Determining the Effect of Prescription Drug Prices on the Supply of New Drugs

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Abstract: In order to determine the effect of prescription price on the supply of new drugs by the American pharmaceutical industry, I studied data concerning prices of prescription drugs, research and development investment, and National and Medicare expenditure on pharmaceutical products in relation to the number of new drugs approved for sale by the Food and Drug Administration annually. I used time series to determine the nature of these relationships. I discovered very little correlation between the supply and the independent variables. This lack of correlation indicates that pharmaceutical prices have little effect on the supply of new drugs on the market. Investment in R&D has an equally uncorrelated relationship to approved drugs. The number of approved drugs is an auto correlated function that increases and decreases over time, in contrast to the steadily increasing average price of prescriptions. These results suggest that price reduction would not have a direct effect on drug approvals, and thus the supply of new drugs into the market, contrary to what previous literature on the subject indicates.

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Introduction: In the United States, the cost of healthcare per individual has steadily increased in recent years. A portion of this rising cost is the increasing cost of prescription drugs. Few families remain untouched by these high prices. Occasionally there are horror stories on the news about elderly Americans having to choose between paying for food and paying for their medications (Owen-Phelps 2008). In the 2008 presidential election between Barack Obama and Senator John McCain, and even in the Democratic primary before that, concerns about the affordability of health care for Americans was one of the top issues for the candidates to consider. With over fifteen percent of Americans living without health insurance, high drug prices are a serious issue lawmakers must deal with (Sherman 2008). However, it has never been an easy one. The pharmaceutical industry is one of the most research-intensive sectors in the United States economy (Phrma 2007), and firms warn that their high prices are what drive their ability to innovate.

Working as a pharmacy technician in Rite Aid Pharmacy, I would hear complaints from my patients about the high cost of their prescriptions. Many of them believed that the government should impose controls on the pharmaceutical companies to ensure that prices got lower and stayed lower. These patients believed that price controls would benefit them. The response that my superiors told me to give when patients asked me why the price of pharmaceutical products was so high was that the high prices financed research and development

projects, which would supply newer and better drugs in future years. However, I was never quite sure if what I was saying was entirely accurate.

The other side of the question of higher prices of prescriptions is the innovation that results from pharmaceutical firms' efforts. In the world today, approximately 36 million people are living with AIDS. Doctors diagnose approximately 11 million people with cancer each year and 6.7 million people die of it (Cancer Research UK 2008). The world looks to pharmaceutical firms, specifically those in the United States, to find a cure or a vaccine to AIDS, and cancer, and to treat symptoms of conditions like depression or heart disease, or diabetes. There is no question that there is a trade-off policy makers must consider when considering price controls on pharmaceutical products. Should society allow pharmaceutical companies to charge exorbitant prices, causing suffering, and unaffordable medications for many consumers today, in the hopes that they will be able to fund research projects to find newer cures and treatments? The more troubling question is whether these high prices actually lead to new drugs, as pharmaceutical firms continue to promise their patients.

In the following study, I endeavored to discover whether increases in prices patients pay for pharmaceutical products does in fact have a direct relationship to the supply of new drugs in the future. I used historical data concerning the pharmaceutical industry in the United States for the past thirty years in order to answer this question. Specifically, I studied trends in Gross Domestic Product (GDP), pharmaceutical prices, firm investment in Research and Development (R&D), National and Medicare expenditure on pharmaceutical products, and the number of drugs approved by the Food and Drug Administration (FDA) each year. My hope was to come to a definitive answer about the effect prices have on United States pharmaceutical firms' ability to produce innovative drugs.

Literature Review:

There is a collection of previous studies on the relationship between prescription prices and research and development in pharmaceutical products. Most studies have found that a reduction in prices, such as with the introduction of a price control, would result in greater affordability of drugs for consumers in the present, but a lack of newer drugs in the future, due to a reduction in R&D investment. However, most of these studies focused on the effect reduced prices have on R&D investment without considering the relationship between R&D investment and the number of drugs approved for sale in the market.

Thomas Abbott (2007) considers the effect of price controls on the future supply of new drugs to the market. Abbott asserts that price controls are likely in the United States considering the current rhetoric of legislative bodies. He uses his model to determine how price controls will effect pharmaceutical firms' decision concerning the early stages of product development. Using a net present value framework, Abbott concludes that price controls of up to thirty to fifty percent will lead to a sixty percent reduction in initiated research and development projects. Pieter Jong (2007) reports that pharmaceutical companies directly invest large returns from sales in R&D projects. Thus, price controls, which would limit revenues generated by pharmaceutical firms, will, according to Jong, result in less R&D investment, and a smaller supply of new drugs in the future. Both Abbott, who considers early stage research and development, and Jong, who considers investment in R&D development, neglect to study the relationship between these factors and the number of drugs actually approved for sale on the market, historically.

Before lawmakers implement any policies involving price controls, it becomes necessary to predict the overall benefits to society of cheaper drugs, in terms of changes to consumer and producer surplus, and the resulting effect these newer prices will have on the supply of new drugs on the market. Rexford Santerre (2006) studies the short-term costs and long-term benefits of price controls on US pharmaceutical firms by imposing a hypothetical price restriction on historical data. The price restriction takes the form of a policy that uses the consumer price index between the years 1981 and 2000 and does not allow the prices in drugs to increase beyond that amount. Using this hypothetical price control, Santerre asses the costs and benefits of this policy by comparing consumer surplus gains to estimates of the value of new drugs that would have been lost if the policy been enacted. Santerre calculates that under this price control the reduction in pharmaceutical revenues would lead to a 38% reduction in investment in pharmaceutical R&D. He then applies this 38% reduction to the number of chemical entities approved by the FDA in that time period, and states that price controls would have led to 38% less pharmaceutical products introduced to the market, leading to a net loss to the average consumer. He does not examine the exact relationship between investment in R&D and approval by the FDA, however.

The United States is not the only company to face the question of the necessity of price controls for pharmaceutical products. Many nations in the European Union have decided in favor of some type of price regulation. Eduardo Gonzales (2003) studies the effects of changes in the patent system and newly imposed price controls on the Spanish pharmaceutical industry. He compares the productivity of the industries before and after these changes occurred. He finds that the government implemented price controls, a deceleration in R&D projects occurred, due to the industry's uncertainty about future profits. Gonzalez also finds that, due to the large

economies of scale present in pharmaceutical industries, as a response to price controls, many mergers between firms occurred, such as between Upjohn/Pharmacia and Ciba-Geigy/Sandoz. This results in a decline in research and development due to a reduction in competition in the industry, as the number of firms decreases. Overall, he states that there was a decline in the Spanish pharmaceutical industry, which he attributes to the lack of new products and a reduction in the prices of old products due to price controls, as well as a wide ranging dispersal of revenues between sales and R&D efforts. He is able to calculate this by measuring the productivity of Spanish firms before and after the price controls were implemented. Gonzalez measures productivity using net sales from eighty Spanish pharmaceutical firms as the output variable in his model, and labor and other costs, as well as depreciation of capital as the input variables. He concludes that the increase in regulation faced by Spanish pharmaceutical companies led to its eventual reduction in new products introduced.

The nations of the European Union have imposed several price controls on pharmaceutical drugs, which allow for greater current affordability to medication for consumers (European Federation of Pharmaceutical Industries and Associations, 2008). There are three general types of pricing regulation: product price control, reference pricing, and profit control. The United Kingdom favors product price control, whereas Germany and the Netherlands have pioneered reference pricing, in which insurance policies cover only the lower priced drugs in a therapeutic class. Patients wishing to use higher priced substitutes must cover the difference in price on their own. This leads to a relative increase in demand for older, less expensive drugs. However, European pharmaceutical companies are less profitable than their American counterparts are and spend a proportionally smaller amount on research and development, according to a study by Jospeh Golec (2006). Golec studies profits acquired by pharmaceutical

companies in different countries and compare them with spending on R&D. He observes a phenomenon of reduced prices leading to reduced R&D expenditures, which creates an opportunity cost in terms of present affordability of drugs and the health of future generations. Paulina Ramirez (2006) also studies the impact of European price controls and finds that they lead to an increased number of European multinational pharmaceutical companies setting up headquarters in the United States. She determines that this is essentially due to the high profits of the pharmaceutical private sector in the United States. This high profitability causes the public sector to acquire great interest and investment in R&D, leading to more cooperation between the public and private sectors in the United States than in Europe. Thus, the area with fewer regulations, the United States, is as a place of greater innovation, and is thus more attractive to firms than European countries with greater regulations.

The loss of newer pharmaceutical products poses a great risk because there is a large body of evidence that indicates newer drugs are inherently superior to drugs currently on the market. Frank Lichtenberg (2002) determines this by testing what he calls the pharmaceutical embodied technological progress model. He compares post-treatment health of individuals who were using older and newer medications. The endogenous variables that he studies include survival rates and side effects, while the exogenous variables are the year that the FDA approved the drug, and the individual's health before treatment. Lichtenberg's results indicate that individuals using newer drugs are in better health than those using older drugs, in terms of survival and their own perceived health. They also tend to have better insurance coverage and income, which are indirect results of better health status. Other than this medical support for the importance of research and development of new drugs, there is also the purely economic benefit

of more goods on the market. This is always beneficial to consumers because it provides them with more choices.

Pharmaceutical firms in the United States research and develop new drugs at a high cost to American citizens, but once developed, patients around the world have access to these drugs. Abdulkadir Civan (2006) asserts that nations, which implement price controls, have avoided the problem of decreased health of their citizens by depending on United States research and development. Civan finds that the US market drives the majority of all pharmaceutical advancements around the world. Demand for medication needed by American consumers provides the direction for pharmaceutical research and development, while the high cost of drugs in the United States finances it. Thus, price controls in the US would have an effect on the drugs available to the rest of the world as well.

The wealth of literature concerning the effects of price control on pharmaceutical research and development has concluded that a reduction in prices will lead to a reduction in revenues for the firms, leading then to a reduction in R&D investment, and thus a reduction in the number of new drugs to enter the market. However, these claims do not consider the relationship between investment in R&D projects and the number of new drugs actually approved for use by the FDA in corresponding years. In the following study, I consider this relationship.

Economic Model:

The model I am studying is a supply and demand model meant to estimate the effect of prices of pharmaceutical products on the supply of new drugs (see Figure 1). It incorporates a previous assumption, concerning the benefits to consumers of lower prices in terms of drugs already available on the market. The assumption is that as prices decrease, the total number of

drugs on the market will become more affordable to consumers, while the supply of total drugs on the market will decrease. It predicts a net consumer benefit, which previous literature has proven (Santerre, 2006). My model assumes a direct relationship between the price of pharmaceutical products and the supply of new drugs. I differentiate the supply of new drugs from the supply of total drugs. In this model, as a corollary result of price reductions, the supply of new drugs in the future decreases, leading to further cost to the consumer in terms of a loss of future products. Thus, the result reduced prices would be an overall cost to the consumer, despite short-term increased affordability of drugs already on the market. Whereas, the result of increasing prices is the supply of new, more effective drugs. The long-term cost is the focus of the model. Previous literature has defined the supply of new drugs as a function of pharmaceutical investment. In this model, I define the supply of new drugs as the number of new drugs approved by the Food and Drug Administration annually.

I consider the prices of pharmaceutical products to be an input of the supply of new pharmaceutical drugs. In order to validate this model, I collected data on the number of drugs approved by the FDA and used this data for my dependent variable. The main independent variable chosen was prescription drug prices. Controls were national GDP, investment in R&D, and National and Medicare expenditures on pharmaceutical goods. I chose Gross Domestic Product as a control in order to determine whether the overall income of that nation affected new drugs supplied, rather than simply an increase in prices. I used the relationship between approved drugs and pharmaceutical investment in R&D as a check to determine whether increased investment results in increases in the number of drugs supplied. This would indicate that if prices alone increase, without increased investment, supply could not be expected to increase. The direct relationship between prices, investment, and supply of new drugs is an

assumption made in previous literature on the subject. I studied National expenditures, which include consumer out-of-pocket payments as well as employer insurance plans, and public expenditures, which include government insurance plans as well as Medicare Part D benefits, in order to ascertain its effects on the supply of new drugs to the market in comparison to the effects of Medicare on its own.

I made sure to take the time lag between the initial investment in a R&D project and its eventual approval by the FDA into account in my model. I did so by considering drugs approved in year *T* as investment projects started by firms in year *T-12*. Thus, I related the number of drugs approved in 2006 to the economic conditions in 1994, which would have existed when firms made the decision to invest. Because the GDP, prices, investment in R&D, National and Medicare expenditure in pharmaceuticals all increased between the years 1970-1995, which were studied, it was assumed, considering the previous literature on the topic, that the number of new drugs supplied each year would a positive trend during those years. This would indicate a direct relationship between price of prescription drugs and the supply of new drugs, indicating that price controls would in fact lead to a decrease in the supply of new drugs, and a long-term net cost to the consumer, despite short-term increases in affordability.

Empirical Results

Statistical Model: The model (see Figure 1) estimated the relationship between prices of prescription drugs on the market in year *T-12* and the number of drugs approved for sale in the market in year *T*. I specified it in this way so that it could serve as an addition to previous literature on the subject, which suggests that price reductions lead to initial greater affordability of drugs for consumers, but a long-term net cost due to a reduction in the supply of new drugs in the future. Previous literature estimated the supply of new drugs as a function of pharmaceutical

investments. However, in this model the supply of new drugs is defined as the number of new drugs approved for sale in the market by the FDA in year *T*, if year *T-12* is the year in which the pharmaceutical industry data is being studied. I specified the model in this way because I could not verify the assumption of a direct relationship between pharmaceutical investment and the supply of new drugs.

In order to determine the relationship between prices and the supply of new drugs, time series of two variables, as well as controls for GDP, pharmaceutical investment in R&D, national expenditure, and Medicare expenditure were constructed (see Figures 2-8). I chose to use time series because regression analysis did not provide useful results due to the autoregressive correlation of the supply of drugs. Time series allow for a comparison of trends over the years between the dependent variable and each of the independent variables. I chose this model because a correlation between the supply of new drugs and pharmaceutical prices would indicate an effect of price reductions on the supply of new drugs, and therefore the net change in consumer benefit due to price reductions. Time series were an appropriate means to determine the relationship between the variables as the independent variables followed an increasing pattern throughout the years, whereas the supply of new drugs did not. A sharp contrast between trends in the dependent variable and trends in the independent variables was apparent from the graphs.

Description of Data: I collected data from several government agencies as well as the Pharmaceutical Research and Manufacturers of America (Phrma). In order to measure the changes in prices of prescription drugs, I used data collected by the Bureau of Labor Statistics in their CPI. I gathered data on GDP and from the Bureau of Economic Analysis. Phrma provided data on pharmaceutical sales and investment in R&D as a percentage of sales. Although Phrma

did not provide data on investment in R&D in dollar terms, using the percent investment figures provided, as well as total sales, I was able to calculate them. I took national expenditure information from the Centers for Medicare and Medicaid Services. The Centers for Medicare and Medicaid services provided data on all healthcare expenditures within the United States, and separated these expenditures by sector, then further by National and Medicare expenditure. I determined the supply of new drugs from the number of approved drugs per year. I gathered this information from the US Food and Drug Administration Center for Drug Evaluation and Research. I compiled archival information concerning the number of drug approvals per month into annual data to represent the supply of new drugs per year. Effects of inflation were controlled using Bureau of Labor Statistics inflation figures; all dollar amounts used are in 1980 dollar values.

Limitations in the data consist mainly of the lack of specific information about the drugs that the FDA eventually approved. Data were not available indicating when each firm began their R&D project that resulted in an approved drug. Nor was there data detailing exactly how long it took each project to be finished and then approved. In order to surmount this limitation, I used an average completion time of twelve years. The twelve-year number was estimated using information from Phrma (Pharmaceutical Research and Manufactures of America, 2007). According to Phrma, the drug pipeline that represents the R&D process is composed of four stages. The first is drug discovery, in which scientists and researchers identify a molecular compound as having possible medicinal value. The second stage is preclinical testing, which involves testing on animals in order to determine the safety of the compound and its effectiveness in treating the target illness or condition. Preclinical testing can take between three to six years. The next stage is clinical testing, which involves using human subjects to determine

the safety and effectiveness of the compound in question. Completion of clinical testing can take between three and six years as well. There are three phases of clinical testing. The first uses a small group of healthy volunteers. Researchers study their consumption of the compound in order to determine rate of absorption, duration of action, and other qualities that are termed pharmacokinetics. The second stage involves a larger group of volunteers who have the disease or condition the proposed medication is supposed to treat. Researchers use placebo tests in order to determine whether the proposed medication has the targeted effect. The third stage is a larger scale version of the second stage, involving volunteers from hospitals and clinics. This stage produces statistically significant data on effectiveness and side effects. After the third stage is completed, researchers compile a new drug application (NDA), which they send to the FDA for approval. The approval process can take over a year. Phrma estimates that the entire process of the drug pipeline takes an average of twelve years to complete. Thus, I used a twelve-year time lag between the date of approval and the economic inputs studied for the year firms' began investment in successful projects when constructing my time series graphs.

The average cost of research and development projects over time would have been interesting to study as well, but again specific numbers on the cost of research projects was not available. Phrma suggests simply that the cost of research projects is increasing, and averages about $800 million (Phrma, 2007). Another limitation of the data is that pharmaceutical sales and investment includes only firms that are part of Phrma. There are several smaller pharmaceutical companies not part of Phrma, but it proved difficult to ascertain their sales and investment numbers, thus their data could not be included.

Table 1: Descriptive Statistics

	Mean	Std Dev	Number of Observations
US GPD (millions)	3627572	955343.24	37
Prescription CPI	5.645741	3.40	37
Phrma R&D % of sales	17	3	37
Investment R&D (millions)	7862.027	12761.03	37
National Expenditure Pharm. products (millions)	31385.39	24154.97	36
Medicare Expenditure (millions)	752.3457	2639.11	36
Approved Drug Applications	105.58	29.67	37

Sources: Bureau of Labor Statistics, 2009, Bureau of Economic Analysis, 2008, National Economic Accounts Bureau of Economic Analysis, 2007,
Survey of Current Business, for Medicare and Medicaid Services. "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2006". Pharmaceutical Research and Manufacturers of America, 2007, "Pharmaceutical Industry Profile: 2006". Washington D.C. US Food and Drug Administration, Center for Drug Evaluation and Research, FDA Drug Approvals List 1982-2007.

Table 2: Descriptive Statistics NDAs Approved

	Mean	Standard Deviation	Number of Obervations
2006-2002	90	19.55760722	5
2001-1997	91.6	20.23116408	5
1996-1992	87.2	26.88308018	5
1991-1987	70	9.797958971	5
1986-1982	110	19.74841766	5
1981-1977	90.6	18.5148589	5
1976-1972	67	13.72953022	5
1971-1967	72.6	66.27442946	5
1966-1962	70.4	26.86633581	5
1961-1957	243.2	67.37729588	5
1956-1952	312.6	104.4021073	5
1951-1947	237.6	80.33865819	5
1946-1944	127.6666667	12.09683154	3

Table 3: Investment in R&D, Millions of Dollars by Five Year Period, Descriptive Statistics

	Mean	Standard Deviation	Number of Observations
2007-2003	13251.522	841.5708878	5
2002-1998	10135.664	1259.969556	5
1997-1993	22915.8884	31643.96594	5
1992-1988	7064.35464	1612.979201	5
1987-1983	3484.62536	726.636433	5
1982-1978	1637.90414	441.2852155	5
1977-1973	891.71744	140.9775324	5
1972-1970	616.2201333	47.03975493	3

Table 4: Investment in R&D, % of Sales by 5-year Period, Descriptive Statistics

	Average Investment as % of Sales	Std Dev	Number of Observations
2005-2007	19	0.00	3
2000-2004	18	0.00	5
1995-1999	21	1	5
1990-1994	20	2	5
1985-1989	17	2	5
1980-1984	25	1	5
1975-1979	12	0.00	5
1970-1974	12	0.00	5

Table 5: National Expenditure on Pharmaceutical Products, Five Year Period, Descriptive Statistics

	Mean	Standard Deviation	Number of Observations
2006-2002	81075.636	6248.437324	5
2001-1997	51681.848	9810.937362	5
1996-1992	31218.064	3232.951999	5
1991-1987	23239.384	2969.588975	5
1986-1982	15534.92	2092.871424	5
1981-1977	12278.572	210.734649	5
1976-1972	12497.236	139.811429	5
1971-1970	11815.6	200.1960719	2

Table 6: Medicare Expenditure on Pharmaceutical Products, Five Year Period, Descriptive Statistics

	Mean	Standard Deviation	Number of Observations
2006-2002	4269.542	6632.270199	5
2001-1997	875.282	190.8227246	5
1996-1992	300.294	139.1308619	5
1991-1987	112.09	67.81850006	5
1986-1982	10.15	14.49369173	5
1981-1977	0	0	5
1976-1972	0	0	5
1971-1970	0	0	2

Results and Interpretation: The data could not prove the prediction that price reductions will result in a decrease in the supply of new drugs true or false. Results indicated no direct relationship between GDP, pharmaceutical prices, investment in R&D, National or Medicare expenditure on pharmaceutical products and the number of drugs approved for release annually by the Food and Drug Administration. Thus, I could not estimate the net cost or benefit to consumers of price reductions in terms of the supply of new drugs. Regressions of the variables proved unusable due to large error terms and the cyclical nature of the supply of new drugs over time. Time series of each of the variables showed that GDP, pharmaceutical prices, National and Medicare expenditure all increased over time. Investment in R&D also increased over time as a dollar amount. However, investment in R&D as a percentage of sales increased until the mid-1980s, saw a sharp decrease, remained constant until the mid-1990s, and then saw another small peak. A time series of the number of drugs approved annually by the FDA showed an autoregressive correlation. The supply of new drugs was therefore not shown to be correlated with any of the variables studied, but rather with a seasonal cycle, likely due to inputs not related

to price of pharmaceutical products. This is a sharp departure from results of similar studies in the literature. This is likely due to the model's definition of the supply of new drugs as the annual number approved by the FDA, rather than a function of the dollar amount of investment in R&D reported by firms. By studying the actual number of new drugs released to the market annually, and comparing it to industry figures, I have found myself questioning the idea that higher prices of drugs and further investment in R&D leads to further innovation.

These results suggest that prices of drugs do not have a direct observable relationship to the number of R&D projects that end up approved by the FDA. Although pharmaceutical firms have been steadily increasing the prices of their products, and have been generating increasing amounts of sales, this does not indicate that they are supplying the market with an increasing number of innovations, as suggested by Phrma literature (Phrma, 2005). Although investment in R&D has increased in dollar terms, it has shown a decrease in percentage terms from the mid-1980s, indicating that the increase in sales resulting from the increase in drug prices is not fully going toward further R&D efforts. The lack of a relationship between the amount of drugs approved by the FDA and the inputs studied suggests that new drugs, as a good, do not follow a typical supply and demand model. This suggests that there are factors other than the inputs studied which determine the number of new drugs supplied to the market. One possibility would be that the prices of new R&D projects are increasing due to increased complexity. According to Phrma, the direct reason that prescription drugs have been increasing in cost is due to the increased cost of innovation (Phrma, 2005). However, if this was the case, there would be a steady decrease in the number of new drugs approved to reflect the higher cost of new projects, or at least some sort of stabilization due to the rising prices that are meant to make up for increased cost of innovation, rather than the observed autoregressive serial correlation.

Another possibility is that the FDA has a system for approving new drugs that result in this cyclical nature of the supply. However, there is no information from the Food and Drug Administration to support this idea at all. The approval process consists of a series of applications, which base approval on the testing administered throughout the drug pipeline to determine the safety, usefulness, and effectiveness of the drug (Phrma, 2008). There are no quotas for approval.

While it is true that the results of this research could not prove or disprove the initial prediction, they do serve to shed some doubt on claims made by the pharmaceutical industry about spending and R&D costs. In particular, the time series of the number of drugs approved by the FDA annually is truly puzzling considered the widely propagated assertion that higher prices are due to increased innovative measures by firms. It could be possible that firms are striving towards further innovation due to their higher prices, but are simply meeting with a large number of failures, and are unable to produce a greater supply of new drugs than in previous history despite these efforts. If that is the case, it seems likely that the higher prices are perhaps leading toward incentives to be wasteful, or to engage in risky research endeavors, which have a low likelihood of success.

The crux of the interpretation of this data is that more research is needed, specifically because it seems likely that higher prices are not leading to a greater supply of new drugs in the future, and that there is no justification for the financial strain these high costs are putting on average Americans. However, a caution is necessary because the benefit of one new drug that could prevent or cure AIDS, for example, would be immeasurable. If price reductions would cause pharmaceutical firms to scale back on R&D efforts, and possibly prolong or eliminate the invention of this drug, it would be a tragedy. Even though the data seems to suggest that price

reductions would in fact benefit the consumer because they have no observable relationship to the supply of new drugs, a higher degree of certainty is necessary before making this claim is advisable.

Conclusion:

The rising cost of healthcare has been a topic of discussion in American news and political discourse, including the recent presidential election. With many Americans calling for government regulation of soaring pharmaceutical prices, price controls are one of many possible options. A major critique of using price controls is that they will cause a reduction of new pharmaceutical products released to the market in future years. However, the evidence seems to suggest that this may be an incorrect assumption. When determining the effect of price controls on the supply of new drugs in the future, previous literature has assumed a direct relationship between investment in R&D projects and the number of new drugs approved for sale in the market. However, regressions using the number of drugs approved as the dependent variable with GDP, pharmaceutical sales, investment in R&D, National and Medicare expenditure on pharmaceuticals as independent variables found very little correlation in any of the tests. Time series data of each of the variables similarly indicated that there is no a direct relationship between any of the variables studied and the number of drugs approved by the FDA. This suggests that price controls cannot have a direct identifiable effect on the number of drugs approved for sale in the market.

Because of the inconclusive nature of the results of this research, I recommend that a further examination of the spending habits of pharmaceutical firms take place. Literature from Phrma states strongly that the reason prices in the pharmaceutical industry have increased is due to R&D efforts. However, the fact that both the supply of drugs, and even the trend of

investment as a percentage of sales, does not quite match this claim, it would be interesting to ascertain exactly where the revenue made on account of increasing prices is going. It would be interesting to note how expenditures within firms on marketing have increased or decreased over time. If it could be determined that the increase in prices over time is attributable to marketing costs, then I would feel safe to say that a decrease in price would not result necessarily in a decrease in the supply of new drugs. In this case, I would recommend to policymakers that a cap on spending on marketing could be a viable avenue in lowering overall healthcare costs for consumers.

I would also recommend a study of how large a percentage of firms' sales is going toward pharmaceutical representative budgets. Firms send pharmaceutical representatives to doctors' offices and community pharmacies with the purpose of trying to convince healthcare workers to choose to prescribe their firm's products over other firms' similar products. This seems like another possible line of activity where revenues accrued from higher prices could actually be going.

In essence, further research on this topic should attempt to prove or disprove pharmaceutical companies' assertion to lawmakers and consumers that increased drug prices are due to R&D efforts. If this is not the case, then moderate regulation, could, in fact, lead to further consumer benefits in the short and long run.

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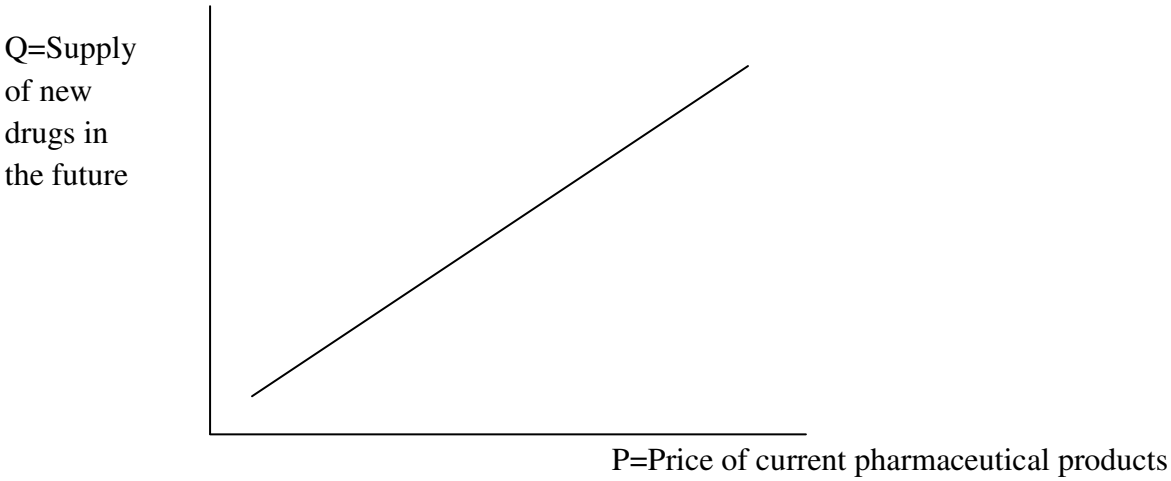
Figure 1

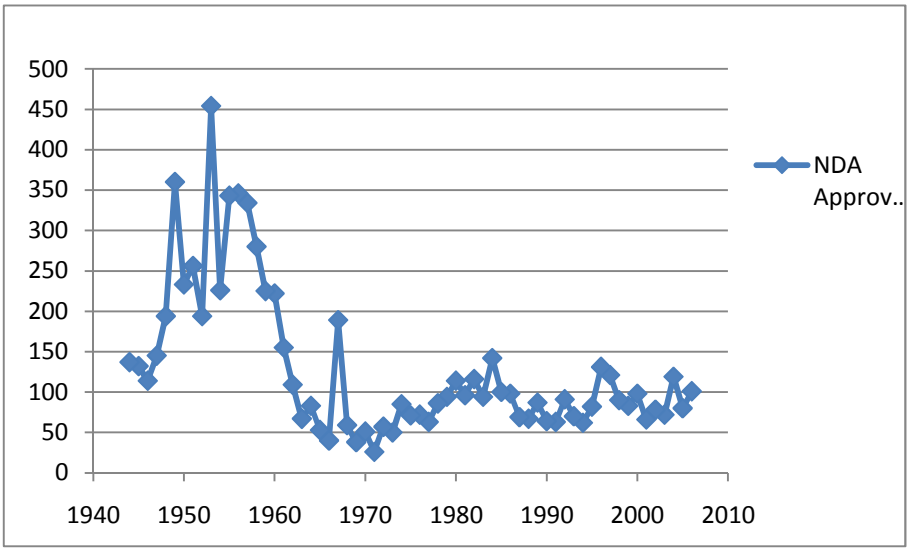
Economic Model – Supply of future new drugs as a function of the price of pharmaceutical products



A direct relationship between the price of pharmaceutical products and the supply of new drugs in the future was assumed due to Phrma literature discussing the issue of high drug prices. Following from this model, a reduction in prices is assumed to lead to fewer new drugs in the future.

Figure 2

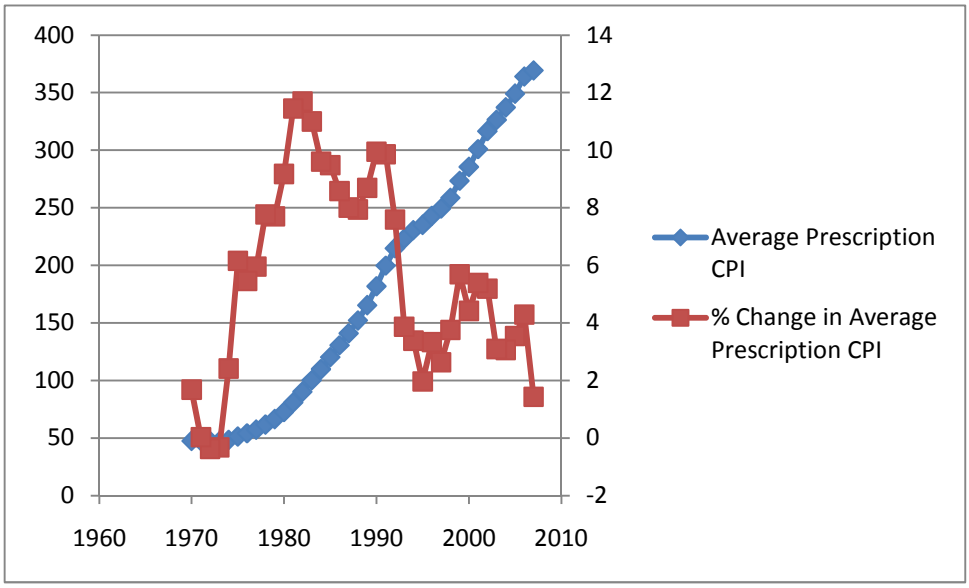
Number of New Drug Applications (NDAs) Approved Yearly from 1940-2006



The supply of new drugs shows an autocorrelated function which is unexpected considering the steady rise in prescription prices.

Figure 3

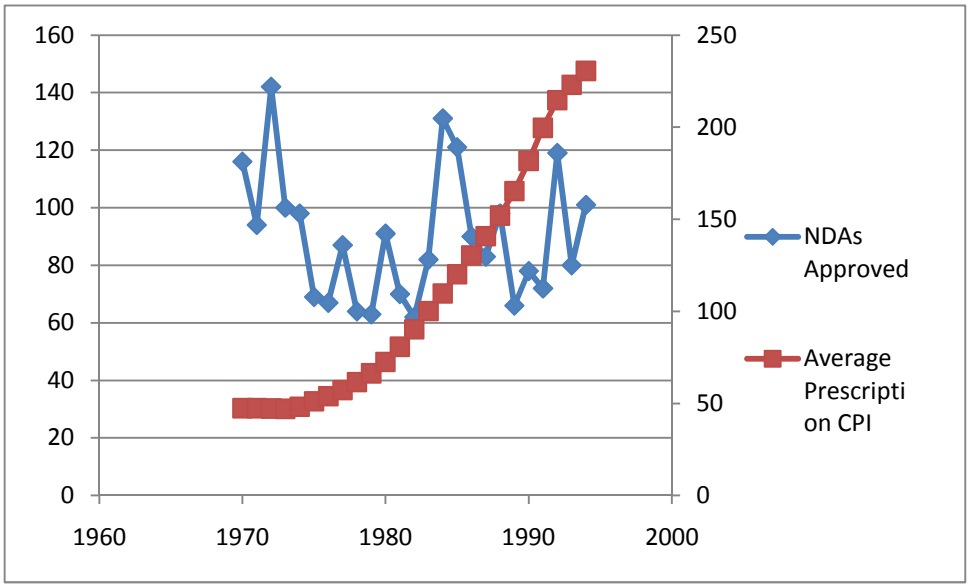
Prescription Price as Represented by BLS CPI 1970-2007



Prices have been steadily increasing although the rate of increase has shown a decreasing trend since 1990

Figure 4

Number of NDAs Approved and Average Prescription CPI*



*The years used for the NDAs Approved incorporate a 12 year lag. Thus, the number of NDAs approved in 2006 is compared to the average prescription price in 1994 when the decision to invest in research is approximated to have occurred.

Figure 5

NDAs Approved, Average Prescription Price and GDP (millions)*

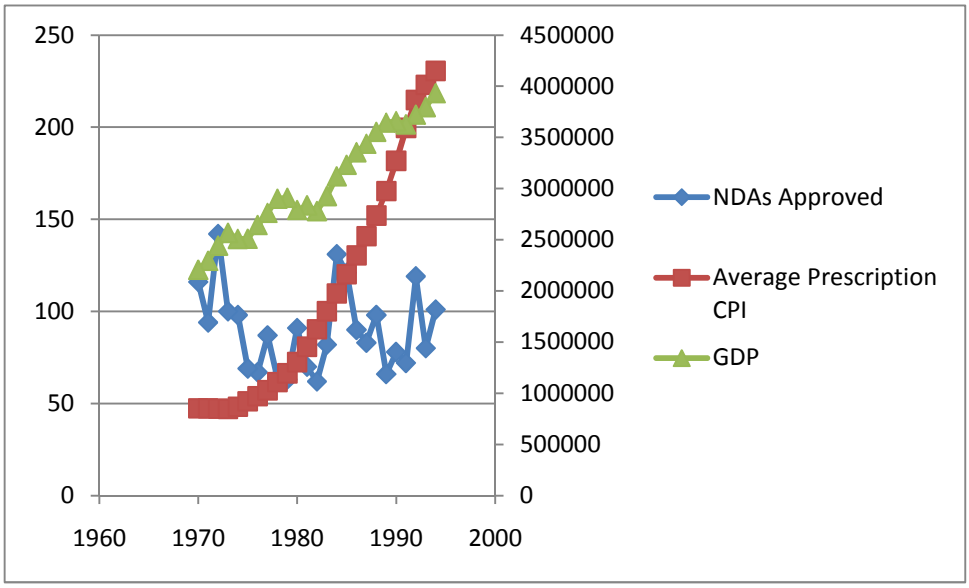
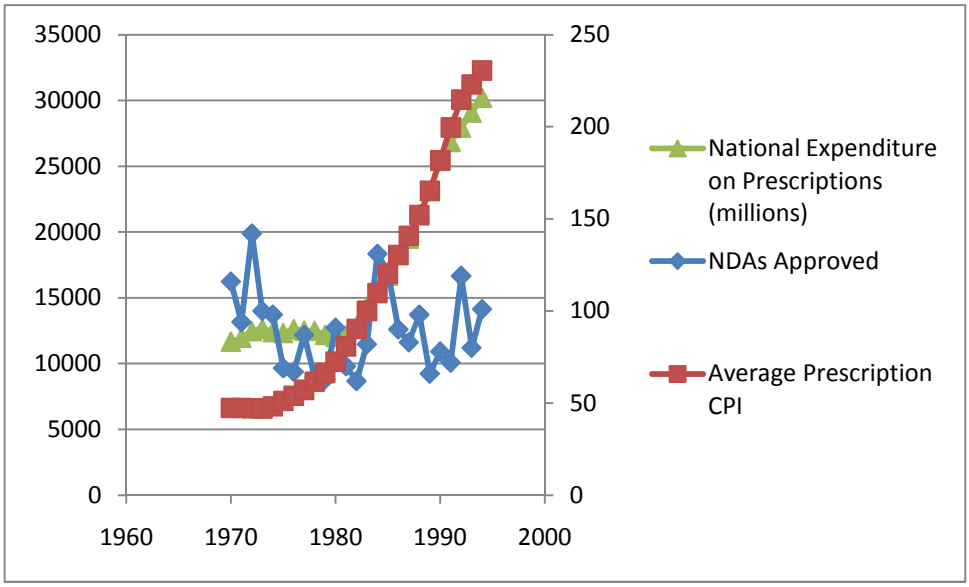


Figure 6

NDAs Approved, Average Prescription Price and National Expenditure on Prescriptions (millions)*



As would be expected, national expenditure on prescriptions as well as their average CPI increase at a similar rate. However, the number of NDAs that are approved for sale in the market follow an unrelated autoregressive pattern.

Figure 7

NDAs Approved, Average Prescription Price and Medicare Expenditure on Prescriptions (millions)*

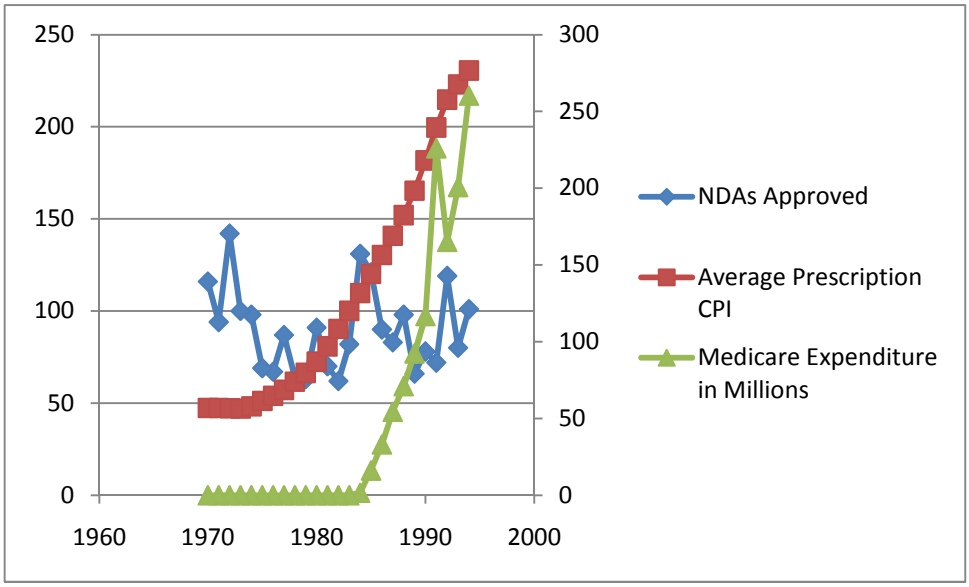
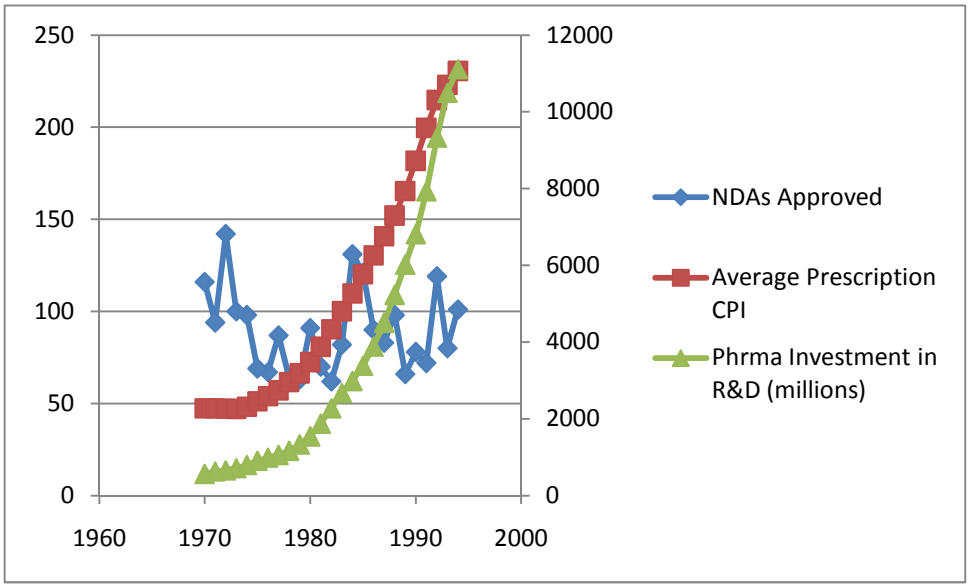


Figure 8

NDAs Approved, Average Prescription Price and Phrma Investment in R&D (millions)*



These figures also call into question the assumption that investment in R&D has a direct relationship to the supply of new drugs in the future

Appendix A – Data Set (all dollars are 1980 dollars according to BLS inflation rates)

Year	US GDP in billions	Phrma Investment R&D millions	National Expenditure in Millions
2007	5487.25	14090.63	
2006	5386.41	14093.36	88573.87
2005	5240.99	13039.25	84255.58
2004	5097.5	12902.29	82350.71
2003	4908.53	12132.08	77994.73
2002	4795.41	11726.13	72203.29
2001	4712.29	10947.36	64364.59
2000	4697.57	10202.98	57699.14
1999	4584.13	9133.27	51737.9
1998	4421.8	8668.58	44759.38
1997	4263.39	79404.85	39848.23
1996	4105.24	7140.12	35966.63
1995	3999.81	6426.69	32914.58
1994	3932.18	11112.1476	30191.65
1993	3796.33	10495.6344	29077.22
1992	3722.21	9330.527	27940.24
1991	3627.48	7930.5055	26850.18
1990	3658.57	6812.1105	25400.89
1989	3644.47	6018.0144	23096.59
1988	3554.97	5230.6158	21345.99
1987	3437.81	4502.9634	19503.27
1986	3355.24	3880.0432	18261.82
1985	3231.9	3381.0275	16690.59
1984	3119.3	2987.0977	15557.66
1983	2925.94	2671.995	14331.48
1982	2779.4	2270.5606	12833.05
1981	2835.87	1874.42	12145.16
1980	2789.5	1544.3066	12049
1979	2909.31	1331.4125	12194.29
1978	2900.05	1168.821	12500.28
1977	2761.49	1060.2496	12504.13
1976	2643.32	985.924	12630.8
1975	2509.22	906.2339	12332.43
1974	2507.1	795.3672	12405.13
1973	2566.09	710.8125	12651.37
1972	2441.05	656.4726	12466.45
1971	2293.16	627.6778	11957.16
1970	2205.47	564.51	11674.04

Year	Medicare Expenditure in Millions	% Change in Rx Prices
2007		1.433
2006	16125.63	4.291667
2005	1640.83	3.54167
2004	1436.87	3.0583
2003	1050.6	3.09166
2002	1093.78	5.19166
2001	1109.68	5.3916
2000	973.3	4.4166
1999	916.49	5.6916
1998	757.78	3.758
1997	619.16	2.633
1996	507.84	3.33
1995	367.66	1.9667
1994	260.21	3.383
1993	200.73	3.8667
1992	165.03	7.5916
1991	226	9.858
1990	116.63	9.95
1989	92.37	8.6916
1988	71.05	7.9416
1987	54.4	8.008
1986	33.08	8.583
1985	16.08	9.483
1984	1.59	9.6
1983	0	11
1982	0	11.6916
1981	0	11.45
1980	0	9.175
1979	0	7.7
1978	0	7.766
1977	0	5.958
1976	0	5.458
1975	0	6.158
1974	0	2.4166
1973	0	-0.325
1972	0	-0.375
1971	0	0.033
1970	0	1.68

Years for CPI	Average Rx CPI	Twelve Year Lag	NDAs w lagged years
1970	47.38333333		
1971	47.39166667	1994	101
1972	47.21666667	1993	80
1973	47.05833333	1992	119
1974	48.2	1991	72
1975	51.16666667	1990	78
1976	53.95833333	1989	66
1977	57.175	1988	98
1978	61.61666667	1987	83
1979	66.35833333	1986	90
1980	72.45833333	1985	121
1981	80.76666667	1984	131
1982	90.20833333	1983	82
1983	100.1	1982	62
1984	109.7083333	1981	70
1985	120.1	1980	91
1986	130.4166667	1979	63
1987	140.85	1978	64
1988	152.0333333	1977	87
1989	165.2583333	1976	67
1990	181.7083333	1975	69
1991	199.65	1974	98
1992	214.7166667	1973	100
1993	223.0083333	1972	142
1994	230.55	1971	94
1995	235.0416667	1970	116
1996	242.8666667		
1997	249.2666667		
1998	258.625		
1999	273.375		
2000	285.425		
2001	300.8416667		
2002	316.475		
2003	326.2666667		
2004	337.1083333		
2005	349.0416667		
2006	363.9666667		
2007	369.191		

Year	NDAs Approved
2007	
2006	101
2005	80
2004	119
2003	72
2002	78
2001	66
2000	98
1999	83
1998	90
1997	121
1996	131
1995	82
1994	62
1993	70
1992	91
1991	63
1990	64
1989	87
1988	67
1987	69
1986	98
1985	100
1984	142
1983	94
1982	116
1981	96
1980	114
1979	94
1978	86
1977	63
1976	72
1975	71
1974	85
1973	50
1972	57
1971	26
1970	51
1969	38
1968	59

1967	189
1966	40
1965	53
1964	83
1963	67
1962	109
1961	155
1960	222
1959	225
1958	280
1957	334
1956	346
1955	343
1954	226
1953	454
1952	194
1951	256
1950	233
1949	360
1948	194
1947	145
1946	114
1945	132
1944	137