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CAN LITIGATION PROMOTE FAIRNESS IN HEALTHCARE?: THE JUDICIAL REVIEW OF RATIONING DECISIONS IN BRAZIL AND ENGLAND

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Declaration

I certify that the thesis I have presented for examination for the MPhil/PhD degree of the London School of Economics and Political Science is solely my own work.

I declare that my thesis consists of 88,358 words.

Statement of inclusion of previous work

I can confirm that parts of Chapter 2 and 3 were the result of previous study I undertook at the LSE Department of Philosophy, Logic and Scientific Method and were published, with modifications, as an article at the *Health Economics, Policy and Law.*

Abstract

This thesis analyses “health care litigation” in Brazil and England. By health care litigation I mean those lawsuits in which claimants demand from the State the provision of a certain health treatment based on their entitlement to receive health care from the public health system or funded by it. The question that guides this thesis is whether courts intervening in rationing decisions make the public health system more or less fair. The concept of fairness I use in this thesis draws on the idea of “accountability for reasonableness” developed by Norman Daniel and Charles Sabin. This research will analyse the case-law of courts in Brazil and England, and the impact of litigation on the public health system. Based on this research, I argue that health care litigation in Brazil, where courts interpret the right to health as an individual trump against rationing decisions, is making the public health system less fair. Conversely, in England, where courts mainly control the procedure rather than the substance of the rationing decisions, litigation contributed to make health authorities more accountable and rationing decisions more public and based on better reasons, robust evidence and fair principles. Interestingly, even though courts in both countries have judged their cases in different ways, in the long term, litigation was one of the reasons for the creation of health technology assessment systems that try to legitimate rationing decisions through more public and better reasoned decisions: CONITEC in Brazil and NICE in England. The analysis of healthcare litigation in Brazil and England also contributes to the broader debate about social rights adjudication. These cases provide empirical and nuanced evidence that can be compared with the experience of other jurisdictions to shed light on the potential, risks and limits of courts controlling the allocation of resources in social policies using the language of social rights.

CONTENTS

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1. Introduction

Background and context

An ageing population that is well educated, highly informed, less acquiescent and has high expectations in relation to what health treatments can do to allow its people to live longer and better lives increases the demand for health care. A very profitable pharmaceutical industry that invests heavily in the development and marketing of new and expensive medical technologies expands what it is technologically possible to do in healthcare. Finally, and especially in countries where there is legislation guaranteeing universal and comprehensive healthcare coverage, governments under budgetary constraints need to set priorities in healthcare and to establish the level of priority that should be given to healthcare in comparison to other policies. What is more, the more successful a public health system, the higher the financial pressure to meet the population's health. People who live longer lives will need more and more expensive health care.

This scenario describes the Sisyphus work that is expected from health care systems in both developing and developed countries (on this, see Coulter & Ham, 2000; OECD, 2006). Since there is an increasing mismatch between what the healthcare patients expect (and demand) to receive and the care public health systems can afford to provide, health care rationing has become more visible. This increases the pressure on health authorities who have to set priorities in healthcare and, therefore, to make "tragic choices" (Calabresi & Bobbit, 1978).

This thesis will analyze one source of pressure on health authorities: litigation. In recent years courts have been expanding their review power to cover issues of public

policies that in the past were left to the complete discretion of politicians and bureaucrats (on a broad analysis of this phenomenon, see Tate & Vallinder, 1995; Hirschl, 2008). Healthcare is certainly one of these areas in which the expansion of judicial power is present. Apart from the reasons already mentioned that make healthcare a constant cause of dissatisfaction among citizens in relation to the government, there has also been an increasing recognition of the entitlement to receive healthcare (occasionally translated into the language of the right to health) in legislation, constitutions and international treaties (Backman et al, 2008). There is also generally less trust placed in public authorities and politicians by citizens. Moreover, there has also been better access to justice and widespread use of litigation in a society of less acquiescent citizens. This is a scenario that brings rationing decisions to the review of courts and prompts the phenomenon that I will call here "health care litigation".

By "health care litigation", I mean those lawsuits in which claimants demand from the State the provision of a certain health treatment based on their entitlement to receive health care from the public health system or funded by it. These lawsuits are generally lodged by those negatively affected by rationing decisions and who expect courts to review these decisions. "Rationing", in this thesis, means the non-provision of a health treatment because of limited resources or because the health authorities are not convinced that it is effective or cost-effective[1].

[1] Some authors define rationing as the non-provision of treatments only because of limited resources, which excludes from this definition cases in which patients are not offered treatments that are considered not effective (see, for instance, Herring, 2008, p.52). I opted for including in my definition of "rationing" the non-provision of treatments for effectiveness reasons because when it comes to deciding about the provision or not of a treatment, it is normally very difficult to disentangle them from economic reasons. Cost-effectiveness analysis, one of the most used methods to decide on the provision of health care, functions with considerations of both cost and effectiveness. Moreover, in an ideal world where resources are not scarce, it would be perfectly rational to provide drugs which have low effectiveness. However, in real health systems, every treatment carries opportunity costs (Ford, 2012, p.29).

The involvement of courts in decisions about the provision of healthcare is a worldwide phenomenon and has caught the attention of many specialists. Hogerzeil et al. (2006) surveyed low-income and middle-income countries and found judicial claims for health treatments in 12 countries. Yamin & Gloppen (2011), Gauri & Brinks (2008) and Langford (2008) have all published collections that not only analyse the phenomenon in many countries, but also compare various jurisdictions so as to offer important insights on how courts decide, what litigants' claim, and the impact of litigation on the public health systems and the population's health. Other scholars have also researched specific jurisdictions such as Brazil (e.g., Ferraz, 2011A), Colombia (e.g., Landau, 2012), Canada (e.g., Flood & Chen, 2010), South Africa (e.g., Young, 2012; Liebenberg, 2010), Germany (Hess, 2006) and India (e.g., Fredman, 2010). In this thesis I make an in-depth analysis of just two jurisdictions - Brazil and England[2] - that have never been compared before.

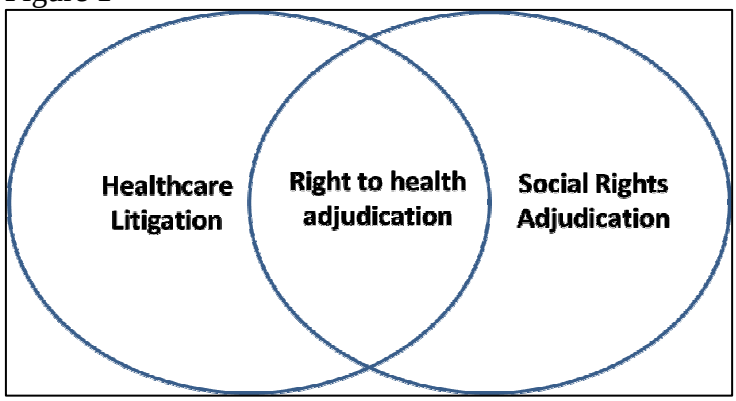
Many of the aforementioned scholarly works analyse the involvement of courts in decisions about the provision of healthcare as instances of right to health adjudication and, therefore, within the framework of social rights adjudication. The "right to health" has been progressively recognized in national constitutions and has allowed, in many jurisdictions, that demands for health care be voiced as legal entitlements to be enforced against the State via courts (Backman et al., 2008, 2077-2078). Nonetheless, this thesis does not consider that health care litigation is necessarily an instance of the judicial protection of the right to health: the lawsuits challenging healthcare rationing decisions do not always use the language of the "right to health"; and courts may scrutinize and

[2] I will use "England" as meaning "England and Wales". The cases analyzed in this research were judged by the Courts of England and Wales and the National Institute for Health and Care Excellence provides guidance for health authorities in England and Wales.

review rationing decisions without considering themselves to be adjudicating social rights (see Figure 1).

There is no doubt that, because of the widespread use of the "right to health" language, the discussion about health care litigation overlaps with many of the topics debated in the literature on social rights adjudication. Therefore, the scholarship on social rights adjudication will be useful for analysing health care litigation in this thesis and, likewise, the latter can bring important contributions for the former.

Figure 1



Justification for the comparison of the cases

It would be reasonable to ask why and how to compare two jurisdictions that seem, at first sight, to be so different. England is a developed country with a common law system, no written constitution and no constitutional right to health; whereas Brazil is a developing country with civil law system, a written constitution and a constitutional right to health. However there are similarities that make the comparison worthwhile for my argument in this thesis.

Firstly, both countries have universal national public health systems financed by general taxation from which citizens are entitled to receive comprehensive healthcare free of charge. This is more than a mere coincidence since the creation and organization of the Brazilian public health system (the *Sistema Único de Saúde*) in 1988 was inspired by the English NHS (Tanaka & Oliveira, 2007). Even though there is no constitutional right to health in English law, there is an explicit framework of legal rules concerning the provision of health services that entitle citizens to receive healthcare. Moreover, the NHS Constitution has recently adopted the language of rights, such as the right to receive comprehensive care from the public health system (NHS, 2013).

Secondly, in both countries there are a significant number of health care litigation cases, spread over many decades. Thus, differently from most studies analysing health care litigation in other jurisdictions, my analysis is not based on a few cases in one jurisdiction or a collection of cases picked from different countries. The two case-studies in this thesis allow me, in each case, to set out a narrative of the transformation of the way in which courts have been deciding these cases and to track the interaction between courts, health authorities and legislatures through the years.

Thirdly, in spite of the differences in the health systems in terms of quality and actual coverage, health care litigation in both countries is mainly driven by the claim for new and expensive treatments against the public health system. The same drugs that are litigated for in England are also claimed in Brazil. Courts and health authorities in both countries are therefore facing the same challenges and dilemmas.

Fourthly, even though courts in each country decide health care litigation cases in different ways, in the long term litigation has contributed to the creation of similar schemes for health technology assessment in their public health systems: NICE in

England, and CONITEC in Brazil. Thus, the comparison between both cases helps to understand the impact of health care litigation on the way decisions are made in the public health system and how the experience in one country can shed light on the experience of the other.

Finally, let us assume that when courts decide claims for health treatment based on patients' legal entitlement to receive health care, they have to choose between three positions: 'usurpation' (i.e., to issue positive orders against the prevailing political or administrative view); 'abdication' (i.e. to cede to executive bodies a *lettre blanche* to decide about the provision of policies); or an intermediate solution (that can have many forms) between the two (Michelman, 2003, p.16). The case-studies here provide a perfect description of usurpation (Brazil) and of abdication (England before the case *Child B*[3]), and an example of the form of intermediate solution that I will be arguing for as the most suitable for courts, namely the procedural enforcement (England after the case *Child B*[4] and, possibly, Brazil after the creation of CONITEC). Thus, these cases are useful in helping our understanding of the impact of different patterns of litigation on the public health system and the limits, potentials and risks of courts getting involved in rationing decisions of this sort.

Health care litigation: improving or foreclosing fairness?

The question that guides this thesis is whether courts intervening in rationing decisions make the public health system more or less fair. The concept of fairness I use draws on the theory of Norman Daniels and Charles Sabin (Daniels, 2009; Daniels &

[3] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[4] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Sabin, 2008). Assuming that in a context of scarce resources we will not be able to meet all health needs, the question is how to make sure that we are meeting what we can in a fair way (Daniels, 2009, ch.4). Probably there are as many answers to this question as there are theories of justice, and many of them are equally plausible. Therefore, reasonable people may disagree about the best way to distribute health care resources because there is no broadly accepted consensus about which distributive principle – utilitarianism, egalitarianism, prioritarianism, and so on – is the best guide for a fair allocation of resources (Daniels & Sabin, 2008, p.4; Daniels, 2009, p.107).

In light of this, Daniels and Sabin propose a practical solution, that of procedural legitimacy. According to this approach, the fairness of a health system should not be measured according to some general principles of distributive justice but rather according to the fairness of the procedure through which the decisions are made. They argue that a fair public health system is one in which there is "accountability for reasonableness", i.e, decisions about the allocation of health care are made explicitly through a procedure that fulfils the following conditions: (i) publicity (transparency and openness); (ii) relevance (based on evidence, reasons and principles that are accepted by fair-minded people); (iii) revisions and appeals (mechanisms to allow interested parties to challenge decisions); and (iv) regulation (public regulation to ensure the first three conditions are fulfilled). Thus, based on the framework suggested by Norman Daniels and Charles Sabin, when I ask whether courts intervening in rationing decisions make the public health system more or less fair, I am asking whether courts interfering in rationing decisions promote or impair such optimal procedure as is advocated by Daniels and Sabin.

The relationship between accountability for reasonableness and litigation was

mentioned by Daniel and Sabin, but not developed further. In the debate among health policy experts about whether rationing should be explicit or implicit, part of the literature that defends implicit rationing affirms that one of the reasons why rationing should not be made explicit is fear of litigation, given that explicitness would "open the door to attack" from dissatisfied patients and their lawyers. On the other hand, there are those who affirm that courts will be less likely to substitute their own decisions about a provision of new technologies if they see health authorities using "robust, careful, deliberative procedures and base their conclusions on reasonable arguments that appeal to the evidence produced in the evaluations" (Daniels & Sabin, 2008, p.50). Norman Daniels recognises that arguments on both sides suffer from being speculative since "there is no evidence that failing to provide reasons protects an organization against litigation or that giving them opens it up to more litigation or successful litigation" (Daniels, 2009, p.122).

In light of this controversy, this thesis will use the Brazilian and the English cases to bring empirical evidence to bear on what are at present the "speculative" claims that are being made on both sides of this debate. Rooted in my findings, my argument is that keeping rationing implicit does not and will not foreclose litigation. Patients are well informed and willing to demand treatments not provided by the public health system. The "door to attack" is already open and the challenge is how to control the cases that should pass through it.

This research will be also concerned with the impact of litigation on the public health system. Based on the analyses of health care litigation in Brazil and England, my argument is that the impact of litigation depends not on whether but on how courts review rationing decisions.

In *Brazil*, the Federal Constitution declares the right to health to be a fundamental right and a duty of the State. The Constitution also established a public health system based on the principles of universality, equality of access and comprehensive coverage. These principles have entitled those who have been denied health treatments by the public health system to lodge lawsuits against the State, which, coupled with courts interpreting the right to health as an individual trump to receive healthcare irrespective of the costs against rationing decisions, has led to thousands of lawsuits. Brazil is a typical case of what (as we have seen) Michelman (2003) calls "usurpation". I argue that this model of health care litigation is based on an unrealistic assumption that the State can provide every health treatment needed by anybody. Apart from the significant economic impact of such cases on the public budget, there is empirical evidence that health care litigation is requiring the public health system to spend significant amounts of resources without use of good evidence (courts are forcing the provision of health treatments with low cost-effectiveness or the effectiveness and safety of which are not proven); based on an unreasonable principle (those who have capacity to litigate have access to treatments that are not available for the other beneficiaries of the public health system) and with no broader discussion about the needs of the rest of the population that should be considered. In other words, Norman Daniels and Charles Sabin's test is not being met.

Courts that use the right to health as a trump and protect the interest of individual litigants without taking into consideration the economic impact of the decisions, as in Brazil, end up forcing public authorities to apply the "rule of rescue" for litigants and this forecloses the possibility of making rationing explicit. Thus, health authorities have less incentives to make rationing explicit because the reasons for their

decisions are not important for courts, and people that know they are receiving sub-optimal care will probably be successful in forcing the provision of the rationed treatment through courts. Therefore, this pattern of litigation does not contribute towards making rationing decisions more transparent or decision-makers more accountable, but rather encourages implicit rationing for fear of litigation.

Nonetheless, health care litigation in Brazil has become such a dramatic problem in the last years that a new system for making health care rationing more explicit has had to be instituted. The Federal Law 12.401/2011 was recently enacted and created the National Health System Commission for the Incorporation of Technologies (CONITEC), an institution responsible for assessing and deciding on the provision of new health technologies in the public health system. This is an attempt by the government to make use of a more legitimate decision-making procedure – more transparent; based on better reasons, evidence and principles; and with possibility of challenge by interested parties –, in line with Daniels and Sabin's idea of accountability for reasonableness, in order to convince courts to be more deferential to rationing decisions made by health authorities. This law tries to push the Brazilian model of health care litigation from "usurpation" to a more intermediate position, one which is similar to where health care litigation in England currently is and that, I argue, is the most suitable for courts when deciding health care litigation cases.

The case of Brazil is also important as a place to test the suggestions made by authors who believe that courts can be reformed so as to be more legitimate and to have their institutional capacity to judge social rights issues increased. It is expected that courts that are more open to participation from interested parties, coupled with judges that are better trained, assisted and informed about health care policy issues, are better

equipped to make fair decisions about the provision of healthcare. Reforms of this sort have been put forward in Brazil. Nonetheless, based on a comparative institutional analysis, I argue here that these changes do not enhance courts' capacity and legitimacy to an extent that would justify allowing judges to claim the power to allocate scarce resources.

In stark contrast to Brazil, the English courts were initially a perfect example of the "abdication" model used by Michelman (2003). Courts were very deferential and avoided interference in the way health authorities rationed health care. They restrained themselves to a minimal level of scrutiny of rationing decisions and there was more trust than has been evident in Brazil that health authorities had made the best decision. However, after the well-known decision of the case *Child B*[5], English courts started to expect authorities to provide good reasons for their decisions and to prove that they had done the best possible job in gathering and assessing data, in considering alternative policies, and finally in clarifying the principles underpinning their decisions.

This turn in health care litigation in England was one of the reasons that health authorities started making rationing explicit, i.e., explaining how and why decisions had been made as they had as a way to cope with progressively demanding courts and the negative publicity caused by these legal claims. I argue that health care litigation in England has helped to engender a dialogue between courts and health authorities that has led to fairer decision-making procedures for the incorporation of new health technologies. This process has culminated in the creation of the National Institute for Health and Care Excellence[6] – NICE –, the institution responsible for assessing health

[5] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[6] NICE's original name when created in 1999 was National Institute for Clinical Excellence.

technology in the NHS based on the idea of accountability for reasonableness developed by Daniels and Sabin. I also present evidence to suggest that making health care rationing explicit in England – being transparent and public about procedures and reasons – has been an efficient policy in controlling the increase of health care litigation and has allowed health authorities to defend rationing decisions in courts.

Thus, if courts control the quality of the decision-making process (whether it is open, transparent, based on acceptable evidence, reasons and principles that are accepted by fair-minded people and with opportunities for interested parties to challenge the decision) instead of allocating scarce resources themselves by deciding whether an individual claimant should have access to a treatment, they force health authorities to ration explicitly and by doing it in this way create incentives for fair decisions. Being able to articulate the reasons for their decision becomes a strategy for authorities by which to defend their decisions in litigation. Courts, therefore, meet the "regulative principle" in Daniels and Sabin's theory: they ensure the other conditions for accountability for reasonableness are fulfilled.

This analysis of the impact of judicial review on bureaucracy and the impact of bureaucratic decision-making procedure on litigation deals with important topics, albeit in this field they are still underexplored in the socio-legal literature on judicial review (Cane, 2004). My research on the relation between health authorities and courts in Brazil and England will draw on this literature and, hopefully, contribute to it.

Moreover, the analysis of the impact of health care litigation on the public health systems in Brazil and England can also contribute to a broader debate on social rights adjudication. Social rights adjudication is a phenomenon present in many jurisdictions and has triggered a heated debate on the limits, risks and potential of

litigation in this area. In a nutshell, those who advocate that courts should adjudicate on social rights argue that courts can hold health authorities accountable, force the implementation of rights' protective policies and be an institutional voice for groups and individuals who are not heard in the legislative and administrative arena. Those who are sceptical about social rights adjudication claim that courts have no institutional capacity and legitimacy to second-guess the decisions made by policy-makers, and that this may create inequality in the access to welfare benefits because they will mainly benefit those who have capacity to litigate (for an overview of this debate see Gearty & Mantouvalou, 2011).

As already indicated, Brazilian courts have basically interpreted the constitutionally based right to health as an individual right to have healthcare needs fulfilled, and it is clear that Brazil is a case in which very activist courts vindicate the arguments of those who are more sceptical about the capacity and legitimacy of courts in adjudicating social rights and its consequences in regards to unequal access to the public health system. Decisions are often based on poor evidence, non-consideration of the needs of the rest of the population and with an arbitrary preference being extended to some groups in the access to healthcare. Post *Child B*[7] English courts, in contrast, control decision-making procedure rather than substance. This approach does not give to courts the role of second-guessing health authorities' allocative decisions (which, I argue, would be beyond courts' capacity and legitimacy), but it can make sure these decisions are made through a fair procedure that is transparent, participative, based on good evidence and fair principles of justice, and made by accountable authorities (i.e., the Norman Daniels and Charles Sabin's optimum procedure).

[7] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

The cases of Brazil and England provide good examples that flesh out the usurpation/abdication dilemma in healthcare litigation. However, they also allow us to go beyond this dichotomy by providing insights towards a more nuanced view of the different ways through which courts can decide cases regarding access to social policies. Therefore, this thesis can also contribute to the general debate about social rights adjudication.

Brazil and England post-*Child B*[8] can be used as models for two ideal-types of social rights adjudication: "individual enforcement" and "procedural enforcement", respectively. These two types are not the only existing ones, and they can be compared with other models developed by the literature that has analysed other jurisdictions - especially South Africa, India and Colombia - where courts propose different ways to adjudicate social rights, which I will collect under the rubric of "strong structural enforcement" and "weak structural enforcement". I expect the comparison of each type of enforcement – strong structural, weak structural, individual and procedural – will contribute for the literature on social rights adjudication by showing an evidence-based and nuanced view of the limits, risks and potential of social rights adjudication.

My argument is that procedural enforcement, if compared to the other three models, is the type of adjudication can avoid the objections frequently raised against social rights adjudication (lack of institutional capacity and legitimacy, and unfairness) while, at the same time, providing the benefits of legal accountability which are suggested by social rights adjudication advocates, such as promoting accountability; demanding transparency and justification; reviewing discriminatory and abusive decisions; guaranteeing procedural fairness; and correcting unfairness in concrete cases.

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[8] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Based on this broader analysis of social rights adjudication and connecting it to the more specific debate about health care litigation, I argue that, in other for litigation to promote fairness in healthcare, the right to health should be interpreted by courts as the right to access a health system in which resources are allocated through a fair procedure, rather than as a substantive right to a certain claimed treatment.

In sum, my thesis is built on Norman Daniels and Charles Sabin's concept of what a fair public health system is (one in which decisions about resource allocation are made through a procedure that is accountable for reasonableness) and the impact of litigation on the public health system will be assessed according to whether it promotes or hinders such an optimal procedure. I expect the lessons from an in-depth evidence-based analysis of two jurisdictions in health care litigation to contribute to the scholarship on how courts impact on the way public authorities make their decisions (and *vice-versa*), and also to the broader debate about social rights adjudication.

Structure of the thesis

In addition to the Introduction and the Conclusion, this thesis will consist of five chapters. The first two chapters will be on the Brazilian case. Chapter 2 will analyze the health care litigation phenomenon in Brazil based on empirical data. The chapter is mainly based on a literature review of empirical research on this topic. Fortunately, the data on this phenomenon is abundant and has been relatively well studied by legal scholars and public health specialists. This chapter answers the following questions: what is demanded by claimants?; what is the litigant's usual socio-economic profile?; what are the economic impacts of the decisions on the public health budget?; and how do courts judge these cases? The answers to these questions ground

my argument that health care litigation in Brazil has a mainly negative impact on the public health system because it forecloses the use of good evidence, the consideration of other needs that have to be met by the public health system, and the application of fair principles of justice to allocate healthcare. Applying the terminology to which I referred in the Introduction, courts are making the public health system less fair. This conclusion sets the scene for what follows.

Chapter 3 analyses the responses that have been put forward by the highest institutions of the judicial branch – the Supreme Federal Court (STF) and the National Council of Justice (CNJ) – and by federal legislation – the Federal Law 12.401/11 – to the agreed need to control the impact of health care litigation in Brazil. The STF organized a public hearing to discuss the topic with specialists and stakeholders in order to bring legitimacy, information and expertise to the court to decide health care litigation cases. It also established some guidelines regarding how courts should judge health care litigation cases. The CNJ put forward recommendations to enhance courts' institutional capacity by training judges to deal with claims for health care and by making doctors and pharmacists available to advise them on these cases. As already briefly referred to, the Federal Law 12.401/2011 created the National Health System Commission for the Incorporation of Technologies (CONITEC) and an administrative procedure for the incorporation of new technologies, as a further attempt to improve the quality of decisions in terms both of procedure and evidence. I argue that the proposals from the judicial branch (STF and CNJ) still do not take the problem of rationing seriously and expect courts to perform administrative and political tasks that can be better accomplished by other institutions. Conversely, the Federal Law 12.401/11 opens

up a new possibility for dealing with health care litigation in fairer way. This response is similar to that already implemented in England.

The next two chapters analyze health care litigation in England. Chapter 4 aims to make a comprehensive analysis of the English High Court and the Court of Appeal case-law. Based on the literature (e.g. Jackson, 2010; Newdick, 2004; Syrett, 2007) and on my own interpretation of the decisions, I suggest that English courts have transited from a very deferential approach in the end of the 1970s to one in which, since the case *Child B*[9], health authorities are expected to provide justifications for the policy they had chosen. From the first cases until *Child B*[10], English courts avoided scrutinizing the decisions made by health authorities arguing that this was not a function for courts to perform. However, after *Child B*[11], courts became very proactive in demanding reasons from health authorities to prove that the decisions they made were based on a fair procedure. In contrast to Brazil, where an enormous number of cases make quantitative analysis possible, in the English case the analysis is mainly qualitative and focused on the reasoning underpinning the decisions that are considered.

Chapter 5 aims at assessing the impact of courts on the NHS, and the impact on litigation on the way rationing is achieved. In comparison to Brazil, in which the amount of cases has had a direct impact on the public health system, in the case of England, the impact has been mainly indirect[12]. This is because what courts have said and the publicity of the cases have been more important than the outcome of the decisions *per se,* and there has been impact as well in the less accessible aspects of the

[9] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[10] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[11] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[12] On the concept of "indirect impact" of litigation see Sunkin & Richardson (1996, p.90) and Sunkin (2004, p.63)

government, such as the management system and decision-making culture. I argue that the publicity of the legal challenge to some rationing decisions – such as *Child B*[13] and *Pfizer*[14] – and the change in courts' attitude towards rationing decisions made rationing more visible, contributed to put pressure on health authorities and forced the implementation of a fairer procedure. This process culminated in the creation of NICE in 2000, which, I argue, was an effective response to health care litigation. The similarities between CONITEC and NICE make my argument here of direct relevance for the future direction of Brazil with its new regime.

It is against this background of careful empirical discussion that in Chapter 6 I use the cases of Brazil and England as entry points into the debate about the role of courts in the protection of social rights. I discuss some theories commonly used to justify social rights adjudication and argue that they overestimate courts' capacity and legitimacy in comparison to other institutions. This has resulted in theories of social rights adjudication which have lacked an adequate account of judicial restraint. In response to these theories, I develop a typology of social rights adjudication to compare different types of enforcement – strong structural, weak structural, procedural and individual – and analyze each of them in terms of courts' capacity and legitimacy to adjudicate social rights, and the benefits of adjudication for litigants and for those in the same position as them. Based on this typology and echoing Norman Daniels' theory, I suggest a concept of a right to health to be applied by courts when judging health care litigation as the right to access a healthcare system in which resources are distributed

[13] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[14] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

according to a fair process, i.e., transparent, participative based on adequate evidence and shared principles of justice, and decided by accountable decision-makers.

2. Health Care Litigation in Brazil: causing unfairness by protecting rights

The Brazilian Federal Constitution declares that the right to health is a fundamental right of all and a duty of the State. Furthermore, the Constitution established a public health system based on the principles of universality, equality of access and comprehensive coverage.

Based on the Constitution, some citizens who were denied health treatments by the public health system have lodged lawsuits against the State, claiming that the Constitution gives them a right to receive any treatment they need, free of cost. In most cases, courts have ruled in favour of the claimants by ordering the public health system to provide them with the claimed treatments. The number of lawsuits demanding treatments from the public health system has been increasing astonishingly since the last years and its impact on the public health budget is becoming increasingly relevant. Hence health care litigation has become a frequent issue faced by health authorities and judges and is also a regular topic in the academic debate.

In this chapter, I analyze the health care litigation phenomenon in Brazil by answering the following questions: what is demanded by claimants?; what is the litigant's socio-economic profile?; what are the economic impacts of the decisions on the public health budget?; and how do courts judge these cases?. The answers to these questions allow me to make the argument that health care litigation in Brazil is making the public health system less fair. It creates a two-tier public health system - one for those who can litigate and have access to any treatment irrespective of cost, and the other for the rest of the population who have access to more restricted care - and it

compels the provision of drugs based on poor evidence and without considering any cost-effectiveness analysis or the relevant public health priorities.

The negative consequences caused by health care litigation in Brazil are not particular to this country since a similar pattern of litigation and judicial decisions is also found in countries such as Argentina, Colombia and Costa Rica (Yamin & Gloppen, 2011). These consequences are not surprising either. They can be theoretically explained by the fact that courts are ill equipped to make allocative decisions and the judicial process tends to reduce issues with broader impacts to an individualized problem (Gearty, 2011). The Brazilian case vindicates the concerns of those scholars who affirm that activist courts making substantive allocative decisions should be "tamed" rather than encouraged (Gearty, 2011).

Researching health care litigation in Brazil is not an easy task. The number of health care litigation cases in Brazil amounts to hundreds of thousands and it would be impossible to research what are more than 5,500 municipalities, 26 states, 1 Federal District and the Federal Government to assess what is demanded, the profile of litigants and the economic impact on public health budgets of the decisions that are made. Even though there has never been such an effort to analyze health care litigation in the country as a whole, many researchers have already tried to understand the phenomenon locally in some entities of the federation, and they have come up with important data on this topic.

This chapter will be based on studies analysing health litigation in the Federal Government; the states of Sao Paulo, Rio de Janeiro, Minas Gerais, Santa Catarina, Rio Grande do Sul and the Federal District; in the cities of Sao Paulo, Rio de Janeiro and

Florianopolis, (the capitals of the states of Sao Paulo, Rio de Janeiro and Santa Catarina, respectively)[15].

This chapter has two limitations that should be acknowledged. Firstly, I will be only looking at a few local jurisdictions within Brazil, albeit these are the most important ones for the purposes of this thesis. According to Ferraz (2011A), most of the litigation is concentrated at the federal level and in the states of Santa Catarina, Rio de Janeiro, Minas Gerais, Sao Paulo, Rio Grande do Sul, Parana and the Federal District. Therefore, with the exception of the state of Parana, about which no comprehensive research was found, the literature used in this section provides data on the local jurisdictions where health care litigation is more frequent and on the capital cities (where the population is concentrated) of three of these states.

The second limitation is the fact that these studies do not use the same research method and are not all making the exact same questions. For that reason, the differences in regards to sampling size and method, coding, analysis technique and research question are mentioned throughout this chapter (see, in special, Table 1) in order to make clear the basis and limitations of the conclusions I draw from this literature.

Notwithstanding these limitations, that can be expected when working with empirical data in a country of continental dimension organized in a federal system, this chapter provides an up-to-date and comprehensive account of the health care litigation phenomenon in Brazil, pointing out common patterns and sensitive to local variation.

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[15] The Brazilian National Health System is organized in a federative way, in which the responsibility to provide and finance healthcare is distributed among the Federal Government, states and municipalities. The Brazilian courts have constantly decided that a citizen can judicially claim health treatment against any level of government (Wang et al., 2012). This means that a citizen in Sao Paulo can sue the City of Sao Paulo, the State of Sao Paulo or the Federal Government. He can equally decide to sue two of them or even all of them.

Table 1 – Empirical studies on health litigation in Brazil[16]

Paper	Location	Period	Number of cases	Most prevalent disease among litigants	% drugs without registry at ANVISA	% of lawsuits claiming drugs not included in health policies	% of litigants represented by private lawyers	% of litigants with prescription from private practice	Expenditure to comply with judicial decisions (*Brazilian Reais*)
BRAZIL (2013)	Federal Government	2009-2011	34,500	not available	not available	not available	not available	not available	501,635,002.66
Afonso da Silva & Terrazas (2012)	State of Sao Paulo	2007	160*	Diabetes (23.7%); Cancer (20%); Arthritis (18%)	not available	not available	60	60.6	not available
Biehl et al. (2010)	State of Rio Grande do Sul	2002-2009	1,080*	Circulatory system (21%); endoctrine, nutritional and metabolic (13%); mental and behavioural (12%)	not available	56%	34.7	36.8	not available
Ferraz (2011)	Federal Government	2003-2009	5,323	Rheumatoid arthritis; Mucopolissacaridosis; Diabetes; Hepatitis C	not available	not available	not available	Not available	159,000,000
Machado et al (2011)	State of Minas Gerais	2005-2006	827	Rheumatoid Arthritis (23,1%); Diabetes (6,5%); Arterial Hypertension (5,5%)	*5*	56,7**	60,3	70.5	73,800,000 (2005-2008)
Macedo et al. (2011)	State of São Paulo	2005-2009	81*	Not available	not available	66.2**	not available	Not available	not available
Filho et al. (2010)	State of São Paulo	2005-2010	23,003	Diabetes	not available	not available	not available	60	512.550.717,72***
Pepe et al. (2010)	State of Rio de Janeiro	2006	98*	Arterial hypertension (11.3%); Diabetes(9.2%)	1	80.6	17	Not available	not available
Pereira et al. (2010)	State of Santa Catarina	2003-2004	622	Arthiritis; Hepatitis C; Arterial Hypertension	1.4	62.2**	59	55.8	9,494,645.97
Ventura et al. (2010)	City of Rio de Janeiro	2007-2008	289*	not available	not available	not available	not available (suggested that most litigants received legal aid)	not available	not available
Figueiredo (2010)	City of Rio de Janeiro (State of Rio de Janeiro)	2007-2008	1,263*	Digestive system and metabolism (21,6%); Nervous system (14%); Infectious diseases (8,6%)	0.4	92.5	not available	9.5	not available

[16] In this table were included only the articles that analysed healthcare litigation in a certain jurisdiction without limiting the scope to a subgroup of patients or diseases.

Chieffi & Barata (2009)	State of Sao Paulo	2006	3,007	Digestive system and metabolism (17%); Cardiovascular system (17%); Nervous system (16%)	3	77**	74	47	65.000.000
Sant'Anna (2009)	State of Rio de Janeiro	2006	27*	Cardiovascular system; Nervous system; Respiratory system	0	81.5	29.6	44.4	not available
Leite et al (2009)	City of Florianopolis (State of Santa Catarina)	2003-2006	2,426	Diabetes; Arterial hypertension ; Cancer	not available	68**	not available	Not available	374,659.21
Romero (2008)	Federal District	1997-2005	221*	HIV; Cancer; hepatitis C; Arthrosis	not available	not available	not available	21	not available
Vieira & Zucchi (2007)	City of Sao Paulo (State of São Paulo)	2005	170	Diabetes only (37%); Cancer (22%); Arterial Hypertension and Diabetes (9%)	2	38**	54	40.8	867,000
Marques & Dallari (2007)	State of Sao Paulo	1997-2004	31*	not available	not available	not available	67.7	not available	not available
Santos et al. (2006)	Federal District	2005-2006	160	Arthiritis; Ankylosing Spondylitis; Osteoporosis	not available	66	78.8	42.5	19,920,000
Messeder et al (2005)	State of Rio de Janeiro	1991-2002	389*	Nervous system (21%); Cardiovascular system (17.5%); Digestive system and metabolism (15.8%)	not available	not available	27	16	not available

*value based on a sample, does not represent the total number of cases in the period.

** percentage of drugs among all those demanded, not percentage of lawsuits claiming drugs not included in health policies.

*** average amount per year.

2.1. What is demanded

Health litigation in Brazil is mainly focused on the provision of drugs for individuals (Ferraz, 2011A). The first health litigation cases started in the mid-1990's and were mainly claims for HIV drugs (Scheffer *et al.* 2005). After 1995, a significant number of new drugs for HIV were developed and proved to bring a significant increase to patients' life expectancy and an improvement in their quality of life. In that period, the Brazilian policy for HIV included the provision of drugs free of charge, albeit not the modern ones that patients were willing to use in the place of, or in combination with, those already provided.

Therefore, some HIV patients went to courts claiming that their right to health was being violated because the treatments available in the public health system were no longer effective for them and thus, they needed the more modern drugs. And because courts were deciding in favour of patients, these first cases were followed by more litigation with the same claim. Cases demanding HIV drugs were predominant during the first years of health litigation in Brazil. In the Supreme Federal Court, from 1996-2004, one third of health care litigation cases claimed drugs for HIV (Wang, 2009). In the state of Rio de Janeiro, from 1991 to 1998, more than 90% of the lawsuits claiming drugs were lodged by HIV patients (Messeder, 2005). As a result, in 2001, 80% of the HIV policy budget was spent to comply with judicial decisions ordering the provision of drugs for patients, mainly those not provided by the public health system at that time (Scheffer *et al.* 2005).

Lawsuits claiming HIV drugs have decreased significantly in recent times,

probably because the Ministry of Health created a comprehensive and internationally praised policy for HIV (WHO, 2004; UNIADS, 2003), which includes the newest treatments to virtually all patients who need them. However, litigation is still used by patients when there is a shortage of these drugs in the public health system[17].

The HIV patients' successful litigation at all levels of the judicial branch has become an example for patients suffering from other diseases. Nowadays, the variety of diseases to which treatments are demanded is astonishing and includes very rare diseases – such as Gaucher's disease, Duchenne muscular dystrophy, epidermolysis bullosa – as well as diseases that affect a large sector of the population. Currently, research shows that most lawsuits demand drugs for chronic diseases, such as diabetes, cancer, arthritis, hepatitis C and arterial hypertension, alongside other health problems related to the digestive system and metabolism, the cardiovascular system and the nervous system (See Table 1).

What is more, and similar to what happened during the HIV period, the main

[17] Some authors claim that part of the HIV policy success was due to the constant pressure of patients on the health system by means of individual lawsuits (Scheffer et al, 2005; Camara, 2000; Brinks & Gauri, 2012, p.19). However, it is difficult to demonstrate that litigation played a central role to the success of this policy. Even though litigation was widely used by HIV patients and encouraged by NGOs, the pressure for a making a good and comprehensive policy came from many places. The public and the media were especially aware of the disease because it affected people who held a high profile and influence on the public opinion: such as artists and well-educated professionals (Fonseca et al, 2003). These patients were also more capable of organizing themselves in associations and lobby for better public policies for HIV (Nunn et al., 2007) and participated actively in designing the policy inside the Ministry of Health and through other participative fora (such as national and local health councils). Some of the so-called "HIV activists" were eventually offered positions in the Ministry of Health and became part of the government themselves. Furthermore, the importance of a good policy for HIV was also felt by the National Congress, which enacted the Federal Law 9.313/96 that guarantees the access to drugs for HIV patients. Finally, international organizations such as the World Bank were also pressuring for and funding policies for HIV (Pereira & Nichita, 2011). In conclusion, one has to be wary not to overestimate the role of litigation in promoting a good policy when compared with the influence of the media, public opinion, international organizations and the proximity between activists and the Ministry of Health and the National Congress. On the difficulty of measuring the indirect and long term impact of litigation see Section 6.2.

driver of litigation is the set of new drugs that are not included in the pharmaceutical policy of the public health system. The percentage of cases in which claimants demanded drugs not included in the public health system's pharmaceutical policy is high – 80.6% in the State of Rio de Janeiro, 92.5% in the City of Rio de Janeiro and 66.2% in the Federal District (See Table 1). Other papers, instead of analysing the percentage of lawsuits in which a non-included drug was demanded, assessed the percentage of non-included drugs among all drugs judicially claimed – 62.2% in the State of Santa Catarina; 68% in the City of Florianopolis; 77% and 66.2% in the State of Sao Paulo; and 38% in the City of Sao Paulo (See Table 1).

It is important to highlight the difference between these two methods for calculating the data. The second method - which counts the number of non-included drugs among all those judicially claimed - may be underestimating the importance of the claim for new drugs as the main driver of right to health litigation. In many cases, patients demand more than one drug. For example, in the case of the State of Rio de Janeiro (Pepe *et al.,* 2010), it was found that among the drugs judicially claimed, 52% were not included in pharmaceutical policy. However, when analysing the number of cases in which at least one of these drugs is claimed, the number rises to 80.6%. Sant'Anna (2009) found similar information: 42.6% of the claimed drugs are not included in pharmaceutical policies whereas 81.2% of the lawsuits demand at least one of these drugs. An analogous situation was found in the State of Sao Paulo. Wang, Terrazas & Chieffi (2012) found many cases in which patients were litigating for drugs already provided by the public health system, including very basic, cheap and essential medicines. After analysis, they found that in 87% of cases, the already included drugs are litigated together with non-included drugs. But why does it happen?

One explanation is that when people go to court to litigate for an expensive medicine, they make the most of their effort and include all the medicines that are in the same medical prescription that contains the expensive drug that is really motivating the litigation (Wang, Terrazas & Chieffi, 2012; Machado, 2010). People would do it because if they have a judicial decision in their favour, they will receive all the drugs together and without queue or bureaucracy. The Federal Government, for instance, when complying with a judicial decision, delivers the drug by mail to the patient's house (BRAZIL, 2013B). Moreover, patients make sure that their supply will not be interrupted, since health authorities will not stop providing the drugs because disobeying a judicial decision (contempt of court) is a criminal offense in Brazil. Then, in some cases, drugs included in the pharmaceutical policies are "free riders" and are claimed together with drugs not provided by the health system.

It was also noticed that in many cases, patients went to courts claiming drugs that belong to the pharmaceutical policy because they were prescribed for off-label or off-protocol use. Off-label use means the prescription of a drug for unapproved clinical indications or unapproved subpopulations (Stafford, 2008). Off-protocol use means the prescription of drugs that are incorporated in the public health system to patients who do not meet the clinical criteria established by clinical protocols. For instance, Macedo *et al.* (2010, p.709) analyzed high cost drugs that are regularly provided by the public system and found that in 81.3% of the cases, the clinical guidelines did not recommended their use for claimants' health needs. Similar findings were presented by Machado *et al.* (2011); Wang, Terrazas & Chieffi (2011); Figuiredo (2010); Messeder *et al.* (2005).

Lastly, in some cases, even if all the criteria were met, the administrative procedure to receive a drug could take more time than a claim through the courts (Machado *et al.*, 2011), especially if patients have a provisionary decision in their favour. Therefore, going to the courts may be an effective way to jump the queue to access high cost drugs in the public health system.

There is also a small percentage of litigants claiming drugs that are not registered at the Brazilian National Health Surveillance Agency (ANVISA), the agency responsible for barring unsafe and unproven drugs for use in the country (See Table 1). In cases where courts order the provision of drugs not registered at the ANVISA or authorise off-label and off-protocol use, they are ordering the provision of treatments the effectiveness and safety of which have been not tested or proved. Besides the risks for patients, the cost can be very expensive. For example, in the State of Sao Paulo, around £14.6 million was spent to comply with judicial decisions ordering drugs for cancer from 2005 to 2006. However, 17% of this amount was spent on drugs without any scientific evidence that they could bring any benefit to patients who were claiming them, either because the drug was not registered at the ANVISA or because it was not recommended for the patients' kind of cancer according to clinical guidelines (Lopes *et al.*, 2010).

Similar data were found by Vieira & Zucchi (2007). According to them, 3 out of 10 kinds of drugs for cancer provided by the City of Sao Paulo in compliance with judicial orders were not registered at the ANVISA and most of the others lacked evidence of their efficacy for the claimants' cases. It is also important to highlight that drugs for cancer are extremely expensive. In the City of Sao Paulo, just 7.2% of the drugs supplied to comply with judicial order were drugs for cancer. However, 75% of

the total spent to buy judicially ordered medicines was spent on oncology (i.e. cancer-related) drugs (Vieira & Zucchi, 2007). Thus, even though drugs for cancer were not so relevant in quantity, they had the most significant impact in terms of budget expenditure with health care litigation.

Besides drugs, there are other examples of decisions that ordered the provision of other kinds of treatments without evidence of safety and effectiveness. In the case STA 223[18], the Supreme Federal Court (STF) decided that the health system should pay for surgery that could only be provided by an American surgeon, who had to be brought to Brazil with all the expenses (flight, hotel and a US$150,000.00 bill for the surgery) paid for by the State. The surgery was not approved by the American FDA and was never assessed by the ANVISA. Another example is the case RE 368546[19], in which the STF decided that 6 people had the right to receive treatment for pigment rethinosis in Cuba, with all the expenses (flight, hotel, treatment) covered by the State, in spite of the medical consensus that the treatment for pigment rethinosis in Cuba does not work. The Brazilian Ophthalmology Association, the institution that represents ophthalmologists in the country, participated in the judicial procedure and confirmed before the Court that the treatment is ineffective. Nevertheless, the Supreme Federal Court decided that the patients' right to health included the right to receive treatment abroad, even when there is strong evidence that it is ineffective.

The assessment of effectiveness and safety of treatment is important and should be one of the first things to be taken into consideration when designing healthcare policies. However, there is another aspect that cannot be neglected: the

[18] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 223* (2008)
[19] Supremo Tribunal Federal – *Recurso Extradordinario 368546* (2011)

treatments' cost-effectiveness. Even if it is proved that a new treatment is safe and effective, it is important to assess whether it is better than the existing treatments and, if they are more effective, if their costs compensate the gains achieved by the use of the new treatment in place of the old one. Ideally, patients should be cared for with the best treatments available, but the scarcity of resources is a ubiquitous reality and should be taken into consideration by those who decide which drugs should be provided to patients.

Ferraz & Vieira (2009) calculated that if the public health system in Brazil decided to supply all hepatitis C and rheumatoid arthritis patients (1% of the population) with the most modern (and expensive) drugs for these diseases, then 4.32% (around £35.8 billion) of the Brazilian GDP would have to be spent on these drugs. This is more than what the government (federal government, states and municipalities together) spends on healthcare. This means that if no rationing was made in these cases, the health system would have to spend on 1% of the population more than what is spent on the public health system as a whole. The modern drugs for hepatitis C and rheumatoid arthritis – Pegylated Interferon; Infliximab; Etanercepte and Adalimumab – are some of the most judicially claimed drugs and are commonly granted by courts in Brazil.

According to Machado *et al* (2011) and Vieira & Zucchi (2007), among the drugs provided by judicial order and are not included in pharmaceutical policy, between 73% and 80% of them have cheaper alternatives available in the public healthcare system. Similarly to what happened in the case of HIV drugs, patients are demanding modern (and usually more expensive) treatments which are allegedly better than the already provided drugs.

The case of the analogous insulin is another interesting example. Analogous

insulin is the most litigated treatment in the state of Sao Paulo and the cities of Sao Paulo and Rio de Janeiro (Afonso & Terrazas, 2011; Wang *et al.* 2011; Figueiredo; 2010). The public policy for diabetes offers human insulin to patients, but litigants want to have free access to so-called analogous insulin, which is much more expensive, but the use of which is much more convenient (Siebenhofer, 2009). The Brazilian Ministry of Health has steadily refused to provide the analogous insulin, claiming that there is no scientific evidence that it is more effective than human insulin for the control of diabetes (BRAZIL, 2008). Even though it is not explicitly stated, the fact that analogous insulin is much more expensive than the human version is certainly an important reason for not providing what some patients (and their doctors) prefer. Just to give an example of the impact that the substitution of analogous insulin for their human versions would cause, in 2011 approximately 4.8 million vials of NPH insulin (a human insulin) were supplied by the public health system in the state of São Paulo, which total cost was about R$15 million (around £5 million). If the public health system had provided the analogous insulin *glargina* instead of the NPH, the cost would have increased to R$936 million (around £292 million), which means that the expenditure would have been 62 times higher[20]. For most judges, however, if the patient has a prescription for the analogous insulin, then the right to health will trump rationing considerations (Wang *et al.* 2011).

Norheim & Gloppen (2011) evaluated some of these drugs provided via courts in terms of priority for the population. They calculated Quality Adjusted Life Years (QALY) for each disease and, based on the country GDP per capita, created thresholds

[20] This data was calculated and provided by Ana Chieffi, pharmacist of the State of Sao Paulo Secretary of Health.

to grade health treatments according to levels of priority for the population. Applying this methodology to a sample of litigated drugs in Brazil, Norheim & Gloppen (2011, p.313) concluded that most of them should be classified as having a low priority, since they provide small or marginal health benefits at a high opportunity cost for the healthcare system.

The case STA 558[21], judged by the Supreme Federal Court, is one example of how expensive a treatment granted judicially can be. Two patients who suffer from a very rare disease - *epidermolysis bullosa dystrophica* - lodged a lawsuit in order to oblige the health system to supply them with treatment that would give them a better quality of life and longer life expectancy. The cost of the treatment for each patient, according to health authorities, was calculated as £360,000 per year. Nevertheless, the Court decided it was the duty of the State to provide the treatment to these patients.

In sum, health litigation in Brazil is mainly driven by the demand for (1) new (and more expensive) treatments in substitution for those already included in Brazilian public health system pharmaceutical policy and (2) off-label and off-protocol use of treatments. There is also evidence that litigation is forcing the health system to provide drugs whose safety and effectiveness are not proven, and also drugs the supply of which is controversial because they provide low marginal gain at high cost for the public system.

[21] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 558* (2011)

2.2. Who demands

In the previous section, we saw that health litigation in Brazil is mainly driven by individual claims for drugs not included in the public system's pharmaceutical policies or for off-label/off protocol use of those already included. But what is the profile of these individuals? Are they the worst-off, who found in the judiciary an institutional voice for their unaddressed health needs and a means of putting pressure on sluggish and unresponsive governments and bureaucracy? Or are they the most privileged who have more information and resources to afford the costs of litigation for drugs that their private health insurance does not provide them and that are too expensive for an out-of-pocket payment?

This question is extremely important for a country characterized by huge social inequalities (Brazil still has one of the highest GINI indexes in the world (UNDP, 2010, p.27)) and health inequalities, where the poor have a higher probability of being sick and a lower probability of accessing healthcare (Medici, 2011; Piola *et al.*, 2009).

Three papers tried to analyse litigants' income (Biehl et al., 2012; Afonso da Silva & Terrazas, 2012; Wang & Ferraz, 2013[22]). However, the problem with this variable, as stated by all these authors, is the risk that people will under declare their income when responding to surveys. For instance, in the sample analysed by Biehl et al. (2012) more than 50% of the litigants declared to have an income of less than one minimum wage. However, only 18% of them declared to be unemployed and the majority of litigants were pensioners. Since no employee or pensioner can legally

[22] This research surveyed only the cases in which patients were represented by public lawyers in the City of Sao Paulo. Therefore, it is not representative of the whole population of litigants.

receive less than a minimum wage in Brazil, there seem to be some inconsistency in these data.

Most researchers have tried to use other proxies for socio-economic condition. They identified the profile of litigants by analysing the type of legal representation (private or public lawyers); source of medical prescription (private or public health unit); and area of residence. The type of legal representation and the source of medical prescription are used as a proxy of social economic conditions, as it is assumed that poor people, in general, cannot afford a private lawyer and all the costs related to litigation; and neither purchase private health insurance or treatment in private health units. These are the most common proxies used to estimate socio-economic condition by researchers because this information is normally available in legal processes.

Legal representation

The data gathered on this variable shows that, with the exception of the City of Rio de Janeiro, the State of Rio de Janeiro and the State of Rio Grande do Sul, most litigants are represented by private attorneys (See table 1). For some researchers, this indicates that litigation is driven by people with a privileged background because they can afford private legal representation (Afonso da Silva & Terrazas, 2011; Machado *et al.*, 2010; Vieira & Zucchi, 2007; Chieffi & Barata, 2009).

It is true that we can presume that those represented by public defenders[23] are below a certain poverty threshold; otherwise they would not be eligible for free legal

[23] Public defenders are public attorneys responsible for representing litigants that declare themselves unable to afford private lawyers and the costs of litigation.

aid. It is also true that this threshold may vary according to each state's law on legal aid. For example, in Rio de Janeiro, the threshold is higher and some people who receive free legal aid there would not be eligible for it in other states. This can partially explain why Rio de Janeiro (both the State and the City) is an outlier when it comes to patients' legal representation (Pepe *et al*, 2010). The same explanation may also apply to the State of Rio Grande do Sul, where there is no strict income threshold above which people would not be eligible for legal aid[24].

But is it true that those represented by private attorneys are well off? As we have already seen, part of the literature tends to think so, but this idea has to be taken with a pinch of salt (Medeiros et al., 2013). The role of NGOs has also to be considered because some of them may actually help to fund litigation.

Afonso da Silva & Terrazas (2011) sought to assess the role of NGOs by asking litigants directly whether someone else was paying for their lawyers. They found that more than 20% of litigants received free legal assistance provided by NGOs, which covered all the litigation costs. Interestingly, most of the individuals that declared to be legally represented by an NGO acknowledged either that they did not know the name of the NGO, or that they did not know where it was located. What is more, those who could not even remember the name of the NGO sponsoring the litigation were claiming drugs for rheumatoid arthritis. The authors suggest that the only answer to this puzzle situation is that the associations are sponsored by pharmaceutical companies that want through judicial orders to force the public health system to buy their drugs.

[24] The lack of economic capacity to afford private legal representation is assessed by a public defender through a questionnaire and a declaration signed by the applicant. See the official website of Rio Grande do Sul Public Defensory Office in http://www.dpe.rs.gov.br/site/faq.php

Marques & Dallari (2007) analyzed in depth 31 lawsuits that judged the State of Sao Paulo Court of Appeal and found that almost 24% of them were sponsored by NGOs. Sant'Anna (2009) also analyzed a small number of cases (27) in depth and found that 50% of the patients represented by private lawyers were sponsored by an NGO. Messeder et al. (2005) found that some of the private law firms representing litigants claiming treatments from the public health system have connections with patients' NGOs.

The relationship between the pharmaceutical industry and NGOs that claim to represent patients is well known (Folha de Sao Paulo, 2008; Lopes et al., 2010; Soares & Deprá, 2012). Moreover, suspicious connections between pharmaceutical companies and health litigation are also being investigated by the police. The companies are being investigated for funding individual lawsuits claiming their own drugs as a strategy to defraud public procurements and force the public health system to buy treatments that are either experimental, not cost-effective or have cheaper alternatives (O Estado de São Paulo, 2008).

Finally, even if an NGO does not directly sponsor litigation, it can promote litigation in other ways. For example, there are NGOs representing diabetes patients, sponsored by pharmaceutical companies, who promote campaigns to inform patients about the benefits of new kinds of insulin not provided by the public system and about the possibility of having access to these through courts. For those who cannot afford a private lawyer, the NGOs suggest them to apply for free legal assistance from public

lawyers[25]. Coincidence or not, analogous insulin is the most litigated drug in the State of Sao Paulo and in the cities of Sao Paulo and Rio de Janeiro (See table 1). It is also the most litigated drug by public lawyers in the City of Sao Paulo (Wang & Ferraz, 2013).

Another piece of evidence of the relationship between pharmaceutical companies and health care litigation was raised by Lopes *et al.* (2010). They analyzed 1,220 cases and found that one physician was responsible for 40% of the prescriptions of a certain drug and one lawyer alone was responsible for 70% of the demands for another drug. Moreover, just five attorneys were responsible for most of the lawsuits claiming oncology drugs. They suggest that some physicians and lawyers may be in direct or indirect relationship with pharmaceutical companies (Lopes *et al.,* 2010, p.625).

Chieffi & Barata (2010) analyzed 1,309 lawsuits and found a similar phenomenon. They found that 36 lawyers were responsible for 76% of the lawsuits. Among these 36 lawyers, 11 of them were responsible for 47% of the cases. For some drugs, more than 70% of the lawsuits claiming them were lodged by the same lawyer. The authors also suggest that these lawyers are working for pharmaceutical companies and using courts to oblige the public health system to buy drugs that are not included in pharmaceutical policies. In one of the most comprehensive studies of the phenomenon in the State of Sao Paulo, Filho *et al.* (2010) analyzed 20,000 cases during 5 years – and found that just 27 lawyers were responsible for 25% of the lawsuits (5,000 lawsuits).

[25] This information was given by Adriana Daidone, lawyer and member of two important NGOs that represent diabetes patients in an interview made in her office in July, 2009. The interview was conducted by Octavio Ferraz and myself.

Medeiros et al. (2013) analysed 166 claims for drugs for a rare disease, mucopolysaccharidosis, lodged against the Ministry of Health. The treatments for these diseases are very expensive: almost R$220 million (£73 million) was spent to comply with the decisions ordering their provision in these 166 lawsuits. It was found that more than half of the suits were filed by only three lawyers. Considering the concentration of lawsuits under the representation of a few lawyers, the geographic dispersion of the population that suffers from mucopolysaccharidosis, and the fact that the treatments for this disease is monopolised by a few companies, the authors suggest that there is a network connecting patients and lawyers. They also suggest that this network is probably funded by pharmaceutical industries or the companies that distribute these drugs (Medeiros et al., 2013).

One article published by a weekly magazine in Brazil (Epoca, 2012) illustrates the link between patients, pharmaceutical companies, doctors, lawyers and NGOs. A patient was diagnosed with a very rare disease called *Paroxysmal Nocturnal Haemoglobinuria* (*PNH*) and there are two types of treatment available: a bone marrow transplant (offered by the public health system) or the drug *Solaris* (which is not registered in Brazil). According to the article, there are *pros* and *cons* for each treatment. However, the difference in cost is striking: the transplant would cost the health system £16,000, whereas the treatment with *Solaris* would cost £266,000 per year for the rest of the patient's life. The patient could have received the transplant free of charge from the health system, but he was encouraged "by many people" to sue the State in order to receive *Solaris* free of charge. He was recommended to a doctor, a specialist in treating PNH with *Solaris,* who explained this drug's benefits and prescribed it. This doctor also recommended to the patient a lawyer who is a specialist in claiming this drug via the

courts. Interestingly, this doctor did not charge patients any fee. He affirms that he does it "out of scientific interest", in spite of the fact that he is paid by the pharmaceutical company who owns the marketing rights to *Solaris* to "give talks about the drug for other doctors". The lawyer he recommended to his patient is paid by an NGO that, coincidently or not, is funded by the same pharmaceutical company.

In sum, it can be said that, in general, the majority of the patients are represented by private lawyers. This can be evidence, albeit not conclusive, that it is not the poor, in most cases, who benefit from health litigation. There is also evidence suggesting that pharmaceutical companies may be using right to health litigation in order to sell their products to the public health system, either by using lawyers and doctors or simply by engaging in campaigns to inform patients about their products and the possibility to access them for free via courts.

Source of prescription

In Brazil there is a universal public health system. Nevertheless, a significant part of the population pays private health insurance in order to avoid waiting lists and other forms of healthcare rationing, and also because they expect to receive better healthcare as a result. In Brazil, there is a clear association between high income and access to private health insurance (Mello *et al*, 2010; FUNDAP-CEBRAP, 2009). According to Mello *et al* (2010), 55.6% of the population in Sao Paulo does not have private insurance and this proportion varies according to socio-economic conditions. For example, in one of the richest areas in Sao Paulo, *Moema*, 71.4% of the population

is covered by private health insurance, whereas in one of the poorest areas, *Engenheiro Marsilac*, the number decreases to 31.7%[26].

Why would someone with private health insurance sue the public health system in order to get a drug? The answer is straightforward: most private insurance contracts do not cover the provision of drugs for outpatients. According to a survey led by a think tank in Brazil (FUNDAP-CEBRAP, 2009), only 7% of those insured by private health care are covered with the supply of drugs, which probably also explains the fact that pharmaceutical policy is used by people from high income backgrounds, more than any other public healthcare policy (FUNDAP-CEBRAP, 2009). Hence in most cases, people will have to pay for drugs prescribed by private doctors in spite of having private health insurance. Therefore, if the drug is too expensive (e.g. drugs for cancer) or if they have to be used long term (e.g. insulin), it would be rational to have them provided by the public health system. Therefore, if the public system denies the drug, going to the courts presents itself as an alternative.

The regional variation on this variable does not allow the drawing of general conclusions (see Table 1). In some areas, around at least half of those who receive treatments through courts had their prescription issued by a private health unit. This allows some authors to conclude that the fact that a significant amount of those who benefited from health litigation have access to private healthcare, means that litigation

[26] It is important to remark that access to private health insurance has been increasing in Brazil recently. This is partially because poverty is decreasing in the country, which allows people to purchase more services such as private health insurance. However, it is also because insurance companies are offering a wide range of cheaper health insurances that are affordable for low-income people but, on the other hand, offer a lower coverage. It was noticed that people with middle income actually frequently use both public and private health services (FUNDAP-CEBRAP, 2009), which may indicate that for them, public and private systems are complementary. Future research will have to take this element into consideration. Instead of simply differentiating among those with or without health insurance, some index concerning the quality of the health insurance will have to be used.

benefits “the middle-class and the upper-middle-class above all or, at the most, workers employed in big companies, which usually provide health insurance for their employees” (Afonso da Silva & Terrazas, 2012).

Even though it is reasonable to assume that those who have access to private healthcare probably belong to more privileged sectors of the population, can we assume that those who have prescriptions from public health units belong to the least privileged sector of the population, because they do not have access to private health insurance? The answer is less conclusive than we might have thought because patients who have private health insurance may have presented a prescription from a public hospital for three main reasons.

Firstly, in some cases, courts ask claimants to present a prescription from a public health unit as a guarantee against fraud. Public lawyers also require patients to present a prescription from a public health unit. Secondly, in terms of litigation strategy, having a prescription from a public health unit is a good argument to use against health authorities’ decisions to deny treatment. In some cases, patients remark on the contradiction between having a prescription from the health system and, at the same time, having the drug denied by the same system. For these two first reasons, even if a patient is not a regular user of the public health system, it is thought a good litigation strategy to go to a public health unit to get the prescription[27]. Thirdly, there are some very expensive and technology-intensive treatments that are not covered by health insurance, such as organ transplantation, dialysis and treatment for cancer, but are covered by the public health system. This means that even people who can afford

[27] It is not uncommon in Brazil that doctors work in the public system and also at private health units or have their own clinics. In this case, patients do not even need to go to a public health unit for a prescription from a public health unit.

private insurance may have to use the public health system for some high cost treatment not covered by insurance companies (FUNDAP-CEBRAP, 2009). Finally, experimental treatments and cutting edge technologies in health are usually applied in hospitals associated with public universities, which are centres of excellence and are a reference point for both the public and the private healthcare sectors in Brazil. This may explain why a significant number of those who have prescriptions from public units received care from university hospitals (Afonso da Silva & Terrazas, 2011; Messeder *et al.*, 2005; Vieira & Zucchi, 2007, Romero, 2008; Biehl et al., 2012; Medeiros et al, 2013).

Place of residence[28]

At a national level, Ferraz (2011A) found a high concentration of lawsuits in states with a better Human Development Index (HDI). The ten states with better HDIs in Brazil constituted 93.3% of the lawsuits at federal level, whereas only 6.7% of the lawsuits come from the seventeen states with a lower HDI. This correlation remains when adjusted for population size (Ferraz, 2011A, p. 88).

At the local level, Vieira & Zucchi used the Index of Social Exclusion (*Indice de Exclusão Social*) and found that in the city of Sao Paulo, 63% of litigants live in areas with the least social exclusion, namely the best areas of the city. To the authors, that means that litigation is being used by those who are already well-off.

[28] Even though an area of residence is widely used as a proxy for people's socio-economic condition, this data has to be taken with a pinch of salt because each area can be internally unequal: well-off people can live in not so good areas and worse-off people may live in privileged areas. However, I consider area of residence a good proxy because people's quality of life is partially caused by reasons that are geographically determined, for example, access to schools, basic sanitation, healthcare facilities and other public services. In addition, the access to these services, which is geographically distributed, can impact on individuals' quality of life.

Similar findings were published by Chieffi & Barata (2009). They used the Index of Social Vulnerability for the State of Sao Paulo (*Indice Paulista de Vulnerabilidade Social*). This index ranges from 1 to 6, where "1" is for areas where social vulnerability is the lowest and "6" are areas where social vulnerability is the highest. According to Chieffi & Barata, 74% of the litigants live in areas 1, 2 or 3, which correspond to areas with low levels of social vulnerability. Compared with the distribution of the population as a whole, where 53% of the population lives in these areas, they concluded that well-off people are over-represented in health litigation. They also found that most of the drugs for cancer – the most expensive drugs – are claimed by patients in areas 1 and 2 and that analogous insulin – the most claimed drug – is mostly claimed by patients living in area 2.

Wang & Ferraz (2013) analyzed the right to health cases represented by public defenders in the city of Sao Paulo. Because only those below a certain income threshold are eligible to receive this public service, it was expected that those represented by public defenders would be poor and living in the least privileged areas of the city. Indeed, from an income perspective, most of them are poor according to the most commonly used threshold of poverty, which is actually lower than the one used by the Public Defenders' Office in Sao Paulo to select eligible applicants for legal aid. However, those living in areas where the Human Development Index is low and where the Health Need Index[29] is high, are less than 50% of the litigants represented by public

[29] The Health Need Index (Indice de Necessidade em Saúde) was developed by the City of Sao Paulo Secretary of Health in order to identify which areas of the city of Sao Paulo should be prioritized in the distribution of health care services. It is calculated using data related to demographic, epidemiologic and social conditions in each district. The districts are distributed according to the level of their health needs. The higher the HNI, the more urgent are the population health needs (Wang & Ferraz, 2013).

attorneys, and people from these areas are also underrepresented when compared with the population of the city as a whole.

At least in the City of Sao Paulo, there is evidence that citizens from the better-off areas of the city are overrepresented among litigants. Similar analysis should be made in other areas, especially those in which most patients are represented by private attorneys and used private healthcare, in order to answer some questions that were left open by the state-of-the art in the research on healthcare litigation in Brazil

In conclusion, in the survey among states at the national level there is a correlation between higher human development index and higher level of litigation. At the local level, this kind of analysis – trying to find a geographical distribution of litigants – was made only in the City of Sao Paulo with the conclusion being the same: litigants from the best areas are overrepresented among litigants, even if the research is narrowed to analyse only those that are represented by public defenders. When using source of prescription and legal representation as proxies for socio-economic status, there is evidence that suggests that better-off litigants are the main beneficiaries of health care litigation, even though there is regional variation and the data has to be analysed with some caveats.

2.3. How courts judge

In Brazil, health litigation cases can be judged by many courts. Each one of the 27 states and the Federal district has a State Court of Appeal (*Tribunal de Justiça*) and hundreds of local-level courts. In the whole country, there are also five Federal Courts

of Appeal (*Tribunal Regional Federal*) and hundreds of federal local-level courts. There is also the Superior Court of Justice and the Supreme Federal Court[30].

It would be impossible to undertake such a Herculean piece of research that would be entailed in analysing every court. It would also be unnecessary since a good amount of data have been produced on this issue. Besides relying on the existing data, I will focus on Brazilian Supreme Federal Court (STF) case-law. STF is the highest court in the Brazilian judicial branch hierarchy: it is the last court of appeal and the constitutional court.

Duran *et al.* (2004) analyzed 144 cases demanding HIV drugs that were not included in public policy for HIV treatment – as we have seen the most common claim in early health care litigation – and found that the Sao Paulo Court of Appeal judged 85% of them in favour of the patient. Moreover, in lower courts, the rate of success is absolute: all cases were judged in favour of the patient. By analysing the reasons given in reaching these decisions, the research concluded that the Sao Paulo Court of Appeal's predominant view is that the right to health is an individual right. Only in a small number of cases did the Court consider that economic and policy reasons can be used to justify the non-supply of a drug needed by a patient. Marques & Dallari (2007) analyzed cases judged by lower courts in the State of Sao Paulo and found that patients won in more than 90% of the cases and that in more than 80% of the decisions, the judge affirmed that the patient's right to comprehensive health care should be guaranteed and moreover should not be restricted by budgetary or policy considerations.

[30] For a good description of the the Brazilian judicial system in English language see Taylor (2008, ch.2)

Pepe *et al.* (2010) and Santa'Anna (2008) found that in the State of Rio de Janeiro, patients won 100% of the cases in lower courts. Santa'Anna (2008) found that patients won all the cases in the Court of Appeal. In the sample analysed by Ventura et al. (2010) in the City of Rio de Janeiro, all the claimants had injunctions decided in their favour. At the State of Rio Grande do Sul, in 93% of the cases the claimant had an injunction granted by the lower courts; in 96% of the cases the final ruling in the lower courts were completely or partially in favour of patients in lower courts; and 89% of the cases that reached the Rio Grande do Sul Appeal Court were decided in favour of patients (Biehl et al., 2012).

Wang *et al.* (2011) analyzed how 12 courts (Supreme Federal Court, Superior Court of Justice, 5 State Courts of Appeal and 5 Federal Courts of Appeal) judged cases in which analogous insulin was demanded. 502 cases were analyzed and it was found that patients won in 88% of them. Furthermore, in 5 courts, the rate of success is 100% and in 2 of them, it is more than 95%. The case of the analogous insulin is especially interesting because, as said before, there is scientific debate about the benefits of its use instead of regular insulin. This is an argument used by health authorities before the court to justify the non-provision of the analogous insulin. But in 84% of the cases, courts considered that it is up to patients' doctors, rather than health authorities, to decide which treatment should be given to them. Hence, according to the courts, as long as patients have a prescription affirming that the analogous insulin is necessary, the public health system should provide it. In most cases, courts also considered that the cost of the treatment does not justify the non-provision of a treatment that may protect patients' health and life. Lastly, in most cases in which the costs issue was raised, the courts have disregarded the "cost of the treatment" argument because, according to the

judges, health authorities could not prove that the supply of the insulin to a specific patient would have a significant impact on the public health budget and possibly impair the provision of health services to other citizens.

Similar finding regarding the quality of evidence used by courts was found by Ventura et al. (2010): in 97% of the cases judges decided based solely on the medical information provided by the claimants' doctors and no further evidence regarding the quality of the treatment, the real need of the patient and the alternative treatments was considered.

2.3.1. The Supreme Federal Court case-law[31]

Supreme Federal Court (STF) health care litigation case-law is very similar to the other Brazilian courts in terms of the patients' success ratio. Among the 68 cases judged so far[32], in almost 90% of cases the patient won the treatment claimed before the Court. Among the rest, there are some cases of partial success – treatments were provided under certain conditions, such as the limits established by a clinical guideline – and only 4 cases in which the patient's claim was completely dismissed.

Besides the quantitative analysis, the importance of the STF – which is the last court of appeal and the constitutional court – makes it necessary to carry out a qualitative analysis of its case-law. STF health care litigation case law can be divided into three stages: (1) non-acceptance of healthcare rationing; (2) recognition of the need

[31] Part of this section is based on my MSc dissertation written at the Department of Logic, Philosophy and Scientific Method at the LSE. It was supervised by Alex Voorhoever and was published in the *Health Economics, Policy and Law Journal.*

[32] The research was based on the cases available online at the court's official website: www.stf.jus.br and the cases published by court's daily newsletters.

for rationing, but unwillingness to establish standard criteria; and (3) establishment of criteria to define cases in which rationing decisions should be judicially reviewed.

During the first stage, from 1997 (when the first case was judged) to 2006, the STF judged 31 cases and always decided in favour of the patient. It also refused to admit the need for healthcare rationing. The Court constantly reaffirmed that the right to health should not be subject to limits imposed by the scarcity of resources and budgetary constraints. In the first case (*Peticao 1246*[33]), in which the claimant suffered from *Duchenne Muscular Dystrophy* and demanded the public health system to pay for an experimental treatment only available in the United States (the costs included transportation, treatment and foreign living expenses), Justice Celso de Mello made a statement that was constantly quoted in subsequent decisions by other Courts and by the STF itself:

> [In choosing] between protecting the inviolability of the right to life, an inalienable Constitutional fundamental right, or a financial and secondary interest of the State, I believe — once this dilemma is established — ethical and legal reasons leave the judge with only one possible option: unwavering respect for life. (PET 1246[34])

This interpretation of the right to health was reaffirmed in other cases decided during the same period, in which the STF declared that the right to health cannot be subject to limits imposed by the scarcity of resources and budgetary constraints. It said that "limitations of public resources" and "problems with the public budget" cannot

[33] Supremo Tribunal Federal – *Peticao 1246* (1997)
[34] Supremo Tribunal Federal – *Peticao 1246* (1997)

restrict the right to health (e.g., *Recurso Extraordinario 195192*[35], *Recurso Extraordinario 198263*[36] and *Recurso Extraordinario 342413*[37]). The Court stated that "in such an important topic as health, there is no space for less important debates about legislation or public resources, it is a matter of priority." (*Recurso Extraordinario 198263*[38])

The second stage started in February 2007, when the STF judged the first two cases in which it upheld the government's decision not to fund a treatment – *Suspensao de Tutela Antecipada 91*[39] and *Suspensao de Seguranca 3073*[40] (the patients were respectively suffering from chronic renal disease and cancer). In both cases, the Court recognized that the public health system should be managed so as to "rationalize the cost-benefit of the treatments that will be offered free of charge to the population, in order to benefit as many people as possible" and that the right to health should be "concerned about public policies that will affect the population as a whole and not individual cases". The Court also gave the power to set priorities in healthcare allocation back to the health authorities, stating that the public health system should only be obliged to supply medicines already included in its pharmaceutical policy. It seemed that the Court was making a U-turn and reversing the opinion presented in previous cases.

However, in subsequent cases, the Court has retreated from its more deferential stance to governmental policy choices and returned to an approach that has focused on

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[35] Supremo Tribunal Federal – *Recurso Extraordinario 195192* (2000)
[36] Supremo Tribunal Federal – *Recurso Extraordinario 198263* (2001)
[37] Supremo Tribunal Federal – *Recurso Extraordinario 342413* (2004)
[38] Supremo Tribunal Federal – *Recurso Extraordinario 198263* (2001)
[39] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 91* (2007)
[40] Supremo Tribunal Federal – *Suspensao de Seguranca 3073* (2007)

the specific needs of the applicant patient rather than on public policy concerns. Neither the decision, nor the arguments and criteria have been the same. There has been no reference to previous arguments that affirmed that the right to health should be concerned with the population as a whole and not with individual cases. In some cases - *Suspensao de Seguranca 3205*[41] , *Suspensao de Seguranca 3158*[42] , *Suspensao de Seguranca 3429*[43], *Suspensao de Seguranca 3452*[44], *Suspensao de Tutela Antecipada 181*[45]- the Court has even ordered the health system to provide medicines that were not included in pharmaceutical policy, thus violating the criteria it had itself established. From 2007 until 2009, besides *Suspensao de Tutela Antecipada 91*[46] and *Suspensao de Seguranca 3073*[47], two more rationing decisions were upheld by the Supreme Federal Court: *Suspensao de Seguranca 3263* and *Suspensao de Tutela Antecipada 185*[48]. In both cases, patients were claiming non-life-saving treatments: drugs for female infertility and sex reassignment surgery respectively.

In sum, during this second stage, although the need to set criteria for restricting the judicial intervention in reviewing rationing decisions was recognized, the court was still going back and forth between recognizing an unlimited individual right to health and admitting that resources are scarce and hence priorities should be set.

In April and May 2009, the STF held a public hearing with public health experts, public authorities, legal scholars, representatives of legal professions, and civil

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[41] Supremo Tribunal Federal – *Suspensao de Seguranca 3205* (2007)
[42] Supremo Tribunal Federal – *Suspensao de Seguranca 3158* (2007)
[43] Supremo Tribunal Federal – *Suspensao de Seguranca 3429* (2007)
[44] Supremo Tribunal Federal – *Suspensao de Seguranca 3452* (2007)
[45] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 181* (2007)
[46] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 91* (2007)
[47] Supremo Tribunal Federal – *Suspensao de Seguranca 3073* (2007)
[48] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 185* (2007)

society to discuss the health care litigation phenomenon (see section 3.1.1). According to the then Supreme Federal Court's President, the aim of this was to supply the Court with "technical, administrative, scientific, political and economic" information in order to help the Court judge these cases (Mendes, 2009).

In March 2010, based on the information gathered in this public hearing, the STF judged several cases in which it established guidelines defining those treatments citizens can demand from the public health system. This inaugurates what I am calling here the third stage or phase in the Supreme Federal Court health care litigation case law.

The STF stated that the health system cannot supply all the treatments patients demand and that priorities in health care should be set by health authorities and respected by courts, especially to avoid forcing the provision of drugs the evidence of which is not proven (I describe and analyse the criteria in Chapter 3). However, even after the public hearing and establishment of the criteria, and in spite of the progress in the establishment of these guidelines, the Court failed to examine the most fundamental and difficult healthcare distribution dilemmas, such as the non-provision of possibly life-saving treatments that are not cost-effective from the public health perspective.

As a consequence, in the cases following the establishment of these criteria, the Supreme Federal Court judged in favour of the patients even though in the majority of cases, treatment was not included in pharmaceutical policies. Decisions were based on the specific needs of the patient applying and no consideration was given to the impact

on public health as a whole[49].

It is also worth mentioning again and quoting the case *Recurso Extradordinario 368546*[50], in which the government was obliged to provide treatment for pigment rethinosis in Cuba for 6 people despite scientific consensus that it is ineffective. One of the Justices (Marco Aurelio) dismissed the extensive evidence against the effectiveness of the treatment and the objections against its high costs for the public health budget by affirming that:

> I cannot accept that the lack of economic resources can be articulated to deny health care for a citizen (…) according to what I read in the media, the successful treatment to this disease is indeed in Cuba[51].

Similarly, another Justice (Luiz Fux) reasoned that

> I am very determined when it comes to hope. I never believed in the version that the pigment rethinosis could not be cured in Cuba. Quite the opposite, I think that they [Cubans] are specialists in this area and there should be

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[49] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 175* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 211* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 278* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3724* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 2944* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 2361* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3345* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3355* (2010), Supremo Tribunal Federal – *Suspensao de Liminar 47* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 260* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 283* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 424* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 434* (2010), Supremo Tribunal Federal – *Suspensao de Liminar 256* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3941* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 4045* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3962* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3852* (2010) and Supremo Tribunal Federal – *Suspensao de Seguranca 3989* (2010).

[50] Supremo Tribunal Federal – *Recurso Extradordinario 368546* (2011)

[51] In the original: "Eu não posso compreender que se articule a inexistência de lastro econômico-financeiro para se negar um tratamento à saúde a um cidadão (...) Pelo que leio nos veículos de comunicação, o tratamento dessa doença, com êxito, está realmente em Cuba"

hope concerning the cure[52].

This decision makes clear the Court's unwillingness to show restraint and follow the criteria formerly established to judge health litigation cases. The scarcity of resources and the lack of scientific evidence were not acceptable reasons to deny healthcare. Thus, after almost 15 years going back and forth in trying to establish criteria for the judicial review of rationing decisions, and in spite of the public hearing held by the court, the interpretation that the right to health entitles patients to receive any health treatment they need, because people's health and life trump "financial and secondary interests of the State", is still an approach that is prevalent within Brazil's highest court.

In sum, in most cases, including the most recent ones, the STF has ruled that individuals are entitled to have all their health needs fulfilled by the public health system with the most advanced treatment available, irrespective of the treatment's cost or the impact on the provision of treatment for others.

To conclude this section, it can be affirmed that, in Brazil, when a patient can reach courts and prove (based solely on a medical prescription) that they have an unsatisfied health need, the predominant interpretation is that their right to health is being violated. And in the improbable hypothesis that she loses in local or appeal courts, she will probably win in the STF.

[52] In the original: "Eu sou muito determinado nessa questão da esperança. Nunca acreditei na versão de que o tratamento em Cuba da retinose pigmentar não tinha cura, pelo contrário, eu entendo que se eles são especialistas nisso, deve haver uma esperança com relação a essa cura"

2.3.2. Collective claims

Even though health care litigation in Brazil is mainly driven by individual lawsuits, there are also cases of collective claims. As with individual claims, a significant number of collective lawsuits also claim access to drugs not regularly provided by the public health system[53]. However, instead of claiming a treatment to one of a few identified patients, collective lawsuits expect courts to order the provision of a certain treatment to a group of identified patients or to all patients in a given subnational jurisdiction (which can be a city, a state or the federal government). The former are very similar to individual lawsuits and the only difference is that there is more than one patient. Courts decide these cases in the same way as they decide individual claims. The latter lawsuits, on the other hand, raise different issues because they are demanding what is commonly called structural change (see section 6.2.1). These are the cases that will be analysed in this section.

I decided to analyse the cases demanding structural enforcement separately due to their small number and also because of the way courts judge these cases. The same courts that show almost no restraint in reviewing rationing decision in individual cases are reluctant to decide in favour of claimants when the claim is collective. The rate of success in collective claims is much lower than in individual ones (Hoffman & Bentes, 2010, pp. 224-225; Wang & Ferraz, 2013; Wang et al., 2011).

As already shown, in individual cases courts tend to ignore the economic impact of the decisions on the public health budget, the impact of the expenditure to comply with judicial decisions on the other users of the public health system, the needs

[53] There are also lawsuits requiring the improvement of health facilities (see Wang & Ferraz, 2013).

of health authorities in terms of setting priorities in health expenditure, and the capacity and legitimacy of courts to assess scientific data and to make allocative decision. When it comes to collective claims, however, all these elements are considered by courts to justify their deference to a rationing decision made by health authorities (Hoffman & Bentes, 2010, pp. 224-225; Wang et al., 2011).

As shown by Wang et al. (2011), some of the same courts that grant access to analogous insulin to practically any patient who goes individually to claim them because they have the right to health, turn down claims for these insulin to be incorporated among the treatments that are regularly provided by the public health system. In collective claims, courts tend to argue that resources are scarce and judges are not in the best position to second-guess the decisions made by health authorities.

Two recent decisions by the Supreme Federal Court (STF) make clear the choice of adjudicating the right to health individually rather than collectively: *Suspensao de Liminar 256*[54] and *Suspensao de Tutela Antecipada 424*[55]. The latter involved a request for universal provision of three medicines (not included in the official lists) for treating microcephalia. In the former, the complaint wanted the public health care system to pay the transport, food and accommodation costs of patients of the city of Araguaína who needed to receive treatment in another city. The STF rejected both claims, arguing that the judiciary should not require health care authorities to fulfill duties that are overly 'general', because this may unduly affect the public budget and would be an 'obstacle to the adequate provision of public services by the Public Administration'. In these cases, the Court argued that a judicial decision cannot order

[54] Supremo Tribunal Federal – *Suspensao de Liminar 256* (2010)
[55] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 424* (2010)

the health care system to provide the treatments requested to all patients who need them because it would ‘‘impair the regular functioning of health system administration, reduce efficiency in patient care and limit the available resources’’.

Nonetheless, both decisions emphasized that the drugs in one case and the transport, food and accommodation in the other must be provided if the need is proved individually. In the case *Suspensao de Liminar 256*[56], apart from the general demand for the health care system to pay for the transport, food and accommodation for all citizens of Araguaína, there was also a request for the provision of these services to particular individuals, which was granted by the Court.

The fact that courts decide individual and collective cases differently can be explained by the fact that in individual lawsuits there is the impression that an individual decisions has no potential to cause much impact whereas a collective claim can have large-scale policy implications (on this, see section 6.2). This impression is false because, as seen in this chapter, the aggregate effect of individual lawsuits can be enormous, albeit not immediately felt. Moreover as will be discussed in Section 6.2, the choice for individual enforcement creates inequality between those who can litigate and others with similar needs but with no resources, support or information to go to courts.

2.4. Economic impact of health care litigation

This expansive interpretation of the right to health and the activist role of courts in reviewing the public health system’s decisions have led to an exponential growth in health litigation in Brazil in recent years.

[56] Supremo Tribunal Federal – *Suspensao de Liminar 256* (2010)

At the federal level, the Ministry of Health expenditure to comply with judicial decisions ordering the supply of health treatments increased from R$ 2.5 million (£830 thousand) in 2005 to R$ 244 million (£81 million) in 2011: a solid 9,660% increase in six years. The aggregate expenditure by the Federal Government from 2003-2011 was *circa* R$ 588 million (£196 million), 85% of which was spent in 2009-2011 (the figures were calculated by using the data provided by the Ministry of Health, see BRAZIL, 2013B). The impact of a few very expensive drugs is also noteworthy: in 2011, the amount spent with the 20 most expensive drugs, that were claimed by 632 patients (0.05% of the total of litigants in that year), represented 78% of the total spent by the Ministry of Health to purchase drugs in compliance with judicial orders. Ferraz (2011A, p. 81) found that the amount spent by the Federal Government with judicially ordered drugs in 2009 was equivalent to 0.4% of the Ministry of Health total budget and 4% of its budget for drugs. This figure is certainly higher now given the increase in the amount spent to provide drugs ordered by courts.

At sub-federal level – states and municipalities – the sheer scale of the impact of health care litigation is also impressive. The State of Minas Gerais had a massive increase in expenditure to comply with health litigation decisions. The amount increased from R$ 8.5 million in 2002 (£2.8 million) to R$ 42.5 million (around £14 million) in 2008 and R$ 61.5 million (£20.5 million) in 2010 (Machado *et al*, 2011; Castro, 2011).

The State of Sao Paulo spent R$400 million (£133 million) in 2008, R$512.5 million (£170.8 million) in 2009, and R$ 700 million (£233.3 million) in 2010 (Filho et al., 2010; Epoca, 2012; BRAZIL, 2013B). The number of drugs the supply of which was ordered by judicial decision increased from 799 in 2005 to 14,563 in 2010: a 1,722.65% increase in 5 years (Filho *et al*, 2010). Filho *et al.* (2010) found that the State

of Sao Paulo spends 4.5 times more to comply with judicial decisions than on hospitalization for organ transplantation. The total amount is also equivalent to 90% of what was spent with 123 million clinical diagnoses made by the public health system in the whole State of Sao Paulo; 28% more than what is spent on dialysis; and 29% more than what is spent on chemotherapy and radiotherapy. The most recent data indicate that the amount spent by the State of Sao Paulo on health care litigation in 2010 represents almost 50% of the whole budget for the pharmaceutical policy (Epoca, 2012). Currently, there are 25,000 patients receiving drugs through litigation whereas the population of the State is more than 41 million (Epoca, 2012). In other words, 0.0006% of the population is using the equivalent almost 50% of what is available to treat the rest of the people in the State of Sao Paulo.

In the State of Santa Catarina, the amount spent increased from R$ 38,362.07 (£12,700) in 2001 to R$ 6,510,045.48 (around £2.2 million) in 2004 (Pereira *et al.* 2010) and, according to more recent data, R$ 93 million (£31 million) were spent in 2010 (CNJ, 2011). Another interesting finding in the State of Santa Catarina is that the drugs claimed through the courts are getting more and more expensive. In 2001, the average cost per drug was R$ 2,019.06 (£673), whereas in 2004, it increased to R$ 8,157.95 (£2,719). That means that not only are more drugs being litigated for, but also that more expensive drugs are being claimed through litigation (Pereira *et al*,. 2010).

At the Federal District, according to Santos et al. (2006, p.13), the number of lawsuits demanding health care increased from 281 in 2003 to 682 in 2007. The amount spent on drugs the supply of which was demanded by the Court is equivalent to 70% of the budget for essential drugs and 34% of the budget for high cost drugs which are included in the pharmaceutical policy. The number of lawsuit in the State of Rio Grande

do Sul increased from 1,126 in 2002 to 17,025 in 2009 (a 1,412% increase) (Biehl et al., 2012). The amount spent by State of Rio Grande do Sul with health treatments ordered by courts in 2008 represented 22% of the total amount spent by the State on pharmaceutical drugs that year and 4% of the state's projected health budget for that year (Biehl et al., 2009).

At municipal level, the increase in litigation and its costs are also relevant. In the city of Florianopolis, there was a 3,944% increase in expenditure with drugs ordered by judicial decision: from R$3,398.96 (£1,130) in 2003 to R$137,429.05 (£45.6 thousand) in 2006 (Leite *et al.,* 2009). In the City of Sao Paulo it was estimated that the amount to comply with health litigation decisions in 2011 was around R$ 8.9 million (around £3 million). This amount represented, in that year, 6% of the whole budget for the pharmaceutical policy in Brazil's richest city (Wang et al, 2011).

In small cities with smaller budgets, the impact of health care litigation can be even more dramatic. For example, in *Buritana*, a small city of 15,000 inhabitants, more than 50% of the budget for drugs was spent providing treatment ordered by the courts and one single patient won in court the right to receive a treatment that will cost the municipality 16% of its entire budget for drugs (Epoca, 2012).

In 2009, a survey sent by email and post to all the 5,564 Brazilian cities tried to measure the impact of health litigation at municipal level. 24% (1,276) of the cities answered the survey. It was asked whether there was an increase in health care litigation and in the economic impact of the phenomenon on their budgets. The result was that more than 50% of the cities affirmed that they were facing an increase in health care litigation cases. One third of the respondents affirmed that health litigation was an "important problem" for them. Respondents were also expected to provide information

concerning the number of lawsuits they had to respond to and the amount of money that was spent to comply with cases decided in favour of patients. The result was that the number of lawsuits and the amount spent to comply with decisions in the 1st semester of 2009 had already outpaced the total amount in 2007 and also not far from the total in 2008 (Ferraz, 2011A).

Even though there has never been an attempt to calculate the economic impact of the health care litigation phenomenon on the whole country, the Ministry of Health calculated, based only on the data provided by the Federal Government plus nine states (which means that the expenditure in 17 states, the Federal District, and 5,500 municipalities were not included), that the amount spent in 2010 was approximately R$950 million (£316 million). Because of the missing data, this figure is seriously underestimated. Nonetheless, it represents one-seventh of the whole national budget for the pharmaceutical policy in that year (BRAZIL, 2013B).

In conclusion, litigation is not only increasing at an astonishing rate, but also creating an enormous expenditure for health authorities and having a very significant budgetary impact on the public health system.

2.5. Conclusion of the chapter

This chapter allows us to draw several conclusions concerning health care litigation in Brazil. Brazilian courts consider that the right to health is an individual entitlement to any treatment needed. This right can also be judicially enforced and should trump rationing decisions made by health authorities, even when the evidence on benefit or cost-benefit of the treatment should not recommend their provision. The consequence of this kind of adjudication is that the number of lawsuits has been steadily increasing for years, causing significant impact on public health policies in terms of the amount of resources spent to comply with judicial decisions.

It has also been established that health care litigation in Brazil is mainly driven by individual litigants claiming access to drugs not included in the pharmaceutical policies or for off-label/off-protocol use of those already included. These litigants claim drugs for an enormous variety of diseases, but it is a small number of very expensive drugs that are responsible for the biggest share of what is spent by the health system to comply with judicial decisions.

The data also indicate, although less conclusively and with regional variation, that claimants from higher socio-economic groups tend to be over-represented among litigants when compared with the rest of the population. It would be sensible, however, to expect that health care litigation will progressively become a phenomenon less restricted to the better-off. The information about the possibility of accessing health care through courts is becoming widespread; there has been significant improvement in the institutions that promote access to justice in Brazil; and pharmaceutical companies have

incentives to stimulate (occasionally funding) litigation. All these factors can contribute to allow less privileged people to litigate for health care.

This can make health care litigation a less unequal phenomenon in one aspect, but does not obliterate the unfairness produced by it. The mere fact that litigation creates a two-tier public health system is problematic enough in terms of fairness. It distributes resources according to an arbitrary principle – the capacity to litigate – without regard to others in the same condition or the other needs of the population (see section 6.2.3). The fact that more people who happen to have the capacity to litigate will go up to the upper tier means that the impact of litigation will be even greater, affecting more severely those who did not litigate and belong to the lower-tier created by health care litigation. Moreover, given that litigation is mainly driven by individual claims, courts will force the increase in the expenditure in goods that can be individually consumed (e.g., drugs) rather than in public goods that benefit whole populations (e.g., preventive health programs). The fact that already privileged groups are the main beneficiaries of litigation, as seems to happen currently, just increases the inequality created by health care litigation.

It would certainly be possible to cherry pick some decisions in which application of the right to health as an individual trump to review rationing decisions delivered a right decision, i.e, granting health care for a patient who was denied a treatment that was actually safe, effective, cost-effective, affordable and needed. This denial could happen either out of intransigence, incompetence, inattentiveness[57], bias or malice; or because the data on these treatments were not available at the moment of the decision. However, this is not a good argument to justify courts applying the right to

[57] Intransigence, incompetence and inattentiveness were categories borrowed from Young (2010, p.417).

health like most of the judges do in Brazil. If courts order the provision of almost any treatment that patients claim to need, then both right and wrong decisions will be delivered without much criteria to distinguish between them. A broken clock may tell the right time twice a day, but it is still not a reliable device for knowing the time. What is needed is a procedure that meets Daniels and Sabin's framework of accountability for reasonableness. This was not provided by courts and, what is more, litigation forced the public health system to provide treatments in a way that was opposed to what any kind of accountability for reasonableness framework would recommend.

In sum, the courts, through the adjudication of hundreds of thousands of individual cases, have become a major player in the design and implementation of health policies in Brazil. The impact on the public health system is already far from negligible and the effects are arguably negative because health care litigation is making the health system less fair.

The conclusion of this chapter, nevertheless, is not that courts should have no role in the protection of the right to health. It is rather that the “usurpation” approach applied by Brazilian courts causes more harm than good to the public health system. Forthcoming chapters will discuss policies to reduce health care litigation and different forms of adjudication that can avoid the downsides of the “usurpation” model and help to build a fairer public health system. I start this inquiry by looking first at how Brazil itself has sought to address the problems we have been discussing in this chapter.

3. Health care litigation in Brazil: responses to the problem and the problems in the responses

In Chapter 2, I described the health care litigation phenomenon in Brazil and analyzed the impact of hundreds of thousands of individual lawsuits on the public health system. As that chapter made clear, health care litigation consumes a significant, and increasingly large, amount of the public health budget, which is spent to provide treatments without considering their cost-effectiveness and their priority regarding the population's health needs. Courts are also distributing health care without concern for distributive justice, since resources are allocated according to the capacity to litigate, possibly benefiting mainly better-off citizens and pharmaceutical companies that use litigation as a means to sell their products to the public health system.

Brazilian courts are "usurping" the decisions about the provision of health care, and apart from making the public health system less fair, this creates a potentially unsustainable situation for the public health system. Therefore, it is necessary to change this pattern of case law and several policies have been put forward in order to do so. This is the topic with which this chapter will engage.

Some local health authorities have tried to reduce the level of health care litigation and its impact on the public budget by incorporating the most litigated treatments into their health policies for regular and universal supply so as to make litigation unnecessary. This certainly avoids the litigation-related costs and allows the public health system to purchase some of the claimed treatments through public procurement instead of buying them every time there is a decision ordering their provision, which tends to be much more expensive. There are also partnerships between

local health authorities and public attorneys that create pre-judicial committees to consider the provision of treatments and try to settle a case before a lawsuit is lodged.

These responses have had some impact in reducing the level of litigation where they have been implemented (Wang 2009; Fanti, 2009; Oliveira & Noronha, 2011; Yoshinaga, 2010; Wang, Terrazas & Chieffi, 2012). However, they will not be discussed here because they have only a limited reach. These are local policies focused on specific cases and they do not tackle the problem at the national level. Furthermore, they may avoid some claims reaching courts, but they are unable to avoid litigation on a larger scale since health authorities will not be able to incorporate all the claimed treatments nor provide them via pre-judicial committees.

One possible comprehensive reform to prevent Brazilian courts from "usurping" substantial decisions on the provision of health care could be a constitutional amendment withdrawing the "right to health" from the Constitution or declaring that the right to health is non-justiciable (e.g., the art. 37 of the Constitution of the Republic of Ireland). In this chapter, however, I will not analyze this alternative because the proposals to promote it were never widely discussed and find no declared support among legal professionals and scholars. Furthermore, it is not evident that removing the right to health or its justiciability from the constitution would prevent litigation. Courts willing to challenge health authorities' decisions to deny the provision of health treatment, such as in Brazil, could base their decisions on the legislation regarding the duties of the public health system – e.g. England (see chapter 4) –, on the right to life – e.g. in India (see Fredman, 2008) –, or on international human rights treaties – e.g. Argentina (see Bergallo, 2011).

Therefore, in this chapter I will only analyze the more comprehensive proposals that were brought forward or implemented and that aimed at having a major impact on the way health care litigation cases are judged in Brazil. The only proposals that will be analyzed in this chapter therefore come from the highest institutions of the Judicial branch – the Supreme Federal Court (STF) and the National Council of Justice (CNJ) – and from federal legislation – the Federal Law 12.401/11. These responses have the potential for large scale impact and can shed some light on academic debates about the limits and potential of judicial review.

All these proposals have in common the fact that they try to establish a sphere of judicial restraint, in which courts should defer to the decisions made by health authorities. Thus, they try to oppose the Brazilian courts' prevailing interpretation that there is an individual right to receive health care that cannot be restricted by health authorities´ priority setting decisions. These proposals try to reaffirm the idea that health authorities are the primary decision-makers regarding the provision of health care, and that they are only obliged, *prima facie*, to provide the treatments that are already incorporated by the public health system.

However, they disagree on what courts should do when there are claims for drugs not incorporated in the public health system's pharmaceutical policies. And this is a central issue since, as I have discussed in chapter 2, these claims are the main drivers of health care litigation in Brazil.

3.1. Self- restraint and institutional capacity: responses from the Judicial branch

Concerns about courts' lack of institutional capacity and the limits of the adjudicative process are some of the most common critiques against courts deciding on the provision of social policies. Judges, according to this argument, have no knowledge and neither the expertise, qualification nor experience to decide on multifaceted issues of policies, especially those involving the allocation of scarce resources. They are trained in law and legal process, and this is their field of expertise.

Besides the problem with judges' expertise, qualification and experience, the adjudicative process itself may also add some obstacles. The judicial process is not suitable to deal with polycentric problems because it "cannot encompass and take into account the complex results" that may arise from a judicial decision (Fuller, 1978, p.394). Polycentric problems, in practice, will probably "involve many affected parties and a somewhat fluid state of affairs" (Fuller, 1978, p.394). The adversarial model of adjudication reduces problems that affect an enormous number of people to bilateral disputes and is poorly prepared to gather and analyze complex social data. Courts will know a lot about a case, but little about its milieu and will not be able to see the trade-off problems that they are dealing with, such as the competition for budgetary resources or political follow-through (Horowitz, 1982, p.137). Moreover, there is the problem of representativeness, "since courts do not choose their cases, but instead cases choose their courts" (Horowitz, 1982, p.136).

On the other hand, those who advocate for a more proactive role of courts in social rights adjudication affirm that courts, when protecting civil and political rights, also deal with complex issues that may be very similar to those raised by social rights

adjudication. Thus, the judicial protection of social rights creates challenges for courts that are not so different from those they commonly face (Langford, 2008).

Furthermore, judges can be provided with relevant information by the parties, their lawyers, witnesses and court appointed individual experts and bodies (Nolan at al., 2007, p.14-15). Some individual judges can also specialize in social rights adjudication through experience and legal education, in the same way that they specialize in other different fields of law (Nolan at al., 2007, p.15). Finally, the judicial process can be made more participatory – open to amici curiae and public hearing – to enable courts to deal with the complex issues brought before them in cases involving social rights (Mantouvalou, 2010; Gargarella, 2011).

The responses to health care litigation advanced by the Supreme Federal Court (STF) and the National Council of Justice (CNJ) are inserted into this debate about the capacity of courts and the adjudicative process to decide properly on the provision of welfare policies. Both institutions recognize that courts have institutional limitations and therefore can only be secondary decision-makers on the issue of health care provision, but, at the same time, they try to overcome these limitations in order to give to courts a prominent role in the judicial review of rationing decisions on a case-by-case basis.

The responses advanced by the STF and the CNJ can be better understood as two complementary parts of the same policy engaged with health care litigation. This is not surprising since there is a strong connection between both institutions. They are part of the judicial branch, although with different functions. The STF is the highest court in Brazil, whereas the CNJ has no judicial power and is responsible for regulating the administrative and financial activities of every court and the enforcement of judges'

professional duties. The CNJ is a formally autonomous institution, but it is expected that the STF, especially its president, will have a significant influence on the CNJ. According to the Article 103-B of the Federal Constitution, the presidency of the CNJ, which has a great deal of responsibility in setting the institution's agenda, will be chaired by the president of the STF. Moreover the STF has the prerogative to appoint other two members of the CNJ. The affinity between the recommendations of the CNJ and the decisions of the STF will be made clear in the next sections.

3.1.1. The Supreme Federal Court: public hearing and self-restraint

The public hearing on health care litigation

As I briefly mentioned in Chapter 2, the Supreme Federal Court (STF) – the highest court in the Brazilian Judicial branch – promoted a public hearing in 2009 with health experts, public authorities, academics, lawyers and civil society gathered to supply the Court with "technical, scientific, administrative, political and economic" information regarding health care litigation cases (Mendes, 2009). In total, 50 specialists were heard by the STF.

The public hearing was motivated by acknowledgment that the lawsuits claiming access to health treatments were having a significant impact on the public health system and that the court needed support from different specialists and stakeholders in order to make better decisions (Mendes, 2009). Justice Gilmar Mendes, the then president of the STF, held the public hearing and declared in his opening address that "either the idea that courts should have no role on health care issues or that there is a right to any health treatment is untenable" and that a balanced view should be

found, taking into consideration "all the judicial decisions' implications without compromising (…) the right to health" (Mendes, 2009, p.9). Lastly, he affirmed that he expected the "public hearing would result not only in technical information conducive to assisting in the court's analysis of the cases, but also in support for a broader and pluralist debate for the improvement of health policies" (Mendes, 2009, p.10).

Accordingly, if public health policy is a complex issue in which judges are not knowledgeable and the adjudicative process is unable to grasp all its complexity, then a participative and plural forum with specialists and stakeholders is arguably a sound alternative to compensate for the court's lack of institutional capacity and the narrow limits of adjudication.

Moreover, initiatives like the public hearing can be seen by those who advocate for a more active role for courts not only as a device to defend them against critiques concerning their institutional capacity and legitimacy, but also as a tool for helping courts to implement their potential for enhancing democracy and participation. According to this argument, there is an expectation that courts can be a forum to ensure that norms are created and applied through a deliberative process or, in other words, a "collective and inclusive discussion" (see Gargarella, 2011, p.237-238 and also Nolan, 2011, p.194-195). Courts can fulfil this task, for instance, by promoting open discussion about the solution to rights violation via public hearings. The public hearing on health care litigation organized by the Brazilian Supreme Federal Court was praised by analysts as a good example of what courts should do in regard to the protection of the right to health (Gargarella, 2011, p.237; Nolan, 2011, p.195).

In this section, I will not discuss whether the expectation that courts can create collective and inclusive discussion is sound and neither will I look here at whether the

public hearing is a conducive mechanism to reach that goal (I discuss this topic in Chapter 6). I will just analyze what seems to be the only direct consequence of the public hearing for the Supreme Federal Court itself: the establishment of criteria to guide the court in cases involving health care litigation.

Setting the limits of an unlimited right to health

Based on the conclusions drawn from the information presented by the speakers in this public hearing, in March of 2010 the STF judged nine cases and established guidelines defining those duties citizens can immediately demand from the public health system[58]. The same criteria were reaffirmed in further decisions[59].

In these cases, the Supreme Federal Court stated that, even though the health system cannot supply all treatments patients demand and that priorities in health care should be set, courts have the power to oblige the public health system to offer a treatment needed by the patient but denied by the government if:

> 1) It has its safety, efficiency and quality recognized by the Brazilian National Health Surveillance Agency (ANVISA), which excludes experimental treatments.

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[58] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 175* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 211* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 278* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3724* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 2944* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 2361* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3345* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3355* (2010) and Supremo Tribunal Federal – *Suspensao de Liminar 47* (2010).

[59] Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 260* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 283* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 424* (2010), Supremo Tribunal Federal – *Suspensao de Tutela Antecipada 434* (2010), Supremo Tribunal Federal – *Suspensao de Liminar 256* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3941* (2010), Supremo Tribunal Federal – Suspensao de Seguranca 4045 (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3962* (2010), Supremo Tribunal Federal – *Suspensao de Seguranca 3852* (2010) and Supremo Tribunal Federal – *Suspensao de Seguranca 3989* (2010).

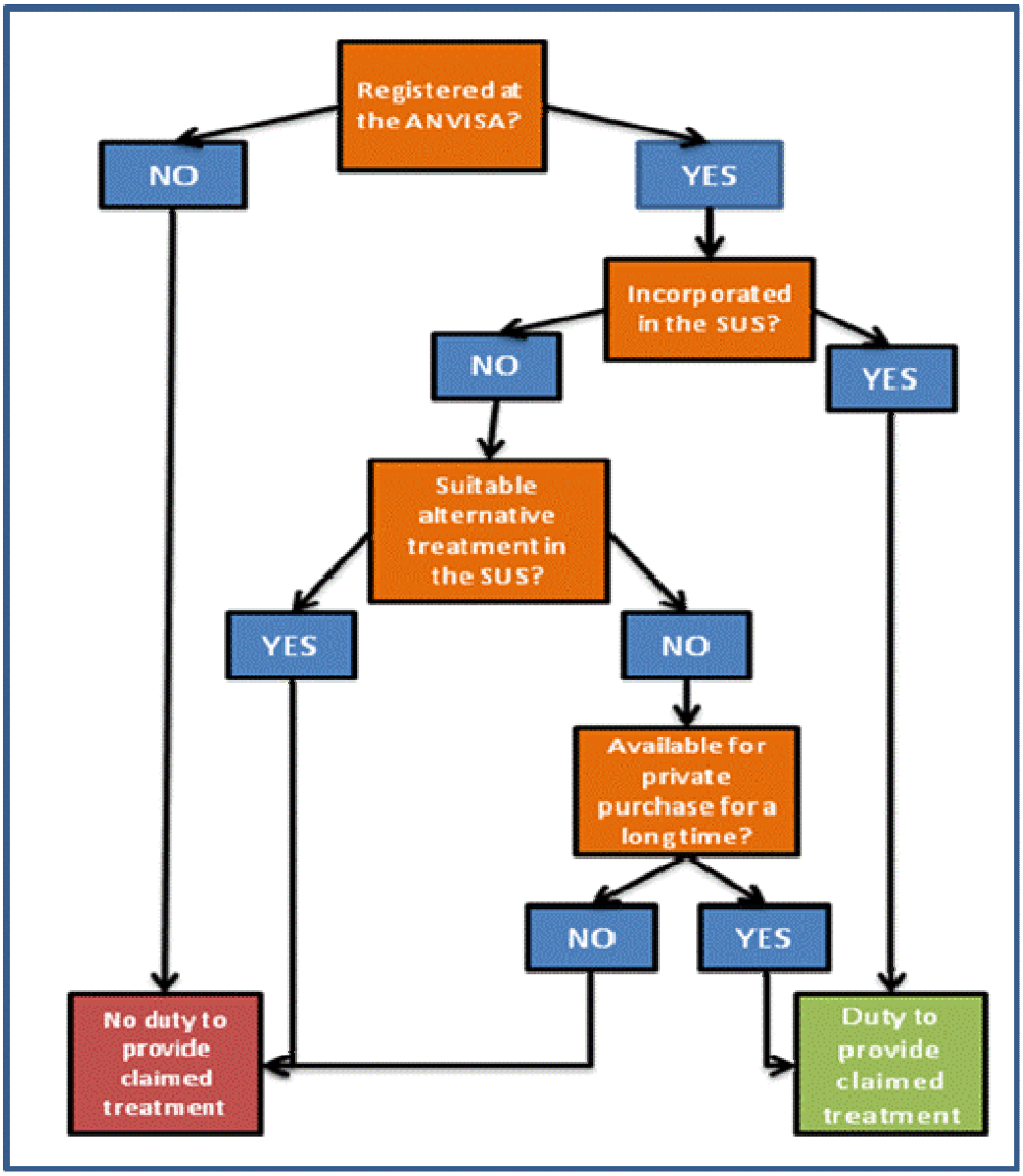
2) It is already included in the public health policies, which means included in the public health system – the National Health System (SUS) – official list of medicines and treatments and recommended by clinical guidelines.

3) In the case the petitioner claims for a treatment not included in the public health system (SUS), but registred at the ANVISA, she has to prove that no treatment is offered or that the treatments already offered are not appropriate to her; and

4) The non-included treatment has to be successfully used “for a long time” by patients who can afford it but its inclusion in the official lists and clinical guidelines by the health bureaucracy is “very slow”.

The Chart below was created based on the criteria set by the STF in these decisions and illustrates the way they are expected to be applied in health care litigation cases.

Figure 2 – Criteria established by the STF after the public hearing



The STF, therefore, admitted that the public health system has to define priorities in the allocation of scarce resources; thus, not all claimed treatments can be offered by the public health system. This may seem a trivial statement of what is widely recognized elsewhere (even in the most developed countries), namely that no health system can afford to offer all health treatments to all health needs for every citizen. But,

as we saw in Chapter 2, this statement has not been widely accepted within courts in Brazil, not even within the STF itself.

The establishment of the criteria aimed at creating a sphere in which courts should be deferential to administrative decisions, but also one in which courts could legitimately intervene. However, I argue that these criteria actually remove from health authorities the possibility of making choices based on cost-effectiveness and end up consolidating the "rule of rescue", a principle that states that whoever has a health need should receive health care, no matter the costs or the budgetary impact. Therefore, despite its best intentions the STF is in fact foreclosing the possibility of creating a fair procedure for rationing healthcare. Let me make the point by looking more closely at what was decided.

The first criterion established by the court is hard to disagree with: the public health system should not be obliged to supply medicines that are not registered by the National Health Surveillance Agency (ANVISA), i.e., treatments whose efficiency and safety are not scientifically proven.

The STF also established that the government cannot deny citizens treatments already incorporated in the public health system. Hence, once a drug or treatment is included in the official list of treatments and recommended by clinical and therapeutic protocols, its provision by the State becomes an entitled right for citizens. According to the court, judgments ordering the provision of treatments in these cases are more legitimate because they are not setting priorities for health care allocation in place of health authorities. Rather, courts are simply enforcing the provision of a preapproved set of goods and services.

The problem with this criterion is that it does not consider cases in which the treatment offered by the public health system cannot be provided in quantities that ensure universal provision. In these cases, health systems must ration, not by excluding the treatment or medicine from the range of treatments it offers, but by either selecting beneficiaries according to their clinical characteristics, or by establishing waiting lists (Syrett, 2007, pp 46-50). Thus, that a treatment is included in the official list or recommended by clinical and therapeutic protocols does not always preclude the need for rationing.

A meaningful example is one case judged by the STF itself, *Suspensao de Liminar 228*[60] , in which the Public Prosecutors' Office (Ministério Público) lodged a lawsuit to oblige the government to provide care in an intensive care unit (ICU) to all patients in the city of *Sobral* who needed it. It was not only demanded that the State should allocate patients to the existing ICU in *Sobral* and neighbouring cities, but also that the State had 90 days to more than treble the city's number of ICU (from 9 to 30).

The STF decided in favour of the Public Prosecutors' Office based on a Ministry of Health Ordinance (Portaria MS/GM n. 1101/2002) that estimates the necessary number of ICU per 1000 inhabitants. Because *Sobral* had fewer ICU than are recommended by the Ministry of Health, the STF argued that the government failed to comply with the health policy guidelines.

However, matching the Ministry of Health's ordinance numbers does not guarantee rationing will not occur. Even in other areas in Brazil where the number of ICUs exceeds the numbers established by the Ministry of Health Ordinance, demand

[60] Supremo Tribunal Federal – *Suspensao de Liminar 228* (2008)

outstrips supply (O Estado de Sao Paulo, 2010). Furthermore, lawsuits demanding access to ICUs are not uncommon, even in areas where the ordinance numbers have been met (O Estado de Sao Paulo, 2010).

Finally, the order for the government to more than treble the number of these units in 90 days raises the question as to whether the Court should mandate such an expense. Although the Ministry of Health established the guideline for an adequate provision of ICUs, there is no requirement that these guidelines be met within 90 days. Even if resources exist, the opportunity costs of trebling the number of ICUs in such a short time should be evaluated against the risk of compromising other health services.

Thus, it is clear that courts must carefully consider citizens judicially enforceable right even to treatments included in the health care system's official lists. Judicial decisions may allow some people to "jump the queue" in the access to health care. Even if, in theory, courts could eliminate the need for rationing of a given treatment and make waiting lists and exclusion unnecessary by ordering the universal provision of a treatment via a structural injunction, the effort to do so may divert resources away from other treatments offered by the health system that compete for the same result (on the impact of structural enforcement of social rights, see section 6.2.2).

The next criterion suggests that in the cases when the treatment was not incorporated, the court should check whether there is an effective alternative treatment provided by the public health system. If not, and the claimed treatment has been available for private purchase and used by patients who can afford it, then its provision should be judicially ordered.

It was not said, however, how the court will assess whether the alternative treatment offered by the public health system is an effective alternative, especially when

claimants (coupled with their lawyers and doctors) and health authorities disagree on this issue. This brings us back the problem of courts' institutional capacity and may help to explain at what the recommendations of the National Council of Justice to build courts' institutional capacity are aiming (see section 3.1.2).

It is not clear, either, if the alternative offered by the public health system has to be only effective for the patient's health problem or, at least, as effective as the claimed treatment. A new treatment may be marginally better than the already provided one, but at a much higher cost. The decision about whether a new treatment that is more effective but more expensive should be provided in the place of another that is less effective but cheaper (in other words, if an increase in price is justified by the improvement in effectiveness) is one of the main concerns of health economists and one of the biggest challenges for health systems around the world (see Schmidt & Kreis, 2009; Sorenson & Chalkidou, 2012). This is why cost-effectiveness analysis and methods such as the Quality Adjusted Life Years (QALY) are fundamental devices for making good health care policies.

Even though the STF was not clear about what an "adequate alternative" means, the criterion that allows the court to oblige the supply of a treatment for no reason other than that it has been available for private purchase for a long time (although not specified how long) indicates that cost-effectiveness analysis is not among the court's concerns when establishing the criteria. This criterion is also deeply problematic because it rules out cost-effectiveness analysis and policy considerations in deciding on the provision of health care. The fact that a drug is available for private purchase means only that it is efficient and not harmful (according to the National

Health Surveillance Agency – ANVISA), but says nothing about its cost-effectiveness, level of priority and affordability for the public health system.

New technologies can be effective and safe, but can also be extremely expensive (especially when protected by intellectual property rights that grant pharmaceutical companies monopolies, effectively ruling out the possibility of cheaper alternatives) and increase the costs of health care, which makes rationing and priority setting even more necessary.

As mentioned earlier, Ferraz & Vieira (2009) estimated that the cost of offering the most modern medicines to all Brazilian Rheumatoid Arthritis and Chronic Hepatitis C patients (1% of the population suffer from these diseases) would be around US$56 billion, a figure that is roughly 4.5% of the national GDP and more than double the yearly national health care budget (Ferraz & Vieira, 2009, pp. 235-238).

The provision of all new existing health technologies is not only unfeasible, but may also make the public health system inefficient because a huge amount of resources may be used to produce marginal health benefits for the population. In this case, the opportunity costs can be very high, which is unfair with those who may have been potentially benefited by the alternative use of the resources.

In conclusion, even though the STF made an effort to grasp all the complexity of the issue through a public hearing and tried to establish some criteria for the judicial provision of health care, it considered the right to health from an individual perspective and forced the public health system to apply the “rule of rescue”, a sense of immediate moral duty to attempt to do everything possible to rescue an identifiable person whose life and/or health is in danger, irrespective of cost (NICE, 2008, p .20; Cookson & Dolan, 2000, p. 324).

The application of the rule of rescue does not make healthcare rationing unnecessary; rather it makes it implicit and therefore unfair. Rationing will simply not be explicit and life/health saving treatments will be offered without considering their cost and the impact on the healthcare of the rest of the population. The rule of rescue may make the distribution of healthcare inefficient and unjust because more resources will be spent benefiting a few people at a higher cost and producing less total benefit from the population perspective. As Daniel Callahan affirmed (2011, p.172-174), thinking about medical care in terms of a set of individual rights to benefits rather than from the perspective of a societal good rules out from the start the possibility of choosing the treatments that will do the most good from a population perspective and thus makes the control of costs in health care impossible. I would also add that it precludes any debate about the fairest way to distribute health care resources.

3.1.2. The National Council of Justice: building courts' institutional capacity

The National Council of Justice (CNJ) is an agency created in 2009. It is composed of 15 members, most of them judges and justices, and as we have seen the presidency is chaired by the Justice President of the Supreme Federal Court (STF). According to the Federal Constitution, the CNJ is part of the Brazilian Judicial branch, but has no judicial power and cannot review judicial decisions. As we have seen it is responsible for regulating the administrative and financial activities of the judiciary and the enforcement of judges' professional duties. It can issue resolutions and recommendations for courts in order to improve their functioning in terms of strategic planning and administration. The CNJ's recommendations, as the name says, are not binding on courts.

The CNJ issued the Recommendation 31 in 2010 proposing some policies to control the harmful effects of health care litigation in Brazil. The proposals reinforce and complement what was already put forward by the STF and are, according to the Recommendation itself, derived from the public hearing promoted by the STF. For the reasons already presented, the affinity between the CNJ and the STF was to be expected. The President of the CNJ at the time when the Recommendation 31/2010 was issued, Justice Gilmar Mendes, was also the President of the STF who organized the public hearing on right to health and the Justice who wrote the decisions in which the criteria mentioned in section 3.1.1 were established.

Recommendation 31/2010

The Recommendation 31/2010 "recommends to courts the implementation of measures aiming at supporting judges and other legal professionals, in order to assure better solution for the judicial claims regarding health care". The document affirmed that some of the main problems regarding health care litigation in Brazil were (1) the lack of clinical information available to judges concerning these cases and (2) the claim for drugs not approved by the National Health Surveillance Agency (ANVISA). The Recommendation also stated that the health authority's managerial capacity, the already existing public policies, the organization of the public health system and the need to guarantee the sustainability and manageability of the National Health System have all to be respected and taken into consideration by courts.

Therefore, the CNJ recommended that the Brazilian courts should:

> a) Make technical support from doctors and pharmacists available to assist judges in assessing the

> clinical evidence presented by the litigants in healthcare related cases;
> b) Advise judges to, among other things, analyze the cases based on complete and comprehensive information; avoid the provision of drugs not registered at the ANVISA or experimental drugs; and consult, whenever it is possible, health authorities before an interim decision be made;
> c) Include medical law legislation as a subject to be examined in the public entrance exams for judges;
> d) Promote tours that will take judges to visit public health units.

Recommendation 31/2010 also recommended that the schools responsible for preparing those admitted in the public entrance exams to become judges[61] should include Health Law (Medical Law) in their curricula. These schools should also organize seminars with judges, public prosecutors and health authorities in order to promote common views in the field.

The CNJ's recommendation tries to establish a sphere of deference by affirming that administrative decisions need to be respected and taken into consideration and, at the same time, aims at building courts' institutional capacity to make better decisions in health care litigation cases.

The CNJ reinforced the idea formerly established by the Supreme Federal Court that courts should consider the choices made by health authorities and "avoid" the judicial provision of treatments not registered by the National Health Surveillance Agency. The CNJ also added that judges should be better informed about the claims and consult health authorities "whenever it is possible" before making an interim decision. This can filter out absurd claims for treatments: based on insufficient information or without evidence about its safety or effectiveness. However, they deserve the same

[61] In Brazil, lower level courts' judges are chosen via public entrance exams.

critique I have made of the STF's criteria: they are unable to deal with the most difficult cases, when the evidence is not clear or there is evidence of effectiveness but insufficient funding.

Building courts' institutional capacity

The CNJ innovated in trying to build courts' institutional capacity to decide on the provision of health treatments[62]. It emphasized that judges need to be better trained and more knowledgeable about the legislation concerning health care, the functioning of the health care system and public health related issues. It is not clear, however, what is intended with the attempt to make judges more knowledgeable in these topics. Better training and more knowledge are certainly good in themselves, but how can they impact on health care litigation? Two answers present themselves.

Firstly, judges who know more about the health care system would be more deferential to the health system's rationing decisions. They will understand, for instance, that the public health system has to make "tragic choices" (Calabresi & Bobbit, 1978), there are opportunity costs, rationing is necessary, and that decisions on the provision of healthcare are not always arbitrarily made. This interpretation would be harmonic with the suggestion brought by Recommendation 31/2010 that (as we have already seen) courts should consider health authority's managerial capacity, the already existing public policies, the organization of the public health system and the need to guarantee its sustainability and manageability. Thus, making courts more knowledgeable about the

[62] Some courts have already implemented some of the recommendations made by the CNJ. The Courts of Appeal in the States of Rio de Janeiro and Rio Grande do Sul created "technical support services" composed by doctors, nurses, pharmacists and nutritionists to advise judges in health care litigation cases (Valor Economico, 2010).

public health system and public health issues will give courts a broader perspective to the problem than one that is narrowed to their decision on a claim for an individual need. Therefore, that would avoid the prevalent interpretation that the right to health means that whenever there is a health need, there is an individual right to receive health care irrespective of the costs.

The other alternative is that better trained judges can make good substantial decisions since they are more capable of second-guessing health authorities' decisions concerning the provision of health treatments. Given that the CNJ's recommendation was created in the same context of the STF public hearing, this interpretation is probably sound. According to the criteria established by the STF, courts can always order the provision of treatments incorporated in the public health system's policies and, when there is evidence that the patient needs the claimed treatment and no effective alternative is offered, non-incorporated drugs can also be provided via judicial order.

Thus, the effort to train judges in health law and health related issued may be an attempt to provide them with information and expertise to decide if the alternative treatment offered by the public health system is effective or if the patient really needs the treatment available in the private market but not provided by the public health system. By the same token, the recommendation to make technical support from doctors and pharmacists available to assist judges in health care litigation cases has the same purpose of helping courts to identify when there is actually an unfulfilled health need.

If, generally speaking, what impairs courts from dealing with factual problems is the judges' lack of training and the absence of a dedicated staff to acquire and evaluate factual information (Yowell, 2012), then the proposals advanced by the CNJ to build institutional capacity seem plausible: train judges and surround them with doctors

and pharmacists who can provide technical advice. However, I will argue that expecting courts to review health authorities' decisions and replace them with their own substantial decisions, even if judges are better trained and assisted, is not a good response to the problems caused by health care litigation.

If the proposals advanced by the CNJ are aimed at helping courts to deal with the health care litigation cases' complexity then it is necessary to clarify that "complexity" is itself a complex phenomenon. When one says that a legal problem is complex, it may mean that it is factually complex, polycentrically complex or morally complex[63].

Factual complexity can be separated into two groups: technical and social facts. Technical facts are those that need technical analysis from experts and for which it is expected that there is a right answer to be found according to the scientific consensus. An expert (or a group of experts) can assess if a patient's disability was caused by her doctor's malpractice; if the bullet that killed the victim was shot by the suspect's gun; if the DNA examination proves that Miss Smith is the child's biological mother; or if the level of pollution in a river is above an acceptable level that baths in it should be prohibited. These are, indeed, problems that courts have been dealing with in any area of law relying on the support of expert witnesses, so why not in deciding whether a treatment should be provided to a claimant or not? This reasoning is advanced by some social rights adjudication advocates who argue that the fact that judges are generalists and without training on technical issues is not an obstacle to them deciding technically

[63] This classification was partially inspired by Montgomery (2008).

complex cases as long as they are surrounded by specialists who can provide technical advice and explanation.

As Nolan at al. (2007, p.15) put it:

> If the courts are considered capable of evaluating and drawing conclusions on the basis of complex technical and medical evidence in, for example, a criminal or tort law context, then there can be no presumption that they are unable to do so in a social and economic rights context.

Social facts, on the other hand, are findings about societal issues that help to decide on broad questions of law and policy (see Horowitz, 1977) and bear similarity with what Davis (1942) called "legislative facts". Social facts demand empirical investigation and analysis from social sciences in order to make causal inferences or interpretations of social phenomena. The level of certainty is lower: the method to choose the relevant data and analyze them may be controversial; the data available may be limited; there will probably be different interpretations of the results; and the best action to follow the acquired knowledge may be disputable. Furthermore, the quality of the social science research may vary enormously (Monahan & Walker, 2007, p. 157). The role of courts in using social facts in its decisions is much more controversial because the results of the social science research may be inconclusive and there is significant risk that the court may misread the social data (see King, 2008, p. 413).

For instance, the German Constitutional Court decided that laws banning smoking in restaurants, pubs etc. in some German states were unconstitutional based on a press release asserting that there was a higher decrease on the revenues of the gastronomic industry in states with the ban than in states without it, which, according to the court, violated the professional freedom of the owners of the venues. However, the

court did not consider the fact that other variables not related to the smoking ban may influence the decrease in the revenues and that the difference may not be statistically significant (Petersen, 2011, p.16).

Problems can also be complex because they are polycentric in the sense that they do not affect only those involved in a judicial dispute, but may have unpredictable consequences beyond the interests brought forward for a court's decision. In his own words (Fuller, 1978, p.395):

> We may visualize this kind of situation by thinking of a spider web. A pull on one strand will distribute tensions after a complicated pattern throughout the web as a whole. Doubling the original pull will, in all likelihood, not simply double each of the resulting tensions but will rather create a different complicated pattern of tensions. This would certainly occur, for example, if the doubled pull caused one or more of the weaker strands to snap. This is a "polycentric" situation because it is "many centered" - each crossing of strands is a distinct center for distributing tensions.

Polycentric problems "will normally involve many affected parties and a somewhat fluid state of affairs" (Fuller, 1978, p.353). Differently from social facts, the uncertainty here is not due to the difficulty in making causal inferences or interpreting social phenomena, but rather the difficulty is to foresee who will be affected and how. Social sciences can also be used to shed light on the problem, but the number of parties affected and the changing circumstances makes it very difficult to predict accurately the impacts of a measure. And the uncertainty will be as big as the impact of the decision is widespread. Given the uncertainty, the complexity in polycentric problems is more difficult to solve merely through the appeal to specialists. The amount of data and the plurality of perspectives may be enormous and our cognitive capacity has limits, hence decisions have to be made partially based on intuition, experience and speculative

prediction about the consequences (on decision-making under uncertainty, see Vermeule, 2013). It also demands a high level of flexibility from decision-makers in order to adapt to unforeseen consequences and changing circumstances.

Finally, there is also the moral complexity of some issues and the need to accept reasonable disagreement (Rawls, 1993; Waldron, 2009). The liberal thought is founded on the premise that in society, reasonable people - who seek mutually justifiable decisions - may have different concepts of justice and hence disagreement, as long as it is reasonable, should be tolerated. Narrowing the discussion to health care, there are competing tenable and coherent conceptions of what a fair distribution of health care should look like – egalitarianism, utilitarianism, prioritarianism, and so on and so forth – and reasonable people may disagree about which of them should be applied (Daniels, 2009). In the face of this moral disagreement, a fair procedure – based on fair principles and transparent deliberation – should be applied (Daniels, 2009). This solution is not justified because it will produce a "correct ethical view", but because deliberation under conditions that are fair to all parties can hold decision-makers accountable for the reasonableness of their decisions, i.e., "a conclusion that people can agree rests on considerations all believe are [ethically] relevant" (Daniels, 2012, p.44).

In brief, technically complex problems are those for which we expect to have a single answer, even though it may not be immune to controversy or difficult to find out. The dichotomy is whether the answer for the problem is right or wrong. Social facts and polycentric problems are those for which we cannot find a single right answer, the latter because it is impossible to preview all the consequences and the former because the level of certainty about causal inference and interpretation of social facts tend not to be high. Hence, in both cases decisions are made under conditions of uncertainty and

against a background of risk preferences and there are many answers that can be considered rational in the sense that cause/consequence and means/ends relations are coherent. Thus, the answer cannot be right or wrong but rather rational or irrational. Morally complex problems are those to which we know there is no single right answer because there are different and reasonable concepts of justice that would come up with different answers. Thus, answers to moral problems are either reasonable or unreasonable.

Going back to the Recommendation issued by the National Council of Justice, it seems to expect that well trained judges surrounded by doctors and pharmacists will be able to make scientifically sound decisions, which would avoid some of the problems caused by the complex issues regarding health care litigation. That would be an appropriate response if the provision of a treatment by the public system were merely a technically complex problem to which a specialist could come up with a right answer. However, it is not merely a technically complex issue and other kinds of complexity – of the sort we have just been discussing – are also involved.

Even if we try to reduce it to a mere technical issue, it would be unrealistic to expect that a group of doctors and pharmacists will have the needed diversification of expertise to be able to make a comprehensive scientific assessment of the effectiveness of all treatments that are being litigated for. This task is more difficult taking into consideration that the main driver of litigation is a wide array of new medical technologies for a huge diversity of health problems. These new treatments' effectiveness and safety may still be controversial in the scientific literature and the amount of information may be insufficient to draw safe conclusions. There are also epistemological concerns that could be raised. How are these health professionals going

to make the assessments? Based on which methodology and data? What are their qualifications and what kind of conflict of interests might they have? What are the risks of courts misrepresenting or misunderstanding the research results? How will courts balance evidence pointing to different conclusions?

The already mentioned example of the litigation for analogous insulin can illustrate this problem. The Brazilian public health system provides regular insulin for the treatment of diabetes, but patients go to courts claiming the provision of analogous insulin because they allegedly reduce the cases of hypoglycemia, a side-effect caused by the treatment with insulin. There is an enormous scientific controversy on whether analogous insulin reduces the cases of hypoglycemia when compared with the regular version. A research project analysing how courts deal with this scientific uncertainty showed that even though in most cases judge decide based solely on the medical prescription, in others they require assistance from an expert doctor to decide whether the analogous insulin should be provided. The result is that the scientific controversy is reflected in the different answers given by legal experts: some say the analogous insulin should be provided and others that it should not because it is not better than regular insulin (Wang et al., 2011). Thus, when courts require the support of an external expert, there is an "expert lottery" and the access to the analogous insulin through courts may depend on the expert to which the case is sent for analysis.

Nonetheless, let's assume for the sake of the argument, that courts manage to create a system that is good enough to assess health technologies' effectiveness and safety and health professionals working for the court are able to make a decision grounded on good scientific evidence about the treatment. That will still not solve all the problems caused by health care litigation. The provision of health care in the public

health system is not merely a technical problem that science can solve. It is also a matter of public policy. Doctors and pharmacists will not be able to conduct research about cost-effectiveness, its affordability given the budget made available for health care, the opportunity costs of providing the claimed treatment, its level of priority regarding the other health needs of the population and the expected impact on public health.

Even if we add health economists to the group of legal experts to produce cost-effectiveness analyses of the claimed treatments, it would still be naïve to expect that their decision would give a ready-made answer to whether or not a treatment should be provided. Priority setting involves problems of social fact (e.g. how a certain disease affects the population's health), polycentricity (e.g. the socio-economic effects of providing a given treatment on the public health system) and morality (how to distribute health care fairly given that we cannot give everything to all) that cannot be reduced to a technical decision that can be objectively made by a body of experts attached to courts.

Decisions on public policies have to rely on scientists and social scientists, but it is also an issue that is inescapably speculative and the impact of which is hard to predict. As affirmed by Davis (1971, p.118), these cases involve the exercise of an informed judgment that takes into consideration not only knowledge and understanding of general facts and scientific information, but also experience, intuition, estimation and guessing. This is the role of managerial capacity to make and review decisions according to the consequences and to respond promptly to changing circumstances. And this is also the importance of the decisions' procedural legitimacy. Since there is no unequivocal right decision, it is essential that it is made according to a fair and open procedure.

From this perspective, the expectation that courts make good administrative and political decisions with better trained judges and expert assistance, but without the other benefits of an administrative expertise and a politically accountable and representative process, seem untenable. Moreover, those advantages of the political and administrative decisions may be undermined by decisions of reviewing courts which reverse their decisions from the political and administrative sphere based on a different source of evidence (Davis, 1971; see, also, Chapter 6).

To overcome some of these obstacles, one could imagine the CNJ recommending that health economists be invited to advise courts about the treatments' cost-effectiveness, and public health specialists, epidemiologists, health authorities and civil society to advise about the treatments' priority for the public health. Let's say that it could be accomplished through the organization of public hearings (similar to the one organized by the Supreme Federal Court) for every health care litigation case or the creation of a "bureaucracy under judicial auspices" that could then provide research service and fact finding resources on empirical and social facts[64]

This transformation of courts into a quasi-legislative or quasi-executive institution would probably be unfeasible, considering the time and resource constraints on conducting such a comprehensive and reliable analysis for each treatment in every lawsuit. Monahan & Walker (2007) made the following caveat about the use of social sciences in courts: it may be an inefficient use of courts' time and, I would add, resources. According to them:

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[64] The idea of a bureaucracy under judicial auspices to assist courts in cases involving legislative facts was as suggested by Davis (1971) in his seminal article and recently advanced by Yowell (2012).

> The same testimony about the same research studies must be heard in case after case whenever a framework for a given type of factual determination is sought. Second, introducing frameworks as social facts is expensive. The pool of expert witnesses is limited to a small group of basic researchers in each topical area and those researchers must be transported and paid to repeat their testimony in each new case (Monahan & Walker, 2007, p.161)

Even if we assume, for the sake of the argument, that it would be feasible to create such a complex decision making system, it can be called into question whether it would be rational to create it to decide on the provision of health care in each case instead of relying on the procedure used by health authorities, who have the bureaucratic structure and expertise to do so. I will discuss this argument further in the section that follows and in the conclusion of this chapter.

3.2. Towards control of procedure: the Federal Law 12.401/11

Besides the responses from the Judicial branch, there was also a legislative reaction to health care litigation: the Federal Law 12.401/2011. The legislative response is not focused on making court's "usurpation" better qualified but rather on making the procedure for assessment and incorporation of new health technologies in the public health system better: more transparent, participative, based on robust evidence and on clear and standard criteria.

The Federal Law 12.401/2011 was based on two draft bills proposed in the Senate: the 338/2007, by the Senator Flávio Arns (hereafter Arns' Bill); and the 219/2007, by the Senator Tião Vianna (hereafter Vianna's Bill). Both draft bills declare explicitly that the fact that patients are going to courts to claim drugs that are not provided by the public health system is the main justification for their enactment.

Nevertheless, they see the problem from different perspectives and put forward different solutions for it.

In his official justification for the Arns' Bill, Senator Arns declares that he agrees with those patients who litigate for health treatments that the access to health care cannot be restricted by clinical protocols and official lists of treatments. According to him, the official lists of treatments are not frequently updated, restricting patients' access to new technologies. Furthermore, the draft bill aims at tackling the problem that the assessment and incorporation of health technologies is not made through a formal administrative process, which means that there is no deadline for the assessments to be concluded by, no right to administrative appeal, no participation from civil society and the decisions are made exclusively by the Ministry of Health.

Arns' Bill, therefore, proposed that "[I]t is guaranteed that the provision of drugs and health products that belongs to the lists created by the National Health System's authorities does not exempt the State from providing other drugs and health products that are not included in these lists" . It also proposed the creation of an institution - composed of representatives from the government and civil society - responsible for assessing health technologies and deciding on its inclusion in the public health system's lists of treatments. Such decisions would be made through a formal administrative procedure open to public participation and based on scientific and economic analysis. The decision would have to be reasoned and made within 180 days.

Even after this administrative procedure was established, the final word on the provision of a health treatment would nevertheless still not be in the hands of health authorities. The draft bill stated that the fact that the assessed treatment was not included in the official lists would not exempt the public health system from providing

it if (1) the previously incorporated treatments are not effective and (2) there is a medical prescription declaring that the treatment is necessary to avoid death or serious harm to the patient's health. Thus, the Arns' Bill was proposing something similar to the criteria established by the Supreme Federal Court and the National Council of Justice: the patient's needs to prevail over rationing decisions or scientific dispute; and courts to be the institution responsible for guaranteeing this.

Vianna's Bill, which is also concerned with health care litigation, had a different entry point. In the draft's justification, Senator Vianna affirms that the provision of drugs ordered by courts is forcing the public purchase of high cost treatments the effectiveness of which is not always proven. According to him, this is harmful for the public health system because it gives to pharmaceutical companies the power to lobby patients and doctors trying to convince them that the treatment they sell is the best and that patients can access these treatments for free through courts. Senator Vianna concluded the draft bill's justification by affirming that because resources are scarce, priorities have to be set by the public health system so as to benefit the largest number of people.

Vianna's Bill proposed that the public health system should only provide treatments that are incorporated in the official lists and prescribed by doctors working for the public health system. It also excluded experimental and aesthetic treatments from the public health system coverage, as well as any other treatment not registered at the Brazilian National Health Surveillance Agency (ANVISA). Thus, Vianna's Bill would give health authorities the final decision on the provision of health care and would make non-justiciable claims for treatments not included in the public health system's official lists.

In spite of the different perspectives and opposing proposals, Arns' Bill and Vianna's Bill were analyzed conjointly by the National Congress because, according to the Senate, "they legislate about the same issue". Vianna's Bill was rejected and the Arns' Bill was approved and enacted with amendments to become the Federal Law 12.401/2011. Vianna's Bill was formally turned down, but the proposals it put forward were introduced as amendments to Arns' Bill. Thus, the Federal Law 12.401/2011, as enacted, is actually an amalgam of both draft bills: it incorporated the rule that the public health system should only provide treatments that are incorporated in the health policies (as proposed by the Vianna's Bill) and also created an institution responsible for assessing health technologies through a formal administrative procedure (as proposed by Arns' Bill).

Restricting the right to health care

As seen in Chapter 2, comprehensive coverage is one of the principles underpinning the Brazilian public health system. This is often interpreted by courts as meaning that the public health system is obliged to provide any treatment a patient may need, no matter if they are incorporated or not in the public health system's lists of treatments or clinical protocols.

To avoid this unrealistic interpretation, the Federal Law 12.401/11 established in Art. 19-M that: "The comprehensive therapeutic care (…) encompasses: I – the provision of drugs and health care related products whose provision is according to the clinical protocols and therapeutic guidelines for the disease or ailment to be treated (…); II – the provision of therapeutic procedures (…) incorporated in the lists issued by the National Health System's federal health authority (…)".

The Federal Law 12.401/11 also established that in cases for which there is no clinical protocol, the provision of treatments will be made according to the official lists of drugs issued by the National Health System (Article 19-P). It also banned the provision of or reimbursement for experimental treatments and drugs not registered at the Brazilian National Health Surveillance Agency (ANVISA) or not authorized by it (Article 19-U).

These rules are not so different from those established by the STF's criteria, which were confirmed by the CNJ's recommendation: the government should provide treatments registered at the ANVISA and incorporated in the public health policies. The difference is the regime proposed for the treatments not incorporated in the public policy and claimed for off-protocol use, which are constantly claimed by patients. The CNJ and the STF give to courts the power to decide in these cases, whereas the Federal Law 12.401/11 does not allow this exception. It creates an administrative procedure to be realized by a specialized administrative institution responsible for assessing new technologies. Thus, non-incorporated treatments, according to this Law, should be dealt with by the public health system rather than by courts.

Health technology assessment

Besides restricting the array of treatments that can be demanded from the health system, the Federal Law 12.401/11 also established that "the incorporation, exclusion or alteration of new drugs, products or procedures, by the National Health System, as well as the creation or alteration of clinical protocols or therapeutic guidelines, are under the responsibility of the Ministry of Health, assisted by the National Council for Incorporation of Technologies in the National Health System".

Thus, the law created a new institution responsible for assessing health technologies in order to assist the Ministry of Health in deciding about their provision in the public health system and the creation of clinical protocols and therapeutic guidelines: the National Council for Incorporation of Technologies in the National Health System (CONITEC). It also established that the incorporation, exclusion or alteration of treatments has to be made through an administrative procedure open to public participation by means of public audiences and public consultancy. The decision has to be made within 180 days starting from the beginning of the administrative process, and extended by a further 90 days, if necessary. The treatments' assessment is based on the scientific evidence regarding the treatment's effectiveness, accuracy and safety. Economic analysis will also be taken into consideration. Assessed drugs will be compared with those already incorporated in terms of costs and benefits (Art. 19-Q).

Apart from these criteria, the Presidential Decree 7646/2011 also added that the impact of the incorporation of the treatment on the public health system should be taken into consideration. This decree regulated the functioning of CONITEC and established that it is under the structure of the Ministry of Health and is composed of representatives from many health related public institutions and civil society, but with most of the members being affiliated to the Ministry of Health. This Decree also added that the CONITEC's reports will be forwarded to the Ministry of Health Secretary for Science and Technology for the final decision on their incorporation.

Thus, after the CONITEC's scientific and economic assessment of the technology, the final decision falls to be made by the Ministry of Health. If the Secretary for Science and Technology decides to incorporate the assessed drug or create

a clinical protocol and therapeutic guideline, it has to be made available in the National Health System within 180 days (Article 25).

This new system for health technology assessment was based on Arns' Bill. However, there are some differences that make clear the intention of the Federal Law 12.401/11 to give the power to decide on the provision of healthcare back into the hands of health authorities rather than courts, as had been suggested in the draft bill. Before the final version of the Federal Law 12.401/11 was approved, the President of the Republic vetoed the article which stated that if the deadline for the conclusion of a technology's assessment was reached, and no decision had been issued, then the technology should have to be available in the public health system until the decision be eventually published by the Ministry of Health Secretary for Science and Technology (Art. 19-R, §2). She also vetoed the Art. 19-S, which says: "The economic impact of the incorporation of a drug, product or procedure to the lists of the National Health System is not a reason to deny its incorporation or to justify its exclusion from the lists, except when disease or ailment against which the product is aimed at is fully and explicitly encompassed by clinical protocols and therapeutic guidelines".

The justifications given by the President of the Republic for both vetoes are very similar. The President asserted the importance of scientific and economic assessment of a health technology before any decision on its provision is made. Providing non-assessed treatments "can bring risk to patients' health and is an inadequate way to allocate public resources". Likewise, not being able to consider the economic impact of a treatment to decide on the incorporation of a treatment "would impair the public health system from negotiating reduced prices with suppliers in order to optimize and rationalize the allocation of public funds".

Taming health care litigation

Differently from the criteria established by the Supreme Federal Court and the recommendations of the National Council of Justice, the Federal Law 12.401/2011 establishes a different regulation for the treatments not incorporated in public health policies. According to the Supreme Federal Court and the National Council of Justice, the last word on the provision of non-incorporated drugs should be given by courts, who, if convinced that the patient needs the treatment, can order their provision by the public health system.

Conversely, as we have seen, the Federal Law 12.401/11 does not permit such an exception. It opts, instead, for creating a specific institutional and administrative process through which decisions about the incorporation of new technologies is to be made. The institution and the procedure were created, according to Arns' Bill, because the former system for health technology assessment was controlled exclusively by the Ministry of Health and without a formal administrative process, which means without deadlines for the conclusion of the analyses, with no obligation to promote open hearings and public consultancy, and with no right to administrative appeal against decisions. It was also envisaged as a way to bring more plurality to the system by including representatives of civil society, practitioners, states and municipalities in the discussion about the incorporation of new technologies in the public health system. The reform was thus intended to accelerate the incorporation of new technologies and make it more open for participation and control from other stakeholders apart from the Ministry of Health.

According to the first Director of CONITEC, Clarice Petramale, the pressure for the incorporation of new health technologies comes from many groups in society, including patients, pharmaceutical industries and practitioners, but she has been especially concerned with the demands via courts because they force the provision of drugs assuming "the right to health as an individual rather than a collective right" (Petramale, 2011). According to her, there is a common opinion among judges and civil society that if a high cost drug is not provided, it is because the "public health system is badly managed or because the public policy does not fulfil the constitutional requirements". Within this context "it is necessary to review the public policies for health technology assessment", for instance, by increasing the number of clinical protocols and updating them more frequently and making the procedure for incorporation of new technologies more transparent and participative (Petramale, 2011). She also affirmed that the Federal Law 12.401/2011 was a consequence of the debates that took place in the public hearing on this topic organized by the Supreme Federal Court in 2009.

Thus, considering the history of the Federal Law 12.401/2011 and the analysis of its first director, it is possible to affirm that the government is working on the assumption that a better process for health technologies assessment is conducive to promote a more deferential attitude from courts and, consequently, control health care litigation and reduce its impact on the public health policies. This conclusion can be also inferred from the General Solicitor of the Union's (AGU), the institution responsible for the legal representation of the federal government, new strategy for responding to these lawsuits

After the enactment of the Federal Law 12.401/11, the AGU issued several Legal Advices (*Pareceres*) (in spite of being called "advices", they bind all the members of the General Solicitor of the Union) that the institution and procedure created by the Federal Law 12.401/11 should be mentioned and explained to courts in health care litigation cases so as to defend rationing decisions against judicial review.

The Legal Advice 810/2012 affirms that judicial claims for drugs are mostly based only on a medical prescription and hence the attorneys that represent the government (i.e., member of the AGU) should, among other things, take into consideration if the assessed drug was already assessed by CONITEC in order to respond properly to the lawsuit.

The benefits of mentioning CONITEC in the legal disputes is stated in the Legal Advice 803/2012, which affirms that, in response to the increase in the number of lawsuits claiming treatments against the public health system, it is important for its members to demonstrate that the National Health System's pharmaceutical policy is based on stringent scientific criteria, making reference to the procedure created by the Federal Law 12.401/11, which takes into consideration "the scientific consensus based on scientific investigation, methodologically stringent and free from economic interests and subjectivisms".

The same idea was also expressed in Legal Advice 805/2012, which affirms that, given the procedure created by the Federal Law 12.401/11, "it can be legitimately assumed that when a treatment is included in a clinical protocol it is safe, effective, has the best cost-effectiveness for the public health system and, hence, should have preference in relation to other treatments (…)". The Legal Advice concludes by saying that the public attorneys, when defending the public health system against claims for

drugs not incorporated in the public health policies, should provide convincing scientific evidence in order to prevent courts from ordering the provision of drugs the effectiveness of which was not robustly proved.

The idea that the Law 12.401/11 brings new elements that should be taken into consideration by courts when judging health care litigation cases was expressed in the Legal Advice 804/2012. According to the this document, the Federal Law 12.401/11 overcame any doubt about "the legitimacy of the technical criteria chosen by the public health system (…) to guarantee that the treatments offered by the public health system are safe, effective and, at the same time rationalize and optimize the allocation of financial resources". The same document also suggests a different role for courts in health care litigation cases: judicial review should be used to order the assessment of the claimed drug (start a new procedure according to the Federal Law 12.401/11) and control the legality and reasonableness of the administrative decision to incorporate (or not) the claimed treatment.

Finally, the Legal Advice 804/2012 clearly states that since stakeholders can initiate an administrative procedure, and this procedure has to be concluded under certain time constraints, there is no reason for courts reviewing rationing decisions. Thus the Federal Government, through its legal representative, is expecting that courts should control the procedure of the administrative decision, rather than making the decision in the place of health authorities. As we will see in the next chapter, this is what English courts normally do when judging this kind of case.

According to these Legal Advices issued by the AGU, the government made clear its intention to use CONITEC and the new administrative procedure to convince courts to be more deferential to rationing decisions. It is expected that a more legitimate

administrative procedure – more transparent, participative, accountable and scientifically sophisticated – will force a more deferential attitude from courts. In sum, a rationing scheme along the lines of what was suggested by Daniels & Sabin idea of "accountability for reasonableness" has emerged in Brazil as the right response to the increase in health care litigation, although its effectiveness is not guaranteed since it depends on courts accepting the legitimacy of the new health technology assessment system (see Chapter 7).

As seen in the Introduction, part of the literature that defends implicit rationing affirms that one of the reasons why rationing should not be made explicit is fear of litigation, given that explicitness would "open the door to attack" from dissatisfied patients and their lawyers. On the other hand, there are those who affirm that courts will be less likely to substitute their own decisions about provision of new technologies if they see health authorities using "robust, careful, deliberative procedures and [basing] their conclusions on reasonable arguments that appeal to the evidence produced in the evaluations" (Daniels & Sabin, 2008, p.50).

Considering that in Brazil, where rationing was never made so explicit as it is now with the enactment of Federal Law 12.401/11, the door is already wide open to attack from litigants claiming health care, a more explicit rationing scheme presents itself as a sensible response and as a way of transforming a pattern of litigation that is making the health care litigation less fair into one that can promote accountability for reasonableness.

3.3. Conclusion of the chapter

In this chapter, I analyzed three responses aimed at tackling the problems caused by the health care litigation in Brazil. The Supreme Federal Court (STF) and the National Council of Justice (CNJ) recognized that health authorities, rather than courts, are the primary decision-makers on the provision of health care. The STF and the CNJ are not unaware of the problems of legitimacy and institutional capacity that can be raised when courts do what they are currently doing when reviewing health authorities' decisions on the allocation of health care resources.

Nevertheless, they state that courts should have the power to review the rationing decision and order the provision of a treatment if the patient alleged needs are not fulfilled by what is regularly offered by the public health system. Thus the STF and the CNJ insist on interpreting the right to health as the trump of the individual to access health care, in spite of the policy considerations that have to be observed when it comes to managing a public health system. There is a mismatch between the idea that, for reasons of legitimacy and institutional capacity, some decisions are better made by health authorities and therefore should be respected, with them being eventually nevertheless given to courts to review rationing decisions whenever the treatment is proven necessary to the patient.

The STF tried to bypass this inconsistency by basing its criteria on the public hearing organized to discuss the topic with specialists and stakeholders in order to bring legitimacy, information and expertise to the court. The CNJ, in its turn, put forward recommendations to increase courts' institutional capacity by training judges to deal with claims for health care and by making doctors and pharmacists available to advise them on these cases. The idea is that if courts want to control public policies, which encompass factual, polycentric and morally complex issues, they have to go beyond the

limits imposed by the traditional adjudicative model and incorporate elements that are normally seen in the administrative and legislative arena.

As Horowitz (1982, p.141) observed, "[I]nstitutions in competition with each other tend to resemble each other. Each assumes the characteristics of the other in order to minimize competitive disadvantages". Thus, if courts want to review rationing decisions, they may try to somehow emulate the ideal conditions for making a good administrative or political decision on this subject. As courts try to control health authorities' substantial decisions, they tend to become more like health authorities. This is perceived as a way to make sure that the health authorities do a good job and, if they don't, to substitute judicial rulings for their decisions.

But why should courts be concerned with building institutional capacity and legitimacy to make substantial decisions on the provision of health care when there is an administrative procedure and institution created and structured specifically to make these decisions? If the administrative procedure is good (transparent, accountable and based on fair principles), then why replicate it under the auspices of courts? As already discussed, it would be naïve to expect that courts make a procedure to decide on the provision of health care that is better than the one that can be made at the administrative level. If the health authorities' procedure is defective (wrong factual assessment, limited access to stakeholders, lack of due appraisal of all relevant information, lack of transparency or discriminatory treatment) and leads to a wrong, irrational or unreasonable decision, then it would be better if courts controlled the procedure, occasionally ordering the decision to be remade. It would be unnecessarily costly and practically unfeasible to try to create a procedure for health technology assessment in

the judicial level to judge the cases, ignoring more or less entirely what was decided by health authorities in the administrative level (see Section 6.1.3).

To conclude, the proposals from the judicial branch do not take the problem of rationing seriously and as a result expect courts to perform administrative and political tasks that can be better accomplished by institutions with administrative expertise and a politically accountable and representative process. Conversely, the Federal Law 12.401/11 opens up a new possibility for dealing with health care litigation in a more explicit and, ergo, fairer way.

The Federal Law 12.401/11 creates the conditions for a more deferential attitude from courts. If judicial intervention is not always appropriate in every case and every context, then courts have to ask themselves whether they "have enough expertise, competence and/or legitimacy to interfere with this decision" (Kavanagh, 2010, p.250, see, also, Kavanagh 2009, part II). Thus, the quality of the public authorities' inquiry into the specific case should be taken into account by courts and, if persuasive reasons can be formulated, should deserve judicial respect (see Kavanagh, 2010, p.248; Allan, 2011, p.98).

If Brazilian courts accept the argument that a more legitimate procedure by health authorities justifies deference and judicial restraint, this would transform their current "usurpation" approach into a more intermediary one, in which courts demand that political and administrative decisions on health care rationing be made in a fair way, i.e., through a procedure that is open, transparent, participative and based on evidence, reasons and principles that are accepted by fair-minded people. This intermediary approach is the one I advocate for in Chapter 6 as the most suitable for

courts when adjudicating social rights, and is also the one that is found in the English case-study, as will be seen in the next two chapters.

4. Health Care Litigation in England: from "Wednesbury unreasonableness" to "accountability for reasonableness"

In this chapter I analyse health care litigation in English courts[65]. As mentioned in the Introduction, in contrast to Brazil, where an enormous number of cases make quantitative analysis necessary, in the English case, the analysis is qualitative and focused on the reasoning underpinning the decisions that are considered.

English courts case-law in health care litigation evolved from a deferential attitude towards health authorities' discretion to a very strict appraisal of rationing decisions in the public health system and can be separated into two stages. In the first stage of health care litigation case-law, courts simply applied the "Wednesbury unreasonableness" test to the policies´ general principles, i.e., without scrutinizing their application in concrete circumstances. Hence administrative decisions rationing healthcare should only be judicially reviewed if they were irrational in the sense of being absurd, i.e., a decision no rational mind would find acceptable. The first stage goes from the case *Hincks*[66] through to *Child B*[67]. The case *Child B*[68] can be considered a turning point towards the second stage because the decision of the High Court in this case inaugurated a new approach to health care litigation in England.

Subsequently, in the second stage, after *Child B*[69], the approach changed and courts started to make health authorities "accountable for reasonableness" (Daniels,

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[65] As explained in the Introduction, in this thesis I will use "England" as meaning "England and Wales".
[66] *R v Secretary of State for Social Services and Ors ex parte Hincks* [1980] 1 BMLR 93
[67] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[68] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[69] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

2009; Daniels & Sabin, 2008). They started to demand and scrutinize the reasons, procedure and values grounding health authorities' decisions. Thus, according to courts, being reasonable became more than just acting in a non-absurd way, but rather deciding through a procedure that resembled the demands of accountability for reasonableness that have been proposed by Norman Daniel and Charles Sabin, albeit with no explicit reference to their theory.

After analysing the two stages, I will contextualize the evolution of health care litigation in England within broader movements that were changing the legal culture and courts' approach to judicial review in England: the introduction of the language of rights and the public authorities' duty to provide reasons for their decisions.

4.1. First stage: "Wednesbury unreasonableness"

In the first stage, courts restrained themselves to a minimal level of control of rationing decisions and trusted that health authorities made the best decisions. There was not a detailed scrutiny of the decision made by health authorities and courts applied the "Wednesbury's unreasonableness" test to the questioned policy´s general principles. "Wednesbury's unreasonableness" is an expression of judicial restraint (Taggart, 2003, p.322) and means the court would only review those decisions that are so absurd that no reasonable person addressing herself to the question would have come to the same conclusion (Newdick, 2004). In other words, the "[d]ecision has to be absurd, outrageous in its defiance of logic or accepted moral standards that no sensible person who had applied his mind to the question to be decided could have arrived at it" (Newdick, 2004). Under this test a public body is placed under no obligation to explain

the decision reached unless the applicant for judicial review can make a case for its irrationality (Syrett, 2007, p.166).

The reasoning under such a legal regime was straightforward and decisions usually covered only a few pages: resources are scarce, so rationing has to be made; health authorities are the most capable to do it, so courts have no reasons to review health authorities´ decisions unless they were made in an absurd way. Thus, ringing the toll of scarcity and rationing in a way that is not absurd was sufficient for courts to defer to health authorities' decisions. Given courts' self-restraining interpretation of their role in reviewing rationing decisions and the difficulty in showing that a decision is absurd, it is not surprising that during this first stage no claimant won her case against health authorities.

The first stage in the English case law is composed by the following cases decided by the High Court and the Court of Appeal: *Hincks*[70], *Walker*[71], *Collier*[72] and *Seale*[73]. Two other cases, although not directly related to healthcare rationing, bring important insights regarding courts' interpretation of their own restraint capacity to decide on patients' access to health care: *Minor J-A*[74] and *Minor J-B*[75].

In the case *Hincks*[76], the applicants lodged a lawsuit claiming that the health services in the area where they live were insufficient because the plans approved for providing orthopaedic services at a hospital were not carried out for lack of resources. The applicants alleged that this is the reason why they had been on a waiting list for

[70] *R v Secretary of State for Social Services and Ors ex parte Hincks* [1980] 1 BMLR 93
[71] *R v Central Birmingham Health Authority, ex parte Walker* [1988] 3 BMLR 32
[72] *R v Central Birmingham Health Authority, ex parte Collier* [1988], 151
[73] *R v Sheffield Health Authority ex parte Seale* [1994] 25 BMLR 1
[74] *Re J (a minor) (wardship: medical treatment)* [1991] Fam. 303
[75] *Re J (a minor) (wardship: medical treatment)* [1992] 4 All ER 614
[76] *R v Secretary of State for Social Services and Ors ex parte Hincks* [1980] 1 BMLR 93

orthopaedic surgery for years. They sought a declaration in Court that the Secretary of State was in breach of his duty under the Section 3(1) of the National Health Service Act – 1977 to provide comprehensive healthcare. The patients claimed that the Secretary of State´s duty under the NHS Act is "plain and imperative". The Secretary of State affirmed that the need for improving the facilities in the area where the claimants lived was undeniable. However, they could not do it immediately since they had to consider the needs of other areas in the region and that priorities needed therefore to be set.

The High Court accepted the health authorities´ argument that resources are limited and the health system has to do "the best it can with the total allocation of financial resources". And because resources are scarce, Section 3(1) of the National Health Service Act cannot impose an absolute duty to provide all sorts of services. Moreover, the Court judged that it is impossible to focus upon one particular department of one particular hospital and pinpoint any breach of statutory duty on the part of the Secretary of State because the conditions there are unsatisfactory. The responsibility is much wider and the services have to be provided to 12 hospitals in that particular area.

The Court of Appeal agreed with the High Court's decision and dismissed the appeal, confirming that Section 3(1) of the NHS Act does not impose an absolute duty. According to the decision, the lack of financial resources is at the root of the problem in this case and, given that resources are scarce, the Secretary of State is not under obligation to meet all demands for hospital facilities and treatments. The health system has to do the best it can with the total allocation of financial resources and cannot be expected to provide all the latest equipment, machines, pills or organ transplants in every case where people would benefit from them. The decision shows clearly that

health authorities were highly trusted by the Court: "[t]he Secretary of State says that he is doing the best he can with the financial resources available to him: and I do not think that he can be faulted in the matter" (Lord Denning MR, 1 BMLR 93, p.96). Furthermore, the Court of Appeal made a broader statement about the use of courts as a means of challenging health authorities´ rationing decisions:

> They (claimants) share the misfortune with thousands up and down the country. I only hope that they have not been encouraged to think that these proceedings offered any real prospects that this court could enhance the standards of the National Health Service, because any such encouragement would be based upon manifest illusion (Bridge LJ, 1 BMLR 93, p.97).

In the case *Walker*[77], a premature child needed a heart operation that was postponed in favour of more urgent cases, given a shortage of nurses and beds in intensive care units after the operation. Her mother sought a mandamus for the operation to be carried out and a declaration that the decision not to operate on her child was unlawful.

The High Court affirmed that the jurisdiction to intervene existed but had to be used with extreme caution. According to the Court, in this case there was no illegality, procedural defect or any unreasonableness because, given resources constraints, the surgery for the litigant´s child was postponed in favour of more urgent cases. It was affirmed that "the fact that the decision is unfortunate, disturbing and in human terms distressing, simply cannot lead to a conclusion that the court should interfere in a case of this kind" (McPherson J, 3 BMLR 32, p.34). The court reaffirmed the opinion that

[77] *R v Central Birmingham Health Authority, ex parte Walker* [1988] 3 BMLR 32

courts are not in position to review rationing decisions and thus judicial review should not be used to challenge health authorities' choices:

> This court can no more investigate that on the facts of this case than it could do so in any other case where the balance of available money and its distribution and use are concerned. Those, of course, are questions which are of enormous public interest and concern – but they are questions to be raised, answered and dealt with outside the court … I am wholly convinced that this decision of the health authority is not justiciable … it is not a matter in which courts should intervene. ... The court would do a great disservice to those who have to work in difficult and straitened circumstances… I deprecate any suggestion that patients should be encouraged to think that the court has a role in a case of this kind (McPherson J, 3 BMLR 32, p.35).

By the same token, the Court of Appeal affirmed that health authorities are amenable to judicial review in circumstances in which there are reasons to believe that the authority is in breach of duties laid on him by public law and not because resources were not allocated in the way in which others would think they should be allocated. The Court recognized that no matter the level of funding, resources are finite. Hence it was not for any court to substitute its own judgement for the judgement of those who are responsible for the allocation of resources, unless such allocation was unreasonable or involved a breach of a public law duty. The Court of Appeal also added that a more activist role for courts in this kind of cases could undermine the capacity of health authorities to run the NHS properly:

> If the Court is prepared to grant leave in all or even most cases where patients are, from their point of view, very reasonably disturbed at what is going on, we should ourselves be using up National Health Services resources by requiring the authority to stop doing the work for which they were appointed and to meet the complaints of their patients (Sir John Donaldson MR, 3 BMLR 32).

In the case *Collier*[78], the applicant sought an order of certiorari or mandamus against the health authority's decision not to conduct an operation and provide proper medical care for his baby, who had a missing heart valve and required an urgent operation. The baby had had two operations but the problem was not solved and a third attempt was required. Even though the child was at the top of the waiting list, the surgery was cancelled three times due to shortage of intensive care beds and intensive care nurses required for post-surgery treatment. This claim was also based on section 3 of the National Health Service Act 1977 which asserts that the Secretary of State is under a general duty to promote a comprehensive care service and to provide, or secure, the effective provision of services. The claimant argued that there was a breach of a public law duty or a failure to provide treatment in accordance with the statute.

The Court of Appeal[79] dismissed the application and used the case *Walker*[80] as a precedent, stating that the Court is not in position to judge how health authorities allocate scarce resources. There is a lack of sufficient resources to enable every bed to be in use at the hospital, but there is no suggestion that the hospital authority behaved in bad faith. Concerning the claimant's suggestion that more resources should be made available to enable hospital authorities to ensure that the treatment is immediately given, the Court affirmed that "this is not a forum in which a court can properly express opinions upon the way in which national resources are allocated or distributed" (Stephen Brown LJ). Furthermore, the judges said that if there is no evidence that the allocation of resources was unreasonable in the Wednesbury sense, then there can be no

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[78] *R v Central Birmingham Health Authority, ex parte Collier* [1988], 151

[79] The decision by the High Court was unreported, although it was reported in the Court of Appeal's decision that the application was refused.

[80] *R v Central Birmingham Health Authority, ex parte Walker* [1988] 3 BMLR 32

arguable case and courts should not intervene. In this decision, the Court of Appeal, again, explicitly rejected the idea that litigation could be a forum where reasons and justification for the allocation of scarce resources by health authorities should be demanded:

> [T]his court and the High Court have no role of general investigators of social policy and of allocation of resources (Ralph Gibson LJ).

The Court also affirmed that it would be good if health authorities provided reasons and justification for the allocation of scarce resources, but this should not be enforced by Courts. In opposition to the predominant position in the second stage of the English case-law (which will be analysed in the next section), the Court of Appeal made clear that it would not be the role of courts to demand and scrutinise the reasons for the choices made by health authorities:

> They may be very good reasons why the resources in this case do not allow all the beds in the hospital to be used at this particular time. We have no evidence of that, and indeed, as the Master of the Rolls has said, it is not for this court, or any court, to substitute its own judgment for the judgment of those who are responsible for the allocation of resources (Stephen Brown LJ).

> If I were the father of this child, I think that I would want to be given answers about the supply to, and use of, funds by this health authority. No doubt the health authority would welcome the opportunity to deal with such matters so that they could explain what they are doing and what their problems are. But this court and the High Court have no role of general investigators of social policy and of allocation of resources (Ralph Gibson LJ).

In the case *Seale*[81], the applicant sought National Health Service funding for in vitro fertilisation. The funding was denied because she was 37 years old and the local health authority affirmed that, due to competing health priorities and limited resources, they decided only to provide the treatment for women between 25 and 35 years old. The reason provided was that the treatment is generally less effective for women aged over 35 years. The claimant argued that the denial of funding was illegal because the Secretary of State had not made any restriction to the access of the treatment which had been based on age and thus the local health authority could not do so. Secondly, the decision was said to be irrational because it was not based on sustainable clinical approach, given that the age threshold is scientifically controversial and there are experts who affirm that there is chance of success up to the age of 42. Moreover, establishing the age of 35 as a blanket cut-off point takes no account of individual circumstances.

The High Court refused the application. It judged that the fact that a service is provided does not mean that it has to be provided to any individual patient for whom it may work, regardless of financial and other constraints upon the authority. The Court also affirmed that it cannot analyse the rightness or wrongness of competing medical views on the effective cut-off age for the utility of the treatment. On the argument about the need for considering each case individually, the High Court affirmed that "there is no doubt good sense in such a submission" (Auld J., 25 BMLR 1, p.4), however it is not Wednesbury unreasonable for an authority to look at the matter in the context of the financial resources available to it to provide the treatment. Thus, it cannot be considered absurd for an authority to take into account the decreasing efficacy of the treatment after

[81] *R v Sheffield Health Authority ex parte Seale* [1994] 25 BMLR 1

a certain age and take that as an appropriate criterion. It is noteworthy that the Court judged lawful that health authorities did not consider the individual circumstances of the patient. This will be one of the main reasons for judicial review during the second stage of the English case-law, as will be discussed in the next section.

In sum, *Hinck*[82], *Walker*[83], *Collier*[84] and *Seale*[85] represent an approach to health care litigation that had been prevalent in English courts for 15 years. It was based on the judges' trust that health authorities were performing their duties properly; on the twin assumptions that, firstly, courts are not the forum to call into question the reasons for health authorities' decisions and, secondly, that health authorities do not have the duty to consider individual needs and exceptional circumstances against a general policy.

Two more cases decided in this period, although not directly related to claims for health care or dispute about health care rationing, deserve to be mentioned because there are excerpts in which the Court of Appeal manifested its opinion concerning the role of courts in allocating scarce resources: *Minor J-A*[86] and *Minor J-B*[87]. In both cases the Court of Appeal judged whether it would be legal not to provide life prolonging intensive therapeutic measures to a severely handicapped baby with short life expectancy should she suffer a life threatening event or, conversely, whether there is in fact a duty for doctors to do everything possible to keep these patients alive in this circumstance.

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[82] *R v Secretary of State for Social Services and Ors ex parte Hincks* [1980] 1 BMLR 93
[83] *R v Central Birmingham Health Authority, ex parte Walker* [1988] 3 BMLR 32
[84] *R v Central Birmingham Health Authority, ex parte Collier* [1988], 151
[85] *R v Sheffield Health Authority ex parte Seale* [1994] 25 BMLR 1
[86] *Re J (a minor) (wardship: medical treatment)* [1991] Fam. 303
[87] *Re J (a minor) (wardship: medical treatment)* [1992] 4 All ER 614

In both decisions the Court of Appeal rejected the idea that there was a duty to keep the baby alive. The decisions were mainly based on the fact that the children would suffer more if they had their lives prolonged and doctors are in the best position to judge what is best for the patient. However, there were comments regarding the allocation of scarce resources which reinforced the opinion that courts should not influence the way resources are allocated.

In *Minor J-A*[88], the Court stated that

> [i]n an imperfect world, resources will always be limited and on occasion agonising choices will have to be made in allocating those resources to particular patients. It is outwith the scope of this judgment to give any guidance as to the considerations which should determine such an allocation (Lord Donaldson MR, 33 Fam., p.42).

Minor J-B was an appeal against a High Court decision ordering doctors to prolong the patient's life. The Court of Appeal considered this decision erroneous "because it did not take into account of whether the health authority would have sufficient resources to treat the patient" (Lord Donaldson MR, 4 All ER, p.616). If, for lack of human or material resources, it may not always be possible to treat all patients, then health authorities have the duty to make choices. Moreover, the Master of the Rolls stated that

> [t]he court when considering what course to adopt in relation to a particular child has no knowledge of competing claims to a health authority's resources and is in no position to express any view as to how it should elect to deploy them (Lord Donaldson MR , 4 All ER, p.624).

[88] *Re J (a minor) (wardship: medical treatment)* [1991] Fam. 303

A similar opinion was presented by Balcombe LJ, who said that it would be undesirable that a court make an order to compel a doctor or a health authority "to make available to a particular child, without knowing whether or not there are other patients to whom those resources might more advantageously be devoted". Thus, if the court requires the provision of intensive therapeutic care to a certain patient, they would possibly be denying the benefit of these limited resources to another child who would more likely benefit from it.

Finally, to the *Child B*[89] case. As already suggested this represented an important turning point. In this case, a child suffered from non-Hodgkins lymphoma and myeloid leukaemia. She was given two courses of chemotherapy, one course of total body irradiation and bone marrow transplant. According to the doctors who had taken care of the child, no further treatment could be usefully administered and the child had only a short life expectancy. Her father did not accept this diagnosis and found an expert in the United States who affirmed that another course of chemotherapy should be tried in order to achieve a complete remission of the cancer and hence make a second transplant possible. The diagnosis made by the American specialist was not accepted by the child's doctors on the basis that the treatment would cause too much suffering for the child and that the new treatment's chances of success were too low. Moreover, because the treatment had an experimental nature, the Department of Health decided not to fund it.

The decision not to provide the treatment was quashed by the High Court for being "Wednesbury unreasonable". The Court considered that (1) the health authority

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[89] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

failed to have regard for the wishes of the patient; (2) the treatment should not be considered experimental given the estimates of success presented by the American practitioners; (3) even though the prospects of success were small, the patient should enjoy a "worthwhile chance of life"; (4) the cost of the treatment was overestimated by health authorities; (5) the argument concerning the lack of resources consisted only of "grave and well-rounded generalities"; (6) when the life of a child is in risk, then health authorities "must do more than toll the bell of tight resources" and "must explain the priorities that have led them to decline to fund the treatment" (Laws J, 25 BMLR 5, p. 10-18).

Mr Justice Laws based his decision on section 3 of the National Health Service Act 1977 and on the "fundamental right to life". The right to life was based on the European Convention of Human Rights (ECHR), which is to be "vindicated as sharing with other principles the substance of the English common law" and that even though the ECHR was not (then) a statutory text, it may be applied by judges as a "persuasive legal authority to resolve outstanding uncertainties in the common law" (Laws J, 25 BMLR 5, p. 14). According to the High Court, even though the law gives a public authority discretion, it is not to be permitted to perpetrate infringement to rights unless it can show a substantial objective justification on public interest grounds. Thus, health authorities have the burden to prove the reasonableness of their decisions.

The innovations in this decision by the High Court cannot be underestimated. Even though still applying the language of "Wednesbury unreasonableness", the case was analysed in a way that earlier English courts had explicitly affirmed they would not do. Firstly, it called into question the PCT's medical/scientific appraisal of the treatment; secondly, it transferred the burden of proof to health authorities, who were

expected to provide reasons for choosing not to provide the drug; thirdly, it considered that the mere fact that resources are scarce and the NHS must run the system for an entire population, does not give to health authorities a *carte blanche* to ration health care; fourthly, it affirmed that the patient's individual circumstances should be taken into consideration; and lastly, it established that the health authorities' level of discretion was narrowed given the important right that was being jeopardized.

The health authority appealed and the appeal was allowed by the Court of Appeal. The Court of Appeal reaffirmed the self-restraint approach that had prevailed until then. It declared that the Court is not arbiter of the merits of cases but is strictly confined to ruling upon the lawfulness of decisions. According to the Court of Appeal, no real evidence was needed to satisfy the court that no health authority is in the position to purchase everything which in the interest of patient it would wish to do. The decision of the Court affirmed:

> [i]t would be totally unrealistic to require the authority to come to the court with its accounts and seek to demonstrate that if this treatment were provided for B then there would be a patient C, who would have to go without treatment. No major authority could run its financial affairs in a way which would permit such a demonstration (Sir Thomas Bingham, MR, 2 FCR 485, p. 495)

According to the decision, courts cannot shut their eyes to the real world in which health authorities are constantly pressed to make ends meet and are legally charged with making difficult and agonizing decisions. It cannot be expected that courts scrutinize and review the decisions made by health authorities unless they had acted in a way that exceeded their powers or unreasonably in the sense of being absurd:

> They [health authorities] cannot pay their nurses as much as they would like, they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot

> carry out all the research they would like; they cannot build all the hospitals and specialists units they would like. Difficult and agonizing judgements have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. This is not a judgement which court can make. In my judgement, it is not something that a health authority can be fairly criticized for not advancing before the court (Sir Thomas Bingham, MR, 2 FCR 485, p. 494).

Child B[90] was not only the first case in which a court – the High Court – quashed an administrative decision not to provide a treatment, but as things have turned out subsequently it has inaugurated a new approach to deciding cases regarding health care rationing. Even though the legal reasoning of former cases prevailed in the Court of Appeal, this was the first case in which there was "noise" in the judicial interpretation of the role of courts in scrutinizing healthcare rationing decisions. What is more, the reasoning of the decision quashed by the Court of Appeal – the demand for better evaluation of the facts, transparency of reasoning and consideration of the patient's individual circumstances – went on to become prevalent in health care litigation cases in English courts. Thus it can be considered that *Child B*[91] was a turning point in the English case law on health care litigation. The High Court decision was reviewed in this case, but its reasoning has been echoing in the case law ever since.

4.2. Second stage: "accountability for reasonableness"

During what I call the second stage of health care litigation in England, courts started demanding satisfactory reasons for the decisions under review (see, also, Palmer,

[90] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[91] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

2007, p.209; Syrett, 2007). Principles and procedures for a policy had to be justified, as well as the application of the policy to individual cases (Newdick, 2004, p.107). The assumption that health authorities are the most capable to make decisions on the allocation of resources was not challenged. However, the assumption that they are doing their work properly, unless proven that their decision is absurd (Wednesbury unreasonable), and that their choices cannot be scrutinized by courts were no longer prevalent among judges. Courts started to make health authorities accountable for reasonableness, which relies on a transparent and public procedure and "insists on being explicit about the grounds for decisions once those grounds have been deliberated about in the context of a specific case" (Daniels, 2009, p.135).

Hence the burden of proof has switched from patients to health authorities. In the first stage, there was the assumption that health authorities did the right thing and the patient had the burden to show that the decision was absurd. Conversely, in the second stage, the health authorities´ arguments that resources are scarce and that they are the most capable to set priorities were not alone sufficient to convince courts not to review rationing decisions. A very strict accountability for reasonableness started to be applied by courts and health authorities started to have to prove that they acted "synoptically", i.e., that they did the best possible job given the circumstances in terms of gathering facts, evaluating alternatives and articulating the values that led to the decision (on the concept of "synopticism" see Shapiro, 1992).

I will divide the cases in the second stage into two groups: before and after the creation of the National Institute for Health and Care Excellence (NICE). The reason for this separation will be made clearer in the next chapter, where I analyse the connection between health care litigation and the creation and functioning of NICE.

4.2.1 Pre-NICE decisions

The cases decided in what I called "the second stage" but before the creation of NICE are: *Fisher*[92], *Coughlan*[93]; *A and Others*[94]; and *Pfizer*[95] judged by the High Court. The decisions in these cases draw heavily on the reasoning advanced by the High Court's decision in *Child B*[96] and in each case the outcome was the quashing of health authorities' decisions.

In *Fisher*[97], the claimant suffered from relapsing remitting multiple sclerosis and was prescribed Beta-Interferon. However the pharmacist blocked the prescription and referred the matter to the Neuro-Sciences Clinical Directorate to determine whether the drug should be provided given the funds allocated. Due to insufficiency of funds (the health authority argued that their expenses were already surpassing their funds), the provision was denied. Health authorities also argued that they were not convinced about the effectiveness of beta-interferon because it was not sufficiently tested and believed it was not cost-effective. They affirmed that results of clinical-trials with Beta-Interferon should be awaited before the provision was authorized.

The claimant sought judicial review against this decision. He claimed that the local health authority was not implementing a policy ordered by NHS executives: it was not making arrangements for the treatment to be provided and was creating a blanket ban on treatment with Beta-Interferon instead. This claim was based on the fact that the

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[92] *R v North Derbyshire Health Authority ex parte Fisher* [1997] 8 Med LR 327
[93] *R v North and. East Devon Health Authority ex parte Coughlan* [2001] QB 213
[94] *R v North West Lancashire Health Authority, ex parte A and Others* [1999] All ER (D) 911
[95] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[96] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[97] *R v North Derbyshire Health Authority ex parte Fisher* [1997] 8 Med LR 327

NHS had issued an executive letter (EL(95)97) asking purchasing authorities and providers to develop and implement local arrangements to manage the entry of beta-interferon for multiple sclerosis into the NHS and to initiate and continue the prescription of the drug through hospitals to patients who are most likely to benefit from the treatment.

The High Court accepted that the local authority did not have to comply with the national policy. However, it had failed to give clear and rational reasons for doing so. It was judged that health authorities were actually establishing a blanket ban on Beta-Interferon treatment, which was contrary to the national policy of targeting the provision of the drug to patients who were most likely to benefit from it. Moreover, the Court affirmed that, in this case, the respondent had funds available but chose not to allocate them. In conclusion, the High Court granted a declaration that the policy adopted by the respondent was unlawful, quashed health authorities' decision not to fund the drug and made an order of mandamus requiring respondents to formulate and implement a policy which took full and proper account of the national policy. Thus, in this case, the High Court decision was based on (1) the fact that good reasons were not provided; (2) the non-consideration of the patient's individual circumstances; and (3) the availability of funds by health authorities.

In *Coughlan*[98], a severely disabled patient who lived in a hospital was moved to another health facility in 1993. She was promised she would be allowed to live in the new place for as long as she wanted. In 1998 health authorities decided to close the place where the patient was living and move her and the other patients to another

[98] *R v North and. East Devon Health Authority ex parte Coughlan* [2001] QB 213

location. Health authorities argued that overriding public interest outweighed honouring the promise made to the patient because the costs of maintaining the facility were too high. It had become a “white elephant” and providing care for patients there was draining resources that could be used to provide care for other disabled people or for other services.

The High Court admitted that health authorities can set priorities when fulfilling their duty to provide nursing care, but the decision on how to allocate the relevant resources has to be made reasonably, which had not been done in this case. The promise made to the patient created a legitimate expectation and was not lawfully weighed by the authority, who failed to conduct an individual assessment of the patient’s needs, as well as the psychological and physical impact of moving her to another place. Moreover, alternative places to host the patient were not identified. At last, the consultation carried out by authorities to discuss the issue with the interested parties was not procedurally fair since not enough time was given for residents’ participation. In conclusion, the promise created a legitimate expectation that a certain benefit would be available, which was frustrated by the decision to close the health facility. According to the High Court, the promise could have not been enforceable if there were an overriding public interest to justify a departure from what was promised, but in this case the interest was not proven.

An order of certiorari was granted and an appeal was duly undertaken. The Court of Appeal judged that the consultation carried out by authorities was procedurally fair because interested parties had participated during the whole process and had enough time to make an intelligent response to the arguments raised by health authorities for closing the facility. Thus, the consultation was not unlawful, in spite of being open to

criticism. However, the Court of Appeal considered that the overriding public interest alleged by health authorities to justify the end of activities in the health facility had not been demonstrated. Thus, there were no acceptable reasons to justify breaking the promise made to the patient and frustrating the legitimate expectation[99]. According to the Court of Appeal, the Health Authority failed to weigh the conflicting interests correctly. One excerpt in this decision illustrates the new approach of the courts towards the scrutiny of health authorities' decisions:

> In drawing the balance of conflicting interests the court will not only accept the policy change without demur but will pay the closest attention to the assessment made by the public body itself (Lord Woolf MR, All ER(D), p.90).

In *A and Others*[100], the health authority refused to fund gender reassignment surgery for three patients who suffered from 'gender identity dysphoria' (transexualism). The patients applied for judicial review contending that they were seriously ill and that the decision to deny them this treatment was based on an irrational policy. They claimed that Sections 1 and 3 of the NHS Act – 1977 obliged the health system to provide them the required treatment. The health authority justified its decision on the basis that, according to the National Health Service Act, it has an obligation to care for all and limited financial resources forced it to give lower priority to some medical conditions – such as sex reassignment surgery – in relation to others. In 1995 the NHS adopted a policy – 'Medical Procedures of No Beneficial Health Gain or No Proven Benefit' – attributing low priority for public funding of procedures that (1) are

[99] Even though *Coughlan* is peculiar if compared to other cases analysed in this chapter because there is a discussion about the legal entitlement created by a "legitimate expectation", it is a good example of courts' willingness to scrutinize public authorities' reasons and procedures in health care.
[100] *R v North West Lancashire Health Authority, ex parte A and Others* [1999] All ER (D) 911

only marginally related to the promotion of health gain according to doctors and (2) the clinical effectiveness of which was not demonstrated in research trials. These treatments, which included gender reassignment surgery, would not be provided ‘except in cases of overriding clinical need’.

The High Court considered that transsexualism is an illness for which the health authority was obliged to have regard in discharge of the duty to promote a comprehensive health service under Section 1 of the 1997 NHS Act. It was judged that the decision to deny funding for the claimants was unlawful and irrational because it did not consider relevant matters concerning what is a proper treatment or what is recognized as the illness involved in gender identity dysphoria. The Court quashed the health authority´s decision and an appeal was lodged.

The Court of Appeal reaffirmed the idea that finite resources oblige health authorities to set priorities in funding different treatments. Moreover, the precise allocation and weighting of priorities is clearly a matter of judgment for each authority, as long as the reasonable requirements are met. In this case, giving gender reassessment low priority was not irrational provided that it allowed provision in exceptional circumstances. Despite the medical divergence about whether the patients’ cases were exceptional, the Court decided that medical judgement is a matter for the authority, not the court. However, the Court of Appeal considered that the policy was flawed in two important aspects: it did not consider transsexualism an illness, but as an attitude or state of mind; and the manner of considering the exceptions in individual cases actually amounted to a blanket policy against funding treatment for the condition. The Court judged in this case that the health authorities did not consider the individual cases correctly. Furthermore, the Court of Appeal affirmed that even though health authorities

can refuse treatment for a particular condition for both medical and financial reasons, this has to be "taken in accordance with equally well known principles of public law" (Buxton LJ, 2 FCR 525, p.549), namely rationally based upon a proper consideration of the facts. It was also affirmed that cases that affect people´s health will require substantial consideration and that their rationality can be subject to careful scrutiny by the court.

From the Court´s perspective, the authority had not demonstrated that degree of rational consideration that can reasonably be expected when deciding not to fund a procedure supported by specialists and professionals: the health authority could not demonstrate that gender reassignment was not a proven treatment, since there are specialists who considered the treatment effective in some cases. If there is divergence, then health authorities cannot simply determine that a procedure has no proven clinical benefit while giving no indication of the grounds for this decision. In the decision, it was affirmed that:

> There is no evidence that the health authority reached its conclusion on gender reassignment after any review in which gender reassignment was assessed in terms of clinical need and its cost and benefits compared, even in the most outline way, with treatments for other conditions (Lord Justice Buxton, 2 FCR 525, p.550).

The appeal was dismissed and the Court of Appeal remitted the matter to the health authority for reconsideration of its policy which should take into consideration transsexualism as an illness and make provisions for exceptions on individual merits.

In *Pfizer*[101], the Department of Health issued the circular 1998/158 advising general practitioners not to prescribe sildenafil (Viagra) and the NHS Trusts not to fund it other than in exceptional circumstances. Although there was no question concerning the drug's effectiveness, health authorities feared that the provision of Viagra would cause considerable expenditure by the NHS and divert funds away from other priorities.

The pharmaceutical company (claimant) argued that the ban on Viagra was preventing doctors from carrying out their statutory duties to exercise their clinical judgment and prescribe this treatment according to what they considered to be necessary for a particular patient. The claimant also argued that the circular was violating European Law, for instance, the rule that publicity should be given by governments on the criteria applied to restricting or excluding treatments covered by their national health systems (Directive 89/105/EEC). Pfizer argued that no reasons based on "objective and verifiable criteria" were given, expert opinions or recommendations were not provided, and no comparison with other treatments that were being provided was made.

The High Court decided in favour of the claimant arguing that the circular impaired doctors' clinical judgment and that the Secretary of State for health failed in being transparent about the reasons for issuing the circular and did not publicize the relevant criteria for this decision.

In brief, the cases analysed in this section present courts willing to challenge health authorities' decisions. They not only demanded and scrutinized the reasons on which their policies were grounded, but also expected authorities to analyse and to consider exceptional circumstances of individuals. The cases also show that health

[101] *R v Secretary of State for Health ex parte Pfizer Ltd.* [2002] EWCA Civ 1566

authorities were not prepared to do so, and the consequence was that they had all their decisions eventually quashed by courts during this period.

4.2.2 Post-NICE decisions

In this section I will present the cases decided after NICE was established. During the second stage, courts had started to demand that health authorities prove that they had good reasons to make their policy choices and, as will be seen in the next chapter, this forced health authorities to reorganize the way they made their decisions. These pre-NICE early cases contributed to creating the context in which NICE was made necessary.

In the case *Pfizer*[102] (judged by the Court of Appeal) the health authority appealed against the High Court's decision and argued that the judgment on the affordability of the product was an essentially political judgement and did not require explanation by reference to some comparative analysis with other products. The restriction was not based on its clinical or cost-effectiveness but rather on the consideration that the use of Viagra should be given lower priority when compared to other calls on NHS funds.

The discussion, then, was about what sort of analysis and explanation was required from health authorities when they restrict access to a certain treatment. NICE, established after the High Court ruling and before the appeal decision, was cited by the Court of Appeal as one mechanism to make good analysis because it provided a comprehensive and empirically based framework for the assessment of new

[102] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

technologies. The Court of Appeal, nevertheless, considered that cost-effectiveness is not the same as affordability. Affordability is a matter of political choice since there is no comprehensive ranking of NHS priorities based on ethical and rational values. It would be inappropriate that each decision applying the criteria should be subject to the detailed scrutiny and exposition of the merits and economics of particular medical products that the applicants seek to achieve in this case. The Court of Appeal overruled the High Court's judgment with its decision being closer to those decided during the first stage: allocation of resources is a political issue that should not be second-guessed by courts and courts should not scrutinize the "merits and economics of particular medical products". This decision could be seen as a return to a more deferential attitude of courts before rationing decisions, in which it was accepted that rationing is a political decision to be taken by the government and which should not be second-guessed by courts, rather than an approach in which courts should demand more transparency from the decision-making process (Syrett, 2004).

In the case *Rogers*[103], the claimant had breast cancer and was not responding anymore to the conventional treatments. Her son found on the internet the information that her type of cancer could be treated with Herceptin, a then unlicensed drug which had shown promising results in trials for early stage breast cancer treatment. Her doctor wrote to the PCT reporting some successful experiments with Herceptin and asked if the patient could pay for the drug while remaining a NHS patient, exempting her from paying for the medical input. The PCT answer was negative and thus the patient decided to start a private treatment. She could only raise funds for the first two courses of the

[103] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392

treatment but not for the complete treatment and then she filed a lawsuit against the health authority based on the National Health Service Act 1977 in order to receive the drug funded by the PCT.

The patient claimed that the refusal to fund the drug was arbitrary and irrational, and therefore unlawful. She argued that other trusts were providing the drug to patients who needed it. The respondent Trust argued that the drug had not yet been appraised by NICE for early stage breast cancer and that it would provide the drug "if and when NICE guidance is published" unless there was an exceptional circumstance, which was not the case of the claimant, according to the PCT. Health authorities considered that her condition was the same as all other women under the same PCT who could be eligible to receive treatment with Herceptin but who did not receive it.

The High Court affirmed that the fact that other PCTs provide the drugs does not make the Swindon PCT´s decision irrational since "rationality in law is not determined by counting heads" (Mr Justice Bean, EWHC 171, par.68). In spite of the fact that there was medical opinion in favour of using Herceptin to treat early stage breast cancer, health authorities should give careful consideration to the existing system of licensing and the appraisal of treatments. The Court concluded that a judge cannot decide whether waiting for NICE guidance (as Swindon PCT was doing) is a better policy than providing it before the guidance is issued (as other PCTs were doing) and hence the PCT's general policy not to supply a drug that was off licence and not approved nor assessed by NICE is rational and thus legal. The court accepted the defendant's argument that it would be wrong to introduce a dangerous precedent of disregarding the health technology assessment process and that the cautious approach of not funding Herceptin, but in exceptional circumstances, was entirely rational. The High

Court, then, was legitimizing not only the decision made by health authorities in this case, but the whole new system for health technology assessment that had been created. Accordingly, the judge can only evaluate whether the policy in this case is irrational and thus unlawful, which, according to the High Court, was not the case. The application was dismissed.

The patient appealed. The Court of Appeal, based on the case *Child B*[104] and other precedents, affirmed that it is perfectly acceptable not to fund a drug for priority-setting reasons. If the denial to supply Herceptin were based on grounds of cost, the Court of Appeal would not judge that such a policy was arbitrary or irrational. However, health authorities affirmed that the denial to fund Herceptin was not grounded on economic reasons. Moreover, the policy itself admitted that the drug would be provided in exceptional cases when there are overriding clinical needs that would justify its use. The problem, according to the Court of Appeal, was that the policy did not envisage the circumstances in which an exception would be considered an overriding clinical need, which, in practice, meant a complete refusal of assistance and this had the effect of making the policy irrational. The Court of Appeal considered that the PCT did not provide convincing examples of cases in which a patient's clinical condition would be considered an exception to the general rule of not providing the drug. Thus, there was no rational basis to distinguish between patients within the eligible group on the basis of exceptional clinical circumstances. Once the health authority admitted that it would fund the drug for some patients and not for others, it had to bring rational criteria to differentiate both groups.

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[104] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Furthermore, Sir Anthony Clark MR affirmed that the correct approach to irrationality at Common Law in this sort of case was established by Bingham MR in the case *Smith*[105]: "the more substantial the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable" (Bingham MR, 1 All ER 257, p.263). The Court of Appeal decided that the policy of the PCT was irrational and that the PCT should reconsider its policy and reformulate a lawful policy upon which to base decisions in particular cases, including that of the appellant. In this case, it was the Court of Appeal that overturned a more self-restraining judicial review and scrutinized the reasons for the choices made by health authorities, demanding clearer criteria for the exceptions to the general policy.

In *Gordon* [106], the claimant, with terminal lung cancer for whom the conventional treatment was not effective, sought judicial review against the PCT refusal to fund treatment with the drug Tarceva and a final injunction requiring the defendant to fund the drug "for so long as the claimant's oncologist advises it to be funded". The patient had been treated with this drug for almost 4 weeks (privately funded) and was claiming for public funds to continue this treatment for 4 weeks more and for continuing treatment if the patient's response was good. According to the report, 4 to 8 weeks treatment would make clear if the patient was responding to the new treatment, and if not, the treatment should be interrupted. This drug was not routinely funded by the NHS and NICE's decision on its approval was still pending. The PCT's commission that analysed this specific case considered the treatment not to be cost-effective. The claimant argued that the individual circumstances of the patient were not properly

[105] *R v Ministry of Defense, ex parte Smith* [1996] 1 All ER 257
[106] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392

considered, the evidence of the treatment's effectiveness published in an academic journal was ignored by the commission and that the PCT had a "blanket policy of refusing Tarceva".

The High Court decided that it should not be the arbitrator in the dispute about the drug's effectiveness:

> […] unless it could be shown at a substantive hearing that the PCT's conclusion in relation to that matter was irrational […] the claimant cannot succeed. This court cannot decide which of two differing opinions is right. That is not the role of the court (Ousely J, EWHC 2462, par. 31).

However, given the reasons advanced by the PCT, the High Court judged that there is indeed a general refusal policy in regards to Tarceva, no matter the individual circumstances of each patient. According to Ousely J., this may not be "a necessarily unlawful decision", but the PCT's reasons to do so have to be "grappled with explicitly" (Ousely J, EWHC 2462, par. 42). Thus, because the PCT had not considered the case properly, it should "consider afresh" its policy and hence the permission to apply for judicial review was granted, making clear that it may be impossible to challenge a refusal of further funding "if the decision is explained and grapples with the relevant issues" (Ousely J, EWHC 2462, par. 44). The case *Rogers*[107] was used as a precedent, albeit noting that the question of resource allocation had not arisen in that case but was arising in this case now. Additionally, Ousely J.required the PCT "to fund the Tarceva treatment for the claimant until the conclusion of the eight week period from when she started it" although the court considered "untenable" the relief to provide treatment for

[107] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392

so long as the treating oncologist advised" (Ousely J, EWHC 2462, par. 48). The PCT conceded the judicial review and there was no appeal.

In *Otley*[108], the claimant who suffered from metastatic colorectal cancer had tried several treatments that were not effective and her doctors eventually considered that no new attempt should be made. Her sister discovered on the internet a new drug called Avastin that could shrink the tumour and permit resection. This drug was not licensed in England, it was not available for routine prescription within the National Health Service and NICE had not recommended its use based on cost-effectiveness reasons. The patient had paid privately for the five first courses of the treatment and applied for public funding to continue it. Health authorities affirmed that the treatment would not cure her, but only give her a few more months of life than the conventional treatment without Avastin. They also considered that the routine provision of this drug would not be a cost-effective use of NHS resources and it should only be provided in exceptional circumstances. Probably to avoid the argument that there was a blanket ban to the drug, as raised in *Rogers*[109] and *Gordon*[110], a list of cases in which the drug could be provided was defined.

The High Court considered that health authorities ignored one point in the NICE guidance, which is that there is a slight possibility that treatment with Avastin could bring long term survival by reducing the cancer to a point that would permit resection. The judge also called into question the conclusion that Avastin was not

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[108] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)
[109] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392
[110] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392

effective for the patient, based on reports prepared by a specialist oncologist who was critical of the PCT's scientific assessment. Also based on the critique of this specialist, the judge considered mistaken the assessment that the patient's case was not exceptional since she fitted most of the conditions to be considered an exception. The Court quashed the health authority decision on the basis that the reasons it provided were not rational and the procedure was flawed. Moreover, even though the Court recognized that the scarcity of resources is a decisive feature, it considered that in this case the provision of the drug would require the allocation of only relatively small resources, which did not require the PCT to put at risk the interest of other patients or the whole population. The Court quashed the decision and invited representations about what should happen in the future. It was eventually agreed that the defendant would fund five cycles of Avastin, subject to review after the fifth cycle.

Hence, in this case the court challenged the PCT's medical assessment and the application of the NICE's guidance based on the opinion of another specialist. Moreover, it also made considerations about the economic impact of the provision of Avastin in light of the Trust's budget and the interests of other patients. As we have seen, courts in the first stage explicitly and repeatedly affirmed they would not enter in these spheres.

Eisai[111] was the first case that challenged a guidance issued by NICE, rather than demanding drugs that had not yet been assessed by the institution or arguing that the local authority had not considered the guidance thoroughly. Eisai Limited held the marketing rights for the drug Doneprezil (Aricept) for Alzheimer's disease. The

[111] *R v National Institute for Health and Clinical Excellence ex parte Eisai Limited* [2007] EWHC 1941 (Admin)

claimant, together with another pharmaceutical company and a charity for people with dementia, was challenging the guidance of NICE which concluded that acetylcholinesterase inhibitors (AchEIs) – a group of drugs for Alzheimer in which Doneprezil is included – are not cost-effective except for patients with moderate dementia. The NICE assessed Doneprezil in terms of its cost-effectiveness and concluded that the cost per QALY was far above the threshold below which a drug would be provided within the NHS. The drug was only recommended for those with moderate dementia, according to the MMSE score – a test for defining the severity of Alzheimer.

The claimant argued that the procedure through which the assessment of the drugs was made was unfair because the pharmaceutical company did not have access to a full executable version of the economic model used to calculate the cost-effectiveness. Only a "read-only" version was available and the claimant argued that this would hinder the understanding and assessment of the merits and quality of the analysis made by NICE. Another argument raised by the pharmaceutical company was that the use of MMSE was discriminatory because a rigid adherence to its scores is inflexible and impairs the individual judgment of each patient's case for funding. The rigidity of MMSE may discriminate against certain groups of the population. For instance, people with other cognitive difficulties or whose first language is not English may have their level of dementia overestimated and those with high IQ may have their level underestimated. These people may be refused treatment because MMSE would consider that they do not have a moderate level of dementia. On the other side, NICE affirmed that it was not required to provide the fully-executable model and it could not disclose confidential information due to the intellectual property rights of the owner of the

model. Moreover, NICE affirmed that the information already provided was enough for the interested parties to provide an intelligent response to the guidance and that NICE did not refuse to assist with any assumption about the model that the company could not identify.

There was also a discussion both about whether NICE assessed the benefits of the drugs correctly and about the quality of the evidence used. The Guidance considered that the benefits of the drugs would last for six months whereas the claimant argued that there was not sufficient evidence to justify the conclusion that the benefits would not last more. NICE affirmed that it is the institution with expertise and legitimacy to assess the scientific evidence and a court should "avoid substituting its own views for those of expert decision-makers, acting in good faith with knowledge of the facts". Lastly, the claimant argued that the drugs´ benefits for the carers in terms of time and costs were not adequately taken into consideration. NICE included these benefits in its calculus, but the claimant argued that they were underestimated and no explanation was given about how the benefit was calculated. NICE argued that the benefit was calculated according to the existing literature on the topic at the time.

Considering the first argument, the High Court decided that NICE is the body responsible for obtaining the Model and ensuring that it has been quality-assured and that the company had no right to "quality-assure" it. The company was not denied any important information to make "an intelligent response" to NICE's conclusions and it participated actively in the decision-making process. Moreover, NICE had an obligation to protect the intellectual property rights of those who developed the model. Concerning the argument that the guidance is discriminatory, the High Court considered that NICE did not consider properly the concerns that the MMSE scores would be discriminatory

towards some atypical groups. Even though the Guidance allows clinicians to consider exceptional cases, it does not explain how they should do it and according to which parameters. The guidance had also failed to avoid discrimination against people whose first language is not English and those with learning disabilities.

Concerning the debate about the long-term benefits of the treatment, the Court affirmed that it would not assess the decision´s rationality as if the court had to adjudicate between competing expert opinions brought by litigants, but as if it were in the same position as NICE´s decision-makers. The Court agreed that the existing evidence available was well assessed and that the long-term benefit of the treatment claimed by the pharmaceutical company was not sufficiently proven by scientific trials. Moreover, the Court judged that NICE was aware of the limitations of the trials it used and gave reduced weight to the one for which reliability was being contested. About the benefits for carers, the Court judged that the decision of the NICE was rational: "[t]he fact of disagreement between experts does not, of itself, render the decision irrational" (Dobbs J, EWHC 1941, par. 132).

In conclusion, the High Court only accepted the argument that the guidance was discriminatory and directed the institute to amend it so as to ensure compliance with duties and obligations under anti-discrimination legislation. The claimant appealed on the basis that not disclosing a full executable model made the procedure illegal[112].

The Court of Appeal analysed the debate between specialists and decided that it was not in a position to resolve the dispute whether the "read-only" version would make it possible for the appellant to check the formulae of the model. However, the

[112] NICE cross-appealed against the costs order made by the High Court.

Court decided that a read only version would make it impossible for interested parties to carry out sensitivity analyses and test the assumptions of the model. Even though NICE is the decision-maker responsible for checking the reliability of the model, it should be evaluated with other consultees. Preventing them from doing this made the procedure unfair because it limited the capacity of the appellants to apply the model under alternative assumptions and to carry out sensitivity analysis. The argument that providing a fully executable version would make the assessment procedure less efficient (demanding time and resources) was considered important by the Court of Appeal since making the process slower and more expensive should weigh heavily in the balance with fairness. However, the Court considered that in this case this argument was not strong enough to trump the importance of the pharmaceutical company being able to evaluate the reliability of the model. The loss in efficiency caused by the disclosure of a fully executable model could be compensated by the removal of some degree of inefficiency in other aspects of the assessment process. The Court also decided that the contract between NICE and the developers of the model did not preclude the institute from providing a fully executable version to consultees. In conclusion, the Court of Appeal decided that procedural fairness – transparency and disclosure of relevant information – required the release of the fully executable version of the model. The guidance was not quashed because the claimant did not seek this outcome; rather it just wanted to have access to the fully executable version and have an opportunity to make representations on it.

In *Murphy*[113] a patient who had kidney cancer was submitted to therapy with drugs and had one kidney removed, which had however not stopped the onward march of the tumour. Her doctor considered treating her with Sunitinib, a drug not ordinarily available on the public health system but which could extend her life span by some months. An application was made for exceptional funding from the NHS based on seven factors aimed at demonstrating that this patient's case was exceptional. The PCT denied the request because none of the seven factors brought by the patient could make her case an exceptional circumstance that would justify the provision of the treatment. The patient lodged a lawsuit claiming that the decision was irrational because it failed to consider a series of material factors and that the PCT had misapplied its own policy.

The High Court reaffirmed that not all treatments that could benefit patients can be afforded within the funds available to the NHS. Consequently, health authorities are constantly forced to make difficult decisions on priority setting for competing needs and the QALY can be a mechanism to evaluate the costs and benefits of the treatment and to compare it with other health interventions. The Court admitted that the drug claimed in this case was indeed too expensive to be justified in the ordinary course of cases. However, the High Court accepted the argument that the Commission Panel that decided not to fund the drug had evaluated separately each of the seven factors brought by the patient to advocate for her exceptional case and did not look at the factors "in the round". According to the Court, the case of the patient should be considered holistically and not by analysing each circumstance individually. In conclusion, the High Court decided the decision had to be taken again because the procedure was irrational.

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[113] *R v Salford Primary Care Trust ex parte Murphy* [2008] EWHC 1908 (Admin)

In *Ross*[114], the claimant suffered from multiple myeloma and was prescribed a new cancer drug, Lenalidomide, the provision of which was however denied by the defendant PCT. Lenalidomide was his only and last chance of halting the progress of the cancer given that the conventional treatment had resulted in side effects and had become intolerable for the patient. The patient lodged a legal challenge based on the National Health Service Act 2006. The drug had not been evaluated by NICE at that time, but was provided by some PCTs. It was also available in continental Europe and was recommended by the British Committee for Standards in Haematology. However, the defendant considered that current evidence did not adequately support the use of Lenalidomide and that the cost of the drug was too high when compared to the potential benefit. Moreover, the PCT considered that this claimant's condition case was not exceptional in comparison with other patients.

The High Court affirmed that it is lawful for the defendant to have a policy not to fund a treatment, as long as it is possible to envisage exceptional circumstances. Moreover, it affirmed that the role of Courts is only limited to ruling upon the lawfulness of the decision by submitting the decision making process to a rigorous scrutiny. The influence of the case *Child B*[115] can certainly be noticed in this case since in regard to the idea of "rigorous scrutiny", the Court affirmed:

> the more substantial the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable; the court must subject their decision to anxious scrutiny because the claimant's life is at stake (Grenfell J, EWHC 2252, par. 39).

[114] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)
[115] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

The High Court considered that the PCT did not evaluate the scientific evidence correctly because it misunderstood some of the scientific evidence and did not consider relevant facts and the clinical situation of the patient. According to the Court, if the patient's case were correctly evaluated, it would be considered an exception according to the PCT own policy's guidelines because the treatment would be cost-effective. The High Court also accepted the argument that the PCT panel that made the decision did not have a specialist in the field of oncology, which may have contributed to its lack of understanding about the facts in this case. The Court relied on a specialist who affirmed that the drug was cost-effective but whose report was not considered by the PCT because, according to the defendant, it did not bring new evidence and came from someone who is not specialist in this field either. The High Court also judged that the way in which the PCT was applying the concept of "exceptionality" would in practice make no case exceptional because it was using the term "exceptionality" as meaning "unique".

In conclusion, the PCT decision was quashed and considering the urgency of the patient's case, the Court decided that the treatment should commence "at the earliest time" (Grenfell J, EWHC 2252, par. 95). If the PCT, taking into consideration the elements in this case, eventually concluded that the treatment should not be given, then the provision should cease. The court not only applied a very strict scrutiny of the scientific and policy grounds of the administrative decision, adjudicated among divergent expert opinions, but also ordered the PCT to provide the drug unless it can prove convincingly that it should not.

In *Bristol-Myers*[116], the claimant was the producer of the drug Abatacept for rheumatoid arthritis, which was not recommended by the NICE for use in the NHS. During the drug assessment process, NICE invited the pharmaceutical company to participate by constructing the model and calculating the drug´s cost-benefit. The company's model was submitted to academic experts chosen by NICE. The experts questioned many assumptions made in the model and reached the conclusion that the benefits of the drug were overestimated and that its cost per QALY exceeded the threshold established by NICE. Thus, NICE issued a guidance declaring that the provision of Abatacept by the NHS was not recommended for cost-effectiveness reasons. The claimant lodged a lawsuit seeking to quash the guidance issued by the NICE in regard to its drug and an order for disclosure of a fully executable model as modified by the experts chosen by the Institute.

The High Court recognized that NICE has developed a very sophisticated procedure for assessing drugs´ cost-effectiveness. However, according to the decision, "just because a decision under challenge is made by a public authority does not of itself import requirements of fairness" (Blake J, EWHC 2722, par. 50). And, according to the Court, fairness is a requirement in every area of public law process where serious consequences result to individuals and thus should be controlled by courts. This statement, once more, makes clear that a deferential attitude of courts grounded on the trust in health authorities has been left in the past.

[116] *R v National Institute for Health and Clinical Excellence ex parte Bristol-Myers Squibb Pharmaceuticals Ltd* [2009] EWHC 2722

In this case the High Court considered that, unlike the case *Eisai*[117], the pharmaceutical industry was the author of the original model and, based on the information disclosed by NICE, it could have included the alterations into the model and could have run it. Moreover, the points in dispute were not about the sensitivity of the calculation, but about its assumptions, which were clarified and justified by the information already disclosed. The High Court, after scrutinizing the decision making procedure without finding any flaw, concluded that the guidance was legal and should not be quashed.

In *Fraser*[118], NICE published a guideline on patient care for those suffering from Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CSF/ME). This guideline rejected some treatments on the basis that there was not enough evidence that they were effective and recommended that psycho-social treatments should be used instead. A group of patients suffering from this disease lodged a lawsuit claiming they did not want nor need the treatments recommended by NICE's guidelines; rather they needed those that the guideline turned down. They alleged that some specialists chosen by NICE to carry out the assessment were biased towards an approach favourable to psycho-social treatments and that they should not have been chosen because of this conflict of interest. Moreover, the litigants claimed that the decision was based on inadequate material and overlooked the danger of the recommended therapies.

The High Court considered that it was for NICE to evaluate the weight to be attached to the evidence brought since it is the authority entrusted to make this decision.

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[117] *R v National Institute for Health and Clinical Excellence ex parte Eisai Limited* [2007] EWHC 1941 (Admin)

[118] R (on the application of Fraser and another) v National Institute for Health and Clinical Excellence and Another [2009] EWHC 452 (Admin)

The High Court also considered that the risks involved in the use of psycho-social treatments were not overlooked. The argument of bias was also dismissed because it was based on a series of false premises. In any event the panel that made the decision was composed of many specialists and the fact that some of them had a certain view about the disease does not make the procedure biased. The NICE guideline was upheld by the High Court.

In *Servier*[119], the claimant had the market rights of the drug Protelos, for Osteoporosis. This drug was assessed by NICE and recommended only for a defined and limited group of patients. According to NICE, it was insufficiently effective and too expensive to justify a wider recommendation for its use. The pharmaceutical company, supported by the National Osteoporosis Society as the interested party, lodged a lawsuit claiming that NICE should reconsider its decision because: (1) the procedure was not fair and transparent since the economic model and underlying data upon which the conclusion of NICE was drawn was not disclosed, neither in a "read only" version nor a fully executable version; (2) the procedure did not take account of data submitted by the claimant; and (3) the decision discriminated against certain categories of disabled patients. NICE argued that part of the data could not be disclosed because it had agreed to keep in confidence essential information and that all the relevant data that was provided to the applicant was enough to assess the quality of the appraisal made by the Institute.

The High Court affirmed that it cannot review the substance of the decisions, but only whether NICE had acted unlawfully or irrationally. After discussing the case

[119] *R v National Institute for Health and Clinical Excellence & Anr ex parte Servier Laboratories Limited* [2010] EWCA Civ 346

Eisai[120], the Court considered that NICE must not always and without exception disclose its economic model. A duty to disclose all information may have as a drawback that those who hold important and confidential information will be unwilling to disclose it to the NICE because they know that the Institute will be obliged to make it public. Therefore, there is the need to balance transparency and the duty of confidentiality. As a general rule, information should be disclosed, except in cases when the information is very important and a serious effort has been made to obtain permission to disclose it. The court called it "the exceptional imperative of confidentiality" (Holman J, EWHC 281, par. 115), which has to be justified and can be reviewable by a court. In this case, the High Court considered that NICE did not take all the reasonable steps to seek permission for the release of the data.

Concerning the appraisal of the data submitted by the pharmaceutical company which brought evidence that the drug was cost-effective, the Court judged that the NICE took consideration of the data and explained in a sufficient, reasonable and intelligible way the reasons why it disagreed with its results. Moreover, the High Court considered that the weight to be attributed to the evidence brought was a matter for the NICE to decide because it is a highly specialized topic and the Court should be careful not to stray into this question.

The argument that the guidance is discriminatory was based on the fact that there are some groups whose health condition does not allow them to take drugs other than Protelos. According to the NICE´s guidance, Protelos is recommended only for these patients in a more advanced stage of the disease, which means that some patients

[120] Eisai Limited v National Institute for Health and Clinical Excellence (NICE) [2007] EWHC 1941 (Admin)

will be left without any treatment for osteoporosis and have to wait until the osteoporosis develops to a more severe stage. The claimant argued that this is discriminatory and against their human rights. NICE replied that patients will not receive the drug not because they are being discriminated against, but because the treatment is not sufficiently cost-effective since the cost of treatment exceeded the upper limit set by NICE. This argument was accepted by the High Court, who considered that the position held by NICE was reasonable and correct since it had to balance between these patients' needs and the need to secure a cost-effective use of NHS resources. The Court affirmed that "[i]t is necessary for NICE not to make a more generous recommendation for the protection of the rights of other persons, namely other patients who also require a fair share of the resources of the NHS" (Holman J, EWHC 281, par. 224). Thus, NICE was not unlawfully discriminating against any group.

In conclusion, the High Court only accepted the argument that the reasons for not disclosing the economic model were not well justified. The Court decided that NICE must negotiate the disclosure of the economic model and allow all consultees to make further submission or representations in response to the disclosed data.

An appeal was lodged by Servier on the basis that NICE failed to take into account data derived from a study in which the results were more favourable for the company's argument that the drug was cost-effective. The Court of Appeal considered that the reasons provided by NICE to undermine the evidence provided by the claimant were "inadequately explained" because they were too general and did not go into details about the scientific reasons underpinning it. It was decided that NICE should make a fresh decision since there were doubts about its rationality. Lord Justice Wilson added "NICE will, I am confident, consider the efficacy of this drug in a comprehensive and

open-minded way" (EWCA Civ 346, par. 69). The appeal was allowed and NICE´s decision quashed. The Court of Appeal disagreed with the High Court regarding whether courts should scrutinize the way the evidence was assessed and weighed by the NICE.

In *AC*[121]**,** the patient was diagnosed with gender identity disorder and applied for funding from the PCT to pay for breast augmentation surgery. Her doctor affirmed that the surgery was necessary because gender dysphoria was causing the patient psychiatric illnesses such as adjustment disorder and depression. According to the NHS's policy for gender identity disorder, the kind of surgery the claimant was demanding is considered a non-core procedure, which means that it is only provided in exceptional circumstances. The patient argued that the PCT did not give proper attention to the clinical importance of breast augmentation therapy to a transfemale who had undergone hormone therapy. However, the PCT affirmed that there was not strong evidence that the surgery would be effective to treat the patient's psychological problem. Moreover, funding the surgery for the claimant would discriminate against natal women who were also dissatisfied with their body.

The PCT's argument was accepted by the High Court, who considered that, given the lack of consensus regarding breast implant surgery for people with gender identity disorder, the appraisal made by the PCT regarding the treatment's effectiveness and cost-effectiveness was not irrational. The Court recognized that health authorities are under financial pressure and affirmed, citing the Court of Appeal decision in *Child*

[121] *R v Berkshire West PCT ex parte AC* [2011] EWCA Civ 247

B[122], that they cannot be expected to offer all the care patients may want. It also found that there was no discriminatory treatment against transgenders because they were being treated in the same way as natal women who may have psychological problems due to the size of their breasts.

An appeal was lodged and the Court of Appeal considered that the PCT´s decision was not irrational because there was an absence of evidence that the operation was likely to be clinically effective to improve the appellant's health. Concerning the argument that the policy was discriminatory, the Court of Appeal considered that the decision to equalize the situation of the patient with those of natal girls unhappy with their body is an ethical and clinical judgment made by the PCT and that should not be reviewed by Courts, unless it transgresses the law.

I turn now, finally, to two cases that could be considered deviant, for polar opposite reasons, from the predominant analysis made by courts when judging right to health cases during this second stage.

In the most recent case, C*ondliff*[123], the PCT refused to fund laparoscopic gastric by-pass surgery for a patient who suffered from morbid obesity associated with various co-morbidities. The PCT policy was to fund the surgery for people whose BMI was above 50, but the patient´s BMI was 40. The PCT policy was more restrictive than the NICE guidance on this treatment. The patient applied for special funding claiming that his situation was exceptional because his health condition was very poor and his life

[122] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[123] *R v North Staffordshire Primary Care Trust ex parte Condliff* [2011] EWCA Civ 910

was in serious risk. The PCT considered that his case was not exceptional since the co-morbidities are expected in people who suffer from morbid obesity.

The High Court accepted that resources are limited and that the PCTs have to act rationally in setting priorities for the allocation of medical resources and treatments, even if it means that some people will be denied treatment from which they would benefit. Moreover, it is not for the Court to second-guess such decisions but only to evaluate whether the decision-making was within the law. Thus, the Court accepted a rationing decision by health authorities, without a detailed analysis of the reasons or procedure, based on the fact that because resources are scarce not all needs can be fulfilled. The High Court also analyzed this case in the light of the Human Rights Act and the European Court of Human Rights case-law and concluded that a refusal to fund treatment to an applicant is not a breach of rights because the state has a wide margin of appreciation in such an exercise. Hence there is not a duty to provide individual treatment to a patient, but rather a duty on the PCT to allocate resources considering that there are not enough to provide for everyone's medical requirements. There is no underlying "right" to any particular medical treatment, only a target on the PCT to provide it. The claim for judicial review failed.

An appeal was lodged based on the fact that the PCT had not taken into consideration the patient's exceptional circumstances and other non-clinical circumstances, grounded on Article 8 of the ECHR. The decision was mainly focused on analysing whether the ECHR demanded health authorities to take into consideration non-clinical circumstances. The Court of Appeal agreed with the High Court that there was no breach of European or domestic law in refusing the treatment demanded by the claimant. The Court of Appeal considered that the PCT is entitled to set policy

grounded on what it reasonably considers to be the fairest way to treat patients and what is a fair balance between the interests of individual's needs and those of the community.

Condliff[124] can be considered deviant from the predominant case-law in the second stage because it was judged similarly to the way cases were judged during the first stage. The PCT decision was respected and trusted as reaching the right balance between the claimant's needs and those of the rest of the community.

The other deviant case is *Watts*[125]. In this case, the patient was diagnosed with osteoarthritis and needed hip replacement surgery. This service is regularly provided by the NHS. The patient was put on the waiting list and the operation was expected to be carried out in one year. Afterwards, the patient was reassessed by a doctor at her PCT, who considered that her health had deteriorated significantly and her case should be re-categorized in order to receive the treatment in 3-4 months. Because she was suffering from severe pain and serious disability, she applied for authorization to make the treatment abroad funded by the NHS. Her claim was based on the right guaranteed by the European Community law – article 49 of the European Community Treaty and article 22 of Council Regulation 1408/71 – to receive health treatment abroad when the Member State is unable to provide it without undue delay.

The patient asked her Primary Care Trust to support her application to make available hip replacement surgery in France immediately. The PCT refused support based on the fact that the patient's situation was not different from others waiting for similar operations. She was as deserving of immediate treatment as any other patients with severe arthritis who were also on the public health system waiting list and she

[124] *R v North Staffordshire Primary Care Trust ex parte Condliff* [2011] EWCA Civ 910
[125] *R v Secretary of State for Health ex parte Watts* [2004] EWCA Civ 166

should not be allowed to jump the queue by seeking treatment abroad. Health authorities affirmed that if patients were entitled to receive treatment abroad funded by their own country´s health system without prior authorization, then there would be "adverse consequences" for the setting of priorities for medical treatment and the management of waiting lists according to clinical judgments and medically determined priorities. The PCT also affirmed that the European Community law concept of "undue delay" should be interpreted as meaning cases in which the delay was beyond the NHS normal waiting times. Thus, according to the PCT, only in these cases could a treatment abroad at the expense of the NHS be considered. Notwithstanding the refusal, the patient went to France and had the operation performed there. After the surgery was performed, the patient lodged a lawsuit against the Secretary of State for Health claiming reimbursement of the full costs of the treatment abroad.

The High Court, based on the European and domestic law, concluded that the NHS can refuse prior authorization for publicly funded treatment abroad only if the same or equally effective treatment can be obtained without undue delay within the NHS. And the Court rejected the PTC argument that "undue delay" should be assessed based only on the grounds that there are waiting lists. This argument, according to the court, would be based on "consideration of purely economic nature" which in itself cannot restrict patients´ right to have medical services provided abroad. The Court considered that "undue delay" should not be understood by reference to cases in which the delay is beyond the normal waiting times in the health system, but according to the patient´s state of health and the probable course of her disease. The High Court also rejected the argument that authorizing treatment abroad in this case would prompt a flow of NHS patients seeking the same benefit and consequently put in risk the public

system capacity to work efficiently. The court considered that this is a “speculation unnourished by common sense” because patients will do it only if they are experiencing delays in the access to healthcare in their home country.

In conclusion, the High Court considered that it is “almost self evident” that a one year delay in treating a patient in such condition is, “on any sensible view”, an undue delay. However, because the delay was reduced to 3-4 months, the Court considered that the period of wait was tolerable and did not constitute undue delay. Thus, according to the decision, the patient should not be reimbursed for what was spent with the operation in France only because the period of 3-4 months had not reached an “undue” threshold yet, whereas a 1 year wait would entitle the patient to receive the treatment abroad.

Both litigants appealed. The Court of Appeal raised many concerns about the High Court´s judgment in this case. Among them, the Court of Appeal wondered by what criterion a one year delay was considered “undue” whereas a 3-4 months wait was not. Moreover, the Court of Appeal also called to question whether a court has the capacity to conclude that attributing to the NHS the duty to fund treatments abroad without previous consent would not have economic impact or undermine the system of waiting lists. According to May J, if there are waiting lists, it is because there are limited resources, and “we should be surprised” if ordering the health system to accept claims like the one in this case would not have financial effect (May J, 2 CMLR 55, par. 105).

It was also said that, according to the precedents, if the patient had sought judicial review of the waiting times in order to receive immediate treatment from the NHS, the claim would have failed, as well as if the patient had claimed treatment from

private services in the United Kingdom. The Court of Appeal expressed serious concern about the High Court´s decision in terms of its impact for the NHS. The Court of Appeal then decided to defer deciding this case until the European Court of Justice consider a few questions made by the Court of Appeal itself concerning the duty of the State to fund treatment in other member-States.

The High Court's decision seems similar to the one Brazilian courts predominately use when judging right to health cases, which focus on the patient's needs (patient centred approach) while disregarding the population's needs (population centred approach) and without even considering the reasons that lie behind establishing the policy. This has not happened in other cases, where courts, even when quashing health authorities' decisions or ordering the provision of treatments, have looked carefully at the reasons for rationing health care to evaluate whether they are convincing or not given the circumstances.

4.3. Reasons for the change

Part of the literature on this topic has explained the change from a very self-restrained judicial review (what I call here the first stage) to a model in which reasons have been demanded and scrutinized (what I call the second stage) by the move from implicit towards explicit rationing in the NHS (Syrett, 2007, p. 171; Syrett, 2009, ch.6; Syrett, 2011A; Jackson, 2010, p.77; Newdick, 2004, p.93). Thus, according to this argument, courts demand more from health authorities because rationing became more visible, patients know more and, therefore, question more. Consequently, the more explicit the rationing (the more you tell patients), the harder will be courts' look at the case. Conversely, when rationing is implicit the legitimacy problem is much less

prevalent because the exercise of clinical judgement serves to obscure the moral conflict inherent in the decision and there is no public expectation that rationales will be provided for decisions to deny access to treatment and service (Syrett, 2009, p.166).

The following excerpt from Syrett (2011A, p.111) illustrates well this position:

> Given that the environment in which rationing takes place is significantly altered from that which existed in the late 1980s – and, in particular, that awareness of the existence, scope, and processes of rationing is much greater as a consequence of a general shift towards explicitness – such a transformation in judicial attitudes is perhaps unsurprising.

I will discuss this argument in the next chapter, but I just want here to make the point that explicit rationing is an incomplete explanation for the change in courts' attitude towards health care litigation. Courts were certainly not isolated from the pressures and the changes raised by explicit rationing, but this explanation fails to take into consideration that there are other reasons internal to the legal system and legal culture that also account for the transformations in health care litigation cases and that made the judiciary, in the eyes of litigants and public opinion, a new battlefield for challenging rationing decisions.

The health care litigation case-law I have analysed in this chapter is best seen within a broader context in which the legal culture and courts' attitude towards judicial review was changing significantly, which resulted in courts intervening more in decisions about public policies and allocation of resources.

The change in the way courts review rationing decisions in England can be better understood when contextualised within the increase in courts´ assertiveness in regards to its own role in protecting rights and demanding reasons when reviewing administrative acts. Traditionally, probably due to the absence of a written constitution,

mechanisms for the control of constitutionality and a strong attachment to the principle of separations of powers, English courts have played a marginal political role and avoided interference in "policy questions". They tended to refuse to substitute their decisions on the merit of a policy for that of the primary administrative or political decision-maker (Sunkin, 1995, p. 67; Harlow & Rawling, 2009, p.95-96).

However, it is clear that the use of courts to challenge local and central authorities decisions had been growing since the second half of the 1980s (Sunkin 1995, p.69; Treasury Solicitor's Department, 1987, p.1) and that there have been increasing pressures from European law – especially the European Convention of Human Rights (ECHR) – on the constitution of the United Kingdom and upon its legal culture for a bigger participation by courts in political and economic decision-making (Sunkin, 1995, p.75). According to Lester (2011, p.76) the judgments of the European Court of Human Rights against the United Kingdom contributed to making courts "more sensitive to the fault-line in the British legal system that had resulted in repeated failures to give sufficient legal protection to individual rights". Thus, judges started to take Convention law more seriously and rights were invoked in courts as sources of principles or standards of public policy even before they were introduced in domestic legislation (Leister 2011, p.76-77; Poole, 2005, p.706). Thus, even before the HRA, judges often applied the ECHR as representing norms and values inherent in the English law, which started to construct a "new rights-base for judicial review" (Harlow & Rawling, 2009, p.114). We have seen a good example of that in the *Child B*[126] case.

Lastly, the Human Rights Act was enacted in 1998 and brought to England the "politics of rights", which tends to increase the political power of the institutions

[126] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

responsible for enforcing these rights, namely the courts, *vis-à-vis* those responsible for making policies, namely political and administrative institutions. According to Allan, the incorporation of the language of rights eroded the barriers based on the authority of the formal source of power and the respect to administrative discretion that had foreclosed judicial scrutiny (Allan, 2006, p.671). The expected consequence was the shift of a substantial part of decision making procedure to the judicial branch and the increase in courts' political power, which encourage them to develop doctrines and legal theories compatible with their new role (see Poole, 2007).

Indeed, due to the ECHR and later to the HRA, English courts were expected to do and were doing more than just testing if an impugned decision was absurd (Poole, 2007, p. 266). As affirmed by Craig (2008, p.620), the level of unreasonableness which has to be proven by authorities after the language of rights was introduced in legal decisions is "less extreme than the traditional *Wednesbury* formula". The classical "Wednesbury unreasonableness" test - a symbol of English courts self- restraint and of the barrier between political and legal decisions - can hardly describe judges' new attitudes towards judicial review. A good example of the discrepancy between language and practice is the High Court's decision in the cases *Child B*[127] and *Otley*[128], when the court concluded that health authorities' policy was "Wednesbury unreasonableness" after making a detailed scrutiny of the choices, scientific evidence and values underpinning the administrative decision and mentioning the right to life in the ECHR.

As noticed by Craig (2008, p.641):

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[127] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[128] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)

> The desire to remain within the traditional frame is reinforced by the fact that the courts' role in fundamental rights' cases is expressed in terms of *Wednesbury* unreasonableness. The idea that this can be seen simply as a variant of the original *Wednesbury* test is, however, strained.

In opposition to what was meant by this test's doctrine, courts started quashing decisions based on evidence that a different way of exercising the discretionary power would be better. In some cases, courts even said how this power should be exercised, for instance, by establishing the criteria that should guide decision-makers.

In tandem with the affirmation of the language of rights, there was also a tendency in English Law for a more detailed scrutiny of public authorities' decisions. Writing in 1986, Richardson (1986) found that the duty to give reason was starting to be developed in the UK, albeit in a milder version than the hard look doctrine in United States Administrative Law (see, also, Shapiro, 1992, p.179). The principle that the administration has a duty to give reasons started to be articulated in the early 1990s and to be applied in a wide array of cases and against a long established principle in English law that authorities have no general duty to provide reasons (Elliot, 2011, p.58; Craig, 1994). The duty to provide reasons was seen as a device to allow courts to perform their supervisory function, ensure that decisions were made in a thoughtful and non-arbitrary way, and legitimize public decisions before individuals who are affected by them (Craig, 1994, p.283).

The increasing judicial demand for reasons from public authorities was felt by the public administration. In the many editions of the document *The Judge Over Your Shoulder*, a guideline prepared by the Treasury Solicitor's Office to inform authorities on how to make decisions that are less vulnerable to judicial review, it can be noticed

that the need to provide reasons was initially seen as exceptional to some circumstances, but later became the rule to protect administrative decisions in the courts. The circumstances when this is not required became rare (see the different editions of The Treasury Solicitor's Department, 1987, 1994, 2000, 2006)

The duty to give reasons is not restricted to human rights cases. For example, in the United States it was mainly applied to control the acts of regulatory agencies with no necessary relation to human rights (see Mashaw, 1985). The language of human rights does not necessarily imply the duty to give reasons either. For instance, rights can be simply used by courts as "trumps" (Dworkin, 1984) against policies or to allow moral balance between competing interests via proportionality or other similar tests.

However, the language of rights and the duty to provide reasons found an elective affinity in English courts. According to Hunt (2003, p.342), English public law was already "feeling its way" towards a "culture of justification" and the HRA accelerated the pace of this process. This "culture of justification" requires that administrative decision makers should be able to justify the reasons behind their decisions and the adequacy of these reasons is what courts should be concerned with (Dyzenhaus, Hunt & Duggard, 2001, p.6).

One of the expected impacts of the Human Rights Act, which proved to be true, was precisely that judges would begin to articulate the reasons why they should warrant deference to a challenged decision in a particular case (Hunt, 1999, p.100). Courts started to decide right to health cases similarly to the way Laws (1993), who decided the case *Child B*[129] at the High Court, prescribed the role of courts should be:

[129] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

> Accord[s] the first priority to the right in question unless we can show a substantial, objective, public justification for overriding it (...)The greater the intrusion proposed by a body possessing public power over the citizen into an area where his fundamental rights are at stake, the greater must be the justification which the public authority must demonstrate.

A similar declaration was made by Sir Thomas Bingham MR (as he then was) in the case *Smith*[130]: "The more substantial the interference with human rights, the more the court will require by way of justification before it is satisfied that the decision is reasonable". Even though Bingham MR participated in the judgment at the Court of Appeal that overruled the High Court decision in *Child B*[131], his decision in the same year in *Smith*[132], 1995, made clear that judicial review was marching toward a new stage.

It is important to observe that the language of rights was incorporated in the legal culture but rights did not come to the forefront of the legal analysis. No decision on health care resource allocation so far has been based on the ECHR or the HRA. This finding is coherent with what Poole (2005, p.709) observed when analyzing human rights cases decided by English courts: even though in most cases there were preliminary considerations about the importance of the rights affected by the challenged administrative or political decision, they were not the primary centre of attention and discussion. Rights were never used as trumps against policies. Rather, the cases were decided mainly on an analysis of the authorities' expertise and the legitimacy of judicial review in the constitutional balance (Poole, 2005).

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[130] *R v Ministry of Defense, ex parte Smith* [1996] 1 All ER 257
[131] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[132] *R v Ministry of Defense, ex parte Smith* [1996] 1 All ER 257

The idea that courts should protect rights found affinity with the idea that courts should demand reasons from public authorities, but whereas the former was underlying the courts' new perception of their own role, the latter came up as the explicit method for the control of health authorities' decisions. In many of the cases analyzed in this chapter, not much was said about "rights" and often it happened that they were not even mentioned, although the control of the reasons for the decision was very severe. The idea that the more substantial the interference with a right, the more rigorous the scrutiny of the reasons should be, was, nonetheless, explicitly articulated in many decisions (for instance, *Child B*[133], *Rogers*[134] and *Ross*[135]).

To translate the language of rights and a more pro-active role of courts into the practice of administrative law's control of procedure and reasonableness certainly transcended the traditional frontiers of English courts' self-restraint and deference, but, at the same time, re-established new boundaries for the action of courts. After the mid 90's, deference from courts is not guaranteed by simply mentioning administrative discretion or constitutional authority, but "must be earned by the primary decision makers" by demonstrating the reasons and justifications for their decisions (Hunt, 2003, p.340).

The "Wednesbury unreasonableness" test gave way to an "accountability for reasonableness" assessment. This seems to be the balance English courts have found between "adjudication" and "abdication" (Michelman, 2003), the dilemma mentioned in this thesis' introduction as confronting courts when deciding health care litigation cases.

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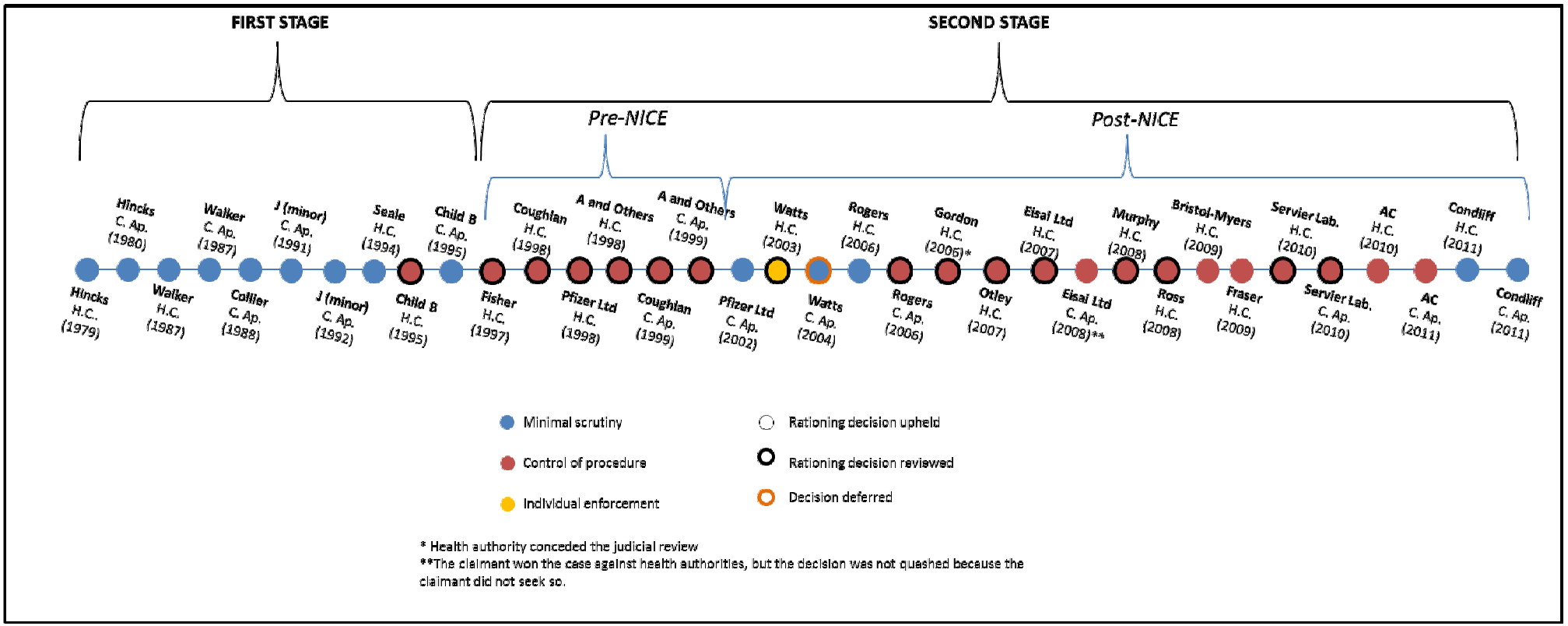
[133] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[134] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392
[135] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)

4.4. Conclusion of the chapter

In this chapter I have attempted to demonstrate that English courts' case law in health care litigation can be divided in two stages. One before the case *Child B*[136], when courts presumed that health authorities were making the right decision in terms of setting priorities for the use of scarce resources and were unwilling to demand and scrutinize the reasons for the administrative decisions. And the other after *Child B*[137], in which courts tended to be less deferential and started to expect health authorities to demonstrate that their decisions on the general policy as well as its application in individual cases were based on fair and rational reasons, given the evidence available. There was a move from "Wednesbury unreasonableness", which allowed only a very restrained judicial review, to "accountability for reasonableness", which opened the possibility for more activist courts (see Chart 2).

[136] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[137] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Figure 3: Health care litigation cases decided by English Courts



The belief that a health authority was "doing the best he can with the financial resources available to him" and thus cannot "be faulted in the matter", as stated in the case *Hincks*[138], had no echo in English courts during this second stage. Courts became more suspicious of health authorities and became willing to scrutinize the decision making process in detail. Courts started to demand satisfactory reasons to justify rationing healthcare to patients and started to scrutinize a policy´s underlying reasons and procedures, as well as the application of the policy to individual cases and the review of that application in exceptional circumstances. In some cases, as we have seen, the court even adjudicated between competing expert opinions and, in others, ordered the provision of treatments to patients.

The change is even more impressive if we consider that courts in the second stage were not only judging cases differently from the first stage, but they were also judging in a way that decisions in the first stage explicitly and unequivocally affirmed they should not do. Thus "accountability for reasonableness" became similar to a demand for "synopticism", which raised the burden of proof for health authorities.

Contrary to part of the literature that explains this change by the fact that rationing became more explicit, I have argued that the changes in English courts' case law in health care litigation can be better explained by broader changes that were occurring in the English legal system and culture and, more specifically, in the institution of judicial review: the affinity between the incorporation of the language of rights and the demand for reasons from public authorities. This point will be discussed further in the next chapter.

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[138] *R v Secretary of State for Social Services and Ors ex parte Hincks* [1980] 1 BMLR 93

The analysis of the English case-law provides an interesting counterpoint to the Brazilian case-law. Instead of making individual interests trump policy considerations and give to courts the last word on controversies about the allocation of health care resources, English courts preferred to demand and scrutinize health authorities' reasons for their decisions and make sure the procedure was fair. Moreover, differently from the Brazilian courts, English courts rarely ordered the reallocation of resources, but commonly quashed decisions and referred back to the decision-maker for reconsideration in light of the judgement. There were only two cases – *Ross*[139] and *Gordon*[140] – in which the Court decided that a treatment should be provided before the results of the health authorities' reappraisal were known and only one in which the patient's needs trumped policy considerations – *Watts*[141].

The difference between these two models for judicial intervention (Brazil and England after *Child B*[142]) in the allocation of health care is profound, and so are the different consequences that they have on their respective public health care systems in terms of how health care is rationed. In Brazil, courts force the public system to apply the rule of rescue and hence keep rationing implicit, although as we have seen this eventually prompted the creation of a new system for health technology assessment. English case law produced a different effect and forced health authorities to ration health care at the NHS in a way that is along the lines of the standards of fairness proposed by Daniels and Sabin. It is to this story that I now turn.

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[139] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)
[140] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392
[141] *R v Secretary of State for Health ex parte Watts* [2004] EWCA Civ 166
[142] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

5. Health care litigation in England: the mutual impact of litigation and rationing

In this chapter, I analyse in more detail the relationship between health care litigation and rationing in the National Health Service. I argue that at the same time that health care litigation was the reaction to a context in which rationing was becoming more explicit, it also contributed to creating and accelerating this process.

The changes in health care litigation were partially the consequence of the transformations in the way health care rationing was made in the NHS and perceived by the public. However, at the same time, courts also played a central role in making rationing decisions in the NHS more explicit, a process that culminated in the creation of the institution that is now called the National Institute for Health and Care Excellence (NICE). And more explicit rationing also had consequences on litigation. In sum, there is a mutually reflexive relationship between health care litigation and the way healthcare is rationed by the NHS.

The first section of this chapter describes the changes in health care rationing in the NHS during the last 30 years. The second analyses the connection between health care litigation and the changes in the way NHS rations health care, considering that latter was both a consequence of and a driver for the former. The third and final section analyses the impact of NICE on health care litigation in English courts.

5.1. Rationing in the NHS: from implicit to explicit rationing

Initially, it is important to be clear that the concept of explicit rationing has two aspects whose difference is commonly overlooked in the literature. Analysts commonly

use “explicit rationing” without making clear to the reader what aspect of “explicitness” they have in mind, and this can cause confusion and misunderstanding.

In one aspect, “explicit rationing” means that the outcomes of the decisions about the provision of health products and services are clear and public, and hence patients know what they can or cannot receive from the public health system. I will call this aspect of explicit rationing hereafter “explicit about what”.

The second aspect of explicit rationing means that (1) the principles, criteria and evidence underpinning decisions about the provision of treatments are publicly known; and (2) the decisions are made through an inclusive, transparent and accountable procedure. This aspect of explicit rationing is similar to what Norman Daniels and Charles Sabin calls accountability for reasonableness, which relies on a transparent, participative and public procedure and “insists on being explicit about the grounds for decisions once those grounds have been deliberated about in the context of a specific case” (Daniels, 2009, p.135). I will call this second aspect of explicit rationing hereafter “explicit about why and how”.

This clarification is important because these two forms of explicitness do not necessarily come together. Authorities may publicly announce the results of their deliberations without necessarily sharing the reasons and procedures for their decisions (Daniels, 2009, p. 109). Thus, treatments can be publicly denied to patients (“explicit about what”) without disclosing the reasons that justify this decision or the procedure through which it was reached (“explicit about why and how”). This distinction is important in this chapter because it helps us to understand the different stages in the process from implicit to explicit (in both aspects) in the NHS and will also assist in avoiding misunderstandings when analysing the influence of courts in this process.

The literature on health care litigation in England is consensual in affirming that in the beginning of the 1990s the transition from implicit to explicit rationing began. However, this literature does not always make clear that there was a second step, from being "explicit about what" to being explicit "about why and how". And this second step is what makes the English case different in comparison with other countries and it is therefore one of the reasons it is worthy of study for the purposes of this thesis. The landmark for the second step was the creation of the then called National Institute for Clinical Excellence in 1999, not coincidently inspired by the idea of "accountability for reasonableness".

5.1.1 From implicit to explicit rationing "about what"

The NHS, like any other health care system in the world, always had to restrict access to healthcare. For many years this restriction took the form of implicit rationing, which means the public are not informed about the economic reasons underpinning a decision to deny treatment and, *a fortiori*, are also ignorant about the principles and methods used to include or exclude health care treatments. Rationing decisions were mostly hidden in clinical appraisals made by practitioners who were aware of the budgetary constraints set by central government (Klein, 1997, p.85; Doyal, 1997, p.139, p.7; Klein, Day & Redmayne, 1996, p. 42). Doctors rationed by telling patients that nothing else could be done to benefit their health or by managing waiting lists (deciding which patients are admitted, when and for how long) rather than saying explicitly that treatment could not be provided because resources were not available or were to be used for other priorities (New & Le Grand, 1996; Coast, 1997, p.149; Aaron & Schwartz, 1984).

The NHS, through a technocratic paternalism grounded on a "deep reservoir of deference to doctors", was able to dampen down patients' expectations and this made implicit rationing sustainable for many years (New & Le Grand, 1996, p.6). According to New & Le Grand, universal and comprehensive health system can sustain a scheme of implicit rationing as long as patients' demands and expectations do not exceed the supply the health system can offer by too great margin (New & Le Grand, 1996, p.8). Implicit rationing, by keeping demand for health care low through limited information and the withholding of facts, shielded rationing decisions from public opinion and patients and thus curtailed pressure on health authorities (Klein, 2006, p.213; Spiers, 1999, p.6).

The reasons for maintaining such scheme are obvious: rationing healthcare is a politically sensitive issue and thus no authority wants to do it or at least admit to do it (Newdick, 2004, p.47). Implicit rationing was too convenient for politicians and health authorities to be changed, unless the costs of maintaining it become much higher than those of changing it.

But it also resulted in the allocation of scarce resources in a way about which the public and patients were poorly informed (Spiers, 1996, p.5). Decision-makers did not have their choices monitored and were not accountable for the way in which public funds were distributed to fulfil patients' needs in healthcare (Sheldon & Maynard, 1993, p.5; Klein, Day & Redmayne, 1996, p.67). There was also a lack of information about cost-effectiveness, and thus the marginal benefits and costs of healthcare practices (including opportunity costs) were unknown (Sheldon & Maynard, 1993, p.10). All this probably made the NHS much less efficient and more unfair than it could have been.

This implicit rationing scheme started to become unsustainable in the 1990s. The reasons for the erosion of the implicit rationing scheme in the NHS, although interrelated, can be divided into two groups: the institutional and the social.

Institutional reason

The *institutional reason* was the 1991 Health Reform, which created the provider-purchaser split and introduced the internal market into the NHS. The purchaser – mainly the local primary care groups – gained autonomy and became responsible for determining the local priorities in health care provision through the signing of contracts with providers in which the services that should be provided to the population were selected (New, 1997, p.80; Klein, 1997, p.85).

Subsequent to the reform, a group of health authorities announced that they would cease purchasing certain treatments and others determined that some procedures would be restricted to a cohort of patients or provided only in exceptional cases (Klein, Day & Redmayne, 1996, p.68; Locock, 2000).

One of the consequences was that "the veil has been lifted" (Klein, Day & Redmayne, 1996, p.67). The health reform made visible that some services would not be provided and also who was responsible for these decisions (Syrett, 2003, p.718) and was the first step towards explicitness "about what". Rationing became explicit "about what" because it was clear that the decision by a health authority not to provide a treatment could not be based solely on clinical reasons since other local health authorities were providing the same treatment.

The uneven provision of healthcare according to the patients' area of living rather than their needs came to be known as the "postcode lottery". Rationing became more visible in the sense that the public was now aware that the provision of healthcare was not only a matter of a treatment's capacity to benefit the patient, but was also a matter of a policy choice about how to allocate scarce resources. The "postcode lottery" made the public aware that there was a link between government decisions about priority and the basket of services available to individual patients.

The "postcode lottery" was noted by the media and cases in which patients were denied a treatment that patients in other areas were receiving were highly publicized (Coulter, 1999, p.122; Klein, 2006, p.213). Some famous cases in which the postcode lottery was made especially apparent were the uneven provision of Beta Interferon and in vitro fertilization among local health authorities. Press stories about these shocked a public opinion accustomed to believe that the NHS was an equitable service and that there was no rationing in the health system (Coulter, 1999, p.122-123) and so had the effect of putting NHS rationing decisions under rigorous scrutiny on a regular basis (New, 1997, p.80).

The internal-market (and the veil it lifted), coupled with the publicity given by the media in cases when treatment was denied, progressively stripped the mystique of the medical profession under which rationing decisions had previously sheltered. Doctors started to be also seen as non-clinical managers (Sheldon & Maynard, 1993, p.4).

The variation in the provision of healthcare was not the only reason for concern. The variation in the criteria used to make rationing decisions was also worrisome. The fact that treatments were unevenly purchased by different but adjacent

public authorities also made clear that health authorities had no clear and systematic criteria for deciding the treatments to be provided to patients and that information was kept suppressed from the public (Spier, 1996, p.46-47). This indicated a lack of coherence and consistency of principles and criteria in the allocation of health care resources (Lenaghan, 1997, p.125-126; New & Le Grand, 1996, p.12; Klein, Day & Redmayne, 1996, p.124).

Thus, using the conceptual distinction between the two ideas of explicit rationing, it can be affirmed that the internal market created by the health reform (coupled with media publicity) was a driver for making explicit what treatments would be excluded or restricted by the NHS. However, the explicitness "about what" to ration was not immediately followed by the explicitness "about why and how" rationing was made.

Social reasons

As already seen, implicit rationing depends on trust in clinical judgments made by doctors and on limited information accessible to patients: patients should be willing to accept doctors' diagnosis that no further treatment could benefit them, instead of trying to search for different opinions or new treatments. However, in the 1990s, patients started to be less passive in accepting this kind of information concerning their health (Newdick, 2004, p.51).

Even though this is partially explained by the institutional change that "lifted the veil" of implicitness, there are other reasons that may help to explain citizens' change of attitude towards access (or the lack of it) to health care. And these reasons are

not exclusive of the English health system since they led to a growth in the pressure for access to health care all around the world, which in turn has provoked a reassessment of implicit health care rationing schemes in many countries (Sorenson & Chalkidou, 2009).

A society with higher living standards will have higher expectations especially when pharmaceutical companies are creating and marketing an ever expanding menu of what it is technologically possible to do in health care (Klein, 1999, p. 2; Stevens & Milne, 2004, p.12; Sorensen, Drummond & Kanavos, 2008). Better educated, better informed and less acquiescent citizens with a wide array of treatments available will increase demand on the public health system and hence undermine the equilibrium between patients' expectations and healthcare provision that sustained an implicit rationing system. This is a phenomenon experienced by many developing and developed countries (OCDE, 2006; Sorensen, Drummond & Kanavos, 2008).

The development of new medical technologies has created a steady expansion of health care needs over the past 40 years. Health conditions that were considered untreatable are now finding suitable treatments as an effect of the development of costly new medical technologies (Fleck, 2011, p.157; Callaham, 2011, p. 152; Steven & Milner, 2004, p.12), which have raised patients' expectations to be treated with the latest and best the medical industry can offer.

These expectations are also fuelled by pharmaceutical companies that discovered in health treatments a profitable market and so have kept investing in the production and marketing of new products to doctors and never-satisfied consumers who are always aspiring for a longer and better quality of life. In some cases, the demand for a drug comes directly from the patients, even when doctors are convinced

that the treatment is ineffective and expensive. This can be partially attributed to the marketing strategies of pharmaceutical companies (Jones & Irvine, 2003; Goldacre, 2012). Apart from the marketing aimed at doctors and patients, pharmaceutical companies will also pressure governments to sell their own products to the public health system through lobbying, public campaigns, media briefing, and (as we have already seen particularly in Brazil) litigation. They claim that their products are not being offered for budgetary reasons and challenge these reasons whenever possible[143].

Furthermore, the Internet can easily diffuse information about new treatments and use of it makes it easy for patients to be more informed about their own diseases and the existing treatments, providing them with other sources of information apart from their doctors. This reduces the conformity of decisions made solely on the basis of medical authority (Daniels, 2009, p.134; Spiers, 1996, p.5; Ham & Pickard, 1998, p.33). For example, in the cases *Rogers*[144] and *Otley*[145] it was reported in the decisions that the patients were demanding treatments their relatives found online.

In England, the influence of the media is also particularly relevant. If the impact of media in reporting rationing cases was almost negligible in the 1980s and did not represent a source of pressure on the NHS (Aaron & Schwartz, 1984, p. 110), from 1990s they started to play a central role. Their interest in rationing cases is not only restricted to cases in which there is "postcode lottery", but includes other stories in which needs were unmet and treatments that could arguably benefit patients were denied because resources were scarce (Lenaghan, 1997; New & le Grand, 1996, p. 29).

[143] For a broader and critical view of the pharmaceutical companies' market strategies, see Goldacre (2012) and Angell (2005).
[144] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392.
[145] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)

And these headlines cause a significant impact on public opinion for the tragic choices they make public (Mullen & Spurgeon, 1999, p.3), especially when presented in a "melodramatic style" (New, 1998, p.4). Besides the stories of denied access, media coverage of the latest discoveries in health technology also brings to the population information about new treatments, contributing to a raise in patients' expectations and creating extra pressure on doctors and the health system for using technologies where the effect or cost-effect is yet to be assessed (Wilson *et al.*, 2008; Goldacre, 2012, chapter 6).

Other causes of the rising demand for healthcare are the demographic and epidemiological transitions. Longer life expectations and the development of medical technology that transforms acute diseases into chronic diseases are increasing the pressure on health care spending. People are using more health care, for a higher price and for a longer time (Callaham, 2011, p.115; Crippen & Barnato, 2011; Steven & Milner, 2004, p.12). The result is that new technologies, especially for the treatment of chronic diseases and terminal patients, are by far the main driver of the increase of health care costs, in spite of frequently offering only marginal benefit (Callahan, 2009; Chalkidou, Lopert & Gerber, 2012; Okunade & Murthy, 2002).

In sum, implicit rationing in the past was feasible because patients knew less and doctors had less to hide from them, whereas now it is impossible to make patients believe that there is nothing else that can be done or that what is being offered is always the best that medicine can do. Patients have easy access to an enormous amount of information about the advances of medical technology that makes many more treatments available. They are also more willing to challenge clinical decisions denying treatment and to be more assertive in demanding what is denied to them (Klein, 2006,

p.214), occasionally via judicial means (which will be discussed in the next sections). Patients also started to organize themselves into associations to spread information about diseases and treatments, and also to put pressure on the government for the incorporation of treatments they consider important.

Rationing has become explicit "about what" because the progressive development of new health technologies coupled with a better informed and more demanding population made the demand (expectations) for public health outpace the health system provision capacity. This made impracticable the application of implicit rationing in the way the NHS used to do before the 1990s. The consequence of the panorama described is that health authorities were in a dilemma between choosing ever heavier economic costs of providing new and expensive treatments or ever greater political costs for not providing them, or perhaps having to bear both costs together (Klein, 1999, p.1).

5.1.2. From explicit rationing "about what" to explicit about "why and how"

As seen in the previous section, patients and public opinion became aware that the public health system denies treatments for cost reasons. Moreover, they are also willing to put pressure on health authorities complaining about the exclusion of treatments.

The response to the problems brought by explicit rationing "about what" was to try to make health care rationing "explicit about why and how". It started with the effort of local health authorities to provide better scientific grounds for their decisions. If the medical mystique was being challenged, then consistent scientific technology had to be

used to justify rationing decisions (Sheldon & Maynard, 1993, p.13). The Department of Health also showed a clear and growing enthusiasm for "evidence-based medicine" so as to identify and exclude procedures and treatments that were not cost-effective (Klein, Day & Redmayne, 1996, p.53). In the NHS Management Executive 1994, the Department of Health had urged local authorities to base purchase decisions on evidence of clinical effectiveness.

Local health authorities felt the need to provide better reasons for their decisions after some high profile cases, such as the case *Child B*[146]. Given that there will often be controversy over tragic choices in health care, those responsible for making decisions felt compelled to demonstrate that they had followed due processes and had been rigorous and fair in arriving at their decisions (Ham, 2000, p.113).

Ham & McIver (2000, p. 55-56) analysed health authorities' rationing decisions made after *Child B*[147] and reached the conclusion that local health authorities, when faced with difficult choices, had tried to decide through a more complex process – involving external advisors and the establishment of committees – and tried to apply an explicit priority-setting framework by using clear and standard criteria against which services and treatments could be assessed.

The problem was that there was little information available to health authorities on treatments' cost-effectiveness and hence the quality of the information provided by them was not satisfactory (Pickard & Sheaf, 1999, p.54). Local health authorities' failure to provide information for justifying the exclusion or restriction of treatments is

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[146] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[147] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

also explained by their lack of expertise in producing evidence-based decisions (Klein, Day & Redmayne, 1996, p.123). For example, in the case *Child B*[148] the then Chief Executive of Cambridge Health Authority complained about the "invidious position" in which he was put because he had to make difficult decisions without any guidelines to help (Pickard & Sheaf, 1999, p.48).

Cost-effectiveness analysis depends on scientific and economic expertise and is time and resource consuming. It would be too burdensome for each local health authority to provide a comprehensive and well documented assessment for each treatment claimed. This would lead to unnecessary duplication of efforts and an overall confusion and inefficiency in the system (Sheldon & Maynard, 1993, p.12). Moreover, the post-code lottery would still persist since each health authority had its own criteria and method, and therefore drew different conclusions from the assessments.

The use of ambiguous, obscure or conflicting criteria by health authorities when assessing competing claims on resources did not help in making rationing explicit "about why and how". Consequently, it did not help in avoiding economic, political and judicial pressure on the health system caused by explicit rationing "about what". The NHS still lacked clear and consistent processes and principles for making rationing decisions. There was no uniform, transparent and rational method by which to compare the benefits of different treatments for different people (Spiers, 1999, p.59).

Thus, this situation created pressure for building in the NHS a stronger lead from the centre for deciding about rationing, coordinating technology information analysis and creating nationally agreed standards (Honigsbaum; Holmstrom & Calltorp,

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[148] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

1997, p.68; Sheldon & Maynard, 1993, p.12). The first case in which the Department of Health made a decision on banning a treatment in the NHS was the banning (except for patients who suffered from some predisposing condition) of Viagra (Dewar, 1999, p.139) (this case will be discussed further in the next section). The decision was considered an important landmark in the history of the NHS because it suggested for the first time that the Department of Health recognized the inevitability of rationing and, on top of that, grappled with the problem in a public way (Dewar, 1999, p.143; Abbasi, 1999). Viagra was a drug whose effectiveness was not in doubt and there was evidence that it was even more cost-effective than other treatments available at the time (Klein, 2002, p.178). The Government's Standing Medical Advisory Committee, the committee consulted by the government for advice on the case *Pfizer*[149], affirmed that there were no medical reasons for refusing to make Viagra available for prescription in the NHS.

Thus, the Department of Health justified the ban by basing it on the consideration that the benefits of Viagra did not justify the cost of supplying it for all the patients to whom it could be prescribed. In this case, the problem was not only scarcity of money, but also of information. The decision was criticized because there was not a clear set of evidence-based reasons for rationing Viagra (Dewar, 1999, p.143; Crisholm, 1999). The controversy around this case, which included a lawsuit filed by the pharmaceutical company who owned the patent of the drug (which I have already discussed, in Chapter 3), showed to health authorities that they needed to be more open and to provide better arguments to justify rationing treatments (Dewar, 1999, p.149; Smith, 1999; Crisholm, 1999; Locock, 2000).

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[149] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

In sum, healthcare rationing has put a lot of pressure on politicians and health authorities. They have had to deal with the problem of "postcode lottery" and also had to find good reasons and a legitimate procedure to restrict patients' access to some treatments based on economic grounds. The public was aware that rationing existed and not addressing this issue was becoming less politically expedient than tackling it directly (King & Maynard, 1999).

The then new Labour government issued in 1998 two consultation documents recognizing the challenge raised by rationing and indicating a strategy to deal with it: *The New NHS: modern and dependable* and *A first class service: quality in the new NHS*.

These documents recognized that the NHS was "facing more challenges than ever". These challenges came from, among other causes: greater and faster medical advances; better informed and more demanding public; ageing population; undermining of the public confidence in the NHS prompted by the "postcode lottery"; lack of any coherent assessment of which treatments work best for patients; and because the NHS had never been sufficiently open and accountable about the quality of its services. These documents also stated that geographic variation in the provision of healthcare service was unacceptable and should end. Moreover, they affirmed that clinical decisions should be based on the best possible evidence of effectiveness, that high quality and cost effectiveness ("value for money") are "two sides of the same coin"; and that the government should provide new tools to ensure that they are achieved.

Finally, the proposal for the creation of the National Institute for Clinical Excellence (NICE) was set forth by the documents. The idea was to create an institution able to "produce guidance for clinicians about which treatments work best for patients"

and to “assess new drugs, treatments and devices for their clinical and cost-effectiveness”. The creation of NICE was suggested because the guidance provided by the NHS so far was either confusing or insufficient to guide local staff about the use of new technologies. NICE was aimed at creating a coherent national system for the appraisal of new technologies, in substitution for the plurality of bodies that made this kind of analysis using different methods, variable quality and which sometimes duplicated efforts and created confusing evidence that was not suitable to help clinicians and local health authorities. NICE was eventually established in 1999 as an independent special health authority (since 2013, it has been an executive non-departmental public body).

The creation of NICE represented the recognition by politicians that a centralized, national, more rational and transparent mechanism for deciding on priorities was necessary (Coulter, 1999). Not surprisingly NICE’s *Guide to the Methods of Technology Appraisal* affirms that “it is essential that the evidence and analysis and their interpretation are of the highest standard and are transparent to scrutiny” (NICE, 2008 B).

Besides the official justifications for its creation, NICE was also a strategy to protect politicians and the NHS against the unpopular political cost of rationing health care (Klein, 2006, p.214; Klein, 2010, p. 390; Jones & Irvine, 2003, p.25). If the advance of new and expensive health technologies made rationing more than ever inescapable, the creation of an institution aimed at providing scientific appraisals conducted by a board of experts would narrow possibly heated political debate into ones of technical analysis. According to Klein (2002, p. 182) and Syrett (2002, p.729), NICE was an attempt to depoliticize the issue by invoking the expertise of neutral specialists.

Since its creation, NICE has passed through many changes, including in its name. NICE was born the National Institute for Clinical Excellence; in 2005 it became the National Institute for Health and Clinical Excellence; and, most recently, the 2012 Health Act changed its name to the National Institute for Health and Care Excellence. Although the acronym was kept the same, the changes in the institute's name reflected the increasing number of functions assigned to NICE.

NICE is currently responsible for the following activities:

a) Health technology assessment (technology appraisal): provides guidance on the use of health technologies based on clinical and cost-effectiveness analysis;

b) Clinical guidelines: provides guidance on the appropriate care and treatment for people with specific diseases or health conditions based on treatments' clinical and cost-effectiveness analysis;

c) Interventional procedure: provides guidance on efficacy and safety of interventions that involves entering the body by making a hole, via a body cavity, or electromagnetic radiation;

d) Public health: provides guidance on promotion of healthy life style and prevention of diseases based on effectiveness and cost-effectiveness of public health activities;

e) "Medical Technologies Evaluation" and "Diagnostic Assessment" programmes: review of medical technologies and diagnostic agent according to their efficiency and cost-effectiveness;

f) Social care guidance: provide practical support to practitioners working in children's and adult's social services, and people that use these services and their carers.

NICE has adopted four moral principles: respect for autonomy (respect for patients' choices); non-maleficence (not to inflict harm); beneficence (to benefit individuals); and distributive justice (to provide services in a fair and appropriate manner) (NICE, 2008).

Distributive justice is probably the most innovative and interesting aspect of NICE in terms of institutional experience. The institute affirms that it will emphasize "procedural justice", which means that "the processes by which healthcare decisions are reached are transparent, and that the reasons for the decisions are explicit" (NICE, 2008, p.9). According to the first chairman of NICE, Michael Rawlins (2013, p.S13), and the document *Social Value Judgments: Principles for the Development of NICE Guidance* (NICE, 2008, p.10), procedural justice was explicitly inspired by Daniels and Sabin's theory of "accountability for reasonableness", which encompasses four characteristics:

> a) Publicity: decisions on the allocation of resource and the grounds for reaching them must be made public;
>
> b) Relevance: the grounds underpinning the decisions must be relevant in a certain context and acceptable by fair-minded people;
>
> c) Challenge and revision: the procedure should offer opportunities for challenging decisions and a transparent system should be available for revising decisions if new evidence becomes available;
>
> d) Regulation[150]: NICE has to be accountable to the public for its reasonableness and citizens should have the opportunity to be involved in decisions about the allocation of scarce resources within the NHS.

Procedural justice is also composed of several principles that ground NICE's guidance (NICE, 2008, p.13-15; NICE, 2013A, p.2-3): scientific rigour regarding the evidence and the methodology used; inclusiveness of all parties with a legitimate interest in the guidance; transparency concerning decisions and the reasons for the decisions; independence of the experts responsible for the decisions; right of consultees and stakeholders to challenge decisions (appeal); review to incorporate new evidences; support for local health authorities for implementing the guidance; consideration of

[150] Daniels and Sabin name the last principle "Enforcement", but the content of this principle is the same as the one NICE called "Regulation".

social values and equity; and timeliness without compromising quality.

For what concerns this thesis, the health technology assessment is the most important aspect of NICE's work and one that will deserve more attention in this section. The process for the assessment of health technologies encompasses three stages: scoping, assessment and appraisal. At the scoping stage NICE defines the questions that will be addressed by the technology appraisal. The assessment process is undertaken by an independent academic centre and is composed of a systematic review of the relevant evidence available about the technology and an economic evaluation of its cost–effectiveness for a specific indication. The appraisal process is undertaken by a 'technology appraisal committee' whose members (NHS staff, relevant academic disciplines, pharmaceutical and medical device industries and lay members) are appointed by NICE and is responsible for analysing and interpreting the "assessment report". This committee's role is to make recommendations to NICE regarding the clinical and cost effectiveness of treatments for use within the NHS. Finally, after a process of consultation with the possibility of appeal, guidance is issued by NICE. Once a drug is recommended by NICE's health technology assessment, then its provision is compulsory in the NHS and it becomes a right of the patient to receive it (see NHS, 2013; NICE, 2013B).

NICE makes use of QALY (Quality Adjusted Life Years) to analyse health treatments' cost-effectiveness. Based on this methodology, drugs that do not prove to be sufficiently cost-effective do not have their provision recommended. NICE established thresholds based on cost-effectiveness to determine whether a treatment should be recommended for provision within the NHS. Treatments whose cost per QALY gained is less than £20,000 are recommended, whereas those above this value but cheaper than

£30,000 should only be recommended if there are relevant factors that justify this. If the cost per QALY is more than £30,000, the treatment will not be recommended unless an even stronger case for supporting it can be made (NICE, 2013B).

The idea behind NICE was to create a central, credible and independent institution able to make explicit rationing "about why and how" by being clear about the criteria for the decisions taken with high technical quality and through a transparent and inclusive process. In other words, NICE was a policy response to a context in which implicit rationing was becoming progressively unsustainable; explicit rationing "about what" was raising the political costs for politicians and health authorities; and the local solutions for making rationing explicit about "why and how" were not coping with the problem properly.

There is some controversy about whether NICE was a sufficient response for the problems it aimed to tackle. NICE was unable to eliminate completely the problem of postcode lottery and the uncertainty about the cost-effectiveness of some treatments for several reasons. Firstly, as expected, NICE economic and human resources were insufficient to appraise every health technology available. Most existing treatments will not be evaluated by NICE, especially when the number of new treatments increases year after year. Secondly, health technology assessment is a long process but many patients have immediate needs and cannot wait for the NICE guidance to be published. Thus the demands for the treatments not assessed by NICE or for which an assessment conclusion is still pending (the so-called "NICE blight") is a source of pressure on health authorities. Thirdly, there is also the problem of implementation. Once a treatment is considered cost-effective and a recommendation is issued by NICE, it has to be offered by local health authorities. However, there is a problem of compliance

with the guidance since even treatments that are cost-effective can be very expensive and cause a significant impact on local health authorities' budgets. Thus, the problems of postcode lottery are raised again in cases in which there is no guidance or when there is uneven compliance with NICE's guidance (Syrett, 2003; Klein, 2010, p. 393; Rawlins, 2012).

Lastly, there is also an issue of credibility, independence and transparency sparked by cases in which NICE reviewed its own appraisals and criteria after the pressure of interest groups, politicians and public opinion (Syrett, 2003, p.724-725; Poole, 2008; Klein, 2010, p. 391). That calls into question whether NICE has been able to shield rationing decisions behind scientific and economic evidence. If not, then the problems of legitimacy for rationing decisions and the political pressure that it may create may not be adequately tackled by the Institute (Syrett, 2003).

In conclusion, explicitness "about what" in the NHS was not a policy that was entirely desirable to politicians and health authorities since implicit rationing could do a better job in decreasing the economic and political pressure on them. On the other hand, explicitness "about why and how" was a policy deliberately developed to deal with problems raised when patients became aware that they could have more and were willing to claim it through many channels, including litigation. This is the topic of the next section.

5.2 Explicit rationing and litigation

This section will analyse the relation between explicit rationing (in both senses) and heath care litigation in England. As indicated in the introduction to this chapter, I will try to show that the interaction between explicit rationing ("about what"

and “about why and how”) and litigation exists and that it goes both ways, which brings evidence to the theory that judicial decisions are influenced by the very context that they help to create (Sunkin, 2004, p.67).

Firstly I will discuss the argument that it was explicit rationing that caused health care litigation and a more activist role of courts. I will argue that this argument is incomplete because it overlooks the different aspects of explicitness (“about what” and “about why and how”) and ignores how litigation played an important role in the process of making rationing more explicit (in both senses), which is the argument I will secondly advance. Thirdly, I will argue that explicit rationing about “how and why”, in its turn, has also had a significant impact on health care litigation.

It is important to make clear that this chapter will not try to determine any strong causality between litigation and explicit rationing or vice-versa, in the sense that one was necessary and sufficient for changing the other. Its ambition is only to show that health litigation interacted with other influences that altogether prompted explicit rationing “about what”; helped to create a context in which there were incentives for decision-makers to create mechanisms for explicit rationing “about why and how” which, in its turn, impacted back in the health care litigation phenomenon.

5.2.1 Has explicit rationing prompted litigation?

As indicated at the beginning of this chapter, many misunderstandings may arise if the two aspects of “explicit rationing” – “about what” and “about why and how” – are not clearly distinguished. This is especially true in this section, where I try to analyse the argument that explicit rationing prompted health care litigation.

Some commentators affirm that the increase in the number of cases and the change from judicial deference to a hard look scrutiny of rationing decisions was prompted by the move from implicit towards explicit rationing in the National Health Service (Syrett, 2004, p.297; Syrett, 2007, p. 171; Syrett, 2009, ch.6; Syrett, 2011A; Jackson, 2010, p.77; Newdick, 2004, p.93). According to this argument, the collapse of implicit rationing raised legitimacy problems for health authorities and led to the more frequent use of courts as a mechanism for challenging now visible rationing decisions. The more people know that they are being denied treatment, the more they will litigate. And the more judges know about the reasons why treatments have been denied, the harder will be their scrutiny. Conversely, if rationing is implicit the legitimacy problem is much less prevalent because the exercise of clinical judgement serves to obscure the moral conflict inherent in the decision and there is no public expectation that rationales will be provided for decisions to deny access to treatment and service (Syrett, 2009, p.166).

At first sight, this argument seems to be plausible given the fact that in England there is a correlation between explicit rationing, increase in litigation and a more activist role of courts. This could be evidence that those arguing that litigation is a side-effect of explicit rationing are right. Moreover, the case-law shows that the awareness of postcode lottery and the easier access to information, which impaired implicit rationing, were the reasons behind many of the judicial claims for health care.

The "postcode lottery" injustice was argued in several cases – *Seale*[151]*; Fisher*[152]*; Rogers*[153]*; Murphy*[154]; *A and others*[155] and *Ross*[156] – to undercover the

[151] *R v Sheffield Health Authority ex parte Seale* [1994] 25 BMLR 1
[152] *R v North Derbyshire Health Authority ex parte Fisher* [1997] 8 Med LR 327

inconsistency of the health policy and to call into question the reasons underpinning rationing decisions. The patients' eagerness for new technologies and the easier access to information clearly motivated most cases. Patients (or their relatives) were aware of the existence of treatments abroad (*Child B*[157], *Watts*[158]), found treatments that could fit their needs on the internet (*Rogers*[159] and *Gordon*[160]), and were claiming drugs that had not yet been assessed (see chapter 3). Pharmaceutical companies were also active in challenging rationing decisions, especially against NICE (*Pfizer*[161], *Eisai*[162], *Servier*[163] *and Bristol-Myers*[164]).

It is true that people were litigating and questioning more because they knew more and this is reflected in the case-law. Indeed, there would be no litigation if patients did not know they were being refused treatment that could potentially benefit them. Hence, from this perspective, the literature is right in affirming that health litigation and hard look scrutiny were prompted by explicit rationing.

However, I argue that this argument would only be correct if by explicit rationing these commentators mean explicitness "about what". If explicit rationing is used in the sense of explicitness "about why and how", then the argument would be

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[153] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392
[154] *R v Salford Primary Care Trust ex parte Murphy* [2008] EWHC 1908 (Admin)
[155] *R v North West Lancashire Health Authority, ex parte A and Others* [1999] All ER (D) 911
[156] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)
[157] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[158] *R v Secretary of State for Health ex parte Watts* [2004] EWCA Civ 166
[159] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392
[160] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392
[161] *R v Secretary of State for Health ex parte Pfizer Ltd.* [2002] EWCA Civ 1566
[162] *R v National Institute for Health and Clinical Excellence ex parte Eisai Limited* [2007] EWHC 1941 (Admin)
[163] *R v National Institute for Health and Clinical Excellence & Anr ex parte Servier Laboratories Limited* [2010] EWCA Civ 346
[164] *R v National Institute for Health and Clinical Excellence ex parte Bristol-Myers Squibb Pharmaceuticals Ltd* [2009] EWHC 2722

wrong because it was not explicit rationing that led English courts to require more transparent and reasonable decisions from health authorities. It was rather the opposite: it was the harder scrutiny of courts in the control of rationing decisions that contributed to force health authorities to provide clear and transparent reasons through an accountable procedure.

By analysing the cases chronologically, it is possible to observe that the detailed scrutiny on rationing decisions came before more explicit rationing. Cases in which decisions not to provide drugs were quashed because, according to the judges themselves, health authorities could not bring good reasons before courts. In many cases the health system was clearly lagging behind in terms of the quality of decision making they could demonstrate and what courts were expecting from them. As judged in the case *Gordon*[165], health authorities' decisions had to be "grappled with explicitly". Moreover, in many cases after the introduction of NICE, courts highlighted the importance of this institution in making decisions concerning health care allocation that would be legitimate before courts. Courts were expecting better reasons and were willing to respect the decisions when health authorities could demonstrate that they had made the best decisions given the circumstances. The case-law shows that the more rigorous the scrutiny made by courts, the more refined are the justifications for policy choices made by health authorities. Health authorities reacted by incorporating the courts´ considerations into the decision-making process in order to avoid future litigation and that explains the increased complexity in the courts' analysis of the cases and claimants' argumentation.

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[165] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392

Even if this argument is narrowed merely to mean that litigation was caused by explicit rationing "about what", it would be correct but still incomplete because it would fail to take into consideration that courts played an important role in making rationing explicit "about what". The publicity of some high profile cases that reached the newspapers and were part of the public discussion contributed to eroding the feasibility of keeping rationing implicit. Again, as we will see in the next section, courts were part of the context they helped to create.

5.2.2 Litigation influence on explicit rationing

This section will debate the influence of health care litigation on the process of explicitness (in both aspects) that culminated in the creation of the NICE.

As already stated, courts were not a mere reflex of the changes in the way rationing was being made by the NHS. Even though explicit rationing "about what" is one of the reasons for the increased level of healthcare litigation and the less deferential judicial review, this is not a one way causality phenomenon. These are inter-related and mutually reflexive phenomena and the latter (increase in litigation and more activist courts) also contributed to the former (explicit rationing "about what"). Courts were also one of the sources of pressure and contributed to the movement from explicit rationing "about what" to explicit rationing "about why and how".

According to Pick (2001), judicial review can be assessed in light of two roles it may perform when reviewing administrative decisions. It can be both a threat to the administration because it undermines its decisions, but also a source of guidance for legitimate and good practices. Accordingly, the administration learns "to live with the prospect of judicial review and, as it were, to place the prospect of litigation in

perspective" (Pick, 2001, p. 760; see also The Treasury Solicitor's Office, 1987, 1994, 2000, 2006).

I will try to show that this argument applies to the case of health litigation and two important cases show this process clearly: *Child B*[166] and *Pfizer*[167]. I have selected them because of the impact they have had on the way health authorities make decisions regarding health care rationing.

It is important to make clear that I am not arguing that litigation was a sufficient or necessary condition for the changes in the way health care is rationed in the NHS. This argument would be implausible and difficult to prove since there were too many factors that influenced the process towards explicit rationing. Litigation is one of them within a 'soup of influences' on decision-making. As previous research on the impact of litigation on bureaucracies has indicated, one should be wary of overestimating the role of courts since it is difficult to isolate the influence of judicial decisions where decision-makers are continuously reacting to multiple pressures (Richardson, 2004; Sunkin, 2004).

The impact of courts may be clearer when it is direct, for instance, when certain changes performed by the bureaucracy were ordered by a judicial decision or when a policy is explicitly aimed at responding to a judicial decision or a group of decisions (this was the case of Federal Law 12.401/11 in Brazil). On the other hand, it would be much more complicated to prove the indirect impact of courts, for example, when litigation provoked changes on the policy implementation in the context of bureaucratic decision-making (Richardson, 2004, p.114; Cane, 2004).

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[166] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[167] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

The indirect impact of litigation is more difficult to track firstly because it may be diffuse and informal (Richardson, 2004, p.114), and have influence on the less accessible aspects of the government, such as the internal and informal working practices of departments, their management system and decision-making culture (Sunkin, 2004, p.63). Secondly, the indirect impact of judicial review is not based solely on the outcome of a judicial decision. What the courts say and the publicity brought by the case can be more influential than the decision *per se* (Sunkin & Richardson, 1996, p.90). As affirmed by Harlow & Rawlings (2007, p. 713), "the mere existence of judicial review may influence future administrative behaviour" and the "shadow of law" may prompt important changes in administrative decisions.

Nonetheless, in the case of health care litigation in England, there is enough evidence to show the mutually reflexive relation between litigation and the way the public health system rations healthcare.

The case Child B[168]

As already seen in chapter 4, the case *Child B*[169] is important because it was the first in which a court quashed a rationing decision made by health authorities (even though this was overturned on appeal). However, the meaning of this judicial case goes beyond this decision and also beyond the legal sphere.

The judicial dispute in this case was widely reported by the newspapers and gave explicit rationing "about what" an extraordinary visibility (Mullen & Spurgeon, 1999, p.3; Heginbotham, 1997, p.50; New & Le Grand, 1996, p.1; Price, 1996, p.167).

[168] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[169] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Child B[170] contributed to lifting the veil of implicit rationing for public opinion and sparked an unprecedented national debate about rationing, which multiplied the pressure on health authorities and politicians (Klein, Day & Redmayne, 1996, p.78; Pickard & Sheaff, 1999, p.40).

According to some authors, the media interest on this case began with the court case (Ham & Pickard, 1998, p.49; Entwistle *et al.*, 1996, p.92). The legal case was on the front page of all the national newspapers, was the subject of many editorial comments and was also prominent on television programs (Ham & Pickard, 1998, p.49; Entwistle *et al.*, 1996). Some newspapers, especially tabloids, emphasized significantly the financial reasons for denying treatment and many criticisms against doctors and health authorities were made (Ham & Pickard, 1998, p.52; Watt & Entwistle, 1996, p.153). The case *Child B*[171] also triggered media interest in other rationing cases (Entwistle *et al.*, 1996, p.127).

Furthermore, *Child B*[172] showed to those responsible for making tragic choices that they would be likely to be severely scrutinized and hence they had to show that they were rigorous in assessing evidence and fair in choosing the values guiding them to their decisions (Ham, 2000, p. 112-113). This case showed the importance of a good procedure to justify rationing decisions, and that improvements were necessary to deal with future cases (Ham, 2000, p. 116). Its lessons changed the way decisions were made by health authorities.

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[170] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[171] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[172] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

Ham & McIver (2000) made an in-depth analysis of some rationing cases after *Child B*[173] to research the changes in the way health authorities were making their rationing decisions and whether these changes were due to the lessons learned by health authorities in *Child B*[174]. They made extensive use of interviews in order to try to understand the reasons and justification given by decision-makers.

They found that decision makers were unanimous in recognizing that *Child B*[175] had taught them that, in order to lend legitimacy to their rationing decisions, they needed a better and more transparent procedure and had to provide better explanations (Ham & McIver, 2000, p. 72). A better explanation, according to the interviewee, encompassed the establishment of committees for dealing with rationing decisions; the advice of independent external specialists; a search for more evidence; a more detailed look at the evidence; a deeper understanding of the ethical issues involved; an adoption of appeal procedures; and more explicitness about the criteria against which the claimed treatments should be assessed.

This effort made by health authorities is explained by the considerable media interest in rationing cases after *Child B*[176], when patients who were refused drugs were constantly appearing in newspaper headlines, constraining health authorities to explain the basis for their decision to the public opinion (Ham & McIver, 2000, p. 69).

Furthermore, fear of litigation was also a common explanation for changing the decision-making procedure. Finding reasons that would be accepted by courts and the public was a permanent concern in the cases analysed by Ham & McIver. The fear of

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[173] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[174] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[175] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[176] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

litigation was caused by the experience learned from the *Child B*[177] case and because patients were now aware that judicial review was possible and they were willing to go to courts or at least to invoke the possibility of using legal action to convince health authorities to review the denial of treatment (Ham & McIver, 2000, p.61). In one case, the health authority received a solicitor's letter stating that she had advised her client (the patient) to apply for a judicial review of the decision and that "leave has already been granted in two similar cases against health authorities" (Ham & McIver, 2000, p.30).

The lessons learned from *Child B*[178] exemplify Sunkin's (2004, p.52) theory that the impact of the decision is not necessarily linked to the legal success of the challenge. The publicity of cases – which includes media coverage – concerning ethically and socially controversial decisions may have more impact than the decision itself, although indirect (Sunkin, 2004, p.53). In this case, health authorities promoted changes to safeguard their decisions from legal challenges and avoid similar difficulties in the future.

The case *Child B*[179] also prompted an academic debate about the role of courts when assessing this kind of case. Many commentators criticized the Court of Appeal's decision for not demanding from health authorities better reasons for not funding a life saving treatment and for not engaging with the High Court's argument that just claiming that resources are scarce is not enough to justify any rationing decision (James & Longley, 1995; Parkin, 1995; Ham & Pickard, 1998, p. 77-80; Newdick, 2004; Syrett, 2007). As seen in Chapter 4, the courts themselves eventually bought the arguments of

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[177] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[178] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[179] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

the High Court decision that was overruled by the Court of Appeal in *Child B*[180] and applied them to judge several cases afterwards.

In sum, *Child B*[181] contributed to showing health authorities that rationing had to be more explicit in order to secure legitimacy for their decisions and that a wide national debate for priority setting was needed (Ham & Pickard, 1998, p.98-93). This experience has probably contributed to the creation of NICE by the British government, which, according to Norman Daniels, has "no doubt" learned the importance of open communication from cases of inadequate transparency such as *Child B*[182] (Daniels, 2009, p. 120).

The case Pfizer[183]

As already seen, the ban on Viagra was considered an important landmark in the history of the NHS because it was the first time a central authority made an explicit decision to restrict access to a drug. In this case the justification for rationing was the cost of the treatment and its affordability for the public health system, but health authorities lacked evidenced reasons on which to base their decision.

As we saw in chapter four, a lawsuit was filed by Pfizer, the pharmaceutical company who has the marketing rights of the drug, and the High Court ruled in favour of the company on the basis that the European Union Transparency Directive affirmed that any exclusion of a drug from a national health system requires a statement of reasons based on objective and verifiable criteria. This was something the Secretary of

[180] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[181] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[182] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[183] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

Health could not provide because detailed assessment of cost-effectiveness had not been undertaken (Mossialos & McKee, 2003, p.372).

The fact that this case reached the courts is significant because it showed that pharmaceutical companies were willing to challenge health authorities through litigation (Dewar, 1999, p. 147). Moreover, the success of Pfizer in the High Court showed that courts were prone to demand better reasons from health authorities and that a rationing decision may not be upheld if it is not justified by rational and explicit reasons.

The case *Pfizer*[184] is chronologically very close to the creation of NICE. Harris (2008) argues that NICE was created as a response to the lawsuit lodged by Pfizer against the ban on Viagra, when health authorities realised that they needed a standard method of rationing to defend themselves against individual claims as well as lawsuits from pharmaceutical companies against decisions to restrict the supply of new and expansive drugs in the NHS. Chalkidou (2009, p.3) also associates the creation of NICE with the case *Pfizer*[185], which made clear that the NHS lacked a sufficiently transparent, accountable, consistent, scientific and accountable procedure for health care policy making.

NICE itself has also identified the case *Pfizer*[186] as one the main reasons for its creation. Besides the need to improve the quality of care, and the pressure on costs by new and expensive health care products, there was also the problem of inconsistent rationing, which created the unfairness of the "postcode lottery". And when the

[184] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[185] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[186] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

government tried to centralise these decisions (e.g. *Pfizer*[187]), there were questions about the "ad hoc and opaque fashion in which decisions were made" (NICE, 2004, p.2).

A "NICE like" procedure (Appleby, 2000) was necessary to justify the ban of Viagra but at that time NICE was "still nothing more than a policy dream" (Dewar, 1999, p. 148). The High Court's decision showed that an increasing openness and the provision of sound reasons would be required from health authorities and NICE was seen as the institution capable of performing this task (Dewar, 1999, p. 150).

When the case reached the Court of Appeal, the NHS argued that the decision to exclude the drug was based on the cost of the treatment and the other priorities that the health system had to meet. Interestingly, in this case the government did not refer the case for the assessment of NICE. Syrett (2004, p.300) supposes that the government did not do that because it was afraid that a favourable appraisal by NICE would increase the political pressure to supply Viagra. The government's litigation strategy was to insist that it was a problem of affordability rather than cost-effectiveness and to rely on a more deferential attitude of the Court of Appeal. Pfzier, on the other hand, argued that decisions about what drugs to fund should be based on cost-utility analysis, which had not been made by the government. Pfizer's argument is noteworthy because the pharmaceutical company admitted that rationing of a treatment would be acceptable if based on sound cost-effectiveness reasons. The Court of Appeal accepted the reasons given by the government, judging that in this case a cost-utility analysis was not necessary to justify the restriction on the provision of the drugs since it was a matter of affordability rather than cost-effectiveness.

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[187] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566

Even though the strategy advanced by health authorities worked in this case, it did not work in subsequent cases when courts showed themselves willing to scrutinize the process and reasons that led the health system to ration healthcare and, therefore, NICE played an important role in healthcare litigation. The reasons given by NICE, once created, were not only considered, but were also the object of a meticulous scrutiny by courts.

Just as in *Child B*[188], in *Pfizer*[189] the health authorities lost in the High Court, won in the Court of Appeal, but the reasoning put forward by the High Court and the publicity of the case had an impact that echoed much beyond the final outcome of the litigation. Even though it is not possible to say that the cases *Child B*[190] and *Pfizer*[191] were a necessary or sufficient condition for the creation of NICE, it is possible to infer that they, together with many other judicial cases, were central to creating a context of explicitness "about what" and demand for explicitness "about why and how" in which NICE was made necessary. The battle in courts indicated that patients and pharmaceutical companies were willing to challenge rationing decisions through litigation and the experience since *Child B*[192] shows that judicial deference to rationing decisions should not be taken for granted.

NICE is certainly the most high profile aspect of the transition towards explicit rationing and an example of how litigation contributed to changing the way the NHS rations healthcare. However, other sources of evidence can be brought to show the

[188] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[189] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[190] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898
[191] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[192] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

impact of litigation on the way health authorities ration healthcare.

Firstly, it should be mentioned that, given the courts' demand that health authorities' general policies restricting the access to health treatment must consider exceptional cases and be able to articulate which cases can be classified as such, PCTs have established Exceptional Case Panels to assess individual funding requests (IFR) for treatments which are not routinely funded for other patients (Ford, 2012, p.6; NHS Confederation, 2008).

Moreover, the duties of transparency, fairness and reason-giving that have been demanded by courts have become rights to which patients are entitled, according to the NHS itself. The same administrative law language used by courts in judicial review is now part of the regular procedure of the NHS to decide about the provision of care (on this topic see Syrett, 2011A, p. 111).

For instance, the NHS Constitution declares that:

> You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.

Other statutory directions reaffirm that patients denied treatment have the right to receive a written explanation of the reasons. In the document that provides guidelines for the PCT to consider individual funding requests (IFR) for cases that are arguably exceptional, it is made clear that the "PCT must be able to explain coherently their decisions to clinicians, patients, the public and the courts" (NHS Confederation, 2008, p. 3). Additionally, concern about what courts might think of the decisions made by

health authorities and how to proceed in a way that will lessen the risk of being reviewed by judges is evident throughout the document. It is even recommended that, in administrative appeals against the authority's decision, the PCT act in a judicial-like way, using the same tests that courts apply to scrutinize their decisions (NHS Confederation, 2008, p. 7-8). Thus, health authorities are shaping their decision-making procedures according to the bars set by courts. Interestingly, in contrast to Brazil, where there are policies aiming at making courts more similar to policy-makers, in England policy-makers are incorporating elements of the judicial process in its decision-making.

The following duties were also recommended by the NHS itself to the local authorities: to provide arrangements to deal with exceptional cases; to give written justification to patients that are denied a certain treatment clarifying the reasons for the decisions; to ground these decisions on robust evidence and consistent criteria; and to document the procedure and rationale for each decision (Department of Health, 2009A, 2009 C).

It is also common for barristers and legal scholars to give presentations and write papers aimed at the NHS staff explaining what they should do to avoid having their decisions being quashed by courts. Based on the health care litigation case-law, barristers and academics have explained to the NHS staff what judicial review is; how courts scrutinize their decisions; and what a legal use of their discretion is. Moreover, they have helped to interpret the judicial decisions and provide guidelines concerning how decisions should be made and the importance of recording and providing reasons so as to show that each case has been considered in a comprehensive and attentive way (for instance, see Lock, 2009; Newdick, 2008).

A comprehensive survey on how PCTs make allocative decisions and set

priorities has affirmed that the risk of judicial review is one of the reasons that justify making decisions more explicit and hence more legitimate (Robinson et al., 2011). According to this research's preface,

> The exacting nature of the financial challenge facing the National Health Service (NHS), combined with increasing demand for NHS services, means that commissioners will have to make difficult decisions about how NHS resources are used. Processes for reaching and enacting these priorities will need to be robust and transparent, and capable of withstanding judicial review. (Robinson et al., 2011, p.7).

As analysed by Short (2012), when decision makers are required by courts to give reasons, they will probably do it more carefully and in a way that is publicly justifiable, by considering the evidence and opinions for and against a certain policy and being more consistent with former decisions. The judicial demand for reasons also shapes and constrain public authorities' future decisions in accordance with previous judicial rulings in similar cases.

5.2.3 The impact of NICE on health care litigation

In this section, I will analyse whether the creation of NICE had an impact on health care litigation, affecting the kind of cases brought to courts, the legal reasoning in the cases and the volume of lawsuits. As in earlier sections, the same methodological caveat has also to be born in mind since the impact of NICE is mainly indirect and it is one among other influences that have been in action simultaneously in health care litigation.

If health care litigation was one of the problems to which NICE was a response, then it is important to assess whether this response was effective. By looking

at the number and outcome of cases it could be said that it was not, given that the number of judicial challenges increased after the creation of NICE and most of them have been decided against the government (see Figure 3 in Chapter 4).

The problem with this answer is that it is vulnerable to counterfactual reasoning. It could be speculated that, if NICE had not been created, the level of litigation would have been higher than it actually was. It could also be suggested that without NICE the government would have lost many more cases because it would have been unable to present the justifications courts would have required. In other words, it could be argued that NICE has avoided the uncontrolled increase (the Brazilian case shows that the sky is the limit) of a phenomenon already on course – explicit rationing "about what", patients willing to litigate, and less deferential courts – and has made the problem manageable. According to Elliot (2011, p.64), when good reasons are provided by the administration people can make better informed decisions about whether to seek judicial review and thus the number of hopeless challenges is reduced. Accordingly, because NICE provides better reasons through a fair process, it could be that it has discouraged the transformation of dissatisfaction into lawsuits by giving *a priori* legitimacy to the rationing decision in issue.

A quantitative statistical projection of what would have probably happened in a world without NICE was considered as a method to test this hypothesis, but the number of cases is too small to reach a reliable conclusion. Furthermore, other variables that are difficult to control would have to be taken into consideration in any such quantitative analysis, such as the inclination of patients to file lawsuits, the disposition of health authorities to settle cases before lawsuits are lodged and the willingness of courts to grant permission for judicial review (on this topic, see Bondy & Sunkin, 2009).

Moreover, assuming that health litigation is also influenced by the explicit health care rationing it helped to mould, the dependent-independent variable relation is very difficult to establish. Furthermore, the impact on litigation of some of the changes in the bureaucracies' decision-making process tends to be indirect and thus very difficult to assess via statistical analysis.

Hence, I will try a different approach and analyse the change in the profile of health litigation cases and the way they were decided after the creation of NICE. I will argue that the comparison of the cases *pre* and *post* NICE shows the impact of the institution on health litigation and provides evidence that the establishment of NICE was an effective policy decision. I am also aware that the analysis of the impact of explicit rationing on the reported cases leaves uncovered the effects on other aspects of judicial review, such as the legal disputes that were never filed, those that did not receive permission for judicial review or that were settled before a decision was issued, and those that were not reported. However, the importance of the reported cases for the legal system and for legal scholarship is sufficient to justify the relevance of the study I present in this section. The reported cases become precedents and spread the opinion of judges to stakeholders and all the participants in the legal system (Hall & Wright, 2007, p.31).

The post-NICE health care cases can be classified into three groups[193]: those in which NICE had not acted; those concerning the application of NICE's guidance; and those against NICE's guidance.

[193] *Watts*, which involved a problem with waiting lists and a discussion about European Law, is not a case that NICE would be concerned with and will not be discussed in this section.

Concerning the first group, the cases *Rogers*[194], *Gordon*[195], *Murphy*[196] and *Ross*[197] are very similar in the sense that in all of them the patients were claiming new and expensive drugs that had not yet been assessed by NICE. Because the publication of NICE's guidance was pending and there was scientific controversy about their cost-effectiveness, each local health authority had a different policy concerning their provision. In these cases the respondent health authorities had decided not to supply drugs non-approved by NICE except in exceptional cases. In the case *AC*[198], NICE had no guidance for gender dysphoria (NHS, 2010 B) and the PCT gave low priority to the treatment claimed by the patient. These cases are examples of "NICE blight" and are typical of one of the main problems that NICE was created to deal with – to provide reasons and assess scientific evidence – but unfortunately the timing of the technological assessment is different from those of some patients in urgent need (see section 5.1.2). With the exception of *AC*[199], the patients eventually won these cases.

The second group encompasses the cases *Otley*[200] and *Condliff*[201]. The case *Otley*[202] was about the application of NICE guidance to an exceptional case. NICE had not recommended the treatment claimed by the patient for cost-effectiveness reasons but the patient claimed that the PCT ignored NICE guidance which indicated that the treatment could be suitable in some specific circumstances and that her case was one of

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[194] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392
[195] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392.
[196] *R v Salford Primary Care Trust ex parte Murphy* [2008] EWHC 1908 (Admin)
[197] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)
[198] *R v Berkshire West PCT ex parte AC* [2011] EWCA Civ 247
[199] *R v Berkshire West PCT ex parte AC* [2011] EWCA Civ 247
[200] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)
[201] *R v North Staffordshire Primary Care Trust ex parte Condliff* [2011] EWCA Civ 910
[202] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)

them. In *Condliff*[203] the claimant demanded a surgical intervention that, according to the NICE appraisal, should be performed. However, this was not a mandatory guidance (Lock, 2011) and the PCT had established more strict criteria than NICE, which made the claimant ineligible for treatment in that PCT. The patient won in *Otley*[204], in which a detailed scrutiny was applied, but lost in *Condliff*[205], when (as we have already seen) the court had a more deferential attitude towards the health authority's decision.

The cases *Eisai*[206], *Servier*[207], *Fraser*[208] and *Bristol-Myers*[209] belong to the third group, in which NICE's guidance to not recommend the provision of treatment by the NHS was challenged. The challenges were mainly based on procedural issues such as a lack of transparency and fairness in the procedure, the overlooking of relevant evidence, and the lack of expertise on the part of the specialists chosen by NICE. In the cases *Eisai*[210] and *Servier*[211] it was also argued that the guidance was discriminatory against certain groups.

With all the caveats to which I have earlier drawn attention, the analysis of the three groups of cases nevertheless allows me to draw some conclusions concerning the impact of NICE on health care litigation: the profile of the cases and litigants has changed, as well as the way courts judge the cases before them.

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[203] *R v North Staffordshire Primary Care Trust ex parte Condliff* [2011] EWCA Civ 910
[204] *R v Barking & Dagenham NHS PCT ex parte Otley* [2007] EWHC 1927 (Admin)
[205] *R v North Staffordshire Primary Care Trust ex parte Condliff* [2011] EWCA Civ 910
[206] *R v National Institute for Health and Clinical Excellence ex parte Eisai Limited* [2007] EWHC 1941 (Admin)
[207] *R v National Institute for Health and Clinical Excellence & Anr ex parte Servier Laboratories Limited* [2010] EWCA Civ 346
[208] R (on the application of Fraser and another) v National Institute for Health and Clinical Excellence and Another [2009] EWHC 452 (Admin)
[209] *R v National Institute for Health and Clinical Excellence ex parte Bristol-Myers Squibb Pharmaceuticals Ltd* [2009] EWHC 2722
[210] *R v National Institute for Health and Clinical Excellence ex parte Eisai Limited* [2007] EWHC 1941 (Admin)
[211] *R v National Institute for Health and Clinical Excellence & Anr ex parte Servier Laboratories Limited* [2010] EWCA Civ 346

First, the scope of health litigation has been reduced to a minor dimension of the rationing decisions. Before NICE, patients who were denied treatment litigated for treatments based merely on the claim that they needed a heath treatment and the NHS had a general duty to provide comprehensive healthcare. After NICE, the patients' claims were narrowed down to the cases in which NICE had not decided or in which they could argue that the NICE's guidelines restricting the provision of a treatment should not apply to their allegedly exceptional case. In other words, patient driven litigation was not aimed at the core of a certain rationing policy, but at the margins of the policy, i.e., when there was no guidance or when an exception to the guidance was trying to be proved (groups 1 and 2). In these cases, the core of a rationing decision – restricting access to most cases – was not threatened and even in cases in which there was no guidance the mere fact that the appraisal was pending was enough to make the rationing decision legitimate *a priori*.

Second, the cases in which a rationing policy was challenged were driven by pharmaceutical companies and patients groups (group 3). Because the procedure became more sophisticated and complicated, to prove that a rationing decision involving NICE should be quashed became a very complicated task – demanding sophisticated legal reasoning and highly technical expertise. Not surprisingly, in these cases against NICE the claimants were resourceful pharmaceutical companies and/or patients' associations rather than the individual patient. Thus, it can be noted that the scope of the litigation driven by individual patients has narrowed and, in cases in which a policy was challenged, the profile of the litigants has been restricted to pharmaceutical companies, occasionally with the support of patients' associations.

Third, the onus of the proof in health care litigation cases changed after the establishment of NICE. As analysed in Chapter 4, in the first stage of health care litigation in England there was no onus of proof on health authorities and the application of "Wednesbury unreasonableness" gave to patients the burden of demonstrating that the rationing decision was "overwhelmingly" irrational, which was very difficult to prove. During the second stage courts started to demand reasons from health authorities that their decision was the best that could have been achieved given the circumstances, which meant, with proper regard of the procedure, principles, evidence and exceptions. Thus, during the second stage the onus of proof was transferred to health authorities.

For the cases in which there was guidance from NICE (groups 2 and 3), courts considered that the rationing policy was *a priori* legitimate and the onus of proof switched sides again, back to the claimants. Before NICE, litigants could simply claim a general duty on the part of the NHS to provide health care and health authorities had to make a massive effort to prove that there were good reasons not to fulfil this duty in some cases. However, when NICE had acted, it was the claimant who had to strive to find flaws in the decision-making procedure of the guidance or to prove that it was not correctly interpreted or wrongly applied for exceptional circumstances.

Even in cases in which NICE guidance was pending, courts have recognized that it was rational not to provide the treatment until a decision of the institute was issued, as long as the justifications were provided and reasonable. In these cases, unlike the judgments before NICE during the second stage of the English case-law, local health authorities did not have the onus of justifying the general policy to deny treatment while guidance was pending, but rather had to prove that there was a consistent policy for exceptional cases when claimants argued so. Thus, even when NICE had not issued

guidance, it reduced health authorities' burden of proof; and the lack of an assessment made the onus of proof to be shared between patients and health authorities.

It is true that in spite of the changes in the burden of proof, courts not only kept scrutinizing the cases but, on top of that, they also became increasingly meticulous in the analysis of reasons and procedures concerning the provision of treatments. This could be understood as evidence of an increasing judicial activism that NICE could not control. Nonetheless, given that courts only respond to the arguments of the litigants, I propose a different interpretation. Courts became meticulous because of the way claimants were framing their lawsuits. It was the claimants who had to go into details in the cases because they had to justify the exceptions to the rationing policy (groups 1 and 2) or find details in NICE's guidance and procedures that could be challenged as flaws in the decision making (group 3), since the rationing decision was now more legitimate.

In brief, NICE reduced the scope of health litigation to exceptional circumstances, made the challenge to rationing decisions more complicated, and in most cases transferred the onus of proof to claimants. These elements altogether have certainly reduced the pool of potential cases and also of potential claimants, probably making the level of health litigation lower than it would have been otherwise.

5.3. Conclusions of the chapter

This chapter aimed at explaining the connection between rationing and litigation in England. This chapter's first contribution was to highlight how explicit rationing has two senses (explicit "about what" and explicit "about why and how"), which is surprisingly commonly overlooked by specialists in the field. This clarification opens the path for the following argument: the development of rationing in England –

from implicit to explicit "about what" and then to "explicit about why and how" – and the changes in the health care litigation case law – from almost a complete deference to a very strict scrutiny of reasons and procedure – are interconnected in a way that means that a narrative of any one of them would be incomplete without mentioning the other.

Health care litigation was certainly influenced by the context in which patients were less acquiescent to the decisions made by their doctors and health authorities but, at the same time, the publicity legal cases gave to the issue also contributed to making rationing an issue of wide public interest. Litigation also played an important role in changing the way rationing decisions were made by health authorities. The process towards explicit rationing "about why and how" was partially motivated by the pressure that came from courts who were demanding better reasons and procedures. This process of mutual influence was what I tried to show through the analysis of the cases *Pfizer*[212] and *Child B*[213].

The process towards explicit rationing "about why and how" culminated in the creation of what as we have seen is now called the National Institute for Health and Care Excellence (NICE), explicitly based on the framework of accountability for reasonableness developed by Norman Daniels and Charles Sabin (NICE, 2008). NICE was created as a central, credible and independent institution able to make explicit rationing "about why and how" by being clear about the criteria for the decisions taken with high technical quality and through a transparent and inclusive process. NICE was a policy response to a context in which implicit rationing was becoming progressively unsustainable; explicit rationing "about what" was raising the political costs for

[212] *R v Secretary of State for Health ex parte Pfizer Ltd*. [2002] EWCA Civ 1566
[213] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

politicians and health authorities; and the local solutions for making rationing explicit about "why and how" were not coping with the problem properly.

Explicit rationing "about why and how", in its turn, also had a significant impact in the type of cases that are judicialised and in the way courts decide them. I have argued that courts accepted that NICE brought more legitimation to rationing decisions, which can explain a narrower scope of health care litigation and the reduction of the onus of proof that health authorities have to fulfil to defend their policies in courts or the transfer of this onus to claimants. Hence, there is evidence that explicit rationing "about why and how" was an effective policy response to the increase of health litigation in a context of progressive development of new and expensive technologies; well informed patients who are aware that litigation can be used to claim treatments denied by the NHS; and courts that are less deferential and disposed to demand good reasons and fair procedures from health authorities.

In sum, there is evidence that this relation between rationing and litigation in England have contributed to making the public health system fairer, although the risks and trade-offs in courts' control of procedure should not be underestimated (see section 6.2.4 and 6.3). The case of health care litigation in England exemplifies the approach that, as I argue in the next chapter, is the most sensible for courts when reviewing rationing decisions, if compared to the alternatives suggested by part of the literature that writes on social rights adjudication or to the experience of courts in other jurisdictions.

The narrative in this chapter has an important parallel with the Brazilian case. Firstly, health care litigation in England has forced health authorities to act in a judicial-like way, i.e., to decide using the same tests that courts apply to scrutinize their

decisions. In Brazil, on the other hand, courts have been suggested by the Judiciary itself to decide in a more administrative-like way, trying to encompass more stakeholders and specialists to decide on polycentric issues (see section 3.1).

Moreover, one direct effect of litigation in Brazil was the enactment of the Federal Law 12.401/11 that creates CONITEC, an institutional similar to NICE, which was set up in England in a context that litigation contributed to create. The circumstances that led to the creation of these institutes are different: in England courts were demanding reasons and hence were willing to take them into consideration, whereas in Brazil courts still have to be convinced that sometimes there are good reasons to deny treatment. However, the intention is the same: to reconcile the fact that health authorities are not immune to surveillance and are responsible for providing reasons for those affected by their decisions and, on the other hand, to avoid courts interfering in a way that can make the health system more unfair.

6. Social rights adjudication: ideals, limits and forms

In this chapter, I put the cases of health care litigation in Brazil and England in the context of the discussion on social rights adjudication, so as to present the contribution that can be drawn from analysis of these cases for the scholarly debate on the role of courts in the protection of social rights.

In order to do so, I will engage with the literature on social rights adjudication that has been recently published in the English language. I will **first** argue that the part of the literature that advocates a more interventionist role for courts builds its argument on premises that are much more controversial than their theories assume. They tend to present a dystopian characterization of the legislative and executive branches in order to compare them with an idealised description of what courts are and what they can become. They also undermine the distinction between civil and political rights and social rights when they argue that social rights adjudication is less problematic than it actually is. Moreover, they suggest reforms in the judicial institutions and the legal process to make them more suitable for social rights adjudication, but they overlook the trade-offs in these reforms. **Second,** I will draw on the theories of social rights adjudication, my analysis of health care litigation in Brazil and England, and the practice of other courts to build a typology of the different ways through which courts can enforce social rights – strong structural enforcement, weak structural enforcement, procedural enforcement, individual immediate enforcement – taking into consideration the advantages and shortcomings in each type. **Lastly,** I will connect the discussion about social rights adjudication to the debate on health care litigation and propose that procedural enforcement is the type of adjudication that can deliver direct benefits for

litigants and others in the same condition and for which courts have more legitimacy and capacity. Based on the conclusions drawn from previous chapters of this thesis, I propose that procedural enforcement, along the lines of what is proposed by the idea of "accountability for reasonableness" proposed by Daniels and Sabin, should base the concept of the right to health to be applied by courts in health care litigation cases. Namely, the right to health should be adjudicated as the right to access a health system in which resources are fairly distributed.

Social rights adjudication raised a broad debate that allows many entry points. It is, therefore, important to clarify to which part of it my analysis of the Brazilian and English cases can contribute.

According to the typology created by Henry Shue (1996), that was later incorporated by the United Nations and the World Health Organization (CESCR, 2000; UNCHR & WHO, 2008), social rights create different kinds of duties for the state: duties to respect, protect and fulfil. For instance, the right to health entails the duty for the state to fulfil this right by adopting a national health policy and ensuring the provision of health care and other policies to improve the social determinants of health. It also encompasses the duty to respect (not harm) citizens' health by not torturing, not interfering in their sexual and reproductive freedom, not discriminating against some groups by excluding them from the access to healthcare, not obliging them to participate in non-consensual medical treatments and experimentation and so on (see CESCR, 2000). The right to health also creates the duty to protect them from being harmed by other people or private organizations, which entails, for instance, health surveillance policies, the regulation of the medical profession and industrial and commercial activity, and protection against physical assault.

My focus is exclusively on the debate about whether courts should adjudicate social rights in a way that creates positive duties to allocate scarce resources for the provision of healthcare (duty to fulfil) and the dilemmas they may face if they do so. If courts issue positive orders against the prevailing political or administrative decision, they may be criticized for "usurping" a function that belongs to executive and legislative branches and thus "getting themselves disastrously mixed up in matter beyond their province and ken as judges of law" (Michelman, 2003, p.16). On the other hand, if courts refuse to adjudicate these rights, they may be accused of "abdicating" their role of controlling the executive and political authorities, giving them "an unreviewable privilege of indefinite postponement" of social rights (Michelman, 2003, p.16). Michelman also argues that, in between these opposite poles of usurpation and abdication, there are different ways in which courts may intervene to avoid either criticism. This is precisely the debate to which this thesis can contribute by calling to question some assumptions based on which part of the literature develop its arguments and by identifying and comparing the different ways of adjudicating social rights.

Even though violations of the duties to respect and protect can be framed as violations of the right to health, their judicial enforcement will not be discussed in this thesis. This is not because they are less important, but rather because the judicial enforcement of these duties is normally less controversial, or at least it is not more controversial than the intervention of courts in other areas of law. The protection against most of the violations of the duties to respect and protect is already consolidated in most Western legal systems using the language of civil and political rights, administrative law, regulation, family law, criminal law and so on.

This clarification is important because it seems that some of the controversy about social rights adjudication lies in the fact that those in favour of the judicial protection of social rights include the enforcement of the duties to protect and respect as examples of social rights adjudication, whereas those who are more sceptical are only against giving to courts the power to allocate scarce resources based on a social right (see, for instance, the debate in Gearty & Mantouvalou, 2011).

Nor will I debate the obligations of the State before the international community created by social rights in international treaties and declarations. The recognition of social rights in the international law and the mechanisms for making States accountable before the monitoring bodies of international organizations raise a set of questions that go beyond those that I will engage with in this chapter (on this see Tobin, 2012; Hunt & Backman, 2008; Backman et al, 2008; MacNaughton & Hunt, 2009).

Lastly, I will not enter into the discussions about the use of the language of social rights, whether these rights should be recognized in national constitutions, nor do I consider the moral or political duties their constitutional recognition may create for governments. Even though the constitutionalization and judicialization of social rights are very closely connected ideas, one does not necessary come with the other. There may be constitutionalized social rights that are not judicially enforceable (e.g., the article 37 of the Constitution of the Republic of Ireland) and there may exist judicial protection of social rights without its constitutionalization (e.g., India, where courts use the language of the right to life and human dignity).

Some authors associate being sceptical about social rights adjudication with being against welfare protection or redistributive policies (see, for instance, O' Connell,

2011; Nolan, 2011, p.157). However, a position that recognizes the moral and political importance of social rights but is opposed to giving to courts the power to use these rights to impose the allocation of resources on public authorities is perfectly tenable (see Gearty, 2011; Ferraz, 2011B; similar arguments are raised by Waldron, 2006, p.1366, in regards to rights and judicial review in general). As affirmed by Komesar, people may agree on the goals, but disagree on which institution is better to carry out this goal: "just societies are based not on the announcement of broad principles but on the design of real world institutional decision-making processes and the designation of which process will decide which issues" (Komesar, 1994, p.5; see also pp.94-95).

6.1. The incomplete defense of social rights adjudication

Some authors in favour of social rights adjudication build their theories based on the following premises: (1) social rights and civil and political rights are similar in terms of status, vagueness and they can all generate positive duties in which adjudication may demand resources from the State and, therefore, there is nothing peculiar about social rights that would impair their adjudication; (2) legislatures and bureaucracies' superior institutional capacity and democratic legitimacy to deal with issues or resource allocation *vis-`a-vis* courts is overstated because the political and administrative processes have many shortcomings; and (3) courts, especially if some reforms in the judicial process are implemented, can be more inclusive and correct some deficiencies in the functioning of representative democracy and bureaucracy that end up marginalising some groups and policies from the political agenda.

For the purposes of this thesis, I will call these authors – Mantouvalou, 2011; Nolan, 2011; Nolan at al., 2007; Fredman, 2008; Liebenberg, 2010; Langford, 2008;

Bilchitz, 2009 – "social rights advocates" hereafter[214]. Even though the theory of each author has important differences in terms of theoretical background and the recommendations made, they all share these three assumptions.

In this section, I do not argue that these arguments are wrong or irrelevant in the debate about social rights adjudication. I rather suggest that they are incomplete and make the argument in favour of social rights adjudication stronger than it actually is. The consequence is that these authors end up underestimating many of the trade-offs that should be taken into consideration before advocating that courts should have the power to decide on the entitlements created by social rights and enforce them against the State. In other words, they create a theory of social rights adjudication without a proper theory of judicial restraint.

6.1.1. Similarities between social rights and civil and political rights

Social rights advocates aim at deconstructing the separation between non-justiciable social rights and justiciable civil and political rights. This separation is based on the assumption that social rights, if compared to civil and political rights, are hierarchically inferior, vaguer and their enforcement entail costs. Hence socio-economic rights would make them ill-suited for judicial enforcement.

I will not discuss the first distinction (hierarchy) because social rights have been elevated to the same level as other human rights in several constitutions and legal documents. Even though it can be a philosophically controversial issue, this distinction

[214] I am aware that there are advocates for social rights in general or social rights adjudication specifically who do not share the assumptions of the authors I am collecting under the label "social rights advocates" in this chapter. Here this label refers only to a determined group of authors and should not be interpreted broadly.

is already outdated from a legal perspective. I will neither discuss the second distinction (vagueness) because it is true that most human rights are deliberately formulated in broad and open terms, although, as will be discussed in this chapter, there is the question of which institution should give them concreteness. Hence, only the last distinction (costs) is important for the debate I am addressing in this section.

The argument social rights advocates are responding to affirms that social rights, because they involve positive duties that have costs and which force the allocation of scarce resources with distributional impacts, should not be constitutionalized or, if constitutionalized, should not be justiciable. Civil and political rights, on the other hand, because they demand only negative duties from the State (restraint, non-interference), can be protected by courts without raising the same sort of problems.

To respond to this typology, social rights advocates make use of the already mentioned theory that all rights – no matter if social or civil and political – create duties to respect, protect and fulfil and they also affirm that all the duties – including the negative – have costs. The book by Holmes & Sunstein (2000), in which the authors blur the distinction between positive and negative rights by arguing that the respect for civil rights can only be guaranteed by costly institutions and policies, is commonly mentioned by social rights advocates in this context. For instance, the right to vote depends on the existence of a functioning and well supervised electoral system; the right to a fair trial cannot be fulfilled without an independent judiciary; the right to property entails the existence of a police force and judicial institutions that protect owners against violators. All of them are positive duties and certainly have costs that should not be underestimated.

Thus, social rights advocates' syllogism can be constructed in the following way: if both social rights and civil and political rights may generate costly duties, and there is no objection to courts adjudicating civil and political rights because of cost, then there should therefore be no objection to courts adjudicating social rights for this reason. As affirmed by Bilchitz (2008, p.130), "judicial duties in relation to socio-economic rights will not differ greatly from those they perform in relation to civil and political rights".

This argument would be correct if its purpose was to demonstrate that there is no objection to courts protecting social rights in regards to the duties to respect and protect (or at least it would not be more objectionable than the judicial protection of other rights). As already stated, this is not disputed by those sceptical about social rights adjudication, although it can be questioned whether framing these duties as deriving from social rights creates something really new in the legal sphere or is just putting a new label on rights that were already protected and adjudicated using the language of civil and political rights, administrative law, regulation, family law, criminal law and so on.

However, this is a bad argument if it is intended to show that the judicial enforcement of the duty to fulfil social rights would not be objectionable. In some cases the adjudication of civil and political rights, when they imply the allocation of resources, will raise the same sort of objections as those mentioned in social rights' adjudication. Holmes & Sunstein's (1999) book, *The Cost of Rights*, is actually arguing that courts should be aware of the distributive and economic impacts of their decisions when protecting civil rights. According to them, courts should bear in mind that they

> [A]re not well positioned to oversee the tricky process of efficient resource allocation conducted, with more or less

> skill, by executive agencies (…) Judges do not have the proper training to perform such functions and they necessarily operate with inadequate and biased sources of information (…) Because they cannot survey a broad spectrum of conflicting social needs and then decide how much to allocate to each, judges are institutionally obstructed from considering the potentially serious distributive consequences of their decisions. (Holmes & Sunstein, 1999, p.94-95)

The authors, when mentioning the courts' limited institutional capacity, are not discussing the right to health, housing or education. They are discussing the right to be protected by the State against abuse and their conclusion is that when a case involves the allocation of scarce resources, "courts should be very hesitant to substitute their own judgment for that of executive agencies" (Holmes & Sustein, 1999, p.96). This book, which goes against the idea of "minimal state" ("Why liberty depends on taxes" is the book's subtitle), is in favour of a very marginal role for courts in the allocation of scarce resources.

One case mentioned by Ferraz (2009B) illustrates well the fact that the same dilemmas courts face when deciding social rights cases can also come up in civil rights cases: *R v Chief Constable of Sussex Ex Parte International Trader's Ferry Limited* [1995] 3 WLR 802. In this case, a company that exported livestock was having its commercial activity threatened by a group of animal rights' demonstrators. In order to protect the company's property and employees' physical integrity, the police decided to convoy the company's lorries to the port from which their goods would be exported two days a week. The company, however, expected to have the protection five days a week and filed a lawsuit against the State.

A similar issue was raised in Brazil, where a class action was filed against the government of the State of Parana claiming the police staff in a city was insufficient to

protect the population[215]. This class action demands the State of Parana (in Brazil, the police force is a service provided in the State level) to allocate a certain number of police officers to that city.

These two cases involve the protection of many civil rights (e.g., property, body integrity, life), but because police force is a scarce good, the issues of distributive justice, court's institutional capacity and democratic legitimacy are as relevant as in cases in which courts are expected to decide on the allocation of healthcare or housing.

It is true that the protection of any right has costs, but their adjudication in a concrete case will not necessarily have an economic impact. In most cases involving civil and political rights, the allocative decisions happen at the political level (how much will be spent on the judicial system, regulatory agencies, watchdogs and police force), but its enforcement by courts itself in individual cases may not generate extra costs. It is correct that there would be no right to *habeas corpus* without an expensive functioning judicial system, but a decision granting it to someone unfairly jailed will normally not create extra cost or have impact on the same right for other prisoners. In social rights, on the other hand, when it comes to the duty to fulfil, each decision normally creates an extra cost. Using the economics' terminology, the protection of every right has fixed costs, but judicial decisions ordering the fulfilment of social rights may add significant marginal costs, whereas the judicial protection of civil rights normally produces small or zero marginal cost. When civil and political rights also produce significant marginal costs, then the same concerns about courts distributing scarce resources will rise. Thus, the difference between them is a matter of frequency and intensity in which marginal

[215] On this class action, see the State of Parana Public Prosecutor's Office official website: http://www.mp.pr.gov.br/modules/noticias/article.php?storyid=1770

costs are created by judicial decisions, which may explain why there is the impression that costs in social rights adjudication is an issue whereas in the judicial protection of civil and political rights it is not.

In conclusion, to affirm that social rights and civil and political rights can all occasionally create costly positive duties is correct, but does not undermine the objections raised against social rights adjudication. It only shows that the same objections may be raised against civil and political rights and equally challenge their adjudication in some cases. I am not affirming that courts should refrain from adjudicating a right whenever the judicial decision may have allocative financial impact upon the public budget (on this, see King, 2007). Costs do not trump rights, but judges should consider the questions regarding their legitimacy, institutional capacity and the consequences of the decisions that create public expenditure (this argument will be further developed in section 6.2).

It is noteworthy that the same authors that advocate social rights on the grounds that their nature and structure is not different from civil and political rights, when writing about how courts should decide the cases, expect courts to pay extra attention to the impacts of their decisions and also suggest many reforms in the judicial process to compensate for the court's lack of institutional capacity and democratic legitimacy. Thus, they are somehow admitting that social rights adjudication may demand courts to perform a role that they have not been traditionally dealing with when adjudicating civil and political rights. The question whether courts should adjudicate social rights cannot be answered by just looking at the similarities between social rights and civil and political rights.

6.1.2. The limits of the political process

Social rights advocates also try to address the concerns about courts' lack of institutional capacity and democratic legitimacy by comparing them with legislatures and bureaucracies. They suggest, mostly based on ideas derived from the interest group theory, a more realist approach in relation to how democratic representation and bureaucracies work to understand how distant actual politics are from ideal democratic values. This would arguably make the case for the judicial protection of social rights stronger because not only is the political system imperfect, but also because courts can also compensate for their imperfections[216].

However, when comparing courts with other institutions, they tend to compare how democratic systems work (listing all their imperfections) with how courts should work (listing all their benefits and how the imperfections can be overcome by reforms). This is inadequate because it overlooks the fact that the comparison between institutions is always a choice among highly imperfect alternatives (Komesar, 1994, p.5) and thus the upsides and downsides of all the compared institutions should be considered before attributing the decision on a certain issue to one institution rather than the other.

This failure can be partially explained by the fact that social rights advocates, albeit trying to incorporate interdisciplinary elements in their analysis, overlook the theoretical and empirical literature on comparative politics, social policies, institutions and the welfare state that have already tested and discussed many of the premises that they are simply assuming to be true. This is a mistake that, according to Hirschl (2001, p.209), is commonly made by legal scholars.

[216] Interest group theory has been widely used by legal scholars to make the case for more intrusive judicial review. For a thorough and critical review of this line of reasoning, see Elhauge (1991).

Regarding the political system, some authors affirm that representative democracy tends to become the "tyranny of majority" and to marginalise minorities. Nolan (2011, p.55), writing on children's socio-economic rights, affirms that the political process is vulnerable to failures to include and be responsive to minoritarian groups. According to her, because legislative majorities are under capacity constraints (for instance, the time-consuming nature of the legislative process) and will avoid divisive questions, "there will necessarily be little space for legislative majorities to prioritise rights-based claims advanced by a relatively small minority". Nolan (2011, p.54) also mentions that because the socio-economic status of those who suffer rights violations are different from that of elected politicians, the latter may be less sensitive to the needs and voices of the former.

Mantouvalou affirmed that rights are above politics and thus "[s]ocial rights, like civil and political rights, have a high priority and ought to be removed from political bargaining" (2011, p.108). She also affirmed that legislative and executive representatives, because they are concerned with re-election, may neglect the poor by avoiding unpopular decisions. In other words, they are likely to succumb to "populist pressures" (Mantouvalou, 2011, p.125). On the other hand, in countries where the majority is poor, the country is ruled by small elite that neglects the interests of the poor (Mantouvalou, 2011, p.125).

Bilchitz (2008, p.103) suggests that "there are several reasons for thinking that majority decision-making may be likely in many cases to fail *substantively* to treat the lives of all individuals in a society as being equally important". Once a majority is in power, it "can tend to marginalize minorities in such a way that minorities are effectively unable to express their views and compete for power on equal terms"

(Bilchitz, 2008, p.104). Representatives are often driven "by popularity rather than principle", they tend to reflect the interests of the majority, and they are under the pressure of party leaders, colleagues, friends and lobbyists (Bilchitz, 2008, p.122).

Some social rights advocates criticize representative democracy from the opposite direction, arguing that political representatives are only marginally accountable to their constituency and governments are controlled by interest groups. Fredman (2008, p.35) affirms that "casting a vote in periodic elections gives barely any real participative power to individual voters". Her argument is that democratic governments are actually the product of bargaining and negotiation by interest groups and that the strongest organized interests tend to prevail (Fredman, 2008, p.112). Even though she mentions the risk of majorities overriding the rights of minorities, her argument is that "[d]ecision-making is in practice skewed towards those with power in society" (Fredman, 2008, p. 103).

Langford (2008, p.33), combines the two critics of the democratic system by affirming that the majoritarian democracies - when dominated by a political or social class, corruption or patronage - fail to pay sufficient attention to minorities and that the minority might actually be a "numerical majority". Liebenberg (2010, p.34-35) affirmed that "the official avenues of political representation and participation frequently fail to provide protection for the rights of marginalised groups because legislators and policy makers are 'captured' by interest groups (…) [and] function under the constraints of limited time, resources and bureaucratic pressures".

The fact that these authors present paradoxically opposite views about the reasons for the malfunctioning of representative institutions does not mean that one side is wrong and the other right, rather it suggests that they are all incomplete. According to

Komesar (1994, p.27), democracies are under both opposite tensions: the overrepresentation of concentrated interests (minoritarian bias) and the overrepresentation of dispersed larger interests (majoritarian bias). It is a trade-off between them that is constitutive of a democracy. Majorities, through their greater number, can countervail the force of minoritarian groups. Minorities can oppose the majorities because they have higher stakes and special interests in some issues (Komesar, 1994, p.54). Any attempt to reduce one bias will increase the other (Komesar, 1994, p.220). These biases are not shortcomings of a malfunctioning representative system, but they are rather constitutive of its virtue in terms of flexibility and can guarantee against the hegemonic dominance of either the majority or any minority.

It could be argued that no matter which bias prevails, it will go against poor and marginalised people who have less power to influence political decisions and hence will benefit less from the democratic decision-making process. This seems a common concern among social rights advocates and that is said to legitimate the intervention of courts. However, if social rights advocates argue for a more realist approach towards democracy, then they should have taken this argument further and they should bring empirical evidence to ground their claims.

It is true that democracies in many countries have failed to address the needs of the worst-off. However, this does not allow us to draw a simplistic general principle that the incapacity to address the claims of the neediest is an inherent pervasive shortcoming of democracy. The democratic representative system in some countries has done a better job in dealing with poverty and extreme poverty than others and it is important to understand why some succeed whereas others have failed in tackling social and

economic deprivation. There are so many hypotheses trying to explain why democracies fail to reduce inequality and poverty that just mentioning them would surpass the ambitions of this chapter (for a review of the literature on this topic, see Shapiro, 2003, ch. 5; Keefer & Kenami, 2005). However, there are two hypotheses that are particularly important for the debate on the role of courts in the protection of social rights.

The first hypothesis is that democracies fail to protect social rights because courts do not enforce them. This argument is based on the idea advanced by social rights advocates I have discussed in this section: democracies are unable to give voice to the marginalised groups (minorities or majorities) and the adjudication of social rights is necessary to correct this shortcoming in the representative institutions.

The problem with this hypothesis is that it contradicts the history of the successful welfare states in Europe, which were created through the victory of left-wing parties in the political process (Przeworski, 1986). Even in late democracies, it is not difficult to find representative governments that are supported by the poor and create policies that have a relevant impact in improving their lives.

For instance, in Brazil, the political party currently in government was re-elected twice with massive support from poor people against an opposition mainly supported by the high and upper middle classes (Singer, 2009). During its term in government, the extension of universal policies and the creation of policies focusing on the poor and the extremely poor – the most internationally famous of them being the cash transfer program called *Bolsa Familia*[217] – played a direct role in increasing life expectancy, reducing income inequality and bringing down illiteracy, child mortality

[217] Rasella et al. (2013), in a nationwide research, demonstrated that *Bolsa Familia* had a significant impact in the decrease in childhood mortality, especially for deaths attributable to poverty-related causes such as malnutrition and diarrhea.

and the level of poverty and extreme poverty in the population to unprecedented low levels. The country achieved many of the United Nations Millennium Development Goals and was praised by the representative of the United Nations Development Program as an example for the world in the fight against poverty and inequality (BRAZIL, 2013A; for an economic analysis of the phenomenon in English see Neri, 2009).

Langford (2008, p.33) mentioned Brazil as an example of how the political representation can fail to address the needs of socially disadvantaged groups and this is what, according to him, led to the judicialization of social rights. This argument ignores the importance of the policies aimed at poor people and their massive support for the incumbent government. It also fails to consider that the policies that benefit the poor were not produced by judicialization and in any event, as we have seen in chapter 2, that poor people are not the main beneficiaries of social rights litigation in Brazil (at least, not in the case of the right to health). Hirschl (2011, p.457), when discussing the relation between social rights realisation and democracy, also mentions the case of Brazil, but as an example of a country that alleviated poverty via "targeted government policies" rather than by constitutional reforms or constitutional jurisprudence.

From a cross-country comparative perspective, as demonstrated by Hirschl (2011) and Hirschl & Rosevear (2011), there is no correlation between the level of constitutionalization or justiciability of social rights and the breadth and quality of the welfare state in a jurisdiction. It is not difficult to find countries where social rights are not protected in constitutions or justiciable, but that provide generous social protection for their populations based on an egalitarian conception of social justice (e.g., the nordic countries). Hirschl & Rosevear have also tested the impact of generous constitutions

with great judicial review on different countries in terms of social inequality and the human developed index. Their conclusion is that the impact is "[q]uite negligible" (Hirschl & Rosevear, 2011, p. 223-224).

In sum, the way democracy is portrayed by social rights advocates is theoretically incomplete and can be contradicted by empirical evidence. Democracy is not a guarantee that social inequalities will be reduced and social needs will be fulfilled. However, neither is the lack of social rights adjudication an obstacle for democracies to provide decent welfare protection.

It could be argued that even though it is true that democracies can protect the poor and reduce social inequalities without social rights adjudication, they could perhaps do even better if there are institutions, such as courts, that can correct them when they fail to do so or do it imperfectly. Even if social rights adjudication may not be necessary, they can be a supplement and my argument does not allow us to conclude that their existence is an obstacle for policies aimed at the poor either.

This brings us to the second hypothesis to explain why democracies may fail to reduce social inequality and provide welfare services for the poor: redistribution is more difficult when the institutional arrangement creates a greater number of veto points, which may have the effect of impairing and/or retarding innovative and encompassing welfare policies designed to ameliorate inequalities (Shapiro, 2003, p. 109). Veto point can be defined as an institutional arena with jurisdictional power for political actors to overturn legislation or policies that threaten those actors' interests or objectives (Immergut, 2008; Immergut, 1992, p. 27-28; Taylor, 2006, p.338). They include, for instance, bicameral legislatives, federalist systems, minoritarian parties in coalition governments, referenda, separation of powers and judicial review.

I propose that, in order to have a more realistic account of the courts' role in democracies, it is necessary to see what courts are – veto points – (see Taylor, 2006; Taylor, 2008) and not what we would like them to be – a "voice for the poor", a correct for blind spots and inertia, a promoter of accountability and of responsiveness, a counterbalance to minoritarian/majoritarian bias, an enhancer of participation or an "energizer of the political process". All veto points, including courts, can promote all these functions but it is important to look at what political science has discovered on their actual impact on policies aimed at the poor.

Lijphart (1999) ran a study which included many democracies around the word and found a correlation between less veto points and more encompassing welfare policies. Shapiro, drawing on an extensive literature on the functioning of many veto points, concludes that they limit the institutional capacity to distribute (Shapiro, 2003, p. 110).

Focusing on more in-depth analysis, Ellen Immergut (1992) tried to answer why governments' proposals to create a universal health care system succeeded in Sweden, were partially successful in France and failed in Switzerland. According to her, political parties and politicians in these countries saw national public health systems "as a vivid expression of their distinctive ideological profiles and as an effective means of getting votes" (Immergut, 1992, p.1). On the other hand, interest groups – especially doctors – saw these proposals as a threat to their autonomy and privileged status and income. This conflict was present in all the three countries, but what explains the different level of success of the interest groups against these proposals was the existence of accessible veto points. In Sweden, the parliamentary system gave to the executive dominance over the legislative process without fearing vetoes from the legislative or

other institutions. In France, the executive had less control over a very fragmented Parliament, which was much more open to the influence of interest groups. In Switzerland, interest groups could launch a referendum, in which, historically, legislation and policies were more often rejected than accepted, and thus the Swiss government was forced to withdraw the proposals for more comprehensive reforms (Immergut, 1992, p. 147-148).

The case *Chaoulli*[218], in which the Supreme Court of Canada struck down provisions in Quebec's legislation that banned private medical insurance in this province, opening the path for a two-tier public health system in Canada, is also an example of how interest groups with concentrated interests were able to make use of a veto point against a universal public health system. In this case, however, the veto point was the court and interest groups were speaking the language of rights[219].

Each veto point is a new arena in which different resources will have to be mobilized. For instance, if courts intervene in the field of health care allocation, it will not only be sufficient to mobilise resources in the political sphere (through lobbying, demonstrations, voting etc.), it will also be necessary to defend the same interests in the judicial sphere, demanding a completely different language and resources.

Those who are proposing social change will have to be skilful and resourceful enough to win their battles in these very different arenas. Therefore, the association between more arenas of participation and higher the costs of policy implementation created by veto points should not be overlooked (Taylor, 2008 p.159).

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[218] *Chaoulli v. Quebec (Attorney General)* [2005] 1 S.C.R. 791, 2005 SCC 35

[219] For an analysis of this case and its consequences, see King (2006) and Flood (2006).

Moreover, the fact that a neglected voice was heard at court does not guarantee that those who were heard before (at administrative or legislative level) will now be heard again or their voices given adequate weight. As already discussed, there is an extra burden for those who were benefited by the administrative or political decision and have to defend their interests or present their arguments before courts. Especially in cases of common goods such as universal welfare policies, where the aggregate benefits are vast and dispersed, but costs are concentrated, those who would have been benefited if the original decision had not been reviewed may not even know that they were affected by a veto or may not have the incentives and resources to act. This is a general assumption about the use of veto points that also applies to courts (see Komesar, 1994, p.129; Taylor, 2008, ch.4; Elhauge, 1991, p. 77).

Even if veto points may be overturned by governments, there are always transaction costs in doing so, and these reduce a government's capacity to enact policies and legislation. For instance, if a government desired to overturn a Constitutional Court decision in systems of strong judicial review, it would be necessary to amend the constitution, convince judges to change their minds (for instance, the famous "the switch in time that saved nine" in the Supreme Court of the United States during the New Deal) or wait until new judges substitute for those who made the decision.

It could be asked whether courts, when adjudicating social rights, can be analysed as veto players, since they are not formally blocking a decision, but rather forcing a decision to be made. However, in a context of limited resources and competing interests and needs, any decision ordering the government to do something will be indirectly vetoing the possibility of an alternative use of the same resources. Investing in what was ordered by courts impeaches the government (either the

legislative or the administrative branch) from allocating the resources according to its own preference or criteria. Therefore, when courts force the mobilisation of resources to meet a certain need, they overcome the priority setting formerly planned by the primary decision-maker to a certain extent.

The effect of veto points is obviously two-fold. A political system with many veto points makes more difficult the creation of large welfare states, but can also make more difficult its retrenchment. Governments that concentrate decision-making power and do not have to overcome veto players can cut social benefits more easily, although this can be balanced with that fact that it will also be easier to make them politically accountable to voters because the responsibilities for the decisions will not be diffused across many institutions (Bonoli, 2001). Veto points can be used by those who have lost in the political process to take the dispute to a different arena, and this can be used either by those who want to bar the development of redistributive policies, as well as to prevent these policies from being cut.

In other words, governments facing many veto points - such as courts - will have more difficulties to enact rights-abusive legislation and policies or deconstruct them when they already exist, but they will also find it more difficult to enact rights-protective ones (on this, see Tushnet, 2011, p.302; Fudge, 2001, p.357). This is a trade-off that needs to be considered more seriously when advocating for social rights adjudication and also when discussing the different types of adjudication (see section 6.2).

To conclude, the same interest groups that can bias democratic systems against the poor and marginalized can also make use of litigation. Thus, in order to justify an expansion of social rights adjudication, social rights advocates should do more than just

argue convincingly that the political process produces undesirable outcomes. They need to demonstrate that there is something different about courts and the judicial process that makes them less vulnerable to the same bias they identify in politicians and the political process. This sets the scene for the section that follows.

6.1.3. Idealising what courts are and what they can be

As argued by Komesar (1994) and Elhauge (1991), if analysts want to compare two institutions, it is a methodological mistake to compare how one institution actually works with how the other institution should work. This is what social rights advocates do in order to build the argument that courts should have a major role in reviewing resource allocation decisions: they not only present the problems and limitations of the democratic process, but they also idealise what courts and judges are and what they can become. This is what Vermeule (2006, p.17) called "asymmetrical institutionalism" that creates a "nirvana fallacy" – a "pseudo-institutional analysis" to compare a jaundiced view of one institution with a rosy view of the other.

A heroic view of courts

Sometimes, it is just assumed that courts are the institution that protects social rights. For instance, Fredman, after critically describing how the democratic system works and how exclusive it is, proposes that courts can contribute to strengthening democracy through human rights (2008, p.93):

> Opponents of justiciability argue that if the political system is defective in the extent to which ordinary people participate, the answer is to improve the political system rather than taking away more power from the people and giving it to the courts. However, this is a false juxtaposition. It has already been established that human

> rights and particularly positive human rights duties are essential to protect the basics of democracy, including the socio-economic conditions necessary to ensure substantive equality in the right to vote (Fredman, 2008, p.103).

The same reasoning can also be found in Nolan (2011, p.180- 182) and Langford (2008, p.32), who each affirm that judicial enforcement of social rights is necessary and legitimate because courts have the obligation to protect rights. Nolan argues that

> [w]ithin modern constitutional democracies, the task of reviewing state action for compliance with fundamental human rights is generally assigned to the courts or a similar adjudicative body (…) A judicial refusal to enforce children's socio-economic rights essentially operates to render the elected branches of government, rather than the courts, the ultimate arbitrator of socio-economic rights issues, resulting in a distortion of the roles of the respective institution in a democracy (Nolan, 2011, p.181).

These arguments are begging the question, assuming what they want to prove: courts can adjudicate social rights because their institutional mission is to protect rights. However, whether courts are really necessary to protect social rights, to what extent or if they are the most appropriate institution to do so are exactly the questions in debate, and cannot be just assumed.

There is some level of idealisation about how courts work and what judges are. Firstly, courts are seen as immune to economic, social, political, or collective power and moved only by their professional duty and commitment to human rights (Fredman, 2008, p.106). For instance, Fredman (2008, p.106) affirms that "judges are required to come to the process open to the possibility of being persuaded by one side or the other, and the outcome is often a synthesis of the arguments of both sides".

A similar idea was advocated by Bilchitz, according to whom political representatives make policies driven "by popularity rather than principle" and may not be used to detach themselves from their own partisan interests and personal beliefs. They are focusing on defending their argument, they "fail to give a fair characterization to opposing arguments" and are under the pressure of party leaders, colleagues, friends, lobbyists, media and time-constraints. Courts, on the other hand, decide through deliberation and discussion between judges and are not vulnerable to "the rules of media and politics, which impose hefty time constraints upon debate and encourage emotional and rhetorical flourishes to win debates". In courts, it follows, "detailed and lengthy submissions can be made in relation to complex matters and a careful, reasoned judgment must be written when deciding such matters, forcing judges to articulate clear reasons for their conclusions". Moreover judges "have been trained since their student days to reason about matters of fundamental rights", which "usually involve separating out illegitimate 'personal reasons' from those that can be offered legitimately as a basis of public justification". To conclude, he affirms that "as in most countries, the very definition of a proper exercise of judicial power is that the law be applied 'impartially and without fear, favour and prejudice'" (Bilchitz, 2008, p.121-126).

Courts are also seen as "the guardians of the constitution", the "beneficent agency" to protect the rights of those who are excluded from democracy, given that they "cannot assume that the legislature and the executive will protect their rights" (Nolan, 2011, p.182). As an argument in favour of social rights adjudication, Nolan (2011, p.54) also mentions that because those who suffer violations of their socio-economic have a different socio-economic status from that of elected politicians, the latter may be less sensitive for the needs and voices of the former.

In the same way that broad statements about the democratic system fail to pass a more rigorous scrutiny that takes into consideration the variety of democratic systems and the nuances in their functioning, the description of courts and judges these authors offer is also too general to be regarded as invariably accurate.

The belief that the attitude of judges will be more sympathetic towards human rights protection, the interest of marginalized groups or other altruistic values relies on a simple individual preference of the judge and there is no evidence that their legal training or institutional role will make them more committed to these values and groups than legislators or bureaucrats (see Tushnet, 2011, p. 306-307; Vermeule, 2006, p.258; Waldron, 2009; Elhauge, 1991, p.85; Hirschl, 2007).

Even though it is possible to mention some cases in which courts actually protected groups that were not receiving equal consideration from elected governments (the Warren Supreme Court in the United States and the post-apartheid South African Constitutional Court are commonly mentioned), there is also consistent evidence that courts generally not only fail to protect these groups against oppressive legislation or policies, but also contribute to making their situation worse by blocking redistributive reforms put forward by democratic politics (for an international comparative analysis see Hirschl, 2007). The idea that courts are counter-majoritarian forces is questioned by research that has found that courts tend to reflect the public opinion or the agenda of national political elites (see, for instance, Tushnet, 2001; Graber, 2005; Dahl, 1957; Powe, 2000; Landau, 2012, p.403; Vermeule, 259). At least in the long term, if the political elite or public opinion are mainly progressive, courts will be progressive; if the formers are conservative, so will be the latter.

From the side of politicians, in a culture where human rights are given due importance, voters, media and opposing political parties will give a hard time to candidates whose views and actions show a low level of commitment to human rights in general and to some underprivileged groups in particular. It is also not very difficult to spot in most democracies politicians whose career was built upon the protection of some discriminated groups (women, gays, indigenous groups, handicapped people etc.).

The argument that politicians will be less sensitive to the needs of the worst-off because they will probably come from different socio-economic backgrounds is also very problematic. If it is true that politicians will generally not come from underprivileged classes, the same could be said of judges. In fact, it is probably more frequent to find politicians from underprivileged backgrounds (elected with the support of social movements, communities, trade unions or for personal charisma) than judges, who are necessarily highly educated lawyers[220]. Therefore, it would not be surprising if judges reflect the values of the professional upper-middle class from which they are drawn (Hart, 1980, p.58-59).

Moreover, it is far from certain that courts, when deciding social rights cases, will actually make a more reasoned and detached decision achieved through deliberation (in the sense that they will search for the best argument). Judges have a certain level of political insulation guaranteed by life tenure and other institutional rules, but that does not mean they are isolated from pressure. For instance, as we have seen in cases involving health care in England, courts were under huge pressure from public opinion, newspapers' headlines and patients (see chapter 4). The cases were framed in a

[220] According to a survey by Blackwell (2012), the members of the English judiciary are mainly men, educated in elite schools, from affluent family background with connections to the legal profession.

way that made it very difficult for courts to balance properly the needs of an identified individual human being against the unidentified statistical lives of others competing for the same resources. In this situation, courts (such as in Brazil) applying the "rule of rescue" to avoid being held morally responsible for not saving a life is certainly understandable. Courts, for good or ill, are anything but isolated from interests and the context in which the cases are brought to their decision.

There is also a certain level of idealisation in the image of courts (especially appeal courts and constitutional courts) deciding through deliberation among judges who engage in an intellectual principle-laden exchange and provide thoughtful justifications, in opposition to politicians who decide by aggregating votes that result from interest-laden dispute and bargaining.

No empirical evidence is offered by social rights advocates to support such a general claim about how decisions are made in courts. In order for courts to be a deliberative forum, judges have to honestly engage with opposite views and be open and humble to changing their minds when presented with good arguments. This assumption relies much on the individual characteristics of the judge and may be an inaccurate description of how decisions are made. Judges, like politicians, tend to be strong-willed and opinionated individuals, especially in constitutional courts where their selection is partially based on the opinions they hold on certain topics (Sen, 2013). It is true that because judges have been trained as lawyers, they have learned to hear both sides of a dispute and also to try to make impartial and unbiased decisions based on public principles of justice (as affirmed by Bilchitz, 2008). However, as law advocates, they have also been trained to take sides, to defend a case by presenting their arguments in the best possible way and to undermine their opponent's arguments. Thus, the argument

that courts deliberate better than other branches of government is not very convincing if it has to rely on the individual characteristics or training of judges. As affirmed by Tushnet (2002, p.48), if the incentives for judges to provide reasons for their decisions is the desire to do a good job (given that there is nobody to punish them if they fail to do so), the same could be said about legislators "willing to listen to complaints from constituents and to explain publicly, in newsletters, speeches, and the like, why the legislator does what she does".

The deliberative capacity of courts also has to rely on the courts internal decision-making procedure creating incentives for deliberation (Ferejohn & Pasquino, 2002). In some courts (e.g., the Supreme Court of the US and the Brazilian Supreme Federal Court) each judge issues her own decision (*seriatim*) and the decision of the court will be the decision of the majority. That makes it very improbable that a judge, after issuing her decision, will admit she was actually wrong and change her view because a colleague presented better arguments. A judge has to be very modest and self-confident to admit to the public, peers and the intellectual community that she made a mistake and a colleague did a better job. This may happen, but the incentives to do it are not high and it rarely occurs (Ferejohn & Pasquino, 2002; Afonso da Silva, 2013). The analyses of how the Supreme Court of the US and the Brazilian Supreme Federal Court actually deliberate indicate that the quality of deliberation is very poor (Sen, 2013; Afonso da Silva, 2013), and may not be so different from how social rights advocates describe the deliberative process in parliaments.

Other courts (e.g., the Constitutional Court of Germany) do not issue individual decisions, but just a collegiate decision with dissenting votes, if there are any. This institutional arrangement makes it easier for deliberation among judges to occur because

the discussion happens in internal sessions behind closed doors, making them more open to counterarguments and to acknowledging what they do not know or are not sure about, added to which there is the expectation that they will reach a consensus (Afonso da Silva, 2013). However, all this serves only to make the deliberation in courts less transparent and accessible, both key elements in any deliberative enterprise (Sen, 2013). Because they are less accessible, it is difficult to know whether the judges reproduce "behind closed doors" the poor quality of deliberation found in courts that decide more openly. Sen (2013), based on historical and empirical research, affirms that what makes the decision-making process in the Supreme Court of the US similar to the decision-making in Congress is what happens behind the stage, in inter-chamber conferences and the exchange of private memos: bargaining, lobbying and cajoling.

The comparison made by social rights advocates between courts and bureaucrats is also highly inaccurate. It is sometimes assumed that the overruling of executive decisions by courts would face a less serious barrier than the overruling of legislative decisions, because the former's legitimacy is not so strongly grounded on equal political participation (Nolan, 2011, p. 101). Thus, the democratic legitimacy objection does not apply in the review of administrative decisions. It is also noted that bureaucracies can be: overwhelmed by the amount of work; make mistakes; be biased, inert or indifferent; carry out their duties in bad faith; work under political pressure; lack resources, time, transparency and public scrutiny; and be vulnerable to capture. Let's assume that this is all true, but can't the same be said, in different degrees, about courts and judges? Courts can also be described as bureaucrats deciding cases under constraints of time, information, transparency and expertise, and vulnerable to the influence of interest groups and public opinion (Sunstein & Vermeule, 2002, p.39-40).

Moreover, as I will discuss in the next section, the more courts want to intervene in the way policies distribute resources, the more they will be vulnerable to the same problems that administrative bureaucracies face, but without having the capacity to achieve the same level of expertise.

The idea that courts are impartial, detached from external pressure, decide matters based on reason, deliberation and commitment to high principles, reproduces the classical theory advocated by some constitutional law scholars that separate politics (aiming at immediate results, bargains, compromises; captured by interest groups and with no duty to give reasoned explanation in one side) and adjudication (above the normal political dispute and based on reason and principled appraisal) to deal with the counter-majoritarian difficulty of judicial review (for a description and critical analysis of these theories see Graber, 2002, p.323).

This separation, as already seen, not only lacks empirical evidence but it is also harmful for the legal scholarship because it promotes what Graber called "constitutional ignorance". It forecloses the interdisciplinary dialogue between legal scholars and social scientists who inquire about what courts really do by looking at them as political agencies, making political decisions and embedded in a political context (Graber, 2002; Shapiro, 2002).

According to Sunstein & Vermeule (2002, p.3), the idealised view of courts by legal theorists ends up creating a "heroic picture of judicial capacities and, as a corollary, a jaundiced view of the capacities of other lawmakers and interpreters, such as agencies and legislatures". This characterization of the institutions is not grounded on evidence and creates a "radically incomplete" institutional analysis" (Sunstein & Vermeule, 2002, p.22).

When it comes to social rights, this opposition between courts, on one hand, and politicians and bureaucrats, on the other, is even more obscure. Speaking from a different context, but one which perfectly applies to social rights, Kennedy (2004, xxiii) described the difficulty of those using the language of law and rights to accept that when advocating in favour of universal values to defend certain groups or policies, they are making distributional choices among winners and losers. This kind of decision requires "pragmatism of consequences", which takes legal professionals into the terrain of politics. To avoid this uncomfortable situation, human rights experts try to resolve conflicts and ambiguities "on the basis of a process of 'interpretation'" which they claim to be different from, and more legitimate than, politics and by "fetischiz[ing] the judge as someone who functions as an instrument of the law rather than as a political actor" (Kennedy, 2004, p.22).

The problem with social rights realisation is not interpretative, but budgetary, because it is a dispute among competing interests and needs, and any decision implies denial, negotiation, compromise and balancing (Waldron, 2010). As alerted by Griffith (1979, p.15), "[o]ne danger of arguing from rights is that the real issues can be evaded. What are truly questions of politics and economics are presented as questions of law".

Social rights (or a bill of social rights) do not settle the policy disagreements and distributive dilemmas about the allocation of resources in social care. No matter the interpretative technique to find out whether social rights in concrete cases have been violated by the non-provision of a certain good or service and whether this violation should now be judicially redressed, – proportionality/balancing (Contiades & Fotiadou, 2012; Alexy, part 9), reasonableness (Young, 2012, p.127) or minimum core (Bilchitz, 2008) –, courts aiming at identifying the substantive content of social rights and the

extent of the State's duty to fulfill need to make the same kind of analysis that is expected from legislatures and bureaucrats when deciding on the allocation of scarce resources. They have to consider the public interest, economic efficiency, administrative appropriateness, social causality, competing values and needs, principles of distributive justice and so on.

One of the consequences of the use of the language of rights to translate the benefits expected from a policy is that "[f]rom providing limits to administrative and bureaucratic discretion, rights became dependent on it" (Koskenniemi, 2010, p.49). The conflict of rights becomes a representation of the social conflict to access scarce resources (Shapiro & Sweet, 2002, p.180; Wesson, 2012) the solution of which depends on resources and skills that will normally be rarer in courts than in the primary decision-makers whose decisions are scrutinised by judicial review.

If an idealised view of courts fits uncomfortably in the judicial function as traditionally known, it is even more problematic if courts go through some reforms to overcome the problems of institutional capacity and democratic legitimacy to adjudicate social rights. Social rights advocates expect that to the virtues of ideal courts can also be added the benefits of making the judicial process more open and with improved capacity. In the next section, I will explore the contradictions in these ideas.

Reforming courts and the judicial process

Reforms to the "traditional judicial function" are also suggested by some social rights advocates to respond to the argument that courts lack expertise, knowledge and technical information to deal with complex and polycentric issues that can be raised in cases regarding social rights. The suggested reforms include courts specialised in social

rights; judges trained in social rights and socio-economic issues who can acquire expertise through on-the-job experience; and a more open and participative judicial process in which courts can receive information from other sources apart from the litigants, their lawyers and witnesses (via wide standing rules, amici curiae, public hearings, court-initiated fact finding, special inquiry committees, and research bodies with court appointed experts) (see Nolan at al., 2007, p.14-15; Nolan, 2011, p.195; Mantouvalou, 2011, p.118; Langford, 2008 p.36; Fredman, 2008, p.107-108) .

The critique that courts lack democratic legitimacy is also addressed by the proposal of more open and participative judicial process, coupled with legal aid, less complex language, the permission to anyone acting in the public interest to bring an action, and a simpler and more accessible procedure. Apart from bringing more information to courts, these reforms would, it is said, compensate for the lack of democratic legitimacy caused by the non-representativeness of judges by promoting deliberative and participative aspects of democracies, especially for voices excluded from the legislative and executive arenas.

A final set of reforms are aimed specifically at allowing courts to guarantee the enforcement of their decisions. It is suggested that courts can issue structural interdicts and complex mandatory orders that with "careful phrasing and the inclusion of a good level of detail in an order may reduce the likelihood of non-implementation" (Nolan at al. 2007, p.18; see also Liebenberg, 2010, p.74). Courts can also give themselves supervisory jurisdiction with the possibility of requiring periodical reports on the implementation of their decisions; create structures to monitor the implementation of judicial orders; and delegate to appointed individuals, experts and bodies the task of supervising the implementation of the decisions.

The **first problem** with the argument that courts and judicial systems can be reformed and thus be in a better position when compared to the other branches is that the comparison is between what bureaucracies and legislatures *are* vis-à-vis what the judiciary *can be*. Fredman (2008, p.93) argued that the response to a defective political system is not its reform. Nonetheless, as seen in the last section, different democratic political systems lead to different levels and kinds of participation; and different levels and kinds of participation lead to different policy outcomes.

Social rights advocates normally neglect the fact that the decision-making process in the legislative and administrative branches can also be reformed and improved. Some initiatives in the legislative and administrative branches are identical to some reforms suggested for the courts. Public hearings and public consultation to stakeholders and specialists can and do occur during the legislative process. The administrative process can also be made more open, transparent, accountable, participative and scientifically more sophisticated. The NICE in England and CONITEC in Brazil analysed in this thesis are only two examples among others that could be cited. Thus, a good comparative institutional analysis should compare what the courts and judicial process can be when reformed with what the administrative and legislative branches can achieve if certain reforms are made.

A similar argument to the one I am elaborating here was made by King (2008A, p.114) when discussing the idea that a theory of deliberative democracy would support judicial review:

> why should a theory like deliberative democracy support hard remedies (like striking down statutes) instead of stronger participation rights at the legislative and administrative stages? And on that point, the mechanisms provided in those stages on some views compare quite favourably with judicial procedures

Acknowledging this will allow us to understand the contribution courts can give when adjudicating social rights via the judicial control of policy-making procedures, as will be discussed in Section 6.2.

The **second problem** is that the suggested reforms to make courts open for broader social participation and better equipped to deal with social policy issues will actually transform them into quasi-legislative or quasi-executive powers. Instead of an arbiter of a dispute responding to the claims of opposite parties, the adjudicative role will be intertwined with roles that are more similar to those of policy makers responsible for assessing the public good and the interests of a plurality of parties (Allan, 2003, p.196-198).

As affirmed by Koskenniemi (2010, p.54), because the conflict of rights is a conflict of interests between right holders, it "will push human rights experts [and judges] to participate in increasingly detailed and technical analyses of economic efficiency, security, administrative appropriateness, and social causality relating to the alternative patterns of distribution". Thus, the better courts carry out this activity, the more they will resemble policy-makers.

However, I have already discussed elsewhere (see Section 3.1.2) how it would be improbable that a judge (or a court), even when trained and assisted by a group of specialists, would have the same capacity as those in the ministries and secretaries of government with expertise, training, experience, structure, time and other resources specifically designed to deal with these issues. Bureaucrats and politicians may obviously make bad decisions because they are biased, captured, had access to partial data, had a wrong understanding of facts etc. However, the same could be said about

judges and their teams. In order to argue that courts should create a parallel bureaucracy to order structural injunctions and supervise the implementation of their orders, it should be demonstrated that this bureaucracy under judicial auspices would be at least as good as the governmental one it has to supervise and less vulnerable to the same problems that may affect any bureaucratic body.

Additionally, a court trying to resemble administrators or legislators will not only be a less capable copy of either of the latter, but it will also reproduce the defects that social rights advocates identify in them. The more politically influential courts become, the more likely stakeholders will try to influence judicial decisions. The politicization of the judiciary is the flip side of the judicialization of politics (Hirschl, 2012, p. 319; Ferejohn, 2002, p.64; Rios-Figueroa & Taylor, 2006, p. 377; Elhauge, 1991, pp 81-83). If specialized courts and supervisory bodies under the auspice of courts are created, the risk of capture of and political influence on courts increase. Administrative agencies are especially vulnerable to capture because they are fixed targets and there are incentives for interested parties to invest time and resources to influence their decisions (Komesar, 1994, p.140). For the same reason, specialized courts and their staff may face the same problem and this would inevitably jeopardize the institutional detachment that is arguably one of the main advantages of the judicial process. There is a trade-off between courts' independency and accountability (Rios-Figueroa & Taylor, 2006, p. 377) that social rights advocates commonly overlook when they advance ideas of making courts more participative and responsive to social needs.

To transform courts into a deliberative forum (via public hearing, amici curiae and so on) also brings the problem of (a lack of) representativeness that affects legislatures or any other deliberative forum. If the court decides who participates, then

there is the problem of which criteria should be applied to select participants and how representative they (public interest lawyers, non-governmental organizations etc.) are in relation to those whom they claim to represent. When courts have the power to decide the third parties who can participate in a legal process, there is the risk that the selection of participants will reflect "preconceived ideas of the critical interest at stake" (Allan, 2003, p.197). Therefore, there is the problem regarding the protection of the interests of those who do not participate, either for lack of resources, representation, information or incentive because the benefits of a policy are too diffuse (as in the case of common goods such as universal social policies).

Moreover, there is the risk that those in a deliberative forum themselves become an elite claiming legitimacy to speak in the name of groups or the "public interest" but without being accountable themselves (Urbinati, 2010, p.74). And there is no reason to believe that the socio-economic or political power differences that affect participation and influence in the political system and bureaucracies will not be reinforced by law and adjudication (Fudge, 2001, p.357; Elhauge, 1991). These are problems that any legislative or deliberative body has to face.

Finally, it is important to highlight that the idea of deliberative democracy, that inspires some social rights advocates, comprises not only an inclusive and free discussion grounded on convincing public reasons, but also that the resulting state action be responsive to such deliberation (Zurn, 2007, p.69-70). Therefore, even assuming that courts can overcome all these participatory issues, there is no guarantee that courts will understand the issue before them correctly, give proper weight to all participations or take into consideration all the information brought to them (Elhauge, 1991, p.84). When there is a large amount of conflicting data and interpretations of

complex facts, there is the risk that judges "may cherry-pick from available studies to support a foregone conclusion" (King, 2012, p.242). The outcome of the dispute (the judicial decision) may not reflect the deliberation about it and judges cannot be punished for not grounding their reasons on the views of participants (Tushnet, 2008, p.94).

For instance, the Brazilian Supreme Federal Court, in its judgements post-public hearing, did not deliberate on most of the 50 opinions that were presented on that occasion. It just picked a few contributions to set some criteria that, as I argued in Chapter 3, did not consider some of the most important aspects of the issue. Moreover, in these decisions there was even a factual mistake: the Court affirmed that most of the healthcare litigation is driven by claims for drugs already included in the pharmaceutical policy and hence courts were not creating policy, but rather just enforcing it. As saw in Chapter 2, however, this conclusion is against the existing evidence. Finally, in recent decisions the Court has simply ignored the discussions during the public hearing and decided as if the right to health were a "trump" and policy considerations were negligible (see Chapter 2).

In sum, the more courts look like legislative and administrative bodies, the more they will have to face the same difficulties as those confronting the latters, coupled with the problems due to their own institutional limits.

It could be argued that a quasi-legislative or administrative judicial process does not have to be superior to the decision making in legislature and public administration, so long as it adds a new layer in which the decisions can be reassessed and mistakes of the primary decision makers can be corrected. However, it is important to note that the virtues of courts' assessments do not merely aggregate to those of the

administrative or legislative level. The advantages of the political and administrative decisions may be simply undermined by decisions of reviewing courts which reverse decisions from the political and administrative sphere based on a different source of evidence or opinion (Davis, 1971; King, 2012, p.114; Vermeule, 2009, p.50). As formulated by Vermeule (2009, p. 50):

> Suppose that we have a well-specified many-minds argument, (…). Still, the superior epistemic judgments of many minds may simply be unusable by the legal system. The problem is that those judgments will at some point have to be funnelled or refracted through the judgments of a much smaller group, perhaps a single mind, and this will result in a kind of *epistemic bottleneck*, or chokepoint. The judgments of many minds may be the input to a decision-making process, but if the structure of that process requires or allows few minds to accept or reject the many-minded judgment, or even just to interpret it, then the resulting decision may be little better than if the one mind had simply decided for itself, right from the start.

The **third problem** is that the more open the court, the less time it will have to be an ideal forum of principles, reflection and deliberation. The idea that courts have plenty of time to decide upon cases is far from uncontroversial, since courts tend to be characterized by overload: there are normally more claims than there are institutional resources for the proper adjudication of each (Poole, 2005, p.716). It may be correct, though, when applied to courts that have broader discretion to choose the cases they want to hear and thus have control over their workload. For instance, in the Supreme Court of the United States, in 2011, more than 7,000 lawsuits are filed per year but less than 1% received permission to be argued (Supreme Court of the United States, 2012); in the Administrative Court of England and Wales in 2006, only 22% of the 3,390 applications for judicial review that reached the leave stage were granted permission to proceed (Bondy & Sunkin, 2009). In both countries it was noticed that while there was a

steady increase in the number of cases that were filed in the last decades (McLauchlan, 2005; Bondy & Sunkin, 2009), courts were able to control the impact of the increase on their workload by using their discretionary power to choose the cases to be judged.

On the other hand, the Brazilian Supreme Federal Court (STF) had no discretionary power to choose the cases to be judged based on their substance until 2004, when the 45th Constitutional Amendment allowed the court not to hear a case if it had no "general repercussion". Because the "general repercussion" rule applies to only one sort of appeal ("Recurso Extraordinário") and the STF has jurisdiction to judge many other kinds of legal actions, even after this Constitutional Amendment the STF judged 80,730 cases in 2012, a figure that impresses any analyst of the court.[221] In Colombia, citizens can file a legal action called "*tutela*" when they have their constitutional fundamental rights violated. This action can be filed informally (orally or via telegram) without the need of a lawyer, has a summary procedure and has to be decided by the court within 10 working days starting from its filing. As a result, 405,359 "tutelas" were filed in Colombia in 2011. It does not matter if the decision in the lower courts grant the "tutela" or not; the case has to go to the Constitutional Court, which then has the power of *certiorari* to decide which cases to analyse. In 2011, the Constitutional Court heard 629 cases (0.15% of the total) (Defensoría del Pueblo, 2012).

The examples I mention here are designed not only to show that the workload of courts differ according to the rules of the legal system, but that there is a trade-off between more accessible courts and their capacity to decide cases without time-constraints and in a deliberative and attentive way. If the procedural rules make courts

221 Data available in the Supreme Federal Court's official website. For a brief description of the functioning of the Brazilian constitutionality control system in English see http://www2.stf.jus.br/portalStfInternacional/cms/verConteudo.php?sigla=portalStfSobreCorte_en_us&idConteudo=120199. For a more analytical description see Verissimo (2008).

very accessible (e.g., the Brazilian Supreme Federal Court), then they will probably be overloaded by an enormous amount of cases and one could question the capacity of judges to reason carefully and deliberate properly with colleagues before deciding them. On top of that, if it is also expected that courts be open to the participation of interested parties and specialists (via amici curiae, public hearings etc.), issue detailed structural injunctions and be responsible for supervising the implementation of the decision, then the capacity of courts to judge carefully an enormous workload is even further jeopardized (see Landau, 2012).

On the other hand, if the power of *certiorari* is used to allow courts to choose the cases they want to judge according to their own rank of priorities (see Vermeule, 2006, p.269), then one could question whether the power of agenda setting in social policies should be given (even if partially) to courts, which have less democratic legitimacy and institutional capacity to make this kind of decision when compared to the other branches of power. Especially in countries with serious social problems in almost all areas (housing, education, health care etc.), if all the people in need have an equal chance of reaching courts, and judges are expected to decide carefully, deliberate and take into consideration the opinions of all interested parties, then the judicial system would be overwhelmed to the point of collapse or forced to filter out complaints according to their own perception of what are the most important demands that should receive their attention.

6.2. Typologies of social rights adjudication

In the last section I discussed the argument advanced by social rights advocates that the problems of courts' democratic legitimacy and institutional capacity in social rights adjudication are overestimated or can be overcome through reforms in courts and

judicial process. I argued that adjudication is not a form of decision-making that is above politics, and that courts should be analysed as just one institution, among others, available to solve problems (on this, see King, 2012, p.150).

This does not deny the potential benefits of adjudication, such as promoting accountability and participation; demanding transparency and justification; reviewing discriminatory and abusive decisions; guaranteeing procedural fairness; and correcting unfairness in concrete cases. However, these potential benefits have to be considered without idealizing courts and judges. They have to be compared with those of other institutions, grounded on evidence and weighed against the problems of institutional capacity and democratic legitimacy that cannot be underestimated or believed to be attenuated by reforms without creating different sorts of problems.

It is true that social rights advocates recognize courts as secondary decision-makers that should be aware of the risks implied in social rights adjudication (see, for instance, Nolan, 2011, p.191-192; Fredman, 2008, p.109; Bilchitz, 2008, p.132). This point is invariably explicitly stated, but not further developed. This creates either a mismatch between premises and conclusions of the arguments; or recommendations that are developed to be applied by ideal judges because give significantly more weight to the benefits that can be expected from adjudication, rather than to the judicial fallibility and the systemic impact of judicial rulings. Using a spatial metaphor, the theories of social rights advocates are very clear about where courts should go, but much less so about when and why they should stop. I consider this a serious flaw in these theories because a good theory of social rights adjudication should encompass a good theory of judicial restraint (King, 2012, p.121).

This chapter is based on the premise that judicial review is justified when either the reviewer can do better than the reviewed or when the former has a different capacity or is in a different position that can make the decision of the latter better. This is why the kind of enforcement applied by courts matters. The dichotomy abdication/usurpation (Michelman, 2003) provides a very good framework to analyse the dilemma courts face when they have to decide cases regarding social rights. Nevertheless, a more nuanced assessment of what courts do is necessary to balance the potential benefits of litigation on one side and, on the other, courts' institutional capacity and democratic legitimacy, their fallibility, and the limits, potential and risks of the different ways social rights can be judicially enforced.

I suggest here a typology of the different types of judicial enforcement of social rights and analyse each type in terms of (1) courts' institutional capacity and legitimacy; (2) the direct benefits for the litigants; and (3) the direct benefits for those in the same situation but who did not participate in the judicial process.

Drawing on Jeff King's (2012) work, I consider that courts' institutional capacity and legitimacy will be inversely proportional to (i) the democratic pedigree of the decision, as long as it does not ignore a rights issue and does not address the rights of someone belonging to marginalized group (King, 2012, ch.6); (ii) the polycentric impact of the decision in terms of the number and diversity of interests implicated, and the depth and breadth of the impact (King, 2012, ch.7; see also King, 2008B); (iii) how much the resolution of the issue depends on technical competence, large amounts of data and interpretation of complex social science evidence (King, 2012, ch.8); and (iv) the need for flexibility for responding to unforeseen information or developments (King, 2012, ch.9).

By “direct benefit for litigants” I mean the capacity of the decision to change the *status quo* in which the claimants’ right is considered violated. The “direct benefits for those who are in the same position as the claimant” is the capacity of the decision to deliver benefits not only to those who litigate, but also to a certain class of people who are in the same situation (in terms of the need for a certain social provision) as the claimant. I emphasize the idea of “direct” benefit because social rights adjudication can have “indirect” benefits (for instance, see Brinks & Gauri, 2012; Hoffman & Bentes, 2010, Prado, 2013), but they are generally less predictable, circumstantial and difficult to analyze and interpret, especially if long term effects are considered (see Tushnet, 2012; Kapiszewiski & Taylor, 2012). The cases of Brazil and England in this thesis (see particularly Chapters 3 and 5) have shed light on the relevance of the indirect effects of litigation, but the lack of data on the systematic and long term indirect effects of litigation in other jurisdictions do not allow broader comparisons.

To build a typology of the judicial enforcement of social rights is certainly not a new idea and the one I propose here draws heavily on the work of David Landau. Landau (2012, p.413) identifies four types of remedies in social rights adjudication: individualized enforcement, negative injunction, weak-form enforcement and structural enforcement. Each type is classified according to the following variables: legitimacy/capacity costs for courts; effectiveness at changing practice and likely beneficiaries. His conclusion is that individualized enforcement creates low costs for courts in terms of legitimacy/capacity, does not alter bureaucratic behavior and benefits middle and upper class groups; negative injunctions create moderate legitimacy/capacity costs for courts, strike down laws but maintain the status quo and benefits middle and upper class groups; weak-form enforcement has low

legitimacy/capacity costs for courts, will not cause any change and thus nobody will benefit; lastly, structural enforcement creates high legitimacy/capacity costs for courts, may alter bureaucratic practice and may target lower class groups.

I do not use Landau's typology as a whole because (1) negative injunctions (for instance, decision to strike down cuts in pensions for public servants) are not analysed in my thesis, which (as we have frequently seen) is only about demands for positive obligations to fulfill; (2) I consider that individual enforcement creates high legitimacy/institutional capacity costs for courts; (3) I do not analyse legitimacy/institutional capacity costs but legitimacy/institutional capacity *tout court*; (4) remedies like those applied by English courts when controlling the procedure of health authorities, which I call procedural enforcement, do not fit in his typology; (5) I do not analyze the beneficiaries in terms of social class but in terms of impact on litigants and those who are in the same condition as them; (6) I narrow the analysis of effectiveness to consider short-term benefits, given that, as already mentioned, long term-impacts of litigation are mainly indirect and more controversial to measure.

I organize my typology and the variables in the Table 2 below:

Table 2 – Types of judicial enforcement of social rights

	Institutional capacity and legitimacy	*Benefit to litigants*[222]	*Benefit to others in the same situation*
WEAK STRUCTURAL ENFORCEMENT	**HIGH**	**LOW**	**LOW**
STRONG STRUCTURAL ENFORCEMENT	**LOW**	**HIGH**	**HIGH**
INDIVIDUAL ENFORCEMENT	**LOW**	**HIGH**	**LOW**
PROCEDURAL ENFORCEMENT	**HIGH**	**HIGH**	**HIGH**

The attempt to build a typology to weigh the upsides and downsides of each type follows the advice of King (2012, p.8), who criticizes theorists who develop highly theoretical arguments and try to fit in a few decided cases, "instead of showing how that argument can function predictably in the hands of real judges". The typology is also important because it should allow us to distinguish our support or critique to a particular decision and our opinion about a certain type of adjudication. Every type can produce outcomes that we may agree or disagree with, but the point in this chapter is to identify the characteristics of each type in order to understand how they operate and the likely consequences that can be expected from their application.

6.2.1. Weak structural enforcement

By structural enforcement I mean a model of adjudication in which the cases are not decided as a dispute between two parties, but by thinking in prospective terms with a view to putting forward a far-reaching reform that aims at affecting a multiplicity

[222] Or those people petitioners want to benefit, in cases of public interest litigation.

of parties and taking into consideration an “array of competing interests and perspectives” (Fiss, 1982, p.123).

It is sometimes suggested that the problem of courts’ institutional capacity and legitimacy to adjudicate social rights is overestimated because courts do not necessarily have the last word. The idea of weak remedies is ubiquitously mentioned to make the point that there is no significant risk that courts will take over the power to decide on the allocation of resources in welfare policies because they will not have the last word on the issues. The power of courts to act as veto points (see section 6.1.3) is reduced because it is easier to overturn a weak enforcement than a strong structural enforcement decision.

In weak forms, courts can point out blind spots and burdens of inertia (Dixon,2007) and propose changes, but primary decision-makers have the possibility of, without much cost, responding to courts and possibly revising the judicial decision if they find it mistaken (Tushnet, 2008, p.23). Among weak structural remedies can be included declaratory decisions and a requirement that the State develop plans aimed at eliminating the violation of rights within a reasonably short but unspecified time period, with high discretion in terms of implementation and with light oversight on those implementing it (Tushnet, 2008, p.248).

These weak remedies are not aimed at providing “personal and present” benefits (Tushnet, 2008, p.242). It is expected that judicial decisions will promote dialogue and deliberation among branches of government and among government and other stake-holders rather than concluding the discussion on the provision of social

rights. The case *Grootboom*[223] in South Africa is commonly mentioned as an example of a weak form of social rights enforcement: the Constitutional Court simply declared that the government's policy was inconsistent with the right to housing of those in urgent need but did not enforce coercively a change in the housing policy against the State (Tushnet, 2008; Dixon, 2007; Sunstein, 2001). The decision also used somewhat subjective concepts such as the government's duty to take "reasonable" measures toward the "progressive realization" in order to protect people living in "intolerable conditions" (Kapiszewski & Taylor, 2012).

Even though weak enforcement raises fewer objections regarding courts' legitimacy and capacity when compared to strong enforcement, the downside is that it may not accomplish much. Weak forms are criticized for providing very limited benefits to litigants and failing to protect the social rights of poor people (Nolan, 2011, p.234). According to Landau (2012, p.404): "[s]ystematic failures in both legislative and bureaucratic politics in developing countries make dialogic approaches unlikely to work in those countries—the intended recipient of the dialogue is unlikely to respond effectively". If the government fails to give effect to the decision, courts have no enforcement power to make the expected change happen (Dixon, 2007; Nolan, 2011, p.211) and the lack of more concrete outcomes can discourage people from approaching courts claiming that their social rights are being violated (Brand, 2003, p.52-53)

Even though I present weak and strong remedies (strong structural remedies will be discussed in the section below) as ideal types, in practice they are opposite poles of a continuum. As analysed by Young (2012) when presenting her typology of social

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[223] *Government of the Republic of South Africa and Others v Grootboom and Others* [2001] (1) SA 46 (CC)

rights adjudication, there are many possibilities in between these poles. Instead of analyzing each of them, I intend to emphasize the trade-off between weak and strong remedies. The more a remedy goes closer to what I call weak review, the less problematic it will be in terms of institutional capacity and legitimacy, but the less direct benefits can be expected from it. On the other hand, the closer they are from strong remedies, more direct benefits can be expected, but the less institutional capacity and legitimacy courts will have to do it. No matter where a structural remedy stands in the continuum, this trade-off will be felt.

If we expect courts to have more "teeth", then we have to accept that they will have power to force the implementation of their decisions when the government fails to comply with them by not providing the judicially ordered benefits. On other hand, if we expect courts to be aware of their limitations, then we may want to reduce the costs for the other branches of government of disagreeing with them.

6.2.2. Strong structural enforcement

Strong structural enforcement occurs when courts issue orders for the realization of concrete changes in a certain policy or the enactment of comprehensive programs. This may happen via robust remedies such as structural injunctions, complex and detailed mandatory orders that can establish the goals to be achieved for the State, mechanisms for monitoring administrative authorities' compliance with the judgment, periodical reports about the implementation of the order, and the possibility of finding public authorities in contempt of court if they fail to do so.

In strong remedies, the court itself defines the level of fulfillment of a right that is constitutionally required and makes a very tight and continuous oversight of its

ruling's implementation (Tushnet, 2008, p. 233). In contrast with weak forms, even though the public authorities may have some flexibility and there may be dialogue between them and courts, courts have the final say about the goals and the adequacy of means (Nolan, 2011, p.210). Young affirms that strong judicial review tends to coincide with ideas of minimum core or a substantive justiciable minimum (2012, p.85).

The following description of the Indian Supreme Court by Fredman (2008, p.129) describes what a court using strong remedies looks like:

> The Indian Supreme Court has not only used mandamus to issue detailed directions to States or the central government of India to implement its orders, it has also developed the remedy to give it ongoing supervisory powers, using the device of interim orders and 'continuing mandamus', which keep the case open and require ongoing reporting to the Court on the extent of compliance. Litigants and interested parties return to the Court periodically, generally every two to three months, to report on implementation and request new orders, allowing flexibility as circumstances change. Commissions appointed by the Court are also given the responsibility of supervising implementation, and report regularly to the Court. This makes it possible for the Court to frame far-reaching, forward-looking remedies which can include structural changes, and then to supervise progressive implementation. All of this is backed up by the contempt power, which the Court is not loath to use, even against high-profile government or elected officials.

There are different levels of strength, depending on how intrusive the judicial decision is and how much flexibility is given to the authorities to comply with it. Some authors suggest that courts should make allocations in the budgetary level. For instance, Bilchitz (2008, p.132-133) suggests that in order to respond to the problem of an insufficient budget to fulfill the basic needs of the population, a court can

> [S]end the policy back to the executive for a reallocation of resources that meets the priorities in question. It may on occasion be able to ascertain that there are already sufficient resources in the coffers such that competing needs would not be prejudiced by an order requiring the provision of some service. In other cases, it will have the power to pronounce upon a clear mis-allocation of resources and order that this be remedied.

The examples of strong structural remedies in social rights come from the Constitutional Court of Colombia and the Indian Supreme Court. The experience of strong structural remedies in these countries in terms of effectiveness is mixed but, when compared to weaker forms of remedies, they seem to be more effective in inducing change and therefore benefiting litigants (or, in cases of public interest litigation, those people petitioners want to benefit) and others in the same situation as them (Landau, 2012, p.406; Pillay, 2010, p.82; Fredman, 2008; Young, 2012, p.204; Parmar & Wahi, 2011, p.182).

Strong remedies tend, however, also to exacerbate the concerns about courts' capacity and legitimacy (Young, 2012, p.406). They are more difficult to overturn by a government that disagrees with their decisions. Moreover, their compliance tends to involve the allocation of huge amounts of resources from public budgets and may affect a great number of people, which raises the problem of giving to courts the power to decide how scarce resources should be spent and who should benefit from this expenditure. Designing or supervising policies demand a lot of information and expertise, a high amount of resources from courts in terms of time, personnel and money, and the consequences of the decision on all the interests affected are uncertain. According to Pillay (2010, p. 92), one of the problems with social rights litigation in India is that courts failed to consider the implications of their decisions.

It is important to highlight that even the most perfect procedure – perfect information, full participation and decisions made by ideal decision-makers under ideal conditions – will produce outcomes with which reasonable people will disagree and which may have unexpected or improbable backlashes. Thus, strong structural enforcement raises the problem of lack of flexibility: once the court establishes a program, then it may be difficult for the government to withdrawn or redesign it, even if future evidence shows that it has more disadvantages than benefits or that the costs do not justify the gains.

There is also a question of courts' political will and the available political capital for imposing strong and interventionist measures on the governments and accepting the burden of judicial overreach and public and political backlash (Young, 2012, p.192; Landau, 2012; Ferejohn, 2002, p.66; Kapiszewski & Taylor, 2012). Courts may pick some cases, invest all their time, energy and political resources, and point to the beneficiaries to show that strong remedies delivered good results. However, it is highly questionable if courts will have all these resources to make these kinds of decisions systematically, oversee and guarantee governments' compliance with them, for the wide range of social problems in which it is possible to claim that social rights are being violated (Landau, 2012, p.458; Young, 2012, p.198). As affirmed by Landau when analyzing the structural injunctions by the Constitutional Court of Colombia (2012, p.437):

> The Court is a fairly small institution, and each case has required a large amount of time of some of the judges and law clerks, and (…) the hiring of additional staff. It would be difficult for the Court to perform more than a few of these structural interventions at any one time.

Lastly, it is not difficult to make one or a few successful policies and sporadic achievements prompted by strong judicial enforcement when budgetary limits are not an issue because resources are diverted to it. However, it would be necessary to go beyond isolated cases to analyse whether this model is replicable so as to encompass a wide array of structural and social problems given the impact of these costly judicial decisions on the policy as a whole and the opportunity costs of complying with them. The choice is hardly between courts doing something *vs.* nothing being done, but between courts doing something *vs.* the alternative use of the same resources. The impact of the strong structural decisions, because they involve significant allocation of resources and impact on many interests, cannot be assessed only by looking at those who benefit by winning cases.

6.2.3. Individual enforcement

Individual remedies are those in which courts decide that the State has the obligation to provide a certain benefit claimed by an individual plaintiff/claimant grounded on their interpretation of a social right. It is by means of an individual remedy that courts in Brazil (see chapter 2) and some other Latin American countries (see Yamin & Gloppen, 2011) normally decide health care litigation cases. An individual remedy is also what Mr. Soobramoney was expecting from the South African judiciary in *Soobramoney*[224]. Elements of an individual remedy were also present in cases decided in England: *Ross*[225] and *Gordon*[226], in which the Court decided that a treatment

[224] *Soobramoney v Minister of Health, KwaZulu-Natal* [1997] ZACC 17, 1998 (1) SA 765 (CC), 1997 (12) BCLR 1696 (CC)
[225] *R v West Sussex Primary Care Trust ex parte Ross* [2008] EWHC B15 (Admin)
[226] *R v Bromley NHS Primary Care Trust ex parte Gordon* [2006] E.W.C.A. Civ 392

should be provided before the results of the health authorities' reappraisal were known; and *Watts*[227], in which the High Court considered that the patients' need should be fulfilled in spite of others in the same condition waiting in the queue.

The compliance with individual remedies tends to be very high because normally what is claimed by an individual will be affordable and will not demand significant changes in public policies. Thus, an individual remedy will have lower political and financial costs for courts, lower budgetary and policy implications for the government and the claimant will benefit. This may give the impression that such an individual remedies should not raise concerns regarding the courts' capacity and legitimacy.

This is a false impression because, as the case of Brazil shows, the aggregate effect of the decisions can be massive and the overall result is to make policies less fair. As discussed in Section 6.1.3, even if courts try to take into consideration the implications of individual remedies and make a more comprehensive analysis of the problem about which it is deciding, it would be very difficult for courts to assess the obligation to provide a specific good for a specific individual *vis-à-vis* the needs of others, the resources available, the opportunity costs and the most rational and fairest way to allocate resources.

Even though litigants will be benefited, the massive number of individual remedies will have widespread impact that cannot be controlled or foreseen by courts. Moreover, it creates injustice between those who can litigate and those who cannot, despite having the same needs. The direct benefits of individual remedies create a two-tier welfare system, one for those who can litigate and have access to almost whatever

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[227] *R v Secretary of State for Health ex parte Watts* [2004] EWCA Civ 166

they need and another for the rest of the population, which will have a much more limited basket of services and goods. And this basket is probably smaller because resources are diverted to benefit those on the upper tier.

Lastly, if there is a problem of access to justice, then an individual remedy will be even more unfair because it will directly benefit only those who have information and resources to litigate (normally the better-off citizens), albeit the impact on the whole will be small. If there is easy access to justice, even though more people will go up to the upper tier, the impact will be greater and affect more severely those who did not litigate.

Both individual and strong structural enforcements raise problems of courts' legitimacy and capacity because they are costly to be overridden by the government and can hardly be said to fit the idea of dialogue between branches of government. Dialogue presupposes a relation between equals (Cross, 1999, p.1308), but individual and strong structural enforcements are better described as a "command and control" hierarchical relation. Although there may be some space for negotiation about the content of the command and the intensity of the control, it is still courts that have the last word that is very costly to reverse.

6.2.4. Procedural enforcement

The idea of procedural enforcement suggested in this section is inspired by the English health care litigation case-law after the case *Child B*[228]. In this type, courts control the reasonableness of the procedure through which the decision was made to assess whether it was transparent, participative, grounded on good evidence and

[228] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

reasons, based on fair principles of justice and decided by accountable decision-makers. If not, then courts quash the decision and order the policy to be remade through a corrected procedure.

The role of the courts in this model of procedural enforcement would be similar to the one advocated by Habermas (1996), Zurn (2007) and Dyzenhaus (2012). According to their theories, a legitimate role of courts would not be to substitute judicial moral and political opinions for those of the political branches. It would be rather to scrutinize the procedure and reasons through which these decisions were made and guarantee adequate conditions for a fair decision making procedure (on the same line, see Sunstein, 1996; Nino, 1994)[229].

In procedural enforcement, courts do not engage with the question of whether the non-fulfilment of a certain need of the litigant or if a certain level of provision of welfare services violate a social right. Thus, they do not need to balance the need of a claimant against those of others and hence do not need to take into consideration the polycentric implications of its fulfilment on the public budget and on other competing priorities.

In sum, the procedural enforcement of social rights requires courts to do what they have done in administrative law. For this reason, compared to other types of social rights enforcement, the control of procedure raises fewer concerns about courts' capacity or legitimacy. The benefits are also very concrete. Since the decision has to be remade, the litigants can benefit if the reviewed decision had deprived him or her of a

229 All these four authors develop their theories within the framework of deliberative democracy. However, I believe that role they propose for courts as guarantor of the adequate procedure can suit any theory, even if its account of what an adequate procedure is does not fully subscribe to the idea of deliberative democracy advocated by these authors.

benefit that they should have received if it were not flawed. Apart from the litigants, once the quashed policy is remade, it applies to all people in the same situation.

In this procedural enforcement model, the case is decided on the administrative level rather than on the constitutional level. Thus, there will be more flexibility to adapt the decision to changing circumstances. This is called the principle of constitutional avoidance (on this see King, 2012, p.281), according to which, under circumstances of serious uncertainty, courts should prefer to decide cases on non-constitutional rather than constitutional grounds.

It is important to remark that the control of procedure does not mean judicial abdication, in the sense that a *carte blanche* will be given to public authorities. This is a confusion made by Young (2012, pp.392-395) who argued that the decisions of the case *Soobramoney*[230] and *Grootbom*[231] were examples of "deferential review". In her theory, the "deferential review" means that "the Court intervenes only when it detects a clear legislative mistake—one "so clear that it is not open to rational question". In the mentioned cases, courts were deferential (*Soobramoney*[232]) to and did not impose an obligation to (*Grootboom*[233]) the primary decision-maker, but did so only after the reasons and choices of the government were scrutinized. The deference in these cases was not for reasons of authority, like in the cases *pre-Child B*[234] in England, but for epistemic reasons – the courts found they were not in the best position to order the

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[230] *Soobramoney v Minister of Health, KwaZulu-Natal* [1997] ZACC 17, 1998 (1) SA 765 (CC), 1997 (12) BCLR 1696 (CC)
[231] *Government of the Republic of South Africa and Others v Grootboom and Others* [2001] (1) SA 46 (CC).
[232] *Soobramoney v Minister of Health, KwaZulu-Natal* [1997] ZACC 17, 1998 (1) SA 765 (CC), 1997 (12) BCLR 1696 (CC)
[233] *Government of the Republic of South Africa and Others v Grootboom and Others* [2001] (1) SA 46 (CC)
[234] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

provision of housing or dialysis (on the difference between deference for epistemic reasons and for reasons of authority, see King, 2012, p.136; see, also, Kavanagh, 2008, p. 192). Her description of "deferential review" fits better in the cases decided before *Child B* in England, whereas the "control of procedure" I am analysing in this section is inspired by the cases after *Child B.*

It is also important to distinguish weak structural enforcement from procedural enforcement. For instance, Sunstein (2001) mentioned *Grootboom*[235] as an example of a weak remedy, affirming that it was decided using "the ordinary material of administrative law, governing judicial control of administrative agencies: a requirement of reasoned judgment, including reasonable priority-setting". *Grootboom*[236] is correctly labeled as an example of weak review, but its "weakness" is not due to the kind of analysis made, but to the remedy: a declaratory order. A procedural enforcement would have to pass through the same analysis, but the remedy would be stronger: a quashing of the impugned decision and an order that it be remade with the corrections pointed out by the court.

It is true that procedural enforcement, depending on how it is applied, can be similar to a strong structural remedy. When courts expect authorities to act synoptically - that is, "to set clear policy priorities, consider all possible alternative rules to achieve those priorities, gather all the relevant facts, and adopt the rule that had the very best chance of achieving the chosen priorities in light of the facts" (Shapiro, 1992, p.186) -, then they may indeed be putting themselves in a position to second-guess administrators making decisions and, depending on how strict the scrutiny will be, as a result they can

[235] *Government of the Republic of South Africa and Others v Grootboom and Others* [2001] (1) SA 46 (CC)
[236] *Government of the Republic of South Africa and Others v Grootboom and Others* [2001] (1) SA 46 (CC)

reduce administrators' range of discretion to an extent that practically pre-determines the outcome of the policy (Shapiro, 1992, p.188).

Procedural enforcement can also come close to an individual remedy. For instance, English courts consider that health care rationing cannot have the form of a blanket ban for a treatment, with the judges insisting that exceptional circumstances have to be considered (see chapter 4). However, every person is different from others somehow and if the concept of exceptionality is taken very broadly, it can be used to benefit patients with treatments that are not available to others in very similar clinical situations. In these cases, a concept of exceptionality can be used to treat one patient (the litigant) differently from others with the same condition (Ford, 2012).

6.3. Health care rationing and the right to health

This section connects the debate about social rights adjudication to the discussion about health care litigation and right to health specifically. Judicial control of welfare policies can deliver many benefits (promote accountability, demand transparency and justification; review discriminatory and abusive decisions; guarantee procedural fairness; correct unfairness in concrete cases; demand justifications etc.), but a more realistic account of what courts and judges are and what they can become in comparison to the legislative and the executive should be taken into consideration. Therefore, considering the trade-offs involved in different types of social economic rights enforcement, I propose that the procedural enforcement is the best way to adjudicate the right to health.

In Brazil, courts decide health care litigation mainly via individual enforcement. The consequence, as already seen, are: unequal access to care; low quality of evidence; massive budgetary impact on the public health system; and significant

interference in the allocation of resources by the public health system. It has also kept rationing implicit by forcing the health authorities to apply the "rule of rescue", rather than allowing rationing to be more explicit about why and how decisions about the allocation of resources are made. Thus, instead of creating fairness via "accountability for reasonableness", health care litigation's direct impact was to foreclose it.

The reforms proposed by the judicial branch to build courts' institutional capacity and to self-establish some criteria to decide on the individual provision of health care would keep the final decision regarding the content of the right in the judicial level by bringing the deliberative and technical aspects of the decision to the judicial process, and this is not the best solution from a comparative institutional perspective.

The Federal Law 12.401, that creates the National Health System Commission for the Incorporation of Technologies (CONITEC), aims at moving health care litigation in Brazil from an individual enforcement model to the procedural enforcement model by improving the technical and deliberative aspects of the decision-making process in the administrative level.

The experience of England after the Child B case, where procedural enforcement became the prevalent way in which courts chose to oversee rationing decisions made by health authorities, is evidence that such an approach is capable of protecting the interest of patients against decisions that are not based on a fair procedure, good evidence and fair principles of justice, but without attributing to courts functions for which they are ill-suited when compared to other institutions. Litigation has created incentives for making health authorities more accountable by forcing decisions to be more "explicit about why and how" and by having had this impact these

cases have contributed to the creation of the National Institute for Health and Care Excellence.

Procedural enforcement, however, also raises some risks. The first is the already mentioned possibility that, depending on how it is applied, it may become similar to a strong structural or individual enforcement. Especially in cases in which authorities have to decide under uncertainty, when relevant information is non-existent or too costly to obtain, there is the risk that courts may "demand the impossible" by expecting the provisions of reasons when they cannot be supplied and hence overturn administrative decisions for lack of rational grounds (see, for instance, Vermeule, 2013, p.20; Mashaw, 1985). As seen throughout this thesis, decisions under uncertainty are common in health care policies and an over demanding judicial scrutiny would open the way for more incisive judicial enforcement of rights in health care litigation, even when courts themselves would not be able to do a better job. Harlow & Rawlins (2009, p.124) argue that this is what the English Court of Appeal did in *Rogers*[237], namely, the Court obliged the health authority to reconstruct the decision in a way that "made an answer favourable to the appellant virtually inevitable".

Moreover, procedural enforcement creates a trade-offs between making the governments' choices accountable on the one hand and, on the other, expecting them to make prompt decisions or to make more decisions. Apart from the fact that judicial review may delay administrative action, especially if the administrative decision is quashed and a new policy has to be set, there is also the risk of what has been described as "ossification". Because authorities know their decisions can be strictly scrutinized by

[237] *R v Swindon NHS Primary Care Trust, Secretary of State for Health ex parte Rogers* [2006] EWCA. Civ 392

courts, they will “play defense” and spend a lot of time and resources to make each aspect of what they determine defensible before courts and trying to use in the administrative level the same tests that courts may apply to scrutinize their decisions. This can be very time and resource consuming especially when it is not clear what courts are expecting in terms of justification and the reasons they may accept (Cross, 1999, p.1280; Cross, 2000; McGarity, 1992). The following excerpt of the document *The Judge Over Your Shoulder* (TSOL, 2006, p.21), a guideline for public servants in England advising them on how to make decisions that can survive judicial review, is a good reflection of this tension:

> Failures of consultation (and indeed other lapses in due process) usually occur through inadvertence on the part of the decision-maker; because he is in a hurry; and so on. When such a lapse forms the basis of a challenge to the decision, the decision-maker may be tempted to say: "But it was an open and shut case. Consultation [or an oral hearing; or full disclosure of reasons] would have made no difference. The decision would inevitably have been the same." That may well be true, but the Court is unlikely to be sympathetic to such a response. And for good reason: the principle is that only a fair procedure will enable the merits to be determined with confidence, and must therefore come first.

Finally, procedural enforcement, if successful, can also frustrate the expectation that litigation provides a forum for the worst-off to call into question decisions from health authorities. Even though health authorities will have the burden to prove that their decisions have been based on good evidence, the assessment of the evidence provided by the authorities can be too complex for anyone but specialists. Not surprisingly, after the creation of NICE in England, pharmaceutical companies and associations, who have resources to afford specialist advice, emerged to the forefront of health care litigation rather than individual patients.

Thus, I do not idealize procedural enforcement. It can deliver all the benefits of the judicial control of public policies, but it also has downsides. My argument is that it is preferable when compared to the other types of judicial enforcement of social rights discussed throughout this thesis but particularly in this chapter.

However, what is the relation between procedural enforcement and the right to health? Does procedural enforcement strip the right to health of any meaning or utility? Drawing on the discussion by Norman Daniels about the human rights approach to health (Daniels, 2009, p.328-330), I suggest a concept of right to health to be applied by courts when judging health care litigation cases that can fit the idea of procedural enforcement: the right to health is the right to access a healthcare system in which resources are distributed according to a fair process, which includes duties of transparency, use of adequate evidence and principles of justice, participation of stakeholders, and accountable decision-makers. This connects the idea of right to health with the idea of accountability for reasonableness.

Therefore, courts can enforce the "regulative condition" in the framework provided by Norman Daniels and Charles Sabin (Syrett, 2011B; Syrett, 2002). In their theory of "accountability for reasonableness", the function of the regulative condition is to ensure that the other conditions that make a decision making process fair (publicity, relevance and revisability) are met. This role is be assigned to an independent agent and, I argue, it can be performed by courts. The adjudicative process and the expertise of courts in controlling procedures and rules can be used to make sure that decision-maker abide by the rules that make the allocation of healthcare fair (Daniels, 2009, p.133).

I am not saying that the right to health should have no substance, since politicians, international organizations, moral philosophers, public health specialists and

legal scholars can propose and debate what they understand should be protected by the use of the language of rights. What I argue is that this substance should not be for courts to define and use as a parameter to judge whether a certain allocation of resources violates someone's right to health. If courts want to "fill" the right to health with substance (for instance, by determining a minimum core for the right to health or the use of proportionality) and enforce via individual remedy or strong structural orders, then they will have to consider the resource limits and the needs of others that can also be translated into the language of rights (Daniels, 2008, p.332).

Thus, the problem of the conflict between different right to health holders is "structurally very similar to the one of priority setting in health care" (Daniels, 2009, p.315). In other words, courts would have to do what we expect policy-makers to do when setting priorities for healthcare, albeit being ill-suited to do so when compared to the other branches of government. Nonetheless, via procedural enforcement, courts can make sure that accountable legislatures and health authorities do it fairly, through a procedure that is transparent, participative, accountable, based on good evidence and on fair principles of justice.

The concept of "right to health" that I propose here fits uncomfortably in those theories that expect rights to act as moral trumps which allow courts finding the essential values against which public policies are to be confronted, defining the entitlements on a concrete case based on a general principle, or establishing the priorities among various needs competing for resources. However, I propose that this concept of right to health suits the idea that rights are "second-order considerations", reflecting concerns about the decency and integrity of the political and administrative system (Poole, 2005, p.712-713; see, also, section 4.3 in this thesis). This concept

would also be in accordance with the idea that the right to health care is not only about the right to certain outcomes, which I argue should not be determined by courts, but also concerns a transparent, participative and non-discriminatory process (Hunt & Backman, 2008, p.9; Potts, 2008), which can be judicially controlled.

As stated by Hunt & Backman (2008, p.14):

> Should the Government build a new teaching hospital, establish more primary healthcare clinics, strengthen community care for people with disabilities, improve sanitation in the capital's slum, improve access to antiretrovirals, or subsidise an effective but expensive cancer drug? Human rights do not provide neat answers to such questions, any more than do ethics or economics. But human rights require that the questions be decided by way of a fair, transparent, participatory process, taking into account explicit criteria (…)

In sum, this is a concept of justiciable right to health that is especially suitable to deal with common goods, such as a public health care system, because it does not disconnect individual interest (or the interest of some groups) from those of the community and gives to courts a role that they are institutionally capable to perform.

If we accept the concept of right to health as the right to access a health care system in which resources are distributed according to a fair process, then we will reach the interesting conclusion that English courts are contributing to protecting the right to health, even though there is no constitutional right to health, and that they are doing this by forcing health authorities to prove that decisions were made in a fair and accountable way; whereas Brazilian courts, albeit having the recognition of the right to health as a constitutional right, are actually harming it by creating an unfair access to a health care system that is, consequently, made less fair.

6.4. Conclusion of the chapter

In this chapter I have connected the analysis of health care litigation in Brazil and England with the literature on social rights adjudication as a route to proposing a concept of right to health that can be applied by courts to deliver the benefits of judicial review while raising fewer objections about courts' institutional capacity and legitimacy.

I have argued that part of the literature on social rights, that of what I have called the social rights advocates, tries to justify social rights adjudication by overestimating courts' capacity in comparison to other institutions, and that this has resulted in theories of social rights adjudication which have not had an adequate account of judicial restraint.

To respond to the objections that social rights have costs, their argument is structured on the premise that social rights are not structurally different from other civil and political rights because they can all create costly duties. Thus, the adjudication of social rights would not be so problematic since the same institutional capacity and legitimacy that allow courts to adjudicate civil and political rights can be transferrable to social rights. The argument can be organized in the following syllogism:

P1: Civil and political rights and social rights create costly duties;
P2: There is no objection to civil and political rights adjudication for cost reasons;

C: There is no objection to social rights adjudication for cost reasons.

I have argued that even though the first premise is correct, the second premise is incomplete because in some cases courts should not adjudicate civil and political rights for the same reasons that they should not, in some ways, adjudicate social rights:

when adjudication can create significant marginal costs and there is another institution with more capacity and legitimacy to allocate scarce resources.

To respond to the critique that courts lack institutional capacity and legitimacy to adjudicate social rights, we have seen that social rights advocates have invariably proposed a comparative institutional analysis that is however methodologically flawed because they have been comparing the limits and problems of the legislative and executive branch with the idealized virtues of the judiciary. Their argument is also based on an almost "heroic" view of what courts and judges are and what they can become, as if adjudication was above the mundane political process and the protection of social rights did not imply a decision on competing interests in a context of scarce resources. Their conclusion is a not sufficiently critical approach to social rights adjudication.

A comparison based on evidence shows that the intervention of courts is not only far from necessary for democracies desiring to address the social needs of the poor and marginalized citizens, but it can also make social transformation more politically costly because courts can be used as veto points.

The critique to these general assumptions about social rights, the political process and courts does not aim at defending a sphere of non-justiciability for complaints about the provision of health care that would give to health authorities a "immunity from the obligation to comply with fundamental rights" (Allan, 2011, p.112; see, also, King, 2007). It aims rather at allowing a more nuanced analysis of the limits, risks and potentials in social rights adjudication. I developed a typology of social rights adjudication to compare strong structural, weak structural, procedural and individual

enforcements in terms of courts' capacity and legitimacy to make this kind of decision and the benefits for litigants and those in the same position as them.

My conclusion is that procedural enforcement, applied by English courts in health care litigation cases and which the Brazilian Federal Law 12.401/11 aims to implement, is a type that is comparably less objectionable in terms of institutional capacity and legitimacy and can deliver benefits for both litigants and others who may also benefit from the change in a certain policy. Procedural enforcement relies on the judicial application of the right to health as the right to access a public health system in which resources are distributed in a fair way, i.e., through a process that is transparent, participative, based on adequate evidence and fair principles of justice, and decided by accountable decision-makers.

7. Conclusion

Let's imagine a health policy with the following features. First, treatments are provided without previous analysis of their effectiveness or safety. Even in cases when there is evidence not recommending the treatments, this is not a reason to impair its provision. In other words, scientific evidence plays almost no role in this policy. Second, the treatments' cost-effectiveness will not be assessed either. The price of the treatment and its affordability in comparison to the benefits it can deliver are not relevant. Thus, the efficiency in the public spending – treating more people, and possibly better, with the same amount of resources – is ignored by this policy. Third, there will be no public procurement. The suppliers can basically charge the price they want and the authority has no room for negotiation because they cannot refuse to buy it. Fourth, a very significant amount of the health budget will be allocated to this policy. Fifth, the distribution of beneficiaries in this policy will not be made according to any coherent theory of distributive justice in health, but according to an individual's capacity to find a lawyer and litigate, a capacity which is possessed by a small part of the population, one that happens to have more resources, information or the support of NGOs and pharmaceutical companies. Finally, health authorities have no discretionary power concerning the implementation of this policy nor are they able to debate its choices with the stakeholders possibly affected by it. No matter if other needs are more urgent, the wish of elected representatives or other stakeholders, or the possibility of better alternative use of the resources, the health authorities will have to implement this policy, and immediately. Health authorities can only act reactively, which means, they cannot make any plan for the implementation of this policy, but only follow orders from

a group of public servants (judges) whose job is basically to receive demands from those who can reach them via a lawyer.

From any perspective this would be a bad policy and would never fulfil the criteria of a fair public health system that I am using in this thesis, i.e., one in which distributive decisions are made by accountable authorities through a procedure that is transparent, participative, based on good evidence and reasonable principles of justice. However, as I argued in Chapter 2, this is how Brazilian courts are allocating a significant amount the public resources when enforcing the right to health as an individual entitlement to receive healthcare provided by the State.

In Chapter 3, I argued that it is difficult to envisage how courts willing to enforce social rights individually could do a better job, even when better trained or assisted, as proposed by the responses put forward by the Brazilian judicial branch. It is true that one of the indirect consequences of litigation has been to force health authorities to improve the quality of their decisions via a new institution – the CONITEC – and an administrative procedure that tries to create a more open, transparent, accountable and scientifically robust administrative procedure to decide on the provision of new health technologies. This is an important step for making the Brazilian public health system fairer and was prompted by the overwhelming impact of many thousands of health care litigation cases on the public health system. However, this is far from suggesting that courts were doing the right think when these cases were decided without taking into consideration the consequences of their decision. Things did not have to become so bad in order to make rationing more explicit "about why and how".

As the example of the English case-law shows, there were alternatives that could have led to the same result without the drawbacks I have pointed out in the analysis of the Brazilian case. In Chapter 4, I showed that English courts case-law in health care litigation moved from a very deferential approach to rationing decision made by health authorities, when "Wednesbury unreasonableness" was the prevalent test, towards one, after *Child B*[238], in which courts started to demand health authorities to demonstrate that their decisions on the general policy as well as its application in individual cases were based on fair reasons and procedures. I explained this move by the changes that were occurring in the English legal system and culture and, more specifically, in the institution of judicial review: the affinity between the incorporation of the language of rights and the demand for reasons from public authorities.

I argued in Chapter 5 that this significant turn in the case-law contributed to making health care rationing in the NHS more explicit "about why and how". Health authorities started to change the way their decisions were made in order to meet courts requirement for a more transparent and reasoned decision-making process. The progression towards explicit rationing "about why and how" culminated in the creation of what is now called the National Institute for Health and Care Excellence (NICE), based on the framework of accountability for reasonableness developed by Norman Daniels and Charles Sabin (NICE, 2008). A more explicit rationing, in its turn, has brought more legitimation to rationing decisions, which can explain a narrower scope of health care litigation and the reduction of the onus of proof that health authorities have to fulfil to defend their policies in courts or the transfer of this onus to claimants.

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[238] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

English courts approach to health care litigation after *Child B*[239], which translates the language of rights and a more pro-active role of courts into the practice of administrative law's control of procedure, has established a sensible approach to the judicial review of rationing decisions. As I argued in Chapter 6, this approach leaves the decisions on the allocation of scarce resources to health authorities, who, from a comparative institutional analysis perspective, have more capacity and legitimacy to make decisions that are fair (in the sense proposed in this thesis). At the same time it holds health authorities accountable for their decisions but without giving to courts the responsibility to decide on the provision of healthcare in concrete cases based on general principles. It gives courts mechanisms for enforcing the "regulative condition" in Daniels & Sabin theory of "accountability for reasonableness", namely, making sure that health authorities will do their job properly, i.e., they will decide through a procedure that is open, transparent, based on acceptable evidence and principles, and allows the challenge by interested parties.

Based on this analysis of the role of courts and on the theoretical framework of "accountability for reasonableness", I proposed that courts should apply the right to health as the right to access a healthcare system in which resources are distributed according to a fair process, which includes duties of transparency, use of adequate evidence and principles of justice, participation of stakeholders, and accountable decision-makers. This account of the right to health expects from courts what they have capacity and legitimacy to do well: analyse "second-order considerations", reflecting concerns about the decency and integrity of the political and administrative system. Instead of aiming at being the deliberative themselves and trying to reach substantial

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[239] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

decisions, courts can rather guarantee the adequate conditions for a fair decision making procedure (see Habermas, 1996; Zurn, 2007).

The English courts' model of adjudication in health care cases can be applied to social rights adjudication in general. It is one that can provide all the benefits of judicial review without demanding from courts more than what they can offer if compared to other decision-makers and reducing the risk of courts creating unfairness by adjudicating social rights. Although the problem of ossification and the risk that procedural enforcement grows into an individual or strong structural enforcement model need to be recognised, this approach provides a good balance between "adjudication" and "abdication", and avoids the pitfalls of trying to transform courts in quasi-legislative or quasi-administrative institutions.

It could be argued, nonetheless, that such an approach to social rights' adjudication would give rights and courts no "teeth", in the sense that judicial review will be unable to be the route to question public authorities when social rights are not met. My response would be that the English case shows that this approach has the potential not only to benefit litigants in concrete cases, but can also contribute to enduring and overarching changes in the way rationing decisions are made by public authorities. Given that public services (health care, education, housing etc.) are common goods, making them fairer, in the sense used in this thesis, brings concrete benefits to all that benefit from its services. This expectation while ambitious is realistic.

It is important to remark that this thesis does not idealize the rationing scheme in England. There are problems such as the uneven implementation of the guidelines and the lack of capacity on the part of NICE and local authorities to assess the enormous number of treatments available (see Chapter 4). Moreover, a more explicit health care

rationing and the creation of NICE did not, and were not intended to, close the debates about rationing and neither avoided criticisms about rationing decisions (see Section 5.1.2). Syrett (2003, p.743) is correct to affirm that

> Those seeking to apply lessons learned from the example of NICE—whether to publicly or privately funded health care systems—may therefore be led to conclude that, notwithstanding attempts to address the problem through mechanisms designed to secure independence, accountability, and participation, the legitimacy of decision makers who set health care limits through technocratic means will continue to be called into question.

Even a scheme in which the reasons and procedures to ration healthcare are more explicit will never make the tragic choices about the allocation of scarce resources in health care uncontroversial. However, the quality of the controversy is raised to a higher level in terms of evidence, reasons, principles, participation and accountability, and this tends to make the decision more legitimate and the outcomes fairer.

The creation of CONITEC in Brazil is an attempt to nudge Brazilian courts towards the direction followed by English courts after *Child B*[240]. This thesis argues that this is a sensible response to health care litigation in Brazil in light of the description of the mutual relation between litigation and rationing in England described in Chapter 5 and if compared to the alternative approaches discussed in Chapter 3 (the responses put forward by the National Council of Justice and the Supreme Federal Court) and in Chapter 6 (strong structural, weak structural and individual enforcements).

It is important, nonetheless, to follow up on how Brazilian courts will take into consideration the decisions of CONITEC. In England, courts have scrutinized NICE's decisions, but have granted them legitimacy. English courts became more deferential to

[240] *R v Cambridge Health Authority, ex p B* [1995] 2 All ER 129, [1995] 1 WLR 898

health authorities' decisions for epistemic reasons and not for reasons of authority. This is what the Brazilian government expects to happen with CONITEC, but the success of this policy will depend on whether courts will be willing to be deferential for epistemic reasons or will prefer to judge the right to health an individual trump against rationing decisions. In England, it was reasonable to expect NICE to be accepted by courts because this institution provided what courts were demanding: a public procedure in which decisions were based on good reasons, principles and evidences, and one in which interested parties could participate and challenge decision makers. In Brazil, however, it is not clear that courts will be willing to change the way health care litigation cases are judged, even though a new scheme for the assessment of health technologies is in place. Courts may keep judging the right to health as an individual trump or try to emulate, at the judicial level, an optimal administrative procedure that can be better accomplished by agencies like CONITEC. This is a question to be answered by future research.

Future research should also pay attention to the reforms put forward by current Coalition government in the United Kingdom which raised concerns that the explicit rationing scheme in which decisions are made through a public and transparent process is being deconstructed in favour of a regime of implicit rationing (see, for instance, Nelson III, 2011, p. 212). The government proposed, in 2010, to remove NICE's power to decide that drugs should not be provided based on cost-effectiveness determinations (Nelson III, 2011, p.267-268), although this plan was eventually removed from the 2012 Health and Social Care Bill. The government also created the Cancer Drugs Fund to provide cancer treatments that are not routinely provided by the NHS, namely, those whose cost per QALY are above NICE's thresholds, creating a loophole in the health

technology assessment system that may be widened if patients suffering from other diseases successfully claim the same benefit. Moreover, the transfer of the power to make allocative decisions from PCTs, (which have been abolished) to physicians or consortia of physicians in "clinical commissioning groups" also raises concerns about the capacity of the latter to ration health care explicitly. Physicians in clinical commissioning groups may not have the same expertise as PCTs to decide on the provision of health care in an explicit ("about why and how") way and, on top of that, there may be confusion between the duties of the doctor to do the best for her patient and the need of the health system for efficient resource allocation, and this may in time undermine patients' trust in their doctors (see section 5.1.1).

As already mentioned in this thesis, to remove an explicit rationing scheme will not eliminate the need for rationing, but will rather force it to be more implicit. England may be risking a return to a model of implicit rationing which, apart from being unfair, has already proved to be unsustainable, especially if courts continue expecting health authorities to provide consistent reasons for decisions not to provide health treatments. Depending on how this process will unravel in the next years, perhaps the England I describe in this thesis will also be a good model for England itself in the future.

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