Univerzita Karlova v Praze
Fakulta sociálních věd

Dizertační práce

2015 **Karel Čada**

Univerzita Karlova v Praze
Fakulta sociálních věd
Institut sociologických studií

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

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2015

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

V Praze dne 5. 3. 2015 Karel Čada

On my way, I have received helpful references and stimulation from many colleagues and friends. I would like particularly mention Fridays' conversations with Tomáš Dvořák, Veronika Frantová, Martin Volek and later Filip Vostál at the Institute of Sociological Studies Faculty of Social Sciences Charles University in Prague. I am also indebted to the Centre for European Studies at the Australia National University in Canberra, where I stayed from December 2011 to May 2013. Many thanks to the generous director of the Centre prof. Jacqueline Lo and Andrew, Bruce, Danielle, Dorota, Elisabetta, Jane, Huong, Melissa, Kerstin, Rob, Will and many others. My thanks are also owed to the School of Sociology. I appreciated conversations on the sociology of health with Dr. Kevin White and grateful thanks to Catherine Wong for organizing reading groups. I am also very grateful the Centre for Deliberative Democracy with its director John Dryzek for its intellectually stimulating and friendly atmosphere. I'm also very grateful to reviewers of the prevous versions of dissertation, Dr. Michal Prokeš, Dr. Miroslav Barták, and Dr. Tereza Stöckelová. Fragments of thesis were presented and discussed on conferences in Grenoble, Lodz, Canberra, Palmerston North, Wanegingen, Olomouc and Hoješín, many thanks for stimulating debates. Two fragments (Chapter 1 and part of Chapter 6) have been published, thanks to their reviewers. I have learned much during my work and endless discussion with Ivan Gabal, Jan Snopek and Jan Hanzlík. Many breakthroughs have been born and forgotten during our debates with Tomáš Čížek. All parts dealing with a private capture were written with him on my mind. Last but not least, many thanks to my supervisor Jura Kabele for navigating me through sociology landscape. This thesis is dedicated to Kateřina Ptáčková and to Matylda.

CONTENTS

INTRODUCTION

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

Deborah Stone (1988: 208)

Over the last decades, the pharmaceutical policies of 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 asked (2007) how it is possible that small fluctuations in blood pressure have become the object and product of mechanisms which bring together science and politics, economics and doorstep selling. Pharmaceutical markets thus represent one of the crucial and fastest-growing fields, the analysis of which can help us understand the social dynamics of late modern societies and its consequences for public regulation.

The aim of my thesis is to study the mutual relations, interplay and possible contradictions between institutions (including relevant organisational fields) and narratives. This general goal has been heavily influenced by interpretive policy analysis. Bevir and Rhodes (2003: 17) define interpretive approaches to political studies as those focused on "meanings that shape actions and institutions, and the ways in which they do so." By following literature (Hajer 2009; Fischer and Gottweis 2012) that recognises the importance of language in policy making I intend "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 this point of view, politics is seen as a sequence of staged events in which actors interact over the meaning of events and over their consequences. Policy narratives, therefore, present a way how past is recollected and enacted to construct fu-

ture expectations. Although the policy making process might be regarded as involving rent seeking or other forms of strategic manoeuvring, actors still need to legitimise their positions and win their cases publicly.

Narratives play an important role in organising public policy reforms: "[they] involve temporal chains of interrelated events or actions, undertaken by characters." (Grant et al. 2004: 64) They present "critical junctures", in terms of historical institutional theory (Hall 1993; Pierson and Skocpol 2002), or make self-evident norms, frames and conventions, in terms of sociological institutional theory (DiMaggio and Powell 1983; Beckert 2003). Narratives organise experience with the help of a scheme assuming the intentionality of human action and defining both empirical and moral dimensions of action.

The range of narratives in health care policy includes fiscal-centred narratives tackling financial or organisational aspects of health care provision (Starke 2006); ones contesting, at a more general level, the process of medicalisation or the character of care (Lofgren, de Leeuw, Leahy 2011); society-centred critiques of increasing inequalities in access to health (Graham 2009, Wilkinson, Pickett 2009); public-health-centred narratives about the impacts of lifestyle choices such as stress, obesity or substance abuse (Ebelling et al. 2002; Campos et al. 2006); or narratives of failed or delayed translation of best scientific knowledge into medical practice, linked to prescriptions for more 'evidence-based' policy (Cooksey 2006). Such a contradictory and contesting area represents for me an ideal ground to study my general questions about the roles of narratives, discourses, and cultural codes.

For instance, Kitchener's (2002) study of institutional change in healthcare describes the way in which public and expert discourses engaged in the production of narratives that institutionalised a solution to the organisational problems of competitiveness and efficiency. Generally speaking, survival of modern organisations does not depend predominantly on their organisational efficiency, but rather on their ability to incorporate socially legitimated elements

in their formal structure and maximise their legitimacy (Meyer and Rowan 1977); narratives play an important role in this process of social legitimisation.

Narratives transform incoherent, fragmented and disordered issues into treatable problems. They define the institutions intended to fix them, and the rules of accountability that apply to those institutions. In other words, through narration, events, statistics or rules are organised in stories in which responsibility is attributed and narrative structure is used as a mechanism for ordering social life. Furthermore, narratives allow actors to construct a temporal sequence between the cause and the problem in order to challenge the problem's uniqueness and show that all identical situations give rise to similar problems (Zittoun 2014: 29). Public problems are recognised as meta-narratives that embrace events, phenomena, statistics and experiences articulated in primary narratives as symptoms of a more general condition.

In contrast to the traditional institutional approaches which see institutions as stable structures of human behaviour, I examine the relation between narratives and institutions as a driving force of change, evolution and social dynamics. Similarly to Hay's (2006) constructivist institutionalism, my thesis seeks to describe institutional disequilibria and the ideational preconditions of institutional change.

Let me remark on the ways I focus on relationships between different elements of policy narratives. Hendrik Wagenaar (2011) discusses three types of interpretation of policy texts: (1) hermeneutic; (2) dialogical; (3) and discursive. Hermeneutic interpretation explains a puzzling or obscure phenomenon by situating it in a wider context. It focuses on how linguistic devices are used to frame public issues and how they are employed by individual agents in relation to their understandings and interpretations. Dialogical approaches are action-oriented and help us study meaning as it emerges in interactions between actors and between actors and the world. Dialogical interpretation focuses on the fundamentally social and practical nature of meaning. Discourse analysts see meaning as emerging from an interplay of the structural ele-

ments of discourse. At the heart of this approach are macro frameworks, very often unnoticed by individual agents, which work both as grids of possibilities (making certain practices and beliefs possible) and conceptual horizons (by making other practices and beliefs incomprehensible, bizarre, or illegitimate).

Obviously, the meaning of policy narratives is shaped by interplay between different agents' understandings and a broader cultural and discursive context. Actors are able to frame and symbolically organise issues in order gain control over public debate. These frames are promoted and protected by policy entrepreneurs (Kingdom 1984) in the pursuit of their interests. The more visible "surface level" of policy narratives consists of policy options and their proponents. This level refers to observable contests that are waged between actors pushing their own solutions forward.

However, agents cannot deploy language completely deliberatively. There are deep ideational structures structuring the accounts of individual agents. There are some systems – discourses – that limit their choices, define what is possible and bring certain categories and objects into being. Those discourses rely on institutions, institutional arrangements, regulations or scientific statements. "[I]deas allow agents to reduce uncertainty, propose a particular solution to a moment of crisis, and empower agents to resolve that crisis by constructing new institutions in line with these new ideas." (Blyth 2002: 11) Particular ideas, such as fiscal austerity or medicalisation of everyday life, lead to the formation of transnational discourses promoting particular understandings of reality and proposing adequate ways to make the world a better place. Laclau and Mouffe (1985: 113) speak about "nodal points" from which all other ideas take their meaning in an ideological system. Bevir and Rhodes (2003) use the term "webs of belief" to describe similar structures that produce incremental changes and constitute political tradition over time. This corresponds to Peter Hall's (1993) definition of a policy paradigm as

an overarching set of ideas or standards that specifies the perceived nature of problems, the goals which might be attained and the tools that can be used to that end.

However, despite those transnational policy paradigms, one can see that distinct national histories and institutional cultures which are penetrated by the same discourses produce different forms of institutional arrangements. As Douglas and Wildavsky (1982) point out, there is a cultural bias which includes or excludes some types of accounts, and structures the various positions people take based on their values and beliefs. The culture of society can be understood as a set of fundamental distinctions between what is moral and immoral – and such distinctions help us encompass narratives and discourses in the cultural context.

The interplay between surface and deep ideational structures, between paradigmatic discourses and cultural codes, and the tensions between narratives and institutions lie at the heart of my dissertation. In my thesis, I focus on the following theoretical questions: (1) what roles transnational discourses play in policy narratives, (2) what is the role of general cultural patterns in policy narratives; and (3) what kind of relation there is between transnational discourses and cultural codes.

Health policy debates are a laboratory for broader shifts in the role of the state in welfare provision (Pierson 2002; Rothgang 2010). For the last couple of decades, health care systems of developed states have been subject to permanent reform attempts. Just in the last few years, the United States Congress passed a health care reform, the government of Germany worked on a reform of its national system, the Health and Social Care Act 2012 made provisions for a number of changes to the British National Health System (NHS), and in France, François Hollande promised in his electoral campaign to protect the national health service, expand complementary coverage, lower the price of medicines and fight against health disparities. Health care has become a battle zone in which it is being fought for the character of modern welfare state – and discursive and cultural aspects have been the best part of these battles.

Therefore, some scholars (for example, Castles 1999) suggest that since the 1970s differences in public healthcare spending have been influenced by bureaucratic cost-containment policies rather than political variables, and political competition has only morphed into discursive wars for how to frame these issues for the general public. Notwithstanding the consensus on dominant discursive imaginaries across the political spectrum, I argue that there is a political competition of contesting narratives proposing different institutional arrangements. Although almost all political parties agreed on the importance of medical innovations and fiscal responsibility, they differed in their explanations of why and how to achieve those goals.

The unfolding narratives of health care reforms, caught in between the promising discourses of Western medicine and the fiscal limits discourses of contemporary welfare state, provide the best ground for exploring these questions. It is for this reason that my case study focuses on pharmaceutical regulation in the Czech Republic after the fall of communism. I intend to classify, chart, and compare patterns of argumentation and narration. I map alternative and competing narratives 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. Indeed, I look at the ways in which these storylines are embedded in a broad complex of thought and cultural codes. The Czech Republic is an ideal case for this study because the regulatory paradigm is still unfolding and there is a great deal of debate. This enables me to understand the shifting narratives and alliances in a relatively fluid policy arena. However, I do not see this case study as a description of transformation form socialist health care to modern capitalist one; on the contrary, I intend to read the story of Czech health care reforms in relation to similar streams and trends in Western capitalist countries.

Since the fall of the communist regime, the institutions of politics and health care in the Czech Republic have undergone a period of rapid change. Between 1990 and 1994, the first period of transformation focused on basic market-oriented reforms such as to establish public

health insurance or to improve health care facilities (Rokosová et al. 2005; Potůček 1999). Although health care changed significantly in the two decades after the fall of communism, a second major reform was proposed in 2006. Post-communist reforms of health care have usually been interpreted using structural or agent-based explanations, either from an economic perspective (Rechel, McKee 2009; Kutzin et al. 2010; Björkman and Nemec 2013) or from an institutional perspective (Roberts 2009; Saxonberg and Sirovátka 2009; Sitek 2010). Less has been written about the narrative facets of the reforms. The institutionalists usually describe post-socialist health care systems as an unbalanced combination of pluralist health insurance with tight state control over the system and poor patient participation. The historical-narrative approach employed in the present thesis seeks to explain why the system has evolved in this way and how its institutional characteristics have been influenced by broader discursive and cultural patterns.

In the first chapter of my thesis, I describe the methodological-theoretical foundations of interpretive policy analysis, define my theoretical vocabulary and introduce my explanatory model. Policy narratives rely on an underlying structure of discourse and cultural codes. Narrativisation is seen as an ordering practice determined by existing configuration of dominant discourses, as policy paradigms, and cultural codes, as basic grammars for structuring the making of meaning in any particular social order. The explanatory model is intended to grasp relations between the surface and underlying levels policy narratives and to describe narrative dynamics.

The second chapter recapitulates the language of contemporary theories of regulation and tries to find a pattern in an "interpretive cacophony" (Lodge and Wegrich 2011) of different frames, justifications and problematisations. The chapter sets out to classify regulatory vocabularies with respect to four different ways of problematisation: (1) individualist, (2) egalitarian, (3) hierarchist and (4) fatalist. Each of these approaches provides a guide on the questions to be solved and the possible answers. Styles of problematisation affect institutional lives

and impel institutions to act in particular ways and provide content for particular narratives in contesting regulatory frames.

In the effort to further conceptualise the narrative foundations of pharmaceutical policies, two discourse genealogies are discussed: health promises and fiscal limits. In the early 1980s, Claus Offe (1984) described two main and often contradictory functions of the welfare state: (1) to maintain or create conditions in which profitable accumulation of capital is possible, and (2) to maintain or create conditions for social solidarity. The former function can be associated with incentives to investment and personal responsibility, the latter with increasing demands of citizens, rising inequalities and control functions of welfare states. With respect to this distinction, pharmaceutical policies are facing two demands: to maximise health benefits and to minimise waste of public funds. These two demands represent different values and rationalities and there is an ineluctable conflict between them.

The idea of *medicalisation* – one of the key sociological themes of the second half of the twentieth century –is described in Chapter 3 in relation to other notions associated with the lifestyle changes proper to late modern societies, and in particular the Foucaultian concept of *governmentality* (see, e.g., Dean 2010, Rose 2007). In addition, I present the main revisions of the medicalisation argument and further elucidate it by taking three specific drugs as examples – Prozac, Paxil and Viagra. Chapter 3 is based upon my chapter in the book Ways of Life in the Late Modernity (Čada 2013).

However, acceleration is not the only dynamics in the field of health care; budgetary pressure has produced a range of public policy dynamics which might be seen as contradictory to the progressive discourse of medicalisation. The genealogy of fiscal responsibility is described in Chapter 4, which introduces austerity as a fundamental "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)

However, both medicalisation and permanent austerity can be seen as future-oriented concepts. Whereas the medicalisation discourse can be identified with the politics of hope, austerity revolves predominantly around the politics of caution. In the former, promises of modern technologies and medicines give rise to a dream that policies are supposed to pursue. The latter constructs a nightmare – a possible future that policies should try to avoid. Both discourses reveal two fundamental notions of future in modern societies – promises and risks, respectively.

In the European Union, a variety of pharmaceutical policies is implemented to try to balance effective spending on pharmaceuticals against the need to promote innovation in the industry. In Chapter 5, I introduce European pharmaceutical regulation and describe some influential examples of regulatory approaches of particular member states. The framework within which the regulatory policies of individual states are made is described with respect to both the hard power of European legislation and the soft power of policy transfer at the level of national policies.

The historical context of Czech health policy is described in Chapter 6, which examines the frames of pharmaceutical regulation in the Czech Republic between 1990 and 2008. The chapter is an extension of the article (Čada 2014), which examines a public discussion on health reform in the Czech Republic between 2006 and 2008. I follow the dynamics between sustainability constructions and cultural codes in narratives of pharmaceutical regulation. I analyse three main periods in the history of post-socialist pharmaceutical regulation: (1) transformation, (2) consolidation of rules and (3) neo-liberal reform. The analysis includes newspapers and weekly magazines, and allows me to explore the role of discourses of medicalisation; the role of discourses of fiscal limits in defining policy goals; and the ways policy narratives are embedded in more general codes of regulatory cultures. Consequently, the narrative dimension of post-socialist institutional change can be elaborated.

Interrogating the ways in which public policy is narratively constructed allows us to better understand how contemporary governments justify themselves. It helps us contemplate policy making not only as a process of solving public problems but also as a means of defining and disputing the legitimacy of institutional arrangements. Furthermore, it prompts us to understand political competition differently. To reveal the narrative character of public policy means also to question the political character of public policy. "While fundamental public issues such as social inequality remain generally insoluble, continuously renewed activities show that some solution can contribute to resolving them, even partially, and are not only at the centre of political activity, but assemble what holds society together: politics." (Zittoun 2014: 11)

PART 1.

METHODOLOGICAL-THEORETICAL PRINCIPLES

CHAPTER 1.
INTERPRETING REGULATION: DISCOURSES, NARRATIVES AND CODES

The actors and objects of the policy process are constituted by discursive practices. They have to be understood through the 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. 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, policy has a symbolic character. To analyse the conceptualizations, explanations and solutions that one can see in the government sector, therefore, requires a specific attention to discourse.

Illuminating discourse, according to Maarten Hajer (2009), allows us to grasp public controversies not in terms of rational-analytical argumentation but in terms of the particular argumentative logic that people bring into the 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)

As Hajer (2009: 59) notes, the recognition of the importance of language as 'systems of signification' in policy and politics has given rise to diverse literature, ranging from narrative analysis to discourse analysis, from the study of the role of metaphor to the study of frames and

reframing (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 focused 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 (Gumperz 1982; Roe 1994; Schön and Rein 1994; Yanow 1995; Potter 1996). "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)

Similarly to Hajer, Sanford F. Schram (2012) distinguishes two levels of policy discourse: (1) a surface level and (2) an underlying level. Whereas the analysis of the former is focused on strategic interaction, the latter 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 comprise the saga told about the policy, its problem, and the people associated with dealing with it. The policy narratives rely on the underlying structure – discourse and identification of citizens as agents assumed to be the focus of concern, blame and praise.

In my explanatory model, which will be described later, I use Schram's perspective of two levels of policy discourse. In contrast to Schram, I identify two levels of the underlying structure – discourses and cultural codes (see Table 1). Along paradigmatic discourses, under-

stood as complexes of thought, there are cultural structures composed of deeply sedimented dichotomies that serve as a basis for structuring the making of moral meaning in any particular social order. These codes are at the heart of the narratives. They represent the grammar deep within them and contribute to their embeddedness in broader cultural context.

Table 1: Levels of policy discourse (adapted from Schram 2012: 241)

Surface Level
Narrative Often including a story of how a policy problem and its solution came to be **Category, Metaphor** Always present in any policy narrative referencing an underlying discourse for making sense of the narrative
Underlying Structure
Discourse Comprising critical distinctions for making sense of particular policy narratives
Cultural Code The characteristic requirements of the most legitimate forms of justification

NARRATIVES AS TEMPORAL ORDERING

As Maarten Hajer (2009) reminds us, policy statements often take the form of narratives: people convey facts by telling a story. The narrative paradigm reflects two general modes of thinking: (1) the logico-scientific mode and (2) the narrative mode (Bruner 1986). The logico-scientific mode attempts to fulfil the ideal of a formal, mathematical system of description and explanation. It employs categorization or conceptualization and certain operations by which categories are established, manifested, idealized, and related to one another to form a system. On the contrary, the narrative mode leads to good stories, gripping drama, believable historical accounts. It works with human or human-like intention and action and the vicissitudes and consequences that mark their course. It strives to put timeless streams into the particulars of experience, and to locate the experience in time and place.

The narrative mode represents the core of political communication. French philosopher Jacques Rancière (1999) points out that political speech relies upon poetic, world-opening devices, such as stories, through which collective subjects are articulated. Politics means contesting the very definition of the community and resisting the domination resulting from the exclusion from political arena.

"Politics exists because the logos is never simply speech, because it is always indissolubly the account that is made of this speech: the account by which a sonorous emission is understood as speech, capable of enunciating what is just, whereas some other emission is merely perceived as a noise signaling pleasure or pain, consent or revolt." (Rancière 1999: 22-23)

Political action involves forcing an opposing side to acknowledge not only demands for inclusion but also the speech of those making the demands. For Rancière, in contrast to rational oriented policy, the objects of politics and the status of its actors are aesthetic and can never be determined logically. Politics starts with conflicts, different meanings, multiple perspectives and inequalities. For these reasons, political accounts are inherently narratives. The narrative mode characterizes political discourses and policy change should be primary interpreted with respect to its narrative character.

From the linguistic point of view, a narrative is a story with a temporal sequence of events organized in a plot characterized by dramatic moments, symbols and characters that concludes in a moral lesson. The essence of a narrative lies in the temporal dimension: 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 "the distanciation of the saying in the said" (Ricoeur 1981: 134) – in other words, abstraction from particular situa-

tions, virtualisation with respect to time, and potential inscription of a speech act in text. Narratives work as causal stories which describe how world works and prescribe responsibilities of different actors (Stone 1988). They create cognitive schemas for describing and understanding an otherwise chaotic and complex series of situations, events, and behaviours.

One can distinguish organizing and communicative functions of a narrative. The organizing 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 the ability to persuade a broader audience of the legitimacy and appropriateness of a particular version of a situation (Schmidt 2002). The communicative function emphasizes the importance of expression, argumentation, and persuasion in generating and validating interpretations of the situation. This often involves a sort of narrative competitions, as individual actors or organizations construct and project their own interests in ways that position them in the field (Golant, Sillince 2007).

The fascination of the social sciences with narrative and stories started with the Russian linguist Vladimir Propp and his influential book Morphology of Folktale (1968) which classified Slavic fairy tales according to their component parts and to the way that the parts contributed to the meaning of the whole. Later, French semiologist (of Lithuanian origin) Algirdas Greimas (Greimas and Courtés 1982) further developed Propp's prepositions into a model. Greimas introduced the notion of narrative program – a change of state produced by any agent affecting any other agent. Subsequently, narrative programs are chained in a logical succession, forming a narrative trajectory. Greimas replaced the term 'character' with the term 'actant' –

someone or something accomplishing or undergoing an act. Actants may change their roles throughout the narrative trajectory through causally connected episodes. “Thus the hero will be the hero only in certain parts of the narrative – s/he was not the hero before and s/he may well not be the hero afterwards.” (Greimas and Courtés 1982: 6)

Czarniawska (2004) points out that actants become ‘characters’ if they manage to keep the same (or the same but transformed) role throughout a series of actions. Therefore, it is the plot that is the central feature of a narrative and that produces characters.

With regard to the narrative dimension of institutional change, Tzvetan Todorov’s (1977) definition of a minimal plot represents a key concept: a minimal plot consists in the passage from one equilibrium to another. An ideal narrative starts with a stable situation, which is then disturbed by some power or force. This disturbance results in a state of disequilibrium. By the action of a force directed in the opposite direction, the equilibrium is re-established. Sequencing from equilibrium through disequilibrium to renewed equilibrium corresponds with the capacity to reconcile order and disorder described by Philippe Zittoun (2014). He considers the cycle between order and disorder as the heart of policy-making process. In such cycles, narratives play an important role both in creating social disorder and in defining, propagating and legitimizing solutions during the re-establishment of order. Zittoun distinguishes four stages of the problem definition process: (1) labelling a situation and qualifying it as a problem; (2) categorizing society by identifying the victims; (3) designating the causes, blame, and responsible authorities; (4) making an apocalyptic future. In line with problem definition process, he identifies also five stages of solution defining process: (1) labelling solutions and their owners; (2) identifying the consequences and beneficiaries; (3) coupling with a problem to resolve; (4) integrating the solution in a public policy that needs to be changed and (5) linking the solution to a referential framework and values to guide it. With respect to the narrative theory, his stages

represent a narrative trajectory from qualifying something as a problem to integrating a proposed solution in the broad complex of public policy and other referential frameworks.

While analysing the ways public problems are narrated it is necessary to pay attention to the category-making process. As public policies identify and name groups of people for whom a solution is sought, they often create sets of categories that simultaneously structure the policy problem and imply certain solutions. Different categories imply different stories of motive and responsibility and have different implications for what should come next. According to Yanow (2000: 49), categories both entail and reflect a set of ideas about their subject matter. "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)

Harvey Sacks (1992) observes that our reading of categories is informed by the way we infer that some elements 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 the 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 rank higher than others. Collections of categories are derived from broad discourses and cultural codes and, vice versa, they are their visible representations on the surface level.

Besides category making, Yanow (2000: 41–48) identifies metaphors as an important language tool which helps integrate narrative into general frameworks. Metaphors work as vehicles transporting meaning from familiar issues to unknown ones. This metaphoric process of transferring meaning from a better-known entity to a lesser-known one characterizes several language forms other than proper metaphor: analogy, translation, exchange, contradiction, synecdoche, and metonymy (Yanow 2000: 42). Metaphors also generate concepts, categories, labels or activities belonging to the same language. "Metaphors no longer only present new insights into the situations they describe: they also suggest possible action in response to those situations. Metaphors may express some prior, unarticulated understanding of the situations. That is, metaphors can be both models *of* a situation and models *for* it." (Yanow 2000: 43; emphasis in original) Metaphors also contribute to the process of losing singularity of the narrative, by pinpointing that all identical situations give rise similar problems, in order to be recognized as symptoms of a more general condition. In this sense, metaphors can interconnect narratives with broader context of thought.

GENEALOGIES OF DISCOURSES: FROM MYTHS TO IMAGINARIES

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. Traditional public policy theories overlook discursive aspects of policy change. Those which did involve this aspect considered discourse only as a spectacle which masks the reality of practice (Edelman 1988), rather than a practice structuring the discussions and agreements which constitute decisions. Maarten 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.[1]

Hajer represents a non-Foucaultian approach to discourse, focusing on the linguistic and pragmatic production of meaning. From this perspective, discourse is an ensemble of ideas and concepts somehow related to one another. This approach puts too much emphasis on visible aspects of discursive practice at the expense of its underlying dimensions. A Foucaultian perspective on discourse is, on the other hand, more interested in knowledge than in language and

[1] Hajer (1995, 2003b, 2006) identified different elements of discursive practice which an 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: an ensemble of particular storylines, the actors that employ them, and the practices through which the discourses involved exert their power; (5) practice: operational routines or 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 captures 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 system for measuring air pollution; (10) indexicality: performances are scripted and staged in a way that draws on 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.

it corresponds better to its position within the underlying level of policy communication. Michel Foucault (1985) defines discourse as a wide set of social practices. But instead of focusing on the form and content of linguistic and semiotic practices only, he examines the rules governing the production of such statements and practices. He is concerned neither with the truth nor with the meaning of actual statements, but with their 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 subjectivities, capacities, and social relations.

Feindt and Oels (2005) highlight four characteristics which distinguish Foucaultian discourse analysis from other types of discourse analysis: (1) the focus is on the productive function of discourses; (2) power relations are present in all forms of social interaction; (3) discourse enables and constrains them by shaping their field of opportunities and by limiting their freedom; (4) the realm of power relations extends to the construction of subjectivity. Foucaultian scholars understand discourse as the primary means through which actors deal with reality. In this sense, discursive practice is both action and interaction on its own. It constitutes actions that do not exist alone, have consequences and involve specific forms. Discourse should not be studied only as a linguistic construction, but its material existence needs to be taken into consideration as well. Discourse materializes within concrete time and space. It can be seen as a technology of thought, commanding attention to particular devices of analysing and communicating. In terms of construction of subjectivity, discourse is not only an expression of knowledge, a means of action, or a site where interaction takes place, but it is also an arena where positions and subjectivities are constructed. Discursive practices are not only knowledge but acknowledgment as well.

Foucault distinguishes between an archaeology and a genealogy of discursive studies. While archaeology helps explain '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 the ongoing character of debates (Foucault 1981: 70–1). According to Gavin Kendall and Gary Wickham (1999), genealogy (1) describes statements with an emphasis on power; (2) introduces power through a history of the present; (3) describes statements as an ongoing process; (4) concentrates on the strategic use of archaeology to answer problems about the present. Following a history of the present, one can explain what has made a current solution possible. Genealogical description provides us with the account of how current perceptions of individual and state responsibilities are embedded in histories and how history is internalized in current debates and current discursive practice.

In his study of governing, Foucaultian scholar Nikolas Rose (2000: 57–58) uses the language of "questions" and "answers". He suggests that we should consider the genealogies of issues as imprisonment, marketization, and community care as answers, and we should seek for questions behind them. "[I]n reconstructing the problematisations which accord them intelligibility as answers, these grounds become visible, their limits and presuppositions are opened for interrogation in new ways." (Rose 2000: 58) Therefore, governing is facilitated through styles of problematisation that affect institutional lives and impel institutions to act in particular ways.

"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." (Miller, Rose 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.

However, Rose's approach posits an important question, how discourse can systematize incoherent policy arguments. A response to this problem involves the concepts of nodal points and social imaginaries (Howarth and Stavrakakis 2000). They are privileged signifiers or reference points that bind together a particular system of meaning or chain of signification. Nodal points are always open and somehow empty. The social field can never be closed, and political practice seeks to fill this void. "In other words, even if the full closure and fullness is not realizable in any actual society, the idea of closure and fullness still functions as an (impossible) ideal. Societies are thus organised and centred on the basis of such (impossible) ideals." (Howarth and Stavrakis 2000: 8) Nodal points are central to establishing social imaginaries. Ernesto Laclau (1990: 63) defines social imaginary as a horizon or an absolute limit which structures the field of intelligibility. He introduces the distinction between myths and social imaginaries. A myth constructs new spaces of representation that attempts to joint the dislocated space in questions. From their emergence to their dissolution, myths can serve for the inscription of a variety of social demands and dislocations. However, when a myth has proved to be successful in neutralising social conflicts and incorporating a great number of social demands, then it has been transformed to an imaginary. "The term 'imaginary' is reserved for those cases where a particular group succeeds in moving beyond its particular interests onto a universal terrain." (Norval 2000: 229) Myths and social imaginaries, in this sense, act as horizons of imagination through which most societal demands can be articulated. Foucaultian genealogy is partly the method in which a trajectory from myth to imaginary can be reconstructed, analysed and criticized.

CULTURAL CODES AS INTERPRETATIVE GRIDS

Articulation of global discourses such as medicalization or fiscal responsibility seems very often to be influenced by the local cultural context. Despite those transnational policy imaginaries, one can see that distinct national histories and institutional cultures produce different forms of institutional arrangements, even though they have been penetrated by the same discourse. Why can different stories be narrated under the same social imaginary? Because they use the languages of different cultural codes. Analysis of cultural codes starts with the assumption that a culture is grounded in an interpretative grip comprising distinctions about what is good and bad, moral and immoral, natural and cultural, rational and emotional, and so on (Balkin 2002). The interpretative grip that informs, mediates and constitutes our social relations becomes the basis for both factual assessments and moral judgments (Alexander and Smith 1999). For Balkin (2000), cultural codes operate as software that provides a set of nested oppositions trading on each other in order to create hierarchies that privilege one side at the expense of another.

In contrast to discourses as future imaginaries, cultural codes provide a critical basis for current performances. Cultural codes are vehicles though which different identities, myths, and imaginaries are ordered and organized and reconciled under the order of society as whole. Whereas discursive imaginaries define the horizons, cultural codes construct and naturalize the ways in which they can be achieved. They reflect different ways in which different actors and cultures understand society and in which values of actions are prescribed.

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 grammars of worth and repertoires of evaluation used in different settings to give weight to different elements of the same discourse. Lamont and Thévenot (2000: 6), in their

attempt to sum up Boltanski and Thévenot's research agenda, focused specifically (1) on "the content of criteria or orders of justification used to draw boundaries between the more and the less valuable"; (2) on "whether and how different criteria compete with one another and are used in conjunction with one another"; (3) on "how actors demonstrate the situational appropriateness of their criteria of evaluation" and on "'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 suggested that the cultural repertoires prevailing in the United States make market references readily available, whereas the French repertoires make the 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 limited number of situations.

According to Jeffrey Alexander (2006, 2013), cultural codes represent entities through which solidarity of a community exists, is exhibited and is sustained. Cultural codes underscore civic solidarity and they are critically important in constituting the very sense of society. From Alexander's perspective, cultural codes work in binary oppositions and they supply the structured categories of pure and impure into which every member, or potential member, of society is fit. Collective representations institutionalize civil society by creating messages that translate general codes into specific evaluations and descriptions. With respect to political life, Alexander distinguishes democratic and anti-democratic codes as a basis of modern societies. He identifies the former with activism, autonomy, rationality, reasonableness, equality, inclusivity, law, impersonality and contractuality. On the contrary, the anti-democratic code can be described in terms of passivity, dependence, irrationality, hierarchy, power, personality and ascription. In his cultural codes, Jeffrey Alexander introduces an influential classification scheme that defines the boundaries of democracy and justifies them against their opponents. However,

his scheme is not sufficient to explain the ways qualities within democratic systems are constructed and justified and the ways different patterns can be classified and compared.

In order to classify and compare argumentation patterns towards regulatory approaches, I am going to tap the cultural theory developed by Mary Douglas and Aaron Wildavsky (Douglas and Wildavsky 1982; Douglas 1992; Thompson, Ellis and Wildavsky 1990). This theory is particularly valuable for a culturally sensitive analysis of regulation since it turned its attention towards the importance of risk and blame. The dual system of two contrasted forms of social organization, used very often in cultural analysis (for example in Jeffrey Alexander's work), is taken merely as a starting point by Mary Douglas. She splits each of these forms to arrive at four kinds of culture. The distinctions between social environments are defined by the ways society constrains individual members and the latter defy or circumvent the rules and boundaries of their particular social environment. Douglas sees risk as a political weapon used by a society to blame those who have responsibilities, according to different cultural orders, for what happens to the rest of us. Who you blame for what is a central marker of your culture and attitudes. Cultural codes provide narratives with classification schemes of basic assumptions, villains and heroes, and moral principles. Each code emphasizes different aspects of the issue, and is defined in contradistinction to the narratives based upon other codes.

Cultural theory developed by Mary Douglas (1992) points to four rival world-views, with their contrasting and competing diagnoses and solutions to regulatory problems (see Table 2). These views emerge from distinctions on two dimensions: (1) grid which defines the extent to which individual behaviour is bound by rules; (2) group which defines the extent to which an individual regards herself or himself as being embedded within group processes. In line with logics, Douglas identified four cultural types: hierarchism, individualism, egalitarianism, and fatalism. The former two types are much more associated with processes in modern societies whereas the latter two can be found in more traditional societies or they cover more traditional

aspects of social life. For example, modern trends such as centralization, integration, standardization, specialization, economic efficiency, and incentivization can be associated with hierarchism and individualism but less with egalitarianism or fatalism (Baldwin et al. 2012: 51).

These codes are essential for prescribing blame in society. In the individualist worldview, blame attaches to those who are considered personally irrational or inefficient, and failure is attributed to lack of individual ability or motivation. In the hierarchist worldview, blame attaches to those who do not follow rules and established procedures. In the egalitarian worldview, blame attaches to those who ignore popular opinion or do not have group support. In the fatalist worldview, blame does not arise from any clear social logic.

Table 2: Cultural codes of regulation (Baldwin et al. 2012: 51)

		Group	
		Low	**High**
Grid	**High**	**Fatalism** Control through unpredictable processes/inherent fallibility	**Hierarchism** Anticipative solutions, forecasting, management, response to enhanced authority and hierarchical ordering
	Low	**Individualism** Control through rivalry and choice, incentive to underpin market and individual choice processes	**Egalitarianism** Control through group processes, network styles and participation

Each cultural code produces a specific type of institutions. Individualist institutions (e.g., markets) are based on exchanges and contracts between individuals. Hierarchist institutions are based on the top-down bonding of individuals within a social group (for example, bureaucracies). Egalitarian institutions rely on bonding insiders together against outsiders. Fatalist institutions are based upon external and inevitable processes, and cannot be effectively controlled by society.

According to Hood (1998: 24–28), responses to scandals or catastrophes in public management – such as police brutality, major safety lapses or dramatic financial misappropriations – may be key indicators of cultural bias. The individualist perspective brings in a different approach to diagnosis and prescription. From this perspective, many of the typical failures of public management stem from too much collectivism. Such practices may reinforce the ability of those in powerful institutional positions to 'blame the victim' and walk away from responsibility when disaster strikes. In a hierarchist response to crisis, the problem could have been averted if only there had been more coordination, better procedures, enhanced 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 rules and structures of authority. The egalitarian approach, on the contrary, blames enclosed enclaves such as authorities and expert communities. 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. Finally, the fatalist response sees failure as a unique, one-off event.

Hood's analysis (see Table 3) suggests that crises are not always objectively identifiable and universally recognized and they are a litmus test for attitudes towards justice and blame. For events that are recognized as crises, recipes for what to do in order to improve matters also vary according to different worldviews, and emerge as the sort of organizational prescriptions.

Table 3: Four responses to crises in a cultural theory frame (adapted from Hood 1998: 26)

Response	Stress on	Blame	Remedy	Watchword
Fatalist	unpredictability and unintended effects	the 'fickle finger of fate' (or 'chaos theory' interpretation of how organization works)	minimal anticipation, at most an *ad hoc* response after the event	'resilience'
Hierarchist	expertise, forecasting, and management	poor compliance with established procedures, lack of professional expertise	more expertise, tighter procedures, enhanced managerial 'grip'	'steering'
Individualist	individuals as self-interested rational choosers	faulty incentive structures through over-collectivization and lack of price signals	market-like mechanisms, competitions and leagues, information to support choice (e.g., rating systems)	'enlightened self-interest'
Egalitarian	group and power structures	abuse of power by top-level government or corporate leaders, systemic corruption	participation, communitarianism, whistle-blowing	'community participation'

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, the market economy was a continuous, unpredictable cycle of boom and depression and it was impossible to anticipate the next crisis. Any response was destined to be futile or perverse. In the individualist frame, the financial crisis was a product of poor incentives and moral hazard generated by governments. Solutions were found in reducing regulatory intervention in order to minimize government failure. In the hierarchist framework, the crisis was a symptom of lack of order, and it was necessary to create stronger rules and regulatory bodies. The egalitarian frame saw the crisis as a symptom of excessive individualism and failed exercise of authority. The remedy lay in increasing transparency, enhancing public participation and tightening the limits of discretionary authority and markets. The authors used this framework to compare patterns of argumentation in Germany, the UK and the US. Their study points to the im-

portance of institutionalized cultural models and practices, and to the ways they converge or vary cross-nationally.

CONCLUSION: INTERPRETING REGULATION: DISCOURSES, NARRATIVES AND CODES

In my explanatory model, policy narratives rely on an underlying structure of discourse and cultural codes. This underlying structure results from long-term processes and forms a basis through which goals and means of policies are articulated. Genealogical description provides us with an account of how current perceptions of individual and state regulatory responsibilities are embedded historically and how history is internalized in current debates and current discursive practice.

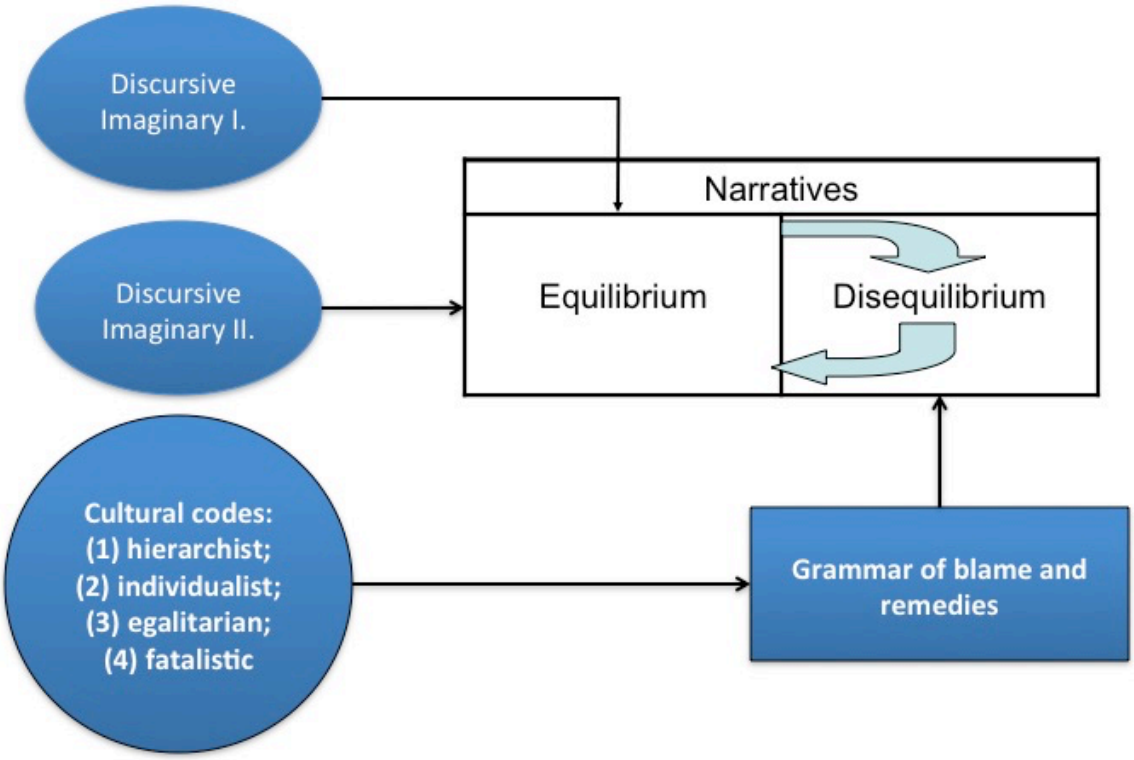
Policy narratives can be seen as sequences from equilibrium through disequilibrium to re-establishing equilibrium. Disequilibrium is created by labelling a situation as a problem, identifying victims, designating causes and predicting an apocalyptic future. On the other hand, re-establishing equilibrium involves labelling solutions, identifying their consequences and beneficiaries, coupling solutions with problems to resolve, and integrating them in a broad complex of public policy and in a referential framework. In this process, important roles are played by category-making as a way of claiming the boundaries of a problem and identifying victims and beneficiaries, and metaphors as a way of embedding narratives in the broader context. Narrative practice selects newsworthy elements from a multiplicity of events, statistics or rules, and constructs which aspects of life are newsworthy and, on the contrary, which ones are largely ignored.

Discursive practice can be seen as an ordering practice putting the possibilities and rooms for manoeuvre determined by discourse as an underlying structure together with various elements of regulation narratives such as facts, norms, competing discourses, rules and inter-

ests. Discourses are understood as broad complexes of nodal points with their genealogies and materiality constructed in order to create subjectivities and collective imaginaries.

A narrative can stem from one imaginary nodal point or emerge from a combination of different nodal points. Indeed, some nodal points are in conflict with each other, while others may reinforce each other. Discursive imaginaries act as horizons that determine the future orientation of policy narratives. In contrast to discourses as social imaginaries, cultural codes provide a critical basis though which different imaginaries are ordered, organized and reconciled within a single social order. In cultural codes, the rules of society as whole are involved. With respect to elements of narrative, cultural codes determine the ways causes, victims and beneficiaries are identified.

Figure 1: Architecture of the explanatory model



In the next chapter (2), I summarize how cultural codes might help us to structure a variety of problematisations in regulatory theories and systematise the different justifications of regulatory responses. The following two chapters (3 and 4) present a genealogy of two discourses configuring recent health policies – health hope and fiscal limits. I consider the two concepts as the main concepts structuring recent forms of pharmaceutical regulation in developed countries. I will map their genealogies, grasp their institutionalization and structuration, and reconstruct the imaginaries they produce. In my genealogy of post-socialist pharmaceutical regulation in the Czech Republic (chapter 6), I put emphasis on the effects of cultural codes and discursive imaginaries on the construction of patients' roles and the shaping of particular policy narratives.

CHAPTER 2.
VOCABULARIES OF REGULATORY REGIMES

The field of regulation studies started with a dramatic expansion of regulatory frameworks in the late 1960s and early 1970s, followed by waves of deregulation in the late 1970s and 1980s, and the setting of networks and international standard in the 1990s and 2000s. Recently, regulatory scholars cannot find a common framework to grasp their ongoing discussions on regulation. Therefore, the current era is characterized by an "interpretive cacophony" (Lodge and Wegrich 2011) of different frames, justifications and problematisations with different regulatory frameworks competing and coexisting with one another. Such a cacophony is present in both public and scientific discourses about regulation and this chapter intends to identify and classify the different vocabularies they use. In this chapter, existing theoretical regulatory approaches are charted and classified with respect to what problems they articulate and what remedies they propose. Each of the four presented approaches relies on a specific regulatory culture that corresponds with one of the cultural codes presented in the previous chapter. Each type uses a different grammar to identify issues to stress, people to blame and possible remedies to be proposed.

When speaking about regulation, one 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 emphasis on sustained and focused control implies that regulation is not achieved simply by passing a law, but requires detailed knowledge, monitoring and deep involvement. The reference to socially desirable activities excludes issues which are dealt with by the criminal justice system and it also suggests that only activities considered as worthwhile in themselves and hence in need of protection and control are regulated. (Majone 1996: 9)

Baldwin et al. (2012: 3) think about the word regulation more broadly, in different senses than Selznick: (1) as a specific set of commands – where regulation involves the promulgation of binding rules to be applied by a body devoted to the purpose; (2) as deliberate state influence – where regulation covers all state actions that are designed to influence business or social behaviour which might be based on sets of commands as well as on 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 – or mechanisms affecting behaviour – whether these arise from the state or from other sources (e.g., markets); and (4) as an activity that restricts behaviour and prevents the occurrence of certain undesirable activities. In contrast to Selznick's narrow definition based upon control over activities, Baldwin and his colleagues propose a broader definition, focusing on about steering events rather than controlling them.

Similarly, John Braithwaite (2008: 1) understands regulation as *a large subset of governance that is about steering the flow of events, as opposed to providing and distributing*. A broad definition is also used by Christopher Hood and colleagues (2001) who consider regulation as any control system in art or nature which contains a minimum of three components: (1) the capacity for setting standards to distinguish between more and less preferred states of the system; (2) the capacity for gathering information or monitoring to produce knowledge about current or changing states of a system; and (3) the capacity for modifying behaviour to change the state of the system. (Hood et al. 2001: 23)

The difference between the first generation of regulation scholars represented by Selznick and the second generation represented by Baldwin et al., Braithwaite or Hood illustrates very well the general difference between the traditional *hard law* approach to regulation based upon monitoring and controlling over market activities and later approaches combining hard laws with *soft laws* based upon incentives and other techniques, including voluntary standards

and self-regulation, to modify the architecture of behavioural choices. While the first generation draw a clear line between the realm of the market and the realm of the state, for the second generation of scholars the line has been much more fluid and negotiable.

An effort to allocate price to all goods and services through the market brings various problems associated with externalities, public goods or transaction costs. Those problems cannot be solved only through the market. For these reasons, pollution is regulated through quotas; licensing helps consumers identify good suppliers; and standards guarantee food safety. In each instance, the allocation of resources that a market would achieve is not ideal, giving rise to rationales for regulation. "Regulation in such cases is argued to be justified because the uncontrolled marketplace will, for some reason, fail to produce behaviour or results in accordance with the public interest." (Baldwin et al. 2012: 15) The crucial point for all public interest theories is the definition of what counts as a public interest. Indeed, an agreed concept of public interest may be hard to identify and regulation takes place amidst clashing claims about public interests. The character of the relation between the state and the market is decisive for a classification of vocabularies of regulatory regimes. In this relation, one can identify four moments of problematisation, which correspond with the four cultural codes discussed above.

The economic approach simply suggests that regulation is a response to imperfections known as market failures. Consequently, regulatory policies seek to increase the efficiency of a market, but not to produce distributive consequences beyond this. For this reason, the rhetoric of economic problematisation involves both *market failure,* when a state regulates too little to increase the efficiency of a market, and *government failure,* when too stringent regulations decrease the efficiency of a market. The narrow economic approach corresponds with the logic of the individualist cultural code.

In contrast to the individualist code of market failure, approaches that assume the existence of values other than economic efficiency resonate more with the egalitarian code. Non-

economic goals of regulation are derived from constitutional principles of societies such as human rights or social solidarity, or from democratic discussion – in short, from principles holding society together. Most regulators can properly be seen as seeking to further social objectives, rather than simply to correct market failures (Prosser 1986) and in many contexts, regulation is prior, not secondary, to the market and it is the first-choice method of organising social relations (Shearing 1993).

Questions about the reputation of regulatory bodies point to the problem of credibility of regulation. This critique, often articulated in the hierarchist code, emphasises compliance with established procedures and criticizes avoidance thereof. It links 'accountability' with the ladders of responsibility, and sees some form of oversight as the answer to the many failures which continually appear in regulatory frameworks.

However, there is also a fatalist problematisation of regulation. It shows us that *regulation itself* might also be problematized. A special problem, in this fatalist view, may lie in the natural tendency of regulatory systems to lose focus and direction or in the uncertain effects that emerge from the complexity of the regulatory space where different layers interact with one another.

These four problematisations can be distinguished according to five key parameters: (1) criteria used to justify regulation; (2) methods applied to measure these criteria; (3) general policy problems intended to resolve; (4) proposed specific questions for policy makers; (5) preferred answers within a regulatory framework.

PROBLEMATISATION 1: THE INDIVIDUALIST CODE

Market failure literature has identified a large number of potential problems associated with the operation of the market mechanism. Majone (1996: 27–28) speaks about monopoly power, insufficient information to consumers, and inadequate provision of public goods. Ogus

(2004) mentions four types of behaviour which the public should be protected from: (1) monopoly behaviour, (2) destructive competition, (3) abuse of private economic power, and (4) externalities. Baldwin and colleagues (2012: 15–24) provide a very extensive list of market failure rationales, including the following events: monopolies and natural monopolies,[2] windfall profits,[3] externalities,[4] information inadequacies,[5] continuity and availability of service,[6] anti-competitive behaviour and predatory pricing,[7] public goods and moral hazards,[8] unequal bargaining power,[9] scarcity and rationing,[10] rationalisation and coordination,[11] and planning.[12]

[2] A natural monopoly occurs where it is less costly to society for production to be carried out by one firm, rather than several or many. However, 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 a single one would do, it may be more efficient to give one firm a monopoly subject to regulation of such matters as prices and network access. (Baldwin et al. 2012: 15–17)

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

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

[5] The market may fail to produce adequate information 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 be incentives to falsify information, the information produced may not be of sufficient assistance to the consumer, or collusion in the marketplace may reduce the flow of information. (Baldwin et al. 2012: 18–19)

[6] The market may not provide socially desired levels of continuity and availability of service. Regulation may be used to sustain services during troughs – for example, by setting minimum prices at levels covering fixed costs temporarily. (Baldwin et al. 2012: 19)

[7] Markets may produce undesirable effects because firms behave in a manner not conducive to healthy competition. A principal manifestation of such behaviour is predatory pricing. This occurs when a firm prices below its costs in the hope of driving competitors away from the market, achieving a degree of domination, and then using

With respect to public services, there are several arguments for why markets alone cannot ensure the most efficient or equitable allocation of scarce resources and require state intervention. According to Kenneth Arrow (1963), market regulation is necessary in fields characterized by extremely high levels of uncertainty, where accurate information becomes a very valuable commodity. For example, in health care, patients' uncertainty about the effectiveness of medical treatments, the informational asymmetry between patients and physicians, and the imperfect marketability of information provided by physicians would result in market failure.[13]

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its position to recover the costs of predation and increase profits at the expense of consumers. (Baldwin et al. 2012: 19–20)

[8] 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, at instances of moral hazard when someone other than the consumer pays for a service, there may be excessive consumption regardless of the resource costs imposed on society. (Baldwin et al. 2012: 20)

[9] 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)

[10] Regulatory mechanisms may be justified to allocate certain commodities that are in short supply. (Baldwin et al. 2012: 21)

[11] When it is extremely expensive for individuals to negotiate private contracts so as to organise behaviour 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 coordinating the market. (Baldwin et al. 2012: 21)

[12] Markets may not be able to meet the demands of future generations or to satisfy altruistic concerns (e.g., the quality of other people's environment). (Baldwin et al. 2012: 21–22)

[13] From the perspective of sociology of medicine, the phenomenon of informational asymmetry was described by Eliot Freidson (1970). He argues that more social resources have become directed to fighting illness, the medical profession's power has increased markedly, and little scope remains to question its activities or use of resources.

According to Bloom, Standing and Loyd (2008), there are several other rationales for regulations beside information asymmetry and high levels of uncertainty. Regulation is particularly welcome when (1) a field involves 'public goods', which would be undersupplied if left to the market; (2) some goods have positive externalities in that an individual's consumption confers benefits on others; (3) markets tend to under-insure against risks; (4) markets cannot compensate for inequalities in access to resources.

However, the rhetoric of market failure articulates market imperfections as exceptional situations, which means that the state has a residual role to play. The minimal role of the state is usually underpinned by John Stuart Mill's argument that the individual is "the person most interested in his own well-being, the interest which any other person, except in cases of strong personal attachment, can have in it is trifling, compared with which he himself has." (Mill 1869 in Sunstein 2014: 8) State intervention is justified only when the social returns on investment might be higher than the private returns – in cases like pollution, harms to people's health or too high prices due to limited competition. For this reason, Jordana and Levi-Faur (2004) speak about regulation-for-competition where the responsibilities of regulatory authorities are confined to a single sector or industry and the main goal of regulation is to help markets work more effectively.

However, according to the proponents of the market failure rhetoric, not every market imperfection calls for government action. Government action must meet two criteria: address some serious imperfection in the private marketplace, and be designed so that their benefits outweigh their costs. The language of cost-benefit analysis is very often used to frame the case

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The power of medical practitioners stemmed from their professional status and the autonomy achieved by controlling 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, then, the stronger the sanctions supporting its authority." (Freidson 1970)

for limited government intervention (Eisner 2011: 130). Market failure justifications are framed as technical ones, with a predominance of expert calculation of the costs and benefits of different scenarios and regulatory settings. As Ha-Joon Chang (2014: 302) points out, what constitutes a market failure depends on one's theory of how markets work. The same market dominated by a monopoly can be seen as highly successful by the Schumpeterian or the Austrian school and as the most abject failure by neoclassical scholars. "A Neoclassical economist might praise free trade for allowing all nations to maximize their incomes, *given* their resources and productive capabilities, but a Developmentalist economist might criticize it for preventing more backward economies from *changing* their production abilities and thus maximizing their incomes in the long run." (Chang 2014: 303; emphasis in original)

PROBLEMATISATION 2: THE EGALITARIAN CODE

Apart from the depoliticized and technical vocabulary of economic approaches to regulation, there are also assumptions that the political system defines the social norms about what counts as good in political, economic and social life. Regulatory intervention requires substantiation as to the degree to which it matches the substantive goals of society. "In this respect, the relatively well-understood 'market failure' is supplemented by a range of other defects in market ordering." (Sunstein 1990: 47) Instead of regulation-for-competition, one can speak about regulation-of-competition. Competition is not seen as a value per se, but rather as an efficient model for particular types of social arrangements only. Beside this field, there are numerous areas where the state should set visions and lead.

Marianna Mazzucato (2013) uses a similar approach when she calls for thinking beyond fixing market failures. She suggests that this task requires the state to have the vision and the desire to make things happen using not only bureaucratic skills but also encouraging technolo-

gy-specific and sector-specific discussions. This visionary and strategic role of the state cannot be explained or justified by pure market failure rhetoric.

Cass Sunstein (1990) discusses a range of non-economic substantive goals justifying regulatory intervention: (1) public-interested redistribution, (2) reducing social subordination, (3) promoting diversity of experience, (4) preventing harm to future generations, (5) embodying a 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 interpretive 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 with both the liberal and the republican tradition lying in the centre of the American constitutional order, Sunstein defends the use of "background principles" by disaggregating their various functions and by suggesting that it is both desirable and inevitable.

Sunstein suggests that many statutes have goals other than economic efficiency, and that they are legitimate. Some statutes embody collective desires, including aspirations, preferences, or judgments, and they cannot be understood as an attempt to aggregate private interests. People have a capacity to fulfil altruistic interests as well as individual and collective aspirations in political life. With respect to altruistic interests, political decision making might vindicate meta-preferences (wishes about wishes) and people might pre-commit themselves to a course of action in general interest. However, they are not willing to satisfy their altruistic preferences, unless they are sure that others will do so as well. For this reason, people tend to place altruistic principles into constitutional principles of states and concrete regulation comes from interpretation of the principles. "[W]ell-functioning constitutional orders try to solve problems, including problems of deliberative trouble, through reaching incompletely theorized agreements." (Sunstein 2001: 50) In other words, people who disagree on a definition of what hate

speech is may still accept free speech principles, or those who argue about homosexuality or gender equality may agree with the general principle of antidiscrimination.

Julia Black (2000) would describe the perspective that Sunstein proposed as a narrow conception of proceduralisation in which principles holding a society together remain unchanged. Regulation relies on preconceived norms that are embedded in broader political cultures, constitutional principles or electoral systems, and interpreted by particular institutions. In contrast to the narrow conception of proceduralisation, truly deliberative political processes attempt to avoid prescribing the concrete political goals or values underlying regulation. "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' flavour without specifying the substantive goals that justify regulation." (Morgan and Young 2007: 37)

Tony Prosser (1986) suggests that the concept of *ideal speech act* developed by Jürgen Habermas (1984) provides a standard that can be used to criticise the processes within a particular regulatory regime. Possner translated the abstract criteria of an ideal speech situation into two concepts that are more familiar to lawyers and political scientists. (1) Participation should guarantee that a policy debate is wide enough to encompass a range of interests involved and a range of accessible information. (2) Accountability should guarantee the development of procedures and arenas through which justification and explanation for action are communicated.

The lack of accountability and participation might result in regulatory capture, which occurs when officials within regulatory institutions develop such close relationships with those they regulate that they promote the narrow interests of that group instead of the broader public interest. Ayers and Braithwaite (1992) develop a model of regulatory capture in which the regulated firm must choose to "comply with" or to "evade" the regulations; the agency must choose to adopt a "cooperative" or "deterrent" enforcement strategy. Over time, the agency and

the regulated industry obtain enough information about each other to be able to exchange favours without excessive risk of cheating by the other party to the collusive arrangement (Martimort 1999). Braithwaite (1984) describes *revolving doors* as another mechanism through which industry can penetrate regulatory agencies. People begin their careers as regulators and then move on to join the industry, or they start their professional life in the industry and then work for some years for the regulatory body until they take a better position in the field. Both mechanisms may contribute to bringing industrial values into the regulatory field and to maintaining friendly relations between regulators and the industry. Lexchin (1990) characterises this closeness as "clientele pluralism" in which regulators transfer some of their responsibilities to the industry.

James Q. Wilson (1980) classified policy proposals for regulatory intervention by distribution of costs and benefits as perceived by the involved parties. In some proposals, there is a greater demand for strict rules than in others. Considering both economic and non-economic parameters, Wilson delineated the following four types of politics in which regulatory policies originate (see Table 4): (1) client politics, (2) interest-group politics, (3) majoritarian politics and (4) entrepreneurial politics.

Table 4: Origins of regulatory policies (adapted from Wilson 1980: 365-371)

		Costs of regulation	
		Concentrated	Diffused
Benefits of regulation	Concentrated	**Interest-group politics** *Two or more interest groups in conflict over agency goals*	**Client politics (capture)** *A dominant interest group favourable to agency goals*
	Diffused	**Entrepreneurial politics** *A dominant interest group hostile to agency goals*	**Majoritarian politics** *No important interest group continuously active*

Benefits from a hierarchically higher position can be associated predominantly with *client* and *entrepreneurial politics* in which the competition between policy actors is more lim-

ited. *Interest-group politics*[14] is the most appropriate in situations where both costs and benefits are narrowly concentrated and each party has a strong incentive to organise and exercise political influence. In *majoritarian politics*,[15] both costs and benefits are widely distributed, and interest groups have little incentive to form around such policy issues because no definable small segments of society (an industry, an occupation, a locality) can expect to capture a disproportionate share of burdens. According to Croley (1998), group success is constrained in two ways: (1) the costs of mobilising, communicating their reasons for regulatory decisions, and providing legislators with electoral success, and (2) competition from rival groups with incompatible regulatory preferences.

Client politics can be associated with regulation that originates in industrial capture. "Some small, easily organized group will benefit and thus has a powerful incentive to organize and lobby; the costs of the benefit 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) exemplified Wil-

[14] "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 declining regions in the wealthier countries, the overall effect of the policy is to transfer resources from one well-defined group of contributing countries to another equally well-defined group of receiving countries." (Majone 1996: 76)

[15] "Not all measures that seem 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)

son's framework on oligopolistic firms in European car, electronics, chemical or pharmaceutical industries.

On the contrary, *entrepreneurial politics* may be proposed in a 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 provides many points at which opposition can be registered," passing such regulation "requires the efforts of a skilled entrepreneur who can mobilize latent public sentiment" (Ibid: 370). Majone (1996: 77) points out the importance of capitalising on crisis which puts the opponents of regulatory measures on the defensive and associates legislation with widely shared values such as clean air and water, health and safety, or equal rights for men and women.

PROBLEMATISATION 3: THE HIERARCHIST CODE

Since the 1970s, consumer and environmental groups have increased interest group competition in regulatory politics and made regulatory rent seeking by business groups much more difficult. Instead of the existence of one dominant group that is able to capture a regulatory process one can speak about the co-existence of countervailing group forces. In the context of competing interests of different stakeholders, the demand for expert-driven regulation has increased. Behind this demand, there has been a belief that public-interested technocrats are able to provide expertise in order to deal with issues of long-term salience while countering concentrated interests and balancing with public pressure. Accordingly, regulation should be exercised in a structured way that minimises the discretion of all parties to safeguard certainty in the regulatory process by reducing the potential for arbitrary (and discretionary) decision making. Authoritative and responsible experts are accountable to general public via expert oversight and review.

According to Daniel Carpenter (2010), a regulatory organisation's reputation relates to the justness of the processes by which its behaviour is generated. Organisational reputation is described as a set of symbolic beliefs about the unique or separable capacities, roles, and obligations of an organisation that are embedded in audience networks. Carpenter developed a four-dimensional model of organisational image that distinguishes (1) performative, (2) moral, (3) technical, and (4) legal reputation. Performative reputation lies in the organisation's ability to display sufficient vigour and aggressiveness in the pursuit of some of its aims so as to encourage compliance. Moral reputation is based upon morally and ethically defensible means and ends. Technical reputation encompasses variables such as scientific accuracy, methodological prowess, and analytic capacity. Legal or legal-procedural reputation relates to the organisation's code of conduct. An organisation's reputation, then, shapes the behaviour of its "members" as well as those "outsiders" who interact with it.

From the perspective of reputation, the delegation of authority is a crucial dimension. The legislator delegates authority to a regulatory agency, which is assumed to have greater expertise in tackling complex problems. However, the delegation raises concerns about democratic accountability and possible capture by special interests. The problem of guardianship, as formulated by Susan Shapiro (1987), brings our attention to a series of failures of trust resulting from accumulation of more and more layers of guardianship. Agencies that regulated a single industry were obvious targets for capture and industry actors tended to work very hard to influence them. In order to avoid those problems, the regulatory programme should be structured by usual bureaucratic routines: selection and training of personnel, detailed specification of administrative tasks, specialisation and division of labour, coordination via rules and hierarchical lines of authority, and hierarchical review of the accuracy and efficiency of decision making.

A credible regulatory framework requires at least three central elements: detectors (for gathering information), effectors (for modifying behaviour) and a standard-setting machinery. These three elements are essential in order to navigate the system within a preferred subset of all its possible states. For these reasons, Martin Lodge (2004: 124–143) lists five crucial dimensions that require separate analysis and consideration in any discussion of accountability and transparency: (1) the decision-making process involved in the setting of rules and standards (by means of legislative and technocratic decision-making); (2) the rules to be followed (by means of professional standards); (3) the activities of regulated actors (by means of supervision by experts); (4) regulating actors (by means of reporting duties); and (5) so-called feedback processes (by means of reviews by experts).

Majone (1996: 291–296) reveals two distinct dimensions of the legitimacy of the regulatory branch: a procedural dimension and a substantive one. Procedural legitimacy implies that the agencies are created by statutes which define their legal authority and objectives; that the regulators are appointed by elected officials; that regulatory decision making follows formal rules, which often require public participation; that agency decisions must be justified and are open to judicial review. Substantive legitimacy, on the other hand, relates to the expertise and problem-solving capacity of the regulators, their ability to protect diffuse interests and the precision of the limits within which they are expected to operate.

The hierarchist problematisation of regulation can be characterised by a focus on normality and appropriateness at both the procedural and the substantive level – "regulation of regulation". Hierarchists tend to process information in the 'logic of appropriateness' (March and Olsen 1989). In when their critique of regulation and evaluation of regulatory bodies, issues like proliferation of private and public interests, role of expertise and justness of processes are taken into consideration as the main parameters.

PROBLEMATISATION 4: THE FATALIST CODE

Finally, there is a fatalist version of regulation critique. Murray Edelman (1964), for example, dismissed all government attempts to regulate business as symbolic politics supplying citizens with a pleasant myth rather than tangible benefits. George Stigler (1971) argued that the firms in any given industry are fewer in numbers that the persons outside of industry, and therefore, per-capita gains to them are likely to be high and government officials are rationally self-interested to maximise their votes, their wealth, or both. The larger population of individuals or firms bearing the burdens of reduced competition pay only a small per-capita cost. For these reasons, most citizens are largely uninformed about regulatory decisions whereas interest groups monitor legislators, rewarding those who prepare favourable regulation and punishing those who fail to do so. According to Stigler, regulatory bodies inevitably fall into the trap of close cooperation with the industry and regulatory control becomes ineffective in the long term.

In one of the earliest accounts of the fatalist approach, Marver H. Bernstein (1955) depicted the life cycle of a regulatory agency as ageing from original enthusiasm to act in the public interest to giving priority to protecting industrial rather than public interests. Even though initially infused with a radical spirit, agencies develop close relations with the regulated industry as they mature; 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 an agency or commission 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)

Another fatalist account, Braithwaite's (2007) notion of regulatory ritualism inspired by Robert K. Merton (1968), could be described as "regulation for regulation". For Merton, ritualism entails accepting institutionalised means for securing regulatory goals while losing focus on achieving the goals or outcomes themselves. When regulators have an excessive number of standards to check, arbitrary factors will cause particular standards to be checked in some homes, neglected in others, resulting in endemic unreliability. Hand in hand with the paradox of reliability comes a paradox of discretion. More and more specific standards are written by lawmakers in the misplaced intent to narrow the discretion of inspectors. "The ritual of pretending to solve a problem by writing a new rule aggregates at the micro level in a way that at the macro level makes the system of rules unreliable and unserviceable for regulatory purposes" (Braithwaite 2007: 144) As Michael Power (1997) reminds us, such rituals of comfort can be found in quite a variety of domains. This pathology of protocols is just a specific illustration of the more general problem of formalised regulation forgetting that policy problems are determined by numerous interdependent and highly variable factors.

The ossification of regulatory institutions, rituals of comfort, or reverse mechanisms could be explained by the self-referential nature of regulatory systems. Teubner (1986) considers traditional models of regulation as unsatisfactory because they see the relation between the regulated and the regulator as a one between a system and its environment. In this scheme, the regulator maintains and controls the goals and processes of the regulated. In contrast to this traditional model, he defines regulation as a system consisting of elements that interact with one another in order to maintain themselves and keep their reproductive organisation constant.

Furthermore, actions and intentions of regulatory agents are embedded in larger systems and institutional dynamics. This approach rejects the dichotomous language of public au-

thority versus private interests, pointing out that, in reality, many risks and social problems are controlled by networks of regulators. Regulatory authority is very often shared by private and public actors and ways of regulation depend on location, timing and history. In its description of dispersion of power, this approach shares the following assumption with the multi-level governance framework: governance is not either public or private, but it is frequently shared by all levels (from local to supra-national) and diffused over various societal actors whose relations with one another are constantly changing (Kooiman 2003: 3). These networks are described as 'self-organising' to reflect the government's limited capacity to control them (Rhodes 1997: 46–53) and the blurred lines of their accountability are emphasised (Bache and Flinders 2004: 38).

CONCLUSION: VOCABULARIES OF REGULATORY REGIMES

One can see the described theories of regulation either as competing explanations of the origins of regulation or as different vocebularies grasping different aspects of policy narratives. Each of those vocebularies represents a different dimension of how one can possibly look at and talk about regulation. In each of them one can use specific criteria for evaluating regulation, such evaluation is based on specific epistemic sources (methods), different entities are translated into policy narratives, and different questions are raised (see Table 5).

Table 5: Elements of regulatory narratives

	Criteria	Methods	Problems	Question	Answer
Individualist	Imperfection of market, efficiency	Expertise, cost-benefit analysis	Market failure	What market failures can be identified?	Competition
Egalitarian	Participation, accountability	Interpretation, deliberation	Principles of society	What norms justify regulation?	Empowerment
Hierarchist	Reputation, trust, justice	Investigation	Lack of expertise or procedural legitimacy	What rules protect (or endanger) good regulation?	Public administration
Fatalist	Inevitability, unavoidability, compliance	Explanation	Ossification, bureaucratisation, external constraints	What are the limits of regulation?	Reform, resilience

In the individualist code, the main criteria through which a regulatory framework is evaluated are market imperfection and efficiency. This perspective tends to blame faulty incentive structures and inadequate price signals. It is inclined to remedies emphasising market-like mechanisms and competitive aspects of governance. Expert cost-benefit analysis is main method to justify regulatory tools; however, conflict between different experts cannot be ruled out.

The language of the egalitarian code is less professional and more political. It prescribes community participation, accountability and legitimacy as remedies against abuse of power and regulatory capture. It may be justified by interpretation of constitutional principles or deliberative practice. However, even statutes based on non-economic grounds tend to be promoted in the most cost-effective manner and values other than economic efficiency can be translated into economic concepts. A number of approaches – such as financial valuation of ecosystem services or quality of life – have emerged in the last couple of years. Therefore, one can find instances when the individualist and egalitarian problematisations of regulation interfere.

The language of the hierarchist problematisation can be described in terms of reputation, trust and justice. Identity, and especially its reputational facet, is a valued asset. Once it crystallises and becomes recognised, officials with authority in an organisation may take measured steps to protect, maintain, and enhance their identity. Problems come with poor compliance with established procedures and lack of professional expertise; possible consequences include regulatory capture or lack of reputation. Whereas egalitarians would prescribe greater public participation as a solution to conflicts between stakeholders, the hierarchist perspective sees a solution in more in-depth expertise and stringent rules.

The fatalist problematisation pays attention to inevitable aspects of regulatory work, including natural characteristics of institutional biographies and life or external constraints. It puts emphasis on unpredictability and unintended effects.

In my study of regulatory narratives, all these dimensions guide the research questions, suggesting what codes are supposed to be recognised in such narratives and what criteria are applied. These four views are not meant to provide an exhaustive account of contemporary debates regarding theories of regulation, but they delineate different approaches that involve competing values and priorities; they emphasise some issues, while downplaying others.

PART 2.

GENEALOGIES OF DISCURSIVE IMAGINARIES

CHAPTER 3.
THE GENEALOGY OF HEALTH HOPES

As with all other social institutions in late modernity, medicine itself has become an increasingly reflexive enterprise in terms of its knowledge base, social organisation and everyday practice. Hartmut Rosa (2013) identifies the three main motors of such acceleration: (1) the economic motor, (2) the social-structure motor of functional differentiation, and (3) the motor of cultural promise of acceleration. In the health care sector, one can witness all these types of acceleration.

In the last decades, the most visible has been acceleration in the economical-technical dimension. After prescription drug sales were almost static as a percentage of GDP in western societies between 1960 and the early 1980s, they tripled to nearly US$400 billion worldwide from the early 1980s to 2002 (Angell 2004: 1–5). During the period up to 2009, health spending outpaced economic growth all OECD countries and spending on pharmaceuticals significantly contributed to the overall rise in total health expenditure. In terms of time, new drugs were approved, on average, sixteen months faster in 1999–2001 (about 5.92 years) than in the 1994–1998 period (about 7.25 years). In the US, the average length of the final stage – approval by the Food and Drugs Agency (FDA) which is responsible for drug regulation in the US – dropped from 27 months in 1993 to 19 months in 2001 (Lexchin 2005) and the regulator was 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% of all pharmaceutical research was conducted in academic medical centres, compared to only about 25% in 2005. (Fisher 2009: 12–13) The pro-

liferation of small private pharmaceutical research companies was part of larger trends towards outsourcing and cutting production costs. Outsourcing clinical trials to for-profit companies became one of the pharmaceutical industry's answers to the growing pace of 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. It is also determined by existing social structure. Social historian and theoretician of medicine John A. Pickstone (2000) characterises the second half of the twentieth century 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 was centred on the doctor-patient dyad. During the twentieth century, power gradually shifted towards "'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 care, he experienced being treated as though his life (his feelings, fears, concerns and views about illness and treatment) were unrelated to the object of 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 colonize a number of new fields: genetic testing and neuroimaging techniques had an impact on the justice system, modern sexology and assisted reproduction became far more present in the sphere of intimate life, and questions of nutrition were increasingly framed in scientific terms. On the other hand, the differentiation is accompanied by an ever-louder criticism of the dehumanisation of medical care. We have seen the creation of many patient self-help groups and other patient empowerment initiatives (such as the antipsychiatry movement); alternative treatments

based on a holistic approach to the body and disease are steadily gaining in popularity, while simultaneously broadening their coverage (Scambler 1997: 35–46).

Hartmut Rosa's (2013) three motors of acceleration give us a realistic account of current trends in healthcare as driven not only by economic factors but rather by a combination of economic and technological factors, organisation structures and societal expectations; pharmaceuticals have played a crucial role in the healthcare acceleration process. As Adriana Petryna and Arthur Kleinman (2006) argue: "Worldwide, images of well-being and health are increasingly associated with access to pharmaceuticals," which have become one of the synonyms of modern medicine. One Czech physician summarises this approach as follows: "Disease is something that can be treated with an existing drug."

MEDICALISATION OF SOCIETY

Peter Conrad (1992: 209) coined the term medicalization to refer to the process through which medicine has been taking control over different areas of life. According to him, in the process of medicalisation, previously non-medical problems are defined 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, and 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 medicalisation in today's society. One, medicine as an institution defines the limits of normal behaviour and assigns responsibility for it. Two, it categorises problems as individual and individually manageable (though obviously with expert help). Three, it classifies problems as products of nature –

as resulting from a genetic or biological dysfunction. As a process, medicalisation 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: 220).

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 medicalised to a different degree, Conrad argues (2007:11). In practice, the degree of medicalisation therefore determines to what extent the right to express views about a phenomenon, to take measures against it and to use it as a source of legitimisation for exerting social control over others becomes the prerogative of a single institution – modern western medicine. The process of medicalisation always involves negotiation between various groups, which frequently express conflicting views. There are also a number of limits such as competing definitions, medical care costs, medical taxonomy, or health insurance caps.

Medicalisation is also related to the opposing process of demedicalisation. 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, disability rights movements seek to demedicalise their members' identities and to reframe 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 medicalising and demedicalising discourses. The discussion between the supporters of natural versus medically assisted birth

revolves around 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, identity, social inequality. In all of these cases, the results will differ according to who is assigned responsibility for what.

Conrad mentions two main theoretical sources of inspiration for medicalization theory: 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. Parsons was the first to conceptualise medicine as a form of social control. In his understanding, illness frees the patient from many of the expectations connected to his various social roles; accepting the role normalises him and even justifies certain deviations from the norm and from the related expectations. On the other hand, the patient is now also subject to other, specific norms pertaining to his new role. Parsons 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) they must keep trying to get better; (4) they are defined as an object of medical assistance which allows returning to normality. Parsons' theory is a good starting point for thinking about medicalisation because it presumes certain 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, labelling theory endowed the medicalisation approach with its emphasis on process and definition.

A number of authors also refer to the work of sociologist Ivan Illich who claims that unrealistic ideas about health are 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* (1976), Illich

calls this phenomenon *iatrogenesis* – harm caused by medicine – and distinguishes between clinical, social or cultural harm. According to Illich, virtually all aspects of human life are gradually being brought into the sphere of physical or mental health: childbirth and child rearing, dealing with problems and hardships, criminal behaviour, sadness, ambition, all kinds of physical and mental abnormalities, but also death; 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 characterises its representatives as follows: "They see a symbiotic relationship 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 seeks to change our dependency on medical technologies, decommodify medicine, regulate the interests of pharmaceutical companies, insurance companies and medical professionals, and redirect financial and other resources to regulating 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 individually targeted campaigns; on the other hand, governments fail to make large companies responsible for creating a more healthy environment, 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 are defined as pathological and the fewer conditions as normal, the more drugs, tests and technological measures will be required to treat them.

The medicalisation thesis was formulated in the 1970s and reflected the state of medicine and its relations with society at that time. Since then, we have seen a number of changes. The field of social control has become greatly diversified and subject to collision between numerous agencies and institutions. American social anthropologist Adele Clarke and her colleagues have gone still further to suggest that the idea of medicalisation should be replaced with the concept of *biomedicalisation* (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 power over life. It better reflects the rise of new areas of medical genetics and transplantation medicine, as well as new medical technologies which further intensify medicalisation in new, complex and interlocked spheres of modern science and technology. While the original concept of medicalisation 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 political 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 production 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)

Clarke et al. (2003) emphasise the following post-1985 changes: privatisation of research centres continued; scientific knowledge was increasingly commodified; the role of managerial decisions in medicine increased significantly; and care became far less universal. More so than during the previous decades, today's medicine can adapt to both the patient's body and his/her financial resources. Although healthcare is increasingly dependent on modern technologies, which also allow for both existing and potential patients to be supervised more easily and efficiently, it is also becoming more marketised.

MEDICALISATION AS A FORM OF GOVERNMENTALITY

Hasmanová Marhánková (2008) argues that today's medical discourse defines every pregnancy as potentially pathological and, referring to Lee and Jackson (200: 122, in Hasmanová Marhánková 2008), she adds that a pregnancy can only be defined as normal after successful childbirth – it "only receives the label of normality retrospectively." However, the authors quoted also point out that the limits of what is considered normal pregnancy or childbirth are constantly shifting. Women who have refused prenatal screening have defied the dominant medical discourse and, as a consequence, they had first-hand experience of medicalisation practices. As Hasmanová Marhánková comments on one of her interviews: "While the obstetrician formally accepted her decision, Ms Ivana continued to feel his disagreement throughout 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 became, so to say, the odd one out, and

was viewed as irresponsible or as a troublemaker. Ida Kaiserová addresses the question of social control in pregnancy even more eloquently:

"From the moment of conceiving my first child, I was subjected to normative interest of a number of institutions such as the genetics laboratory, the maternity unit of the university hospital, the gynaecological surgery, the register office, the department of social welfare, the paediatrician'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 also expressed demands for my compliance. Becoming a parent 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)

The processes described correspond with contemporary culture's general trend towards a much stronger future orientation than before. "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. They are active constructers of their lives, and biological determination is not accepted as fate. An ethic organised around the ideals of health and life, Rose concludes, produces anxiety, fear or dread of 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, individuals in mod-

ern societies are supposed to take their biological fate in their hands, and, in return, they expect state regulation not to hinder their self-determination.

In this respect, medicalisation 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 (2008: 50), this self-management is no longer coerced, but instead shaped by the power of truth, rational capacities and the enchanting promise of efficiency. Medicalisation corresponds to Foucault's concept of pastoral power, i.e. 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/her herd and is responsible for its protection, managing the herd for its own good, which gives this form of power its seemingly benevolent character. 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 decisions. It is about how people constrain themselves rather than being forcibly constrained by external agents, involving not generally explicit moral codes but a shared understanding of what a 'good person' is in a particular community" (Lupton 1995: 12). The key to understanding medicalisation then lies in examining how people restrain themselves in order to become good citizens. Nikolas Rose points out that modern pastoral power long ago ceased to be unidirectional. As Rose argues and Kaiserová's example above shows, in real life pastoral power is often translated into a number of micro-technologies. At times, the individual shepherds may even oppose and mutually undermine each other – they can appropriate our

bodies, health or quality of life in a myriad of rhetorical ways, protect their different aspects and issue conflicting instructions as to what is best for us.

THE SUCCESS OF MEDICAL CONSUMERISM

Lupton (2003: 90–1) associates professional excellence in medicine with scientific prowess and laboratory research rather than library-based knowledge and empathetic "bedside skills". Pickstone (2000) argues that science, technology and medicine can be characterised in terms of four historically successive but overlapping ideal types: biographical medicine, analytical medicine, experimental medicine and techno-medicine. In contemporary techno-medicine, certain products of medical research have become commodities. Pickstone distinguishes three other types of medicine according to its priorities and drivers: productionist, communitarian and consumerist. While elements of all three coexist today, the emphasis has shifted from the former to the latter. Productionist medicine gave priority to the health and reproductive powers of the workforce; communitarian medicine stresses the public-service health care by a providential or welfare state; and medical consumerism highlights medicine's position as a commodity in free markets.

Medical consumerism is reflected in the growth of private medical insurance, in the increasing consumer demand for a wider range of choice of medical treatments, in the privatisation of formerly public services, in the development of internal markets within nationalised 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 the consumerist mode, western patients consider medicine only one, even if 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." However, Deborah Lupton (1995) makes a convincing argument that the discourse of the holistic approach to health and lifestyle in fact only helps foster 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.

PHARMACEUTICALS AND OUR UNDERSTANDING OF HUMAN IDENTITY

As for pharmaceutical policy, the progressive medicalisation of western societies can be shown on the milestones which medication has reached in its post-war quest to colonise new areas of human life (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 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 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), 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 psychophramacology*. He argues that for a great many patients Prozac became the proof of biology's victory over the psyche.

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 publicised drugs. In this sense, Conrad (Conrad 2005: 6) and others speak 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 in the general public. In 1997, U.S. regulations on

advertising drugs to the wider public were loosened considerably after years of growing pressure from pharmaceutical companies (Lyles 2002). Following this legislative change, the marketing expenditure of the U.S. pharmaceutical industry grew six-fold between 1996 and 2000, reaching $2.5bn annually.

I do not intend to argue that the diagnoses or medication effects presented in promotional campaigns are fabricated or artificial. There is no doubt that those pills work, some types of patients really need them and they can really improve the quality of their lives. However, pharmaceuticals have expanded the horizons of what society considers as a disease and what it expects from medicine. Prozac seemed to be a great idea, claimed to be the first drug whose molecule had been fabricated to influence only one aspect of the neurotransmitter system without the side effects produced by previous antidepressants such as shuffling gait, dry mouth or tremors. Prozac promised to make depression treatment more effective and comfortable at the same time, thus opening the market for people previously not considered as clinically depressed. Of course, one can admit that this kind of prescription practice is "off the label" and highly problematic from the ethical or scientific point of view; however, Prozac and its promotion made this practice possible.[16]

[16] Similar lessons can be drawn from other pharmaceuticals, too. American studies (Perring 1997) indicate 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 has also been widely discussed in the last decades (Roumie et al. 2005). Other studies (Conrad and Muñoz 2010) documented the influence of over-the-counter medications such as Aspirin, Ibuprofen, and Naproxen on medicalization of chronic pain and suppressing alternative treatments. The roles of vitamin pills in the construction of an ideology of healthism (Crawford 1981) have also been discussed in recent sociology of health literature. All these mentioned categories of products derived their influence from the success of the dominant scientific bio-medical paradigm and raising patients' expectations of com-

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 for treating social anxiety disorder (SAD, an intense fear of social situations, which may include a sense of shame) and generalised anxiety disorder (GAD, characterised as chronic and excessive anxiety or worry lasting for more than six months). The decision was motivated primarily by the concern that the drug might commercially fail facing the already fierce competition on the antidepressant market. 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, since 1980, but its diagnosis had remained fairly uncommon until the late 1990s.

"Since the FDA approved the use of Paxil for SAD in 1999 and for GAD in 2001, GlaxoSmithKline has spent millions of dollars on well-choreographed disease awareness campaigns to raise the public visibility of SAD and GAD. The pharmaceutical company's savvy approach to publicising 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).

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modified medical products. In the end, this type of practice tends to suppress alternative ways of treatment such as rehabilitation, lifestyle changes or behavioural therapy.

The company portrayed the disease as both normal and abnormal – as a normal biographical 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 the massive advertising campaign. Just before its patent expired in 2002, its sales stood at $2.1bn in the United States and $2.7bn globally. "The case of Paxil demonstrates how pharmaceutical companies are now marketing diseases, not just drugs," Conrad concludes (2007: 19). Once again, I do not intend to argue that social anxiety disorder does not exist as an illness or people suffering from it are not in serious discomfort; I use this as an example of how pharmaceuticals might contribute to changing the public image and public perception of a 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 into question and cannot be confused with the concept, the idea and the presentation of disease.

The border between disease and normality was likewise blurred when Viagra caused a marked increase in the diagnosis of sexual dysfunctions. Before Viagra, the treatment of sexual disorders was limited to only very serious conditions such as those requiring prostate surgery. After its introduction, it became possible to treat even lighter dysfunctions or indeed 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 expectations, 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 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 suggests that what may indeed be common (claiming 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. It was presented as a serious treatment, on the one hand, and as an enrichment of sexual life, on the other hand. While Paxil cashed in on the loosening of advertising restrictions, Viagra tapped the new opportunities of 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). She continues: "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)" (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, while 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 problems with erection throughout the history of humankind and have always sought help. What changed after Viagra came was the social meaning of having erection problems and how one should deal with them. In the age of Viagra, erection problems are considered much more in physiological terms than in psychological ones.

CONCLUSION: THE GENEALOGY OF HEALTH HOPES

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 and of a bio-technological discourse that expands the horizons of

our social imaginary. What all of the analysed 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 self of their own volition. With their help, mental states such as sadness, anxiety in front of an audience or dread can be defined as avoidable and manageable. These drugs also contribute to a 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 normality, not as an added value. Within this identity-forming regime, these drugs are therefore not understood as a threat to authenticity but a means of achieving it.

From the perspective of cultural self-understanding in the age of modernity, Rosa (2013: 175) argues, the ongoing acceleration is not a matter of adaptation to external forces, but rather a moment of self-determination. The unfolding of the economic or organizational dynamics described above 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 many different types of hopes of diverse actors: the hope of patients and their families for effective treatment; the hope of those managing health services to minimise the impact of common disorders such as stroke or cancer; the hope of those with a family history of genetic disease for protecting their children from the same fate; 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 increase profits and share value; the hope of scientists and researchers for career growth and fame. Hope represents the fundament of our biomedicalised social imaginary with specific power relations, opportunities and subjectivities.

Last but not least, these pharmaceuticals have fuelled the hopeful discourse of health as a matter of personal choice and responsibility. Medicine offers us various choices we can make to be content, free of anxiety and enjoying a good quality of life. It is everyone's responsibility to decide whether or not to benefit from these choices. These innovations therefore contribute to the discourse of the "imperative of health" (Lupton 1995), which relies on, among others, the presumption that the individual is largely responsible for his or her health. Every individual can be blamed for not following proper diet, not getting enough exercise, drinking too much or too little alcohol, taking too few vitamin pills, not providing his/her 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 the public healthcare system.

As the self is seen as a reflexive project for which the individual is responsible, 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. We should all know how many carbohydrates and proteins there are in each food item, how these should be combined, how much water we should drink daily, what pulse we should maintain while running or what activities we should 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, the expansion of the field had not undermined the possibilities of governmentality – in fact it has further strengthened them.

CHAPTER 4.
THE GENEALOGY OF FISCAL LIMITS

Spending on medicinal products represents a large share of the health budgets in many European countries – they account for 18% of health spending in OECD countries and 20–60% in low-and middle- income countries (WHO 2013). In light of the global economic downturn, some governments have been reducing pharmaceutical budgets using an array of policy instruments, including pricing and reimbursement mechanisms. Pharmaceutical policies are, thus, embedded in broader discourses of thinking about the role of public budgets and economic governance in Western countries.[17]

[17] In the late 2000s many parts of the world entered an era of intense economic austerity. Several countries reported cuts in their national health budgets. For example, in Bulgaria and Latvia, the health budgets were reduced by over 20%. Some Italian regions and France 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 to health insurance. 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 ministries of health, health insurance funds or other agencies. The crisis also motivated efforts to regulate pharmaceutical prices more strictly.

As examples of common policy measures tackling pharmaceutical consumption in the aftermath of the economic crisis, Vogler and Schmicki (2010) mention (1) price reduction; (2) changes in co-payments; (3) VAT rate change; (4) changes in the distributors' margin.

Generally speaking, expenditure cuts are not only deeply unpopular among electorates, but previous expansion of the welfare state has produced its own constituency in the form of a number of strong interest groups ready to mobilise 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 the role of communities promoting such concepts.

As Mark Blyth (2013) argues, the intellectual history of the austerity concept is both short and indirect; rather than a well-elaborated body of ideas or doctrine, it is a derivative of a wider set of beliefs about the appropriate role of the state in the economy. There are both ideological and material reasons for the application of austerity. However, austerity programmes could be described as a product of a change of intellectual climate that emerged from the spheres of economics and politics, rather than driven by interest-group pressures. In this chapter, I focus on the imaginary of neoliberal fiscal responsibility an why the discourse of fiscal responsibility is so popular and resilient in contemporary world

THE ORIGINAL PRINCIPLES AND THE RHETORIC OF JEOPARDY

With respect to the ideological history of the core principles of austerity, Mark Blyth (2013) starts his investigation in early economic thought. "Austerity was not a policy consistently argued for from the seventeenth century onward, since the condition of its realization – big states that spend lots of cash that can be cut – do not arise until the twentieth century. Rather, austerity emerges over time as a derivate consequence of other shared beliefs – a sensibil-

ity – concerning the nature and role of the state." (Blyth 2013: 100) Blyth associates the intellectual dawn of austerity with John Locke, David Hume and Adam Smith. According to Locke, the power of the legislature is limited to the public good of the society, which is defined as freedom from government intervention into private affairs, especially ownership, unless citizens consent to it. It is his contractual minimalist foundation for what the state can that later liberals built upon. Since money follows trade, the class of merchants, not the state, must be placed at the centre of the economy. David Hume turned attention to the existence of public debt, problematizing he fact that it has no limit and it is easy to create since its costs are hidden and intergenerational. For Adam Smith, saving leads to investments, there are no lags and leakages of income; debt has no positive role in the system. Saving is both good and natural for individuals yet it is not natural for states (even if it is good for them). Smith fears easy money coming from credit because it might upset the 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 summarises Smith's moral economy of debt.

While Blyth looks predominantly at the moral economy of state, other authors have explicitly followed the link between moral expectations from the state and from individuals. In her book *Bourgeois morality* (1956), Polish sociologist Maria Ossowska attempted to classify the historical consequences of thrift, distinguishing between two meanings of the word: (1) parsimony, indicating a virtue which is related to individuals, and (2) efficiency, which means the ability to rationally use resources associated with institutions. According to Ossowska, there are different moralities applicable to individuals and economy.

On the contrary, Daidree McCloskey (2010) described a set of bourgeois virtues that do not differ between the realms of individuals and states. They are a mix of the cardinal virtue of temperance and of prudence in things economic. Because of their foundation in Christian mo-

rality, they are significant to the economic policy of both states and families. “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) Whereas Ossowska identified the first virtue with individuals and the second one with institutions, for McCloskey, they present two sides of the same coin.

The ideas of early liberals such as Locke, Hume or Smith and the principles of early bourgeois morality were later echoed in the body of work of Joseph Schumpeter (1942) who explicitly linked his critique of welfare state with the death of saving, the end of family virtues, and the triumph of bureaucracy. From his point of view, the socialist state with its excessive spending produces unbalanced public budgets and makes budgets more prone to fiscal crisis; but it also produces families with no incentive to invest or to save and it expands the bureaucratic structure. Schumpeter warned that capitalism would ultimately pervert itself through its own success. The more capitalism advances, the more entrepreneurs will be replaced by bureaucratically-minded managers and solid ownership by mere shares. This logic can be heard also in later critique of capitalism, for example in Jürgen Habermas’s (1987) critique of the subordination of the life-world to system imperatives at the expense of freedom due to increased bureaucratic control over everyday activities.

HOW STRICT RULES CAN DISCIPLINE THE STATE

However, traditional individualist concepts of liberalism are just one side of late-modern thinking on fiscal responsibility. One cannot understand the forming of the fiscal responsibility discourse without taking German ordo-liberalism into consideration, namely its emphasis on rules and the rule of law in relation to fiscal discipline. In contrast to traditional Anglo-Saxon liberals, ordo-liberals favoured strong government as a precondition for the free market because the mass society and governments lack the moral fabric to absorb economic adjustment, preferring short-term policy responses. In their approach, the state is naturally prone to the moral hazards of over-spending and living on budgetary deficits. As Adam Smith reminds us, savings are unnatural but rational for states, so rules are necessary to guarantee that they will act rationally. For these reasons, strict rules should be imposed to make governments act more responsibly in the long term. German ordo-liberalism represents a crucial step in the genealogy of fiscal responsibility. In contrast to traditional liberal virtues carried by individuals, ordo-liberals introduce a hierarchical system of rule of law.

In the tradition of German ordo-liberalism, the policymaker should provide a legal framework (rules of the game) for relevant actors in the system. To prevent market failure, incentives should be provided for relevant actors either by introducing public regulation or by enhancing 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-party payers and public service providers. Thus, 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.

Ordo-liberalism was shaped by the Freiburg school of economics. Inspired by US anti-trust law, Walter Eucken, Franz Bohm, and Hans Grossmann-Doerth argued that Germany's

basic economic problem in the 1920s was the legal system's inability to prevent accumulation and misuse of private economic power. According Walter Eucken (1952), capitalism is composed of two fundamental structural orders: (1) transactional economy and (2) 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 so that the state enables and enhances the market. Michel Foucault (2008) emphasised that German ordo-liberals were the neoliberal family's avant-garde, developing better solutions to the shortcomings of traditional liberalism. They redoubled their efforts to understand the relation between law and economics, attempted to address issues of social cohesion, and offered an alternative solution – the social market economy.

These arguments guided the economic reconstruction of Germany when the centrist Christian Democratic Union was looking for a new set of ideas that spoke to its constituency's interests. "German *Ordoliberalismus* 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 concentrations of combined political and economic power." (Crouch 2011: 165) The ordo-liberal ideology relies upon three essential invariants: (1) preserving the market economy as a source of dynamics; (2) preserving a social cohesion in order to suppress conflicts; and (3) securing stability and economic growth through competition and financial policies.

In the late 1970s, when Europe was stagnating, Germany suffered the least and recovered the quickest of all major Western European states. Its ability to overcome the recession gave ordo-liberal discourse the strength to become a role model for other states. Its principles were incorporated into the European Commission's competition policies and the rules 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) European integration can be described as way in which the neo-liberal policy of market freedom is inscribed in depoliticised constitutional devices associated with German ordo-liberalism and thus embedded within laws and regulatory institutions (Bonefeld 2012; Moss 2000).

THE WAYS OF DISSEMINATION

Although the different intellectual histories of neoliberalism tend to juxtapose German ordo-liberalism and Austrian neoliberalism, interaction between both groups did exist. They participated in the project of Mont Pelerin Society – a community of liberal economists and a breeding ground for their ideas. In 1947, the society was founded, under the leadership of Albert Hunold and Friedrich August von Hayek, to uphold the principles of free market, limited government, personal liberty, and rule of law. It was named after the place where the first meeting was held. A number of liberal intellectuals from Europe and the United States assembled in Mont Pelerin, a village close to Lake Geneva.

The members of the Mont Pelerin Society believed that classical liberalism had failed and that the only way to diagnose and rectify its failures was to renew this project in a discussion group of like-minded intellectuals. The society was modelled after the Collogue Walter Lippmann, an international congress organised by philosopher Louis Rougier in Paris in 1938. The Collogue consisted of twenty-six businessmen, top civil servants, and economists from several countries, including Friedrich Hayek, the architect of the German social market model Wilhelm Röppke, or Alexander Rüstow (Denord 2009). The Collogue laid the founding stone of a neoliberal thought collective upon which the Mont Pelerin Society was built as a community of neoliberal intellectuals. The comparison of these two communities illustrates the rising

American hegemony after World War II. US participants formed a minority (3 of 84) in the Collogue Walter Lippmann, compared to almost half of the participants in the Mont Pelerin Society founding conference in 1947. (Plehwe 2009: 16–17)

In 1958, the first American meeting of the Mont Pelerin Society took place in Princeton. The panel programme included papers by Milton Friedman, who immediately became the most visible face of the society and definitely swung mainstream thinking in society away from ordo-liberalism towards individualist liberalism. When he led the society between 1970 and 1972, Friedman argued against monopoly regulation. In contrast to the ordo-liberal emphasis on the role of state, Friedman (1962) concluded that, in any case, private monopoly should be preferred over public monopoly and public regulation of monopoly.[18] In contrast to Hayek's Road to Serfdom, Friedman had no interest in conducting a dialogue with socialists; he proposed that corporate income tax should be abolished, and education and health care privatised and open up to competition.

The interest in welfare state retrenchment, privatisation and deregulation was sparked by the coming into office of Margaret Thatcher in 1979 in the UK and of Ronald Reagan in 1981 in the US, both determined to radically cut back on the welfare state. In their view, the welfare state had become a significant source of social and economic problems instead of their

[18] For example, Friedman (2001) associates the rise in medical costs with increases in third-party 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)

solution. Neoliberalism came to dominance when Keynesian demand management (Crouch 2011)[19] experienced its own crisis in the context of 1970s inflation.

Philip Mirowski (2009) identified the Mont Pelerin Society as a source of neoliberal economic experts and vehicle of the spread of neoliberal discourse. Members of the Mont Pelerin Society were highly active in Chile's market reform during Pinochet's era. Fischer (2009: 319) points to a significant role of Milton Friedman and other members in legitimising Chile's

[19] Colin Crouch (2011) uses the term Keynesian demand management to refer to a period after the Second World War when ideas of British economist John Maynard Keynes were particularly influential in Scandinavian countries, the UK, Austria and to a lesser extent in the USA, but were also taken up by international agencies like 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 utilisation led to increasing returns and faster productivity growth. The Keynesian model recommends states to go into debt in times of recession, when confidence is low, in order to stimulate the economy with public spending. In times of growth, it recommends to reduce government spending and pay off the debts. The model implied large state budgets. However, Eichengreen (2008) argues that the Keynesian revolution is believed to be responsible for this new-found stability after the Second World War, but in fact there was little active use of monetary policy. Fiscal policy worked best when left on autopilot, allowing automatic stabilizers to work. Generally speaking, the Keynesian model suffered from its inflationary tendencies. Crouch (2011) points out that countries with both Keynesian policies and a weak neo-corporatism were highly vulnerable to inflationary shocks. This defect of demand management came to be seen as an intolerable fatal flaw following waves of commodity price rises in the 1970s; particularly the oil crises of 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.

radical neoliberal program of shock therapy. John Williamson, author of the so-called Washington Consensus in 1989,[20] was also associated with the Mont Pelerin Society.

Dorothee Bohle and Béla Greskovits (2012: 57–58) describe how ideas of the Mont Pelerin Society profoundly influenced Central and Eastern European reform efforts after 1989. Western policymakers and advisors with their Eastern colleagues built a transnational coalition for rapid and comprehensive marketisation. This coalition was backed by the IMF's practice of conditionality for financial assistance. These reformers saw their mission in respecting and allowing freedom of choice and going "against the thinking of individuals who have interventionist and social engineering ambitions (typically the 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 the purposes are evident to them." (Klaus and Ježek 1991) Reformist think tanks were set up in all post-communist countries. They popularised the neoliberal discourse, provided reform expertise, and stabilised and renewed neoliberal thought. Their in-

[20] The Washington Consensus was a summary of ten "must-do" policies to solve economic crisis in developing countries. The full list comprised of (1) fiscal discipline; (2) reordering public expenditure priorities; (3) tax reform; (4) liberalising interest rates; (5) a competitive exchange rate; (6) liberalising trade; (7) liberalising inward foreign direct investment; (8) privatization; (9) deregulation; and (10) legal guarantees for ownership rights. Blyth (2013) points to a couple of states that did not pursue such policies – for example, France, Italy, and all of Scandinavia. Even successful developing states such as Korea, Taiwan, and lately China never applied these recommendations. Even though governments accepted these policies more than reluctantly, the Washington Consensus met with accolades by international institutions – the International Monetary Fund (IMF) and the World Bank. "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 privatization, maximize liberalization of finance." (Blyth 2013: 162)

tegration in transnational networks such as the Mont Pelerin Society constituted an additional important asset (Bohle and Neunhoffer 2006).

THE RHETORIC OF NEOLIBERAL REFORMS

With respect to the retrenchment and critiques of welfare state, Albert Hirschman (1991) identifies three different arguments: (1) the futility thesis; (2) the jeopardy thesis; and (3) the perversity thesis. The futility thesis simply holds that attempts at social transformation will be unavailing and fail to make even a small progress. The jeopardy thesis argues that the cost of purposive action is too high as it endangers some previous accomplishments. According to the perversity thesis, any purposive action to improve features of the economic, social or political life only serves to exacerbate the condition it was intended to remedy. These are the most important arguments in the genealogy of fiscal limits. Whereas the first one discourages policy makers from any attempt to strengthen the welfare state, the last two are truly reactionary because they call for reforming the welfare state and abandoning its principles.

Found in the arguments of Schumpeter or Friedrich von Hayek (1944), the rhetoric of jeopardy can be characterised by its warnings that an expansion of government power and extensive redistribution of taxes will destroy the fundamental values of capitalism such as freedom, temperance or prudence. Global economic downturns, in the Schumpeterian view, are opportunities to renew those fundamental values and to limit government intervention.

The renewal theme in the rhetoric of jeopardy can be traced back to early nineties. David M. Tucker (1991), for example, speaks about a decline of thrift in the US. Based upon the Puritan or Protestant work ethic, thrift was considered an important virtue from the beginning of American history until the 1950s, with regard to both the moral fibre of the country and its continuing economic well-being. Deferring immediate pleasures to accumulate wealth for in-

creased future value was considered virtuous by citizens as well as government. However, Tucker criticises that thrift then became an outdated, outmoded concept, holding it largely responsible for the recent economic downturn. A new ideal of growing standard of living – supported by spending, consumption, and debt – undercut the old productive virtue of thrift. Throughout the twentieth century, advertising, consumer credit, and a self-indulgent psychology have eroded the practice of frugality. With a falling savings rate and an immense expansion of tax revenues, Tucker sees economy not only as largely dysfunctional but even, more importantly, as morally deficient.

Recently, one could identify a similar set of arguments behind Tomáš Sedláček's *Economy of Good and Evil* (2011). "Too happily have we run away from these moral principles, principles on which economics should rely. Economic policy has been set loose, and a deficit psychosis in the form of a gigantic debt is the result." (Sedláček 2012: 321) In line with Tucker, Sedláček as well calls for returning to the fundamental economic principles since they are both moral and functional.

In contrast to the rhetoric of jeopardy, the main trope of entrenchment reforms in the 1970s and 1980s corresponds with the perversity thesis. The best example could be found in Charles Murray's Losing Ground (1984). In his book, Murray used data and techniques elaborated earlier in predominantly liberal think tanks to argue that the liberal welfare state was to blame for a diversity 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 but it had actually made things worse for the poor. Even though Murray's argument proved easily demolished and was criticised by a number of poverty experts (see, for example, O'Connor 2001), the book became an ideological manifesto and preserved its influence over the neoliberal discourse of the welfare state.

The perversity thesis is anchored in two central subjectivities: (1) the deserving autonomous, self-sufficient individual and (2) the undeserving dependent, irresponsible object of welfare policies. It combines classical liberal economy with Protestant morality to suggest that "contrary to the apparent reality that offering financial aid to the 'poor' was a kind and charitable act of assistance, such intervention actually undermined the natural order of things and corrupted individuals who accepted such succor, so that they lost the ability to practice self-discipline and exercise personal responsibility." (Schram 2012: 247)

Both tropes the welfare state as inefficient as well as morally problematic. They also create a basis for questioning welfare state expansion and claiming certain boundaries of personal responsibility. Furthermore, reliance on welfare is metaphorically articulated as illness. People suffer from welfare dependency, which, like other addictions, is something the client needs to be freed from. Austerity programmes or welfare retrenchment are promoted as both a way in which public budgets can be saved and bureaucracy diminished and a way in which the moral order based upon autonomy and responsibility can be renewed. "Programs are designed to emphasize suspicion, surveillance, and a reluctance to provide aid except under the most extreme circumstances in which people demonstrate that they are in desperate need for assistance." (Schram 2012: 261).

During the last three decades, this rhetoric has been instrumental in turning the golden era of expanding health care provision into an era of accountability, control and attempted retrenchment.[21] Health care has been transformed from a concept of public welfare into a commodity with an economic value and the potential to be traded in markets. Kay and Williams

[21] There is evidence that suggests that liberalisation in healthcare creates inequalities 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).

(2009) observed a rapid development of indirect techniques for leading and controlling individuals without being responsible for them. Citizens become 'responsibilised' or made to conceive health risks and outcomes such as illness or disease as their own individual responsibility; as a result, the policy problems of health governance become framed as way of encouraging 'self-care'. The situation in health care has followed similar trends as those previously described for the labour market and social welfare. It is our responsibility to remain free of illness, preserving the ability to work and care for our relatives such as children and elderly parents.

CONCLUSION: THE GENEALOGY OF FISCAL LIMITS

The elements described in this chapter each represent a number strands, characters, and plot devices woven together in one liberal imaginary. As Foucault (2004) emphasizes, the new art of government 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 given, is not ready-made. On the contrary, freedom has to be craftily produced and organized. Liberalism is forced to determine the precise extent to which competing individual interests constitute a danger for the interest of all. The consequence of liberalism is the considerable extension of procedures of control, constraint, and coercion balancing different freedoms. It resulted in the emergence of governmental mechanisms increasing freedom at the expense of introducing additional control and intervention. Paradoxically, liberalism brought into life the rhetoric of suspicion and surveillance. The resilience of neo-liberal ideas can be explained by a combination of three possible factors: (1) the ideological history of its core principles; (2) the channels of dissemination of neo-liberal ideas; and (3) the rhetoric of neoliberal reforms.

At the heart of the neoliberal imaginary lies the idea that the *home oeconomicus* who follows his or her self-interest in his or her own way can act hand in hand with the *homo spectatus* who follows his or her own honour depending upon the honour and glory of his community (Kabele 2000). To behave economically is not only morally appreciated but also natural. In the field of government policy, this line of thinking has resulted in austerity – efforts to purge the system and cut spending as the essence of recovery, not only in economic but also in moral terms.

However, in contrast to the imaginary of health promises, this is not a progressive but a reactionary one. Looking apprehensively to the possible future, it urges us to return to the basic principles of modern society. Public budgets are associated with a chronic spending disease that will weaken the system. This medical metaphor conveys a sense of impending doom – the prognosis is bad and there is serious concern about a sick fiscal future. Because of excessive spending, the systems of government have deviated from what is natural both economically and morally. There is also a note of urgency that the cure cannot be further postponed. Both states and individuals need fasting to pure their bodies and renew their vitality.

This imaginary is supported by the international epistemic community. For example, the Mont Pelerin Society legitimises neoliberal discourse and is legitimised by it at the same time. The society was designed to create a space where like-minded people could engage in a process dedicated to advancing a common neoliberal cause in a 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 who 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 due to diffusion and mutual learning. According to Fleck (1979), thought collective is a community of persons mutually exchanging ideas or maintaining intellectual interaction. It "is even more stable and consistent than the so-called individual, who always consists of contradictory drives." (Fleck 1979: 42) Looking at the Mont Pelerin Society as an epistemic community or thought collective gives us a chance to observe the construction of fundamental values and principles constituting neoliberal thinking as a transnational phenomenon.

The current neoliberal project was founded in the neo-classical economy of the first four decades of the 20th century. In the aftermath of the Great Depression and the World War II, the influence of that paradigm weakened in favour of Keynesian economic policy. However, in the seventies, neo-liberal economists were able to take advantage of a crisis of the latter paradigm and returned to the centre of fiscal policy arenas. The co-existence of traditional individualist liberal approaches with hierarchical statist ordo-liberalism gave plasticity to the neoliberal imaginary. The traditional liberal rhetoric of jeopardy was exemplified by David Cameron's Big Society, an attempt to revive community relations and to cut down public service provision at the same time. In contrast, ordo-liberal philosophy was reflected in attempts to impose fiscal boundaries such as the Stability and Growth Pact with its strict limits for public debts and budget deficits.

PART 3.

REFORMS OF PHARMACEUTICAL REGULATION

CHAPTER 5.
PHARMACEUTICAL REGULATION IN THE EU CONTEXT

Making safe and effective pharmaceutical products available and affordable to individuals is a central challenge to pharmaceutical policies. There is, however, a myriad of obstacles to achieving and maintaining availability, affordability and quality of medicines. There are also different views of what availability, affordability and quality could mean. Health economists would equate efficiency with quality, doctors and patients would define quality as treating the patient appropriately, and governments' pharmaceutical policies would link affordability to sustainability of public budgets.

National regulatory frameworks are integrated in supranational structures by both the soft power of policy transfer practices and the hard power of international commitments. Furthermore, national debates very often echo discussions and controversies in supranational discourse and reflect on practices proposed at that level. With respect to this supranational character, this chapter aims to provide a brief introduction to pharmaceutical policy tools and contextualises the Czech case within the history of EU regulatory framework. This chapter serves to anchor the analysis of the transformation of Czech pharmaceutical policy in the context of transformations of the European regulatory framework in the same time period. In this chapter, the tools that governments have for regulating pharmaceutical markets are introduced and the roles of the EU framework and member states' legislatives are delineated.

PHARMACEUTICAL POLICY TOOLS

Generally speaking, pharmaceutical policies are related to pricing, reimbursement, market entry and control of expenditures, targeting specific agents such as distributors, physi-

cians and patients. Pharmaceutical regulation is a very complex field where populations' characteristics meet with state policies and the behaviour of health care providers, producers and distributors. Regulations apply throughout the product life cycle – including testing, patent protection, authorisation, marketing, and monitoring when a pharmaceutical is already on the market. Clinical trials are conducted in stages, each of which must be successful before advancing to the next stage. In the first stage, the safety of the drug is evaluated and its metabolic and pharmacologic properties are measured. Afterwards, trials on a small number of diseased patients are performed to determine efficacy. The final stage involves hundreds or thousands of patients. At this point, the safety and efficacy of the drug are further examined, dosages are determined, a risk analysis is performed and drug interactions are explored. After clinical trials, there is room for patenting and authorisation. After authorisation, the marketing of a pharmaceutical product is regulated and the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems are studied. In the end, a variety of pharmaceutical regulations are used to balance effective spending on pharmaceutical in the inpatient (mostly hospitals) and outpatient (mostly pharmacies) sectors.

Policy makers face overlapping and competing regulatory tasks. It is their responsibility to guarantee that only safe, good-quality and efficacious medicines enter the market. Their second task is to balance health care budgets by controlling health expenditures and pharmaceuticals costs. And their third task, in many countries, given the economic importance of the sector, is to promote a regulatory environment conducive to business. As such, pharmaceutical policies represent a field where existing medicalised imaginaries, pushing policies towards high-quality preparations, innovative cures, efficacious treatments and access to medicine, interfere with fiscal responsibility discourses which are present in cost-containment policies, regulating policy agents' behaviour.

According to Permanand and Altenstetter (2004), in pharmaceutical regulation, there are competing interests of health care policy, industrial policy and public health policy, each relying on different regulatory rationales and different tools (see Table 6).

Table 6: Competing policy interests in pharmaceutical regulation (Permanand and Altenstetter 2004: 39)

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-sized enterprises	Patient access to medicines
Ensuring access to medicines	Contributing to a positive balance of trade	
	Sustaining the academic research base	

Despite the common European regulatory framework, there is an immense diversity of pharmaceutical policies among the 28 member states. According to OECD (2014), total (public and private) spending on outpatient pharmaceuticals in EU member states varied from 0.6 to 2.5% of GDP. As expected, given the size of its population, Germany is the biggest pharmaceutical market in the EU, followed by France, Italy, Spain, and UK. These five countries account for over 70% of European pharmaceutical turnover. Countries with high total pharmaceutical expenditure as a percentage of GDP (above 2%) include Greece, Hungary, Croatia and Slovakia; those with low pharmaceutical expenditure or total health expenditure in terms of GDP include Denmark, Luxembourg or Sweden. In the EU, the public hand is responsible for around 60% of total pharmaceutical spending. Some countries, including 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, countries such as Bulgaria, Denmark, Cyprus, Latvia, Luxembourg and Romania spend relatively little public money on pharmaceuticals compared to GDP. The Czech Republic belongs to countries with a relatively high share of public expenditure, even it has been decreasing for the last couple years.

Castles (1999) suggests that until the 1970s variation in public healthcare spending was heavily influenced by political variables (such as left-right orientation), however, since the 1980s, bureaucratic cost-containment policies have dominated. In the early 1970s, European health policies were still on an expansion course with prevailing medicalised social imaginaries. Numbers of modern pharmaceuticals and additional healthcare services included in health insurance schemes increased in this period. Nevertheless, the recessions of the 1970s provided the signal for start of cost-containment measures in this field. Indeed, health care followed other policies of welfare state in the way towards fiscal responsibility horizons. This shift corresponded with the birth of neoliberal policies and the withdrawal from Keynesian demand management, which was described in a greater detail in the previous chapter.

In 1980s, pharmaceutical expenditures per capita increased in all EU states in the same period (Mossialos, Walley, Mrazek 2004), however, voters were reluctant to elect parties committed to increased taxation to pay for higher healthcare (Dilnot 1996). For these reasons, Western European states imposed policies proposing cuts in public health budgets. Between 1980 and 2000, the public share of total expenditure on pharmaceuticals shrunk in vast majority of the old EU member states (Mossialos and Le Grand 1999).

In relation to reduction of health care costs, one can see a plethora of individualist accounts in favour of cost-sharing practices. Generally speaking, cost sharing combats public budgets loss by restoring the price signal negated by insurance, thereby reducing ‘excess’ utili-

sation. Direct forms of cost sharing include: (1) flat-rate payments, which are fixed fees per item prescribed or per prescription; (2) co-insurance based on a fixed percentage of the total cost of a good or service; (3) deductibles, which require the user to bear a fixed quantity of the cost (Thomson and Mossialos 2004). Reference pricing, which refers to the maximum price for a group of equal or similar drugs that the insurer will cover, is an indirect form of cost sharing that has been applied in several Western European countries. Along with cost sharing, other different market-driven tools such as public tendering or risk-sharing arrangements promoting an increase in competition have been also spreading across the Europe (Rothgang et al. 2010).

On the other hand, Western European states employed hierarchy-based tools, such as direct pricing, price freezes and cuts, positive and negative lists, prescription guidelines or budgets limits (Tuohy 1999, Thomson and Mossialos 2004, Mladovsky et al. 2012). Historically, common hierarchy-based regulatory instrument has been the adoption of explicit listing indicating whether or not a specific product may be adopted for reimbursement. All European countries have also introduced limits on drug wholesalers' margins, either via bureaucratic mechanisms or through established practice with the public health care sector. In the last decade, the expert-driven method of health technology assessment has been increasingly used in European countries (Carone et al. 2012). Expert boards gather evidence from comparative economic and technological evaluations to decide whether the price of the drug was too high and thus whether the drug should be excluded from reimbursement or included to it.

Basic tools and principles, according to Carone and his colleagues (2012), are summarised in the following table (Table 7).

Table 7: Tools of pharmaceutical regulation and policies applied within the EU (adapted from Carone et al. 2012)

Policies related to pricing, reimbursement, market entry and expenditure
Price regulation
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. It is applied in all EU member states except Denmark, Sweden, the UK and Croatia.[22]
Internal reference pricing:[23] the maximum price to be reimbursed by a third payer ("reference price") is determined by comparing prices of equivalent or similar products in a given chemical, pharmacological or therapeutic group. The patient pays the difference between the retail price and the "reference price", in addition to any co-payment. The "reference price" applies to all pharmaceuticals within the corresponding group of products. It is applied in 20 EU member states.
Price updates: updating regularly in accordance with pricing regulations.
VAT: medicines may have a value-added tax below the standard rate. The rate may depend on the group of pharmaceuticals.
Product reimbursement
Health technology assessment: based on an assessment of the marginal cost effectiveness of an innovative medicine relative to existing treatment options, reimbursement is conditional upon meeting specific clinical and/or economic effectiveness criteria. 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 specify which specific pharmaceuticals are reimbursed and negative lists exclude specific pharmaceuticals from reimbursement. Positive lists are applied in all EU countries, negative lists in some of them.

[22] In general, each country defines a basket of economically comparable and geographically close countries. Choosing countries with similar levels of economic wealth is perceived as a good parameter for choosing an appropriate price level, whereas geographic closeness may ease updating pricing through external reference pricing. For example, East European countries have the lowest average prices (around 70% of EU average), whereas Germany have the highest price level of all EU member states. The most often referenced European 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 (Carone et al. 2012).

[23] Some countries (for example Denmark, Italy, Portugal) base their reference groups upon substance level, whereas other countries (for example, Germany or the Netherlands) also consider therapeutically similar substances as interchangeable (PPRI 2008).

Market entry
Time to market entry: the Transparency Directive regulates the time frame for taking pricing and reimbursement decisions.[24]
Expenditure controls
Discounts/rebates: imposed upon manufacturers and pharmacists so that they return a part of their revenue.
Clawback: pharmacies are required to pass a part of their turnover to third-party payers.
Payback: manufacturers are required to refund a share of their revenue when a pre-specified ceiling of public pharmaceutical expenditures is exceeded.[25]
Risk-sharing arrangements: financial or performance-based schemes which trigger lower prices or refunds from manufactures if pre-agreed targets are not reached.[26]
Price freezes and cuts: imposed by law or as an outcome of a negotiated agreement.[27]
Public tendering: public procurement in the outpatient sector to decrease the prices of pharmaceuticals. It is applied, for example, in The Netherlands and Germany.[28]

[24] However, the time from a company's application and the decision varies across the EU. In Germany and the UK both steps are immediate. Denmark, Finland, Hungary, the Netherlands, Sweden have deadlines of up to one month. Belgium, the Czech Republic, Latvia, Romania and Slovakia have average waiting times of over half a year. (Carone et al. 2012)

[25] Paybacks increase the predictability of public pharmaceutical expenditures; on the other hand, as Carone et al. (2012) warn, over-consumption is incentivised if the budget is set too high compared to actual health care needs. If the target budget is set too low, then the industry is penalised by the payback for serving the actual health care needs of the population.

[26] There are various risk-sharing schemes: (1) price-volume agreements – financial schemes triggering refunds from the manufactures if pre-agreed sales are exceeded (refunds may take the form of lower reimbursement or payback); (2) patient access schemes granting pharmaceuticals for free or at a lower price for a limited time period; (3) performance-based models triggering refunds if a pre-agreed performance level or health gain is not reached.

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

[28] Public procurement is mostly used in hospital settings, covering up to 25% of all purchased medicines. In outpatient care, it is less relevant, although an increasing tendency has been observed. (Leopold et al. 2008, Kanavos et al. 2009)

Policies targeted at distributors, physicians and patients
Wholesalers and pharmacists
Generic substitution: inducing or mandating pharmacists to dispense the cheapest bioequivalent medicine. It is mandatory in 8, indicative in 14 and disallowed in 7 EU member states.[29]
Markups: regulating the reimbursement of distributor services, at least for reimbursable medicines, mostly by means of regressive, but sometimes also linear markups and profit margins. 23 EU member states apply legal limits for markups to wholesalers, and all EU member states to pharmacists. These can be linear, regressive, fixed-fee (NL) fee-for-service (SI, the UK).
Physicians
Prescription behaviour monitoring: To some extent, e.g., by using electronic prescriptions, it is applied at least in 22 EU member states
Clinical practices/prescription guidelines: in a few countries, physicians must prescribe by the international non-proprietary name (INN) instead of trademark. INN is mandatory in five, indicative in 18 and disallowed in four EU member states.
Pharmaceutical budgets: maximum budgets per period, region, field of specialty or physician are applied at least in 9 EU member states.
Prescription quotas: defining target percentages of generics to be prescribed by each physician or target average costs of prescriptions. They are applied at least in 6 EU member states.
Financial incentives: rewarding or punishing physicians for following or ignoring prescription guidelines, quotas and budgets. They are applied in at least 11 EU member states.
Education and information: prescribing advice, IT decision support etc.
Patients
Information/education campaigns: raising awareness of rational use of medicines, e.g., for antibiotics and generics.
Co-payment: differentiated reimbursement rates such as 100% for essential, 80% for chronic and 60% for other pharmaceuticals. Often, specific rules exist to protect vulnerable groups from excessive out-of-pocket payments.
Prescription fees: fixed amounts per prescription or prescribed item.

Although the imaginary of fiscal responsibility has prevailed in European pharmaceutical regulation for the last two decades, the discourse of health promises and technological hopes never disappeared completely from pharmaceutical policies. Risk-sharing arrangements can be named among the tools which tackle this horizon of pharmaceutical policies. Mrazek (2002) describes the example of a risk-sharing scheme for multiple sclerosis drugs in the UK.

[29] Currently, roughly 43% of the volume of pharmaceuticals in the EU is supplied as generics, but this is just 18% of total cost. The shares of volume and cost vary largely across countries: 79% of all pharmaceuticals sold in Latvia are generics, but only 27% in Austria; similarly, generics account for 12% of total cost in Sweden and 40% in Poland and Romania. (Carone et al. 2012)

Treatment of multiple sclerosis is covered by the National Health Service, and patients who meet certain criteria receive prescriptions for particular innovative products. The price for each product is set according to evidence on health outcomes obtained by patients participating in the scheme. If the actual outcomes fall short of targets within a margin of tolerance, the pharmaceutical company will have to make a repayment in accordance with a scale agreed in advance (Mrazek 2002). Risk-sharing arrangements with payback mechanisms, which require manufacturers to pay back a share of their revenue if a pre-specified budget ceiling for public pharmaceutical expenditures is exceeded, are among the tools which combine fiscal responsibility with the biomedicalised imaginaries of rising hopes and expectations.

The only existing measure in the field of pharmaceutical pricing and reimbursement, Directive 89/105/EEC or the so-called *Transparency Directive*, came into force in 1989. It was originally intended as a first step in a series of EU regulations of national price and profit control, but it seems to be also the last one. Despite subsequent reviews of its impact and effectiveness, the European Commission could not establish sufficient consensus among the member states to move towards a stricter regime and the Transparency Directive was the lowest common denominator that could be agreed upon (Mossialos, Mrazek, Walley 2004). The Directive obliged member states to adopt 'verifiable' and 'transparent' criteria for medicines pricing and reimbursement under their national health systems. Despite an extensive interpretation of the Directive by the Court of Justice,[30] it has been particularly challenging to implement its

[30] 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.

provisions in national law effectively enforce its principles, in particular by the Commission (European Commission 2012). The transparency directive has been in force for more than 20 years, but pharmaceutical coverage decision making in Europe is more heterogeneous than ever.[31]

PHARMACEUTICAL REGULATION IN THE EU

Although pharmaceutical policy is primarily determined at the national level, by individual EU members, there is nevertheless a considerable body of relevant regulation at the EU level. The starting point for pharmaceutical regulation in Western Europe was the thalidomide scandal in the late 1950s and early 1960s, when sleeping pills named Contergan caused thousands of birth deformities.[32]

In two decades after the World War II, the numbers of newly developed pharmaceuticals were increasing, their production was becoming industrialised, and sales were growing. In Europe, the applicable instruments for marketing control and authorisation of pharmaceuticals

[31] In seven countries, reimbursement decisions are taken immediately by the ministry, while based upon expert bodies' recommendations. Spain is the only member state where the ministry of health has a sole responsibility for the reimbursement process. In the rest, a variety of institutional solutions can be observed, ranging from ministerial commissions (Slovakia) or government agencies (Poland) to more-or-less independent public health care institutions for which reimbursement recommendations are only one of many tasks (e.g., Belgium, France). In countries where the ministry is not responsible for decisions (Czech Republic, Denmark, Finland, Italy, Sweden), a crucial role is played by independent government agencies which often do not only deal with coverage decisions but are also responsible for market authorisation. Beside independent government agencies, parts of the public health administration (Hungary, Ireland) or self-governance bodies (Austria, Germany) may also deal with the decision making.

[32] The total number of babies damaged throughout the world is estimated at 10,000 in 45 states, among them the UK, Sweden, Italy, Ireland, The Netherlands, Belgium, Finland, Denmark and Austria.

by public authorities remained rather limited, and the responsibility to ensure pharmaceutical safety was left to producers (Krapohl 2008: 63). This was an era of unrealistic ideas about health, as later criticised by Ivan Illich (1976). The thalidomide scandal shocked the general public and shook its trust in medical professionals and pharmaceutical companies.

Thalidomide was heavily promoted in a medicalised discourse. It is believed that around 700,000 Germans took it on a regular basis. "Parents even gave it to their children, earning Contergan the nickname, 'West Germany's baby-sitter.'" (Deammrich 2004: 61) In many respects, the drug gave rise to the same kind of hopes and expectations as Prozac, Paxil or Viagra. Thalidomide was originally prescribed as a "wonder drug" for morning sickness, headaches, coughs, insomnia and colds.[33] The thalidomide scandal serves very often as an example of social risks that cannot be calculated.

Two years after Contergan had entered the German market, the first adverse effects of the sleeping pill were observed (Krapohl 2008: 60–4). However, the producer's answer to steadily increasing concerns was belated and only partial. One year after the first neural reactions had been communicated to the company, Grünenthal, added a warning to the package leaflet. After German paediatrician Widukind Lenz proved the connection between birth deformities and the intake of Contergan by pregnant women, the company finally withdrew the pill from the market (Daemmrich 2002).

Parallel to those processes, the European Economic Community (EEC) started to harmonise the legal framework for pharmaceuticals in order to create the preconditions for a single market. While member states' regulatory systems developed primarily to protect patients in the aftermath of the Thalidomide scandal, the underlying aim of the EEC regime was to liberal-

[33] The Food and Drugs Administration strictly followed the precautionary principle inscribed in its institutional guidelines and the drug was never marketed in the United States.

ise the pharmaceutical market throughout Europe. There have been numerous initiatives aimed at harmonising legal, scientific and administrative procedures governing the marketing of medicinal products, with a rapid pace of change during the 1990s.

One can distinguish three phases of developing a pharmaceutical regulation framework in the EU: (1) harmonisation of standards (1965−1990); (2) institutionalisation (1990s) and (3) consolidation (2000s). The first phase – the harmonisation of standards – started with Directive 65/65/EC and ended with the first revision of the pharmaceutical regulatory framework in the 1990s. Mandatory approval based on Directive 65/65/EEC based on the criteria of safety, quality and efficacy contributed significantly to the establishment of pre-authorisation controls of pharmaceutical products. In 1975, the first authorisation procedure was established by Directive 75/319/EEC, which was based on the mutual recognition of national assessments.[34] Directive 83/570/EEC introduced a simplified mutual recognition procedure and set up the Committee for Proprietary Medicinal Products (CPMP) comprised of representatives from the member states' regulatory agencies.[35] In this stage, rather than an independent regulator, the EU established a regulatory network in which national government officials exchanged information, coordinated national policies, and worked together to address common problems (Dehousse 1997; Majone 1997; Slaughter 2003). However, partial harmonisation of pharmaceuticals regulation and authorisation proved to be insufficient to harmonise access to the sin-

[34] The procedure allowed a company that obtained authorisation in one Member State (so-called reference state) to apply for recognition in other member states by asking the reference state to forward the copy of the original evaluation to other countries. This means that the EU procedure could only be started if the pharmaceutical product had already received positive authorisation from one member state. The other concerned member states had to decide whether they accepted the authorisation of the reference member state.

[35] CPMP served to provide scientific advice for pharmaceutical authorisation. If disagreements between member states occurred, it issued opinions.

gle market. "[T]he procedure was not popular with industry. Only 41 applications were made in the eight years it operated, and these were mostly for generic or 'me-too' products, rather than [new active substances]." (Abraham and Lewis 2000: 85) How to make the authorisation scheme more attractive for industry was conceived as the main challenge by European legislators. In 1988, the Association of the British Pharmaceutical Industry published its influential Blueprint for Europe with explicit demands for change in the authorisation process towards faster approvals.

The phase of institutionalisation started with the revision in early 1990s and climaxed in the installation of the *European Agency for the Evaluation of Medicinal Products* (later replaced by the *European Medicines Agency*). The policy developments between 1990 and 2000 strongly focused on procedural and approval aspects of the regulatory system. Whereas national pharmaceutical policies were influenced by the fiscal responsibility dimension of the neoliberal paradigm, the EU regulatory framework was influenced by its liberalising dimension. Approval times became key features of a proposed new 'efficiency regime' in Europe. The Commission finally adopted a system that very closely resembled the original proposals by the pharmaceutical industry. Abraham and Lewis criticised the regime for its "neo-liberal corporate bias" in which industry interests entered the political arena and became part of the extended state, "a position from which other groups, even if they too held political power, were still excluded." (Abraham and Lewis 2000: 202) Industry favoured the efficiency regime of the European regulatory state because it accelerated and levelled out drug approval times and put pressure on national agencies to conform to the short deadlines laid down in EU regulations.

In the 2000s, the regulatory framework moved into the phase of consolidation and differentiation. The existing regulation was integrated and further deepened. The *European Medicines Agency* assumed new competences in relation to pharmacovigilance, including a single

drug safety database. Consequently, this period saw the cementing of the close cooperation between regulatory bodies and business which had emerged in the previous phase. A different example of the pressure of the pharmaceutical sector was Directive 2001/20/EC (so-called Clinical Trials Directive) laying down principles and detailed guidelines for good clinical practice as regards "investigational medicinal products" for human use, as well as requirements for authorisation of the manufacturing or importation of such products.

"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)

Krapohl (2008: 26) argues that the pharmaceutical sector has been successful in promoting its interests because it has not suffered from any crisis of consumer confidence and consumers as well as producers of medicines are satisfied with the authorisation process. However, the current wave of criticism shows that the public climate has been changing. A Patient View (2013) survey exploring the opinions of 600 international, national, and regional patient groups from 56 countries (72% from Europe) indicates that the overall reputation of the pharmaceutical industry declined in recent 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) Furthermore, the EU regulation of clinical trials has been largely criticised for a lack of public access to information, selective reporting and changes to the trial protocol, too much stress on the commercial development of pharmaceuticals and inadequate inspection and monitoring (Gøtzsche 2012). The risk

assessment practice of the *European Medicines Agency* also has been a target of heavy criticism since it relies too much on documents written by pharmaceutical companies (Goldacre 2012).

CONCLUSION: PHARMACEUTICAL REGULATION IN THE EU CONTEXT

The EU cannot directly influence drug prices or prescription policies. On the other hand, important concerns such as patent protection, advertising, wholesale distribution, the content of package leaflets and labelling, are covered by EU policies. Permanand and Mossialos (2005) point out that, despite the existence of the 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 Scharpf's (2002) classical hypothesis of constitutional asymmetry in the European social policy model.[36] In the field of drug authorisation, European legislation creates

[36] 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) The hypothesis of constitutional asymmetry is considered to be an attempt to complement existing explanations which focus exclusively on purposive agency by analysis of the (institutional) structure within which agents must define their strategic choices. According to Sharpf (2010), European policy is a highly structured field where processes, decision rules and institutions are bound to create strong asymmetries, favouring 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 other words, 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 point out, that Sharpf reconciled the effects of structure and agency on European policies only partially. "It (constitutional asymmetry) offers an

a very strong regulatory framework, while in the field of pricing and movement of goods, the European Commission remains quite weak. Whereas hard law prevails in the former area, soft methods of coordination are applied in the latter one. As result, the centralised authorisation procedure allows very fast and flexible introduction of new pharmaceuticals, while the pricing and limits of free movement guarantee each member state control over access to and prices of pharmaceuticals. European pharmaceutical regulation is a combination of hard law (uniform rules for member states with possible sanctions) and soft law based on non-binding instruments of peer review, benchmarking, and persuasion.[37]

With emphasis on accelerating approval and access to modern pharmaceutical products, the European Commission can be counted as a strong institutional promoter of the social imaginary of health hopes, namely in its biomedicalised mode. Nevertheless, the neoliberal discourse of fiscal responsibility is present in the liberalisation aspect and in the understanding of the industry as a vehicle of technological progress. This configuration led to a neoliberal corporate bias of the European regulatory state. The industry as a policy entrepreneur was able to use the open 'policy window' and capture the transformation of regulatory networks into independent regulatory agencies and took control over the processes of marketing authorisation. In

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understanding of the apparent policy deadlock, but provides little insight into stakeholder behaviour within it." (Permanand and Mossialos 2005: 689) Wilson's (1980) 'politics of policy' typology helps them understand how stakeholders pursue their interests. Wilson classifies policy proposals for regulatory interventions according to the perceived distribution of their economic and non-economic costs and benefits among involved parties with regard to existing institutional frameworks (see Chapter 2).

[37] Furthermore, the impact of global players cannot be overlooked either. For example, King (2007: 186) mentions the influence of US Food and Drug Administration (FDA) on investigation by EU regulatory bodies. There is also a significant influence of international organisations such as WTO on intellectual property rights and patent protection, or WHO on vaccination.

contrast to the 1980s crisis of integration, it seems that the current framework is starting to suffer from a crisis of confidence. It is still a question whether the crisis will be profound enough to open new policy windows and create critical junctures to push through a new institutional solution.

On the other hand, pharmaceutical policies of individual member states seem much more concerned with tackling the fiscal responsibility horizons than the horizons of health hopes. As Castles (1999) reminds us, since the 1980s, there has been a consensus among developed states that cost-containment policies are inevitable. However, the primary dynamic ceased to be one between policy expansion and policy retrenchment, but rather one between individualist market-oriented tools and hierarchy-oriented tools of policy retrenchment. However, it cannot be said that the horizon of health hopes is completely missing in national regulatory frameworks. Its influence cannot just be ignored and governments need to seek for ways to take it into consideration in policy proposals and their justifications. Both dynamics, the one between market-oriented and hierarchy-oriented tools and the one between the horizons of health hopes and fiscal responsibility, are explored in the following chapter that analyses transformations of Czech health policy after 1990.

CHAPTER 6.
NARRATING REGULATION IN TRANSFORMATION – A CASE STUDY OF THE CZECH REPUBLIC

Justification in public discourse is an inevitable part of the policy process when states attempt to regulate accelerating markets. In this process, policymakers define problems to be solved and attribute qualities to good policy. Discursive imaginaries and cultural codes play an important role in defining and solving problems and in attributing qualities. The latter are constantly negotiated, and to analyse them is essential for understanding the processes and ways in which different actors take control of political debates.

The last part of my dissertation examines a public discussion on pharmaceutical policy reform in the Czech Republic between 1990 and 2008. 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 organisational structure and outdated 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, investing in technology and improving health facilities. In the next period between 1997 and 2001, the consolidation of regulatory frames was dominant. The period between 2002 and 2005 was marked by conflicts between different stakeholders over regulatory rules and their application. The empirical analysis is closed by a description of the Tomas Julinek's neo-liberal reform of 2006–2009.

I decided for this time period because it covers one cycle of the regulation history. The cycle began with the crisis of the system, followed by setting a new regulatory framework, its consolidation and internal crisis, and concluded with a new critical moment and an attempt to reform the framework. Such a timeframe allowed me to examine unfolding regulation narratives and continuous interplays between different discursive imaginaries and cultural codes over the entire policy cycle. It provided me with a sufficient corpus of data to answer the ques-

tion of how competing social imaginaries and cultural codes shaped the institutional setting of the regulatory framework.

A BRIEF HISTORY OF HEALTH CARE TRANSFORMATION

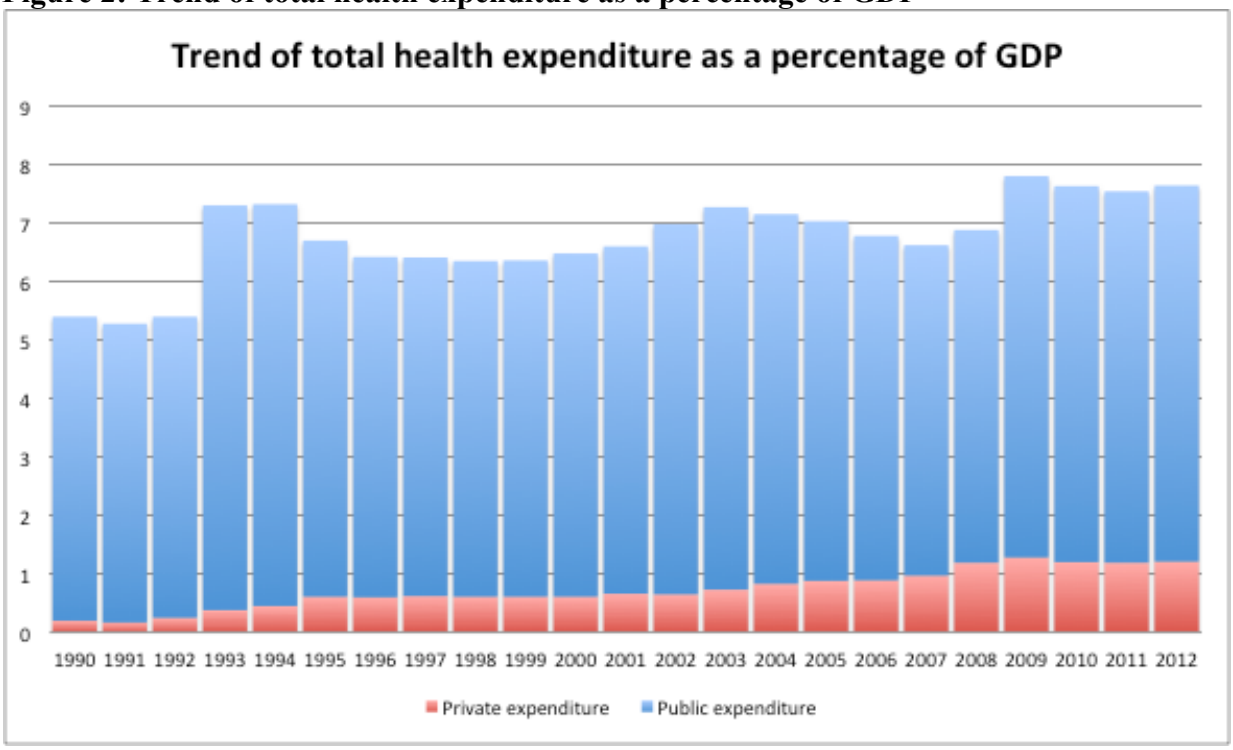
Until the fall of communism in 1989, the Soviet Semashko model of health care provision existed in the former socialist countries of Central and Eastern Europe. It was a centralised, tax-based health care system with physicians as state employees. In the 1960s, this system reached its limits and its rigidity limited its responsiveness to emerging health problems. Consequently, the main health status indicators stagnated between the 1960s and 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 at al. 2011: 18)

After 1989, the Semashko model was replaced by a universal-coverage public health insurance system. In the Czech Republic, the insurance package is rather generous and encompasses necessary health care. Němec et al. (2013) identified as the main problem of the Czech health insurance system the combination of pluralist provision of health insurance with 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 "insured by the state" (persons who lack income like students, pensioners, prisoners) the cabinet decides on the per-capita amount to be contributed. At present, almost 60% of all those insured in the system are insured by the state. The share of private health insurance is rather negligible; coverage of the public health insur-

ance scheme is comprehensive and there is little space for deployment of viable and profitable supplemental health insurance products (Němec et al. 2013).[38]

As shown in Figure 2, the Czech Republic has been witnessing relative stability of public health care expenditure as a share of GDP since the early nineties, and a growth of private expenditure. However, the share of private expenditures is still relatively low in comparison with Western European countries. In terms of total health expenditure compared to GDP, one can see a steep increase in the first transformation period followed by a slightly increasing trend in next years and peaks in 2003 and 2009. Health economists (Němec et al. 2013) explain the former increase by the fact that the Czech health care system was rather liberal in the early nineties, on the one hand, and heavily reliant on public funding, on the other hand.

Figure 2: Trend of total health expenditure as a percentage of GDP



Source: National Institute of Public Health.

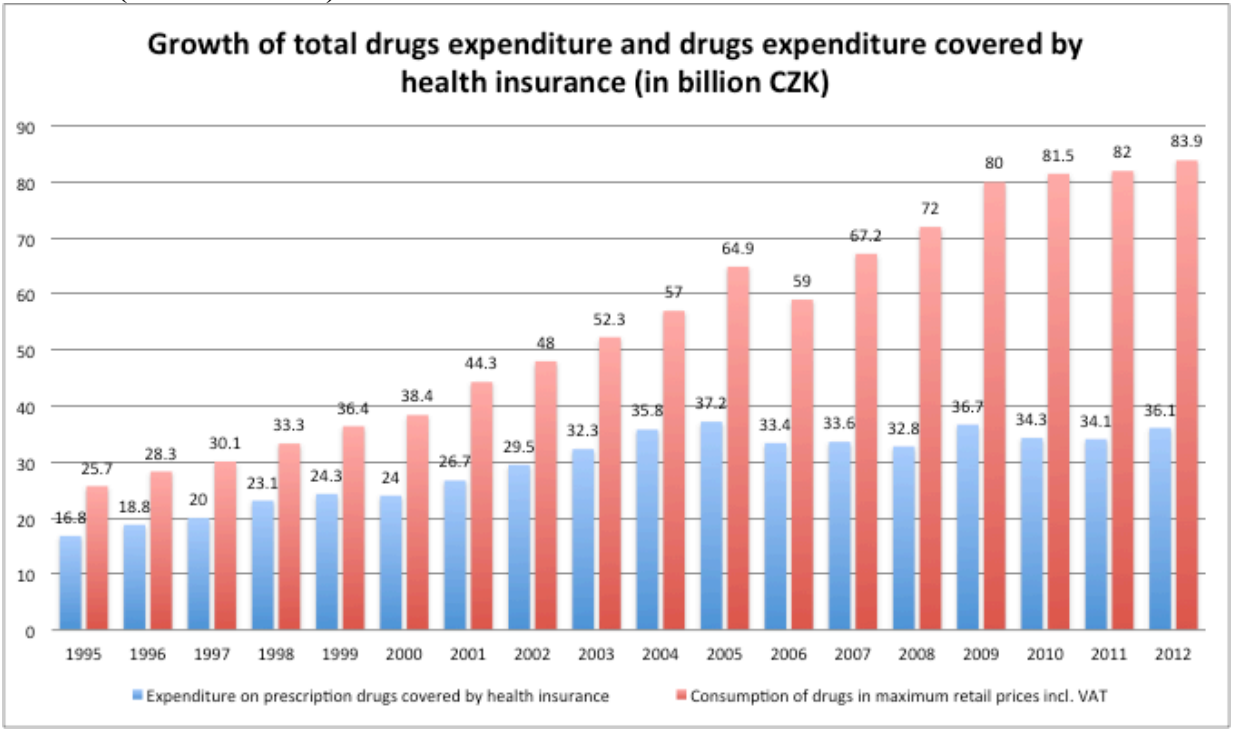
[38] Němec et al. (2013) estimate the total volume of premiums collected for the category of private health insurance products is less than 1% of total health care expenditures. Private insurance plays a major role only for persons not qualified for the public health insurance scheme, for example non-EU nationals without formal employment.

However, in general, the share of health care expenditure in gross domestic product more influenced by the volume of GDP than by nominal expenditure. The following picture (Figure 3) illustrates the nominal volume of health care expenditure on the case of pharmaceuticals, which exhibit a steady growth. Nevertheless, the increasing trend in overall consumption was not matched by consumption covered by health insurance. At least since 2006, the amount of health insurance money covering pharmaceuticals has been stagnating. Although the overall consumption has been rising, the expenditures of the health insurance system have remained approximately the same.

The share of private expenditure is increasing steadily because of higher levels of cost sharing in the public health insurance scheme.[39] For example, public insurance covered 82% of total expenditure for drugs in 1996 but less than 59% in 2011 (Němec et al. 2013). From the historical point of view, even if the Czech system predominantly relies on public funding, the relevance of private money has been strengthening throughout the transformation period.

[39] Cost sharing is required for selected drugs, dental services and some medical aids.

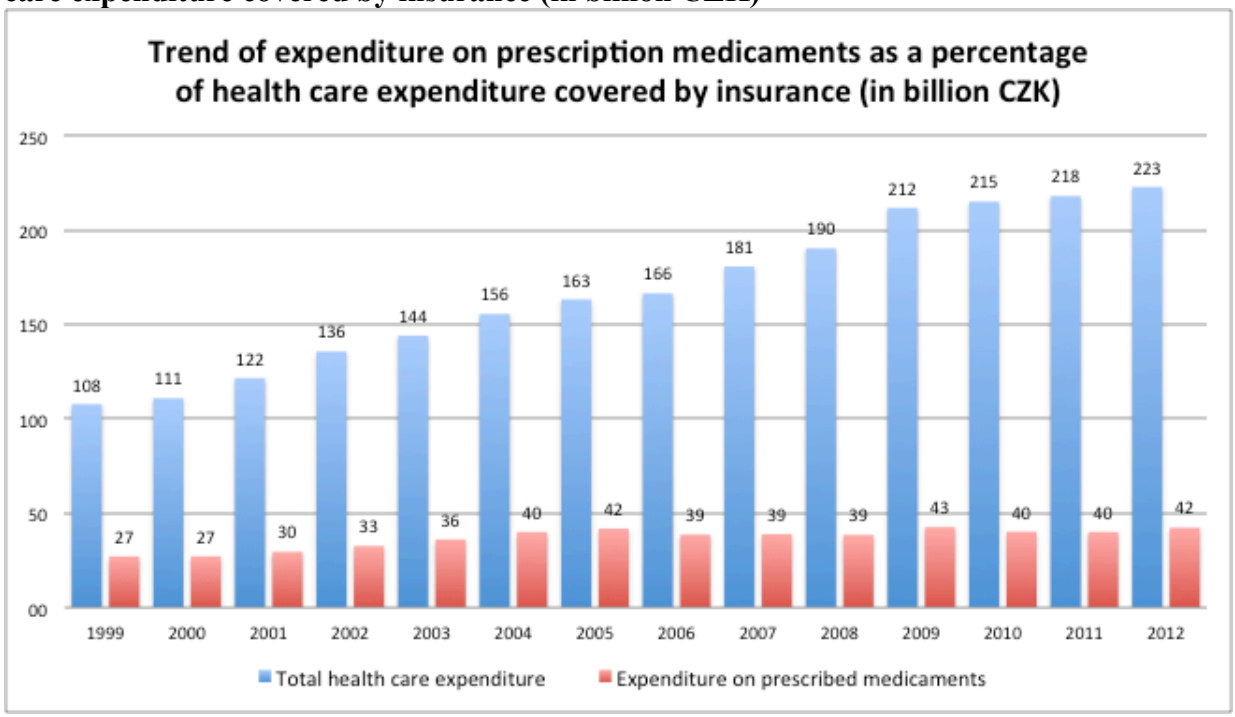
Figure 3: Growth of total drugs expenditure and drugs expenditure covered by health insurance (in billion CZK)



Source: National Institute of Public Health

The same trend could be identified also in the proportion of expenditure on prescription medicaments in total public insurance expenditure on health care. Even though the expenditure on other segments such as outpatient care, inpatient care, dental care or prevention programs has been increasing, the costs of prescription pharmaceuticals have been stagnating. In 1999, they made up approximately 25% of the health insurance budget, compared to 19% in 2012. The significant drop happened between 2005 and 2008.

Figure 4: Trend of expenditure on prescription medicaments as a percentage of health care expenditure covered by insurance (in billion CZK)



Source: Czech Statistical Office

Generally speaking, economic data indicate that regulation was somehow able to cope with increasing expenditure in the mid-1990s, revealing an increasing trend in private expenditure. The statistical patterns, however, provoke questions about what kind of institutional tools were behind these trends and how those institutional tools were justified in the public arena. My analysis focuses on the institutional and narrative dimensions behind these trends. Private expenditure – something completely missing before 1989 – became an inevitable part of the Czech health care system. I assume that this change could not be related only to the introduction of different rules but also to changes in our ways thinking and narrating about our institutions and the character of our social order. How did rising expectations from health care contribute to the post-socialist liberal welfare state and did the state, constrained by fiscal pressures, manage to cope with them? Generally speaking, how was the post-socialist welfare state narratively constructed? This chapter seeks to understand how the reforms were justified to the

general public. The analysis is organised around the identification and analysis of narrative patterns and collections of categories in discussions about pharmaceutical regulation reforms.

APPLYING THE METHODOLOGICAL FRAMEWORK

The analysis examines the frames of pharmaceutical regulation in the Czech Republic between 1990 and 2008. It uses the narrative approach described in Chapter 1 and the cultural codes theory (see Chapters 1 and 2) to classify, chart, and compare argumentation patterns and policy values. I put emphasis on the factor of time – how regulation narratives evolved throughout the time period analysed. My aim is to explain the role of narratives in institutional change in a particular historical period. Methodologically, my approach could be described as interpretive historical institutionalism. I borrowed from historical institutionalism an emphasis on time and historical specificity as well as a focus on dynamics in public policy. However, in contrast to most historical institutionalists, who have been strong proponents of positivist social causation, I focus more on ideational aspects of institutional life. I study how the language of regulation has evolved and how it has shaped the institutional framework.

As I demonstrated in Chapter 3 and Chapter 4, the expectations of and thinking about modern health care have been influenced by two dominant discursive imaginaries – the discourse of health hopes and the discourse of fiscal limits – which both define the imaginable horizons of policy solutions. Alongside cultural codes, I focus on how these dominant imaginaries structure debates at a particular national level. Given this ambition, the analytical phase of my research has been organised along the following lines:

1. discursive imaginaries defining the horizons of policy solutions (Foucault 1985; Rose 2000; Howarth and Stavrakis 2000; Laclau 1990; Norval 2000) – the discourse of health hopes (see Chapter 3) and the discourse of fiscal limits (see Chapter 4);

2. cultural codes – the value system of four core codes (Douglas 1992; Thompson, Ellis, Wildavsky 1990; Hood 1998; Lodge, Wegrich 2011) and its application to the vocabularies of regulation (see Chapter 2);
3. elements of narrative practice – dramatic moments, symbols, characters, plots, equilibria and disequilibria, designing causes and identifying consequences (see Chapter 1);
4. categories and collections of categories – category-bounded activities and hierarchies of relevance (Lepper 2000), labelling situations and measures and qualifying them as problems or solutions (Zittoun 2014) ;
5. Elements of discursive practice (Yanow 2000; Hajer 2009) – metaphors, discourse coalitions, emblematic issues, citations, etc.

In my analysis, I aim to reconstruct the trajectories of arguments made by different actors. This type of coding helps me reconstruct the main policy storylines. In analysing utterances, I put emphasis on the ways in which they articulate answers to the following questions: (1) what regulatory failures are identified; (2) what norms justify regulation; (3) what tools are preferred within a particular regulatory regime; (4) who should benefit and lose from regulation; (5) what are the internal and external limits of regulation; (6) what are the cultural patterns behind regulation. In each of this segment, particular attention is paid to how blame is prescribed.

Cultural theory's system of four core codes – hierarchism, individualism, egalitarianism, and fatalism – is used as an analyst's compass into the landscape of frames that comprises the patterns of blame and proposed remedies and integrates narratives into a broader moral order of society. My analysis of argumentation I extract claims demanding particular types of regulatory action, and categorise these claims according to cultural codes (Lodge, Wegrich, and McElroy 2010; Lodge and Wegrich 2011).

The individualist cultural code was indicated by concepts such as: *perverse rules*, *market-based solution*, *competition*, *effectiveness, patients as consumers*, *self-regulation*, *individual responsibility*, *individuals as rational actors*, *individual choice*. The hierarchist code was captured by concepts such as: *corruption*, *need for prudential regulator*, *expand scope of regulation*, *strengthen existing institutions*, *central role of government* and *expertise*. The fatalist code was identified with concepts such as: *crisis always happens*, *inevitability*, *nobody has any idea what is going on*, *unpredictable effects*, *regulators will always fall behind markets*, *regulation will always be undermined*, *population ageing* and *the EU wants it.* The egalitarian code was indicated by concepts such *clientelism*, *abuse of power*, *information sharing*, *inequalities*, *access to health care* and *participation.*

The imaginary interlinking the variety of hopes of diverse actors fuels the discourse of health promises as a matter of both citizens' rights and their choice and responsibility. In my analysis, I connected this type of imaginary with concepts such as *better patient care*, *transformation and modernisation of medicine*, *medical innovation*, *no more dependence on inefficient care*, *health for future*, *better value for patients*, *patient-centred care*, *life style* and *obesity*.

The fiscal responsibility discourse can be characterised by the co-existence of traditional individualist, liberal approaches with hierarchist, *étatist* ordo-liberalism. In my analysis, I connected this type of imaginary with concepts such as *increasing government debt*, *healthcare spending*, *spending limits, fiscal future*, *unregulated monopoly*, *concerns about future of system*, *self-interested private actors*, *free market ideology*, *collapse of public system*.

The corpus includes articles in newspapers and weekly magazines. With respect to the historical character of my study, I decided for media articles because they represent a coherent corpus of data written in the same genre and covering the entire period. Given its internal valid-

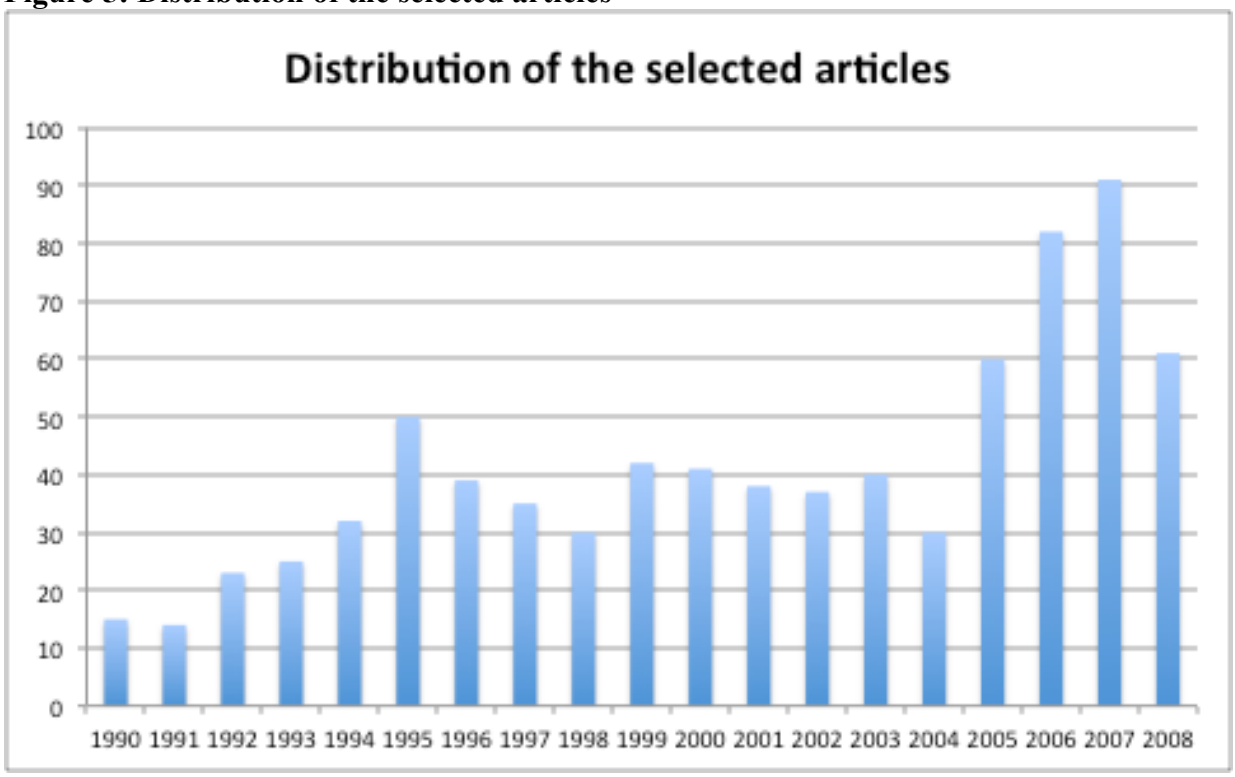
ity and comparability, I decided not to use different sources of data such as observation, interviews or focus groups. Including such data in the analysis would have made it impossible to distinguish the effects of time and the effects of genre.

Using Newton Media Search, 785 articles were extracted and coded along the conceptual lines developed in the previous theoretical chapter. For searching in media archive, the key words *pharmaceuticals*, *pharmaceutical*, *pills*, *health*, *hospitals, policy*, *law*, *pharmacy, the Czech Republic* and their combinations were used. The search covered the time period from the beginning of 1990 to the end of 2008.[40] From these search results, only articles related to pharmaceutical policy were selected for further analysis. The final corpus contained a broad range of genres – news articles, features, interviews with policy makers and practitioners, letters to the editor, etc.

[40] The Newton Media Search archive does not cover the period between 1990 and 1995 completely. For this reason, the corpus of data was enriched by using articles which had been scanned by the author from newspapers archived in the National Library Prague.

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

Figure 5: Distribution of the selected articles



The entire corpus also comprises the transcriptions of 14 debates on health care broadcast on Czech public TV in the weekly political debate series, "Questions of Václav Moravec". This series features representatives of political parties, relevant stakeholders and experts and provides them with a relatively sufficient space for discussion (each session lasts around 120 minutes), representing the main arena for public debates among top-level politicians in the Czech Republic. The entire 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 general public.

According to Chouliaraki (2005), the analysis of a television text poses two main procedural issues: (1) how to analyse 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, namely the linguistic and the visual. The focus here is on the discursive ideas that are presented in a debate; hence I deliberately decided to ignore the visual component of the debates. Dealing with the first issue was, however, much more difficult. I decided to organise the debates along same lines as the print media corpus. Although this solution suppressed the conversational features, it allowed me to put two different parts of my corpus under a single explanatory umbrella.

THE 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 national and regional health institutions were dissolved and health care facilities obtained a high degree of legal and economic autonomy. Even though the 1966 Act on Public Health Care still remains the core of health care legislation, it was amended by a series of reforms which either enacted new laws or amended existing laws.

In the period from 1990 to 1997, successful implementation of new medical technologies caused both a declining trend in mortality rates and a growing demand for investment in health. Life expectancy increased from 67.6 to 71.1 for men and 75.4 to 78.1 years for women, while 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 the first transformation years. Hand in hand with a dramatic increase in prices during the same period, spending on pharmaceuticals was rising rapidly.

In the general elections of 1990, The Civic Forum won more than half the vote and two-thirds of the seats in the Czech parliament. Neurologist 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 also from the Civic Forum, Bojar had a major reform plan. In relation to pharmaceutical policy, two main problems were identified by this group of policymakers and supported by the media: a shortage of modern medicaments and a breakdown of supply from the other socialist countries. The existing choice of pharmaceuticals was presented as insufficient and outdated. Furthermore, problems with supply started to pop up.

Problems with supply were caused by the fact that the Czech system relied too much on domestic production and the domestic pharmaceutical industry had a limited production capacity for certain drugs. On the Czech and Slovak market, a total of 45 drugs – including 11 imported and 34 from domestic manufacturers – were missing.[41] In 1990, over 800 kinds of pharmaceuticals in 1,300 dosage forms were produced in Czechoslovakia. "Compared with developed countries, it is too much. Elsewhere, they produce half of that, and purchase the rest, because foreign pharmaceutical industry has got more room to develop new drugs," Jindřich Kadrnožka, Deputy Minister of Health, described. The Czech pharmaceutical industry was associated with backwardness, which was ascribed to lack of competition.

The health care system was portrayed as rigid, sclerotic and in need of replacement with a new flexible one. This need was also underscored by evidence of widespread public support for changing the previous health care system. Alongside western products, the future health care system was also identified with private elements. In a 1990 survey, 70% of the population endorsed privatisation 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 privatised. Moreover,

[41] Tomešová L: Proč chybějí léky? Rudé Právo (22 Jun 1990), p. 5.

28 private distributors entered the market just in the first year after the fall of the old regime.[42] Along with the distribution network, pharmacies were also privatised during the first transformation years.[43]

However, the transition towards a new health care system was not smooth. Sanitas as a main distributor of pharmaceutical products did not have the necessary funds to purchase pharmaceuticals abroad and there was no entity willing to guarantee a possible bank loan to the company. In the first half of 1991, the Institute for Public Opinion Research conducted a survey to identify the obstacles which people had to overcome in the procurement of pharmaceuticals: 20% of respondents mobilised networks of their friends, 18% declared that they were forced to cruise across numbers of pharmacies, 13% bought pharmaceuticals abroad, 5% asked a friendly physician for a favour, and 5% bribed physicians.[44]

"Distribution will probably change, but the point is that we have started up competition," Petr Palouš of the Ministry of Health summarised the first transformation year. Competition was a crucial characteristic of the upcoming new system. Policymakers declared that they did not know what the system would look like, but they started up competition. Competition was understood as a magic wand which can solve distribution problems. The concept of competition was based upon an important imaginary which followed the dictum of the Washington Consensus: to stabilise, to privatise and to liberalise.

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[42] Pergr, V.: Od ledna recept za pět korun (Interview with Petr Palouš, Director, Pharmacy Department, Ministry of Health), Rudé Právo (16 Dec 1991), p. 3.

[43] In the Czech Republic, nowadays, the privatisation resulted in the majority of primary and specialised outpatient care facilities are private, mostly run by independent practitioners. On the other hand, the privatisation of hospitals was stopped and most inpatient care is now under the control of regions and municipalities. The hospitals also run their own outpatient departments.

[44] Tomešová L: Sanitas na lopatkách? Rudé Právo (23 Aug 1991), p. 13.

The notion of competition allowed portraying the nascent system in a steep contrast with the hierarchical and sclerotic management of the past. The new moral order was articulated with a strong emphasis on the individualist code, with choice and competition as dominant values. On the other hand, the old system was described as hierarchist one, with a complicated system of rules and unequal access to health (as the communist *nomenklatura* had enjoyed a completely different health care than others). Perverse rules of state socialism were mentioned in contrast to market-based solutions. Individual responsibility and individual rationality were stressed in this code. On the other hand, there was a strong inclination to a social market model based on moral choice and solidarity. "Medication is not like a dress which you can buy when you don't need it. You must buy it. Many of us need our medication daily," the media reported.[45]

A new construction of patients' roles was intended to change hierarchical relations between patients and doctors into a partnership of equals. For patients, it also brought free choice of doctor and hospital. "Above all, communism affected the individual level and led to a decline of relations between patients and doctors," Minister Martin Bojar said in an interview for the Respekt weekly. This perspective brought also an emphasis on patients' responsibilities. In relation to patients' constructions, responsibility was also a key word of the first transformation years. This is a very important point. The hierarchical system based upon rules was to be abolished not only for its ineffectiveness but also for its morality, which had ruined the relations between patients and practitioners and produced irresponsible patients.

The competitive character of health care was also mirrored in the dominant construction of patients' roles. The media portrayed patients both as victims of the old regime, when modern care was just for the *nomenklatura,* and as pupils who had to learn how to use the new system.

[45] Tomešová L: Sanitas na lopatkách? Rudé Právo (23 Aug 1991), p. 13.

"The public should realise that health care is not for free. People will have to pay at least a part of their prices. However, we are going to categorise drugs. For painkillers and vitamins, citizens will pay more. However, for medicaments which people cannot choose to consume because they are dependent on them, there will be a rather symbolic co-payment," Minister of Health Bojar described the philosophy of the reform in 1991.[46]

This narrative evolved around the construction of co-payment and categorisation of pharmaceuticals as the main regulatory devices of the time period. Co-payments were presented as a natural and ideal state in which costs would be shared across the entire society so that modern care could be guaranteed.[47] Co-payments were also presented as a teaching tool for patients to use health care in a responsible way. In relation to their educational significance, co-payments as an institution did not have only their economic meaning but also a moral, symbolic one.

With respect to the stagnating health indicators and the perceived backwardness of socialist health care, the discourse of health hopes also represents an important social imaginary of the time period. The dominant imaginary was to shift away from an outdated and inefficient care towards modern and imported care. The legacy of backwards health care was predominantly conceived as a burden to alleviate. However, the costs of health care were not presented as a problem. The primary locus of health care transformation was modernisation, privatisation,

[46] Šindelářová M: Bojím se velkého třesku (rozhovor s českým ministrem zdravotnictví MUDr.Martinem Bojarem), Respekt (11 Feb 1991), p. 5.

[47] 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 categorisation 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.

competition and innovation as the ways in which health care services could be improved. In terms of future horizons, the original transformation horizon was definitely progressive. "We are not building the health care system for the next year, but for 2000 or rather 2003," Minister Bojar declared.[48]

Generally speaking, this narrative is connected with the post-communist discourse called "civic enthusiasm" by John Dryzek and Leslie Holmes (2000). 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 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) describe such a discourse.

In 1992, a liberal government led by the Civic Democratic Party (ODS) that replaced the Civic Forum oversaw the implementation of the new system. Twenty-seven insurance companies entered the healthcare market, far more than the market could bear.[49] The General Health Insurance Company (*Všeobecná zdravotní pojišťovna*) was established. The categorisation of drugs for reimbursement and co-payment was implemented.

The first categorisation decree was released in September 1992. Pharmaceuticals were divided into three groups: (1) fully covered from the health insurance system; (2) partially cov-

[48] Šindelářová M: Bojím se velkého třesku (rozhovor s českým ministrem zdravotnictví MUDr.Martinem Bojarem), Respekt (11 Feb 1991), p. 5.

[49] 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 Company. Currently there are nine insurance companies with no real competition, and many feel that the situation is not optimal.

ered from the health insurance system; and (3) non-reimbursable. In the first category, there were about 1,440 products (52.2%). The second category comprised about 970 drugs which were almost the same in terms of treatment effect, but different in price or in some other characteristic. The categorisation procedure determined to what extent the price of those drugs would be covered by the health insurance system and by patients themselves. The third group consisted of drugs that patients paid the full amount. This group included approximately 350 types of analgesics, vitamins, laxatives, etc. (12.7%). The categorisation was prepared by a committee that consisted of medical experts, representatives of the Ministry of Health and representatives of health insurance funds.

In 1993 and 1994, alternative narratives questioning the reform and criticizing the government appeared in the public discourse. Since such critical reflections of the starting reforms were underpinned by a strong individualist code, an "interpretive cacophony" emerged. In this period, what had been homogeneous policy narratives from the beginning started to scatter along different lines. Nevertheless, those different accounts did not question dominant social imaginaries as public policy horizons but rather they served to correct the dominant individualist code or for particular actors to build their positions.

Some expert groups, for example, used the hierarchist code to establish their position within the regulatory setting. Representatives of medical associations claimed that specific expert knowledge was needed in order to prescribe particular medicines, general practitioners did not have that knowledge, and indeed, a hierarchic order was needed. As a result of their pressure, prescription restrictions were established to control pharmaceutical spending. Only specialists were allowed to prescribe some of the most expensive drugs, and the most expensive drugs required approval by a physician reviewer. These limitations were discussed in the cate-

gorisation committee with representatives of medical associations.[50] This case illustrates that different cultural codes can operate under the same system. Whereas the individualist code was the order of justification within general public, the hierarchist code was used as a principle of ordering by particular, in this context professional, communities.

Using the egalitarian code as a challenge to the dominant individualist worldview, some critics pinpointed the negative social impacts of co-payments. An increase in co-payment for pharmaceuticals was criticised by the Czech Helsinki Committee, which warned against its possible impact on the financial situation of seniors. Minister of Health Luděk Rubáš dismissed this appeal with reference to an official statistic showing that the average Czech pensioner was spending 15 CZK for reimbursed medicines and 178 CZK for over-the-counter medicines.[51] The minister strictly refused to reflect social factors such as age or income in his co-payment policy. Health status was to be the only factor taken into considerations. Co-payments were also legitimised, in a fatalist sense, as inevitable. "There is no country in Western Europe where citizens do not directly contribute financially to their care," the Minister of Health declared.

Healthcare providers, on the other hand, still criticised bureaucratisation and a lack of communication. A physician complained in the Czech media: "I cannot imagine that in case of every medicine I prescribe I will be skimming through the two heavy books released by the ministry (in order to know the level of reimbursement). ... The question therefore is not whether

[50] According to Prokeš (2012), there are two reasons for such a tool: (1) guaranteeing appropriate diagnosis; (2) knowledge of both desirable and undesirable effects of the drug. It is supposed to increase cost effectiveness and patient safety. On the other hand, it may hinder health care accessibility and lead to overusing (more expensive) specialist health care.

[51] Pergr, V.: Loni důchodce zaplatil za léky na recept 15 a bez receptu 178 Kč, Rudé Právo (13 Dec 1994), p. 3.

or not doctors inform patients about the amount of co-payments for drugs, but whether they are able to do so because of the incompetent work of the staff of several ministries."[52]

However, in the beginning of 1995, increases in health care expenditure began to be discussed intensively and fiscal sustainability was foregrounded. "In 1994, absolute consumption of packaged medicaments increased by 22% compared to the previous year. Every citizen, including infants, consumed around 34 packages. It can be hardly said that it was due to an increase in prices. The Ministry of Finance sets the maximum prices once a year. Last year, prices even fell down by 2%. In 1985, the average price of a package was 13.65 CZK, compared to 50.20 CZK in 1993. ... This shift does not reflect a shift in prices, but a change in the structure of prescription drugs," Josef Suchopár, director of the pharmaceutical policy office at the Ministry of Health, explained.[53]

In comparison with the situation before 1989, three main changes occurred: (1) pharmaceuticals were no longer sold for prices lower than the production cost; (2) the Czech market opened up to foreign manufactures; (3) doctors could prescribe pharmaceuticals without significant restrictions. Two social imaginaries collided – the successful discourse of health hopes became a danger for the discourse of fiscal responsibility.

However, ministry representatives initially did not blame anyone. In line with the fatalist code, they considered a steep increase in expenditures as an inevitable and natural consequence of transformation of a post-communist health care system and as a proof of their success. In some way, this narrative could still be tied to narratives stressing the fact that the benefits of reform would be consumed by next generations. However, the fatality of this narrative

[52] MUDr. Ludvík Kychler, Valtice, Lékař neřekne pacientovi, kolik doplatí za léky, protože to neví, Z redakční pošty, Rudé právo (18 Apr 1994), p. 3.

[53] Šircová, Z.: Pojišťovny utahují opasky (lékařům), Týden (16 Jan 1995), p. 44.

made room for further regulation. Immense progress had been made in catching up with Western countries and modernising the system, and now came the time for regulation. The government's narrative used one of the advantages of the fatalist code – to justify changes without blaming anyone.

In relation to the steep increase in the expenditures, Minister of Health Ludek Rubáš from the right-wing Civic Democratic Party (ODS) declared faster and more intensive reforms of health care, including unpopular steps, in order to make health care provision much more effective. "The period of pressure from the left-wing advocates of gradual and slow changes to health care, too mild to citizens, has come to an end. The changes will influence even the community of medical professionals. The Civic Democratic Party criticised existing policy and is calling for much intensive and faster reforms now," Rubáš said.[54]

The original apolitical narrative, based upon shared discursive imaginaries of the individualist code, was newly reframed as a political struggle between the left and the right. The right-wing Minister Rubáš labelled some measures such as lower co-payments for the elderly as a leftist solution and put it in contrast to his plans. His proposed changes included prescription limits – the same solution was labelled as a left-wing proposal a decade later – and individual health insurance accounts. He expected to increase co-payments of patients to 20 or 25% of the overall health budget.[55] On the other hand, he refused the proposal made by the International Association of Pharmaceutical Companies (MAFS) to cover from health insurance only life-saving medicines.

[54] Pergr, V.: Rubáš chystá razantní změny i za cenu nepopulárních kroků, Rudé Právo (21 Feb 1995), p. 1.

[55] Pergr, V.: Rubáš: Za dva tři roky by pacient měl přímo hradit až čtvrtinu zdravotní péče, Rudé právo (15 Mar 1995), p. 3.

Rubáš's reforms plans were met with a heavy critique of medical professionals, who promoted solving the health care financial crisis by co-payments only. According to them, these were not proper right-wing solutions and echoed left-wing attitudes too much. Both the Czech Medical Chamber and the Czech Dental Chamber refuted to communicate with the Minister. The communication between the chambers and the government had to be revived by 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 Jan Stráský replaced him.

In 1995, a reference pricing system was introduced in the Czech Republic, setting maximum prices for reimbursement by the health insurance funds. The reference price was calculated on the basis of the amount of substances contained in each pharmaceutical product. The unit cost of each substance was defined by a ministerial decree while the law laid down basic principles. The reference pricing system helped slow the growth in expenditures: although the General Health Insurance Company's *(VZP)* per capita spending on drugs had risen by 39% in 1994 and even 43% in 1995, the increase slowed down 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 the supply chains. At the end of 1995, health insurance companies owed pharmacies almost 320 million CZK. According to the Czech Pharmaceutical Chamber, six insurance companies owed more than 20 million to pharmacies (in average 250,000 CZK per pharmacy) and the biggest pharmacies had each up to three million CZK in accounts receivable[56] In general, pharmacies and hospitals owed almost one billion CZK to pharmaceutical distributors because of delays in

[56] Pechová, R.: Lékárny chtějí platby v hotovosti. Lidové noviny (11 Nov 1995), p. 5.

payments from health insurance companies.[57] "In areas where the majority of people are insured by one of those insurance companies, pharmacies do not have the money to buy pharmaceuticals," Jan Horacek, spokesman of the Czech Pharmaceutical Chamber, explained. Pharmacists declared to be ready to collect payments for pharmaceuticals in cash directly from people. "We prefer to violate the law and risk our licence," Jindřich Oswald, president of the Czech Pharmaceutical Chamber, said. The government approved an amendment that would guarantee 80% of the debts of insurance funds in bankruptcy.

At the same time, a different problem emerged on the supply side: particular medicaments were running out in pharmacies. In order to get their products on the top of the list of fully reimbursed drugs, pharmaceutical companies pushed their prices down drastically. However, the demand was higher than expected and the companies were unable or not willing to deliver such a large amount of packages. "The possibility to get at least one medicament in every group fully covered by the health insurance system has become only theoretical because of the absence of fully covered drugs on the market," the Czech Pharmaceutical Chamber warned.

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

The General Health Insurance Company (*VZP*) warned that physicians had begun to prescribe more care than patients actually needed in an effort to raise their own revenues. In addition to its warning, the insurance fund also proposed three regulations: (1) lower payments to doctors exceeding the average number of medical procedures; (2) penalisation of doctors

[57] Pergr, V.: Nemocnice dluží za léky miliardu Rudé Právo (4 Aug 1995), p. 2.

prescribing more pharmaceuticals than the average; (3) lower per-day payments for hospitalisation.

The beginning of the year 1996, which was also a parliamentary election year, was marked by ongoing struggles between the government and representatives of medical professionals, mainly the Czech Doctors' Trade Union *(LOK-SČL)* led by young and ambitious David Rath. In contrast to the pharmacists' narrative, *LOK-SČL* told a different story in two strategic documents (long-term and short-term) for Czech health care it published.[58] In their story, they blamed foreign pharmaceutical companies, on one hand, and patients' overconsumption, on the other hand, for the increasing expenditures. "Pharmaceutical companies will, as always, adapt and reduce their extraordinary profits in order to keep their products fully covered. ... Reducing the margin of distributors and pharmacies will stimulate the sales of cheaper drugs," *LOK-SČL* representative Milan Kubek publicly declared.[59]

Kubek[60] described the problem with patients' irresponsibility in the following 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 problem lies in patients who are convinced that foreign medicine is always better than a Czech product."

LOK-SČL proposed to reduce prices for all drugs by 5 or 10% and introduce 10 or 20 CZK user fee for each prescription. *LOK-SČL* intended thus to solve the main problem of Czech health care provision – low wages of doctors and nurses. In its individualist vision, the

[58] 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.

[59] Kubek, M.: České zdravotnictví je nadále vážně nemocné, Hospodářské noviny (25 Jan 1996), p. 9.

[60] Kubek, M.: Nemravnosti obchodu s léky, Právo (29 Feb 1996), p. 4.

system was not working well because patients had not been educated enough, and money (or co-payments) could change that.

In its long-term strategy, *LOK-SČL* proposed to differentiate health insurance beneficiaries into 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-income groups. This negative solidarity was intended to motivate people to contribute more to the system and reward those who paid more. In the area of prescription, people in the basic type of insurance would get the cheapest pharmaceutical in each 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 price difference. Higher-income beneficiaries would be entitled to a refund of a part of those expenses according to their contribution to the health insurance system. In contrast to Rubáš's vision of pure health solidarity, which did not take social consequences into consideration, *LOK-SČL* framed health insurance as a reward to people who were successful in economic terms. It is paradoxical that this extremely individualist proposal was made by a trade union organisation. The Ministry of Health strictly refused the *LOK-SČL* proposal. It was clear that the Ministry was not willing to prepare any proposal like that one three months before parliamentary election.

All three narratives (proposed by the Czech Pharmaceutical Chamber, the General Health Insurance Company and the Czech Doctors' Trade Union) pointed out that competition and choice did not work in health care transformation. Whereas the former two narratives stressed that health care could not be associated with a free market and rules were needed, the latter narrative, proposed by *LOK-SČL*, blamed imperfect competition. This last narrative blamed patients for irresponsible behaviour, which had resulted from a lack of incentives. Pharmaceutical companies, hence, were able to misuse holes in the regulatory framework as

well as patients' attitudes. If patients paid the real price for pharmaceuticals they would opt for cheaper products instead of overpriced foreign products.

After the parliamentary election, a government was formed by the Civic Democratic Party (ODS), the Christian and Democratic Union – Czechoslovak People's Party (KDU-ČSL) and the Civic Democratic Alliance (ODA); Jan Stráský (ODS) was re-appointed as Minister of Health. In terms of pharmaceutical policy, the government promised to enact a regulatory mechanism on the supply side (categorisation and prescription control). Stráský ruled out any increase in patient co-payments. "I know that in Europe, patient contribution is around 25% of overall budgets, while it is just 8% in the Czech Republic. But a substantial increase would imply such a high social compensation that it makes no sense," the Minister said.[61] In the same interview, he also accepted the increase in pharmaceutical expenditure as a natural fact. Jan Stráský ruled out any further increase in co-payments because voters would not accept it. His statements were an important re-framing of the role of patients as voters – an active voice in policy making.

From the point of view of theory of regulation, whereas the first phase of transformation was framed mainly in the individualist code, the second phase, which began in 1996, was marked by negotiations between the individualist and hierarchist codes. In the first phase, a lack of competition was considered as the main problem by proponents of policy reforms, whereas in the second phase, a lack of order started to be considered as a problem, too.

This construction of policy rationales was shared across the political spectrum. Any increase in co-payment was considered unacceptable because of risk of losing voters, and policymakers focused their attention on the need to consolidate rules. This shift may have been

[61] Šircová, Z.: Stráský: Nový zákon o pojištění nezatíží pacienty vyššími platbami, Zemské noviny (7 Aug 1996), p. 9.

connected with a change in the general discourse about post-communist democracy, when the previous dominant discourse of civic enthusiasm was replaced by what Dryzek and Holmes (2000) called "disaffected egalitarianism". People were dissatisfied with the individualist code based upon choice and competition, concepts they considered as facets for new hierarchies and inequalities. "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 corruption and money politics that became central issues in Czech politics in the mid-1990s." (Dryzek and Holmes 2000: 1059) The change of discursive environments made room for policy narratives describing abuse of power and clientelism, based upon the egalitarian code, and narratives describing the necessity of expertise and rules, based upon the hierarchist code.

THE PERIOD OF CONSOLIDATION OF RULES (1997–2001)

In this period, important changes took place in the legal area. The main changes were connected with the accession of the Czech Republic to the European Union. The legal system was harmonised with EU law. Dlouhy and Hava (2003) called this period "the era of regulation" when an open system was quickly replaced by tight regulation. Changes in the reimbursement system ensured the essential modification of economic incentives for health providers. In particular, the fee-for-service system with its incentives for over-utilisation[62] was replaced by motivations to make it economically rational for physicians to minimise the volume and cost of services. Negotiations between health insurance funds and organised groups of pro-

[62] Specialists in outpatient services were still paid through the fee-for-service system, but with tight time limits and expenditure ceilings, which in practice meant budgeting of these services. (Dlouhý and Háva 2003)

viders at the national level were also introduced. The objective of the negotiations was to set fees and certain growth of expenditure ceilings.

In 1997, Act No. 79/1997 Coll., on pharmaceuticals, was passed. The act was considered as the crucial regulation covering the research, manufacture, preparation, distribution, inspection, and elimination of medicinal products and active substances. The new act was justified by the need to provide citizens with safe, effective and quality pharmaceuticals, make more accessible the remedies which did not threaten human lives, and bring Czech law in line with the EU's regulatory framework.[63] Ministry of Health was made responsible for the following: (1) preparing a strategy of assuring pharmaceutical supply; (2) setting detailed rules for research, manufacturing, and distribution of medical products for human use, including their registration, prescription and distribution; (3) authorising the use of the non-authorised medicinal products in cases of threat to human life; (4) publishing in the Bulletin of the Ministry of Health decisions regarding the approval of pharmaceuticals; (5) establishing an ethics committee to issue opinions on clinical trials of human medicinal products; (6) publishing a Czech Pharmacopoeia. (European Health Observatory 2000: 49) According to the Act, unconsumed pharmaceuticals were to be returned to pharmacies, which had to ensure their elimination. The obligation that patient information leaflets must be in Czech was introduced by the Act. Another new rule prohibited pharmacists from selling a medical drug to a person younger than 15 years.

Along with the Act on Health Insurance, the Act on Pharmaceuticals was intended to order and codify the institutional setting established after 1989. To make the system compatible with EU standards was another criterion of justification, which could be seen as an extension of the "catching up with Western countries" rhetoric of the 1990s. However, the discussion about

[63] Stráský, J.: První čtení zákona v Poslanecké sněmovně (4 Oct 1996)

rules in the hierarchical system also opened a discussion on positions of different actors involved in pharmaceutical policies and their institutionalisation in a regulatory framework.

The most controversial point of the proposal was selling pharmaceuticals outside pharmacies (for example in chemist's shops, groceries or petrol stations). The following case study serves to describe the emerging narrative in a greater detail, not only as a recapitulation of one controversy but also as an insight in the new vocabulary of regulation. In the original proposal, 156 out of 1600 non-reimbursable drugs were to be sold outside pharmacies. Advocates of the proposal stressed that this kind of liberalisation was usual in Western countries and could be seen as another step towards a modern pharmaceutical market. The proposal, which was presented in the individualist code as a way to give citizens easier access to pharmaceuticals for everyday conditions, with 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 exposed to greater risk when they get a medication without professional advice," Chamber spokesman Jiří Hlaváček warned.[64] In this narrative, the Chamber claimed clear boundaries between patients as lay actors and experts who could provide them with advice. This reframing was typical of this time period. Patients were supposed to be neither educated nor respected, but merely protected.

The Chamber also accused the Ministry of Health of being influenced by the lobbying of pharmaceutical producers and distributors.[65] The Chamber framed the discussion in a general critique of the path of health care transformation in the Czech Republic and, on the eve of the parliamentary election in 1996, it accused the government of being too individualist and captured by private firms. Its argumentation resonated with the general pre-election discourse

[64] Šircová, Z.: Nákup léků u benzinových čerpadel ohrozí pacienty, Zemské noviny (19 Feb 1996), p. 1.

[65] Česká lékarnická komora: Léky, to jsou miliardy, Profit (16 Apr 1996), p. 19.

of disaffected egalitarianism. "I argue that the Civic Democratic Party is responsible for the management of the resort, but it has not managed this task properly. We disagree with absolute domination of health care by the market and disagree with liberalism to the extent that it is currently applied," president of the Chamber Jindřich Oswald said. [66]

Pharmacists particularly mentioned a limited possibility to recall dangerous products from the market, a possible lack of advice from seller or dissemination of counterfeit medicinal drugs. The Chamber also insisted that pharmaceuticals were not a normal commodity and it was in public interest to distribute them through a professional network. The hierarchist code of justification also constructed hierarchical positions along with different kinds of risk as rationales to take control over the process, and along with a particular type of knowledge.

"Weakening of the position of pharmacies has brought an extremely important negative effect. Bypassing pharmacies means losing an important feedback. Pharmacists oversee and examine whether the packaging is intact, whether the drug produces the expected effects, and also whether the expiration date did not pass. They provide patients with necessary information as they request. Last but not least, they also check whether the doctor prescribes medication properly, especially when it comes to the amount of the active ingredient," president of the Chamber Jindřich Oswald enumerated. [67]

This discussion resulted in a kind of compromise. Some medical drugs were withdrawn from the list of freely distributed products – for instance aspirin because of a risk of gastric ulcer bleeding. Only certain medicinal substances were authorised for sale outside pharmacies. In comparison with the original proposal, the final law tightened the retail conditions; for exam-

[66] Lékárníci zásadně proti vládní koncepci, Hospodářské noviny (1 Apr 1996), p. 1.

[67] Česká lékarnické komora: Za peníze a dražší, Profit (1 Jan 1997), p. 15.

ple, a special licence was required and inspection was supposed to be the same as in pharmacies. In the end, this possibility did not give rise to massive interest among entrepreneurs.[68]

The pharmacists also warned against the idea of pharmacies run 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 in a professional quality of services, and that established professional pharmacies would not be able to compete with sellers pushing prices down at the expense of quality of staffing.[69] In the beginning of 2001, a battle between the Czech Pharmaceutical Chamber and representatives of drugstores burst out in the public discourse. The Chamber did not approve a licence for a pharmacist-in-chief in Brno who intended to run a combination of 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 uneducated staff from the rest of the shop who would also provide them with advice. On the other hand, the firm behind the pharmacy argued that the Chamber could evaluate merely the personal qualification of the pharmacist-in-chief, not technical parameters. It brought the Chamber to court for breach of competences. The court agreed with the firm. In 2004, the first drugstore combined with pharmacy was finally opened.

The ban on dispensing pharmaceuticals directly by physicians was another problematic issue in the new law. "Such a practice existed 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," a regional Health Officer informed.[70] Even the Ministry of Health admitted that due to

[68] O prodej léčiv už nemají podnikatelé velký zájem, Mladá fronta DNES (13 May 1998), p. 1.

[69] Cikrt, T.: Lékárna, anebo drogerie?, Zdravotnické noviny (30 Mar 2001), p. 16.

[70] Havlík, K.: Zákon o lécích trápí šumavské lékaře, Právo (24 Mar 1998), p. 12.

the new rules, the accessibility of pharmaceutical had deteriorated for ordinary citizens.[71] The prohibition of distribution of medical drugs to persons younger than 15 years was met with a critique too. "For example, mothers who are sick at home cannot send their child to pick up a medicament. They often have to ask for help their neighbours," one pharmacist complained.[72] In contrast to the previous story, these cases revealed one contradiction of the hierarchist order – it was inflexible and inclined to regulatory ritualism when more and more specific standards were making the system of rules unreliable and unserviceable. The ministry, therefore, proposed an amendment allowing pharmacists in rural areas and small towns to open dispensaries as well as to dispense, in some cases, medical drugs to children younger than 15 years. Even though the hierarchist code was becoming dominant in this period, it was constantly being confronted with an individualist critique of perverse rules and bureaucratic colonisation of everyday life.

In 1997, Act No. 48/1997 Coll. and additional legal norms were introduced. The new law defined 521 groups of reimbursable pharmaceutical products, based on an anatomic, therapeutic and chemical criteria, and specific conditions for reimbursement in each group. The level of reimbursement for substances covered by the Act was to be defined by a ministerial decree. The decree was updated regularly based on recommendations from the ministerial *categorisation committee* – an expert body with representatives of medical associations and chambers, health insurance funds, government and patients associations. Both maximum and reference prices were determined by the Ministry of Finance.[73] Based on the decree and the decisions of

[71] Ministerstvo zdravotnictví uznává, že dostupnost léčiv se zhoršila, Zemské noviny (18 Apr 1998), p. 2.

[72] Pavlovský, P.: Děti nedostanou v lékárně ani léky na předpis?, Mladá fronta DNES (5 Mar 1998), p. 3.

[73] Until 2003, the Ministry of Finance also set the maximum price of non-reimbursable pharmaceutical products.

the Ministry of Finance, the General Health Insurance Company (VZP) issued a complete list of reimbursable pharmaceutical products.

The June 1998 elections brought five parties into Parliament. Miloš Zeman's CSSD won, but Václav Klaus's ODS was not far behind. This led to an agreement between ODS and CSSD which was dubbed the "Opposition Agreement". 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 Milos Zeman's government, Ivan David became the Minister of Health. David went on with the construction of vulnerable patients who had to be protected against commercial interests.

Ivan David declared an intention to pass additional regulations. *Inter alia,* the minister sought to reduce the number of groups in which at least one pharmaceutical had to be fully reimbursed, arguing that the taxonomy was too detailed compared with other European countries. He blamed pharmaceutical companies for taking advantage of such a complicated scheme. "For example, one pharmaceutical can appear in several groups. As a result, we pay for several drugs with the same effect but with significantly different prices. Thus, foreign pharmaceutical companies are guaranteed full payment, although, in terms of drug efficacy, they do not bring any benefit," Ivan David explained.[74] David also intended to reduce the profit 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 an external threat. At that time, a metaphor presenting the Czech Republic as a gold mine first appeared, while the imaginary of health hopes disappeared almost completely. Policies were oriented almost exclusively on fiscal stability and balancing health budgets.

[74] Vláda chce výrobce léků přimět ke snižování cen, Hospodářské noviny (28 Jan 1999), p. 1.

However, Minister David's key proposals were refused by the Parliament because of his inability to form any functioning coalition with key stakeholders in the sector, and Ivan David was dismissed at the end of 1999.

In 1999, health insurance funds were allowed to set spending limits for pharmaceuticals for each health care provider and impose penalties in case of overspending. In the same year, the Parliament voted for a new law regulating advertising and transposing European Directive No. 92/28/EC, and a new law bringing intellectual property regulation in line with TRIPS standards (Agreement on Trade-Related Aspects of Intellectual Property Rights) pushed by the WTO. Furthermore, the Act on Pharmaceuticals was amended to comply with EU regulation passed between 1999 and 2004.

In terms of pharmaceutical policies, representatives of the Ministry of Health declared that it could not be expected to push prices further down. The Ministry pointed out that Turkey was only European country where prices were lower than in the Czech Republic. They proposed stricter reference pricing, a list of necessary drugs, reducing the margin for distributors and pharmacists, user fees per prescription, positive lists for hospitals, stricter antibiotics regulation, national programmes of the pharmacotherapy of rare diseases with extremely expensive treatment, prescription guidelines, and a system of information feedback.[75]

Europeanisation also appeared in the public discourse,[76] bringing to life various examples of nationalisation of patients. In 2000, the discussion culminated when the Cabinet submit-

[75] Podstatných úspor ve výdajích na léčiva lze dosáhnout dobrou antibiotickou politikou, Zdravotnické noviny (17 Sep 1999), p. 1.

[76] For example: Náklady na léky musí růst pomaleji, Hospodářské noviny (29 Dec 1999), p. 5; ČR slaďuje ochranu patentů, Zdravotnické noviny (19 Nov 1999), p. 12; Speváková, Š: Česká kúra pro léčiva, Ekonom (25 Mar 1999), p. 14;

ted an amendment of the patent law extending the protection of original products by five years. Domestic manufactures, therefore, asked for compensations and a possibility of testing generic drugs even in the period when the original patent was still valid. On the other hand, representatives of foreign pharmaceutical companies were, indeed, strong advocates of the new regulation. From the narrative point of view, however, the media did not frame this controversy as a battle between domestic and foreign producers but rather as one between the national interest and the EU.

THE PERIOD OF CHAOS AROUND CATEGORISATION (2002–2005)

In 2002, the process of categorisation came under fire from different stakeholders. The Ministry led by Social Democrat Bohumil Fišer changed arbitrarily the committee's decision on reimbursement levels and was met with a wave of protests by both pharmaceutical firms and expert bodies.[77] In a nutshell, the committee decided which pharmaceuticals would be fully covered from the health insurance system, and for this reason, it came under careful scrutiny and critique of a variety of stakeholders in pharmaceutical policy. The ministry pointed out that the categorisation committee followed only medical criteria, in contrast to government policy that took also social criteria into consideration. "In some cases, the Minister must assess to what extent the expert decision is in line with political intentions and whether the ministry can identify with the expert decision," Deputy Minister of Health Michal Pohanka explained.[78]

[77] Cikrt, T.: Kategorizace léčiv: Výrobci protestují, ministerstvo ale považuje svůj postup za správný, Zdravotnické noviny (15 Mar 2002), p. 8.

[78] However, pharmaceutical expert and 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.

The ministry insisted on the construction of a vulnerable patient and used this construction to justify corrections to the reimbursement decision. In this particular case, the ministry used an egalitarian grammar of moral choice to justify its objections to a strictly hierarchist evidence-based policy. The ministry could not compete with the expert committee in the medical discipline but it could underpin its authority as a political body taking the social aspect into consideration and contextualising its expert decision.

This controversy brought attention to the way in which the reimbursement decisions were produced. The decree was very often described as a product of the committee only. However, critics challenged procedural aspects and foregrounded particular points of uncertainty. Instead of one decision, there was a series of translations between the committee decision and the released decree by the ministerial department of pharmaceutical policy. The General Health Insurance Company *(VZP)* evaluated the list in relation to maximum prices. After this evaluation, the producers commented on the nascent decree. Although the entire process was presented as expert-driven and unambiguous, there was room for manoeuvre for political interests. During the process, approximately 80 or 90 changes were usually made. In contrast to the publicly available committee decisions, those changes were very often invisible and their author could be hardly traced.

"The Ministry has the right to disregard the Committee's decision when it is wrong. However, I have credible information that it was because of lobbying. Pharmaceutical companies hired lobbying agencies to promote their interests," pharmaceutical expert and member of the committee Jan Švihovec said.[79] His narrative strongly resonated with the private capture vocabulary based on client politics and the ongoing discourse of disaffected egalitarianism. He reframed the ministerial storylines of protecting public interests against one-dimensional expert

[79] Riebaurevá, M.: O lécích rozhoduje pár lidí, Mladá fronta Dnes (27 Feb 2002), p. 1.

decisions using the private capture narrative of how the ministry abused its power to promote private interests.

Švihovec was not alone in his complaints. Even the General Health Insurance Company *(VZP)* decried that the ministry had unexpectedly raised reimbursement for particular drugs against arthritis (rofecoxib and celecoxib), hepatitis C (ribavirin) and anti-obesity drugs (sibutramine and orlistat), implying additional expenditures in millions of CZK. Furthermore, Czech public television revealed a different case when the ministry granted an exemption to 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, but the critique continued. In 2003, pneumologists complained about a delay in categorisation of tiotropium for patients with chronic obstructive pulmonary disease (COPD). This medicament had been waiting for inclusion in the list for three years. Every time the Committee recommended putting this drug onto the list of fully reimbursed medicines, 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 there," Vice President of the Pneumological Society Viktor Kašák complained.[80]

In relation to pharmaceutical policy, Marie Součková pushed through amendments transposing European regulation into the Czech legal system. She prepared a new decree categorising pharmaceuticals and determining the levels of reimbursement, which was later rejected by the Legislative Council of the Czech Government for lack of compliance with both Czech and EU regulations.

[80] Kluzáková, P., Bláhová, I.: Kategorizaci léčiv především chybí transparentnost, Zdravotnické noviny (14 Nov 2003), p. 14.

Součková came under fire from her political opponents and her colleagues in the party. After she lost a Senate election, it was pretty clear that Social Democratic voters were not fond of her either. In April 2004, 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 profound programmatic changes were possible in this turbulent time.

Nevertheless, Milada Emmerová's policy triggered an avalanche of foreign firms' protests as she explicitly declared support to domestic pharmaceutical industry. "Thanks to the offer from the largest domestic manufacturer it will be possible to reduce the reimbursement of certain drugs without imposing additional burden on patients," the minister said.[81] The struggle between experts in the categorisation committee and the Ministry continued. Emmerová dissolved the committee for lack of confidence, using the same arguments as Minister Fišer. According to her, the decree which had been prepared by the committee burdened patients too much. Ultimately, the Ministry itself prepared a revised decree.

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. 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. MAFS lodged a complaint with the Office for the Protection of Economic Competition (ÚOHS), pointing out that the categorisation process infringed on the EU Transparency Directive with regard to selection of pharmaceutical products and decisions by controlling authorities. "Complaining to the EC is

[81] Dohoda se Zentivou za zavřenými dveřmi, Zdravotnické noviny (5 Nov 2004), p. 1.

our last resort," MAFS executive director Pavol Mazan said. MAFS was also considering lodging a complaint with the Czech Constitutional Court.

In 2005, the ministry appointed new members of the committee. At the very first meeting, a ministerial official proposed the decree to be signed. "They presented a list of 8000 items and they wanted it approved, without any discussion," Karel Němeček, representing the General Health Insurance Company on the committee, said.[82] The committee rejected the request by a majority of its members. At the same time, MAFS lodged a complaint with the European Commission for the infringement on the Transparency Directive.[83]

The chaos culminated in mid-2005 when the Ministry released the new decree. Experts counted 86 categories in which fully reimbursed drugs were either totally missing or not available for different reasons.[84] In July, a group of opposition Senators from the Civic Democratic Party lodged a complaint with the Czech Constitutional Court. In October, Prime Minister Jiří Paroubek pushed David Rath, a controversial president of the Czech Medical Chamber, to become Deputy Minister of 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, and even though it was less than a year till the next parliamentary elections, he declared the intention to conduct profound reform steps.

The entire period was marked by the ongoing controversy between experts in the categorisation committee and the ministry. The representatives of the ministry used the egalitarian code of "taking the social dimension into consideration" to justify their attempts to correct the committee's decisions. They considered the experts' view as reductionist, following medical

[82] Kučera, P.: Emmerové se „vzbouřila" léková komise, Lidové noviny (4 Apr 2005), p. 14.

[83] MAFS si stěžuje u Evropské komise, Medical Tribune (4 Apr 2005), p. 1.

[84] Kučera, P.: Statisíce pacientů si od července připlatí za lék, Lidové noviny (18 Jun 2005), p. 1.

criteria only. On the other hand, the discourse coalition of opponents, including experts and representatives of foreign pharmaceutical firms, put emphasised a different side of the egalitarian code, namely the private capture narrative, and accused the ministry of being under the influence of lobbyists. They identified the Czech system with corruption and clientelism and put it in contrast with the transparency of European law. Discursively, this period can be characterised as a battle over justifications of who can act on behalf of patients. Patients did not have their own voice but their interests were mobilised for different reasons and they were represented in different ways. Their social interests were represented by the Ministry, and with regard to their health, expert medical groups spoke on behalf of them. All claims were justified by public interest and criticised from the perspective of private capture.

As a result, the political narrative about the Ministry correcting the committee's decisions for moral reasons was outvoiced by narratives about the Ministry ignoring expert advice in favour of stakes held by pharmaceutical companies. The latter construction was also underlined by the rapid succession of ministers. The hierarchist narrative of expert communities definitely prevailed. It was supported by an increasing dissatisfaction of the Czech citizens with politics (Linek 2010) and a relatively high prestige of medical professionals and scientists in the Czech media (Čada et al. 2006).

The Ministry of Health led by David Rath completed the new reimbursement decree. As usual, it was met with a strong critique from pharmaceutical companies and pharmacists. The ministry declared that manufactures and distributors were able to reduce their prices much more: "The political task for the expert committee was how to get the same amount of pharmaceuticals for a smaller amount of money," committee chair Karel Němeček declared. He explicitly admitted the political dimension of the activities of the categorisation committee as an expert group.

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%, to postpone of elective surgeries and to limit treatments. The ministry also introduced very tight prescription limits. Its narrative was predominantly fiscal. However, a very strong fiscal imaginary was articulated in the hierarchist code. Expanding scope of regulation and strengthening of existing institutions the ministry intended to push on pharmaceutical firms to lower their prices and hospitals to take cost-containment measures.

In January 2006, representatives of the Czech Pharmaceutical Chamber threatened strike action. According to the decree which the Cabinet approved in December 2005, the Ministry of Health decreased the distribution margins, which were partially reimbursed from public health insurance, from 32 to 29%. This change angered the pharmacists, who claimed their total annual income would decline. Representatives of the Chamber also warned that around 550 out of the existing 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.

Social Democratic Member of Parliament Eduard Zeman proposed an amendment to exclude a representative of the Czech Pharmaceutical Chamber from the categorisation committee, and the Parliament agreed.[85] In response to the pharmacists' protests, Rath and Prime Minister Jiří Paroubek agreed to set up a commission to determine ways to cut health insurance expenditure on pharmaceuticals. The commission, which included pharmacists, drug suppliers,

[85] Lékárníci ve stávkové pohotovosti, Zdravotnické noviny (13 Jan 2006), p. 6.

and ministry representatives, reached no conclusion.[86] The public discussion became too polarised to reach any feasible solution.[87]

David Rath's crisis narrative was very much in line with the fiscal responsibility imaginary, but with strong emphasis on the hierarchist and egalitarian codes. The fiscal problems were not caused by overconsumption of patients but rather by immoral benefits of pharmaceutical companies and pharmacists. The main goal of Rath's policy was to guarantee the same amount of care for a smaller amount of money. Rath's storyline was strongly polarised with patients, medical professionals and ministry as goodies, and pharmacies and pharmaceutical companies as baddies. Rath incorporated the narrative of regulatory capture by pharmacies and pharmaceutical firms that had been used against previous ministers, turning it against its original proponents. According to Rath, pharmacists and pharmaceutical firms protested because the Ministry had confined them to the boundaries of strict rules and limits, restricting their unregulated monopoly.

JULINEK'S REFORM (2006–2008)

Czech health care changed significantly in the two decades following the fall of communism, with the second biggest reform proposed after the parliamentary elections in 2006. A 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 Par-

[86] Schejbal, J.: Jedna bitva končí, válka nikoli, Profit (20 Mar 2006), p. 14.

[87] At the same time, the Association of Drug Distributors (AVEL), which covers 95% of the Czech pharmaceuticals market, halted deliveries to three hospitals – Bulovka and Thomayer, both in Prague, and St. Anne's University Hospital 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 already stocked up.

ty. Although the Czech Social Democratic Party won, it was unable to find any coalition partner to form government. Thus, 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," Minister for Health Tomáš Julínek noted while justifying his proposed steps.[88] He referred to his reform as a "revolution". Julínek's team comprised experts with experience in a similar reform in Slovakia. Julínek immediately dismissed Milan Sojka, the director of the State Institute for Drug Control *(Státní ústav pro kontrolu léčiv, SÚKL)*, who had been appointed by David Rath.[89] He also withdrew a representative of the Czech Medical Chamber from the ministerial committee, and newly formed it by four representatives of health insurance funds (as payers of health care), three representatives of the Ministry ("as a guarantee of protection of public interests") and three representatives of medical professional societies ("as a guarantee of quality of health care").[90] As observers without voting rights there were representatives of the Czech Medical Chamber, the Czech Dental Chamber, patients' organisations, the International Association of Pharmaceutical Companies (MAFS) and the Czech National Association of Pharmaceutical Firms.[91]

Following its withdrawal from the committee the Medical Chamber articulated its protests in terms of private capture. "We consider these steps as severe restrictions of public scrutiny of the pharmaceutical policy of the Czech Republic, a direct violation of the principles of democracy, and a restriction of rights. We assume that it is not in the interest of citizens, but

[88] T. Julínek představil svůj program, Medical Tribune (18 Sep 2006), p. 1.

[89] Pergr, V.: Šéf SÚKL padne, Rath v tom vidí mstu, Právo (15 Sep 2006), p. 06.

[90] Julínek jmenoval novou kategorizační komisi. MInisterstvo zdravotnictví (9 Oct 2006)

[91] Julínek jmenoval novou kategorizační komisi. MInisterstvo zdravotnictví (9 Oct 2006)

only in the interest of the pharmaceutical lobby," President of the Chamber Milan Kubek publicly announced.[92] It is symptomatic that the medical professionals' representatives identified themselves as representatives of the public. The very weak patient participation in decision-making processes allowed expert stakeholders to speak on behalf of them.

At the same time, the media reported that certain pharmaceutical companies had funded the preparation of Julínek's health reform. The sponsors explained it as a support for expert meetings and their contribution to promoting expert dialogue.[93]

In line with his election promises, the Minister prepared several new proposals aiming both at the privatisation of large hospitals and health insurance funds and at cost containment in health care provision. His reform program was originally articulated strongly in the dominant individualist code. He stressed the need to enhance individual responsibility and motivate patient self-regulation through flat user fees and higher co-payments. He also stressed market-based solutions, modernisation of health care, and the need to innovate and shift away from inefficient care. The Minister declared two goals when the reform was being launched: "The two main goals of the reform are to improve the status of the patient and to deal with the effects of ageing of society. The Czech Republic is one of the most vulnerable countries in the European Union. In 2050, there will be public funds for less than half the care needed. In 2015, we will miss at least thirty billion."[94]

These principles were inscribed in a new decree released in February 2007. The decree lowered reimbursements for inefficient and outdated medicines and medical drugs that did not

[92] Kubek, M.: Julínek omezil veřejnou kontrolu, Česká lékařská komora (19 Oct 2006)

[93] Vašek, P.: Julínek zveřejnil sponzory své reformy, Hospodářské noviny (8 Aug 2006), p. 1.

[94] Otázky Václava Moravce, Česká televize (4 Nov 2007)

treat the causes of disease, but rather its consequences. It was expected to save 1.5 billion CZK, which would be used on modern treatments.[95]

"We have three criteria. First, 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 and effective medicines to the lowest level in the EU. Third, we have lowered the reimbursement for drugs where the effectiveness has not been proved, and where a more developed treatment exists, or in the case of supportive treatment which is not required," Deputy Minister of Health, Pavel Hroboň, explained.[96]

The goal of the proposed policy was to keep pharmaceutical expenditure at the same level, with no increase, and shift money away from outdated medical drugs to modern ones. This goal corresponds with the discursive imaginary of health hopes. However, the reform was also stressed as a way to make patients more active and more interested in their health. The second goal corresponds with the discursive imaginary of fiscal limits, with emphasis on choice and responsibility.

One can see easily the construction of patients as rational and informed actors. This construction was further developed in next stages of the reform. "Patients will find that they will have to pay more. And they will begin to wonder why. And they will be provided with advice that it is an outdated medicine which has been replaced by a modern medical drugs with minimal or even no co-payment," Minister Tomáš Julínek explained.[97] However, this justification was in sharp contrast with the dominant media narrative of a steady increase in pharmaceutical prices. Since 1990s, the media had talked about growing prices every time a new decree

[95] Vašek, P. Mařík, M.: Na málo účinné a zastaralé léky si lidé připlatí, Hospodářské noviny (1 Feb 2007), p. 1.

[96] Vašek, P.: Pacienti budou od dubna za léky doplácet víc než dosud, Hospodářské noviny (1 Feb 2007), p. 4.

[97] Julínek, T.: Co všechno se změní pro pacienty, Mladá fronta DNES (7 Feb 2007), p. 4.

was published. The increase in co-payments was considered normal, indeed, and there was no reason to wonder why.[98]

In the beginning of 2008, the country's pharmaceutical policy changed completely. Until then, the committees of the Ministry of Finance and the Ministry of Health had shared responsibility for reimbursement levels and maximum prices and the European Commission had heavily criticised it. Julínek made *SÚKL* newly responsible for pricing and reimbursement decisions. The maximum price was originally defined as the lowest price in eight EU countries of reference (Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece and Spain),[99] later as the average of the three lowest prices in those reference countries. *SÚKL* became responsible also for setting the levels of reimbursement from public health insurance. Those pharmaceuticals considered as interchangeable were included in the same reference group and the reimbursement limit was set at the price of the least expensive drug within the group. The Act on Public Health Insurance defines 300 groups for which at least one pharmaceutical must be covered in full by public health insurance. Co-payment for prescription drugs was required for pharmaceuticals whose price exceeded the reference reimbursement level (as is also the case in Spain, France, The Netherlands, and other countries). In 2008, more than 50% of distributed

[98] Kučera, P.: Pojišťovny ušetří. Na úkor pacientů, Lidové noviny (28 Mar 2007), p. 3.

[99] The concept of the cheapest product in each category was another controversial point. "It reminds me of the movie in which the main character covered the part of the 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 chose the cheapest meal – three eggs in a glass," pharmaceutical expert Jan Suchopár explained. In different European countries, the reasons for low prices of pharmaceuticals may be different – for example, an agreement between regulators and manufactures decreasing the price of one medical drug at the expense of increasing the price of another. If you put it in a different context it cannot work, Suchopár noted. See Úhrady léků – vždy je co vylepšovat, Zdravotnické noviny (7 Apr 2008), p. 17.

pharmaceuticals did not require any payment other than the flat-rate user fee charged for all prescription drugs.

In January 2008, flat-rate user fees were introduced for patients who were hospitalised, visited a physician or purchased drugs at a pharmacy. The fees of CZK 30 (1.20 EUR) per visit, CZK 60 (2.40 EUR) per hospital day, and CZK 90 (3.60 EUR) per use of outpatient services outside of standard office hours were expected to motivate patients to use health care reasonably. A flat user fee of CZK 30 (1.20 EUR) was also introduced for prescription pharmaceuticals. The government employed two standard arguments for expanding the role of user fees: (1) they can help make up for deficits in public funding and (2) they make people more aware of their healthcare choices.[100]

Tomáš Julínek presented all of his reforms steps in an evidence-based and depoliticised way.[101] The discussion gradually boiled down to the fiscal responsibility goals. Controlling healthcare costs became top priority in the discourse, which was driven by a combination of

[100] According to Thomson et al. (2010), policy makers supporting user charges assume that patients have enough information to decide, they understand the information and they are able to make a rational choice. However, the decision making of health care consumers is not always rational. Due to a strong information asymmetry between patients and medical professionals, patients may not always understand the value of a particular treatment. People may forgo the 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 substantiated by studies exploring access to health care in Greece. Greek patients were less likely to visit GPs and outpatient facilities; there was a 24% rise in admissions to public hospitals between 2009 and 2010, and an 8% rise in the first half of 2011 compared with the same period of 2010. (Kentilekenis et al. 2011)

[101] Julínek, T.: Léky dramaticky nepodraží, Medical tribune (9 Jun 2008), p. 1.

factors, including arguments over resource scarcity, population ageing and patient responsibility. The prevailing focus on savings was mirrored in the way that the reform's achievements 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 decreased significantly and more prescription drugs have been sold. As a result of the new system, nearly two billion CZK were saved in the last quarter of the year," Minister for Health summed up.[102] Savings became a key measure and wasting of money was attributed mainly to choices made by individual patients who allegedly over-consumed healthcare because of insufficient financial motivation. "The main rationale for the reform was to reduce public expenditure; moreover to achieve a psychological breakthrough and make the patient aware that health care costs money and it is necessary to weight one's actual needs," the Minister explained.

The transfer of responsibilities to *SÚKL* was heavily criticised by medical professionals and experts – because of the concentration of responsibilities. "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 rely on the existence of expert consultative or advisory bodies. The professional community has lost the opportunity to significantly contribute to the formulation of health policy," the Czech Medical Chamber complained.[103] Critics also pointed out delays that *SÚKL* had in the process of re-evaluation of drugs.

In 2008, Tomáš Julínek promised to make some amendments – for example, to exempt from user fees children younger than three years. The Czech Constitutional Court also considered the reform but the fees were retained. The proposed laws were immediately met with sharp

[102] Otázky Václava Moravce, Česká televize (8 May 2008)

[103] Kubek, M.: Proč platíme za předražené léky?, TEMPUS Medicorum (28 Mar 2008), p. 14.

critical reactions from opposition parties, unions and some experts. Critics warned against increased reliance on neoliberal measures and principles such as a privatising hospitals or loosening the regulation of health insurance funds (Hava, Maskova-Hanusova 2009).[104] Critics of such measures particularly mentioned worsening access to health care for pensioners and lowest-income workers. Bolstered by the egalitarian code, they stressed deteriorating access and increasing inequalities. They also considered the reform unsustainable in terms of moral choice –the logic of private self-interest would possibly lead to a collapse of the public system.

The reform's proponents justified savings in some sectors as a way to ensure more spending or stability in other parts. They were trying to put under one umbrella both imaginaries – the discourse of health hopes and the discourse of fiscal responsibility. How did they do it? When Julínek's reform was being debated, the issue revolved around two general regimes of care: health efficiency and economic efficiency. The first regime represented modern treatment, which was promised to be guaranteed regardless of the costs, while the second regime represented a domain where more expensive drugs could be replaced by cheaper products and patients could pay more for their care. While outpatient 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) way of distribution (see Table 8). In the health efficiency regime, care was associated with the concepts of originality, novelty, foreign medicaments, acute states, and cancer treatment. This type of care was in the hands of professionals in hospitals, who distributed it

[89] By introducing user fees and changing co-payments for partially reimbursed pharmaceuticals, the reform achieved a significant increase in what patients were required to pay; however, the share of health in final household expenditure was still relatively low in comparison with other European states. The greatest share of out-of-pocket payments was related to pharmaceuticals. (Krutilova 2012)

reasonably. Julínek's reform proponents argued that strict regulation was not needed. On the other hand, the economic efficiency regime associated care with standard quality, domestic products, chronic illnesses and outpatient care. This regime was seen as wasting money and in need of regulation. This categorisation replicated the dominant media representations of professional medicine as a way to treat sickness competently and successfully by doctors in hospitals using latest technology and fast-acting drugs (Lupton 2003: 57).

Table 8: Architecture of health care categories and their dimensions in Julínek's reform

Dimension	Health efficiency regime	Economic efficiency regime
Uniqueness	Unique	Standard
	Original	Generic
Novelty	Modern	Old
Origin	Foreign	Domestic
Price	Expensive	Cheap
Indication	Acute	Chronic
	Cancer	Unspecified
Way of Pharmaceuticals Distribution	Hospital care	Outpatient care
	Professional responsibility	Individual responsibility

The alternative narrative of a coalition of the oppositional Social Democrats and representatives of the domestic manufacturers producing mainly generic drugs stressed a worsening access to medicines and extensive support for foreign pharmaceutical companies. Health effectiveness was questioned and modern treatments were associated with the profit of foreign companies. "Modern, new and expensive drugs are the flagships of the pharmaceutical companies, bringing them huge profits. It is, therefore, abundantly clear in whose name the Minister is playing."[105]

[105] Sýkorová, V., Křenková, K.: Léková politika v ČR, Haló noviny (4 Jun 2007), p. 8.

In the health reform, the individualist code associating the wasting of money in health care with inadequate financial motivation of patients and outpatient care prevailed. 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 the reform, however, Czech patients refused to be identified with wasting in the health care system and voted against parties standing behind the discourse.

In autumn 2008, the Czech Social Democratic Party focused on user fees as a central issue in the regional elections campaign. The electorate refused to be blamed for health care costs and governmental right-wing parties lost significantly in this election. Consequently, major government reforms were stopped and the author of these reforms, Minister of Health Tomáš Julínek, was dismissed. Two years later in the 2010 parliamentary election campaign, health care played just a marginal role (Sedláček and Herot 2011). Regarding Down's (1972) theory of attention cycles, a period of intensive organisational activity was replaced by a decline in interest by 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 score a great 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.

CONCLUSION: NARRATING REGULATION IN TRANSFORMATION

According to Thatcher and Rein (2004), conflicting values are a central characteristic of policy issues. "Policy actors do sometimes try to strike a 'balance' among conflicting values, … 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) Narratives

define various forms of social disorder, or disequilibrium, as well as propose remedies or institutional innovations through which order, or equilibrium, could be re-established.

Policy narratives can generally be characterised by the following series of elements: (1) who is speaking; (2) how disorder is defined; (3) who is identified as victims; (4) who is blamed; (5) what kind of apocalyptic future is enacted; (6) which solutions are proposed in order to avoid the apocalyptic future; and (7) what kind of future is desired. Using this framework, the following table (Table 9) summarises the narratives identified in debates about Czech pharmaceutical regulation. The table also connects these narratives with the level of policy implementation. Policy implementation is considered successful when proposed institutional vehicles of change were actually introduced in the regulatory framework.

Table 9: Narratives of Czech pharmaceutical regulation

Period	Author	Defined disequilibrium	Perpetrators	Victims	Undesired future	Principles of change	Institutional vehicles of change	Desired equilibrium	Policy implementation
1992–3	Ministry	Stagnating health indicators, ruined relationships	Communist regime	Patients as both victims and pupils	Sclerotic system unable to keep up with the West	Liberalisation, competition,	Privatisation, cost sharing, co-payments, categorisation of pharmaceuticals	Modern health care, choice and responsible patients	Successful
1993–4	Medical associations	Practitioners without appropriate knowledge can prescribe	Too much liberalisation	Public budgets and patients	Unsustainable funding and harms to patients	Hierarchy of knowledge	Prescription limits	Efficient and effective prescription	Successful
1993–4	Czech Helsinki Committee	Seniors cannot afford health care	Privatisation of health care	Vulnerable groups	Unequal health care system	xxx	xxx	xxx	xxx
1993–4	Medical professionals	Bureaucratisation and lack of communication	Incompetent policymakers	Professional community	Heavily bureaucratised system	xxx	xxx	xxx	xxx
1995–7	Ministry	Increasing expenditures	Inevitability	Consequence of modernisation	Unsustainable funding	More regulation	Reference pricing system, Pharmaceutical Act	Balanced budgets	Successful
1995	Czech Pharmaceutical Chamber	Shortage of pharmaceuticals, delays in payment	Too liberal environment, inconsistent rules	Patients and pharmacists	Patients without medicines, pharmacies bankrupt	xxx	xxx	xxx	xxx
1995	General Health Insurance Company (*VZP*)	Physicians prescribe more care than patients need	Physicians' effort to raise incomes	Public funding	xxx	Further regulation	Prescription limits	xxx	Successful
1996	Czech Doctors' Trade Union *(LOKSČL*	Low wages of medical professionals	Patients and pharmaceutical companies	Medical professionals	Shortage of medical professionals	Cost sharing and savings	Price reduction, user fees	Satisfied medical professionals	Unsuccessful

Period	Author	Defined disequilibrium	Perpetrators	Victims	Undesired future	Principles of change	Institutional vehicles of change	Desired equilibrium	Policy implementation
1996	Czech Pharmaceutical Chamber	Pharmaceuticals can be sold outside pharmacies	Ministry under influence of producers and distributors	Patients	Lack of expertise	Hierarchy of knowledge	To withdraw the proposal	Competent pharmacies	Successful
1998	Regional health officers, patients	Ban of dispensing of pharmaceuticals directly by physicians in places without a pharmacy	Ministry and too much bureaucratisation	Ordinary citizens.	Deteriorated accessibility of pharmaceutical	Regionally sensitive regulatory framework	Dispensaries in rural areas and small towns	Better access to pharmaceuticals	Successful
1998	Ministry	Increasing expenditures and profits of pharmaceutical firms	Companies taking advantage from the complicated scheme	Public funding	Czech health care system as a gold mine	Transparent regulation	Simplification of pharmaceutical taxonomy, margins for distributors	Sustainable budgets	Unsuccessful
1999–2004	Ministry	Europeanisation	Inevitability	Inevitability	xxx	Transposition of EU legislative framework	Implementation of norms	xxx	Successful
2000	Domestic producers	EU law as a danger for Czech patients	Czech government, EU	Czech patients and Czech industry	Costly pharmaceuticals for Czech patients	Negotiating better conditions	Compensations and legalisation of testing generic drugs	Affordable pharmaceuticals	Unsuccessful
2002–5	Ministry	Lack of social sensitivity in expert decisions	Expert decision making	Vulnerable patients	Insufficient access to pharmaceuticals for particular groups	Social sensitivity and politicisation of decisions	Ministry as a veto player	Socially sensitive health care	Successful
2002–5	The categorisation committee, producers	Corrupt ministry and lobbying of pharmaceutical companies	Policymakers and pharmaceutical companies	Transparent rules	Abuse of power and clientelism	xxx	xxx	xxx	Unsuccessful

Period	Author	Defined disequilibrium	Perpetrators	Victims	Undesired future	Principles of change	Institutional vehicles of change	Desired equilibrium	Policy implementation
2005–6	Ministry	Increasing expenditures	Foreign companies, pharmacists	Patients and medical professionals	Czech health care system as a gold mine	Spending limits	Tight prescription limits, raising margins, spending cuts	Balanced budget	Partly successful
2005–6	Czech Chamber of Pharmacists, foreign producers	Threat of bankruptcy of pharmacists/Unaffordability of modern pharmaceuticals	Ministry	Pharmacists	Shortage of pharmacists and pharmaceuticals	xxx	xxx	xxx	Partly successful
2006–7	Ministry	Lack of incentives in health care	Rules which motivate neither patients nor professionals	Previous governments	Unsustainable and outdated health care	Competition and rationalisation	User fees, co-payments, change in public administration	Modern health care, choice and responsible patients	Unsuccessful
2006–7	Opposition groups	Ministry under the influence of pharmaceutical companies	Ministry and pharmaceutical companies	Patients	Czech health care system as a gold mine	xxx	xxx	xxx	Successful

One can see that some of the narratives do not comprise the entire series of elements. Protest narratives miss proposals for particular change and constructions of a desired future. They aim to criticise a dominant narrative and its principles. However, all of them emphasise some form of sustainability. Health system reforms are usually justified by sustainability of the system, a desired future which seems to be a central category for thinking about health debates in developed societies. The sustainability paradigm reflects a growing concern about the long-term consequences of decisions, and it implies increasing dissatisfaction with current practices (Cox and Béland 2013).[106] Sustainability discourses attempt to reframe issues that may be perceived as difficult, unpalatable, and contentious problems in the short term into durable solutions in the long term.

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 explored how these concepts were modified and deployed in the process of forming discourse coalitions of actors to promote particular policy solutions. Based on their extensive research of Canadian policy debates, Bhatia and Orsini identified four sustainability

[106] The attractiveness of the idea of sustainability is a quality Cox and Béland (2013) refer to as 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 and positive valence generate strong attractiveness and therefore 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)

articulations: (1) fiscal sustainability; (2) value for money; (3) sustainability as moral choice; (4) the emergence of a new social contract. Each of these narratives states different goals for policy proposals and different tools to achieve those goals.[107] These two concepts, however, can be interpreted as derivatives of two dominant imaginaries: (1) the discourse of health hopes and (2) the discourse of fiscal responsibility (see Table 10).

Table 10: Dominant concepts of sustainability (using fremowork developed by Bhatia and Orsini 2013)

	Fiscal responsibility discourse (YES)	Fiscal responsibility discourse (NO)
Medicalisation discourse (YES)	Value-for-money narrative *The first transformation period, Tomas Julínek's reform*	New social contract narrative
Medicalisation discourse (NO)	Fiscal sustainability *Narratives in the consolidation period*	Sustainability as moral choice *Disputes between Ministry and categorisation committee*

The discourse of health hopes is very strongly present in the value-for-money concept, typical for the first transformation period and Tomáš Julínek's reform. This concept defines the imaginary of health hopes as confined to the fiscal boundaries within which the system must

[107] The narratives can co-exist in public discourse. In policy making in some developed states one can observe a mechanism putting them together and seeking for possibilities to negotiate between them. For example, health technology assessment (HTA), promoted by the WHO or European commission, might be one of those mechanisms. HTA is way of assessing the ways science and technology are used in healthcare and disease prevention. It covers medical, social, economic, and ethical issues. HTA tools which involve expert studies and public deliberation can start a dialogue between different preferences and differences conceptions of sustainability. However, evaluation of 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 interpretive policy analysis, HTA can be understood as an expert arena for conflicts, negotiations or reconciliation between existing policy narratives.

operate. However, expenditure is one of a number of parameters along which reform of the health care system must be considered. There is a need for transformation, modernisation, and innovation in the way services are delivered, a shift away from outdated dependence on expensive and inefficient acute inpatient care. The distinction between the regimes of economic efficiency and health efficiency plays an important part in those narratives.

A different side of the health hopes discourse among the public policy narratives is represented by the concept of new social contract, which comprises of life-style choices (for example, pinpointing the role of the obesity epidemic in the expanding health care costs). Unlike the value-for-money concept, the new social contract narrative of sustainability – or unsustainability – is escalated in doomsday scenarios (futuristic scenes of systems on the verge of collapse) and it is based upon personal responsibility. It is derived from the discourse of an "imperative to health" (Lupton 1995), which relies on, among others, the presumption that the individual is largely responsible for his or her health. In contrast to the Canadian case, the new social contract narrative based on life style options played a very marginal role in the Czech context, which might be associated with a relatively weak position of health promotion in the transformation period.

The discourse of fiscal limits is present both in the fiscal sustainability narrative and in the value-for-money narrative. In both the spending disease narrative and the new social contract narrative, 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 expenditure is ringing alarm bells, urging us to find more effective and efficient means of providing for the health needs of the population. Unlike the others, the moral choice narrative focuses on private sector expenditures, which are rising faster than public sector costs.

Cultural codes are understood as grammars of blame and solution. The main conflict line was drawn between the individualist and hierarchist codes of justifying regulation, while the egalitarian and fatalist approaches played just a marginal role. Individualism put emphasis on market-based solutions, patients as consumers, superior self-regulation, individual responsibility and individual rationality. Hierarchism was associated with corruption, the need for a prudent regulator, expanding the scope of regulation, strengthening existing institutions and the central role of hierarchies. The former was dominant during the reform periods and the latter in times of consolidation. Moreover, the hierarchist code was also presented in the Europeanisation discourse, which was dominantly driven by the fatalist code of inevitability of transposing European law.

However, cultural codes may also act separately in different realms of society. Even though the individualist code prevailed in the first years of transformation, the hierarchist code was present in narratives promoted by medical professionals' associations. Whereas the entire health care system was justified in individualist terms, the medical field, as a particular institution, was driven by the hierarchist code. The hierarchical approach to knowledge inscribed in the discourse of Western biomedicine could be identified in the institutional setting of prescription limits or in controversies around the categorisation committee. Even the individualist code of Julínek's reform used the hierarchist code in relation to authority and expertise of health professionals within the health efficiency regime.

Using the individualist code, a combination of both the health hopes imaginary and the fiscal responsibility was articulated. On the contrary, the imaginary of fiscal responsibility was articulated in the hierarchist code. This configuration influenced significantly the character of post-socialist welfare in the following way: the positive imaginary was always connected with individualist codes and modernisation of health care was associated with market-driven reforms. On the other hand, the strengthening of rules and hierarchies was much more connected

with the doomsday scenarios of a gloom fiscal future and wasting of public resources. In addition, those scenarios contributed to the image of policy making as a dirty game in which clientelism and corruption matter.

In both regulatory codes, one can find a model of patient deficit. First, individualism portrayed patients as rational actors who need to learn skills for a new model of health care. This is a deficit of skills, and the individual is responsible. The system needs tools through which patients are educated to make "good choices" – and money is the medium of education. The individualist deficit model overlooks the knowledge asymmetry ascribed in the relation between patients and medical professionals. Second, in the hierarchist code, one can speak about a deficit of knowledge. Patients do not have enough information to make right choices. Hence, institutional tools must be designed to protect patients. The responsibility is dealt with at the institutional level. Both codes resulted in the exclusion of patients from decision-making processes and in poor participation of patients.

CONCLUSION: HOW NARRATIVES SHAPE REGULATION

The dissertation explored the relationship between discourses, narratives and institutional change, which was conceived as a driving force of social dynamics. The empirical section dealt with changes of healthcare and was based on the idea that the narrative perspective is ideal for studying the institutional dynamic of welfare states, which is characterised by a tension between citizens' rising expectations, on the one hand, and the imperative of permanent austerity, on the other hand. Narratives temporally order various series of events into an intelligible whole, structure the past and create a relation between the past, the present and the future. From the narrative perspective, governance is a kind of reflexive developmental trajectory connecting the past with an anticipated future. Governments articulate themselves as actively shaping their policies through acts of choice in the name of a better future. However, in this globalised and interconnected modern world, governments are not able to define the better future on their own, and their acts of choice are embedded in certain transnational discursive imaginaries that define the horizons of public policy.

With respect to those imaginaries in the field of pharmaceutical regulation, the second half of the twentieth century was marked by a shift to "techno-medicine" (Pickstone 2000) or a shift from medicalisation to biomedicalisation (Clarke et al., 2003). Medicine moved deeper and deeper into the structures of human body and biotechnologies became important in the constitution of modern identities. The medical discourse also spread into a number of fields: from genetic testing through the justice system to assisted reproduction. Generally speaking, medicine defines the limits of normal behaviour, categorises problems as individual and individually manageable, and classifies these problems as the result of biological dysfunction. Con-

temporary biomedicine interlinks a diversity of hopes, generates a diversity of possible futures, and offers us various choices we can make to enjoy a good quality of life. It is everyone's responsibility to decide whether or not to benefit from these choices, and people expect from the state to create an environment where they can pursue their choices easily. This discursive imaginary of health hopes is connected with promises of better care, medical innovations, shifting away from an outdated and inefficient care, and increasing life expectancy and quality of life. It urges us to think that modern medicine makes our lives better and longer. This imaginary structured significantly the first period of post-socialist transformation and Tomáš Julínek's reform after 2006. In both cases, this imaginary was contrasted sharply to the hierarchical and sclerotic systems of the past that were too inflexible to react to acceleration of the biomedical field. Under the same imaginary, hierarchies of knowledge and a superior position of medical experts were constructed and maintained. From the institutional point of view, this imaginary put into being tools to enhance the implementation of medical innovation and responsibility in the medical sense.

However, since the 1980s, the health budgets of Western European countries have been under constant pressure. At the same time, patients' expectations have been rising and, in turn, expenditures have been rising as well. The tendency of doctors to overuse medicines and the monopoly power of pharmaceutical companies are both long-standing justifications for public policy efforts to reduce the prices of pharmaceuticals. During the period up to 2009, all OECD countries saw their health spending outpace economic growth. This excessive spending is believed to produce unbalanced public budgets and make budgets more prone to fiscal crisis; but it allegedly also ruins temperance and prudence as the fundamental moral principles of the modern capitalist state. For these reasons, the policy narratives of fiscal reforms have been framed not only as a way in which public budgets can be cured but also as cures to moral order, renewing personal responsibility, transparency and rule of law. Under the same imaginary, one

can encounter either depictions of corrupt individuals consuming health care irresponsibly, or with images of greedy pharmaceutical companies which are able to capture policymakers to act in their interest. This imaginary is connected with concepts such as increasing government debt, healthcare spending, insecure fiscal future and economic responsibility. From the institutional point of view, these discursive imaginaries justified the tools that limited expenses and enhancing responsibility in the economic sense.

These transnational imaginaries directly influenced the national policies but also steered them through supranational structures such as the EU. National policy makers reflect on institutional development in other member states, and the EU itself has some powers over pharmaceutical regulation. With emphasis on making modern pharmaceutical products accessible in the European market, the European Commission can be counted as a strong institutional promoter of the social imaginary of health hopes, namely in its biomedicalised mode. Besides, the European Union promotes also the elements of fiscal stability through the European Central Bank or the euro convergence criteria. The Union, however, produces these contradictory discursive imaginaries as institutionally separated. Because there is no common European budget for pharmaceuticals, conflicts between medical innovations and fiscal responsibility do not have to be reconciled at the European level and are left by the European commission, as an institutional actor, to individual states.

Consequently, at the national level, both discursive imaginaries can produce different narratives, justifying different institutional solutions related to broader cultural systems of rules and values of community solidarity. Using the cultural theory developed by Mary Douglas and Aaron Wildavsky (Douglas 1993; Thompson, Ellis and Wildavsky 1990), narratives can be defined according to how they articulate societal constraints for individual members and how they defy or circumvent the rules and boundaries of their particular social environment. Cultural codes organise narratives along specific classification schemes of basic assumptions in

which each code is defined in contradistinction to the narratives based upon other codes. Each code proposes a different grammar of policy narratives as well as a different theory of regulation, which differently explains the origins of regulation. They act as grammars representing different dimensions of how regulation might be problematised or articulated. In each of this dimension, different criteria can be used in order to evaluate the regulation and different questions can be raised. From the institutional point of view, cultural codes propose different institutional tools modelling market, hierarchical or egalitarian relations. Under some circumstances, they can also produce the feeling of fatality, which postulates no institutional change or passively accepts external pressures.

Different regulatory codes also construct different types of disorder. Whereas crisis in the individualist code is connected with lack of incentives, crisis in the hierarchist code is associated with lack of reputation. Both dominant regulatory codes used in the transformation period proposed a model of patient deficit. The individualist code depicted patients as rational actors who need to learn skills to work in the new model of health care. In contrast, a deficit of knowledge is articulated in the hierarchist code, calling on professional authorities to protect patients' interest because patients are not able to do so themselves.

Classification of narratives based simultaneously upon discursive imaginaries and cultural codes allows me not only to grasp the horizons anticipated by policy narratives, but also to grasp the way in which these horizons can be reached and responsibilities can be distributed within the medical field. Using Alfred Schutz's (1966) terminology, the broad discursive imaginaries represent future-oriented *in-order-to motives* and cultural codes represent *because motives*. Particular policy narratives rely both on policy discourses defining goals and on cultural codes defining actors' and tools' positions within the moral order of society.

After 1989, the first period of transformation was characterised by a dominant individualist code, focusing mostly on basic market-oriented reforms such as a pluralistic health insur-

ance model to guarantee up-to-date treatments. It resulted in a growth of total health care expenditure. In the context of accession to the EU in 2004, as reforms of public administration and transposition of European norms were being conducted, a hierarchist code stressing the need to consolidate rules prevailed. The last complex reform was proposed after the parliamentary elections in 2006. The reform plan corresponded with a global shift towards a neoliberal paradigm in health care, focusing on consumer-oriented services obtained in the market and patients as responsible and rational actors.

In the Czech context, the individualist code served predominantly to articulate a combination of the health hopes imaginary and the fiscal responsibility imaginary. On the contrary, the hierarchist code was often employed to express the fiscal responsibility imaginary. This historical configuration marked significantly the character of post-socialist welfare, because the positive imaginary of modernisation of health care was always associated with the individualist discourses of market-driven reforms. Efforts to strengthen rules and hierarchies, on the contrary, were much more underscored by fiscal doomsday scenarios.

However, unsuccessful Tomas Julínek's reform demonstrated that the hierarchist code resonated much more with actual public perceptions of health care. Czech public opinion was strongly convinced that health care is a public good that should be guaranteed by the state (Buchtik 2013). This case illustrates the fact that policy narratives are read with respect to the ways the public understands the workings of democracy and the role of government.

In this case, the shift away from a discourse of civic enthusiasm, typical for the first transformation years, towards disaffected egalitarianism seemed to be a crucial one. Disaffected egalitarianism represents disillusion with the political system, a "democracy in name only, that masks growing social inequality, as well as hierarchy, corruption and bureaucracy" (Dryzek and Holmes 2000: 1059). Supported by increasing dissatisfaction of Czech citizens

with politics, this discourse made the pharmaceutical sector untrustworthy and gave rise to different private capture narratives.

However, it seems that policy makers did not echo this egalitarian code in their narratives but rather they translated it into narratives structured by the hierarchist code. Instead of enhancing of public participation or public oversight through third parties, such as NGOs, they intended to solve the problem by writing new rules and further increasing the complexity of the system. Complex rules such as the categorisation practice led to an increase in the share of private cost and co-payments without making it publicly visible and disputable. The technicality of the rules displaced them from the public political arena. Even though the Czech public refuted the individualist approach of Tomáš Julínek's reform, the steady increase in private expenditure, as evidenced by economic statistics, was well understood by the public. Inscribed in the system's technical rules, however, such trends were not reflected in the policy narratives and broad discussions.

Generally speaking, cultural theory uses cultural codes for classification of different societies. My analysis proposes to consider them rather as orders of justification, which define boundaries within society. For example, even in periods of dominance of the individualist code, the medical field continued to be described in the hierarchist code. At the same time, the political arena distinguished itself from the expert arena by using the egalitarian code, and the requirements of European law were displaced from the political arena using the fatalist code. From this perspective, cultural codes are not only used to blame perpetrators, identify victims and categorise solutions, but they serve also to construct the position of author and to define different moral orders for different realms of society.

This interplay between different codes under one umbrella can explain the categorisation rules underlying the distinction made during Tomáš Julínek's reform between the regimes of health efficiency and economic efficiency. Whereas health efficiency was articulated in the

hierarchist code with emphasis on specialized knowledge of medical professionals, the economic efficiency regime relied on the individualist code. It seems that where discursive imaginaries are in conflict, cultural codes play a crucial role in defining boundaries between different orders of justification of evaluation.

As it was said in the introduction of my thesis, survival abilities of modern organisations do not rely on their organisational efficiency, but rather on their ability to incorporate socially legitimated elements in their formal structure. Consequently, such incorporation relies on a narrative practice which constructs, through interconnecting the past with future imaginaries via cultural codes, specific disequilibria and ways in which new equilibria can be established. These constructions of disorder formed the foundation of specific rights and authorities for particular institutional changes. The explanatory model based upon an interplay between paradigmatic discourses and cultural codes in narrative structures provides us with a key to critical examination of institutional dynamics in modern societies. My analysis demonstrated that a combination of Foucaultian discursive analysis with cultural sociology might provide the explanatory model to grasp this interplay in its complexity and with respect to the main structural elements.

SHRNUTÍ

Cíle předložené disertační práce jsou primárně konceptuální – léková politika má sloužit jako příklad oblasti, kde lze zkoumat souhru diskursů, politických narativů a kulturních kódů v dynamickém institucionálním poli. Lékové politiky, stejně jako další výdobytky sociálního státu, jsou typické napětím mezi rostoucími očekáváními ze strany občanů na straně jedné a důrazem na trvalá úsporná opatření na straně státu. Strategie zvládání tohoto managementu hodnot tvoří osu mé práce, přičemž se zaměřuji zejména na roli vyprávění v tomto procesu.

Jak říká Adrian Kay (2006), narativní dimenze 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. Zvolil jsem vyprávění regulace jako centrální pojem své práce z několika důvodů. Narativní zkoumání transformujících se veřejných politik postkomunistických zemí Střední Evropy bylo dosud ve stínu dominujících tradičních institucionálně analýz. Obdobná situace na poli bádání o regulaci jako celku. Temporální dimenze je navíc klíčová pro pochopení dynamiky současných politik, a to právě ve zkoumání vyprávění a v něm použitých kódů, které slouží samotným aktérům k tomu, aby nastolovali časový pořádek a vytvářeli dynamický vztah mezi minulostí, přítomností a očekáváním od budoucnosti.

Práce sleduje vztah politických narativů k širším diskursům a regulačním kódu. Její přínos spočívá v tom, že chce propojit dosud izolované oblasti interpretativního studia veřejných politik – diskursů jako širších myšlenkových celků, narativů jako sekvenčních celků, regulačních kódů jako režimů připisování viny a kategorií jako vymezování hranic - do jednoho analytického rámce. Politická vyprávění poskytují důvěryhodné principy, jak číst minulost, pří-

tomnost a budoucí události a propojují racionální a emotivní dimenzi našeho uvažování o politikách.

Celková spotřeba léků v ČR se zvýšila ze 25,7 korun v roce 1995 na 83,9 korun v roce 2012. Farmaceutické trhy představují jedno z klíčových prudce expandujících polí, jehož analýza může přispět k celkovému poznání sociální dynamiky pozdně moderních společností. V tomto poli se kombinuje technologická akcelerace hnaná ekonomickým motorem, s akcelerací sociální změny hnanou motorem funkční diferenciace v moderní medicíně, kdy medicínský diskurs proniká do řady oblastí, kde dosud nebyl, a kulturní dimenzí zvyšujících se očekávání od pacientů (blíže viz Rosa 2013). Spotřeba léků funguje, s využitím pojmosloví Maartena Hajera (2009), jako emblematické téma. „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."

Konkrétní politické narativy studuji ve vztahu k diskursu medikalizace a rozpočtové udržitelnosti, které definují horizonty politik. Diskursy chápu, podobně jako Sanford Schram (2012) či, již citovaný, Maarten Hajer (2009), jako širší myšlenkové celky definující sociokulturní kontext a konceptuální vrstvy, ze kterých vycházejí konstrukce politických idejí a programů. V souladu s Ernestem Laclau (1990) o diskursech hovořím jako sociálních imaginacích, které definují horizonty možného a k nimž jsou vztahovány univerzální sociální požadavky a nároky. V mém případě jde o diskurs zdravotních nadějí a diskurz rozpočtových omezení.

Vedle těchto diskursivních sociálních imaginací sleduji také logiku kulturních kódů. Tuto gramatiku viny a nápravných opatření definují kódy vycházející z kulturních hranic představ o společenském řádu. Kulturní kódy vytvářejí gramatiku pro vřazení konkrétních politických narativů do obecných představ o dobru a zlu. Vysvětlují, proč se politiky od odchylují od obecných cílů a uspořádávají jednotlivé elementy regulačních vyprávění. Pro kulturní teoretiky

regulace, pluralita možných cest k regulování je zakořeněna ve fundamentálních dimenzích lidské organizace. Jejich variace pak odkazují k systemizaci různých postojů a přesvědčení ohledně sociální spravedlnosti, vině, spojení jednotlivce s jeho prostřední a k obecnému charakteru vládnutí. Tato teorie ovlivňuje studie rétoriky regulace (či obecně veřejné správy) tím, že identifikuje vzájemnou hru a dynamiku různých rétorických forem stanovující způsoby, jak administrovat regulační opatření.

Ve první kapitole své práce se věnuji roli vyprávění, diskursu a regulačních kódů při analýzy politik. Představuji teoreticko-metodologická východiska práce. V kapitole představuji koncepty interpretativní analýze v analýzy veřejných politik. V kapitole jsou dále popsány čtyři kulturní kódy regulace identifikované Mary Douglas a rozpracované Aaronem Wildavskym (Douglas, Wildavsky 1982, Douglas 1992, Thompson, Ellis, Wildavsky 1990). Tato teorie vychází z teorie mřížky Mary Douglas a je postavena na kombinace silného a slabého vztahu na jedné straně ke kolektivitě a na druhé straně k pravidlům. Pro fatalismus je typický důraz na pravidla a menší důraz na kolektivitu, pro rovnostářství silný důraz na kolektivitu a slabší důraz na pravidla, pro hierarchii silný důraz na pravidla a silný důraz na kolektivitu a pro individualismus slabší důraz na pravidla i kolektivitu. Na uvedené tabulce jsou uvedeny identifikované kódy definující jednotlivé regulační kódy. Původně strukturalistická teorie popisu kultur je v současné literatuře používaná spíše jako typologie měnících se regulačních slovníků.

V druhé kapitole jsou popsány teorie regulace, jak je lze najít v teoretické literatuře: teorie veřejného zájmu (ekonomický přístup, přístup vnějších cílů a procedurální přístup), teorie soukromého zájmu a institucionální teorie. Neprezentuji je jako konkurenční teorie, ale spíše jako různá líčení ospravedlnění regulace. Na rozdíl od dominující výkladů je neorganizuji podle zavedených teoretických kategorií, ale klíčem ke strukturace těchto přístupů jsou různé způsoby problematizace, které postulují. Čtyři hlavní problematizace - individualistická, rov-

nostářská, hierarchická a fatalistická – korespondují s kulturními kódy představenými v předchozí kapitole.

Medikalizační teze je popisována v třetí kapitole práce. Na půdorysu změn moderní medicíny kapitola poskytuje vhled do základních konceptů sociologie zdraví. Na půdorysu změn moderní medicíny kapitola poskytuje vhled do základních konceptů sociologie zdraví. Jsou představeny přístupy Talcotta Parsonsa (1951), Ivan Illicha (1976) či Deborah Lupton (1995). Podrobněji je diskutována teorie medikalizace Petera Conrada (1992) a její hlavní teoretické revize (Clarke a kol. 2003). Medikalizace popisuje proces, kdy jsou původně nemedicínské problémy definovány v termínech nemoci. „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). Diskurs zdravotních nadějí je ilustrován na příkladu tří léků – Prozacu, Paxilu a Viagry. Tyto preparáty se staly jednou z forem přispívající k diskursu zdraví jako osobní volby a osobní zodpovědnosti. Tyto inovace tak přispívají k diskursu imperativu zdraví (Lupton 1995) opírající ho se o Giddensovu definici self v pozdně moderních společnostech: „já (self) se stalo reflexivním projektem, za který je jedinec zodpovědný. Nejsme již tím, čím jsme, ale tím, co ze sebe děláme.“ (Giddens 1991: 75) Imperativ zdraví tak přispívá na jedné straně ke stupňujícím se očekáváním pacientům od zdravotní péče a domáhání se svých biologických práv, na druhé straně k tlaku na občany zdravě žít a realizovat svůj biologický potenciál.

Ve čtvrté kapitole je popsána genealogie diskursu rozpočtových limitů. Je diskutován koncept úspornosti (austerity) jako formy dobrovolného omezení, kdy ekonomika je vyrovnávána sadou nástrojů jako je snižování mezd, cen a veřejných výdajů ve snaze obnovit její konkurenceschopnost. Lékové politiky byly vinou kombinace stárnutí obyvatelstva a medicínského pokroku v rozvinutých státech pod rozpočtovým tlakem minimálně od osmdesátých let. Tlak na omezení veřejných výdajů a udržitelné rozpočty může být vnímán jako protipól medikali-

zační dynamiky. Paul Pierson (2002) pro kontext současných reforem veřejných politik, kdy je rozpočtový tlak všudypřítomný, využívá pojmu trvalá úsporná opatření. V souladu s Markem Blythem (2013) představuji úspornost jako jeden ze základních konceptů moderního státu. Od počátku byla střídmost či šetrnost zmiňována nejen jako hodnota ekonomická, ale i jako hodnota morální (Ossowska 1956). Stala se tak součástí kánonu buržoazních hodnot (McCloskey 2010). V moderní podobě byly tyto principy rozvedeny Schumpeterovým (1942) přístupem ke krizi jako ozdravění ekonomického systému, německým ordo-liberalismem a ekonomickou teorií Friedricha A. von Hayeka (1944). V celosvětovém kontextu pak byly principy střídmých ekonomických politik propagovány epistemickou komunitou politiků, expertů a businessmanů, jež ztělesňuje například Mont Pelerin Society (Mirowski 2009), která sdružovala ekonomy typu Miltona Friendmana či Gordona Tullocka s bankéři a politiky. Na konci 80. let se tyto myšlenky přelily do podoby tzv. Washingtonského konsenzu. Dorothee Bohle a Béla Greskovits (2007) pak přesvědčivě dokumentují, že tyto ideje významně ovlivnily ekonomické změny po pádu komunismu ve střední a východní Evropě. I tuto diskursivní imaginaci můžeme identifikovat ve dvou polohách – jako snahu o úspornost, kdy se zdůrazňují kvantitativní úspory veřejných rozpočtů, tak snahu o hospodárnost, kdy jde o to efektivně alokovat veřejné rozpočty – veřejné rozpočty jsou tak chápány jako reziduální kategorie, která zajistí ty veřejné statky, jež si občané nemohou sami dovolit.

Následující pátá kapitola popisuje evropský kontext lékové regulace. Obecně lze rozlišit tři fáze budování lékového regulačního rámec v EU: (1) harmonizace norem (1965 - 1990); a (2) institucionalizace (90. léta) a (3) konsolidace (po roce 2000). První fáze - harmonizace norem - začala se směrnicí 65/65/EC a skončila s první revizí farmaceutického regulativního rámce v roce 1990. Další fáze – institucionalizace a konsolidace - začala s revizí regulačního rámce po roce 1990, následnou instalací evropské lékové agentury EMEA (později nahrazenou EMA) a autorizačního systému zahrnujícího národní, decentralizovaný i centralizovaný

postup v roce 1995. Tato část práce mi slouží jako uvedení do kontextu nástrojů regulačních politik. Její koncepce ilustruje Scharpfovu (2002; 2010) tezi o konstituční asymetrii, kdy evropské politiky jsou silně harmonizovány v oblastech ekonomické integrace, liberalizace a soutěžního práva, ale v oblasti sociálních práv panuje silná diverzita členských států v závislosti na jejich sociální normách a aspiracích vlád. Evropská komise, jako institucionální hráč, vystupuje jak jako silný promotér imaginací zdravotní příslibů, tak jako promotér fiskální udržitelnosti. Nicméně obě tyto oblasti řeší odděleně a praktické vypořádání s tímto dilematem nechává na jednotlivých členských státech. Tato část legitimizuje, proč je nosné analyzovat situace jednoho členského státu a vysvětluje nástroje i evropských kontext, ke kterému je v případové studii ČR odkazováno.

V osmé kapitole dizertace se věnuji vývoji české lékové regulace po roce 1989. Při praktickém zkoumání role narativů a regulačních kódů v české lékové politice jsem vyšel z analýz médií. Na počátku jsem analyzoval diskusi o reformě Tomáše Julínka, na kterou byl zaměřen původní projekt, nicméně v průběhu práce jsem zkoumaný vzorek rozšířil i na předchozí porevoluční období. Média jsem zvolil, protože představují korpus dat, který pokryje celé zkoumané období. V mé výzkumné otázce mi šlo o to, abych zachytil strategie ospravedlnění, či legitimizace, regulačních opatření, proto jsem se soustředil na veřejnou stránku rozpravy. Na rozdíl od koncepcí, návrhů zákonů, důvodových zpráv a parlamentních rozprav média také zahrnují vyjádření většího spektra aktérů.

Pro potřeby analýzy bylo pomocí Newton Media Search extrahováno a kódováno celkem 729 článků z novin a 14 přepisů televizních debat Otázky Václava Moravce. Při kódování jsem se zaměřil na otázky: jak aktéři ospravedlňují regulaci, jaké normy v těchto ospravedlněních používají, jaké procesy zmiňují, jak jsou artikulovány ztráty a zisky jednotlivých hráčů s případné regulace, jaké je institucionální okolí a jaké jsou kulturní vzorce studovaných líčení. Specificky jsem se zaměřil i na to, komu jednotliví mluvčí přisuzují vinu za současný stav. Ve

druhé fázi jsem se soustředil na kódy spojené s jednotlivými kulturními kódy regulace a diskursivními imaginacemi. V této fázi dostalo původně silně induktivní kódování deduktivní dimenzi. Kódy vzniklé v této fázi byly výsledkem jak studia odborné literatury, tak přeskupováním kódům vzniklých v první fázi kódování.

Ve vztahu k lékové regulaci odlišuji několik období, jež lze obecně nazvat – transformace (1990-1997), konsolidace pravidel (1997-2001), krize pravidel (2002-2006) a pokus o reformu. Tato linie rekonstruovaná na základě narativů v zásadě odpovídá institucionálně laděným klasifikacím, použitých například Němcem (2013) či Hávou a Maškovou-Hanušovou (2009).

První období se neslo v duchu kombinace silné imaginace zdravotních příslibů s fiskální udržitelností, kdy cílem byla modernizace zdravotní péče, ale i hospodárné využití peněz s tím, že se na péči mají více podílet i samotní pacienti. Tento narativ byl artikulován formou individualistického kódu, kdy důraz na volbu a odpovědnost byl dáván do protikladu se socialistickým zdravotnictvím. Diskurs zdravotní péče byl silně na budoucnost orientovaný s očekávánými výnosy v dlouhodobém horizontu. V rámci diskuse lékových regulací se objevovaly jako klíčové konflikty mezi volbou a solidaritou, dále konstrukce řešení jako pravicových a levicových a debaty o tom, co lze řešit na systémové a co na individuální úrovni. Pacienti byli konstruováni jako oběti komunismu, ale v souvislosti s individualistickým narativem hodnoty za peníze i jako žáci, kteří se musí naučit, že zdravotní péče není zadarmo.

Zatímco v první fázi zastánci politických reforem považovali nedostatek konkurence za hlavní problém, ve druhé fázi po roce 1996 byl hlavním problémem nedostatek řádu a nekonsolidovaná pravidla. Tento důraz na pravidla společně s příkrým nárůstem výdajů na léčiva se odrážel v dominantním diskursu fiskální udržitelnosti. Tato konsolidace pravidel byla symbolizována zákonem o léčivech. Tato konsolidace pravidel je umocněna nutností hormonizovat

český regulační rámec s evropskou legislativou. Konsolidace pravidel také znamenala vyjednávání institucionálního rámce, včetně definování pozic jednotlivých aktérů.

Pokračující krize pravidel souvisí jednak s rychlým střídáním ministrů. V tomto období se také intenzivněji objevuje jazyk v hierarchickém kódu. Obecný diskurs zklamání z politického vývoje a politických elit se projevuje v jednotlivých kontroverzích v rámci lékové regulace. V tomto období jsou znovu sjednávány kompetence jednotlivých aktérů. Určují se mantinely expertního a politického rozhodování během. Příkladem budiž spory mezi odbornou kategorizační komisí a ministerstvem, které provází konflikt mezi hierarchickým a egalitářským diskursem. Ministerstvo používá egalitářský kód společenských důsledků jako legitimaci svých změn ve výnosu kategorizační komise. Tyto výroky jsou však delegimitizovány s odkazem na soukromé zájmy. Období politiky s důrazem na pravidla vrcholí přísnými lékovými limity Davida Ratha. Pacienti jsou tvůrci politik v tomto období prezentováni jako rukojmí, kteří musí být chráněni – před soukromými zájmy, dopady změn úhrad či evropskou regulací. Zdůrazňována je asymetrie vztahu mezi pacientem a dalším složkami regulačního systému.

Posledním sledovaným obdobím je reforma pravicového ministra Tomáše Julínka. S touto reformou přichází znovu do hry individualistický na incentivech postavený regulační kód s důrazem na individuální volbu a odpovědnost. Ospravedlnění jeho reformních kroků se nese v duchu kombinace diskursu zdravotních příslibů a fiskální odpovědnosti, kdy hranice mezi ekonomickým a zdravotním režimem hraje dominantní úlohu. Hranice mezi těmito režimy odráží soubory kategorií charakterizující jednotlivé režimy. Zatímco režim zdravotní výhodnosti je charakterizován zahraničními preparáty, onkologickou léčbou, moderními léky, distribucí léků v nemocnicích, režim ekonomické výhodnosti je charakterizován adjektivy jako zastaralá léčba, domácí léčiva, chronické nemoci, distribucí v lékárnách. Tato hranice tak odrá-

ží dominantní představu o medicíně, kde závažné problémy jsou léčeny profesionály ve specializovaných medicínských pracovištích.

Dominantní dynamiku lze vysledovat mezi narativem hodnoty za peníze a fiskálním narativem. S tím, že první se pojí v českém kontextu s reformními fázemi a druhý s fázemi konsolidace pravidel. V českém kontextu se individualistický kód pojí především s kombinací imaginací založených jak na diskursu zdravotních příslibů, tak na diskursu rozpočtové odpovědnosti. Naopak hierarchický kód často vyjadřuje jen rozpočtovou odpovědnost. Tato historická konfigurace významně poznamenala charakter post-socialistického sociálního státu, protože pozitivní vize byla vždy asociována s individualistickým diskursem tržních reforem. Naopak snahy posilovat hierarchie a pravidla byly častěji podporovány temnými vizemi fiskální budoucnosti. Julínkova reforma ale ukázala, že hierarchický model rezonuje významně s představou české společnosti o zdraví. Na druhou stranu narativ deziluze občanů z politické sféry a narativ korupce a klientelismu hierarchický kód nabourává, a to s využitím rovnostářského kódu. Rovnostářský kód však nerezonuje v dominantních politických narativech. Místo posilování participace, veřejné kontroly či účasti třetích stran, jako jsou nevládní organizace, na rozhodování, jsou naopak vytvářena další pravidla umocňující nepřehlednost a komplexitu systému zdravotní péče. Technikalita těchto pravidel depolitizovala nárůst soukromých výdajů a vytlačila z veřejné arény rostoucí privatizaci zdravotní péče.

V obou nejčastěji používaných 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 diskurs. Definovaná odpovědnost je individuální. Pomocí ekonomických nástrojů pacienti mohou být vzděláváni, aby činili „dobré volby“. Tento deficitní model přehlíží znalostní asymetrii vepsanou do vztahu mezi lékařem (či lékárníkem) a pacientem. Na druhé stráně, 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 vylučování z rozhodování, a to jak na individuální, tak na politické úrovni.

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

V úvodu práce jsem uvedl, že schopnost přežití moderních organizací nezáleží tak na jejich technické efektivitě, ale na to, jak dokáží inkorporovat sociálně legitimní elementy do své organizační struktury (Meyer, Rowen 1977). Tato schopnost záleží na narativních praxí, které propojují minulost s imaginacemi budoucnosti prostřednictvím kulturních kódů, vytvářet nerovnováhy a cestu, jejichž pomocí může rovnováha znovu nastavena. Vysvětlující model založený na souhře diskursů a kulturních kódů v narativní struktuře poskytuje vhodný klíč k tomu, jak zachytit institucionální dynamiku moderních společností. Moje analýza demonstrovala, že kombinace Foucaultovské diskursivní analýzy a kulturní sociologie poskytuje dostatečné nástroje k tomu, aby vytvořila model, který tuto souhru zachytí ve své složitosti a vzhledem k jejím hlavním strukturálním elementům.

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