Courts and health care rationing: the case of the Brazilian Federal Supreme Court

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Abstract: The recognition that access to health care is a constitutional right in Brazil has resulted in a situation in which citizens denied treatments by the public health care system have brought lawsuits against health authorities, claiming that their right to health was violated. This litigation forces the courts to decide between a patient-centred and a population-centred approach to public health – a choice that forces the courts to assess health care rationing decisions. This article analyses the judgments of the Brazilian Federal Supreme Court in right to health cases, arguing that the Court’s recent decisions have been contrary to their long-standing stance against rationing. In 2009, the Court organized a public hearing to discuss this topic with civil society and established criteria to determine when rationing would be legal. However, I argue that these criteria for health care rationing do not adequately address the most difficult health care distribution dilemmas. They force the health care system to keep their rationing criteria implicit and make population-centred concerns secondary to individual-centred ones.

1. Introduction

The Brazilian Federal Constitution declares that the right to health is a fundamental right of all and a duty of the State (articles 6 and 196). Furthermore, the Constitution established a public health care system based on the following principles: universality of access – no one should be excluded from the coverage of the public health care system; equality of access – no discrimination between citizens regarding access to the system; and comprehensive coverage – the system should cover everything from basic to complex health treatments.

The declaration of health as a fundamental right and the creation of a public health care system entitled those who do not have their health needs fulfilled to file lawsuits against the State claiming a violation of their fundamental right to health. These lawsuits seek funding from the public health care system for the cost of an individual’s treatment.

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The exponential growth of right to health litigation in Brazil in the past decade, coupled with the very high rate of claimants’ success against the State, has created a phenomenon called the ‘judicialization’ of the right to health. This phenomenon has provoked a number of academic and legal debates, and creates challenges for health authorities in the public system as well as for the courts.

The challenge for the courts is that legal cases generally involve problems of commutative justice (rules concerning the transition of fair transfers and exchanges) and retributive justice (rules concerning crimes and punishments), whereas deciding about what the public health care system should offer to citizens is a matter of distributive justice (rules concerning the allocation of scarce goods in society).

For health authorities, the ‘judicialization’ of the right to health presents challenges, because judicial decisions may oblige the health care system to offer medicines or treatments that are expensive, not cost-effective or even ineffective. Empirical evidence shows that these kinds of demands are far from uncommon (Vieira and Zucchi, 2007; Afonso da Silva and Terrazas, 2011; Chieffi and Barata, 2009).

Some also argue that judicial interference in public health expenditure not only introduces inefficiencies, but also creates inequalities among citizens (Newdick, 2004: 103; Ferraz, 2009). Recent work shows that citizens living in districts with higher incomes are overrepresented among the beneficiaries of right to health litigation, making access to health care in the public system less egalitarian. Further, a considerable number of those citizens who can afford private health insurance (23.4% of the population) have pressed the courts for state funding for treatments that are either not covered by insurance or are too expensive for out-of-pocket payment. (Vieira and Zucchi, 2007; Afonso da Silva and Terrazas, 2011; Chieffi and Barata, 2009; Wang and Ferraz, 2010).

The conflict between health policymakers and the courts is a conflict between those who are expected to have a population-centred approach to the right to health – concerned with the prudent allocation of shared resources and taking into consideration the health needs of all members of society rather than one individual’s specific needs (Daniels and Sabin, 2008: 72) – and those who are commonly trained to protect rights from an individual-centred perspective, occasionally using these rights as constraints to public decisions or even as ‘trumps, to overcome the interest of a greater group.

Nonetheless, when courts are called upon to decide whether a given health need implies a right to health claim, paid for by the public health care system, they are introduced to problems and dilemmas policymakers often face, such as scarcity of resources, opportunity costs and trade-offs between values and interests. In other words, these cases force a confrontation with health care rationing.

In this paper, I will analyse how the Brazilian Federal Supreme Court (BFSC) – the most important (and precedent-setting) court in the Brazilian judicial system has
dealt with problems and dilemmas associated with the need to ration health care. I identify three patterns from their judgments in the last 15 years: (1) non-acceptance of health care rationing; (2) recognition of the need for rationing, but unwillingness to establish standard criteria; and (3) establishment of criteria to define cases in which rationing is legal.

The focus will be a critical analysis of the criteria established by the Court after the public hearing in 2009. It will be argued that the Court did not face the most challenging health care rationing decisions and that an almost completely patient-centred approach to the right to health – which gives central attention to individual patient needs (Daniels and Sabin, 2008: 72–73) – is still prevalent, and takes precedence over a population-centred approach.

2. BFSC case law (1997–2006): a refusal to set limits to the right to health

In 1997, the BFSC heard the first case in which it had to consider whether the right to health entitles a citizen to treatment unavailable in the public health care system. In this case, the claimant suffered from Duchenne muscular dystrophy and demanded that the public health care system pay for experimental treatment only available in the United States (the cost included transportation and living expenses abroad). The Court ruled that the government must pay for this treatment, regardless of the fact that it was experimental and expensive. It argued:

[In choosing] between protecting the inviolability of the right to life, an inalienable Constitutional fundamental right, and 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)

From this decision until case ADPF (Arguição de Descumprimento de Preceito Fundamental) 45 in 2006, the BFSC constantly reaffirmed that it would intervene when the State did not fully respect or fulfil the right to health. The following quotation appears in many decisions¹ from this period:

FREE DISTRIBUTION Of MEDICINE TO PEOPLE IN NEED. It becomes essential that the constitutional declaration be completely respected and fully complied with, especially in cases where a right – such as the right to health – entails a judicial prerogative to ensure the right of the citizen to demand positive action from the State … The judiciary’s action in those situations is legitimised where the State refuses to respect the constitutional commandment, whether by arbitrary and intolerable default, or by any other form of governmental deviant behaviour.

However, the statements do not define ‘arbitrary’, ‘intolerable’ and ‘deviant’. The fact that all cases were decided in favour of those suing the State makes it

¹ AgRg no. RE 271286; RE 232335; AgRg no. RE 273834; RE 248304; RE 198265; RE 267612, AI 570455, AgRg no. RE 271286, RE 198265, RE 248304, AgRg no. RE 273834 and RE 393175.
difficult to understand in which circumstances the BFSC would have considered the refusal to provide a health treatment to be legal.

In other cases decided during the same period, the BFSC 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 restrict the right to health.² For instance, 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”. (RE 198263)

The BFSC adopted an entirely patient-centred approach to the right to health and refused to consider population-centred aspects, such as scarcity of resources, trade-offs and opportunity costs, as arguments that would justify health care rationing.

This interpretation of the right to health is inconsistent with the reality of any health care system in the world. No health care system – no matter how rich the country or how high the health expenditure per person – is able to offer unrestricted access to all treatments that may improve citizens’ health (Syrett, 2007; Daniels and Sabin, 2008; Daniels, 2009: 318; Singer, 2009).

The inability to meet all health-related needs is all the more apparent when we consider that health is affected not only by the access to health care, but also by adequate sanitation, nutrition, clean water and health education. In Brazil, many of these basic health services are still not universally provided (National Commission on Social Determinants of Health, 2008).

Moreover, it is wrong to assume that in ‘right to health’ cases there is a conflict between an individual’s ‘right to health’ and the ‘financial interest of the State’. Rather, the conflict should be seen as a tension between the different needs of citizens competing for public resources.

It must be recognized that competition for scarce resources requires the State to set priorities. If everybody in society enjoys a right to health, then an individual’s entitlement to health care does not depend solely on the fact that she has a health need, but also on the amount of resources available for health care and what priority should be given to meet her individual need when it is compared with the needs of others.

3. BFSC case law (2006–2009): recognizing limits to the right to health

In the 2006 case ADPF 45, the BFSC recognized that the fulfilment of the right to health depends on the availability of public resources and that the Court should not ignore the scarcity of funds. Although this was not a case in which a particular health treatment was demanded,³ the judgment introduced a new

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² RE 195192, RE 198263 and RE 342413.
³ Case ADPF 45 was a complaint regarding a presidential veto on the health budget proposal presented by Parliament. The President eventually withdrew his own veto before the case was decided.
interpretation of the right to health. It was stated that “the judicial branch – especially this Supreme Court – does not have the institutional function of formulating and implementing public policies”. Further,

The fulfilment of social and economic rights depends on financial resources that are subject to the government’s available budget (…) once it is objectively shown that the State does not have the financial capacity, it cannot be obliged to fulfil these constitutional duties.

Additionally, the Court’s evaluation of the State’s obligation depends on the ‘reasonableness of the demand’ and the ‘availability of resources’. On the other hand, this decision argued that the State cannot deny its citizens the minimum conditions for subsistence by acting in an ‘illegitimate’, ‘arbitrary’ and ‘condemnable’ way – in such cases, courts are authorized to intervene and protect the violated right to health.

Even though there was an initial recognition of the complexity of judging right to health cases in ADPF 45, this decision did not introduce explicit criteria for identifying those cases where a failure to provide treatment is an ‘illegitimate’, ‘arbitrary’ or ‘condemnable’ decision.

In February 2007, the BFSC heard the first two cases in which it upheld the government’s decision not to fund a particular treatment or drug – STA 91 and SS 3073 (the patients were suffering from chronic renal disease and cancer, respectively). In both cases, the Court recognized that the public health care system should be managed in a way that will ‘rationalize the cost–benefit of the treatments that will be offered free of charge for the population, in order to benefit as many people as possible’. It seemed the Court was raising the possibility of using a form of cost-value analysis in health care allocation, reversing the opinion of previous cases.

These decisions also affirmed that the constitutional right to health should be “concerned about public policies that will affect the population as a whole, and not individual cases” (STA 91 and SS 3073). It was also recognized that if the Court forced the public health care system to supply the treatment demanded by the litigants, it would ‘reduce the availability of other health services for the rest of society’.

Thus, the population-centred approach to health care was recognized and taken into consideration for the first time in a BFSC judgment about the right to health. Finally, the Court established an important limiting criterion: the State is only obliged to supply medicines included in its official lists of medicines, which are approved by the Ministry and Secretaries of Health.4 (This shall henceforth

4 The Brazilian Health System compiles three main lists of medical treatments provided to the population free of charge: (1) the list of “essential medicines”, the basic drugs for the most common diseases; (2) the list of “strategic medicines”, drugs for endemic diseases that may pose a wider threat to public health (e.g., AIDS and malaria); and (3) the list of “exceptional or high cost medicines”, drugs for rare diseases, which affect a small number of people. Beyond these main lists, there are specific lists of drugs for Diabetes and Cancer.
be referred to as the ‘list-inclusion criterion’.) This effectively meant that the Court gave the power to set priorities in health care allocation back to the health authorities.

However, in subsequent cases the Court retreated from its more deferential stance to governmental policy choices and returned to an approach that focused on the specific needs of the patient/applicant. Neither the decision nor the arguments and criteria were the same. In these cases, the analysis was centred on the patients’ needs, the severity of the disease and the effect of the drug they requested. There was no reference to previous arguments that affirmed that the right to health implied public policies based on a population-centred approach.

Furthermore, in the cases SS 3205, SS 3158, SS 3429, SS 3452, STA 181, the Court ordered the health care system to provide medicines that were not included in the official list, ignoring the list-inclusion criterion established in STA 91 and SS 3073. No reference was made to the criterion, nor was it made clear whether (and if so why) these cases were exceptions. Rather, the only argument provided was that the treatment in question was necessary for the patients. In these cases, the population-centred approach was overcome by the individual-centred approach to health care.

After the return to the individual-centred approach, the BFSC found refusals by health authorities to supply specific treatments to be lawful in two more cases. In the first case, the claimant demanded drugs for female infertility (SS 3263), which was not included in the official lists of medicine. In the second case, a class action suit claimed that the public health care system should provide free sex reassignment surgery (STA 185). In both cases, the arguments used by the BFSC to deny the claims were based on a cost–benefit analysis of the treatments, as well as the impact of their provision on the access to health care for the rest of the population.

These cases provide a sharp contrast to STA 223 (April 2008), in which the Court decided that the State should pay for a surgery whose efficacy was not proven [it was not approved by the American Food and Drug Administration (FDA) and was never evaluated by the Brazilian health authorities] and that could only be provided by flying an American surgeon to Brazil at the (considerable) expense of the State. This is the first ‘right to health’ case that provoked disagreement among the BFSC Justices. The dissenting judgment stated that because the treatment was experimental and expensive, the State should not be compelled to provide it. However, the majority disagreed, holding that the surgery should be paid for by the State. In this case, one of the Justices affirmed that “constraints on public finances are secondary to human life”. This statement shows that the prevailing interpretation of the right to health before 2006 – which refuses to set limits for the right to health – is still defended by some Justices; occasionally it is the winning argument in a judgment.

5 SS 3205, SS 3158, SS 3183, SS 3231, SS 3263, SS 3429, SS 3452 e STA 181.
In the second semester of 2008, the BFSC reaffirmed – in cases SL 228, STA 238, STA 268 and STA 277 – that the scarcity of resources is a relevant consideration and that courts should be cautious when interfering in decisions about health care allocation. The ‘list-inclusion criterion’ was also reaffirmed, i.e. that courts may legitimately intervene when the State fails to supply treatments and services included in the official lists. Furthermore, when citizens demand something not included on those lists, the Court has the power to evaluate whether the treatment can be provided without harming other citizens’ rights.

Nonetheless, even after this list-inclusion criterion was re-established, there was a case (STA 278) in which it was held that the State should supply a medicine not included in the official list, but no satisfactory explanation was given to justify the non-application of the normal rule. The reasons given for this decision were the gravity of the disease and the patient’s need.

Thus, we can see that between 2006 and 2009, the BFSC oscillated between a patient-centred and a population-centred approach to health care. There were some attempts to establish stable criteria for health care provision. However, these criteria were not followed by the Court itself.

4. BFSC case law (2009–2010): public hearing and establishment of criteria

In April and May of 2009, the BFSC held a public hearing with experts, health authorities, academics, lawyers, public servants and civil society to discuss the ‘judicialization of the right to health’. According to the President of the Court, the aim was to supply the BFSC with ‘technical, administrative, scientific, political and economic’ information in order to help the Court to decide right to health cases (Mendes, 2009).

In March of 2010, the BFSC decided nine cases and established guidelines defining those duties citizens can immediately demand from the public health care system. These rulings were based on the information gathered in this public hearing. These criteria were reaffirmed in further decisions.7

In these cases, the BFSC said that the health care system cannot supply all treatments that patients demand and that priorities in health care should be set. However, courts have the power to compel the government to offer a clinically effective treatment, which it has denied on grounds of cost if:

1. It is already part of public health policy, which means it is included in the public health care system official list of treatments and recommended by a National Health System clinic and therapeutic protocol (Protocolos Clínicos e Diretrizes Terapêuticas).

6 STA 175, STA 211, STA 278, SS 3724, SS 2944, SS 2361, SS 3345, SS 3355 and SL 47.
7 STA 260, STA 283, STA 424, STA 434, SL 256, SS 3941, SS 4045, SS 3962, SS 3852 and SS 3989.
2. Its safety, efficiency and quality have been recognized by the official department responsible for their control, which is the National Health Surveillance Agency (ANVISA).[^8]

3. Its use is supported by scientific consensus, which excludes experimental treatments.

In practice, when criterion (1) is fulfilled, criteria (2) and (3) will also be. No treatment will be included in public health policy if not registered in the ANVISA, or not recommended by scientific consensus. Conversely, not all treatments that fulfil the criteria (2) and (3) will necessarily be offered by the health care system.

It was stressed that criterion (1) is flexible and should be evaluated on a case-by-case basis. Courts may intervene and overturn the health care system decision not to offer the treatment when:

4. The petitioner can prove that the treatment offered by the public health care system is not appropriate to her, due to her specific health needs; or that no treatment is offered at all.

5. The treatment has been successfully used ‘for a long time’ by patients who can afford it but its inclusion in the official lists and therapeutic protocols by those who administer the health care system has been ‘very slow’.

These decisions establish a comprehensive set of criteria that present a more refined and realistic interpretation of the right to health than was exhibited in previous BFSC case law. The Court admitted that the public health care system must set priorities when allocating scarce resources; therefore, not all treatments that patients request can be offered free of charge.

The recognition by the Court that the public health care system can afford to offer all citizens unlimited access to the best treatment for every health need, may seem a trite statement. But, as we saw in Section 2, for 10 years the BFSC had ruled that there could be no restriction on the treatments that should be available for citizens.

The Court also established a reasonable criterion: the public health care system should not be obliged to supply treatments the efficiency and safety of which have not been scientifically proven. Note that this criterion had not always been accepted by the BFSC: in 2008, the Court ordered the State to pay for a very expensive surgery whose efficacy was not proved (STA 223).

The establishment of clear criteria to serve as guidelines for future decisions is also important. In Section 3, we saw that different criteria were used in different cases, making it unclear which duties and entitlements are derived from the constitutional right to health. Now that comprehensive and clear guidelines have been made explicit, one can expect that decisions will be underpinned by clearer arguments, which will in turn help the BFSC build a more consistent right to health case law.

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[^8]: The Brazilian ANVISA has responsibilities equivalent to the FDA in the United States of America. Only drugs registered by the ANVISA can be commercialized in Brazil.
In terms of applying the criteria, in all cases cited in this section (see footnote 8; with the exception of STA 424 and SL 256), the treatment demanded was not included in the official lists, but the Court nonetheless ruled that it must be provided, with appeal to criteria (5) and (2). In these cases, the claimants were able to prove either that the public health care system offered no alternative treatment or that the alternative offered was not effective for them and hence they needed more modern and expensive treatments [criterion (4)].

Cases STA 424 and SL 256 were decided differently because they are collective complaints. Case STA 424 involved a request for universal provision of three medicines (not included in the official lists) for treating microcephalia. In case SL 256, 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 outside of the city.

The BFSC rejected these claims, arguing that the judiciary should not require health care authorities to fulfil 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’. 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 SL 256, 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 the BFSC granted.

5. Are the BFSC’s criteria sufficient?

5.1 Inclusion in the public health care system

The BFSC established that health authorities cannot deny citizens treatment already offered by the public health care system [criterion (1)]. Hence, once a health care treatment is included in the official list or recommended by clinical and therapeutic protocols, citizens are entitled to demand that the State provide it. The BFSC stated that judgments ordering the provision of treatment in these cases are more legitimate because the Court is not setting priorities for health care allocation in the place of health authorities. Rather, it is simply enforcing the provision of a preapproved set of goods and services.

The problem with this criterion is that it does not consider the scenario in which the treatment offered by the public health care system cannot be provided in quantities that ensure universal provision. In these cases, health care systems must ration, not by excluding the specific medical treatment from the range of treatments it provides, but instead by either selecting beneficiaries according to their clinical characteristics, or by establishing waiting lists (Syrett, 2007: 46–50).

9 If a treatment fulfils criterion (1), it will consequently fulfill criteria (2) and (3); (see Section 4).
Thus, the fact that a treatment is included in the official list or recommended by clinical and therapeutic protocols does not always preclude the need for rationing.

An important example of this is a judgment of the BFSC, SL 228 (see Section 3), in which the Public Prosecutors’ Office (Ministério Público) filed a lawsuit seeking to force the government to provide places in an intensive care unit (ICU) for all patients in the city of Sobral who needed it. Not only did the claim demand that the State should transfer the relevant patients to the existing ICU in Sobral and neighbouring cities but it further stated that the State should be given only 90 days to more than triple the city’s number of ICU spaces (from 9 to 30).

The BFSC decided in favour of the claimant based on the Ordinance of the Ministry of Health (Portaria MS/GM no. 1101/2002) estimates of the necessary number of ICU per 1000 inhabitants. Because Sobral had fewer ICU places than the Ministry of Health recommends, the BFSC argued the government had failed to comply with health policy guidelines.

However, again, providing the Ministry of Health’s estimated number of ICU places does not guarantee rationing will not occur. Even in the areas in Brazil where the number of ICUs exceeds the Ordinance numbers, demand outstrips supply (O Estado de São Paulo, 2010). Lawsuits demanding access to ICUs are not uncommon, even in areas where the Ordinance numbers have been met (O Estado de São Paulo, 2010).

Finally, the order that the Government more than triple the number of these units in 90 days inevitably raises the question whether the Court should make such an order, given the cost of compliance. Although the Ministry of Health established a guideline for an adequate provision of ICU places, there is no requirement that these guidelines be met within 90 days. Even if the resources to do so are available, the opportunity costs of tripling the number of ICU places in such a short time should have been borne in mind, in light of the risk of reducing the provision of other important health services.

Thus, courts should carefully consider citizens’ judicially enforceable right to any treatment included in the health care system’s official lists. A favourable court ruling may allow some people to ‘jump the queue’ in the access to health care. And, even if it is possible to eliminate the need for rationing of a given treatment and thus make waiting lists and exclusion unnecessary, the efforts required to do so may divert resources away from other services offered by the public health care system.

### 5.2 Effective, safe and necessary

By examining criteria (2), (3), (4) and (5) set by the BFSC, we can see the Court assumes that the elimination of ineffective, unnecessary and unsafe treatments, coupled with the use of the cheapest alternative among effective treatments, would be sufficient to preclude the need to ration health care.
Indeed, in the most recent cases the Court ordered the State to provide drugs not offered by the health care system [contravening criterion (1)], but needed by the patient, arguing that their efficiency has been recognized by the ANVISA and that the health care system’s alternative treatments were not sufficient to meet the patient’s needs. Nonetheless, excluding ineffective treatments will not make rationing unnecessary. Resources for the delivery of health care are finite, but their demand is potentially infinite (Mooney, 1986; National Prescribing Centre, 2010). Moreover, health care is not the only important good for society and it has to compete for public resources with other goods, such as education, child care, job creation and pension funds (Daniels and Sabin, 2008).

The development of new health technologies makes the mismatch between resources and needs in health care ever more apparent. There is evidence that the financial pressure on public health budgets in many countries is caused primarily by the development of new health technologies (Okunde and Murphy, 2002; Syrett, 2007: 38-42; OECD, 2010). Technologies raise the price of health care through the introduction of new treatments in place of the old ones. This effect can be seen in the case of new drugs that are protected by intellectual property laws that grant pharmaceutical companies monopolies, effectively ruling out the possibility of cheaper alternatives.

New technologies also produce an ‘expansion of treatment effect’ (Syrett, 2007: 39). In other words, new treatments make it possible to treat health problems that were previously considered untreatable, and transform acute conditions into chronic diseases [for instance, diabetes, human immunodeficiency virus (HIV) and cancer], which tend to be more expensive to treat because patients require extended medical care.

When people with chronic diseases live longer, their diseases also evolve, ensuring that the need for new technologies is pervasive. One clear example can be found in the case of medication for HIV/AIDS (acquired immune deficiency syndrome). Since these viruses become resistant to treatments, patients require new drugs to control the viruses that have become immune. Thus, new technologies are necessary for patients and the resulting drugs are sold by pharmaceutical companies at higher prices. In Brazil, the distribution of new generations of patented antiretroviral drugs is the main driver in the significant rise in the cost of the health care policy of distributing free antiretroviral drugs. The ratio of total costs to number of treated patients more than doubled from US$1220 in 2003 to US$2577 in 2005 (Nunn et al., 2007).

New technologies can be not only effective and safe but can also be extremely expensive and increase the costs of health care, which makes rationing and priority setting ever more necessary. The Brazilian Federal Government’s total expenditure on drugs increased 222% from 2003 to 2007 (Vieira, 2009). During the same period, the share of drug costs in the Federal Government total spending on health care rose from 5.4% in 2003 to 10.7% in 2007 (Vieira, 2009). When the expenditure is analysed according to the kind of drug purchased, it is
noteworthy that the spending on essential (basic) drugs increased 75%, whereas the increased spending on exceptional (high cost) drugs was 252% (Vieira, 2009).

It is possible to conclude that high cost drugs are one of the most direct causes of the increase in Brazilian public health costs. Even though these drugs are used to treat diseases that affect a small number of people, their heavy impact on the health budget is caused by the fact that they are usually new and protected by intellectual property laws (Guise et al., 2010: 115). Thus, not only must new technologies be evaluated according to their safety and efficacy, but they also raise concerns about the economic feasibility and fairness of their provision.

An interesting example was given by Ferraz and Vieira (2009), who calculated that the cost of offering the most modern medicine to all Brazilian Rheumatoid Arthritis and Chronic Hepatitis C patients (1% of the population suffer from these diseases) would be an estimated US$56 billion, a figure that is roughly 4.5% of the national gross domestic product and more than double the yearly national health care budget (Ferraz and Vieira, 2009: 235–238).

Some treatments may be more effective, but at significantly higher costs. The evaluation of whether health benefits to the population produced by new treatments compensate for their additional cost is currently one of the biggest challenges for health care systems.

In conclusion, the incorporation of all new existing health technologies is not only unfeasible, but may also make the public health care system unfair and inefficient because a huge amount of public resources may be used to produce marginal health benefits for the population. In this case, the opportunity costs can be very high.

5.3 Rule of rescue

The criteria discussed in Section 5.2 show that a patient-centred approach to the right to health still prevails in the BFSC. If a treatment is the only existing alternative for a patient, and there is scientific evidence that it is efficient and not harmful, then the patient is entitled to receive it.

Such rulings force the public health care system to apply the ‘rule of rescue’. The rule of rescue can be defined as 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 (National Institute for Clinical Excellence Social Value Judgments, 2008: 20; Cookson and Dolan, 2000: 324).

One consequence of the application of this theory is that, because it is not possible to save everyone in need, rescuing one person no matter how much it costs often implies that others cannot be rescued. And this consequence can introduce unfairness in health care distribution because the effort to rescue an identifiable person may prevent the health care system from fulfilling the needs of the present and future patients who are anonymous and who do not have

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10 For the official definition of essential (basic) and exceptional (high cost) drugs in Brazil see Section 4.

The role of the public decision maker is to make impartial, dispassionate judgments about resource allocation between groups of unidentified people and their ‘statistical’ lives. Partiality and compassion towards particular identified individuals are inappropriate considerations that the public decision maker should not allow to interfere with his decision making, as it is arbitrary and unfair to discriminate in favour of people who happen to be identified and against those who have not yet been identified.

The application of the rule of rescue does not make health care rationing avoidable. Rationing will simply not be explicit and life/health saving treatments will be offered without considering their cost and the impact on the health care of the rest of the population. As we saw in Section 5.2, the likely consequence is a higher ratio of payment for expensive new treatments to total expenditure in health care. This may make the distribution of health care 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.

However, it is not difficult to understand the reason why it is so difficult to set criteria to limit the entitlements derived from the right to health, especially in cases when the patient’s life and health is in danger and something can be done. There is a considerably different emotional response to a situation where we can identify an individual who may benefit from a treatment compared with a situation where people benefited are only ‘statistical’ and cannot be individually identified (Hope, 2001: 182). As Small and Loewenstein, 2003 have shown, we are more inclined to help the former than the latter, a bias they termed the ‘identifiable victim effect’.

Courts (in most cases) know the individual patient litigating for treatment. Courts will know her name, history, personal problems and occasionally her face. On the other hand, Courts have no capacity to gather a much broader range of information about the health needs of those anonymous citizens whose health care may suffer because resources were diverted to comply with a judicial decision. Courts know who wins, but cannot identify who loses.

This fact, coupled with the fact that judges are trained to protect rights from an individual-centred perspective, makes the decision to deny treatment especially difficult for courts.

It is no wonder that in the most recent decisions the only two judgments in which the claim for health treatment was denied by the BFSC were cases of a collective claim to benefit a group rather than an individual patient (see Section 4). In these cases, the Court argued that a judicial decision cannot order 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” (STA 424 and SL 236).
In individual cases, on the other hand, the Court alleged that the health care system could not prove that the provision of the treatment in question would impair the public budget and the capacity of public authorities to offer other health services for other citizens. Indeed, it is hard to prove that one decision alone has the capacity to ‘impair the regular functioning of health system administration, reduce the efficiency in patient care, and limit the available resources’.

However, the ‘judicialization of the right to health’ has the aggregate capacity to do so. According to data gathered by Ferraz (2011), Brazil spends roughly $1.2 billion (USD) complying with judicial decisions ordering that a particular health treatment must be provided. At the state level, 20% of the health budget of the State of Rio de Janeiro is spent complying with judicial rulings; and in the State of Sao Paulo the amount spent on drugs supplied in response to a judicial order is around 30% of the total budget for drugs.

Thus, although it is not possible to prove that one single judicial decision may impact on the health budget available to the health care of the whole population; the analysis of the spending derived from the judicialization of the right to health indicates that there is a significant and identifiable aggregate impact.

5.4 Last-chance therapies

Above we saw that the criteria established by the BFSC results in the ‘rule of rescue’ for the allocation of health care, though some limits to that rule are also evident: treatments must be proven effective and safe, and there must not be a cheaper alternative.

However, it is as yet uncertain whether the ‘rule of rescue’ may overcome the limits the BFSC has established. The BFSC has said that potentially life-saving treatments with proven efficacy and safety should be provided to citizens, even when the public health care system had not decided to cover them. The Court also ruled that there is no obligation for the health care system to provide treatments whose efficacy and safety are unproven. But what about promising life-saving treatments that are not completely proven and to which there is no alternative?

Daniels and Sabin (2008: 72) argue decisions about whether patients with life-threatening illnesses will receive coverage for unproven treatments that may save their lives are the ‘most difficult and explosive responsibility for any health care system’.

In 2008, the majority decision of the BFSC was that the State should pay for a surgery, which was not approved by the American FDA or the Brazilian ANVISA (STA 223, see Section 3).

More recently, in the case RE 368546 (2011), the majority decision of the BFSC obliged the health care system to provide treatment for pigment rethinosis in Cuba for a group of patients, despite strong scientific evidence that this treatment is ineffective (the treatment is not recognized as effective by the Brazilian Association of Ophthalmologists). Thus, if the BFSC decided in favour
of the patient in a case in which there was no threat to the patients’ life and there was strong evidence about the ineffectiveness of the treatment, then it is reasonable to suppose that the judgment would not be different in cases involving last-chance therapies.

In sum, the Court had explicitly stated that the health care system is not obliged to provide experimental treatments. However, it seems that the imperatives of the ‘rule of rescue’ may overcome this limitation.

6. Accountability for reasonableness and the BFSC

Deciding which health needs should be protected by the right to health is theoretically challenging. There are probably as many answers to this question as there are theories of justice (Buchanan, 1985) and fair-minded people will disagree about which reasonable principles should be used to set limits and priorities in health care (Daniels, 2009).

However, we may agree that rationing is necessary and that a fair process aimed at a robust form of public accountability in which “the reasons and rationales for important limit-setting decisions should be publicly available” is appropriate for this task (Daniels 2009: 117). This fair process is called ‘accountability for reasonableness’ (Daniels and Sabin, 2008; Daniels, 2009).

One of the conditions that clarifies this notion of accountability for reasonableness is ‘publicity’ (Daniels and Sabin, 2008; Daniels, 2009). When the rationale behind decisions to ration health care is publicized, rationing thereby becomes explicit. Additionally, there are some good reasons why rationing should be explicit, and why the reasons justifying rationing should be public:

1. The public contributes to the health care system and is entitled to its services. They have the right to understand how health authorities set priorities in allocating public resources, and the reasons why various treatments are included. This is especially important for patients whose health and life are endangered and can be helped by the provision of health care.
2. When reasons are publicly given, they force consistent decisions and allow for the assessment of whether similar cases are treated similarly – an essential requirement for fairness (Daniels, 2009: 121).
3. If rationing is concealed, social awareness of limits to health care provision is prevented, and the public will not be able to debate and deliberate on the choices to be made nor challenge them when they are based on unreasonable or arbitrary principles.

Some theorists believe that courts can perform the important task of making the rationales underlying health care allocation decisions more public. They argue that courts can therefore make health authorities publicly accountable, enhancing deliberation and stimulating a broader debate within political institutions and civil society. (Gloppen et al., 2004; Gargarella, 2006: 29; Syrett, 2007;
Brinks and Gauri, 2008: 346). This role is especially important in Brazil, where there is a lack of transparency and standardization in the assessment of new technologies by the health care system (Souza, 2010).

The BFSC made an effort to make health care allocation more public and transparent by organizing a public hearing in which a broad range of representatives of many different groups could express their opinion about the judicialization of the right to health.

However, the outcome of the public hearing – the criteria established by the BFSC – still precludes explicit rationing, and thus cannot lead to ‘accountability for reasonableness’. Even though the Court admitted that resources are scarce and rationing in some form is necessary, it did not consider the most complicated and controversial health care distribution dilemmas, forcing the health care system to comply with the ‘rule of rescue’. This does not make rationing unnecessary; rather, it makes it implicit.

Implicit rationing is problematic because it does not allow for public debate about the priorities and policies that the health care system should choose. Additionally, implicit rationing makes it more difficult to evaluate the consistency of the distribution of health care and whether the decision to give priority to some people or policies is due to arbitrary bias or unjust principles. If those who resort to lawsuits are benefited by the ‘rule of rescue’ as applied by the courts, this may come at the expense of other policies such as health education and preventive measures. Or it may cause a disadvantage to those who cannot, for whatever reason, resort to litigation. The variable ‘capacity to litigate’ of citizens is morally arbitrary and certainly not a good criterion for health care allocation.

7. Conclusion

Rationing health care typically involves ‘tragic choices’ because it involves the distribution of scarce goods; decisions that impact directly on human health and lives (Calabresi and Bobbit, 1990). Governments are loathe to lead public debates on this topic (Newdick, 2004: 45) and the BFSC has also tried to avoid the most controversial issues.

For almost 10 years, the BFSC refused to place limits on the duties derived from the right to health; consistently affirming that scarcity of resources cannot justify rationing health care.

Even after the BFSC accepted that priority setting is an inevitable part of public health policy, it oscillated between a patient-centred and a population-centred approach to health care. Although tentative criteria for rationing health care were established by the BFSC itself, the Court has applied them inconsistently.

In 2009, the BFSC organized a public hearing to allow various stakeholders to debate over what principles should apply to the allocation of health care resources. As a result, in subsequent decisions the Court attempted to define
clear criteria by which to assess the legality of refusing to provide treatment on grounds of cost.

The approach of the BFSC to the right to health has certainly evolved since its first decision in this area in 1997. The Court now accepts that the individual right to health cannot be protected in a way that adversely affects health care provision for the whole population.

However, the Court failed to examine the most fundamental and difficult health care distribution dilemmas, such as prioritizing some patients to the exclusion of others; whether to provide new and very expensive health technologies that are necessary for some individuals; and the funding of last-chance therapies with unproven efficacy.

A more serious problem is that the Court also failed to apply these criteria to a recent case, as seen in Section 5.4, which may indicate a return to a completely patient-centred approach. If this is so, it would be a step backwards for the BFSC’s case law, so close attention should be paid to future decisions.

The consequence of these failures is that the ‘rule of rescue’ becomes the crucial factor governing the allocation of health care. This will make this allocation inefficient and unfair, because population-centred concerns will come second to the ‘rule of rescue’. Furthermore, the real criteria governing health care rationing are kept implicit, and without explicit criteria ‘accountability for reasonableness’ is not possible.

It is important to note that this paper does not suggest that the Court should have no role in the protection of the constitutional right to health, or that it should refrain from accepting individual and collective claims that the right to health has been violated. There are persuasive reasons for judicial protection of the right to health in some cases (Gloppen et al., 2004; Gargarella, 2006: 29; Syrett, 2007; Brinks and Gauri, 2008: 346; Syrett, 2011).

However, courts cannot ignore the tragic necessity of health care rationing. Courts have to consider the most difficult issues in health care rationing when judging right to health cases. The alternative is that they will frequently resort to the ‘rule of rescue’ in their judgments, hence forcing public health authorities to make health care rationing decisions implicit and therefore unjust.

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