Why Does Price Control Policies Do Not Apply in the US Pharmaceutical Market, as Opposed to Many EU Markets?

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Abstract

The pharmaceutical market is always the most profitable industry in the US, and private companies dominate the healthcare market. The US ranks the highest globally on healthcare spending due to the high price of healthcare. As a result, American citizens face increased difficulties affording basic health insurance. The main reason behind this problem is that the US does not apply price control policies. Compared with the US, most EU countries' pharmaceutical markets have government interventions, such as price control policies; hence EU countries have a much lower amount of healthcare spending.

This article describes the history of pharmaceutical markets in the US and EU and analyzes why the US does not apply price control policies. This article also critically elaborates on the positive and negative implications of why the US does not apply price control policies. Although there are many benefits to the US does not apply price control policies in the pharmaceutical market, in this research, the disadvantages of applying price control policies outweigh the benefits. As the US does not apply price control policies, this would lead to a higher profit for pharmaceutical companies. In addition, this likely incentivizes pharmaceutical companies to dedicate more funds to research and development. In the long term, without price control policies in the US could increase human longevity.

Keywords: price control policy, US pharmaceutical markets, EU pharmaceutical markets, health policy, healthcare spending

1. Introduction

For more than a century of continuing parallel development between public and private health insurance in the US, there has been no cost control nor attempts to seek to maximize redistribution through universal coverage; this makes the US system an exception among other developed countries (Daemmrich, 2013). The US pharmaceutical market operates largely without price controls, meaning that drug manufacturers can set and stretch the prices of their products at whatever level they believe the market will bear to the maximum extent (Kyle, 2007). This could lead to high prices for some medications, particularly those in high demand or with no other substitutes. In contrast, many European Union (EU) countries have implemented price control policies for pharmaceuticals, direct price controls or permutations of direct price controls (Vogel, 2004).

Before further elaborating on this topic, I will first define the concept of price control policy. Health care price control policy is a law legislated by the government that aims to ensure that medications are priced at a level that is affordable for both patients and the healthcare system, often by the government negotiating with pharmaceutical companies (Puig-Junoy, 2010). The EU pharmaceutical market is regulated by price controls; thus, drug prices in the EU are generally lower than the US. To understand the difference in the implications between the US and the EU pharmaceutical market, this essay is structured as follows. First, the history of both US and EU pharmaceutical market and price control will be briefly described. Second, the pros and cons of such

implications for both US and the EU pharmaceutical market will be discussed. Last, based on my research, I will express some of my suggestions towards the implications of price control policies for both the US and the EU market.

2. Literature Review

2.1 History: US Pharmaceutical Market

Since the 19th century, the US pharmaceutical market has undergone various gradual transformations, such as the generation of new streams of innovative legislation, policies, and reforms (Daemmrich, 2013).

The history of the US pharmaceutical market is centred around private health insurance starting around the 1930s (Daemmrich & Mohanty, 2014). By 1951, more than 50% of hospital patients held private health insurance. Later, to attract individuals and companies, insurance companies expanded medical coverage such as broadening prescription drugs (Daemmrich & Mohanty, 2014).

The public insurance in the US was originated and introduced after the civil war but failed to gain Congressional approval not until 1930s where public insurance was consolidated by the Veterans Administration by providing medical care to veterans (Daemmrich & Mohanty, 2014; Marmor, 2017). In 1965, President Johnson created Medicare and Medicaid to provide health insurance for poor and old Americans (Marmor, 2017). Since then, the Veterans Administration has become the largest healthcare provider in the entire country (Beste *et al.*, 2017). Later, public health insurance programmes (e.g., Medicare) started to further expanding coverage of pharmaceuticals in 2013, aiming to decrease the coverage gap (Daemmrich & Mohanty, 2014).
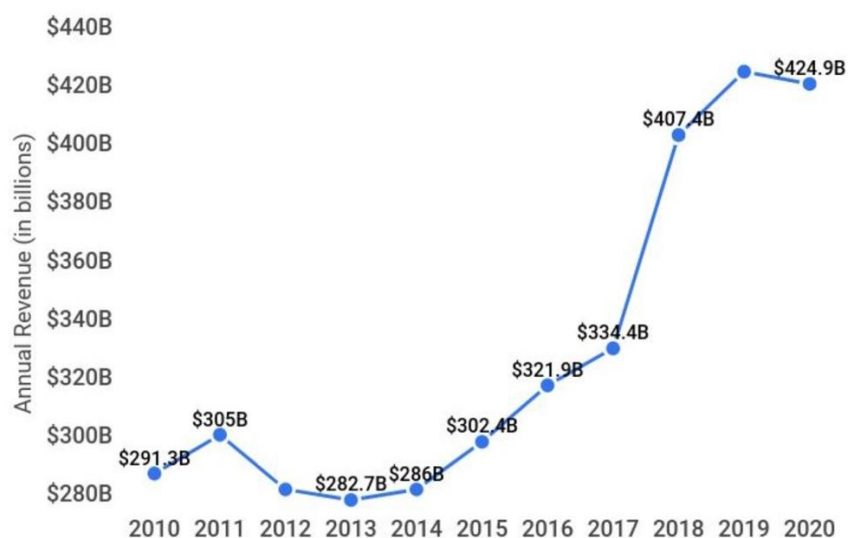

Figure 1. The US pharmaceutical industry revenue between 2010–2020 (Kolmar, 2022)

The private health insurance market currently consists of a complex mix of national, regional, and local insurers. The three healthcare companies with the largest share of the US pharmaceutical market are UnitedHealth Group Inc., Anthem Inc. and Centene Corp (Kolmar, 2022). Shown in Figure 1, the US pharmaceutical market revenue has risen dramatically, reaching around $424.9 billion in 2020.

2.2 History: EU Pharmaceutical Market

2.2.1 European Union Pharmaceutical Market

The present EU pharmaceutical market has a relatively higher health service coverage compared with the rest of the world and is considered as a single pharmaceutical market (Vogler *et al.*, 2011). The journey will be described below.

The history of pharmaceutical regulation in Europe began in the 1960s (Krapohl, 2007). In 1965, EU began to harmonize the legal rules for pharmaceuticals, and Council Directive laid down regulating the proprietary medicinal products (Straub, 2002), meaning for any medicinal product to be placed on the market, the pharmaceutical authority of the particular member state must authorise it. In 1975, the multi-state procedure was established, meaning European member states should recognise each other's marketing authorizations (Jefferys & Jones, 1995). The above transformations taken by individual European member states and the EU as a whole

have signified a monumental first step towards establishing a regulatory network for pharmaceuticals within the EU. The single EU pharmaceutical market was finally formed in 1993 after the creation of the European Medicines Evaluation Agency (Gehring & Krapohl, 2007). However, even though member states are harmonized at many levels, such as pharmaceutical regulations, some member countries still have their own price policies, ranging from free pricing to fixed prices resulting in large price difference between the member states (Heuer *et al.,* 2007). The parallel trade was created to fix the above issue. From 2004 to the present, the EU has applied European Health Insurance Card (EHIC) to enhance of free movement rights stemming from the Single Market (Bartle, 2006). EHIC is issued free of charge and is available to all residents covered by a member state's healthcare scheme (Stan *et al.*, 2021).

2.2.2 European Union Price Control Policy

This section will briefly summarise the background of the price control policies adopted by European Union countries.

Originally, western European countries such as France, Italy and Spain set the price based on the cost (research and development and marketing) of pharmaceutical companies but were later abandoned due to difficulties in estimating the cost (Garattini *et al.,* 2022). The second attempt was trailed by Germany and soon adopted by Netherlands, Italy and Spain, where similar drugs categories were grouped and shared similar prices (Garattini *et al.,* 2022). However, this could lead to pharmaceutical companies reducing the development of new drugs due to the lack of incentives (low profit margin).

The four main effective methods for price control policies in the EU are listed below: fixed pricing, cost-effectiveness pricing, profit controls and reference pricing (Mrazek, 2002). Figure 2 below shows the various price control policies adopted by EU members.

EU country	Free pricing	Fixed pricing	Cost-effectiveness pricing	Profit controls	Reference pricing	Applies to in-patent drugs	Applies to multi-sourced drugs[a]	Applies to OTC[b]
Austria		√				yes	yes	yes
Belgium		√				yes	no	no
Denmark	√		√			yes	no	yes
					√	no	yes	no
Finland		√	√			yes	yes	no
France		√	√			yes	yes	no
Germany	√					yes	no	no
					√	no	yes	yes
Greece		√				yes	yes	yes
Ireland		√	√			yes	yes	no
Italy		√	√			yes	no	no
Luxembourg		√				yes	yes	yes
Netherlands		√			√	yes	yes	no
Portugal		√	√			yes	yes	no
			√			yes	no	no
Spain		√				yes	yes	yes
					√	no	yes	no
Sweden		√	√			yes	yes	yes
					√	no	yes	no

Figure 2. Approaches to the regulation of pharmaceutical prices in EU countries until 2002 (Mrazek, 2002).

Fixed pricing's objective is to fix pharmaceutical prices at an affordable level (for the public health system) but reasonable (for pharmaceutical companies). Priced are generally fixed through negotiation and generally take costs, therapeutic benefits and innovativeness into consideration (Mrazek, 2002). Figure 2 shows that fixed pricing is the most common type of price control policy in the EU and is applied (or has applied)

Cost-effectiveness pricing refers to prices controlled based on an economic evaluation of pharmaceuticals. The economic evaluation will generally assess the cost and benefits of a given therapy compared to some alternatives (Mrazek, 2002). Shown in figure 2, cost-effectiveness pricing method is the second most common approach used by EU countries.

Profit control method will limit the pharmaceutical price by setting a profit limit (for the particular drug) (Mrazek, 2002). However, since this method is only used by the UK and UK is no longer within the EU since 2020, this method will not be further discussed.

Reference pricing sets fixed reimbursement limits for pharmaceuticals assigned to the same group (depending on countries). This method gained increasing attention as it can decrease the price differences between therapeutic alternatives and create a more transparent pharmaceutical market (Giuliani *et al*., 1998).

In summary, the EU does apply price control policies, but there could be slight variations between members. A common EU pharmaceutical pricing strategy is to negotiate directly with pharmaceutical companies. Some relatively smaller countries, such as Austria, Belgium and Luxemburg, attempts to negotiate the drug pricing with pharmaceutical companies as a group to increase their purchasing power (Garattini *et al.,* 2022). Unlike the EU, the UK practices nation-wide insurance coverage, named as the National Health Service (NHS). Thus, the total healthcare spending for UK citizens is the lowest among EU countries.

3. Analysis

3.1 Analysing the US Pharmaceutical Market

The pharmaceutical market in the US is an exception among other developed countries because they developed parallel public and private insurance without controlling costs or seeking to maximize redistribution (Daemmrich, 2013). Research by Daemmrich (2013) suggested that the US using market forces to operate their pharmaceutical market can result in both advantages and disadvantages. The first advantage is that no price control policy would attract more capital investments into the US pharmaceutical market. This could lead to high profits due to increased funds. Furthermore, increased profits, more funds could be allocated for biomedical research for research and development, thus resulting in medical innovations. This has led to medical technological advancement in the US and the fact that the US has the highest level of cancer survival could prove the point (Daemmrich, 2013).

For the disadvantages, first, the average US family spending on healthcare (insurance, patient care) is around 60% more than in other developed countries. It accounts for around 17% of the US GDP (Daemmrich, 2013). This extremely high spending is a high burden, and even Americans with health insurance can find it challenging to afford it. This could lead to a relatively high infant mortality rate. The second disadvantage is that high healthcare spending could result in high medical debts; resulting in over 60% of US family bankruptcies in 2007 (Daemmrich, 2013).

Leary (1994a) suggested that the reason why the US did not apply the price control policy back in the days is simply because price control policy is implying a socialistic approach which is conflicting with the current American free market economy. Daemmrich (2013) suggested that the main reasons why the present US failed to apply price control policy is because the power of entrenched private interests, such as pharmaceutical companies and a wide range of public objections to price controls on prescription drugs or other healthcare services.

3.2 Analysing Price Control Policy in European Union

The EU pharmaceutical market applying price control policies can also have both advantages and disadvantages. For the advantages, the EU applying a price control policy can effectively reduce public expenditure on pharmaceutical products (Ess *et al.*, 2003). The EU expenditures on pharmaceutical products have increased dramatically as a proportion of the total health expenditure in the past 30 years. Therefore, controlling medical expenditure has been the primary issue for the EU since 1998. At present, due to the implementation of a price control policy, the EU has successfully managed the expenditure on pharmaceutical products. The second advantage is that the EU has guaranteed that most of the provision of quality healthcare are at an affordable price, which is also the objectives in all European countries (Ess *et al.*, 2003).

For the first disadvantage, Danzon et al. (2006) suggested that price control policies usually delay the launching of new drugs, which could negatively impact public health. Through a parallel trade model, a low-price ceiling for drugs (forced pharmaceutical companies to sell at a lower price) in one EU member's market may affect other EU member's markets. Thus, a rational pharmaceutical companies will choose a longer delay or not to launch rather than accepting a relatively low price (Danzon *et al.*, 2006). Research by Giaccotto et al. (2005) has estimated that drug price control might result in a decrease for up to more than 360 new drugs from launching within a 30-year period. This is equivalent to almost a decrease of one third of all potential new drugs from launching. Lichtenberg (2005) studied data from all the drugs introduced in, and diseases borne by people in, 52 countries during the period 1982–2001 and discovered new drug launches have a significantly positive health effect (an increase of 0.56 years of average annual life expectancy). As price control policies could decrease the launching of new drugs, it caused a negative influence on the welfare implications. Second, price control policies may promote perverse outcomes in many cases, such as physician budgets. Physician budgets is limiting the number of prescriptions for physicians in a certain period. Once physicians exceed the certain limit, they face penalties. For instance, in Germany, to find a particular drug, some patients need to seek a physician who has not yet exceeded their annual prescription limit (Schwermann *et al.*, 2003). Physician budgets aim to reduce prescription expenditure but may lead to an increase in spending in other areas of healthcare and could lead to a reduction in new drug research (Comanor, 1986). In simple, savings would come at the expense of decreasing pharmaceutical innovations (Daemmrich, 2013). The following sections will discuss the positive and negative

implications of the US not applying price control policies.

4. Discussions

4.1 The Positive Implications: US Not Applying Price Control Policies in the Pharmaceutical Market

In the above Literature Review and Analysis section, Daemmrich (2013) and Leary (1994) both agree that there are two main advantages for the US pharmaceutical market to operate without price control policies. First, a relatively higher level of investments will be injected into the pharmaceutical market as pharmaceutical companies are motivated due to a relatively higher potential profit margin and return on investments. Second, as the result of the high initial investment into the US pharmaceutical market, the US has become the world's leader in the field of pharmaceutical technology which would benefit not only the health aspects but also the economy of the country on both micro and macro scales. The rest of this section would focus on some of my perspectives on the advantages of no price controls in the US pharmaceutical market.
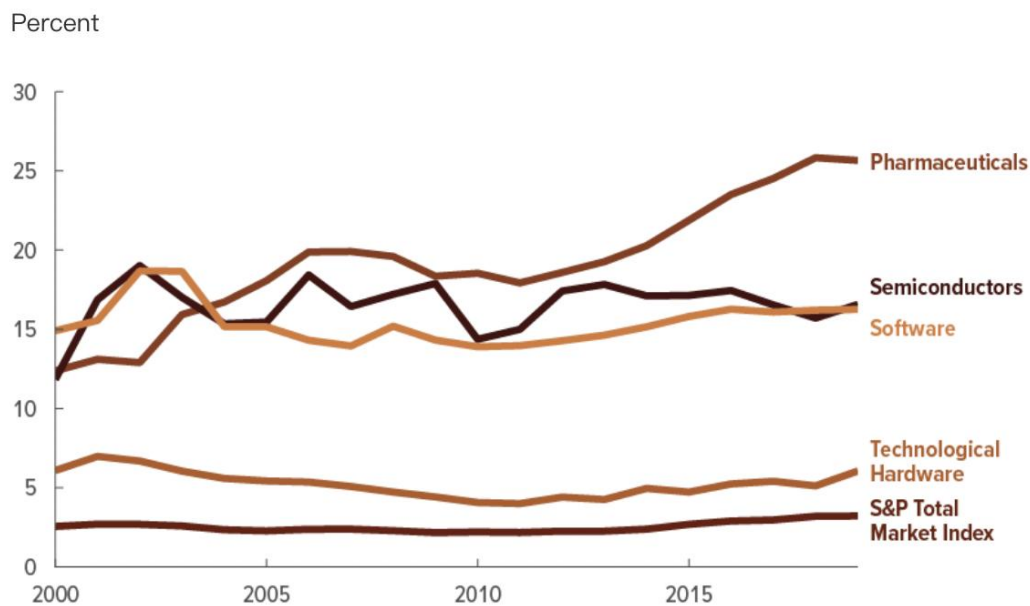

Figure 3. Average R&D Intensities for Publicly Traded US Companies (CBO.gov, 2021).

My first perspective is similar to Daemmrich (2013) and Leary (1994); however, I will back up my view with some data. There will be a higher level of innovation in the US pharmaceutical market due to higher incentives for pharmaceutical companies. As shown in Figure 3, pharmaceutical companies have increased their reinvestment of net revenues into R&D activities, averaging around 19% over the past two decades (2000-2020), which is the highest compared to other research-intensive industries, such as software and semiconductors (average 15%) (CBO.gov, 2021). Vernon (2005) expected a significant decrease in US pharmaceutical companies' profit margins if price controls were implemented in the US market. This would also lead to a decrease in US Research and Development investments by around 23% to 32% (Vernon, 2005). The success rate of average medical trials for pharmaceutical companies is between 12.5% to 34% (Mestre-Ferrandiz *et al.,* 2012). The revenue should fully cover the high upfront costs and risks for pharmaceutical companies once new medicines enter the market. The nature of the free US pharmaceutical market environment has increased the confidence of pharmaceutical companies to conduct such clinical trials and attempts to innovate.
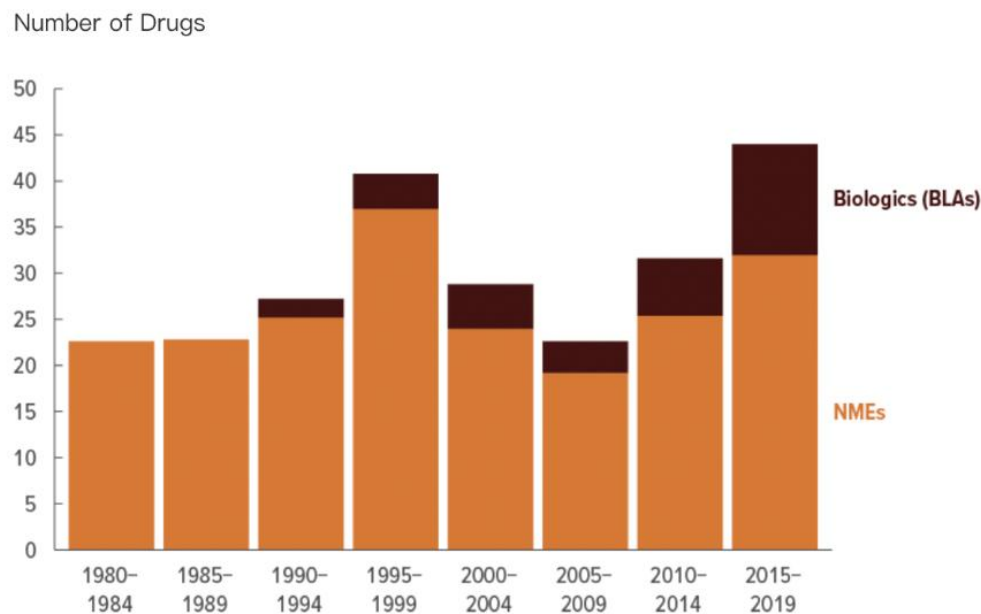
Number of Drugs

Figure 4. US Average Annual Approvals of New Drugs by Food and Drug Administration between 1980–2019 (CBO.gov, 2021).

My second perspective is that high innovation in the pharmaceutical market in the US will facilitate the speed of launching new drugs. As mentioned in the above analysis section, price control policy will delay the launches of new drugs. However, as shown in Figure 4, between 2015 to 2019, the Food and Drug Administration (FDA) received more than double of new drug applications (BLAs) than a decade earlier and the number of drugs (NMEs) is also showing an increasing trend. The increasing innovation of new drugs would likely increase the average longevity of humans in the future (Lichtenberg, 2005).

My third perspective is with the free pricing policy, the US would be able to import global talents into the country (high profits for pharmaceutical companies leading to high salaries). For instance, global talents can apply the US Global Talent visa (Kerr, 2020). In the present knowledge-intensive economy, talents are the most valuable resource, especially in the pharmaceutical industry (Kerr, 2020). Therefore, global talents are able to create a positive loop for the US pharmaceutical market in the following way. Talents lead to medical innovation lead to higher profit lead to attracting more talents. This positive loop will continue and increase as the US pharmaceutical/ healthcare industry is the most profitable sector (Westhealth.org, 2019).

4.2 The Negative Implications: US Not Applying Price Control Policies in the Pharmaceutical Market

In the above Analysis section, Daemmrich (2013) suggest two main drawbacks for the US pharmaceutical market to operate without price control policies. Firstly, health expenditure is exceptionally high, contributing to 17% of the GDP in the US, causing some Americans cannot afford it. Secondly, most bankruptcies in the US are caused by high health debts, which negatively impact the economy of the US. Next, I will discuss the disadvantages from my perspective.

My first perspective is affordability; without a price control policy, medical expenses are extremely high and most people would find it difficult to afford medical treatment. Even people in the US that are covered by health insurances, the cost of medical expenses cannot be fully covered (Daemmrich, 2013). The campaign of Harris Wofford of Pennsylvania for election to the United States Senate said "If criminals have a right to a lawyer, working Americans have a right to a doctor." (Leary, 1994a). I agree with Harris Wofford's statement because it is the right of every human being to be treated when they are ill, demonstrating the fairness and justice of any healthcare system. Society has a moral obligation to achieve health equity to help everyone. Due to free pricing in the US, it is likely that some patients need urgent life-saving medicines, but these medicines are highly unaffordable. For instance, Horizon Therapeutics' Ravicti (used to treat urea cycle disorder) is the second most expensive drug in the US but patients relay on this drug to keep them alive. The drug cost is around $55,341 per month. However, the US average monthly salary is around $4,516, meaning most American patients cannot afford this medicine (Sagonowsky, 2020). In total, the average US patient spending on pharmaceuticals is around $1,026, which is ranked the highest in the world, evidenced by Figure 5.
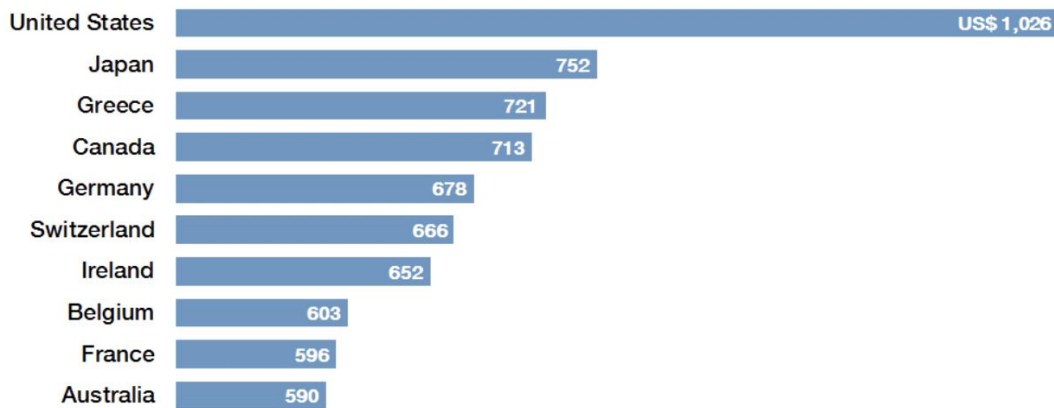
Figure 5. Pharmaceutical spending per capital, US$ in 2013 (Weforum.org, 2015)

My second perspective is that the innovation cost for pharmaceutical companies is generally higher than its return in a price-controlled pharmaceutical market. Lichtenberg (2014) suggests that the value of the reduction in loss days (work, school) and hospital admissions can be attributed to pharmaceutical innovation, which is estimated to be three times the cost of pharmaceutical innovation. For example, clinical trial Phases I-III duration ranges between 61 and 86 months (Mestre-Ferrandiz et al., 2012). However, the success rate is only around 25%. If the newly developed medicines are ineffective, all the medical sources, labour and capital will be wasted. For instance, Light (2022) concluded that for 40 years, 90% of newly launched medicines had had little or no improved medical effects compared with existing medicines. Consequently, due to the low success rate and the fact that 90% of new drugs are showing no significant improvements, the cost of innovation is high, with uncertain returns.

4.3 What Is the Best Choice for the US?

In my opinion, the drawbacks of applying a price control policy in the US outweigh the benefits in the US. Thus, I agree with the current US no price control policy in the pharmaceutical market. Lakdawalla (2008) created a model to understand what would influence the US when price control policy is applied to the pharmaceutical market.
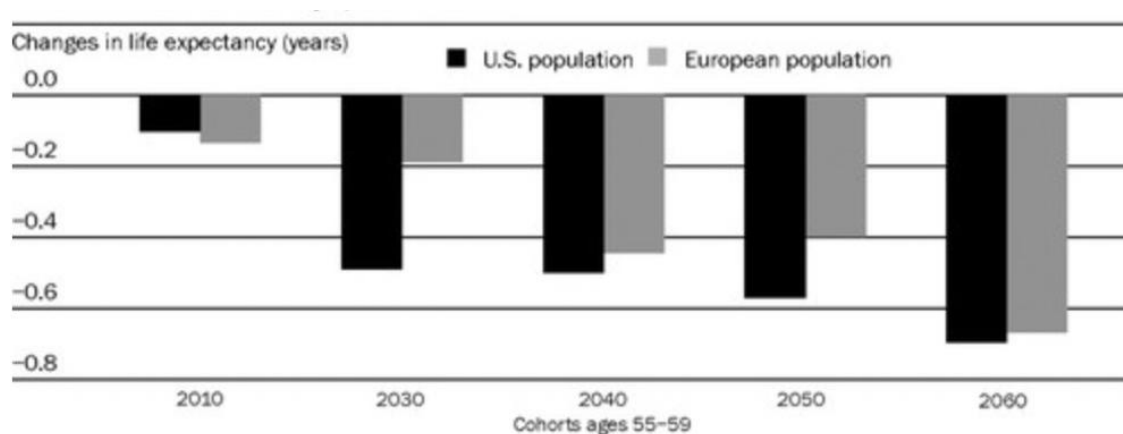

Figure 6. Effect Of US Price Controls on Global Longevity, Ages 55–59 In the US and Europe, 2010–2060
(Lakdawalla, 2008)

As shown in Figure 6, Lakdawalla (2008) concluded that introducing price controls would reduce life expectancy by 1/5 of a year (73 days) for Americans between 55-59 years old in 2010. Furthermore, the model predicts that the decrease in life expectancy will only increase over time. This is because price controls take time, so the longevity effects are more significant for the older groups. In summary, although a price control policy could solve affordability issues in the short term, the policy would negatively influence human longevity in the long term. However, Leary (1994a) encourages the US to apply a price control policy to decrease health

inequalities and control healthcare expenditures. Furthermore, by combining the advantages and the disadvantages of the current US pharmaceutical policy (Daemmrich, 2013; Leary, 1994a), the US government could subsidies patients who cannot afford their bills independently. Overall, I believe the current US policy (no price control) is the ideal scenario as this would make sure pharmaceutical companies have enough motivation to innovate.

5. Conclusion

In the past 20 years, price control policy has been at the centre of a controversial opinion discussion in the US medical field. The main advantages for the US to operate with no price controls will be summarised below. First, without price controls, pharmaceutical companies have high motivation because they can gain a higher profit; as reinvestments occur, more funds would be dedicated to the research and development of new, innovate medicines that could increase human longevity. Additionally, a potential positive loop would occur. The best pharmaceutical companies would attract the best global talents, which lead to even more innovation and profit, thus attracting even more talent. This would benefit the US both within the pharmaceutical sector and the entire US economy. Next, the disadvantages of the US operating with no price controls will be summarised below. Without price control, even Americans with health insurance would be difficult to afford medical treatment and pharmaceuticals due to high prices. Additionally, as the upfront cost for research and development is high with a low clinical trial success rate, pharmaceutical companies are unlikely to innovate new effective drugs. Overall, I believe the US should continue apply the free pricing in the pharmaceutical market to make sure pharmaceutical companies have enough motivation to innovate which would be beneficial in the long term.

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