



University of Bergen

Department of Administration and Organization Theory

Radical policy change in Germany's health system in 2011:

The case of patented drug regulation

By

Christina Lichtmanegger

A thesis submitted to the Department of Administration and Organization Theory in partial fulfilment for the degree of Master of Philosophy in Public Administration

Spring 2012

TABLE OF CONTENTS

Table of Contents	I
List of Tables	V
List of Figures	V
Abstract	VI

CHAPTER 1: INTRODUCTION

1.1 Summary of the political and the health system in Germany	1
1.2 Significance of the study	3
1.3 Background of the study	3
1.4 Statement of the problem	5
1.5 Research Questions	5
1.6 Theoretical framework	5
1.7 Methods	6
1.8 Organisation of the study	6

CHAPTER 2: THEORETICAL FRAMEWORK

2 Introduction	7
2.1 Perspectives and Concepts on policy change	7
2.1.1 Overview of three major approaches of policy change	8
2.1.1.1 Multiple Streams Framework –Kingdon (1995)	8
2.1.1.2 Baumgartner and Jones – Punctuated – equilibrium theory	9
2.1.1.3 Sabatier (1988) - the advocacy coalition framework	11
2.1.2 Commonalities, differences and shortcomings of the three approaches	12
2.1.2.1 Commonalities	12
2.1.2.2 Shortcomings and Differences	13
2.1.3 Collective Action – the role of pharmaceutical industry and policy makers	13
2.2 Theoretical Framework for my study	15
2.2.1 Kingdon (1995): Multiple Stream approach	15
2.2.2 The application of Kingdon’s (1995) theory to the study	22
2.2.3 Operationalization of dependent and independent variable	23

2.3.1 The dependent variable for the study	23
2.3.2 The independent variables for the study	24

CHAPTER 3: RESEARCH METHODOLOGY 26

3.1 Research strategy	26
3.2 Research design	27
3.3 Documentary sources	28
3.3.1 Governmental documents	29
3.3.2 Statements of interest groups and self-governing institutions	29
3.3.3 Newspapers	30
3.3.4 Literature	30
3.4 Interviews	30
3.5 Data analysis	31
3.6 Validity and Reliability	32
3.6.1 Validity	32
3.6.2 Reliability	32
3.7 Limitations of the study	33

CHAPTER 4: HEALTH SYSTEM IN GERMANY 33

4.1 The characteristics of the German health care system	33
4.2 Responsibility of the state	35
4.3 Statutory health insurance	35
4.3.1 Health insurance funds	35
4.3.2 Federal Joint Committee (G-BA)	36
4.3.3 Institute for Quality and Efficiency in Health Care	36
4.3.4 Development of statutory health insurance and health insurance funds	37
4.4 Pharmaceutical industry	39
4.5 The influence of self - governing institutions and interest groups in decision – making process	41
4.5.1 Decision-making process in Germany’s health system	41
4.5.2 Influence of interest groups in decision-making	42
4.5.2.1 Interest groups	42
4.5.2.2 Commissions as source for influence	44

4.6 Patented and generic drugs	44
4.7 Reimbursement and pricing regulations	45
4.7.1 Explanation of reimbursement and pricing regulations	45
4.7.2 Reimbursement and pricing regulations in the three cases 1992, 2003 and 2011	47
4.7.3 Comparison of pricing and reimbursement regulations of Germany with other European countries	47
4.8 Regulation of innovative drugs since 2011	50
4.9 Developments of drug costs	52
CHAPTER 5: PRESENTATION OF THE COMPARATIVE CASES	57
5.1 Enquete Commission – Matrix for the following reforms	54
5.2 The Case 1992	56
5.2.1 Issues and disputes	57
5.2.2 The Arguments	60
5.3. Reform 2004	63
5.3.1 Issues and disputes	63
5.3.2 The Arguments	72
5.4 The Case 2011 – policy change in patent drug pricing	75
5.4.1 Issues and disputes	75
5.4.2 The Arguments	85
CHAPTER 6: ANALYSIS AND INTERPRETATION	93
6.1 Problem definition	94
6.2 Policy proposals	95
6.3 Political stream	98
CHAPTER 7: CONCLUSION	102
7.1 Summary of the thesis	103
7.2 Discussion	105
7.2.1 Result	105
7.2.1.1 Is radical policy change in the German health care system possible?	105
7.2.1.2 Independent factors	106
7.3 Limitations of the study	108
7.4 Contribution to the state of research	109

7.4.1 Theoretical contribution	109
7.4.2. Empirical contribution	109
CHAPTER 8: REFERENCES	111

List of Tables

Table 1: Instruments for reimbursement in international comparison

Table 2: Pricing instruments of patented drugs

List of Figures

Figure 1: Development of sales volume of the pharmaceutical industry in Germany from 1999 – 2007, in Mrd. Euro

Figure 2: Regulation of innovative and patented drugs

Figure 3: Prescription - and sales volume of the drug market 1991-2009

Figure 4: Sales volume of patented drugs in %

Abstract

This present thesis is an analysis of radical policy change in Germany's health system. The pharmaceutical industry was stopped to determine freely the prices of patented drugs in 2011; this is what is defined as radical change in the study. This thesis is based on Kingdon's (1995) multiple stream approach and has three main objectives: first to understand the timing of this radical change in 2011, second to explain the change of behavior of political parties towards this change in 2011. Third objective is to explain why Germany was a latecomer compared to the other European countries to stop the pharmaceutical industry from free price setting. Germany was with Malta and Denmark the only European countries where the pharmaceutical industry enjoyed this freedom until 2011.

The decisive explaining variables which made a policy change in 2011 possible in contrast to various attempts in the past were that the pharmaceutical industry and CDU/CSU and FDP did not block this radical change. The explanation why CDU/CSU and FDP and the pharmaceutical industry did not block it has a strategically explanation: The policy change in 2011 was dominated by problem solving in the sphere of politics, which was, finding a way to prove CDU/CSU and FDP was capable of action. Germany has a very big and strong pharmaceutical industry compared to other European countries which leads to the suggestion that this is the explanation why Germany is such a latecomer in matters of drug regulation.

CHAPTER 1

INTRODUCTION

1 Introduction

Germany is a latecomer in the matter of drug regulation of patented drugs. Until 2011 the drug regulation of the German drug market differed in many aspects from the ones of other European countries which had all similar ones. The pricing regulations of patented drugs were missing and reimbursement regulations of patented drugs were ineffective constructed. In contrast to other European countries the pharmaceutical industry was freely allowed to set prices of patented drugs.

This led especially to a problem by a small group of patented drugs which have a “therapeutic added benefit”¹. In my thesis I use also the name “innovative drugs” as synonym for drugs with therapeutic added benefit. In respect to these innovative drugs the pharmaceutical industry is not only allowed to set the prices as high as they want but also the health insurance funds have to reimburse the full price of the drug. In contrast the pricing of patented drugs which have no therapeutic added benefit is regulated and the health insurance funds do not have to reimburse the whole price.

In 2011 it came to a radical policy change in respect to innovative drugs with therapeutic added benefit: The pharmaceutical industry is not anymore allowed to determine freely the prices of these highly innovative drugs but price negotiations between sickness funds and the pharmaceutical industry define now the price of the new drugs. Moreover it gets better controlled which drugs have a therapeutic added benefit: Because a huge problem is that a lot of drugs are treated – reimbursed by sickness funds – as they would be innovative - but in truth they are not.

The concern of my study is to explain why radical policy change happened in 2011 and not earlier because various attempts were started before to regulate innovative drugs. Moreover to find an explanation why two parliamentary parties and the pharmaceutical industry changed suddenly their attitude towards this regulation after they defeated it two decades long. The third concern of the study is to explain why Germany was a latecomer in order to regulate drugs with therapeutic added benefit.

¹ Therapeutic added benefit: “being more effective, having lesser side-effects, or by being less costly at equal effectiveness as existing drugs. (Kiffmann/Neelsen 2010, 45).

1.1 Summary of the political and the health system in Germany

Bundestag (Lower House of Parliament) and Bundesrat (Upper House of Parliament) are the two federal legislative bodies in Germany. Bundestag serves as lower house and Bundesrat as upper house. The decision – making process in Germany is defined as long process shaped by compromises between these two bodies because most of the time the opposition parties in Bundestag holds the majority in the Bundesrat and by most laws the Bundesrat has to approve in order that Bundestag is able to pass a bill.

Germany's health system is defined as a complex system of self-governance. These self-governing institutions are: The sickness funds and the Association of Statutory Health Insurance Physicians (Kassenärztliche Vereinigung). They are not directly under governmental administration. The government only gives the framework requirements to the self-governing institutions and controls it. Most important in our context of the study is the common self-governing institution the Federal Joint Committee (G-BA). With the help of this institution the Association of a Statutory Health Insurance Physicians (KBV), the German hospital association (DKG) and the statutory health insurance shall agree on compromises.

The decision-making in health care is characterized by the inclusion of various interest groups: Associations of the pharmaceutical industry, sickness fund boards, Federal Association of statutory health insurance, accredited Physicians, hospital groups, the pharmacists' association and other interest groups are included in the political decision-making process. In total around 70 interest groups express their positions in parliamentary hearings on health care reform bills (Busse/Schreyögg/Henke 2005, 330). They have the right to voice their positions regarding legislative proposal in special committees. Because of the variety of actors involved in decision – making in Germany, there is very little chance that the different actors agree fast on a consistent approach for cost-containment. This involvement of various interest groups in decision-making can be seen as a „form of corporatism in decision - making or the enforcement of private interests“ (Busse/Schreyögg/Henke 2005, 330).

Moreover the pharmaceutical industry is highly organized with several associations. “Its associations either influence politicians and bureaucrats by giving them papers, outlining their performance or trying to influence the public through press releases and other activities. Sometimes pharmaceutical industry lobbying groups are able to block a passed law from being implemented.” (Busse/Schreyögg/Henke 2005, 331).

1.2 Significance of the study

This study deals with radical policy change in Germany's health policy. There is not much research done on radical policy change in Germany's health system. The reason is that only once a radical change happened before 2011 in Germany's health system and the radical change in 2011 happened recently; therefore was too less time that a lot research would exist. Existing studies on policy change in Germany's health system explain either incremental change (Leiber et al. 2010) or explain why hardly radical policy change happens in Germany's health system (Altenstetter/Busse 2005, 122; Carrera/Siemens/Bridges 2008).

The thesis describes the policy development of the pricing regulation from 1992 until 2011. As far as my research goes, this is the only study which demonstrates that the first attempts to stop the pharmaceutical industry from freely price setting was in 1992. Moreover the only study which describes the policy development from 1992 until 2011 in detail. Various other studies only focus on the development of the reimbursement regulations since 1992 (Siebert 2010).

In this thesis are various citations included from stenographic protocols and newspapers. These statements derive from politicians, actors of interest groups and experts. Through this various citations a real - life - context is created. As far my research goes a study in Germany's health care does not exist with this creation of real – life - context.

1.3 Background of the study

The pharmaceutical industry in Germany was until 2011 allowed determining the price of drugs with therapeutic added benefit and health insurance fund had to reimburse the whole price. Aggravating was that around 40% of these patented drugs with therapeutic added benefit which were launched between 1992 and 2008 had no therapeutic added benefit. In the other European countries this problem did not exist: There existed effective regulations in order to separate patented drug with therapeutic added benefit from ones without and in no other European countries except Germany, Denmark and England was the pharmaceutical industry allowed to determine the price of patented drugs.

Patented drugs are characterized that no other drug exists with the same quality performance characteristics, strength, dosage form and route of administration. In this thesis we distinguish also between patented drugs and patented drugs which have "therapeutic added benefit". A

therapeutic added benefit is defined by Kiffmann and Neelsen (2010, 45) “additional value by being more effective, having lesser side-effects, or by being less costly at equal effectiveness as existing drug”. In the following thesis I will use for drugs with “therapeutic added benefit” also the term “**Innovative drugs**” in order to make it more easily readable.

The stop of the pharmaceutical industry of determining the price of innovative drugs in 2011 is what is defined as radical policy change in this thesis and why this change happened will be explained with the help of this thesis. The history of this change started already in the 80th. A paradigm change happened back at that time in Germany’s health care system. It was planned to introduce more competition in health policy. Since this time competition was introduced step by step in Germany’s health system. In line with this paradigm change it was the first time planned in 1992 to change policy radically and stop the pharmaceutical industry to set the prices of innovative drugs. Back in 1992 a very similar regulation was planned in order to solve the problem of innovative drugs: Price negotiations between sickness funds and the pharmaceutical industry were suggested already in 1992 but the instrument in order to separate innovative from patented drugs differed.

This radical change in 2011 is highly interesting to explain of three reasons: First of all radical policy change is in Germany a very rare because of its path dependency, institutional continuities, and a semisovereign state policy-making model (Katzenstein 1987), characterized by a strong division between civil society and the state. Second it took twenty years until this radical change, which I describe in my model, finally happened.

The third aspect is the most interesting one: The Free Democratic Party “FDP” and Christian Democratic Union “CDU” initiated this radical change in 2011. The paradoxical aspect these two parties defeated and blocked the regulation since 1992.

The last important information is that this pricing regulation means actually a high financial pressure for the pharmaceutical industry. However in Germany politicians designed it with a lot of loopholes for the pharmaceutical industry. Experts doubt that it will lead to high savings and that the regulation does not put high financial pressure on the pharmaceutical industry in contrast to pharmaceutical industries in other European countries.

1.4 Statement of the problem

The research problem is that radical policy change happened in a health care system which is defined by factors which make radical policy change hardly possible: These factors are path dependency, institutional continuities, and a semisovereign state policy-making model (Katzenstein 1987), characterized by a strong division between civil society and the state. The second “sub” research problem is that CDU/CSU and FDP who defeated this regulation for 20 years all sudden initiated it in 2011. Social Democratic Party (SPD) and Green Party started attempts to enact it but CDU/CSU and FDP blocked it. The third research problem is that Germany did not enact this regulation more early even nearly all European countries except Malta and Denmark enacted this regulation a long time ago.

1.5 Research Questions

The main research questions which are addressed with this study are “why took radical policy change place in 2011? This regulation which was enacted in 2011 is similar to the regulation of pricing and reimbursement of other countries. Therefore is another research question: Why did Germany differ from other European countries in pricing and reimbursement regulation until 2011? In this study we will also deal with the question “How did the regulations of pricing and reimbursement change in 2011?” in order to figure out which interests were served or protected with this regulation. They maintained that this change would decisively contain costs in health care. Moreover the study will trace the question “Why did these parliamentary parties, FDP and CDU/CSU, who opposed this issue initiate and enact it in 2011?”. Since the regulation changes a decisive freedom of the pharmaceutical industry, I asked “How did the pharmaceutical industry influence this change and the content of change?” Moreover the study examined in how far the new regulation burden the pharmaceutical industry in fact?”

1.6 Theoretical framework

The study aims to explain radical policy change. Kingdon’s (1995) multiple stream theory is taken as main approach since he focuses on the timing of change. The main research questions concerns the moment of change. “Why did radical policy change happen in 2011?” The possible explaining factors for radical policy change coalition change, focusing event, pharmaceutical industry, policy and problem window, arguments and framing were mainly taken from Kingdon’s (1995) concept. In order to find an answer to another central research question, which was “Why the two central parties CDU/CSU and FDP changed their attitude

towards and regulation all sudden in 2011?”, I added during the study more strategically theoretical approaches from Beland (2010) and Leiber (2005). I got from Beland’s (2010) theory the explaining variable “framing” and from Leiber et al. (2010) the idea that a policy process can be characterised by a grand coalition finding a way to be capable of action.

1.7 Methods

The radical policy change which needs to be explained took place in 2011. In order to give validity to the factors variables which I assumed would explain the case in 2011, I used the “Method of Difference” of John Stuart Mill. I chose there very similar cases but only in one case happened the radical policy change that the pharmaceutical industry could be stopped from setting the price on their own. The method works in this way that the assumed explaining variables for radical policy change are tested in each case. These explaining variables which only co-vary in the case 2011 are the explaining variables.

1.8 Organisation of the study

Chapter 2 is the theory part of the study. Here three major theoretical perspectives on radical policy change are presented; in detail the hypothesis and (in) dependent variables are presented of each study. Afterwards commonalities, differences and shortcomings of the three approaches are discussed. After discussing these major approaches the theoretical model of my study was presented, which is mainly based on Kingdon’s (1995) concept of radical policy change. In *chapter 3* research strategy, the design of the study, the data collection methods, validity and reliability of this case study is described. *Chapter 4* includes all the basic information which is necessary in order to understand the study. It describes the structures of the German health care system, the decision-making system and the reimbursement and pricing regulation is described in detail and compared with other countries. *Chapter 5* is the empirical chapter where the policy process of all three cases is described which present together the policy development of pricing and reimbursement since 1992. The aim of this chapter is to present findings on the nine variables in form of citations of politicians, interest groups and experts from stenographic protocols and newspapers. The presentation of the cases is designed in the same way in order to make comparisons of the three cases possible. First the disputes and upcoming issues are presented and then the arguments of the different actors to these disputed issues. In *chapter 6* follows the analysis which is structured in the same way as Kingdon (1995) structured his theoretical concept and the analysis is embedded in a brief summarization of his concept. This way of presenting the analysis is chosen since it warrants

a clear structured analysis. *Chapter 7* is the conclusion which rounds the study. First the most important steps in the study are summarized, second it discussed if it was really radical policy change in my case since it is such a rare phenomenon in Germany, third the independent factors are summarized and last it is discussed how my study is a contribution to theoretical and empirical research.

Chapter 2:

THEORETICAL FRAMEWORK

2 Introduction

The aim of this chapter is to develop a framework for analyzing policy change in the German health system in 2011. This chapter discusses theoretical models, their independent variables and hypotheses. Moreover it focuses on determining from this theoretical background possible factors and actors in order to explain policy change. This chapter discusses public policy, policy change and some approaches, which have dominated research on policy change. After reviewing theoretical models and perspectives, a theoretical framework is developed for analysing factors and actors, which are assumed to explain policy change in Germany's health sector.

2.1 Perspectives and Concepts on policy change

In this section are three major approaches of radical policy change discussed in order to get familiar with factors which explain radical policy change. Radical policy change is according to Howlett and Ramesh (2010, 202) to be understood “as fundamental transformation of policy – making and involves changes in basic sets of policy ideas, institutions, interests and processes”. This study deals with a radical policy change in respect of processes. The regulation of pricing and reimbursement in Germany changed in 2011 to be more similar to the regulations in other European countries after being an exception over two decades.

These three approaches are the Advocacy approach of Sabatier (1988), the punctuated equilibrium model of Baumgartner and Jones (1998) and Kingdon's multiple stream model. I chose them because they dominated the theories of radical policy change since the 90th according to Real-Dato (2009) and John (2003). The same impression – that these theories are

very dominating - I got in my research for the theoretical part of my study. Nearly all examined studies which dealt with radical policy change used in their theory part at least one of these theories. Each of these theories has their own explanation of the policy process and focus on different stages of the policy cycle. Sabatier (1988) focuses on implementation, Kingdon (1995) on agenda – setting and decision - making and Baumgartner and Jones (1988) on issue definition and agenda - setting. Since they consider the policy process differently, they also explain change differently.

First the outline of these three studies is presented. Second the critics, commonalities and differences of these three studies are discussed mainly according to Real-Dato (2009). For our study it is very decisive which role interest groups and the parliamentary parties in order to change policy radically. Therefore is the last point in this chapter a comparison of the three theories in respect to the role of interest groups and parliamentary parties.

2.1.1 Overview of three major approaches on policy change

2.1.1.1 Multiple Streams Model – John Kingdon (1995)

The multiple streams theory explains how national governments make policies under conditions of ambiguity. The framework explains primarily policy formation but it is possible to extend the framework and explain with its help the whole policy process. It is a theory of choice and therefore it deals with three questions: “How is attention rationed? How and where is the search for alternatives conducted? How is selection biased?” (Zahariadis 2007, 65). The framework considers three existing streams which flow through the policy system – problems, policies and politics. Each stream has its own dynamics and rules. At special points in time – termed policy windows – policy entrepreneurs link these streams. The opening of a policy window enhances dramatically the chance that policy gets changed.

Kingdon (1995) put the basic outline of the multiple stream approach forward on the basis of the garbage can model of organizational choice of Cohen, March and Olsen (1972). Collective choice is the result of structural forces and cognitive and affective processes which are highly context dependent and not only the derivative of individual efforts (Zahariadis 2007, 66). Kingdon (1995) tries to find an answer with his theory on the question: “[...] [W]hy changes occur and why some subjects are more prominent than others”.

The unit of analysis of this theory is the entire system or a separate decision. Similar to system theory it considers choice as the collective output of formulated by the push and pull

of several factors. In contrast to Baumgartner and Jones (1991) – their theory will later be described – Kingdon (1995) sees systems constantly evolving and not mandatorily changing into equilibrium.

The political process is seen as a political struggle to define winners and losers and to carry out their self-interest. A decisive concept is information and it is strategically manipulated. The information of policy entrepreneurs includes self-interest but this is not the main aim of the role of the policy entrepreneur: His aim is to “create meaning” for those policy makers which have dangerous or ineffective preferences.

The MS approach differs from other lenses in so far that it does not employ rationality or persuasion. Therefore Kingdon (1995) does not assume that his actors are utility maximizers as rationalists consider. Kingdon (1995) differentiates between two groups of individuals: The ones who get manipulated and who manipulate. Kingdon (1995) considers that policy makers have problematic preferences and get manipulated. In contrast policy entrepreneurs are goal-driven manipulators. However the final decision if a policy is good enough in order to enact it is decided by policy makers. Political manipulation involves that policy makers have not made up their minds in order to be convinced about the one right decision. So there is no belief system which needs to be changed.

According to Kingdon (1995) it is important to understand “how information is presented and processed” (Zahariadis 2007, 70). Labels and symbols are used by policy makers in order to make emotional effects and cognitive referents. With this strategy one dimension of choice is highlighted over others. “It’s the strategic use of information in combination with institutions and policy windows that changes the context, meaning and policies over time.” (Zahariadis 2007, 70).

2.1.1.2 Baumgartner and Jones – Punctuated – equilibrium theory

Baumgartner and Jones (1991, 1052) made a case study about the “nuclear power industry in the United States” and build up their theory on policy change on basis of this study. They consider that political processes are generally characterized by stability and incrementalism but occasionally they produce large – scale departure from the past. They criticise that most theories only explain either stability or change and they try to explain both. The theory focuses on issue definition and agenda-setting (True/Baumgartner/Jones 2007, 156).

They based their model on the emergence and the recession of policy issues from the public agenda. According to Baumgartner and Jones (1998) the political world is hardly in the equilibrium and the points of stability are destroyed by “critical junctures throughout the process of issue development” (Morales 2003, 1). “The same institutional system of government organizations and rules produces both a plethora of small accommodations and a significant departure from the past.” (True/Baumgartner/Jones 2007, 156). This aspect is broadened by Baumgartner and Jones (1991) and is placed on a “dual foundation of political institutions and boundedly rational decision-making” (True/Baumgartner/Jones 2007, 156).

Issues are defined in public discourse in various ways and raise and fall in the public agenda. Therefore issues can be fostered or questioned. Reinforcement creates the possibility to change and questioning prevents change.

Neither rational theories nor incrementalism match to the punctuated equilibrium approach. “However if we add the simple observation that attention spans are limited in governments just as they are in people, then we have a theory of decision-making that is consistent with punctuated equilibrium theory and with what is actually observed” (Baumgartner/Jones 1991, 156).

The interaction of multilevel political institutions and behavioral decision-making explains best the marginal and large scale policy changes. The theory focuses on bounded rational decision-making, the dynamic of the interplay among institutions, interests and attentiveness. Not all issues which confront a political system are discussed. More realistic is that different issues get discussed in issue – orientated subsystems. Baumgartner and Jones (1991) explain that one single interest can dominate a subsystem.

If a subsystem is dominated by a single interest then it is best understood as policy monopoly. Baumgartner and Jones (1991) consider that the primary interest of every interest group is establishing a monopoly (Morales 2003, 2). A policy monopoly which is successful can avoid change by preventing pressure for change. But this is not possible forever. However, if pressure from the public occurs then new actors and governmental institutions get involved. This leads to a substantial change in policy image. If it comes additionally to a successful change in “venue” policy change happens. Because as soon as the issue is new defined new actors exert their authority. These change of actors is responsible for changing the balance of power and they define the rules new. This will be supported by new institutional structures. The former dominating institutions have to share their power with the ones who got

legitimacy through the changing image. This new equilibrium can stay in place again for decades.

2.1.1.3 Sabatier (1988) - the advocacy coalition framework

Sabatier (1988, 130) designed a framework to explain policy change, which takes place over one or several decades. He (1988, 132) uses two sets of exogenous variables, in order to describe the constraints and opportunities of actors. One set is more stable and the other one is more dynamic. Radical policy change depends on changes in respect to the dynamic variables, which are changes in socio-economic conditions; change in or of systematic governing coalition and influence of other subsystems (Sabatier 1988, 133).

Sabatier (1988) defines his theory on the basis of a subsystem and there are all actors included, “who play an important role in the generation, dissemination, and evolution of policy ideas” and who are dealing with a certain policy problem (Sabatier 1989, 131). These actors are: administrative agencies, legislative committees, researchers, journalists, and policy analysts. “Advocacy coalitions” play also a decisive role in Sabatier’s (1988) theory: This is a group of actors, which often act together, because they share normative and causal beliefs and they are from various organizations. Moreover “policy brokers” are also important in Sabatier’s (1988) theory since they mediate conflict. Advocacy coalitions are decisive in Sabatier’s (1988) explanation why radical policy change happens. If there are changes in socio-economic conditions or governing coalitions, then the recourses of the advocacy coalition changes which can lead to a change in core beliefs what means that a major policy change can happen.

Public policies “can be conceptualized in the same manner as belief systems” (Sabatier 1988, 131) because public policies involve similar as belief systems “value priorities, perceptions of important causal relationships, perceptions of the world state, and perceptions of the efficacy of policy instruments” (Sabatier 1988, 32). Beliefs are structured in three levels: “deep core of basic beliefs, policy core beliefs and secondary aspects” (Real-Dato 2009, 119). Deep core of basic beliefs and policy core belief are hard to change through new information, since they are connected with individual identities. In contrast secondary aspects can be altered with policy learning. Policy learning is seen in this theory that “members of various coalitions seek to better understand the world in order to further their policy objectives” (Sabatier 1988, 133). “They will resist information suggesting that their basic beliefs may be invalid or/and attainable and they will use formal policy analysis primarily to buttress and elaborate these

beliefs and (attack their opponents’).” (Sabatier 1988. 133). If there is not anymore a wholesale agreement between the members of an advocacy coalition about the necessity to continue with the status quo and because of this hard positions were softened, then certain degree of policy learning has happened. Policy learning is the result of trial and error learning and policy analysis.

External events, which are macro-economic conditions, the rise of a new system governing coalition, policy impacts and decisions and impacts from other subsystems, on the other hand can lead to major policy change (Sabatier 1988, 134). Sabatier (1988, 142) decided define belief systems instead of interests which link advocacy coalitions since they are more inclusive and verifiable. He explains that “of course, coalition stability could be the result of not of stable beliefs bur rather of stable economic/organisational interests”. He continues that this would raise very difficult methodological problems, since self-interest and belief systems are highly correlated and the causation would be reciprocal. The advantage of belief systems models would be that they are able to include self-/organizational interests but they allow actors also to have other goals. Moreover he adds that it is difficult to specify “a priory a clear and falsifiable set of interests for most actors in policy conflicts” (Sabatier 1988, 142).

Sabatier (1988, 147) also refer to the importance of discourse or the way how the actors communicate: “Insofar as policy discussions among insiders are based on reasoned argument, actors are holding blatantly inconsistent or unsubstantiated positions will lose credibility.”

Policy change within a subsystem can be seen as the result of two processes: First the advocacy coalition managed to “translate the policy cores and secondary aspects of their belief system into governmental programs” (Sabatier 1988, 148). Second the change of external perturbation, which has influence on the recourses of the actors.

After having presented the outline of these three major approaches to policy change commonalities, differences and shortcomings of these three approaches will be presented.

2.1.2 Commonalities, differences and shortcomings of the three approaches

2.1.2.1 Commonalities

In this section we will proceed in the following way: First the commonalities and then the shortcomings including the differences are presented.

In contrast to other theories on policy process – e.g. the heuristic stages cycle – these theories have their “commitment with true causal explanations” (Real-Dato 2009, 2). Moreover the subsystem is their basic unit of analysis which is defined in the following way: They define a subsystem as “decisional system formed by the interactions of the set of actors interested in a policy issue or problem and the set of rules regulating those interactions” (Real-Dato 2009, 2). Furthermore these theories have in common that their explanations are based on the behaviour of rational – bounded actors which act in the boundaries of the subsystem. The actors get their causal role mainly by ideational factors which are “actors’ interpretations, ideas, and beliefs about public policies” (Real-Dato 2009, 2). Moreover they agree in some major explaining variables. These are dramatic events or crisis, changes in governing coalitions and administrative and legislative turnover (Schlager 2007, 310).

2.1.2.2 Shortcomings and Differences

Even these theories are famous and are often cited, three shortcomings are described in literature which also point out the differences of these three approaches (Real-Dato 2009, 2): “the incompleteness of the generative causal processes they identify; [...] their limited explanatory scope; and [...] the problem of the explanandum.” (Real- Dato 2009, 2).

The incompleteness of the generative causal process includes three “sub problems”: First they hardly address micro-level processes: Real-Dato (2009, 9) means with it that these theories do not mention how actors deal with collective action and coordination. Second they do not explain enough the role of institutions. Institutions are understood as constraints made by humans who shape human activity and define rules and norms. Since their role is hardly explained in these theories it does not become clear how and in how far institutions influence the behavior of actors. Third they address too less boundary relationships which are the relationships between subsystems and its environment (Real-Dato 2009, 3). This criticism is of high importance since all three approaches consider institutions and other actors outside the subsystem as decisive explaining variables. Therefore how exogenous factors influence policy change is insufficiently explained (Real-Dato 2009, 3).

The “limited explanatory scope” refers to the tendency to favor a particular causal path of policy change. This limits their ability to deal with the complexity of policy dynamics. The MS approach favors environmental factors outside the policy subsystem in contrast to policy learning or policy entrepreneur’s strategic behavior. Instead the PET approach considers policy entrepreneurs who expand the problem outside subsystems as main explaining

variable. However the ACF explains policy change with several causal paths: In Sabatiers (1988) first versions he considered only policy learning and external shocks explaining variables. In his revised versions he added shocks of the internal subsystem and negotiated agreements between coalitions (Real-Dato 2009, 3).

The last weakness of these approaches – addresses the problem of explanandum what defines „what changes when policy changes“(Real-Dato 2009, 3). The ACF links policy change to change in the belief system of the dominant advocacy coalition. In contrast to it the MS and PET links change to changes in the „decisional agenda and the level of policy production“(Real-Dato 2009, 4). According to Real – Dato (2009, 4) this is misleading: „On the one hand, mediating between beliefs and the content of policy programs are a number of institutional structures and strategic dynamics [...] so policy designs may not fully reflect policy beliefs. Similarly, changes in the agenda do not necessarily correspond to changes in the policy program actually implemented. “

In the next section the role of interest groups and policy makers is compared in an extra section since these is not addressed by Real-Dato (2009) but highly decisive for our study. Therefore how the theory deals with “collective action” was very decisive for the choice of the reference theory for our study.

2.1.2 Collective Action – the role of pharmaceutical industry and policy makers

Since the pharmaceutical industry plays a decisive role in my study and actors of the parliamentary parties, I needed a theory which explains adequately collective action.

Each of the three theories is grounded in a model of the individual, how individuals come together, organize themselves and promote policy change; therefore policy change is caused by collective action (Schlager 2007, 302).

Despite this commonsense the theories differ how they explain collective action. The multiple streams theory pays less attention to “collective action as process of individuals coming together to achieve a shared end” in contrast to Sabatier’s (1988) and Baumgartner and Jone’s (1998) approaches (Schlager 2007, 302). Instead Kingdon (1995) focuses on the decisive roles played by certain individuals, or policy entrepreneurs, and the “conditions that support broad – based collective action that leads to radical policy change” (Schlager 2007, 302). “One nice property of this picture of agenda change involving entrepreneurial activity is that it makes some sense of ‘great man’ theories of history....Policy entrepreneurs do not control events, but they can anticipate them and bend events to their purposes to some degree.”

(Kingdon 1994, 220-221, cit. a. Schlager 2007, 302). The conditions which advance broad-based collective action are those that “support the coupling of streams and the activities of policy entrepreneurs” (Schlager 2007, 302).

In the punctuated equilibrium theory policy entrepreneurs play also a decisive role. Their actions and strategies play an important role in explaining policy change. In contrast to Kingdon (1995), Baumgartner and Jones (1991) consider that change can be explained also by a collection of interest groups, groups of policy makers or mass mobilization. The punctuated equilibrium theory analyzes the results of collective action, these are changes in policy images and changes of venues (1998, 303).

The advocacy approach pays also very careful attention to collective action. Since Sabatier (1988) explains policy change with a change in the belief system of the advocacy coalition.

2.2 Theoretical Framework for my study

In the following I will construct my own theoretical framework for my study. Kingdon's (1995) multiple stream approach offered nearly all explaining variables which I assumed that would explain the radical policy change of this study. From Kingdon (1995) I got the explaining factors role of the pharmaceutical industry, change in coalition, focusing events, policy entrepreneur, policy and problem window, argumentation. From Beland's (2005) theory I got the explaining factor “framing”.

2.2.1. Kingdon (1995) – Multiple Stream approach

Kingdon wrote a whole book “Agendas, Alternatives, and Public Policies” (1995) with around 160 pages in order to present his theory on agenda –setting and radical policy change. Kingdon (1995, 2) presents a simplified view of the policy process at the beginning of the book: “(1) setting of the agenda, (2) the specification of alternatives from which a choice is made, (3) an authoritative choice among those specified interests, as an legislative vote or a presidential decision, and (4) the implementation of the decision” (Kingdon 1995, 3). Kingdon (1995, 5) focuses mainly on the first two points. Kingdon (1995, 15) explains policy change with two kinds of explaining variables: actors and processes. Kingdon (1995) differentiates between governmental and non - governmental actors and processes are differentiated in a problem-, policy- and political process. These three streams develop themselves mostly independently from each other and under certain conditions these three streams meet. When these three streams meet than the chance of a policy change is decisively

enhanced. In the following is explained how policy formation and policy change is influenced in detail by actors and processes according to Kingdon's (1995) theory.

Before the theory is summarized two basic concepts of Kingdon's study have to be explained in order to understand the following explanations of his theory: First of all Kingdon (1995, 4) differs between governmental and decisional agenda. Kingdon (1995, 4) explains that the governmental agenda is "the list of subjects that are getting attention" and the decisional agenda is "the list of subjects within the governmental agenda that are up for an active decision". He distinguishes these two kinds of agendas since both are affected by different processes. The next basic concept of Kingdon's (1995, 4) theory is the differentiation between a "set of subjects or problems on the agenda" and "alternatives of governmental action".

If the cost of medical care is a prominent agenda item, for instance, officials could seriously consider a number of alternatives related to this problem, including indirectly regulating hospital costs, introducing incentives into the system to encourage market regulation, paying consumers costs through comprehensively national health insurance, enacting such partial insurance plans as catastrophic insurance, nationalizing the system in a scheme of socialized medicine, or doing nothing. (Kingdon 1995, 4).

The following explanation of the theory is structured according to Kingdon's (1995) presentation of the theory in his book "Agenda, Alternatives and Public Policies". It starts with describing the role of actors for policy change and explains afterwards the role of the processes and at the end their interaction in order to explain radical policy change.

Actors: Governmental Actors

Kingdon (1995, 21) describes in detail how much power different governmental actors have in the policy formation process. However he works in his theory with the political system of America. In the following I tried to confer his theory to the German system and described the distribution of power of the German political actors and institutions.

Federal Government

The Federal government includes the Federal Chancellor and the minister. The Federal Chancellor has strong powers in agenda - setting because of his political position. The minister have hardly influence to set the agenda but influence the choice of alternatives. The power of the Federal Chancellor results from his high attention in media. In contrast to the minister the Federal Chancellor is not that included in specifying the alternatives. The minister's competence of specifying alternatives results from negotiating with interest groups and parliamentary parties of the Bundestag.

Bundestag and Bundesrat

The role of the Bundestag in agenda - setting is weak (Sieberer 2007, 49). In contrast the Bundestag plays an important role in specifying the alternatives. Parliamentary commissions have the function to suggest, discuss and develop alternatives. The Bundesrat has also a weak role in agenda – setting but is also decisive by the choice of alternative since the Bundestag needs often the approval of the Bundesrat in order to pass a bill.

Actors: Non - governmental actors

Interest groups are the most important actors of non-governmental actors. Kingdon (1995, 47) showed in his case studies that provider groups, like pharmaceutical industry, are very important in seven of his eleven case studies in health care. Kingdon (1995, 49) argues that the main role of interest groups in policy change is not in bringing an issue on the agenda, but more in promoting new agenda items and advocate them. Government officials lobby interest groups and the other way around.

The Communication channels between these inside and outside the government are extraordinary open, and ideas and information float around through these channels in the whole issue network of involved people, somewhat independent of their formal positions. (Kingdon 1995, 45).

For the present thesis of high importance is the following finding of Kingdon (1995): The activity of interest groups is most of the time not positive promoting but instead negative blocking. So they try to protect their interests in the legislative process and block disliked policy changes. “The opposition of medical care providers to health insurance and other new health programs that they are belief run counter to their interests is by now legendary.” (Kingdon 1995, 49). Interest groups with a broad organizational and economical background have better chances to block policy change.

Hypothesis 1: The pharmaceutical industry has influence on radical policy change.

The next role of actor in the policy process which Kingdon (1995) explains are experts and media: Experts influence only the choice of alternatives but not the agenda – setting. In contrast to other theories sees Kingdon (1995) the influence of media less important than often explained in other theories.

The next step in order to present Kingdon’s (1995) concept and my theoretical framework of this thesis, is to explain the three streams in detail; these are the political-, policy- and problem streams.

Processes: Problem-Stream

The problem stream deals with the issue that some problems call attention and some not. Reasons for this different attention can be: policy feedback, indicators and crisis or events. Moreover also the formulation and articulation of the policy problems have influence on the importance of a policy problem.

Focusing events

Focusing events like crisis or other kinds of special events can give the impetus that politicians realize that a certain problem exists. Focusing events cannot be seen as the one explaining variable why a certain issue is put on the agenda and change finally happens. Always various factors have to come together that radical policy change can happen. However a focusing event can be a very decisive factor which facilitates policy change since it points out the importance of reforming and regulating a particular issue.

Hypothesis 2: Focusing events have influence on radical policy change.

It is not only depending on the extent of the problem if it gets attention. It depends more on politicians if they give attention to the problem and do not cover it. These politicians which focus on a problem because they have a suggestion how to solve the problem are called policy entrepreneurs.

Processes: Policy - Stream

Kingdon (1995, 117) imagines the development of policy as selection process similar like in biology. He draws the picture of a primeval soup in which ideas of experts of a certain policy community float around and either assert themselves or disappear again.

Policy communities are groups of experts in certain policy areas. According to Kingdon (1995, 117) they know each other personally and have private contact or are in contact because of their job. Policy communities differ in their extent of fragmentation. For example health policy communities are more closed and less fragmented. Therefore actors in health policy communities know each other better and interact more as actors in policy areas which are not that closed. Moreover less fragmented policy communities share more likely the same paradigms. Important in less fragmented policy community's – like in health care - policy change happens not that rapid and surprisingly as in more fragmented ones. The function of these policy communities is to discuss and develop alternatives. These different alternatives

are highly important later in the decision - making process. First of all because as more alternatives exist as higher is the change that one alternative is taken to solve the existing problem. If the alternative is finally not taken and enacted it is possible that this alternative gets redrafted again and again in the policy community. It is possible that the redrafted alternative is used after years to finally solve the delayed problem.

In these policy communities exist policy entrepreneurs. They are highly decisive in order to explain policy change. It is not only enough that a problem and a solution (alternative) and as will be later explained the political context is appropriate but also somebody who realizes that these three conditions right now exist and offer a good opportunity to change policy radically. The role of this policy entrepreneur is to highlight problems, push for one kind of problem definition and instead of another and develop proposals for their ideas. Therefore it happens that policy entrepreneurs construct a problem in order to be able to enact a certain policy. Beland (2005,1) developed an own theory in which he explains that political actors would frame alternatives in order “to sell them to the public while constructing the need for reform”. „Frame“ in Beland’s (2005, 14) definition is the „discourses that help policy-makers sell policy alternatives to the public“. Moreover he explains that political actors would frame these „alternatives in ways that could increase their popular support, before and even after their enactment“. Therefore I hypothesis that also framing in Beland’s (2005) definition took place in the case 2011 and had influence on radical policy change.

Hypothese 3: Frames influence radical policy change.

In some cases not only one but more policy entrepreneurs exist. This policy entrepreneur(s) is willing to invest resources like time, money and reputation in order to push his idea. As compensation they expect to foster their carrier, accumulate votes or self - presentation. Kingdon (1995, 180) explains that in his 23 case studies policy entrepreneurs were 15 times coded as very important and only as three times as not important. However they are not solely responsible for policy change but they are central figures in the drama. Policy entrepreneurs can be governmental and non- governmental actors, they only have to have good connections to decision- makers and have to have good negotiations skills.

Since I assume that the health minister is the policy entrepreneur in 2011, the theory of Dudley and Richardson (1996) is added. They point out the decisive role of ministers in policy change since they have a powerful position and since they “exhibit a mobility –or

indeed promiscuity – in their relationship with interest groups, which they can turn into advantage in bringing about much needed policy change” (Dudley/Richardson 1996, 567).

Ministers would act because of self - interest or because of values or they can also be influenced by external pressures. Often they can also be seen just willing to search with solution for problems to adapt (Dudley/Richardson 1996, 568). The ministers can change the interest groups they support during their time in office or they can also decide to not foster any interest group (Dudley/Richardson 1996, 570). Ministers do not have to represent the interests of their policy community (Dudley/Richardson 1996, 567). They also point out the importance of framing for the success of ministers (Dudley/Richardson 1996, 567).

Hypothese 4: Policy entrepreneurs have a decisive role on radical policy change. The position as minister supports positively the role of a policy entrepreneur.

Actors in the primeval soup do not act rational, therefore decision - makers often do not choose the best alternative. However, not exclusively power, strategy, influence and pressure are responsible if an idea comes on the decision - agenda. The content of ideas and how the actors argument this content is decisive if a good idea will be finally enacted.

By most informed accounts, for example, the arguments of academic economists in favor of airline deregulation really did play a major role in its passage. One of my respondents, in fact, took me through the arguments marshaled by the airlines against deregulation, and showed me how their arguments were ‘simply destroyed’ during the course of the hearings” (Kingdon 1995, 125).

At this point it is interesting to refer to the study of Doran and Henry (2008) who point out the power of arguments and explain that arguments can change policy. They argue in their study that the argument that price control for innovative drugs would be an “impediment to drug innovation and industry growth” would lead to a deregulation of price control (Doran/Henry 2008, 106). In respect to my thesis I argue in similar vein: Germany had because of similar economic arguments in respect to protect Germany’s economy no price control of innovative drugs.

Hypothese 5: Economical arguments influence policy change.

As mentioned above some ideas of the primeval soup are further developed, some disappear and some get combined with each other. There are some criteria which explain why some ideas survive longer than other: 1) feasibility, 2) values which are the basis of the idea have to be accepted. Therefore depending on the parties direction (liberal or conservative) different

ideas will have a chance 3) Cost-effectiveness 4) public opinion and representatives agree on the idea.

Consensus building in the policy stream works through spreading of ideas. Moreover actors can build consensus through argumentation. If an alternative is not accepted in a policy proposal, then the draft has to be overworked as long until it gets accepted. Sometimes in the same legislative process it gets accepted, sometimes years later in another policy process or never. The quality of the alternative(s) is also decisive if an issue gets at all on the agenda.

Processes: Political - stream

The political stream deals mainly with actors which are visible in public and therefore are under pressure of public opinion. Influencing factors are in the political stream: public opinion, the ideology of ruling and opposition parties in parliament and changes in high legislative and executive level (Kingdon 1995, 142). Changes in the political-stream are decisive for changes of the agenda.

Public opinion

This approach considers that most people in one country share the same opinion about a particular policy issue. Moreover Kingdon (1995, 146) thinks that from time to time this opinion changes. This influences issues on the Agenda and the results of decision-making. This public opinion can influence actors to put an issue on the agenda or to defeat it (Kingdon 1995, 146). Among other things politicians get the public opinion from the media. However politicians also influence media. A change in public opinion is able to make disliked ideas to serious considered ones.

Government in the political stream

Ruling parties or actors with high positions can influence policy change in two ways: Either then politicians in office change their priorities of issues which they push or there is a legislative turnover and the new politicians in office have other new priorities. Changes in government are highly influential on the agenda and on radical policy change. (Kingdon 1995, 153).

Hypothese 6: Radical policy change is depended on the change of coalition.

Policy- and problem window

A policy- and problem window describes the situation that advocates of proposals can push their alternative with high chance that it gets on the decisional agenda. And a higher chance of enactment and policy change exists. A problem window opens when a focusing event happens in the problem stream and a policy window opens when a change of coalition happens. However, in order to change a policy an open policy window is not enough. A policy entrepreneur has to realize that the situation is good to push an idea and link all three streams: “A problem is recognized, a solution is developed and available in the policy community, a political change makes it the right time for policy change, and potential constraints are not severe.” (Kingdon 1995, 165).

Hypothesis 7: Policy and problem window are decisive to explain radical policy change.

2.2.2 The application of Kingdon’s theory to the study

Kingdon’s (1995) theory was chosen because of various reasons: First of all it focuses on policy formation (agenda-setting and decision- making). In contrast Baumgartner and Jones (1991) theory focus on issue definition and agenda setting and Sabatier (1988) on implementation.

Moreover Kingdon’s (1995) concept takes a decision as unit of analysis. Since our methodological framework is a comparative approach and the policy development of my thesis is divided into three parts which are my comparative cases. Therefore I focus more on examining three moments of time instead a whole development. Since Baumgartner and Jones (1991) and Sabatier (1988) explain policy change because of what has happened around an issue over long period of time it did not seem as appropriate for our study as Kingdon’s (1995) who explains policy change with the accumulation of factors at one point of time.

Furthermore I decided to choose Kingdon (1995) since he assumes that policy entrepreneurs are the decisive actors for policy change. Like Hasenteufel (2010) I also argue that Sabatier’s (1988) advocacy group includes too much actors in order to explain policy change.

As mentioned before the pharmaceutical industry as interest group plays a decisive role in our study. Kingdon (1995) credits them an important role on policy change and explains their role as policy blocker. Sabatier (1988) and Baumgartner and Jones (1991) give interest groups an even more decisive role in order to explain policy change. In contrast to Kingdon (1995) they point out more their influence on policy initiators and not only as policy blocker. Nevertheless

we decided on Kingdon's (1995) theory since in our case the pharmaceutical industry has only the role of a policy blocker and not initiator.

One more motivation in order to take Kingdon's (1995) theory was that he sees his actors either driven by self-interest or by ideology. The aspect of self-interest is very important in my case since I assume that the politicians in my case acted less because of ideology and instead of self-interests or rather interests of their party and coalition.

Kingdon's (1995) concept was also taken because of his understanding of the "opinion" of actors. He considers that individuals are not sure what they want which solution they find the best, so their opinion can be changed more easily as Baumgartner and Jones (1991) and Sabatier (1988) assume. Baumgartner and Jones (1991) and Sabatier (1988) assume that individuals have an imagination what would be the best idea and this imagination would change over time.

Another aspect which made me choose Kingdon's (1995) approach is that he does not assume that new information would influence policy makers about their attitude towards an idea but rather the different presentation of existing information by policy entrepreneurs (Zaharidias 2007, 70). Since in our study no new information existed but was only differently presented Kingdon (1995) seemed to be the right choice.

2.3 Operationalization of dependent and independent variable

2.3.1 The dependent variable for the study

The dependent variable of this thesis is radical policy change and is defined in the following way:

"[Radical policy change is a] fundamental transformation of policy – making and involves changes in basic sets of policy ideas, institutions, interests and processes" (Howelett/Ramesh 2010, 202). In this study the radical change is a change in "processes". Germany was an exception of all European countries how it regulated patented and innovative drugs (drugs with alleged therapeutic added benefit). In 2011 Germany enacted a regulation of innovative drugs which is similar to the ones of other European countries. This new regulation stopped the pharmaceutical industry from freely setting prices of innovative drugs. This change to stop the pharmaceutical industry from freely price setting of innovative drugs, I define as radical policy change in this study. According to Kingdon (1995) radical change goes along with change in the decisional agenda. At this point I have to deal with the problem that Kingdon

(1995) neglects the problem that a change in the decisional agenda does not necessarily correspond to changes in the policy programs; the chances are only very high. However since it is decisive for my study to differ between having a regulation on the decisional agenda or being enacted we expand the theory and define radical policy change as change which is indeed enacted and not only on the decisional agenda. It is important to make this separation in so far since in all three cases the regulation of innovative drugs was on the decisional agenda but only in 2011 it was finally enacted.

2.3.2 The independent variables for the study

In this section I operationalize the factors and actors which might explain or influence radical policy change in 2011. These factors are the pharmaceutical industry, focusing event, policy entrepreneur, change of coalition, argumentation, framing and policy window.

Influence of the pharmaceutical industry

The influence of the pharmaceutical industry was operationalized according to Lewi's (2005, 61) definition. According to her is influence is the "demonstrated capacity to do one or more of the following":

Shape ideas about policy, initiate policy proposals, substantially change or veto others' proposals, or substantially affect the implementation of policy in relation to health. Influential people are those, who make a significant difference at one or more stages of the policy process.

I argued that the pharmaceutical industry is decisive in order to explain policy change in 2011. In order to define in how far they influenced radical policy change I examined in all three cases in how far they influenced in respect to Lewi's (2005) definition the policy process.

Focusing events

I examined if in the three comparative cases a focusing event took place which would have pointed out that a problem exists. Or if politicians constructed a focusing event in order to construct the need for reform.

Policy entrepreneurs

I hypothesized that policy entrepreneurs have a decisive role in order to explain radical policy change because they have to realize that the perfect situation exists in order to push a policy idea. Therefore I defined in all three comparative cases the policy entrepreneur and described how they pushed their idea on basis of governmental documents. Moreover I asked in the questionnaire who was the actor who initiated and pushed through the new policy in 2011.

Change of coalition

I hypothesized that a change of ruling coalitions is decisive in order to explain radical policy change. I described in each case if a change in coalition took place. Moreover I described in each case the attitudes of the different ruling and opposition parties towards this regulation. The attitudes towards the planned regulation of the ruling and opposition parties I got from newspaper articles, stenographic protocols and literature.

Argumentation

I listed all arguments which were used from the advocacy and the adversary parliamentary parties. I examined which kind of arguments were used to protect and change the status quo and if the argumentation of the actors changed over time or if one discourse coalition got support by new actors.

Framing

Closely related with “Argumentation” I examined and tried to describe how in each case the discourse (Beland 2005) or story line (Hajer 1991) looked like in order to justify the policy decision pro or contra the enactment of a regulation which would have stopped the pharmaceutical industry from freely setting the prices of innovative drugs.

Policy window

I examined if a policy window or problem window opened in each case. I examined the whole condition of each case if a problem was recognized or constructed, a suitable alternative available in the policy stream and if a political change made it the perfect time for a policy change and if interests groups were blocking this change.

CHAPTER 3

RESEARCH METHODOLOGY

3 Introduction

The aim of this methodological chapter is to describe and discuss the research strategy, the design of the study, the data collection methods, the analysis of the cases and validity and reliability of this case study.

3.1 Research strategy

Germany's pricing and reimbursement regulation differed in many aspects from these from other European countries despite some attempts of adaption. However, in 2011 a radical policy change took place and now regulations of pricing and reimbursement are similar to these of other European countries. Especially the change in pricing in order to stop the pharmaceutical industry from freely setting the prices of innovative drugs was a clear formulated goal since 1992 but it failed until 2011. This radical change in respect to pricing regulation is defined as radical policy change in our study and needs explanation. Especially that the following fact makes it even more paradox and interesting to explain: CDU/CSU and FDP, two German political parties, were defeating this pricing regulation as they were ruling and opposition parties since two decades. However in 2011 as CDU/CSU and FDP came after a long period of time again together in power, they initiated and enacted it.

The study was a qualitative explanatory case study with the main purpose to explain why policy changed radically in 2011. Moreover it aims to explain why policy did not change more early; even some attempts existed to change it. The qualitative approach seems to be more appropriate for my study than quantitative or mixed approaches since qualitative approaches are more explorative designed.

A case study was chosen since "how" and "why" questions are the research questions of the study, contemporary events are examined and since the researcher cannot manipulate the behaviour of the involved actors (Yin 1994, 6). According to Yin (1994, 3) the reason in order to choose a case study is the "desire to understand complex social phenomena". The "complex social phenomena" which is explored in this study is radical policy change initiated by two

parliamentary parties who defeated it two decades despite the fact that nearly all European countries enacted this regulation.

3.2 Research design

A research design is defined as “the logical sequence that connects the empirical data to a study’s initial research question and, ultimately, to its conclusions” (Yin 1994, 19). A research design deals inter alia with this three components: “1) a study’s questions, 2) its propositions, if any, 3) its unit (s) of analysis (Yin 1994, 20).

The questions which are addressed with this study are why took radical policy change place in 2011? Why did Germany differ from other European countries in pricing and reimbursement regulation until 2011? How did the regulations of pricing and reimbursement change in 2011? Why did these parliamentary parties who opposed this issue initiate and enact it in 2011? How did the pharmaceutical industry influence this radical change and the content of change? How effective was this change? How far does the new regulation burden the pharmaceutical industry?

Since this change of pricing regulation implied in the other European countries a huge burden for the pharmaceutical industry and FDP and CDU/CSU are industry friendly parties, my presumptions of the study were that these two parties played a decisive role that policy did not change until 2011. Since I assumed that they had a decisive role that policy did not change until 2011, I assumed that they must also have an important role in explaining that radical policy change could finally happen in 2011. Moreover I assumed that they influence the content of this change decisively.

These presumptions made me to search for theoretical explanations which include the role of interest groups and political actors in explaining radical policy change. The units of analysis are the decision – making processes in respect to reimbursement and pricing regulation in the health care reforms in 1992, 2004 and 2011.

According to (Yin 1994, 31) is external validity enhanced if more cases support the same theory. I chose for my study three comparative cases. According to King (1994, 23) it is critical to explain precisely why in particular this small number of cases was chosen. I chose my cases following the “Method of Difference” of John Stuart Mill (Bandelow 2005, slide 3). This is an appropriate method if only few cases exist. I had to choose very similar cases where in one case the dependent variable differs. Or in other words only in one case happens the

phenomenon which needs to be explained; in the case of the thesis the phenomena and dependent variable is “radical policy change”. In case 2011 radical policy change happened: The pharmaceutical industry was stopped to set freely the price. In the other cases 1992 and 2004 it was tried to stop the pharmaceutical industry from freely price setting but radical policy change did not happen. John Stuart Mill (Bandelow 2005, slide 3).explains in order to find the explanation why in the one case radical policy change could happen the researcher has to search for differences in these three similar comparative cases. These explaining factors which are only positive in case 2011, and not in one of the other cases 1992 and 2004 explain why radical policy change could happen in 2011. In order to make it easier to compare these cases, I structured the presentation of the cases in the same way: 1) issues and disputes and 2) the arguments.

3.3 Documentary sources

The major recourse of data collection was documentary data. This decision was taken because actors which would have been most interesting to interview had all high positions. Therefore I did not expect to get an interview with these actors. Moreover the issues with which I deal in this study a very sensitive: It is about financial interests, the pharmaceutical industry and about the question why politicians missed out on regulating pricing if the chance existed. Therefore if politicians would have agreed on an interview, I would not have expected honest answers. Therefore the choice to work with governmental documents and newspapers was taken. Another reason to work with documentary data is that it is more flexible because it can be reviewed repeatedly if the researcher figures out that his first assumptions in order to explain the case were wrong.

Another important aspect why I worked with documentary data was because it makes comparisons possible. Since I compared three cases and two of them were a long time ago, documentary data was appropriate. However, it is according to Yin (1994, 82) very important to note that each document is “written for specific purpose and some specific audience *other than* of the case study being done” (Yin 1994, 82). Therefore it is important to identify the intended purpose of the particular documents in order to correctly interpret the information’s in these documents. “Few people realize for instance, that even the “transcripts” of official U.S. congressional hearings are deliberately edited - by the congressional staff and others who may have testified – before being printed in final form.” (Yin 1994, 81).

3.3.1 Governmental documents

I used a variety of governmental documents like minutes, written reports, written requests, law proposals and laws. These documents are published on the homepage of the Bundestag. The Bundestag offers search engines in order to find the decisive documents for a certain issue. Yin (1994, 82) points out to consider proposals of the same kind of document since “subtle changes often reflect key substantive developments in the project”.

In order to find decisive data for the case 1992, I searched with the word “Positivliste” (positive list) in these search engines in the time period 1990-1994. I read all documents which were found by the system. Even it was broad material; it was less than in the two other cases. In the case 2003 I searched with the key word “GKV – Modernisierungsgesetz” (SHI - Modernization Act) in the search engines of the Bundestag in the time period from 2002 to 2005. A huge amount of documents were found. In order to reduce the material, I opened each of these documents and searched with the search function for words in these documents. The key words “Nutzenanalyse” (benefit evaluation), “Kosten - Nutzenanalyse” (cost-effectiveness evaluation) and “Positivliste” (positive list) were used to search in these governmental documents. In the case 2011 I searched with the key word “Arzneimittelneuordnungsgesetz” (German Pharmaceutical Market Reorganisation Act). In contrast to the “GKV- SHI- Modernization Act was the focus of the whole German Pharmaceutical Market Reorganisation Act the regulations of pricing and reimbursement. Therefore I read all the material which I found with the key word “Arzneimittelneuordnungsgesetz” (German Pharmaceutical Market Reorganisation Act) without more reduction.

3.3.2 Statements of Research Based Pharmaceutical Companies

Another source of documentary data was the homepage of the Research Based Pharmaceutical Companies (Verband der forschenden Arzneimittelhersteller (vfa)). The required information to our benefit and cost-effectiveness evaluation is easily found under the button “positions” and “statements” on their homepage since they only offer to few issues information.

3.3.3 Newspapers

I gathered data from newspapers “Die Welt” and the “Frankfurter Allgemeine Zeitung” because they have the biggest editions. The “Süddeutsche Zeitung”, the magazines “Der Spiegel” and “Focus” were used as sources because of their high quality.

Access to all newspapers and magazines was for free except to the Süddeutsche Zeitung. Each newspaper and magazine offers search functions on their homepage. With these search functions the decisive articles can easily be found. The problem with the expensive access of the Süddeutsche Zeitung was solved with the help of the University library in Munich which offers free access to the articles from the archive. In the archives of each newspaper and magazine I searched with “Positivliste” (positive list) and “Gesundheitsstrukturgesetz” (Health Care Structural Reform Act) (from 1991 until 1992, with “Kosten - Nutzenanalyse” (cost – effectiveness – evaluation), “Nutzenanalyse”(benefit – evaluation), “Positivliste” (positive list) and “GKV-Modernisierungsgesetz” (SHI – Modernization Act) from 2002 until 2004 and with “Nutzenanalyse” (benefit evaluation), “Kosten - Nutzenanalyse” (cost – benefit evaluation), “Verhandlungen” (negotiations) and „Arzneimittelneuordnungsgesetz“ (German Pharmaceutical Market Reorganisation Act) from 2009 until 2011.

3.3.4 Literature

I read various scientific papers about the different possibilities of regulating pricing and reimbursement and about their dis- and advantages. This was important in order to be able to judge in how far the arguments of the governmental actors are biased when they argued that the pricing and reimbursement regulations of our case would be not appropriate. Moreover I read scientific articles about the role of the pharmaceutical industry in Germany in order to get an impression how important the pharmaceutical industry is for Germany’s economic. This is important in order to be able to understand why particular German politicians try to protect the pharmaceutical industry

Moreover literature was used in order to describe the legislative process of the cases. The case in 2011 is based on a presentation of the health care reform 2011 from the “Bundeszentrale für politische Bildung”. The case in 2004 is based on a overview of main points in the legislative process of the reform in 2004 from Hinrichs and Nowak (2005). The case study in 1992 is based on a headword - overview of the legislative process by Bubendorff Valerie (2000) and several governmental documents.

3.4 Interviews

As already explained because of the sensitive issues of my study, I did first not work with interviews. However, towards the end of the study I wanted to assure my assumptions and send to 25 politicians (five to each of the parliamentary parties in Bundestag CDU/CSU, SPD, FDP, Green Party and LINKE) and 2 experts in Germany's health policy questionnaires per email. As expected only few politicians answered – no experts and only one of each parliamentary party SPD, CDU/CSU and Green Party.

In detail I tried to interview decision - makers or responsible persons which are informed about opinions of key actors and about the situation. Therefore I addressed delegates of the parliamentary health commission in 2011 which were mentioned in the stenographic protocols several times or fraction referents. Fraction referents are therefore decisive since they provide delegates with information in order to have enough expertise to take part in commissions. Fraction referents have expertise and are near to decision – making processes within one fraction. Moreover because of their conceptual – content job profile, they are of high interest to ask by analysing decision - making processes (Püschner 2009, o.S.). The health expert I wrote to was Eberhard Wille leader of the Advisory Council of Health.

It was important to get statements of the political parties who were against and pro the regulation in the first two cases and I got both. In detail the respondents were Stephan Wilke (CDU), who is the staff of fraction referent in health care Katja Kohfeld (CDU). Guido Laue (SPD) the staff of Karl Lauterbach (SPD) who is member of the parliamentary party and parliamentary health spokesperson of SPD in Bundestag. Moreover we got answers from the staff of a delegate of the Green Party. However she asked me neither to mention her name nor to name the party when I cite her.

3.5 Data analysis

“Data analysis consists of examining, categorizing, tabulating, or otherwise recombining the evidence to address the initial propositions of a study.” (Yin 1994, 102). The analyse of the study worked in the following way: All of the collected text material was read and data on the possible explaining variables of each case collected. I made a separate list for each of the six explaining variables and for each case. To each explaining variable I ordered statements which give information on it. The most decisive data in respect to our possible explaining variables was presented in the empirical chapter 5, embedded in the description of the

legislative case. The explaining variables which seemed decisive in case 2011 and did at the same time not exist in 1992 or 2004, I defined as the explaining variables in 2011.

3.6 Validity and Reliability

3.6.1 Validity

In order to enhance validity not only Kingdon (1995, 242) but two other people read the text material. Kingdon discussed with these other two experts if and in how far they see each factor as decisive explaining variables. Therefore they created validity by adjusting their results or their opinion of the importance of the factors as explaining variables. In this study the proceeding was similar. My supervisor had the same role as Kingdon's two other persons. She read my empirical chapter and asked me various questions which helped her to judge which the decisive explaining variables were. If we did not come to the same conclusion of the importance of the factors we discussed it and came to a result. This second opinion of my supervisor raised validity.

External validity – in order to generalize about the influence of the pharmaceutical industry on policy change - is enhanced since three cases supported the same theory that interest groups play a decisive role on policy change; mainly in permitting, preventing policy change and influencing their content. This is analytic generalization which is to use “a previously developed theory [...] as a template with which to compare the empirical results of the case study” (Yin 1994, 31). Yin (1994, 31) adds “[i]f two or more cases are shown to support the same theory, replication may be claimed” and may considered more potent and validity is enhanced.

It is possible to generalize from this case study about the influence of the pharmaceutical industry to other policy changes in Germany.

3.6.2 Reliability

Reliability measures in how far a researcher would get the same results in case he would do the same study again (Yin 1994, 36). Reliability is given since I explained my proceeding in detail. Moreover I made various lists where I collected different statements and information which give evidence to the different explaining variables.

In order not to run the risk of reporting bias I studied scientific papers to get enough knowledge, in how far the delegates from the stenographic protocols bias facts about the

examined regulation or to judge if journalist write biased articles or have missing knowledge. This was one of the most challenges to get into health policy and understand (dis) advantages of the different reimbursement and pricing regulations. Moreover it is reliable because documents and newspapers from which I got the information are easily accessible.

3.7 Limitations of the study

Since this is a qualitative study causal inferences are not measured, they are only described. It is dangerous that my subjective assumptions are misleading and make wrong inferences. Moreover it is not possible to determine to what extent the different explaining factors influenced radical policy change.

Furthermore generalization is only possible for radical policy change in Germany and in particular in Germany's health policy but not for radical policy change in other countries. The reason for this limited generalization is that other countries have another political system and the role of the pharmaceutical industry differs.

CHAPTER 4

HEALTH SYSTEM IN GERMANY

This chapter explains the characteristics of the German health care system, the responsibility of the state in Germany's health care system, the statutory health insurance and his most important organizations, the role of the pharmaceutical industry in Germany and how interest groups are included in the decision-making process. Moreover this chapter explains in detail reimbursement and pricing regulation, their development and how they are constructed in the other European countries.

4.1 The characteristics of the German health care system

Social insurance

Countries differ in respect how they finance their health care system. There are three possibilities: Health care can be financed by the state. In this case health care is financed by taxes. Second health care can be financed by a private insurance or third by social insurance. In Germany the health system is financed by the latter. 90 percent of all Germans are insured by social insurance and it is an obligatory insurance. An exception exists only for persons who

earn more than 5000 Euros per year. They can choose if they want to be insured by the statutory health insurance (SHI) (Gesetzliche Krankenversicherung) or by the private health insurance (Private Krankenversicherung) or not at all.

The statutory health insurance is conceptualized as employee insurance. This means the contribution to the health insurance depends on the level of income.

Self-governing organizations

Another characteristic of the German health system is self - administration. The sickness funds and the Association of Statutory Health Insurance Physicians (Kassenärztliche Vereinigung) are self - governing institutions (Bundeszentrale für politische Bildung o.J., o.S.). They are not directly under governmental administration. The government only gives the framework requirements to the self- governing institutions and controls it. Most important in our context of the study is the common self - governing institution the Federal Joint Committee (G-BA). With the help of this institution the Association of a Statutory Health Insurance Physicians (KBV), the German hospital association (DKG) and the statutory health insurance shall agree on compromises. Among a lot of other rights the Federal Joint Committee decides, which benefits the statutory health insurance has to reimburse (Bandelow 2004, 46). Since this study deals with pricing and reimbursement regulations, this institution plays an important role in our study. This board governs the medicare in Germany (Siebert 2010, 17).

Corporatism

The third important characteristic of the German health care system is corporatism. It is closely linked with the characteristic of self - governing. It means the transfer from decisions of the government to these self-governing institutions. At federal level the Association of Statutory Health Insurance Physicians and statutory health insurance conclude master agreements, which decide the general issues of the regional contracts (Bundeszentrale für politische Bildung o.J.a, o.S.).

After a short presentation of the main characteristics of the German health care system the main actors will be shortly presented.

4.2 Responsibility of the state

The state has in federal level the duty to allocate an ordinal political framework. This framework should give the involved organizations the necessary exchange-, negotiation-, and coordination processes in order to control the resources (Striegel o.J., o.S.). The intervention capability is relatively limited since governmental intervention in the sphere of activity of the organizations is only allowed if the bodies of self-government cannot agree on a solution.

4.3 Statutory health insurance

As just explained most people in Germany are covered by the statutory health insurance (GKV). It is next to employee -, pension-, accident-, long term care insurance part of the German social insurance system.

The job of the statutory health insurance is to preserve, recover or improve the health status of the insurant. All insurant have the same claim for benefits. The extent of this claim for benefit is fixed in the Volume V of the German Socialinsurance Code (SGB V) (Fünften Buch Sozialgesetzbuch" (SBG V)). According to this statute the benefits have to be appropriate, sufficient, cost – effective and are not allowed to exceed the degree of necessity. The different health insurances which exercise the duties and responsibilities of the statutory health insurance are allowed to differ slightly in respect to their benefits which they offer to the insurant. Therefore competition exists between sickness funds since the 90th.

In the following are the most important organizations of the statutory health insurance described. The Health insurances, Federal Joint Committee (GB-A), Institute for Quality and Efficiency in Health care (IQWiG). Moreover the development of the statutory health insurances since 1992 is described in detail.

4.3.1 Health insurance funds

The duties and responsibilities of the statutory health insurance are exercised by the health insurance funds. There are five different health insurance funds: Allgemeine Ortskrankenkassen, Betriebskrankenkassen, Landwirtschaftliche Krankenkassen, Ersatzkassen, Innungskrankenkassen und Knappschaft. They are bodies governed by public law and with self – administration. The various kinds of health insurance funds work by various contract designs together. The health insurance fund regulates their budget self - dependent. They have to offer particular legislative planned performance (compulsory benefit) and can also decide to offer more benefits as dictated by law. The health insurance

funds work with pay – as – you –go which means that they charge as much contributions from the insurant as they need at the moment to finance the spending.

4.3.2 Federal Joint Committee (G-BA)

The Federal Joint Committee is the supreme decision board of the self – government institutions in Germany’s health care system (Schneider 2010, 85). It determines with directives the list of covered services of the statutory health insurance for 70 million insurant. Moreover it tries to find binding decisions on the basis of scientific data if the self-governing institutions of physician, dentist, physician therapist, hospitals and sickness funds cannot agree on a solution. Moreover the G-BA is in charge of securing the quality of health care. The G-BA is in charge of the evaluation of physical examination and therapy methods. The G-BA checks if new and old services and drugs have a diagnostic or therapeutic added benefit, if they are medical necessary and if they are cost-effective. The G-BA is together with the Institute for Quality and Efficiency in Health Care (IQWiG) in charge of benefit and cost-benefit evaluation of drugs which is central issue in our study.

The evaluation starts with the position of a concrete question. This question includes which group of persons should be treated with which medical method and with which factors the success of the therapy can be measured. The next step is that the subcommittee of the G-BA makes extensive research about the current level of scientific research on this drug (Gemeinsamer Bundesausschuss 2012, o.S.). Clinical studies, evidence - based guidelines, systematic reviews and from the G-BA commissioned reports are considered. The next presented institution is the Institute for Quality and Efficiency in Health Care (IQWiG) which helps the Federal Joint Committee.

4.3.3 Institute for Quality and Efficiency in Health Care

The Institute for Quality and Efficiency in Health Care (IQWiG) is an independent scientific institute in health care which helps the G-BA in assessing the benefit and the cost – effectiveness of a drug.

It is funded by the contributions of the insured persons of the statutory health insurance. It was established with the “SHI – Modernization Act” in 2004. The most important job of the Institute for Quality and Efficiency in Health care (IQWiG) in the context of our study is the evaluation of the benefit and cost-effectiveness of drugs. The IQWiG gets its commissions

which drugs to evaluate from the G-BA or from the Federal Ministry of health. However the institute is also allowed to evaluate drugs on its own initiative (IQWiG 2011, o.S.).

The IQWiG operates in the following way: It compares different medical products, for example drugs, and determines their disadvantages and advantages. Important to notice is that the institute does not conduct studies on its own. Instead it searches for available studies with reliable results and makes a benefit – and cost – effectiveness analysis on basis of these studies.

If the IQWiG was commissioned by the G-BA to do a benefit evaluation or cost – effectiveness evaluation, the IQWiG gives a recommendation to the G-BA if the drug has a therapeutic added benefit or is cost –effective. The decisive difference between the IQWiG, as supporter of the G-BA, and the G-BA is that the IQWiG is not in charge of deciding if the drug gets finally reimbursed by the statutory health insurances because of the results of the therapeutic added benefit or cost-effectiveness evaluation. Only the G-BA is in charge of this final decision.

4.3.4 Development of statutory health insurance and health insurance funds

In the following is the development of the statutory health insurance and health insurance funds described from the 80th on. The reason is that it describes in detail how the right for health insurances started to compete with each other in the 80th and was extended step by step until 2007. I am not arguing that these developments of competition possibilities of sickness funds are an explaining variable why radical policy change happened in particular in 2011. I am only arguing without this development no radical policy change would ever happen since the price regulation in 2011 is a competitive pricing regulation.

In the late 80th a change in paradigm happened, the idea: The statutory health insurance should be more market orientated and competitive designed. The aim was that competition between sickness funds should contain costs in health care and enhance at the same time quality.

The first step in order to make the statutory health insurance more competitive was in 1992 with the Health Care Structural Reform Act (Gesundheitsstrukturgesetz). It started that each insured could choose between the different health insurance funds from 1996 on. This was the start that sickness funds started to compete with each other in order to get more insurants. The possibilities of the different benefits which could be offered by sickness funds were extended

step by step. At the same time guild sickness funds (IKK) and company health insurance funds (BKK) which were actually company health insurance funds were opened for all insurants. Since competition between health insurance funds started a huge reduction of sickness funds took place (Schroeder/Paquet 2007; 121/Paquet 2011, 12). The reduction of health insurance funds was enormous:

In Juli 2010 existed 163 health insurance funds. Ten years ago existed 420 and in 1994 even 1152. (Paquet 2011, 13, my translation).²

Moreover a risk structure compensation scheme was introduced in order to prevent that health insurances only compete about insurance which have a good income.

As just mentioned sickness funds got step by step more possibilities about what to compete with each other. Sickness funds could first only compete in respect to administrative services and were allowed to raise different amount of contributions. This was too less in order to have a functioning competition between sickness funds. As a consequence sickness funds asked for competition on the supplier side in order to have different choices by purchasing (Paquet 2011, 122). Back at that time sickness funds started to ask for contract competition. They asked for individual contracts since so far only collective contracts were possible: In the case of single contracts health insurance funds or their organizations are allowed to make contracts with individual contracts and suppliers. In the case of collective contracts organizations of health insurance funds or single health insurance funds negotiate are only allowed to negotiate with the *organizations* of doctors and other suppliers.

The health insurance funds were the first time allowed to make individual contracts in a grand style in 2002 after 50 years of collective contracts. The “Economic Optimization of Pharmaceutical Care Act” (Arzneimittelversorgung – Wirtschaftlichkeitsgesetz) in 2006 made competition between health insurance funds and suppliers also in respect to drugs possible because drug discount contracts were introduced (Schröder/Paquet 2012, 122). The next step was in 2007 with the “German Act to Reinforce Competition between the German Statutory Health Insurances” (GKV – Wettbewerbstärkungsgesetz) which improved the conditions for competition with individual contracts. It focused on replacing individual contracts from collective ones more and more.

² So gab es im Juli 2010 noch 163 gesetzliche Krankenkassen. Zehn Jahre zuvor waren es noch 420, im Jahr 1994 sogar noch 1152. (Paquet 2011, 13).

In 2011 a pricing regulation of innovative drugs was introduced which I discuss in this thesis as radical policy change. This pricing regulation is negotiations between sickness funds and the pharmaceutical industry. This makes now competition in the innovative patented drug sector possible, too. Before 2011 only competition existed in the generic drug sector and the patented drugs sector since 2004 but with innovative drugs it was made possible in 2011. Therefore the pricing regulation in 2011 which is the radical policy change of our study since it stopped the pharmaceutical industry from freely price setting, can be seen as a late consequence of the paradigm change in the 80th to introduce more competition to the statutory health insurance.

In the following is the economic importance of the pharmaceutical industry in Germany described.

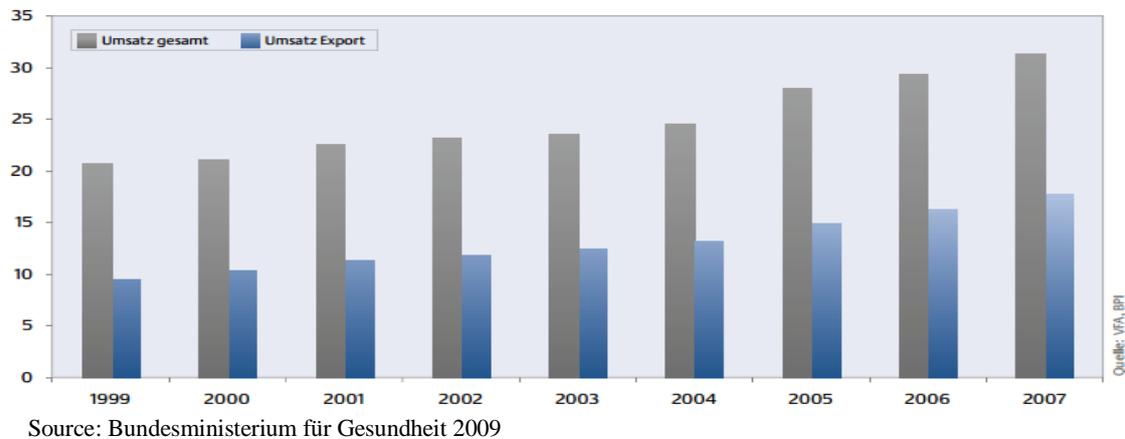
4.4 Pharmaceutical industry

The pharmaceutical industry is one of the highest- performance and most active branches of trade in Germany (Bundesministerium für Gesundheit 2009, 5). “The production of pharmaceutical products increased 48% in Germany between 2000 and 2007, whereas the production in the working business increased 21% in the same period.” (Bundesministerium für Gesundheit 2009, 5, my translation).³ The pharmaceutical industry in Germany lost importance in international comparison but it is still the fourth important manufacturing base in the world. The pharmaceutical industry in Germany registers increasing numbers of employment: “Since 2003 increased the number of employees in the German pharmaceutical industry from 116.046 to 127.036 until 2007. (Bundesministerium für Gesundheit 2009, 5, my translation).⁴ Not only was the number of employees growing in the pharmaceutical industry in the last years but also the sales volumes (Bundesministerium für Gesundheit 2009, 5).

³ Während die Produktion pharmazeutischer Erzeugnisse in Deutschland zwischen 2000 und 2007 um 48 % zunahm, wuchs die Produktion im verarbeitenden Gewerbe im gleichen Zeitraum insgesamt nur um 21 %. (Bundesministerium für Gesundheit 2009, 5).

⁴ Seit dem Jahr 2003 ist die Zahl der Beschäftigten in der deutschen Pharmaindustrie von 116.046 auf 127.036 im Jahr 2007 angewachsen. (Bundesministerium für Gesundheit 2009, 5).

Figure 1: Development of sales volume of the pharmaceutical industry in Germany from 1999 – 2007, in Mrd. Euro



In 2007 existed 1.042 pharmaceutical concerns in Germany (Schneider 2010, 91). 336 of these pharmaceutical concerns have more than 20 employees. The most important pharmaceutical industries are the Bayer AG, the Boehringer Ingelheim GmbH & Co.KG, the Merck Kommanditgesellschaft, the ratiopharm GmbH and the Stada AG (Schneider 2010, 91). The biggest pharmaceutical concern is the Bayer-Schering AG. This concern has 106.200 employees.

Pfizer incorporated is the worldwide leading pharmaceutical concern of the pharmaceutical concerns which are doing research. The sales volume of Pfizer incorporated in Germany was 1,6 milliards in 2007. This is the only big concern which is doing research in Germany and is therefore central for our study since innovative drugs are mainly a concern of drug concerns which do research.

The pharmaceutical industry produced pharmaceutical products amounting to 23,7 milliards Euro in Germany in 2006. In 2007 there were 8.834 products. In this branch were 113.234 persons employed. (Schneider 2010, 94).⁵

Insgesamt wurden durch die pharmazeutische Industrie in Deutschland im Jahre 2006 pharmazeutische Erzeugnisse im Wert von 23,7 Milliarden Euro hergestellt. Es gab 2007 in Deutschland 8.834 Präparate. In der Branche waren 2006 genau 113.234 Personen beschäftigt. (Schneider 2010, 94, my translation).

⁵ Insgesamt wurden durch die pharmazeutische Industrie in Deutschland im Jahre 2006 pharmazeutische Erzeugnisse im Wert von 23,7 Milliarden Euro hergestellt. Es gab 2007 in Deutschland 8.834 Präparate. In der Branche waren 2006 genau 113.234 Personen beschäftigt. (Schneider 2010, 94).

4.5 The influence of self - governing institutions and interest groups in decision – making process

In following section the decision – making process in Germany is shortly summarized. The particular characteristic in health politics is that various interest groups are involved. The influence of the most important interest groups for this study will be also discussed in this section.

4.5.1 Decision-making process in Germany's health system

Decision - making in the German health system is a long process and shaped by compromises between coalition parties in Bundestag and the majority in Bundesrat and by “contradictory interests of stakeholders” (Busse/Schreyögg/Henke 2005, 330).

On average 70 interest groups express their positions in parliamentary hearings on health care reform bills (Busse/Schreyögg/Henke 2005, 330). Therefore there is very little chance that the different actors agree fast on a consistent approach for cost - containment. In contrast various ideas and positions need to be discussed and compromises are made. “The system is determined by diversity of interests and claims. [...] They are all stakeholders in a complex system of self - governance.” (Busse/Schreyögg/Henke 2005, 330).

The legislative process is complicated since the formal approval of the Bundesrat (Upper House of Parliament) and Bundestag (Lower House of Parliament) is necessary to pass a law. The Bundesrat has 600 members and their elections are every four years. It has influence on governmental politics, carrying through federal laws and electing the Chancellor. The Bundesrat consists out of the 3-6 members of each of the 16 German states. Their office is to approve bills, which are passed by the Bundestag. It is possible that the overrules a negative vote of the Bundesrat. This is the case in about half of the cases. Both chambers have to commit the law in case it is an important one for the Federal States like laws regarding financial affairs or the states administrative powers (Busse/Schreyögg/Henke 2005, 331). One important factor for ineffective legislation is that “the political majority in each chamber is typically held by opposing parties or coalitions”, therefore it is getting difficult, if both chambers have to pass the bill (Busse/Schreyögg/Henke 2005, 330).

As mentioned above self - governing institutions play an important role in the German health care system. They have the right to voice their position regarding legislative proposal in special committees (Busse/Schreyögg/Henke 2005, 330). “This can either be seen as a form of

corporatism in decision - making or the enforcement of private interests.” (Busse/Schreyögg/Henke 2005, 330). Associations of the pharmaceutical industry, sickness fund boards, Federal Association of statutory health insurance – accredited Physicians, hospital groups, the pharmacists’ association and other interest groups are included in the political decision-making process. “The pharmaceutical industry is highly organized with several associations. Its associations either influence politicians and bureaucrats by giving them papers, outlining their performance or trying to influence the public through press releases and other activities. Sometimes pharmaceutical industry lobbying groups are able to block a passed law from being implemented.” (Busse/Schreyögg/Henke 2005, 331). Because of this fact I hypothesized – as shown in the theoretical chapter - that the pharmaceutical industry plays a decisive role in order to explain the radical policy change in 2011.

After this short presentation of the decision – making process in health politics, the the influence of the involved actors in decision – making which are central in the context of pricing and reimbursement regulation will be discussed in the following section.

4.5.2 Influence of interest groups in decision-making

4.5.2.1 Interest groups

Interest groups can influence the political process and foster their interests in the two following ways: Either they influence the parliament, parties, delegates, government, administration or they exert influence with the help of mass communication (Schneider 2010, 98).

How interest groups are able to influence political institutions becomes clearer by describing the various contact point between interest groups and parliament, parties, delegates, government or their administration. Since most draft laws in health policy come into existence in a particular department of the Ministry of Health, it is decisive for successful action that interest groups exert influence in an early stage on interest groups (Schneider 2010, 99). “In the years 1949 until 1984 was the degree of linkage between interest groups and ministerial bureaucracy was 70%.” (Schneider 2010, 99, my translation).⁶ In ministries even advisory boards exist in which the interest groups represent their ideas. It helps the departments to get expert knowledge.

⁶ In den Jahren 1949 bis 1984 wies die Beziehung zwischen den gesellschaftlichen Interessengruppen und der Ministerialbürokratie sogar einen Verflechtungsgrad von fast 70% auf. (Schneider 2010, 99).

The interest groups have most interest in the particular commissions and task forces of different fractions in Bundestag because they play a main role in the legislative process. Bundesrat and Federal Chancery are not very important for interest groups.

Delegates who belong to an interest group are very important in order to influence the legislative process. Often delegates are not only “normal” members but honorary or key members in certain organizations. For example: In our first case, the reform in 1992, 40% of all delegates were members in organizations (Schneider 2010, 100). It is common that certain parliamentary parties make coalitions with different organizations.

The delegates of CDU/CSU act very often for the interests of the trade association [...]. The delegates of the SPD act very often for the interests of social political stakeholders. The delegates of FDP concentrate on trade associations [...]. The delegates of the Green Party represent normally the interest of the environment organization and ideational political associations. . (Schneider 2010, 100, my translation).⁷

40 % of CDU/CSU and FDP delegates, 30 % of SPD and Green Party delegates and 10% of Linke delegates were at the same time members of organizations in the period 1990 until 1994.

The second possibility how interest group can exert influence on politicians is mass communication (Schneider 2010, 101). The aim is to influence the public opinion in the interest of the organization. According to Schneider (2010, 103) has the pharmaceutical industry very good recourses (personal and financial) in order to influence public opinion.

The pharmaceutical industry

The pharmaceutical industry is has a lot of influence in the decision – making process and in contrast hardly any influence in the implementation process of laws since they are too less included in the self – governing institutions. In contrast the influence of the pharmaceutical industry in the decision – making process is much higher judged than the influence of the self - governing institutions. Since the pharmaceutical industry is such a big branch in Germany, Striegel (o.J., o.S.) assumes that the pharmaceutical industry can mostly determine the rules of their actions on their own. Interesting that despite this fact the pharmaceutical industry is comparatively less included in negotiations - and organization networks in the federal health

⁷ Die Unionsabgeordneten vertreten sehr oft die Interessen der Wirtschaftsverbände [...]. Die sozialdemokratischen Abgeordneten vertreten sehr oft die Interessen der [...] der sozial-politischen Interessenvertreter [...]. Die FDP –Abgeordneten konzentrieren sich eher auf [W]irtschaftsvereinigungen [...]. Die Abgeordneten der Grünen repräsentieren naturgemäß eher Umweltorganisationen und ideelle politische Vereinigungen. (Schneider 2010, 100).

sector. The success of the pharmaceutical industry to prevent governmental interventions can be among other things explained with the fact that they have numerous and important recourses like money and contact to media.

4.5.2.2 Commissions as source for influence

Commissions are highly important in the decision - making process. According to Schneider (2010, 113) they are even more important than political parties in the Bundestag and Bundesrat. Therefore interest groups - like the pharmaceutical industry - try to influence members of commission in order to achieve their interests.

They are that important because commissions are able to circumvent the formal political institutions and can open the administration of ministers for interest groups they favor and they are successful to break ideological barriers of parties (Schneider 2010, 114). They have the important role to decide about pre - decisions in case of fundamental decisions. Therefore the choice of the commission members is of high importance because it decides about the tendency of the solution of the problem.

In the last years advisory boards were consciously adapted in order to override the complicated decision structures of the governmental system. The Government gave important politicians from the opposition parties a decisive role in the adversary boards in order to get early over potential resistance of the opposition parties and create together course of action. (Schneider 2010, 113, my translation).⁸

The advantage of commissions is that it is possible to include all important players at the beginning of a reform in the decision-making process. Therefore the chance of fast consensus is higher (Schneider 2010, 114).

4.6 Patented and generic drugs

In the German health care system mainly two kinds of drugs exist: generic and patented drugs. A generic drug is comparable to an original patented drug in quality, performance characteristics, strength, dosage form, route of administration and intended use (Centre for Drug Administration and Research o.J., 7). It may differ in respect to additives and producing technology from the original drug. A patented drug is a drug with an innovation. Patented drugs are ordered in a reference pricing system. If the doctor prescribes a drug which is above the level of the reference price the insurants have to pay the difference plus 5 to 10 Euro out

⁸ In den letzten Jahren wurden Beratungsgremien bewusst eingesetzt, um die komplizierten Entscheidungsstrukturen des deutschen Regierungssystems mit seinen enormen Konsenszwängen zu übersteuern. Indem die Regierung sogar prominenten Oppositionspolitikern in den Gremien eine entscheidende Rolle zuwies, versuchte sie frühzeitig potenzielle Widerstände zu überwinden und gemeinsame Handlungsoptionen zu schaffen. (Schneider 2010, 113).

of their own pocket. The object of our study innovative drugs with a therapeutic added benefit and I call in my study simply “innovative drugs”. These drugs are excluded from the reference pricing system and therefore the pharmaceutical industry was free to set their price and sickness funds had to reimburse it. The study is concerned with the change that these special group patented drugs with a therapeutic added benefit get regulated.

Generic drugs are often one third of the price of patented drugs. In the last decades generic drugs were step by step effectively regulated with the effect that spending of the statutory health insurance for generic drugs declined; even the number of prescription of generic drugs was rising. Contrary was the development of patented drugs: Less patented drugs were described in the last years but the spending of the statutory health insurance was increasing in this sector. According to Kiffmann and Neelsen (2010, 43) mainly highly innovative drugs were responsible that spending in the patented drugs sector raised that much. This is explainable with the following aspects:

- (1) The pharmaceutical industry was allowed to set freely the price of innovative drugs on its own. Important is that also health insurance funds had to reimburse these innovative drugs with high prices.
- (2) The second problem which led to high costs in respect to innovative drugs was that an effective control was missing which tested if these “innovative drugs” have really a therapeutic added benefit or if the pharmaceutical industry only claims that they have one. For this assessment studies from the pharmaceutical industry were needed. Since the pharmaceutical industry were not obliged to hand in the studies, sometimes years passed by until the pharmaceutical industry put out these studies. In these passed years the health insurance funds reimbursed these high prices.

4.7 Reimbursement and pricing regulations

4.7.1 Explanation of reimbursement and pricing regulations

In the following are four different kinds of reimbursement regulation and one kind of pricing regulation presented. These are very common regulations in other European countries. Germany does one of them not have and the other ones are totally ineffective designed. However in 2011 a radical change happened in Germany and the existing reimbursement regulations got more effective designed similar to the other European countries and a pricing regulation was introduced the same as most other European countries have. In the following these regulations are described in detail:

Reimbursement regulation

In the following three reimbursement regulations are described. All of them have the main aim to assess if the drug has a therapeutic added benefit which is defined as “additional value by being more effective, having lesser side-effects, or by being less costly at equal effectiveness as existing drugs” (Kiffmann/Neelsen 2010, 43).

Benefit - evaluation

The benefit - evaluation has the aim to determine if the drug has a therapeutic added benefit.

Cost – effectiveness - Evaluation

The cost – effectiveness - evaluation determines like the benefit evaluation if a therapeutic added benefit exists. In how far a benefit of new drug exists compared to an old one. Additionally the cost - effectiveness- evaluation determines if the therapeutic added benefit is in relation with the costs. “[...] by an economic assessment the appropriateness and the reasonability of the cost absorption by health insurance funds has to be considered.” (§35b SBG V).⁹

Positive list

The positive list lists these drugs which are reimbursed by health insurance funds. These are this drugs which successfully passed a benefit and cost – effectiveness – evaluation.

So far only reimbursement regulations are described. In 2011 following pricing regulation was introduced:

Pricing regulation

One very common pricing regulation in European countries which was introduced in 2011 was price negotiations between sickness funds and the pharmaceutical industry. Depending on the therapeutic added benefit sickness funds and the pharmaceutical industry negotiate about the price.

In the following section the pricing and reimbursement regulation of other European countries get presented and compared with Germany.

⁹ „[...] bei der wirtschaftlichen Bewertung [muss] auch die Angemessenheit und Zumutbarkeit einer Kostenübernahme durch die Versicherungsgemeinschaft, angemessen berücksichtigt werden.“ (§35b SBG V).

At the beginning of the thesis is mentioned that Germany is a latecomer in respect to innovative drug regulation. In order to make clearer to what extent Germany was a latecomer; the reimbursement and pricing regulations of the other European countries are presented and compared with Germany.

4.7.2 Comparison of pricing and reimbursement regulations of Germany with other countries

At the beginning of the thesis is pointed out that Germany is a latecomer in respect to innovative drug regulation. One research question even addresses the question why Germany differs in contrast to all other European countries in pricing and reimbursement regulation of innovative drugs. In the following section is explained how and to what extent Germany is an exceptional case and to what extent the radical change in 2011 led to an adjustment of Germany's regulation in pricing and reimbursement to other European Countries.

Reimbursement

Above I explained that the commonality of all reimbursement regulations is the assessment of the therapeutic added benefit. Germany and England were for a long time the only countries where the assessment of the therapeutic added benefit was after the drug was admitted to the market (Wasem, Gress, Niebuhr 2005, 34). This is a huge problem: If the assessment of the therapeutic added benefit is not a condition for drug admission to the market than the assessment of the therapeutic added benefit is sometimes years after the drug got admitted to the market. In this period between drug admission to the market and the assessment of the therapeutic added benefit the pharmaceutical industry gets the full price of the alleged drug reimbursed. The reason why the assessment takes sometimes place years later is that the pharmaceutical industry is not obliged to hand in studies which the Federal Joint Committee or the Institute for Quality and Efficiency in Health Care needs in order to assess therapeutic added benefit, this leads to the fact that the pharmaceutical industry just does not hand out the studies and the assessment cannot take place.

The following list shows the reimbursement regulations of various European Countries in order to make the differences between Germany and other European Countries clear.

Table 1: Instruments for reimbursement in international comparison

<i>Countries</i>	<i>Positive list</i>	<i>Benefit evaluation</i>	<i>Cost-effectiveness evaluation</i>
<i>Germany</i>		<u>X</u>	+
<i>Denmark</i>	X	X	++
<i>Belgium</i>	X	X	++
<i>Finnland</i>	X	X	++
<i>France</i>	X	X	++
<i>Greece</i>	X	X	+
<i>Great Britain</i>	X	X	+++
<i>Japan</i>	X	X	+
<i>Ireland</i>	X	X	++
<i>Italy</i>	X	X	++
<i>Luxemburg</i>	X	X	+
<i>Netherlands</i>	X	X	++
<i>Norway</i>	X	X	++
<i>Portugal</i>	X	X	++
<i>Sweden</i>	X	X	++
<i>Schwiss</i>	X	X	+
<i>Spain</i>	X	X	+
<i>Austria</i>	X	X	+

Legend: X =exists; + = cost-effectiveness evaluations at the beginning; ++ = cost-effectiveness evaluation is obligatory but no criteria for exclusion of reimbursement; +++ = cost-effectiveness evaluation leads to exclusion of reimbursement

Source: Wasem, Gress, Niebuhr (2005)

The list shows that the positive list exists in all countries except in Germany. The benefit - evaluation existed in Germany since 2004 but was hardly used in Germany until 2011 because of the above described problems that the pharmaceutical industry did not have to hand in the studies. The cost-effectiveness evaluation was designed in such a way that it was even less used as the benefit – evaluation namely never.

In 2011 it changed in so far that the pharmaceutical industry must hand in now the studies in order that the Federal Joint Committee and the Institute for Quality and Efficiency and Health Care can assess the therapeutic added benefit. Moreover the assessment of the therapeutic added benefit has to happen after the first year of drug admission.

Price regulations

In Germany drug producers were until 2011 free to set the price of patented drugs. Germany was with Malta and Denmark the exception where no regulation of price setting of patented drugs existed. The fact that not only the pharmaceutical industry was free to set the price of patented drugs but also that health insurance funds had to reimburse the full price in the case of innovative drugs led to high costs. In 2011 it changed that the pharmaceutical industry was not anymore allowed to set the price on its own: Instead price negotiations between sickness funds and the pharmaceutical industry defined the price on the basis of the therapeutic added benefit.

The following list compares how different European countries regulate their prices.

Table 2: Pricing instruments of patented drugs

<i>Countries</i>	<i>Regulation of price setting of patented drugs</i>	<i>Price negotiations</i>	<i>Reference price system</i>
<i>Germany</i>	X	X	X
<i>Denmark</i>	X		X
<i>Belgium</i>	X		X
<i>Finnland</i>	X	X	
<i>France</i>	X	X	
<i>Greece</i>	X		
<i>Great Britain</i>	X		
<i>Japan</i>	X		
<i>Ireland</i>	X	X	
<i>Italy</i>	X	X	
<i>Luxemburg</i>	X		
<i>Netherlands</i>	X		X

<i>Norway</i>	X		X
<i>Portugal</i>	X		
<i>Sweden</i>	X	X	X
<i>Schwiss</i>	X	X	
<i>Spain</i>	X		X
<i>Austria</i>	X	X	

Source: Wasem, Gress, Niebuhr (2005)

The figure shows that all European countries regulate prices of patented drugs. Germany was a latecomer and started in 2004 with the regulation of patented drugs and used therefore the reference pricing system. Other European countries started in the 90th to regulate the prices. It has to be mentioned that Germany regulated the prices of patented drugs in the period from 1989 until 1996 but then Germany stopped in order to encourage pharmaceuticals innovation.

However innovative drugs, drugs with a therapeutic added benefit, were excluded from the reference pricing system. Other European countries did not exclude drugs with therapeutic added benefit from their pricing regulation.

These drugs with therapeutic added benefit get regulated in Germany since 2011. They are not ordered in the reference pricing system but price negotiations between sickness funds and the pharmaceutical industry defines the price of these drugs. In the next section is the regulation of innovative drugs explained in detail; how it is since the radical policy change in 2011.

4.8 Regulation of innovative drugs since 2011

In the last sections I explained that radical policy change happened and that the regulation of innovative drugs changed decisively. Moreover I explained that the idea to regulate innovative drugs in such a way was various times on the agenda but at the end it collapsed in the decision – making process or in the implementation process. In this section the regulation shall be explained in detail:

If a new drug enters the market than pharmaceutical companies have produce a scientific dossier in order to prove that the new drug has a therapeutic added benefit (Ognyanova/Zentner/Busse 2011, 12). This is the first important difference to the regulation before: Before the pharmaceutical companies were not obliged to hand in studies. The Federal

Joint Committee reviews the dossiers in order to evaluate the therapeutic added benefit of the drug or authorizes the Institute for Quality and Efficiency in Health Care to do it.

The drug evaluation has to be finished after three month and the Federal Joint Committee has to publish it on their homepage. Depending on the decision of the Federal Joint Committee, if a drug has a therapeutic added benefit or not, two different courses of action are following:

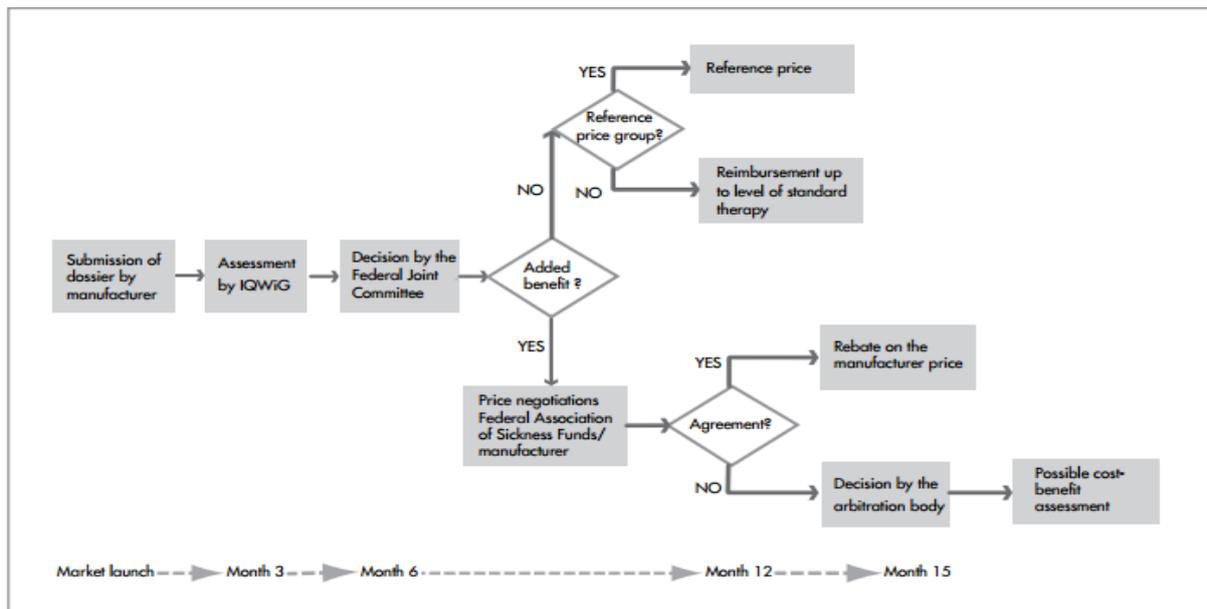
In case a drug has no therapeutic added benefit compared to a treatment alternative, the drug will be put in the reference pricing system. If the pharmaceutical company does not agree with the result, he can ask for a renewed assessment after one year.

In case pharmaceuticals have a therapeutic added benefit the process is more complicated: The Federal Association of Sickness Funds and the respective pharmaceutical company, including the Association of private Health Insurance Companies, negotiate about the price of the new drug. These negotiations have to happen during the first year after drug admission.

If they cannot agree on a price an arbitration body decides on the price within three month by taking into consideration the international price. This arbitration body consists out of representatives of the health insurance funds, the pharmaceutical industry and neutral members (Ognyanova/Zentner/Busse 2011, 13). In case the health insurance funds or the drug makers are not satisfied with this price, they can appeal the decision of the price. In order to have a chance that the price gets changed, the pharmaceutical industry has to ask the Federal Committee in order to evaluate the cost-effectiveness of the drug.

Sickness fund are individually and collectively allowed to conclude contracts with selected pharmaceutical companies.

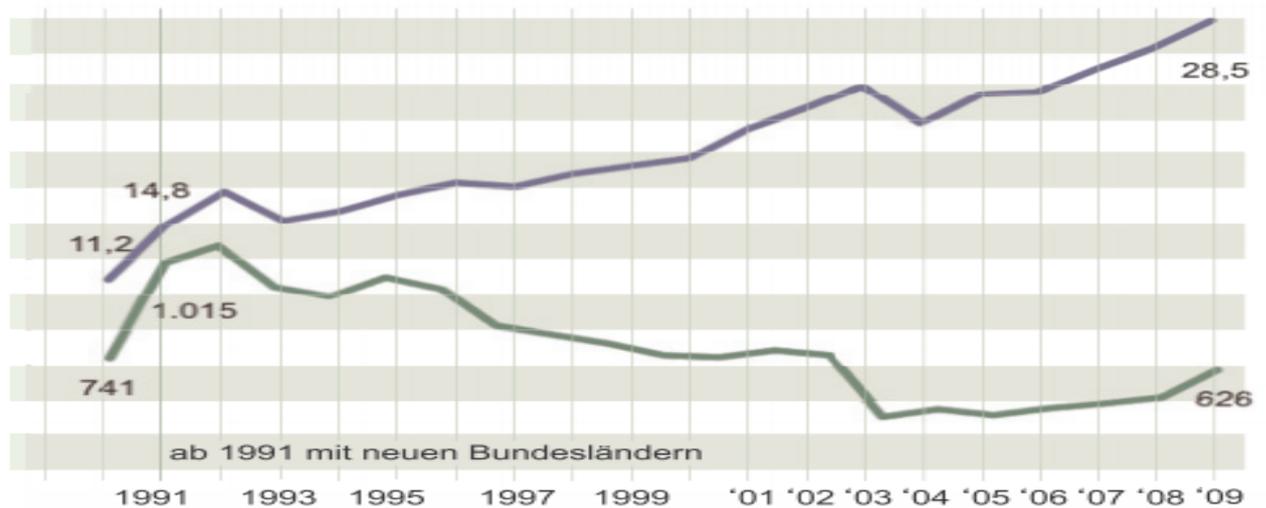
Figure 2: Regulation of innovative and patented drugs



Source: Ognyanova, Zentner and Busse (2011)

4.8 Developments of drug costs

Figure 3: Prescription - and sales volume of the drug market 1991-2009



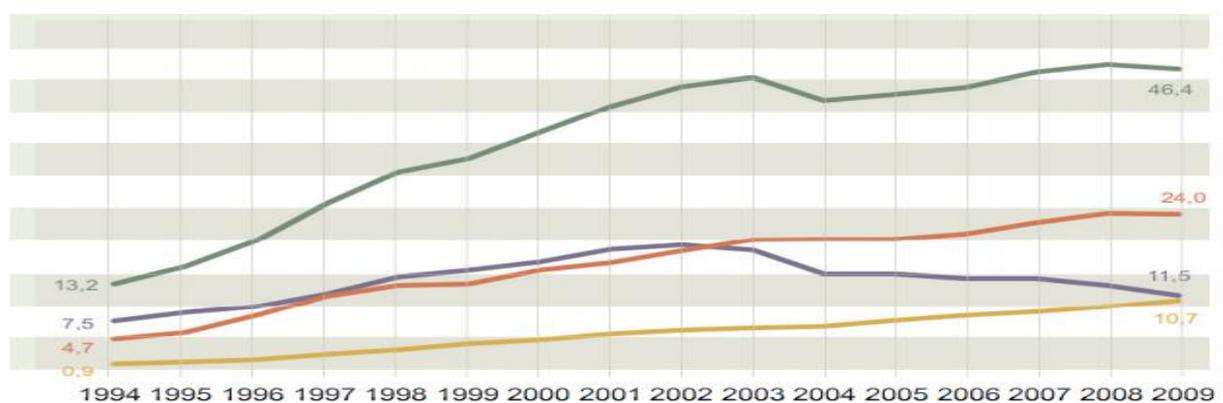
Line above: sales volume (Mrd. Eur)
Line below: prescription (Mio)

Source: AOK Bundesverband (2010/2011)

In 2009 spend the statutory health insurance fund 32,4 milliards Euro in drugs, these amount of costs was never reached before. In average the costs grew in the last ten years 5 percent per

year. This increase is mainly caused by patented drugs (Kiffmann/Neelsen 2010, 43). The revenues of patented drugs were growing 15 percent from 2008 to 2009. Therefore this segment was responsible for 35 percent of all pharmaceutical spending in 2009 (IMS Health 2010). Ten years ago, the PPD spending share was 27 percent (Kiffmann/Neelsen 2010, 43). Especially the drugs without therapeutic added benefit caused the raising costs. In 2010 3, 5 milliards of 14, 2 milliards sales volume of the pharmaceutical industry were earned by innovative drugs which pretended to have therapeutic added benefit but actually did not have one (WidO 2011, 3).

Figure 4: Sales volume of patented drugs in %



- Yellow: drugs without therapeutic benefit which got reimbursed like drugs with therapeutic added benefit
- Green: patented drugs in total
- Red: drugs with therapeutic added benefit

Source: Bundesverband AOK (2010/2011)

Kiffman and Neelsen (2010, 44) explains that in the period from 1992 until 2008 42 percent of patented drugs were drugs without therapeutic added benefit but the pharmaceutical industry claimed that the drug would have one. Moreover they explain that costs of these drugs raised from 2, 3 billion Euro in 1999 to 5, 1 billion Euro in 2008.

If patented drugs without therapeutic added benefit would be replaced by generics then around 1,7 Milliarden Euro of savings would be expected (Kiffmann/Neelsen 2010, 22). Since generic drugs were effectively regulated among other things with a reference pricing system the spending for generics declined in the last years even the prescriptions of generics raised in the at the same time. These numbers show that it was more nearby to regulate patented drugs instead of generic drugs in order to stop raising costs.

This chapter had the aim to give all background information which is necessary to fully understand the next empirical chapter.

CHAPTER 5

PRESENTATION OF THE COMPARATIVE CASES

In 2011 radical policy change happened: The pharmaceutical industry was stopped to determine the prices of innovative drugs freely. In 2011 was not the first attempt to regulate innovative drugs and stop this free price setting. In contrast it was various times tried before. In the following are two cases presented in which it was tried to regulate innovative drugs and it failed in the decision – making process and the case in 2011 where radical policy change happened. It is expected to find the decisive explaining variables by comparing these two cases where the phenomena radical policy change could not happen with the case where radical policy change finally happened.

In order to make the three cases good comparable their presentation is structured in the same way: First the legislative process is presented by pointing out the discussed issues and disputes and second the argumentation is presented which was used in respect to the discussed issues.

Before the three cases will be presented the work of a think tank in the 80th is presented since it decisively influenced all three cases. This is the work of the Enquete - Commission in 1987 - 1990 in health policy.

5.1 Enquete Commission – Ideological background for the following health care reforms

Enquete-commissions are constituted by the Bundestag and are task groups including different parliamentary groups in order to solve long term questions. The Enquete-commission in the 80th dealt with question how to save costs in health care and how to make the health system more competitive.

Enquete-Commission 1987-1990 – think tank for the health care reform (s)

The reform in 1992 has its roots back in the in the late 80th as regulative discussions came up about deficits in health care and a paradigm change happened: The change was that health care – like other market sectors - should be more competitive orientated (Rainers 2010, 37).

After few ineffective cost containment reforms time was come for a basic and structural reform of the statutory health insurance which should mirror this change in paradigm. In order to develop basic principles of the upcoming reform the Social Democratic Party (SPD) applied for an Enquete - Commission. The Commission started to work in 1987 and the final report was published in 1990. A lot of ideas were achieved in the following health care reform in 1992 but at the same time a lot of outstanding ideas not. In the following health care reforms in 2004 and 2011 ideas of this commission were again picked up and tried to enact. Therefore the report of the Enquete – Commission was not only decisive for the health care (Rainers 2010, 37).¹⁰

The final report of this Enquete - Commission had 436 pages and covered each reform field of the statutory health insurance. To improve the efficiency and quality of drug policy was one important part of the report. This report was divided in problem analysis and suggestions for regulations. In the section about how to improve the efficiency and quality of drugs the problem of innovative drugs was the first time discussed and solutions presented.

The first time was criticised that the therapeutic added benefit gets not assessed before a drug get admitted to the market and instead only “quality, effectiveness and harmlessness” have to be proved in order to admit a drug to the market and to get reimbursed by the sickness funds. The three criteria for drug admission “quality, effectiveness and harmlessness” were enacted with the German Pharmaceutical Act (Arzneimittelgesetz) back in 1978. Back at the 80th the Enquete-commission already published the numbers of launches of drugs without therapeutic added benefit but of which the pharmaceutical industry claims that they have one (1990, 247):

According to expert opinion have most drugs which are admitted to the market no significant therapeutic added benefit for drug therapy and patient. This shows an analysis of the 1986 and 1987 new admitted drugs. New active agents included of 764 (1986) and 241 (1987) only 16 (1987) and 22 (1987). Experts assessed that only four (1987) and two (1986) were real innovative progress.¹¹

For the analysis it is highly interesting that in the late 80th this problem was already recognized and numbers presented of the extent of the problem of non – innovative drugs; drugs of which is claimed that they would have a therapeutic benefit but do not have one. The second problem which was finally solved in 2011 but was already recognized as a problem in back at the 80th by the Enquete-Commission was that the pharmaceutical industry was

¹⁰ “Die Enquete-Kommission formulierte [...] die Eckpunkte für nachfolgende GKV-Reformen und die sich darum rankenden Kontroversen.“(Rainers 2010, 37).¹⁰

¹¹ Der weitaus überwiegende Teil der neu zugelassenen Arzneimittel beinhaltet nach Ansicht der Experten keinen bedeutsamen zusätzlichen Nutzen für die medikamentöse Therapie und dem Patienten. So zeigt eine Analyse der 1986 und 1987 neu zugelassenen Fertigarzneimitteln, daß sich unter den 764 (1986) und bzw. 241 (1987) lediglich 16 (1987) bzw. 22 (1987) mit neuen Wirkstoffen befanden. Von kompetenter Seite wurden hiervon für 1987 lediglich vier als echte therapeutische Fortschritte gewertet, 1986 waren es nur zwei. (Enquete-Kommission 1990, 246).

allowed to set freely the price of innovative drugs. This free price setting of patented drugs was only not prohibited in Germany, Malta and Denmark.

In contrast to nearly all other European countries exist in Germany no governmental or administrative controls when the pharmaceutical industry determines the prices except cartel regulations.¹²

On basis of this analysis of the drug sector the Enquete - Commission explained that measures have to be done to solve the problem of patented and innovative drugs in order to assure quality and contain costs. Despite the reorganization of the existing problems, the Enquete-Commission made only limited suggestions how to solve this problems: In respect to the therapeutic added benefit the Enquete – Commission explained that it would be very difficult to assess additionally to quality, effectiveness and harmlessness a fourth criteria – the therapeutic added benefit - in order to admit a drug to the market (Enquete-Kommission 1992, 246). In contrast in respect to stop the pharmaceutical industry from freely setting the prices of innovative drugs the Enquete – Commission suggested price negotiations between the pharmaceutical industry and health insurance funds:

One more possibility is direct price negotiations between single sickness funds and single pharmaceutical concerns. These models of price negotiations are only acceptable if they are locally structured on both sides. This means that the single sickness fund negotiates with single drug producers about the price – perhaps even regional. (Enquete-Kommission 1990, 255).¹³

Rainers (2010, 37) explains that not only the ideas of the Enquete - Commission shaped the health care reforms in the next two decades but also the members of the Enquete – Commission since some of them got important positions in the following reforms. Hassenteufel et al. (2010, 532) argues that “[t]his commission can be considered the matrix of the reform ideas”.

5.2 The Case 1992

This case – the health care reform in 1992 - was chosen to compare it with the case I want explain – the health care reform in 2011 - because in the health care reform in 1992 it was the first time tried to stop the pharmaceutical industry from freely setting the prices of innovative drugs. The stop of the pharmaceutical industry to freely setting the price of innovative drugs is described as radical policy change in this thesis. The suggested regulation back at that time

¹² Im Gegensatz zu fast allen europäischen Nachbarstaaten ist die pharmazeutische Industrie in der Bundesrepublik Deutschland – abgesehen von kartellrechtlichen Bestimmungen – bei der Festlegung ihrer Preise keinerlei staatlichen oder behördlichen Kontrollen unterworfen. (Enquete-Kommission 1990, 246).

¹³ Als eine weitere Möglichkeit werden direkte Preisverhandlungen zwischen einzelnen Krankenkassen und einzelnen Herstellern angesehen. Derartige Preisverhandlungsmodelle sind allerdings nur dann akzeptabel, wenn sie auf beiden Seiten dezentral strukturiert werden. Dies bedeutet, daß letztlich die einzelne Krankenkasse mit einzelnen Arzneimittelherstellern Preise – möglicherweise auch regional – aushandelt (Enquete-Kommission 1990, 255).

to achieve this aim was price negotiations between sickness funds and the pharmaceutical industry. The same regulation was enacted in 2011. In 1992 the positive list was suggested in order to assess the therapeutic added benefit which would have been the basis for the price negotiations. In 2011 was enacted that assessment for the therapeutic added benefit has to be done with the benefit – evaluation and not with the positive list. In the following the legislative process of the health care reform in 1992 are described and the issues and disputes in respect to regulate innovative drugs and stop the pharmaceutical industry from freely price setting are pointed out.

5.2.1 Issues and disputes

The key aims of the reform were the hospital sector, ambulant medical patient-centred care, organization reform of the statutory health insurance and the supply with drugs (Oberender/Zerth 2005, 25).

The first draft of the Health Care Structural Reform Act (Gesundheitsstrukturgesetz) included in respect of the supply of drugs neither the positive list nor price negotiations in order to regulate pricing and reimbursement of patented drugs. Despite the fact that the Enquete-Commission suggested price negotiations they were not considered in the policy proposal in the health care reform in 1992. The positive list as reimbursement regulations in order to separate innovative from non-innovative drugs was neither included in the first draft of the Health Care Structural Act in 1992 despite the fact the problem of the missing regulation of non – innovative drugs was known. In the report of the Enquete - Commission statistics were presented which showed the extent of the problem that a lot of drugs are launched as innovative drugs which are not innovative, which means that they do not have any therapeutic added benefit.

Nevertheless this problem did neither get a lot of attention from politicians and neither was it in public discussion. The reason for this missing attention to this policy problem was perhaps the statement of the Enquete - Commission that the positive list would incriminate the pharmaceutical industry too much. Other European countries had a different opinion on this regulation: Back at that time already a lot of European countries enacted a positive list since it was effective to reduce drugs on the markets and to prevent reimbursement from non-innovative drugs.

The positive list played not until the first draft was finished and shown by the ruling parties CDU/CSU and FDP to the opposition parties SPD and the Green Party a role. However

Rudolf Dreßler, the head of the parliamentary health commission explained that they would not agree on this draft. This was in so far a problem since SPD had the majority in the Bundesrat and the approval of the Bundesrat was needed in order to carry out the whole reform. Dreßler announced that without positive list SPD will not agree on the other points of the reform. CDU/CSU had no choice and included SPD in decision – making in order to find a compromise and designed a second proposal.

From the beginning the SPD made clear that they would not agree on the draft of the Health Care Structural Reform Act of CDU/CSU and FDP. They would neither give their votes for it in the Bundestag and Bundesrat. (Kirschner (SPD) 9.12.1992, 10918, my translation).¹⁴

In order to find a compromise, negotiations were made in “Lahnstein”. Lahnstein is a village and known for the fast compromise in respect of the health care reform in 1992 between CDU/CSU and SPD. Main actors in this compromise were the head of the parliamentary health commission, Rudolf Dreßler (SPD), and health minister Horst Seehofer (CSU). The main object of the compromise was the positive list and price negotiations between sickness funds and the pharmaceutical industry. Horst Seehofer (CSU) agreed on the positive list but not on the price negotiations.

It is no secret that the SPD wanted not only the positive list but also to change the regulation of patented drugs. We (SPD) wanted price negotiations between sickness funds and the pharmaceutical industry; therefore it would have been a sensible free market instrument. It was not possible for us to enact this instrument against the opposition of the pharmaceutical industry and against the self - appointed market economists of the CDU/CSU and FDP. Nothing is more frightening for such kind of market economists as to announce to introduce in fact free market economy. (Dreßler (SPD) 5.11.1992, 9923, my translation).¹⁵

The SPD pointed out that it is paradox that that FDP and CDU/CSU who are famous for their affection for market orientation and competition are not in favour of negotiations between sickness funds and the pharmaceutical industry. I assume because the pharmaceutical industry disliked this regulation.

In the final version of the Health Care Structural Reform Act was decided that the construction of the positive list should be finished by 1996. Moreover an institution was planned which should be in charge of selecting innovative drugs from non - innovative drugs

¹⁴ Die SPD ließ von Anfang an keinen Zweifel daran aufkommen, daß dieser von CDU, CSU und F.D.P. vorgelegte Entwurf eines Gesundheitsstrukturgesetzes keine SPD Stimmen im Bundestag und auch im Bundesrat bekommen würde. (Kirschner (SPD) 9.12.1992, 10918).

¹⁵ Es ist kein Geheimnis, dass die SPD auch Änderungen der **Arzneimittelpreisgestaltung** herbeiführen wollte. Wir wollten Preisverhandlungen zwischen Krankenkassen und pharmazeutischen Herstellern, also ein marktwirtschaftlich vernünftiges Instrument. Wir haben uns mit diesem Instrument gegen die selbsternannten Marktwirtschaftler in der CDU/CSU und F.D.P. und gegen die pharmazeutische Industrie nicht durchsetzen können. [...]Man kann Marktwirtschaftler solcher Art durch nichts mehr erschrecken als durch die Ankündigung als durch die Ankündigung die Marktwirtschaft jetzt wirklich einzuführen. (Dreßler (SPD) 5.11.1992, 9923).

by assessing the therapeutic added benefit and construct the positive list. The last version of the Health Care Structural Act was fast passed through the second and third legislative reading in the Bundestag; in 1.1.1993 the act came into force.

However this was not the end of the story of the positive list, it just started. At the end of 18.12.1995 CDU/CSU abolished the positive list again. CDU/CSU explained that the commission which is in charge of making the positive list figured out that the positive list would not fulfil the expectations because it would not lead to the expected savings (Stenographic protocol Zöller (CDU/CSU) 23.11.1995, 06183). It is important to know that “independent” experts expect 800 millions of savings with the positive list.

According to media and statements of politicians the positive list was abolished because of the pharmaceutical industry (Seehofer 1.1.2003, 1-1 - 1,24 min./Dreßler (SPD) 5.11.1992, 9923). The most impressive statement in order to prove that the positive list was abolished because of the interests of the pharmaceutical industry was given from health minister Horst Seehofer in an interview in the TV broadcast “Frontal” in 2003:

The Positivliste failed, like this draft in 2003, again and again. Why? This had the former health minister Horst Seehofer to experience. Today Seehofer admits it for the first time: The pressure of the pharmaceutical lobby was too big.

Frontal: “Does this mean that the pharmaceutical industry really was too strong for politics and you had to recall your proposal?”

Seehofer: “Exactly this is what happened. Since thirty years until today sensible structural changes, like more social market economy, are not possible because of the blocking of the pharmaceutical industry.”

Seehofer’s state secretary, Baldur Wagner, gave one copy of a shredded Positivliste to Hans Rüdiger Vogel, the boss of the federation of the pharmaceutical industry. The lobby of the pharmaceutical industry asserted itself – with massive pressure.

Seehofer: “I only can describe that it works in this way. And that it works in this way very effective.”

Frontal: “But this shouldn’t be possible that the pharmaceutical industry has more power than politics! At the end politics should have enough power to decide and say no! (Seehofer 1.1.2003, 1-1, 1,24 min, my translation).¹⁶

¹⁶ In Deutschland ist die Positivliste, so wie dieser Entwurf 2003, immer wieder gescheitert. Warum? Das hat der ehemalige Gesundheitsminister Horst Seehofer erfahren müssen. Heute gibt er erstmals zu: Der Druck der Pharmedialobby war zu groß.

Frontal: „Heißt das denn, daß die Pharmedialobby wirklich so stark war gegen die Politik, und Sie quasi dann da zurückziehen mußten?“

Seehofer: „Ja. Das ist so, seit 30 Jahren, bis zur Stunde, daß sinnvolle strukturelle Veränderungen, auch im Sinne von mehr sozialer Marktwirtschaft, im deutschen Gesundheitswesen nicht möglich sind wegen des Widerstandes der Lobbyverbände.“

Seehofer’s Staatssekretär Baldur Wagner hat seinerzeit (1995) dem Chef des Bundesverbandes der pharmazeutischen Industrie, Hans Rüdiger Vogel, sogar ein geschreddertes Exemplar der Positivliste überreicht. Die Pharmedialobby setzte sich durch – mit massivem Druck.

Seehofer: „Äh, es – ich kann Ihnen nur beschreiben, daß es so ist. Und daß es so abläuft, und zwar sehr wirksam.“

Frontal: „Aber es kann doch nicht sein, daß die Industrie stärker ist als die Politik! Also, letzten Endes muß es doch heißen, die Politik muß sagen, nein, so geht’s nicht.“

Seehofer (zuckt mit den Schultern): „Ja – ich kann Ihnen da nicht widersprechen. (Seehofer 1.1.2003, 1-1, 1,24 min).

In the next section are the arguments presented which were used from CDU/CSU and FDP and the pharmaceutical industry and SPD and Green Party in order to argue their opinion of positive list and price negotiations.

5.2.2 The Arguments

In the above presented legislative process two problematic issues existed: The positive list and price negotiations. Since price negotiations were not even considered only the positive list lead to high discussions. In the following the arguments from CDU/CSU and FDP contra positive list and from SPD and Green Party pro positive list are presented. In the following will be shown that CDU/CSU, FDP and the pharmaceutical industry used decisive economical arguments (cut of working places, conservation of the production location Germany, migration of pharmaceutical concerns) in order to argue against the positive list. These were stronger arguments as SPD, Green Party and health insurance funds opposed in respect to the effectiveness of this regulation in order to contain costs and improve the quality of drugs on the Germany drug market:

The advocacies of the positive list, SPD, the Green Party and the health insurance fund argued that more drugs are on the German drug market which are necessary. In other countries would be much less drugs on the drug market as in Germany and people in other countries would be as healthy as Germans.

In the federal republic about 100.000 drugs exist which are reimbursed by sickness funds. This is a huge number. It points out the necessity of rearrangement of the pharmaceutical market. Swiss offers only 8.000 drugs and even America has only around 46.000 drugs. I do not think that Swiss and American are not as healthy as Germans. (Dreßler (SPD) 5. 11.1992, 9923, my translation).¹⁷

In contrast this high variety of drugs would even have various disadvantages: It leads to an in transparent drug market. This would be a problem for doctors since the choice of the right drugs is as more difficult as more drugs exist on drug market. This leads again to non-economical behaviour of doctors since they sometimes associate expensive drugs with high quality which is a wrong assumption. Therefore the positive list would be necessary in order to reduce the high number of drugs and show which drugs are most cheap even they have the same benefit.

¹⁷ In der Bundesrepublik gibt es derzeitig ca. 100.000 auf Kassenrezept verordnungsfähige Arzneimittel. Dies ist eine gewaltige Zahl. Sie unterstreicht die Notwendigkeit einer Neuordnung. Während die Schweiz mit etwa 8.000 Präparaten auskommt und die rießigen Staaten von Amerika mit ca. 46.000, leistet sich die Bundesrepublik einen solchen Arzneimittelwulst. Ich kann nicht sehen, daß Schweizer oder Amerikaner kränker sind als Deutsche aus diesem Grund, meine Damen und Herren. (Dreßler (SPD) 5. 11.1992, 9923).

The Ministry of Health writes in a press release in April 2003: 'In Germany for doctors exists an unmanageable assortment of drugs. Important conditions are missing which afford a pharmacotherapy with quality and efficiency. (Hinrichs/Nowak 2005, 116).¹⁸

Moreover the positive list is important in order to sort out these drugs which have no therapeutic added benefit but are reimbursed by health insurance funds like they would have one.

The Federation of medical insurance plan published in his drug report impressive numbers. In the last year spend the sickness funds 24, 4 milliards DM for drugs. 6,1 milliards were spent for drugs which were low or contested. 6, 1 milliards is exactly one quarter of the drug costs in total. (Stenographic protocol 9.12.1992 Schmidt - Zadel (SPD), 10960, my translation).¹⁹

Moreover the advocates of the positive list argued that the arguments of the adversaries that the positive list would damage the pharmaceutical industry are not true. "The argument that this law would endanger the productivity of the pharmaceutical industry is totally absurd, ladies and gentlemen." (Stenographic protocol Dreßler (SPD), 9.12.1992, my translation).²⁰ SPD and Green Party argue that the pharmaceutical industry could reduce costs for example by advertisement and corruption because they would spend much more money on this as for research of innovative drugs. "By the way, if a branch spends milliards for merchandising then it has money left in order to lower prices." (Dreßler (SPD) 9.12.1992, 10936, my translation).²¹

The adversaries of the positive list, CDU/CSU, FDP and the pharmaceutical industry argue since a lot of illnesses are not treatable yet good research conditions have to be created for the pharmaceutical industry in order that they are willing to do research for innovative drugs also in the future (Enquete-Commission final report 1990, 248). However the positive list would destroy the willingness of the pharmaceutical industry to do research. "Drug research loses his foundation with the positive list." (Süddeutsche Zeitung 23.05.2003, 0.S.).²²

¹⁸ So schreibt das Gesundheitsministerium in einer Pressemitteilung vom April 2003: „In Deutschland gibt es auch für Ärztinnen und Ärzte ein unübersehbares Arzneimittelangebot. Wichtige Voraussetzungen für eine an Qualität und Wirtschaftlichkeit orientierte Arzneimitteltherapie fehlen. (Hinrichs/Nowak 2005, 116).

¹⁹ Der Bundesverband der Ortskrankenkassen hat in seinem Arzneimittelreport 1992 eindrucksvolle Zahlen genannt. Im vergangen Jahr haben die Krankenkassen für Medikamente 24,4 Milliarden DM ausgegeben. Davon gingen 6,1 Milliarden DM für solche Medikamente weg, deren Wirkung als gering oder umstritten gilt oder galt. 6, 1 Milliarden DM, ist genau ein Viertel der Medikamentenkosten für Medikamente mit mehr als zweifelhaften Nutzen. (Plenarprotokoll 9.12.1992 Schmidt-Zadel (SPD), 10960).

²⁰ Die Behauptung jedenfalls, dieses Gesetz gefährde die Leistungsfähigkeit der pharmazeutischen Industrie, ist doch wohl blanker Hohn, meine Damen und Herren. (Stenographic protocol Dreßler (SPD), 9.12.1992).

²¹ Im Übrigen, wer als Branche Milliardenbeträge für sogenannte Absatzförderung zur Verfügung hat [...] hat Luft mit den Preisen [...].(Dreßler (SPD) 9.12.1992, 10936).

²² Damit [Positivliste] wird der Arzneimittelforschung in diesem Land die Grundlage entzogen. (Süddeutsche Zeitung 23.05.2003, 0.S.).

It is not possible to heal a big part of illnesses. This fact points out the necessity that research on innovative drugs has to be done in the future in order to provide a perfect pharmacotherapy. (Enquete-Kommission 190, 248, my translation).²³

Innovations would be not only necessary from this medical aspect but from economical aspects, too. First the research intensity would be also important because of national and international market competition. Negative research conditions would lead to a migration of pharmaceutical concerns abroad and this decisively damage Germany as drug manufacturing base and lead to high losses of working places.

Nobody will invest one million Euro for a drug, if it is not sure that it will be put on the positive list. But only there where research is done for a new drug, it will be clinically developed. And only where it is developed, it gets produced. Enough rich countries exist in the world, which can afford research for new drugs. The question will be: Will any drug be produced in the future in Germany if the positive list gets enacted? (Süddeutsche Zeitung 23.05.2003, O.S., my translation).²⁴

I just want to point out that the positive list endanger working places and will probably lead to a cut of working places. This is confirmed by various people. (Bauer (CDU) 10.04.2003, 3358, my translation).²⁵

Moreover according to the VFA the positive list would distort competition.

The VFA prevent all past attempts in order to enact a positive list initiated by sickness funds and medical association. The reason was alleged distortion of competition. (Coalition against Bayer 22.07.2003, o.S.)²⁶

Conclusion:

This description of the legislative process showed that the positive list failed because of CDU/CSU who acted for the interests of the pharmaceutical industry. The compromise of Lahnstein was an opportunity for the parliamentary health spokesperson Rudolf Dreßler (SPD) to push the positive list through the decision – making process. Despite the compromise, which is a perfect opportunity to push issues through the decision – making process which are against the interests of the ruling parties, price negotiations did not have any chance at all. Moreover even the positive list failed at the end because of the interest of

²³ Insbesondere die Tatsache, daß ein großer Teil der zahlreichen Krankheitsbilder bisher noch nicht kausal therapierbar ist, macht deutlich, daß eine weitere Arzneimittel mit neuen Wirkstoffen, unerlässlich sind, um eine optimale Arzneimitteltherapie zu ermöglichen [...] nicht zuletzt um die Forschungsintensität der Pharmaindustrie unnötig zu gefährden. (Enquete-Kommission 190, 248).

²⁴ Niemand werde eine Milliarde Euro in ein Medikament stecken, wenn er fürchten müsse, es damit anschließend nicht oder erst nach Jahren auf die Positivliste der Bundesregierung zu schaffen. Nur dort aber, wo ein neues Medikament erforscht werde, werde es anschließend auch klinisch entwickelt. Und nur, wo es entwickelt werde, werde es am Ende auch produziert. [...] es gebe mittlerweile genügend wohlhabende Länder in der Welt, die sich die Erforschung neuer Medikamente leisten könnten. Die Frage werde also sein: Wird irgendeines dieser Medikamente noch in Deutschland produziert? (Süddeutsche Zeitung 23.05.2003, O.S.).

²⁵ Ich möchte nur darauf hinweisen, dass die Positivliste – das wird von vielen bestätigt – Arbeitsplätze gefährdet und wahrscheinlich zum Arbeitsplatzabbau führen wird. (Bauer (CDU) 10.04.2003, 3358).

²⁶ Alle vorherigen Versuche zur Aufstellung einer Positivliste durch Krankenkassen und Ärztekammern verhinderte der VFA durch Millionenklagen – wegen angeblicher Wettbewerbsverzerrung. (Coalition against Bayer 22.07.2003, o.S.)

the pharmaceutical industry. The problem of not - innovative drugs existed but did not really political or public attention even the Enquete – Commission and health insurance funds published statistics which described the extent of the problem. The decisive arguments which used CDU/CSU to argue against the positive list were: The positive list would endanger the production location Germany. Moreover the pharmaceutical industry which does research would migrate and a lot of working places would get lost.

5.3 Reform 2004

The choice of this comparative case can be explained with two aspects: First of all also in this case it was tried to stop the pharmaceutical industry to set freely the price of innovative drugs but the attempt failed. Second it shows best the development of the reimbursement regulation which is in my opinion decisive that radical policy change happened in 2011. The reason: Pricing and reimbursement regulation are closely linked and in my opinion because of this development in respect to reimbursement regulation a pricing regulation could be designed in 2011 which did not burden the pharmaceutical industry. And since it did not burden the pharmaceutical industry it could be passed through the decision – making process. It will be shown in this case that the pharmaceutical industry in Germany is very strong and plays a decisive role if laws can be passed in health care or not. Moreover patented drugs were included in the reference pricing system. However innovative drugs – drugs which would have reputed a therapeutic added benefit – are excluded from the reference pricing system; therefore still the full price gets reimbursed by health insurance funds.

5.3.1 Issues and disputes

Since this case - health care reform in 2004 - is far more complicated than the former case – health care reform in 1992 - first the legislative process will be summarized and then presented in detail.

The aim of the reform in 2004 – was like in 1992 - to restructure the statutory health insurance in order to solve the problems of quality, supply and finance.

The reform in 2004 included two legislative processes which are important for our study. The first one is the “Positive List for Drugs Act” (Arzneimittel – Positivlistengesetz) in order to enact the positive list. The second one is the SHI - Modernization Act (GKV-Modernisierungsgesetz). In its first draft it included a substitute for the positive list - the cost-effectiveness evaluation and the governmental institute „Center for Quality in Health Care”

which should be in charge of the cost- effectiveness evaluation. Moreover it included that patented drugs are again ordered in a reference pricing system and innovative drugs with a therapeutic added benefit should be excluded.

However at the end it was not possible to realize the positive list, the cost-effectiveness evaluation and the Center for Quality in Health Care. As substitute for the positive list and cost - effectiveness evaluation was the benefit - evaluation planned. As substitute for the governmental institution, Center for Quality in Health Care was the nongovernmental institution planned “Institute for Quality and Efficiency in Health Care (IQWiG)”. Both institutions have the same purpose: The assessment of the therapeutic benefit in order to select drugs with therapeutic added benefit from drugs without therapeutic added benefit. However it was successful to regulate patented drugs with the reference pricing system but only if innovative drugs are excluded.

Moreover in the design of the benefit evaluation a lot of decisive changes happened during the legislative process which made the German reimbursement regulation compared to the ones of other European countries ineffective:

In order that a drug gets admitted to the drug market and doctors are allowed to prescribe it, three criteria have to be fulfilled in Germany: quality, harmlessness and effectiveness. In most other European countries a fourth criteria has to be fulfilled before a drug gets admitted to the drug market: the therapeutic added benefit. At the beginning of the health care reform it was planned – like in the other European countries - to control if a drug has a therapeutic added benefit before drug admission. However in the final version of the act it was decided that the drug gets on the drug market and later it will be tested if the drug has a therapeutic added benefit. This led to the advantage of the pharmaceutical industry in Germany over the pharmaceutical industries in other European countries that they got the full high prices reimbursed by health insurance funds until after years the Institute for Quality and Efficiency in Health Care that this drug has actually no therapeutic added benefit. The pharmaceutical industry did not have to pay back the money they got unjustified.

In the following I will proceed step by step and describe the legislative process of the Positive List for Drugs Act and SHI - Modernization Act. In order to avoid confusion the legislative process of the Positive List for Drugs Act and the SHI - Modernization Act overlap. The reason: Health minister Ulla Schmidt started to develop an emergency plan in order to

substitute the positive list before the Positive List for Drugs Act definitely failed. She already guessed it would be not possible to enact and implement it.

Various changes in respect to reimbursement regulation:

The legislative process of the Positive List for Drugs Act started before the health care reform began; before the main points of the health care reform in 2004 got published. The Positive List for Drugs Act had the aim of enacting the positive list.

In 20th of November 2002 the ruling coalition, SPD and Green Party, which was in the health care reform in 1992 opposition parties, gave the first proposal of the Positive List for Drugs Act to the pharmaceutical industry. The proposal included the positive list. The positive list includes all drugs which passed a benefit evaluation and cost-effectiveness evaluation successfully and get therefore reimbursed by sickness funds. Until today the pharmaceutical industry defeats the positive list because the enactment of the positive list includes that a drug gets also tested if it is cost – effective (Vfa 14.05.2003, o.S.). This means if the benefit of a drug justifies the price. Moreover the positive list includes that the therapeutic added benefit gets assessed before drug admission; one issue the pharmaceutical industry totally dislikes.

Ulla Schmidt (SPD) assumed that the positive list has less chance to be enacted because of the CDU/CSU and the pharmaceutical industry. Therefore she included the cost - effectiveness evaluation as substitute for the positive list and the „Center for Quality in Health Care“ in the main points of the health care reform (Siebert 2010, 13). Moreover she planned to regulate patented drugs with the reference pricing system and exclude innovative drugs; drugs which have a therapeutic added benefit.

The important difference between positive list and cost - effectiveness - evaluation is the following: In order that a drug is put on the positive list, its cost - effectiveness has to be evaluated before drug admission. In contrast the cost-effectiveness evaluation can be designed that the evaluation happens before or after drug admission.

Ministerial president from Hesse, Roland Koch (CDU/CSU), was strongly defeating the positive list. According to newspapers he was one decisive figure, why the positive list was not enacted at the end. The pharmaceutical industry produces mainly in Hesse which explains the interests of Roland Koch to protect his production location.

In Hesse, the federal country of ministerial president Roland Koch, are the pharmaceutical companies Aventis (Frankfurt) and Merck (Darmstadt). He instructed the CDU/CSU negotiations - group with a clear order: "Abolishing the list." (Spiegel 28.07.2003, o.S., my translation).²⁷

In 12.03.2003 the health minister Ulla Schmidt (SPD) and Federal minister Wolfgang Clement (SPD) brought into force the so called "Task force for drug policy". This task force should discuss the law before it gets discussed in parliament. Members of this group are interest groups: Agencies of the economy and health resorts, trade union coal mining, chemical industry and energy, federal association of the pharmaceutical industry, the association of drug producers, who do research and the federal association of drug producers (Hinrichs/Nowak 2005, 119). Most members of the task force were from the pharmaceutical industry. I think it is highly interesting that most of the members of the task force were from the pharmaceutical industry since they were the ones who defined the basic concept of an act in drug policy. (Bundesministerium für Gesundheit 2009, 30). The main goal of this commission was to advance the "conditions governing location" and the innovation opportunities of the pharmaceutical industry in Germany (Bundesministerium für Gesundheit 2009, Deckblatt).

The Bundesrat declined the positive list in 23.05.2003 since CDU/CSU hold the majority. According to the Süddeutsche Zeitung (22.05.2003, o.S.) was Hesse Prime Minister Roland Koch and Hesse economic minister Lautenschläger decisive for this decision. Hesse is an important federal country in order to fight against the positive list because the pharmaceutical industry is mostly in Hesse. "The pharmaceutical industry is nearly only in Hesse strongly presented."²⁸ (Siebert 2010, 14, my translation). Roland Koch's reasoning for his fight against the positive list was that he sees Germany's interests as business location in danger. "The Hesse Prime Minister supports the pharmaceutical industry in their struggle with the Federal Government. The planned reforms destroy the production location Germany." (Süddeutsche 22.05.2003, o.S., my translation).²⁹

Since the Bundesrat was against the positive list a dispute started if an authorized approval by the Bundesrat is necessary in order to enact the positive list. SPD and Green Party negate this and CDU/CSU and FDP had the opinion that an authorized approval would be necessary. Nevertheless the ruling parties planned to bring the positive list into force in 01.03.2003, even

²⁷ Hessens Ministerpräsident Roland Koch, in dessen Bundesland unter anderem die Pharmakonzerne Aventis (Frankfurt) und Merck (Darmstadt) vertreten sind, hatte der CDU/CSU-Verhandlungsgruppe schon zuvor einen klaren Auftrag erteilt: "Die Liste muss weg." (Spiegel 28.07.2003, o.S.).

²⁸ Die Pharmaindustrie ist fast nur noch in Hessen stark vertreten. (Siebert 2010, 14).

²⁹ Der hessische Ministerpräsident unterstützt die Pharmaindustrie in ihrem Kampf gegen die Bundesregierung. Die geplanten Reformen in der Gesundheitspolitik zerstörten den Standort Deutschland. (Süddeutsche 22.05.2003, o.S.).

the Bundesrat and the opposition parties of the Bundestag, CDU/CSU and FDP were against the positive list. The parliamentary health commission decided pro positive list in 17. June 2003.

Since Ulla Schmidt doubted that the positive list would have a chance to be enacted she included a cost - effectiveness evaluation, the governmental institution „Center for Quality in Health Care“ and the reference pricing system for patented drugs in the draft law of the Statutory health care Modernization Act.

In June the Statutory health care Modernization Act was discussed in the Bundestag and first ideas were transferred in the commissions for further development. The coalition decided against a second and third reading in the Bundestag and instead consensus talks were hold. At the end of June the positive list, the cost - effectiveness evaluation and the Center for Quality in Health Care collapsed during the consensus talks. According to the magazine Spiegel (28.07.2003, o.S.) was Health minister Ulla Schmidt not too unhappy about abolishing the positive list because critics came not only from Hesse minister president Koch (CDU) but also from 50 CDU associates. According to Schmidt they were afraid of the working places in their electoral ward.

Health minister Schmidt hardly defend herself [against abolishing the positive list], she even seemed to be relieved. Because not only Koch from CDU/CSU, but also around 50 associates complained by Schmidt. Schmidt explains that these politicians from CDU/CSU were afraid that the positive list would endanger working places. In Schmidt's home federal country NRW, where she has her electoral ward, is the pharmaceutical giant Bayer at home. (Spiegel 31/28.07.2003, o.S., my translation)³⁰

CDU/CSU had the majority in the Bundesrat. Therefore their approval was at the end necessary in order to enact the act even if they discussed if it would be perhaps possible to enact the act without approval at the beginning. Since CDU/CSU did not seem to agree on the proposal from SPD and Green Party, CDU/CSU was included in order to design a new proposal and the former draft was abolished. The Bundesrat was also against regulating the prices of patented drugs with the reference pricing system but nevertheless it did not change during the legislative process and was finally enacted.

The failing of the positive list, the cost - effectiveness evaluation and the Center for Quality in Health Care was justified in the draft law of SPD, Green Party and CDU/CSU with the

³⁰ Gesundheitsministerin Schmidt wehrte sich kaum [gegen die Abschaffung der Positivliste], ja sie schien sogar erleichtert. Denn nicht nur der Unionsmann Koch, sondern auch etwa 50 Genossen hatten sich bei ihr beschwert. Denen, sagte die Ministerin in kleiner Runde, sei es um Arbeitsplätze in den Wahlkreisen gegangen, die durch die Positivliste angeblich in Gefahr kämen. In ihrem Stammland NRW, wo die Aachenerin ihren Wahlkreis hat, ist der Pharmariese Bayer zu Hause. (Spiegel 31/28.07.2003, o.S.)

argument that these regulations would be not necessary anymore because of the new benefit evaluation.

The rules and regulations in § 33a about the introduction of a list of drugs which get reimbursed by sickness funds (positive list) get reversed. New regulations, which were introduced in the context of the health care reform in order to foster quality and effectiveness in supply of pharmaceuticals, make the enactment of a positive list unnecessary. This new regulation are: economic incentives in order to regulate the prescription behavior of doctors, changed effectiveness tests in the health system, the assessment of the benefit of drugs by the institute for Quality and Efficiency in health care and a new reference pricing system for patented drugs [...].(BT – Drucks. 15/1525, 4, my translation).³¹

According to Katrin Vogler, member of the parliamentary Green Party in the Bundestag, (11.11.2010, 7666), it was the CDU/CSU who avoided an effective cost - effectiveness evaluation. “It was the CDU/CDU back then – also this is part of the truth-, which prevented the introduction in a real cost-effectiveness evaluation.” (Bender (Green Party) 11.11.2010, 7666, my translation).³² The positive list was also in the reform 2003 abolished because of CDU/CSU.

The positive list was abdicated in course of the compromise with CDU/CSU even if experts asked for it and the SPD originally was also in favor of the positive list. With the help of the positive list the number of drugs which health insurance funds have to reimburse would have been cut down to half, which is around 20000. (Süddeutsche Zeitung 30.9.2003, o.S., my translation).³³

In September 2003 a legislative proposal was developed and included only the benefit evaluation instead of the cost - effectiveness evaluation. The cost-effectiveness evaluation is in so far not as harmless as the benefit evaluation since not only the therapeutic added benefit gets assessed but also if the benefit is in relation with the costs gets examined. According to the magazine Spiegel this change from cost – effectiveness evaluation to benefit evaluation was in particular because of the efforts of CDU politician Andreas Strom from Darmstadt. He was concerned of the moderation of the regulation since the pharmaceutical concern Merck is in his electoral ward (Spiegel 31/28.07.2003, o.S.).

Also other plans which would have burdened the pharmaceutical industry went straight into the trash during the negotiations. First the SPD planned to create with the cost - effectiveness evaluation a fourth

³¹ Die Vorschriften in § 33a über die Einführung einer Liste über verordnungsfähige Arzneimittel in der vertragsärztlichen Versorgung (Positivliste) werden aufgehoben. Neue, im Rahmen der Gesundheitsreform zur Förderung von Qualität und Wirtschaftlichkeit in der Arzneiverordnung vorgesehene Regelungen machen die Einführung einer Positivliste entbehrlich. Zu den neuen Regelungen gehören insbesondere neue finanzielle Anreize zur Steuerung des Ordnungsverhaltens, veränderte Wirtschaftlichkeitsprüfungen, eine Nutzenbewertung von Arzneimitteln durch das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, eine neue Festbetragsregelung für patentgeschützte Arzneimittel sowie die grundsätzliche Herausnahme nicht verschreibungspflichtiger Arzneimittel und so genannte Lifestyle-Arzneimittel aus dem Leistungskatalog der gesetzlichen Krankenversicherung. (BT – Drucks. 15/1525, 4).

³² Es war damals die Union – auch das gehört zur Wahrheit dazu –, die den Einstieg in eine echte Kosten-Nutzen-Bewertung verhindert hat. (Bender (Green Party) 11.11.2010, 7666).

³³ Auf die von Experten geforderte und ursprünglich auch von der SPD angestrebte Positivliste, mit der die Zahl zu erstattender Medikamente auf 20.000 etwa halbiert werden sollte, wurde im Zuge des Gesundheitskompromisses mit der Union allerdings verzichtet. (Süddeutsche Zeitung 30.9.2003, o.S.).

hurdle which means that the therapeutic added benefit gets assessed before the drug is admitted to the drug market. This plan was fast damped. Andreas Storm from Darmstadt – in his electoral ward is big pharmaceutical concern Merck – was holding a harangue speech for the pharmaceutical industry which does research. ‘The pharmaceutical industry is an important economic factor.’ The result: Now is planned that the drugs will only pass through a comparatively harmless “benefit assessment”. Nobody talks anymore about the costs. (Spiegel 31/28.07.2003, o.S., my translation).³⁴

Moreover the governmental institution Center for Quality in health care was also not enacted because of CDU/CSU. However not only CDU/CSU was against this institution also sickness funds, hospitals, doctors and the pharmaceutical industry criticized it because it was governmental.

The SPD and Green Party planned a governmental institution “Center for Quality in health care”. This institute would have led to a paternalism of doctors and to a standardization of the course of action of treatment but it was possible to ward it. (Glos 23.07.2003, o.S., my translation)³⁵

Because of this opposition they established the “Institute for Quality and Effectiveness in health Care” which was resident by the Federal Joint Committee and therefore not a governmental institution. Since the Institute for Quality and Effectiveness in health care is resident by Federal Joint committee sickness funds, hospitals and doctors were satisfied in contrast to the pharmaceutical industry (Siebert 2010, 14).

The most powerful lobbyists in health care support CDU/CSU. Medical association, hospitals, panel doctors, sickness funds – nearly all of them are doubtful towards this regulation, because they have to fear guidelines with the aim of more economical supply. Karl Lauterbach, the senior consultant of Schmidt, points out the “high importance” of the institute for the whole health care reform. According to the ministry of Schmidt, might it be possible to make advances to CDU/CSU and to construct the institute with not that close links to government. (Spiegel 24.06.2003, o.S., my translation).³⁶

However the CDU/CSU was still not satisfied with the regulation. At the beginning of October the CDU/CSU parties in the Bundesrat pointed out the economical problems the regulation would lead to. They explained that they are afraid that the regulation of patented drugs with the reference pricing system would lead to too high burdens for the pharmaceutical industry and would have negative consequences for research of patented drugs.

³⁴ Auch andere Pläne zur Belastung der Branche wanderten während der Verhandlungen in den Papierkorb. Dachte die SPD zunächst daran, durch eine Kosten-Nutzen-Bewertung neuer Präparate eine weitere Zulassungshürde einzuziehen, wurde dieses Vorhaben schnell abgeschwächt. CDU-Mann Andreas Storm aus Darmstadt - in seinem Wahlkreis residiert der Pillenmulti Merck - hielt ein flammendes Plädoyer für die forschenden Arzneimittelhersteller: "Die pharmazeutische Industrie stellt einen wichtigen wirtschaftlichen Wachstumsfaktor in Deutschland dar." Das Ergebnis: Nun sollen die Medikamente nur noch eine vergleichsweise harmlose "Nutzen-Analyse" durchlaufen. Über die Kosten wird nicht mehr geredet. (Spiegel 31/28.07.2003, o.S.).

³⁵ Das von der rot - grünen Koalition geplante staatliche Zentrum für Qualität in der Medizin, das eine Bevormundung der Gesundheitsberufe und eine Standardisierung der Behandlungsabläufe von Patienten beinhaltet hätte, konnte abgewehrt werden (Glos 23.07.2003, o.S.).

³⁶ Die mächtigen Lobbyisten im Gesundheitswesen weiß die Union dabei hinter sich. Ärztekammer, Kassenärzte, Kliniken, Krankenkassen - fast alle lassen reichlich Skepsis gegen das Institut erkennen. Denn von dort müssen sie künftig Vorgaben mit dem Ziel sparsamer Versorgung befürchten. Ministerin Schmidts Chefberater Karl Lauterbach unterstreicht deshalb die "sehr große Bedeutung" des Instituts für die Gesundheitsreform. Um der Union entgegen zu kommen, heißt es aus Schmidts Ministerium, könnte man bereit sein, das Institut etwas staatsferner anzulegen. (Spiegel 24.06.2003, o.S.).

The Bundesrat is worried about the input of the pharmaceutical industry that the pharmaceutical industry which does research can perhaps not burden the costs which comes up when patented drugs get ordered in the reference pricing system. This would endanger the willingness of the pharmaceutical industry to invest capital and produce innovations. (BR-Drucks.³⁷ 675/1/03, 2, my translation).³⁸

In order that the CDU/CSU agreed in Bundestag and Bundesrat at all on the assessment of the benefit and the Institute for Quality and Efficiency in Health Care the SPD agreed on the compromise that the institute starts with the assessment of therapeutic added benefit *after* drug admission. “The assessment of the therapeutic added benefit after drugs admission was a points win of the pharmaceutical industry.” (Siebert 2010, 14, my translation).³⁹“ The act came into force in 1 of January 2004.

The agreement is mainly stamped by CDU/CSU and FDP. They have successfully advocated the privileges of the lobbyists, and the CSU - social expert gets greetings because he asserted himself against Schmidt in a lot of issues. (Süddeutsche 21.07.2003, o.S., my translation).⁴⁰

The statement of the head of the parliamentary health commission in 1992 is also highly interesting that the pharmaceutical industry favours a reference pricing system compared to price negotiations. I assume that the choice of reference pricing system was also influenced by the pharmaceuticals industries preference.

I do not understand the strategy of the pharmaceutical industry, how they present their interests in the context of health policy. I did not understand them before and after the consensus talks in 1992. The associations of the pharmaceutical industries abstained from price negotiations between supplier and consumer before Lahnstein and instead they wanted a one way fixing of prices, called reference prices (Dreßler 2000, 20, my translation).⁴¹

Describing the legislative process and the issues and disputes which came up should have shown that a lot of changes were made from the draft law to the final law on the advantage of the pharmaceutical industry. The main culprit was CDU/CSU who was influenced by the pharmaceutical industry. However the introduction of the patented drugs in the reference pricing system was possible against the interests of the pharmaceutical industry. I assume because still various loopholes existed for the pharmaceutical industry to make profit, mainly that innovative drugs were excluded. It was easy for the pharmaceutical industry to claim that

³⁷ Abbreviation: „BR-Drucks.“ means “Bundesrat Drucksache” in German and translated into English: “printed matter of the Bundesrat”

³⁸ Der Bundesrat ist im **Hinblick auf dem Beitrag der pharmazeutischen Industrie** besorgt, dass die insbesondere von den forschenden Arzneimittelherstellern zu tragenden Belastungen sowie durch die Einführung von Festbeträgen auf patentgeschützte Arzneimittel ein Ausmaß erreichen, das die Investitions- und Innovationsbereitschaft dieses Industriezweiges am Standort Deutschland nachhaltig gefährden kann. (BR-Drucks. 675/1/03, 2).

³⁹ Die nachträgliche Bewertung des Nutzens durchzusetzen war ein Punktesieg der Industrie.

⁴⁰ Die Einigung trägt weitgehend die Handschrift von Union und FDP. Die Privilegien der Lobbyisten haben sie erfolgreich verteidigt, der CSU-Sozialexperte Horst Seehofer darf Glückwünsche entgegennehmen, hat er sich doch in vielen Punkten gegen Ulla Schmidt durchgesetzt. (Süddeutsche 21.07.2003, o.S.).

⁴¹ Ich verstehe die Strategie der Pharma-Industrie nicht, sich im Gesamtkontext der Gesundheitspolitik mit ihren Interessen zu positionieren. Ich habe sie vor und während der Lahnsteiner Konsensgespräche nicht verstanden, und ich begreife sie auch heute nicht. Die Pharma-Verbände haben vor Lahnstein darauf verzichtet, die Preisgestaltung für Arzneimittel auf dem verordnungsfähigen Markt am Grundsatz einer Verhandlungslösung zwischen Anbieter und Nachfrager zu orientieren und statt dessen auf eine einseitige Preisfestsetzung durch die Nachfrager gesetzt, genannt Festbeträge. (Dreßler 2000, 20).

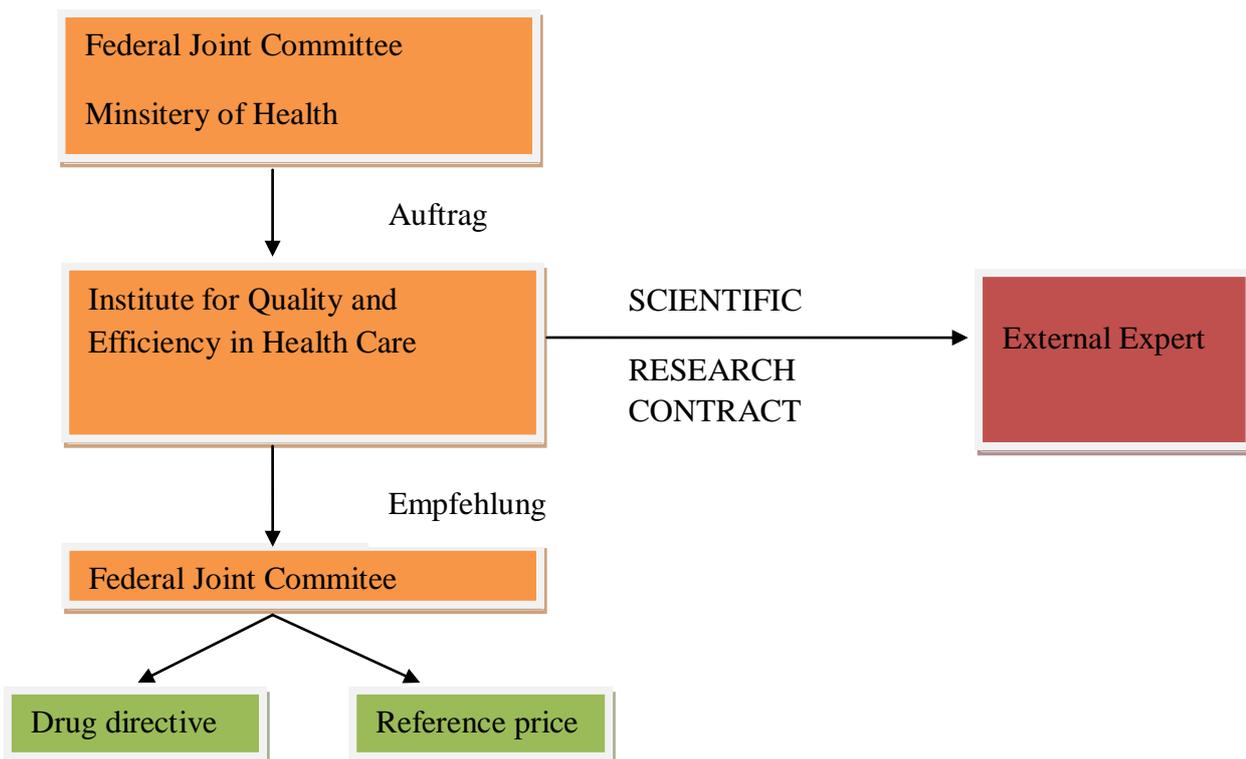
the drug would be an innovation and then not included in the reference pricing system with the consequence that it was fully reimbursed by sickness funds.

In the *Süddeutsche Zeitung* was the results of the health care reform summarized (21.07.2003).

The health system will not become more efficient or clear: In contrast: The administration will increase. In the future patients will be neither protected from overpriced drugs because a lot of the control plans – like the positive list – were garbled. The positive list which would have led to more clearness on the drug market, was put in the trash and the cost-effectiveness evaluation, too. The planned institute for quality in medicine was empowered. An independent control of drugs and therapies does so hardly take place – except you hope that frogs dry their own marsh. (Süddeutsche 21.07.2003, my translation).⁴²

In conclusion the benefit assessment gets described with the help of a figure.

Figure 2: Benefit assessment of drugs 2004 §35 SBG V



Source: Weiser (2003)

⁴² Das Gesundheitswesen wird auch nicht wirtschaftlicher und durchschaubarer. Im Gegenteil. Die Bürokratie wird eher zunehmen. Vor überteuertem Pillen-Unsinn bleiben die Patienten auch künftig kaum bewahrt, weil viele Kontrollpläne bis zur Unkenntlichkeit verstümmelt wurden. Die Positivliste, die für mehr Durchblick auf dem Medikamentenmarkt gesorgt hätte, landete im Papierkorb, die Kosten-Nutzen-Bewertung für Arzneien ebenfalls. Das geplante Institut für Qualität in der Medizin wird entmachtet, da es unter dem Dach von Ärzten und Kassen wirken soll. Eine unabhängige Kontrolle von Arzneien und Therapien findet so kaum statt - außer man hofft, dass die Frösche ihren eigenen Sumpf trocken legen. (Süddeutsche 21.07.2003).

5.3.2 Arguments

The issues which were disputed in the reform 2004 were the positive list, the cost-effectiveness evaluation and the moment of the assessment of the benefit and the Center for Quality in Health care and the Institute for Quality and Efficiency and the regulation of patented drugs.

Positive list

The arguments in respect to the positive list did not change between 1992 and 2004.

Cost-effectiveness evaluation

The adversaries of the cost - effectiveness evaluation argue that a cost - effectiveness evaluation would not lead to new information. Quality, efficiency and harmlessness gets already assessed and this would be enough (VfA 20.02.2003).

Drug producer already must prove quality, effectiveness and harmlessness in order that a drug gets admitted to the drug market. New information is not expected from the cost - effectiveness evaluation. (VfA 20.02.2003, o.S., my translation).⁴³

The Federal state Mecklenburg -Vorpommern argues in the Bundesrat that a cost-effectiveness evaluation is necessary in order to improve the quality and efficiency of drugs. Only the assessment of the benefit of drugs would be not enough (BR-Drucks. 675/2/032, 2). In similar vein argued Ulla Schmidt who explained that a cost - effectiveness evaluation would be very important since some drugs have only 5% until 10% more therapeutic added benefit but more than 300 percent more costs (Häussler 2006, 96).

The positive list includes a cost – effectiveness evaluation. The same economic arguments, like a loss of working places and endangering the drug production location, are used in order to argue against the cost – effectiveness evaluation.

The moment of benefit evaluation

The adversaries were arguing that the benefit evaluation before a drug gets admitted to the market leads to longer waiting times for innovative drugs for patients .

The VFA is against the implementation of a cost-effectiveness evaluation before a drug gets admitted to the pharmaceutical market. The consequence would be that patients have to wait a long time for

⁴³ Die Hersteller haben bereits im Rahmen eines aufwendigen Zulassungsverfahrens die Qualität, Wirksamkeit und Unbedenklichkeit ihrer Produkte belegt. Ein zusätzlicher Erkenntnisgewinn ist folglich nicht zu erwarten. (VfA 20.02.2003, o.S.).

important drugs until the decision is taken if these drugs get reimbursed by the health insurance funds. (VfA 20.02.2003, o.S., my translation).⁴⁴

Moreover the drug producers argue that the assessment is not possible before drug admission since the drug has to assert itself on the market in all application areas.

In contrast SPD and the Green Party argue that the benefit evaluation has to happen before drug admission. A reimbursement regulation which makes it easily possible that non - innovative drugs get on the market and get reimbursed by health insurance funds causes a research inhibiting climate (BR-Drucks. 14/8205, 14). The reason is that companies do not have to put effort in real innovative drugs because they get as much money for cheating with non – innovative drugs. SPD and Green Party argue that the benefit evaluation before drug admissions is even an advantage for the pharmaceutical industry:

[..] especially the introduction of the assessment of the therapeutic added benefit before drug admission leads to the fact that the pharmaceutical industry could better calculate. Drug producer could concentrate on the development of cost - effective innovative drugs and at the same time be sure that health insurance funds would fast reimburse it because they are innovative. (BR-Drucks. 14/8205, 14).⁴⁵

Centre for Quality and Efficiency in Health Care

First it was planned to establish the governmental “Centre for health care”. The pharmaceutical industry, statutory health insurances, doctors association and CDU/CSU criticised the design of this institute because they were afraid that the Ministry of Health would get too much power. “It is obvious who will have the power: the Ministry of Health and the health insurance funds. They decide on the institute.” (Ärzteblatt 2003, 248, my translation).⁴⁶

Finally the Institute for Quality and Efficiency in Health Care (IQWiG) was established and resident by the Federal Joint Committee and not by the Ministry of Health. Here SPD and Green Party argue that the IQWiG was empowered because in contrast to the Center for Quality in Health Care it is not independent anymore.

⁴⁴ Der VFA wendet sich entschieden gegen die Einführung einer solchen standardisierten Arzneimittelbewertung („Vierte Hürde“). Das hätte zur Folge, dass Patienten auch auf lebenswichtige neue Medikamente warten müssen, bis darüber entschieden ist, in welchen Maße die Präparate als erstattungsfähig angesehen werden. (VfA 20.02.2003, o.S.).

⁴⁵ [...] gerade die Einführung einer „vierten Hürde“ eine erhöhte Planungssicherheit bietet. Die Arzneimittelhersteller können sich auf die Entwicklung kosteneffektiver Arzneimittel konzentrieren und sich gleichzeitig der raschen Möglichkeit der Erstattungsfähigkeit durch die gesetzlichen Krankenkassen sicher sein. (BR-Drucks. 14/8205, 14).

⁴⁶ [Es] ist schon klar, wer das Sagen haben wird: das Bundesgesundheitsministerium und die Krankenkassen. Diese bestimmen im Zentrum. (Ärzteblatt 2003, 248).

The planned institute “Centre for health care” was empowered because it is decided that it is now resident by the Federal Joint Committee. Therefore no independent control of drugs takes place, except you expect that frogs dry their own marsh (Süddeutsche 21.7.2003, my translation).⁴⁷

Reference pricing system

According to the new law the drug gets ordered in a reference pricing system if it is not innovative. However innovative drugs with a therapeutic added benefit are excluded from this new regulation. The critics on this change were mainly economical ones which also explain why innovative drugs were excluded from the reference pricing system.

The regulation of patented drugs with the reference price system endangers the research base Germany. This will lead to the emigration of the drug producers which do research (with all negative consequences of the job market and research in general). (Lengsfeld CDU/CSU 23.09.2003, 5520, my translation).⁴⁸

Moreover the health and economic commissions of the Bundesrat are also afraid of the economic consequences of ordering patented drugs in the reference pricing system.

This branch of German industry had in the past a unique position in respect of worldwide competition. Especially in the area of innovative drugs was Germany leading. Germany lost this position because of various reforms which had to be made in order to save costs. It can be expected that with the new burdens in this present reform, the Germany’s position in worldwide competition will even degrade again. Therefore it is highly important that drugs with patent also in future will not be regulated. (BR-Drucks. 675/1/03, 14, my translation).⁴⁹

Conclusion:

The description of the legislative process shows that CDU/CSU and the pharmaceutical industry blocked various policy ideas of the SPD which led to various changes of the policy proposals. The reimbursement regulation changed from the positive list to the cost-effectiveness evaluation, from the cost-effectiveness evaluation to the benefit- evaluation. The design of the benefit evaluation got also changed: First the benefit evaluation before drug admission was planned and finally the benefit evaluation after drug admission to the drug market was enacted. These changes led to a more industry friendly regulation as originally planned. Moreover was a reference pricing system introduced for patented drugs but innovative drugs were excluded. Since the assessment of the therapeutic added benefit was

⁴⁷ Das geplante Institut für Qualität in der Medizin wird entmachtet, da es unter dem Dach von Ärzten und Kassen wirken soll. Eine unabhängige Kontrolle von Arzneien und Therapien findet so kaum statt - außer man hofft, dass die Frösche ihren eigenen Sumpf trocken legen. (Süddeutsche 21.7.2003).

⁴⁸ [D]ie Aushebelung des Patentschutzes durch Festbeträge gefährden Forschungsstandort Deutschland. Das wird zur Abwanderung von forschenden Arzneimittelherstellern (mit allen negativen Folgen für den Arbeitsmarkt und die Forschung insgesamt) führen (Lengsfeld CDU/CSU 23.09.2003, 5520).

⁴⁹ Die ehemals einzigartige Bedeutung dieses Industriezweigs in Deutschland im weltweiten Wettbewerb, insbesondere im Bereich innovativer Produkte, ist nicht zuletzt auf Grund vieler unter Kostendruck zu Stande gekommenen Reformbestimmungen bereits heute deutlich gesunken. Es ist zu befürchten, dass dieser Trend durch die neuerlichen Belastungen nachhaltig verstärkt wird. [...] Daher ist es für die langfristige Sicherung der Investitionen in den Forschungsbereich von entscheidender Bedeutung, dass patentgeschützte Arzneimittel auch weiterhin von der Festbetragsregelung ausgenommen werden. (BR-Drucks. 675/1/03, 14).

not very effective a lot of drugs were unjustifiably excluded. A policy or political window did not open. The argumentation was the same as in 1992: Most decisive arguments for the various changes were economical ones. The production base Germany would be endangered, working places cut and the research on innovative drugs would be stopped.

5.4 The Case 2011 – policy change in patent drug pricing

5.4.1 Issues and disputes

Agenda-setting

In September 2009 the elections of the Federal Government took place. CDU/CSU and FDP got elected as the new coalition. Last time these industry friendly parties CDU/CSU and FDP hold this office together was in 1998. After the elections the goals for health policy were fixed in the new coalition agreement. The main points relating to drugs were that the FDP and CDU/CSU wanted to deregulate the drug market, to make the drug market more competitive, change regulations in respect to innovative drugs and improve cost - effectiveness evaluations (Koalitionsvertrag 2009, 87). These plans were very surprising since CDU/CSU and FDP did always block the plans of SPD and Green Party in order to regulate these issues in the past. According to Siebert (2010, 29) were interests of the pharmaceutical industry included in the coalition agreement since the text was partly written by the pharmaceutical industry. “The pharmaceutical industry gave the draft for this passage.” (Siebert 2010, 29, my translation).⁵⁰ It concludes that the Institute for Quality and Efficiency in Health Care (IQWiG) will be empowered. This was decided in a conference of the federal economic minister of the Länder, which was a few months before. Rösler – at that time minister of economic affairs – explained in a common statement with other minister of economic affairs that the IQWiG would endanger the drug manufacturing base Germany. “Rösler called (...) the work of the IQWiG as ‘danger for the manufacturing base Germany.’” (Siebert 2010, 28, my translation).⁵¹ CDU/CSU politicians decided that the chief executive of the IQWiG should be fired and the IQWiG new structured which meant in fact that the IQWiG got empowered. “Jens Spahn, Rolf Koschorrek and other politicians from CDU/CSU suggest to restructure the IQWiG. This new structure includes also a new head of the IQWiG.” (Spiegel 15.03.2010, o.S., my translation).⁵²

At the beginning of the reform health minister Rösler favoured more regulations which would have incriminated the insurers. However health insurance funds raised surprisingly

⁵⁰ Für diesen Passus hat die VFA die Vorlage geliefert. (Siebert 2010, 29).

⁵¹ Rösler hatte (...) die Arbeit des IQWiG als ‚Gefahr für den Standort Deutschland‘ bezeichnet.” (Siebert 2010, 28).

⁵² [...] Jens Spahn, Rolf Koschorrek und andere Unionsleute [schlagen] vor, die Arbeit des IQWiG „neu zu ordnen“. Diese „Neuausrichtung muss sich auch in der personellen Spitze des Hauses niederschlagen“, fordern sie. (Spiegel 15.03.2010, o.S.).

additional fees which had to be paid additionally by the insurants. The reason health insurance funds were running out of money. Health minister Rösler spread the idea in the public that the reason why health insurance funds have too less money and raised these additional fees was because of the high costs in the patented drugs sector and in detail because of innovative drugs. This additional fees and the pressure from his stronger coalition partner CDU/CSU made Rösler focus on the regulations of the supplier side.

FDP behaves normally soft with the big concerns. But because of the lately happened additional fees, Rösler confronts the pharmaceutical industry with regulations and wants to reduce the prices for drugs. (Süddeutsche 10.02.2010, o.S., my translation).⁵³

Especially the CDU/CSU politicians federal consumer minister Ilse Aigner (CSU), the Bavarian health minister Markus Söder (CSU), health expert Johannes Singhammer (CSU) were the ones who pushed Rösler to focus on regulations on the supplier side. Another factor which made Rösler focus on the supplier side was a survey of the public opinion about Röslers reform plans as he was still focusing in the insurant side. 72% of German inhabitants disliked the plans of the coalition (Gerlinger 2011, email).

According to my interviewee Wilke and Rausch it was – next to the pressure of the public - necessity which made health minister Rösler incriminating the supplier side by regulating patented drugs. First of all the costs for statutory health insurance raised a lot in respect to drugs and according to experts it was mainly because of missing regulation of patented drugs. 28 percent of the prescriptions are responsible for 80 percent of the costs (Jens Spahn 11.11.2010, 7671).

Due to development of costs in the drug sector, it was necessary to act immediately. The raise of costs was caused by drugs without fixed amount (2009: +8,9%), while the GKV-volume of sales was reduced (2009: minus 2%) (Wilke (CDU), Interview 28.11.2011, my translation).⁵⁴

The prices for patented drugs raised a lot in recent years. In the generic drug sector in Germany is only less scope in respect to prices. (Rausch (SPD), Interview 21.12.201, my translation).⁵⁵

Since health minister Rösler stated in various newspapers that he would quit his office if the reform is not effective he was somehow forced to regulate patented drugs (Spiegel 6.07.2010,

⁵³ Die FDP bewegt sich normalerweise auf Schmusekurs zu den großen Konzernen. Doch angesichts der jüngsten Beitragserhöhungen für viele Kassenpatienten geht Gesundheitsminister Philipp Rösler (FDP) nun auf Konfrontation zur Pharmaindustrie und will die Preise für Medikamente senken. (Süddeutsche 10.02.2010, o.S.).

⁵⁴ Aufgrund der Kostenentwicklung im Arzneimittelbereich bestand ein sofortiger Handlungsbedarf. [...]Der Kostenzuwachs wurde durch Arzneimittel ohne Festbetrag verursacht (2009: + 8,9%), während die GKV-Umsätze mit Festbetragsarzneimitteln gesunken sind (2009: minus 2%) (Wilke (CDU), Interview 28.11.2011).

⁵⁵ Die AM-Preise im patentgeschützten Bereich stiegen in den letzten Jahren deutlich an. Bei den Generika ist in Deutschland [...] nur noch wenig Spielraum im Bereich der Preise. (Rausch (SPD), Interview 21.12.201).

o.S.). Also Herbert Reichelt, directorate of the AOK medical insurance plan, agreed on the fact that patented drugs need to be regulated urgently (AOK Bundesverband 11.02.2010, 2).

Decision-making process

After health minister Rösler decided to develop regulations in the drug sector, he pointed out some important aspects, which should be included in the new drug regulations (AOK-Medienservice 11.02.2010, 3). “This includes a cost – effectiveness evaluation which has consequences on the price. Such an evaluation should be obligatory and could be done simultaneously to drug admission or in between a particular time span.” (AOK - Medienservice 11.02.2010, 3, my translation).⁵⁶

In the *Süddeutsche Zeitung* (19.03.2010, o.S.) health minister Rösler even mentioned that it would be very important that the cost - effectiveness evaluation is *before* the admission to the drug market like in other European countries. “This evaluation has to happen already in advance of the obligatory price negotiations between health insurance funds and the pharmaceutical industry [...]” (Süddeutsche 19.03.2010, o.S., my translation).⁵⁷

The opposition was surprised about health minister Rösler’s reform ideas. According to the opposition was the concept of the new regulation stricter against the pharmaceutical industry than what the SPD and the Green Party had tried to pull through in the last decades.

It is surprising that CDU/CSU and FDP enact this regulation, dear college Spahn. I also want to tell you why: In 2003 SPD and the Green Party made a policy proposal and suggested it CDU/CSU and FDP. FDP immediately left because they did not want to burden the pharmaceutical industry. CDU/CSU refused the cost - effectiveness evaluation. I only can say: Good that you improved (Bender (Green Party 9.07.2010, 5886, my translation).⁵⁸

Interesting is that politicians from Rösler’s own party FDP criticized him to regulate the pharmaceutical industry too hard. In contrast CDU/CSU, sickness funds and experts from the expert adversary board for expertise and development in health care argued that the regulations are not strict enough (Frankfurter Allgemeine 07.03.2010, o.S.).

⁵⁶ Hierzu gehört vor allem eine Kosten-Nutzen-Bewertung, deren Ergebnis sich auf den Preis auswirkt. Eine solche Bewertung könnte zeitgleich mit der Zulassung oder innerhalb eines bestimmten Zeitraums nach der Zulassung verpflichtend erfolgen.

⁵⁷ Auch schon vor dem Beginn der geplanten verpflichtenden Preisverhandlungen zwischen Pharmafirmen und Kassen müsse es eine solche Bewertung geben [...] Süddeutsche 19.03.2010, o.S.).

⁵⁸ Es ist allerdings überraschend, dass Schwarz-Gelb so etwas macht, lieber Kollege Spahn. Ich will Ihnen sagen, warum. Im Jahre 2003 sind wir mit einem rot-grünen Reformentwurf an den Verhandlungstisch zu Union und FDP gekommen. Die Gelben sind sofort davongesprungen, weil sie auf keinen Fall der Pharmaindustrie etwas tun wollten. Die Union hat damals die Kosten-Nutzen-Bewertung abgelehnt. Ich kann nur sagen: Schön, dass Sie etwas dazugelernt haben. (Bender (Green Party 9.07.2010, 5886).

My interviewee of the Green Party answered to the question why health minister Rösler as FDP politician suggested these regulations on the costs of the pharmaceutical industry was the following:

CDU/CSU and FDP had to face their responsibility since they are ruling parties. Therefore they gave up their blocking position in the patented drugs sector; at least partly. (Rausch SPD 21.12.2011, interview, my translation).⁵⁹

The answer of Guido Laue (CDU) (interview, 21.11.2011, my translation) was: “Philipp Rösler wanted to be celebrated as fighter against the pharmaceutical industry in order to defeat the impression that the FDP would be a pure clientele party.....what it is and remains.”⁶⁰

Proposal of the main points

At the 7th of March some first points of the policy proposal got public: (1) Sickness funds and drug producers should negotiate about the price of drugs with therapeutic added benefit. (2) If they are not able to agree on a price during *one year*, the IQWiG would start a cost-effectiveness evaluation and set the price (Frankfurter Allgemeine 07.03.2011, o.S.).

In contrast to the case of 1992 the pharmaceutical industry, CDU/CSU and parts of the FDP were in 2009 in favour of price negotiations in order to foster competition in the statutory health insurance. This change of attitude of CDU/CSU and FDP will be highly important for our analysis in order to explain the radical change of stopping the pharmaceutical industry from freely price setting.

Nevertheless, we as drug producers which do research recognize that politicians did not only close doors but also opened other ones. For example the planned revaluation of negotiations of reimbursement conditions between sickness funds and the concerns are an important and right step – or rather a historical step. The industry always wanted more competitive regulations and still favors it. In respect of this competitive orientated part of the drug sector is only to say: The direction is right about details we have still to talk (VfA 30.06.2010, 4, my translation).⁶¹

Interesting is this statement of the “Research Based Pharmaceutical Companies” (vfa) in so far that they claim that they would have always fostered competition of the statutory health insurance what is not true: This shows the statement of the head of the parliamentary health

⁵⁹ Union und FDP mussten sich in der Regierungsverantwortung dieser Frage stellen. Sie haben daher ihre bisherige Blockadehaltung zu Regulierungen im patentgeschützten Arzneimittelbereich (teilweise) aufgegeben. (Rausch 21.12.2011, email).

⁶⁰ „Ex-Gesundheitsminister Philipp Rösler wollte sich als Kämpfer gegen die Pharmaindustrie feiern lassen um damit dem Eindruck entgegenzusteuern, die FDP sei keine reine Klientelpartei... Was sie aber ist und auch bleibt.”

⁶¹ Gleichwohl sehen wir forschenden Pharma-Unternehmen auch, dass die Politik nicht nur Türen zerschlagen, sondern auch andere geöffnet hat. So ist die geplante Aufwertung von Verhandlungen von Erstattungsbedingungen zwischen Kassen und Firmen ein wichtiger und richtiger –sogar fast historischer- Schritt. Die Industrie hat immer für mehr wettbewerbliche Strukturen geworben und zieht auch mit wenn es zum Schwur kommt. Für diesen -wettbewerblich inspirierten - Teil der Neuordnung im Arzneimittelsektor kann man nur sagen: Die Richtung stimmt über Details muss man noch reden. (VfA 30.06.2010, 4).

commission in 1992, Rudolf Dreßler, from 2000 which proves that the pharmaceutical industry was against price negotiations in the past:

I do not understand the strategy of the pharmaceutical industry, how they present their interests in the context of health policy. I did not understand them before and after the consensus talks in 1992. The associations of the pharmaceutical industries abstained from price negotiations between supplier and consumer before Lahnstein and instead they wanted a one way fixing of prices, called reference prices for drugs (Dreßler 2000, 20, my translation).⁶²

In contrast to price negotiations which the pharmaceutical industry favoured in 2011, the cost-effectiveness evaluation was still refused as in the past. Since the pharmaceutical industry disliked the cost - effectiveness evaluation a substitute the evaluation of the benefit was suggested. The benefit evaluation does not lead to as high financial pressure as cost - effectiveness evaluation for the pharmaceutical industry. Various newspapers point out that the idea of cost - effectiveness evaluation was not the first time replaced during a legislative process by a benefit evaluation because of the interests of the pharmaceutical industry. "In June 2003 the cost – effectiveness evaluation was still included in the draft law and in September 2003 it was cancelled – this was also a success of the pharmaceutical industry." (Siebert 2010, 18, my translation).⁶³ However the cost - effectiveness evaluation was not totally cancelled. The cost - effectiveness evaluation was still in the policy proposal but designed in a way that it hardly gets used. Only when drug producers and sickness funds cannot agree on a price during one year then a cost - effectiveness evaluation will be done. According to the magazine Spiegel this suggestion of the design of the regulation was taken from the pharmaceutical industry.

If both negotiation partners do not agree on a price until a certain deadline, a cost - effectiveness evaluation will be done with the fixing of a maximum price", suggested VFA lobbyist Yzer. Rösler wrote now in his policy proposal: "If both negotiation partners do not agree in one year, then the Institute for Quality and Efficiency in Health Care starts a cost - effectiveness evaluation with the fixing of a maximum price." (Spiegel 15.03.2010, 0.S., my translation)⁶⁴

The health spokesperson of the SPD Karl Lauterbach states: "This policy proposal was dictated from the pharmaceutical industry." (Spiegel 15.03. 2010, o.S., my translation).⁶⁵

⁶² Ich verstehe die Strategie der Pharma-Industrie nicht, sich im Gesamtkontext der Gesundheitspolitik mit ihren Interessen zu positionieren. Ich habe sie vor und während der Lahnsteiner Konsensgespräche nicht verstanden, und ich begreife sie auch heute nicht. Die Pharma-Verbände haben vor Lahnstein darauf verzichtet, die Preisgestaltung für Arzneimittel auf dem verordnungsfähigen Markt am Grundsatz einer Verhandlungslösung zwischen Anbieter und Nachfrager zu orientieren und statt dessen auf eine einseitige Preisfestsetzung durch die Nachfrager gesetzt, genannt Festbeträge. (Dreßler 2000, 20).

⁶³ "Im Juni 2003 steht die Kosten-Nutzen-Bewertung noch im Gesetzesentwurf, im September 2003 wird sie gestrichen – auch das ein Erfolg der Pharmaindustrie." (Siebert 2010, 18).

⁶⁴ „Wenn man sich innerhalb einer bestimmten Frist nicht einigt“, so schlug VFA-Lobbyistin Yzer zudem vor, "greift die zentrale Kosten-Nutzen-Bewertung mit der Festsetzung eines Höchsterstattungs Betrags". Bei Rösler heißt es nun: "Wenn nicht bis spätestens nach einem Jahr Verträge abgeschlossen wurden, beginnt eine Kosten-Nutzen-Analyse durch das Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), an dessen Ende eine Höchstpreisfestsetzung steht. (Spiegel 15.03.2010, 0.S.).

⁶⁵ Aus dem Papier spricht die Diktion der Pharmaindustrie." (Spiegel 15.03. 2010, o.S.).

Another issue about which the pharmaceutical industry complained was that Rösler wants to put price negotiations in the hand of the monopoly of sickness funds (vfa 26.03.2010, o.S.). Therefore in the final draft of the law is written that the statutory health insurance negotiates with the pharmaceutical industry but as option is included that also single sickness funds can negotiate with the pharmaceutical industry.

In between the legislative process it even seemed a short time that Rösler would concede and prevent negotiations between the pharmaceutical industry and the monopoly the statutory health insurance.

In February Cornelia Yzer, chief executive of Research - Based pharmaceutical companies (VFA), suggested that in order to launch drugs decentralised contracts about the price should be made between suppliers and health insurance funds. Rösler's proposal includes now that first a fast benefit evaluation should take place and if there is no alternative drug on the market, then each sickness fund should negotiate with the drug producer and agree on a price.

The decisive formulations are "decentralized" (Yzer) and "each" (Rösler). This means not the statutory health insurance but each single sickness fund of the 169 ones should negotiate with the pharmaceutical industry about the price of a new drug. (Spiegel 15.03. 2010, o.S., my translation).⁶⁶

In respect to the next issue was the influence of the pharmaceutical industry again more successful: Peter Sawicki the head of the Institute for Quality and Effectiveness was fired because of the interests of the pharmaceutical industry. Ursel Siebert (2010), a journalist which did several years research on the interests of the pharmaceutical industry and the magazine Spiegel (15.03.2010, o.S.), describe Peter Sawicki's lay-off as planned allegation. Siebert (2010) and Spiegel explain that the politician's claim that Peter Sawicki was incorrupt is not true. And explain the real reason for his lay-off is that he is responsible for high losses of the pharmaceutical industry since he discovered innovative drugs without therapeutic added benefit.

Peter Sawicki has been a thorn in your flesh since a long time – I mention again the word clientele. This is no wonder, if Peter Sawicki the chef of the Institute for Quality and Efficiency, who is in charge of the benefit evaluation, figures out: The pharmaceutical industry sees Germany as self-service outlet. (Leutert (SPD) 19.03.2010 2956, my translation).⁶⁷

⁶⁶ Mitte Februar schlug Cornelia Yzer, Hauptgeschäftsführerin des Verbandes Forschender Arzneimittelhersteller (VFA) vor, dass zur Einführung neuer Medikamente "dezentrale Verträge zwischen Herstellern und Kassen" über den Preis geschlossen werden sollen. In Rösler's Entwurf steht nun, dass zuerst eine Nutzen-Schnellbewertung stattfinden soll, und wenn es sich um eine alternativlose Neuheit handelt, soll "jede Krankenkasse mit dem pharmazeutischen Unternehmen eine Erstattungsvereinbarung" treffen. Die entscheidenden Wörtchen sind "dezentral" (Yzer) und "jede" (Rösler). Also nicht der Spitzenverband der Gesetzlichen Krankenkassen, sondern jede einzelne der 169 Kassen soll mit der Pharmaindustrie über den Preis eines neuen Medikaments verhandeln. (Spiegel 15.03. 2010, o.S.).

⁶⁷ [Peter Sawicki] war natürlich Ihnen und der Pharmaindustrie – ich nenne wieder das Stichwort Klientel – seit langem ein Dorn im Auge. Das ist ja auch kein Wunder, wenn der Chef des Instituts, welches für die Kosten-Nutzen-Bewertung von Arzneimitteln verantwortlich ist, feststellt: Die pharmazeutische Industrie betrachtet Deutschland als Selbstbedienungsladen. (Leutert 19.03.2010 2956).

Sawicki himself states that the decision of his lay-off was influenced by the pharmaceutical industry: “Of course influences the pharmaceutical industry politicians. A lot of delegates tell me: ‘Every day somebody from the pharmaceutical industry visits me and complains about you.’”(Frankfurter Rundschau 5.2.2010, 1, my translation).⁶⁸

At the end of April the main points of the proposal for the planned regulation got declared. The Federal government accepts the proposal with the main points of the planned act. This includes the following decisions: (1) Drug makers have to prove the therapeutic added benefit of *all* drugs, which come new on the market (Bundesministerium für Gesundheit 28.04.2010, 1). (2) The Federal Joint Committee (G-BA) is in charge of assessing the therapeutic added benefit. (3) Drugs which have no therapeutic added benefit are ordered in the reference system, which implies a high loss of money for the pharmaceutical industry. (4) In case there is a therapeutic added benefit health insurance funds and drug producers negotiate.

Draft and final law

In June 2010 the draft law was enacted and the complete version of the new regulation presented. The opposition SPD and Green Party criticized various points: SPD and Green Party saw the main problem in the fact that the pharmaceutical industry was still allowed to set freely the price of the drug for the first year. The regulation was arranged in that way that the pharmaceutical industry got one year time to negotiate with the sickness funds on the price and until they agreed on a price the price set by the pharmaceutical industry had to be reimbursed by sickness funds. The opposition parties and experts expected that the pharmaceutical industry would ask for enormous prices in the first year to balance their financial loss afterwards; therefore experts and the opposition party expect less savings with this regulation (for discussion in detail compare 5.3.3). This aspect of the design of the regulation is therefore highly interesting since the aim of the act was to stop the free price setting of the pharmaceutical industry.

One more disputed issue is the exclusion of the orphan drugs from the assessment of the therapeutic added benefit. Orphan drugs are drugs to treat very rare diseases. Since they are so rare only few patients need them and therefore they are not very lucrative for the pharmaceutical industry to do research on them. CDU/CSU and FDP excluded orphan drugs from the new regulation – therefore the pharmaceutical industry can still determine the price

⁶⁸ “Natürlich beeinflusst die Pharmaindustrie die Politiker. Viele Abgeordnete erzählen mir: „Jeden Tag ist jemand von der Industrie bei mir, der sich über Sie beschwert.“(Frankfurter Rundschau 5.2.2010, 1).

of them. The opposition parties understand this as loophole for the pharmaceutical industry and argue that this exclusion was made because of the interests of the pharmaceutical industry: “But also in respect to another issue it becomes clear who tells you what to do: You excluded whole groups of drugs from the assessment of therapeutic added benefit, namely drugs against rare diseases and cheap drugs.” (Volkmar (SPD) 11.11.2010, 7670, my translation).⁶⁹

Moreover SPD and Green Party argue that Rösler empowered the Federal Joint Committee only to satisfy the interests of the pharmaceutical industry: Not anymore the Federal Joint Committee but the Ministry of Health should decide per decree law about the criteria of the benefit and cost - effectiveness evaluation. According to politicians was the reason of this “empowering” that politicians would decide on more industry friendly criteria of the benefit and cost-effectiveness evaluation as the Federal Joint Committee, which represents Physicians, dentists, hospitals, sickness funds and patients.

Today you showed for whom interests you act. Mr Singhammer explained in an interview why the Ministry of Health and not the Federal Joint Committee decides about the criteria for the cost - effectiveness evaluation. This said Herr Singhammer word by word to the newspaper “Financial Times Deutschland”: Politic has to determine this process. We want that the pharmaceutical production location remains attractive. I ask you: Is this a reason why the criteria should be decided by the Ministry of Health? Only because in this way can be decided on more industry friendly criteria? You negate this constantly. But which other reason exists to empower the Federal Joint Committee? (Volkmar (Green Party) 11.11.2010, 7670, my translation).⁷⁰

According to the opposition parties SPD and Green party the new regulation includes even more loopholes for the pharmaceutical industry:

The benefit assessment has to be finished three month after the drug is admitted to the market in order that health insurance funds and the pharmaceutical industry can start to negotiate about the price. The opposition parties argue that a more detailed assessment of the drugs would be necessary. However the new regulation defines that only if the health insurance funds and the pharmaceutical industry cannot agree on a price a more detailed assessment will be done and if they agree no detailed assessment will be done. Therefore the opposition

⁶⁹ Aber auch an anderer Stelle wird klar, wer Ihnen die Feder führt. Sie haben ganze Arzneimittelgruppen aus der Nutzenbewertung herausgenommen, nämlich Arzneimittel gegen seltene Erkrankungen sowie Arzneimittel [...] keine hohen Ausgaben verbunden sind. (Volkmar (SPD) 11.11.2010, 7670).

⁷⁰ Was bzw. wer Sie antreibt, haben Sie heute deutlich gemacht. Herr Singhammer hat gegenüber der Presse erklärt, warum nicht die Selbstverwaltung, sondern das Ministerium selbst die Kriterien für die frühe Nutzenbewertung festlegt. Ich zitiere Herrn Singhammer aus der Financial Times Deutschland: Die Politik muss künftig den Daumen auf dem Verfahren haben. Wir wollen, dass der Pharmastandort Deutschland attraktiv bleibt. Ich frage Sie: Sollen die Regelungen deshalb vom Bundesgesundheitsministerium getroffen werden, weil so pharmaindustriefreundlichere Bestimmungen verankert werden können? Sie verneinen das vehement. Aber welchen anderen Grund gibt es dann, die fachlich versierte Selbstverwaltung derart zu beschneiden? (Volkmar (Green Party) 11.11.2010, 7670).

argues that CDU/CSU only foster the negotiations between health insurance funds and the pharmaceutical industry but no regulation which would lead to a clear separation of innovative drugs and drugs without therapeutic added benefit in order that health insurance funds would only have to fully reimburse those drugs with a therapeutic added benefit.

This kind of fast benefit evaluation which you plan helps only in order to find the price. For giving evidence to the actual benefit of a drug, a detailed benefit evaluation is necessary afterwards. This will be only possible in exceptional cases. You always want to abstain from a detailed evaluation of the benefit if sickness funds and drugmaker agree on a price. You are only interested to regulate prices. You are not interested that sickness funds only reimburse such drugs which have a variable therapeutic added benefit. (Volkmer (SPD) 11.11.2010, 71, my translation).⁷¹

Next to this fast benefit evaluation for new drugs, which come in the future on the market, exists still the benefit evaluation for drugs which were already on the market. According to the opposition parties SPD and Green Party, CDU/CSU and FDP would have even changed the procedure in order to assess the therapeutic added benefit for drug which are already on the market to the worse. The Federal Joint Committee has now to prove the inappropriateness of a drug in order to exclude a drug from reimbursement and not like before to prove that a drug has a therapeutic added benefit in order that it gets reimbursed. According to experts and the opposition parties this is practical not possible.

The verification of the non existence of the benefit is a scientific impossibility, says the head of the IQWiG, Jürgen Windeler: 'You can proof that something exists, you can proof the therapeutic added benefit with studies, you can also say, there is no proof of a therapeutic added benefit. But you cannot proof that something does not exist: I cannot preclude that on the backside of the moon lives Pumuckl, in a cave perhaps'. (Taz.de 21.10.2010, o.S., my translation).⁷²

The opposition parties maintain that this change happened because of the pressure of the pharmaceutical industry since the demonstration of the inappropriateness would be practical not possible:

Not only opposition criticise the planned procedure but also the self- government of doctors and health insurance funds. The change in the law is based on the expert evidence of a law firm which was authorized by the Research Based Pharmaceutical Companies (vfa). According to the magazine Spiegel this amplifies the accusation of clientele politics. (Naturheilkunde und Naturheilverfahren Fachportal 2010., o.S., my translation).⁷³

⁷¹ Die von ihnen vorgesehene frühere Nutzenbewertung dient der Preisfindung. Für Aussagen über den tatsächlichen Nutzen eines Arzneimittels ist eine spätere Nutzenbewertung unabdingbar. Diese sind aber nur in Ausnahmefällen möglich. Sie wollen auf eine ausführliche Bewertung von Arzneimitteln regelhaft immer dann verzichten, wenn es eine Einigung zwischen den Arzneimittelherstellern und Kassen bei der Preisfindung gegeben hat. Ihnen geht es nur um eine Regelung für die Preise, sie wollen aber nicht, dass die Krankenkassen nur noch solche Arzneimittel bezahlen, die einen nachweislichen Nutzen haben. (Volkmer (SPD) 11. 11. 2010, 7667- 7668).

⁷² Der Nachweis der Nichtexistenz des Nutzens ist eine wissenschaftliche Unmöglichkeit, sagt der Leiter des IQWiG, Jürgen Windeler: 'Man kann beweisen, dass etwas da ist, man kann durch Studien den Nutzen beweisen, man kann auch sagen, es gibt keinen Beleg für einen Nutzen. Aber man kann nicht beweisen, dass etwas nicht da ist: Ich kann nicht ausschließen, dass auf der Rückseite des Mondes der Pumuckl wohnt, in einer Höhle vielleicht.' (Taz.de 21.10.2010, o.S.).

⁷³ Das geplante Vorgehen stößt nicht nur bei der Opposition sondern auch bei der Selbstverwaltung von Ärzten und Kassen auf scharfe Kritik. Dass die Grundlage für die Gesetzesänderung das Gutachten einer Anwaltskanzlei im Auftrag des Verbands Forschender

The opposition parties SPD and Green party note at least one positive change in the reform in 2011 because of the pressure of the opposition parties. Before 2011 the pharmaceutical industry was not obliged to hand in studies even the IQWiG or the Federal Joint Committee asked for it. Therefore the pharmaceutical concerns blocked the assessment of the therapeutic added benefit. Since 2011 the pharmaceutical industry has to hand in dossiers on basis of studies of each new drug, of which they claim that it is innovative, in order to assess the therapeutic added benefit and negotiate about the price. This was a very important change.

I have to compliment you because at least in one point you got over your resistance to accept an advice. In respect to the obligation to publish studies of drugs you got over your normal residence to accept an advice. After the hearing you changed the policy proposal in respect to our suggestions and these of experts. (Vogler (Linke) 11.11.2011, 7666, my translation).⁷⁴

However even the pharmaceutical industry must now hand in the studies still the opposition parties and experts criticize that the studies are made by the pharmaceutical industry and are therefore not independent.

The case in 2011 describes a legislative process where a lot of changes took place from the draft law to the final law – according to newspapers and political actors - because of the pressure of the pharmaceutical industry. This various changes led to disputes between opposition and ruling parties, experts, self-governing institutions of physicians and health insurance funds, and the pharmaceutical industry. In the following are the argumentations presented which were used in these discussions. In order to conclude the section a statement of the Green Party is added which describes that the pharmaceutical industry was confident with this law because Rößler accommodated the pharmaceutical industry various points: It is not surprising that you a got a lot of critics from various experts but the pharmaceutical industry were the only one who was extremely quiet. (Vogler (Linke) 11.11.2010, 7666, my translation).⁷⁵

Even FDP and CDU/CSU softened the regulation on the advantage of the pharmaceutical industry it can be maintained that a radical policy change happened because of the following changes: First of all the pharmaceutical industry is not anymore allowed to set the price of innovative drugs during the whole duration of the patent. Second a long planned regulation –

Pharmaunternehmen (VFA) ist, wie der „Spiegel“ berichtet lässt zudem den Vorwurf der Klientelpolitik wieder lauter werden. (Naturheilkunde und Naturheilverfahren Fachportal 2010., o.S.).

⁷⁴ Wenigstens in einem Punkt - da muss ich sie wieder loben - haben sie ihre übliche Beratungsresistenz überwunden. Bei der Pflicht zur Veröffentlichung von Arzneimittelstudien haben sie ihre übliche Beratungsresistenz überwunden. Bei der Pflicht zur Veröffentlichung von Arzneimittelstudien haben Sie nach der Anhörung nachgebessert und sind der Kritik der Sachverständigen sowie unseren Anregungen teilweise gefolgt. (Vogler (Linke) 11.11.2011, 7666).

⁷⁵ Es verwundert nicht, dass sie in den Stellungnahmen der Sachverständigen von alle Seiten fast verheerende Kritiken bekommen haben, nur die Pharmedia war extrem leise. (Vogler (Linke) 11.11.2010, 7666).

price negotiations between sickness funds and pharmaceutical industry - was finally enacted. Third the benefit evaluation is now done for each new drug which enters the market.

The various loopholes do not change the fact that radical policy change took place but it lead to the question if the regulation was effective and leads to savings. In respect to various experts and the opposition party no savings are expected (Laue (SPD), interview 21.11.2011). In contrast CDU/CSU explains it would be too soon to judge the success, savings will be visible in two or three years (Rausch (CDU), interview 15.11.2011). Because of these facts I summarize that a formally a radical policy change happened but informally not because of expected missing success. The question is also in how far it burdens indeed the pharmaceutical industry, since Rößler claimed at the beginning that the regulation would burden the pharmaceutical industry to a high extent. According to experts and the opposition parties this was only hot air (Spiegel 6.07.2010, o.S.).

However the annual report of the Federal government of the economic development in Germany describes that the German Pharmaceutical Market Reorganisation Act as a whole – not only the new regulation of patented drugs - could reduce the spending of the statutory health insurance in the drug sector.

The spending for drugs was reduced around 6 vH compared to the previous year because of the drug rebate and the German Pharmaceutical Market Reorganisation Act (**AMNOG**) [...]. In respect to the good financial situation can be concluded that despite the good cyclical development – a clear improvement of the financial situation of the GKV could be achieved at least in this short time period. In particular got the spending for drugs in fact less (BT-Drucks.⁷⁶ 17/7710, 328/329, my translation).⁷⁷

5.4.2 The Arguments

In this section the arguments of CDU/CSU, FDP, SPD, Green Party, the pharmaceutical industry and sickness funds are presented. The aim is on the one hand to show that in Hajer's (1998) wording the discourse coalition changed. CDU/CSU and FDP argued suddenly in 2010 in the same vein as SPD and Green Party did in the former cases: Pro regulating the pharmaceutical industry and paradoxically even the pharmaceutical industry argued in the same vein.

⁷⁶ Abbreviation: „BT-Drucks.“ means “Bundestags- Drucksache” in German and translated into English: “printed matter of the Bundestag”

⁷⁷ So haben sich die Ausgaben für Arzneimittel infolge der Erhöhung des Arzneimittelrabatts und des Inkrafttretens des Arzneimittelmarkt-Neuordnungsgesetzes (**AMNOG**) gegenüber dem Vorjahreshalbjahr um fast 6 vH reduziert [...]. Im Hinblick auf die gute Finanzlage kann trotz Begünstigung durch die erfreuliche konjunkturelle Entwicklung festgehalten werden, dass – **zumindest in der kurzen Frist** – eine deutliche **Verbesserung der Finanzsituation der GKV** erreicht werden konnte. Insbesondere haben sich die Ausgaben für Arzneimittel tatsächlich reduziert (Ziffer 544). (BT-Drucks. 17/7710, 328/329).

The second aim of this chapter is to explain and show that the regulation was not effectively designed in so far that it would lead to savings and put high financial pressure on the pharmaceutical industry.

Up to one year free price setting for the pharmaceutical industry

The opposition parties argue that the fact that the pharmaceutical industry is allowed to set the price for the first year is a huge loophole for the pharmaceutical industry. The parliamentary Green party argued that the pharmaceutical industry will raise an enormous price in the first year in order to get a high amount of money and start into the price negotiations with a high starting offer which would include then a discount factor (BT-Drucks. 21.4.2010, 1/Ognyanova/Zentner/Busse 2011, 13):

For this reason an enormous inducement will arise for the pharmaceutical industry to assess the starting price as high as possible in order to get in the first year a high profit. Moreover this high price at the beginning has the advantage to start the price negotiations with a high starting offer. (BT-Drucks. 21.4.2010, 1, my translation).⁷⁸

Therefore Karl Lauterbach (SPD) (Laue, interview 21.11.2010) expects no savings with this regulation. “Drug producer include the rebates which they decree during the price negotiations already in the starting price. At the end of the negotiations there will be the same high price of the innovative drugs as is usual today.” (Lauterbach, interview 21.11.2010, my translation).⁷⁹

The Green party perhaps even expects a raise of drug prices and therefore of costs for the statutory health insurance: “Raising prices for drugs are therewith presaged. It is not clear at all if the additional costs of the first year can be balanced in the long run. Because it is unclear if the drug producer will significantly reduce the costs in the price negotiations.” (BT-Drucks. 21.4.2010, 121.04.2010, my translation).⁸⁰

In contrast to it the coalition parties – FDP and CDU/CSU - argue that it would be important that drugs are reimbursed by sickness funds the first day after the drug gets admitted to the market even if -according to CDU health spokesperson Spahn (11.11.2010, 7671) – Germany is one of the last countries in which drugs get reimbursed without assessing the therapeutic

⁷⁸ Damit wird ein enormer Anreiz für die Pharmaindustrie entstehen, die Einstiegspreise für ihre Präparate möglichst hoch anzusetzen, um innerhalb des einjährigen Zeitfensters einen hohen Profit zu erzielen und in die anschließenden Preisverhandlungen mit dem GKV-Spitzenverband mit einem hohen Start-gebot gehen zu können. (BT-Drucks. 21.4.2010, 1).

⁷⁹ Pharmahersteller werden zu gewährende Rabatte bereits im Ausgangspreis berücksichtigen. Am Ende der Verhandlungen steht ein heute üblicher Preis. (Lauterbach, interview 21.11.2010).

⁸⁰ Steigende Arzneimittelpreise sind damit vorgezeichnet. Ob diese dann in den Preisverhandlungen wieder deutlich gesenkt und innerhalb des ersten Jahres entstandene Zusatzausgaben langfristig wieder ausgeglichen werden können, ist völlig offen. (BT-Drucks. 21.4.2010, 121.04.2010).

added benefit before (Süddeutsche 1.2.2010). If the assessment of the therapeutic added benefit and the price negotiations would be done before health insurance funds start to reimburse the price of the new drug, too much time would pass by until patients would get the drug who urgently need it according to Spahn (11.11.2010, 7671). “Your (Lauterbach) argumentation in the debates about drug prices annoys me sometimes. You totally ignore the fact that thousands and ten thousands of critically ill people connect with innovative drugs a lot of hope to reduce their pain.” (Spahn (CDU/CSU) 9.07.2010, 5883, my translation).⁸¹ Moreover “[...] new drugs for the therapy of cancer, HIV/Aids, Parkinson’s are connected with huge hopes of patients in order to decrease pain. Therefore we want that drugs get reimbursed after the first day of market launch and useable for patients.” (Spahn (CDU/CSU)11.11.2010, 7671, my translation).⁸²

The economic and chief executive of the Expert Committee, Eberhard Wille, suggested similar to the coalition parties CDU/CSU and FDP that the pharmaceutical industry should be allowed to set the prices for innovative drugs even for the first three or four years freely: One possibility would be to admit drug producers of innovative drugs to set freely the price the first one or two years. (Frankfurter Allgemeine 22.2.2010, o.S., my translation).⁸³

On the other hand the independent experts of the German health care systems Ognyanova, Zentner and Busse (2010, 13) argued that this would be another loophole for the pharmaceutical industry and no costs will be contained.

Independent studies

The problem of dependent studies was surprisingly not an issue in the case 2003 even the problem existed. The reason was perhaps that the benefit evaluation was that ineffective designed that anyways hardly drugs were evaluated and that therefore dependent studies was only a small problem compared with the design of the whole regulation.

According to the Green party 75% of the used studies were made by the pharmaceutical industry or were indirect financed by the pharmaceutical industry from 2004 until 2007 (Antrag 2.3.2010, 1). However since from 2011 on the therapeutic added benefit of each new

⁸¹ Das stört mich manchmal an den Debatten, wie Sie sie führen, wenn es um die Entwicklung der Pharmapreise geht: Sie blenden den Aspekt völlig aus, dass für viele Tausende und Zehntausende schwerkranker Menschen mit neuen Medikamenten auch viele Hoffnungen auf Minderung von Leid verbunden sind. (Spahn (CDU/CSU) 9.07.2010, 5883).

⁸² [...] neue Medikamente für die Behandlung von Krebs, HIV/Aids, Multipler Sklerose und Parkinson sind mit der großen Hoffnung der Patienten auf Leidminderung [...] verbunden. Deswegen wollen wir, dass neue Medikamente grundsätzlich ab dem ersten Tag nach der Markteinführung erstattungsfähig und damit für die Patienten zugänglich sind. (Spahn (CDU/CSU)11.11.2010, 7671).

⁸³ Man könnte Herstellern neuartiger Arzneimittel [...] erlauben, den Preis für die ersten zwei oder drei Jahre nach Ermessen festzulegen. (Frankfurter Allgemeine 22.2.2010, o.S.).

drug will be assessed since it is the basis for price negotiations the problem gains on importance and was therefore object of criticism:

You only enacted price negotiations. These are made on basis of price suggestions of the pharmaceutical industry and on basis of studies which are made by the pharmaceutical industry. These are only negotiations on the basis of studies which are presented by the pharmaceutical industry to a board, which cannot make studies on their own. (Lauterbach (SPD)11.11.2010, 7662, my translation).⁸⁴

Orphan drugs

It seems that politicians make continuously exceptions of the pricing regulation in order to protect the pharmaceutical industry. In the case 2003 patented drugs which are highly innovative were excluded from the reference pricing system and in 2009 orphan drugs.

The parliamentary parties of SPD and the Green Party were against the exclusion of orphan drugs since this would lead again to the problem which the reform tried actually to solve: The pharmaceutical industry would set the price of orphan drugs as high as they want and this price would get reimbursed by health insurance funds 15 years long. The parliamentary party of CDU/CSU and FDP argues that no loophole exists because orphan drugs are not excluded from the assessment if the sales volume exceeds 50 million Euros (Vogler (Linke) 11.11.2011, 7665).

Also potential useless drugs have to be reimbursed by health insurance funds if the sales volume is less than 50 million Euros. You can recalculate on your own: Only 20 of these orphan drugs cost 1 milliard Euro per year. More money fast accumulates than Herr Sinhammer counted that we save with the new regulation. (Vogler (Linke) 11.11.2011, 7665, my translation).⁸⁵

However the opposition parties counter that only few drugs get very often prescribed – and exceed therefore a sales volume of 50 million Euros- and therefore a loophole would indeed exist:

Dear colleagues, in the last year were 36 drugs were admitted to the market. Only 5 of them were more often than 10 000 prescribed. You see: This exclusion rule opens a loophole as big as a barn door. The pharmaceutical industry will use this loophole to abscond from the benefit evaluation. (Vogler (Linke) 11.11.2011, 7665, my translation).⁸⁶

According to the opposition parties the pharmaceutical industry will cheat: They will apply for an orphan drugs status when the drug helps against a rare and a common disease. Even if

⁸⁴ Sie haben lediglich Preisverhandlungen eingeführt. Diese werden auf Grundlage von Preisvorschlägen der Pharmaindustrie und auf der Grundlage von Studien geführt die die Pharmaindustrie selbst vorlegt. Das ist nichts anderes als eine Feischerei auf der Grundlage von Studien, die von der Industrie einem Gremium vorgelegt werden, dass selbst keine Studien erstellen kann. (Lauterbach (SPD)11.11.2010, 7662).

⁸⁵ Auch potenziell nutzlose Mittel müssen die Kassen bezahlen, wenn diese nicht mehr als 50 Millionen Euro Umsatz pro Jahr machen Sie können es selbst nachrechnen: Nur 20 solcher Medikamente auf dem Markt belasten die Kassen mit bis zu 1 Milliarde Euro jährlich. Dabei kommt ganz schnell mehr zusammen, als uns Herr Singhammer gerade an Ersparnissen vorgerechnet hat. (Vogler (Linke) 11.11.2011, 7665).

⁸⁶ Liebe Kolleginnen und Kollegen, von den 36 im letzten Jahr neu eingeführten Medikamenten sind nur 5 mehr als 10 000-mal verschrieben worden. Sie sehen also: Hier öffnen Sie ein Schlupfloch groß wie ein Scheunentor, durch das sich die Firmen der Nutzenbewertung entziehen können und werden. (Vogler (Linke) 11.11.2011, 7665).

the drug will be sold finally for this common disease the pharmaceutical industry made finally more profit by registering the drug as orphan drug:

We all know that the pharmaceutical industry is very creative in respect to maximize profit. They define drugs for smaller and smaller groups of patients. For example the pharmaceutical industry did not register that a drug for bowel cancer [...] is also effective by blindness of age. Instead they produced a very similar active component for blindness of age in order to register it as innovative and then they get 50 times as much money. (Bender (Grüne) 11. 11. 2010,7666, my translation)⁸⁷

The parliamentary party of CDU/CSU and FDP argues that they want to give an incentive for the pharmaceutical industry to do research on orphan drugs in order to help people with rare diseases and they want to ensure working places (Singhammer (CDU/CSU) 11.11.2010, 7664, my translation). “We achieved that medium sized companies do not get financial problems even they do for years research for one or two drugs. [...] We save working places in these middle sized companies, which we see as highly important.” (Singhammer 11.11.2010, 7664, my translation).⁸⁸

In contrast to the argumentation of parliamentary spokesperson Singhammer the opposition parties argue that this regulation for orphan drugs would not bring any advantage but even a disadvantage for people with rare diseases. Bender (Green Party 11.11.2011, 7667) explains this argument with an example:

Six drugs exist for a particular kind of cancer. Three of them have orphan drug status and three not. All six of them were never compared with each other, only the one without orphan drugs status. Therefore we do not know which drug is most beneficial of these drugs. You want that this problem still exist in the future. I ask myself: Who is missing sympathy for people with rare diseases. This is obviously you (Singhammer) (Bender (Green Party 11.11.2011, 7667, my translation).⁸⁹

Moreover Spahn (11.11.2010, 7672) adds that the European Communion fosters drug concerns, which do research on orphan drugs. Therefore CDU/CSU and FDP argues that they enact regulations which are in line with the European Commission. Therefore they want to allow German patients fast access to orphan drugs.

⁸⁷ Wir wissen doch alle wie erfinderisch die Pharmaindustrie ist wenn es um Profitmaximierung geht. Schon jetzt schneidet sie Medikamente auf immer kleinere Patientengruppen zu. So wird beispielweise ein Medikament wegen Darmkrebs-sie kennen alle den Fall- das auch bei einem bestimmten Fall von Altersblindheit wirkt, vom Unternehmen für genau diese Indikation, nicht zur Zulassung angemeldet. Stattdessen wird ein ganz ähnlicher Wirkstoff neu patentiert und zum 50-fachen Preis in den Markt gedrückt. (Bender (Grüne) 11. 11. 2010,7666).

⁸⁸ Wir haben auch erreicht, dass mittelständische pharmazeutische Unternehmen, die oft jahrelangen Forschungsaufwand für nur ein oder zwei Medikamente betreiben, nicht in eine finanzielle Schieflage geraten. [...] Damit sichern wir Arbeitsplätze bei diesen mittelständischen Unternehmen, um die es uns auch geht. (Singhammer 11.11.2010, 7664).

⁸⁹ Für eine bestimmte Art von Krebserkrankung gibt es sechs Arzneimittel. Drei davon haben den Orphan Drug-Status, drei nicht; und alle sechs sind noch nie gegeneinander geprüft worden. Wir wissen also nicht, welches Arzneimittel für den Patienten nutzbringender ist. Sie wollen nun, dass das so bleibt. Da fragt man sich doch: Wem fehlt hier das Mitgefühl für diejenigen, die an seltenen Krankheiten leiden? Das sind doch offenbar Sie. (Bender (Green Party 11.11.2011, 7667).

Benefit evaluation instead of cost-effectiveness evaluation

Apparently the pharmaceutical industry dislikes the cost - effectiveness evaluation. “Rösler accommodates with this the pharmaceutical industry, who massive block the cost – effectiveness evaluation of the IQWiG.” (Spiegel 15.03.2010, o.S.).⁹⁰ In 1992 the positive list was abolished because of the interests of the pharmaceutical industry and the positive list includes the cost -effectiveness evaluation. In 2003 the positive list was first planned, then again abolished; afterwards the cost-effectiveness evaluation was suggested and then replaced by the benefit evaluation in the final draft. In 2011 the same process happened: First a cost - effectiveness evaluation was planned and replaced by the benefit evaluation.

Highly interesting is the change of argumentation in respect to the assessment of the therapeutic added benefit. CDU/CSU were in the former cases arguing that the assessment of the therapeutic added benefit would endanger the drug manufacturing base Germany and hinder pharmaceutical concern’s ability to compete internationally: In 2000 Dreßler (SPD) already argued that he does not understand CDU/CSU and the pharmaceutical industry’s argumentation since the assessment of the therapeutic added benefit would have advantages for Germany’s international competition. In 2010 Singhammer (CDU) (11. 11. 2010, 7665) changed his way of argumentation and argues in the same vein as SPD and the Green Party that an effective assessment of the therapeutic added benefit would foster Germany’s ability to compete internationally.

We want to make Germany again to the drug store at least of Europe. Where is written that the time is past as Germany comes up with innovations. We will set standards with the innovative approach of the therapeutic added benefit and this not only for patients. This gives also the opportunity to companies to set a standard with attested products which is also significant for markets out of Germany. (Singhammer 11. 11. 2010, 7665, my translation).⁹¹

Negotiations between sickness fund and drug producers

The pharmaceutical industry, Rösler and the FDP had the opinion that each single sickness funds should negotiate with the pharmaceutical industry. In contrast SPD, Green Party, CDU/CSU and the sickness funds had the belief that the monopoly – the statutory health insurance – should negotiate with the pharmaceutical industry. The arguments of these both groups that either the pharmaceutical industry or the monopoly gets too much power.

⁹⁰ Damit kommt Rösler den Wünschen der Industrie, die sich massiv gegen eine Kosten-Nutzen-Bewertung des IQWiG stellt, sogar entgegen. (Spiegel 15.03.2010, o.S.).

⁹¹ Wir wollen Deutschland wieder zur Apotheke zumindest Europas machen. Wo steht geschrieben, dass die Zeit entgültig vorbei sei, dass von Deutschland Innovationen ausgehen, wir werden mit dem innovativen Ansatz des Zusatznutzens Standards setzen und zwar nicht nur für die Patienten. Das bietet auch Unternehmen eine Chance auf dem Leitmarkt Deutschlands mit zertifizierten Produkten einen Standard zu setzen, der auch für die Märkte außerhalb Deutschlands Bedeutung hat. (Singhammer 11. 11. 2010, 7665).

Moreover the advocates of the single contracts argued that it would be against the anti-trust law if a monopoly negotiates with the pharmaceutical industry.

You argue in this context with the competition law. Please! In the past sickness funds were allowed to negotiate together. Thereby they were strong negotiation partners compared to the pharmaceutical industry. All sudden you tell that if sickness funds negotiate together with the pharmaceutical industry it would contradict with the competition law and that each small sickness fund has to negotiate alone with the pharmaceutical industry. You want to weaken the statutory sickness funds. This is all you want. (Gysi (Linke) 12.11.2010, 7855, my translation).⁹²

Even if it would have been the interest of the pharmaceutical industry that the regulation defines that they negotiate with each single sickness fund, it was not changed in this way. The regulation changed only in so far that the option exists that each single sickness fund can also negotiate with the pharmaceutical industry.

It is not hard to guess who is advantaged when a small sickness fund negotiates with a huge pharmaceutical concern like Pfizer in the future: Either the small sickness fund accepts this offer – or members of the sickness fund do not get anymore the drug reimbursed. In this case a lot of insured would change sickness fund. “This only strengthens the position of the pharmaceutical industry.”, says Wolf-Dieter Ludwig, chief of the Drug Commission. (Spiegel 15.03.2010, o.S., my translation).⁹³

As mentioned in the first two lines of this passage CDU/CSU was also against the regulation that each single sickness fund has to negotiate with the pharmaceutical industry what explains why this regulation was not enacted.

Economic arguments

Like in 1992 and 2003 various “economic” arguments are used in order to justify the loopholes for the pharmaceutical industry. In 2011 Jens Spahn and Johannes Singhammer were much focused to point out that a “balance” has to be found. Politicians have to regulate on the one hand the pharmaceutical industry and on the other hand they have to secure good research conditions that the pharmaceutical industry keeps doing research for innovative drugs and does not leave to produce abroad.

We pay attention to a fair proportion and balance because we want that in Germany research will be done. We want research in Germany. This is on behalf of the patients; with research is a lot of hope

⁹² Sie argumentieren in diesem Kontext auch mit dem Kartellrecht. Ich bitte Sie! Früher durften die gesetzlichen Krankenkassen zusammen verhandeln. Dadurch waren sie starke Verhandlungspartner gegenüber der Pharmaindustrie. Jetzt sagen Sie, dass das dem Kartellrecht widerspricht und dass jede kleine Krankenkasse ganz allein mit der Pharmaindustrie verhandeln muss. Sie wollen die gesetzlichen Krankenkassen schwächen. Das ist alles, was Sie diesbezüglich anstreben. (Gysi (Linke) 12.11.2010, 7855).

⁹³ Wer dabei am längeren Hebel sitzt [würde], wenn künftig etwa eine kleine Betriebskrankenkasse mit einem Pharmariesen wie Pfizer verhandelt, ist unschwer zu erraten: Entweder schluckt die kleine Kasse das Angebot - oder ihre Mitglieder bekommen das neue Medikament nicht mehr erstattet. In diesem Fall würden wohl viele Versicherte die Kasse wechseln. "Das stärkt nur die Position der Pharmaindustrie", sagt Wolf-Dieter Ludwig, Vorsitzender der Arzneimittelkommission der deutschen Ärzteschaft. (Spiegel 15.03.2010, o.S.)

associated. Therefore you have to look after the balance and not condemn the pharmaceutical industry per se. (Spahn 11.11.2011, 7672, my translation).⁹⁴

In particular the empowering of the Federal Joint Committee – that instead of the Federal Joint Committee the Ministry of Health defines per decree law the criteria for the benefit evaluation – was justified by economic aspects: “The Ministry of Health shall regulate the benefit evaluation. [...] The coalition admits forthright that this would be a message to the pharmaceutical industry that Germany as production location would stay attractive.” (Stern 10.09.2010, o.S., my translation).⁹⁵

However according to the opposition parties and experts has the pharmaceutical industry not those high expenditures as they always maintain:

The lobby of the pharmaceutical industry always explains that the high prices for new drugs are necessary in order to finance research. Pretended the development of a new drug costs around 600.000 million Euro. US scientists proved few years ago that the real costs are often not even 50 million Euros. (Vogler (Linke) 9.07.2010, 5885, my translation).⁹⁶

Also in 2011 the pharmaceutical industry threatens with the cut of working places:

In this context I address the pharmaceutical industry because they threaten again with the cut of working places: (Henrich (CDU) 9.07.2011, 5890, my translation).⁹⁷

Conclusion:

This case describes that radical policy change – the stop of the pharmaceutical industry in order to determine freely the price of innovative drugs – took finally place. However was the legislative process determined by various changes of the first planned design - various changes which were made in order to satisfy the interests of the pharmaceutical industry. The cost – effectiveness evaluation was substituted by the benefit evaluation and the benefit evaluation was postponed after drug admission. Moreover various loopholes are included for the pharmaceutical industry in order to prevent financial losses: Orphan drugs are excluded from the regulation and studies are independent. The biggest loophole is that the pharmaceutical industry is again allowed to set the price for the first year and health insurance funds have to reimburse it.

⁹⁴ Wir achten aber auf ein faires Verhältnis und auf die Balance, weil wir wollen, dass in Deutschland geforscht wird. Wir wollen Forschung in Deutschland. Das ist im Interesse der Patienten, mit der Forschung werden viele Hoffnungen verbunden. Daher muss man auf die Balance achten und die Pharmaindustrie nicht per se verdammen. (Spahn 11.11.2011, 7672).

⁹⁵ So soll das Bundesgesundheitsministerium die Nutzenbewertung regeln [...]. In der Koalition bekennt man freimütig, dass dies auch ein Signal an Pharmaindustrie sei, damit der Pharmastandort Deutschland attraktiv bleibe. (Stern 10.09.2010, o.S.).

⁹⁶ Die Pharmedien erklären uns ja immer gerne, dass die Mondpreise für neue Medikamente sein müssen, um die Forschung zu finanzieren. Angeblich kostet die Entwicklung eines neuen Medikaments über 600.000 Millionen Euro. US Wissenschaftler haben aber schon vor einigen Jahren nachgewiesen, dass es real oft nicht einmal 50 Millionen Euro sind. (Vogler (Linke) 9.07.2010, 5885).

⁹⁷ In diesem Zusammenhang richte ich einen Appell an die Arzneimittelindustrie, die jetzt schon wieder teilweise den Arbeitnehmern droht: (Henrich 9.07.2011, 5890).

In contrast to the other cases coalition changed right before the health care reform. Moreover additional fees were raised which had to be paid by the insurant. problem window opened. Politicians were under pressure to solve the problem of raising costs in health care. The problem of the missing pricing regulation of innovative drugs existed, however Rösler exaggerated it and also the effect of the regulation in order to save costs in health care.

The argumentation of CDU/CSU changed. In the former cases they argued that the pharmaceutical industry should be not regulated in order to protect the production location Germany and to ensure that the pharmaceutical industry still does research in the future of innovative drugs. In 2011 they argued that regulating the pharmaceutical industry would be necessary since they charge as much as they want for innovative drugs.

CHAPTER 6

ANALYSIS AND INTERPRETATION

In the following the analysis and interpretation of the study is presented. In the study Kingdon's (1995) concept of radical policy change was used in order to analyze the change of pricing regulation in Germany. Radical policy change is "a fundamental transformation of policy – making and involves changes in basic sets of policy ideas, institutions, interests and processes" (Howlett/Ramesh 2010, 202). The radical policy change of our study is the observation that Germany was the only country in Europe which regulated innovative drugs different as the other ones and this changed in 2011. In detail the new regulation stopped the right of the pharmaceutical industry to determine freely the price of innovative drugs which mean that the pricing of innovative drugs got the first time regulated. The new regulation is price negotiations between health insurance funds and the pharmaceutical industry on basis of a reimbursement regulation which assesses the therapeutic added benefit. In 2011 a regulation of innovative drug pricing was introduced, which does not anymore exclude highly innovative drugs and which is similar to the regulation existing in other countries. It was a big step since price negotiations are market orientated instrument in drug policy. This policy change has been analyzed as radical policy change in my study.

In order to define the hypotheses and variables which explain the case in 2011 Mills (1950) "Method of Difference" is used. This means as explained in the methodological chapter that I

chose two comparative cases but only in one case happen the phenomena which need to be explained. If the conditions in all cases are the same only some factors are different then these factors are assumed to explain the phenomena; which is in our case radical policy change.

Kingdon's (1995) theoretical concept is not only the basis of this analysis but it also structures the presentation of this analysis. The aim of embedding the analysis in Kingdon's (1995) concept was a better understanding of the analysis. Nearly all possible explaining variables were taken from Kingdon's (1995) concept: the role of the pharmaceutical industry, change of coalition, policy entrepreneurs, focusing event, policy windows and argumentation. Only "Framing" was taken from Beland's (2005) concept which is also based on Kingdon's (1995) concept.

Kingdon (1995) tries to explain with his theory why radical policy change happens at a certain point in time. Moreover Kingdon (1995) explains with His theory the choice between *alternatives*. The alternative is in our case the regulation of pricing in order to solve the problem of growing costs in health care or more in detail of drug costs. Therefore this theory helped to answer our main research questions **why did radical policy change happen in 2011** and **why did it not change earlier?**

As just mentioned I will structure the presentation of the analysis like Kingdon (1995) structured his theory. First I will present the problem, then policy and last the political stream. This proceeding helps us to analytically distinguishing between problem definition, policy proposals and politics.

6.1 Problem definition

Focusing events

One possibility that a problem gets attention are focusing events, this are events which attract media attention like unexpected developments or crisis. I hypothesized that in my study a focusing event played a decisive role for the radical policy change in our study. I argue that in my study this *focusing event* was the raise of additional fees which had to be paid by the insurant. According to the *Süddeutsche Zeitung* (10.02.2010, o.S.) were additional fees the reason why health minister Rösler started to design a regulation which burdens the pharmaceutical industry. Moreover was the raise of additional fees very surprising. I assume this focusing event is in so far highly important since the public attention focused on the financial problems in health care since the insurant had to pay these additional fees. Because of the additional fees and even more pressure was put on the politicians to solve the problem

of raising costs. My assumption of the importance of these additional fees is confirmed by Freeman (1998, 397). “Even in Germany, the relative radicalism of the 1993 reform might best be explained by the increased pressure on public budgets which resulted from unification.” Therefore I verify the hypothesis that a change in the problem stream –the additional fees as focusing event - was decisive to explain policy change.

6.2 Policy proposals

Policy experts from interest groups, governments and academic institution develop, discuss and frame constantly policy alternatives. Policy alternatives are different solutions to a problem. For example in order to contain costs of drugs a reference pricing system, price negotiations between sickness funds, various reimbursement regulations are alternatives which would solve the problem of raising costs. Kingdon (1995) argues that the decision to take an alternative which was disliked before depends mostly on redrafting and recombining of the alternative. In the case of my thesis the alternative which was disliked in 1992 and 2004 was the pricing regulation of innovative drugs. The suggested alternative was price negotiations between sickness funds and the pharmaceutical industry on the basis of the therapeutic added benefit. This alternative was not enacted in 1992 and 2004. In 2011 a pricing regulation – negotiations between sickness funds and the pharmaceutical industry – on the basis of the therapeutic added benefit were enacted. Even it seems to be the same, important details of the regulation are different. Since 1992 the reimbursement regulation in order to define the therapeutic added benefit changed from positive list, to cost – effectiveness evaluation to a benefit evaluation before admitting a drug to the market to a benefit evaluation after the drug gets admitted to the market. Therefore the design how to assess the therapeutic added benefit changed. In 1992 the negotiations would have been combined with the positive list which is totally disliked by the pharmaceutical industry because it also tests if the price of the drug is in relation with the therapeutic added benefit. In 2011 the price negotiations got combined with the benefit evaluation which only assesses the therapeutic added benefit without examining if the benefit is in relation with the price. Moreover the positive list implies assessing the therapeutic added benefit before the drug gets admitted to the market and the benefit evaluation was designed that the drug gets evaluated after drug admission. Therefore I argue the redrafting and recombining of the alternative “regulation of pricing of innovative drugs” is decisive that it was enacted in 2011.

Framing and Argumentation

I hypothesized that framing is an important explaining factor in order to explain policy change. Beland's (2005) concept of framing together with Leiber's (2010) hypothesis of "problem solving" helped me to explain why CDU/CSU decided to choose a regulation which they defeated for more than 20 years. In advance I do not think that they changed their general opinion towards this regulation. I see more a strategically consideration in enacting this regulation.

Leiber et al. (2010) explain that the health care reform in 2007 was mainly "dominated by problem solving in the sphere of politics that is, finding a way to prove the grand coalition was capable of acting". In my opinion this explains also the radical change in 2011:

I argue CDU/CSU and FDP decided upon this regulation since it became obvious that the whole health care reform is ineffective and CDU/CSU and FDP seemed to be incapable of action in order to contain money with the reform.

Especially the pressure rose to reduce costs in health care since the additional fees were raised. Therefore I argue in order to seem capable of action politicians constructed a minor problem – the raising costs in drug policy – because to this problem a solution already existed – the regulation of pricing of innovative drugs.

Beland (2010) developed the theory for policy change that political actors would frame alternatives in order "to sell them to the public *while constructing the need for reform*". In my opinion this hypothesis fits perfectly in order to explain how CDU/CSU made themselves capable of action again in order to seem to solve the problem of raising the costs of drugs. I argue that CDU/CSU made Rösler construct the need for reforming the regulation innovative drugs because it was one reason for raising costs in health care and because the solution *how* to regulate innovative drugs existed. Therefore public got the feeling that with this regulation not only the problem of rising costs of drugs get solved but also the raising costs of the whole German health system. And the main aim was reached to seem again capable of action.

Only to make clear: I do not argue that the problem of innovative drugs did not exist. In contrast the study describes that this problem existed all the years and CDU/CSU and FDP did not pay any attention to it. Moreover the problem of raising costs in health care existed as well. But I argue that CDU/CSU and FDP "constructed" in so far a problem since they argued that the problem of patented and innovative drugs would have become much bigger in 2009. I

see it as exaggerated and therefore false and as construction of a problem which did not exist in that way.

I see one more explanation in the choice of this regulation. In public the question came up for the culprit of raising costs. I argue by framing the missing regulation of innovative drugs as one main factor of rising costs, Rößler could perfectly present the pharmaceutical industry as culprit because they were the ones who charged freely the high prices of innovative drugs.

Rösler presented himself presented as fighter against the evil pharmaceutical industry. This line of argumentation in order to justify a regulation defines Beland (2005) as “frame” which is in his wording a “discourse that helps political actors sell policy choices to the public”.

Hajer (1998) calls this line of argumentation which Beland (2005) calls “frame” *story line* and developed a theory which explains policy change with change of discourse coalitions. Policy change is explained by a change of discourse coalitions and I argue this happened in this thesis. The story line in 2011 was as just described that the pharmaceutical industry was presented as evil and the cause of all problems which needs to be regulated. In detail their freedom has to be changed that they are allowed to set the prices for innovative drugs. This story line existed in the cases 1992 and 2004, too. However the actors which backed this story line changed – which is in Hajer’s (1998) wording that the discourse coalitions changed.

In 1992 SPD and the Green Party were in opposition and in 2004 they were ruling parties. In both cases they had a different story line as in CDU/CSU and FDP. However in 2011 CDU/CSU adapted the same story line as SPD and Green Party. Therefore the discourse coalition got with CDU/CSU as ruling party important new members and gained therefore on importance and was stronger as the story line which was presented by CDU/CSU and FDP in the cases 1992 and 2004.

This story line of CDU/CSU and SPD in 1992 and 2004 was that no regulation of the pricing of innovative drugs is possible because the pharmaceutical deserves protection because they are important for Germanys economic and it is important that they do research in order to be able to heal illnesses. The story line of 1992 and 2004 of CDU/CSU and FDP still existed in 2011 but was overpowered by the one of the story line of the evil pharmaceutical industry which needs to be regulated since because of them the costs in health care are that high. The story line of 1992 and 2004 was only eased used in 2011 to justify why the regulation of innovative drug pricing was at the end not that hard against the pharmaceutical industry as originally planned.

6.3 Political stream

As just explained policy experts constantly discuss *alternatives* in their policy communities. However in order that policy changes a problem which needs to be perceived as important has to be associated with an alternative. For linking a problem with an alternative a major political actor is necessary who backs this alternative.

Policy entrepreneur

In 2011 this was health minister Philipp Rösler. Even though he was health minister of the minor coalition party he had power because there was not really any political opposition against this regulation. CDU/CSU had the idea of regulating the pricing of innovative drugs and made Rösler advocating and pushing this regulation. The opposition parties SPD and the Green Party did neither defeat this regulation since they tried to enact it since 20 years. They only criticized some aspects of the design but not the basic idea of regulation innovative drugs. The only resistance was from Rösler own party members. Parts of the FDP did not back this regulation. However most politicians of the Bundestag agreed on this regulation and favored it. Moreover Rösler's power was even more strengthened since very rare phenomena in German politics happened: At the beginning of the health care reform CDU/CSU and FDP hold the majority in the Bundestag and not as usually the opposition parties. In 1992 Rudolf Dreßler (SPD), head of the parliamentary health commission, backed the positive list and price negotiations between sickness funds and pharmaceutical industry. Since SPD hold the majority of the opposition parties in Bundestag and in Bundesrat, the coalition parties needed the agreement of SPD in order to be able to enact the health care reform at all. Therefore Dreßler (SPD) enacted the positive list because of a compromise with CDU/CSU; the regulation of pricing had no chance. It came to the compromise that the CDU/CSU got the agreement to enact the rest of the reform and Dreßler got the positive list. However CDU/CSU abolished it again because of the pressure of the pharmaceutical industry. In 2004 the health minister Ulla Schmidt (SPD) also gave up to fight for the positive list because of CDU/CSU and the pharmaceutical industry. As Ulla Schmidt was health minister, SPD was ruling party with the Greens. However CDU/CSU and FDP had the majority in Bundestag and blocked her suggestions of the regulation. From this follows that the role of the policy entrepreneur is decisive. However the policy entrepreneur can only be really successful when the political context gives him power and the possibility to act. In 2011 it was because there was no real opposition in order not to enact this regulation. In 1992 a compromise made the

enactment of the positive list possible and in 2004 there was no chance for Ulla Schmidt to enact the regulation because of the missing approval of CDU/CSU.

What we can clearly see in this analyzes is that the CSU/CDU played a decisive role if policy change could happen or not, probably because CDU/CSU is next to the SPD one of the two strongest parties in Germany. Therefore I argue that the hypothesis is right that the role of the policy entrepreneur is decisive. However, only if the political context gives the policy entrepreneur power then the policy entrepreneur can successfully act and push their ideas. The importance of the political context is decisively shown by the case of 1992. On the one hand since the political context made a compromise possible, Dreßler was able to enact the positive list. On the other hand however, since CDU/CSU was ruling parties they abolished it. Therefore I argue that only if the political context is right change can happen and stay because the policy entrepreneur can successfully act.

Change of coalition parties

In our study we can limit the political context pretty much to the influence of CDU/CSU. In the first two cases they blocked policy and in 2011 they initiated it. I argue that change in coalition is very decisive in order to explain policy change. According to Kingdon (1995) a change in coalition is most decisive that agenda can change and radical policy change can happen. CDU/CSU and SPD were until 2009 ruling parties and then the coalition FDP and CDU/CSU came to power. I argue the change in coalition was in so far decisive since the chance was seen by CDU/CSU to enact this regulation in such way that it does not “hurt” the pharmaceutical industry too much. Especially since even the majority in Bundesrat was hold by FDP and CDU/CSU. Normally always the opposition parties of the Bundestag hold the majority in Bundesrat. This means a huge decision for FDP and CDU/CSU. I argue in this way because CDU/CSU and FDP are known as industry friendly parties and they always defeated this regulation because it would have hurt the pharmaceutical industry.

Therefore I argue the coalition change made it the perfect time to put the regulation of drugs on the agenda in order to make long considered changes but in way which was not possible before because of the wrong constellation of ruling parties. I argue coalition change was decisive because CDU/CSU and FDP designed this basically industry adversary regulation in an industry friendly way.

The pharmaceutical industry

As explained above I see one main explanation of our case in the changes in respect to reimbursement which linked up the radical change in pricing. The argumentation of the role of the pharmaceutical industry is strongly connected with this redrafting of the policy proposals.

According to Kingdon (1995) and Beland (2005) are interest groups and perceived state of public opinion factors which can prevent policy change. They can be the reason that policy fades again away from the agenda. As I showed with various statements of politicians and experts the pharmaceutical industry prevented policy change in 1992 and 2004. In contrast in 2011 the pharmaceutical industry agreed mostly on the new regulation and did not block. The question is why the pharmaceutical industry did not block as in the former cases? Here I argue because the reimbursement regulations were that often redrafted until it was possible to link a pricing regulation to it without burden the pharmaceutical industry too much. Therefore I argue policy could only change because the regulation was that often redrafted until the pharmaceutical industry did agree on the regulation. Especially the case in 2011 underlines my argumentation. From the beginning until the end of the process design of the pricing regulation on basis of the reimbursement regulation changed very often because of the interests of the pharmaceutical industry. Therefore I verify my hypothesis that the pharmaceutical industry played a decisive role in order to explain policy change.

Policy window

According to Kingdon (1995) enhances a policy window the chance that even a radical policy change can happen. I hypothesized a policy window would explain why in 2011 policy change happened. This hypothesis can be verified. A policy window opened because of the coalition change in 2011. One issue which was put high on the agenda was cost containment in health care and more in detail in drug policy. Moreover also a problem window opened: Additional fees which led to public discussion and put the coalition even more under pressure in order to contain costs in health care. An alternative existed as solution – price negotiations between sickness funds and pharmaceutical industry – in order to contain costs. The political situation was perfect since CDU/CSU and FDP were ruling parties and had the majority in Bundesrat in order to make an industry friendly regulation out of a regulation which actually burdens the pharmaceutical industry. Therefore the pharmaceutical industry did not block and the policy entrepreneur could successfully use the policy window. I also had the thought that CDU/CSU enacted the regulation since it was again and again on the agenda in the last 20

years and wanted to prevent that this regulation would be later enacted and not in such a industry friendly way.

In 1992 was the situation that a compromise was made between Dreßler (SPD) and CDU/CSU. In order that CDU/CSU got the approval from SPD in order to enact the whole health care reform, Dreßler demanded the positive list and price negotiations. However price negotiations had no chance at all and the positive list was enacted but later abolished because of the interests of the pharmaceutical industry. According to Kingdon (1990) a compromise opens a policy window. However even if a policy window opened in 1992 the regulation of pricing could not be enacted and the positive list got abolished again.

I do not want to argue that a policy window is not important in order to explain policy change in 2011 because it also existed in 1992. Instead in my opinion it shows the importance of the pharmaceutical industry and the incremental changes in reimbursement which linked up change in 2011. As I explained I think most important I see these two factors which can be combined in order to explain the case. I think because of all these small changes in reimbursement a regulation could be constructed in 2011 which did not burden the pharmaceutical industry to such an extent and therefore they did not block the regulation.

Conclusion:

I argue radical policy change was possible because the coalition change opened a policy window. Cost containment in health care and in detail in drug policy was put on the agenda. Moreover a problem window opened because of the additional fees. Politicians were under pressure to solve the problem of raising costs in health care.

Since they were not capable of action in order to explain this problem they constructed a problem and framed the alternative in order to seem capable of action again. Rösler constructed the problem that the missing regulation of innovative drugs would have been worse and that it has huge influence on the raising drugs cost. I agree that the missing regulation of innovative drugs was a costly problem but I argue the he “constructed” the problem in so far that the problem did not exist to such an extent and that it would have become that much more urgent in the last year. The alternative in order to solve the problem were price regulations of innovative drugs. Rösler framed or constructed the story line that the regulation of innovative drugs would solve the problem of raising costs in health care and that the pharmaceutical industry would be the main culprit on the problematic situation in health care since they charge as much as they want for new drugs. The strategically explanation of

this proceeding was that people should get the feeling that CDU/CSU are capable of action and are able to solve the problem of raising costs.

CDU/CSU and FDP chose in my opinion the regulation of innovative drugs – even they disliked it 20 years long - because the reimbursement regulation was that often changed that a pricing regulation could now be constructed which does not anymore hurt the pharmaceutical industry. The pricing regulation – negotiations between sickness funds and the pharmaceutical industry – are always on basis of a reimbursement regulations. Therefore I argued the changes in reimbursement regulation are decisive in order to explain the radical change of pricing regulation.

The last point in my argumentation is the pharmaceutical industry. I see their role as most decisive. I argued they did not block the regulation since it did not really hurt them. This industry friendly construction was possible because of various changes of the reimbursement regulation.

Chapter 7

CONCLUSION

7.1 Summary of the thesis

The multiple stream theory of Kingdon (1995) is the main theory of the present thesis and is one major theory which explains radical policy change. The theory was taken because Kingdon (1995) focuses on explaining the moment of change. Since our research questions was “Why did policy change in 2011 (and not earlier)?”, the theory seemed to be appropriate. Moreover a lot of other studies on policy change in Germany health system use either Kingdon’s (1995) concept of policy and problem window or construct on basis of Kingdon’s (1995) concept their own theory. The theory is therefore so appropriate because his diffusion of problem, policy and political stream makes it easily possible to analytically analyze policy proposals, problems and political context.

Kingdon (1995) argues that the policy -, political -, and problem stream are existing independent from each other. Further he argues when a change in the political stream (coalition change) or in the problem stream (crisis, focusing event) happens then a policy or problem window opens and then time is perfect in order to change policy. This happens when

a policy entrepreneur links all three streams. His theory was also for my study very appropriate to start out with. However, Kingdon (1995) failed to explain in the problem stream *how* actors construct problems. He only mentioned that sometimes not really pressing problems were presented as real problems but did not really describe this strategically behavior in detail. Why and how politicians would do this. These gaps I close with two authors from different studies. Leiber et al. (2010) offers an explanation why politicians would do this in order to seem capable of action. Beland (2050) explains what to do exactly in order to manipulate problems: He argues politicians frame alternatives in order “to sell them to the public while constructing the need for reform”. These two more strategically hypotheses I included in my study in order to explain why after FDP and CDU/CSU disliked this regulation two decades long, they all sudden enacted it.

The method of this thesis was to work with stenographic protocols and newspaper articles since key informants would have been important politicians and heads of the pharmaceutical industry and sickness funds, which are not reachable in the context of a master thesis. Moreover the “Method of Difference” of John Stuart Mill was used. I chose three cases and searched for the explaining factors why radical policy change happened not in case 1992, 2004 but in 2011. The dependent variable was according to the university professor Matthias Kiffmann and assistant professor Seven Neelsen (2010) defined as radical policy change. Kiffmann and Neelsen (2010) defined it as radical policy change since the pharmaceutical industry is not anymore allowed to set prices by themselves instead a complex pricing system with various steps was created. I think Kiffmann and Neelsen’s (2010) definition of “radical” policy change is right because it is a “fundamental transformation of policy” since changes in an important “process” happened; this is how Howlett and Ramesh (2009) defined radical policy change “as fundamental transformation of policy – making and involves changes in basic sets of policy ideas, institutions, interests and processes”. The independent variables were pharmaceutical industry, focusing events, framing, argumentation, policy entrepreneur, change of coalition parties and policy and problem window.

The result of my analysis was that in the case 2011 a policy and problem window opened. The policy window opened because of coalition change from CDU/CSU and SPD to a very industry friendly coalition FDP and CDU/CSU. Since the FDP and CDU/CSU had also the majority in the Bundesrat, these parties had huge agenda setting and decision power. Since they defeated the regulation for two decades the question came up why these parties initiated this regulation in 2011. I chose a strategically explanation from Leiber et al. (2010): In their

explanation why policy changed in 2007 in Germany's health system, they argued that the policy process was dominated by the ruling coalition finding a way to show that the coalition is capable of action. Since the raising costs of health care were impossible to deal with for CDU/CSU and FDP they needed a strategy to seem at least to solve the problem. This strategy was in my opinion to exaggerate and therefore construct in a way the problem of the missing regulation of innovative drugs and to frame the alternative of price regulation as solution. Exaggerated in so far since the missing pricing regulation of innovative drugs led two decades ago to as high costs as today but CDU/CSU and FDP argued that the missing pricing regulation of innovative drug would be that much more of a problem since 2010. Therefore I argue they constructed a problem according to Beland's (2005) definition. Since the missing pricing regulation of innovative drugs was presented as one main problem of raising costs in health care, public got the feeling that politicians were capable of action to stop raising costs in health care, by solving the problem of innovative drugs.

Moreover a "real" problem existed which opened a problem window. Additional fees were raised, which had to be paid by each insurant. This put politicians under pressure to solve the problem of raising costs. The story line – the way of arguing in respect of the regulation-changed: Before 2011 CDU/CSU and FDP argued that the pharmaceutical industry needs protection because it produces innovative drugs and is important for the production location Germany. In 2011 CDU/CSU and FDP argued that the pharmaceutical industry charges as much as they want for drugs and that a regulation is necessary.

The pharmaceutical industry plays a decisive role in order to explain the case. They blocked policy in the first two cases but not in 2011. I see the explanation for not blocking in the fact that they were not burdened as much as in the proposals of the former regulations of pricing of innovative drugs in 1992 and 2004. This is explainable because of the various policy changes in respect to the reimbursement regulation. Because of these various changes – from positive list to an ineffective benefit evaluation - a complex pricing system of innovative drugs with few steps could be created which does not burden the pharmaceutical industry. Both regulations positive list and benefit evaluation assess the therapeutic added benefit. The decisive difference however that the positive list also tests if the benefit is in relation with the costs and in case of the positive list the assessment would be before drug admission. CDU/CSU and FDP recognized this chance to enact a long planned industry burdened regulation in a way that the pharmaceutical industry gets not burdened.

Germany is a latecomer in respect to pricing regulation compared to all other European countries. Since Germany has a very strong pharmaceutical industry compared with other European countries it can be assumed that this is the reason.

7.2. Discussion

7.2.1 Result

7.2.1.1 Is radical policy change in the German health care system possible?

One main problem of my study was to decide if the policy change which is explained in this thesis is a „radical one“. Kiffmann and Neelsen (2010, 51) defined it as “radical” one: „The new government’s reform proposal represents a radical change in policy. It practically eliminates the right of manufacturers to set PPD prices freely [...].” Matthias Kiffmann is professor at the University in Hamburg and and Sven Neelsen is PhD student in Munich. I defined my dependent variable according to Howlett and Ramesh (2009) “as fundamental transformation of policy – making and involves changes in basic sets of policy ideas, institutions, interests and processes”. I argue the policy change in 2011 was a fundamental transformation in policy – making since the pharmaceutical industry is not anymore allowed to set prices and instead a complex pricing system with few steps was created. Therefore it was a change in processes. A change in institutions did not take place. The Institute for Quality and Efficiency in Health Care, which is in charge of assessing the therapeutic added benefit got empowered, but no institution was created or abolished. I think a change in basic sets of ideas took place at least formally - away from the idea that the pharmaceutical industry needs protection because it does research on innovative drugs and is important for Germany as production location towards the idea that the pharmaceutical industry needs to be regulated since Germany is like paradise for pharmaceutical concerns. No change in respect to interests happened in my opinion. Even CDU/CSU and FDP initiated the new regulation and pharmaceutical industry agreed, it was ineffective constructed with a lot of loopholes for the pharmaceutical industry. Therefore I argue that no change of interests happened or only formally.

Because of all these reasons I defined my dependent variable as “radical policy change”. However there are experts who argue that radical policy change in Germany can hardly happen (Busse/Altenstetter 2005). Their argumentation is presented in following in order to oppose it and explain why I nevertheless decided on radical policy change.

Altenstetter and Busse (2005) argue that „path dependency, institutional continuities, and a semisovereign state policy-making model (Katzenstein 1987), characterized by a strong division between civil society and the state“– make radical policy change hardly possible.

I argue that Altenstetter and Busse (2005) is basically right. I see the stop of the pharmaceutical industry of free price setting with the regulation formally as radical policy change. However informally I see this regulation not as radical change since the regulation is constructed with various loopholes for the advantage of the pharmaceutical industry, experts do not expect a lot of savings for the statutory health insurance and argue that the pharmaceutical industry is not burdened. Therefore I argue radical policy change can happen in Germany but only formally. Informally no radical change is possible and especially it is hardly possible on the costs of the pharmaceutical industry.

Another fact which enabled radical policy change is that in the case 2011 the problem of the semisovereign state, which is mentioned by Altenstetter and Busse (2005) as hindering factor of radical policy change, is limited. In the case 2011 the very rare phenomena happened that the ruling parties had also the majority in Bundesrat.

In contrast to Altenstetter and Busse (2005), Siemens, Bridges and Carrera (2008) argue that they could imagine that radical policy change could soon happen in Germany's health system:

In the case of Germany, considering the sectoral, stepwise implementation of reforms, the confluence of sustained frustration of the business community with the high cost of doing business, public discontent with the level and quality of care, and greater political dividends resulting from change could precipitate the kind of reform that policy makers have long shied away from and may well be the answer to the question of the sustainability of health care financing.(Carrera/Siemens/Bridges 2010, 999).

Even if they mean a radical reform of the whole health care system, I think it confirms my argumentation that radical policy change happened at least in respect to a particular process.

7.2.2.2 Independent factors

Pharmaceutical industry

The three comparative cases showed the power of the pharmaceutical industry on policy change and policy proposals. This thesis could confirm which the first two comparative cases Kingdon's (1995) theory that the pharmaceutical industry blocks policy change. The pharmaceutical industry blocked the regulation in the first two cases. In the third case in 2011 the pharmaceutical industry favored all sudden the disliked pricing regulation of innovative drugs however a lot of aspects on the design of the regulation were criticized by the

pharmaceutical industry. Most points about which the pharmaceutical industry complained were changed.

Abraham (2002) wrote an article: “The pharmaceutical industry as political player”. In this article he concluded that still unsafe, unnecessary and ineffective drugs are on the drug market and that the health system must be more robust in order to prevent the influence of the pharmaceutical industry in order to change this deficit. Abraham (2002) took America as case but this thesis showed the same problem for Germany: In this thesis I dealt with the problem of unnecessary drugs. Pharmaceutical industries pretend that drugs have a therapeutic added benefit and get therefore as innovative drugs on the drug market and the full price gets reimbursed by health insurance funds. In reality often these drugs have no advantage compared to existing drugs what makes the unnecessary.

Change of coalition

Change of coalition from CDU/CSU and **SPD** to CDU/CSU and **FDP** is highly decisive in order to explain policy change in 2011 since the coalition was not only ruling parties in Bundestag but also hold the majority in Bundesrat. Since industry friendly parties CDU/CSU and FDP had this strong decision power because of majority in Bundestag and Bundesrat change towards an industry friendly regulation was possible. Since CDU/CSU and FDP designed the regulation in way that the pharmaceutical industry was hardly financially burdened, the pharmaceutical industry did not block it. In the cases 1992 and 2004 the parties who were in opposition in the Bundestag hold the majority in the Bundesrat.

Focusing events

I see the raise of additional fees as focusing event as highly decisive in order to explain policy change. In the other cases no focusing event happened or crisis.

Framing and Argumentation

Framing and argumentation is highly decisive in order to explain radical policy change in 2011 since the discourse coalitions of the story lines changed: In 2011 CDU/CSU argued the first time in a similar vein as SDP and the Green Party. In 2011 this three parties argued that the pharmaceutical industry needs to be regulated because they are allowed to set freely the prices of innovative drugs and they charge this high prices often for drugs without therapeutic added benefit. Moreover CDU/CSU all sudden argued that a better assessment of the therapeutic added benefit would help to enhance the Germany’s chance in international

competition. Before 2011 CDU/CSU together with FDP and the pharmaceutical industry needs to be protected from regulation of innovative drugs in order that they do not migrate abroad and no working places get cut. Moreover a regulation of innovative drugs would endanger Germany as production location.

Moreover the problem of innovative drugs was constructed in so far that it was presented as a problem which became now important but it was a problem in the last two decades and to the same extent. Moreover a public discourse was framed that the missing regulation of innovative drugs would cause the rising in costs and drug policy and therefore of the statutory health insurance. Therefore this missing regulation and the pharmaceutical industry cause the additional fees which are raised and had to be paid by each insurant.

Policy window and problem windows

In our study a problem and policy window opened. The additional fees opened a problem window and put politicians under pressure to stop the raising costs in health care or at least giving public the feeling that they can handle the situation. A policy window opened because a coalition change happened right before the health care reform. In contrast in 2004 no policy or problem window opened but in 1992. In 1992 the head of the parliamentary health commission Rudolf Dreßler (SPD) and health minister Horst Seehofer (CDU) had to find a compromise. Compromises are a window of opportunity. However price negotiations could nevertheless not be enacted and the positive list was again abolished in 2011.

7.3 Limitations of the study

The decisive interview partner would have been actors with high positions in politics, of the pharmaceutical industry, sickness funds and medical association. However in the context of a master thesis this interview partners were not reachable. At least three politicians agreed to answer questions per email. The main part of data I got from stenographic protocols and newspaper articles. One limitation of my study are that face to face interviews are missing. This could be an issue for further research to include in my study face to face interviews. The second limitations are that my study has only three cases. On the other hand there exists only one more comparative case - the health care reform in 2007. Here changes in respect to the reimbursement regulation happened and competition rights were expanded. Since four case studies would have been too time-consuming, I decided to take only three cases. This is also an idea for further research to study this fourth case in comparison to our three cases in order to strengthen validity.

7.4 Contribution to the state of research

7.4.1 Theoretical contribution

The theoretical contribution is on the one hand that my study is another example that Kingdon's (1995) theory works very well. First the pharmaceutical industry blocks policy change if they dislike it. Second drafts in the policy streams get as long redrafted until the situation is right and the proposal can be combined with a problem and does not get blocked from an interest group. Moreover the study showed the importance of policy and problem windows that a radical change can happen.

Moreover my study is another example which confirms Leiber's et al. (2010) theory that policy processes are dominated by finding a way to show that the coalition is capable of action and this leads to policy change. Leiber et al. (2010) build up this theory in order to explain policy change of the health care reform in Germany in 2011. I think it is a very interesting finding which deserves further research.

Our study confirms also the theory of Beland (2010). He argued that politicians would frame alternatives in order "to sell them to the public while constructing the need for reform.

7.4.2 Empirical contribution

The study is a contribution to radical policy change in Germany and in detail on radical policy change in Germany's health care. The object of study was to explain a lately happened radical policy change in 2011. Because of its actuality not much research is done on this policy change. So far there is no theoretical reworking of this change and no explanation why it changed, there are only descriptions that pricing regulation was enacted, that policy changed, and how useful this regulation is expected to be (Kiffmann/Neelsen 2010). Moreover there no study exists which describes the whole development of reimbursement and pricing regulation from the beginning 1992 until the end 2011 in detail. There are only studies who explain survey- like this development (Kiffmann/Neelsen 2010; Siebert 2010). Moreover hardly studies explain the differences of reimbursement and pricing regulations and the dis- or advantages of their design. Niebhur, Greß and Wasem (2005) compare Germany's pricing and reimbursement regulation with other countries and show the dis- and advantages. However there comparison is not up to date since it is from 2005. I did not find any study which shows how the pharmaceutical industry influenced during a long period of time one regulation in

detail. Moreover there are so far that I know no studies which presented survey- like how the argumentation in respect to pricing regulation changed.

8 REFERENCES

Altenstetter, Christa/ Busse, Reinhard (2005). Health Care Reform in Germany: Patchwork Change within Established Governance Structures, in: *Journal of Health Politics, Policy and Law*, 30 (1-2), 121-142.

AOK Bundesverband (2010). Krankenkassen halten kurzfristige Kostenbremse für unverzichtbar, 11.02.1010. Available at: http://www.aok-bv.de/presse/medienservice/politik/index_02056.html (25.10.2011).

AOK Medienservice. (2010). Information des AOK Medienverbandes. Politik online. Available at: http://www.aok-bv.de/imperia/md/aokbv/presse/medienservice/politik/ams_politik_1010.pdf (15.10.2011).

Ärzteblatt (2003). KBV-Vertreterversammlung: Geschlossen gegen die Gesundheitsreform, Juni 2003. Available at: <http://www.aerzteblatt.de/archiv/37277/KBV-Vertreterversammlung-Geschlossen-gegen-die-Gesundheitsreform> (30.03.2003).

Baumgartner, Frank/Jones, Bryan (1991). Agenda Dynamics and Policy Subsystems, in: *The journal of politics*, 43 (4), 1046-1065.

Bandelow, Nils (2004). Akteure und Interessen in der Gesundheitspolitik. Vom Korporatismus zum Pluralismus, in: *Politische Bildung* 37/2, 2004, 49-6.

Bandelow, Nils (2005). Strategien vergleichender Forschung nach John Stuart Mill und Adam; power point presentation. Available at: Przeworski/Henri Teune <http://www.nilsbandelow.de/fallauswahl.pdf> (25.05.2011).

Beland, Daniel (2005). Ideas and Social Policy: An Institutionlist Perspective. *Social Policy and Administration*, 39 (1), 1-18.

Bender, Birgit (Green Party) (2010). Neuordnung des Arzneimittelmarktes, 9.07.2010. Available at http://www.gruene-bundestag.de/cms/bundestagsreden/dok/347/347235.neuordnung_des_arzneimittelmarktes-print~1@pl.html (25.03.2012).

Bender, Biggi (Green Party) (2010). Request to speak, in: *Stenographic protocols*, 11.11.2010, Legislation period 17, Session 71, 7666-7669. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Bubendorff, Valerie (2000). Das Gesundheitsstrukturgesetz in der überregionalen Tagespresse der Bundesrepublik Deutschland: dargestellt am Beispiel einer inhaltsanalytischen Untersuchung der Berichterstattung über die 2. Stufe der Reform in „Frankfurter Allgemeine Zeitung“ und „Süddeutsche Zeitung“, Univ. Diss.; Bochum.

Bundesministerium für Gesundheit (2009). Dritter Bericht der Task Force „Pharma“. Zur Verbesserung der Standortbedingungen und der Innovationsmöglichkeiten der pharmazeutischen Industrie in Deutschland, Berlin.

Bundesrats-Drucksache (14/8205). Unterrichtung durch die Bundesregierung Ergänzung zum Gutachten 2000/2001 (Bände I bis III) des Sachverständigenrates für die Konzertierte Aktion im Gesundheitswesen Bedarfsgerechtigkeit und Wirtschaftlichkeit Zur Steigerung von Effizienz und Effektivität der Arzneimittelversorgung in der gesetzlichen Krankenversicherung (GKV); 05.02.2002. Available at: <http://dip21.bundestag.de/dip21/btd/14/082/1408205.pdf> (05.05.2012).

Bundesrats-Drucksache (675/2/03). Antrag des Landes Mecklenburg-Vorpommern Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GKV-Modernisierungsgesetz – GMG) TOP 7 der 792. Sitzung des Bundesrates am 17. Oktober 2003, 14.10.2010. Available at: <http://dipbt.bundestag.de/doc/brd/2003/0675-2-03.pdf> (25.05.2010).

Bundesrats-Drucksache (675/1/03). Empfehlungen der Ausschüsse zu Punkt...der 792.Sitzung des Bundesrates am 17. Oktober 2003. Gesetz zur Modernisierung der gesetzlichen Krankenversicherung (GKV-Modernisierungsgesetz - GMG). Available at: http://www.umwelt-online.de/PDFBR/2003/0675_2D1_2D03.pdf (20.05.2012).

Bundesrats-Drucksache (17/7710). Unterrichtung durch die Bundesregierung Jahresgutachten 2011/12 des Sachverständigenrates zur Begutachtung der gesamtwirtschaftlichen Entwicklung, 11.11.2011. Available at: http://dipbt.bundestag.de/dip21.web/searchDocuments/drs_search_text.do(25.10.2011).

Bundestag-Drucksache (17/1418). Antrag der Abgeordneten Birgitt Bender, Fritz Kuhn, Maria Klein-Schmeink, Elisabeth Scharfenberg, Dr. Harald Terpe, Kerstin Andreae, Katrin Göring-Eckardt, Markus Kurth, Beate Müller-Gemmeke, Dr. Wolfgang Strengmann-Kuhn und der Fraktion BÜNDNIS 90/DIE GRÜNEN Qualität und Sicherheit der Arzneimittelversorgung verbessern – Positivliste einführen – Arzneimittelpreise begrenzen, 21.04.2010. Available at: <http://www.bpb.de/sosi/material/AAD296.pdf> (25.10.2011).

Bundesverband AOK (2010/2011). Zahlen und Fakten. Available at: http://www.aok-bv.de/imperia/md/aokbv/zahlen/aok/zuf_2011.pdf (25.03.2012).

Bundeszentrale für politische Bildung (o.S.a, o.J.): Gesundheitspolitik. Bismarcks Erbe: Besonderheiten und prägende Merkmale des deutschen Gesundheitswesens. Available at: http://www.bpb.de/themen/WZDR7I,0,Gesundheitspolitik_Lernobjekt.html?lt=AAB383&guid=AAB119 (21.03.2012).

Busse, Reinhard/Schreyögg,Jonas/ Henke, Klaus-Dirk (2005). Regulation of the pharmaceutical markets in Germany: improving efficiency and controlling expenditures?, in: The international Journal of health planning and management, 20(4), 329-349.

Carrera, Percivil/Siemens, Karen/Bridges, John (2008). Health Care financing reforms in Germany. The Case of rethinking the Evolutionary approach to reforms, in: Journal of Health Politics, Policy and Law, 33(5), 979-1004.

Coalition against Bayer Dangers (2003). Kniefall vor Pharmalobby. Positivliste für Medikamente erneut verhindert. Die Kassen bezahlen wirkungslose Präparate, 24.03.2003. Available at: <http://www.cbgnetwork.org/528.html> (22.03.2012).

Dreßler, Rudolf (SPD) (1992). Request to speak, in: Stenographic protocol of the Bundestag 9.12.1992, Legislation period 17, Session: 127, 10935-10936. Available at: <http://dip21.bundestag.de/dip21/btp/12/12127.pdf> (22.03.2012).

Dreßler, Rudolf (2000). Tagung, November 2000. Available at: <http://library.fes.de/fulltext/asfo/00690002.htm> (26.03.2012).

Doran, Evan/ David Henry (2008). Australien Pharmaceutical Policy: Price Control, Equity, and Drug, Innovation in Australia, in: Journal of Public Health Policy, 29 (1), 106-120.

Dudely, Goeffrey/Richardson, Jeremy (1996). Promiscuous and Celibate Ministerial Styles: Policy Change, Policy Networks and British Roads Policy, in: Oxford Journals, 566-583

Enquete- Kommission (1990). Endbericht der Enquete-Kommission. „Strukturreform der gesetzlichen Krankenversicherung“ gemäß Beschluss des deutschen Bundestages vom 4. Juni 1987 und vom 7. Oktober 1988, Drucksache 11/6380 vom 12.02.1990. Available at: <http://www.bundestag.de/> (25.03.2012)

Ferner, Elke (SPD) (2010). Request to speak, in: stenographic protocols of the federal parliament, 09.07.2010, Legislative period 17, session: 56, 5883-5884. Available at: <http://www.bundestag.de/dokumente/protokolle/plenarprotokolle/plenarprotokolle/17056.txt> (25.03.2012).

Frankfurter Allgemeine Zeitung (22.02.2010). Spielraum bei den Preisen. Available at: <http://www.faz.net/aktuell/wirtschaft/im-gespraech-eberhard-wille-spielraum-bei-den-preisen-1940037.html> (18.10.2011).

Frankfurter Allgemeine (07.03.2010). Rösler regelt Preisbildung für Arzneimittel neu, Available at: <http://www.faz.net/aktuell/wirtschaft/wirtschaftspolitik/gesundheitspolitik-roesler-regelt-preisbildung-fuer-arzneimittel-neu-1956813.html> (25.03.2012).

Frankfurter Rundschau (5.2.2010). Wir dürfen uns nicht von Ängsten leiten lassen. Available at: <http://www.fr-online.de/home/pharmakritiker-sawicki-das-rezept-der-profiteure,1472778,3176806.html> (3.3.2010).

Freeman, Richard (1998). Competition in context: the politics of health care reform in Europe, in: International Journal of Quality in Health Care, 10 (5), 395-401.

Gemeinsamer Bundesausschuss (2012). Gesetzlicher Auftrag und Arbeitsweise. Bewertung von Untersuchungs- und Behandlungsmethoden. Available at: http://www.infofakt.de/artikel_15.html (22.03.2012).

Glos, Michael (2003). Argumentationspapier zu den Eckpunkten der Konsensverhandlungen zur Gesundheitsreform, 23.07.2003. Available at: http://www.glos.de/portal/alias__glos/lang__de-DE/mid__13479/ItemID__373/tabid__6968/default.aspx (25.04.2012).

Gysi, Gregor (2010) (Linke). Request to speak, in: Stenographic protocols. 12.11.2010, Legislation period 17, Session 71, 7853-7857. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17072.pdf> (25.03.2012).

Hassenteufel, Patrick/ Smyrl, Marc/Genieys, William, Moreno-Fuentes, Francisco Javier (2010). Programmatic Actors and the Transformation of European Health Care States, in: *Journal of Health Politics, Policy and Law*, 35 (4), 517-538).

Häussler, Betram (2006). *Weißbuch Diabetes in Deutschland. Bestandsaufnahme und Zukunftsperspektiven*.

Hajer, Maarten (1993): Discourse Coalitions and the Institutionalisation of Practice: The Case of Acid Rain in Great Britain. In: Fischer, Frank/Forester, John (Ed.): *The Argumentative Turn in Policy Analysis and Planning*. Durham/London. S. 43-67.

Hennrich, Michael (2010). Request to speak, in: stenographic protocols of the federal parliament, 09.07.2010, Legislative period 17, session: 56, 5890-5892. Available at: <http://www.bundestag.de/dokumente/protokolle/plenarprotokolle/plenarprotokolle/17056.txt> (25.03.2012).

Hinrichs, Ulrike/Nowak, Dana (2005). *Auf dem Rücken der Patienten. Gesundheitsbedienungsladen Gesundheitssystem*, Links Verlag, Berlin.

Hood, Christopher (1996). 'United Kingdom: From Second Chance Effects to Near-Miss learning', in Olsen, James/Peters Guy (ed.): *Lessons from Experience. Experiential Learning in Administrative Reforms in Eight Democracies*, Oslo Scandinavian University Press, 36-70.

Howlett, Michael/Ramesh, Anthony (2009). *Studying Public Policy. Policy Cycles&Policy Subsystems*, Oxford.

Institute for Quality and Efficiency in Health Care (2011). Responsibilities and objectives of the IQWiG. Available at: <https://www.iqwig.de/about-us.21.en.html> (21.03.2010).

Institute for Quality and Efficiency in Health Care IQWiG (2012). IQWiG zieht positive Zwischenbilanz bei AMNOG. Wiederholt missverständliche Darstellung in den Medien/ Gespräche mit Herstellern konstruktiv, 10.02.2012. Available at: <https://www.iqwig.de/sida60bdf57ts0ldr98ei06htbbb74qjsc/iqwig-zieht-positive-zwischenbilanz-bei-amnog.1418.html> (25.03.2012).

Gerlinger, Thomas (2010). *Gesundheitsreform Chronologie 02/2010*, email, 10.04.2012.

John, Peter (2003). Is there life after policy streams, advocacy coalitions, and punctuations: using evolutionary theory to explain policy change? *The policy studies journal*, 31 (4), 481-498.

King, G, Keohane, R, and Verba, S. (1994). *Designing social enquiry: scientific inference in qualitative research*. Princeton: Princeton University Press.

Kingdon, John (1995). *Agendas, Alternatives and public policies*, 2nd edition, New York.

Koalitionsvertrag (2009). Wachstum, Bildung, Zusammenhalt. Der Koalitionsvertrag zwischen CDU, CSU und FDP. Available at: <http://www.cdu.de/doc/pdfc/091026-koalitionsvertrag-cducsu-fdp.pdf> (25.10.2010).

Kiffmann, Mathias/Neelsen, Sven (2010). Germany's Struggle for patent-protected drugs, in: Cesifo Dice Report, (3), 43-52.

Kirschner, Klaus (SPD) (1992). Request to speak, in: Stenographic protocol of the Bundestag 9.12.1992, Legislation period 17, Session: 127, 10917-10920. Available at: <http://dip21.bundestag.de/dip21/btp/12/12127.pdf> (22.03.2012).

Lauterbach, Karl (2010). Request to speak, in: stenographic protocols of the federal parliament, 09.07.2010, Legislative period 17, session: 56, 5881-5883. Available at: <http://www.bundestag.de/dokumente/protokolle/plenarprotokolle/plenarprotokolle/17056.txt> (25.03.2012).

Lauterbach, Karl (2010). Request to speak, in: Stenographic protocols, 11.11.2010, Legislation period 17, Session 71, 7662-7668. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Leiber, Simone/Greß, Stefan/Manouguian, Maral-Sonja (2010). Health Care System Change and the Cross Border Transfer of Ideas. Influence of the Dutch Model on the 1007 Health Care Reform, in: Journal of Health Politics, Policy and Law, Vol. 35, No.4.

Lengsfeld CDU/CSU 23.09.2003, 5520).

Leutert, Michael (Linke) (2010). Request to speak, in: Stenographic protocol of the Bundestag, 19-03.2010, Legislation period 17, Session: 32. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17032.pdf> (25.03.2012).

Lewi, Jenny (2005): Health Policy and Politics: networks, ideas and power, IP Communications Melbourne.

Naturheilkunde und Naturheilverfahren Fachportal (2010). Gesundheitsreform: Die Pharmaindustrie profitiert erneut. Available at: <http://www.heilpraxisnet.de/naturheilpraxis/gesundheitsreform-pharmalobby-profitiert-erneut-3617.php> (23.03.2012).

Niebuhr, Dieter; Greß, Stefan; Wasem, Jürgen (2005): Zentrale und dezentrale Steuerung von Arzneimittelmärkten im internationalen Vergleich. Wirtschaftspolitische Blätter 52 (4): 549-58.

Ognyanova, Diana/Zentner, Annette/Busse, Reinhard (2011). Pharmaceutical reform 2010 in Germany: Striking a balance between innovation and affordability, in: Eurohealth, 17 (1), 11-52.

Paquet, Robert (2011). Vertragswettbewerb in der GKV und die Rolle der Selektivverträge. Nutzen und Informationsbedarf aus der Patientenperspektive, in: WISO Diskurs. Expertisen und Dokumentationen zur Wirtschafts -und Sozialpolitik, Friedrich-Ebert-Stiftung.

Paquet, Robert; Schroeder, Wolfgang 2009: Gesundheitsreform 2007 – Akteure, Interessen und Prozesse, in: Schroeder, Wolfgang; Paquet, Robert 2009: 11 - 29.

Peterson, Mark (1993). Political influence in the 1990s. From iron triangles to policy networks, in: Journal of health politics, policy and law, 18 (2), 395- 437, Duke University.

Pharmazeutische Zeitung (2012). Sorge um die Nutzenbewertung. Available at: <http://www.pharmazeutische-zeitung.de/index.php?id=35312> (25.03.2012).

Püschner, Michael (2009). Der Fraktionsreferent ein politischer Akteur? In: Politik und Zeitgeschichte, 2009 (38). Available at: <http://www.das-parlament.de/2009/38/Beilage/006.html> (25.04.2012).

Rainers, Hartmut (2010). Ideenschmiede für die Gesundheitspolitik. in: Gesundheit und Gesellschaft, 13(1), 37-41. Available at: http://www.aokbv.de/imperia/md/aokbv/mediathek/gg/gg_beitrag_0110.pdf (25.4.2012).

Real-Dato, Jose (2009). Mechanism of Policy Change: A Proposal for Synthetic Explanatory Framework, in: Journal of Comparative Policy Analysis, 11 (1), 117-143.

Rösler, Philipp (2010) Request to speak, in: Stenographic protocols. 11.11.2010, Legislation period 17, Session 71, 7660-7663. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Sabatier, Paul (1988). The Advocacy Coalition framework of policy change and the role of policy oriented learning therein. Policy Sciences , 129-168.

Saetren, Harald (2009). Explaining radical policy change against all odds: the role of leadership, institutions, program design and policy windows, in: Raffel, Jeffrey/ Leisink, Peter/ Middlebrooks, Anthony (Ed.): Public Sector leadership. International Challenges and Perspectives.

Schlager, Edella (2007). A Comparison Frameworks, Theories and Models of Policy Processes, in: Sabatier, Paul (Ed.), Theories of the Policy Process, 293.321.

Sherwood, Ted (o.J.). Generic drugs, Power point. Available at: <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm127615.pdf> (5.03.2012).

Schneider, Thomas (2010). Krankenversicherung in Europa – Deutschland- Schweden und die Niederlanden im Vergleich. Neue Lösungsansätze einer europäischen Gesundheitspolitik.

Schmidt-Zadel (SPD) (1992). Request to speak, in: Stenographic protocol of the Bundestag 9.12.1992, Legislation period 17, Session: 127, 10958-10962. Available at: <http://dip21.bundestag.de/dip21/btp/12/12127.pdf> (22.03.2012).

Seehofer, Horst (CDU/CSU) (2003). Interview, in: ZDF, broadcast “Frontal” in 1.1.2003. Available at: http://www.youtube.com/watch?v=DCy1D1HGeeA&feature=player_embedded#! (25.03.2012).

Siebert, Ursel (2010). *Gesunder Zweifel. Einsichten eines Pharmakritikers- Peter Sawicki und sein Kampf für eine unabhängige Medizin*, Berlin Verlag, Berlin.

Sieberer, Ulrich: Agenda setting in the German Bundestag. A weak government in a consensus democracy, *German Politics*, 2006: 15, issue 1, p. 49-72.

Singhammer, Johannes (CDU/CSU) (2010). Request to speak, in: Stenographic protocols. 11.11.2010, Legislation period 17, Session 71, 7664-7665. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Spahn, Jens (2010). Request to speak, in: Stenographic protocols. 11.11.2010, Legislation period 17, Session 71, 7671-7679. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Spahn, Jens (2010). Request to speak, in: stenographic protocols of the federal parliament, 09.07.2010, Legislative period 17, session: 56, 5882-5886. Available at: <http://www.bundestag.de/dokumente/protokolle/plenarprotokolle/plenarprotokolle/17056.txt> (25.03.2012).

Spiegel (24.06.2003). SPD und Union wünschen sich Gesundheit. Available at: <http://www.spiegel.de/politik/deutschland/0,1518,254446,00.html> (22.03.2012).

Spiegel (28.07.2003). Pakt gegen die Patienten. Available at: <http://www.unisalzburg.at/pls/portal/docs/1/1617200.PDF> (25.03.2012).

Spiegel (10.03.2010). Rösler droht Pharmakonzerne mit Preislimits. Available at: <http://www.spiegel.de/wirtschaft/soziales/0,1518,682696,00.html> (25.03.2010).

Spiegel (15.03.2010). Operation Hippocrates. Available at: <http://www.spiegel.de/spiegel/0,1518,683761,00.html> (25.03.2012).

Spiegel Online (2.6.2010). Opposition zerfetzt Gesundheitsreform, Schwarz Gelber Kompromiss. Available at <http://www.spiegel.de/politik/deutschland/schwarz-gelber-kompromiss-opposition-zerfetzt-gesundheitsreform-a-705036.html> (25.03.2010).

Stern (2010). Schwarz-Gelb folgt Pharmedien, 10.09.2010. Available at: <http://www.stern.de/gesundheitsreform-schwarz-gelb-1602301.html> (25.04.2012).

Striegel, Henrik (o.J., o.S.). Das deutsche Gesundheitssystem. Available at: http://www.infofakt.de/artikel_15.html (21.03.2012).

Süddeutsche Zeitung (22.03.2003). Roland Koch will Positivliste für Arzneien stoppen. Available at: <http://www.sueddeutsche.de/wirtschaft/gesundheitsreform-roland-koch-will-positivliste-fuer-arzneien-stoppen-1.511489> (22.03.2012).

Süddeutsche Zeitung (21.07.2003). Triumph der Lobbyisten. Available at: <http://www.sueddeutsche.de/politik/kommentar-triumph-der-lobbyisten-1.894201> (25.03.2012).

Süddeutsche Zeitung (30.09.2003). Viele unnütze Pillen. Arzneimittelkosten auf Rekordhoch. Available at: <http://www.sueddeutsche.de/wirtschaft/arzneimittelkosten-auf-rekordhoch-viele-unnuetze-pillen-1.818458> (27.03.2012).

Süddeutsche (01.02.2010, o.S.).

Süddeutsche Zeitung (10.02.2010). Rößler gegen den Pharmariesen. Available at: <http://www.sueddeutsche.de/wirtschaft/arzneimittelpreise-roesler-gegen-die-pharmariesen-1.72920> (10.02.2012).

Süddeutsche (19.03.2010). Rößler verschärft Druck auf Pharmakonzerne. Available at: <http://www.sueddeutsche.de/geld/gesundheitsystem-roesler-verschaerft-druck-auf-pharmakonzerne-1.11010> (22.03.2012).

Taz.de (2010). Die Invasion der Nutzlospillen. Schwarz-Gelb entmachtet Pharma – TüV, 21.10.2010. Available at: <http://www.taz.de/!60105/> (25.10.2010).

True, James/ Jones, Brayen/ Baumgartner, Frank (2007). Explaining Stability and change in public policy making, in: Sabatier, Paul (Ed.), Theories of the Policy Process, 155-189.

(Vfa 14.05.2003, o.S.)

Vfa (2010). „Arzneimittel-Atlas 2010. Lenkungsinstrumente auf dem Prüfstand“, Pressegespräch, 30.06.2010. Available at: www.vfa.de/download/am-atlas-2010-statement-plischke.pdf (25.03.2012).

VfA (2010). VfA zu Röslers Eckpunkte, Pressemitteilung, 26. 03.2010, Available at: <http://www.bpb.de/sosi/material/AAD239.pdf> (25.10.2011).

VfA (2003). VfA – Stellungnahme: Eckpunkte des Gesundheitsministeriums zur Gesundheitsreform sind Stückwerk., 20.02.2003. Available at: <http://www.vfa.de/de/wirtschaft-politik/stellungnahmen/bmgeckpunkte.html> (24.03.2012).

Vogler, Kathrin (Linke) (2010). Request to speak, in: stenographic protocols of the federal parliament, 09.07.2010, Legislative period 17, session: 56, 5885-5887. Available at: <http://www.bundestag.de/dokumente/protokolle/plenarprotokolle/plenarprotokolle/17056.txt> (25.03.2012).

Vogler, Kathrin (Linke) (2010). Request to speak, in: Stenographic protocols. 11.11.2010, Legislation period 17, Session 71, 7664-7666. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Volkmer, Marlies (SPD) (2010). Request to speak, in: Stenographic protocols, 11.11.2010, Legislation period 17, Session 71, 7670-7672. Available at: <http://dipbt.bundestag.de/dip21/btp/17/17071.pdf> (25.03.2012).

Weiser, Martin (2003). Nutzenbewertung von Arzneimitteln im Rahmen des GKV – Modernisierungsgesetzes; power point presentation. Available at: http://www.dphg.de/lib/indpharm_vortr_weiser.pdf (25.05.2011).

Welt (10.03.2010). Rößler greift Pharmamonopol der Pharmabranche an, 10.03.2010. Available at: <http://www.welt.de/politik/deutschland/article6710705/Roesler-greift-Preismonopol-der-Pharmabranche-an.html> (23.04.2010).

Wissenschaftliches Institut der AOK (WidO) (2011). Umsatz mit patentgeschützten Medikamenten legt weiter zu, Pressemitteilung. Available at: http://www.wido.de/fileadmin/wido/downloads/pdf_arzneimittel/wido_arz_pk_avr2011_0911.pdf (25.03.2012).

Yin, Robert (1994). "Case study Research: Design and methods." 2nd edition. California. Sage Publication.

Zahariadis, Nikolaos (2007). The multiple streams Framework; Structure, Limitations, Prospects, Paul (Ed.), Theories of the Policy Process, 65-93.