it cost \$231 million and in 2000 it cost \$802 million (DiMasi, 2000). Why has drug development costs increased so drastically? Have the number of failures increased before a success occurred; are there unseen inflated expenses or just an exploitation of a market by researchers to charge more for their services? In the United States the average time before a drug can be placed in the market has changed from 16 months in 1996 to 25 months in 2002. This increase in the amount of time for approval has increased the research and development costs by \$200 million. (Bloom, 1997) Another problem is the amount of money that is being wasted on the “me-too” drugs. If the same firm produces the “me-too” drug, the monopolistic coverage of the drug is extended for another 20 years with a new patent. One way to combat this is with generic drugs.

Gradually since 1984 the share of the market that is captured by generic drugs is increasing. As the generics' share of the prescription drug market increases, this should decrease the cost of brand name drugs because of competition and the decrease in market power. This is as long as the information is available and there is little noticeable difference in the therapeutic benefits of the different drugs. In October 2002, President George Bush opened the market even wider to generic drug entry by announcing that the US Federal Drug Administration will only allow a single use of a 30 day extension described in the 1984 Hatch-Waxman Act, which aimed to promote competition in the pharmaceutical market by giving brand name drug manufacturers the option of a 30 month extension on their patent as they were going through litigation of patent infringement on their drug by a generic drug manufacturer. This extension was abused, as multiple extensions were requested and granted, delaying the competitive nature of a multiple drug option market.

Generics' Share of U.S. Prescription Drug Market 1984-2005



Note: Generic share of countable units, such as tablets.

Source: 1984-2000 data: IMS Health, National Prescription Audit Plus™, 2001; 2004 projection: S&P analyst Herman Safflas; 2001-2005 forecasts based on a regression line calculation by National Economic Research Associates

As generic drugs become a larger market of the non-patented drug market it will force the market to become more competitive, but the monopoly market present during the patented life of the drug raises concerns about whether the fair prices that the consumer should pay are set. How much of the fixed cost burden should be transferred to the consumer and, more importantly, which consumer should be paying for these fixed costs? A kind of price discrimination, charging people or groups different prices for the same product depending on their different “willingness” to pay for the same product, can be seen when comparing how much the United States consumers of a drug pay compared to the amount paid by other countries consumers. Though part of the difference in prices are due to government regulation of the prices, the high prices that the US consumer pays allow the company to exploit the US consumer’s “willingness” or necessity to pay and

make a larger profit. This paper will not cover the discrimination topic, but the high prices in the United States could be attributed to this fact and if the prices were not regulated at all prices might converge multilaterally to an equilibrium price.

Regulation is a hotly debated topic in the pharmaceutical industry, and there is no clear answer on how to deal with it. The pharmaceutical firms want there to be a free pricing system to “make –up” high fixed cost and consumers argue that these fixed cost are not as high as the firms claim because they do not devote revenue to as much research and development as stated, and even that research and development gets heavily subsidized by the government through grants and university research..

III.THE ARGUMENT for REGULATION

When a government decides to regulate a monopolistic industry, regulators aim to set the price as close to the competitive equilibrium as possible. In a normal competitive market, the price is determined by adjustments between supply and demand until the two meet, and an equilibrium price is created. This can be done because there are multiple companies in the market that can make-up for low supply or high demand. In some markets there are not other firms competing because of some force that limits the entries. An example is seen in utilities, where only one company can place power lines because of large start-up expenses. There is no competition with only one firm, yet for two to go into the market would decrease the profits and opportunity to make-up the cost of installing the lines. In this type of market the government will intervene and regulate the market to protect the consumer from being take advantage of by the natural monopoly.

Patents also create monopolies. The patent system was created so that people would spend money on the initial set-up of a product or market, but then be the only supplier in the market for a time so that they can recover some of their fixed cost that were incurred to create the market. Without the patent system, the incentive to innovate by a private firm would be low because the opportunity to recover fixed costs for a short time in the market would be lost. In a market that has no property rights, the firm has a disincentive to create new products because the costs that they incur to create a new product are sidestepped when another firm comes along and copies the final product. Part of the solution is to allow governments to issue patents that protect the intellectual property rights that a company has to a product. The patent system, in most industries, allows the firm to spend research and development money on a product and then they can make the costs up in profit later due to monopolistic qualities of the market they will be creating or entering. Most firms use a majority of their own capital to raise funds for the research and development of the product.

The pharmaceutical market is one of these markets. There are large fixed costs yet the marginal cost, or unit cost, to the firm of producing the product is relatively small. Therefore in the pharmaceutical market consumers find they are in a monopolistic market that can charge whatever price they want, but the monopoly is created by the government through patents. The consumer can feel cheated because of high prices, yet they will rarely be heard complaining of the variety of innovation available created by a monopolistic market. What the government has done to encourage innovation is subsidize the market by creating research facilities funded by the government that will absorb a lot of the fixed costs and risk normally incurred by companies and thus

eliminating the need for a long-term recovery of fixed cost or extended use of a monopoly market.

When a government regulates a market they tend to set the price using a short run marginal cost of a product and tend to ignore long term fixed costs. For example a drug costs very little to produce, and if the government only allows the firm to charge a certain percentage over the marginal cost of producing the drug the company will make a profit in the short run, but they will have no incentive to create new drugs because the government doesn't take into consideration the cost of actually producing the drug or the lost money from developing a dud drug. If regulation is not done correctly a price could be set too low and will only cover the cost of a company in the short run. Since the research and development cost are a long run decision, a company will not stay in the market if they can not recover these costs. In the United States they have not used a regulating pricing method and as shown in the table below the prices for common drug in the United States compared to drugs on Europe is dramatically different.

Prescription Drug Prices

Outrageously High Drug Prices For a 30-day supply:		
DRUG	U.S. PRICE	EURO. PRICE
Allegra 120	\$69.99	\$20.88
Atarax	\$28.62	\$4.20
Biaxin 250	\$113.25	\$61.74
Claritin	\$63.06	\$16.05
Coumadin	\$37.74	\$8.22
Glucophage	\$30.12	\$4.11
Lipitor	\$52.86	\$41.25
Premarin	\$17.10	\$9.90
Prozac	\$71.94	\$44.10
Zestril 5	\$25.92	\$5.52
Zithromax 500	\$486.00	\$176.19
Zyrtec	\$50.10	\$17.73

From looking at these prices many consumers feel that the prices they pay are doing more than just covering the cost of research and development for the failed drugs; firms are stuffing their pockets with the profit. A report by Families USA in July of 2001 released “Off the Charts: Pay, Profits and Spending by Drug Companies.”

“Based on their numbers, the industries repeated refrain about R&D is extraordinarily misleading. As this report demonstrates, the major pharmaceutical companies spend considerably more on marketing, advertising, and administration than they spend on R&D. Most pharmaceutical companies make considerably more in net income than they spend on R&D. Indeed, the pharmaceutical industry continues to be the most profitable U.S. industry, with profit margins in 2000 nearly four times the average of Fortune 500 companies. Additionally and perhaps least well known, the drug companies are big spenders when it comes to compensating their top executives.” (Off the Charts)

Company	Revenue (Net Sales in Millions of Dollars)	Percent of Revenue Allocated to:		
		Marketing/ Advertising/ Administration	R & D	Profit (Net Income)
Merck and Co., Inc.	\$ 40,363	15%	6%	16%
Pfizer Inc.	\$ 29,574	39%	15%	13%
Bristol-Myers Squibb Company	\$ 18,216	30%	11%	26%
Pharmacia Corporation	\$ 18,144	37%	15%	4%
Abbott Laboratories	\$ 13,746	21%	10%	20%
American Home Products Corporation	\$ 13,263	38%	13%	18%
Eli Lilly and Co.	\$ 10,862	30%	19%	28%
Schering-Plough Corporation	\$ 9,815	36%	14%	25%
Allergan, Inc.	\$ 1,563	42%	13%	14%

These numbers show that though the research and development is a large percentage of the sales dollars, it is sometimes half what is spent on the marketing, advertising or administration expenses. This percentage that is going to the research is typical for a company that has this type of returns like other high technology companies. The big difference is that most highly based technology companies don't get the type of government subsidization that is available to the pharmaceutical companies. For this purpose consumer advocate groups question why the government does not get involved on the regulation of the drug prices. Some consumer try to go out of the country to get their prescription drugs because of price discrepancies, but recently Wyeth threatened to not sell prescription drugs to Canadian suppliers because of the quantity of drugs that were being bought for United States consumption.

There are several forms of price regulation. Many countries have a social health care system, where the government pays the majority of the prescription drug expense. When a government becomes concerned over their budget deficits, they look to regulating the price of the pharmaceutical drugs to decrease their costs. Drug prices have steadily increased as the population has aged and business have become more aware of the profit available. New drugs that now control or even cure a disease are substitutes to the surgeries available decades ago.

The United States finds itself in a different situation. There is no real social health care system that is running out of money; instead, consumers complain that the prices are too high. In 1994 the General Accounting Office of the United States did a study of four countries that have heavy regulation in the drug industry and found that "controls on

pharmaceuticals have succeeded in restraining prices in the four countries but have not prevented increases in drug spending, owing to higher consumption and newer, more expensive drugs.” The countries that do regulate prices for the sole purpose of decreasing government spending find that they are spending the same amount on a larger quantity.

Here are some examples of how some countries regulate their drug prices.

	Denmark	France	Germany	Greece	Italy	Spain	UK
Control							
Price Control		X		X	X	X	
Average Price					X		
External Ref. Price				X		X	
Profit Control					X		X
Internal Ref. Price		X				X	
Negative List			X			X	X
Price Freezing							X
Price Cuts						X	X
"Cost" Pricing				X			
Listing	X		X				X
GP Budgets			X		X		X
Expenditure Ceiling					X	X	
Generic Promotion	X		X				
Pharmacoeconomics		X			X		X
Price/Volume Contracts		X					

One method is Drug Price Regulation. This pricing scheme requires approval when increasing the price of a drug already on the market and approval for new drugs if they are to be reimbursed by the social insurance system. Approval is rarely granted on price increases. This regulation is common to France, Italy and Spain (Danzon, 1997).

Another is Reference Price Limits on Reimbursements. The drugs are put into groups of other drugs with the same therapeutic value and then given a price. The manufacturers are free to charge any price, but the government will pay only a certain amount, and the

patient is the responsible for the difference.³ This system is common to Germany, the Netherlands, New Zealand, and Denmark (Danzon, 1997).

Next is the Rate-of-Return Regulation. Under this system a manufacturer negotiates the rate-of-return allowed for a drug, usually between 17-21%. If the profit from the drug exceeds the designated amount, then the excess revenue must be reimbursed or discounts given on the drugs. This system has been implemented in the United Kingdom (Danzon, 1997).

Physician Drug Budgets place a budget on the physician around the amount of money their patients spend on prescription drugs. It was found that physicians were prescribing drugs that required frequent return visits which happened to be more costly drugs. This regulation reduced prescription drug spending by 18% in Germany (Danzon, 1997). The Japanese System of Drug Reimbursement allows physicians to dispense the drug directly, and the reimbursement comes directly to them—it is not the actual cost of the drug, but a set rate, with the marginal difference is kept by the physician. In this case the manufacturers have the incentive to charge lower than the reimbursement rate, so that their drugs are more frequently prescribed (Danzon, 1997). The Patient Co-Payments plan makes patients responsible for a fixed fee for a prescription drug. Some countries make it a percentage of the cost of the drug. In 1994 though, 50% of all US prescription drugs were paid out-of-pocket. (Gondeck 1994)

In the United Kingdom “The National Health Service differs from national health care providers in other countries because it does not negotiate the prices of individual

³ The Maximum Allowable Charge (MAC) system used in US Medicaid and many managed care programs only applies to generics.

drugs with manufacturers. Instead, drug companies in the United Kingdom are free to establish their own prices for individual drugs. However, under the countries pharmaceutical laws, the maximum profit that drug manufacturers can earn in sales in the United Kingdom is limited. Companies that set prices so high that they exceed maximum allowable profit rates must reimburse the government. Allowable profits are based on several factors, including companies' investments in the United Kingdom and the level of long-term risk. Generally, companies are allowed to earn returns of 17% - 21% on capital investments. The pricing system in the United Kingdom results in brand name drug prices that are on average 31% lower than prices in the United States (Danzon, 1997).

Japan, like other industrialized countries, has a national health care system, and drug prices are generally determined via a reference system. Prices for new drugs are determined comparing them with similar drugs that are already in the market. Prices are based upon safety and effectiveness of the drug; drugs that are more effective or innovative than existing drugs are priced higher. In there is no comparable drug on the market, the price of the drug is determined by factors such as manufacturing cost and the prices of the drug in other countries.

The French pricing system allows pharmaceutical companies to sell their products at any price. However, if these companies want the national health care system to reimburse patients for the cost of the drug, the companies must agree to a lower negotiated price. These negotiated prices are reimbursement rates paid by the healthcare system are based on the therapeutic value of the drug and the price of the drug in other

countries. The French pricing system results in the brand name drugs prices that are on average 45% lower than prices in the United States (Danzon, 1997).

Germany has a decentralized national health care system. With the exception of innovative drugs that have been patented since 1996, pricing is determined by a reference system, with prices for new drugs based upon the prices of existing drugs that provide the same therapeutic benefit. Prices for innovative drugs that were patented after 1995 are not restricted by the government. However, each individual insurance fund can negotiate with pharmaceutical manufacturers on behalf of their covered patients. The German pricing system results in brand name drug prices that are on average 35% lower than prices in the United States (Danzon, 1997).

The United States is the exception to the industrialized world in government regulation of pharmaceutical drugs. This could be in part due to the type of health care system we have in our country. There are no current pricing regulations in the United States beside negotiated prices between drug manufacturers and the Department of Veteran Affairs and the Medicaid Program.

As can be seen, the way in which a government intervenes to ensure low costs to the consumer of pharmaceutical drugs varies. Though pharmaceutical companies argue that they must have the right to charge their high prices to cover the large risk involved in research and development, they do not mention the fact that much of the initial risk is taken on by public universities during educational research projects. Though it may be true that only 5% of all drugs get to the market, the other 95% did not all fail in the private companies labs and their R&D dollars were not effected (Elgie 2001). Many of

the failures have occurred in the university labs and only the ones that have potential are actually licensed out to the companies. The government takes on a majority of the initial risk. Common in this age is the acquisition of the smaller pharmaceutical companies that become acquired by the larger pharmaceuticals. Again, the smaller company takes on the risk, and if successful, the larger company that has the manufacturing capabilities merges.

IV. Other Studies

I will present two case studies that deal with the effect of government regulation on innovation. Both opinions were that government regulation would have a significant negative effect on innovation. In the short run firms would have sustainable growth, but in the long run there would be no incentive to innovate and there would be a loss to the pharmaceutical market of new drugs. These views are consistent with economic views of how regulation effects innovation, but the pharmaceutical market may be an exception due to the unusual subsidization of the research and development. In both case studies the amount of subsidization done by the government was not taken into account.

The first study, Global Competitiveness in the Pharmaceutical Industry by Madhu Agrawal, examines the effect of population size, application time, market size, price regulation, foreign investment, R&D expenditures by the firm and industry growth on innovation. Agrawal found that application time was not a significant effect on innovation, but that the other independent variables were a significant effect on innovation. Her study models all seven variables against each other and finds that innovation investment is slightly negatively affected by the regulation of the market. In

my model I used the population size, market size, and research and development by the government as the explanatory variables for the amount of innovation. Therefore the difference that I am trying to model finds a potential argument for government regulation is the amount of research and development that is funded by the government.

The other study that I would like to refer to is titled “Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation,” by Roger Edwards. Edwards examines the effect of the size of a pharmaceutical company’s research and development budget, the level of venture capital activity attracted to the industry, and skilled labor force available to the companies on research and development, and concludes that by regulating the market, the value of these pharmaceutical companies would shrink because the individual investors would not enjoy the current returns. This would lead to a decrease in innovation and ultimately in the new drugs coming to the market. Again this article does not take into account the amount of government dollars that are spent on initial research and development whether through grants or through the universities. The fact that less people may invest in the market may be true, it still remains that the rate of return in the pharmaceutical industry is still above average for the same type of heavy research and development based companies.

In neither article was there any mention of government dollars in pharmaceutical research and development. In pharmaceuticals, the government subsidizes the “bottom” or the initial research, and does not always cap prices in the market or top. An example of the government subsidizing the “bottom” and then “capping” the top is the agricultural market. The public universities receive federal grant money taking upon themselves some of the risk of developing a new drug. By doing this, the firms do not have the

ability to state that they are recouping cost for failed research. More money is spent on the marketing, advertising, and administration than the research and development. Even more astonishing is that the returns to the investors of pharmaceutical companies are equal, if not greater than other industries that have the same associated risk. The government has given the companies the ability in the past to fairly price the drugs in a low competition market and it has been taken advantage of.

V. THE EVIDENCE

So why do people want regulation of drug prices? The governments end up paying for research and development, and then they go and allow this research to be exploited by the private sector and turn around and charge whatever they want to make large profits.

How does the government pay for the research and development, through university research and grants? Universities perform just 11 percent of total national R&D, but 44 percent of the nation's basic research. (AAU, 2002) Along with creating new knowledge and the foundation for new products and processes, U.S. universities use their research activities to educate students who will become the next generation's scientists, teachers, and leaders in government and industry. Because there is broad consensus that university research is a long-term, national investment in the future, the federal government supports 58 percent of the research performed at universities. In 2000, federal research support to universities was \$17.5 billion: \$12.9 billion in basic research, \$3.3 billion in applied research, and \$1.3 billion in development. (AAU, 2002)

In the following model I try to take into account the amount of money that the government puts into the research and development of pharmaceutical products, using data from OECD and NERAC. The World Patent Organization has decided to begin a database project that will be able to categorize the patents into country specific data and also into category or industry specific patents. The separation of patents into categories is difficult because of the early stages of the innovation and the possible multiple uses of a single innovation. Therefore, there may never be a clear distinction of which patent belongs to which classification. The reason for the broad scoped independent variables is in part due to the limited availability of information.

The meaning of the variables:

- V_{Pop} – This variable is the population of the country
- $W_{\% \text{ GDP on Pharmaceutical}}$ – This variable will be the percent of GDP that is spent on pharmaceuticals and other medical non-durables.
- X_{ANBERD} – This variable is the dollar amount of analytical business expenditure on research and development specifically for pharmaceuticals
- Y_{BERDGOV} – This variable is the percent of business expenditure on research and development that is financed by the government.
- Z_{HERD} – This variable is the dollar amount spent by higher educational research and development
- $D_{\text{Gov Regulation}}$ – This will be a dummy variable. A value of 1 will be given if there is government regulation of any type on the pharmaceutical industry and a zero if there is no regulation in the market.

The dependent variable is the number of patents that have been issued in each country in the category of cardiovascular and diabetic research. The equation will look as follows:

$$Y_{\text{New Patents}} = \beta_1 + \beta_2 V_{\text{Pop}} + \beta_3 W_{\% \text{ GDP on Pharmaceutical}} + \beta_4 X_{\text{ANBERD}} + \beta_5 Y_{\text{BERDGOV}} + \beta_6 Z_{\text{HERD}} + \beta_7 D_{\text{Gov Regulation}} + e$$

The model was run in SHAZAM. If the coefficient is positive then that means when the variable is negative it will decrease the dependent variable. The opposite is true if the coefficient is negative. If the variable is negative it will increase the dependent variable. After I get the estimated coefficient I will test the “beta” of the government regulation and HERD variable to see if there would be any difference if the “beta” were zero therefore the independent variable would have a near zero effect on the dependent outcome. This would mean that regulation or HERD had no effect on the number of patents coming out of a country. After entering all the data that I had collected into the SHAZAM program I received the following output.

SHAZAM OUTPUT

VARIABLE NAME	ESTIMATED COEFFICIENT	STANDARD ERROR	T-RATIO 29 DF	PARTIAL P-VALUE CORR.
POP	-0.38313E-06	0.1818E-06	-2.107	0.044-0.364
PHARMGDP	-2342.0	844.4	-2.773	0.010-0.458
ANBERD	0.49815E-04	0.6920E-04	0.7199	0.477 0.133
BERDGOV	-0.64572	0.3952	-1.634	0.113-0.290
HERD	0.17401E-02	0.9695E-03	1.795	0.083 0.316
REG	-49.488	20.04	-2.470	0.020-0.417
CONSTANT	113.66	40.86	2.782	0.009 0.459

The SHAZAM table above is interpreted as follows. The sign that is in front of the estimated coefficient will tell the effect of the independent variable on the dependent variable. The next column to focus on is the T-RATIO column. This subtracts the estimated coefficient from zero and then is divided by the standard deviation of the

variable or the variability of the data for that variable. The higher the T-ratio, the more significant or likely that the effect of the independent variable on the dependent variable is not zero. The probability of this variable not being zero can be seen in the P-VALUE. The lower the p-value the more likely it is significantly different from zero.

I found that some of the coefficients did not have the expected signs, probably due to the small data set that was available and the broad scope of some of the variables. However, government regulation does have a significant negative effect on the number of patents, which I had not expected. The HERD variable was as predicted, and showed that the more research done at the higher educational institution, the more patents. The other significant variables were the population size and the ANBERD, but the estimated coefficients have the wrong sign. Overall the findings from the data is similar to the other studies that concluded regulation would have a negative effect on patents, but the part of the analysis that was not mentioned in the other studies was the significant effect that higher educational research and development had on the number of patents. One could argue using this analysis that if a government were to regulate the pharmaceutical market, to maintain the number of patents coming from their country, they would need to support more “higher educational research and development.”

VI. THE CONCLUSION

Should drug prices be regulated? Many consumer advocate groups would say yes. What happens when a country's government subsidizes the bottom end of a market yet does not cap the top end, as in the US? In the United States pharmaceutical market there are tax write-offs for the research, there are universities that do the initial research

in areas which decrease the risk in the initial innovation process, and then there is a twenty year patent granted to the firm for the invention. The write-off and the decrease in risk should shift the average total cost curve down and decrease the prices of the drugs. This is not done, so higher prices are being charged.

Countries that have price regulations in place still have quite an incentive to invest in R&D because the United States market will still allow them to price their drugs freely, encouraging risky research. If every country begins to regulate drug prices, will that be the final straw that discourages the innovation because there is nowhere that a company can run to recoup R&D costs? There is always that possibility that if the United States were to begin regulating the price of pharmaceutical drugs, then there would be no incentive for companies to innovate. The government, as it is doing in part now, would merely have to step up and allow more funding to the public research facilities so that they do the innovation and the private firms license the intellectual property that is closer to FDA approval and market it.

This might save innovation, but there is another problem. The United States government is the leader in investing in the innovation process with government funded grants and funding public research universities. Indirectly the United States taxpayers would still be paying the higher price for the drugs because taxes would have to be raised to cover the increased research and development that would be taking place in the higher educational institutions. That is assuming that companies that currently innovate in regulated countries do so only because they know that they will be able to recover their research and development costs in the current unregulated United States market. Those companies that are in regulated countries would need to either demand that their

governments subsidize research and development or they would need to relocate to the United States where research is already being subsidized.

As I have heard numerous times the second greatest idea of mankind was free trade. Currently the pharmaceutical companies are practicing a form of price discrimination, charging different consumers different prices for the same product and not allowing free trade of the product from regulated countries to non-regulated countries. If it was deregulated across the board there would be less of an opportunity to charge different prices because there would be a free trade of goods even across borders. The Federal Drug Administration would also have to agree to this free flow of drugs which currently is highly restricted partially due to pharmaceutical companies, such as Wyeth, that complain about lost profits. The FDA's reason is that the foreign drugs are "not safe." The deregulation and free trade would probably increase the regulated countries drug prices. That may mean that some people in European countries or elsewhere where there are low drug prices through regulation would not be able to afford the medicine, but currently there are people in the unregulated markets that cannot afford the prices. In economics the fair price is usually the unrestricted free market price. Some lose and some win. There will always be the demand for new drugs. Someone has to pay for them, and the best way to do it would be to not regulate any market at all and allow firms to innovate and price their drugs. Those that can afford will buy, and if the companies don't make enough money they will lower their price.

In conclusion it appears that innovation is affected by government regulation of drug prices, but that does not mean that prices should be regulated. According to the data the regulation will discourage the innovation process but the funding of higher

educational research and development or other government projects might be able to offset that negative influence on innovation.

Bibliography

1. "Background Paper On U.S. Department Of Veteran Affairs Formulary Prices" Patented Medicine Prices Review Board Prepared For The Working Group On Price Review Issues. March 1999
2. "Background Paper on the Price Review Process for New Patented Drug Products" Patented Medicines Prices Review Board Prepared for the Working Group on Price Review Issues. June 1999
3. Bloom, Nick, and Van Reenen, John. "Regulating Drug Prices: Where Do We Go From Here?" Institute for Fiscal Studies. London. November 1997.
4. Bloom, Nick, and Van Reenen, John. "Why has the UK Pharmaceutical Industry been so Successful?" Institute for Fiscal Studies. London. November 1997.
5. Calfee, John E. "Why Pharmaceutical Price Controls are Bad for Patients." American Enterprise Institute for Public Policy Research. www.aei.org/oti/oti10198.htm
6. "Controlling the Prices of Patented Medicines on Canada" Patented Medicine Prices Review Board. Brochure. Canada 1998.
7. Danzon, Patricia. Pharmaceutical Price Regulation. The AEI Press. Washington DC, 1997
8. DiMasi, Joseph A. "Price Trends for Prescription: Pharmaceuticals: 1995-1999" Department of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization, and Costs. August 8-9, 2000
9. Edwards, Roger Sc.D. "Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation." Arthur D. Little Inc. May 2002
10. Elgie, Robert G. "Enhancing Transparency in Drug Price Regulation." Presentation to PHARMAC. March 2001.
11. Farquhar, Irina; Summers, Kent; and Sorkin, Alan. Investing in Health: The Social and Economics Benefits of Health Care Innovation. Elsevier Science. New York.
12. "Generic Drug Entry Prior to Patent Expiration" Federal Trade Commission. July 2002
13. Greener, Mark. A Healthy Business. Informa Publishing Group: London
14. "The Hatch-Waxman Act In Perspective" Pharmaceutical Industry Context For

The FTC's Generic Drug Study—FTC File No. V000014 June 18, 2002

15. "How the Federal Government Funds University Research." Association of American Universities(AAU). May 2002
16. Kreling, David H. "Cost Control for Prescription Drug Programs: Pharmacy Benefit Manager PBM Efforts, Effects, and Implications" Department of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization, and Costs. August 8-9, 2000
17. Minority Staff Special Investigations Division Committee on Government Reform. "Prescription Drug Prices in Canada, Europe, and Japan." US House of Representatives. April 11, 2001.
18. NERAC Patent Database. www.nerac.com
19. "A Primer: Generic Drugs, Patents and the Pharmaceutical Marketplace" The National Institute for Healthcare Management Research and Educational Foundation. June 2002
20. "Prescription Drugs Expanding Access To Federal Prices Could Cause Other Price Changes" United States General Accounting Office: Report to Congressional Requestors. August 2000
21. "Prescription Drugs: Spending Controls in Four European Countries" Chapter Report, 05/17/94, GAO/HEHS-94-30
22. "Price Guidelines for Category 3 Drugs: Part I" Patented Medicines Prices Review Board Report of the Working Group on Price Review Issues. March 2002
23. Sentek, Kimberly, and King John. "Top Ten Areas of Research." R&D Directions. Vol 3. No. 9 pg 26
24. Sulston, Sir John. "Cut the Cost." www.oxfam.org.hk/english.PDF
25. "Third In Series On Medicare Reform: Laying The Groundwork For A Rx Drug Benefit" Hearing Before The Subcommittee On Health Of The Committee On Ways And Means House Of Representatives One Hundred Seventh Congress. First Session March 27, 2001 Serial No. 107-7