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**Narrating the Regulation:
The Pharmaceutical Policy in the Czech
Republic as an Example**

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Čestně prohlašuji, že práce byla vypracována samostatně s použitím uvedených pramenů a literatury:

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Karel Čada

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INTRODUCTION

Motto: Policy is more like an endless game of Monopoly than sewing machine repair.

Deborah Stone (1988: 208)

Over the last decades, the pharmaceutical policies of the developed European countries have had to respond to an escalation in the costs of medical drugs. (see for example Práznovcová, Strnad 2005; Iversen 2006; Goodman 2000) In connection with this rise in costs, Jeremy Green has asked (2007) how and why has public health, previously associated with charity and science, become subject to such aggressive marketing. How is it possible that small fluctuations in blood pressure have become the object and product of mechanisms which bring together science and politics, economy and doorstep selling? The pharmaceutical markets thus represent one of the crucial, fastest-growing fields, the analysis of which can help us understand the social dynamics of late modern societies more generally.

Hartmut Rosa (2013) sees social acceleration as a key to understanding modernity and modernisation process. In his view, the three main types of acceleration are technical acceleration driven by economic motor, the acceleration of social change propelled by the social-structure motor of functional differentiation, and the acceleration of the pace of life externally driven by the cultural promise of acceleration. In health care sector, one can witness all these types of acceleration. "Modern society can be understood as an "acceleration society" in the sense that it display a highly conditioned structural and linkages of both forms of acceleration - technical acceleration and an increase in the pace of life due to chronic shortage of time resources - and therefore also a strong linkage of acceleration and growth." (Rosa 2013: 68) Even though Rosa gives no special attention to health care, one can argue that this field might be considered as an area where linkages between different types of social acceleration can be observed very clearly.

In last decades, the most visible is acceleration in the technical dimension. While prescription drug sales were almost static as a percentage of GDP in western societies between 1960 and the early 1980s, from the early 1980s to 2002, prescription drug sales tripled to nearly US\$400 billion worldwide (Angell, 2004: 1–5). During the period up to 2009, all OECD countries saw health spending outpaced economic growth resulting in an increasing share of GDP allocated to health and spending on pharmaceuticals has significantly contributed to the overall rise in total health expenditure. In terms of time, new drugs were approved on an average of sixteen months faster in 1999–2001 (about 5.92 years) than in the period 1994–1998 (about 7.25 years). In the US, the final stage - approval by the government regulator - average approval time dropped from 27 months in 1993 to 19 months in 2001 (Lexchin 2005) and the Food and Drugs Agency which is responsible for drug regulation in the US is required to put too much of its resources into speeding up drug approvals, at the expense of monitoring drug safety, inspecting manufacturing plants, and ensuring truthful advertising. (Angell, 2004: 244) Furthermore, pharmaceutical research moved away from academic departments towards commercial spin-offs. Before 1990, over 80 percent of all pharmaceutical research was conducted in academic medical centres. By 2005, only about 25 percent was conducted in there. (Fisher 2009: 12-13) The proliferation of small private companies used for pharmaceutical research was part of larger trends that emphasize outsourcing and cutting production costs. Outsourcing clinical trials to for-profit clinical trial companies has become one of the pharmaceutical industry's answers to speeding up drug development. (Rainville 2002)

However, Rosa (2013: 75) reminds us, that the tempo of the social implementation of new technologies is neither logically nor causally reducible to technological acceleration itself, however, is also determined by given form of social structure. The question that concerns Rosa in this context is to what extent the principle of functional differentiation - a central developmental principle of modern societies - leads to or necessarily brings about acceleration process-

es. This form of differentiation and complexity driven by rationalization of system can in first place be understood as a mechanism for increasing speed of productive and developmental processes. The social historian and theoretician of medicine John A. Pickstone (2000) describes the second half of the twentieth century as a period marked by a shift from "biographical medicine" to "techno-medicine." In his view, traditional biographical medicine saw disease primarily as a malfunction of individual life and the treatment model centered on the doctor-patient couple. During the twentieth century, the emphasis gradually shifted towards "the power of 'the medical gaze' that has moved deeper and deeper into body structures – from surface anatomy, through X rays to intrabody physiology and now to genetics" (Webster 2002: 445). Arthur Frank (1997) describes how, particularly in hospital, he experienced being treated as though his life (his feelings, his fears and concerns and his own views about the illness and treatment) were unconnected with the object of the doctors' attention.

The result was an increase in the numbers of diagnoses, of medical drugs prescribed and developed, and of medical specializations. The medical discourse also managed to spread into a number of fields from which it had previously been absent: genetic testing and neuroimaging techniques have had an impact on the justice system, modern sexology and assisted reproduction have become far more present in the sphere of intimate life and questions of nutrition are increasingly framed in scientific terms. On the other hand, the differentiation carries on alongside the ever-louder criticism of the dehumanization of medical care. We have seen the creation of many patient self-help groups, there have been various patient empowerment initiatives (such as the antipsychiatry movement) and alternative treatments based on a holistic approach to the body and disease are steadily gaining in popularity, while simultaneously broadening their offer (Scambler 1997: 35-46).

From the perspective of cultural self-understanding of modernity, Rosa (2013: 175) argues, the on-going dynamization is not a matter of adaptation to external forces, but rather an

moment of self-determination. The unfolding of the economic or organizational dynamics is the result of a specific cultural constellation of needs or historic mentality. Carlos Novas (2006) shows how contemporary biomedicine has been driven by interlinking hopes of many different types and of diverse actors: the hope of patients and their families for effective treatment; the hope of those managing health services that are able to minimize the impact of common disorders such as stroke or cancer; the hope of those with a family history of genetic disease for their children; the hope of us all for an old age not marred by Parkinson's or Alzheimer's disease; the hope of the pharmaceutical industry and biotech companies for treatments that will generate increased profits and shareholder value; the hope of scientists and researchers for career advancement and fame. In sociology of medicine, the idea of "hope technologies" was introduced by Sarah Franklin in the context of her study of assisted reproduction (Franklin 1997). The maintenance of hope has become a crucial element, as Novas elaborated, not merely in the reproductive technologies, but more generally within the care for patients with cancer and other life-threatening illnesses.

Anthony Giddens (1997) argues, that contemporary culture is marked by a much more intense future-orientation than before. A society where we live on a high technological frontier generates a diversity of possible futures. "The self is seen as a reflexive project, for which the individual is responsible. We are not what we are, but what we make of ourselves" (Giddens 1991: 75) The self is a kind of developmental trajectory leading from the past to the anticipated future. Nikolas Rose (2007) argues that individuals in advanced liberal democracies are enjoined to think of themselves as actively shaping their life course through acts of choice in the name of a better future. Individual are active constructors of their life and biological determination is not accepted as fate. An ethic organized around the ideals of health and life, Rose concludes, produces anxiety, fear or dread at what one's biological future might hold. "But while this may engender despair or fortitude, it frequently also generates a moral economy in which

ignorance, resignation, and hopelessness in the face of the future is deprecated. At least in part, fears and anxieties about morbidity and mortality are being reframed within an ethos of hope, anticipation, and expectation." (Rose 2007: 27) Generally speaking, in modern societies, individuals are supposed to take their biological fate in their hands, and, vis-a-vis, they expect the state regulation will not hinder their self-determination.

Hartmut Rosa's (2013) three motors of acceleration give us a realistic account for evaluating current trends in healthcare. They urges us to see them not only driven by economic factors but rather a combination of economic and technological factors, organization structures and societal expectations. Indeed, three motors of acceleration interfere and reinforce mutually each other. Adrian Kay (2000) notes that the intellectual underpinnings of dynamic remains unexplored in the public policy theory literature. I argue that pharmaceutical policies are good candidates for this kind of examination. Pharmaceuticals have played a crucial role in the healthcare acceleration process and have been among its most important drivers. As Adriana Petryna and Arthur Kleinman (2006) argue: "Worldwide, images of well-being and health are increasingly associated with access to pharmaceuticals." In their view, the pharmaceutical drug has become one of the synonyms of modern medicine. One Czech physician summarizes this approach as: "Disease is something that can be treated with an existing drug."

The reason why I have decided to study the Czech pharmaceutical policy is fundamentally theoretical one. I do not intend to provide any policy recommendation and I do not even intend to contribute to the pharmaceutical policy literature. The dissertation seeks for unpacking a discourse dynamic in policy-making. For Paul Pierson (2004: 2) the key to temporal analysis is: "systematically situating particular moments (including the present) in a temporal sequence of events and process stretching over extended period." I argue that this temporal sequencing is based upon narrative thinking. The purpose of narrative is to render various series of events into an intelligible whole. Narrative structures a past to create present and future.

Narrative approaches belong to a broad segment of constructivist traditions studying a role of language in public policy. The study of language in public policy reminds us how naming, labeling and ascribing particular meanings or identities are deeply political acts (Bessant, Watts, Dalton, Smyth 2006: 305). It also helps us to see that challenging the meaning given to something or someone offers critical insights for disputing particular ways of seeing – how issues are framed. Problem definition is a process that involves attributing cause, blame, and responsibility. "Causal stories have both an empirical and a moral dimension. On the empirical level, they purport to demonstrate the mechanism by which one set of people brings about harms to another set. On the normative level, they blame one set of people for causing the suffering of others." (Stone 1989: 283)

By following literature (Hajer 2009; Fischer and Gottweis 2012) that recognizes the importance of language in policy making I might be able to "to infer under what conditions a variety of voices emerges in political discussions, how the different contributions can be related to one another in a meaningful way, how conflicts are expressed, and under what conditions such statements can be made with influence on the actual decision making" (Hajer 2009: 66). From the interpretative point of view, politics is seen as a sequence of staged events in which actor interact over the meaning of events and over how to move on. Policy narratives, therefore, present a way how past is recollecting and enacting to construct future expectations. Although policy-making might be regarded as a process involving rent seeking or others form of strategic manoeuvrings, actors still need to legitimize their position and publicly win their cases (Lodge and Wegrich 2011). Paul Pierson (1994, 2001, 2004) identified two sources of limiting success of policy reforms: (1) the electoral incentives associated with retain broad and deep popular support and (2) the institutional stickiness which further constraints the possibilities of policy implementation. Taking discourse elements in consideration the thesis explores predominantly the first source of limitation.

In the effort to further conceptualize the narrative backgrounds of pharmaceutical policies two discourse concepts are discussed: health promises and fiscal limits. The idea of *medicalization* – one of the key sociological themes of the second half of the twentieth century – which is described in chapter 3. The chapter intends to discuss the concept in relation to other notions associated with the lifestyle changes proper to late modern societies – namely the concept of *governmentality*, which expands on the ideas of Michel Foucault (see e.g. Dean 2010, Rose 2007). In addition, I would also like to present the main revisions of the medicalization argument. These will then be used to further elucidate by taking three specific drugs as examples – Prozac, Paxil and Viagra.

However, acceleration of healthcare is not the only dynamics in the field, pharmaceutical policies have been under budgetary pressure in the most democratic and developed countries since 1980s due to the combination of ageing population and acceleration of healthcare development. The fiscal pressure has produced a series of public policy dynamics, which might be seen as contradictory to the innovation dynamics. The discourse genealogy of budget responsibility is described in chapter 4 of my thesis. Even though the concept of austerity as a form of voluntary deflation in which the economy adjust through the reduction of wages, prices, and public spending to restore competitiveness (Blyth 2013: 3) has been broadly discussed since the economic crisis burst, its history has begun much earlier. Following Mark Blyth (2013), the chapter introduced austerity as a fundamental concept of the modern state. "Austerity is not well worked-out body of ideas and doctrine, an integral part of economic, or any other theory. Rather, it is derivative of a wider set of beliefs about the appropriate role of the state in the economy that lie scattered around classical and contemporary economic theory." (Blyth 2013: 23) According to Paul Pierson (2002), the developed states face a context of a permanent austerity. Caught between the rising expectation of citizens, resilience of welfare programs and a context of permanent austerity, the politics of reform have generally centered

on efforts to construct broad coalitions in support of restructuring rather than dismantling of mature welfare states.

However, both the medicalization concept and the permanent austerity concept can be seen as future-oriented ones. Whereas the medicalization discourse can be identified with the politics of hope, the austerity revolves predominantly around the politics of cautious. In the first one, promises of modern technologies and medicines give a rise of dream that policies is supposed to follow. The austerity discourse constructs a nightmare - a possible future that politics try to avoid. The both discourses reveal two fundamental concept of future in modern societies - promises, in the first discourse, and risks, in the second one.

With respect to the existence of both discourses, pharmaceutical policies are facing two demands: maximizing health benefits and minimizing waste of public funds. In chapter 5 it is demonstrated how are these two identities reflecting in sustainability narratives in health policies. These two identities represent different values and rationalities and there is an ineluctable conflict between them. The tendency of doctors to overused medicines because of they do not take costs in consideration and the monopoly that pharmaceutical companies enjoy in the production of medicines under patent protection are both long-standing justification for pharmaceuticals public policy reduce to price of medicine (Bloom and Van Reenen, 1998). Regulation is justified that the uncontrolled marketplace forces fail to produce behaviour or results in accordance with the public interest. (Baldwin at al 2012: 15) It is needed to bear in mind that the field of pharmaceutical policies is complex and involves a dynamic interplay among multiple actors – government and it agencies, patients, physicians, pharmacists and producers and distributors of pharmaceuticals. Mossialos, Mrazek and Walley (2004: 2) argue that many of trade-off, market structures and regulations what we can find in this area do not exist for other industrial sector. "The pharmaceutical markets are unique with regard to the extent and depth of its failure to meet criteria for perfect market. There are market imperfection in both supply

(generally related to patent protection, the process and length of regulatory approval and brand loyalty) and demand sides (there is a four-tiered structure of demand where the physician prescribes, the pharmacist dispenses, the patients consumes and a third party pays." (Mossialos, Mrazek and Walley 2004: 2)

Following my discursive oriented approach I intend to classify, chart, and compare argumentation and narrative patterns along lines of public interest where facts, norms and discourses are translated, private interests where motivation of actors are revealed, institutional logic of external constraints and values that covers general patterns of blame and proposed remedies. The analysis of argumentation involved the extraction of claims that demanded particular types of regulatory action, and coding these claims according to their frames (Lodge, Wegrich, and McElroy 2010; Lodge and Wegrich 2011). I map alternative and competing conceptions as constructed by key stakeholders in health policy networks, and explore how these narratives are modified and deployed in the process of forming storylines to promote particular policy solutions. The Czech Republic is an ideal case for this study because the regulation paradigm is still unfolding, with a great deal of debate. This enables me to generate a 'real-time' understanding of shifting narratives and alliances in a relatively fluid policy space. Particularly, I am interested in roles of rules-based hierarchical codes and incentives-based individualist codes in justification of regulations narratives.

In European Union, variety of regulatory pharmaceutical policies is used to try to balance effective spending on pharmaceutical against the need to promote an innovational industry. In chapter 7, I will introduce the regulation of pharmaceutical law in European Law and description of some influential examples of regulatory approaches of particular member states are provided. This context is necessary for claiming framework within the regulatory policies of individual states are creating in terms of the both hard power of European legislation and the soft power of policy transfer on the level of state policies. The historical context of the Czech

health policy is described in chapter 8. Until the fall of communism in 1989, the Soviet Semashko model health care provision existed in the former socialist countries of Central and Eastern Europe. It was based on a centralized, tax-based, health care system with physicians as state employees. After the fall of communism in 1989, the Czech health care system had to deal with the legacy of the communist regime such as an oversupply of beds, a hierarchical organizational structure and a shortage of modern technologies. Between 1990 and 1994, the first period of transformation focused mostly on basic market oriented reforms such as setting a pluralistic public health insurance model, the investment in technology and improving health facilities. This period resulted in a growth of total health care expenditures. In the context of accession to the European Union in 2004, reforms of public administration and the transpositions of *acquis communautaire* were done.

Although pharmaceutical regulation had changed significantly in the two decades following the fall of communism, the biggest reform changes were proposed after the parliamentary elections in 2006. The Czech reform plan corresponded with a shift from a social democratic state paradigm to a neoliberal paradigm in health care provision. Whereas, in the social democratic state, services are allocated on the basis of need, the consumer, in the neoliberal state, accesses services via the market as a self-responsible, risk-averse and rational actor (Harley et al. 2011). The economic downturn, however, has made the need to change the funding of health care more urgent and it has accelerated a shift towards more budget restrictive policies. We can observe many diverse ways by which governments attempted to deal with the challenges of the financial crisis by reducing the costs of health care. To cut, reduce, or otherwise dismantle policies that were adopted in better times is a potentially unpopular measure. Thus, it is important to examine under which conditions politicians choose to do this and the strategies that they employ to avoid being blamed for the cuts. These health reforms were

based, among other measures, on the introduction of flat user fees and an increase in patient co-payments.

The reforms were stopped in Autumn 2008 when the opposition Czech Social Democratic party clinched a landslide victory in a regional election, which crowned its campaign against government health reforms. Because of the main topic of the campaign the media dubbed the election as a referendum on a health care. The reformists lost significantly. Why was the governmental discourse of controlling healthcare costs, driven by a combination of arguments relating to resource scarcity, the ageing of the population and patient responsibility, strongly refused by a broad public? The following analysis intends to serve as what Lijphart would recognize as a hypothesis-generating case study that "starts out with a more or less vague notion of possible hypotheses, and attempts to formulate definite hypotheses to be tested subsequently among a larger number of cases" (Lijphart 1971: 692)

CHAPTER 1: THEORIES OF REGULATION

When one speaks about regulation usually refers to *sustained and focused control* exercised by a public agency, on the basis of a legislative mandate, *over activities that are generally regarded as desirable to society* (Selznick 1985:363–4). Philip Selznick's notion of regulation as sustained and focused control implies that regulation is not achieved simply by passing a law, but requires detailed knowledge and deep involvement with, the regulated activity providing by independent public institution which has been established on the basis of a legislative mandate. The reference to socially desirable activities excludes issues which are dealt in the criminal justice system and it also suggests that in terms of market, only activities considered as worthwhile in themselves and hence in need of protection and control are regulated. (Majone 1996: 9) Although this definition is widely used and it has been developed in theories of regulatory state, it is, in the same time, heavily criticized mostly for excluding a broad variety of different forms regulatory behavior.

Also Baldwin, Cave and Lodge (2012: 3) suggest to think of the word regulation being used in the different senses than Selznick's narrow definition: (1) as a specific set of commands--where regulation involves the promulgation of a binding set of rules to be applied by a body devoted to this purpose; (2) as deliberate state influence--where regulation covers all state actions that are designed to influence business or social behavior which might be based on sets of command as well as the use of economic incentives (e.g. taxes or subsidies); contractual powers; deployment of resources; franchises; the supply of information, or other techniques; (3) as all forms of social or economic influence--where all mechanisms affecting behavior--whether these be state-based or from other sources (e.g. markets)--are deemed regulatory; and (4) as an activity that restricts behavior and prevents the occurrence of certain undesirable activities (a 'red light' concept).

John Braithwaite (2008: 1) understands it as *a large subset of governance that is about steering the flow of events, as opposed to providing and distributing*. The broad definition of regulation is also used by Christopher Hood and his colleagues (2001) considering regulation as any control system in art or nature which contain a minimum of the three components: (1) capacity for standard setting to allow a distinction between more or less preferred states of the system; (2) capacity for information-gathering or monitoring to produce knowledge about current or changing states of system; and (3) capacity for behavior-modification to change the state of the system. (Hood et al. 2001: 23)

Morgan and Young (2007) divide theories of regulation into three main categories: (1) public interests theories, (2) private interest theories, and (3) institutionalist theories. *All three categories have in common a concern to uncover the processes that lead to the adoption of a particular regulatory regime*. (Ibid: 16)

PUBLIC INTEREST THEORIES

Public interest theories of regulation attribute to legislators and others responsible for the design and implementation of regulation a desire to pursue collective goals with the aim of promoting the general welfare of the community. Those theories suggest that regulation is a response to imperfection in the market known as market failures. "Regulation in such cases is argued to be justified because the uncontrolled marketplace will, for some reason, fail to produce behavior or results in accordance with the public interest." (Baldwin et al 2012: 15)

Inevitable, the crucial point for all public interest theories is definition what should be counted as a public interest. A regulation takes place amidst of clashing images of different public interests. We can distinguish three major theoretical streams identifying a role of public interest in regulatory attempts: (1) welfare economics approach, (2) exogenous value approach, (3) procedural political approach.

WELFARE ECONOMICS APPROACH

This economical approach to public interest theory simply suggests that regulation is a response to imperfections in the market known as market failures. Consequently, regulatory policies should just increase the efficiency of a market, but should not result in distributive consequences beyond this. This approach implies that governments intervene to correct deficiencies in the allocation of resources and the consequent loss of social welfare. A literature has developed on market and transactions failure and has identified a large number of potential problems associated with the operation of the market mechanism. A number of potential failures in markets have been identified.

Majone (1996: 27-28) speaks about monopoly power, insufficient information to consumers, and inadequate provision of public goods. Anthony Ogus (2004) mentions four types of behavior which public should be protected from: (1) monopoly behavior, (2) destructive competition, (3) the abuse of private economic power, and (4) the effect of externalities. Baldwin et al (2012: 15-24) provide a very extensive list of market failures rationales including following events: monopolies and natural monopolies,¹ windfall profits,² externalities,³ information inadequacies,⁴ continuity and availability of service,⁵ anti-competitive behavior and

¹ Natural monopoly occurs where it is less costly to society for production to be carried out one firm, rather than several or many. However, the undesirable consequences such as overpriced goods arise equally to other kinds of monopolies; the remedy does not lie in competition. Thus, rather than have three railway or electricity companies laying separate networks of rails or cables where one would do, it may be more efficient to give one firm a monopoly subject to regulation of such matters as prices and access to the network. (Baldwin et al. 2012: 15-17)

² A firm will earn a windfall profit (sometimes called an 'economic rent' or excess profit) where it finds a source of supply significantly cheaper than that available in the marketplace. Regulation may be called for when it is desired either to transfer profits to taxpayers or to allow consumers or the public to benefit from the windfall. (Baldwin et al 2012: 17)

³ The reason for regulating externalities is that the price of a product does not reflect the true cost to society of producing that good and excessive consumption accordingly results. (Baldwin et al 2012: 18)

⁴ The market may fail to produce adequate information and may fail for a number of reasons: information may cost money to produce, the producer of information may not be compensated by others who use that information, there may also be incentives to falsify information, the in-

predatory pricing,⁶ public goods and moral hazards,⁷ unequal bargaining power,⁸ scarcity and rationing,⁹ rationalization and coordination¹⁰ and planning.¹¹

Bloom, Standing and Loyd (2008) summed up several arguments for why markets alone cannot produce the most efficient or equitable allocation of scarce resources in health and require state intervention: (1) health care includes 'public goods', such as sanitation, which would be undersupplied if left to the market; (2) some health care goods, such as immunization, have positive externalities in that an individual's consumption confers benefits on others; (3) markets will lead to under-insurance against risks of major health expenditure; (4) markets cannot compensate for inequalities in access to health resources; (5) health care markets are characterized by high levels of uncertainty.

formation produced may not be of sufficient assistance to the consumer or collusion in the market-place may reduce the flow of information below. (Baldwin et al 2012: 18-19)

⁵ The market may not provide the socially desired levels of continuity and availability of service. Regulation may be used to sustain services through troughs--for example, by setting minimum prices at levels allowing the covering of fixed costs through lean periods. (Baldwin et al 2012: 19)

⁶ Markets may produce undesirable effects because firms behave in a manner not conducive to healthy competition. A principal manifestation of such behavior is predatory pricing. This occurs when a firm prices below costs, in the hope of driving competitors from the market, achieving a degree of domination, and then using its position to recover the costs of predation and increase profits at the expense of consumers. (Baldwin et al 2012: 19-20)

⁷ The market may fail to encourage the production of services where the exclusion of free-riders is very costly and regulation may be required. Similarly, where there is an instance of moral hazard - someone other than the consumer pays for a service --there may be excessive consumption without regard to the resource costs being imposed on society. (Baldwin et al 2012: 20)

⁸ If bargaining power is unequal, regulation may be justified to protect certain interests. Thus, if unemployment is prevalent it cannot be assumed that workers will be able to negotiate effectively to protect their interests, and regulation may be required to safeguard such matters as the health and safety of those workers. (Baldwin et al 2012: 20)

⁹ Regulatory mechanisms may be justified to allocate certain commodities when these are in short supply. (Baldwin et al 2012: 21)

¹⁰ When it is extremely expensive for individuals to negotiate private contracts so as to organize behavior or industries in an efficient manner--the transaction costs would be excessive, regulation may be justified as a means of rationalizing production processes (perhaps standardizing equipment to create effective networks) and in order to coordinate the market. (Baldwin et al 2012: 21)

¹¹ Markets may not be able to meet the demands of future generations or to satisfy altruistic concerns (e.g. the quality of an environment not personally enjoyed). (Baldwin et al 2012: 21-22)

Substantial evidence shows a range of market failures in terms of pharmaceuticals. Diseases that affect a large proportion of the world's population have been neglected in drug development. Where treatments are available for disorders, drugs are unaffordable for those who need them most. Price competition between patented products is weak and pharmaceutical companies have featured prominently in antitrust court actions.

There is also a long history of debate about the degree to which the health sector is different from other economic sectors. In particular, economists argue that health care markets have inherent structural features that lead to market failures. Kenneth Arrow (1963) recognized that medical care markets are characterized by extremely high levels of uncertainty. Under conditions of uncertainty, accurate information becomes a very valuable commodity. Consequently, an elusive character of information limits its marketability on both the demand and supply sides of the market. "Because medical knowledge is so complicated, the information possessed by the physician as to the consequences and possibilities of treatment is necessarily very much greater than that of the patient, or at least so it is believed by both parties. Further, both parties are aware of this informational inequality, and their relation is colored by this knowledge" (Ibid: 951). According to Arrow, patients' uncertainty about the effectiveness of medical treatments, the informational inequality between patients and physicians, and the imperfect marketability of information provided by physicians would result in market failure.¹²

¹² From the perspective of sociology of medicine, the phenomenon of informational asymmetry was described by Eliot Friedson (1970). He suggests that more social resources have become directed towards illness, and the medical profession's power increased markedly, with little scope to question its activities or use of resources. Power of medical practitioners stemmed from their professional status and autonomy maintaining by their control over medical knowledge. Laws prohibiting patients from obtaining certain classes of drugs without a doctor's prescription increase dependence on physicians. "The more strategic the accessories controlled by the profession, the stronger the sanctions supporting its authority." (Freidson 1970)

EXOGENOUS GOALS APPROACHES

This approach is based on assumption of the existence of values other than economic efficiency and it relies on an assumption that political system define the content of collective agreement on certain ideas about what counts as good in political, economic and social life (Morgan and Young 2007: 36). The claim of common interest itself requires substantiation by leaders against the degree to which regulatory intervention match the substantive goals of the society. Even Anthony Ogus (2004) associating social regulation with market failures also accepts that it has a range of non-economic goals.

Cass Sunstein (1990) discusses a range of non-economic substantive goals justifying regulatory intervention shored up in constitutional tradition: (1) public interested redistribution, (2) reducing social subordination, (3) promoting diversity of experience, (4) preventing harm to future generation, (5) embodying collective desire and (5) shaping endogenous preferences. "Ideally, a fuller perception would account for the distinctive character of law in modern liberal democracies ... acknowledge the inevitable role of background [constitutional] principles in the interpretative process; and use the process of interpretation as a corrective, albeit a partial one, against the occasional pathologies of regulatory legislation" (Sunstein 1990: 9-10) Drawing on ideas associated both with the liberal republican tradition that lies the center of the American constitutional order and with the New Deal and the Great Society programs Sunstein sympathetically portrays the reason of regulation. He defends the use of background principles by disaggregating their various functions and by suggesting that the use of such principles is desirable and in any case inevitable (Sunstein 1990: 9).

Black (2000) would describe it as a thin conception of proceduralization would thus involve participation in which preferences remained exogenous and unchanged, and which was discourse-less. Regulation relies on preconceived norms that are embedded in broader political

culture, constitutional principles or aggregated in electoral system and they are interpreted by particular institutions.

PROCEDURAL POLITICAL APPROACH

Deliberative political processes might be attempting to avoid prescribing the substantive political goals or values which regulation should prescribe. "There are certain constraints placed on regulatory procedures in this view of regulation, and these constraints, by minimizing the effects of power inequalities, give regulation a 'public interest' flavor without specifying the substantive goals that justify regulation." (Morgan and Young 2007: 37) Tony Prosser (1986) suggests that a concept of *ideal speech act* developed by Jurgen Habermas (1984) provides a standard which can be used to criticize the processes within a particular regulatory regime.

"Habermas argues that any smoothly functioning communicative interaction rests on implicit consensus in which various claims are mutually accepted; the claims include the truth of assertion and the correctness of norms referred to in speech. If the consensus breaks down through challenge to the claims, it can only be restored through testing their truth of correctness through discourse, a special form of communication shaped only by the force of the better argument." (Possner 1986: 34)

According to Habermas, this ensures that norms are based on generalizable interests rather than being imposed by the powerful. Possner translated the abstract criteria of ideal speech situation into two concepts more familiar for lawyers and political scientists: (1) participation and (2) accountability. While participation should guarantee an ideal of the widening debate to encompass a range of affected interests and a range of accessible information, accountability should guarantee the development of procedures and arenas through which reasons and explanation for action are demanded.

PRIVATE INTEREST THEORIES

Private interest theories of regulation are based on an assumption that regulation emerges from the actions of individuals or groups motivated to maximize their self-interests (Morgan and Yeung 2007: 43). According to these theories, promoting the public interest is seen as a coincidence and any connection between regulation and the public interest is a contingent one. In 1960s, most scholars studying group politics reached the conclusion that narrow business interests typically prevailed in regulation making and the agenda was concerned with issues of regulatory failure (Moran 2002). One of the earliest accounts to address the issues of independence and capture came in Bernstein's theory of an evolutionary life of agencies. Marver H. Bernstein (1955) depicted a life cycle of regulatory agency as characterized by ageing process from original enthusiasm to act in the public interest to the stage when vitality declines and the agency giving a priority to protect industrial rather than public interests. Even though initially infused with a radical spirit agencies developed close relations with the regulated industry with maturity; and in the end they are captured by the industry. Bernstein delineated four stages: (1) *gestation*; (2) *youth*, (3) *maturity* (the process of devitalisation); and (4) *old age* (debility and decline). When the agency enters its mature phase: "it is unlikely that the commission, in this period, will be able to extend regulation beyond the limits acceptable to the regulated groups...The commission loses vitality...Its goals become routine and accepted...Perhaps the most marked development in a mature commission is the growth of a passivity that borders on apathy. There is a desire to avoid conflicts and to enjoy good relations with the regulated groups." (Bernstein 1955: 87-85)

As Possner (2013) points out, one cannot fully associate ossification and bureaucratization with a capture by business groups. "If regulated firms have the political or organizational resources to take control of the regulators and turn them against their original mission, why couldn't they have shaped the regulatory scheme at the enactment stage? And if they could not

do this but could capture the regulatory agency after the agency began to age and weaken, why couldn't the intended beneficiaries of the regulation, who had had enough political muscle to obtain it in the first place, recapture the agency?" (Possner 2013: 4) David Martimort (1999) finds an answer for these questions in relation to trust and transaction costs. He argues that over time the agency and the regulated industry obtain enough information about each other to be able to exchange favors without excessive danger of being cheated by the other party to the collusive arrangement.

In line with this critique, Murray Edelman (1964) dismissed all government attempts to regulate business as a symbolic politics supplying citizens with a pleasant myth rather than tangible benefits. The subversion of regulatory agencies by the firms they regulate is usually referred by the term of *regulative capture*. According to Abraham (2002), regulatory capture is important especially in pharmaceutical industry because the assessment of drugs has a higher degree of technical uncertainty inherent to toxicology, clinical trials, and epidemiology.

George Stigler argues that: "Regulation may be actively sought by an industry, or it may be thrust upon it ... as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit" (Stigler 1971: 3) Consequently, manners of regulation is mainly about degrees of capture to what extent collective actors are able to promote and defend their interests. Stigler's approach is based on two key assumptions: (1) the firms in any given industry are fewer in number than the person outside of industry, therefore, per capita gains to them are likely to be high, whereas the more numerous individuals or firms bearing the burdens of reduced competition will pay only a small capita cost; (2) government officials are rationally self-interested; they will seek to maximize their votes or their wealth or both. Most citizens are largely uninformed about most regulatory decisions and they lack incentives to become sufficiently informed whereas interest groups do monitor legislators punishing those who fail and rewarding those who provide favourable regulation. Public choice theory of regulation stems

from that position and argues for increased reliance on markets rather than on government regulation.

Braithwaite (1986) describes *revolving doors* as a different mechanism of capture. His term refers to particular organizational culture in which people begin their careers as regulators, but then move on to join industry, or start their professional life in industry, then work for some years for the regulatory body until they take a better position in industrial field. It might contribute to bring industrial values into regulatory field and to maintain friendly relation between regulators and industry. Lexchin (1990) characterizes this closeness as clientele pluralism in which regulators give up some of its responsibilities to industry.

Abraham (2002) points out that even in the US drug regulatory agency (the FDA) that operates in a relatively transparent environment dependent on legislative oversight by Congress and judicial review many senior regulators with a background in industry could bring values to the agency which are sympathetic to pharmaceutical companies. "In 2001, an internal inquiry into the view of regulatory staff at the FDA's Centre for Drug Evaluation and Review reported that a third of respondents did not feel comfortable expressing their scientific opinion, with some reporting pressure to favor the wishes of manufacturers over the interest of science and public health, and receiving requests from senior agency officials to alter their opinion." (Abraham 2002: 1498)

On the contrary, Daniel Carpentier (2013) elaborates on the possibility of regulatory capture at the Food and Drugs Administration and its potential mechanisms in the United States. He concludes that until the late 1990s, there is little strong evidence of systematic or widespread capture of the FDA by the American or global pharmaceutical industry. "To the extent that capture exists in American pharmaceutical regulation, it is certainly weak capture and not strong capture ... Some corrosion may have occurred – although the evidence support-

ing these vague claims is impressionary and far from robust – and yet, the plausible corrosion functions much like the exception that proves the rule." (Carpentier 2013: 26)

Alongside with the pessimist capture theory, the optimist neopluralist theory of private interest in regulation occurred in 1970s. Instead of the existence of one dominant group that is able to capture a regulatory process one can speak about existence of countervailing group forces. "A winning group will gain only up to the point where an opposition group will exert enough resistance to limit the winner's gain." (Croley 1998 in Morgan and Yeung 2007: 45) According to Croley (1998), group success is constrained in two ways: (1) the costs of mobilizing, communicating their cause to regulatory decisions, and providing legislators with electoral success, and (2) competition from rival groups with incompatible regulatory preferences. Croley also points out that the neopluralist theory reflects better than the capture theory the situation after 1970s when the proliferation of consumer and environmental groups increased interest-group competition in regulatory politics and made regulatory rent-seeking by business group much more difficult.

James Q. Wilson's work (1980) on 1970s and 1980s US policy making when the consumer and environmental movement emerged led him to classify policy proposals for regulatory intervention according to the distribution of their cost and benefits perceived by the involved parties. Wilson took both economic and non-economic parameters in consideration and delineated four types of politics: (1) client politics, (2) interest groups, (3) majoritarian and (4) entrepreneurial.

Tab 1: Wilson's variants of the origin of regulatory policies

		Costs of regulation	
		Concentrated	Diffused
Benefits of regulation	Concentrated	Interest groups politics <i>Two or more interest groups in conflict over agency goals</i>	Client politics (capture) <i>Dominant interest group favorable to agency goals</i>
	Diffused	Entrepreneurial politics <i>Dominant interest hostile to agency goals.</i>	Majoritarian politics <i>No important interest group continuously active</i>

Client politics can be associated with the explanation of origins of regulation by industrial capture. "Some small, easily organized group will benefit and thus has a powerful incentive to organize and lobby; the cost of the benefits are distributed at a low per capita rate over a large number of people, and hence they have little incentive to organize in opposition - if, indeed, they even hear of the policy." (Wilson 1980: 369) Giandomenico Majone (1996: 77) using Wilson framework in order to classify European regulatory policies names oligopolistic firms in the car, electronics, chemical or pharmaceutical industries as examples.

Entrepreneurial politics may be proposed in the situation when general and small costs will be borne by small segments of society. "Since the incentive to organize is strong for opponents of the policy but weak for the beneficiaries, and since the political system provide many points at which opposition can be registered." (Ibid: 370) Passing of such regulation requires the effort of skilled entrepreneurs who can mobilize latent public sentiment. Majone (1996: 77) points out the importance of capitalizing on crisis which put the opponents of regulatory measures on the defensive and associate the legislation with widely shared values – clean air and water, health and safety, equal rights for men and women. German decision made in the wake of the Fukushima-disaster to phase-out nuclear power until 2022 can be also considered one of examples of such politics.

Interest groups politics was the most appropriate in the situations in both costs and benefits are narrowly concentrated and each side has a strong incentive to organize and exercise political influence. "The public does not believe it will be much affected one way or another; though it may sympathize more with one side than the other, its voice is likely to be heard in only weak general terms." (Wilson 1980: 368) According to Majone (1996: 76), European structural policy can be a pertinent example. "Although the structural funds aid some industrially declined region in the wealthier countries, the overall effect of the policy is transfer resources from one well-defined group of contributing countries to another equally well-defined group of receiving countries. (Majone 1996: 76)

When both costs and benefits are widely distributed, Wilson expects to find *majoritarian politics*. "Interest groups have little incentive to form around such issues because no small, definable segments of society (an industry, an occupation, a locality) can expect to capture a disproportionate share of burdens. Not all measures that seems to offer a net gain to popular majorities are passed: proposals must first get onto the political agenda, people must agree that it is legitimate for the government to take action, and ideological objection to the propriety of feasibility of the measures must be overcome. (Wilson 1980: 367) Majone mentions social security, national health care or education as examples of such politics in Europe. "In the European context this means that the issues dealt with at the national rather than at supranational level. Hence traditional social policy remains under the control of member states." (Majone 1996: 76)

Elaine Sharp (1994) argues that tracing a given issue over time, one finds that its place in the Wilson typology may change with policy proposals and associated perceptions of costs and benefits, and as the number and character of organized interests in the policy domain. During policy-making process, the discussion about politics with diffuse cost and benefits might be being focused on some areas only where cost and benefits are much concentrated and competi-

tion between policy actors emerges. Consequently, the politics might shift from majoritarian towards interest groups.

Permanand and Mossialos (2007) use Wilson's matrix to describe European pharmaceutical regulatory framework. The on-going pricing and reimbursement debate fits to the scenario of majoritarian politics. The diffuse nature of the cost and benefits involved in harmonization of pricing and reimbursement is reflected in the disparate views and reaction of stakeholders. Demographic differences, disparities in income, cultural factors, and differing of health care system led to country-specific strategies. Industry opposes an EU pricing regime on the basis that it may affect profits; member states fear limitation on their ability to organize and finance their own health systems; and consumers are worried that harmonization would mean an increase in prices. Hence there is a little reason for the stakeholders in pushing a single agenda.

The Supplementary Protection Certificate extending patent protection on medicines is considered as an example of client politics because of the extent to which the industry perceived it would benefit. The costs of patent protection were being spread among the national governments and insurance funds and consumers and the benefits are only to be derived by the research driven companies. Examples relevant to entrepreneurial politics were found by Permanand and Mossialos in the regulation of the content of regulation of information leaflets and packaging. In this case, it was the European Commission who sought and ultimately secured agreement. The different example might be also support for generic substitution.

INSTITUTIONAL THEORIES

Scholars apply a number of distinctions between different approaches towards institutionalism - old and new economic institutionalism, historical, normative, constructive or discursive. The chapter, however, concentrates on three strains in the institutionalist literature in relation to regulation: (1) inter-institutional relations (regarding institutional design questions),

(2) intra-institutional forces (regarding evolution of regulatory regimes over time) and (3) network and regulatory space understanding of regulation. (Baldwin et al 2012: 53)

Inter-institutional relations

According to Baldwin et al (2012), the central concern of inter-institutional relations literature is the question of delegation - why should be the authority for regulatory activity delegated from one institution to regulatory agencies and who guards whom. More specifically, the question is related to three key issues: (1) credible commitment, (2) information asymmetry, and (3) blame avoidance.

The *credible commitment* problem refers to any human exchange in which a promise regarding behaviour in the future is potentially open for renegotiation, thus it is needed to signal a 'good' regulatory environment. "[A] legislature cannot bind a subsequent legislature and a majority coalition cannot bind another, so that public policies are always vulnerable to renegeing and hence lack of credibility. In a such situation, delegation to an extra-governmental agency is one of the most promising strategies whereby governments can commit themselves to regulatory policy strategies whilst maintaining political credibility." (Majone 1996: 4) With the delegation of regulatory competencies to the Commission and the European regulatory agencies, the individual member states can commit themselves to following long-term interests in appropriate regulation instead of the economic short-term interests of their domestic industry. According to Majone (1996), one way to make this commitment credible is to delegate the matter to an agent, institutionally independent from Member States' interests.

If delegation solves the credibility problem, it simultaneously creates another – how regulatory agencies' exercise of power is to be democratically controlled. *Information asymmetries* make the control over delegated actors and their accountability limited, since not all possible states of the world can be predicted, all contracts are incomplete, and monitoring is costly and imperfect. Indeed, such imperfections allow for discretionary activities or drifts. In the case

of politicians and these drifts are related to the chances of reelection; in the case of bureaucrats the drifts might be connected with the prospect of shifts to more lucrative careers outside within the regulated industry, risk avoidance or eliminating of work load. Niskanen's (1974) analysis of budget maximizing bureaucracies avoiding political oversight and seeking to expand power defined as size of budget might be an example of such a drift.

Fiorina (1982) argues that political actors would delegate tasks where these were politically embarrassing or damaging; but keep those tasks where political opportunities costs were positive; they try *to avoid blame*. Although the "shift the responsibility" rationale continues to be widely accepted, Murrey Horn (1995) criticizes some shortcomings of this approach. The shift of responsibility assumes that legislators can avoid their responsibilities by delegating decision making to administrators and that constituents will forgive legislators for costs imposed by their administrative agents. Horn opposes that the best strategy of the rationally ignorant may well be to judge their representatives on the basis of outcomes and not try to apportion blame. The model of blame shift, thus, works only when the lines of responsibility are unclear.

Murray Horn (1995) summarizes the institutional design literature into four dimension: (1) decision-making costs (opportunity costs incurred by those taking political decision); (2) commitment costs (potential costs that a future generation of policymakers will be likely to incur in reversing an initial decision); (3) agency costs (expenses in monitoring a regulative authority); and (4) uncertainty cost arising from the genuine uncertainties.

Intra-institutional relations

The unifying core of inter-institutional literature lies in its interests in regulatory changes driven by forces coming from within organizations. The widely proclaimed importance of path dependence matters. According to Baldwin et al., four lines can be distinguished: (1) gradual institutional change, (2) perversity, and (3) self-referential approaches.

Following Mahoney and Thelen (2009), we can delineate four modal types of gradual institutional change: displacement (the removal of existing rules and the introduction new ones), layering (the introduction of new rules on top of or alongside existing ones), drift (the changed impact of existing rules due to shifts in the environment) and conversion (the changed enactment of existing rules due to their strategic redeployment). In relation to political context, Mahoney and Thelen ask two broad questions: (1) Does the political context afford defenders of the status quo strong or weak veto possibilities; (2) Does the targeted institution afford actors opportunities for exercising discretion in interpretation or enforcement? As the following table suggests, differences in both dimensions are associated with different modes of institutional changes. While powerful veto players can protect the old institutions, they cannot necessarily prevent the addition of new elements. If agents of change face an institution with very little room for discretion in enforcement, then the outcomes of conversion or drift are less likely. In relation to types of change agents, they ask additional two questions: (1) Does the actor seek to preserve the existing institutional rules?; (2) Does the actor abide by the institutional rules? Insurrectionaries seek to eliminate existing institutions or rules, and they do so by actively and visibly mobilizing against them. Symbionts come in two varieties – parasitic and mutualistic – and in both instances rely on institutions not of their own making. In the parasitic variety, they exploit an institution for private gain. Mutualists use established rules in novel ways to advance their interests. Mutualists violate the letter of the rule to support and sustain its spirit. Subversives are actors who seek to displace an institution, but in pursuing this goal they do not themselves break the rules of the institution. Opportunists exploit whatever possibilities exist within the prevailing system to achieve their ends.

Tab 2: Types of Gradual Institutional Changes

	Displacement	Layering	Drift	Conversion
Removal of old rules	YES	NO	NO	NO
Neglect of old rules	X	NO	YES	NO
Changed impact/enactment of old rules	X	NO	YES	YES
Introduction of new rules	YES	YES	NO	NO
Contextual and Institutional Sources of Change Agents	Insurrectionaries	Subversives	Parasitic Symbionts	Opportunists
Change Agents seek to Preserve Institution	NO	NO	YES	YES/NO
Change Agents Follow Rules of Institution	NO	YES	NO	YES/NO
Allies with Institutional Supporters	NO	NO	YES	YES/NO
Allies with Institutional Challengers	YES	NO	NO	YES/NO
Veto Possibilities	Weak	Strong	Strong	Weak
Level of Discretion in Interpretation/Enforcement	Low	Low	High	High

Perversity account is related by Baldwin et al (2012) to ideas focus on competing logics and incremental adaptation. An intellectual lineage goes back to Robert Merton's unintended effects of purposive social action and goal displacement. Sam Sieber (1981) identifies seven reverse mechanism that would pervert intended action: (1) functional disruption (regulation frustrates the functioning of system, thereby worsening the overall outcome); (2) exploitation (opponents succeed in achieving the opposite of the intended effects); (3) goal displacement (the process of regulating drives out the overall objective of regulation); (4) provocation (opposition and antagonism are mobilized, rather than compliance achieved); (5) classification (labelling effects have reverse effects, such as stigmatizing behavior become badges of honour); (6) over-commitment (the resource intensity of seeking to achieve unobtainable objectives reduce the resources to achieve obtainable objectives); (7) placation (the illusion of regulatory compliance distracts from danger signals).

Self-referential accounts have largely been influenced by Niklas Luhmann (1989), Gunter Teubner (1986) and Helmut Wilke (1995). The idea of self-referentiality involves an understanding of society that is increasingly differentiating into subsystems that are shaped by their own codes with own rationality. Teubner (1986) sees attempts at intervention and transplanting regulation as a source of irritation effects with eventual outcomes being highly uncertain. He calls this the 'regulatory trilemma' of the internal dynamics of self-referential structures of both regulating and regulated system which leads to either 'incongruence' of law and society (resulting in ineffectiveness of law), or 'over-legalization' of society (resulting colonization), or 'over-socialization' of law (overstrain). Teubner considers old model of regulation as unsatisfactory because they see the relation between regulating system and the regulated system as a relation between environment and system in which the regulating systems maintain and control goals and the processes of the regulated system. In contrast, he defines the regulated area as a system consisting of elements which interact with each other in such a way that maintain them-

selves and keep their reproductive organization constant. "Regulation do not at all change social institutions, they produce only a new challenge for their autopoietic adaptation." (Teubner 1986: 310) Teubner concludes that a regulatory action is successful only to the degree that it maintains a self-producing internal interactions of the elements in the regulating system, law and politics, which is at the same time compatible with self-producing internal interactions in the regulated system.

NETWORK THEORIES AND REGULATORY SPACE

The idea of regulatory space emphasises a structure of a place where regulation occurs as an element which influences practices within it. A regulatory space approach studies how action and intention of regulatory agents are embedded in larger systems of and institutional dynamic. This approach rejects the dichotomous language of public authority versus private interests pointing out that, in reality, many risks and social and economic problems are controlled by networks of regulators. (Morgan and Yeung 2007: 59) regulatory authority is very often shared private and public actors and ways of regulation are steered by location, timing and history.

In its description of dispersion of power, this approach comes from the same presumption as multi-level governance framework which stresses that governing issues are not public or private, they are frequently shared, governing activity at all levels (from local to supra – national) is becoming diffused over various societal actors whose relation with others are constantly changing. (Kooiman 2003: 3) These networks are described as 'self-organizing' to reflect the government's limited capacity to control them. (Rhodes 1997: 46-53) and their blurry lines of accountability are emphasized (Bache and Flinders 2004: 38). The European regulatory space is described in a greater detail in Chapter 7.

CONCLUSION

One can see described theories of regulation either as competing theories differently explaining origins of regulation or as different grammars grasping different aspects of policy narratives. Each of those grammars represents different dimension how one can possibly look at and talk about regulation. In each of this dimension we can use specific criteria how the regulation can be evaluated, specific epistemic sources (methods) for such evaluation, different entities are translated into policy narratives, different rhetoric's is used and different questions are raised.

Drawing on constructivist tradition in sociology, particularly actor-network theory (Callon 1986; Latour 2005; or Law 1992), the term of translation is used because criteria of justification or evaluation do not exist per se but different tools must be enacted to make them visible. There is no market. To see the market, one needs to mobilize statistics, graphs or mathematic formula. However, such tools are more than representation of a market: they are constitutive parts of economic action, shaping such action and its consequences for market processes. According to Donald MacKenzie (2009), sociology does not ask whether those representations are really true or not. Instead of it, it explores how facts are produced and what secures their facticity so that they are considered as true. Scientific facts are not in general simply 'out there', awaiting the fortunate discoverer who stumbles over them, but it must be produced. (MacKenzie 2009: 8) In a similar way as one can look at facts as produced entities, norms, discourses, interests, rules or culture can be examined.

Tab 3: Elements of regulations' narratives

		Criteria	Methods	Translation	Rhetoric	Question?
<i>Public interest approach</i>	<i>Welfare economics approach</i>	effectiveness	expertise	Facts are translated	logos	What market failures can be identified?
	<i>Exogenous goals approaches</i>	appropriateness	interpretation	Norms are translated	ethos	What norms justify regulation?
	<i>Procedural political approaches</i>	legitimacy	deliberation	Discourses are translated	pathos	What are processes within a particular regulatory regime
<i>Private interest theories</i>	<i>Regulative capture/Concentrated and diffused benefits and costs</i>	transparency	critique	Interests are translated	nature	Who benefits and loses from regulation?
<i>Institutional theories</i>	<i>Inter-institutional relations/Intra-institutional relations/Regulatory space</i>	compliance	reasoning	Rules are translated	context	What is institutional setting of regulation?

Through public interest grammar, rationales of regulation can be expressed. In Goffman's term (1959), one can speak about front-stage of regulation narratives. Policy advocates can defend their proposals by employing facts, norms or procedure. One can regulate since it is effective, it corresponds with broader norms of society, or citizenry decides for the regulation in a democratic procedure. Indeed, the regulation narrative might contain a mix of these rationales. In contrast to the public interest grammar, the private interests grammar reveals a back-stage (Goffman 1959) of regulation. While the first grammar might serve policy advocates to justify a regulation, the second one serves primarily policy opponents to delegiti-

mize a regulation. The institutional grammar grasps constraints for regulation and external context and cultural codes make narrative to be valuable and relevant in a particular cultural setting.

All these dimensions provide guide on what questions research of regulation narratives are supposed to be focused, what codes are supposed to be recognize in regulation narratives and what criteria are applied. Interpretative approach to regulation will be further elaborated in the next chapter dealing with regulatory analysis as an interpretative project.

CHAPTER 2: INTERPRETING REGULATION: DISCOURSES, DISCURSIVE PRACTICES AND NARRATIVES

The actors and objects of policy process are constituted by discursive practices, meaning they have to be understood through concepts and language employed to describe their activities. (Fischer 2003: 83) Consequently, language does not just mirror reality; it actively shapes it. Studying of language in public policy reminds us how naming, labelling and ascribing particular meanings or identities are deeply political acts (Bessant, Watts, Dalton, Smyth 2006: 305). It also helps us see that challenging the meanings given to something or someone offers critical insights for disputing how issues are framed in particular discourses.

As Greenhalgh and Russell describe policymaking, including regulation, as “the messy unfolding of collective action, achieved mostly through dialogue, argument, influence, and conflict and retrospectively made sense of through the telling of stories.” (2006: 36) Generally speaking, governmentality has a symbolic character: to analyse the conceptualizations, explanations and solutions that one can see in the governmental field requires a specific attention to discourse.

Maaerten Hajer (2009: 59) notes, the recognition of the importance of language as 'systems of signification' in policy and politics has given rise to varied literature, ranging from narrative analysis to discourse analysis, from the study of the role of metaphor to the study of frames and reframing, over the last few decades (e.g. Czarniawska 2004; Hajer and Wagenaar 2003; Roe 1994; Schön and Rein 1994; White 1999; Yanow 1995). The majority of these authors took their inspiration from the work of Murray Edelman. Edelman argued that political language should be regarded as political reality in itself and 'language styles' were 'a more sensitive and useful index of political functions in the modern state than the conventional division into executive, legislative and judicial actions' (Edelman 1964: 134). Later some analysts fo-

cused on the identification of broader, well-structured categories of thought (cf. also Fairclough 1992; Laclau 1996; Norval 2007; Howarth 2000), and others specialized in the analysis of detailed interaction patterns (Potter 1996; Gumperz 1982). "While in the first type of discourse analysis the aspect of strategic action seems lost, the latter is so focused on the interaction that the relationship between the detailed interaction and the broader societal developments is often elided." (Hajer 2009: 59)

Illuminating discourse, according to Hajer (2009), allows grasp public controversies not in terms of rational-analytical argumentation but in terms of the particular argumentative logic that people bring to a discussion. "For instance, despite the very high economic stakes involved, the planning process for the redevelopment of Ground Zero was not only about money and fixed interests - the political process was also about the different meanings that people attached to the building-site and the ways in which these related to their reflections on the state of society in general and that of politics in particular." (Hajer 2009: 61)

Sanford F. Schram (2012) distinguishes two levels of policy discourse: (1) surface level and (2) underlying level. Whereas the analysis of the first one is focused on strategic interaction, the later one is much more associated with broader categories of thought. "On the surface, there are key framing metaphors embedded in any policy narrative that point to an underlying discourse that provides reference points for making meaning from the framing metaphors and the ostensible narratives with they are associated." (Schram 2012: 140) The policy narratives provide the saga told about the policy, its problem, and the people associated with dealing with it. The policy narratives rely on underlying structure - discourse and identification of citizen-subject who is assume to be the focus of concern, including blame and praise.

Tab 4: The Levels of Policy Discourse

<i>Surface Level</i>
Narrative Often including a story of how a policy problem and its solution came to be
Framing Metaphors Always present in any policy narrative referencing an underlying discourses for making sense of the narrative and its story
<i>Underlying Structure</i>
Discourse Comprising critical distinctions for making sense of particular policy narratives
Subjectivities Key distinctions that reference why some identities are to be privileged in a policy narrative

Schram (2012:140)

DISCOURSE AS UNDERLYING STRUCTURE

Discourse “circumscribes the range of subjects and objects through which people experience the world, specifies the views that can be legitimately accepted as knowledge, and constitutes the actors taken to be the agents of knowledge” (Fischer and Gottweis 2012: 11). It establishes the broad socio-cultural context and conceptual materials from which policy ideas and programs are constructed.

Michel Foucault (1985) defines a discourse as a wide set of social practices. But instead of focusing on the form and content of linguistic and semiotic practices only, he focuses on the rules governing the production of such statements and practices. He is concerned neither with the truth nor the meaning of actual statements, but with their discursive conditions of possibility. Power is neither a relation of dominance, nor a capacity to act, but the ‘conduct of conduct’ which refers to the ways in which discourse regulates actions by means of shaping the subjectivities, capacities, and social relations.

In line with Rose and Miller (2008), I see policy work located within a wider discursive field in which conceptions of the proper ends and means of government are articulated. A discourse can be seen as a technology of thought, requiring attention to the particular devices of

analysing and communicating that render a realm into discourse as a knowable and administrable object. "Political argument does not have the systematic and coherent character of theoretical discourse. Nonetheless, we suggest, it is possible to specify and differentiate political rationalities in terms of the relatively systematic discursive matrices within which the activity of government is articulated, the particular languages within which its objects and objectives are construed, the grammar of analyses and prescriptions, the vocabularies of programmes, the terms in which the legitimacy of government is established" (Rose and Miller 2008: 30) Thus, rationalities of government are elaborated as assemblages of philosophical doctrines, notions of social and human realities, theories of power, conceptions of policy or versions of justice.

Foucault distinguishes between archaeology and genealogy of discursive studies. While archaeology makes possible the examination of 'forms themselves', genealogy accounts for their contingent emergence and production. Archaeology provides the means to delimit research objects, while genealogy analyses their constitution by recounting the historical practices from which they were constructed. Where archaeology provides us with a snapshot, genealogy pays attention to ongoing character of discourse (Foucault 1981: 70-1).

According to Gavin Kendall and Gary Wickham (1999), a genealogy (1) describes statements with an emphasis on power; (2) introduces power through a history of present; (3) describes statements as ongoing process; (4) concentrates on the strategic use of archeology to answer problems about the presents. Following genealogy of present, one can explain what has made current solution possible. In chapter 3 and chapter 4, I will explain genealogy two discourses of current health policies – discourse of health promises on one hand and fiscal responsibility concept on the other hand. The genealogical description provides us with the account how current perceptions of individual and state responsibilities in regulations are embedded in histories and how history is internalized in current debates and current discursive praxis.

In contrast to Foucauldian notion of discourse as a genealogical complex of thought, Hajer defined discourse in more strategic-interactional sense as an ensemble of ideas, concepts, and categorizations through which meaning is allocated to social and physical phenomena, and that is produced in and reproduces in turn an identifiable set of practices (cf. Hajer 1995: 44). However, in his later work, he realized that ideas, concepts, and categorizations as rational, cognitivist concepts are not enough to explain subtle contours of discursive dynamics. In empirical analysis, he found that less cognitive categories, like storylines, metaphors, or images, played a key role. It therefore led him to rephrase the definition of discourse to include 'notions' as a term referring to such less-cognitive vehicles. Hajer (2009: 60) refers to discourse as an ensemble of notions, ideas, concepts, and categorizations through which meaning is ascribed to social and physical phenomena, and that is produced in and reproduces in turn an identifiable set of practices.

DISCURSIVE PRAXIS

Discourses as underlying structures got their visible shape through discursive praxis. Hajer (1995, 2003b, 2006) identified different elements of discursive praxis, which analyst should pay attention to: (1) discourse: an ensemble of notions, ideas, concepts, and categorizations through which meaning is allocated to social and physical phenomena, and which is produced and reproduced in an identifiable set of practices; (2) metaphor: understanding and experiencing a particular thing/event in terms of another; (3) storyline: a condensed sort of narrative that links an event to one or more discourses and thus provides the basis of 'discourse coalitions'; (4) discourse coalition: the ensemble of particular storylines, the actors that employ them, and the practices through which the discourse involved exert their power; (5) practice: operational routines - mutually accepted rules and norms that give coherence to social life; (6) discursive affinity: arguments that may have very different roots and meanings but that together uphold a particular way of seeing; (7) emblematic issue: a specific policy problem that cap-

tures the imagination at a particular moment in time and fulfils a key role in the general understanding of a much larger problem complex (metonym); (8) discourse structuration: a discourse dominates the way a given social unit (a policy domain, a firm, a society--all depending on the research question) conceptualizes the world; (9) discourse institutionalization: a discourse solidifies in particular institutional arrangements - say, a measuring system for air pollution; (10) indexicality: performances are scripted and staged in a way that draws on previously existing knowledge or experience of audiences, stimulating them to understand the performance as 'such-and-such an event'; (11) intertextuality: a particular statement refers to other texts to enhance the power of the statement; (12) citation: the in situ mobilization of historical events to understand a new situation and/or to exert influence; (13) performativity: a reiteration of a norm or set of norms; (14) positional statement: a claim that, if not rebutted, creates a particular discursive reality.

Following Hajer's approach different elements of discursive praxis will be taken in consideration in my genealogical analysis. I will study how particular pharmaceuticals function as emblematic issues in development of medicalization discourse and how different discourse coalitions shape it. In my analysis of fiscal limits, I focus specifically on importance of discourse structuration and discourse institutionalization, particularly a role of epistemic communities is taken in consideration.

CULTURAL CODES AS A PART OF DISCURSIVE PRAXIS

Articulation of global discourses such as medicalization or fiscal responsibilities seems very often to be influenced by the local cultural context. Lamont (1998; 2000) showed the importance of the variance of criteria of evaluation across the time and space. Boltanski and Thévenot (1987; 1991) proposed an analysis of orders of justification that people deploy to assess whether an action benefits the common good. They distinguished a plurality of grammar of worth and different repertoires of evaluation in different settings through which different ele-

ments of the same discourse might gain weight. "We regard them as elementary grammars that can be available across situations and that pre-exist individuals, although they are transformed and made salient by individuals. We are concerned with documenting how these schemas are evenly present across national cultural repertoires," Lamont and Thévenot (2000: 6) summed up their research agenda. They focused specifically on (1) the content of criteria or orders of justification used to draw boundaries between the more and the less valuable; (2) whether and how different criteria compete with one another and are used in conjunction with one another; how actors demonstrate the situational appropriateness of their criteria of evaluation, and with investments of forms processes by which people and things are defined as belonging to similar classes across contexts. (Lamont and Thévenot 2000: 6-7) They took elements of repertoires to be present across geographical units such as nations or regions, but in varying proportions. For example, they suggest that cultural repertoires prevailing in the United States make market references ore readily available, whereas the French repertoires make principles of civic solidarity more salient. However, this does not mean that market criteria are absent in France, but only that they are used in a small number of situations.

In relation to health care specifically, Arthur A. Daemmrich (2004) advances the concept of therapeutic cultures as shorthand for institutionalized relationship among the stare (including legislatures and regulatory agencies), the pharmaceutical industry, the medical profession, and disease-based organization. Daemmrich compares the United States and Germany. The concept of therapeutic culture helps explain how different constructions of patient shaped drug regulation. In the US, drug regulation became very politicized, social actors competed against each other, and disease based organizations articulated their opposition to governmental paternalism. In Germany, by contrast, drug regulation occasioned fewer conflicts among industry, the medical profession, and the government. "By the end of the twentieth century, patients in the United States challenged the status quo of medical politics and promoted changes to test-

ing methods and regulatory approaches. In Germany, fewer changes took place. The medical profession largely retained its authority to speak for the patient, even as the setting for medical policy politics shifted to the European Union."

Cultural theories of regulations widely stem from usage of cultural theory developed by Mary Douglas and Aaron Wildawsky (Douglas 1993; Thompson, Ellis and Wildawsky 1990) to classify and compare argumentation patterns towards regulation approaches. Cultural theory developed by Douglas and Wildawsky points to four rival world-views, with their contrasting and competing diagnoses and solutions to regulatory problems. These views emerge from distinctions on two dimensions: (1) grid which defines the extent to which individual behavior is bound by rules; (2) group which defines the extent to which an individual regards herself or himself as being embedded within group processes.

Tab 5: Cultural codes of regulation

		Group	
		Low	High
Grid	High	<p>Fatalism Control through unpredictable processes/inherent fallibility</p>	<p>Hierarchy Anticipative solutions, forecasting, and management, response to enhanced authority and hierarchical ordering</p>
	Low	<p>Individualism Control through rivalry and choice, incentive to underpin market and individual choices processes</p>	<p>Egalitarianism Control through group processes, network style and participation</p>

According to Hood (1998: 24-28) responses to scandal or catastrophe in public management - such as police brutality, major safety lapses or dramatic financial misappropriation--are likely to be a key test of cultural bias. Hood summarizes four patterns of blame and proposed remedies following disasters that align with the major organizational world-views of cultural theory. Through its emphasis on patterns of blame and remedies cultural codes added temporal dimension. In Hood's approach, the patterns resemble more to framing concepts or

framing codes than characteristic of culture. They can exist simultaneously in the same cultural milieu. Those codes can be culturally or discursively ascribed but they can be also strategically used.

In the hierarchist's response to disaster, the problem could have been averted if only there had been more coordination, better procedures, more planning, and clearer assignment of authority. The people to blame are those who were not following prescribed procedures properly, and the solution can be to tighten up the rules and the authority structures to prevent a recurrence. An egalitarian approach, contrary, may blame authority and expertise as the reason why a disaster happened.

The individualist perspective brings in a different approach to diagnosis and prescription. From this perspective, many of the typical failings of public management stem from too much collectivism and organization, not too little. Such practices may buttress the ability of those in powerful institutional positions to 'blame the victim' and walk away from responsibility when disaster strikes. The egalitarian solution accordingly involves more 'democracy' and 'empowerment' of people at the bottom to challenge authority and professional self-interest, 'blowing the whistle' over matters of public concern.

Lodge and Wegrich (2011) applied this cultural theory to classify, chart, and compare argumentation patterns reflected in newspaper reporting on the financial crisis. In the fatalist frame, market economy is a continuous, unpredictable cycle of boom and bust and it impossible to anticipate next crisis because of unpredictability. Any response is destined to be futile or perverse. In the individualist frame, the financial crisis is a product of poor incentives and moral hazard generated by governments. Solution can be found in the realm of the regulatory intervention reduction in order to minimize government failure. In the hierarchy framework, financial crisis is a symptom of lack of order and creation of stronger rules and regulatory bodies is needed. The egalitarian frame sees financial crisis as a symptom of excessive individualism

and failed exercise of authorize. The remedy lies in increasing of transparency, higher professionalism and limits of discretionary authority and markets. They use this framework to compare patterns of argumentation in Germany, the UK and US. Their study points to the importance of institutionalized cultural models and practices, and how they converge or vary cross-nationally.

CATEGORIES AS A PART OF DISCURSIVE PRAXIS

Knowledge is culturally and normatively linked to categories of actors and entities in a variety of different ways. Certain categories are treated as entitled to know particular sorts of things or represent particular sort of things, and their reports and descriptions may thus be given special credence (Jayyusi, 1984). According to Yanow (2000: 49), categories entail and reflect a set of ideas about their subject matter. By common-sense definition categories highlight elements deemed similar within the boundaries they draw and different from elements beyond those boundaries. The sameness is crucial organization principle which categories are built upon. As Potter (1997) points out, different categories imply different stories of motive and responsibility and have different implications for what should come next. At the same time categorizations can work to exclude potentially relevant considerations.

Category analysis focuses on the logic embedded in the structure of oppositions and similarities regarding a usually implicit point of view from which they are drawn. "By making a close reading of the categories a society collectively constructs on and through its public policies and administrative practices, the policy analysts can make these ideas more explicit, not as espoused, but as enacted, reflecting the social dimension of category and concept construction, learning and knowing." (Yanow 2000: 49) Category analysis was employed to grasp the grammar of constructing different target populations in a discussion (Schneider and Ingram 1997) As public policies identify and name groups of people for whom the solution is sought,

they often create sets of categories structuring a political problem and implying several solutions.

Harvey Sacks (1992) observes that our reading of categories is informed by the way we infer that some come from the same collection. “We only talk about a collection when the categories that compose it are categories that members do in fact use together or collect together.” (Sacks 1992: 238) He uses a term membership categorization device for “any collection of membership categories, containing at least a category, which may be applied to some population containing at least a member, so as to provide, by the use of some rules of application, for the pairing of at least a population member and a categorization device member”. Membership in some collection of categories is defined by the category bound activities and different categories can be differently localized. Categories in the same collection might also have a hierarchical order when some of them are higher ranking than others.

So in terms of policy analysis, one should not be interested in construction of boundaries between categories only but also in construction of activities holding categories in one collection and hierarchical between different categories within the same collection. In my analysis of Czech pharmaceutical policies I will deal how differently a category of a patient has been constructed and what different activities have been bounded with it.

POLICY NARRATIVES

As Maarten Hajer (2009) reminds us that policy statements embedded in wide discourses often have the form of narratives: people convey facts in story form. Those narratives resulted from different from a discursive praxis, including cultural codes, framing, categories making etc. The essence of a narrative is a temporal dimension. It means that it has a beginning, a middle, and an end. Policy narratives “provide a credible principle upon which to read past, present and future events, and capture people's hearts and minds” (Torfing 2005: 15). At its simplest it can be defined as “the representation of real or fictive situations and events in a time

sequence” (Prince 1982: 179). Narrativisation involves "a distancing of the saying in the said" (Ricoeur 1981: 134), in other words an abstraction from particular situations, a virtualisation with respect to time, and the potential inscription of a speech act in text. Narratives work as casual stories which describe how world works and prescribe responsibilities (Stone 1988). They create a cognitive schema for describing and understanding an otherwise chaotic and complex series of situations, events, and behaviours.

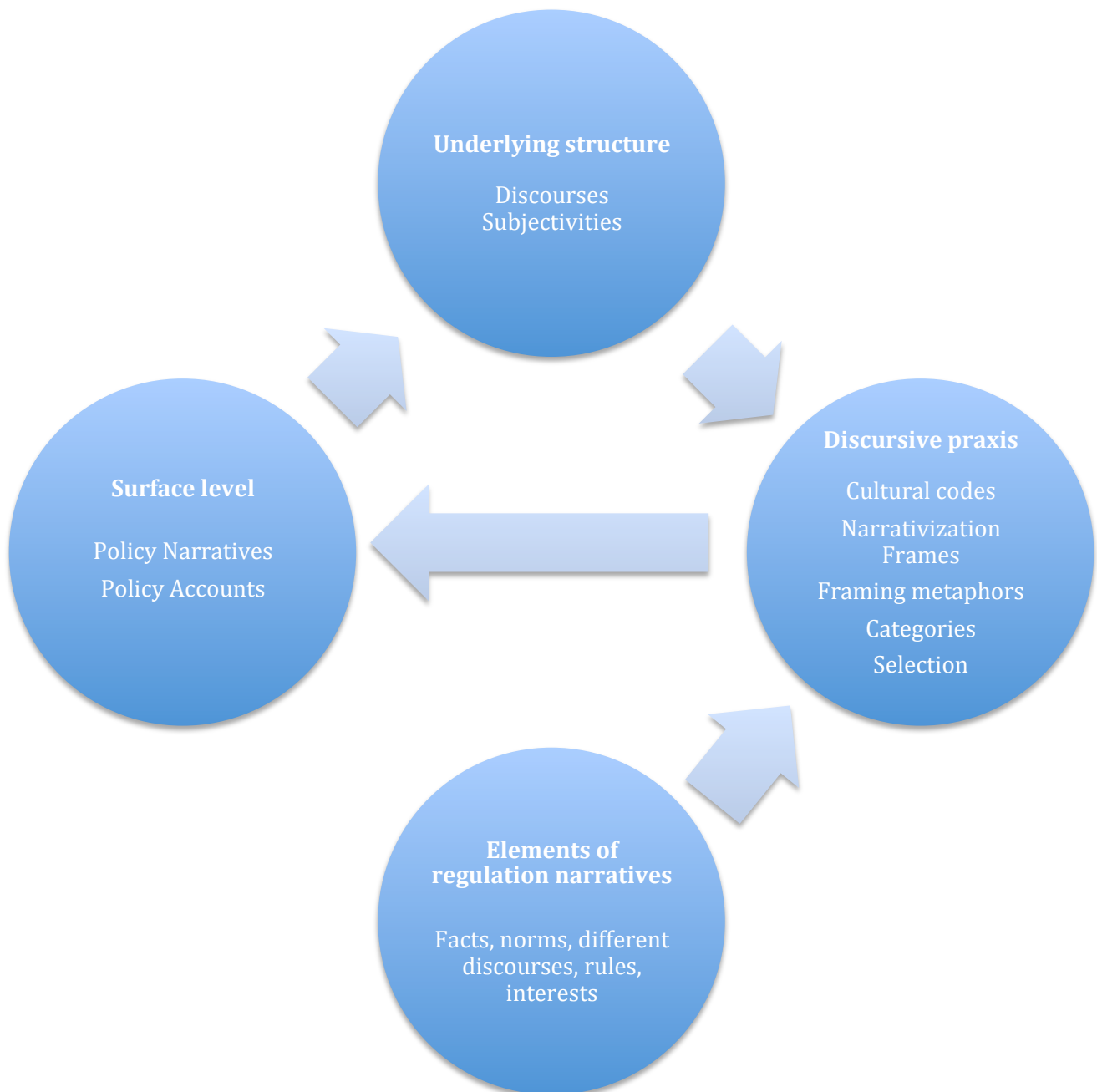
One can distinguish an organizational and communicational function of a narrative. The organizational function of narratives includes naming the problem and scripting the identities and roles of various actors involved in it. Narratives play an important role in organizing (White 1992; Kabele 2010), including both planned and unplanned reorganisation (Kurtz & Snowden 2007; O’Connor 2002). In this way, narratives “fulfil an essential role in the clustering of knowledge, the positioning of actors, and, ultimately, in the creation of coalitions amongst the actors of a given domain.” (Hajer 1997: 63) On the other hand, the communicative function of policy narratives means ability to persuade a broader audience of legitimacy and appropriateness of the particular version of a situation (Schmidt 2002). The communicative function of narratives emphasizes the importance of expression, argumentation, and persuasion in generating and validating consensual interpretations of the situation. This often involves a sort of competitive narrativization, as individual or organizational actors construct and project their own quests in ways that position them as helpers in the quests of more powerful actors in the field (Golant & Sillince 2007).

CONCLUSION

The policy narratives rely on underlying structure - discourse and identification of citizen-subject who is assume to be the focus of concern, including blame and praise. This underlying structure results from long-term processes and forms a basis through which goals and means policies are articulated. The genealogical description provides us with the account how

current perceptions of individual and state responsibilities in regulations are embedded in histories and how history is internalized in current debates and current discursive praxis.

Pic 1: Architecture of Regulation Narrating



Discourses as underlying structures got their visible shape through discursive praxis. Discursive praxis can be seen as an ordering praxis putting together possibilities and manoeuvring space, determined by discourse as an underlying structure, and elements of regulation

narratives such as facts, norms, different discourses, rules and interests. Through discursive praxis, newsworthy elements are selected from multiplicity of events, statistics or rules. Through discursive praxis is constructed what aspects of life are newsworthy and, on the contrary, what aspects are largely ignored. Through discursive praxis, such as selection, framing codes, or categories, those newsworthy events, statistics or rules are organized in narratives in which responsibility is attributed and narrative structure is used as a mechanism for ordering of social life.

In next two chapters, I deal with two discourses configuring recent health policies – genealogy of health hope and genealogy of fiscal limits. I consider both of them as main structuring concepts for recent forms of pharmaceutical regulation in developed countries. I will map their genealogies and grasp their institutionalization and structuration. In chapter 5, I will focus how affinities between these two discourses configure policy narratives of sustainability in health policies. In my genealogy of post-socialist pharmaceutical regulation in the Czech republic, chapter 8, I put emphasis on particular forms of discursive praxis such as regulation codes or categories and their influence on construction of patients' roles and shaping particular policy narratives.

CHAPTER 3: THE GENEALOGY OF HEALTH HOPES

As with all other social institutions in late modernity, medicine itself becomes an increasingly reflexive enterprise in terms of its knowledge base, its social organization and the nature of everyday medical practice. Peter Conrad (1992: 209) called this process medicalization. According to him, medicalization describes a process of defining previously non-medical problems in terms of medical pathology. The term first entered sociological literature in the 1970s. "Medicalization consists of defining a problem in medical terms, using medical language to describe a problem, adopting a medical framework to understand a problem, or using a medical intervention to 'treat' it" (Conrad 1992: 211). In this sense the concept falls under the heading of social constructivism, which has been used to study topics such as mental illness, alcoholism, homosexuality, addiction, hyperactivity and learning disorders, eating disorders, infertility or sexual dysfunction, among others. Kevin White (2009: 51–52) mentions three key characteristics of medicalization in today's society. One, medicine as an institution defines the limits of normal behaviour and assigns responsibility for it. Two, it categorizes problems as individual and individually manageable (though obviously with expert help). Three, it classifies these problems as the product of nature – as the result of a genetic or biological dysfunction. As a process, medicalization is never complete; Conrad therefore talks about different degrees of medicalization.

"In most cases medicalization is not complete; some instances of a condition may not be medicalized, competing definitions may exist, or remnants of previous definition cloud the picture. Therefore rather than seeing medicalization as an either/or situation, it makes sense to view it in terms of degrees. Some conditions are almost fully medicalized (e.g. death, childbirth), others are partly medicalized (e.g. opiate addiction, menopause), and still others are minimally medicalized (e.g. sexual addiction, spouse abuse)" (Conrad 1992: 210).

For example, the fact that insurance companies are unwilling to reimburse certain medical procedures or services does not mean that the condition to which these procedures pertain has not been medicalized, but only that it has been medicalized to a different degree, Conrad argues (2007:11). In practice, the degree of medicalization therefore determines to what extent the right to express views about a certain phenomenon, to take measures against it and to use it as a source of legitimization for exerting social control over others becomes the prerogative of a single institution – the modern western medicine. The process of medicalization always involves a negotiation between various groups, which frequently express conflicting views. There are also a number of limits, such as competing definitions, medical care costs, medical categories or health insurance caps.

Medicalization processes are also related to the opposing processes of demedicalization. A classic example is masturbation: until the nineteenth century it was a disease requiring medical intervention; today it is seen as a common expression of human sexuality. In a different context, the disability rights movements seek to demedicalize its members' identities and to re-frame disability as a different yet equally rich form of biographical experience. In other areas such as childbirth or obesity, we are currently witnessing a tension between medicalizing and demedicalizing discourses. In the case of childbirth, the discussion between the supporters of natural versus medically assisted birth revolves around the problems of rights and various forms of risks. In the case of obesity, the question is the very definition of the condition, which can be discursively framed in terms of an epidemic, as an identity, or a matter of social inequality. In all of these cases, the results will differ according to who is assigned responsibility and for what.

Conrad mentions two main theoretical sources of inspiration for his concept of medicalization: the work of Talcott Parsons (1951), from whom these authors adopt several concepts while at the same time remaining critical of them, and the labelling theory. Parson was the first

to conceptualize medicine as a form of social control. In his understanding, the ill person becomes freed from many of the expectations connected to his various social roles; accepting the role of a patient normalizes him and even justifies certain deviations from the norm and from the related expectations. On the other hand, he is now also subject to other norms, specific to his new role. Parson describes three main components of the patient's role: (1) patients are freed from social obligations which they would normally have to meet; (2) they are not blamed for their condition; (3) ill people must be trying to get better; (4) being ill means being defined as an object of medical assistance which allows returning to normality. Parsons' theory is a good starting point for thinking about medicalization because it sets up a certain presumption of a consensus between the patient and the physician, which then serves as one of the foundations of this discourse. By accepting the role of a patient, the individual extricates himself from particular types of norms and commitments, while paying the price, metaphorically speaking, of subjecting himself to the control exercised by medical institutions. In addition to this, the labeling theory gives medicalization approach its emphasis on process and the importance of definition.

A number of authors also refer to the work of the sociologist Ivan Illich, whose critique of modern medicine warns against the unrealistic ideas about health produced by medical professionals and pharmaceutical companies - ideas that further increase the demand for treatment. In his classic and highly controversial work *Limits to Medicine – Medical Nemesis: The Expropriation of Health* (Illich 1976), Illich calls this phenomenon *iatrogenesis* – harm caused by medicine – which he then characterizes as clinical, social or cultural. According to Illich, virtually all aspects of human life are gradually brought into the sphere of physical or mental health: childbirth and child rearing, dealing with problems and hardships, criminal behavior, sadness, ambition, all kinds of physical and mental abnormalities, but also death; consequently, they become subject to medical control. Any suffering, grief or treatment that lies outside the role of

a patient is defined as a normative deviation. "Powerful medical drugs easily destroy the historically rooted pattern that fits each culture to its poisons; they usually cause more damage than profit to health, and ultimately establish a new attitude in which the body is perceived as a machine run by mechanical and manipulating switches" (Illich 1976). Illich argues that medicine has become the institution defining who is ill, impotent or in need of any kind of repair.

Illich's theses have been further developed by a branch of sociology of medicine which Deborah Lupton calls the political economy of medicine. The Australian sociologist characterizes its representatives as follows: "They see a symbiotic relationship therefore existing between capitalism and health care: capitalism produces health needs which are treated in such a way as to obscure their origins and demands the consumption of commodities to secure the healing process, which in turn supports the capitalist system of production" (Lupton 2003: 10). The political economy of medicine calls for a change in our dependency on medical technologies, for a decommodification of medicine, for the regulation of the interests of pharmaceutical companies, insurance companies and medical professionals, and for a redirection of financial and other resources to regulate the social and environmental causes of disease. On the one hand, modern states subject their citizens to social control in the form of numerous tests, vaccination requirements or by organizing individually-targeted campaigns; on the other hand, governments fail to regulate large companies so that they would create a more healthy environment, they do not take the necessary action against the production and marketing of unhealthy goods such as alcohol or tobacco, and do not act to increase accountability in the testing and development of pharmaceutical drugs. "Medical care thus tends to be oriented toward the treatment of acute symptoms using drugs and medical technology rather than prevention or the maintenance of good health" (Lupton 2003: 10). Within this logic, a simple rule of three applies: the more symptoms we will define as pathological and the fewer conditions as normal, the more drugs, tests and technological measures will be required to treat them.

MEDICALIZATION AS A FORM OF GOVERNMENTALITY

Hasmanová Marhánková (2008) argues that today's medical discourse defines each pregnancy as potentially pathological and, referring to Lee and Jackson (200: 122, in Hasmanová Marhánková 2008), she adds that it can only be defined as normal after a successful childbirth – a pregnancy "only receives the label of normality retrospectively." However, the authors quoted also point out that the limits of what is considered a normal pregnancy or childbirth are constantly shifting. In her article, Hasmanová Marhánková discusses the experience of women who have refused prenatal screening. These women have defied the dominant medical discourse and, as a consequence, they had a first-hand experience of medicalization practices. The author comments on one of the interviews: "While the obstetrician formally accepted her decision, Ms Ivana continued to feel his disagreement throughout the course of their subsequent regular meetings. The fact that she had refused testing therefore had a considerable effect on their relationship." The patient attempted to free herself from the expectations and norms associated with the patient role (see Parsons 1951) and, seen from her doctor's perspective, she did not seek to return to the norm. She therefore became, so to say, the odd one out, and was viewed as such – as irresponsible or a troublemaker. Ida Kaiserová addresses the question of social control in pregnancy even more eloquently:

"From the moment of having conceived my first child, I became the object of normative interest of a number of institutions, such as the genetics laboratory, the maternity unit of the university hospital, the gynecological surgery, the registry office, the department of social welfare, the pediatrician's office, the child cardiology and endocrinology services, the nursery and the primary school, the child psychologist, but also the state railway company, the local bus company, the insurance company or the manufacturer of infant formula. All of them have also expressed a demand for my compliance. Becoming a parent has brought me into contact with a

great many strangers, whose profession entitles them to tell me what to do, without my ever having felt the slightest interest in their views." (Kaiserová 2007)

In this respect, medicalization as a type of manipulation is theoretically elaborated through the concept of governmentality. Governance is a more or less rationally calculated activity exercised by authorities and agencies, which use different techniques and forms of knowledge to pursue modalities of control that act upon other agents' desires, aspirations, interests and beliefs (Dean 2010: 18). From this perspective, the way people manage themselves is seen as something that can be regulated, controlled, shaped and directed, depending on specific goals. As Peter Miller and Nikolas Rose show (1993: 93), this self-management is no longer influenced through coercion, but instead by using the power of truth, rational capacities and the enchanting promise of efficiency. Medicalization corresponds to Foucault's concept of pastoral power, which refers to the development of technologies of power directed at the individual and his or her management. Pastoral power is exerted over a herd: the pastor-shepherd gathers and directs his herd and is responsible for its protection, which gives this form of power its seemingly benevolent character, the shepherd managing the herd for its own good. Subjecting oneself to the power of modern shepherds is never an intentional decision. "The care of the self involves largely, subliminal socialization rather than active, conscious decision. It is about how people constrain themselves rather than being forcibly constrained by external agents, involving not generally explicit moral odes but a shared understanding of what is a 'good person' in particular community" (Lupton 1995: 12). The key to its understanding then lies in examining how people restrain themselves in order to become good citizens. Nikolas Rose points out that modern pastoral power has long ago ceased to be unidirectional. As Rose argues and Kaiserová's example shows, in real life pastoral power is often translated into a number of micro technologies. At times, the individual shepherds can even oppose and mutually undermine each

other – they can appropriate our bodies, health or quality of life in a myriad of rhetorical ways, protect its different aspects and issue conflicting instructions as to what is best for us.

SUCCESS OF CONSUMERISM MEDICINE

Lupton associates (2007: 90-1) professional excellence in medicine came with scientific prowess and laboratory research rather than library-based knowledge and empathetic bedside skills. Because medicine is seen to be informed by objective and rigorous modern scientific knowledge, which is out of the reach of understanding of most lay people, and because medical practice is directed towards therapeutic ends, it has a privileged status by comparison with other authoritative institutions such as law and the clergy (Starr, 1982: 4–5). Medical care is becoming more scientific, with increasing emphasis upon making medical decision-making more rational, quantitative, and formal.

Pickstone (2000) argues that science, technology and medicine can be characterized in terms of four historically successive but overlapping ideal types: biographical medicine, analytical medicine, experimental medicine and techno-medicine. The last one represents the contemporary form when certain products medical research became commodities. Pickstone distinguishes three other type of medicine in relation the priorities and drivers of medicine: productionist, communitarian and consumerist. While elements of all three coexist today, the emphasis has shifted from first to last. Productionist medicine gave priority to the health and reproductive powers of the workforce; communitarian medicine stresses in contrast the shared public-service medicine of a providential or welfare state, while the consumerist medicine highlights the way in which medicine is positioned as a commodity in free markets.

Consumerist medicine is reflected in the growth of private medical insurance, in the increasing demand from consumers for a wider range of choice over medical, in the privatization of formerly public services, in the development of internal markets within nationalized health-care systems, and perhaps most significantly in the blurring of health, lifestyles and fitness.

“The consumerism and fee-based payments associated with medicine in advanced states (such as the US) not only foster increasing specialization, as consumers seek out the latest medical devices and techniques tailored to their individual needs, they also create a situation where the logic of mass public health care enshrined in practices such as national vaccination regimes is challenged. This encourages individuals to seek their own health technology solutions to existing or anticipated health problems - not only in regard to public immunization strategies (as illustrated by the UK controversy in 2002 over the triple (MMR) vaccine compared with single shots for mumps, measles and rubella) but for all health-care problems.” (Brown and Webster 2004: 11)

In consumerist mode, western medicine for patients has become only one, even preferential, of the variants on offer in a vast field of approaches to treatment. Patients can therefore choose classic western medicine, but also another of the proposed alternatives. Sarah Cant and Ursula Sharma (2000) describe this situation as "medical pluralism." Today we may even encounter different approaches in the same consulting room. British studies have shown that 20 per cent of all medical procedures carried out as alternative medicine, most often acupuncture or homeopathic treatments are administered by general practitioners (Thomas et al 2001). In addition to alternative treatments, our health is also increasingly influenced by other new professions: fitness trainers, dieticians, therapists and various personal coaches. It would therefore seem that medicine has lost its primacy of being the only institution to decide about our health. However, although these new versions of medicine are just as eager to gain professional status (by creating schools and standards of training, founding professional associations etc.), a number of studies have shown that western medicine ultimately remains at the top of the pyramid (e.g. Kelner et al 2004 or Cant et al 2011). It is admittedly no longer the only institution in this field, yet it maintains its referential status and for a large share of patients it still remains primary. Deborah Lupton (1995) makes the convincing argument that the discourse of the holistic

approach to health and lifestyle in fact only helps fostering the power of medical discourses over our lives. "In health promotion discourse, lifestyle is pathologized as a source of ill health" (Lupton 1995: 142) This discourse portrays health as a goal achievable through intentional action, one that requires self-discipline, determination, as well as the necessary time and energy.

As the self is seen as a reflexive project, for which the individual is responsible (Giddens 1991: 75), our health is in our own hands, we are constantly making decisions about it and for these moments of decision we must be suitably informed and equipped. How many carbohydrates and proteins are there in each food, how should these be combined, how much water we should drink daily, what pulse should we maintain while running or what activities should we avoid at full moon. Our lives are not ruled solely by the knowledge of western medicine; rather our thinking about health resembles a *bricolage* of scientific facts, unverified claims and traditional practices. However, this widening field does not undermine the possibilities of governmentality - in fact it only further strengthens them

REVISIONS OF THE MEDICALIZATION APPROACH

As I have already mentioned, the medicalization thesis was formulated in the 1970s and reflects the state of medicine and its relations with society of its time. Since then, we have seen a number of changes. The field of social control has become greatly diversified and it is now the point of collision between numerous agencies and institutions, as Rose's conception of pastoral power already holds. The American social anthropologist Adele Clarke and her colleagues have gone still further to suggest that the idea of medicalization should be replaced with the concept of *biomedicalization* (Clarke et al. 2003). The bio- prefix highlights the importance of biotechnologies in the constitution of modern identities, while simultaneously making more explicit the reference to Foucault's concept of *biopower* as a power over life. The complex intertwining of spatially diversified and multidimensional processes characterized as medicaliza-

tion is currently being reconstituted by the various forms and practices of the rapidly evolving field of technoscientific biomedicine. Clarke and other authors believe that the new concept should better reflect this situation, where we have seen the rise of new areas of medical genetics and transplantation medicine, as well as new medical technologies which further intensify medicalization in new, complex and mutually interlocking spheres of modern science and technology. While the original concept of medicalization only focused on the field of medicine, the new approach should pay more attention to medicine's close connections with the biotechnological industrial complex.

"Biomedicalization is reciprocally constituted and manifest through five major interactive processes: (1) the politico-economic constitution of the Biomedical TechnoService Complex, Inc.; (2) the focus on health itself and elaboration of risk and surveillance biomedicines; (3) the increasingly technoscientific nature of the practices and innovations of biomedicine; (4) transformations of biomedical knowledge production, information management, distribution, and consumption; and (5) transformations of bodies to include new properties and the proaction of new individual and collective technoscientific identities. These processes operate at multiple levels as they both engender biomedicalization and are also (re)produced and transformed through biomedicalization over time. Our argument, thus, is historical, not programmatic." (Clarke et al., 2003: 163)

The authors consider this the second significant social transformation of medicine. Paul Starr (1982) has described the first significant transformation as the post-war professionalization and specialization of medicine and healthcare, which included the creation of associated professions, the application of new technological and pharmaceutical innovations and the appearance of specific new forms of medical care (hospitals and state-run or private clinics). In the United States, this period also saw the classification of medicine as a public good, which spurred increased investment in its development. As a result, medicine gradually entered a

number of new areas. According to Clarke et al (2003), the original concept of medicalization was formulated precisely in response to this shift. However, it no longer reflects the post-1985 changes connected with, among other factors, the continuing privatization of research centres and commodification of scientific knowledge, where medicine becomes significantly more ruled by managerial decisions and care is far less universal. More so than during the previous decades, today's medicine can adapt to both the patient's body and his financial resources. Although healthcare is becoming increasingly more dependent on modern technologies, which also allow for both existing and potential patients to be supervised more easily and efficiently, while medical care is simultaneously becoming more marketized, together with Conrad (2007) I do not believe that on the general level this constitutes a radical reformulation of the medicalization argument. Instead we could speak about new drivers of medicalization (Conrad 2005) or about a market-oriented medicalization (Conrad and Leiter 2004).

PHARMACEUTICALS AND OUR UNDERSTANDING OF HUMAN IDENTITY

As for pharmaceutical policy, the progressive medicalization of western societies can be shown on the milestones which medicine has reached in its quest to colonize new areas of human life. The following turning points are often mentioned in connection with the post-war history of medical drug use (see Potter 2002): the 1959 introduction of first-generation oral contraceptives for women, developed by Gregory Pincus and Carl Djerassi in the 1950s; the first marketing of Ritalin, which helped define hyperactivity as a disease, in the 1960s; the 1986 launch of Prozac, a drug which raises the level of serotonin and thus induces a sense of security and well-being; the 1996 introduction, by GlaxoSmithKline, of Paxil as a treatment for social anxiety, and finally in 1998 the mass-marketing of Viagra, which is used to treat erectile dysfunction. What all these drugs have in common is that they allow the individual to manage something previously out of his or her control – conception, mood or sexual arousal.

As the historian of psychiatry Edward Shorter (1997:320) argues, when Prozac entered the scene, depression lost its meaning as a symbol of distress. Shorter (Ibid) quotes one of the physicians working at the Beth Israel Medical Center in Manhattan: "Our phone rings off the hook every time someone does a story about Prozac." He continues: "People want to try it. If you tell them they're not depressed, they say, 'Sure I am!'" In his book *Listening to Prozac* (1993), the American psychiatrist Peter D. Kramer discusses the initial reactions of patients who had tried the drug: most of them described their state as feeling *better than well*. Similarly to cosmetic surgery, which can help people approximate a certain ideal of physical perfection, pharmaceuticals such as Prozac can remove minor imperfections of the human psyche. This is why Kramer calls them *cosmetic psychopharmacology*. He argues that for a great many patients Prozac became the proof of biology's victory over the psyche.

"Prozac – new antidepressant – was the main agent of change. There has always been the occasional patient who seem remarkably restored by one medicine or another, but with Prozac I had seen patient after patient become [...] 'better than well.' Prozac seemed to give social confidence to the habitually timid, to make the sensitive brash, to lend the introvert the social skills of a salesman. Prozac was transformative for patients in the way an inspirational minister or high-pressure group therapy can be - it made them want to talk about their experience. And what my patients generally said was that they had learned something about themselves from Prozac. [...] they believed Prozac revealed what them was biologically determined and what merely (experience being 'mere' compared to cellular psychology) experiential" (Kramer 1993: xv).

But it was not just the patients whose self-perception changed – the same was true for their psychiatrists. „I had come to see inborn, biologically determined temperament where before I had seen slowly acquired, history laden character", Kramer (Ibid) describes his experience. Shorter writes that in 1993, six years after Prozac had begun to be mass-marketed, about

half of all psychiatric consultations in the United States concerned a mood disorder. In addition to patients suffering from clinical depression, Prozac was often used by people who would be considered clinically healthy but were looking to improve their quality of life. It became one of the first widely publicized drugs. In this sense we can speak, as for instance Conrad (Conrad 2005: 6) does, about a time before and after Prozac. "Marketing diseases, and then selling drugs to treat those diseases, is now common in the 'post-Prozac' era" (Conrad 2005: 6).

In the post-Prozac era, the pharmaceutical industry has become more aggressive in promoting drugs, both among clinicians and the general public. In the 1990s, the U.S. pharmaceutical companies gradually began to exert more pressure on loosening the regulations on advertising drugs to the wider public – their efforts bore fruit in 1997, when these rules became much less stringent (Lyles 2002). Following this legislative change, the marketing expenditure of the U.S. pharmaceutical industry grew six-fold between 1996 and 2000, reaching \$2.5b annually.

It does mean that diagnosis using in promotional campaign or the effects of pharmaceuticals are fabricated or artificial. There is no doubt that those pills work, some types of patients really need them and they can really improve quality of their lives. However, those pharmaceutical have expanded horizons what society considers as a disease and what are demands of society from medicine. Prozac seemed like a great idea: its status was based on its claim to be first drug whose molecule had been fabricated to influence only one aspect of neurotransmitter system without shuffling gait, dry mouth, tremors, an the like were produced by the previous antidepressant. Prozac promised to make the depression treatment more effective and comfortable at the same, therefore, it opened up the floor for people who had not considered themselves as clinically depressed beforehand. Of course, one can admit that this kind of prescrip-

tion is “off label” and this praxis can be considered highly problematic from the ethical or scientific point of view, however, Prozac and its promotion made this praxis possible.¹³

Conrad gives another example of a pharmaceutical that contributed to the construction of a disease with a strong impact on lifestyle – Paxil. Eli Lilly launched Prozac in 1988; Paxil only appeared ten years later, when the antidepressant market was already relatively saturated. Its manufacturer GlaxoSmithKline therefore decided to market the drug not as an antidepressant but as an anxiolytic – specifically as treating social anxiety disorder (SAD, an intense fear of social situations, which may include a sense of shame) and generalized anxiety disorder (GAD, characterized as a chronic and excessive anxiety or worry lasting for more than six months). The decision was motivated primarily by the concern that facing the already fierce competition on the antidepressant market the drug might commercially fail. Rather than attempting to compete in an already saturated field, GlaxoSmithKline preferred to conquer a new one. SAD had already been included in the *Diagnostic and Statistical Manual of Mental Disorders* of the American Psychiatric Association, which serves as a coding system for different types of mental diseases, in 1980, but before the late 1990s its diagnosis was fairly uncommon.

"Since the FDA (*Food and Drugs Administration*) approved the use of Paxil for SAD (*social anxiety disorder*) in 1999 and for GAD (*general anxiety disorder*) in 2001, GlaxoSmithKline has spent millions of dollars on well-choreographed disease awareness campaigns

¹³ Similar lessons can be drawn from different pharmaceuticals too. American studies (Perring 1997) have proved unjustified prescription of Ritalin among children with problematic behaviour. There is considerable resistance and worry about the possibility of overmedication which is linked to the resistance to the use of drugs, which is particularly strong for children in the grey area of diagnosis, where it is dubious whether the children really meet the strict diagnostic criteria. Over prescription of antibiotics have been also being widely discussed in last decades (Binder et al 2000). There were also studies (Conrad and Muñoz 2010) documenting influence of over-the-counter medications such as Aspirin, Ibuprofen, and Naproxen on medicalization of chronic pain and suppressing alternative treatments. Roles of vitamin pills in construction of ideology of healthiness (Crawford 1981) have been also discussed in recent sociology of health literature. All these mentioned categories of products derived their influence from the success of dominant scientific bio-medical paradigm and raising patients' expectations from commodified medical products. In the ultimate end, this type praxis tends to suppress alternative ways of treatment such as rehabilitation, lifestyle changes or behavioral therapy.

to raise the public visibility of SAD and GAD. The pharmaceutical company's savvy approach to publicizing SAD and GAD, which relied upon a mixture of 'expert' and patient voices, simultaneously gave the conditions diagnostic validity and created the perception that they could happen to anyone. Soon after the FDA approved the use of Paxil for SAD, Cohn and Wolfe (a public relations firm that was working for what was then SmithKline) began putting up posters at bus stops with the slogan, 'Imagine Being Allergic to People'" (Conrad 2007: 18).

The company portrayed the disease as both normal and abnormal – as a normal biological condition, yet one that represents an abnormal bodily state. Although it is impossible to establish how many doses of Paxil have been prescribed for anxiety disorders and how many for depression, obsessive-compulsive disorder or post-traumatic stress disorder, which are among its other indications, the drug has overall been enormously successful, also thanks to its massive advertising campaign. Just before its patent expired in 2002, its sales stood at \$2.1b in the United States and \$2.7b globally. "The case of Paxil demonstrates how pharmaceutical companies are now marketing diseases, not just drugs," Conrad concludes (2007: 19). Once again, it is not the proof that social anxiety disorder does not exist as an illness or people suffering from it are not in a serious discomfort; I use this as an example how pharmaceuticals might contribute to change a public image and public perception of disease. They work as objects of what Ian Hacking calls kind-making, creating a new category that constitutes a new social reality (Hacking, 1999). However, the real bodily discomfort and perceived aspects of sickness are not taken in question and cannot be confused with the concept, the idea and the presentation of disease.

The border between disease and normality was likewise blurred by Viagra, which caused a marked increase in the diagnoses of sexual dysfunctions. Before Viagra, the treatment of sexual disorders was limited to only very serious conditions, such as in cases requiring prostate surgery. After its introduction it became possible to treat even lighter dysfunctions or in-

deed to use the drug simply to improve one's sexual life. "Viagra's debut is a perfect opportunity to examine the construction of social norms, ideals and expectation, particularly because it renders visible many taken-for-granted social assumptions. I noticed this fixation on 'normal' when I started talking with people about Viagra," writes the anthropologist Meika Loe in her book *The Rise of Viagra* (Loe 2004: 19). Pfizer, Viagra's producer, presented the drug as a way for patients to return to normality. Its advertising suggested that what may indeed be common (it claimed that around half of all men over forty have suffered from or encountered erectile problems), is not, for that matter, normal. Loe shows that from the very beginning, Viagra walked the thin line between a medical pharmaceutical and a recreational drug. On the one hand it was presented as a serious treatment, on the other as an enrichment of sexual life. While Paxil cashed in on the loosening of advertising restrictions, Viagra made use of the new opportunities offered by online retailing. "In part due to its easy availability and association with sexuality, Viagra has become a recreational drug, most commonly used by young people, both gay and straight, in combination with Ecstasy – now known on the street as 'Sextasy'" (Loe 2004: 176). "In an age of identity politics, both Viagra and Prozac have been claimed as tools for the construction of new and improved identities (masculine and feminine, respectively)," she continues (Loe 2004: 21). This is what distinguishes them from drugs treating conditions such as allergies or high blood pressure. The fact is that a simple cold or a number on the blood pressure monitor do not construct our identity - sexuality and depression do. "But the vision of the world is different for each pill: Viagra promises to restore sexual potency to the male populace, and Prozac promises to restore consistency, focus, and contentedness to, mostly, women's lives; in sum, these pills are designed to produce potent men and happy women" (Loe 2004: 21).

Men have suffered with problems with erection throughout entire history of humankind and always they have been seeking for help. However, what has changed after Viagra came it

was a social meaning what it means to have erection problems and how one should deal with them. After Viagra came, erection problems have been considered much more in physiological terms than in psychological ones.

CONCLUSION

The scope of medicalization is often illustrated on the sheer number of the different psychiatric diagnoses. Compared with its 1952 version, the current edition of the aforementioned *Diagnostic and Statistical Manual of Mental Disorders* of the American Psychiatric Association contains three times as many diagnoses (Carrey 2008). We can therefore easily see that today's medicine continues to colonize areas which previously remained outside its rule: from relationship issues to problems in the workplace. It would therefore seem that its strategy has proved greatly successful. However, as the cases of these specific drugs show, medicine itself is at the same time being colonized by other spheres of human activity. It reacts to both the current economic situation and specific expectations and norms. The three pharmaceuticals discussed above may serve as a proof that biomedicine is by no means running out of steam and remains one of the principal drivers of the changes in understanding human identity. On the other hand, we cannot understand these developments as simply determined by technology: "Medical work is constructed as done on and through machines, but not by them" (Prout 1996: 203). The emphasis on the trajectories of specific human artifacts and their social grounding helps us avoid not only technological but also social determinism, which sees artifacts as simply the product of various discourses, ideologies, social structures and human intentions. By studying the trajectories of products such as medical drugs and the human interactions associated with them, we can shed light on the mutual interplay of social and material networks, their interpenetrations and interdependencies.

What all of the analyzed drugs have in common is that they allow the individual to gain control over something – attention, mood or sexual arousal - which was previously impossible

to control and was instead perceived as natural. They also contribute to the construction of identities by allowing individuals to carry out targeted modifications and expand specific aspects of one's self through acts of personal will. With their help, mental states such as sadness, anxiety in front of an audience or dread can be defined as avoidable and manageable. They show that what was previously seen as natural can now be controlled. These drugs also contribute to the redefinition of the categories of the biological and the social. Kramer mentions that Prozac-using patients would often say that they finally saw themselves clearly, once they had been freed of their supposedly biological depression, which had been preventing them from seeing their true self. The effects of Paxil or Viagra are framed in a similar way: as a return to normalcy, not as an added value. Within this identity-forming regime, these drugs are therefore not understood as a danger to authenticity but a means of achieving it.

The author of a British study which interviewed parents of hyperactive children who had been prescribed Ritalin (Singh 2006) comes to a similar conclusion. Some of the parents agreed that it was precisely the medication that allowed them to perceive the true nature of their son or daughter. In this context we therefore encounter a double understanding of normality: (1) the normality of the individual's biography and (2) the normality of the body. The studied pharmaceuticals present the conditions they supposedly treat as normal from the perspective of biography - you have nothing to be ashamed of, many people suffer from the same thing etc. – but abnormal from the perspective of the physical body – your body is not working properly, but it can be fixed. While holistic medicine advocates treating the mind and body together, these drugs highlight the very opposite claim: allow your body not to prevent you from discovering your true self. The task of sociology is then not to judge whether these boundaries are just or not, but to study their reconfigurations in the modern societies, with full respect for all the actors concerned.

Last but not least, these pharmaceuticals have also become one of the elements fuelling the discourse of health as a matter of personal choice and responsibility. Medicine offers us various possibilities to be content, free of anxiety and enjoying a good quality of life. It is everyone's responsibility to decide whether they want to benefit from these possibilities or not. These innovations therefore contribute to the discourse of the "imperative to health" (Lupton 1995), which relies on, among others, the presumption that the individual is largely responsible for his or her health. He or she did not follow proper diet, did not get enough exercise, drank too much or too little alcohol, took too few vitamins, did not provide his body with a sufficient amount of antioxidants or exactly the right amount of omega fatty acids. The reverse side of this structural pressure is then that less attention is paid to areas of health prevention such as work conditions, environmental burden or the weakening of social solidarity within public healthcare system.

CHAPTER 4: THE GENEALOGY OF THE FISCAL LIMITS

According to the WHO, pharmaceutical policies should guarantee citizens an access to essential medicines. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

Spending on medicinal products is a large share of the health budgets in many European countries – in OECD countries they account for 18% of health spending and in low-and middle- income countries it ranges from 20 to 60% of health spending (WHO 2013). In light of the economic recession, some governments have been reducing pharmaceutical budgets and, using an array of policy instruments to cut costs, including pricing and reimbursement mechanisms. Pharmaceutical policies are, thus, embedded in broader discourses of thinking about role public budgets and economic governance in Western countries

In the late 2000s many parts of the world entered an era of intense economic austerity. Several countries reported cuts in the national health budget in response to the financial crisis. For example in Bulgaria and Latvia the health budgets were reduced by over 20%. Some Italian regions and France have reformed their fiscal policies to increase revenue for health system financing. A public health tax on food and drinks with high sugar content was introduced in Hungary. Bulgaria, Greece, Portugal, Romania and Slovenia increased employer and employee contributions. Several countries (Armenia, Czech Republic, Denmark, Estonia, France, Greece, Ireland, Italy, Latvia, Netherlands, Portugal, Romania, Russian Federation, Slovenia, Switzerland, Turkey) increased or introduced user charges for health services in response to the crisis.

Some countries reduced or froze the salaries of health professionals and restructured their Ministry of Health, health insurance funds or other agencies. The crisis also increased efforts to regulate pharmaceutical prices more strictly.

As examples of common policy measures tackling pharmaceutical consumption in economic crisis aftermath Vogler (2010) mentions (1) price reduction; (2) changes in co-payments; (3) VAT rate change on medicine; (4) changes in distribution margin. She concludes that price cuts appear to be applied rather often and continue to be considered as a key policy option. Changes in margins are a common instrument. Retailers (pharmacies) are equally targeted as wholesalers by changes. The changes in the margin are often, but not necessarily cuts. Increase in co-payments appears to be a rather common measure, however exemptions from co-payment were possible. Fewer changes appear in the reimbursement system compared to quick pricing measures, however, a lot of changes on reimbursement are planned or discussed, Vogler summarized her findings.

According to Pierson, cost cuts are not only deeply unpopular among electorates but the previous expansion of the welfare state has produced its own constituency in the form of a number of strong interest groups ready to mobilize resistance against any retreat from the status quo (Pierson 1994: 29-30). In this chapter, the genealogy of the discourse of fiscal limits and its consequences is reconstructed. Specific attention is paid to a role of epistemic communities standing behind such concepts.

As Mark Blyth (2013) argues its intellectual history is both short and indirect; it is not well worked-out body of ideas and doctrine rather it is derivative of a wider set of beliefs about the appropriate role of the state in the economy. Even Derthick and Quirk (1985) described deregulatory reform as a product of a change of intellectual climate that emerged from the spheres of economics, consumerism, and law. Deregulation in the United States in Reagan era

was not driven by interest-group pressures but by an intellectually guided process of economic rationalization.

The first part of this chapter draws from his book *Austerity: The History of Dangerous Idea*. His view on early economic history was also compared with Albert Hirschman's *The Passions and the Interests* (1977). The chapter journeys through the work of Locke, Smith, Hume, economic liberalism in 20th century, the Austrian School, Schumpeter's retreat, German ordoliberalism, the influence of the Mont Pelerin Society, American monetarism to Washington consensus, dismantling policies and current financial crisis.

Austerity can be seen as a part of the current neoliberal projects which basis was put in the neo-classical economy ideas in the first four decades of 20th century. In the aftermath of economic crisis and the World War II, its influence was weakened in favour of Keynesian economic policy. However, in the seventies, neo-liberal economists were able to take an advantage of crisis of previous economical paradigm and return back into the centre of fiscal policies arena.

THE EARLY HISTORY OF AUSTERITY

Mark Blyth (2013) starts his investigation in early economic thinking of seventeenth century. "Austerity was not a policy consistently argued for from the seventeenth century onward, since the condition of its realization - big state that spend lots of cash that can be cut - do not arise until the twentieth century. Rather, austerity emerges over time as a derivative consequence of other shared beliefs - a sensibility - concerning the nature and role of the state in economic thought." (Blyth 2013: 100) Blyth associates the dawn of the intellectual history of austerity with Locke's (1690) statement that the power of the legislature is limited to the public good of the society which is defined as freedom from intervention of government into private affairs, especially concerning property, unless citizens consent to it. It is the minimalist founda-

tion for what the state can that later liberals built upon. Money follows trade. For these reason, merchants' classes must be placed at the center of economy, and not the state.

In line with Locke's thinking, David Hume turned the attention to an existence of public debt. Hume's basic problem with public debt is that it has no limit and it is easy to levy since its costs are hidden and intergenerational. "It is very tempting to a minister to employ such an expedient, as it enables him to make a great figure during his administration, without overburdening the people with taxes." (Hume 1752) In relation to debt, Hume also pinpointed the risk of driving up prices and foreigners possessing a great share of national funds. For Adam Smith, saving leads to investments, there are no lags and leakages of income; debt has no positive role in his system while saving is both good and natural. For Smith, saving is both good and natural for individuals yet it is not natural for states. However, it leads to inevitable sovereign default that might have distributional consequences. "It occasions a general and most pernicious subversion of the fortunes of private people, enriching in most cases the idle and profuse debtor at the expense of the industrious and frugal creditor, and transporting a great part of the national capital from the hands which were likely to increase and improve it to those which are likely to dissipate and destroy it." (Smith 2001:481) Smith fears easy money, which is what credit debt offer and what would upset this natural desire to save and invest. "Saving is a virtue, spending is a vice. Countries that save must be doing the right thing, while spenders must be storing up trouble." (Blyth 2013) Later liberals, such as David Ricardo, replicated the foundations bequeathed by Locke, Hume and Smith. Ricardo imagined a highly competitive economy of small firms in which initially high profits accruing to those first to enter a market converged to a very low averaged rate of profit as more people joined in and technology was diffused throughout an industry. The proper role for the state is to teach the poor the value of independence.

Polish sociologist Maria Ossowska in her book *Bourgeois morality* (1956) attempted to classify what thrift means and its historical consequences. From her historical inspection, it appeared that the concept of thrift had a double meaning: the parsimony, indicating a virtue which is related to individuals, and the economy, which means the ability to rationally use resources associated with institutions. Similarly, bourgeois virtue is described by Daidree McCloskey (2010), however, she does not see them as separate entities. According to her, it can be viewed as a mix of the cardinal virtues of temperance and of prudence in things economic. "Temperance is the cardinal virtue of self-command facing temptation. Lead me not into temptation. Prudence, by contrast, is the cardinal virtue of practical wisdom. Give us this day [a way to make prudently and laboriously for ourselves] our daily bread. It is reason, know-how, *savoir faire*, rationality, getting allocation right. Prudence lacking temperance does not in fact do what it knows it should thriftily do. Temperance lacking prudence, on the other hand, does not know in practice what to do." (McCloskey 2010: 114)

The bourgeois virtues were echoed of discourse of liberal government where state was supposed guarantee such level of freedom and security to guarantee putting individual virtues into the economic life. In 20th century, echoing the role Hume and Smith prescribed to merchants Joseph Schumpeter put an inevitability of liquidation at the center of his analysis of the Depression and what to do about it. The consequence of this line of thinking is austerity - purging the system and cutting spending, which becomes the essence of recovery. This strain about inevitability of cycles, the centrality of entrepreneur, and the importance of failure, coexisted with and was boosted with the argument that business confidence would only be restored if the government credibility signalled that it would allow to start balancing the state budget. In the American context, this line could be attributed to Herbert Hoover's treasure secretary Andrew Mellon in response to the crisis of the late 1920s and early 1930s. The British version of austerity is commonly located in a British government white paper from 1929 called "Memoranda of

Certain Proposals Relating to Unemployment." The main argument of this paper was used also by Winston Churchill in 1929 budget speech: "[w]hen the Government borrows in the money market it becomes a new competitor with industry and engrosses to itself resources which would otherwise have been employed by private enterprise, and in the process raises the rent of money to all who have need of it."

"Then, despite Franklin Roosevelt's being elected to balance the budget, the Roosevelt's administration started to "prime to pump" under the auspices of the New Deal, and the economy began to recover. A broadly similar shift occurred in Sweden. Britain and France, in contrast, held on to austerity, and the Depression persisted in both countries until the start of World War II." (Blyth 2013: 126) Schumpeter's response to the perceived failure of austerity programs was his *Capitalism, Socialism and Democracy* (1942) where he attributed the failure of austerity to two mechanisms: (1) the rise of the large conglomerate at the expense of the small firm and the entrepreneur and (2) the collapse of the risk-taking culture that supported entrepreneurial activity. He considered the Great Depression as transitional period of technological and organizational change that became hyperpoliticized.

GERMAN ORDO-LIBERAL APPROACH

In the forming of the European fiscal responsibility discourse, the German idea of ordoliberalism plays a very important role (Gerber 1994). Ordoliberalism took form under the founders of the Freiburg school of economics. Walter Eucken, Franz Böhm, and Hans Grossmann-Doerth attracted by antitrust law in the US argued that Germany's basic economic problem in the 1920s was the inability of the legal system to prevent the creation and misuse of private economic power. According to Walter Eucken (1952), capitalism was composed of two fundamental structural orders: (1) transactional economy and (2) the centrally administered economy. Even though these orders are incompatible, real economies necessarily combine elements of both. The optimal policy is to make this combination of orders work such that the state ena-

bles and enhances the market. "First principle: the policy of the state should be focused on dissolving economic power groups or at limiting their functioning. ... Second principle: The politico-economic activity of the state should focus on the regulation of the economy, not on the guidance of economic process." (Eucken 1952 quoted in Blyth 2013) Foucault (2008) emphasized that German ordoliberalism were the avant-garde, and they went further than other members of the neoliberal family in addressing the shortcomings of traditional liberalism. The ordoliberals redoubled efforts to understand the relation between law and economics, they attempted to address issues of social cohesion, and they offered an alternative solution - the social market economy.

So forth, the effectiveness of the economy relies on its relation to the political and legal system which must be strong enough only to provide an order-based policy. These arguments became the local economic instruction sheet for economic policy in postwar Germany. The postwar political system was a mess, and the center Christian Democratic Union was looking for a new set of ideas that spoke to their members' interests. "German Ordoliberalism envisaged free markets embedded in a legal system guaranteeing the survival of a property-owning middle class that would in turn prevent the political dominance of big capital and big labour, and was equally concerned to prevent concentration of combined political and economical power." (Crouch 2011: 165) We can denote three indispensable invariants: (1) preserving the market economy as a dynamic order; (2) preserving the social balance which maintains the suppression of conflicts; and (3) securing stability and economic growth through competition and financial policies (Ptak 2009: 125).

In the tradition of German ordo-liberalism, health policy should provide the legal framework (rules of the game) for the relevant actors in the health care system through establishing an adequately designed competition law and solving the problem of inadequate information that currently affects quality of arrangements. To prevent market failure, incentives

should be provided for relevant actors either by public regulation or on more private competition. The logic of a social market economy is based upon a combination of both instruments: appropriate regulations for consumer protection and improved quality based competition among third parties payers and health care providers.

This means that the ordo-liberals favored a strong state as the precondition for the free market because the mass society lacks the moral fabric to absorb economic adjustment, preferring short-term policy responses. Blyth (2013) points out that in the late 1970s when the rest of Europe stagnated, Germany suffered the least and recovered the quickest of all the major European states. Its ability to withstand the period of recession gave ordoliberal discourse strengthens to become the model for other European states and ordoliberal principles were incorporated into the ECB constitution and the EU Commission's competition policies and the rules based approach to governing the Euro project. "If states have broken the rules, the only possible policy is a diet of strict austerity to bring them back into conformity with the rules, plus automatic sanctions for those who cannot stay within the rules. (Blyth 2013: 141) The European integration sought to inscribe the neo-liberal policy of market freedom associated with Hayek through the creation of depoliticised constitutional devices associated with German ordo-liberalism in order to embedded the free market mechanism within regulative laws and institutions (Bonefeld 2012; Moss 2000).

KEYNESIAN DEMAND MANAGEMENT

Colin Crouch (2011) uses the term Keynesian demand management for period after the Second World War when ideas of the British economist John Maynard Keynes were particularly influential in the Scandinavian countries, the UK, Austria and to lesser extent in the USA, but were also taken up by international agencies like a the World Bank, and for three decades constituted a kind of orthodoxy across the western capitalist world.

Keynesian economics taught that the main way in which government could contribute to growth was by stimulating demand. Strong demand ensured healthy profits and investment, enabling producers to use the new technologies embodied in the latest capital equipment. High levels of capacity utilization led to increasing returns and faster productivity growth. Keynesian model recommends to states going to debt in times recession, when confidence is low, in order to stimulate economy with their own public spending. In times of progression, it recommends to reduce their spending and pay off their debts. The model implied large state budgets.

“The Keynesian model protected ordinary people from the rapid fluctuations of the market that had brought instability to their lives, smoothing the trade cycle and enabling them gradually to become confident mass consumers of the products if a therefore equally confident mass-production industry.” (Crouch 2011: 12) Crouch also stressed neo-corporatist industrial relations with a strong unions’ voice as a final component of the postwar demand management.

Eichengreen (2008) argues that it is tempting to credit the Keynesian revolution for this new found stability after the Second World War, but in fact there was little active use of monetary policy. And given the lags in adjusting fiscal policy to economic conditions and the difficulty of tailoring spending by public enterprises to the cycle, fiscal impulses were often destabilizing. Electoral considerations prompted procyclical fiscal actions in Germany in 1965, in France in 1968–1969, and in a number of European countries in the early 1970s. Fiscal policy worked best when left on autopilot, allowing automatic stabilizers to work.

Generall speaking, Keynesian model suffered with its inflationary tendencies. Crouch (2011) points out that countries with both Keynesian policies and weak neo-corporatism were highly vulnerable to inflationary shocks. This defect of demand management came to be seen as intolerable fatal flaw following waves of commodity price rises in the 1970s; particularly the oil price rises in 1973 and 1978. The inflation crisis hit the advanced economies of the West

and their governments started to replace Keynesian model for neoliberal approaches, which had been developing in particular circles of experts since the Second World War.

MONT PELERINE SOCIETY AS AN EPISTEMIC COMMUNITY

Many intellectual histories of neoliberalism tend to juxtapose German ordoliberalism and Austrian neoliberalism in order to emphasize the Germanic state tradition, which is difficult to reconcile with the market radical individualism (Foucault 2008). Even though the German thinkers participated in the project of Mont Pelerin Society that was supposed to provide the community of liberal economists with breeding ground for elaborating their ideas. In 1947, the Mont Pelerin Society was founded to uphold the principles of free markets, limited governments, and personal liberty under the rule of law.

Under the leadership of Albert Hirschman and Friedrich August von Hayek whose *Road to Serfdom* (1944) was a work that assumed a central intellectual and symbolic importance for neoliberalism a number of liberal intellectuals from Europe and the United States assembled in Mont Pelerin, a village close to Lake Geneva. "At least until the 1980s--when the advance of neoliberal ideas and thus the success of the original neoliberal networks led to a rapid multiplication of pretenders to the title of progenitors of neoliberalism--the MPS network can be safely used as a divining rod in order to define with sufficient precision the thought collective that has created and reproduced a distinctly neoliberal thought style in the era of its genesis." (Plehwe 2009: 4) It was designed to create a space where like-minded people could engage in a process dedicated to advancing a common neoliberal cause in transnational *epistemic community* (Haas 1992) or thought collective (Fleck 1979).

According to Haas (1992), an epistemic community consists of professionals from a variety of disciplines and backgrounds, they have (1) a shared set of normative and principled beliefs, which provide a value-based rationale for the social action of community members; (2) shared causal beliefs, which are derived from their analysis of practices leading or contributing

to a central set of problems in their domain and which then serve as the basis for explaining the multiple linkages between possible policy actions and desired outcomes; (3) shared criteria for weighing and validating knowledge in the domain of their expertise; and (4) a common policy enterprise. Those epistemic communities have a transnational character spread by diffusion and mutual learning. According to Fleck (1979), though collective is a community of persons mutually exchanging ideas or maintaining intellectual interaction. "A though collective is even more stable and consistent of contradictory drives." (Fleck 1979: 42)

The members of Mont Pelerin Society believed that classical liberalism had failed and that the only way to diagnose and rectify them was to renew this project in a discussion group of like-minded intellectuals. The model for the Mont Pelerin Society was provided by the Colloque Walter Lippmann, which was organized by the philosopher Louis Rougier in Paris in 1938. The Colloque Walter Lippmann was an international congress consisting of twenty-six businessmen, top civil servants, and economist from several countries, including Friedrich Hayek, the architect of German social market model Wilhelm Röpcke or Alexander Rüstow (Denord 2009). The Colleague Walter Lippmann laid down founding stone of neoliberal tough collective, however, the Mont Pelerin Society unfolded as a community of neoliberal intellectuals. The comparison of these two communities illustrates rising American hegemony after the World War II. While US participants in the Colloque Walter Lippmann had formed minority (3 of 84), alms half of the participants in the Mont Pelerin Society founding conference in 1947 came form the US. (Plehwe 2009: 16-17)

In 1947, a draft of statements of aim deputed to a committee consisting of Eucken, Hayek, Hazlitt, H. D. Gideonse, John Jewkes, and Carl Iverson summarized main theoretical ideas standing behind of creation society such this: (1) individual freedom can be preserved only in a society in which an effective competitive market is the main agency for the direction of economic activity (only the decentralization of control through private property in the means

of production can prevent those concentrations of power which threaten individual freedom); (2) the freedom of the consumer in choosing what he shall buy, the freedom of the producer in choosing what he shall make, and the freedom of the worker in choosing his occupation and his place of employment, are essential not merely for the sake of freedom itself, but for efficiency in production; (3) all rational men believe in planning for the future, but this involves the right of each individual to plan his own life: (4) the decline of competitive markets and the movement toward totalitarian control of society are the result mainly of mistaken beliefs about the appropriate means for securing a free and prosperous society and the policies based on these beliefs; (5) the preservation of an effective competitive order depends upon a proper legal and institutional framework; (6) as far as possible government activity should be limited by the rule of law; (7) the changes in current opinion which are responsible for the general trend toward totalitarianism are part of a movement of ideas which find expression in the field of morals and philosophy and in the interpretation of history; (8) any free society presupposes, in particular, a widely accepted moral code; (9) among the most dangerous of intellectual errors which lead to the destruction of a free society is the historical fatalism which believes in a possibility to discover laws of historical development which we must obey, and the historical relativism which denies all absolute moral standards; (10) political pressures have brought new and serious threats to the freedom of thought and science. (Hartwell 1995, 49–50) This set of ten commandments was redrafted and the main aims were described such this: (1) the analysis and explanation of the nature of the present crisis so as to bring home to others its essential moral and economic origins; (2) the redefinition of the functions of the state so as to distinguish more clearly between the totalitarian and the liberal order; (3) methods of reestablishing the rule of law and of assuring its development in such a manner that individuals and groups not in a position to encroach upon the freedom of others and private rights are not allowed to become a basis of predatory power; (4) the possibility of establishing minimum standards by means not in-

imical to initiative and the functioning of the market; (50) methods of combating the misuse of history for the furtherance of creeds hostile to liberty; (6) the problem of the creation of an international order conducive to the safeguarding of peace and liberty and permitting the establishment of harmonious international. (Hartwell 1995, 41-42) Comparison of these two sets of aims reveals a rather striking diminution of more specific content in the MPS manifesto.

"One can interpret this not only as evidence of a fair amount of dissension within the ranks of the MPS; but also as evidence that the transnational band of participants did not have a very clear idea of where the project was headed in 1947. The only immutable truths to which they were eager to pledge their troth were those of a more general philosophical and normative kind: the fundamental neoliberal values and principled beliefs we can discern in the short list of six major tasks that have guided the neoliberal thought collective." (Plehwe 2009: 25-26)

In 1958, there was the first American meeting of the Mont Pelerine Society taking place in Princeton. The panel program included panels on inflation, including papers by Milton Friedman. Friedman became the most visible face of the Mont Pelerine Society and his influence definitely swung the mainstream thinking in the society away from ordo-liberal thinking. Friedman who later led the Mont Pelerine Society between 1970 and 1972 argued against action regulating monopoly. According to his view, competitive forces tend to limit the power of monopoly. Friedman (1962) concluded that private monopoly should be preferred over public monopoly and public regulation of monopoly. In contrast to Hayek's *Road to Serfdom*, Friedman had no interest to conduct a dialogue with socialists, he proposed the corporate income tax to be abolished, the education and health care should be privatized and open up to competition. His view on health care, he summed up in the article *How to Cure Health Care* (2001) where he associated the rise in medical costs with increase in third parties payments and public regulation.

"Two simple observations are key to explaining both the high level of spending on medical care and the dissatisfaction with that spending. The first is that most payments to physicians or hospitals or other caregivers for medical care are made not by the patient but by a third party--an insurance company or employer or governmental body. The second is that nobody spends somebody else's money as wisely or as frugally as he spends his own ... No third party is involved when we shop at a supermarket. We pay the supermarket clerk directly: the same for gasoline for our car, clothes for our back, and so on down the line. Why, by contrast, are most medical payments made by third parties?" (Friedman 2001)

Philip Mirowski (2009) identified the Mont Pelerin Society with spread of neoliberal discourse. It exists as a part of a rather special structure of intellectual discourse. Although its importance has diminished for the last decade, the Mont Pelerin Society continues to shape the further development of neoliberal ideas. Members of the Mont Pelerin Society used to be very active in Chile's market reform during Pinochet's era. Fischer (2009: 319) points to a significant role of the Mont Pelerin Society members, Milton Friedman in particular, in providing legitimacy for a radical program of neoliberal shock therapy there. The head of Banco Hipotecario de Chile Javier Vial funded Friedman's trip to Chile and was very close to him. In the second phase of Chilean reforms, the proponents of the Virginia school of public choice, which was focused to government failures and represented by the Mont Pelerin Society members James M. Buchanan and Gordon Tullock, played a very important role. They explained all policies, including those carried out in the name of public, driven by economic interests only. The saw public official as rent seeking individuals and public regulation captured by the private interest. "Public choice theory thus sought to limit democracy and to depolitize state in order to enable unconstrained market forces to guide human interaction." (Fischer 2009: 325)

John Williamson, the author of the so called Washington Consensus in 1989, was also associated with the Mont Pelerin Society. The Washington Consensus was a summary of ten

"must do" policies to solve economic crisis in the developing states. The full list comprised from (1) fiscal discipline; (2) reordering public expenditure priorities; (3) tax reform; (4) liberalizing interest rates; (5) a competitive exchange rate; (6) liberalizing trade; (7) liberalization of inward foreign direct investment; (8) privatization; (9) deregulation; (10) legal security for property rights. Blyth (2013) point to couple states that did not pursue such policies - for example France, Italy, and all of Scandinavia, to name but few OECD states. "Outside the OECD the more successful developing states such as Korea, Taiwan, and latterly China, practices these policies even less." Despite governments accepted these policies more then reluctantly, the Washington consensus met with accolades by international institutions – the International Monetary Fund (IMF) and the World Bank in particular - devolving to a mantra of stabilize, privatize, and liberalize. "The result was a series of one-size-fits-all policies that were applied from Azerbaijan to Zambia whose objective was to minimize fiscal deficits, minimize inflation, minimize tariffs, maximize privatisation, maximize liberalization of finance." (Blyth 2013: 162)

Dorothee Bohle and Béla Greskovits (2012: 57-58) describe how the idea of the Washington consensus profoundly influenced the East Central European reform efforts in 1990s. Western policymakers and advisors built translational coalition with their Eastern colleagues sharing together the preference for rapid and comprehensive marketization. These coalition were backed by the IMF's practice of conditionality for financial assistance. These reformers saw their mission as respecting and allowing freedom of choice and "go against the thinking of individuals who have dirigistic ad constructivist ambitions (the typical case of socialist intellectuals), who prefer to be guided by visible and foreseeable "concrete" purposes and who want things to be done now, immediately, because of purposes are evident to them."(Klaus and Ježek 1991) Reformist think tanks were set up in all post-communist countries. They could be considered important actors who popularize the neoliberal discourse, provide reform expertise,

and stabilize and renew neoliberal thoughts. Their embeddedness in transnational networks such as the Mont Pelerin Society constituted an additional important asset. (Bohle and Neunhoffer 2006)

DISMANTLING WELFARE STATE

The work of Paul Pierson (1994, 2001) changed the character of academic debates about the reforms welfare state by claiming that the politics of welfare state retrenchment is fundamentally distinct from the politics of welfare state formation and expansion. Whereas the introduction of new social rights in 1950s and 1960s allowed politicians to compete for votes by taking credit for these new programs, social policy cutbacks met with much political resistance and one can see different strategies of the "blame avoidance". Pierson (1994) deployed a thesis proposed by Weaver (1986) that given public resistance to cuts in popular spending programs, politicians will attempt to avoid blame by making cuts less transparent. Drawing from psychological theories arguments, Pierson notes that difficulties in enforcing of such reforms stem from the reason that the prospect of losing has a much greater emotional impact on people than an equivalent gain (Kahneman and Tversky 1979).

The interest in welfare state retrenchment was sparked by the coming into office of Margaret Thatcher in 1979 in UK and of Ronald Reagan in 1981 in the US: both willing to radically cut back the welfare state. In their view, the welfare state had become a significant source of social and economic problems instead of a solution. According to Colin Crouch (2011) neoliberalism began its dominance when Keynesian demand management entered its own crisis in the inflation of the 1970s.

Herman Schwartz (2001) summarized the main factors contributing to the rise of welfare state retrenchment in 1980s and 1990s. He identified there main groups of factors: (1) external pressure (low-wage international competition, technological advances, and monetary policy constraints); (2) domestic factors (inflation control, low service sector productivity

growth, and ageing) and (3) combination of external pressure and domestic factors (property rights, income streams and political coalitions). Some scholars (Garrett 1998; Ross 2000; Kitschelt 2001; Korpi and Palme 2003) conceive of retrenchment policies as a product of partisan influence and election competition.

Pierson identified three main strategies how governments try to minimize the resistance: (1) obfuscation; (2) division and (3) compensation. In terms of obfuscation, the policy advocates try to lower salience of negative consequences and make for their political opponents more difficult to obtain information about policy reform. The frequent tactic to lower visibility is decrementalism - retrenchment advocates may be able to achieve their goals by freezing a program within growing economy. This tactic, Pierson describes (2001), has two forms: (1) a failure to adjust for higher prices lowers the real value of benefits and (2) implicit privatization in which benefits retain their real value but play a diminishing role in expanding economy. As a result, provision is shifted increasingly toward the private sector. Visibility of effects can be diminished by increasing in complexity of reforms. "Reforms are less likely to generate a popular outcry if television reporters cannot explain the implications of the new policies in fifteen second or less." (Pierson 1994: 31) As Schattschneider (1960) points out, a strategic problem definition usually means manipulating the scope of conflict in the way that can restrict framing of the issue on one hand or expand it on the other. According to the Pierson's logic, in case of cutbacks, policy advocates try to increase a complexity of frames in order to prevent policy opponent from pinpointing a particular aspect of policy to mobilize people against it. Finally, policymakers try to diminish public awareness of their own responsibility of policy change, for example by postponing the implementation of cutbacks. Strategies of division bring our attention to the importance of category making; cutbacks may be designed so that they affect some benefit recipients but not others.

Both the Reagan and the Thatcher administration lowered income ceilings for some means-tested programs. In order to grasp a main trope of these reforms, Sommers and Block (2005) adopt the term of perversity thesis from Albert Hirschman's (1991) path breaking finding that welfare critics since the French Revolution have used the same "rhetoric of perversity"- the assertion that policies intended to alleviate poverty create perverse incentives toward welfare dependency and exploitation and thus inexorably exacerbate the very social ills that they were meant to cure (Hirschman 1991). In the context of the US, this trope was reiterated in Charles Murray's *Loosing Ground* (1984). In that book, Murray used data and techniques earlier honed in predominantly liberal think tanks to argue that the liberal welfare state was to blame for a whole host of social problems, including poverty, family breakup, and crime. The expansion of social welfare since the 1960s had not only failed to improve poverty conditions it had actually made things worse for the poor. Even though Murray's argument proved easy to be demolished and a number of poverty experts heavily criticized it, the book as an ideological manifesto reserved its influence over the neoliberal discourse of welfare state. This discourse is anchored in between two central subjectivities: (1) the deserving autonomous, self-sufficient individual and (2) the undeserving dependent. The perversity thesis combines classical liberal economy with protestant morality to suggest that "contrary to the apparent reality that financial aid to the "poor" was a kind and charitable act of assistance, such interventions actually undermined the natural order of things and corrupted individuals who took such succor so that they lost the ability to practice self-discipline and to exercise personal responsibility." (Schram 2012: 247)

The third strategy, compensation, is represented by efforts to offer compensation to group most likely against retrenchment by provision of transitional benefits or expansion of private benefits. For example, cutback in family support benefits may be compensating by tax reliefs for the same group.

Michael Bauer and Christopher Knill (2012) identified four ideal types of dismantling strategies: (1) dismantling by default; (2) dismantling by arena shifting; (3) dismantling by symbolic action; (4) active dismantling. Dismantling by default is the most subtle strategy which ensures low visibility. It means refraining from adjusting existing levels to changing external conditions. It corresponds with Pierson's strategy of decrementalism. Dismantling by arena shifting is characterized by the fact that decisions are deliberately moved to another political arena. It is associated with decentralization and agencification of state. Effects of this strategy might be associated with transfer of responsibilities, administrative capacities and procedural requirements. Dismantling by symbolic action seeks to ensure that any dismantling intention is clearly and directly attributed to political decision makers that declare to their intentions to dismantle existing policies. At the same time, however, political declarations do not lead to concrete outputs, hence remain symbolic. Dismantling by symbolic action leads to relabeling policies and commissioning consultations or evaluations reports. It resulted in recognition of needs for dismantling without implementation.¹⁴ The final strategy, active dismantling, exhibits high visibility with a strong and clear preference to dismantle. "Dismantling might be rewarding, not only because of political demands, but also because politicians are ideologically convinced that dismantling is the most appropriate solution." (Bauer and Knill 2012: 44)

NEOLIBERAL APPROACH TO HEALTH CARE

The transformation of health from a concept of public welfare or well-being into a commodity with an economic value and the potential to be traded in markets is characteristic of the logic of neoliberalism in health care. (Kay and Williams 2009) The appeal of markets grew as the most appropriate agents to ensure the provision of efficient services that best met indi-

¹⁴ Bernauer and Knill (2012) describe as an example of dismantling by symbolic action the proposal from German Liberal Democrats to complete abolition of the system of waste collection. The likelihood that the proposal would pass through Parliament was very low. However, Liberals made efforts to launch and discuss their proposal. While it did not result in a political decision, this proposal signalled the Liberal's position to voters.

viduals' needs through increasing level of privatization and decentralization. During last three decades, the golden era of expansion in health care provision turned into the era of accountability, control and attempted retrenchment (Marmor et al 1990: 29). There is evidence that suggests that liberalisation in healthcare creates inequities in terms of access to health and health outcomes in many developing countries, with the poor unable to afford basic healthcare or medicines (Barrientos and Lloyd- Sherlock, 2000 and 2003; Hutton, 2004; Mackintosh and Koivusalo, 2005).

According to Kay and Williams (2009), an important aspect of neoliberalism in healthcare is the development of indirect techniques for leading and controlling individuals without being responsible for them. In line with its desire to privatise risk, neoliberal healthcare states use the technique of responsabilisation; citizens become 'responsibilised' by making them see health risks and outcomes such as illness or disease as their own individual responsibility, with the corollary that the policy problem of health governance is framed as one of encouraging 'self-care'. Kay and Williams point out that that this mirrors previous phases of neoliberalism in the labour market where the state rescinded previous responsibilities for managing unemployment and poverty, which were instead placed firmly in the domain for which the individual is responsible. Responsibilisation is present in many of the current debates in advanced capitalism over tobacco, obesity and access to medicines; they reveal the dominant neoliberal thrust in health, it is our responsibility to remain free of illness so as to be able to work and to care for our dependants such as children and elderly parents.

THE EUROPEAN CRISIS AND ITS IMPACTS ON HEALTH

The global financial crisis that began in 2007 represented an unexpected challenge for health systems that has had both a negative effect on the availability of health system resources and a positive effect on the demand for health services. Recessions pose a risk to health due to a combination of deepening conditions of poverty and the psychological burdens of unem-

ployment. The economic decisions of European leaders, justifiable in terms of fiscal responsibility, may, on the other hand, have further exacerbated these health risks. The health budgets of Western European countries have been under constant pressure since the 1980s, the economic crisis, however, has acted as a triggering event galvanizing public and government attention to health care costs. In the context of the economic crisis, governments might be criticized for their reluctance to solve problems as well as for the solutions which they propose.

Mladovsky et al. (2012) summarize that in n many European countries public spending on health has declined since 2008. The countries in which per capita spending on health by government fell relative to the previous year, between 2008 and 2011 are listed in the following table. Countries shown in bold experienced reductions in spending in more than one year. About half of all EU countries experienced a decline in the health share of government spending between 2007 and 2010, including in some of the countries most affected by the crisis (Ireland, Latvia, Lithuania, Portugal, Spain).

Tab 6: Countries with a reduction in per capita public spending on health (national currency units), 2008–2011

2008	2009	2010	2011
Andorra	Andorra	Albania	Andorra
France	Bulgaria	Armenia	Armenia
Luxembourg	Croatia	Croatia	Czech Republic
Malta	Estonia	Czech Republic	Germany
	Hungary	Estonia	Greece
	Ireland	Finland	Ireland
	Latvia	Greece	Netherlands
	Lithuania	Iceland	Portugal
	FYR Macedonia	Ireland	Slovakia
	Romania	Latvia	Spain
	San Marino	Lithuania	United Kingdom
		Montenegro	
		Slovenia	
		Spain	

Mladovsky et al. (2012)

European health systems adopted a wide range of strategies to cope with having fewer resources. Mladovsky et al. (2012) list typical examples. Reductions in coverage were mainly

marginal and sometimes accompanied by efforts to protect poorer people, but a few countries delayed needed expansions in coverage of essential services. Many countries tried to strengthen pharmaceutical policy by lowering drug prices and encouraging greater use of generics. Many also adapted provider payment by reducing salaries or (less commonly) service prices. Several countries reported closing, merging or centralising provider facilities and other organisations to cut overhead costs.

European states also preferred short-term measures with relatively low introductory costs over more complex policy programs. “Very few countries have taken steps to promote cost-effective investment in the health system. At a time of financial pressure we might expect a focus on ensuring that all spending is ‘good’ spending. ... And with the exception of pharmaceutical policy, there has been almost no emphasis on promoting value-based investment in and payment for goods, services, skills, technologies and infrastructure. These failures may reflect undue pressure to make short-term savings at the expense of longer term financial sustainability; lack of information, analysis and capacity for effective decision making; and resistance from stakeholders. The latter is likely to be exacerbated by prolonged cuts, limited opportunity for consultation, poor communication and lack of transparency.” (Mladovsky et al. 2012: 14)

Given delays in publishing health data in many countries, only preliminary conclusions can be drawn about the effects of the current crisis. There is a concern among experts that the deepening level of poverty combined with a lack of quality housing might affect the transmission of infectious diseases. In Greece, which is one of the most severely afflicted countries within the EU there are signs of an increase in several infectious diseases, including HIV (Kentilekris et al. 2011) and malaria (Danis et al. 2011). The financial crisis has also had a serious impact on vulnerable groups such as individuals with psychiatric disorders (Christodoulou et al. 2012). Gili and her colleagues found that the recession in Spain had significantly increased the frequency of mental health disorders and alcohol abuse among primary care attendees, par-

ticularly among families experiencing unemployment and mortgage payment difficulties (Gili et al. 2011).

The other important factor connected with unemployment appeared to be the rate of suicides. Stuckler et al. (2011) showed how the increase in unemployment can be associated with an increase in suicides among people younger than 65 years. "[W]e can already see that the countries facing the most severe financial reversals, of fortune, such as Greece and Ireland, had greater rises in suicides (17% and 13%, respectively) than did the other countries, and in Latvia suicides increased by more than 17% between 2007 and 2008" (Stuckler et al. 2011: 125).

Many studies (for example: Pritchard 1992; 1996) indicate a role for unemployment as an accelerating, rather than causative factor in suicidal behavior. We can understand the connection between unemployment and suicidal behavior on two levels: (i) the financial impact of unemployment and (ii) the effect it has on one's self-esteem. However, recent studies have proved that an increase in the level of suicides during economic downturns is not inevitable. "Research on economic fluctuations in Western Europe over the past three decades showed how those countries with strong system of social protection were able to maintain long-term declines in suicide rates despite rapid increase in unemployment." (McKee et al. 2012: 347) However, programs of social protection like youth training, exchange information on vacancies and measures to support disabled people in the workforce are very often becoming victims of government cuts, concludes McKee and his co-authors. Mladovsky (2012) and her colleagues warn that arbitrary cuts to essential services may further destabilize the health system and increase health and other costs in the longer term.

CONCLUSION

The narratives outlined in this chapter each represent a compilation of multiple strands, characters, and plot devices woven together into a plausible storyline in order to grasp genealogy of discourse of fiscal responsibility. As Mark Blyth (2013) argues, this genealogy starts in

early economic thinking of seventeenth century. The early history of austerity discourse can be traced in Adam Smith's, David Hume's or David Locke's work. As Foucault (2004) emphasizes, the new art of government therefore appears as the management of freedom. "The formula of liberalism is not "be free." Liberalism formulates simply the following: I am going to produce what you need to be free." (Foucault 2008: 63) So, freedom in the regime of liberalism is not a given, it is not a ready-made, however, freedom of behavior has to be produced and organized. Liberalism is forced to determine the precise extent to which and up to what point different individual interest possibly opposed to each other, constitute a danger for the interest of all. The game of freedom and security is at the very heart of this new governmental reason. The consequence of this liberalism is the considerable extension of procedures of control, constraint, and coercion that are the counterpart and counterweights of different freedoms. It resulted in the appearance in governmental mechanisms increasing freedom at the expense of introducing additional control and intervention.

The early history of austerity concept taught us that *homo oeconomicus* who follows his or her own interest in his or own way can meet with *homo spectatus* who follows his or her own honor depending upon the honor and glory of his community. (Kabele 2000). As Adam Smith supposed, saving is both good and natural. To behave economically is no only morally appreciated but also natural. In the field of state politics, the consequence of this line of thinking is austerity - purging the system and cutting spending which becomes the essence of recovery. The predominant metaphors used to frame the problem are medical. Politicians speak about a chronic spending disease that will weaken the system. These metaphors convey a sense of impending doom – fear that the prognosis for the spending disease is not good and concern about a sick fiscal future. Because of excessive spending, the systems have deviated from the economic nature and it necessary to take them back in healthy conditions. There is also a note

of urgency that treatment cannot be put off any longer and the best cure for it is the diet. Developed societies need fasting to pure their bodies and revive their vitality.

For the traditional monetary liberals, this cure lies in cutbacks of public expenses, decrease in the role of state and depolitize state in order to enable unconstrained market forces to guide human interaction. For the ordo-liberals, this cure lies in strict rules limiting budget expenses. Whereas the first logic can be found in Washington consensus the later one is applied by European institutions pushing the fiscal pact. The both treatments are supported by coalitions of politicians, bankers, public officers and experts. Those international epistemic communities are both enacted by the neoliberal discourse and shape it at the same time. Despite of the strong discourse of budget responsibility and austerity, pushing these policies is not without any thread. Difficulties in enforcing of such reforms stem from the reason that the prospect of losing has a much greater emotional impact on people than an equivalent gain. For these reason, advocating of reforms is an exercise in blame avoidance. There are different strategies how to successfully manage this task ranging from obfuscation to division and compensation.

As policy scholar Deborah Stone (1988) observed, a key dynamic in public debate about social issues involves the process of deciding who is to blame: "In politics, we look for causes not only to understand how the world works but to assign responsibility for problems. Once we think we know the cause of a problem, we use the knowledge to prevent people from causing the problem, to make them compensate other people for bearing the problem, and to punish them for having caused suffering." (Stone 1988: 189) Avoiding to be blamed is a key part of dismantling policies described by Pierson and it is also presented in narratives of sustainability. Jordan at al. (2012) suggest that when this approach is taken, the Lasswellian (1936) conception of politics (who gets what, when and how) seems to be reversed (who gets less, when and how).

CHAPTER 5: DISCURSIVE AFFINITIES IN SUSTAINABLE NARRATIVES

In the last two chapters, two main discourses – the discourse of health promises and the discourse of fiscal limits were introduced and their genealogies were described. This chapter focuses on researching discursive affinities between them. Marteen Hajer (2009: 65) defines discursive affinities that arguments that may have very different roots and meanings but that together uphold a particular way of seeing. Hajer mentions that an important example from pollution politics is the discursive affinity shared by the moral argument that nature should be respected, the scientific argument that nature is to be seen as a complex ecosystem (which we will never fully understand), and the economic idea that pollution prevention is actually the most efficient mode of production.

As it was said in the introduction, health system reform is on the agendas of governments around the world because of the increasing costs of providing high quality, comprehensive care for ageing populations in the face of competing demands for scarce public resources. However, reforms are usually justified by sustainability of the system, which seems as a central category for thinking on health debates in developed societies. Cox and Béland's (2013) suggest that the sustainability paradigm reflects a growing concern for the long-term consequences of decisions, and it implies an increasing dissatisfaction with current practices. They argue that sustainability discourses attempt to reframe issues that, in the short term, may be perceived as difficult, unpalatable, and contentious problems into objective, forward-thinking, durable solutions. Health policy debates are, thus, a laboratory of broader shifts in the role of the state in welfare provision undergoes profound shifts in an era of permanent austerity (Pierson 2001; Rothgang 2010). Ageing populations, expensive new technologies, increasing demands and expectations from consumers are among the most commonly cited factors leading to growing

concern about the sustainability of current spending patterns (Appleby 2013; Borgonovi 2013;; Rothgang 2010; Thompson et al. 2009).

The attractiveness of the idea of sustainability is a quality Cox and Béland (2013) call its valence. They define valence as an emotional quality of an idea that can be either positive or negative in its character, or high or low in its intensity. Cox and Béland suggest that ideas with a high, positive valence generate a strong attractiveness and therefore are likely to have a greater potential to influence policy change. In electoral studies, the term “valence issues” is used to distinguish issues that all voters support from “position issues,” where the preferences of candidates and voters preferences diverge, often on ideological grounds. During the past decade, the idea of sustainability has quickly expanded beyond the field of environmental policy and has caught on in a number of policy areas, introduced by policy entrepreneurs who adapted the idea to the particular challenges of their policy domains. Although the notion of sustainability is central, the “debate is rarely, if ever, accompanied by a clear idea of what it means for a health system to be financially sustainable or how we might assess a health system’s financial sustainability or, indeed, what the policy implications of the problem are.” (Thompson et al. 2009, 1-2)

In terms of sustainability of health care, Bhatia and Orsini (2013) mapped the alternative and competing conceptions as constructed by key stakeholders in Canadian health policy networks, and explore how these narratives are modified and deployed in the process of forming discourse coalitions of actors to promote particular policy solutions. The goal of this chapter is to introduced their different sustainability narratives and research their relation to dominant discourse identified in previous two chapters. The chapter intends to demonstrate that discursive affinities the analytical tool to explain roots of their differences.

Based on their extensive research of Canadian policy debates, Bhatia and Orsini identified four policy narratives: (1) fiscal sustainability; (2) value-for-money; (3) sustainability as

moral choice; (4) the emergence of a new social contract. All of these narrative state different goals for policy proposal and different tool how those goals can be achieved.¹⁵

Fiscal sustainability narrative is one that conceives of sustainability in its narrowest sense of fiscal balance between revenues and expenditures. Bhatia and Orsini label this narrative using a metaphor borrowed from one of its creators – the health care spending disease. Because of population ageing, public health care costs are increasing and will eventually consume an unsustainable proportion of government budgets – compromise other public programs, and increase government debt loads. However, there is an alternative storyline about unsustainable health costs attributes the cause to a governance failure, specifically, the state's "unregulated monopoly" over health insurance. The victims of these failures are taxpayers, who are paying the bill for universal access health care system but are not receiving the adequate services in return. In either narratives, the solutions lie in managing the (public-sector) spending disease with private market strategies: financial incentives that will promote competition and hence generate efficiencies, create price sensitivity among users to reduce unnecessary demand, and give more choice to consumers thereby reducing the burden on public system. The tone of the narrative is predominantly negative one – its main goal is to avoid of financial unsustainability of the recent system in the future. The narrative plays with negative emotions connected with the fear of future or wasting of money in presence.

¹⁵ The narratives can co-exist in public discourse. In policy-making in some developed states one can observe mechanism putting them together and seeking for possibilities to negotiate between One of those options might be the health technology assessment (HTA) promoted by the WHO or European commission. Health Technology Assessment is way of assessing the ways science are technology are used in healthcare and disease prevention. It covers medical, social, economic, and ethical issues. Dealing with expert studies and public deliberation the HTA tools can start a dialogue between different preferences and differences conceptions of sustainability. However, evaluating medical treatment is usually one-dimensional: selected parameters are limited in number and have a quantitative biomedical character (ten Have 2004). From the perspective of interpretative policy analysis, Health Technology Assessment can be understood as an expert arena for conflicts, negotiations or reconciliation between mentioned narratives.

Value-for-money narrative defines sustainability as a constraint or boundary within which the system must operate. This storyline also conceives of this constraint as primarily fiscal, however, cost is one among a number of other parameters within which reform of the health care system must be considered. The causes of the sustainability problem in this storyline are broad, overarching factors related to the changing needs of an ageing population to which the system has failed to adapt sufficiently, resulting in inefficiencies and ineffective care. There is a need for transformation, modernization, and innovation in the way services are delivered, a shift away from an outdated dependence on expensive and inefficient acute, hospital-based care. This narrative has much more progressive character than the previous one. In contrast to the fiscal sustainability narratives, the tone of the value-for-money narrative is positive. The 'consumer' focus of the previous narrative is replaced by the consensus among groups that favour this storyline is that the system needs to be patient-centered.

Sustainability as moral choice narrative defines sustainability in terms of moral and ethical choices that guide what should be done. The champions of this narrative are a coalition of socially progressive groups, including organized labor, citizens' groups, social policy activists, anti-globalization advocates, and think tanks. Their legitimacy in health reform debates is twofold. First, they are able to draw on their own diverse experiences and knowledge to convey timely, relevant information in response to specific issues. Second, and more important, they are explicitly normative in their defense of core values that (should) underpin the system. The problem, according to this storyline, is not actually a question of sustainability at all; rather, it is the myth of health care unsustainability. This storyline differs in tone from the previous two in that it explicitly engages norms and values, and the publicly funded, universal health insurance system is a symbol of both the problem and the solution.

The new-social-contract narrative is employed as a container for everything that is wrong with the status quo, and acts as a call to arms to do things differently. While this narra-

tive does not advance a specific definition of sustainability, it does provide some indications of why the status quo is unsustainable, what a sustainable health care system would look like, and what actions might facilitate such a system improvement. This narrative comprises from life-style choices (for example pinpointing the role of obesity epidemics in expanding of health care costs). Like the fiscal sustainability narrative, the new social contract narrative of sustainability – or unsustainability – is steeped in doomsday scenarios, futuristic scenes of systems on the verge of collapse and it is based upon the personal responsibility. In the absence of a concrete definition, sustainability is framed as a gap that must be closed between demand for health services and the capacity to finance that demand. It explains why the battle is over how to make up for that shortfall.

I argue that all narratives described by Bhatia and Orsini (2013) as independent can be classified along two axis: (1) their relation to medicalization and (2) fiscal responsibility discourse. Drawing on Bhatia and Orsini (2013), I contextualized four health sustainability narratives: (1) value-for-money (austerity and medicalization); (2) fiscal (austerity without medicalization); (3) a moral choice (neither austerity nor medicalization); and (4) the new social contract (medicalization without austerity). The advantage of the value-for-money narrative lies in possibility to justify savings (in fiscal responsibility discourse) by medicalization discourse.

Tab 7: Discursive affinities

	Fiscal responsibility discourse (YES)	Fiscal responsibility discourse (NO)
Medicalization discourse (YES)	Value-for-money narrative	New social contracts narrative
Medicalization discourse (NO)	Fiscal Sustainability	Sustainability as moral choice

The discourse of medication is very strongly present at policy narrative - which Bhatia and Orsini (2013) called value-for-money sustainability narrative. Value-for-money narrative defines sustainability as a constraint or boundary within which the system must operate. This

storyline also conceives of this constraint as primarily fiscal, however, cost is one among a number of other parameters within which reform of the health care system must be considered. The causes of the sustainability problem in this storyline are broad, overarching factors related to the changing needs of an ageing population to which the system has failed to adapt sufficiently, resulting in inefficiencies and ineffective care. There is a need for transformation, modernization, and innovation in the way services are delivered, a shift away from an outdated dependence on expensive and inefficient acute, hospital-based care. This narrative has much more progressive character than the previous one. In contrast to the fiscal sustainability narratives, the tone of the value-for-money narrative is positive.

The different side of health hopes discourse in public policy narrative is represented by the new-social-contract narrative which comprises from life-style choices (for example pinpointing the role of obesity epidemics in expanding of health care costs). Like the fiscal sustainability narrative, the new social contract narrative of sustainability – or unsustainability – is steeped in doomsday scenarios (futuristic scenes of systems on the verge of collapse) and it is based upon the personal responsibility.

The discourse of fiscal limits is presented in the fiscal-sustainability and value-for-money narrative. In both the spending-disease and new-social-contract narratives, rising public health costs are presented as having reached, if not surpassed, their maximum sustainable level. In contrast, the value-for-money narrative construes the rising costs of delivering health care as worrying but not catastrophic, an opportunity rather than a crisis. Public expenditures ring alarm bells; they are a warning that more effective and efficient means of providing for the health needs of the population must be found. Unlike the others, the moral-choice narrative focuses on private sector expenditures, which are rising faster than public sector costs.

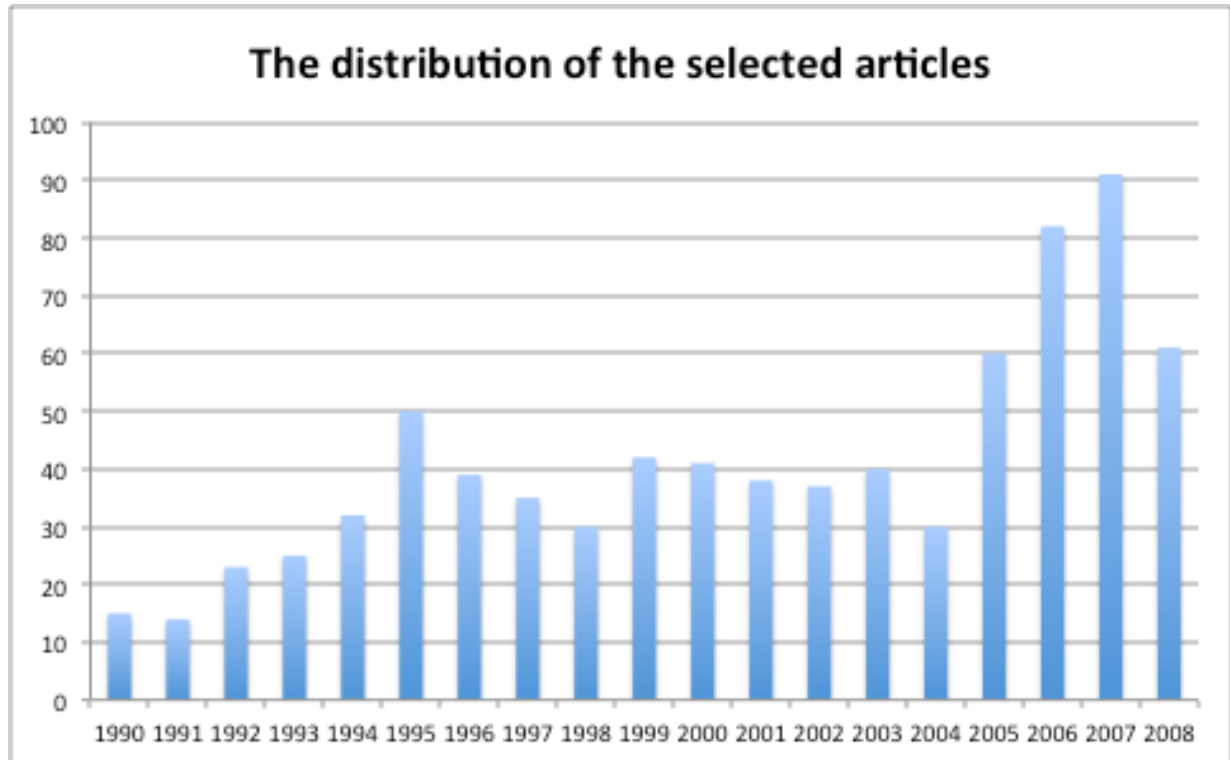
CHAPTER 6: METHODOLOGY

This dissertation examines how the boundaries between aspects of public policy were being constructed when the Czech health care reform was being discussed. The paper seeks to understand how the reforms were justified to the broader public. The analysis used in the dissertation is organized around the identification and analysis of narratives patterns and collections of categories in discussions revolving around regulation. The dissertation examines frames of pharmaceutical regulation in the Czech Republic between 1990 and 2008. It uses cultural theory of regulation (Douglas 1992; Thompson, Ellis, and Wildavsky 1990; Lodge et al 2010; Lodge and Wegrich 2011 - see Chapter 4) to classify, chart, and compare argumentation patterns and policy values. Cultural theory's four core-value system - hierarchy, individualism, egalitarianism, and fatalism - is used as an analyst's compass into a trajectory of frames that covers patterns of blame and proposed remedies. The analysis of argumentation involved the extraction of claims that demanded particular types of regulatory action, and coding these claims according to their frames (Lodge, Wegrich, and McElroy 2010; Lodge and Wegrich 2011). The analysis includes newspaper and weekly magazines. Using the proposed perspective one can see how the different solution to a problem have been constructed; but also how these solutions result from a specific form of problematization.

Using Newton Media Search, 785 articles were extracted and coded along theoretical lines developed in the previous theoretical chapter. For searching in media archive key words “drugs”, “pharmaceuticals”, “pharmaceutical”, “health”, “hospitals”, “policy”, “law”, “pharmacy” and their combination were used. The search period was from the beginning 1990 to the end of 2008.

The following graph depicts the distribution of the selected articles in time:

Pic 2: The distribution of the selected articles



The whole corpus of data also comprises the transcriptions of 14 debates on health care broadcasted on Czech public TV in the weekly political debate series Questions of Václav Moravec. This series features representatives of the political parties, relevant stakeholders and experts and provides them with relatively sufficient space for discussion (each session lasts around 120 minutes). This program represents the main arena for top-level public political debates in the Czech Republic. The whole corpus of transcribed discussions was coded to identify what categories were used, what elements made them belong together, what meanings they signalled, and what was the point of view which made them meaningful together. TV debates represent an ideal unit of analysis because they require politicians to explain their proposals to their opponents and the broader public. According to Chouliaraki (2005), the analysis of a television text posed two main procedural issues: (1) how to analyze the dialogic flow from the perspective of discursive regulation, and (2) how to account for the two distinct semiotic modalities that coexist during the television debate, the linguistic and the visual. The focus here is

the discursive ideas that are presented in a debate; hence I deliberately decided to ignore the visual component of a debate. Dealing with the first issue was, however, much more difficult. The analysis is focused on justifications made by authors of the reform, thus I coded and picked out whole sequences of questions and answers to control a particular conversation setting.

I focused how answers on following questions are articulated by different actors in their utterance: (1) What market failures can be identified?; (2) What norms justify regulation?; (3) What are processes within a particular regulatory regime?; (4) Who benefits and loses from regulation?; (5) What is institutional setting of regulation?; (6) What are cultural patterns behind regulation? In each of this segment, an attention was particularly paid to that how blame was prescribed, following Pierson's (1994) argument about the importance of blame avoidance in promoting of dismantling policies. This type of coding helped in reconstruction of main policy storylines.

Given that the ambitions of my dissertation is mainly theoretical ones, this theoretical driven coding was chosen to ensure a communication between theoretical and empirical part of my thesis.

In the analytical phase, all codes were re-coded along the following lines:

1. Sustainability narratives proposed by Bhatia and Orsini (2013)
2. Regulatory codes in regulation proposed by Douglas and Wildawsky (Douglas 1993; Thompson, Ellis and Wildawsky 1990).
3. Categories and collection of categories, category bounded activities, hierarchies of relevance (Lepper 2000)
4. Different elements of discursive praxis – metaphors, selection of evidence, future expectation, identified problems.

In the third stage of analysis, narratives, codes, collection of categories and elements of discursive praxis were examined in terms of their relations according to theoretical model introduced in Chapter 2.

Tab 8: Examples of sustainability narratives codes (developed from Bhatia and Orsini 2013):

	Examples of codes:
Fiscal sustainability narrative	increase government debt loads; chronic healthcare spending disease; spending limits; spending disease; sick fiscal future; unregulated monopoly; the largest bill; discipline; fear and anxiety about the future of the system
Value-for-money narrative	better patient care through better value; transformation; modernization; innovation; shift away from an outdated dependence on expensive and inefficient care; the health care system of future generations; better value for patients; patient-centred care,
Sustainability as moral choice narrative	moral principles; self-interested private actors; free-market ideology; the collapse of the public system; social consequences
The new-social-contract narrative	life-style; obesity; alternative treatment; rehabilitation; psychosomatic medicine; everyday life

Tab 9: Examples of cultural regulation codes (developed from Lodge, Wegrich, and McElroy 2010; Lodge and Wegrich 2011):

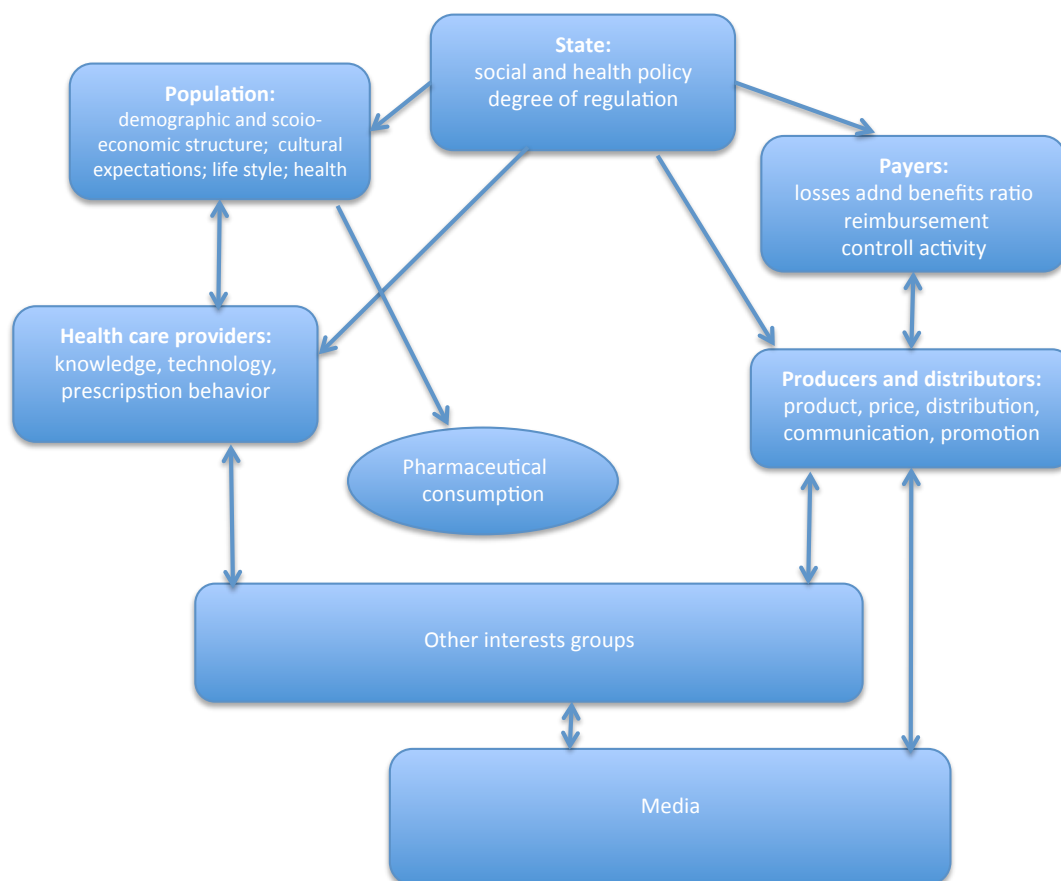
Individualist	perverse rules; market-based solution; patients as consumers; self-regulation is superior; individual responsibility; individuals as rational actors
Hierarchical	capture and corruption are the problem; need for prudential regulator; expand scope of regulation; strengthen existing institutions; the central role of government
Fatalist	crisis always happens; inevitable; nobody has any idea what is going on; unpredictable effects; regulators will always be be-

	hind markets; regulation will always be undermined; ageing of population
Egalitarian	reliance on markets caused melt-down; encourage information sharing; inequalities; access to healthcare

CHAPTER 7: REGULATING PHARMACEUTICALS IN THE EU CONTEXT

A variety of regulatory pharmaceutical policies are used to try to balance effective spending on pharmaceutical against the need to promote an innovation industry. Medicines are consumed in the inpatient (mostly hospitals) and outpatient (mostly pharmacies) sector. Pharmaceutical regulation is very complex field where different factors ranging from populations' characteristics through state policies to the behaviour of health care providers, producers and distributors and payers influence the level of pharmaceutical consumptions.

Pic 3: Factors influencing pharmaceutical consumption



According to Práznovcová (2005)

Policy-makers face overlapping and at times competing regulatory tasks. It is a responsibility to the consumer in terms of guaranteeing that only safe, good-quality and efficacious medicines make it to market. Next is the balancing of health care budgets with regard to controlling health expenditures and drug costs. And third, in many countries, given the economic contribution of the sector, is to promote a regulatory environment conducive to business.

Tab 10: Competing pharmaceutical policy interests

Health care policy	Industrial policy	Public health policy
Cost containment and improving efficiency in health services and care	Promoting local research and development capacity	Safe medicines
Cost-effective medication	Intellectual property rights protection	High-quality preparations
Regulating doctor and consumer behaviour vis-à-vis medicines	Supporting local scientific community	Efficacious treatments
Generic promotion and/or substitution	Generating and protecting employment	Innovative cures
Improving prescribing	Promoting small and medium enterprises policies	Patient access to medicines
Ensuring access to medicines	Contributing to positive trade balance	
	Sustaining the university research base	

Permanand (2002).

Mossialos, Walley and Mrazek (2004) enlist main policy tools of pharmaceutical regulation: (1) legislation and market authorization; (2) measuring, monitoring and evaluating; (3) pricing and reimbursement; (4) monitoring and influencing physician decision making; (5) changing doctor-patient relationship; (6) financial incentives and prescribing; (7) regulating pharmaceutical distribution, retail and hospital pharmacy in Europe; (8) influencing patient demand through co-payments; and (9) regulation of the off-patent and over-the-counter pharmaceutical markets.

In this chapter, a brief introduction to the regulation of pharmaceutical law in European Law and description of some influential examples of regulatory approaches of particular member states is provided. This context is necessary to examine pharmaceutical regulatory frameworks in relation to both hard power of European legislation and the soft power of policy transfer on the level of state policies. Thus, pharmaceutical regulation is a combination of elements of hard law (uniform rules that Member States must adopt, sanctions if they fail to do so, and challenges for non-compliance to be brought in court), and soft law based on non-binding instruments of peer review, benchmarking, and persuasion. Furthermore, the impact of global players cannot be overlooked too. For example King (2007: 186) mentions the example the influence of US Food and Drug Administration (FDA) on investigation of EU regulatory bodies. There is also a significant influence of international organizations such as WTO in terms of for example intellectual property right and patent protection or WHO in terms of vaccination.

Regulations apply across the entire product life cycle in pharmaceutical industry. Compared with other industries, the risk and compliance profile spans the full pharmaceutical product life cycle - from testing, to patent protection, authorization, marketing and monitoring when a drug is already in the market. Clinical trials are conducted in stages, each of which must be successful before advancing to the next one. During Phase I trials, the safety of the drug is evaluated and its metabolic and pharmacologic properties. Phase II trials are performed on a small number of diseased patients to determine the drug's efficacy. Phase III trial involving hundreds or thousands of patients. At this point, the safety and efficacy of the drug are to be further evaluated, dosages are determined, a risk analysis is performed and drug interactions are explored. During the next period, the intellectual property is regulated. Results of clinical trials are basis for an authorization approval. After authorization, marketing of pharmaceutical

product is strictly regulated and the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem should be continuously evaluated.

Although pharmaceutical policy is primarily determined at the national level by individual EU members, there is nevertheless a considerable amount of relevant legislation at the EU level. Pharmaceutical policies represent a domain where regulatory outcomes meet market and industry with public health requirements (the safety, efficacy and quality of new drugs) and the Commission only has competence over the former. The Commission cannot, for instance, directly influence drug prices or introduce measures that affect prescribing behaviour (Permanand and Mossialos 2005). On other hand, important concerns such as patent protection, advertising, wholesale distribution, the content of package leaflets and labeling, are covered by the EU policies.

Permanand and Mossialos (2005) point out that, despite the existence of a European regulatory regime, there is still no single European market in prescription drugs in terms of pricing and free movement of goods. They draw on the classical Scharpf's (2002) hypothesis on constitutional asymmetry in European social policy model. As Sharpf observed, "national welfare states are legally and economically constrained by European rules of economic integration, liberalization, and competition law, whereas efforts to adopt European social policies are politically impeded by the diversity of national welfare states, differing not only in levels of economic development and hence in their ability to pay for social transfers and services but, even more significantly, in their normative aspirations and institutional structures" (Sharpf 2002: 1) However, all welfare-state policies at the national level must be designed with respect to the European law.¹⁶ Permanand and Mossialos use the "constitutional asymmetry" to test the tension between the supranational rules of free movement and national pharmaceutical policies.

¹⁶ The hypothesis of constitutional asymmetry could be considered as attempt to enrich explanations which focus exclusively on the agency of purposeful actors of the analysis of (institutional) structure within which actors must define their strategic choices drawing on Giddens'

While in the field of drug authorization European legislation provides very strong regulation framework, in the field of pricing and movement of goods the same player is quite weak. Hard law prevails in the first area, soft law as a method of coordination is much more applied in the later one. The centralized authorization procedure allows very fast and flexible adoption of new pharmaceutical, the pricing and limits of free movement guarantee particular member states to have the accessibility of pharmaceuticals and their prices under the control.

AUTHORISATION PHARMACEUTICALS IN THE EU

The starting point for pharmaceutical regulation in the Western Europe was the thalidomide scandal in the late 1950s and early 1960s, when the sleeping pills contained thalidomide caused thousands of birth deformities. The total number of babies damaged throughout the world was thought to be about 10 000 in 45 other states, among them the UK, Sweden, Italy, Ireland, the Netherlands, Belgium, Finland, Denmark and Austria. In the scandal, ten European states were involved. Contergan was the top-selling sedative in Germany and according to estimates, some 700.000 Germans took it on a regular basis. (Deamrich 2004:61) The thalidomide scandal provoked political reactions in Germany. In June 1964, the Bundestag amended the German pharmaceutical law, which included two general reforms. (Deamrich 2004: 38-39) The amendment required that pharmaceutical companies demonstrate that newly registered

work (1984). According to Sharpf (2010), European policy is the highly structured field where processes, decision rules and institutions are bound to create strong asymmetries, favoring some actors and some policy goals. As he notes, "the far more likely outcome is 'negative coordination', where each actor considers only its own limited competences and tends to treat the positions of others as given when assessing its own strategic options. In the structural constraints are mutually created and reproduced by strategic actors with distributed powers and non-holistic action perspectives" (Sharpf 2010: 214). On the other hand, Permanand and Mossialos points out, that Sharpf reconciled the structural and agency In European policies only partially. "It (constitutional asymmetry) offers an understanding of the apparent policy deadlock, but provides little insight into stakeholder behavior within it." (Permanand and Mossialos 2005: 689) Wilson's (1980) 'politics of policy' typology helps them to understand how the stakeholders pursue their interests. Policy proposals for regulatory interventions are classified by Wilson according to the perceived distribution of their economic and non-economic costs and benefits to the involved parties with regard to the current institutional frameworks..

products had previously been tested. However, modern regulatory regime for pharmaceuticals was established in 1976. (Krapohl 2008: 66) As in Germany, the strict regulatory framework did not exist in other European countries until 1960s (with France as an exception). National regulatory authorities had been set up in reaction to public pressure from consumers long before a European single market for these products was established. Parallel to those processes, the EU started to harmonize the legal rules for pharmaceuticals in order to create the preconditions for a single market.

The first piece of Community guidelines on common authorization requirement for new drugs was Directive 65/65/EEC, which was agreed in 1965 in the aftermath of the Thalidomide tragedy. The Article 3 requires that no medicinal product may be placed on the market of a Member State without the marketing authorization issued by the competent authority of that Member State. The Directive also stated that application of a new pharmaceutical product must have been accompanied by description of the control methods employed by the manufacturer (incl. qualitative and quantitative analysis of the constituents and of the finished product, special tests, e.g. sterility tests, tests for the presence of pyrogenic substances, the presence of heavy metals, biological and toxicity tests, controls carried out at an intermediate stage of the manufacturing process) and results of chemical, biological or microbiological tests, pharmacological and toxicological tests and clinical trials. However, an applicant did not need to provide the results of pharmacological, toxicological tests or clinical trials if he can demonstrate: (1) either that the medicinal product was essentially similar to a product authorized in the country concerned by the application; (2) by detailed references to published scientific literature proved that medicinal product have a well-established medicinal use, with recognized efficacy and an acceptable level of safety; (3) or that the medicinal product was essentially similar to a product which has been authorized within the Community.

Ten years later, Directive 75/318/EEC provided the framework of analytical, pharmacotoxicological and clinical standards and protocols for testing medicinal product. This Directive extended the framework provided in 65/65/EEC by setting out the particular requirements relating to the authorization. In the same year, the first authorization procedure was established by Directive 75/319/EEC. The procedure was based on the mutual recognition of national assessments. The procedure allowed a company that got an authorization in one Member State (so-called reference state) to apply for an approval in at least five other Member States by asking the reference state to forward copy of the original evaluation to other countries. This means that the community procedure could only be started if the pharmaceutical product had already received positive authorization from one member state. The other concerned member states had to decide whether they accepted the authorization of the reference member state. (Krapohl 2008: 71) "But the procedure was not popular within industry. Only 41 application were made in the eight years it operated, and these were mostly for generic or me-to products, rather than new active substances." (Abraham 2000: 85)

In the 1980s, the original Directive was amended in several ways. Directive 83/570/EEC introduced a simplified mutual recognition approved procedure (so-called *multi-state procedure*) and set up and an expert committee, the so-called Committee for Proprietary Medicinal Products (CPMP). This committee comprised representatives from the member states' regulatory agencies, and it provided with scientific advice for pharmaceutical authorization. If disagreements between member states occurred within the multi-state procedure, the newly introduced committee issued its opinions. However, these scientific opinions were only recommendations and had no compulsory character for the concerned member states. However, the committee was composed of national regulators, not independent scientists, it constituted a regulatory network rather than an independent regulator (Dehousse 1997; Majone 1997).

Anne-Marie Slaughter (2003) describes regulatory networks that are comprised national government officials exchanging information, coordinating national policies, and working together to address common problem. They have a key role in the European committee - a complex web of committees that play advisory, management, and regulatory functions in between the European Commission and the Council of Ministers. According to Majone (1997), networking could help the agencies to enhance their reputation and independence and contributing to a creation a credibility commitment among national regulators. On the other hand, Dehousse (1997) foregrounds benefits of independent regulatory bodies. They contribute to improving of transparency of regulatory process because of their greater visibility. Because of their institutionalization and greater budget, agencies also can be a subject of greater control than committees have ever been.

"In heavily regulated areas such as pharmaceuticals, the establishment centralized procedures are necessary. ... On the one hand, increased uniformity is certainly needed; on the other hand, greater centralization is political inconceivable, and probably undesirable. Regulation by networks is the Community response to this paradox." (Dehousse 1997: 260)

Of 122 applications under the multi-state procedure between 1986 and 1990, not a single authorization was recognized by the other member states. The expert committee had to issue scientific opinions on 92 products. By the end of 1990, only for 45 of these 92 applications had all concerned member states notified their final decisions to the expert committee, and this did not even imply that the decisions followed the advice of the committee. (Krapohl 2008: 91) Industry refusal to utilize the multi-state procedure to any great extent, combined with the Commission's commitment to greater harmonization, led to the replacement of the multi-state procedure in 1995.

When it became obvious that mutual recognition failed to create a functioning single market, industry asked for more centralized solutions. In 1988, the Association of the British

Pharmaceutical Industry published its *Blueprint for Europe*. "Acquiescence in industry's demand for ever faster approvals, along with reduced assessment times brought about by the new regulatory structures and inter-agency competition, are key features of the new 'efficiency regime' in Europe. It is also clear that the Europeanised system of mutual recognition finally adopted by the Commission very closely resembles the blueprint proposed by industry." (Abraham 2000: 89)

A regulation set up the new *European Agency for the Evaluation of Medicinal Products* (EMA), which incorporated the existing expert committee (CPMP) recruited from member states' regulatory agencies. The EMA constitutes the core of the new supranational regime (Abraham 2000; Permanand 2006; Krapohl 2008). This period can be described as a wave of creation of agencies of the EU. In the same period (between 1990 and 1997), eight new agencies were created at European level as a way to facilitate further harmonization.

Like its predecessors, the new system mutual recognition is achieved by asking two or more Member States to recognize the marketing authorization granted by the Member State of first approval - the Reference Member State - within 90 days. The major new provision is that disagreements between Member States had to be resolved at the EU level under the auspices of the EMA scientific committee and the outcome was binding on the Member States concerned. Within the system mutual recognition, the EMA plays a role of an information agency (Majone 1997) acting as a co-ordinator of regulators rather than a central regulator. Alongside the European Environmental Agency, the Lisbon Drug Monitoring Centre, and the European Agency for Health and Safety at Work, the EMA can be described as an information agency. The job of information agencies is to collect, coordinate and disseminate information needed by policy-makers or national regulators. As it was written earlier, the shift from committeeology based upon network of national regulator authorities towards informational agencies with strong competencies of the European commission was generally considered as a way of en-

hancing transparency and expanding the trans-governmental networks. Among these new agencies, the EMEA came the closest to being a fully-fledged regulatory body (Majone 1997). However, even though relatively strong competences over regulatory process what the EMEA got there was still the existing committee providing with the final decision.

According to Abraham (2000: 88), the installation of the EMEA marked the turning point from the weak to the strong European regulatory state. Since 1998, the procedure has been mandatory for all products, except those submitted via centralized procedure (see below), drugs marketed only in one single country, and generics (in which case national authorization is still possible). Under the new system with strict time limits marketing authorization granted by one Member State ought to be recognized in principle by other Member States, unless there are grounds for supposing that the authorization may present a risk to public health. What constitute a risk to public health is open to debate between Member States and it simply referred to three standard regulatory criteria for pharmaceuticals (quality, safety and efficacy). (European Commission 1996:7)

If a member state refused to accept an authorization from another Member State, it had to inform the company, the other Concerned Member States, and the CPMP with representatives of Member States plus Commission, stating the reason for its decision and indicating how the problem with application could be solved. Previously appointed to represent national authorization bodies, there are now officially appointed as individuals based on scientific merit. The arbitration of disputes between Member States arising in the decentralized procedure was prescribed as one of tasks of the CPMP. The arbitration was possible when a Member State refuses to recognize another Member State's authorization; in order to harmonize divergent decision among Member States; and where community interests were claimed to be involved. (European Commission 1975b) It should be noted that there have been few number of arbitration cases since the new system started. Abraham (2000: 95-96) concluded that the introduction of

binding arbitration had forced Member States to discard their national interests even founded on scientific disagreements and to accept EU decisions. Abraham suggested that what were essentially administrative changes (introduction of binding opinions, greater contact between agency officials) had effectively suppressed medical-scientific disputes in the new regime.

In 1987, separate procedures for biotechnology and other innovative drugs have been in force since 1987 when Directive 87/570/EEC set up the so called '*concertation procedure*' (a process of concentration between the Commission and Member States before any national decision was taken on the registration of 'high technology products' aiming to arriving at uniform decisions throughout the Community on such products). This procedure did apply to all biotechnologically produced pharmaceuticals and other innovative products were voluntarily authorized by this procedure. However, less innovative products or generics were still subject to the multi-state and national authorization procedures. The procedure required European-level pre-assessments and pre-evaluations for specific categories of pharmaceuticals before the single national authorities made their nationally valid regulatory decisions. Within the concentration procedure, a product was assessed by a Member State (the rapporteur) on behalf the EU as a whole, though the company was obliged to send a summary to all other Member States. Comments and concerns were sent back to rapporteur who forwarded them to the company and, in turn, assessed manufacturer's responses. The final objections were submitted by Member States to the CPMP. The CPMP finally approved and gave the applicant a European license. However, the committee's recommendations did not oblige the member states to take respective action, and the national regulatory agencies were still free in their authorization decisions.

The *centralized procedure*, which was built upon the previous concertation procedure, came into being in 1995. Like it predecessor, the new procedure is mandatory for biotechnological products, new active substances, or products from human blood or plasma. The CPMP

decides whether the product falls into concerned categories. "The official reason for restricting access to certain types of product is that it was necessary to introduce the new structures gradually, and to ensure a smooth transfer of responsibility for 'centralized' products from Member States to the EU, although in practice the number new active substances has increased rapidly. (Abraham 2000: 97) Evaluation under the procedure was through a single application to the EMEA. Approving of the application meant a single authorization allowing access to the market in all Member States. The key difference compared to the previous procedure was that the opinion of the CPMP was legally binding on all Member States and the applicant could no longer choose the assessing Member State (European Commission 1993; 1996) the CPMP also appointed an individual member to act as rapporteur or co-rapporteur. The main task of rapporteur is to co-ordinate the evaluation of application.

In 1999, special rules were adopted for *orphan medicinal products*, i.e. pharmaceuticals for very rare illnesses. Because investments in such products are often not profitable for pharmaceutical companies, the EU tries to support such investments by providing additional incentives. If the Committee for Orphan Medicinal Products (COMP) confirms that authorised pharmaceuticals meet the criteria of orphan medicinal products, they get additional protection against competitors. (Krapohl 2008: 82)

The subsequent legislative review started in 2001, the most important proposals of the Commission were to extend both the compulsory and voluntary application of the centralized authorization procedure, to reduce the number of member states' representatives within the management board and the expert committee which was renamed the Committee for Human Medicinal Products (CHMP) and to reduce member states' control within the political phase of the authorization procedures. The name of the European agency was changed to the *European Medicines Agency* (EMA) in place of the former the European Agency for the Evaluation of Medicinal Products. The scope of the centralized authorization procedure was expanded, the

recruitment of the expert committee and the management board were opened to independent experts and stakeholder representatives, and member states' control in the political phase of the authorization procedures was reduced. Overall, the EU regulatory regime for pharmaceuticals became more centralized and more independent from influence of the member states. (Krapohl 2008: 81) The EMA clearly dominates the authorization process and is de facto an independent authorization body in recent years.

The centralized procedure became mandatory for new biotechnology products¹⁷, new active substances,¹⁸ and medicinal products containing a new active substance for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. When a marketing authorization application is submitted for a product that is of major public health interest, in particular from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure.

INFORMATION AND PACKAGING

The specifications for such additional information in the form of a leaflet were introduced in 1975 and they became mandatory in the EU in 1989. In addition, the introduction of directive 89/552/EEC banning TV advertising for pharmaceuticals strengthened the regulatory framework regarding the availability of right information.

PHARMACOVIGILANCE - POST-MARKETING EVALUATION

Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The basis of EU activity in this field derives

¹⁷ Such as products intended for gene therapy, vaccines from strains developed by means of recombinant DNA technology, any medicinal product for which a monoclonal antibody is used at any stage in the manufacturing process, and cell therapy products.

¹⁸ For which the therapeutic indication is the treatment of acquired immune deficiency syndrome, cancer, neurodegenerative disorder and diabetes.

from Article II of Directive 65/65/EEC: "The competent authorities of the Member States shall suspend or revoke an authorisation to place a proprietary medicinal product on the market where the product proves to be harmful in the normal condition of use, or where its therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the proprietary product." (European Commission 1965) Directive 75/319/EEC was built upon this framework by requiring Member States to take all appropriate measures to ensure that information relating to drug authorisation was communicating among them.

A renewed interest in pharmacovigilance started with the withdrawal of couple high profile cases, which ultimately led to the suspension of the marketing authorization of the drug in the EU. These cases led to a debate about the ability of the current pharmacovigilance system to identify harm and forced the policy community to critically evaluate the existing pharmacovigilance systems in place. The evaluation of the pharmacovigilance system in 2006 led to the Directive 2010/84/EU, which came into force in July 2012. To support the implementation of the new EU pharmacovigilance legislation, the European Medicines Agency (EMA) is developing a new set of guidelines for the conduct of pharmacovigilance - so-called *Good Pharmacovigilance Practices (GVP)*.

The EMA has a core role in coordinating activities for a regulatory network consisting of the competent authorities in Member States, the European Commission and the EMA itself which is responsible for conducting pharmacovigilance. The EMA is being set up as the host of a single database for drug safety data. Marketing authorization holders submit ADR reports only into EudraVigilance – previously, reports went via the individual national competent authority. This includes reporting of medication errors that result in an adverse reaction. The new legislation further increases public participation by including patient and healthcare professional representatives in the new Pharmacovigilance and Risk Assessment Committee (PRAC). The PRAC is composed of one member and an alternate nominated by each of the 28 Member

States, one member and an alternate nominated by Iceland and by Norway, six independent scientific experts nominated by the European Commission, one member and an alternate nominated by the European Commission after consultation of the European Parliament to represent healthcare professionals, one member and one alternate nominated by the European Commission after consultation of the European Parliament to represent patients organizations.

Pharmaceutical companies are required to produce a Risk Management Plan on their drugs and submit them to the EMA. Risk-management plans are continually modified and updated throughout the lifetime of the medicine as new information becomes available. Companies need to submit the risk-management plan whenever the risk-management system for the medicine is modified, particularly when there is new information that could lead to a change in the medicine's benefit-risk profile or when important pharmacovigilance or risk-minimisation milestones are reached. "These documents are written by the company; and explain the safety studies it has agreed with the regulator; but for absolutely no sane reason that I can imagine, the contents are kept secret, so nobody knows exactly what studies the companies have agreed to conduct, what safety issues they are prioritising, or how they are researching them." (Goldacre 2012: 159) A brief summaries are available to doctors, academics and the public. For about half of these studies, the Risk Management Plan gives only a short description without any further information. The final responsibility for issuing an opinion on the risk–benefit assessment of medicinal products remains with the Committee for Medicinal Products for Human Use (CHMP). "Since this committee is the one that granted the marketing authorisation, it may unconsciously feel bound to uphold its earlier evaluation and decision." (Garattini, Bartela 2011: 1200)

CLINICAL TRIAL LEGISLATION

The annex of Directive 75/318/EEC prescribed in detail the trials that had to be conducted to prove the safety, efficacy and quality of medicinal products. Pre-clinical examina-

tions included physicochemical, biological or microbiological tests, as well as toxicological and pharmacological trials on animals. The following clinical trials on patients had to be controlled by the 'double blind' method, when neither physicians nor patients were to know whether active substances or placebos were applied. (Krapohl 2008: 70-71)

Clinical trials are investigations in humans intended to discover or verify the effects of one or more medicinal products. Requirements for the conduct of clinical trials in the EU are provided for in Directive 2001/20/EC (so-called the *Clinical Trials Directive*) laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products. If the clinical trials are conducted outside the EU, but submitted in an application for marketing authorization in the EU, they have to follow the principles that are equivalent to the provisions of the Clinical Trials Directive. The directive was designed to optimize patient safety, increase the numbers of patients entered into clinical trials, improve the efficiency of trial implementation, ensure best practice in ethical review and regulatory procedures, and harmonize these procedures across Europe.

The directive introduced the notion of a sponsor with legal responsibility for ensuring that the trial is run correctly, including covering the costs of all drugs or devices used in a study. Before the directive, these duties tended to be spread evenly among participating researchers. The sponsor also has to make sure investigators are covered by rigorous new insurance policies, which are more expensive than those that had been previously required. The main problem is with escalating costs for fees for inspections and monitoring. (Hoye 2007) "A new European directive on clinical trials that takes effect this week may seriously damage academic medical research by applying a "one size fits all" approach to the organization of clinical trials that is more suited to trials designed for the registration of new drugs by pharmaceutical companies. ... The fundamental problem with the new directive is that it was initially drafted as

a way of facilitating the commercial development of drugs, based on consultation with the pharmaceutical industry. The needs of non-commercial research were considered only at a late stage." (Mayor 2004) The *Impact on Clinical Research of European Legislation* study (ICREL 2009) identified the same trend. While a negative impact of the Clinical Trials Directive on non-commercial sponsors was detected represented by a decrease of clinical trials by 25% between 2003 and 2007, the number of trials submitted by commercial sponsors slightly (+11%) increased in the same time.

Peter Gøtzsche (2012) summarizes main deficiencies in EU regulation of clinical trials into following categories: (1) public access to information; (2) trial protocols; (3) drug information; (4) informed consent; (5) accountability and archiving; (6) approval of trials and conflict of interests; (7) selective reporting and changes to the trial protocol; (8) trial conduct; (9) reporting of serious adverse events; (10) time for action.

Public access to results of trial probably represents the most highly debating issue connected with clinical trials legislation. Currently the regulation requires submission of only a summary of the results, which must be reported within one year of the end of the trial with a possibility to postpone this for substantiated scientific reasons. Trial protocols say that the data belong to the industry sponsor or that the sponsor has the right to decide whether the results will be published. It restricts a public access to trials results. Drug trial are very often based upon previous trials which do not need to be sufficiently reported and on average only one fifth of previous trials have been cited in trial reports.

PRICING AND REIMBURSEMENT EU LEGISLATION

Given the lack of health care policy competence, EU policy makers have no say over pharmaceutical pricing and reimbursement. The only existing measure in this field, the Directive 89/105/EEC, so-called *Transparency Directive*, came into force in 1989. It was originally intended as a first, but retrospectively is perhaps the last, step in the direction of Commu-

nity regulation of national price and profit control; despite subsequent reviews of its impact and effectiveness, the Commission could not establish sufficient consensus among the member states to move towards a stricter regime (Mossialos, Mrazek, Walley 2004). The Transparency Directive was the smallest common denominator that could be agreed upon.

The Directive obliged member states to adopt 'verifiable' and 'transparent' criteria in setting prices and their reimbursement under national health systems. Although not affecting prices per se, this was to ensure that no collusion between industry and government over prices occurred, and to make sure that no discrimination against medicines imported from elsewhere in the EC was taking place.

The Transparency Directive lays down three major requirements with respect to individual pricing and reimbursement decisions: (1) decisions must be made within a specific timeframe (90/180 days); (2) decisions must be communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria; (3) decisions must be open to judicial appeal at national level.

Despite the extensive interpretation of the Directive by the Court of Justice,¹⁹ the implementation of its provisions in national law and the effective enforcement of its principles, in particular by the Commission, have become particularly challenging (European Commission 2012). This directive has been in force for more than 20 years, but, Böhm and Landwehr (2013) show, pharmaceutical coverage decision-making in Europe is more heterogeneous than ever.

In seven countries, reimbursement decisions are taken immediately by the ministry, however, based upon expert bodies recommendations. Spain is the only country where the min-

¹⁹ Case C-424/99 of 27 November 2001, *Commission v. Austria*; Case C-229/00 of 12 June 2003, *Commission v. Finland*; Case C-245/03 of 20 January 2005, *Merck, Sharp & Dohme*; Case C-296/03 of 20 January 2005, *GlaxoSmithKline*; Case C-317/05 of 26 October 2006, *Pohl-Boskamp*; Case C-311/07 of 17 July 2008, *Commission v. Austria*; Case C-352/07 of 2 April 2009, *Menarini*; and joined cases C-353/07 to C-356/07, C-365/07 to C-367/07 and C-400/07.

istry of health has a sole responsibility for the reimbursement process. In the rest, the variety of institutional solutions can be observed, ranging from ministerial commissions (Slovakia) or state financed institutions (Poland) to more or less independent public health care institutions for which recommendations on reimbursement is only one of many tasks (e.g. Belgium, France). In countries where the ministry is not responsible for decisions, independent state bodies play a crucial role (Czech Republic, Denmark, Finland, Italy, Sweden) which often do not only deal with coverage decisions but are very responsible also for the market authorization. Beside of independent state bodies, part of the public health administration (Hungary, Ireland, EW) or self-governance bodies (Austria, Germany) can also deal with decision-making.

Because further European regulation in this field seemed unobtainable, the Commission followed a softer strategy by fostering cooperation and networking of the relevant stakeholders (Böhm and Landwehr 2013). In 2005, the Pharmaceutical Forum was established and brought together ministers, representatives of the European Parliament, the pharmaceutical industry, health care professionals, patients and insurance funds. Pricing and reimbursement was selected as one of its key themes. Since its establishment, the Pharmaceutical Forum has been calling for further cooperation and exchange of experience and knowledge at the EU level. Apart of it, the European Commission has established a network bringing together important stakeholders in biannual meetings and has funded the 'Pharmaceutical Pricing and Reimbursement Information Project' (PPRI), which gathered and published information on decision-making processes in nearly all EU-countries and was carried out from 2005 to 2007. It involves a network of around around 70 institutions (mainly relevant authorities and third party payers) from all 27 European Union Member States plus more than ten further, mainly European, countries. This project was followed up by the Pharmaceutical Health Information System (PHIS) project, which was co-funded by the European Commission and ran from September 2008 to April

2011. A special focus of the project was on Hospital Pharma, with a European survey of medicines management in hospitals.

Moreover, the European Commission supports the twinning project 'Transparency of the National Health System Drug Reimbursement Decisions' between Poland and France. Poland was criticized by the European Commission for its non-compliance with the Transparency Directive, specifically for the long delay of releasing decisions and missing transparency. In order to improve deficiencies, the project was launched. European experts, coming from various institutions concerned by the issue, mainly from the French Ministry of Health and the National Health Fund (Caisse Nationale d'Assurance Maladie), conducted an analysis of the Polish system and provided advice on reforms. Based on these recommendations, the Polish government prepared reform measures between 2006 and 2008. A first legislative change, in August 2007, modifying the law on health care services financed by public means, introduced some changes in the drug reimbursement procedure towards a better compliance with the directive. Polish experts and persons working in the field were trained by European experts. (Nizankowski and Wilk 2009; Zagorska et al. 2008)

PRICING AND REIMBURSEMENT POLICIES IN THE EU MEMBER STATES

Total, public and private, spending on outpatient pharmaceuticals in the EU Member States varied from 0.6 to 2.6% of GDP in 2010. As expected, given the size of the population, in 2010, Germany is the biggest pharmaceutical market in the EU (Euro 42,383 million), followed by France (€ 36,006 million), Italy (€ 24,872 million), Spain (€ 18,500 million), and UK (€ 18,154 million). These five countries account for over 70% of pharmaceutical turnover in the EU.

Since the 1990s, it has increased as a share of GDP in all EU Member States except for Luxembourg. Countries with high total pharmaceutical expenditure as a percentage of GDP (above 2% of GDP) include Bulgaria, Greece, Lithuania, Hungary, Portugal and Slovakia.

Those with low pharmaceutical expenditure in terms of GDP, as well as a percentage of total health expenditures, include Denmark, the Netherlands, Luxembourg, Sweden and the UK. In the EU, around 60% of total pharmaceutical spending is public spending. Some countries, such as Germany, Greece, Spain, France and Slovakia, have relatively high public spending on pharmaceuticals and a relatively low share of private co-payment. On the other hand, Bulgaria, Denmark, Cyprus, Latvia, Luxembourg, Romania spend relatively little public money on pharmaceuticals in terms of GDP. The Czech Republic belongs to countries where public share in total spending went down, unlike Germany, Netherlands, Finland or UK where went up.

Pharmaceutical policies are related to pricing, reimbursement, market entry and expenditure control, as well as targeted at specific agents such as distributors, physicians and patients. Basic tools and principles are explained in following box.

Tab 11: Tools of pharmaceutical regulation and policies applied within the EU

Policies related to pricing, reimbursement, market entry and expenditure controls
Price regulations
External reference pricing: cross-country referencing and international price comparison benchmarks product prices in one country against prices of the same product in a selected basket of other countries – is applied in 24 EU Member States (except Denmark, Sweden and the UK). ²⁰
Internal reference pricing: ²¹ the system of internal reference pricing determining the maximum price to be reimbursed by a third payer ("reference price") by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group. The patient pays the difference between the retail price and the "reference price", in addition to any co-payment arrangement. The "reference price" applies to all pharmaceuticals within the corresponding group of products – is applied in 20 EU Member States

²⁰ In general, each country chooses a basket of countries which are economically comparable and geographically close. Choosing countries with similar levels of economic wealth may be perceived as a good anchor for choosing a "correct" and affordable price level, whereas geographic closeness may ease updating pricing through ERP. For example, East European countries had the lowest average prices (around 70% of EU average), whereas Germany had the highest price level of all EU Member States. The most-often referenced countries are France and Spain (referenced by 14 EU Member States), followed by Ireland and Spain (11 states). The least referenced countries are Bulgaria, Romania and Malta (3 countries) (Carone et al. 2012)

²¹ Some countries (e.g., Denmark, Italy, Portugal) base their reference groups (i.e. groups of interchangeable pharmaceuticals) on substance level, whereas other countries (among those, Germany, the Netherlands) also consider therapeutically similar pharmaceuticals as interchangeable. (PPRI 2008)

Price updates: updating regularly according to pricing regulations
VAT: medicines might have a value-added tax below the standard VAT rate, the VAT might depend on the group of pharmaceuticals.
Product reimbursement
Health-technology assessment: conditioning reimbursement by meeting specific clinical and/or economic effectiveness criteria, it is an assessment of the additional cost-effectiveness of an innovative medicine relative to existing treatment alternatives. HTA is used in numerous countries: Belgium, Denmark, Sweden, Finland, the Netherlands, England, Ireland, Portugal, Norway, Estonia, Latvia, Lithuania, Poland, Hungary, and Germany.
Positive/negative lists: positive lists specifying which specific pharmaceuticals are reimbursed and negative lists excluding specific pharmaceuticals from reimbursement – positive lists are applied in all EU countries, negative lists is applied in some of them
Market entry
Time to market entry: the Transparency Directive regulates the time span for taking pricing and reimbursement decisions. ²²
Expenditure controls
Discounts/rebates: imposed upon manufacturers and pharmacists, such that they have to return a part of their revenue
Clawback: applied to pharmacies, requiring them to pass a part of their turnover to third party payers
Payback: manufacturers is required to pay back a share of their revenue, a pre-specified budget ceiling when public pharmaceutical expenditures is exceeded ²³
Risk-sharing arrangements: financial or performance-based schemes which trigger lower prices or refunds from the manufactures if pre-agreed targets are not reached ²⁴
Price freezes and cuts: freezing or cutting prices by law or as an outcome of a negotiated agreement ²⁵
Public tendering: public procurement in the outpatient sector to decrease the prices of pharmaceuticals. It is applied for example in the Netherlands and Germany. ²⁶

²² However, the time spanning from companies' request and the decision varies substantially across the EU. In Germany and the UK both steps are immediate. Denmark, Finland, Hungary, the Netherlands, Sweden have waits up to one month. However, Belgium, the Czech Republic, Latvia, Romania and Slovakia have average waiting times of over half a year, considerably delaying the entry of generics and thus foregoing potential savings. (Carone et al. 2012)

²³ Payback also increases the predictability of the level of public pharmaceutical expenditures; on the other hand, if the budget is set too high with respect to actual health care needs, then the over-consumption of pharmaceuticals is incentivised. If the target budget is set too low, then the industry is penalised by payback for serving actual health care needs of the population, which might necessitate spending over the target budget. (Carone et al. 2012)

²⁴ There are various risk-sharing schemes: (1) price-volume agreements - financial-based schemes triggering refunds from the manufactures if pre-agreed sales are exceeded. Refunds may be in form of lowering reimbursed prices or paybacks); (2) patient access schemes granting pharmaceuticals for free or at a lower price for a limited time period; (3) performance based models refunding if a pre-agreed performance level, e.g. a desired health gain, is not reached.

²⁵ The medium- and long-term impact of these policies on cost-containment is not clear-cut, as over time they are often counterbalanced by volume increases (Carone et al. 2012).

²⁶ It is mostly used in hospital settings, although an increasing tendency to use it in ambulatory care can be observed. In hospital care, public tendering can cover up to 25% of all purchased

Policies targeted at distributors, physicians and patients	
Wholesalers and Pharmacists	
Generic substitution: inducing or mandating pharmacists to dispense the cheapest bioequivalent medicine, which is often called "generic substitution". It is mandatory in 8, indicative in 14 and disallowed in 7 EU Member States. ²⁷	
Mark-ups: regulating the reimbursement of wholesalers' and pharmacists' services for, at least, reimbursable medicines, mostly by means of regressive, but sometimes also linear mark-ups and profit margins - 23 EU Member States apply wholesalers' and all EU Member States apply pharmacists mark-ups on the price of the pharmaceuticals as set by law. These can be linear, regressive, a fixed-fee (NL) or fee-for-service (SI, the UK).	
Physicians	
Monitoring of prescribing behaviour: monitoring prescription behaviour to some extent, e.g. by using electronic prescriptions – it is applied at least in 22 EU Member States	
Clinical practices/prescription guidelines: indicative, non-binding prescription guidelines for physicians. In few countries, physicians must prescribe by the international-non-proprietary-name (INN) instead of the medicine name. INN is mandatory in five, indicative in 18 and disallowed in four EU Member States.	
Pharmaceutical budgets: defined a maximum pharmaceutical budget per period, region, field of specialty and physician – it is applied at least in 9 EU Member States	
Prescription quotas: defined a target of the percentage of generics to be prescribed by each physician or may target the average cost of prescriptions – it is applied at least in 6 EU Member States	
Financial incentives: financial incentivising or punishing physicians by following or ignoring prescription guidelines, quotas and budgets – it is applied at least in 11 EU Member States	
Education and information: prescribing advice, IT decision support etc.	
Patients	
Information/education campaigns: information campaigns raising awareness of rational use of medicines, e.g. for antibiotics and generics.	
Co-payment: applying differentiated reimbursement rates, such as 100% reimbursement for essential, 80% for chronic and 60% for other pharmaceuticals (AT, IT, DE, NL and UK have 100% reimbursement). Often, vulnerable groups are protected from excessive out-of-pocket payments through specific rules.	
Prescription fees: fixed fee for a receipt or prescribed medicament	

Carone et al. 2012, Espin and Rovira (2007), PPRI (2008)

medicines in some countries, whilst it is much less relevant in ambulatory care (Leopold et al. 2008, Kanavos et al. 2009).

²⁷ Currently, roughly 43% of the volume of pharmaceuticals in the EU is supplied as generics medicines, but this is just 18% in value terms. Shares in volume and value vary largely across countries: 79% of all pharmaceuticals sold in Latvia are generics, but only 27% in Austria; similarly, in terms of value, the shares of generics vary between 12% in Sweden and 40% in Poland and Romania. (Carone et al. 2012)

Between 2010 and 2012, 23 European countries underwent or were planning a substantial number (estimated to be about 89 by Vogler et al. 2011b) of reforms of pharmaceutical policies. Garone et al. (2013) provide us with the list of most important examples.

Among most often policies they include:

- Discounts/rebates and clawback policies: EE, LT, ES, DE, PT, IT;
- Introduction of payback systems for the industry: PL, RO, PT, EL;
- Price freezes and cuts: CZ, UK, ES, EL, DE, LT, PT, IE, MT;
- Changes in the VAT on medicines: LT, CZ, UK, EL, FI, PT, LV, PL;
- Changes in the external referencing to countries with lower price levels: LT, SW, EE, SK, DE;
- Introducing external referencing as a pricing criterion: BE, DE;
- Changes in internal reference pricing rules: PT, ES, LT, ES, LV, BE, PL, EL; ·
Planned introduction of internal reference pricing in IE;
- Broader clustering at ATC-3 level in RO;
- Introducing positive and negative lists (EL, RO);
- Requiring mandatory value assessment for new medicines in DE, EL, RO;
- Introduction of value-based pricing in 2012 in UK.

Among less often used tools they listed:

- Decreases in distribution margins: ES, EL, LT, PT, BE, IT, DE, PL, LV;
- Revising the reimbursement eligibility for all medicines in CZ;
- Increasing cost-sharing for patients: AT, BE, DK, LV, LT, EL, PT;
- Introducing or enforcing mandatory INN prescribing: LT, CZ, SK, EL, PT, IT;
- Obligation to offer least expensive medicines to patients and have them on stock: LT, EE, PL, EL, PT;
- Introduction or reinforcing e-prescribing: EE, LT, PT, EL, RO;

- Generics promotion campaigns for the public: EE, ES, PT.

According to Espin and Rovira (2007), direct product price regulation is losing its traditional role in Europe, probably because of its decreasing effectiveness in the new context of the Single European Market. Reference pricing is spreading across Europe. Most countries define the equivalent groups in a narrow sense (active ingredient), but a few countries (Netherlands, Germany) have shifted to groups based on therapeutic equivalence. However, great variations are also found in generics policies. Differences between member states are related to the different characteristics and levels of development of the pharmaceutical sector, to general level of income, and to the characteristics of health policy and the health system, Espín and Rovira conclude.

CONCLUSION

There have been numerous initiatives aimed at harmonizing legal, scientific and administrative procedures governing the sale of medicinal products, with the rapid pace of change during 1990s. These initiatives can be slip into two parts: (1) scientific (chemical and pharmaceutical data, pre-clinical tests, clinical studies), and administrative (procedures and practices required for registration). (Abraham 2000: 83)

One can generally distinguish two phases of building of pharmaceutical regulation framework in the EU: (1) harmonization of standards (1965 – 1990); and (2) institutionalization (1990s) and consolidation (2000s). The first policy phase – the harmonization of standards – started with directive 65/65/EC and ended with the first revision of the pharmaceutical regulatory framework in the 1990s. The introduction of mandatory approval based on directive 65/65/EEC including the criteria of safety, quality and efficacy contributed significantly to the establishment of pre-authorization controls of pharmaceutical produce. In 1975, the first authorization procedure was established by Directive 75/319/EEC which was based on the mutual recognition of national assessments. Directive 83/570/EEC introduced a simplified mutual

recognition approved procedure and set up the Committee for Proprietary Medicinal Products (CPMP) comprised representatives from the member states' regulatory agencies. However, partial harmonization of pharmaceuticals regulation and mutual recognition of national marketing authorization proved to be insufficient to harmonize access to the single market. (Krapohl 2006: 26)

The second phase of institutionalization, started with the revision in early 1990s, the subsequent installation of the EMEA (later replaced by the EMA) and the authorization system comprising a national, both a decentralized and a centralized procedure in 1995. The policy developments between 1990 and 2000 strongly focused on procedural and approval aspects of the regulatory system. This period was marked by the attempt to replace on committees based institutional setting of European institution for regulatory agencies based system. However, Lewis and Abraham (2001) criticize the regime for a "neo-liberal corporate bias" in which pharmaceutical industry interests' crossed the political threshold and become part of the extended state: a position from which other groups, even if they too held political power, were still excluded." (Abraham and Lewis 2001: 202) Industry welcome the efficiency regime of the European regulatory state because the EMEA accelerated and leveled out drug approval times and put pressure on national agencies to conform to the rapid review times laid down in EU regulations.

Krapohl (2006: 26) argues that the pharmaceutical sector was successful in promoting its interests because it did not suffered from any fundamental crisis of consumer confidence. Drawing from the study conducted by two consulting companies on behalf of the Commission (Cameron McKenna and Anderson), he stated that consumers as well as producers of medicine are rather satisfied with the authorization process and the European regulatory regime for pharmaceuticals has not produced large regulatory scandals since a single market was established. However, the current wave of criticism of Clinical Trial Directive has shown that the

public climate might have been changing. The Patient View (2013) survey, conducted mid-November to mid-December 2012 and exploring the views of 600 international, national, and regional patient groups from 56 countries (72% from Europe), indicated that the overall reputation of pharma had declined in previous years.

"Only 34% of the 600 patient groups responding to the 2012 survey state that multinational pharma companies had an "Excellent" or "Good" reputation during 2012. The equivalent figure from the 500 patient groups responding to the 2011 survey was 42 %. 40 % of the 600 respondent patient groups state that the reputation of the pharma industry had declined during 2012." (Patient View 2013)

In 2000s, the regulatory framework moved into the phase of consolidation and differentiation. The regulatory framework was integrated and the existing level of regulation was deepening further. The EMA adopted new competences in relation to pharmacovigilance including a single database for drug safety data. Consequently, this period cemented the close cooperation between regulatory bodies and business emerged in the previous phase.

Kropahl (2006) identifies two types of crises in relation to supranational risk regulation, which may influence the path of institutional development: (1) a crisis of confidence in a certain regulatory area (very often connected with a public scandal) and (2) integration crisis when a regulatory body is not able to bring national entities together. Current European regulation is product of the second one. In the 1980s and 1990s, it was widely agreed that a policy project was needed that would revive European integration. The Commission as a policy-entrepreneur was able to use this open 'policy window' to create a harmonization regulatory networks and transform them into regulatory agencies. Using cultural theories of regulation, the individual frame of lack of incentives was the main frame supporting a creation of regulatory state and a single area of market authorization. The current challenge is that whether the crisis of confi-

dence in regulatory setting is going to be profound enough to open policy windows and raise critical junctures to show that the existing institution is no longer an 'equilibrium institution'.

CHAPTER 8: DISCURSIVE PRAXIS IN REFORMS OF THE HEALTH POLICY IN THE CZECH REPUBLIC

“All governments face pharmaceutical expenditures, which, in many countries, are rising at rates greater than gross domestic product and usually greater than other health care budgets. Many countries consider this to be a problem and make attempts to contain these expenditures. But governments have other responsibilities – to improve the quality of care their health service offers by meeting patient need, and to ensure equity in the services provided. They try to stretch limited budgets as far as possible by increasing the efficiency of their services. Some of these policies may be conflicting – for instance, increasing universal access to services and improving the quality of those services will increase costs but may increase efficiency.” (Mossialos, Mrazek, Walley 2004: i). The primary objective of this chapter is to examine comprehensively how those conflicts have been debating in the context of posts-socialist context of the Czech Republic. Especially, the chapter is focused on the dynamics between individualist incentives-based policies and hierarchical rules-based policies.

Following Streeck and Thelen (2005), we can delineate four modal types of institutional change: displacement (the removal of existing rules and the introduction new ones), layering (the introduction of new rules on top of or alongside existing ones), drift (the changed impact of existing rules due to shifts in the environment) and conversion (the changed enactment of existing rules due to their strategic redeployment). Given that the transition of post-communist welfare policies when new rules were being set up, both displacement and layering are the most important. Whereas in the area of labor market and income protection policies which were relatively free from historical legacy (since unemployment benefit schemes, employment agencies or job retraining programs had to be completely rebuilt) the displacement mode prevailed; in family policies since childcare facilities and maternity leave benefit schemes already

had existed new rules and institutions followed the previous ones (Sirovatka and Saxonberg 2009). Healthcare policy presents a middle ground. Healthcare reformers faced existing public service providers such as hospitals and other healthcare facilities but a completely new system also needed to be built.

Until the fall of communism in 1989, the Soviet Semashko model health care provision existed in the former socialist countries of Central and Eastern Europe. It was based on a centralized, tax-based, health care system with physicians as state employees. In the 1960s, this system reached its limits and its rigidity did not allow it to respond adequately to emerging health problems. Consequently, the main health status indicators were stagnating from the 1960s to the 1980s. "Poor accessibility of innovative pharmaceuticals was compensated by import of generics from other Eastern bloc countries, often produced while infringing patent protections." (Szalay et al. 2011: 18) After the fall of communism in 1989, the Czech health care system had to deal with the legacy of the communist regime such as an oversupply of beds, a hierarchical organizational structure and a shortage of modern technologies. Between 1990 and 1997, the first period of transformation focused mostly on basic market oriented reforms such as setting a pluralistic public health insurance model, the investment in technology and improving health facilities. In the next period between 1997 and 2001, the consolidation of regulatory frames was dominant. The following period between 2002 and 2005 was marked by conflicts between different stakeholders over regulation rules and their application. The chapter is closed by description of the Tomas Julinek's neo-liberal reform.

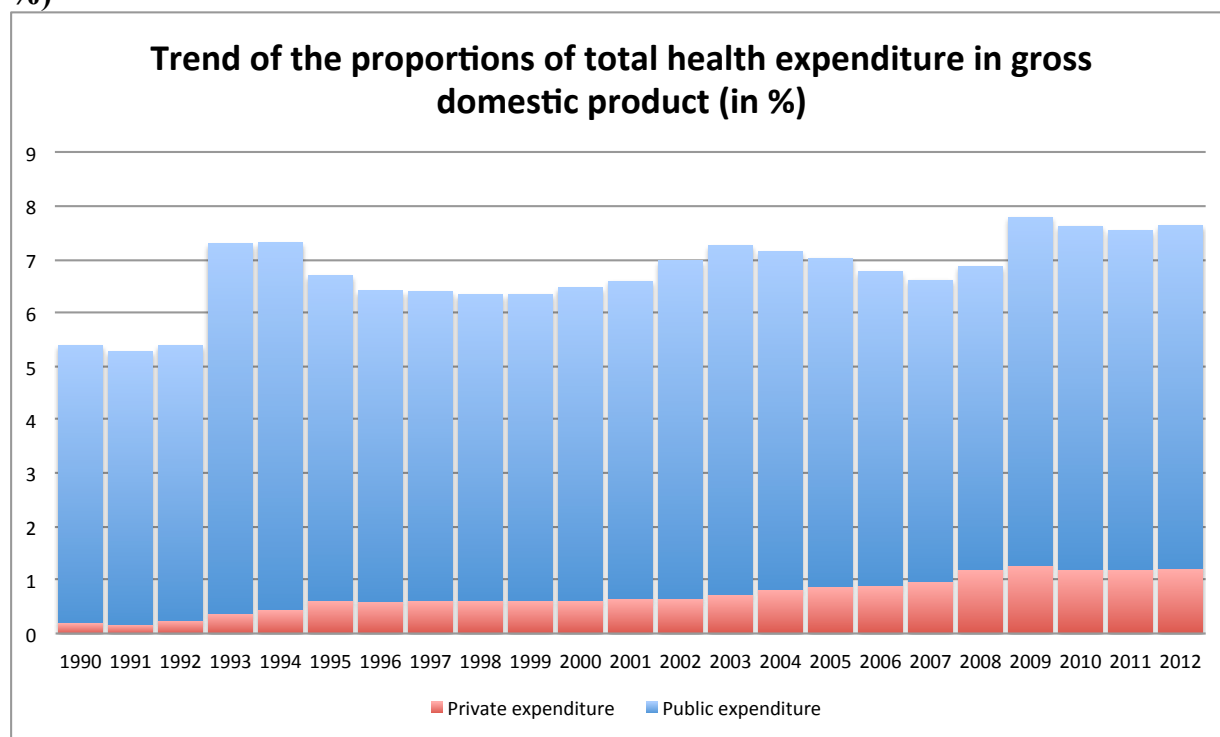
There is universal coverage of the whole population by the public health insurance system. A person remains covered without any restriction even if he or she is able to pay contributions. The insurance package is rather generous and encompasses all necessary health care. According to Němec et al. (2013), the core problem of the Czech health-insurance system is the unbalanced combination of pluralist provision of health insurance with too tight state control

over the system. For employees and self-employed persons the law determines the percentage of wages to be deducted; for those who are “state insured” – that is, persons who lack income, like students, pensioners, prisoners, – the cabinet decides on the amount to be contributed for each. At present the “state insured” are 58% of all those insured in the system.

As you can see in following chart, the Czech Republic has been witnessing relatively steady share of public health care expenditures on GDP since early nineties. The share of private expenditures exhibits a higher growth nevertheless the share of private expenditures is relatively low in comparison with other Western European countries. In terms of total health expenditures in relation to gross domestic product, one can see a steep increase in the first transformation period followed by slightly increasing trend in next years with peak in 2003 and 2009. The first increase was marked by the fact that the Czech health care system was rather liberal in early nineties on the one hand and heavily reliant on public sources of funding on the other hand (Němec 2013).

The share of private health insurance is rather negligible as a comprehensive coverage of the public health insurance scheme because due to the lack of space for deployment of viable and profitable supplemental health insurance products.²⁸

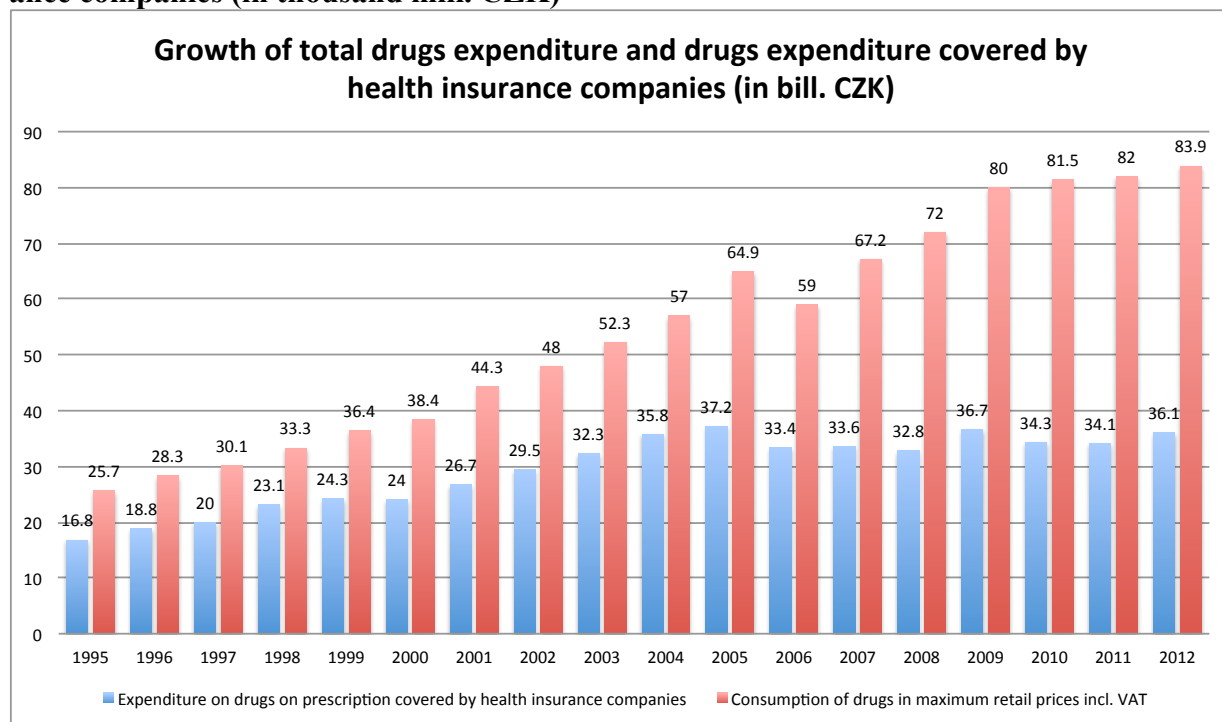
²⁸ Němec (2013) estimates the total volume of premiums written for the category of private health insurance products was 2,563 million Czech crowns. It is less than 1 % of the total health care expenditures. Private insurance plays a major role only for persons living on the territory of the Czech Republic that are not qualified for the public health insurance scheme, for example for persons from non-EU countries without formal employment.

Pic 3: Trend of the proportions of total health expenditure in gross domestic product (in %)

Source: SZÚ

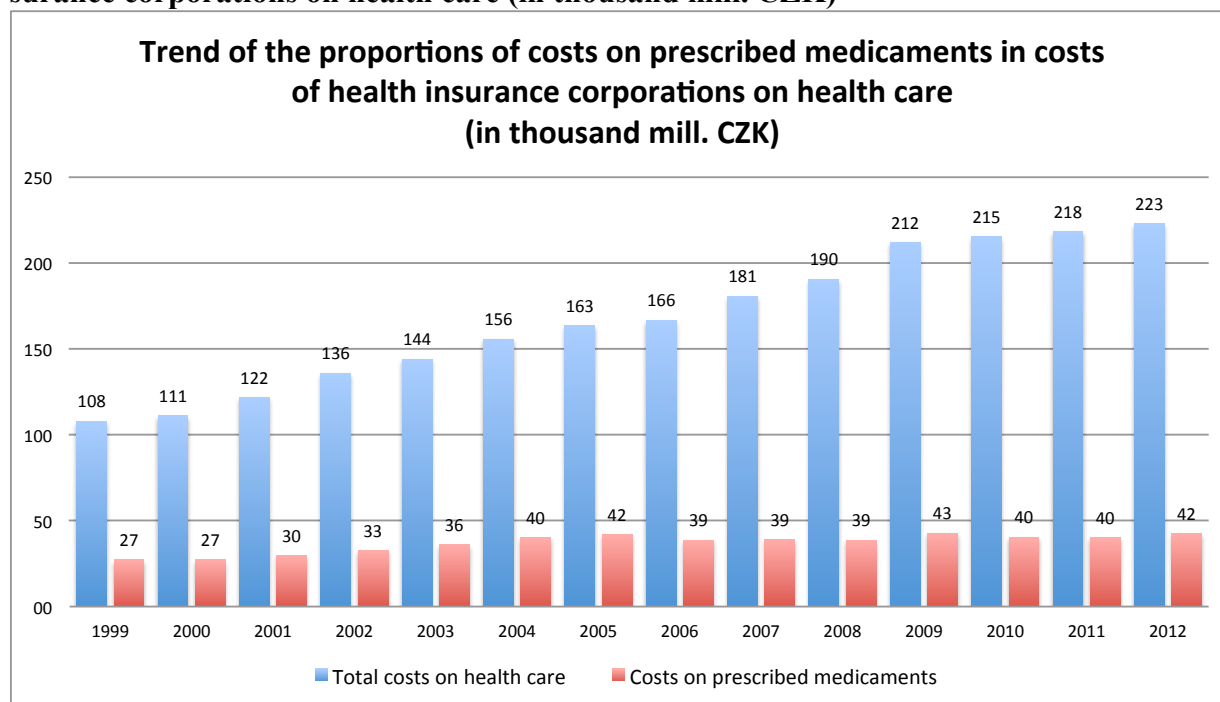
However, share in gross domestic product is more influenced by the volume of gross domestic product than by the volume of health care expenditures. The latter exhibits steady growth. The following chart illustrates such trend in relation to pharmaceuticals. However, one can see increasing trend in overall consumption, which has not been followed by increase in expenditures on prescription covered by health insurance companies. At least since 2006, the amount of money going from health insurance funds has been stagnating. Even though the overall consumption has been rising, the expenditures within health insurance system have remained approximately same. The share of private expenditures is steadily increasing because of higher cost sharing in the public health insurance scheme.²⁹ For example, the public health insurance scheme covered 82% of total expenditures for drugs in 1996 but less than 59% in 2011 (Němec 2013).

²⁹ Cost-sharing is required for selected drugs, dental services and some medical aids.

Pic 4: Growth of total drugs expenditure and drugs expenditure covered by health insurance companies (in thousand mill. CZK)

Source: SZÚ

The same trend one can see in the next chart too. Even though the expenditures for other segments of health insurance funds' budget such as out-patient care, out-patient care, stomatological care or preventive programs have been increasing, the costs on prescribed medicine have been stagnating. In 1999, they made up approximately 25 percent of health insurance funds' budgets, however, it was 19 percent in 2012. The significant drop down happened between 2005 and 2008.

Pic 4: Trend of the proportions of costs on prescribed medicaments in costs of health insurance corporations on health care (in thousand mill. CZK)

Source: Czech Statistical Office

This chapter is focused on discursive praxis of proponent of reform since 1989. In each period I explore dominant narratives of sustainability as tropes in which discourse of health promises and fiscal limits interfered. I also pay attention to regulatory codes as grammar through which policy actors explained why policy had diverted from its original goals. In a nutshell, sustainability narratives tell us how health care system should be and regulatory codes construct accounts why the current state is different from sustainable ideal. In the chapter, other elements of discursive praxis such as category-making or construction of a role of patient are also taken in consideration.

TRANSFORMATION PERIOD (1990-1997)

The level of consumption of pharmaceuticals started to rise after 1990 hand in hand with prices and the level of spending on pharmaceuticals. Between 1990 and 1992, both the national health and regional institutions were dissolved and health care facilities obtained a high degree of legal and economic autonomy. Even though the 1966 Law on Health Care for

the Population remains the basis of health care legislation, it was amended by a series of health care reforms either by establishing new laws or changes to existing laws.

Tab 12: The important pieces of legislation

1991	General Health Insurance Law (Act No. 550/91 Coll.)
1991	Law on the General Health Insurance Fund (Act No. 551/91 Coll.)
1991	Law on the Medical, Dental and Pharmaceutical Chambers (Act No. 220/91 Coll.)
1991	Resolution of the Czech Government – Health Care Order
1992	Law on Branch, Local and other Health Insurance Funds (Act No. 280/92 Coll.)
1992	Law on Non-State Health Care Facilities (Act No. 160/92 Coll.)
1994	Resolution of the Czech Government – Health Care Order
1995	General Health Insurance Law (amending the General Health Insurance Law)
1996	General Health Insurance Law (amending the General Health Insurance Law)
1997	Law on Public Health Insurance (Act No. 48/97 Coll.)
1997	Law on Drugs (Act No. 79/97)

(European Health Observatory 2000: 60)

In the period from 1990 to 1998, the successful implementation of curative technologies has caused both a declining trend in mortality rates and a growing demand for higher investment in health. Life expectancy increased from 67.6 to 71.1 and 75.4 to 78.1 years for men and women, respectively. In the period from 1990 to 1998 infant mortality decreased from 10.8 to 5.2 per 1000 live births. (European Health Observatory 2000: 60) The level of consumption of pharmaceuticals rose significantly during first transformational years. However, as prices have increased dramatically during the same period, spending on pharmaceuticals has also risen rapidly.

In 1990, The Civic Forum won more than half the vote and two-thirds of the seats in the Czech parliament. Martin Bojar, one of the main activists in the Civic Forum of Health Care Professionals became the new Minister of Health. With his main advisors coming from the Programmatic Commission, Bojar had a major reform plan. In relation to pharmaceutical policy, the main problem identified by policy-makers and media was the shortage of modern medicaments and break down of supply from the Comecon countries. The offer of pharmaceu-

ticals was presented as insufficient and backward. Furthermore, the problems with supply started to pop up.

Problems in the supply were caused by a limited production capacity for certain drugs. On the Czech and Slovak market, 45 drugs - including 11 imported and 34 from domestic manufacturers - were missing.³⁰ The Czech system relied too much on domestic production. In 1990, over 800 kinds of pharmaceuticals, it means 1,300 converted in dosage forms, was produced in the Czechoslovakia. "Compared with developed countries, it is too much. Elsewhere, produces half of that, and rest are being purchased. For these reason, foreign pharmaceutical industry has got more room to develop new drugs," Jindřich Kadrnožka, the deputy at Ministry for Health, described. Backwardness was identified with the Czech pharmaceutical industry and innovativeness with western production.

The state system was portrayed as rigid and sclerotic and it was supposed to be replaced by a flexible one. There was also an evidence of widespread public support for changing the previous health care system. Alongside with western products, the future health care system was also identified with private elements. In a 1990 survey, 70% of the population endorsed privatization of primary health care as a means of improving quality. (European Health Observatory 2000: 57) Two state owned firms - *Zdravotnické potřeby* and *Sanitas* - which had been responsible for pharmaceutical distribution under the communist governments were privatized at the beginning of 1990s. Moreover, 28 private owned distributors came into market just in the first year after the fall of old regime.³¹ Pharmacies were also privatized during first transformational years along with the distribution network.³² "Distribution will probably change, but the

³⁰ Tomešová L: Proč chybějí léky? Rudé Právo (22.6.1990), p. 5.

³¹ Pergr, V.: Od ledna recept za pět korun (Interview with Petr Palouš, ředitel odboru farmacie ministerstva zdravotnictví ČR), Rudé Právo (16.12.1991), p. 3.

³² In the Czech Republic, nowadays, the privatization resulted in the majority of primary and specialized outpatient care providers running their private, mostly independent practices. On the other hand, the privatization of hospitals was stopped and the majority of hospitals are now

point is that we have started up competition. This will result in an improved supply," the representative of Ministry of Health, Petr Palouš, summarized the first transformation year. Competition was another important characteristics of the upcoming new system.

The transition towards the new health care system was not smooth. In the first half of 1991, the Institute for Public Opinion Research conducted the survey identifying the obstacles which people must have overcome in the procurement of pharmaceuticals: 20% of respondents mobilized networks of their friends, 18% declared that they were forced to cruise across numbers of pharmacies, 13% bought pharmaceuticals abroad, 5% asked a physician whom they were familiar with for this favor, and 5% bribed physicians.³³

This complication was caused that Sanitas as a main distributor of pharmaceutical products did not have a capital to purchase pharmaceuticals abroad and there was no subject willing to guarantee a possible bank loan for the company. In relation to this storyline, both media and representatives stressed the importance of competition in order to set up well functioning market.

This new system was in a steep contrast with the previous hierarchical and sclerotic management. On the other hand, the discourse was not driven by the neoliberal market-based paradigm only. At the same time, there was a strong inclination to social market model based on moral choice and solidarity. "Pharmaceutical are not like a dress which you can buy but you do not need it. You must buy it. Many of us need our medication daily," the media reported.³⁴

The competitive character of health care was also mirrored in dominant construction of patients' roles. Media portrayed patients both as victims of old regime when the modern care had been just for nomenclature and pupils who had to learn how to work in new system. "The public should realize that health care is not for free. People will have to pay at least a part of under the control of regions and municipalities. The hospitals also run their own outpatient departments.

³³ Tomešová L: Sanitas na lopatkách? Rudé Právo (23.8.1991), p. 13.

³⁴ Tomešová L: Sanitas na lopatkách? Rudé Právo(23.8.1991), p. 13.

their prices. However, we are going to categorize drugs. For painkillers and vitamins, citizens will pay more. However, for medicaments which people cannot choose to consume or not because they are dependent on them, there will be a co-payment rather symbolic. We must balance market access with social aspects," the Minister of Health Bojar described the philosophy of the reform in 1991.³⁵ Co-payments were presented as a natural and ideal state in this narrative when costs are share across the whole society. Co-payments were also presented as an educational tool educating patients to use health care in a responsible way.

It was expected that co-payments would represent between 10 and 15 % of the overall healthcare costs. A poll conducted among doctors in 1991 found 80% in support of this plan (Potůček 1999). A flat user fee of CZK 1 was also introduced for prescription pharmaceuticals. In 1992, the fee was abolished in relation to categorization of pharmaceuticals covered by health insurance. Re-introducing of this fee was discussed later in 1994 in relation to the urgent need to discipline upward spiralling health care expenses.

The new construction of patients' roles was intended to change hierarchical relations between patient and doctor into a flat partnership. For patients, it also brought the possibility of free choice of doctor and hospital. "The suppressed autonomy of health care professional has not influence only malarial and economical level. First of all, it has showed on the individual level and led to the fall of relations between patients and doctors," Martin Bojar, the Minister of Health, said in the interview for the weekly Respekt. On the other hand, it brought also an emphasis on patients' responsibilities. In relation to patients' constructions, the autonomy of responsibility were also key words of first transformation years. However, one must admit that responsibility was presented shared between individuals and state.

In the first transformational years, in Bhatia and Orsini's (2013) sense, the dominant sustainability narrative was a combination of value-for-money narrative with shift away from

³⁵ Šindelářová M: Bojím se velkého třesku (rozhovor s českým ministrem zdravotnictví MUDr.Martinem Bojarem), Respekt (11.2.1991), p. 5.

an outdated and inefficient care and moral choice narrative with the declared effort to minimize an increase in social inequalities. The goal was value-based system with reasonable level of solidarity. In terms of sustainability narratives, the original transformation one was definitely progressive. "We are not building the health care system for next year, but for 2000 or rather 2003," Minister Bojar declared.³⁶

The legacy of backward health care was predominately conceived as the burden to be solved. However, the costs of health care were not presented as a main problem. The primer locus of health care transformation was modernization, privatization, competition and innovation in the way services were delivered in order to improve health care.

In terms of regulation code, the first years of transformation were marked a combination of egalitarian with individualist code. Perverse rules of the state socialism were mentioned in contrast to market-based solutions. Individual responsibility and individual rationality was stressed in this code. On the other hand, threats of an excessive reliance on market and possible sources of inequalities were also reflected.

Generally speaking, this narrative is connected with post-communist discourse called by John Dryzek and Leslie Holmes (2000) civic enthusiasms. The way to a fully developed democratic system is presented as very difficult, but it is worth fighting for because only this system could guarantee for us prosperity and the rule of law. It would enable people to live in a normal society, unlike the communist society we have rejected. "While full democracy may take more than a generation to build, such that our children rather than ourselves may see the true benefits, we should not wait for either economic reform or equality to pursue democracy," Dryzek and Holmes (2000: 1057) describes such discourse. This discourse also interconnected the free-market solution with emphasis on civic norms.

³⁶ Šindelářová M: Bojím se velkého třesku (rozhovor s českým ministrem zdravotnictví MUDr.Martinem Bojarem), Respekt (11.2.1991), p. 5.

In 1992, when a liberal government led by the Civic Democratic Party (ODS) replaced the Civic Forum, the new government oversaw the implementation of the new system. Twenty-seven insurance companies entered the healthcare market, far more than the market could bear.³⁷ The General Health Insurance Fund (*Všeobecná zdravotní pojišťovna*) was established. In relation to the health insurance system, the categorization of drugs for reimbursement and co-payment was implemented.

The first categorization decree was released in September 1992. The pharmaceuticals were divided into three groups: (1) pharmaceuticals fully covered from the health insurance system; (2) pharmaceuticals partially covered from the health insurance system; (3) non-reimbursable pharmaceuticals. In the first category, there were about 1,440 products (52.2 %). The second category was comprised by drugs which were almost the same in terms of treatment, but different in price or in some detail. The categorization procedure determined to what extent the price pharmaceuticals in the second category would be covered by the health insurance system and by patients themselves. The second category represented about 970 drugs. The third group consisted of drugs that patients paid the full amount. These included the analgesics, vitamins, laxatives, etc. It meant approximately 350 items (12.7 %). The categorization had been prepared by the committee under the Ministry of Health consisted medical experts, representatives of the Ministry of Health and representatives of health insurance funds.

At the same time, prescriptions restrictions controlling pharmaceutical spending were established. Only specialists were allowed to prescribe some of the most expensive drugs. The most expensive drugs were supposed to be prescribed only after an approval by a physician re-

³⁷ By 1998, only nine insurers remained. Due to financial problems, 18 smaller insurance funds established between 1993 and 1997 had to be abolished. The health insurance market is dominated by the General Health Insurance Fund. Currently there are nine insurance companies with no real competition, and many feel that the current situation is not optimal.

viewer. These limitations were discussed in the categorization committee with representatives of medical associations.³⁸

During these years, moral choice sustainability narrative disappeared. Value-for-money narrative in individualist code prevailed as a way to advocate the reform. In 1993 and 1994, alternative narratives questioning the reform appeared in the public discourse as a critique of government. In term of egalitarian code and moral choice, some of critiques pinpointed negative social impacts of co-payments. Newly, hierarchical code criticizing expanding scope of bureaucratization appeared.

An increase in co-payment for pharmaceuticals was criticized by the Czech Helsinki Committee, which warned against its possible impact on the financial situation of seniors. The Ministry of Health, Luděk Rubáš, dismissed this appeal with reference to the official statistics. According to them, the average Czech pensioner had spent 15 CZK for reimbursed medicines and 178 CZK for over-counter medicine.³⁹ The minister, however, strictly refused to reflect social factors such as age or income in co-payments policy. The health status was to be only one factor to be taken in considerations. Co-payments were also presented as a natural state. "There is no country in Western Europe where citizens do not directly contribute financially on their care," declared Minister of Health.

Healthcare providers criticized the bureaucratization and the lack of communication predominantly. A physician Ludvik Kychler complained in the Czech media: *"I cannot imagine that in case of every medicine I prescribe I will be listing in the two heavy books released by the ministry (in order to know the level of reimbursement). The first book I got in Brno, 70*

³⁸ According to Prokeš (2012), one can see two reasons for a such tool: (1) guaranteeing the appropriate diagnosis; (2) knowledge of both desirable and undesirable effects of drug. It is supposed to lead to an effective usage of cost and high level of patients' safety. On the other hand, it might hinder health care accessibility and threat of overusing of specialised (and more expensive) health care.

³⁹ Pergr, V.: Loni důchodce zaplatil za léky na recept 15 a bez receptu 178 Kč, Rudé Právo (13.12.1994), p. 3.

*km far away from my workplace, going there especially because of it. How I got the second is for me still a big unknown. The question therefore is not whether doctors inform patients about a level of co-payments for drugs or they do not, but whether they are able to do it because of the incompetent work of the staff of several ministries."*⁴⁰

The both egalitarian and hierarchical strategies did not question the fundament of reform but they worked as corrective mechanism of particular failures.

However, in the beginning of 1995, increases in health care expenditures begun to be intensively discussed and fiscal sustainability was foregrounded. "In 1994, absolute consumption of medicament in packages increased by 22% compared to the previous year. Every citizen, including infants, consumed around 34 packages. However, it can be hardly said that it was due to an increase in prices. The Ministry of Finance regulates maximum prices once a year. The last year, prices even fell down by 2%. In 1985, the average price of a package was 13,65 CZK, while, in 1993, it was 50,20 CZK. ... This shift does not reflect a shift in prices, but a change in the structure of prescription drugs," explained Josef Suchopár, the director of the pharmaceutical policy office at the Ministry of Health.⁴¹ In the public discussion, one could find different kinds of explanations. In comparison with the situation before 1989, three main changes occurred: (1) pharmaceutical were no longer sold for lower prices than production ones; (2) the Czech market opened up for foreign manufactures; (3) doctors could prescribe pharmaceutical without significant restrictions. What was presented as a goal in the first transformation years it appeared to be a problem in the following ones.

However, the ministry representatives did not blame anyone. In line with fatalist code, they considered this steep increase in expenditures as inevitable and natural consequences of transformation in post-communist health system. In some way, this narrative could be still tied

⁴⁰ MUDr. Ludvík Kychler, Valtice, Lékař neřekne pacientovi, kolik doplatí za léky, protože to neví, Z redakční pošty, Rudé právo (18.04.1994), p. 3.

⁴¹ Šircová, Z.: Pojišťovny utahují opasky (lékařům), Týden (16.1.1995), p. 44.

to narratives stressing the fact that benefits of reform would be consumed by next generations. However, the fatality of this narrative opened-up the floor for further regulation. It had been done huge progress in way to keep up with Western countries, the system itself had been hugely modernized so a stricter regulation was presented as a next step by governmental experts. In their narrative they used one of advantages of fatalist code - to justify changes without blaming anyone.

The increase in pharmaceuticals' expenditures was put in contrast to stagnating medical professionals wages. In the public discourse, the explanation based on individualized frames such as patients' over-consumption and patients' demand for foreign and expensive medications appeared hand in hand with the fatalist explanations.

In relation to the steep increase in the expenditures, the Minister of Health, Ludek Rubáš, from the right-wing Civic Democratic Party (ODS), declared faster and more intense reforms of health care, including unpopular steps, in order to make the health care provision much more effective. "The period of pressure from the left-wing advocates of gradual and slow changes, too mild to citizens, to be used to health care, came to the end. The changes will influence even the community of medical professionals. The Civic Democratic Party criticized existing policy and is calling for much intense and faster reforms now," said Rubáš.⁴²

Original apolitical moral choice narrative was newly reframed as political struggle between left and right as a part of consolidation left and right discourse in the post-socialist context. Rubáš's proposed changes included limits for drugs prescription and individual health insurance accounts. He expected to increase co-payments of patients to 20 or 25 % of overall health budget.⁴³ Notwithstanding his proclamation of the unpopular steps, he admitted some limits of co-payments. For example, he refused the proposal made by the International Associa-

⁴² Pergr, V.: Rubáš chystá razantní změny i za cenu nepopulárních kroků, *Rudé Právo* (21.2.1995), p. 1.

⁴³ Pergr, V.: Rubáš: Za dva tři roky by pacient měl přímo hradit až čtvrtinu zdravotní péče, *Rudé právo* (15.3.1995), p. 3.

tion of Pharmaceutical Companies (MAFS) to cover from the health insurance funds only life-saving medicine.

Rubáš's reforms plans met with a heavy critique by medical professionals promoting the solution of health care financial crisis based on co-payments only. Both the Czech Medical Chamber and the Czech Dental Chamber refused to communicate with him. The communication between chambers and ministries had to be revived by the Prime Minister Václav Klaus. However, Luděk Rubáš was dismissed in October 1995 on the basis of long-term struggles with representatives of medical professionals and he was replaced by Jan Stráský.

In 1995, a reference pricing system (maximum prices for reimbursement by the health insurance funds) was introduced in the Czech Republic. The reimbursement level was calculated on the basis of the amount of substance contained in each pharmaceutical product. The unit cost of each substance was defined by the ministerial decree while basic principles were laid down by the law. The reference pricing system helped slow growth in expenditures: while the General Health Insurance Fund's (*VZP*) spending per capita on drugs had risen by 39% in 1994 and even 43% in 1995, the increase slowed to 13% in 1996 and to a mere 4% in 1997. (European Health Observatory 2000: 48)

In the same year, the transforming pharmaceutical market suffered with problems in supply chains. At the end of the year, health insurance companies owed pharmacies almost 320 millions CZK. According to the Czech Pharmaceutical Chamber, six insurance companies owed more than 20 millions. It means in average 250.000 CZK per pharmacy. Nevertheless, the biggest pharmacies had up to three millions CZK in debts.⁴⁴ In general, pharmacies and hospitals owed almost one billion CZK to pharmaceutical distributors because of delays in payments from health insurance companies.⁴⁵ "In areas where the majority of people insured by one of those insurance companies, pharmacies do not have the money to buy pharmaceuticals,"

⁴⁴ Pechová, R.: Lékárny chtějí platby v hotovosti. Lidové noviny (11.11.1995), p. 5.

⁴⁵ Pergr, V.: Nemocnice dluží za léky miliardu Rudé Právo (4.8.1995), p. 2.

explained Jan Horacek, the spokesman of the Czech Pharmaceutical Chamber. Pharmacists declared to be ready to collect payment for pharmaceuticals in cash directly from people. "We prefer to violate the law and risk the registration," said Jindřich Oswald, the president of the Czech Pharmaceutical Chamber. The government approved an amendment that would guarantee debts of the insurance funds in liquidation to 80%.

At the same time, there was another problem in relation to supply. Particular medications run out in pharmacies. In order to get their products on the top of list of fully covered drugs, pharmaceutical companies pushed their prices drastically down. However, the demand was higher than they had expected and companies were unable or not willing to deliver such a large amount of packages. Consequently, the possibility to get at least one medicament in every group fully covered by the health insurance system might have become only theoretical because of the absence of fully covered drug at the market, the Czech Pharmaceutical Chamber warned.

The Czech Pharmaceutical Chamber blamed the liberal institutional environment for causing this supply crisis. Health insurance funds and pharmaceutical manufacturers and distributors took an advantage of the loose regulatory framework to make a profit out of patients and pharmacies, pharmacists justified. Pharmacies paid for inconsistency in rules and someone else's errors.

The beginning of the year 1996, which was also the parliamentary election year, was marked by on-going struggles between the government and representatives of medical professionals, mainly the Czech Doctors' Trade Union (*LOK-SČL*) led by young and ambitious David Rath. The General Health Insurance Fund (*VZP*) warned that physicians began to prescribe more care than patients actually needed in an effort to raise incomes for their own surgeries. In addition to its warning, the insurance fund also proposed three regulations: (1) lower payments for doctors overreaching the average of medical procedures; (2) penalization of doctors pre-

scribing more pharmaceuticals than average ones; (3) decreasing payments per day in hospital in relation to days of hospitalization. Like pharmacists' accounts, this justification fell also on hierarchical code's side. In this storyline, physicians are blamed for the increase in expenditures and their behavior must be regulated.

In contrast to pharmacists' narrative, the Czech Doctors' Trade Unions (*LOK-SČL*) brought a different story with the combination of hierarchical and individualist code's grammar. The Unions released the long-term and short-term strategies of the Czech health care.⁴⁶ In their story, they blamed the foreign pharmaceutical companies on one hand and patients' overconsumption on the other hand. "Pharmaceutical companies will, as always, adapt and reduce their extraordinary profits in order their products will remain fully covered. ... Reducing the margin of distributors and pharmacies will stimulate the sale of cheaper drugs," the representative the Czech Doctors' Trade Union Milan Kubek publicly declared.⁴⁷ The problem on the patients' side was described by Kubek⁴⁸ in this terms: "In the Czech Republic, patients pay only 6% of the price of drugs; in Germany 13%, in France 30%, or even 70% in Switzerland and 85% in the US. No one dares to waste as we do. It is sad that three-quarters of the budget paid for pharmaceuticals disappear into the pockets of foreign companies. Czech pharmaceutical industry is falling apart ... The error is in patients who are convinced that foreign medicine is always better than a Czech product." The arguments about being like the West always worked in the transformational period. The Unions proposed to reduce prices for all drugs by 5 or 10% and introduce 10 or 20 CZK users' fee for a receipt in order to solve according to the Czech Doctors' Trade Union the main problem of the Czech health care provision - low wages of doc-

⁴⁶ Dlouhodobý a krátkodobý program reformy zdravotnictví v ČR. Pracovní skupina: D. Rath, P. Horák, M. Sojka, M. Kubek, J. Štrof, J. Zavadilová, J. Šimon, F. Fremun.

⁴⁷ Kubek, M.: České zdravotnictví je nadále vážně nemocné, *Hospodářské noviny* (25.1.1996), p. 9.

⁴⁸ Kubek, M.: Nemravnosti obchodu s léky, *Právo* (29.2.1996), p. 4.

tors and nurses. In their vision, the system did not work well because patients had not been educated enough and they believed that money, respective co-payments, could change it.

In the long-term strategy, the Czech Doctors' Trade Union proposed to differentiate beneficiaries of a health insurance in three groups in relation to their incomes. People with a higher income who contributed more to the health insurance system would be reimbursed more than low incomes groups. This negative solidarity was intended to motivate people to contribute more to the system and rewarded those who paid more. In the area of prescription, people in the basic type of insurance would get the cheapest preparation in each drug group. They could get a more expensive drug only on the basis of a special application. For other than basic drugs, patients would have to pay the difference in the price compared with a basic one. Insured groups with a higher income are entitled to a refund a part of those expenses according to their contribution to the health insurance system.

In contrast to Rubáš's vision of purely health solidarity, in which health people were solidary with sick ones but social consequences were not taken in consideration, the Unions framed the health insurance as a reward for people successful in economic terms. It is paradoxical that this extremely neo-liberal proposal was made by the union organization. The Ministry of Health strictly refused the Union's proposal. It was clear that the Ministry would not be willing to prepare any proposal three month before parliamentary election.

After the parliamentary election, the government of the Civic Democratic Party (ODS), Christian and Democratic Union – Czechoslovak People's Party (KDU-ČSL) and Civic Democratic Alliance (ODA) was formed; Jan Stráský (ODS) was appointed as the Minister of Health. In terms of pharmaceutical policy, the government promised to enforce regulatory mechanism on the supply side (categorization and prescription control). With respect to the social situation, Minister of Health, Jan Stráský, ruled out any increase in patient's co-payments. "I know that in Europe, patients contribution is around 25% of overall budgets, while, in the

Czech Republic, it is just 8%. But a substantial increase would mean to look for such a high social compensation, that it gives no sense," the Minister said.⁴⁹ In the same interview, he also accepted increase in pharmaceutical expenditures as natural fact, which he could hardly change. Jan Stráský also emphasized couple times that co-payments would not increase in next years because voters would not accepted it. His statements were an important re-framing a role of patients as voters – an active voice in policy-making.

From the point of view of theory of regulation, the first phase of transformation was framed mainly in individual mode, the second phase, which began in 1996, turned into hierarchical mode. The critique based on hierarchical or egalitarian mode had been present before. However, it had been a grammar used by policy opponents in the first transformatio years, after the election 1996, it became an arsenal of policy advocates too.

Whereas, in the first phase, the lack of competition was consider as the main problem by proponents of policy reforms, in the second phase, the lack of order appeared to be consider as a main problem. This construction of policy rationales was shared across the political spectrum. Any increase in co-payment was considered as unacceptable because of risk of potential loss of electorate and policy-makers focused their attention on a need of rules consiladation and as voters they should have been respected rather than educated. This shift might have been connected with the change in general discourse about post-communist democracy. When the previous dominant discourse of civic enthusiasms had been replaced by the discourse which Dryzek and Holmes (2000) called the disaffected egalitarianism. "Disaffected egalitarianism in the Czech Republic represents disillusion with the post-communist order, which is seen as a democracy in name only, that masks growing social, economic and political inequality, as well as hierarchy, corruption and bureaucracy. This discourse was perhaps bolstered by the corrup-

⁴⁹ Šircová, Z.: Stráský: Nový zákon o pojištění nezatíží pacienty vyššími platbami, *Zemské noviny* (7.8.1996), p. 9.

tion and money politics that became central issues in Czech politics in the mid-1990s." (Dryzek and Holmes 2000: 1059)

THE CONSOLIDATION OF RULES RIOD (1997-2001)

In this period, important changes in the legal area took place. The main changes were connected with the accession of the Czech Republic to the European Union. The legal system was harmonized with the EU law. Dlouhy and Hava (2003) called this period the era of regulation when the open-ended system was suddenly replaced by tight regulation. The changes in the reimbursement system made the essential modification of economic incentives for health providers. The end of the fee-for-service system removed the financial incentives for over-utilization;⁵⁰ instead, the motivations to minimize the volume and cost of services became an economically rational behavior of physicians. Negotiations between the health insurance funds and the organized groups of providers at the national level were also introduced. The objective of negotiations was to set fees and percentage growths of expenditure ceilings.

In 1997, the Act No. 79/97 Coll., on pharmaceuticals, passed. The act was considered as the crucial law determined the research, manufacture, preparation, distribution, control, and elimination of medicinal products and active substances. The new act was reasoned by the need to provide citizens with safe, effective and quality pharmaceuticals, make more accessible the remedies which did not threaten human lives, and harmonize the Czech legal regulation to be in line with the EU regulatory framework.⁵¹ According to the act, Ministry of Health was responsible for that: (1) preparing a concept of a pharmaceutical supply assurance; (2) releasing a decree determined rules for research, manufacturing, distribution of medical products for human use, including their registration, prescription and distribution; (3) authorize the use of the

⁵⁰ The specialists in outpatient services were still paid by the fee-for-service system, but with tight time limits and expenditure ceilings, which in practice meant budgeting of specialized outpatient services. (Dlouhý and Háva 2003)

⁵¹ Stráský, J.: První čtení zákona v Poslanecké sněmovně (4. 10. 1996)

non-authorized medicinal product in case of a threat to human life; (4) publish in the Bulletin of the Ministry of Health decision regarding the approval of pharmaceuticals; (5) establishing an ethics committee to issue opinions on a clinical trial on a human medicinal product; (6) publishing Czech Pharmacopoeia. (European Health Observatory 2000: 49) According to the Act, unconsumed pharmaceutical was supposed to be returned to pharmacies, which had to ensure their elimination. The specifications that information in the form of a leaflet must have been in Czech were introduced by the Act. Another novelty was the rule prohibiting pharmacists to sell a medical drug to a person less than 15 years of age.

Along with the Act on Health Insurance, the Act on Pharmaceutical intend to order and codify institutional setting emerged after 1989. To make the system compatible with the EU one was another criterion of justification. The compliance with the EU standards could be seen as an extension of catching up Western countries rhetoric established in 1990s. However, the discussion about rules in hierarchical system also opened up floor for the discussion on positions of different actors involves in pharmaceutical policies and their institutionalization in a regulatory framework.

The most controversial point of the proposal was that whether it would be allowed to sell pharmaceuticals outside pharmacies (for example in chemist's shops, groceries or petrol station). This case study helps to describe the emerging narrative in a greater detail. It serves me not only as a recapitulation of one controversy but also as an insight to the new vocabulary of regulation. On the original list, there were 156 drugs out of 1600 non-reimbursable drugs that were supposed to be sold outside of pharmacies. Advocates of the proposal stressed that this kind of liberalization is usual in Western countries and the proposal was considered as another step towards modern pharmaceutical market. The proposal, which was presented in individualist code as a way to make an access to pharmaceuticals for every day diseases easier for citizens, met with critique of the Czech Pharmaceutical Chamber and some experts. "The

Czech Pharmaceutical Chamber protests against the possibility that drugs will be freely available outside pharmacies. Patients might be imposed to greater risk when they get a medication without professional advice, " Jiří Hlaváček, the spokesman of the Chamber, warned.⁵² In its narrative, the Chamber claimed clear boundaries between patients as unknowledgeable actor and expert who could provide him with advice. This reframing was typical for this period. Patient is not supposed to be neither educated nor respected, patient must have been protected. In contrast to the first transformation years, it was also possible to say that the market is not the right way.

The Chamber also condemned the Ministry of Health to be influenced by the lobbying of pharmaceutical producers and distributors.⁵³ The Chamber framed the discussion in the general mode of critique of path of health care transformation in the Czech Republic and, at the dawn of the parliamentary election in 1996, the Chamber accused the government for having been too much liberal and captured by private firms. Their argumentation resonated with the general pre-election discourse of the disaffected egalitarianism. "I argue that the Civic Democratic Party is responsible for the management of the resort, but it has not done this task properly. We disagree with the absolute domination of the market in health care and disagree with liberalism to the extent that it is currently applied," the president of the Chamber Jindřich Oswald said.⁵⁴

Suddenly, it was not a fatalist approach of inevitability what appeared in the public discourse but typical private capture one when elites were blamed to let the ineffective regulation emerge. One can see how the general discourse of dissatisfaction was articulated in the case of very particular controversy. Metaphorically said, movements of tectonic discourse plates created a local earthquake.

⁵² Šircová, Z.: Nákup léků u benzinových čerpadel ohrozí pacienty, *Zemské noviny* (19.2.1996), p. 1.

⁵³ Česká lékarnická komora: Léky, to jsou miliardy, *Profit* (16.4.1996), p. 19.

⁵⁴ Lékárníci zásadně proti vládní koncepci, *Hospodářské noviny* (1.4.1996), p. 1.

Pharmacists particular mentioned the limited possibility to withdraw dangerous products from the market, the possible lack of advice from seller or disseminations of counterfeit medicinal drugs. The Chamber also objected that pharmaceuticals were not seen as a normal commodity and it was in public interest to distribute them through professional and expert network. The hierarchical mode of justification also created hierarchical positions. The construction of those positions was connected with the construction different kinds of risk as rationales to take a control over the process. Furthermore, it was also related to particular type of knowledge.

"Weakening of the position of pharmacies has brought an extremely important negative effect. By-passing pharmacies means a loss of an important control link. Pharmacists oversee and examine whether the packaging is intact, whether the drug brings expected effects and also whether the expiration date did not terminate. They provide patients with necessary information according to his or her wishes. Last but not least, they also check whether the doctor prescribes medication properly, especially when it comes to the amount of active ingredient," the president of the Chamber Jindřich Oswald enumerated.

The Chamber also justified its claims by public opinion research. According to the public opinion survey conducted by the Factum, almost 60% of the population thought that drugs should have been sold only in pharmacies. With the sale in drugstores would have agreed 32.7% of the population.⁵⁵

This discussion resulted in some kind of compromise. Some medical drugs were withdrawn from the list of free distributed products - for instance aspirin because of a risk of gastric ulcer bleeding. Outside pharmacies was possible to sell certain medicinal substances only. In comparison with the original proposal, the final law tightened conditions for the sale, for example the special license was required and control was supposed to be the same as in pharma-

⁵⁵ Česká lékarnická komora: Za peníze a dražší, Profit (1.1.1997), p. 15.

cies. In the end, this possibility did not give a raise of a huge interest on the side of entrepreneurs.⁵⁶

The pharmacists also warned against the idea of establishing of pharmacies by non-health related business companies, including pharmaceutical distributors or firms involved in other business activities (for example drugstores). They feared that those companies would be more interested in profit than a professional quality of services and established professional pharmacies would not be able to compete with sellers pushing price down at expense of quality of staff.⁵⁷ In the beginning 2001, the battle between the Czech Pharmaceutical Chamber and representatives of drugstores burst in the public discourse. The Chamber did not approve a license for the pharmacist-in-chief in a pharmacy in Brno which had been transformed from drugstore. It was intended as a combination of a pharmacy and drugstore. Even though the pharmacy part of the shop had fulfilled all obligations and had been approved by the State Institute for Drug Control (SUKL), the Chamber objected that patients would get in contact with un-educated staff from the rest of the shop who would also provide them with advice. On the other hand, the firm planning to run the pharmacy argued that the Chamber could evaluate just a personal qualification of pharmacist-in-chief, not technical parameters. The Company brought the Chamber to the court due to be in breach of their competences; the court agreed that. In 2004, the first drugstore combined with the pharmacy was finally opened.

Restriction of dispensing of drugs by physicians was another problematic issue connected with the new law. In contrast to the previous story, this case revealed one contradictory of hierarchical order – being too inflexible and in conflict with life-word. "Such a practice was run for decades in the remote regions and it was in the patients' interest because they did not need to travel for medicine to distant pharmacies in cities," informed the Health Officer in Kla-

⁵⁶ O prodej léčiv už nemají podnikatelé velký zájem, *Mladá fronta DNES* (13.5.1998), p. 1.

⁵⁷ Cikrt, T.: *Lékárna, anebo drogerie?*, *Zdravotnické noviny* (30.3.2001), p. 16.

tovy Ivan Šlajs.⁵⁸ Even the Ministry of Health admitted that in relation to the new rules, the accessibility of pharmaceutical had deteriorated for ordinary citizens.⁵⁹ The prohibition of distribution of medical drugs to person less than 15 years of age met with a critique too. "For example, mothers who are sick at home cannot send their child to withdraw a medicament. They often have to deal with a complicated situation and ask for help their neighbours," one pharmacist complained.⁶⁰

Ministry, therefore, proposed an amendment allowing pharmacists in rural areal and small town to open dispensaries and to dispense again medical drugs to children less than 15 year of age in some cases. Even though the hierarchical code was becoming dominant in this period, it was constantly being confronted with individualist one based upon perverse rules and the colonization of everyday life by bureaucratic system.

In 1997, The Act No. 48/97 Coll. and additional legislative norms were introduced. The new law defined 521 groups of pharmaceutical products based on an anatomico-therapeutic-chemicle principle that could be reimbursed by the health insurance funds and specific conditions for reimbursement in each group. The level of reimbursement of substances covered by law was supposed to be defined by a ministerial decree. The decree was updated regularly based on recommendations from the ministerial *categorization committee*. Both maximum and reference prices were determined by the Ministry of Finance.⁶¹ Based on the decree and the decisions of the Ministry of Finance, the General Insurance Fund (VZP) issued a drug list in which every reimbursable pharmaceutical product was enumerated.

⁵⁸ Havlík, K.: Zákon o léčích trápí šumavské lékaře, Právo (24.3.1998), p. 12.

⁵⁹ Ministerstvo zdravotnictví uznává, že dostupnost léčiv se zhoršila, Zemské noviny (18.4.1998), p. 2.

⁶⁰ Pavlovský, P.: Děti nedostanou v lékárně ani léky na předpis ?, Mladá fronta DNES (5.3.1998), p. 3.

⁶¹ Until 2003, the Ministry of Finance also stated the maximum price of non-reimbursable pharmaceutical products.

The June 1998 elections placed five parties in Parliament. Miloš Zeman's CSSD won, but Václav Klaus's ODS was not far behind. It led in something which was dubbed the "Opposition Agreement" between ODS and CSSD. It imposed various mutual conditions on the two parties, the basis of which was simple: the ODS would tolerate a CSSD minority government under certain conditions. (Stroehlein et al. 1999) In the Milos Zeman's government, Ivan David took a seat of the Minister of Health. David went on with the construction vulnerable patient who must be protected against commercial interest.

Ivan David declared an intention for further regulations, including the reduction of groups of pharmaceutical products. According to David, the number of groups in which at least one pharmaceutical must have been fully reimbursed was too detailed compared to other European countries. He blamed pharmaceutical companies that they took an advantage from such a complicated scheme. "For example, one pharmaceutical can appear in several group. As result, we pay several drugs with the same effect but with significantly different price. So foreign pharmaceutical companies have, thus, guaranteed full payment, although, in terms of drug efficacy, they do not bring any benefit," explained Ivan David.⁶² David also intended to reduce the margin of distributors and pharmacies. It is important to note that pharmaceutical companies were mostly identified with foreign producers. To protect patients against them meant to protect a Czech patient against external threat. At that time, the metaphor presenting Czech republic as Klondike (a gold mine) firstly appeared. However, his key proposals were refused by the Parliament because of David's inability to form any functioning coalition with key stakeholders in the sector and Ivan David was dismissed at the end of 1999.

In 1999, the health insurance funds could set spending limits for pharmaceuticals for each health care provider and impose penalties in case of overspending. (European Health Observatory 2000: 49) In the same year, the Parliament voted for the new law regulating advertis-

⁶² Vláda chce výrobce léků přimět ke snižování cen, *Hospodářské noviny* (28.1.1999), p. 1.

ing that was transposing the European Directive č. 92/28/E, and the new law regulating of intellectual property to be in line with TRIPS standards (the Agreement on Trade Related Aspects of Intellectual Property Right) pushed by the WTO. Furthermore, the text of the act on pharmaceutical was amended to be in line with the EU regulation between 1999 and 2004.

In terms of pharmaceutical policies, the representatives of Ministry of Health, in line with justification by the European standards, declared that it could not be expected to push prices further down. Using benchmarking argument, the Ministry pointed out that Turkey was only one European country where prices were lower than in the Czech Republic. The representatives of Ministry proposed stricter reference pricing, the list of necessary drugs, the decreasing margin for distributors and pharmacists, users' fees for receipt, positive lists for hospitals, a stricter antibiotics' regulation, national programmes of the pharmacotherapy of rare disease with very expensive treatment, prescription guidelines, system of information feedbacks.⁶³

The discussion on Europeanization also appeared in public discourse.⁶⁴ The European discourse was a different example of nationalization of patients in the Czech discourse. In 2000, the discussion culminated when the Zeman's Cabinet submitted the amendment of the patent law in which the protection of original products was extended by five years. Domestic manufactures, therefore, asked for compensations and a possibility of testing generic drugs even in a period when the original patent was still valid. "I do not understand why the government is stricter to the domestic pharmaceutical industry than other countries," the director of Léčiva Jiří Michael said.⁶⁵ He noted that Hungary, Poland or Slovenia are considerably more liberal and he urged the Czech Government to be more active in negotiations with the EU. On the other hand, Czech representatives of foreign pharmaceutical companies were, indeed,

⁶³ Podstatných úspor ve výdajích na léčiva lze dosáhnout dobrou antibiotickou politikou, Zdravotnické noviny (17.9.1999), p. 1.

⁶⁴ For example: Náklady na léky musí růst pomaleji, Hospodářské noviny (29.12.1999), p. 5; ČR sladuje ochranu patentů, Zdravotnické noviny (19.11.1999), p. 12; Speváková, Š: Česká kúra pro léčiva, Ekonom (25.3.1999), p. 14;

⁶⁵ Léky: EU, či národní zájem?, Mladá fronta DNES (7.2.2000), p. 1.

strong advocates of the new regulation. From the narrative point of view, media did not frame this controversy as the battle between domestic and foreign producers but rather as battle between the national interest and the EU and they prompted policy-makers to fight for Czech interests. The positive discourse about Western standards had been transformed into the critical one.

THE CHAOS AROUND CATEGORIZATION (2002-2005)

In 2002, the process of categorization was under fire of different stakeholders. The Ministry led by Social Democrat Bohumil Fišer changed arbitrarily the committee's decision on reimbursement level and raised a wave of protests of representative both pharmaceutical firms and expert bodies.⁶⁶ In a nutshell, the committee decided which pharmaceuticals would be fully covered from the health insurance system and for this reason it was under careful scrutiny and critique of various stakeholders in pharmaceutical policy. Ministry pointed out that the Committee followed only medical criteria in contrast to the governmental policy that took also social criteria in consideration. "In some cases, the Minister must assess to what extent the decision is in line with the Cabinet intentions and whether the ministry can identify with it," the Deputy Minister of Health Michal Pohanka explained.⁶⁷

The ministry stuck to the construction of a vulnerable patient and used this construction in justification of correction in the reimbursement decision. In this particular case, the ministry used an egalitarian grammar of moral choice sustainability narrative to justify their objection towards strictly medical evidence-based policy. Social aspects represented another dimension around which the Ministry could build its expertise. The ministry could not compete with the

⁶⁶ Cikrt, T.: Kategorizace léčiv: Výrobci protestují, ministerstvo ale považuje svůj postup za správný, *Zdravotnické noviny* (15.3.2002), p. 8.

⁶⁷ However, the pharmaceutical expert and a member of the committee, Jan Švihovec, objected that they were not strictly for medical approach only. According to him, the committee would have taken policy criteria in consideration if someone had informed members about them.

expert committee in medical-evidence but it could underpin its expertise as a political subject taking social aspect also in consideration and contextualizing expert decision.

This controversy brought the attention to way how the reimbursement decisions were produced. The decree was very often described as a product of the committee only. However, critics challenged a procedural side and foregrounded particular points of uncertainty. Instead of one decision, there was a series of translations between the committee decision and the released decree. The ministerial department of pharmacy and medical drugs' control had to convert decision of the committee into a decree. The General Health Insurance Fund (*VZP*) evaluated the list in relation to maximum prices. After this evaluation, the producers commented the nascent decree. Although the entire process was presented as expert-driven and unambiguous, manoeuvring space where political interest might have been enforced there either. During the process, approximately 80 or 90 changes were usually had done. Those changes were very often invisible and their author could be hardly traced. In contrast to the publicly available committees' decisions.

"The Ministry has the right to disregard the Committee's decision for being wrong. However, I have credible information that it was because of lobbying. Pharmaceutical companies have hired lobbying agencies to promote their interests in government," the pharmaceutical expert and the member of the committee Jan Švihovec said.⁶⁸ His narrative strongly resonated with a private capture based on client politics and ongoing discourse of disaffected egalitarianism. He reframed the ministerial storylines of protecting public interests against one-dimensional expert decision to private capture narrative that the ministry disused its power to enforce private interests.

Švihovec was not alone in his complaints. Even the General Health Insurance Fund (*VZP*) warned that the ministry unexpectedly raised reimbursement for particular drugs against

⁶⁸ Riebaurevá, M.: O léčích rozhoduje pár lidí, *Mladá fronta Dnes* (27.2.2002), p. 1.

arthritis (rofecoxib and celecoxib), hepatitis C (ribavirin) and anti-obesity drugs (sibutramine and orlistat). According to the biggest health insurance fund, it brought an increase in expenditures of millions CZK. The Czech television revealed a different case that the ministry granted an exemption on insulin manufactured by the Super Vision Company, whose co-owner was employed at the ministry at the same time.

In 2002, Marie Součková replaced the dismissed Bohumil Fišer, however, the critique continued. In 2003, the pneumologists complained about a delay in categorization of tiotropium for patients with chronic obstructive pulmonary disease (COPD). This medicament waited to be enlisted in the decree for three years. Every time, the Committee recommended putting this drug onto list fully reimbursed medicine, however, the Ministry ignored its recommendation. "We left the meeting and there was a general consensus between us and the ministerial officials. Then, the decree was published and the drug was not mentioned in there," the Vice President of the Pneumological Society Viktor Kašák complained.⁶⁹

In relation to pharmaceutical policy, Marie Součková enforced amendments transposing the European regulation into the Czech legal system. She prepared the new decree sorting out pharmaceutical into groups and determining the levels of reimbursement, which was later refused by the Legislative Council of the Czech Government due to not to be in line with both the Czech and the EU regulations. Součková was under fire of both her political opponents and her colleagues in the party. After Součková lost a Senate election, it was pretty clear that Social Democratic voters were not fond of her either. In April 2004, the Prime Minister Vladimír Špidla sacked her and replaced her by Jozef Kubinyi. Nevertheless, four months later, Kubinyi was not re-appointed to the new government formed by Stanislav Gross after Vladimír Špidla's resignation. Milada Emmerová became the Minister of Health. It was not surprising that no deep programmatic changes were possible in such a turbulent time.

⁶⁹ Kluzáková, P., Bláhová, I.: Kategorizaci léčiv především chybí transparentnost, *Zdravotnické noviny* (14.11.2003), p. 14.

Milada Emmerová triggered an avalanche of foreign firms' protests as she declared a support for domestic pharmaceutical industry. "Thanks to the offer from the largest domestic manufacturer it will be possible to reduce the reimbursement of certain drugs without the risk of subsequent burdens for patients," said the minister.⁷⁰ The struggle between experts in the categorization committee and the Ministry continued. Emmerová dissolved the categorization committee because of being untrustworthy. She used the same arguments as Fišer did. According to her, the decree, which was prepared by the committee, burdened patients too much because the level of reimbursement was too low. And the Ministry prepared the revised decree just itself.

Emmerová's effort met with a heavy critique from pharmaceutical companies and experts because of lack of transparency. The International Association of Pharmaceutical Companies (MAFS) raised objections over a deal between the Health Ministry and the country's largest producer of drugs, Zentiva. This accusation was reinforced by the fact that Emmerová's son, Jiří, was one of Zentiva's directors. The International Association of Pharmaceutical Companies (MAFS) blamed her for the conflict of interest. Furthermore, Emmerová admitted that the content of the new decree had been influenced by Zentiva's offer to cut the prices of some of its products. The MAFS lodged a complaint with the Office for the Protection of Economic Competition (ÚOHS). In its complaint, the MAFS also pointed out that the categorization process infringes on the EU Transparency Directive governing the transparent selection of pharmaceutical products and decisions by the controlling authorities. "Complaining to the EC is our last resort," said Pavol Mazan, the executive director of the MAFS. The MAFS was also considering lodging a complaint with the Czech Constitutional Court. Also representatives of the Association of Czech Pharmaceutical Companies (ČAFF) and the Union of Health Insurance Companies (SZP) criticized the controversial decree.

⁷⁰ Dohoda se Zentivou za zavřenými dveřmi, Zdravotnické noviny (5.11.2004), p. 1.

In 2005, the ministry named new members of the committee. At a very first meeting, the ministerial officer proposed the prepared decree to be signed. "They presented a list of 8000 items and they wanted that we should approved it," Karel Němeček, representing the General Health Insurance Fund in the committee, said.⁷¹ The committee rejected the request by a majority of its members. At the same time, the International Association of Pharmaceutical Companies (MAFS) lodged a complaint with the European Commission for the infringement on the European Commission Transparency Directive.⁷²

The chaos culminated in the mid of 2005 when the Ministry released the new decree. Experts counted 86 categories in which fully covered drugs were either totally missing or not available for different reasons.⁷³ Psychiatrists pointed out that the registration for thioridazine, which was the only fully covered drug in the category of antipsychotics and neuroleptics, had been cancelled because its manufacturer had stopped producing it. On the other hand, Jan Sučopar, the pharmaceutical expert, explained that it might have been a tactics how to push distributors of other pharmaceuticals in the same group to push prices down. The General Health Insurance Fund later confirmed this explanation.⁷⁴ In July, the group of oppositional Senators from the Civic Democratic Party lodged a complaint with the Czech Constitutional Court. In October, the Prime Minister Jiří Paroubek pushed David Rath, the controversial president of the Czech Medical Chamber, to be a deputy of the Minister of the Health. Then, the rest of deputies resigned and Milada Emmerova who also protested against David Rath's installation was dismissed. David Rath became the Minister of Health. Even though it was less than year to the next parliamentary elections, Rath declared the will to conduct further reforms steps.

The whole period was marked by the on-going controversy between experts involved in the categorization committee and the ministry. The representatives of ministry used egalitarian

⁷¹ Kučera, P.: Emmerové se „vzbouřila“ léková komise, *Lidové noviny* (4.4.2005), p. 14.

⁷² MAFS si stěžuje u Evropské komise, *Medical Tribune* (4.4.2005), p. 1.

⁷³ Kučera, P.: Státisíce pacientů si od července připlatí za lék, *Lidové noviny* (18.6.2005), p. 1.

⁷⁴ Pergl, V.: Ministerstvo odmítá, že vyhláška porušuje zákon, *Právo* (21.6.2005), p. 5.

code of taking social dimension into consideration to justify their attempts to correct the expert's decisions. They considered the experts' view as too reductionist and following medical criteria only. On the hand, the discourse coalition of opponents including both experts and representatives of foreign pharmaceutical firms put an emphasis on private capture narrative and accused the ministry to be under influence of lobbying of the Czech manufacturer Zentiva. They identified the Czech system with corruption and clientelism and put it in contrast with the transparent European law. Discursively, this period could be characterized as a battle over justification who can act on behalf of patients. Patients did not have a their own voice but their interests were mobilized for different reason and they were differently represented. In terms of their social interests, patients were represented by the Ministry. In terms of their health needs, patients were represented by expert medical group. The ministry mobilized their social needs and expert communities their health needs. All stakes were justified in public interest and criticized from the perspective of private capture.

As the result, the political narrative about the Ministry correcting of the committee's decisions as a moral choice in favor of Social Democratic policy were outvoiced by narratives about the Ministry ignoring expert advices in favour of stakes of pharmaceutical companies. This construction was also underlined by the rapid change of miniters. The second one definitely prevailed. It was supported by increasing dissatisfaction of the Czech citizens with politics (Linek 2010) and relatively high prestige of medical professionals and scientists in the Czech media (Čada et al. 2006).

THE CRISIS CONTINUES (2005-2006)

The Ministry of Health, led by David Rath, completed the new reimbursement decree. As usual, it met with a strong critique from pharmaceutical companies and pharmacists. The ministry declared that manufactures and distributors could reduce their prices much further. "The political task for the expert committee was that how to get the same amount of drugs for a

smaller number of money," the chair of the committee, Karel Němeček, declared. He explicitly admitted the political demand for the committee.

According to the Ministry, the substantial changes to make the Czech regulation to be in line with the EU regulation had been implemented - the appeal committee had been established and decisions of both committees were publicly available. The ministry also urged hospitals to cut services by as much as 20%, causing the postponement of elective surgeries and placing a limit on treatments medical centres can prescribe. The ministry also introduced very strong prescription limits. Its narrative was predominantly fiscal. The ministry left the narrative of moral choice applied by Fišer and Emmerová in favor of fiscal sustainability one only. However, it was articulated strongly in hierarchical mode. Expanding scope of regulation and strengthening of existing institutions the ministry intended to push on pharmaceutical firms to lower prices and hospitals to make cost-containments. The conflict between domestic and foreign producers went on.

In January 2006, representatives of the Czech Chamber of Pharmacists warned that they were ready for strike action. According to the decree, which the Cabinet approved in December 2005, the Ministry of Health decreased margins, which are partially reimbursed from public health insurance, from 32 to 29%. This change angered pharmacists, who claimed their total annual income would drop down. Representatives of the Chamber of Pharmacists also warned that around 550 out of the current 2,400 pharmacies could go bankrupt due to the lower income and delayed payments from health insurers.

"I understand the discontentment of pharmacies and [drug] distributors. ... On the other hand, it will push drug prices down and have a positive impact on patients," David Rath said. Fiscal sustainability was identified with patients' interests.

The Social Democratic Member of Parliament Eduard Zeman proposed an amendment to exclude a representative of the Czech Pharmaceutical Chamber from the expert committee,

and the Parliament agreed.⁷⁵ In response to pharmacists' protests, Rath and Prime Minister Jiří Paroubek agreed to set up a commission, which should determine how to cut health insurance costs on medicine. The commission, which included pharmacists, drug suppliers, and ministry representatives, reached no conclusion.⁷⁶ The public discussion became too polarized to be able to find any feasible solution.⁷⁷

David Rath's crisis narrative was very much in the sense of Bhatia and Orsini's (2013) fiscal narrative only. The main goal of Rath's steps was to guarantee the same amount of care for smaller amount of money. Rath's storyline was strongly polarized with patient, medical professionals and ministry as goodies and pharmacies and pharmaceutical companies as baddies. Fiscal sustainability was identified predominantly with patients' interests. Rath incorporated the regulatory capture narrative by pharmacies and pharmaceutical firms that had been used against Fišer and Emmerová. However, Rath turned it against the original proponents. Pharmacists and pharmaceutical firms protested because the Ministry confined them in strict boundaries of rules and limits and limited their unregulated monopoly, he declared.

JULINEK'S REFORM (2006-2008)

Although health care changed significantly in the two decades following the fall of communism, the biggest reform changes were proposed after the parliamentary elections in 2006. The reformist program was one of the highlights in the election campaigns of the two biggest Czech parties: the right-wing Civic Democratic Party and the left-wing Czech Social Democratic Party. Despite the victory of the Czech Social Democratic Party, because it proved

⁷⁵ Lékárníci ve stávkové pohotovosti, Zdravotnické noviny (13.1.2006), p. 6.

⁷⁶ Schejbal, J.: Jedna bitva končí, válka nikoli, Profit (20.3.2006), p. 14.

⁷⁷ At the same time, the Association of Drug Distributors (AVEL), which covers 95% of the pharmaceuticals market here, halted deliveries to three hospitals - Bulovka and Thomayerova, both in Prague, and U sv. Anny in Brno - that had failed to pay a total of 400 million CZK owed for drugs. Pavel Suchý, the director of AVEL, said distribution would not resume until that debt was resolved. However, hospitals had been already stocked up.

impossible for them to find any coalition partner to form a government, the election resulted in a right-oriented coalition, which decided to bring the proposed reform into being. "Mutual relations between insurance funds, medical facilities and citizens do not motivate any one of them to use health care economically," noted the Minister for Health, Tomáš Julínek when justifying his proposed steps.⁷⁸ He described his reform steps as a "revolution". Julínek introduced also his reform team with key experts with experience in the similar step in Slovakia. Julínek also dismissed Milan Sojka, the director of the State Institute for Drug Control (*Státní ústav pro kontrolu léčiv*), who had been appointed by David Rath.⁷⁹ He also withdrew a representative of the Czech Medical Chamber from the ministerial committee. The Committee was newly formed from four representatives of health insurance funds (as representatives of payers of health care), three representatives of the Ministry ("as guarants of protection public interests") and three representatives of medical professional societies ("as guarants of quality of health care").⁸⁰ As observers without a vote there were representative of the Czech Medical Chamber, the Czech Stomatological Chamber, two representatives of patients organizations, one representative of International Association of Pharmaceutical Companies (MAFS) and one representative of the Czech National Association of Pharmaceutical Firms.⁸¹

It gave a raise to The Medical Chamber's protests articulating their objection in vocabulary of private capture. "We consider these steps as severe restrictions of public scrutiny of pharmaceutical policy of the Czech Republic, a direct violation of the principles of democracy, and restrictions on the rights. We assume that it is not in the interest of citizens, but only in the interest of the pharmaceutical lobby," the President of the Chamber Milan Kubek publicly announced.⁸² It is symptomatic that the medical professionals' representatives identified them-

⁷⁸ T. Julínek představil svůj program, *Medical Tribune* (18.9.2006), p. 1.

⁷⁹ Pergr, V.: Šéf SÚKL padne, Rath v tom vidí mstu, *Právo* (15.9.2006), p. 06.

⁸⁰ Julínek jmenoval novou kategorizační komisi. *Ministerstvo zdravotnictví* (9. 10. 2006)

⁸¹ Julínek jmenoval novou kategorizační komisi. *Ministerstvo zdravotnictví* (9. 10. 2006)

⁸² Kubek, M.: Julínek omezil veřejnou kontrolu, *Česká lékařská komora* (19.10.2006)

selves as representatives of public. As it was said, the patient participation in decision-making processes is very weak in the Czech Republic; therefore it is possible for different stakeholders to speak on behalf patient.

At the same time, the media reported that pharmaceutical companies funded the preparation of Julínek's health reform. Those pharmaceutical companies explained it as a support for expert meetings and their contribution to expert dialogue promoting.⁸³

In line with his election promises, the Minister prepared several new proposals aiming both at the privatization of large hospitals and health insurance funds and the cost containment of health care provision. His reform program was originally articulated strongly in value-for-money narrative with dominant individualist code. He stressed an increase in individual responsibility, patient self-regulation would be motivated through flat users fee and increase in co-payments, market-based solution, modernization of health care, need for innovation and shift away from inefficient care. The Czech Minister of Health, Tomas Julínek, declared two goals when the reform was launched: "The main two goals of the reform are both improving the status of a patient and dealing with the effects of ageing of society. The Czech Republic is one of the most vulnerable countries in the European Union. In 2050, you will have public funds for less than half the needed care. In 2015, we will miss at least thirty-billion."⁸⁴

These principles were inscribed in the new decree released in February 2007. This decree lowered reimbursements for inefficient and outdated medicines and medical drugs that did not deal with the causes of disease, but rather their consequences. It was expected to save 1.5 billion CZK intended to be used on the modern treatment.⁸⁵ "We have three criteria. The first one, if there are more drugs with the same effect, the reimbursement corresponds with the cheapest one. The second principle is that we have reduced the maximum price of expensive

⁸³ Vašek, P.: Julínek zveřejnil sponzory své reformy, *Hospodářské noviny* (8.8.2006), p. 1.

⁸⁴ Otázky Václava Moravce, *Česká televize* (4. 11. 2007)

⁸⁵ Vašek, P. Mařík, M.: Na málo účinné a zastaralé léky si lidé připlatí, *Hospodářské noviny* (1.2.2007), p. 1.

and effective medicines to the lowest level at the EU. Third one, we have lowered the reimbursement for drugs where the effectiveness has not been proved, and where there exists a more modern treatment, or in the case of only supportive treatment, which is not required," the Deputy of Minister of Health, Pavel Hroboň, explained.⁸⁶ The goal of the proposed policy was to keep the pharmaceutical expenditures on the same level with no increase and shift money away from outdated medical drugs to modern ones. It was also stressed that it was a way to make patients be more active and to be more interested in their health. "Patients will find that they will have to pay more. And they will begin to wonder why? And they will be provided with advise that it is outdated medicine which have been replaced by a modern medical drugs with minimal or even no co-payment," explained Minister Tomáš Julínek.⁸⁷

One can easily see the construction of patients as rational and informed actors that was further developed in next stages of the reform. This justification was in a sharp contrast with dominant media narrative on the constant raising the price of pharmaceuticals. Since 1990s, media had been referring about increase in prices every time when a new decree was published. The increase in co-payments had been considered as normal state, indeed, no reason to be wondered. The media also portrayed the new decree as serving to health insurance funds, which would save money at expense of patients.⁸⁸

At the beginning of 2008, the pharmaceutical policy changed completely. Responsibility for the level of reimbursement and maximal prices shared by the committees of the Ministry of Finance and the Ministry of Health heavily criticized by the European Commission disappeared. Since introducing the reforms, the State Institute for Drug Control (*Státní ústav pro kontrolu léčiv*) has been responsible for pricing and reimbursement decisions. The maximum price was originally defined as the lowest price in eight reference EU countries (Estonia,

⁸⁶ Vašek, P.: Pacienti budou od dubna za léky doplácet víc než dosud, *Hospodářské noviny* (1.2.2007), p. 4.

⁸⁷ Julínek, T.: Co všechno se změní pro pacienty, *Mladá fronta DNES* (7.2.2007), p. 4.

⁸⁸ Kučera, P.: Pojišťovny ušetří. Na úkor pacientů, *Lidové noviny* (28.3.2007), p. 3.

France, Italy, Lithuania, Hungary, Portugal, Greece and Spain),⁸⁹ later it was replaced by the average of the three lowest prices for a given pharmaceutical in eight reference EU countries (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain). The State Institute for Drug Control became responsible also for setting the reimbursement price covering public health insurance. Those pharmaceuticals that are considered as interchangeable are included in the same reference group and the reimbursement limit is set at the price of the least expensive within the group. The Act on Public Health Insurance defines 300 groups for which at least one pharmaceutical must be covered in full by the public health insurance. Co-payment for prescribed drugs is necessary in cases where the price of a pharmaceutical exceeds the reference reimbursement level (as is also the case in Spain, France, the Netherlands, among others). At the start of 2008, more than 50 per cent of pharmaceuticals distributed did not require any payment other than the user fee charged for all prescription drugs.

In 2008, flat user fees were introduced for patients who were hospitalised, visiting a physician or who purchased drugs at a pharmacy. Starting in January 2008, flat user fees of CZK 30 (1.20 EURO) per doctor visit, CZK 60 (2.40 EURO) per hospital day, and CZK 90 (3.60 EURO) per use of ambulatory services outside of standard office hours were introduced as a method to make patients more motivated to use health care reasonably. A flat user fee of CZK 30 (1,20 EURO) was also introduced for prescription pharmaceuticals. The government employed two standard arguments for expanding the role of user charges: (1) user charges can

⁸⁹ The category of the cheapest product in every category was another controversial point. "It reminds me the movie in which the main character covered the part of menu with the names of the dishes and looked at the prices only - he did not care what he would eat but how much it would cost. So he choose the cheapest meal - three eggs in a glass," the pharmaceutical expert Jan Suchopár explained. In different European countries, the reasons for low price of pharmaceuticals might have been different - for example an agreement between regulators and manufactures in which manufactures might have decreased the price of one medical drug at expense of increase of price of different one. If you had put it in a different context it could not work, Suchápar noted. See *Úhrady léků – vždy je co vylepšovat*, *Zdravotnické noviny* (7.4.2008), p. 17.

help make up for shortfalls in public funding and (2) user charges make people more aware of their healthcare choices.⁹⁰

Tomáš Julínek presented all of his reforms steps in an evidence-based and depoliticised way. According to him, critics of the reform were driven by lobbying or effort to gain political benefits.⁹¹ Notwithstanding the existence of the two regimes, the discussion was gradually being boiled down to the second regime only. Controlling healthcare costs gained a top priority in the discourse, driven by a combination of factors, including arguments over resource scarcity, the ageing population and patient responsibility. The prevailing focus on savings was mirrored in the way that the successes of the reform were presented to the general public. Pharmaceuticals played a very important part in this process. "Since we introduced the reform, the consumption of prescription drugs has significantly decreased and more prescription drugs have been sold. As a result of the new system nearly two billion Czech crowns have been saved in the last quarter of year," summed up the Minister for Health, explaining the successes of the reform.⁹² Savings became a key measure and the wasting of money was attributed mainly to the behavior of individual patients who allegedly over-consumed healthcare because of a lack of financial motivation. "The main rationale for reform was a reduction of public expenditure;

⁹⁰ According to Thomson et al. (2010), the policy makers supporting user charges assume that patients have enough information to decide, they understand them and they are able to make a rational choice. However, the decision-making of health care consumers is not always rational. Due to the strong information asymmetry between patients and medical professionals, patients may not always understand the value of a particular treatment. People may forgo necessary treatment or fail to adhere to it in order to avoid paying user charges. "Introducing user charges in one area of care - for example, outpatient prescription drugs - can have a squeezed balloon effect, initially lowering expenditure on drugs but increasing the use of other services such as half day or full day admissions to community mental health centers, nursing home admissions, and emergency care." (Ibid: 489) These warnings have been proven by studies exploring access to health care in Greece. Greeks were less likely to visit GPs and outpatient facilities; there was a rise in admissions to public hospitals of 24% in 2010 compared with 2009, and of 8% in the first half of 2011 compared with the same period of 2010. (Kentilekenis et al 2011)

⁹¹ Julínek, T.: Léky dramaticky nepodraží, Medical tribune (9.6.2008), p. 1.

⁹² Otázky Václava Moravce, Česká televize (8. 5. 2008)

moreover an introduction of a psychological breakthrough to make a patient aware that health care costs money and it is necessary to weigh up actual needs," explained the Minister.

The transmission of responsibilities on the State Institute for Drug Control (*Státní ústav pro kontrolu léčiv*) was heavily criticized by medical professionals and experts - because of the concentrations of competencies within one bureaucratic apparatus. "The concentration of all powers in the field of pharmaceutical regulation (registration and pricing and reimbursement) in the hands of a single institution is extremely uncommon in Europe. Unlike many other countries, our new system does not allow for the existence of expert consultative advisory bodies. A professional public has lost the opportunity to significantly contribute to the formulation of health policy," the Czech Medical Chamber complained.⁹³ Critics also pointed out the delay that the State Institute for Drug Control (*Státní ústav pro kontrolu léčiv*) had in re-evaluation of drugs.

Manufactured with controller arranged to reduce rates for other concessions, such as an increase in the price of another product. In 2008, Tomáš Julínek promised to make some amendments - for example to make children less than 3 years of age be free from users' fee. The Czech Constitutional Court also evaluated the reform. However, the fees were in order according to the Court and they were retained. The proposed acts immediately evoked sharp critical reactions from opposition parties, unions and some experts. Critics warned against an increased influence of neoliberal measures and principles such as a privatization of hospitals or loosening of the regulation of health insurance funds (Hava, Maskova-Hanusova 2009).⁹⁴ Critics of such measures particularly warned of worsening access to health care for pensioners and the lowest income workers. The implementation of the mentioned measures might have led to

⁹³ Kubek, M.: Proč platíme za předražené léky?, *TEMPUS Medicorum* (28.3.2008), p. 14.

⁸⁹ Due to the introduction of user fees and changes in co-payments for partially reimbursed pharmaceuticals the reform resulted in a significant increase in what patients were required to pay; however, their share of final household expenditure was still relatively low in comparison with other European states. The greatest share of out-of-pocket payments was made up of expenditure on pharmaceuticals. (Krutilova 2012)

an increase in the financial burden for the most vulnerable groups such as pensioners or inactive individuals and unemployed. The critique was driven by egalitarian code of deteriorating health access and increasing inequalities. It was also pointed that the reform is unsustainable in terms of moral choice - self-interested private logic might have led to the collapse of the public system.

The reform's proponents justified savings in some sectors in favour of an increase of spending or stability in other parts. When Julinek's reform was debating, the issue revolved around two general categories of care: health efficiency regime and economic efficiency regime. The first regime represented a modern treatment which was promised to be guaranteed regardless of costs, while the second regime represented a sector where more expensive drugs could be replaced by cheaper products and patients could contribute more financially to their care. While out-of-hospital care was associated with cheap and generic drugs, hospital care was associated with expensive and unique medicaments.

Using a category analysis of television debates between 2006 and 2007, six main categories of health care have been identified: (i) uniqueness; (ii) novelty; (iii) origin; (iv) price; (v) indication; and, (vi) the way of distribution. In a health efficiency regime, the type of care was associated with originality, novelty, foreign medicaments, acute states, and anti-cancer treatment. This type of care was in the hand of professionals in hospital, who distribute this care reasonably. The Julinek's reform proponents argued that strict regulation was not needed. On the other hand, an economic efficiency regime of care was associated with standard care, domestic products, chronic illnesses and care out of hospitals. This type was connected with the wasting of money and it was seen to require regulation. This categorization replicated dominant media representations of professional medicine as a way to treat sickness competently and successfully by doctors in hospitals using the latest technology and fast-acting drugs (Lupton 2003: 57).

Tab 13: Architecture of Health Care Categories and their Dimension in Julinek's Reform

Dimension	Health efficiency regime	Economic efficiency regime
Uniqueness	Unique	Standard
	Original	Generic
Novelty	Modern	Old
Origin	Foreign medicaments	Domestic produced
Price	Expensive	Cheap
Indication	Acute	Chronic
	Anti-cancer	Unspecified
The Way of Distribution of Pharmaceuticals	Hospital Care	Out-of-Hospital Care
	Professional responsibility	Individual responsibility

The alternative narrative of the coalition of the oppositional Social Democrats and representatives of the domestic manufacturers producing mainly generic drugs stressed that worsening of the access to medicine and extensive support for foreign pharmaceutical companies. Health effectiveness was questioned and modern treatment was associated with the profit of foreign companies. "Modern new and expensive drugs are the flagships of the big pharmaceutical companies, which bring them huge profits. It is, therefore, abundantly clear in which name the Minister is playing."⁹⁵

According to Deborah Stone, policy makers look for causes not only to understand how the world works but also to assign responsibility for problems (Stone 1997: 189). Lawrence (2004) suggests analyzing the responsibility assigned in public debates using "individualizing" versus "systemic" frames. "Individualizing frames limit the causes of a problem to particular individuals, often those who are afflicted with the problem. Systemic frames broaden the focus, assigning responsibility to government, business, and larger social forces" (Lawrence 2004: 57). In the of health reform, individualizing frames associating the wasting of money in health care with a lack of financial motivation on the side of patients and out-of-hospital care pre-

⁹⁵ Sýkorová, V., Křenková, K.: Léková politika v ČR, Haló noviny (4.6.2007), p. 8.

vailed. In this economic discourse, out-of-pocket payments and user fees were considered to be a magic wand which would turn passive patients into active consumers. In the elections following this reform, however, Czech patients refused to be identified with wasting in the health care system and voted against parties standing behind the this discourse.

In Autumn 2008, the Czech Social Democratic Party focused on user fees as a central issue in the campaign elections to regional councils. The electorate refused to be blamed for health care costs and governmental right-wing parties lost significantly in this election. Consequently, major governmental reforms were stopped and the author of these reforms, the Minister of Health, Tomáš Julínek, was dismissed. Two years later in the campaign before the 2010 parliamentary election, health care played just a marginal role (Sedláček and Herot 2011). Regarding Down's (1972) theory of attention cycles, a period of intense organizational activity was replaced by a decline in interest from the main political parties caused by the public refusal of the last reform attempt. The consequences of the health reform were devastating for the Minister of Health and his reform team. The opponents appeared to have scored the greatest political victory but the policy itself did not fail completely. Even if the government gave up the next steps of the planned reform, the changes that had already been implemented still prevail.

CONCLUSIONS

Thatcher and Rein (2004) characterize policy issues by conflicting values. "Policy actors do sometimes try to strike a "balance" among conflicting values, but they often avail themselves of other strategies as well: they cycle between values by emphasizing one value and then the other; they assign responsibilities for each value to different institutional structures; or they gather and consult a taxonomy of specific cases where similar conflicts arose." (Thatcher and Rein 2004: 457) In this chapter, the perspective of narrative dynamics was used to grasp the managing conflicting values in the pharmaceutical regulation in transformation period.

I argue that this type of change resulted from interplay between narratives of sustainability, codes and discourses. Narratives are the surface textual representation of action and events, while discourse is the underlying interpretative context for making sense of those surfaces. In the case of my analysis, the medicalization and austerity are the main underlying discourse. Drawing on Bhatia and Orsini (2013), I identified four health sustainability narratives: (1) value-for-money (austerity and medicalization); (2) fiscal (austerity without medicalization); (3) a moral choice (neither austerity nor medicalization); and (4) the new social contract (medicalization without austerity). Very similarly to Canadian case described by Bhatia and Orsini, the main dynamic is between fiscal sustainability and value-for-money narrative. The moral choice one played an important role in the beginning of transformation and during social democratic governments as a part of the conflict between political and expert policy making. This narrative was used to defend political principles of social equality against reductionist expert evaluation based policy. In contrast to Canadian case, the new social contract narrative based on life style options played a very marginal role. It might be associated with a relatively weak position of health promotion in the Czech health policy.

Regulatory codes are understood as a grammar of blame and solution. In line with Douglas and Wildawsky (Douglas 1993; Thompson, Ellis and Wildawsky 1990), I identified all of their four codes: (1) individualist; (2) hierarchical; (3) fatalist and (4) egalitarian. The main conflicting line is between individual and hierarchical code of justification regulation while the egalitarian and fatalist approach played just a marginal role. The first one put an emphasis on market-based solutions, patients as consumers, superior self-regulation, individual responsibility and individual rationality. The second one was associated with capture and corruption, need for prudent regulator, expanding scope of regulation, strengthening of existing institution and the central role of government. The first one was dominant during the right-

wings governments and second one was articulated more in the leftist one. Moreover, the hierarchical code was also presented in the Europeanization discourse.

Tab 14: Overview of identified narratives, regulatory codes, value conflict and roles of patients

Transformation period		Rules Consolidation		Rules Crisis		Value-for-Money
Sustainability Narratives						
Value-for-Money; Moral choice	Value-for-Money	Value-for-Money/Fiscal	Fiscal	Fiscal/Moral Choice	Fiscal	Value-for-Money
Dominant Regulatory Codes						
Individualism Egalitarianism	Individualism	Individualism Hierarchy	Hierarchy	Hierarchy Egalitarianism	Hierarchy	Individualism
Value Conflicts						
Choice vs. Solidarity	Righ-wing vs. Left-wing	Individual vs. Systemic	Liberalization vs. Regulation	Expert vs. Political	National vs. Foreign production	Economical vs. Health Efficiency
Role of Patients						
Patients as victims of communism	Patients as Pupils	Patients as voters/ Patients as social actors	Patients as Victims (market forces, the EU, social burdens of reforms,			Patients as Rational Consumers

Apart from construction of sustainability, concrete policy narratives are dependent on discourses how public understood the role of democracy and the role of the government. In this case, the shift away from discourse of civic enthusiasms towards disaffected egalitarianism seemed to be crucial one. Disaffected egalitarianism represents disillusion, which is seen as a democracy in name only, that masks growing social inequality, as well as hierarchy, corruption and bureaucracy. This discourse supported by increasing dissatisfaction of the Czech citizens with politics made the political untrustworthy and give a raise of private capture narratives in hierarchical sense.

In both regulatory codes, one can find the deficit model of patient. Whereas, in the first one, patient is portrayed as a rational actor who needs to learn skills to work in the new model of health care. We can speak about deficit of skills, which is typical for individual code in neoliberal discourse. Through economic tools patient could be educated to make “good choices”

and medium of education is money. The deficit model overlooks knowledge asymmetry ascribed in the relation between patient and medical professionals. The responsibility in this model is individual one. On the other hand, in hierarchical code, one can speak about the deficit of knowledge. Patients does not have enough information to make a right choices, therefore, they must be protected. The responsibility is shared on institutional level. On the other hand, patients are excluded from decicion-making both on policy and individual level.

In the end, hierarchical code resonated much more with the public perception of health care. Health care is strongly considered by the Czech public to be a public good which should be covered by public funding. Public opinion appears to use a different criterion for assessing health care to that used to assess social policy. In heath care, the strong sense for egalitarianism and statism which was typical under the socialist model remains; in social policy, the society has already taken much more liberal attitudes to the redistribution of social benefits, education and social housing. The public does not sympathize with market liberalism in the area of health care, but it has accepted these principles on housing and employment. Thus, the Czech people are likely to think that the sick, disabled, pensioners, and families with children should receive more financial support from the state than the unemployed, immigrants, the homeless and socially excluded minorities (Sirovatka and Saxonberg 2009). Following table shows that this trend still prevails.

Tab 15: Citizens' views on priorities in funding from the state budget (the average ranking)⁹⁶

	11/2010	11/2012
Health care	3.19	3.16
Pensions	3.68	3.64
Workers compensation and sickness insurance	4.33	4.68
Disability pensions	4.89	5.11
Financial support to families	5.33	5.17
Benefits of assistance in material need	6.19	6.05
Active employment policy	6.88	6.08
Unemployment support	6.67	6.19
Support in education	6.59	6.97
Social housing	7.21	7.51

Source: (Buchtik 2013: 3)

⁹⁶ Wording of the question: "Could you rank the following areas of social policy according to their importance in terms of funding from the state budget. The first item means that the area was the most important in terms of state funding. Select each of the other areas, with the last one you consider least important in terms of state funding." The score indicates an average ranking. A lower score means a higher importance for respondents.

CONCLUSIONS

The tendency of doctors to overused medicines because of they do not take costs in consideration and the monopoly that pharmaceutical companies enjoy in the production of medicines under patent protection are both long-standing justification for pharmaceuticals public policy to reduce price of medicine (Bloom and Van Reenen, 1998). Pharmaceutical policies were introduced as a dynamic where one can apply all sources of modern social acceleration identified by German scholar Hartmut Rosa (2013). They are driven by economic motor, social-structure motor and cultural motor of acceleration of pace of life. Medicine has been becoming more and more specialized. It resulted in an increase in the numbers of diagnoses, of medical drugs prescribed and developed, and of medical specializations. Expectations of patients have been rising. However, expenditures have been rising as well. During the period up to 2009, all OECD countries saw health spending outpaced economic growth resulting in an increasing share of GDP allocated to health and increased spending on pharmaceuticals has significantly contributed to the overall rise in total health expenditure. What is the role of state regulation in this acceleration field?

According to WHO, the main objective of the pharmaceutical service is to provide efficient, safe, rational and cost-effective pharmacotherapies to those who need them. Therefore, pharmaceutical policies are facing two demands: maximizing health benefits and minimizing waste of public funds. These two identities represent different values and rationalities and there is an ineluctable conflict between them. The first one can be conceptualized by the concept of medicalization – one of the key sociological themes of the second half of the twentieth century. The second one can be explained by the concept of fiscal responsibility. Pierson (1994, 2001, 2002) identified two sources of limiting success of policy reform: (1) the electoral incentives associated with programs which retain broad and deep popular support and (2) the institutional

stickiness which further constraints the possibilities for policy reform. My point of view taking discursive perspective in consideration falls predominantly on the first source's side.

According to Peter Conrad (1992: 209), medicalization describes a process of defining previously non-medical problems in terms of medical pathology. The term first entered sociological literature in the 1970s. Medicalization as a type of manipulation is theoretically elaborated through the concept of governmentality. Governance is a more or less rationally calculated activity exercised by authorities and agencies, which use different techniques and forms of knowledge to pursue modalities of control that act upon other agents' desires, aspirations, interests and beliefs (Dean 2010: 18). It corresponds to Foucault's concept of pastoral power, which refers to the development of technologies of power directed at the individual and his or her management. With increase in alternative treatments, it would therefore seem that medicine has lost its primacy of being the only institution to decide about our health. However, Deborah Lupton (1995) argued that this discourse based upon the holistic approach to health and lifestyle in fact only helps fostering the power of medical discourses over our lives. "In health promotion discourse, lifestyle is pathologized as a source of ill health" (Lupton 1995: 142) This discourse portrays health as a goal achievable through intentional action, one that requires self-discipline, determination, as well as the necessary time and energy.

As for pharmaceutical policy, the progressive medicalization of western societies can be demonstrated on the milestones which medicine has reached in its quest to colonize new areas of human life. Last but not least, these pharmaceuticals have also become one of the elements fuelling the discourse of health as a matter of personal choice and responsibility. Medicine offers us various possibilities to be content, free of anxiety and enjoying a good quality of life. It is everyone's responsibility to decide whether they want to benefit from these possibilities or not. These innovations therefore contribute to the discourse of the "imperative to health" (Lupton 1995), which relies on, among others, the presumption that the individual is largely

responsible for his or her health. He or she did not follow proper diet, did not get enough exercise, drank too much or too little alcohol, took too few vitamins, did not provide his body with a sufficient amount of antioxidants or exactly the right amount of omega fatty acids. The reverse side of this structural pressure is then that less attention is paid to areas of health prevention such as work conditions, environmental burden or the weakening of social solidarity within public healthcare systems.

The discourse of health hopes is very strongly present at policy narrative - which Bhatia and Orsini (2013) called value-for-money sustainability narrative. Value-for-money narrative defines sustainability as a constraint or boundary within which the system must operate. This storyline also conceives of this constraint as primarily fiscal, however, cost is one among a number of other parameters within which reform of the health care system must be considered. The causes of the sustainability problem in this storyline are broad, overarching factors related to the changing needs of an ageing population to which the system has failed to adapt sufficiently, resulting in inefficiencies and ineffective care. There is a need for transformation, modernization, and innovation in the way services are delivered, a shift away from an outdated dependence on expensive and inefficient acute, hospital-based care. This narrative has much more progressive character than the previous one. In contrast to the fiscal sustainability narratives, the tone of the value-for-money narrative is positive.

The different side of health hopes discourse in public policy narrative is represented by the new-social-contract narrative which comprises from life-style choices (for example pinpointing the role of obesity epidemics in expanding of health care costs). In contrast to value-for-money narratives, the new social contract narrative of sustainability – or unsustainability – is founded in doomsday scenarios (futuristic scenes of systems on the verge of collapse) and it is based upon the personal responsibility.

The discourse of fiscal limits is presented in the fiscal-sustainability narrative. The early history of austerity concept taught us that *homo oeconomicus* who follows his or her own interest in his or her own way can meet with *homo spectatus* who follows his or her own honor depending upon the honor and glory of his or her community. As Adam Smith supposed, saving is both good and natural. To behave economically is not only morally appreciated but also natural. In the field of state politics, the consequence of this line of thinking is austerity - purging the system and cutting spending, which becomes the essence of recovery. The predominant metaphors used to frame the problem are medical. Politicians speak about a chronic spending disease which will weaken the system. These metaphors convey a sense of impending doom – fear that the prognosis for the spending disease is not good and concern about a sick fiscal future. Because of excessive spending, the systems have deviated from the economic nature and it necessary to take them back in healthy conditions. There is also a note of urgency that treatment cannot be put off any longer and the best cure for it is the diet. Developed societies need fasting to pure their bodies and revive their vitality.

The critique of this concept, Bhatia and Orsini (2013) called sustainability as moral choice narrative. The champions of this narrative are a coalition of socially progressive groups, including organized labor, citizens' groups, social policy activists, anti-globalization advocates, and think tanks. Their legitimacy in health reform debates is twofold. First, they are able to draw on their own diverse experiences and knowledge to convey timely, relevant information in response to specific issues. Second, and more important, they are explicitly normative in their defense of core values that (should) underpin the system.

Thatcher and Rein (2004) characterize policy issues by conflicting values. In my thesis, the perspective of narrative dynamics was used to depict the managing conflicting values in the pharmaceutical regulation in transformation period. I argue that this type of change resulted from interplay between narratives of sustainability, codes and discourses. Narratives are the

surface textual representation of action and events, while discourse is the underlying interpretative context for making sense of those surfaces. Regulatory codes as a part of discursive praxis represent a grammar how regulation narratives are put together. In the case of my analysis, the medicalization and austerity are the main underlying discourse.

I argue that all narratives described by Bhatia and Orsini (2013) as independent can be classified along two axis: (1) their relation to health hopes and (2) fiscal limits discourse. Drawing on Bhatia and Orsini (2013), I contextualized four health sustainability narratives: (1) value-for-money (austerity and strong health hopes); (2) fiscal (austerity without health hopes); (3) a moral choice (neither austerity nor health hopes); and (4) the new social contract (health hopes without austerity). The advantage of the value-for-money narrative lies in possibility to justify savings (in fiscal responsibility discourse) by medicalization discourse.

Tab 16: Discursive affinities

	Fiscal limits discourse (YES)	Fiscal limits discourse (NO)
Health hopes discourse (YES)	Value-for-money narrative	New social contracts narrative
Health hopes discourse (NO)	Fiscal Sustainability	Sustainability as moral choice

Very similarly to Canadian case described by Bhatia and Orsini, the main dynamic in the Czech discourse can be observed between fiscal sustainability and value-for-money narrative. The moral choice one played an important role in the beginning of transformation and during social democratic governments as a part of the conflict between political and expert policy making. This narrative was used to defend political principles of social equality against reductionist expert evaluation based policy. In contrast to Canadian case, the new social contract narrative based on life style options played a very marginal role. It might be associated with a relatively weak position of health promotion in the Czech health policy.

To grasp a long-term dynamics, the dissertation uses cultural theory of regulation (Douglas 1992; Thompson, Ellis, and Wildavsky 1990; Lodge et al 2010; Lodge and Wegrich 2011) to classify, chart, and compare argumentation patterns and policy values. Cultural theory's four core-value system - hierarchy, individualism, egalitarianism, and fatalism - is used as an analyst's compass into a trajectory of frames that covers patterns of blame and proposed remedies. The analysis of argumentation involved the extraction of claims that demanded particular types of regulatory action, and coding these claims according to their frames (Lodge, Wegrich, and McElroy 2010; Lodge and Wegrich 2011). Perverse rules, market-based solution, patients as consumers, self-regulation as a superior concept, individual responsibility and individuals as rational actors characterize individualist code. Hierarchical code can be identified with capture and corruption, a need for prudential regulator, an expand scope of regulation; strengthen existing institutions, and the central role of government. Fatalist code is described by inevitability of crisis, unpredictable effects, naturally limited knowledge, and natural factors such as ageing of population. Egalitarian can be characterized by reliance on markets caused melt-down, encourage information sharing, inequalities; access to healthcare.

The main conflicting line is between individual and hierarchical code of justification regulation while the egalitarian and fatalist approach played just a marginal role. The first put an emphasis on market-based solutions, patients as consumers, superior self-regulation, individual responsibility and individual rationality. The second one was associated with capture and corruption, need for prudent regulator, expanding scope of regulation, strengthening of existing institution and the central role of government. This game basically means a fight between the rules-based justifications and competition-based justifications. In the context of the Czech Republic, the first one was dominant during the right-wings governments and second one was articulated more in the leftist one. However, this trend cannot be attributed to right or left values only. For example, the right-wing Ministry of Health Jan Stránský used a hierarchical code

in his argumentation. I argue that it might result from the cyclical management of conflicting values – between individual code used in progressive value-for-money narrative and hierarchical code used in stabilizing fiscal sustainability narrative.

In both regulatory codes, one can find the deficit model of patient. Whereas, in the first one, patient is portrayed as a rational actor who needs to learn skills to work in the new model of health care. We can speak about deficit of skills, which is typical for individual code in neoliberal discourse. Through economic tools patient could be educated to make “good choices”. The deficit model overlooks knowledge asymmetry ascribed in the relation between patient and medical professionals. The responsibility in this model is individual one. On the other hand, in hierarchical code, one can speak about the deficit of knowledge. Patients does not have enough information to make a right choices. In contrast to previous construction, this deficit cannot be overcome; therefore, professional authorities must protect them. The responsibility is shared on institutional level. On the other hand, patients are excluded from decision-making both on policy and individual level.

Hierarchical code resonated much more with the public perception of health care. Health care is strongly considered by the Czech public to be a public good that should be covered by public funding. However, policy narratives are also dependent on discourses how public understood the role of democracy and the role of the government. In this case, the shift away from discourse of civic enthusiasms towards disaffected egalitarianism seemed to be crucial one. Disaffected egalitarianism represents disillusion, which is seen as a democracy in name only, that masks growing social inequality, as well as hierarchy, corruption and bureaucracy. This discourse supported by increasing dissatisfaction of the Czech citizens with politics made the political untrustworthy and gave a raise to private capture narratives in hierarchical sense.

SHRNUTÍ

V posledních letech jsou státy vyspělé Evropy podle mnoha autorů (např. Práznovcová, Strnad 2005; Iversen 2006; Goodman in Cooter; Pickstone 2000) svědky eskalace nákladů v rámci lékové politiky. V souvislosti s nárůstem nákladům na léčiva se Jeremy Green (2007) ptá, co se stalo, že veřejné zdraví, dříve spojované s charitou a vědou, se stalo předmětem tak výrazného obchodování. Jak se stalo, že drobné výkyvy krevního tlaku se staly předmětem a produktem mechanismů, v nichž se spojuje věda, politika, ekonomie s podomním obchodováním.

Farmaceutické trhy tak představují jedno z klíčových prudce expandujících polí, jehož analýza může přispět k celkovému poznání sociální dynamiky pozdně moderních společností. Hartmut Rosa (2013) rozlišuje tři hlavní typy akcelerace v moderních společnostech: (1) technologická akcelerace hnaná ekonomickým motorem, (2) akcelerace sociální změny hnaná motorem funkční diferenciací a (3) akcelerace životního tempa hnaná kulturními přísliby. V úvodu své práce ukazují, že ačkoli Rosa péči o zdraví výslovně nezmiňuje, splňuje tato oblast jeho znaky akcelerujícího pole. Významně se zkrátila doba schvalování nových léčiv (Angell 2004: 1-5) Medicínský diskurs proniká do řady oblastí, kde dosud nebyl – genetické metody či metody zobrazování mozku ovlivňují soudnictví, moderní sexuologie a metody upravující reprodukci zasahují vyšší měrou do oblasti lidské intimity či stéle vědecktější uchopení problematiky výživy. Zvyšují se očekávání od pacientů (Novas 2006). A léky v tomto procesu hrají klíčovou úlohu a jsou jedním z jeho klíčových hybatelů. „Všude na světě jsou obrazy štěstí a zdraví stále více spojovány s dostupností moderních léků,” tvrdí Adriana Petryna a Arthur Kleinman (2006). Lék se podle citovaných autorů stal jedním ze synonym moderní medicíny. Tento přístup lze charakterizovat citátem jedno českého lékaře: „nemoc je to, na co existuje lék.“

Práce se věnuje tomu, jaké jsou legitimizovány možnosti státu regulovat toto dynamické pole. Jak říká Adrian Kay (2006), intelektuální předpoklady dynamiky v oblasti veřejných politik dosud nebyly teoreticky dostatečně zkoumány. Ve své práci vycházím z předpokladu, že narativní perspektiva poskytuje ideální možnost, jak se touto dynamikou zabývat. Práce se tak hlásí ke konstruktivistickým přístupům k analýze politik.

Práce popisuje dva silné diskursy formující současné zdravotní politiky: (1) diskurs zdravotních nadějí a (2) diskurs rozpočtových limitů. Zdravotní naděje jsou v současnosti poháněny medikalizací, která podle Petera Conrada (1992: 209) popisuje proces, kdy jsou původně nemedicínské problémy definovány v termínech nemoci. Termín se dostal do sociologické literatury v sedmdesátých letech. „Medikalizace znamená definovat problém v lékařských termínech, použít lékařský jazyk k popsání tohoto problému, přijmout lékařský rámec k porozumění tomuto problému a užít lékařskou intervenci k jeho léčbě“ (Conrad 1992: 211). Australská socioložka Deborah Lupton charakterizuje představitele kritického přístupu k medikalizaci následovně: „Vidí symbiotický vztah mezi kapitalismem a zdravotní péčí: kapitalismus produkuje zdravotní potřeby, kterou jsou léčeny tak, že se zakrývají jejich kořeny a potřeba konzumace komodit zajišťující léčebný proces, který na oplátku podporuje kapitalistický systém produkce“ (Lupton 2003: 10).

Diskurs rozpočtových limitů či střídmosti popisuje situaci, kdy státy vyrovnávají své veřejné výdaje tím, že redukují mzdy a veřejné výdaje, aby obnovily konkurenceschopnost (Blyth 2013). Mark Blyth považuje tento koncept za jeden z fundamentů moderního státu, jehož historie sahá k myslitelům jako je Adam Smith, David Hume či John Lock. Od počátku tak byla střídmost jako zmiňována nejen jako hodnota ekonomická, ale i jako hodnota morální. Stala se tak součástí kánonu buržoazních hodnot (McCloskey 2010). V celosvětovém kontextu pak principy střídmych ekonomických politik byly propagovány epistemickou komunitou politiků, expertů a businessmanů, jež ztělesňuje například Mont Pelerin Society (Mirowski 2009).

Tyto reformy praktikované ve vyspělém světě ve větší míře od osmdesátých let lze také souhrně nazvat jako *dismantling policies*. Podle Piersona (1994, 2001) tvůrci a obhájci těchto nepopulárních politik čelí základnímu problému, jak nebýt viněn z nepříjemných důsledků těchto politik. Kategorizace těch, kdo si pomoc zaslouhují a těch, kdo nikoli, a budování ospravedlnění těchto kategorií patří ke klíčovému z těchto strategií.

Ve práci rozpracovávám koncept Bhatii a Orsiniho (2013) čtyř typů narativů udržitelnosti ve zdravotních politikách: (1) fiskální udržitelnosti, (2) hodnota za dobrou cenu; (3) morální volby a (4) nového sociálního kontraktu. Každý z těchto narativů definuje jiný cíl pro zdravotní politiky a přisuzuje jiné hodnoty jednotlivým dimenzím politiky. Tyto narativy vychází právě z širších diskursů medikalizace a rozpočtové odpovědnosti. Zatímco Bhatia a Orsini je pojímají izolovaně, tak tato práce je představuje ve vzájemných souvislostech, a to podle jejich vztahu k medikalizačnímu a rozpočtově odpovědnému diskursu. Jejich vzájemné vztahy ukazuje následující tabulka. Výhoda narativu hodnoty za peníze tak spočívá v tom, že umožňuje diskurs rozpočtové odpovědnosti legitimizovat diskursem medikalizačním.

Tab 17: Vztahy diskursů

	Rozpočtoví odpovědnost (ANO)	Rozpočtoví odpovědnost (NE)
Medikalizační diskurs (ANO)	Hodnota za peníze	Nový sociální kontrakt
Medikalizační diskurs (NE)	Fiskální udržitelnost	Morální volba

Tyto narativy zobrazující vztah k zdravotní politiky k příčinám současných problémů i způsobů jejich řešení ve své práci kombinuji s kulturními kódy (Douglas 1992; Thompson, Ellis, and Wildavsky 1990; Lodge et al 2010; Lodge and Wegrich 2011). Tyto kódy popisují gramatiku regulačních narativů a způsoby jakým je možné připisovat vinu za současný stav. Kulturní teorie regulace odlišuje čtyři tyto kódy: (1) hierarchický, (2) individualistický, (3)

egelatirianský a (4) fatalistický. Ve své analýze dospívám k zjištění, že pro popis českých reforem je klíčová hra mezi individualistickým a hierarchickým kódem. Tato hra v zásadě znamená, souboj mezi na pravidly založených ospravedlněních či na soutěži založených ospravedlněních. V situaci post-komunistického vývoje České republiky odpovídá dominantní užívání individualistického kódu pravicovým vládám a hierarchické vládám levicovým. Nicméně nelze tento trend přičítat pravo-levým hodnotám. Například pravicový Jan Stránský používal hierarchický kód. Jejich střídání tak spíše odpovídá cyklickému managementu protichůdných hodnot, kdy na základě sílicí kritiky a nižší veřejné kredibility jeden kód oslabuje ve prospěch druhého.

Celkově lze také vysledovat afinitu mezi narativem hodnoty za peníze a individualistickým kódem a rozpočtovou odpovědností a kódem hierarchickým. Narativ morální odpovědnosti hrál důležitou roli v počátcích transformace a odpovídal tomu, co John Dryzek a Leslie Holmes (2000) charakterizovali jako diskurs občanského entusiasmů. Ten však byl v druhé polovině nahrazen diskursem nelajálního rovnostářství, který zdůrazňoval odklon politické sféry od života běžných lidí, korupcí a uzavřenost ekonomických a politických elit. Tento diskurs také dával sílu množícím se narativům zmocnění regulace veřejnými zájmy (*private capture*). Společně s převládající představou české společnosti, že zdravotní péče je primární odpovědnost státu nikoliv jednotlivce vedl k politickým neúspěchům individualistickým narativům. Rozpočtová odpovědnost je tak zřejmě českou společností lépe přijímaná v hierarchickém než individualistickém rámci.

V obou regulačních kódech lze nalézt deficitní model pacienta. Zatímco v případě individualistického kódu je pacient zobrazovaný jako racionální aktér, který se pouze potřebuje naučit jak fungovat v novém modelu zdravotnictví. S ohledem na individualistický kód můžeme mluvit o deficitu dovedností, který je typický pro individualistický neoliberální diskurs. Definiovaná odpovědnost je individuální. Pomocí ekonomických nástrojů pacienti mohou být

vzdělávání, aby činili „dobré volby“. Tento deficitní model přehlíží znalostní asymetrii vepsanou do vztahu mezi lékařem (či lékárníkem) a pacientem. Na druhé straně, v hierarchickém kódu, lze nalézt o deficit znalostí. Pacienti nemají dostatečné informace dělat správné volby, takže musejí být chráněni. Odpovědnost je v tomto sdílena mezi profesionální komunitu. Na druhou stranu pacienti touto konstrukcí ztrácí hlas a jsou vylučováni z rozhodování, a to jak na individuální, tak na politické úrovni.

Narativy regulace jsou odvislé od širších narativů jednotlivých politik a kódu, kterými jsou vyprávěny. Z hlediska jejich dynamiky lze vysledovat vzájemné vymezování různých typů kódů a jejich vzájemné oslabování a nahrazování. Vedle této endogenní dynamiky, svou roli také hraje i exogenní dynamika pohybu diskursů, širšího uvažování o medicíně, demokracii či ekonomice – jakých si tektonických diskusí, jež slouží jako dispozitivu jednotlivých regulačních narativů.

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