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The rise of the Swiss regulatory healthcare state: On preserving the just in the quest for the better (or less expensive?)

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Abstract

Political theories of the modern state describe a rise of the regulatory healthcare state, balancing the imperatives of cost control and quality assurance and welfare norms such as solidarity. This paper analyses the unique case of Switzerland, where the rise of the regulatory healthcare state occurred late and incompletely, with the adoption of the Federal Health Insurance Law in 1994. The Swiss federal state pursues the social objective of universal access to healthcare through social health insurance regulation. This paper demonstrates that economic efficiency has not been the primary goal of healthcare coverage within the Swiss regulatory healthcare state despite rising costs. As another exceptional feature, Switzerland has diverged from the traditional path of judicial behavior in the regulatory state. This paper critically dissects how the Swiss Federal Court has become a crucial actor, imposing limits on access to healthcare and shaping decision-making criteria for social regulation, such as cost-benefit and cost-impact analysis. Through this judicialization of limit-setting, the judiciary engages in an ongoing constitutional dialogue on the limits of the regulatory welfare state and its sustainability for the future.

Keywords: healthcare costs, judicial behavior, limit-setting, regulatory welfare state, social health insurance.

1. Introduction

> *"Healthcare looms large in the modern welfare state; and states loom large in modern healthcare systems" (Moran 1999).*

Ill health is an individual experience first and foremost. However, starting in the mid 19th century, and intensifying over the course of the 20th century, health and disease have become matters of collective concern preoccupying the modern state (Jasanoff 2011; Porter 2011; Beermann 2015). As a result, public funds flow into medical education and infrastructure, and compensation systems are in place to cover healthcare costs.

In many areas of public interest, such as transportation, energy, and communication, technological developments, innovation, and specialization have been pushing for privatization and market liberalization (*e.g.*, Haber 2017). An increasing amount of regulation and a growing sphere of influence of the regulatory state and independent regulatory agencies often accompany these phenomena (Majone 1997; Levi-Faur 2013, 2014).

In healthcare, the focus on individualism and patient autonomy, the medical profession's traditional authority and the pharmaceutical industry's rising power have not led to a retraction of the state. On the contrary, political theories of the modern state describe the rise of the regulatory healthcare state and the collective character of healthcare consumption and its governance (Moran 1999, 2000; Freeman 2000; Hassenteufel 2007; Hassenteufel & Palier 2007).

This paper contributes to the growing literature on the relationship between the regulatory state and the welfare state, or the regulatory welfare state (Benish *et al.* 2017, 2018; Haber 2017; Leisering 2010, 2012; Levi-

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Faur 2013, 2014; Tanzi 2002). The literature on the attributes of the regulatory state in areas of social policy such as healthcare and its financing through social insurances or taxes remains limited (*e.g.*, (Wendt *et al.* 2009; Rothgang 2010). This paper offers a partial response to this lack of scholarship.

The regulatory welfare state is crucial as a framework to analyze and understand access to healthcare, financial access first and foremost, in the current context of imperatives of cost control and quality assurance. Traditionally, access to healthcare is addressed either from a rights' or a market perspective (Wiley 2014). Both paradigms reflect the autonomy discourse in medicine and the movement of increasing individualism in society. They depict the individual as an entitled citizen or a rational manager of her or his health. An exclusive and uncritical focus on either of these paradigms presents significant shortcomings, however.

The analytical accuracy of the individual (social) rights' paradigm, predominant in the health law literature (Tobin 2012; Wolff 2012; Zuniga *et al.* 2013; Flood & Gross 2014), is limited. Flood and Gross argue that in established democracies that are high-income countries with relatively strong public healthcare systems, access to healthcare historically developed with the rise of the modern welfare state, rather than through a rights' discourse (Flood & Gross 2014). Furthermore, critical voices note that due to its individualist nature, the rights' perspective ignores the societal and collective considerations prevalent in healthcare coverage and limit-setting decisions in the modern welfare state (Otto 1995; Sage 2007; Flood & Gross 2014).

The market paradigm also presents shortcomings. Beyond the question of whether health and healthcare constitute commodities, various characteristics of today's healthcare systems make healthcare unsuited for distribution through competition and the use of price mechanisms on a free market (Flood & Gross 2014; Tinghőg *et al.* 2010). Also, access to healthcare goes beyond the pursuit of mere economic interests and includes social goals, such as equality in access, disconnection from the ability to pay, and the "rule of rescue." The market has a potential for welfare ("welfare ends through market means": Taylor-Gooby *et al.* 2004), but only if appropriate regulatory policies provide a framework to realize this potential (Leisering 2012).

The liberal individualist conception of rights and markets is insufficient to analyze healthcare coverage and limit-setting decisions in the modern welfare state. The theoretical framework of the regulatory welfare state relates to the interaction between private actors and social goals connected through regulation (Leisering 2012); *e.g.*, the social regulation of health insurance, which is the main focus of this paper. Allowing for a collective perspective of individual health, this framework is more accurate to comprehend the intricacies of access to healthcare.

Beyond contributing to the emerging literature on the regulatory welfare state, this paper addresses another issue still to be explored: the role of different actors influencing welfare policy and preserving welfare norms in the regulatory state. This paper focuses on the judiciary as an actor in the regulatory welfare state. The existing literature depicts a limited role for the third branch of government in the regulatory state, as its function is not considered suitable to shape policy or trigger fundamental changes in the regulatory sphere, at least in the Global North (Ginsburg 2008; Thiruvengadam & Joshi 2012). In the Global South, scholars have described some exceptions involving more active courts, for example, in areas of social regulation (Gauri & Brinks 2008; Yamin & Gloppen 2011; Thiruvengadam & Joshi 2012).

Switzerland provides a unique case study of the rise of the regulatory healthcare state. It takes place in a social health insurance system, built on regulated competition between private health insurers subject to a public benefits' catalog, within a federal state and its written constitution, offering direct democratic means of political participation. Most importantly, the Swiss case is an outlier as the rise of the regulatory healthcare state occurred late and incompletely, with the adoption of the Federal Health Insurance Law in 1994. Despite rising costs, economic efficiency has not been the primary goal of healthcare coverage within the Swiss regulatory healthcare state. In addition, Switzerland has diverged from the traditional path of judicial behavior in the regulatory state, at least in the context of social regulation of health insurance. In what constitutes an exceptional feature of this case study, the Swiss Federal Court has asserted its role as an actor in the regulatory welfare state and pushed for the judicialization of limit-setting in healthcare, including establishing the relevant regulatory criteria.

Part two explores the *conditio technica-humana* of modern society and the anomaly of limit-setting by the state to contain costs and assure quality in healthcare. Part three introduces the paper's theoretical framework for the regulatory healthcare state. Parts four and five examine the unusual characteristics of the rise of the Swiss regulatory healthcare state, providing the context necessary for understanding the role of the judiciary in the sphere

of social health insurance regulation. Parts six and seven discuss recent constitutional moments and judicial decisions. They offer empirical evidence of a shift in the dynamics of state actors who, through their actions, express the inner workings of the regulatory healthcare state. By highlighting the pivotal "Myozyme" case and its aftermath, part seven depicts how the Swiss Federal Court has become a crucial actor in the regulatory healthcare state, imposing limits on access to healthcare and thus shaping social policy. Based on the Swiss case study demonstrating the intriguing judicialization of limit-setting, part eight analyses judicial behavior in the regulatory welfare state, which balances the good (efficiency) and the just (equity) underlying access to healthcare. Part nine concludes, focusing on the importance of the paper's findings and analysis for comparative research of the regulatory welfare state and the role of the judiciary in this setting.

2. *Conditio technica-humana* of modern society and the anomaly of limit-setting

Let us start with an anecdote. In 1948, the widespread belief was that the establishment of the UK National Health Service (NHS), based on the 1942 Beveridge Report, providing publicly funded healthcare to the entire population, would reduce demand and thus circumvent the need to set limits on healthcare spending. The assumption was that "there existed a finite amount of ill-health in the land, that this could be reduced by improved healthcare and thereafter the maintenance of the good health of the population would be a relatively simple matter" (Salter 1998). At the time of the rise of the modern welfare state, policymakers were still unaware of the drive for expansion in medicine.

Today we know better, as societal, scientific, and technological developments have led and still contribute to rising healthcare costs. The average population is aging, and the number of chronic diseases is increasing (World Health Organization 2014). The improvement over the years of Western societies' income and standard of living has allowed individuals to spend more on healthcare. Patients' needs and expectations are on the rise, as they demand to be treated without delay and with cutting-edge medical products and services.

Scientific progress and new technologies extend the scope of medical intervention (Callahan 1995). The open-ended possibilities of prevention and treatment accelerate the medicalization of society in previously unconcerned areas of life (Conrad 2007; Murer 2012). Also, health has turned into an end in itself. It is no longer just a means to maintain one's ability to work, but a desirable state of life. As a consequence, overdiagnosis and overtreatment have become pervasive within contemporary medicine and are deeply embedded in healthcare systems around the Western world (Welch *et al.* 2011; Trageser *et al.* 2012; Heath 2013; Robertson 2013).

Finally, healthcare is a vital economic sector securing employment and tax revenues (Evans & Stoddart 1990; Moran 1999). The healthcare market generates significant economic benefits for pharmaceutical companies and service providers and is thus highly supply-driven. It also contributes to the impetus for expanding definitions of disease. Many new treatments, such as cancer drugs, come with an exorbitant price tag of up to $100,000 per year and more (Vokinger *et al.* 2020).

These societal, scientific, and technological developments have a common denominator: they push limits, as they increase the areas and scope of medical intervention. The explosion of healthcare costs is the other side of the medal of the much-desirable medical progress.

Contrary to what NHS policymakers assumed in 1948, we witness today an increasing gap between what is medically feasible and what is economically sustainable. Health is priceless, but healthcare generates costs. In public healthcare systems, the state and the community of individuals bound together by the welfare norm of solidarity (Saltman 2015; Levy 2018) cannot cover the full range of treatments that one individual may require, hence the need to set limits.

Limit-setting is an anomaly in the conception of medical practice, even more so in a technological society in which the possibilities for treatment seem to be ever-expanding. This anomaly is imposed by the state through its regulatory framework, which interferes with medicine's individualistic authority regime and therapeutic choice.

3. Theoretical framework

In public health, concerned with the protection of population health through measures such as quarantine or contact tracing to fight the spread of infectious diseases, the state's traditional prerogatives are rarely disputed

(Gostin & Wiley 2016; Trein 2018). As public health has always been part of statecraft, it has - since its inception - reflected an understanding of health as a common good.

In contrast, the practice of medicine focuses on the individual patient. In healthcare, the individual doctor-patient relationship is central (Levy 2017). Also, healthcare consumption is an individual interest and decision. However, as Moran notes, the "character of modern science-based medicine … means that only the fabulously rich could finance it as a normal individual commercial transaction. For the rest of us, consumption is only possible through participation in some schemes of collectively organised risk pooling" (Moran 1999).

As the financial consequences of ill health are born only to some extent by individuals themselves, healthcare consumption becomes a collective concern of the state. Modern welfare states finance healthcare either against the payment of social contributions or premiums (Social Health Insurance; *e.g.*, Germany, Switzerland) or out of revenues from general taxation (National Health Insurance; *e.g.*, UK, Canada) (Freeman 2000). The idea behind both systems is to disconnect the ability to pay from access to healthcare.[1]

In social health insurance systems, the term welfare state is somewhat misleading, since the state did not establish the insurance schemes, nor did it and still does not predominantly finance them. Social insurance bodies, such as sickness funds, were created mainly on a private basis before the state intervened (Palier 2010). Instead of referring to the welfare state, the literature describes more accurately an increasing interference of the regulatory state in the area of social health insurance. Hassenteufel and Palier, *e.g.*, examine the development of social health insurance in Europe and note that "a new 'regulatory healthcare state' is emerging within social health insurance systems, i.e., Bismarckian health insurance systems" (Hassenteufel & Palier 2007).

The theory of the healthcare state was first coined by Moran and subsequently referred to by others (Moran 1999, 2000; Freeman 2000; Hassenteufel 2007; Hassenteufel & Palier 2007). As Moran notes, "alongside pensions healthcare is the biggest single consumer of resources in modern welfare states and states are either directly the dominant financiers of healthcare or are central to the regulation of institutions that provide the money … states occupy a central role in these systems of collective organisation" (Moran 1999).

The predominant tradition of welfare state research draws a major distinction between Bismarckian (conservative-corporatist), social democratic, and liberal welfare states (Esping-Andersen 1990). While other areas of the welfare state, unemployment or pensions schemes, for example, mainly concentrate on monetary transfers, the primary task of healthcare and health insurance is to provide and fund healthcare services.[2] When applied to healthcare systems, Esping-Andersen's approach transpires a lack of concern for welfare services such as healthcare (Moran 2000; Wendt *et al.* 2009). Moran thus formed a theory of the healthcare state based on the need to understand the role of healthcare in society differently.

The healthcare state relates to three governing spheres: consumption, provision, and technology (Moran 1999). Distinctive systems of politics mark each of these three spheres. What is central to Moran's argument about the government of consumption in the healthcare state is the politics and struggles of collective consumption or the collectivization of healthcare consumption (Moran 1999, 2000). The government of consumption is concerned with a collective perspective of individual health in the context of imperatives of cost control and quality assurance.

Freeman identifies two phases in the rise of the healthcare state in Europe (Freeman 2000). The first phase (1880–1980) consisted of establishing and universalizing a public presence in healthcare (welfare expansion/redistribution). The second phase, from around 1975, was concerned with creating new mechanisms of regulatory control (healthcare governance/efficiency). Freeman notes that in contrast to New Public Management, according to which the state withdraws and transfers responsibilities to enterprises and markets, the healthcare state is a story of state advancement rather than withdrawal. New Public Management predicts that the state will have to privatize many of its current activities, whereas the healthcare state perspective presents a narrative of a movement from "private government" (*e.g.*, sickness funds) toward an advancing state, taking a more predominant role in healthcare governance.[3]

The rise of the healthcare state and the need to set limits on consumption have created an expanding institutional sphere of healthcare governance. Hassenteufel and Palier describe increasing state control and interference of actors outside of the traditional medical sphere and the individual doctor-patient relationship (Hassenteufel & Palier 2007). These actors pursue a collective perspective of individual health, through quality insurance, effectiveness evaluation, and economic control (Hassenteufel & Palier 2007; Stafinski *et al.* 2011; Syrett 2011; Calabrò *et*

al. 2018). Governance is realized either through new institutions (*e.g.*, The National Institute for Health and Care Excellence in the UK; the "Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen" in Germany), or the transformation and reinforcement of existing ones (*e.g.*, the Department of Home Affairs and its Office of Public Health in Switzerland). These actors interfere in the practice of medicine with its traditional therapeutic individualism and decentralized authority regime in order to set limits on healthcare consumption.

4. Rise of the Swiss regulatory healthcare state

The Swiss welfare state has developed rather late and in an incomplete manner (Armingeon 2001; Bonoli 2007; Braun & Uhlmann 2009; Häusermann 2010). Switzerland's healthcare system and its financing are built on a Bismarckian-inspired social health insurance system (Armingeon 2001; Bonoli 2007; Braun & Uhlmann 2009; Häusermann 2010). This system has a long history of multiple, mostly community, private health insurers, also called sickness funds, for over a 100 years (2,006 in 1903; 1,000 in 1969; 250 in 1990; 145 in 1996; 51 in 2020) (OECD & World Health Organization 2011). Historically, affiliation was based on trade unions, employment, religion, and geography (Trampusch 2010; Trein 2018). A previous version of the Federal Health Insurance Law, adopted in 1911 and revised only once in 1964, established a basic regulatory framework and imposed minimal conditions on private health insurers for them to receive public subsidies. Health insurers covered the population on an individual basis through voluntary private insurance. Certain cantons imposed mandatory health insurance for specific segments of the population, *e.g.*, school children.

With the adoption of the Federal Health Insurance Law in 1994, Swiss social health insurance was subject to a transformation (Bolgiani *et al.* 2006; Braun & Uhlmann 2009; Häusermann 2010; De Pietro *et al.* 2015; Trein 2018). It developed from a decentralized system operated on a private and voluntary basis by sickness funds to a system in which sickness funds provide a public service through mandatory universal insurance and a centrally regulated benefits' catalog defined by bureaucratic actors, *i.e.*, the Department of Home Affairs and its Office of Public Health. It is through the state's regulation of the solidary financing mechanism of social health insurance that a collective perspective of individual health appeared (Saltman & Dubois 2004).

The adoption of the Health Insurance Law constitutes a key moment for the rise of the Swiss regulatory healthcare state. In a social health insurance system, this rise is noteworthy. In contrast to tax-financed national health insurance (*e.g.*, NHS in the UK), the Swiss federal state does not provide the main funding for healthcare. The financial burden is carried by individual responsibility (cost-sharing mechanisms; out-of-pocket-spending; private insurance; 35 percent), societal solidarity of the community of insured (individual social health insurance premiums paid to health insurers; 30 percent), and financial means of the state (general taxation; 20 percent cantonal funding for hospital care and 5 percent federal and cantonal funding for individual premium reductions). Individuals thus bear the main cost burden (Bolgiani *et al.* 2006; Sturny 2017). Furthermore, the Swiss federal state does not act as a provider of healthcare.[4]

The Swiss federal state thus pursues the social objective of universal access to healthcare not through direct service provision or public spending in the form of tax expenditures, but social regulation of health insurance and state-regulated solidarity. This is characteristic of the regulatory welfare state (Tanzi 2002; Leisering 2010, 2012; Levi-Faur 2013, 2014; Benish *et al.* 2017, 2018; Haber 2017). Social regulation goes beyond providing opportunities in markets. It establishes standards to be imposed on private actors regarding coverage (*e.g.*, mandatory take-up of universal health insurance), benefits (*e.g.*, exhaustive benefits' catalog identical for all insured), procedures, and organizations in areas relevant to individual welfare (Leisering 2012).

Reflecting phase one of the rise of the Swiss healthcare state (Freeman 2000), the Health Insurance Law created mandatory and universal healthcare coverage. Phase two (Freeman 2000) is expressed, most importantly, through increased state power and control in designing the regulatory benefits' catalog of social health insurance. Before 1994, healthcare coverage was mainly dependent on individual insurance plans and discretion exercised by health insurers. The Health Insurance Law established the state's crucial role in defining the benefits' catalog by imposing a centralized decision-making process. It attributed a more limited role to health insurers, which have no discretion to cover benefits beyond the catalog, except for recognized exceptions. Health insurers are also denied judicial standing to appeal the state's decisions updating and expanding the benefits' catalog (Swiss Federal Court Decision (FCD) 142 V 478 of 2016; 127 V 80 of 2001).

With the Health Insurance Law of 1994, a shift of power and control has thus occurred from the pre-existing private health insurers to the regulatory healthcare state. However, phase two of the rise of the healthcare state concerned with the economic efficiency of treatments (Freeman 2000) is still in its early stages in Switzerland (Gress *et al.* 2005; Paris & Docteur 2007; Koch *et al.* 2009; Stafinski *et al.* 2011; Metzger *et al.* 2017). This paper proceeds by revealing and analyzing this unusual feature of the Swiss case study.

Despite rising healthcare costs, the actors of the Swiss regulatory healthcare state have interpreted the regulatory standard of reasonable care guiding healthcare coverage rather generously since the Health Insurance Law's adoption in 1994 (5). This generous interpretation has been accompanied by rising health constitutionalism (6). Recently, phase two of the rise of the regulatory healthcare state has been pushed, though, by the Swiss Federal Court in its case law, which has brought to the forefront the politics of efficiency by imposing limits on healthcare coverage (Freeman 2000). This case law provides crucial empirical evidence on the role of the judiciary as an actor in the regulatory healthcare state (7 and 8).

5. Regulatory standard of reasonable care

The Swiss regulatory healthcare state, through the legal framework regulating social health insurance and its interpretation by the executive and judicial branches of government, adheres to a standard of reasonable care. The Federal Court recognizes that as one of the basic principles of a social health insurance system, individuals are entitled to "reasonable, but not maximum medical treatment" (FCD 123 V 53 of 1997). The standard of reasonable care relies on a collective perspective of individual health and expresses the balancing of interests inherent in the regulatory healthcare state. Entitlements to healthcare coverage through social health insurance are regulated and adjudicated within the limits set by this reasonableness standard.

5.1. Benefits' catalog as a regulatory tool

Contrary to healthcare systems in which financing is organized mainly through private insurance (*e.g.*, USA) or tax-financed national health insurance (*e.g.*, UK, Canada), social health insurance systems operate with an explicit regulatory framework detailing entitlements to be provided by private actors, *i.e.*, health insurers or sickness funds (Flood & Gross 2014).

Not surprisingly, the Health Insurance Law does not define the content of the regulatory benefits' catalog. It contains, however, a delegation of power from the legislator to the Department of Home Affairs and its Office of Public Health. These two crucial actors in the Swiss regulatory healthcare state centrally define the binding benefits' catalog covered by social health insurance for all residents (De Pietro *et al.* 2015). Admission of new treatments occurs on an ongoing basis according to a set of criteria and a regulated process (Stafinski *et al.* 2011).

The Health Insurance Law and its by-laws operate an important distinction as to the content of the benefits' catalog. The regulatory mechanism used to define the catalog is the list principle. For physician services, it establishes a presumption of coverage through social health insurance. In principle, all treatments and diagnostics prescribed by doctors and dispensed by licensed professionals are automatically covered, unless they are explicitly excluded.[5] The catalog hence contains a negative list of services not covered (*e.g.*, IVF), or covered only under certain conditions. In contrast, drugs, laboratory analysis, and medical devices must be included in a positive list to be eligible for coverage. With the admission on the positive list, the Office of Public Health fixes the maximum price to be charged through social health insurance.

The paper focuses on the limit-setting mechanism of the benefits' catalog, its establishment by bureaucratic actors, and its applications by health insurers and the judiciary. There are, of course, other limit-setting mechanisms regulated by the Health Insurance Law.

5.2. Cost-effectiveness as a comparative tool

Article 32 Health Insurance Law expresses the standard of reasonable care through the regulatory criteria of efficacy, appropriateness, and cost-effectiveness (Stafinski *et al.* 2011). These criteria are relevant not only when the Department of Home Affairs and its Office of Public Health admit new treatments to the benefits' catalog

(regulatory benefits' design) but also when health insurers make individual coverage decisions (individual benefits' awarding).[6]

The Health Insurance Law refers to efficacy, adequacy, and cost-effectiveness without specifying these general and abstract terms. Exercising their power to define the content of the benefits' catalog, the Department of Home Affairs and its Office of Public Health have so far interpreted the standard of reasonable care in a generous manner (Gächter 2007a; Paris & Docteur 2007; Meyer 2009; Gächter & Meienberger 2012; Trageser *et al.* 2012). The following paragraphs describe and analyze this generous reasonableness standard.

Based on a by-law to the Health Insurance Law, the Office of Public Health applies the cost-effectiveness criterion as a regulatory tool to compare drugs when fixing the price of a new drug seeking admission (Gress *et al.* 2005; Paris & Docteur 2007; Stafinski *et al.* 2011). It also compares prices when reviewing listed drugs on a three-yearly basis, a regulatory assessment mechanism introduced in 2009.[7] These comparisons involve drug prices from abroad and drug prices of therapeutic competitors. The Office does not apply, however, cost-effectiveness as a tool to exclude or limit healthcare coverage based on cost-benefit or cost-impact analysis (Gächter & Meienberger 2012; Widrig & Tag 2013; Rütsche & Wildi 2016). This generous practice has resulted in extensive coverage of treatments. Most drugs for which pharmaceutical companies seek inclusion in the benefits' catalog are admitted (Paris & Docteur 2007).

Through the judicial review of individual healthcare coverage decisions, the Federal Court is also involved in circumscribing the standard of reasonable care.[8] The Court uses the cost-effectiveness criterion to compare treatments with similar efficacy and adequacy available within the benefits' catalog. As such, cost-effectiveness refers to the choice between adequate treatment alternatives. If efficacy and adequacy are similar, the cheapest treatment for a given indication is considered cost-effective (FCD 145 V 116 of 2019; 142 V 26 of 2015; 139 V 135 of 2013; 136 V 395 of 2010). Efficacy, appropriateness, and cost-effectiveness are closely connected though. If a more expensive treatment presents significant advantages compared to a cheaper one (*e.g.*, fewer complications), it can be justified to cover the higher costs (FCD 145 V 116 of 2019; 142 V 26 of 2015; 137 V 295 of 2011).

The cost-effectiveness criterion only applies if there is a comparison to be made between different treatments (FCD 145 V 116 of 2019; 142 V 144 of 2016; 139 V 135 of 2013). If no alternative is available, the Court has accepted that social health insurance has to cover even expensive treatments. It has not used cost-effectiveness to deny coverage in such cases. Although the Court has sometimes referred to the principle of proportionality imposing an outer limit on healthcare coverage ("gross disparity between medical expenses and expected success of the treatment can give rise to a denial of service") (FCD 120 V 121 of 1994; 118 V 107 of 1992; 109 V 41 of 1983), it has never applied such a limit. Until the landmark case "Myozyme" of 2010 discussed below, the Court has not relied on cost-effectiveness to subject medical treatments to individual cost-benefit or societal cost-impact analysis.

Economic considerations, as expressed by the cost-effectiveness criterion, are external to the confines of medical practice. Through social health insurance regulation, it is the regulatory healthcare state that has introduced economic aspects into the provision of healthcare. However, the standard of reasonable care is not equivalent to reasonable costs. Cost-effectiveness as a comparative rather than an excluding or limit-setting tool is one of the main features of the standard of reasonable care. Based on this generous definition of reasonableness, it is rarely a question of having or not having access to healthcare for a specific condition, but more about treatment options for the same condition available within the benefits' catalog (Paris & Docteur 2007; Gächter & Meienberger 2012; Widrig & Tag 2013; Rütsche & Wildi 2016).

5.3. Why generous reasonableness?

The current interpretation of cost-effectiveness indicates that there is no strict limit-setting of healthcare consumption based on economic considerations (Gress *et al.* 2005). In contrast to phase two of the rise of the healthcare state as described by Freeman (Freeman 2000), economic efficiency is not the primary goal of healthcare coverage decisions within the Swiss regulatory healthcare state. Switzerland's socio-economic situation obviously allows it to maintain high spending on healthcare. However, there are systemic, institutional, and legal attributes of the regulatory healthcare state that underlie the generous bureaucratic and judicial interpretation of the standard of reasonable care.

One piece of the puzzle is the purpose of the Health Insurance Law of 1994. According to the Swiss government's statement, when presenting the law to the legislator, the law aims to achieve three objectives: strengthen solidarity among the community of insured, guarantee high-quality and comprehensive coverage, and contain healthcare spending. The second objective aims very high. It implies that patients are, in principle, entitled to coverage of all medical treatments which are adequate to improve or re-establish their health to the best extent possible.

These objectives are contradictory, though: expand coverage and contain costs. This contradiction indicates that the law's purpose was never strict limit-setting as to the amount of healthcare consumed. The cluster of goals implicates tradeoffs between expanding access to healthcare and controlling the increasing cost of that care. Through the practice of state actors involved in defining the standard of reasonable care, the law's objective of comprehensive coverage was predominant over the last 25 years. While healthcare coverage considerably increased since 1994, the law failed to contain costs (Gress *et al.* 2005; De Pietro *et al.* 2015; OECD & World Health Organization 2011; Morgan *et al.* 2017).[9] Insurance premiums paid by individuals become more expensive every year to cover the costs incurred through the expanding benefits' catalog. In its case law, the Federal Court has confirmed this generous healthcare coverage, stating that the purpose of treatment, within social health insurance, is to eliminate health impairments in the most comprehensive way possible (FCD 138 V 131 of 2012; 137 V 295 of 2011; 130 V 299 of 2004; 127 V 138 of 2001). Generous coverage is thus an inherent aspect of the Swiss regulatory healthcare state.[10]

The federal state structure and the particularities of financing social health insurance provide another explanation for the generous interpretation of the regulatory standard of reasonable care (Armingeon 2001). An essential feature of the Swiss regulatory healthcare state is the disconnection of the power to regulate healthcare coverage from its financing; or, in other words, the design of the benefits' catalog from the financial responsibility for it. The federal state, through the Department of Home Affairs and its Office of Public Health, defines healthcare coverage, even though it pays for it only to a small degree. The cantons, which finance 20 percent of total healthcare spending through their contribution to hospital care, have the regulatory power to define the list of hospitals that provide treatments reimbursed by social health insurance.[11] The primary payers of healthcare, health insurers (*i.e.*, the community of insured) and individuals, are not involved in the regulatory process of defining the benefits' catalog. The regulatory principle "who decides, pays" or "who pays, decides" is thus not applicable in the Swiss healthcare state, except for the cantonal contribution to hospital care.

The Swiss federal state is not directly sensitive to the price and quantity of healthcare consumed. As it does pay for healthcare only indirectly and to a limited degree (through the premium reductions scheme), the Swiss federal state is not required to plan, budget, and monitor healthcare spending. Since there is no central resource allocation for healthcare-related expenditures, healthcare coverage determinations are not subject to direct budgetary constraints or control imposed by the federal government. The process of updating the benefits' catalog through the addition of new treatments does hence not involve balancing the objective of meeting healthcare needs comprehensively with the available financial means.

These features of Swiss healthcare financing are characteristic of social health insurance. Budgetary politics and constraints do not dominate health policy in a social health insurance system (Moran 1999; Böhm *et al.* 2014). The logic of limit-setting in the absence of a cap on state spending for healthcare is a slightly different one compared to tax-financed national health insurance systems in which the government enforces such a limit. Social health insurance being based on reimbursing healthcare expenditures incurred by insured patients, health insurers and the state only know *ex post* how much healthcare has been consumed over the course of a year (Hassenteufel & Palier 2007). Böhm *et al.* show that healthcare systems financed through social insurance contributions tend to be more generous than tax-financed ones (Böhm *et al.* 2014).

Finally, beyond guaranteeing access to healthcare through social health insurance, the Swiss state pursues other public interests. Pharmaceuticals not only add to the bill through social health insurance coverage. The pharmaceutical industry also provides significant tax revenues, employment, and attractiveness of research and innovation (OECD & World Health Organization 2011). Generous healthcare coverage through social health insurance thus also suits collective interests outside the confines of health.

6. Swiss health constitution

6.1. Backbone of the regulatory healthcare state

The Swiss Constitution to this day does not recognize a right to health or healthcare (Guillod & Sprumont 1996; Coullery 2001; Steffen 2002; Kraus & Schmidt 2006; Gächter & Filippo 2015; Müller 2018; Rütsche 2018). The Health Insurance Law of 1994, however, created legal entitlements to social insurance benefits in the area of healthcare. This universalization of access to healthcare achieved 25 years ago, and its evolution since, have to be considered in the context of rising health constitutionalism in the broadest sense (*i.e.*, beyond individual rights), expressing the state's commitment to health and healthcare (Coullery 2003; Kinney & Clark 2004; De Pietro *et al.* 2015; Sprumont & Joset 2016).

Within the Swiss state structure, the 26 cantons are sovereign in all matters, except to the extent that the federal Constitution limits their sovereignty. As a consequence, the written Constitution defines the federal state's commitment to certain public goods. In the area of public health and healthcare, the cantons are historically competent (Trein 2018). However, over the years, health has been increasingly centralized through explicit reference in the federal Constitution (De Pietro *et al.* 2015).

There are two constitutionally entrenched commitments to health, indicating that the state shall legislate on health insurance (article 117) and take measures for the protection of health (article 118; *e.g.*, communicable diseases). Both norms were adopted in the 19th century (1848 for health protection, with a significant expansion of the state's power in 1913; and 1890 for health insurance). Whereas health protection was concretized early on by several legislative acts, health insurance was only fully implemented in 1994 with the adoption of the Health Insurance Law. Although limited to the regulation of social health insurance, and not healthcare provision, which remains a cantonal competence, the Health Insurance Law is today *ipso facto* the core legislation shaping the entire healthcare system (De Pietro *et al.* 2015; Gächter 2006; Trein 2018).

The new Swiss Constitution of 2000 brought about a significant leap, as it includes additional state commitments to health. Access to healthcare constitutes one of the state's social objectives (article 41) (Mader 1996; Gächter 2007b; Harel 2014; Müller 2018). The new Constitution frames the Swiss state as a social state, through the principle of solidarity (preamble), the promotion of collective welfare and equality of opportunity (article 2), and the protection of individual social rights (articles 11, 12, 19). Also, the new Constitution renders federal competences in social and environmental areas (articles 108 ff) more visible (Mader 1999).

6.2. Recent constitutional moments in the Swiss healthcare state

Recent constitutional moments provide empirical evidence of an increasing constitutionalization of healthcare. As the developing health constitution is shifting sovereignty to the federal level (De Pietro *et al.* 2015; Trein 2018), the normative expressions testifying to the attributes of the healthcare state have become more numerous.

Initiated through the direct-democratic tool of a popular referendum, the admission of alternative medicines to the benefits' catalog of social health insurance was constitutionalized (!) in 2009 (article 118a). In 2014, the state's commitment to universal healthcare was made explicit through a constitutional amendment obliging the state to guarantee basic medical coverage (article 117a). With the adoption of article 117a, the federal level has been constitutionally recognized for the first time as carrying responsibility not only for health insurance but also for healthcare provision (De Pietro *et al.* 2015; Gächter & Filippo 2015).

In parallel to the expanding health constitution, norms that oblige the state to act according to economic principles have also been constitutionalized. Through a constitutional amendment of 2008, the principle of cost-effectiveness to be applied in the fulfillment of state tasks obtained constitutional status (article 43a).

These recent constitutional moments present two parallel movements: one of attributing universal healthcare coverage constitutional status, to be considered in an explicitly social state structure, and one subjecting the state to fulfill its tasks in a cost-effective manner.

6.3. Division of labor within the Swiss healthcare state

Various actors in the regulatory healthcare state pushed for these constitutional changes. The federal legislator instigated the constitutional article on fulfillment of state tasks according to cost-effectiveness (article 43a), subsequently adopted in a popular referendum. Political pressure built through a popular initiative launched by the

medical profession led to the amendment constitutionalizing the state's obligation to guarantee basic medical coverage (article 117a).

However, it is the Swiss Federal Court that has brought economic and societal limits to the table when adjudicating cases of healthcare coverage, thus initiating the politics of efficiency as described by Freeman for phase two of the rise of the healthcare state (Freeman 2000). The remainder of this paper critically analyzes the role of the judiciary in the regulatory healthcare state, limiting access to healthcare, and thus shaping social policy.

7. The Swiss Federal Court as an actor in the regulatory healthcare state

7.1. "Myozyme" case

The Federal Court handed down its decision in the "Myozyme" case in 2010 (FCD 136 V 395). Although dealing with exceptional coverage of a drug outside the benefits' catalog, the Court's decision and its underlying reasoning have significant implications. One of the last decade's landmark cases in Swiss law, this decision is pivotal as it carves out the role of the judiciary as an actor in the regulatory healthcare state, bringing about the judicialization of limit-setting.

The claimant, in this case, was suffering from a rare motor neuron disease that leads to severe muscle degradation and gradually reduces the ability to walk and breathe. Treatment with the drug "Myozyme" improves the patient's quality of life, through increased ability to walk unaided and independence from a constant oxygen machine. However, the drug was not part of the benefits' catalog of social health insurance. Treatment costs were estimated at $500,000 a year, and there was no alternative treatment available.

In this case, the Court dealt with the refusal of the health insurer to make an individual exception and cover the drug "Myozyme" for the patient concerned. As the benefits' catalog is binding and exhaustive, health insurers have to adopt a formal perception of equality, offering identical consideration to all insured regardless of individual factors. In principle, health insurers may not exercise discretion in individual cases. The Court has softened this approach in some circumstances, by allowing for individual exceptions based on therapeutic necessity.[12]

In the "Myozyme" case, for the first time, the Court added a cost-benefit analysis at the individual patient's level to the rule of rescue acknowledged in its precedent case law on exceptions. In a novel stance, the Court also noted that when considering a case in the exceptions' regime, the individual cost-benefit analysis has to be linked to societal considerations. It insisted that the state's commitment to health is not immune to costs, as the financial resources to fulfill socially desirable tasks are not infinite. The Court thus introduced cost-utilitarian considerations at a societal level to a healthcare coverage decision in an exceptional case. It debated the financial implications for society should the patient's claim be accepted. Referring to health economics literature, cost-benefit analysis in other healthcare systems, and cost-benefit analysis in other policy areas (*e.g.*, accident and health prevention), the Court stated that a maximum quantitative threshold of $100,000 per additional life-year could be considered acceptable for social health insurance.

The Court then debated the relevant legal principles in this context. Considering the costs of the drug "Myozyme," the Court argued that paying for such an expensive treatment would violate the principles of equal treatment and proportionality because the same sum could not be spent on all patients in a similar condition due to budget constraints. The Court also referred to distributive justice relevant for the provision of healthcare, noting that the principle of equal treatment requires a "capacity to be generalized." Generalizable is only what can be offered in the same way to all who are in the same situation. The Court noted that if costs are not generalizable, they cannot be covered in an individual case for reasons of equal treatment of all.

The Court concluded that suffering from a rare disease does not render irrelevant cost considerations. In an abstract statistical calculation, the Court demonstrated that numerous patients in Switzerland are afflicted with comparable impairments as the patient in the "Myozyme" case. Spending $500,000 a year would lead to an improvement in the quality of life for most of them. If such a sum were covered in this case, one could argue to spend the same sum in all comparable cases. The Court calculated the exorbitant costs of such a generalization. With the "Myozyme" case, the economic sustainability of the social health insurance system thus became relevant when considering healthcare coverage in an individual case.

7.2. Democratic legitimacy

In this landmark precedent, the Court imposed, for the first time, an individual cost-benefit and a societal cost-impact analysis to decide on coverage of an expensive drug. The Court also declared a maximum threshold of $100,000 per additional life-year that may be imposed on social health insurance in an individual case. It is thus the judicial branch of government that has paved the road to explicit cost considerations in the Swiss regulatory healthcare state.

The Court's push toward economic and societal limits when deciding on healthcare coverage raises questions of division of labor and democratic legitimacy within the regulatory healthcare state. Based on the Health Insurance Law's objective to offer comprehensive coverage, the actors in the regulatory healthcare state have so far interpreted the standard of reasonable care rather generously. Neither the legislator nor the government explicitly decided that cost considerations are to be taken into account. The Court introduced, by way of judicial intervention, a cost-benefit analysis of treatments that is not carried out by the Office of Public Health when updating and reviewing the benefits' catalog of social health insurance. Based on the cost-effectiveness criterion imposed by the Health Insurance Law, this bureaucratic actor negotiates drug prices with pharmaceutical companies by comparing costs of different treatments for the same medical condition in Switzerland and abroad. However, the Office does not evaluate whether it is reasonable to spend X amount of money for the medical condition Y. The regulatory standard of reasonable care is not equivalent to reasonable costs. Also, the regulatory framework does not establish a quantitative, maximum threshold for healthcare coverage determinations. It is noteworthy that the Court debated such a threshold.

In addition, the Court carried out a cost-impact analysis. By accepting societal considerations and recognizing "the capacity to be generalized" as a criterion for coverage, the Court looked beyond the individual claim brought before it. Considerations of overall consequences for society and the economic sustainability of social health insurance are not taken into account by the Office of Public Health when updating and reviewing the benefits' catalog. By relying on such considerations, the Court established limits to the welfare norm of solidarity within the community of insured and society more generally.

Through the judicialization of limit-setting, the Court turned itself into a crucial actor in the regulatory healthcare state. However, fundamental judicial interventions that affect social policy and the contours of the regulatory welfare state are controversial if they appear on a case-by-case basis when dealing with individual patients (Burningham 2015; Rütsche & Wildi 2016; Rütsche 2018). In terms of legal certainty and predictability, taking into account costs in an individual case, which may lead to a denial of healthcare coverage, must rely on criteria that are defined on a higher, democratically better legitimized regulatory level (Kinney & Clark 2004; Gächter & Meienberger 2012; Syrett 2014; Gächter 2019).

7.3. Antagonism between the individual case and equal treatment of all

The "Myozyme" case provides convincing evidence that healthcare coverage decisions are torn between the individual and society. The Court's active role highlights the antagonism between just consideration of the individual case and equal treatment of all. As such, the judicialization of limit-setting in the Swiss regulatory healthcare state has taken an intriguing direction.

The Court's recent case law has pushed the balance in the direction of society, adopting a strong, collective perspective of individual health. The Court's stance seems counterintuitive to the identified *versus* statistical life dichotomy (Cohen *et al.* 2015). In considering a treatment's "capacity to be generalized," the Court detaches itself from the concrete individual in a specific case and cares about the unidentified patients with similar needs and, more generally, all individuals insured through social health insurance and their unidentified healthcare needs.

In the context of social benefits (including insurance benefits in a social health insurance system), the role of the Court is not meant to protect individual autonomy against undue state interference. One might assume, though, that its role is to safeguard equity in the individual case against the flattening or standardizing role of general and abstract rules regulating access to healthcare through the content of a benefits' catalog.

In the "Myozyme" case, however, the Court gives precedence to a uniform and statistical rationality of adjudication, concerned with the economic sustainability of social health insurance. Equal treatment is guaranteed but at the cost of equity in the individual case. The Court does not conceive its role mainly as a Court of individual

equity, but as a Court of distributive justice, promoting the common good and upholding a vision of limited solidarity of all individuals insured through social health insurance. It transpires from the Court's case law that in the regulatory healthcare state, the welfare norm of solidarity does not only support individual patients' claims but also limits such claims in favor of collective interests.

The Court's actions stand in sharp contrast to the prevalent dichotomy between judicial and legislative or executive action, according to which, on a common view, courts follow a categorical or deontological logic, whereas the two other branches of government pursue an aggregative or utilitarian logic (Gauri & Brinks 2008; Yamin & Gloppen 2011).

Finally, the Court notes that health, like other public goods, is not immune to cost considerations. In contrast to other actors in the regulatory healthcare state who so far have remained silent on the issue, the Court brought arguments of distributive justice to the forefront. In doing so, it deliberately made visible the inevitability of tragic choices (Calabresi & Bobbitt 1978).

7.4. Turning proportionality upside down

In the "Myozyme" case, the Court reinterpreted the constitutional principle of proportionality in a novel way to limit healthcare coverage through social health insurance. The reference to proportionality underlying the Court's reasoning on limit-setting is puzzling, as it relates to the rule of law transcending the Swiss regulatory healthcare state. This section is deliberately succinct as the question raised goes beyond the scope of this paper.

The principle of proportionality implies that state activity has to be proportionate to the ends sought. According to traditional constitutional law theory, proportionality is a principle relevant to the restriction of fundamental rights (Barak 2012). Its purpose is to protect individuals from undue state interference in negative civil and political rights, such as freedom of expression or movement. In other words, proportionality limits individual rights' restrictions by the state, as is reflected in article 36 Swiss Constitution.

Based on article 5 Swiss Constitution, the principle of proportionality governs all state activities, not only fundamental rights restrictions. It also applies when the state regulates social benefits, such as access to healthcare through social health insurance. State actors have so far rarely relied on proportionality as a regulatory principle in the context of social policy. Recent jurisprudential developments starting with the "Myozyme" case indicate, however, that the principle is used against individuals to limit entitlements to social health insurance benefits (FCD 145 V 116 of 2019; 143 V 130 of 2017; 142 V 144 of 2016; 139 V 135 of 2013; 136 V 395 of 2010).

Proportionality goes beyond a simple comparison between different treatments, favoring the cheapest. It refers to a collective assessment of the costs and benefits of treatment, evaluating its economic sustainability. Paradoxically, proportionality seems thus to become a limit-setting tool that allows the regulatory welfare state to restrict its obligations in the administration of social benefits.

The "Myozyme" case serves as an example of how societal challenges, *e.g.*, the cost explosion in healthcare, can lead to a judicial re-interpretation of powerful constitutional principles such as proportionality. It is also an expression of the creativity of the judiciary as an actor in the regulatory healthcare state, tending to its economic sustainability through legal tools.

7.5. New case law in the aftermath of the "Myozyme" case

The Court-driven initiative toward explicit cost limits in the "Myozyme" case had repercussions on the regular admission procedure for the benefits' catalog of social health insurance.

The "Champix" case of 2011 involved the Office of Public Health's refusal to add a drug that facilitates smoking cessation to the benefits' catalog (FCD 137 V 295). In this case, the Court made a distinctive move reversing its former opposition to admit societal considerations when evaluating cost-effectiveness. The Court accepted that the cost burden for the community of insured is to be examined when the Office of Public Health considers admitting a new drug. This precedent has opened up the possibility to evaluate the cost-effectiveness of a drug through costs calculations across the entire benefits' catalog. It may thus permit refusing admission of new drugs if their overall costs, *i.e.*, cost-impact for the community of insured and economic sustainability of social health insurance, are considered too high.

The precedent on absolute cost limits set in the "Myozyme" decision has resurfaced since. The Court has relied on the same reasoning in cases not related to exceptional rare diseases. It has imposed limits on healthcare coverage arguing that "the effort required by social health insurance and, through it, the insured community – an effort that amounts to more than $100,000 per year – no longer corresponds to economic and rational management of social insurance" (FCD 139 V 135 of 2013).[13] This judicial reasoning is intriguing since, as described in this paper, in many instances, the "management" of social health insurance does not occur according to economic and rational principles. The Court presented itself, again, as the steward of economic sustainability within the regulatory healthcare state.

In a most recent decision of 2019, the Court has slightly backtracked, though (FCD 145 V 116). This case involved a 71-year old patient hospitalized for 421 days, which resulted in a hefty hospital bill of more than two million dollars to be split by the patient's health insurer and a canton. While the canton paid its part, the health insurer was willing to cover only a small share of its bill, invoking a lack of cost-effectiveness for the total amount of costs incurred during the lengthy hospital stay. In its decision, the Court stated that the threshold of $100,000 per year was not an absolute limit for healthcare coverage decisions in social health insurance. Analyzing the health insurer's arguments, the Court noted that cost-effectiveness could not be questioned based on the mere fact that the total costs of a series of treatments were considered too high. Rather, the cost-effectiveness of individual measures taken in a hospital setting would have to be contested and proven unfavorable, which was not the case here. Furthermore, it was one of the explicit goals of the Health Insurance Law to guarantee coverage for an unlimited number of days in hospital care. The Court thus obliged the health insurer to cover its full share of the hospital bill.

In this case, the Court has refined its stance on a maximum threshold of costs that can be imposed on social health insurance in an individual case (Gächter 2019). However, the precedent is very specific, as it relates to the costs of a prolonged and expensive hospital stay, including intensive care and unforeseen complications. The health insurer did not question the cost-effectiveness of a single pricey treatment, but the entire hospital bill. The Court's precedent in the "Myozyme" case – with regard to cost-effectiveness and coverage of highly expensive drugs – is thus not directly concerned by this most recent decision.

7.6. Reaction of political and bureaucratic actors

The political and bureaucratic actors have taken responsibility and reacted to some extent in the aftermath of the "Myozyme" decision. In 2011, the Swiss government closed a regulatory gap and legalized the individual exceptions' regime developed by the Court in a by-law to the Health Insurance Law. The new regulation specifies uniform criteria according to which exceptional coverage may be granted for "off-label use" and "hors limitations use" of drugs already admitted, as well as "hors-list use" and "unlicensed use" of drugs not listed in the benefits' catalog (Rütsche & Wildi 2016). The regulation subjects coverage in such cases to a reasonable cost-benefit ratio, thus establishing an explicit economic reasonableness standard in the exceptions' regime. However, this regulatory solution has only partly addressed the situation of legal uncertainty and unequal treatment criticized by the Court with regard to the overall framework of social health insurance.[14] Also, in a rather perplexing move, the Office of Public Health has added the drug "Myozyme" to the benefits' catalog in November 2011, with restrictive limitations and a lowered price. These developments are symbolic of the overall inconsistencies produced by actors involved in healthcare coverage decisions within the Swiss regulatory healthcare state.

However, in the wave of pricey new drugs that have arrived on the market in the last couple of years, the Court's insistence on cost considerations has influenced the Office of Public Health's practice. In August 2014, the Office considered adding the groundbreaking drug Sovaldi for Hepatitis C patients to the benefits' catalog. Sovaldi is both highly effective and very expensive (at the time around $60,000 for a 12 weeks treatment). The Office admitted the drug, although with important limitations as to the patients who can benefit from it. As a consequence, the drug is available through social health insurance only to a small number of patients who are at an advanced stage of liver failure, whereas the majority of the about 60,000 individuals with Hepatitis C remains uncovered.[15] Justifying its decision, the Office presented the overall costs of adding the drug to the benefits' catalog. It referred to cost-impact considerations, consequences for the community of insured, and economic sustainability to justify the significant limitations, in a clear parallel to the Court's arguments in the "Myozyme" case.

The Office has applied the same approach, or price negotiation technique, for other expensive new drugs more recently to build up pressure on the pharmaceutical industry to lower its prices.[16]

In 2015, the Swiss government launched a health technology assessment program. In 2017, it created a section for this task within the Office of Public Health (Matter-Walstra & Finlayson 2018). This section is not an independent regulatory agency, in contrast to, *e.g.*, the National Institute for Health and Care Excellence in the UK or the "Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen" in Germany (Landwehr & Böhm 2016). The role assigned to this new bureaucratic or regulocratic (Levi-Faur 2013) actor is to re-evaluate the benefits covered by social health insurance and to remove potentially obsolete ones or restrict the obligation to reimburse (Calabrò *et al.* 2018). This new actor has not imposed any drastic steps so far. Its creation has to be seen, though, in the larger picture of shifting unpopular decisions of limit-setting in healthcare from the political to the regulatory field, both for blame avoidance and depoliticization and to enhance "rationality and credibility of decisions as they are made by experts and not politicians" (or judges for that matter!) (Landwehr & Böhm 2016).

Cost considerations have thus become more prevalent among bureaucratic actors of the Swiss regulatory healthcare state. There is anecdotal evidence of intensified price negotiations before admission of certain new drugs and more institutional evidence through the creation of a health technology assessment section within the Office of Public Health. The consequences of the policy shifts discussed remain to be seen, notably as to the question of whether the Office will integrate not only societal cost-impact but also individual cost-benefit analysis. This would imply answering questions such as whether it is reasonable to spend tens or hundreds of thousands of Swiss francs to prolong life for a few months, for example. Considering the boom of highly expensive new drugs, notably for cancer treatment, which provide only limited value to patients in terms of prolonging life or increasing quality of life (Vokinger *et al.* 2020), individual cost-benefit analysis is likely to play a critical role in the regulatory healthcare state in the future.

8. Judicialization of limit-setting in the regulatory healthcare state

The question remains as to why the Swiss Federal Court has positioned itself as an actor in the regulatory healthcare state. In terms of judicial behavior, what drives the judiciary toward pushing for the judicialization of limit-setting in healthcare?

The Swiss Constitution does not allow for judicial review of federal legislation (article 189). With regard to regulation adopted by federal bureaucracy, the power of the Federal Court is more significant, as it can review administrative action such as the by-laws to the Health Insurance Law. In many cases, though, the Court defers either to the margin of appreciation of bureaucratic actors or the decision-making of experts. It does not, generally speaking, have a reputation of an interventionist or activist court.

This fact matches the literature on the judiciary in the regulatory state, which depicts a limited role for the third branch of government in regulatory systems (Ginsburg 2008; Thiruvengadam & Joshi 2012). As Thiruvengadam and Joshi note, the "evolution of the regulatory state in the Global North has been characterized by a low or negligible role for judiciaries" (Thiruvengadam & Joshi 2012). In particular, it does not seem to be part of the proper function of courts to trigger fundamental policy changes in the regulatory sphere, due to a lack of expert knowledge in areas relevant for regulation (Ginsburg 2008). As a consequence, "courts are discouraged from intervening in decisions made by regulators" (Thiruvengadam & Joshi 2012).

This paper demonstrates that the Swiss judiciary diverges from this traditional path of judicial behavior in the context of the social regulation of health insurance. In the Global South, similar exceptions have been noted involving more active courts, as explained, for example, in the context of telecom regulation in India (Thiruvengadam & Joshi 2012) or the regulation of education and health systems in South America and South Africa (Gauri & Brinks 2008; Yamin & Gloppen 2011). The expansive approach of the Swiss Federal Court, in an area where judiciaries are not traditionally expected to play much of a role, is intriguing as it reveals a new finding of an unusual phenomenon.

The Federal Court assumes an exceptional role as an actor in the Swiss healthcare state, beyond the role of courts as guardians of accountability in the regulatory state (Scott 2000; Rose-Ackerman 2008; Syrett 2011; Mejía 2020). It has proclaimed itself as an actor that establishes regulatory criteria for limit-setting in healthcare, such as cost-benefit and cost-impact analysis and a maximum cost threshold. Through its case law, the Court has

shaped social policy and welfare norms such as solidarity. The "Myozyme" case has been widely commented on in Switzerland, as it pushed the boundaries of judicial adjudication in the healthcare state (Guillod 2011; Kesselring 2011; Poledna & Tschopp 2012; Junod & Wasserfallen 2012; Schöne-Seifert 2012; Trageser *et al*. 2012; Gächter & Meienberger 2013; Gächter 2019).

The judiciary is an unexpected actor to set limits on access to healthcare, beyond the issue of democratic legitimacy discussed above. Judges typically do not have the professional and technical expertise to be regulators of social health insurance. A comparative perspective shows that regulatory agencies or committees composed of experts often assume the role of a limit-setting actor in the healthcare state (*e.g*., the National Institute for Health and Care Excellence in the UK or the "Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen" in Germany).

As another exceptional feature of its interventionist attitude, the judiciary established regulatory criteria for limit-setting, with a vision not for the individual reaching the Court, but for the economic sustainability of social health insurance. In contrast to activist courts promoting social rights (Gauri & Brinks 2008; Yamin & Gloppen 2011; Bignami 2016), the Court has not pushed its active role based on fundamental rights, such as the right to health, to protect individuals. It has relied, to the contrary, on legal principles such as proportionality, to limit social benefits and promote collective interests. In some instances, the Court has also expressed its concern for the overall hefty cost burden of rising health insurance premiums imposed on the community of insured (FCD 140 V 574 of 2014; 130 I 26 of 2003). This approach is highly unusual.

A discussion of judicial behavior includes several possible explanations, such as the political scientists' emphasis on ideology and the law community's interest in legal motivations (Gauri & Brinks 2008; Epstein & Knight 2017). An economic analysis of judicial behavior emphasizes that the judiciary often adopts "an instrumental, over-reaching and self-interested approach" (Thiruvengadam & Joshi 2012) when dealing with controversial cases, as it is interested in expanding its power and authority (Baum 2009; Posner 2010; Epstein & Knight 2017).

This paper demonstrates that the Court's behavior goes beyond the pursuit of its interests as an institution. The underlying motivation of the Court's intervention in the "Myozyme" case was not about expanding its power and authority. This case and other precedents in its aftermath can hardly be read as showing that the Court is nothing more than a self-interested actor. On the contrary, the Court appears to have been motivated by the public interest (Prosser 2010) of maintaining the economic sustainability of the social health insurance system.

Finally, the Court's actions have to be considered through the broader picture of the Swiss Constitution. Recent constitutional moments have introduced amendments not only obliging the state to cover basic healthcare in the context of an explicitly social state structure but also forcing the state to act according to economic principles and pursue sustainability. The regulatory healthcare state adheres to a social rationality but also increasingly to an economic rationality.

The Court has criticized the lack of political action and regulatory criteria, concretizing these potentially conflicting rationalities concerning healthcare coverage. This legal uncertainty has raised doubts as to the limits of solidarity of the community of insured within social health insurance. The Court's precedents might thus have been guided by a desire to foster a constitutional dialogue among the diverse actors of the regulatory healthcare state, calibrating the future confines of the standard of reasonable care and the welfare norm of solidarity more generally. The Court has sought to make a constructive contribution to both the actual individual dispute as well as the overall regulatory framework of interest to the entire polity, a finding that resembles the role of the judiciary reported from regulatory states of the Global South (Gauri & Brinks 2008; Thiruvengadam & Joshi 2012).

9. Conclusion

This paper has significant implications for the comparative study of the regulatory welfare state, and, in particular, the role of the judiciary as an actor within this framework. The Swiss federal state pursues the social objective of universal access to healthcare not through direct service provision or public spending based on taxes, but social regulation of health insurance. This is characteristic of the regulatory welfare state.

The Swiss case study may be somewhat exceptional, though. The rise of the regulatory healthcare state occurred late and incompletely. It was only in 1994 that the newly adopted Federal Health Insurance Law

brought about a social health insurance system offering universal coverage, through non-profit private health insurers, based on a binding benefits' catalog. The objectives of this regulatory framework were containing costs, guaranteeing high-quality, comprehensive healthcare, and establishing greater solidarity among the community of insured. 25 years later, the goal of cost containment has not been achieved. Switzerland's healthcare spending, among the highest in the world, is steadily increasing. Insurance premiums paid by individuals become more expensive every year to cover the price and quantity of healthcare consumed. Two-thirds of total healthcare expenditure is financed regressively, *i.e.*, unrelated to income (insurance premiums, cost participations, out-of-pocket payments), which leads to an increasingly heavy, and unequal, financial burden for a growing part of the population (De Pietro *et al.* 2015). This development runs contrary to the purpose of social regulation.

One reason for the phenomenon of rising costs is the regulatory process of updating the benefits' catalog. The admission of new treatments is not subject to budgetary constraints. As is characteristic of social health insurance systems, no central resource allocation for healthcare spending occurs within the Swiss state. While the Department of Home Affairs and its Office of Public Health define the benefits' catalog, premiums are paid by individuals to health insurers, which are obliged to cover the expanding benefits' catalog without having a say in its design.

The actors of the regulatory healthcare state have interpreted the regulatory standard of reasonable care guiding healthcare coverage rather generously since the Health Insurance Law's adoption in 1994. So far, the Office of Public Health has relied on cost-effectiveness to compare drug prices when determining the price for a new drug seeking admission to the benefits' catalog, *i.e.*, in its price negotiations with the pharmaceutical industry. However, the criterion is not applied as a proper cost-benefit or cost-impact analysis, which, if unfavorable, might lead to not admitting a treatment at all. With regard to individual coverage, health insurers use cost-effectiveness to decide between available options, meaning that among several treatments the cheapest one has to be covered. Cost-effectiveness thus serves as a comparative, rather than an excluding or limit-setting tool.

As an exceptional feature of the domestic regulatory context, it is the judiciary that has brought to the forefront the politics of efficiency in the Swiss healthcare state and its regulation of social health insurance. The paper's empirical evidence and discussion of the judiciary as an actor in the regulatory healthcare state testify to its comparative importance.

In the "Myozyme" case of 2010 (FCD 136 V 395), the Swiss Federal Court has paved the road to explicit cost considerations on an individual and societal level. It has asserted its role as an actor in the regulatory healthcare state, imposing limits on access to healthcare and providing decision-making criteria in this area of social regulation, such as cost-benefit and cost-impact analysis. This judicialization of limit-setting in the Swiss regulatory healthcare state is intriguing. It might reveal a new role for the judiciary in the regulatory welfare state more generally: the judiciary as a steward of economic sustainability, and as such an occasional regulator? The paper also demonstrates that judicial reasoning has the power to shape political and public debates. With the "Myozyme" case, the Court has initiated a dialogue among political and bureaucratic actors on how to set limits on healthcare consumption to guarantee the economic sustainability of social health insurance in the years to come.

As a consequence, cost considerations have become more prevalent in the Swiss regulatory healthcare state, *e.g.*, in price negotiations between federal bureaucracy and the pharmaceutical industry. The dialogue triggered by the Court will certainly continue to gain in importance, as will the regulatory criteria of cost-benefit and cost-impact analysis that it recognized. The latest pharmaceutical trend of effective but also highly expensive cell- and gene therapies (*e.g.*, the blood cancer drug "Kymriah" at $400,000) pinpoints to the heart of economic sustainability of social health insurance (Charlton *et al.* 2017).[17] These scientific developments are most likely to have a disruptive effect on the Swiss healthcare state and its regulatory standard of reasonable care.

Finally, this paper has implications for the comparative study of the regulatory welfare state beyond health and Switzerland. It offers a more in depth understanding of how the judiciary projects specific visions of society, of distributive justice, and of welfare norms such as solidarity and how they are integrated into regulation. The empirical evidence of the Swiss case study shows that within a constitutional framework, and social regulation more specifically, the human being appears both as an individual and as an element of society. Despite modern society's individualism, the Constitution is still a bill of individual rights and an expression of the social contract beyond such rights. The welfare norm of solidarity underlying social health insurance, and the regulatory welfare state more generally, sustains individual claims and, at the same time, limits such claims. Unlike medicine, the

regulatory welfare state considers not only the individual case but also its consequences for society and the common good. As such, it pursues a perplexing collective perspective of individual health and other social claims.

The balancing of interests between the just (equity) and the good (efficiency) reaches beyond health. It constitutes an inherent part of the regulatory welfare state. The dilemma of equity in the individual case, as opposed to distributive justice, manifests itself in diverse areas of social regulation (*e.g.*, disability, education in general and for children with special needs: Gauri & Brinks 2008). The judiciary is in a unique position to highlight questions of distribution and make visible the inevitability of tragic choices in areas in which the regulatory welfare state enables public services and access to public goods through social regulation. Future research will have to investigate whether the judiciary continues to assert this crucial role and how to accommodate such a role with the demands of democratic legitimacy and expertise within the regulatory welfare state.

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Endnotes

1 Private health insurance is another mechanism for raising and pooling funds to finance healthcare (*e.g.*, USA).

2 Whereas in its beginnings social health insurance covered only income loss due to inability to work, over time coverage of healthcare costs was added to its core functions.

3 The second phase of the rise of the healthcare state was also accompanied by a renewed interest in public health protection and prevention, as a means to address the cost explosion in healthcare systems. The paradigm change from disease to health, and from *ex post* to *ex ante* responsibility, are inherent features of the prevention state (Peeters 2013).

4 Cantons play a role in healthcare provision and financing in the context of hospital care. They are the owners of public cantonal hospitals. Within the limits set by the Health Insurance Law, cantons finance about half of hospital costs, which corresponds to 20 percent of total healthcare spending. Also, based on uniform regulatory criteria established by the Health Insurance Law, cantons establish a list of (public and private) hospitals that provide services reimbursed through social health insurance.

5 Tariffs for reimbursement of services are negotiated and agreed upon between professional associations of insurers and providers. These contracts then have to be approved by the federal or cantonal governments. If insurers and providers do not reach an agreement, tariffs can be fixed by the federal or cantonal authorities.

6 The criteria of efficacy, appropriateness, and cost-effectiveness apply to all treatments. However, being scrutinized before admission to the positive list of the benefits' catalog, drugs, analysis, and devices are assessed by a more exacting standard than hospital and physician services, which are in principle automatically covered.

7 The periodic assessment of listed drugs has led to some price reductions and cost savings for older drugs, as it allows for renewed negotiations between bureaucratic actors and the pharmaceutical industry. This regulatory mechanism does not address, however, the pricing challenges for new, hugely expensive therapies at the time when a decision is made as to their first admission to the benefits' catalog.

8 According to the Federal Court's constant case law, a treatment is efficace if it is suitable to achieve the desired diagnostic or therapeutic goal. Adequacy asks for the diagnostic or therapeutic benefits of administering a treatment in the individual case, taking into account the risks involved. See, *e.g.*, FCD 145 V 116 of 2019.

9 Between 1996 and 2015, per-insured benefits paid by insurers rose by 4 per cent *per annum*, while consumer prices increased by an average of 0.5 percent (Froidevaux & Kilchenmann 2016).

10 Certain areas of Swiss healthcare do raise, though, issues of access, elderly care in particular (Kley 2018).

[11] In ambulatory care, health insurers pay all the costs above cost-sharing mechanisms. In hospital care, costs are split almost equally between health insurers and cantons (Mader 2011).

[12] The Federal Court created a precedent on individual exceptions for drugs excluded from the exhaustive benefits' catalog. In 2004, the Court admitted the exception for the first time, in a case of off-label drug use for a cancer patient (FCD 130 V 532 of 2004). It imposed three criteria for a treatment to be covered: disease causing a threat to the patient's life or a serious and chronic health impairment; lack of therapeutic alternatives; high therapeutic (curative or palliative) utility (*in abstracto* and *in concreto*). *E.g.*, FCD 139 V 375 of 2013; 131 V 349 of 2005.

[13] A more prudent attitude can be found, however, in FCD 142 V 478 of 2016.

[14] According to the regulatory exceptions' regime, each health insurer (currently 51!) evaluates the reasonableness of cost-benefit ratios and negotiates the price of a drug administered in an individual exceptional case with the pharmaceutical industry. This constitutes an anomaly in the Swiss regulatory healthcare state in which the Office of Public Health fixes drug prices. As a result, health insurers act differently toward patients who suffer from the same disease and need the same medication. Admission of exceptions depends on the drug prices that health insurers are able to negotiate, which leaves patients claiming an individual exception in an even more vulnerable position.

[15] In 2017, several new drugs against Hepatitis C arrived on the Swiss market. The Office of Public Health was able to negotiate lower prices with the pharmaceutical companies concerned and thus agreed to retract some of the limitations imposed for coverage of these drugs through social health insurance.

[16] The Office of Public Health refuses, for example, to admit the new drug Orkambi for the treatment of cystic fibrosis due to the high costs of about $170,000 per year.

17 In December 2019, the Department of Home Affairs decided that two new hospital-based cell therapies (Kymrah and Yescarta) for the treatment of blood and lymph gland cancer were to be covered by social health insurance. Coverage is initially offered for a limited period from January 2020 until the end of 2022. Interestingly, the Department is unwilling or unable to share an estimate of the cost consequences of its admission decision. As mentioned, one therapy costs several 100,000 francs. The exact amount remains unknown, however, as secrecy as to the price negotiated has been agreed upon. This lack of transparency is highly unusual for drugs covered through social health insurance.

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