Understanding Effects of Pharmaceutical Price Control on Firms' R&D Expenditure and Impacts on Social Welfare

THESIS

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Abstract:

Many studies have examined price regulations in the pharmaceutical industry in developed countries and found a negative relation between price control and pharmaceutical research and development (R&D). Nevertheless, the further impact of reduced pharmaceutical R&D spending on drug innovation has been less thoroughly studied. It is unclear whether the public benefits more from the controlled price or loses more from the reduced drug innovation in the future. Therefore, we are led to examine how the tradeoff between price cap and pharmaceutical R&D affects social welfare. By understanding price control's impact on future innovation and the market's demand, this research seeks to continue discussing whether the government should implement strict price control policies in the drug industry.

Methodology: Based on 1084–2020 data for the U.S. pharmaceutical industry, we investigate the impact of price on the industry's R&D intensity. We estimate an aggregated R&D spending elasticity with which the industry responds to the pharmaceutical price level. We also establish a causal link between controlled pharmaceutical prices and consumer surplus in the market. A conceptual model is then used to compare drug innovation in the future with consumer savings at the current time and to discuss social welfare concerning the drug industry.

1. Introduction

Pharmaceutical prices are generally higher in the U.S. than in many developed countries in Europe. A reason for the price difference is the pharmaceutical price regulation in most European countries to reduce pressure from public healthcare expenditure (Ever and Mahlich, 2014). Moreover, countries in the European Union apply similar pricing mechanisms, i.e., the External Reference Pricing of medicinal products, as a cost-containment tool to reduce prices for

in-patent pharmaceuticals in the E.U. As defined by WHO Collaborating Centre for Pricing and Reimbursement Policies, the External Price Referencing is "The practice of using the price(s) of a medicine in one or several countries to derive a benchmark or reference price to set or negotiate the price of the product in a given country ." Therefore, any drug price change in one country in E.U. would possibly influence the prices in some other countries (if it is one of their price match countries, and prices are relatively constant in the Union) (Toumi, Rémuzat, Vataire, PharmD, 2014) . Without similar pharmaceutical price regulations, the market in the U.S. allows companies to set their prices with fewer constraints, often at a monopoly price. Such condition leads to high prices for medicinal products, especially innovative products requiring intensive R&D investment before entering the market.

Price regulation may generate a significant negative influence on pharmaceutical price-cost margins. The margins in the U.S. are, on average, approximately four times higher than the margins in other countries (Vernon, 2003). Reduced profitability thus negatively affects the survival of pharmaceutical firms, especially newer and smaller firms. Under such policies, firms need to shut down their high-cost R&D program, and smaller firms would even be eliminated from the market without extensive external support (Filson and Masia, 2007).

Therefore, while reduced prices would reduce healthcare pressure for the public, the reduced R&D may slow innovative activities in medicine development (Golec and Vernon, 2010). Concerning social welfare, the question arises: do price regulation policies effectively increase social gain, and what is the tradeoff effect between the reduced prices and the reduced innovation in pharmaceutical products? Following the idea of Vernon (2003, 2005), in this paper, we will analyze the pharmaceutical industry's investment in drug R&D under a hypnotized price control policy. The decreased innovation leads to fewer varieties of new drugs produced in the

future and reduces social welfare. Lower drug price increases consumer surplus and boosts public welfare. A dynamic model is then created to quantify the welfare loss and gain associated with the price regulation, thus evaluating the efficiency of government price regulation. Our analysis will first model the relationship between the price regulation policies and pharmaceutical R&D and then compare the price regulation's positive impact on consumer gains with the reduced R&D's negative impact on social return.

2. Literature Review

Several studies analyzed the effects of price control policies on pharmaceutical firms' R&D spending in the U.S. versus Europe. The novel contribution of this paper is to understand the impact of pharmaceutical regulation on social welfare, measured by consumer surplus and new drug valuation.

First of all, the work of Filson and Masia, 2007, modeled the evolution of a firm and estimated the probability that its profit from a future product could cover the R&D spending on an ongoing basis. Filson and Masia's study constructed a computational model to quantify the effects of profit reduction policies on company survival and the development of new drugs. Their model consisted of a single firm with an initial portfolio of discovery programs, candidates for development, and products. Filson and Masia simulated the evolution of 100 firms with different sizes and portfolios over 50 years. The firms were modeled under three policy environments with varying degrees of profit reduction. Their computational results indicated that profit-reducing policies would force firms to shut down their high-cost discovery programs, and smaller firms had to rely on external support to exist. The profit-limiting policy resulted in the gradual diminishing of smaller and newer pharmaceutical firms. Eventually, under such policies, without

further change in productivity to support the profitability of new medicinal products, it was most likely that the industry could restore profitability only by the exit of newer and smaller firms and the concentration of the industry, leaving the consumers with less choice of pharmaceutical products in the future (Filson and Masia, 2007).

John Vernon has published several hypotheses and observations regarding the relationship between pharmaceutical market price and firm R&D spending. One of his earliest papers in 2005 explained how to use the proportion of the market share in the European to represent the degree of price regulation and the proportion of market share within the U.S. to represent a (relatively) "free" market. Vernon constructed the following structural equations of relationships between price regulation, sales, profits, cash flows, and R&D investment:

$$\frac{R_{it}}{S_{it}} = \beta_0 + \beta_1 \frac{\pi_{it}}{S_{it}^P} + \beta_2 \frac{C_{it-1}}{S_{it-1}} + \sum_{i=2}^{n} \beta_{i+1} F_i$$

In the equation, R_{it} was firm i's R&D expenditures in year t, S_{it}, Π_{it}, C_{it-1}, and F_i represented the total sale of firm i in year t, firm i's pre-tax pharmaceutical profits in year t, firm i's cash flow in year t-1, and a dummy variable for firm i, respectively. The coefficients capture the effect that the explanatory variables have on R&D intensity.

In support of the negative influence of price regulation on R&D, Golec, Hedge and Vernon, 2010, used the Clinton administration's Health Security Act (HSA) as a natural experiment. The study tested the cross-sectional relation between HSA-induced stock price decrease and the firm-level R&D expenditure. Golec, Hedge, and Vernon evaluated the value of a firm's R&D portfolio with and without price control. They demonstrated that the HSA price constraints had had significant negative impacts on firm-level R&D expenditures (cutting R&D spending by about $1 billion in 2004 dollars).

Following the approach of John Vernon, Eger and Mahlich (2014) focused on the regulation in the European area. The regression results in their work also supported that the R&D spending of a pharmaceutical company was positively correlated to its share of U.S. sales and negatively correlated with its share of European sales. One conjecture from their study was that R&D investment might not necessarily lead to pharmaceutical innovation because spending was directed to low-risk R&D projects, which did not significantly contribute to existing clinical treatments. With this in mind, besides concerns about the decreased R&D, future research also needs to address the problem of R&D efficiency.

A related but opposite idea was the "Porter's Hypothesis": a well-designed environmental regulation can encourage the discovery of cleaner technologies and improvements, referred to as the innovation effect, thus making production more efficient. At the same time, the saved costs were sufficient to compensate for both the compliance costs of such policies and the cost of innovation (Porter and Linde, 1995). While the question explored in the work of Porter and Linde, 1995, was somewhat different, the idea provided some insights. Porter's Hypothesis has been applied to environmental protections, suggesting that strict environmental regulation promotes the innovation of clean technologies and improves environments. The innovation effect thus triggers commercial competitiveness and encourages innovation (Porter and Linde, 1995). The cost savings that can be achieved are sufficient to overcompensate for both the compliance costs directly attributed to new regulations and the innovation costs. When applied to the pharmaceutical industry, this hypothesis predicts a positive association between price control and R&D intensity, suggesting that an appropriate regulatory policy could incentivize innovation in the drug industry and enhance competition. A regulatory policy might also reduce the development of drugs structurally similar to existing drugs and promote breakthrough

innovations (Eger and Mahlich, 2014). Our recent data analysis would likely produce opposite results to Porter's Hypothesis, and future studies could further discuss how to “appropriately” design regulatory policies.

Santerre and Vernon, 2006, suggested that although the consumer gain from a hypothetical price control policy from 1981 to 2000 would be about $1.1 billion, the gain was a small amount compared to the reduction in pharmaceutical R&D and drug innovations (around 38%). Society might be better off by modifying more efficient methods of price control in order to relieve healthcare expenditure pressure (Santerre and Vernon, 2006). Building from the results, their study also discussed the social return of price regulation policies from new drug diffusion speed perspectives and the valuation of new medicinal products.

According to Patents and Global Diffusion of New Drugs by Cockburn, Lanjouw, and Schankerman in 2016, price controls primarily slowed the speed of imported drugs' launch in a new country. They reduced the number of places where the drug could be diffused to. More interestingly, patents also strongly influenced product diffusion. Long product patents reduced launch lags (the waiting times from when a product is first launched commercially in its original market country) (Cockburn, Lanjouw, and Schankerman, 2016). Therefore, it might be worth studying the distribution and pattern of drug patent registrations in the European and the U.S. market. For instance, if European firms register their patents in the U.S. first, there is a longer launch lag for the companies to launch the drug in Europe than if the patents are registered in the Europe and drugs are first launched there. The longer launch lag in Europe could negatively influence the aggregate consumer gains in the E.U. and U.S. markets.

How should we evaluate the social loss from reduced R&D intensity? In this paper, we design a model to quantify the value of social welfare. The lost value in the future would be compared to the consumer surplus from the current regulated prices. Challenges are identifying available variables in a period and designing efficient models that capture the market trend. We are not modeling the dynamic in drug varieties in this paper, but a discussion on the idea of variety loss is achievable.

Another very related topic is how we incentivize the firm-level R&D intensity. A study by Kremer, Levin, and Snyder, 2020 discussed the design and effects of an Advance Market Commitment (AMC) about a decade ago. The AMC helped purchase pneumococcal vaccines for children in low-income countries and stimulated the development of such vaccines. Compared to a rotavirus vaccine at a similar period without AMC, an AMC-targeted pneumococcal conjugate vaccine (PCV) had a vaccine coverage rate converting to the global rate about five years faster. Meanwhile, the PCV had less severe supply shortages, suggesting that firms expanded capacity faster for PCV than for the rotavirus vaccine. It was also estimated that the PCV with AMC saved 700,000 lives at a highly favorable cost (Kremer, Levin, and Snyder, 2020). However, the design of AMC was also complex: it took into consideration the reservation value of firms and the copayment rate of countries. Meanwhile, policymakers might hold back funds for future tenders and promote competition in the market, which could be essential for controlling long-term prices and avoiding supply interruptions (Kremer, Levin, and Snyder, 2020). The study offered another approach to achieving pharmaceutical price regulation by incentivizing R&D and production efficiency by applying subsidy policies.

3. Data and Trend

This study relies on top U.S. pharmaceutical companies' profits and R&D spending datasets. The European Federation of Pharmaceutical Industries and Association (EFPIA) has provided R&D spending from the EFPIA members since 1986. U.S. firms spent less on R&D than European firms in the 1990s, but starting from 2000, U.S. firms surpassed the European firms in terms of R&D expenditures. A potential problem in this data is that their local market may not fully represent the market share difference between the U.S. firms and European firms, i.e., some U.S. firms could have more sales in Europe than others, and some European firms may have more sales in the U.S. than others.

The Pharmaceutical Research and Manufacturers of America (PhRMA) has reported aggregated R&D spending data of more than 30 top pharmaceutical companies since 1980, where the data distinguishes between domestic R&D spending and abroad R&D spending. The U.S-only and EU-only R&D spending may provide a better understanding of the firms' market share distributions and the degrees of price regulation they undergo.

PharmExec.com recorded R&D spending data of the 50 top companies each year from 2016 to 2020. Again, as the datasets provided by EFPIA, such figures could help us understand the R&D intensity of U.S. firms. At the same time, we are still skeptical about directly comparing these expenditures with that of the E.U. firms. Nevertheless, such reports would provide a look into the amount of drug innovation spending and the trend in the U.S. market. Annual information of the top 30 U.S. pharmaceutical firms, including sales by geographic area and R&D expenditure in recent decades, is available from their annual reports.

Data from multiple sources support our aggregated market-level analysis. The consumer price index (CPI) of medical care services has been provided by the Bureau of Labor Statistics

starting from 1984. CPI of pharmaceutical products can be found in the annual reports by National Center for Health Statistics in the Center for Disease Control and Prevention (CDC). The Center for Medicare and Medicated Services (CMS) provides statistics on annual prescription drug expenditures and the U.S. population from 1984 to 2020. Food and Drug Administration (Center for Drug Evaluation and Research (CDER)) provides data on the number of novel drugs approved annually by CDER from 2008 to 2020. Data on real annual income from 1984 can be retrieved from the Federal Reserve Economics Data report. U.S. Census Bureau provides population records in the period of our study.

There were some difficulties during data collection and interpretation on individual firms. First of all, some firms do not report their expenditures on research and development. The R&D intensities of these firms span an extensive range, from 5% for some firms to more than 25% for some others. We realized that this research might need to sacrifice some firm-level comprehension and rely on the industry-level data (reported by PhRMA). Giaccotto, Santerre, and Vernon (2005) argued, "only at the industry level are data available on pharmaceutical R&D expenditures, as opposed to total R&D expenditures reported by individual firms ."Because most major pharmaceutical firms are diversified across multiple industries, the total R&D on a firm's annual report often includes spending on the R&D of non-pharmaceutical products, such as industrial chemicals and medical supplies. Some previous firm-level studies have been more or less hampered by this feature of the R&D data (Giaccotto, Santerre, and Vernon 2005). For this reason, we believe that an industry-level study is the most reliable when investigating the determinants of pure pharmaceutical R&D, especially when we need to link drug R&D to social welfare.

4. Aggregate Trends and Statistics

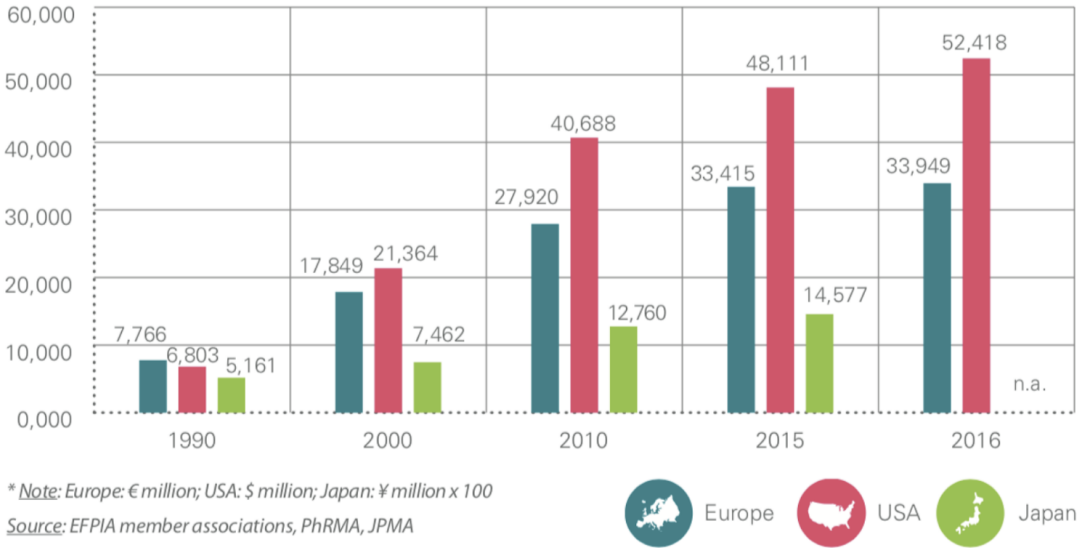

Figure 1 – Pharmaceutical R&D expenditure in Europe, USA and Japan (millions of national currency units), 1990- 2016

Note. The figure is from the European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures*, 2020

EFPIA reports the R&D spending of its members from the 1990s. European firms, in general, spent more on R&D than U.S. firms in the 90s. However, U.S. firms have increased spending on R&D in recent years, and the U.S. R&D expenditure has surpassed that of European firms since the 2000s.

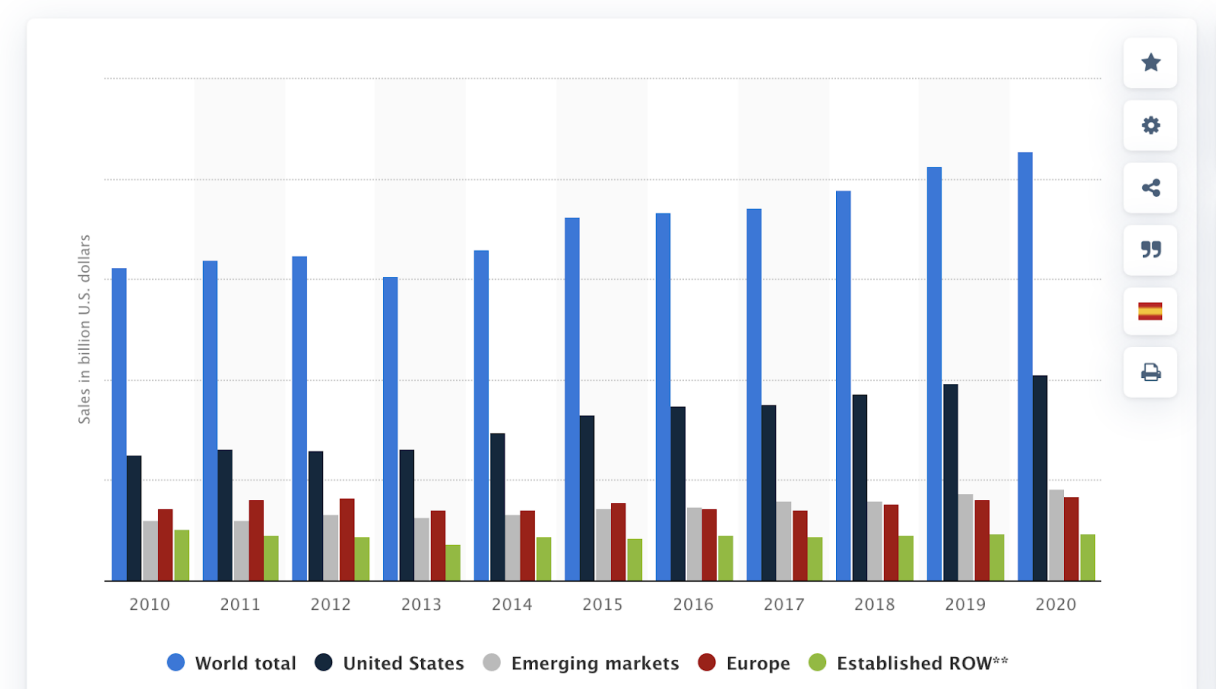

Figure 2 – Global Pharmaceutical sales from 2010 to 2020, by region (in Million US dollars)

Note. The figure is from Statista by Matej Mikulic, Aug 10, 2021, (https:// www.statista.com /statistics/275535/distribution-of-global-pharmaceutical-market-revenue/2020)

Recent data from Statista indicates that the U.S. market mainly drove the global pharmaceutical sales increases in the last decade. In contrast, the European pharmaceutical market sales stayed relatively constant. The sales may suggest less promising profitability of European pharmaceutical firms than that of U.S. firms.

5. Empirical Analysis

5.1 Relative Pharmaceutical Prices and R&D intensity in top U.S. companies

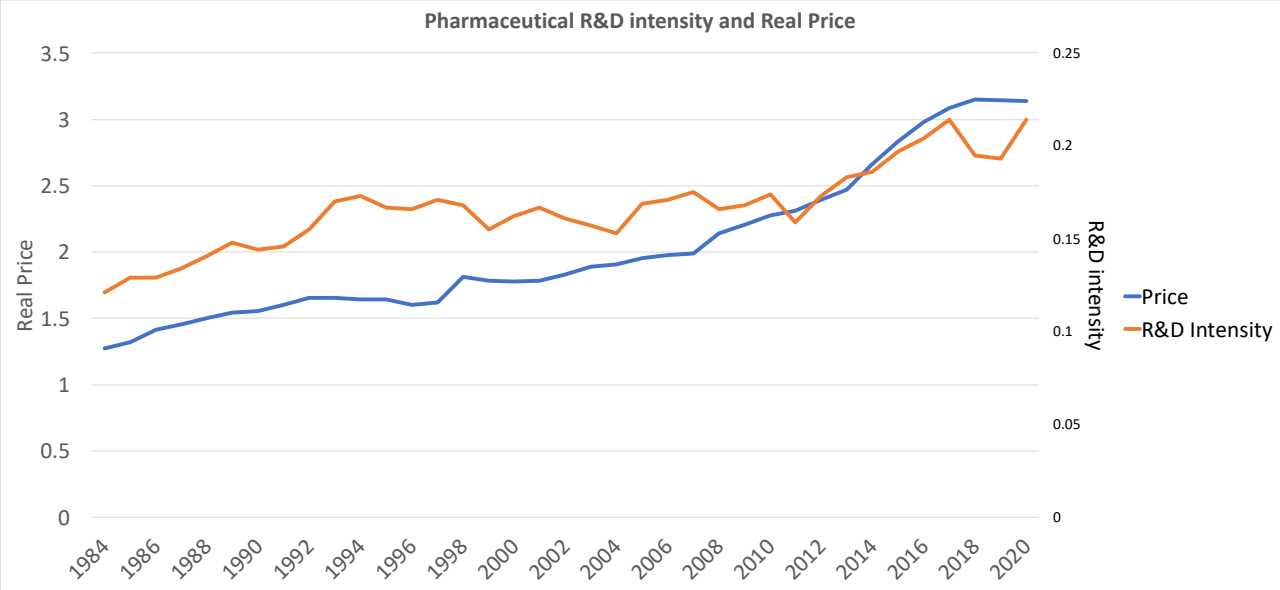

Figure 3 – The real price of pharmaceutical products and pharmaceutical R&D intensity

The relative price of pharmaceutical products for each year is represented by dividing the CPI of pharmaceutical products by the general urban CPI in that year. Firm managers in the pharmaceutical industry employ the R&D-to-sales ratio to make future budgeting decisions (Carmelo Giaccotto, Rexford E. Santerre, and John A. Vernon 2005). In this research, we use the ratio to denote R&D intensity.

Figure 3 plots the relative prices of drugs and R&D intensity reported by members of PhRMA in the past 40 years. The real/relative price of pharmaceutical products is defined as the ratio of pharmaceutical CPI to general urban CPI. The relatively aligned pattern directly relates to pharmaceutical R&D intensity and relative drug price. The data in the figure show that R&D intensity continued to increase from about 13% in the 1980s to about 20% in 2020, and the

changes in R&D intensity share a significant direct relationship with changes in the relative price of drugs, which has more than doubled in the past three decades.

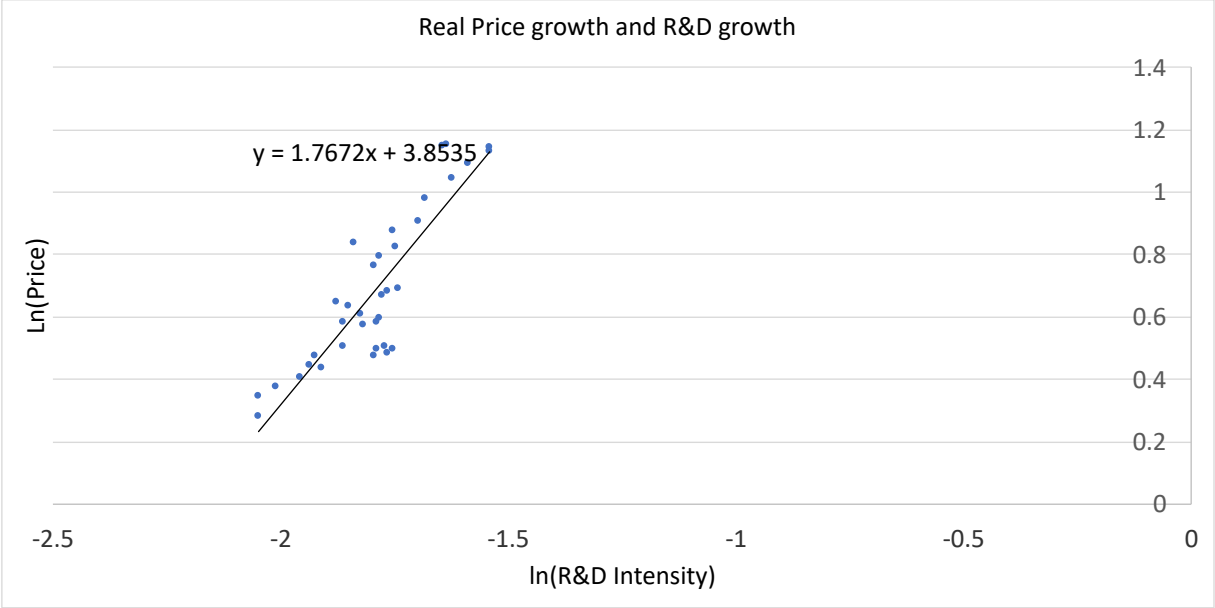

Figure 4 – Growth of Real price of pharmaceutical products and pharmaceutical R&D intensity

The hypothesis is that the change in R&D spending could be explained by the change in relative prices from year to year. In Figure 4, by plotting the natural log of R&D intensity along the x-axis and the natural log of relative drug price along the y-axis, we generate a best-fit linear trendline that supports the idea that the change in R&D intensity increases with the change in real prices steadily. The two data series demonstrate a relatively strong positive correlation.

The time-series data and the linear trendline provide insights into the relationship between relative drug prices and pharmaceutical R&D intensity. However, it is also reasonable to assume that other factors influence R&D expenditure, such as GDP and foreign sales. Therefore, we should hold these factors constant to "isolate the pairwise relation between relative drug prices and pharmaceutical R&D" (Giaccotto, Santerre, and Vernon 2005).

5.2 Regression Analysis

Based on the preceding discussions and our hypothesis, we understand the annual changes in industry-level R&D intensity from 2008 to 2020 by a multiple-regression model specified below:

$$ln(R\&D) = \hat{\beta}_0 + \hat{\beta}_1 lnP + \hat{\beta}_2 lnFS + \hat{\beta}_3 lnGDPpc \qquad (1)$$

We define the variables ln(R.D.) as the natural logarithm of R&D intensity; ln(P) as the natural logarithm of relative/real drug price, ln(F.S.) as the natural logarithm of the foreign to total sales ratio, and ln(GDPpc) as the natural logarithm of real gross domestic product (GDP) per capita. In our model, both the explanatory and the independent variables are logarithmically transformed to interpret the coefficients as the percent increase in price for every one percent increase in the dependent variables. The three slope parameters could then be treated as elasticities.

TABLE 1

ORDINARY LEAST SQUARES REGRESSION RESULTS

Explanatory Variable	Coefficient Estimate	*t*-Statistic	*p*-Value
Intercept	-1.959	-1.580	.124
$\Delta(\log P_{t-1})$	.512	6.070	.000
$\Delta(\log FS_{t-1})$	.211	2.180	.037
$\Delta(\log Y_{t-1})$	.013	.110	.911

Note. — The dependent variable is the logarithm of pharmaceutical research and development intensity. R^2 =.86; F-statistic = 63.15; adjusted-R^2 = 0.84; N = 36.

Table 1 summarizes the model's estimation results by ordinary least squares (OLS), which reports the coefficients, standard errors, t-statistics, corresponding P-values, and 95% confidence intervals.

The elasticity estimate on the relative price variable is positive and statistically significant at < 0.1% level. This supports our expectation that drug companies spend more on research and development as relative pharmaceutical prices increase due to decreasing opportunity costs. Moreover, firms' prospective profits increase due to increasing relative drug prices, thus resulting in increased motivation to invest in research and development because drug innovation brings more profits. Our result is similar to the .58 elasticity estimate by Giaccotto, Santerre, and Vernon (2005).

The elasticity estimate on foreign sales is slightly positive and statistically significant at the 4% level, which indicates that holding other factors constant, the increased foreign sales increase demand and lead to more intense R&D activities. This observation seems unintuitive, because in the previous discussion, we expect foreign sales to inversely influence a firm's R&D. The firms that have foreign shares are usually the large firms that are capable of selling outside the U.S. to supply foreign demand. The positive estimated elasticity indicates that the return from foreign markets has larger effects on R&D intensity than the lower profits in foreign markets compared to the U.S. market. Meanwhile, the regression is based on the industrial level statistics instead of individual firm-level statistics, so the positive elasticity captures the aggregate trend that foreign demand has on pharmaceutical R&D intensity. Again, the estimated elasticity is consistent with the 0.173 foreign sales elasticity estimated by Giaccotto, Santerre, and Vernon (2005).

An increase in real income might increase the aggregate demand for pharmaceutical products and "potentially raise the expected returns to R&D" (Giaccotto, Santerre, and Vernon 2005). Recall that R&D intensity is defined as the ratio of R&D spending to sales. The elasticity estimate on real GDP per capita growth is thus expected to be positive under the assumption that the change in real income will have a greater effect on drug R&D than on drug sales. If firms' decisions in R&D respond to economic growth with a lag after the sales changes, it would be more reasonable to assume a negative elasticity on real GDP. Our result indicates that the elasticity of real GDP per capita is positive but not statistically different from zero. It could result from pharmaceutical R&D spending and sales increasing on a similar scale under a growing economy. So, the value of R&D intensity stays constant.

6. Models

6.1 Conceptual and Empirical Model for Aggregated Pharmaceutical Demand

One significant goal of this paper is to estimate the aggregate demand of the drug market so that we can dynamically understand how the lost R&D could be transformed into a loss in demand. The U.S. aggregated demand, defined as the real pharmaceutical expenses per capita, is calculated by dividing the aggregated nominal drug expenditures over pharmaceutical CPI and the U.S. population.

In this research, we follow the idea of Santerre and Vernon to express the aggregated drug spending of the year as a function of pharmaceutical consumer price index, medical care

service (including doctor visits), consumer price index, income, general consumer price index, and the demand of last period (Santerre and Vernon, 2006).

Results from Table 3 show how we retrieve each explanatory variable's elasticities on aggregate demand. We can write the relationship of Q(demand) and other estimates in the log-log form as

$$ln(Demand) = ln(A) - 0.447ln(\frac{CPI_{pharm}}{CPI}) + 0.452ln(\frac{CPI_{mc}}{CPI}) + 0.620ln(\frac{income}{CPI}) + 0.710ln(Demand_{t-1}) \quad (2)$$

This form allows us to interpret the coefficients above as elasticities. The quantity demand is inversely related to the real price of drugs (-0.447<0). The positive sign of the real price of medical care services indicates that pharmaceuticals and medical services are substitutes (0.452>0). The positive elasticity of real income explains that pharmaceutical products can be treated as normal goods (0.620 >0). Note that our estimated elasticity of -0.447 on the actual pharmaceutical price is similar to the estimates of Rexford Santerre and John Vernon, from -0.333 to -0.484.

TABLE 3

ORDINARY LEAST SQUARES REGRESSION RESULTS

Explanatory Variable	Coefficient Estimate	*t*-Statistic	*p*-Value
Log of real price of drugs (CPI_{drug}/CPI)	-.474	-3.81	.001
Log of real price of medical care (CPI_{mc}/CPI)	.452	3.61	.001
Log of real disposable Income per capita (Y_N/CPI)	.620	12.17	.038
Log of one-year lagged measure of real pharmaceutical expenditures per capita	.710	9.08	.000

Note. — The dependent variable is the demand of pharmaceutical products. R^2 =.99; F-statistic = 766.91; adjusted-R^2 = 0.99; N = 36.

With the estimates and interpretation discussed, we can build a demand curve using data from consumer price indices and the demand of the last period.

$$Demand = A(\frac{CPI_{pharm}}{CPI})^{\sigma_1}(\frac{CPI_{mc}}{CPI})^{\sigma_2}(\frac{income}{CPI})^{\sigma_3}Demand_{t-1}^{\sigma_4} \qquad (3)$$

More simply, we could write

$$Demand = K(\frac{CPI_{pharm}}{CPI})^{-0.447} \qquad (4)$$

Where K is "the amount of drug consumption that results from all factors other than the real out-of-pocket price ."K is defined as

$$K = A(\frac{CPI_{mc}}{CPI})^{0.452}(\frac{income}{CPI})^{0.620}Demand_{t-1}^{0.710} \qquad (5)$$

The value of K could simply be determined by dividing the demand (represented by real drug expenses per capita) by $(\frac{CPI_{pharm}}{CPI})^{-0.447}$ each year between 1984 and 2020 (Santerre and Vernon, 2006). Figure 5 is a simple visualization of the fitness of our model.

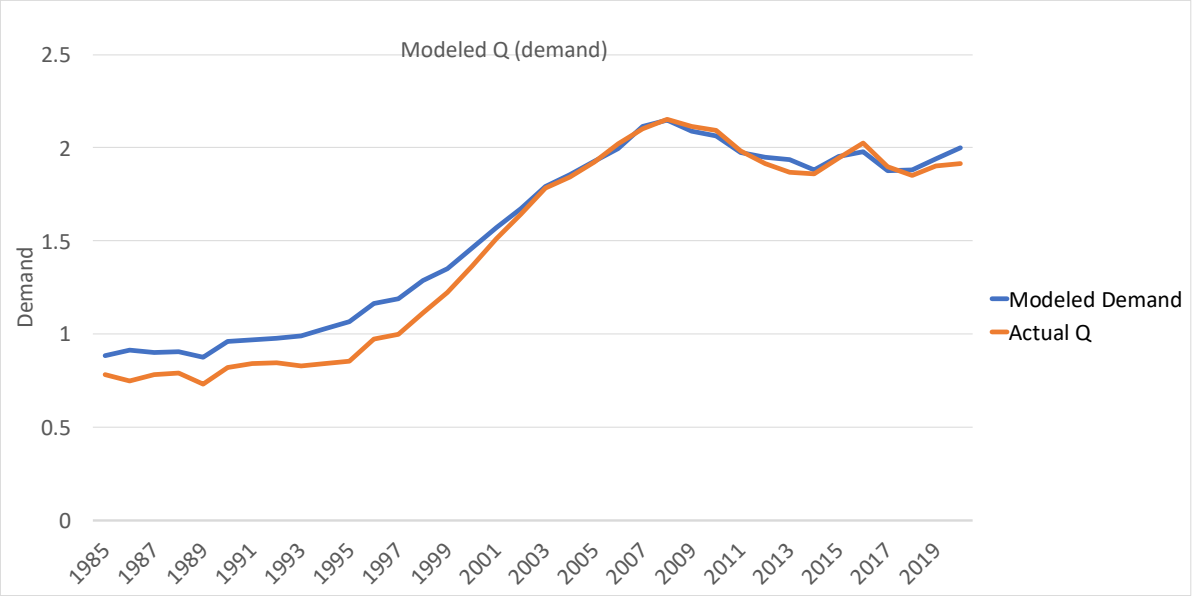

Figure 5 – Modeled pharmaceutical demand and actual pharmaceutical demand

While the model is smoother than the actual demand data in the first decades predicted, it captures the trend of demand fluctuation from 1985 to 2020 and matches the pattern in more recent years. In later discussion, we apply this model to generate a demand curve for the pharmaceutical industry based on historical data of price indices. In this paper, a hypnotized price control policy is constructed such that the growth rate of pharmaceutical products CPI cannot exceed the growth rate of the urban CPI.

We assume that a pharmaceutical firm is monopolistic for at least 20 years after introducing a drug into the market due to patent protection laws. Figure 6 is an example of how we modeled the demand in 2020. The potential consumer surplus brought by a price control policy can be estimated by standard integration techniques. We need to evaluate the area between the regulated price index and demand curve, and the area between the uncontrolled price index and the demand curve. The difference between the two values thus gives us the net consumer surplus change caused by the price control policy. The effect of a price regulation policy is estimated by an increase in consumer surplus at a year t, which is the indicator for social welfare.

For example, in 2020, we obtained the constant K_{20} by dividing the demand quantity of 2020 by the real price of pharmaceutical products to a power of -0.447. The demand curve is then

$$Demand_{2020} = 1.713(\frac{CPI_{pharm}}{261.564})^{-0.447} \qquad (6)$$

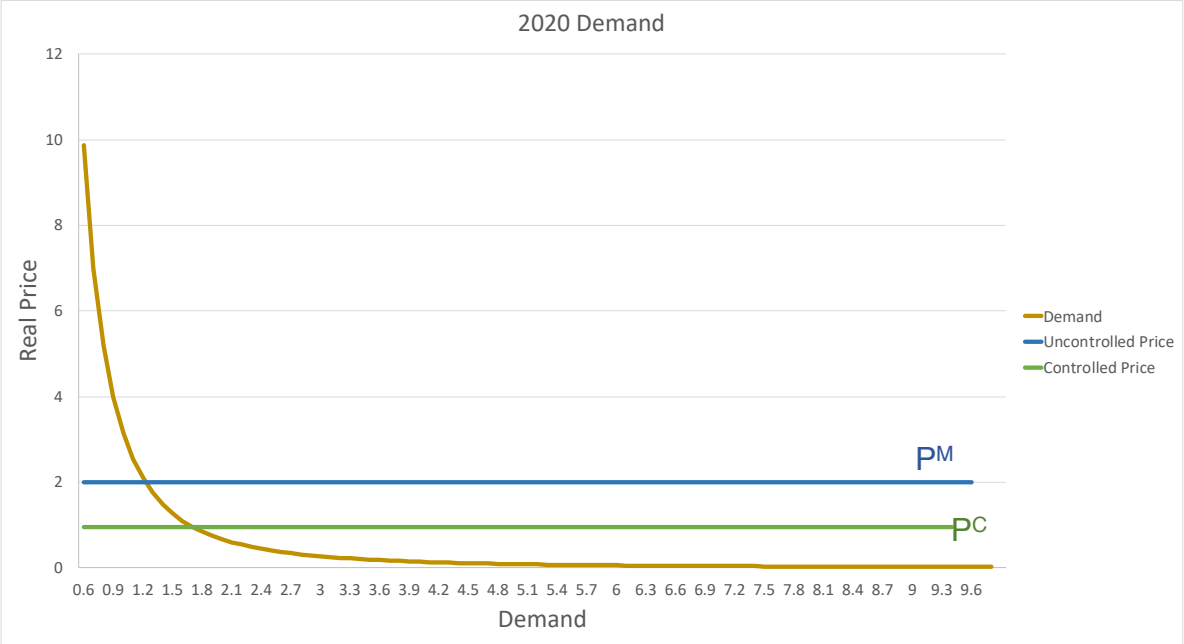

Figure 6 – Pharmaceutical demand and prices in 2020

Figure 6 depicts the demand in 2020. Here we should let P^{M} be the real pharmaceutical price in year t and $P^{.C.}$ be the real pharmaceutical price under a price control policy in year t. The simulation of demand and consumer surplus is demonstrated between the demand curve, the real pharmaceutical price, and the controlled real pharmaceutical price (calculated by lowering the growth rate of pharmaceutical CPI to the same as the growth rate of urban CPI). The integration method is specified as

$$CSgain_t = \int Demand_t \, dq \text{ between actual price and regulated drug price}$$

The model in this section discussed the change in price index under price control. However, we also need to consider the change of expenditures on the drug, i.e., the demand, under a price regulation policy. Therefore, the next session will discuss the effects of a price cap on R&D expenditures and its further impact on drug availability in the market.

6.2 Model for R&D expenditure in Response to Price Control

Previous research advocated for not implementing strict pharmaceutical regulations due to the concern of reduced drug innovation. They made suggestions based on the conclusion that drug price control policies reduce potential R&D spending. It is not sufficient to only realize the reduced expenditures on research and development. We also need to model how the reduced R&D intensity is transformed into the loss of new drugs in the next period. This research will further investigate why reduced R&D spending lowers future social welfare. More importantly, once a price cap policy has been implemented, we will analyze a tradeoff between the current policy's loss in future social welfare and healthcare expenditure savings. That leads us to build a dynamic model to capture the change in public gains and losses.

When the government sets a strict price ceiling rule, drug firms make fewer revenues, and profits decrease because costs are constant. Companies have an incentive to spend on drug innovation because investing in the research and development of drugs becomes less promising when future prices would also be restricted. So, the research outcome might not be as rewarding as in a nonregulated market. Therefore, the first step of our model is to estimate how much less the firms would invest in response to reduced prices. We control other factors such as real GDP per capita and foreign sales. Following our previous discussion on R&D intensity, we consider the effects of regulated drug prices, foreign sales to sales ratio, and the real GDP per capita. The regression model for R&D growth is captured by the natural log of R&D intensity level:

$$ln(R\&D) = \hat{\beta}_0 + \hat{\beta}_1 lnP(regulated) + \hat{\beta}_2 lnFS + \hat{\beta}_3 lnGDPpc \qquad (7)$$

Because the equation is built on the logarithmic transformation of the continuous variables, the three slope parameters of the independent variables can be interpreted as elasticities. The

estimated elasticity on (regulated) real drug price is expected to be positive because R&D intensity is positively related to the expected return associated with the investment.

The foreign sales variable measures the percentage of total industry drug sales outside the U.S. The dependent variable is the natural logarithm of R&D divided by total global sales, while other explanatory variables are measures of the U.S. price index and U.S. GDP. We follow the idea of Vernon to add the F.S. variable as a control to capture the sales in the rest of the world. The elasticity estimated on F.S. is also expected to be positive because increasing foreign sales also drive the demand for R&D, and companies are also more confident in investing in future drug innovation.

The sign of estimated elasticity on GDPpc could be positive or negative because the independent variable is a ratio since the GDPpc impacts both the denominator and the numerator. The sign of elasticity estimate here depends on whether an increase in GDP per capita has a greater impact on the total sales of pharmaceutical products or pharmaceutical R&D expenditure (Giaccotto, Santerre, and Vernon 2005). Table 1 in Section 5.2 summarizes our regression on the log of research and development.

The expected R&D is then estimated by taking the power transformation of Equation 7:

$$E(R\&D_t) = e^{ln(R\&D_t)} \tag{8}$$

Figure 6 visualizes the efficiency of our model. Some fluctuations are not realized because our model is smoother than the real R&D in the period of our interest. The general trend of drug R&D has been captured in the past three decades. Future work may consider other

shocks and improve the accuracy of the model.

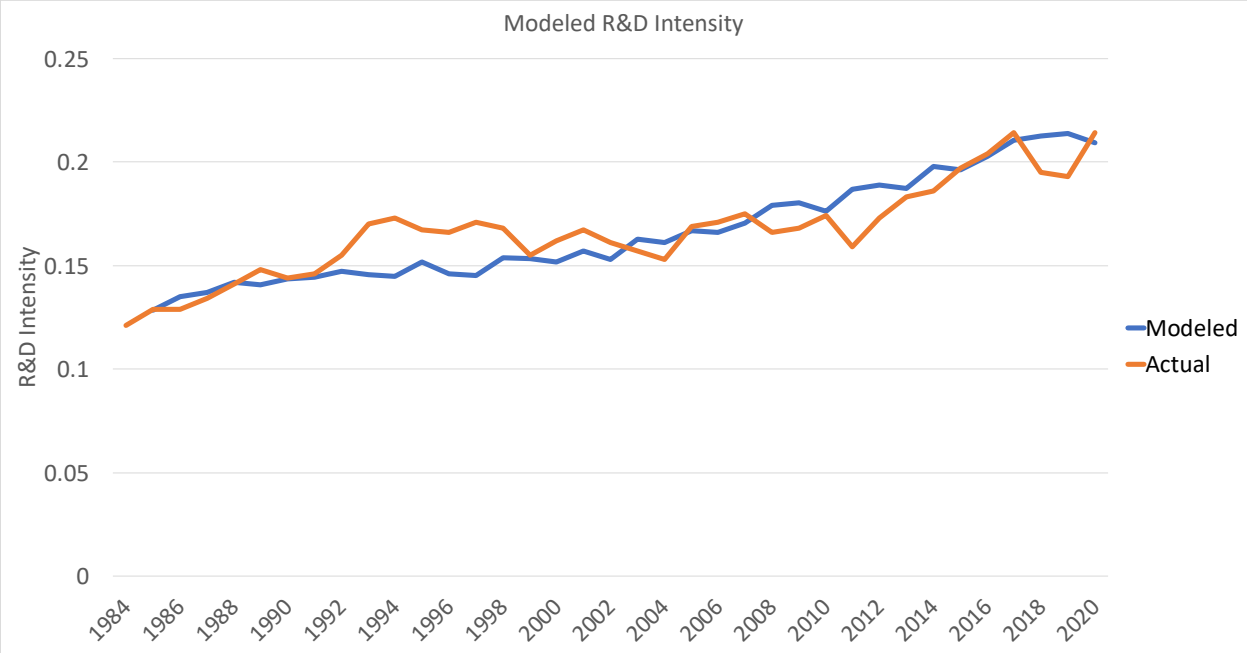

Figure 7 – Modeled R&D intensity and Actual R&D intensity

The next step is to simulate the impact of the price ceiling on aggregated R&D spending. By plotting the estimated R&D under price control and the actual R&D intensity, we can generate a graph representing the differences, an indicator of the extent to which R&D decreases in response to a price control policy.

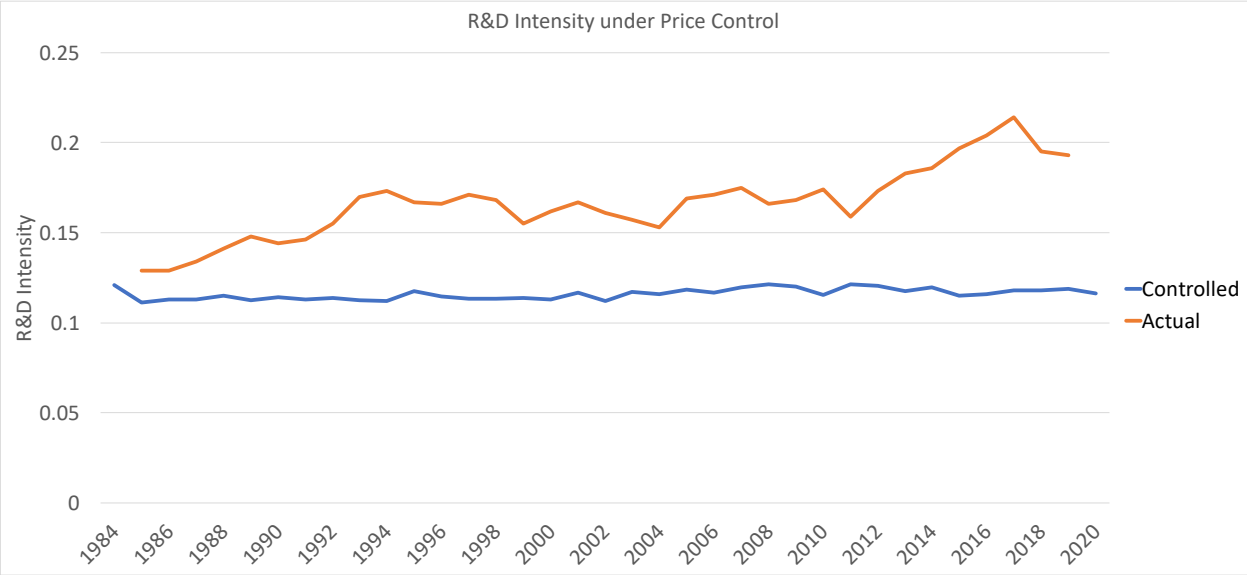

Figure 8 –R&D intensity under price control and actual R&D intensity

The vertical distance in Figure 7 between the real R&D and estimated R&D would represent the loss resulting from a price control policy.

$$R\&Dloss = R\&D_t - E(R\&D_t) \qquad (9)$$

As specified in Equation 7, Potential loss in R&D is simply the difference between actual R&D and estimated R&D under a price control policy. Figure 8 demonstrates the amplified effects of price control policy over the past years. The earlier a price control policy is in the act, the greater its effect on the R&D intensity in later years. A price control policy restricts pharmaceutical price growth rates each year. The effect of price regulation has been aggregated over the years because of the ever-decreasing acceleration rate of a restricted price compared to a free pharmaceutical price.

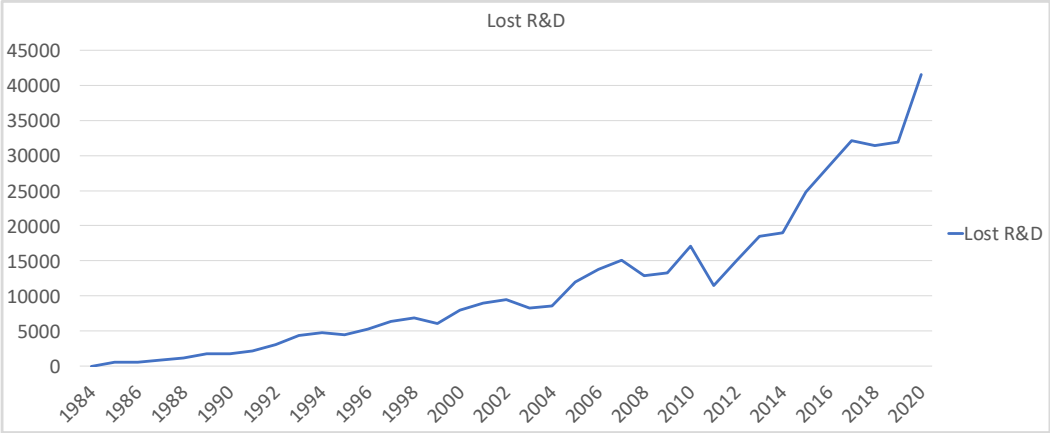

Figure 9 – Increasing loss of R&D intensity due to price control policy

6.3 Converting the loss of R&D to a loss of Consumer Surplus

After investigating the impact of price control on public healthcare savings, we aim to represent the further impact of the price ceiling on drug innovation loss. Based on the previous discussion, we can measure the loss of R&D by subtracting the expected R&D intensity under price control from the real R&D in a year t. The average cost of introducing a new drug to the market is about $1.3 billion. A simple way to estimate the loss of future drugs is to divide the R&D loss by this cost, which indicates how many drugs would have come to the market in year t+1 would not have if there were a drug price ceiling in year t specified in Equation 10.

$$NewDrugLoss = \frac{RDloss}{cost\ of\ introducing\ a\ new\ drug\ to\ market} \qquad (10)$$

Equation 11 represents the percentage of potential new drug loss, dividing new drug loss by the actual number of new drugs in the market in year t+1 reported by the FDA.

$$PercDrugLoss_t = \frac{NewDrugLoss_t}{NewDrug_t} \qquad (11)$$

The demand curve in year t+1 is expected to shift left because there will be fewer drugs for consumption under the price regulation in year t. We assume that the amount of demand that decreases in year t+1 is in proportion to the percentage of drug loss in year t, i.e., the drug loss shrinks the demand curve in year t+1. The expected consumer surplus in year t+1 with price control is calculated by integrating the area between the controlled demand curve and controlled price in year t+1. So, the future consumer surplus loss can be calculated based on the expected future consumer surplus and the loss of drug quantity in the current year, i.e., as quantification of social welfare loss due to the price control policy:

$$NetCSLoss_{t+1} = \int_{p_{t+1}^{M}}^{\infty} Demand_{t+1}(p)\, dq - \int_{p_{t+1}^{C}}^{\infty} (1 - PercDrugLoss_t) * Demand_{t+1}(p)\, dq \quad (12)$$

Recall that we have represented consumer gain in year t by integrating the demand function in year t in Section 6.1. Both the loss and gain of consumer surplus are measured in U.S. dollars. Therefore, we can directly compare the current gain in consumer surplus with the future loss of consumer surplus (in year t+n, where n can represent any period of our interest). The argument of whether the government should take the risk to place price control is backed up by the preceding discussion on the welfare tradeoff.

This paper will demonstrate an application of the model regarding the pharmaceutical market and price regulation in 2019-2020. Further research can be done based on the method discussed in this study.

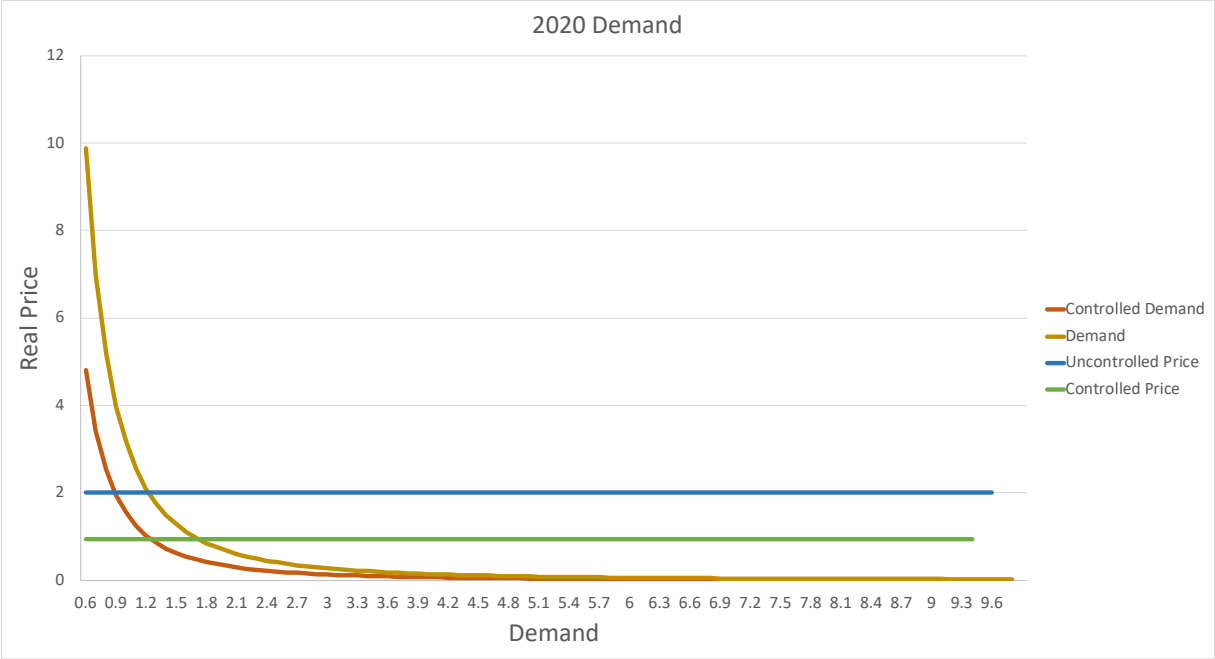

Figure 10 – 2020 Demand with and without R&D loss in 2019

Figure 10 shows the 2020 pharmaceutical product demand if the government implemented a price control policy from 1984 to 2019. The R&D loss in 2019 would be about 31,926 million dollars based on Equation 9 in Section 6.2. According to a study co-authored by the London School of Hygiene & Tropical Medicine and K.U. Leuven, the mean cost of R&D needed to introduce a new drug into the market was 1.3 billion dollars from 2009 to 2018 (Wouters et al., 2020). Dividing the amount of R&D loss by this cost, we estimate that the shortage would potentially generate a loss of 24.6 drugs in 2019. There were 48 drugs introduced in 2019. Therefore, the percentage of drug loss would have been about 51.25% in 2019.

In Figure 10, the modeled demand under price control is (1-51.25%) times the actual demand. Now we integrate between the uncontrolled price and the uncontrolled demand, and integrate between the controlled price and the controlled demand. The difference between them represents the net consumer surplus loss due to price control.

Our model suggests that if the U.S. government implemented a pharmaceutical price regulation starting from 1984 to 2019, we would expect the drug loss in 2019 to produce a net loss in consumer surplus of about 0.1849 dollars in 2020 (real pharmaceutical expenses per capita), which converts to about 191 million dollars in nominal pharmaceutical spending.

7. Limitation and the Next Step

The model above assumes that any future decrease in demand is proportional to the number of lost drugs under price control. The more ambitious idea is to apply the idea of the price index designed by Robert Feenstra, 2014, to measure the value of the drug category in the current year. The major contribution of Feenstra's price index considers the variety of new goods, which fits into our concern about drug innovations. With the model, we could better approximate the value of the drug category with loss of varieties, i.e., loss of new drug R&D due to price regulations can be demonstrated by a decrease in the valuation of the drug category in a year. A continuation of this research may include building more comprehensive dynamic models without the proportion assumption to simplify the analysis progress. For example, applying the idea of Robert Feenstra, we can incorporate the product varieties into a utility function, i.e., the aggregated utility of drugs in the market is

$$\sum_{i=1}^{N_t} U(c_i) \qquad (13)$$

Where not only does the utility of each drug matter, but so does the number of drug types. By creating a model that uses the drug numbers as a parameter, we do not need first to estimate the benefits of a drug price control policy and then calculate its potential harm. The drug numbers

can be passed as an input to the model, which directly quantifies estimated welfare. Because this model will also consider price control, the ultimate output allows us to discuss the policy's impact comprehensively. Another idea is to analyze the mortality rate or other measurements of a country's health condition. Again, building and improving a model that connects price policy to social welfare will be the main focus of the next period of this research.

We encourage researchers to discuss drug and social welfare based on the pharmaceutical patent. Because R&D intensity serves as a measure of investments in drug development, drug patents could be a significant indicator of the research outcome. Patent data can be accessed via the European Patent Office website. Potential obstacles to data processing may happen when a company's patents are registered using different name versions of the firm. While we can overcome the pre-processing challenges of the patent data, it is worth discussing and comparing the patent registration pattern with the research and development expenditure data.

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