
UNIVERSITY of PIRAEUS



**DEPARTMENT OF
ECONOMICS**

M.Sc. HEALTH ECONOMICS AND MANAGEMENT

**A COMPARATIVE STUDY OF INSULIN'S PRICING
POLICY IN THE USA AND THE UK**

Gkrinia Meni Maria Elvira

Master Thesis submitted to the Department of Economics of the University of Piraeus
in partial fulfillment of the requirements for the degree of M.Sc. in Health Economics
& Management.

Piraeus, 2022

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**ΠΑΝΕΠΙΣΤΗΜΙΟ
ΠΕΙΡΑΙΩΣ**



**ΤΜΗΜΑ ΟΙΚΟΝΟΜΙΚΗΣ
ΕΠΙΣΤΗΜΗΣ**

ΠΜΣ «Οικονομικά και Διοίκηση της Υγείας»

**ΣΥΓΚΡΙΤΙΚΗ ΑΝΑΛΥΣΗ ΤΗΣ ΠΟΛΙΤΙΚΗΣ
ΚΟΣΤΟΛΟΓΗΣΗΣ ΤΗΣ ΙΝΣΟΥΛΙΝΗΣ ΣΤΙΣ ΗΠΑ ΚΑΙ
ΤΟ ΗΝΩΜΕΝΟ ΒΑΣΙΛΕΙΟ**

Γκρίνια Μένη Μαρία Ελβίρα

Διπλωματική Εργασία υποβληθείσα στο Τμήμα Οικονομικής Επιστήμης του
Πανεπιστημίου Πειραιώς για την απόκτηση Μεταπτυχιακού Διπλώματος Ειδίκευσης
στα Οικονομικά και Διοίκηση της Υγείας.

Πειραιάς, Ελλάδα, 2022

To Martin.
To Snowball.

A Comparative Study of Insulin's Pricing Policy in the USA and the UK

Keywords: insulin, pharmaceutical policy, pricing, United States of America, United Kingdom, diabetes

Abstract

The paper at hand analyses the pricing policy of insulin in the USA and the United Kingdom, as well as the factors that shape it. It was also deemed meaningful to delve into the epidemiological profile of diabetes in the countries under investigation, in order to draw conclusions for the policy of each country. The main goal of the paper is to find the deeper causes of the pricing policy of insulin in the USA and the UK. Apart from that, another important aspect of analysis are the repercussions or consequences that a sufficient or insufficient policy may bear, in order to highlight its importance for the society's prosperity. Through the analysis, we concluded that it is a wide range of historical, political, and economic factors that affects the pharmaceutical pricing policy in each country.

Συγκριτική Ανάλυση της Πολιτικής Κοστολόγησης της Ινσουλίνης στις ΗΠΑ και το Ηνωμένο Βασίλειο

Σημαντικοί όροι: ινσουλίνη, φαρμακευτική πολιτική, κοστολόγηση, Ηνωμένες Πολιτείες Αμερικής, Ηνωμένο Βασίλειο, διαβήτης

Περίληψη

Η παρούσα εργασία αναλύει την πολιτική κοστολόγησης της ινσουλίνης στις ΗΠΑ και το Ηνωμένο Βασίλειο, καθώς και τους παράγοντες που τη διαμορφώνουν. Κρίθηκε μεταξύ άλλων σκόπιμο να αναλυθεί και το επιδημιολογικό προφίλ του διαβήτη σε αυτές τις δύο χώρες, ώστε να εξαχθούν συμπεράσματα για την πολιτική της κάθε χώρας. Βασικός στόχος της εργασίας είναι να αναδείξει τα βαθύτερα αίτια που διαμορφώνουν την τιμή της ινσουλίνης στις ΗΠΑ και το Ηνωμένο Βασίλειο. Πέρα από αυτό, βασικό ζήτημα ανάλυσης είναι και οι επιπτώσεις ή συνέπειες που έχει μια ανεπαρκής ή επαρκής πολιτική κοστολόγησης ινσουλίνης, ώστε να αναδειχθεί η σημασία ύπαρξης τους για την ευημερία του κοινωνικού ιστού. Μέσα από την ανάλυση, καταλήξαμε ότι είναι ένα ολόκληρο φάσμα ιστορικών, πολιτικών, και κοινωνικοοικονομικών παραγόντων που επηρεάζει την πολιτική κοστολόγησης φαρμάκων σε κάθε χώρα.

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INTRODUCTION

In 1963 Kenneth Arrow published an article that is credited as the introduction of Health Economics as a discipline (1). Health policies already existed, but it was then that the ideas of efficiency, effectiveness, and value, were established as of utmost importance (2). Likewise, Pharmacoeconomics, which are unofficially a branch of Health Economics, use ‘cost-benefit, cost-effectiveness, cost-minimization, cost-of-illness and cost-utility analyses to compare pharmaceutical products’ (3). Health Economics and Health Policy are intertwined and affect each other continuously. In the paper at hand, there is no interest in assessing the cost-effectiveness or efficiency of a pharmaceutical product. Contrariwise, we will assess the policies around the distribution and availability of a well-known product: insulin.

Insulin is the main pharmaceutical product administered to people diagnosed with diabetes. Diabetes is a chronic health condition that is divided in two main types: type 1 and type 2 -we will not include gestational diabetes in the analysis-. Type 1 diabetes is affected by genes and usually shows up during the early life of the individual (4), while type 2 diabetes is affected by one’s lifestyle and it can develop over time, especially after 40 years of age (5). The symptoms of diabetes vary greatly, including nausea, vomiting, blurry vision, proneness to infections, a numbing feeling at one’s hands or feet etc. That said, what we should turn our focus on is that the symptoms can be quite serious, to the point where the individual’s daily life is hindered, and they can be deprived of the possibility of a normal life or equal employment opportunities (6).

That said, diabetes can even lead to death in some cases, particularly when the person suffers from other diseases as well, or when diabetes is left untreated (7). According to data published by the World Health Organisation, diabetes was the ninth leading cause of death in 2019 on a global level. Furthermore, diabetes bears a heavy disease burden, both financially and socially: in 2020 alone, direct health expenditures on diabetes reached \$760 billion globally, while that number is expected to reach \$825 billion by 2030, excluding all the indirect costs of the disease.

Diabetes -either type- has no known cure. In the case of diabetes type 2, positive progress – “reversal”- can be made by improving one’s diet (8). In fact, the most prominent risk factors for the development of diabetes type 2 are obesity and a

sedative lifestyle (9). Insulin works by minimizing the symptoms of diabetes, thus enabling the individual to lead a normal day to day life. Therefore, insulin has become an inextricable part of a diabetic person's life since its invention in 1921. The needs of each diabetic in insulin doses varies, depending on age, type of diabetes, volume of symptoms experienced, and their health in general. Thusly, it seems essential for countries to have efficient pharmaceutical policies about diabetes to protect societies from such a serious illness.

There are many different types of insulin, which can be categorized according to how quickly the drug acts, how long it takes to achieve maximum impact, how long it lasts, its concentration, and whether it is injected under the skin or administered intravenously -injection of insulin can take place with a syringe and needle, an insulin pump, or an insulin delivery pen- (10). The main type of categorization is by onset, and insulin is divided in three types of insulin: (a) fast-acting insulin, which is used to correct high blood sugars during meals. It does not last for long but has an onset of action of maximum 1 hour. Regular Human Insulin and Rapid Acting Insulin Analogs fall under this category. (b) intermediate-acting insulin, which is used to correct blood sugar levels overnight or while fasting has a relatively longer duration and an onset between 1 and 2 hours. Neutral Protamine Hagedorn Human Insulin and Pre-Mixed Insulin fall under this category. And (c), long-acting insulin, which lasts for 12-24 hours and has an onset of about 2 hours. It is also used to control the levels of blood sugar overnight or between meals. Longacting insulin analogs fall under this category.

The countries of interest are the United States of America and the United Kingdom. This choice was guided by several motives. Firstly, they are both capitalistic-built economies, where the market is left free to regulate itself and competition is unlimited. Secondly, they both went through a transition to neoliberalism in the 1980's, guided by Ronald Reagan and Margaret Thatcher respectively. That transition led to countries turning away from social welfare programmes and focusing on private initiative and a self-regulated market. Thirdly, they have somewhat similar diabetes percentages: 7% of the UK population and 10% of the US population live with diabetes. Lastly, while they share the aforementioned, their pharmaceutical policies - and health policies in general- are completely different.

Our aim is twofold: first, to analyse which are the factors that affect the configuration of each policy on insulin. Second, to examine the consequences of each policy on the fabric of society. To achieve this, an extensive systematic review of the literature will

be conducted in order for valid conclusions to be drawn. Specifically, each aspect of the issue will firstly be analysed for each country separately, followed by a section where the results will be synthesized to allow comparisons.

CHAPTER 1

THE PROFILE OF DIABETES IN THE COUNTRIES OF INTEREST

In the following sections we will delve into the health profile of the United States and the United Kingdom, with precision on diabetes and its risk factors, and the socioeconomic factors that seem to affect its prevalence in the population.

1.1: The Epidemiological Profile of Diabetes in the United States

The subject and aims of this paper guide the research away from mere medical information, but towards the socio-demographic data regarding diabetes, which are the disease's trends, and which social groups are affected by it. The reason behind the inclusion of this chapter is that the higher the prevalence of diabetes in a country, the more important it is to have an effective insulin pricing and distributing policy.

According to the National Diabetes Statistics Report organized by the Centers for Disease Control and Prevention -hereby, CDC- in 2020, the prevalence of diabetes in the USA was at 10.5% of the national population, thus 34.2 million American citizens had been diagnosed with either type of diabetes, while about 1.5 million Americans are diagnosed with diabetes every year. Out of those 34.2 million people, 34.1 million were adults. Among the 34.2 million diabetics, 26.9 million had been diagnosed, while 7.3 million satisfied the laboratory criteria, but had not been diagnosed by a physician as diabetics (11). As is for any disease, diabetes prevalence ranges across different ages, genders, races etc. Certainly, the correlations that are highlighted in the following paragraphs do not infer causation between the various factors and diabetes. It is not, however, this paper's goal to examine these relationships, but to take note of them and use them later in the analysis.

Firstly, the prevalence of diabetes in the United States seems to gradually increase with age. The prevalence among people aged 65 years and older is the highest, precisely at 26.8% -including both diagnosed and undiagnosed cases-. This means that older people, whose health is already at risk by a multitude of issues, are also at a higher risk to suffer from the serious symptoms of diabetes as well. Regarding gender, there does not seem to be a correlation between it and diabetes, with the two genders having similar percentages: in particular, 12% of women and 14% of men suffer from

diabetes in the USA. The factor that seems to affect the prevalence of diabetes the most is race. The paper at hand cannot and will not dive in the genetic details that may or may not hide between this correlation, but it will instead focus on the socio-economic issues around it. Precisely, and after dividing the population in the sub-groups of ‘Whites-non-Hispanic’, ‘Blacks-non-Hispanic’, ‘Asians-non-Hispanic’, and ‘Hispanics’, we can observe that the Whites depict the lowest prevalence, while the Blacks depict the highest. Before we are led to conclusions, it would be useful to include the prevalence of pre-diabetes in the same sub-groups. Firstly, pre-diabetes is the situation during which the person has such blood sugar levels and laboratory data, which on the one hand are not high enough to categorise said person as a diabetic, but on the other hand are considered a risk factor for the development of diabetes (12). It is worth noting that 88 million American citizens are in the ‘pre-diabetes’ category currently, or in other words, they are at risk of developing diabetes type 2.

Table 1.1 Prevalence of Diabetes Among Different Ethnic Groups in the USA

Ethnic Groups	Prevalence of Diabetes
Whites-non-Hispanic	11.9%
Blacks-non-Hispanic	16.9%
Asians-non-Hispanic	14.9%
Hispanics	14.7%

Table 1.2 Prevalence of Pre-Diabetes Among Different Ethnic Groups in the USA

Ethnic Groups	Prevalence of Pre-diabetes
Whites-non-Hispanic	15.8%
Blacks-non-Hispanic	16.8%
Asians-non-Hispanic	9.8%
Hispanics	10.8%

What is first and foremost highlighted by Tables 1.1 and 1.2 above, is the role socioeconomic status plays in one’s health. The most common way to avoid the development of pre-diabetes to diabetes type 2, is by modifying one’s diet and

lifestyle for the better, thus avoiding highly processed foods, food products high on sugar such as beverages, and adopting a healthy schedule of physical exercise (13). Here lies the issue of the socioeconomic status factors. There is a 15.8% prevalence of pre-diabetes in the 'Whites-Non-Hispanic' ethnic group and a 11.9% prevalence of diabetes. There is a substantial gap between the two percentages and the reasons behind it will be thoroughly analysed in the following paragraph. Looking at the respective prevalence in the other ethnic groups, the situation seems entirely different. The prevalence of pre-diabetes among the Blacks is at 16.8%, while diabetes has a 16.9% prevalence; the percentage increased. Looking into the percentages regarding the Hispanics and the Asians, the difference between them and the Whites are highlighted even more.

So, what does everything above mean? It is supported by concrete evidence, that socioeconomic factors are closely correlated to diabetes, as well as with any other disease -it was, after all, the Ottawa Charter that declared that socioeconomic status is of utmost importance for the health of the individual- (14). And in this case, correlation most probably infers causation. To be more precise, the development of diabetes has an inversely proportional relationship with the education level and income of each person (15), and the same goes for the risk of death from diabetes (16). Precisely, people with a low or mediocre education level are at a two times bigger risk of developing diabetes, compared to people who have a high education level (17). This is easily explained by two points: first, an individual with a high education level has probably a better knowledge about diabetes and the risks of an unhealthy diet. Second, the higher the education level of a person, the higher their chances of having an adequate income. Similarly, households with a lower income level are at a higher risk of their members developing diabetes, while people with a lower income are at a higher risk of developing diabetes type 2, the development of which is linked to the individual's lifestyle (18). Regarding diabetes type 1, which is considered genetic, and it manifests very early in life, there is a strong possibility that it is also related to socioeconomic factors. Maternal health has been proven to be an important indicator for the health of the fetus, as many diseases are linked to the ante-natal and peri-natal period of life (19).

Going back to the observations we made about the race factor, we should note that race is closely linked to the income level of each individual level in the USA (20). To analyse this thoroughly, we will investigate each ethnic group and their average

income. Asians had the biggest income level in 2019, with an average of 98,174\$, Whites had an average of 76,075\$, followed by Hispanics, who had an average income of 56,113\$, and lastly, come the Blacks, with an average of 45,438\$. In a few words, there is a huge wage gap between the different ethnic groups. The numbers match the diabetes prevalence percentages almost entirely, showcasing the importance of income for one's health. The inequality in income directly leads to an inequality in quality of life and the ability of each person to protect their own health. Those who belong in the lower levels of income, considering that junk food costs less than healthy home-cooked meals in the USA, quite literally cannot afford to protect themselves from developing diabetes. That is also intensified by the practically non-existent food policies in the USA, except for the healthy food programme at schools Michelle Obama had established, before it was targeted by Donald Trump during his presidency (21). This creates a vicious circle, since those more at risk end up developing diabetes, and are burdened with the costs it bears.

Obesity is a risk factor of utmost importance for diabetes. In the USA, 42.5% of adults are obese, a number that rises significantly each year. Similarly, the percentage of those who suffer from severe obesity has risen to 9.2% from 4.7% during the last 20 years (22). Non-Hispanic Black adults have the highest prevalence of obesity at 49.6%, followed by Hispanic adults at 44.8%, consequently followed by White adults at 42.2%. 14.4% of children in the USA are affected by obesity, equaling a prevalence of 19.3% (23). Again, obesity seems to follow the socioeconomic status trends. Regarding physical activity level, which is considered a protective factor, about half of the adult population -53.3%- meet the physical activity guidelines for aerobic exercise (24).

As a last part of this section, it is worth including a brief analysis of the trends of diabetes during the recent decades, and what the mathematical models inform about the future. Between 1958, when CDC started releasing its yearly reports, and 2015, the prevalence of diabetes in the USA has an exponential growth, which is depicted in Table 1.3 below (25).

Table 1.3 Exponential Growth of Diabetes Prevalence in the USA 1958-2020

Year	Diagnosed Diabetics Living in the USA
1958	1.58 million
1968	3.18 million
1978	5.19 million
1988	6.16 million
1998	10.48 million
2008	18.81 million
2015	23.35 million
2020	26.9 million

A multitude of studies have been conducted to predict what the future of diabetes in the USA looks like, and it seems bleak. According to the disease models, in 2030 there will be 39.7 million diabetic adults, out of whom 21 million will be aged 65 years and older. The models suggest that in 2060, 60 million diabetics will be living in the USA, out of whom the 35 million will be over 65 years old (26). This situation highlights the necessity of an effective and fair insulin pricing and distributing policy. Have the USA been up to the task so far?

1.2 The Epidemiological Profile of Diabetes in the United Kingdom

According to the DiABETES UK organisation, the number of UK citizens living with diabetes has risen to 4.8 million in 2020, from 3.9 million in 2019 (27). That means that in 2020 there was a diabetes prevalence of 6%. 90% of the adults who suffer from diabetes in the UK, have diabetes type 2 (28). While that prevalence is relatively low, the increase of 1 million during only one year is substantial. It is worth noting that the calculations are somewhat different between each organisation or health institution. Specifically, PubMed estimated the diabetes' prevalence in the UK at 8% (29). Approximately 1 million people have undiagnosed diabetes type 2, which means that they satisfy the laboratory criteria -their glucose levels satisfy the established criteria- but have not been diagnosed by a physician. Lastly, 1 in 3 of the UK adult population fall into the pre-diabetes category, meaning that their glucose levels are above normal

but not high enough to be categorised / diagnosed as diabetics (30).

Let us look at those numbers in more detail, regarding age, gender, ethnic group, and income. Firstly, it is estimated that 40,000 children suffered from diabetes in the UK in 2020, up from 31,500 in 2015; a substantial rise, meaning that about 3,000 children are diagnosed every year (31). In contrary to adults, where 90% of diabetes cases are type 2, children primarily suffer from diabetes type 1 at the same percentage: 90%. That is explained by the genetic character of diabetes type 1, which primarily manifests during early childhood, while diabetes type 2 is linked to one's diet and lifestyle, manifesting later in adulthood. To be more analytic, out of those people who suffer from type 2 diabetes, only 4.1% are under 40 years old. The percentage skyrockets to 43.1% for people aged between 40 and 64 years. A slightly smaller percentage refers to those aged between 65 and 79 years, and lastly, only 15.1% of diabetics are over 80 years old (32). Regarding gender, there is a mere difference between men and women: 56% of diabetics are men and 44% are women (33).

Ethnic minorities are at a very vulnerable state. They show both higher prevalence of diabetes and are at a higher risk of developing the disease. The ethnic groups of South Asian and black African / Caribbean descent have a higher risk of developing type 2 diabetes, as well as its related adverse outcomes: in fact, the risk is almost 5 times higher than for the white ethnic group (34). To make matters worse, diabetes type 2 has an earlier onset of about 10 years among the ethnic minority groups, compared to the white British population (35). Specifically, while only about 5% of white people under the age of 40 suffer from type 2 diabetes, African / Caribbean communities have a percentage of 20% in under-4-year-olds, and for South Asian minorities it is almost 30%. In following Table 1.4 we will depict the different prevalence percentages among the different ethnic groups in the UK.

Table 1.4 Prevalence of Diabetes Among Different Ethnic Groups in the UK

Ethnic Group	Prevalence of Diabetes
White	5.04%
Asian	7.69%
Black	5.58%
Mixed / Other group	3.42%

Thus, there is a sufficient difference between the different ethnic groups. Even ‘after adjusting for differences in age group, sex, and social deprivation, all minority ethnic groups were more likely to have a diagnosis of type 2 diabetes compared with the White group’ (36). A lower income is also linked with a higher risk of developing diabetes: men belonging in the lowest quintile of income are 2.3 times more likely to develop diabetes compared to those in the highest quintile. Women in the lowest quintile of income are 1.6 more likely to develop the disease. That said, it is worth noting that households comprised of ethnicities of Pakistani, Indian, and White ethnicities tend to be in the higher quintile of income. Deprivation has the same relationship with diabetes: men in the highest deprivation quintile had a 1.8 times increased risk, while women had a 3.1 times increased risk. Those risk factors are directly linked to diabetes type 2, not type 1, since the former is connected to one’s lifestyle. A gym membership, a visit to a dietician, healthy home-cooked meals are costly and time-consuming. If an individual works two different jobs to make ends meet, it is highly unlikely that they will have the energy, time, or funds to adopt a healthier lifestyle. Furthermore, people with a higher educational level have a much lower risk of developing diabetes. That is essentially the role socioeconomic status plays in the development of diabetes type 2. That said, DNA methylation is also linked to the development of risk factors for diabetes type 2 in an individual, meaning that maternal health during the gestation period and the very early life of the individual is also important for their health (37). However, studies on this matter are relatively new, and few meta-analyses have been conducted, so it is early to draw conclusions from this alone.

Before moving on to future projections about diabetes in the UK, we will look into how much the UK population is protected from the diabetes risk factors. The most prominent risk factor is obesity, accounting for over 80% of diabetes cases. 57% of women in the UK are overweight or obese, while men sit at 67% (38). Regarding children, 26% of boys and 29% of girls are overweight or obese. 67.5% of black adults are overweight or obese in the UK, while white British adults are also very likely to be overweight or obese, with a percentage of 63.7%. The aforementioned is rather discouraging, since the UK has a very strict policy regarding drinks high in sugar etc., with the most prominent measure being the Traffic Light Policy, concluding that even in a country with a strict food policy, more needs to be done. The basic protective factor from developing diabetes is physical activity. Among the

citizens of Great Britain, only 29% of women and 39% of men meet the recommended physical activity levels (39).

According to the Diabetes Research and Wellness Foundation, diagnoses of diabetes have more than trebled during the last 20 years, with type 2 diabetes accounting for 90% of the cases. Specifically, the number of people in the UK living with diabetes has risen from 700,000 in 1993 to 2.8 million in 2014, and to 4.8 million in 2020. That increase is striking. Future projections are not encouraging either. According to the models, 5.5 million people will be living with diabetes in the UK in 2030, while more people than ever before are at risk of developing diabetes (40).

1.3 Comparative Conclusions Regarding the Epidemiological Profile of the USA and the UK

In this section we will synthesise the information presented in the previous two sections in order to come to credible conclusions. The USA have a considerably higher prevalence of diabetes, at 10.5% compared to 6% in the UK. However, the annual increase in diabetics is much higher in the UK, considering the much smaller population. More thoroughly, in both countries an increase of about 1 million diabetics is noted every year. In USA, with a population of about 300 million, that is proportionally much less than in the UK, which has a population of about 67 million. Furthermore, in the UK a much bigger part of the population -1 out of 3 adults – belong in the pre-diabetes category (41).

The two countries have a lot in common regarding the groups that are affected by diabetes. In both the USA and the UK, the prevalence of diabetes is increased proportionally with age, with most of diabetics being between 40 and 80 years old. Consequently, both countries show similar prevalence percentages for men and women, with the numbers being very close between the two genders. Likewise, and unfortunately, in both countries the ethnic minorities are at a more vulnerable state than the white population. There are internal differences between the numbers, for example, the ethnic group with the highest prevalence in the USA are Blacks – Non-Hispanics, whereas in the UK the Asians have the highest prevalence of diabetes.

Socioeconomic status plays a predominant role in the shape of the epidemiological profile of both countries as well. Firstly, the lower the income of an individual, the higher their chances are of developing diabetes. Secondly, as we move down on

educational levels, the chances of someone being diabetic become higher. This highlights the social-ecological model of health, moving away from the notion that one's health is merely a biological result, but on the contrary, it is an amalgamation of factors and different sciences.

The countries are differentiated by their nutrition policies. The USA have made a brand of themselves as the country with huge soft-drink cups, candy stores everywhere etc. And the situation sadly is as such, but not really something to be proud of. Nutrition policies are essentially non-existent, and industries are left free to use as much sugar as they please in the drinks that are favorable to both children and adults (42). The policies that do exist are only state-wide in some cases, or they are not practically implemented. The Obama Administration tried to turn a page on this matter, establishing a programme that required schools to offer only healthy meals to children, but it was scrapped by the Trump Administration. The UK, however, has had a very strong stance *vis-à-vis* its nutrition policies, constituting both recommendations as well as fiscal measures. The 'Eatwell Guide' is such a recommendation policy, meaning that citizens can be easily informed about what a healthy diet should consist of (43). There is a multitude of fiscal measures the UK government has taken, with the 'Traffic Light Labelling System' probably being the most known (44). It forced companies to include a label on each of their products, showing how much saturated fat and sugar they contain. Despite all these policies, the UK has an obesity prevalence similar to the USA, perhaps meaning that more strict and efficient measures should be taken.

Lastly, future projections are bleak for both countries, which further intensifies the need for action. That said, the biggest difference between the two countries is their policy regarding the pricing of insulin, as will be analysed in the next chapters.

CHAPTER 2

THE PRICING POLICY OF INSULIN IN THE USA AND THE UK BETWEEN 1980 AND 2000

Before analysing how the prices of insulin have been shaped today, it was deemed necessary to include the trajectories followed by the two countries of interest between 1980 and 2000, two decades when neoliberalism and the ideas of the free market ruled the economies around the globe.

2.1 The Pricing of Insulin in the USA (1980 – 2000)

The 1970's were an extremely challenging decade for the American society: the Vietnam War, tiredness from years of Cold War, the economic crisis of 1974 and the rising crime rates destroyed the idealistic dreams of the previous years and turned Jimmy Carter into a one-term president. Enter Ronald Reagan. The welfare policies and the regulation of the market were thought of as responsible for the economic crisis of the 70's. The New Right supported unregulated market and competition and limited spending on health policies – and social policies in general-. Worldwide, the trend was to roll back welfare policies, except for maybe in Scandinavia, where the welfare state was embedded strongly in the fabric of society.

Reagan, a carrier and symbol of neoliberalism and the New Right, surprisingly was friendly towards the idea of universal health. However, he introduced such strict budget cuts that it is difficult to believe he was pro- universal health after all. Indeed, he was positive towards the elderly having coverage in case they need it, but he opposed mandatory health coverage, because of the high economic cost (45). In his first years in office, he slashed Medicaid spending by 18% and the Health and Health Services Department's budget by 25%, leading to several welfare and health programmes to come to a halt (46). Moreover, his Health Incentives Reform Program led to the minimization of covered costs during one's visit to the hospital (47). He is also infamous for underplaying the AIDS epidemic and for his underfunding of the CDC during that period (48). What is even more of utmost importance, is that the Reagan Administration called for the private industry to enter the health sector and supported an unregulated market dominated by competition.

Regarding the subject of insulin, the Reagan Administration did not issue any

pharmaceutical policies. In 1974 a bottle of insulin costed 1.49\$, or adjusted for inflation, 8.60\$. It would cost about 20\$ for a diabetic to cover their diabetes needs each month, thus 111.28\$ in today's terms (49). That is not actually that low, considering the income was a lot lower back then. In 1984, a bottle of insulin would cost the individual 2.5\$, in other words 6.60\$ adjusted for inflation. Noted that until then only the regular type of insulin was available.

After a somewhat unremarkable Bush Administration, came the era of Bill Clinton. A Democratic president, he attempted a healthcare reform that aimed at more people being covered by insurance, but the bill failed to pass Congress (50). That bill may have been shot down, but Clinton signed the Health Insurance Portability and Accountability Act of 1996 and the Balanced Budget Act of 1997, which had more modest goals. While the market was still left unregulated, the prices kept escalating. Even though the Acts signed by Clinton led to more people being covered by insurance, the way insurance is structured in the USA, people still bore a large part of the costs. In the early 1990's, Medicaid paid 4.43\$ per unit of analogue insulin - 8.66\$- and about 7\$ for the regular type. In 1999 the price for one vial of Humalog had climbed to 20\$. Instead of insulin prices decreasing along with health technology advancements, the prices kept skyrocketing, indicating a problematic start to the new millennium.

2.2 The Pricing of Insulin in the UK (1980 – 2000)

Many critics of Ronald Reagan believed that he did not introduce such radical changes as he had promised before the election, and he did not take as strict measures as they expected, regarding healthcare reform. The same cannot be said about Margaret Thatcher. Thatcherism became a synonym of limited welfare spending. Case in point, in a book about the Nordic model of the welfare state, the author wrote "...a Thatcherite deconstruction of the welfare state was not attempted..." (51). Margaret Thatcher was a carrier of Friedrich Hayek's legacy: social policies were seen as a threat to the freedom of people. She believed in Hayek's liberalist ideas so much so that one day she entered the chamber of the UK parliament, put the book 'The Road to Serfdom' on her desk and declared "This is what we believe" (52). Indeed, Margaret Thatcher ripped the English welfare policies to shreds; she minimized costs on housing, education etc. and increased spending on the police and the army. The

state would no longer interfere in any way in the market and incentives for the private initiative were introduced (53).

While Thatcher deconstructed the welfare state in the United Kingdom, thankfully she protected, and in fact increased the spending for, the National Health Service - hereby, NHS- (54). The NHS, apart from obviously being responsible for one's needs for hospitalization etc., also covers the price of pharmaceutical products for the citizens. Thatcher stayed clear of radical changes to the NHS -albeit, recent documents unveiled that the Conservative Party was seriously considering reforming the Service back in 1982- (55), not because of the goodness of her heart -one day stating "the NHS is not a free service, you have to pay for it"-, nor because she actually believed in it -in 1988 she shamelessly declared that she paid for private insurance for efficiency reasons- (56). The Conservative Party had always supported the NHS and mishandling it would maybe cause displeasure among the party members, as well as its supporters (57).

In the United Kingdom, in order to be entitled to free prescription drugs such as insulin, one needs to have a medical exemption certification, which was also the case in the 1980's, and the insured individual does not bear any costs for insulin. While the market was left unregulated, and the prices for insulin did increase, the citizens were not the ones who bore that weight, since the NHS covered the costs. However, the NHS had to pay increasing costs every year. Other than that, in the 1980's diabetes was not that big of a public health issue in the UK, as quite small numbers of newly diagnosed diabetics were announced yearly, thus one cannot blame the UK for not making insulin policies its number one priority. In the 1990's no noteworthy policies regarding insurance or insulin pricing were issued by UK governments.

2.3 Comparative Conclusions Regarding the Pricing of Insulin in the USA and the UK between 1980 and 2000

The UK and the USA followed a similar political path during the 1980's. Both countries turned to neoliberalism to solve the problems the social policies of the past had allegedly created. Both Reagan and Thatcher, symbols of the New Right, took turns in slashing the budgets of social programmes in their countries and left their markets unregulated. That said, they are completely different when it comes to the pharmaceutical policy they adopted. In the USA, people, even if they had insurance,

had to pay some part of the insulin's price -we will delve into the insurance policy of the USA in the later chapter-, which kept escalating even before the Reagan Administration. Reagan had a complex belief that saw him supporting universal coverage on the one hand, but he also criticized national health insurance as 'compulsory socialized medicine' on the other hand. The situation being as such, the number of people that were legitimate for insurance was minimized, thusly increasing the number of those who had to pay for insulin out-of-pocket. Here, we need to note, that diabetes in the USA had already made its appearance quite strongly in the 1980's, while in 1994 it was declared epidemic and a major public health issue by the CDC (58). So, the fact that no measures had been taken or were taken that instant led to a downwards spiral for the subject of the pricing of insulin in the USA.

Margaret Thatcher, despite all the other measures she adopted during her years in office, ought to be credited for not dismantling the NHS -for political motives-. Not only she did not minimize the service or its spending, but in 1987 she announced that its funding would be increased by 100 million English pounds and in 1988 a review of the service was announced. The fact that the NHS, which is responsible for covering the cost of insulin for the diabetics was left unscathed, was of utmost importance. Thatcher, thusly, adopted an extremely clever neoliberalist policy that left the NHS untouched, so that she would not lose her party's support. Despite the egoistic motives, the result remains the same: diabetics in the United Kingdom had it far easier than diabetics in the United States of America. That said, Thatcher apparently recognized the value of a healthy workforce: if a diabetic, who under different circumstances would work, remained at home, without a job, that would bear a far greater burden on the society, in a time when industry and government needed as much labour as possible. In the 1990's the situation remained quite similar in the UK and the USA, with the prices of insulin increasing on the one hand, but people in the UK did not have to bear that cost, in contrast to the United States of America.

To be fair to Reagan, however, we need to note that Thatcher had it far easier. Regarding the NHS, she did not exactly move towards a positive direction, but she merely did not move towards a negative one either. She just kept the NHS like she found it when she took over after the loss of the Labour Party.

The increase in insulin prices was exponential between 1980 and 2000, notwithstanding, those numbers cannot even come close to what happened after we entered the new millennium.

CHAPTER 3

PRICING OF INSULIN IN THE COUNTRIES OF INTEREST

In the following sections we will analyse the different prices of the various types of insulin in the United States and the United Kingdom and how the two countries compare to each other in that aspect.

3.1 Pricing of Insulin in the USA today

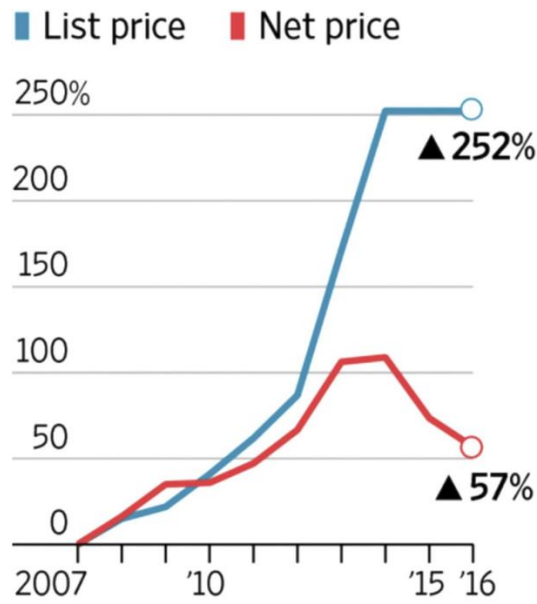
In 1923 the inventors of insulin denied issuing patent rights, selling the patent to the University of Toronto at the symbolic price of \$1. They made that decision because they believed that it would help keep the price of insulin low and that it would be accessible to anyone who needed it (59). Since then, the price of insulin has increased more than 1000%, and that is after adjusting for inflation. Thus, in today's context, Banting, Best and Collip sold the rights to insulin at a price of \$14.

The situation today is extremely different than what the inventors of insulin would have wished for or imagined. Before delving deep into the different prices of insulin, it is essential to analyse the basics of the insurance system in the USA. The criteria for someone to be eligible for public insurance are very strict. One must be either 65 years of age and older, a child, have a disability, or an extremely low income. If an adult is left unemployed, they are also left without insurance after one year. In 2018, 9.2% of Americans were uninsured (60), in other words, they did not meet the criteria to receive public health insurance, nor did they pay for private insurance, which can cost thousands of dollars annually per person (61). Precisely, the cost of private insurance is about \$500 per month per person, an obviously very high price that someone with a mediocre income cannot cover. Despite that, private health insurance is more popular in the USA, exactly because of the strictness of the criteria to be eligible for public insurance. During 2019, 58% of the American population was covered by private insurance, and only 34% by public insurance (62). That said, if someone is insured, that does not mean that they are exempted from insulin costs. In the first place, for any product or service an insured person purchases, they must pay a part of the price out-of-pocket. That practice is called a copayment. That applies even on those who pay for private insurance, meaning added costs on an already high insurance premium (63). Moreover, some private insurance companies make their

clients cover a large sum of money firstly out-of-pocket -called deductible and reaching even \$10,000-, before they can ask the company to cover any added costs.

In the USA there are three main insulin manufacturers: Novo Nordisk, Sanofi, and Eli Lilly. Considering that a diabetic with diabetes type 2 needs about 3 vials of insulin per month, and an insured individual in the USA must pay a copayment of at least \$50 for each vial of insulin, that means that they pay \$150 every month to cover their insulin needs (64). Annually, that means that a privately insured diabetic pays about \$6,000 for their insurance, about \$5,400 for copayments, and at least \$5,000 in deductibles. That reaches a price of almost \$20,000 annually, without counting any other health need the diabetic may experience. The 'lucky' individuals who are eligible for public insurance, still must pay for copayments, a high price, considering that they might probably be elderly, children, or suffer from a disability.

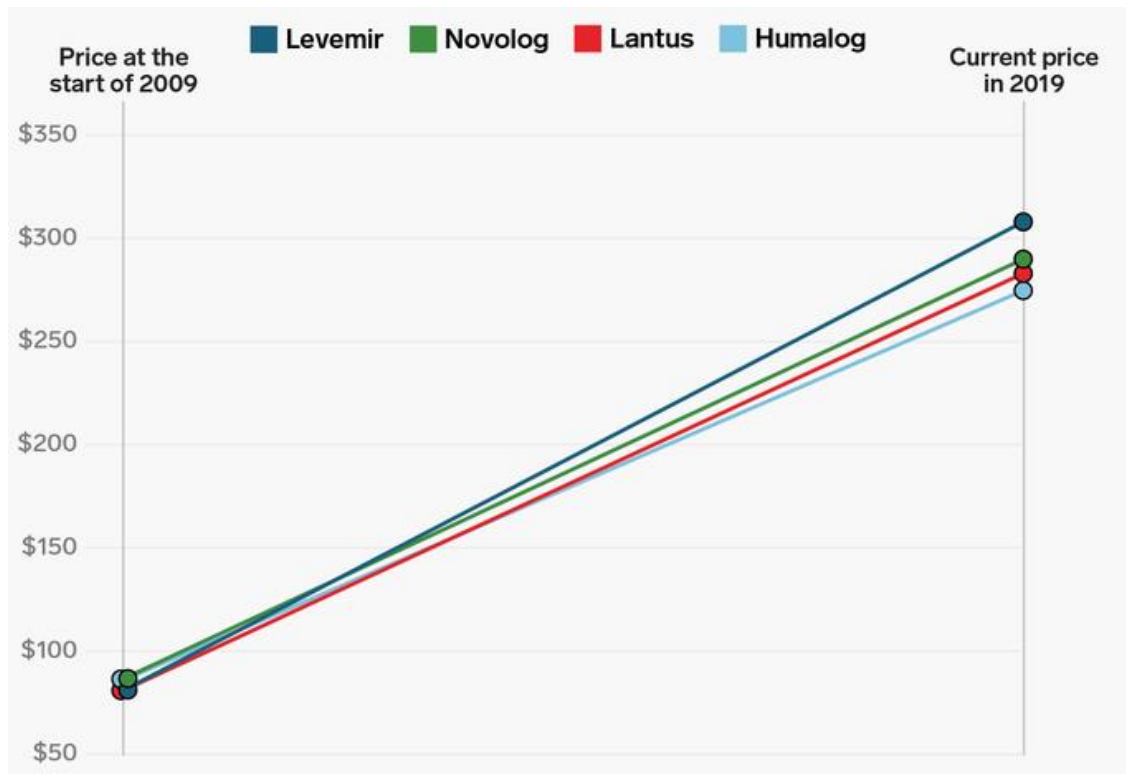
While all of the above is undoubtedly problematic, the situation does not even come close to what uninsured diabetics experience. Note here, that 15% of diabetics are uninsured, and as we analysed in the chapter dedicated to the socio-demographic profile of diabetes in the USA, those with a lower income were at a far greater risk of having diabetes. Moreover, 20% of those who are uninsured in the USA fall under the lowest-income category. It is those people who must bear the price of insulin, which ranges from \$175 to \$300 per vial, depending on which company manufactures it or the type of insulin it is (65). Again, considering that a diabetic with diabetes type 2 needs about 3 vials of insulin per month, and for the sake of the argument let's say that they purchase vials of \$200, that would mean that they would have to pay at least \$7,200 annually for insulin, excluding all other medical needs. All that in a country where the minimum wage per hour is at \$7.25, meaning an annual \$15,080 income. In other words, they have to pay at least half of their income for their insulin needs. It is worthy to note here the difference between the list price and the net price: the list price is the price of the product without any discounts and the net price is the price of the product after taxes and after subtracting any discounts. The uninsured diabetics have to pay for the list price, which is entirely controlled by the pharmaceutical companies, and it has tripled between 2002 and 2013 (66). What is most problematic about that is that the list price far exceeds the net price, as depicted below (67). In fact, the net price has decreased, while the list price is up by 252%.



Source: Truven Health Analytics and Bernstein

Diagram 3.1: Net Price and List Price of Insulin in the USA 2007-2016

In 2009 a unit of insulin would cost about 90\$ and the price skyrocketed to even above 300\$ in 2019 (68), for the exact same product. Between 2002 and 2013 the price of insulin tripled, while between 2012 and 2016 the medical costs for diabetics doubled, with insulin being responsible for about half of that (69). Lastly, only between 2018 and 2020, the cost of insulin for diabetics who use a pump increased by 304% (70).



Source: Truven Health Analytics, Bloomberg

Diagram 3.2: Price of insulin in the USA 2009-2019

This trend shows no stopping, and American citizens are left to pay more money for insulin than in any other country on the planet (71).

3.2 Pricing of Insulin in the UK today

Before delving into the pricing of insulin, it is essential to analyse how the NHS and insurance work in the United Kingdom. The NHS is a rare example of socialized medicine (72). All services and almost all prescription drugs are entirely paid for by the British government -directly- and the taxpayers -indirectly-. The insured individual does not have to pay anything, except for outpatient prescription drugs who are subject to a copayment of £8.80 per prescription (73). Health insurance is optional in the UK (74), and it involves all UK residents who lawfully live in the country. The NHS does have its critics, regarding efficiency and how long it may take to have an appointment with a physician, but its pharmaceutical policy is fair and exempts citizens from costly out-of-pocket payments. That said, there are people who choose private insurance for the sake of efficiency. In fact, 10.5% of the British population

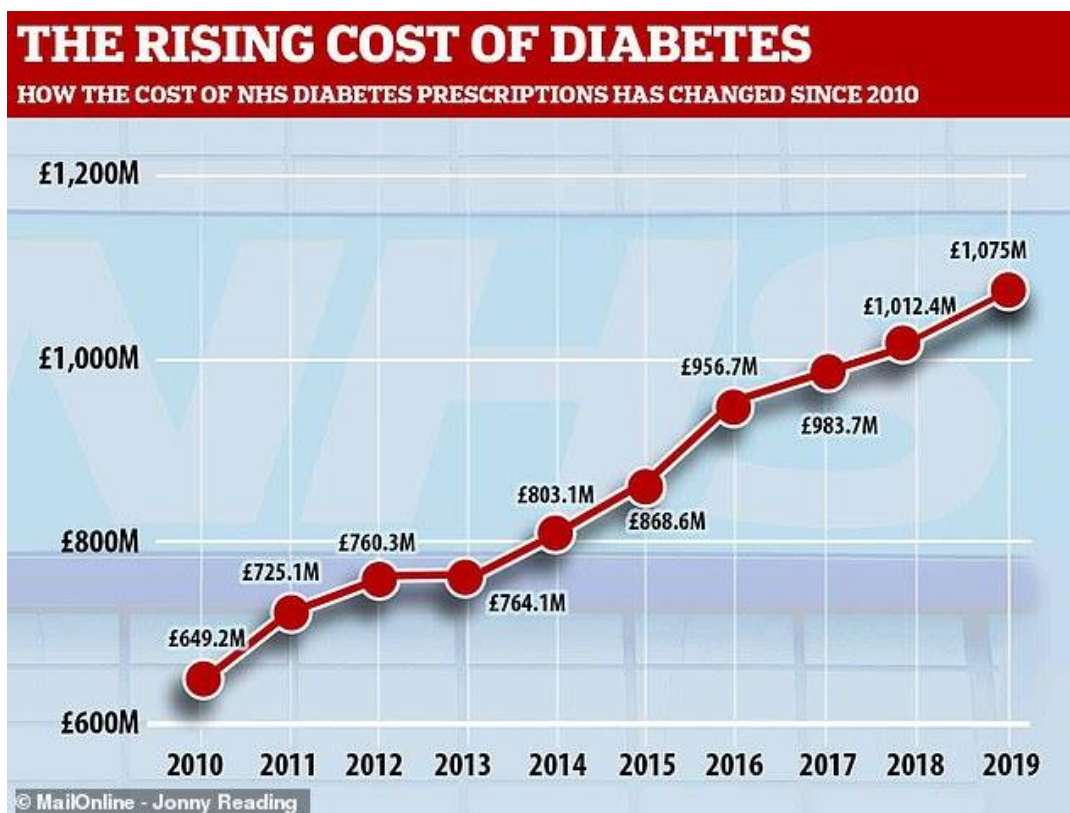
opted for private health insurance in 2016 (75), meaning that approximately 60 million residents of the UK are insured by the NHS.

Regarding insulin, it is one of the prescription drugs that are entirely covered by the NHS, without any copayments for the insured diabetic. Everyone lawfully living in England, Scotland, Wales, and Northern Ireland is entitled for free insulin prescriptions (76). If the individual is under 60 years of age, they must have a medical exemption certificate in order to claim their free prescription. The medical exemption certificate is issued by a physician of the NHS and confirms that the individual suffers from a particular condition – in this case, diabetes-. That document entitles the individual to free prescriptions but does not cover dental treatment or other health costs (77). While the NHS covers all insulin related costs, the individual may have to pay out-of-pocket for “certain insulin-related products, such as insulin pumps, insulin pens and wallets for insulin storage” (78). The main insulin manufacturers in the UK are the same with the USA, including Sanofi, Eli Lilly, and Novo Nordisk, with the most common brands including Iletin, Novoli, Humuli, Humalog and Apidra.

Let us start our analysis with the out-of-pocket costs for the individual. Firstly, an insulin pump is used by diabetics with diabetes type 1, and it provides them with insulin through day and night. It is attached to their body and a tiny tube goes under their skin. There are some criteria issued by the National Institute for Health and Care Excellence -hereby, NICE- to be met in order for someone to receive an insulin pump free of charge. In England and Wales, they have to be over 12 years of age, have diabetes type 1 and (a) cannot get to their target HbA1c without severe symptoms and (b) their HbA1c remains high despite efforts to manage their diabetes. If the individual does not meet these criteria, they have to pay for a pump themselves. It can cost between £2,000 and £3,000 and lasts between 4 and 8 years. There are also additional costs, for example for the infusion set, which reach up to £1,500 per year (79). Again, under certain circumstances, the NHS covers the cost of insulin needles. In case someone does not meet the set criteria, they must pay for them out of pocket, with their price ranging from £3.95 to £30.00 per box (80). Lastly, wallets for the storage of insulin pens are not covered by the NHS at all, and they cost the individual between £15 and £25 (81).

The NHS paid yearly about \$532 -or £393- for the insulin needs of each diabetic in 2018, while the manufacturing cost for that insulin is about \$100 -£75- (82). The average price per unit of insulin in the UK is \$7.52 -or £5.56- (83). While that price

seems relatively low, it has been escalating for the last decade, meaning additional costs on the NHS budget. To be more specific, the annual expenditure of the NHS has increased during the last decade by 130% due to a severe uptake in analogue insulin (84). Diabetes costs are a huge burden for the NHS, which pays about 14 billion English pounds per year for diabetes treatments, or in other words, 10% of the NHS budget is devoted to diabetes. Lastly, a diabetic in the UK paid about \$65 -or £48- for their diabetes needs out-of-pocket in 2016. The costs have been rising since 2010, as depicted below (85), and one can only imagine what will happen in the future, as the number of diabetics living in the United Kingdom increases.



Source: MailOnline

Diagram 3.3: The Cost of Diabetes for the NHS 2010 - 2019

To sum up, while the UK has managed to protect its citizens from paying exceptionally high prices for insulin, the burden on the NHS budget still is increasing at an ever-growing pace.

3.3 Comparative Conclusions Regarding the Pricing of Insulin in the USA and the UK Today

The difference in quality of life between diabetics living in the USA and those living in the UK is chaotic. Perhaps the only similarity between the two countries in this aspect is that the insulin manufacturers are the same in both.

The USA have a very strict public health insurance policy, leading the majority of Americans to the costly choice of a private insurance scheme, which accounts for thousands of dollars annually per person. In contrary, in the UK, all legal residents of the country are eligible for free health insurance under the NHS. A vast difference also applies to how insured diabetics are treated. In the USA, both those who are eligible for public insurance and those who pay for private insurance are subject to large yearly costs due to copayments etc. Again, in contrast to the US, the UK has no copayments for those who receive insulin freely. In the USA, the diabetics are those who metaphorically and literally pay the price because of the rising insulin costs, while in the UK everything is covered by the NHS, which is funded by the taxpayers.

The most striking difference between the two countries is the difference in the prices for the exact same product by the exact same manufacturers. We will make all comparisons in US dollars for the sake of efficiency. The average list price of insulin in the US is \$98.7 when the NHS pays \$7.52 for the same unit. The difference is even bigger if we compare prices for rapid-acting insulin, which in the UK costs about \$8 per unit and in the US \$119 (86). In Table 3.1 below the difference in the price of vials for rapid-acting insulin is depicted (87).

Table 3.1 Difference in Rapid-Acting Insulin Prices Between the US and the UK

	US	UK
Humalog	\$275	\$22
Apidra	\$284	\$22
Novolog	\$289	\$23

In other words, Americans are asked to pay 8-times the price for insulin, compared to other countries, including the UK. This difference in insulin prices results in a huge difference in monthly out-of-pocket costs for diabetics in the UK and the USA. In the

UK a diabetic is expected to spend \$65 in insulin-related products, while in the US the expenses reach \$360 monthly. Diagram 3.4 below depicts the situation quite well.



Source: BBC

Diagram 3.4: Monthly expenses for insulin and insulin-related products in the UK and the US

In conclusion, the difference between the two countries is striking. What has led to this vast gap between two of the biggest economies in the world?

CHAPTER 4

FACTORS INFLUENCING INSULIN PRICING IN THE COUNTRIES OF INTEREST

Having investigated the various prices of insulin in the US and the UK, it is of utmost importance to analyse what drives those prices, which will be done in the sections that follow.

4.1 What Influences Insulin Pricing in the USA?

Having analysed the pricing of insulin in the USA it seems unbelievable that a modern democracy would let its citizens be ruined financially due to their medical needs. Yet that is the case, as the manufacturers have been left free to rapidly increase the prices. A simplistic explanation would be to blame the situation on the free market. However, many countries have adopted the rules of laissez-faire and none of them suffer the same situation with insulin prices. Moreover, it has been proven that the health sector does not adopt the rules of the free market entirely. For instance, there are barriers to enter the pharmaceutical market with a new drug. There are many factors that influence the escalating prices of insulin in the US.

The insulin market in the US is essentially a monopoly / oligopoly ruled by three main manufacturers: Sanofi- Aventis, Novo-Nordisk, and Eli Lilly. They account for over 90% of the market in the country -and globally- (88). That is not by chance. Unlike all other industries and markets, insulin is an area where competition has quite ironically not been free. There are still no biosimilars from any other company in the US market, as there are extremely strict rules that make it almost impossible to enter the market. The only two biosimilar products, which are available since 2015, belong to Sanofi and Eli Lilly respectively. In this manner, new products that would be less expensive and constitute a strong competition against the products by the 'Big Three' are prohibited from entering the market (89). Here would be the point to wonder why would anyone issue legislation and rules that make it so hard for competition to arise. These manufacturers have been in the pharmaceutical market for many decades and have had the chance to create almighty lobbies (90), which help them promote their financial and political agenda and maintain their rule. In fact, over 1,500 lobbyists of the 'Big Three' currently work in Washington and in close quarters with

the members of Congress. This fiscal freedom has left companies to escalate the prices as they please, however, one cannot help but wonder how much of a free market it is, when competition is prohibited from entering.

Another factor that influences the prices of insulin in the US, is the fact that manufacturers freely control the list price, which is paid by uninsured diabetics. That is also the price that keeps skyrocketing, as we have seen in the previous chapter. Except for the 'Big Three', pharmacists and managers of large pharmacies are benefited from a high list price, as they are entitled to a higher commission and they in fact push towards that direction (91). There is also an internal cooperation between pharmaceutical and insurance companies. To be more precise, the pharmaceutical companies have established some discounts, called rebates, for the insurance companies that promote their products to their customers. These discounts, however, do not benefit the insured individuals at all, who also have to pay for copayments and deductibles (92).

The biggest power held by the insulin manufactures is evergreening. Evergreening is a practice that is legal and consists of the companies slightly changing the chemical composition of their products and registering it as a new product, thusly renewing their patent rights and prohibiting any other company from entering the market (93). At the end of the day, manufacturers take advantage of the need of diabetics for insulin. Diabetics do not have the option not to purchase insulin if they want to avoid experiencing severe symptoms. For example, if a diabetic unplugs their insulin pump, they are highly likely to start continuously vomiting after 3-4 hours, and they will most probably be in a coma within 24 hours. Thus, the manufacturers know that there is a huge, vulnerable population that is willing to pay any price for the life-saving drug.

At the end of the day, the pharmaceutical companies do not do anything illegal; they are for-profit companies, and we could not blame them for aiming at profits. The ethics of setting such high prices for a drug that has been around for 100 years is another story, but still every single one of their tactics is legal, including gauging prices. So, if we need to point fingers, we should turn to the US government, which has not issued any legislation or a negotiation organization to hinder these practices. While the FDA checks whether a pharmaceutical product is safe and effective, there is no such institution to check whether its price is set too high. When President Obama signed the Affordable Care Act, millions of Americans gained insurance, meaning

that they would have to pay far less for their medical needs, including insulin if they were diabetic. However, when President Trump was elected, he scrapped most parts of the Affordable Care Act, and millions of Americans lost the chance of being insured. When Congress members, such as Bernie Sanders, speak up about the greed of the insulin manufacturers, they are labelled as ‘radical’ and ‘socialist’, and they are consequently ostracized. Finally, in 2020 the Democratic Party brought to Congress a bill that would enable the US government to negotiate insulin prices, but it was downvoted by the Republican Party (94). Perhaps it all comes down to one’s ideology: in September 2020, then President Trump claimed, “insulin is so cheap, it’s like water” (95).

4.2 What Influences Insulin Pricing in the UK?

Pharmaceutical products in the UK are priced by the manufacturers and there is no direct price control by the government. The manufacturers base their decision on a number of factors, such as how many competitive or similar drugs are on the market or the target audience. While there is no direct price control, there are indirect methods (96). Firstly, negotiation. The NHS covers the medical expenditures of 60 million people, including 5 million diabetics and acts as a company protecting its rights and interests. The NHS is essentially the country’s market, as the private market is tiny in comparison. By being such an important player in the market, the NHS holds great negotiation power, which allows to keep the prices at a low level (97). Right now, the NHS spends about £400 yearly on each diabetic’s insulin needs when the price of an insulin unit is £5.56. If the prices kept escalating, the costs would exceed the Service’s budget and could put a large burden on the taxpayers.

Firstly, we will focus on the mechanisms applied for drugs already on the market. For most branded products, there is a voluntary agreement, called the Voluntary Scheme for Branded Medicines, between the Association of British Pharmaceutical Industries and the Department of Health, which is renewed every 5 years. This agreement stipulates that if for any reason the price of pharmaceutical products exceeds an agreed upon limit, the industries would have to pay back the NHS for the price difference. In 2019, the limit of increase in drug prices was set at 2%: if the price of any pharmaceutical product sold to the NHS has an increase of more than 2%, the NHS must be reimbursed. To sum up, the companies are free to set any price they

want, but they would have to pay back the NHS for the added costs.

When a new pharmaceutical product wishes to enter the market, first and foremost it should be deemed safe and of quality by either the Medicines and Healthcare products Regulatory Agency or the European Medicines Agency (98). If it does not meet the criteria set by these institutions, the product cannot enter the market. After it has been granted a license, a price should be set. That price should both meet the manufacturer's profits, as well as the NHS's ability to pay for it. An impartial party that can make this decision, is NICE. That institute is responsible of assessing the cost-effectiveness of a new medicine that is about to enter the market (99). In other words, it assesses if the new drug offers an economic advantage over the already used treatment and calculates the QALYs provided by using it (100).

Having analysed the mechanisms used by the UK government, it is evident how the price of insulin in the UK has not exceeded £6 per unit. Furthermore, biosimilars are allowed to enter the UK market and are available within the NHS, providing a cheaper solution than the brands sold by Novo-Nordisk, Eli Lilly, and Sanofi-Aventis (101). The UK has also a very strict stance against evergreening practices and its courts have revoked the license of several products over the last years, after deeming their evergreening patents not valid. To be more precise, "Minor modifications of products or the suggestion of appropriate dosage regimes may struggle to be considered as valid, unless they are associated with an unforeseen advantage or were not in any way suggested from the original product" (102). That said, other countries, such as India, have an even stricter set of rules for evergreening, almost prohibiting it entirely. Even if a pharmaceutical company is granted evergreening patent rights in the UK, the country's patent system would still allow a generic company to launch a competitive drug (103).

4.3 Comparative Conclusions Regarding the Factors Affecting Insulin Pricing in the UK and the USA

The difference between the UK and the USA regarding their drug pricing policy is that the latter essentially lacks one. In the USA, after a drug receives a license from the FDA, its manufacturers are free to set a price as they please. In contrast, in the UK there is a negotiation between the NHS and the manufacturers. It would be unfair to accuse the UK of strict government-level price control as it merely protects its

economy (104). If the NHS had to pay the prices set in the US, it would probably go bankrupt. There are enough voices already who accuse the NHS of spending too much on medicines, one can only imagine what would happen if the Service had to pay £74 per unit of insulin. The USA lacks an institution that is exclusively responsible for assessing the cost effectiveness of pharmaceutical products and technologies, such as NICE in the UK.

Regarding negotiating, Medicare, the second main public insurance programme in the US, is not even allowed to negotiate drug prices. Furthermore, the private insurance industry consists of hundreds of different companies, meaning that they have minimum negotiation power against the 'Big Three'. Moreover, in the UK it is allowed and far easier for biosimilars to enter the market, meaning that the three main manufacturers have competition, whereas in the US there are such strict measures against biosimilars, that it is essentially impossible for them to enter the market. Adding to that, in the UK evergreening patents are taken very seriously and many brands have been denied a license. In the US evergreening is considered legal and the 'Big Three' receive renewed patent rights freely.

To sum up, the difference in the policies for the pricing of medicines between the two countries is as vast as the difference in the prices paid for insulin.

CHAPTER 5

THE RESULTS OF THE PRICING POLICY OF INSULIN IN THE COUNTRIES OF INTEREST

The last chapter of our analysis will be dedicated to the consequences -negative or positive- the pricing of insulin has on the countries we have investigated.

5.1 Repercussions of the Pricing of Insulin in the USA

The non-existent pricing policy of insulin in the USA has serious repercussions on the society. Firstly, we need to point out the unfairness of a system that makes the most vulnerable population pay the highest price for insulin, i.e., the list price. It is the uninsured diabetics, who are responsible with paying the impossibly high list price, when their categorization as uninsured automatically hints at their vulnerable financial state. How are they supposed to cover their needs when insulin alone can cost \$1000 monthly?

There are many diabetics who resort to mortgaging their houses, liquidizing their assets, even giving up any non-essential product or activity. Moreover, given that children are covered by their parents' insurance until a certain age -commonly early twenties-, regardless of their financial state or employment status, many young adults are left uninsured and have to pay the list price for their insulin needs. A common practice for uninsured diabetics in the US is resorting to the black market, which offers insulin at a lower price than Eli Lilly, Novo-Nordisk, and Sanofi-Aventis (105). Adding to that, it is common for diabetics to cross the border either towards Canada or Mexico to purchase insulin. What is most striking about that, is that the price of insulin in Mexico and Canada is so much lower than in the US, that diabetics can travel to these countries and their trip -counting the expenditures for insulin as well- would cost less than purchasing insulin at their local pharmacy (106).

However, all the aforementioned applies to those who can afford to travel to Mexico and Canada or have a house to mortgage, and not everyone can afford the prices of the black market. What is to happen then? There are two main practices adopted in this case. First, diabetics end up purchasing cheaper types of insulin, even if it means experiencing serious symptoms. For instance, someone who needs the expensive rapid-acting insulin may purchase another type, because it is less costly (107).

Secondly, there is ‘rationing’. Rationing is the practice of using smaller doses of insulin order for the vials to last longer. 1 out of 4 US diabetics reportedly rations their doses, something that obviously has severe repercussions on their health. The individuals may sometimes avoid the more serious symptoms of diabetes when rationing, but they are still vulnerable, with whatever that entails for their day-to-day life and employment status (108). Lastly, and sadly, there are instances where individuals died due to severe symptoms of diabetes, as they could not afford their insulin (109).

Furthermore, the fact that insulin is so expensive affects negatively an already vulnerable population, diabetics. In 2020 18% of diabetic people were unemployed, in contrast to the national rate of 12% (110). This situation worsened even more during the pandemic, considering that 4 out of 10 people living in the US were in jobs that cannot be done remotely. The unemployment wave brought about by the pandemic, led millions to unemployment and consequently rendered them uninsured. Diabetics were left helpless, needing to pay the escalating prices for insulin with their unemployment benefits (111).

In conclusion, diabetics in the USA have two choices: pay extremely high prices of insulin, risking financial ruin, or limiting their insulin intake, meaning severe repercussions on their health and, consequently, a decrease in their general quality of life (112).

5.2 Consequences of the Pricing of Insulin in the UK

The way the UK has shaped the pricing policy of pharmaceutical products, and its public insurance scheme, have worked wonders for the quality of life of diabetics in the United Kingdom. Since they have always access to insulin, they do not experience severe symptoms that would hinder their every day-to-day life, including their academic activities or work. However, even in the UK, diabetics are at an unfavourable position regarding employment opportunities: studies suggest that diabetes has a negative impact on labour market participation in the UK (113), and that diabetics have a higher unemployment percentage than the national average (114). While this is obviously problematic, the UK’s pricing policy is not to blame, but in contrary, it is the lack of positions that can be done remotely, and the nature of

diabetes itself. If anything, the UK state protects those vulnerable individuals by at least offering them insulin without any cost. Diabetes is such a serious disease, that even with regular access to insulin, diabetics cannot live an entirely healthy and ‘normal’ life. Diabetes causes a significant deficit in quality of life between people with diabetes type 2 and other non-diabetic individuals of the same age group and city of the UK (115). What causes even more concern is that even with therapeutic policies which aim at reducing one’s blood glucose levels, the risk of severe symptoms is decreased, but the quality of life the diabetic individual is not increased (116).

While the UK does offer diabetics insulin with no charge, the NHS is not without its critics: those who say that it spends too much and those who say that is not efficient. Starting from the latter, it is a common notion that the fact that the NHS pays for insulin, does not excuse it for offering inefficient or not enough care to those who need it. For instance, 8 out of 10 diabetes-related amputations could have been avoided if the individuals had received the appropriate care (117). That is a striking percentage, considering how much an amputation could negatively affect one’s life.

Apart from that, there are those who say that by the NHS spending 10% of its budget on diabetes needs, other diseases or social welfare programmes are overlooked (118). Lastly, there are those who say that the NHS spends too much in general, and that it negatively affects the taxes paid by UK residents. In fact, £140 billion was spent on health needs across the UK in 2018 (119). That said, the UK’s taxes have not increased recently, compared to the OECD average, and it is considered a relatively low-tax country (120), so that is not a valid argument of criticism against the NHS. Regarding the argument that it spends too much on insulin, it seems unfair to blame the NHS, instead of the manufacturing companies. It is like blaming a father for spending too much on milk for his children, instead of blaming the companies for selling it at a high price.

5.3 Comparative Conclusions Regarding the Consequences of the Pricing of Insulin in the USA and the UK

The difference in quality of life between diabetics living in the USA and the UK is immense. The UK has such a policy in place, which is not perfect as we analysed in the previous section, but it at least removes the obligation for them to pay for insulin

out-of-pocket. The lower costs for insulin are of utmost importance for a population that has a lower quality of life and higher unemployment risk than the general population due to their chronic illness. While the NHS might not be entirely efficient, and lack of care is noticed, it still does more than the bare minimum to protect its citizens. That said, in case of serious needs that could lead to amputations, obviously there is a lot to improve in that aspect. Lastly, While the high cost paid by the NHS has led to a large number of people complaining about the high spending, the UK has managed to keep its taxes low, while also adopting a very efficient pharmaceutical policy.

In complete contrast, insulin is so expensive in the US, that even young people die because they either choose to purchase cheaper types of insulin, or do not purchase it at all (121). That has horrifying repercussions on the fabric of society. The US is the richest country in the world, and its citizens risk financial ruin or death, because they cannot afford a 100-year-old drug. People having to mortgage their houses or travel to Mexico to purchase insulin is clear-cut sign that the US is doing something wrong. All that on top of the 'automatically' lower quality of life diabetics experience. The fact that prices in the US are higher than those at the black-market sounds like a fabrication but sadly is not. This situation gravely affects people's trust and faith in their government, taking into account that neither the Democrats -who are usually more friendly towards welfare programmes- nor the Republicans have ever done anything of essence to protect their fellow citizens.

CONCLUSION

Diabetes will continue to be a health issue of utmost importance in the decades to come, following the same exponential growth in numbers that has been taking place since the 1990's. In both the USA and the UK diabetes disproportionately burdens those with a lower educational level or income level, including ethnic minorities, meaning that diabetes and its social and financial costs hinder the lives of the most vulnerable populations within societies. Looking at the future that the countries are up against, one cannot help but wonder what they are doing to decelerate the speed at which diabetes prevalence is increasing. That is, diabetes type 2, which is a result of an unhealthy lifestyle. However, prevention was not the subject of the paper at hand. The differences in the health policies of the countries of interest started being noticeable ever since the 1980's, when they both turned to neoliberalism to lick their wounds from the traumatic 1970's. While Reagan was underplaying the AIDS epidemic and minimizing the CDC's funding, Thatcher kept the NHS unscathed from underfunding, allowing it to keep offering medications -including insulin- and services to the lawful residents of the UK. The reason behind this ideological gap in decision making is hard to pinpoint. It would be wrong and naive to claim that Thatcher was 'smarter' or that Reagan was not that good of a politician, but the reasons lie deep below the surface. The Cold War was reaching its fourth decade and the American society loathed anything that included the word 'socialist' in it. So, when Reagan called universal healthcare 'socialised medicine', we can imagine that to most American ears it sounded wrong and dangerous to their freedom. On the other hand, and side of the Atlantic, when the NHS was -and is- being called 'socialised medicine' that term did not have the same meaning for the society of the United Kingdom. At the end of the day, both Reagan and Thatcher made decisions based on their personal and political beliefs and motives, which were differentiated due to the different experiences of their societies.

While Reagan can 'get away with' his policy, the same cannot be said about the US governments that followed. In the 1990's the Cold War was long but ended and the 'West' had been crowned victor. Despite that, US governments continued on the same path, and no policy that would make medications -including insulin- more accessible were issued whatsoever. The three insulin manufacturers were allowed to set their

prices freely, while in contrast, Americans were faced with extremely strict criteria in order to be eligible for public insurance, most of them resorting to the costly choice of private schemes. Simultaneously, the UK kept its policy in place, offering insulin with no charge to its residents.

Entering the new millennium, the prices of insulin skyrocketed and kept skyrocketing until this paper was written. What differentiates the two countries under investigation, is that the UK has an effective, indirect control of the prices of medications sold to the NHS, along with strict legislation that prohibits the practice of evergreening or anti-competitive practices. Contrariwise, the US has no negotiation practices in place, in fact, Medicare is not even allowed to negotiate drug prices with the insulin manufacturers, and the prices keep increasing without any sign of stopping. Thus, in the UK the prices may increase, but not at the same rampant pace as in the US, and it is the NHS that is burdened with the costs, and not the diabetics, which is the case in the US. In the 1980's it was supposedly a political motive regarding the society's experience of the Cold War that kept US governments from issuing any radical policies. However, the fact that nothing has been done even to this day, cannot be justified by merely the fear of socialist measures. Today, one cannot help but think that the lack of insulin price control policies is related to the 1,500 lobbyists currently residing in Washington. This argument is strengthened even further by the fact that surveys suggest that 46 million Americans would be unable to afford quality healthcare in case they need it (122). This is nothing new, as this trend has been continuing for years, and it is not a result of the economic crisis of 2008 or the pandemic, but a result of the general structure of the healthcare system in the US. For instance, in a survey that was conducted in 2000, 17% of privately or publicly-insured Americans reported financial barriers to affording healthcare (123). This non-existent policy about the pricing of insulin in the US has led to severe repercussions on the mental and physical health of diabetics, who end up rationing their doses or purchasing less expensive types of insulin, risking experiencing serious symptoms, even death. While the situation is horrid in the US, in the UK diabetics have access to free insulin. That said, there are many voices that express concern about the deficient care diabetics may face in the NHS, which becomes saturated due to the increasing needs.

All the aforementioned lead to bittersweet emotions. If diabetics still face difficulties in a country where they are exempt from paying for insulin or visits to physicians,

what is to be done? This paper may have focused on insulin, but research should continue taking place about the possibilities to prevent diabetes. Both from a humanitarian, as well as from an economic perspective, it is generally far more effective to prevent a disease than treating it. Thus, countries should work on possible policies that would improve the lifestyle of their citizens. While that may be true, there is still a long way to go, both in a scientific and a political aspect, for efficient health policies to be implemented that would decrease the prevalence of diabetes. Until then, governments can at least protect their diabetic citizens from the repercussions of an uncontrolled pricing of insulin, and this was essentially the aim of this paper, to give prominence to the importance of a pricing policy on a drug that shapes the quality of life of millions of people around the world.

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