HEALTHCARE PRIORITY SETTING IN THE COURTS

A reflection on decision-making when healthcare priority setting is brought to court

WORKING PAPER

version 2

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TABLE OF CONTENTS

ACKNOWLEDGMENTS **1**

1. INTRODUCTION **2**

2. METHODS **4**

2.1 Case Codification **4**

3. CIVIL LAW **5**

3.1 Latin America **6**

3.1.1 Argentina 6

3.1.1a. Campodonico de Beviacqua, Ana Carina vs. Ministerio de Salud Sunitinib Accion Social C.823.XXXV (2000) 7

3.1.1b. Orlando, Susana Beatriz c/ Province of Buenos Aires, Provincia & Ors. O.59.XXXVIII (2005) 7

3.1.2 Brazil 8

3.1.2a State of Mato Grosso v. Marina de Almeida Andrade RE 400040/MT (2005) 10

3.1.2b State of Espirito Santo v. Eduardo Antonio Vieira Tapias RE 523726/ES (2007) 10

3.1.2c Municipality of Caxias do Sul v. Vinicus Carpeggiani AI 797349/RS (2011) 10

3.1.3 Chile 11

3.1.3a N.R.V. v. Ministry of Health and East Metropolitan Health Service 3.599-2001-16 (2001) 11

3.1.4 Colombia 12

3.1.4a Mr. X vs. Instituto de Seguros Sociales (ISS) T-271 (1995) 13

3.1.4b T-760/08, Corte Constitutional (2008) 13

3.1.4c Morrigan, Estrella v. Coomeva EPS (T-310/10), 2010 15
3.1.5 Costa Rica 15
3.1.5a Ms. Vera Salazar Navarro vs Caja Costarricense de Seguro Social, 01-0090007-CO (2001) 16
3.1.6 Panama 16
3.1.6a Ricardo Lachman Sunitinib otros v. Caja de Seguro Social, No. 199812 (1998) 16
3.1.7 Uruguay 17
3.1.7a Marquez Velazquez Antonio Gerardo vs. Ministry of Public Health, 39/10 (2010) 17
3.1.7b Hernandez Gonzalez, Eliu Aquiliano vs. Executive State Power of the Ministry of Public Health, 2-13.991/2011 (2011) 18
3.1.7c Hernandez Edward v. Fondo Nacional de Recursos, No. 393/2011 (2011) 18
3.1.7d Fontes Braida, Oscar v. State—Executive Branch—Ministry of Health, No. 3/2011 (2011), ... 19

3.2 Eastern Europe 20
3.2.1 Latvia 20
3.2.1a Case No. 42755708 (2010) 20
3.2.2 Macedonia 21
3.2.2a Stamen Filipov and Biljana Zhivkovska to the Constitutional Court, 109/2009-0-1 (2010) 21

4. COMMON LAW 22
4.1.1 Israel 22
4.1.1a Gila Louzon v. Government of Israel, HCJ 4013/05 (2005) 23
4.1.1b Victoria Yisraeli v. Health Basket Committee, HCJ 2974/06 (2006) 25

5. MIXED LAW 26

5.1 Africa **26**
5.1.1 South Africa 26
5.1.1a Soobramoney v. Minister of Health, Case CCT 32/97 (1997) 27
5.1.2 Kenya 28
5.1.2a Okwanda v. Minister of Health and Medical Services and Ors., No. 94 (2012) 28

6. DISCUSSION **30**

6.1 Reducing tutela or amparo action in civil law systems **30**

6.2 Differentiating common law systems **32**

6.3 Striking a new balance between the legislature and judiciary in priority setting **33**

6.2 Limitations **35**

6.3 Future Research **35**

6.4 Related Work **35**

7. APPENDIXES **37**

7.1 Appendix A: Codification of Cases **37**

7.2 Appendix B: The judicialization of the right to health in varying legal systems **38**

8. REFERENCES **39**

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1. INTRODUCTION

"Right to health" guarantees play a fundamental role in securing the wellbeing of a population. They offer the opportunity for legal remedy that holds governments, health ministries, and other departments or organizations accountable to maintaining and guaranteeing the constitutionally or otherwise legally mandated right to health of a population. All UN member states have universally recognized a right to health through the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the WHO Constitution recognizes the human right to health as a social right (Wheeler, 2013; Perehudoff, 2008). Article 12 of the ICESCR states:

> The States Parties to the present covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (a) The provision for the reduction of stillbirth-rate and infant mortality and for the healthy development of the child;
>
> (b) The improvement of all aspects of environmental and industrial hygiene;
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness (Office of the High Commissioner for Human Rights).

The Committee on Economic, Social and Cultural rights established States' three right to health obligations in General Comment 14 in 2000: to respect, to protect, and to fulfill (UN Committee on Economic, Social and Cultural Rights).

Many countries require that the rights recognized in international arrangements or agreements be written into domestic law in order to be enforceable (Heymann, Cassola, Raub & Mishra, 2013). Thus, greater than 50% of UN Member States individually recognize a right to health in their constitutions through guaranteeing one or a combination of (1) a right to health generally, (2) a right to public or preventive health, and/or (3) a right to medical care services (Heymann et al., 2013). And this trend is growing stronger, where newer constitutions are almost

guaranteed to include a right to health (Heymann et al., 2013). Even where a country's constitution does not guarantee a constitutional right to heath, arguments for access to health services within that country's constitution are still made under the auspices of a right to life or a right to bodily integrity, which, it is argued, includes a right to health (*For example, see Gila Louzon*, 2005).

Patients have increasingly turned to the justice system to gain access to medications and healthcare services under the argument that a failure to provide access threatens their constitutional right to health—and they are often winning. In many instances, this "judicialization of the right to health" has given low- and middle-income populations the opportunity to secure the healthcare services that they should have, and would have, a right to but for government inefficiencies (Cubillos, Escobar, Pavlovic & Iunes, 2012).

However, the judicialization of the right to health is also threatening the priority-setting efforts of health technology assessment (HTA) agencies or governments who recognize that, with a limited amount of resources with which to secure universal healthcare coverage, services, medications, devices, etc. must be rationed. This is true whether prioritization decisions are made large-scale for the entire population, or on a smaller scale for individual components of, or populations within, the larger healthcare system. This paper sets out to review case law in which government decisions not to offer a certain medication or health service are challenged. In some instances, the overturning of a sound priority-setting decision could threaten HTA or prioritization processes, or could weaken priority-setting institutions. Thus, the court's reasoning in past cases may potentially be used to strategically manage priority setting processes and decision-making in the future, or to anticipate the behavior of similarly structured courts. Some courts are more likely to make decisions based on precedent than others, and the social, political, and economic differences across countries make it impossible to predict the behavior of one court based on another. However, where the legal system and social values of two countries are similar, the decisions of one might shine light on the thought processes that could guide the decision making of the other.

Importantly, not all countries utilize the court system as a first (or even second) line approach to resolve disputes between a patient and a government or health entity regarding access to health services. Some Asian countries, where litigation is less common, may utilize alternative dispute resolution mechanisms through formal complaint systems to resolve these issues.[2] As a result, this report does not

[2] Thailand offers an exception, having heard its first ever priority-setting case this past year, overturning the government decision not to include glucosamine in its health benefit basket.

venture to offer universally applicable rules about priority setting and the court system, but instead review current conflicts and advise others of potential friction—as they move towards adopting priority-setting mechanisms for healthcare resource allocation, will right to health conflicts in the courts become more prominent?

2. METHODS

Cases were accessed through and downloaded from the Global Health and Human Rights Database. Cases were researched and filtered according to their application to right to health and their subject areas on either health care and health services or health systems and financing. Relevant cases were then selected based on one or a combination of the following tags: access to drugs, access to medicines, budget, essential medicines, experimental treatment, health care technology, health expenditures, health funding, health regulation, health spending, non-evidence based treatment, pharmaceuticals, pricing, and/or unauthorized treatment. Each resulting case was then screened and included if it presented a conflict between the provision of health services and a patient trying to access services based on her right to health, life, or human dignity. Full, translated decisions were read and incorporated where available and applicable.[3] Case briefs were also referenced in some instances. The search was supplemented by journal articles on the topic area of access to medicines, priority setting, and right to health. A grey literature search provided the structural background for framing the cases within their respective country's legal and/or political structures.

2.1 Case Codification

Cases of this nature can be codified into three categories (see Appendix A):

1. Cases in which a plaintiff challenges denial of a certain technology as contrary to his or her nationally or internationally guaranteed right to health (or life, or dignity).
2. Cases in which a plaintiff challenges a denial of a certain technology as contrary to the applicable national health law that guarantees certain treatment.
3. Cases in which a plaintiff challenges the national health law as contrary to some constitutional provision guaranteeing a right to health.

[3] English-translated language is quoted below where the original decision was not published in English.

The Plaintiff (individual bringing the case) will decide the issue to argue. If a decision is appealed, the court will typically respond to the issue of law under question; however, it can respond to another issue if it so decides.

In certain cases, discussed later, the individual brings a claim against the method of priority setting. These cases do not challenge a denial of services based on a right to health, but instead challenge the denial of services based on an irrational, or otherwise unfair, method of priority setting.

3. CIVIL LAW

Civil and common law systems are fundamentally different from each other, especially when considering how past decisions can be used to predict future ones. Civil law countries are typically former French, Dutch, German, Spanish or Portuguese colonies. The civil law system is typically ruled by a written constitution that outlines specific codes and enshrines basic rights and duties. Only legislative enactments are binding, except that administrative and constitutional courts can bindingly nullify law and regulations. Because judge-made law is not a part of the civil law system, courts are not required to follow the precedent of previous court decisions on similar matters (Public, Private Partnerships—World Bank). The decisions handed down by the court are therefore "framed within the system conceived by the Constitution…as it would exceed the competence of the Court to order the design of a distinct system, as that is the decision for the legislature" (*See T-760*, 2008).

Unlike the common law system, which is often highly deferential to the laws and policies set by the legislative branch, civil law systems are characteristically more likely to prioritize constitutional rights over law or policy. And, because the constitution in Latin American countries is often expansive, it is rare for the courts to not be able to find a constitutional right that overrules a certain piece of legislation. Thus, it is probably as important to effectively argue against a decision in a certain case, as it is to shape the legislation to prevent such cases in the first place. While judges are greatly restricted by statutes and procedures, the constitution (or international treaties) will always outweigh the law. Where the pharmaceutical lobby can be strong in cases arguing access to medicines, trained lawyers and professionals in government to combat these arguments can be critical (Alonso, 2015).

3.1 Latin America

Courts play a particularly prominent role in healthcare decision making in Latin America. Most countries have a Constitutional Court for *amparo* or *tutela,* which acts as a safe haven court for fundamental rights. Patients appear in court for two types of cases: (1) to gain access to a service that is guaranteed in the public or private plan but delivered inadequately, or (2) to gain access to a service or technology not included in the coverage plan at all. Judges typically consider the patient need and physician recommendation but not the health technology assessment (ISPOR, 2015). Courts may fear that government arguments of resource constraints could be rooted in system inefficiencies, incapacities, or corruption, and so may hesitate to accept such arguments to reject access to care (Cubillos et al., 2012).

In Mexico specifically, the Supreme Court can set binding precedential decisions by a majority decision in five similar cases. Each individual case—a *tecis aislada* (TA)—produces a short decision. Only when five cases are decided similarly will the court issue a *tecis acudis provencia* (TJ) in which the decision is universally binding. While the decision in each *amparo* or *tutela* case is independent and the decision applies only to the person on behalf of whom the case was brought, the plaintiff or defendant in that case may choose to appeal to the Supreme Court. If five cases are appealed and decided similarly, that decision will be binding. Appealing a decision would be risky, however, as the Supreme Court's decision would serve to have a permanently binding effect (Alonso, 2015). Most Latin American countries have a similar system.

3.1.1 Argentina

The constitution of Argentina, founded in 1853 and last revised in 1994, guarantees health protections to consumers, and mandates that the state shall provide for such right, but states no explicit right to health (Hogerzeil, Samson, Cassanovas & Rahmani-Ocara, 2006). It has nevertheless adjudicated cases under the international human rights treaties to which Argentina is a signatory (*See Orlando*, 2005).

Argentina's experience shows that judicialization of the right to health does not necessarily require a guaranteed right to health in the country's constitution. Even without a right to health in the constitution, the Court in *Orlando* found (below) that the government must actively promote the life and health of citizens through no-cost access to medication. Whether or not the National Health Insurance System funded another similar drug at the time was not noted, making it difficult to know

how far the court would go in requiring access to medications. In *Ana Carina* (also below), the National Health Insurance System was required to cover a drug previously covered, but discontinued, by an entity external to the healthcare system. The decision cautions that the courts may require coverage of a drug that the healthcare system did not originally elect to cover.

3.1.1a. Campodonico de Beviacqua, Ana Carina vs. Ministerio de Salud Sunitinib Accion Social C.823.XXXV (2000)

Supreme Court

Parents of a child suffering from Kostman's Syndrome—a severe congenital neutropenia—filed an *amparo* action for the specific medication Nuetromax 300. The child had received the treatment for two years when the National Bank of Antineoplastic Drugs, dependent on the Ministry of Health, stopped the treatment. The Bank argued that it had previously provided the treatment on humanitarian grounds, and it had the right to discontinue treatment at its own discretion. The Constitutional Court, relying on health-based provisions of international agreements such as the ICESCR, ordered the Ministry of Health to require its agency to continue the child's treatment, insisting that fulfilling the right to health was a federal responsibility (*Also see* Hogerzeil et al., 2006; Hogerzeil, Samson & Casanova, 2004).

In making its decision, the court referred to the right guaranteed in Article 12 of ICESCR "of all people to enjoy the highest level of physical and mental health attainable, and the duty of the state parties to secure it. Among the measures that must be adopted to guarantee that right is the development of a plan of action to reduce infant mortality, achieve the health development of children and assure medical service and medical attention in the event of sickness" (9). As the court notes, Article 2 Section 1 of that same treaty states that parties are obligated to use "the maximum of [their] available resources" to fully implement the rights guaranteed in the ICESCR and that the federal government is responsible for implementing the agreement (9).

3.1.1b. Orlando, Susana Beatriz c/ Province of Buenos Aires, Provincia & Ors. O.59.XXXVIII (2005)

Supreme Court

In 2005, Susana Orlando brought a claim of *amparo* against the State and Province of Buenos Aires under Article 45 (consumers of goods and services have a right to protection of their health) and Article 75 (outlining the powers of Congress) of the Argentinian Constitution, and National Act 23.661, which establishes the National Health Insurance System. She sought free access to Copaxone for her multiple

sclerosis as a medicine essential to preserving her life that she did not have the resources to purchase. In considering the international human rights treaties to which Argentina has signed on, the National Supreme Court of Justice upheld Orlando's claim. The Court held that the State bound itself to developing positive measures to guarantee the right to life and health, and it therefore had a duty to develop a scheme to ensure a prompt and continuous medication supply to patients.

3.1.2 Brazil

The constitution of Brazil, established in 1988 and revised in 2014, contains multiple right to health provisions. Article 196 states that "Health is the right of all and the duty of the National Government and shall be guaranteed by social and economic policies aimed at reducing the risk of illness and other maladies and by universal access to all activities and services for its promotion, protection, and recovery." Beyond Article 196, the constitution lays out requirements for the universal health system and responsibilities of the legislators in regards to health.

Because Brazil functions under a civil law system, its judicial system does not follow *stare decisis*. Under the principle of *stare decisis*, courts rely on precedent to maintain consistency between cases. Past judgments act as a guide to inform the court as to how it should decide the case before it (Economist, 2013). Under the Constitution, the Federal Supreme Court may issue a binding legal decision on the judicial branch and direct or indirect public administration. To do so, two-thirds of the Court's members must have repeatedly decided a Constitutional matter in the same way (Library of Congress, 2015).

In Brazil, 73-80% of the medications not included in the pharmaceutical policy that individuals gain access to through the courts have cheaper alternatives available in the health care system (Wang, 2013; Machado, Acurcio, Brandao, Faleiros, Guerra, Cherchiglia & Andrade, 2011; Vieira & Zucchi, 2007). Research suggests that the majority of petitioners may be represented by private attorneys, either self-funded or sponsored by NGOs unfamiliar to the petitioner. Authors speculate that petitioners are either wealthy or supported by NGOs that are funded by pharmaceutical companies seeking coverage for their drugs. The heavy representation of certain physicians and attorneys suggests direct or indirect relationships with pharmaceutical or distribution companies that could be funding these networks (Wang, 2013; Roseman & Gloppen, 2011; Afonso da Silva & Terrazas, 2011; Lopes, Barberato-Filho, Costa & Osorio-de-Castro, 2010). One study found that 97% of Brazilian cases were decided based on the medical evidence provided by the petitioner and his or her physician without any additional

information on the quality of the treatment, the patient's need, and/or alternative treatments (Wang, 2013; Ventura, Simas, Pepe & Schramm, 2010).

In April and May of 2009, the Supreme Federal Tribunal (STF) initiated and held public hearings about health care rationing. Over six days it listened to testimony by government, civil society, academia, and legal professionals on how to address the judicialization of health (Yamin, Parra-Vera & Gianella, 2011). The Court agreed that it could not supply all of the treatments that patients demanded, especially pharmaceuticals for which there was no proven evidence. Following the public hearing, the STF and National Council of Justice adjudicated nine cases through which it established guidelines to define the duties that citizens can demand from the public health system. Recognizing that the system has limited resources, the Court outlined four instances in which the Court may oblige the public health system to offer a treatment to a patient that was previously denied: (1) the safety, efficiency, and quality of the treatment is recognized by the Brazilian National Health Surveillance Agency (excluding experimental treatments), (2) the treatment is already included in the public health priorities, (3) the petition can prove that no treatment is offered to her or the treatment already offered are not appropriate, and (4) the non-included treatment has been used for a long time by patients who can afford it but the inclusion of the treatment in official lists and guidelines is very slow (Wang, 2013). However, the Court has since failed to heed this consensus and has continued frequently to decide that scarcity of resources and a lack of scientific evidence are not adequate reasons for denying access to care (Wang, 2013).

Brazil's Courts hold a heavy hand when deciding access to medicines cases. While the decisions do not provide in depth interpretation of the decision, the crux of the decision may lie in the constitutional phrasing that "health is the right of all…and shall be guaranteed…by universal access to *all* activities and services for its promotion, protection, and recovery" (emphasis added). The phrasing leaves open the opportunity for Courts to interpret the Constitution as allowing access to all drugs and services that might have some health benefit, and not just those on the essential medicines list. However, Courts are much less likely to rule in favor of the petitioners on collective claims. Collective claims are brought on behalf of more than one patient and argue for access for a group of patients or patients in a certain jurisdiction. Arguably, the Court is better able to see the impact on scarce resources that the decision could have when a collective claim, rather than an individual claim, is presented (Wang, 2013; Hoffman & Bentes, 2010).

3.1.2a State of Mato Grosso v. Marina de Almeida Andrade RE 400040/MT (2005)

Federal Supreme Court

In 2005, the State of Mato Grosso appealed a Court of Justice opinion that required the State to provide free medication to an HIV/AIDS patient in need, even though that medication was not included on the essential medicines list. The State argued that such a decision violated the Constitution and that it would be unreasonable to compel the State to pay for benefits that had not been previously allocated in the budget.[4] Agreeing with the Court of Justice, the Supreme Court found the State responsible for providing free treatment and medications to HIV/AIDS patients unable to pay. The Court reminded the State that the right to health is guaranteed in the Constitution, and that the government is responsible for making policies that uphold that right.

3.1.2b State of Espirito Santo v. Eduardo Antonio Vieira Tapias RE 523726/ES (2007)

Federal Supreme Court

In 2007, the State of Espirito Santo appealed another Court of Justice decision that the State was responsible for providing all of the medical treatment and medicines necessary to treat a serious illness, including the provision of Viagra, even though it was not on the essential medicines list to be provided free of charge. The Federal Supreme Court affirmed the lower court's decision, holding that the State must provide free pharmaceutical drugs and healthcare services—including Viagra—to those suffering from disease who could not afford them.

3.1.2c Municipality of Caxias do Sul v. Vinicus Carpeggiani AI 797349/RS (2011)

Federal Supreme Court

The Municipality of Caxias do Sul appealed a decision of the lower court that the federal, state, and municipal governments held joint liability for providing free medication to those financially needy and suffering from serious disease. The Federal Supreme Court upheld the lower court's ruling that all three government branches were liable for securing access to "medicines [for] the preservation of [a person's] life and/or health," and that doing so was "a constitutional duty that the state [could not] fail to meet" (463).

[4] Because the full judgment has not been translated to English, the rationale for upholding access on a Constitutional basis cannot be supplied.

3.1.3 Chile

The Chilean constitution was established in 1980 and revised in 2014. Article 19 of the constitution assures the right to health protection. The Article also recognizes the State's responsibility to protect access to activities for the "promotion, protection and recovery of the health and rehabilitation of the individual."

Article 11 of Law 18, 469, titled "Regulating the exercise of the Constitutional right to the protection of health and creating a Health Benefit Plan" states that "benefits must be granted by dependent services and institutions of the Ministry of Health, pursuant to Decree-Law 2,763, and provided by these bodies through their facilities using the physical and human resources they have available. Subsection 3 stipulates that the Ministry of Health shall establish the rules of access, quality and opportunity in relation to benefits for beneficiaries" (*N.R.V.*, 2011)

Sparse literature exists on the judicialization of the right to health in Chile. However, *N.R.V.* offers an example of a judicial decision in a civil law system that is deferential to national legislation and government process for priority setting. The Court declines to overstep the bounds of the law created by the Ministry of Health regarding access to medicines. Even further, *N.R.V.* acknowledges that limited resources preclude the opportunity of covering an unlimited number of healthcare treatments and resources.[5]

3.1.3a N.R.V. v. Ministry of Health and East Metropolitan Health Service 3.599-2001-16 (2001)

Supreme Court

In a writ of *amparo*, individuals with HIV/AIDS petitioned against the Ministry of Health and the Public Health Service, arguing that access to medicines and treatments for HIV/AIDS qualify as constitutional rights to life and freedom from discrimination. They argued that HIV/AIDS should be considered a public health issue and that the Ministry of Health should implement policies to combat the disease. In response, the Court found a law did in fact regulate the access to the medicines and health treatments that the petitioners sought, and, as a result, they required no legal protection. It found that "Law 18,469 specifically regulates how required benefits should be granted, and it is thus within [law maker] power[] to decide whether or not to grant the assistance requested." In its decision, the Court

[5] Note, however, that other countries have considered access to care for persons living with HIV/AIDS cost- and clinically-effective, and in alignment with societal values. Thus, while deferential to priority-setting legislation, the favorable nature of legislation that denies care to persons living with HIV/AIDS could be debated.

acknowledged that the Ministry of Health is best suited to establish regulations about access to health benefits and account for the various parameters that must be considered such as costs and available funds. In fact, the Court recognized that granting the benefits claimed by the appellants would be arbitrary, giving preference to the appellants and their desired medical treatment "for the sole reason that a writ of *amparo* was sought."

3.1.4 Colombia

The Colombian constitution, established in 1991 and last amended in 2013, recognizes a State responsibility for securing the public health. Article 49 reads, "Public health and environmental protection are public services for which the State is responsible. All individuals are guaranteed access to services that promote, protect, and restore health."

Citizens may appeal to the Constitutional Court to hear actions of tutela – a writ of protection of their fundamental rights. In order to do so, they must fulfill four requirements: (1) a fundamental right must be threatened, (2) the procedure or treatment cannot be replaced by another medication covered by the health care system and boasting the same effectiveness, (3) the patient must be unable to afford the cost of the medication or treatment plan required and must be unable to access health care through an alternative system, and (4) the medication, procedure, or treatment plan must be prescribed by a doctor affiliated with the Health Promoting Entities to which the applicant is insured (ISPOR, 2015).

Often times, judges have inadequate information on cost-effectiveness, and they either disregard or fail to consider whether or not a case complies with the above four requirements. As a result, judges often hear cases and resolve them in favor of the patient—in 2012, 80.6% of the 114,313 *tutela* cases were resolved in favor of the patient (ISPOR, 2015).

A 2014 study by the Ombudsman's Office reported that in 2013, a *tutela* action based on a citizen's right to health occurred every four minutes in Colombia. This statistic demonstrates the frequency of right to health *tutela* actions despite multiple healthcare reforms (Mora, 2014). *T-760* highlights the Constitutional Courts' desire to be deferential to healthcare legislation, but rebukes the healthcare system and legislation for failure to achieve its established goals or guarantees. Yet, the decision still heavily recognizes the guaranteed right to health and alludes towards greatest reliance on the prescribing physician's opinion over that of the Health Promoting Entity. *Morrigan* offers an explicit example where the Court challenges the recommendation of the Health Promoting Entity.

3.1.4a Mr. X vs. Instituto de Seguros Sociales (ISS) T-271 (1995)

Constitutional Court

Mr. X, an HIV-positive individual, challenged the public social security scheme for refusing to provide him with the ARVs that he needed to preserve his health. The cocktail of antiretrovirals was not listed on Colombia's Official Drugs List because of their high cost. The Court, in holding that the right to health is fundamental if even indirectly connected with the right to life, determined that the State was obligated to provide medications that would alleviate the condition of people with serious illnesses (*Also see* Hogerzeil et al., 2004).

3.1.4b T-760/08, Corte Constitutional (2008)

Constitutional Court

In 1993, Colombia passed Law 100—a reform to its healthcare system that created a two-tier benefit system: (1) POS—a contributory regime, and (2) POSS—a subsidized regime with half the benefits of POS. The reform also utilized public and private insurers (Health Promoting Entities) to purchase healthcare for patients. However, the dramatic increase in *tutela* actions following the implementation of the reform showed that the Law was not achieving the quality and efficiency gains it had guaranteed. Residents continued to initiate *tutelas* to demand access to the services now obligatorily included in their coverage plans, but not provided (Yamin & Parra-Vera, 2009). As a result, in 2008 the Constitutional Court joined 22 *tutela* actions to determine whether the regulatory failures to provide access to services denied the respect, protection, and fulfillment of the right to health constitutionally guaranteed to Colombian citizens. 20 of the 22 cases related to well-established guarantees by the Court which insurance companies and providers inadequately incorporated in their policies due to administrative and regulatory failures (Yamin & Parra-Vera, 2009). The Court ruled all 22 actions in favor of the claimants, and ordered the Health Promoting Entities to provide them with the services they requested.

In its decision, the Court identified limits on the right to health by explicitly stating "the benefits plan need not be infinite but can be circumscribed to cover the health needs and priorities determined by the competent authorities in light of the efficient use of scarce resources" (3.5.1). The Court reviewed situations in which it had denied access to services petitioned through *tutelas*, such as: (1) cosmetic services, (2) services to prevent obesity (until obesity poses potentially irreversible dangers to someone's life), as individuals have the obligation of taking care of their own health, (3) dental care, as it is unnecessary to preserve a person's life or personal integrity, (4) alcoholic rehabilitation/detox, and (5) eyeglasses and refractive eye surgery.

The Court noted that the scientific opinion of the physician is the main, but not exclusive, criterion for determining the necessity of a certain health service. Constitutional jurisprudence typically protected access to a service when the attending physician representing the patient advocated that the service was required to protect that patient's right to health. However, in noting the primary importance of the attending physician's opinion as he or she knows the patient best, the Court also highlighted the importance of respecting the opinions of other attending physicians who are appropriately specialized in the area of interest. (4.4.2). The Court recognized the conflicts between the physician and the Scientific Technical Committee of the Health Promoting Entities, but held that the opinion of the physician would prevail over the Scientific Technical Committee when there was a gap between them, "unless the Scientific Technical Committee determines otherwise based on (i) opinions of medical specialists in the field in question, and (ii) a full and sufficient knowledge of the specific case under discussion" (4.4.4).

According to the Constitutional jurisprudence, the right to health of a person requiring a health service not covered in the obligatory plan is violated when "(i) the lack of medical service violated or threatens the rights to life and personal integrity of those who need it, (ii) the service can not be replaced by another that is included in the obligatory plan, (iii) the patient can not afford to directly pay for the service, nor the amounts that the health care provider is legally authorized to charge, and can not access the service by another different plan, and (iv) the medical service has been ordered by a doctor attached to the entity charged with ensuring the provision of the service to those requesting it." (4.4.3).

Referring specifically to Health Promoting Entities and the Scientific Technical Committee, the Court found that the Entity violates constitutional jurisprudence if it denies a requested service to a person only by saying that service is not included in the obligatory health plan. (6.1.3.1.1). The Court explained how the current method for gaining access through the Scientific Technical Committee to those services which are not covered is ineffective and requires reform. The decision analyzed systemic healthcare system problems (T-760, 2008). It implored the government to achieve universal health coverage by 2010 (Yamin & Parra-Vera, 2009).

In January 2011, Law 1438 was enacted to alleviate structural weaknesses in the healthcare system. It aimed, among many other objectives, to pursue universal coverage, to equalize benefits, and to achieve financial sustainability. For strong priority setting, the Law mandated that the benefits plan should be updated using clear and transparent methods and should enlist stakeholder engagement (Vargas-Zea, Castro, Rodriguez-Paez, Tellez, & Salazar-Arias, 2012). It aimed to

restructure the two-tiered benefit system to achieve universal health coverage (Warren, 2014).

3.1.4c Morrigan, Estrella v. Coomeva EPS (T-310/10), 2010

Constitutional Court

A 25-year-old female sought legal protection against her Health Promoting Entity that refused to cover the labiaplasty surgery prescribed by her physician to treat her labia minora hypertrophy. The lower court upheld the Entity's decision not to cover the surgery, as the condition did not threaten her health or her ability to live a life with dignity. The Constitutional Court overturned the lower court's decision on the grounds that the court had not questioned whether the condition threatened her reproductive health. If so, then the labiaplasty could not be considered strictly aesthetic and should have been covered.

3.1.5 Costa Rica

Costa Rica's constitution grants no explicit right to health, but the Supreme Court (Sala IV) plays a prominent role in mandating health rights. Any individual can file a claim directly with Sala IV, at no cost and without legal representation. In 1989, the Constitutional Chamber of the Supreme Court inferred a constitutional right to health from the protection of human life, the right to social security, and the International Human Rights Conventions to which Costa Rica is a signatory (Norheim & Wilson, 2014).

In 1997, in its ruling on resolution number 1997-05934, Sala IV rejected the cost-prohibitive arguments that it had previously accepted to deny access to medications, and ruled to allow access to a new, highly effective triple combination set of ARVs to three HIV/AIDS patients. In its decision, Sala IV argued "what good are the rest of the rights and guarantees…[or] the advantages and benefits of our system of liberties, if a person cannot count on the right to life and health assured?" (Norheim & Wilson, 2014, p. 49). This line of reasoning has since been expanded and clarified in subsequent Costa Rican right to health cases, and continues to dictate the outcome (Norheim & Wilson, 2014).

The petitioner succeeds in approximately 60% of medical *amparo* cases, with the Court determining that the medical doctor or specialist knows the needs of the patients, and a prescription from that doctor outweighs the technicalities of the CCSS's essential drugs list.

A study conducted by Norheim & Wilson, which codified 37 successful *amparo* cases heard by Sala IV in 2008 found that approximately 70% of those cases

secured access to low priority or experimental treatments (Norheim & Wilson, 2014). In other words, 70% of those successful cases provided marginal health benefits to the individual seeking access for a very severe condition, and the treatment came at a high cost the healthcare system. While Costa Rica follows a civil law system, it has chosen to follow the precedent of the 1997 case, which broadened the right to health and the judicialization of that right. Statistically, the country continues to allow access to medications even when they are experimental or of very low priority.

3.1.5a Ms. Vera Salazar Navarro vs Caja Costarricense de Seguro Social, 01-0090007-CO (2001)

Constitutional Court

The Social Security Institution refused to cover the branded drugs prescribed for Ms. Navarro's multiple sclerosis, offering instead to reimburse the cheaper generic option. While the Institution argued that the effects and composition of the generic drug were the same, the petitioner argued that the replacement of the drugs violated her right to health. The Court held that the Social Security scheme must deliver the exact drug that a doctor has prescribed to his or her patient and that the replacement of drugs breached her right to health (*Also see* Hogerzeil, 2004).

3.1.6 Panama

Article 109 of Panama's constitution—established in 1972 and last amended in 2004—mandates that "It is an essential function of the State to protect the health of all the people of the Republic. The individual, as part of the national community, is entitled to promotion, protection, conservation, recovery and rehabilitation of his/her health and the obligation to preserve it, health being understood to be complete physical, mental, and social wellbeing." Article 110 outlines specific duties that the State is obliged to undertake in order to promote and preserve that health and wellbeing.

While literature on Panama's experience with the judicialization of the right to health is also small, *Lachman* offers another example where the Court elects to be deferential to the State's priority-setting policies.

3.1.6a Ricardo Lachman Sunitinib otros v. Caja de Seguro Social, No. 199812 (1998)

Supreme Court of Justice

The petitioner, a physician, brought action on behalf of his patient and the Foundation for the Well-Being and Dignity of Persons with HIV/AIDS against the

Social Security Fund for denying his patient the HIV/AIDS medication he had prescribed. The Social Security Fund denied access to the medications because they were no longer on the Official Medicines List. The petitioner claimed that such denial contradicted the patient's right to health, the obligation of the government to protect that health, and the government's responsibility to implement a program on quality and control of medications for the population.

In finding for the Social Security Fund, the court noted that the Social Security Fund is responsible for providing only those medications that can be found on the Official Medicines List. As a result, the court dismissed the appeal for legal protection under the auspices that it was purely of administrative nature on State medical material policy.

3.1.7 Uruguay

The Uruguayan Constitution was established in 1966 and last amended in 2004. Article 44 of the Constitution specifically directs the State to legislate "on all questions connected with public health and hygiene, endeavoring to attain the physical, moral, and social improvement of all inhabitants of the country."

The Uruguayan court's decisions represent strong conflict between the courts and priority setting methods. On more than one occasion, the courts disagree with the prioritization of treatments as illegitimate or unfair. The courts also place heavy reliance on the opinion of the prescribing physician.

3.1.7a Marquez Velazquez Antonio Gerardo vs. Ministry of Public Health, 39/10 (2010)

2nd Chamber of the Court of Civil Appeals

Physicians sought that the National Resource Foundation (FNR) grant the petitioner access to Sunitinib after Sorafenib failed, arguing that it was the only drug that would increase the patient's survival and improve his quality of life with metastatic kidney cancer. Sunitinib was on the national drug form, but not for use after Sorafenib failed. In requiring that the FNR grant the petitioner access to Sunitinib, the court held that it is not the physician's job to produce results from a treatment, but instead to offer the means by which a person may obtain those results. The court found that Sunitinib has been found efficacious as compared to, and similar to, Sorafenib on multiple occasions. It considered it "manifestly illegitimate" that the FNR fails to cover Sunitinib subsequent to Sorafenib simply because regulation says it must have been proven by Level One studies. The court takes great issue with the notion that the drug has been included on the drug form,

but not for use subsequently to another drug, noting that regulations are unable to consider the "individual and unique circumstances of each patient." Core to the court's argument, there was a high-level of scientific evidence proving the effective use of Sunitinib subsequent to Sorafenib—"the technical feasibility of the drug is undisputed according to expert evidence."

3.1.7b Hernandez Gonzalez, Eliu Aquiliano vs. Executive State Power of the Ministry of Public Health, 2-13.991/2011 (2011)

4th Chamber of the Court of Civil Appeals

Petitioner challenged the Ministry of Public Health for failing to provide Cetuximab to lower his tumor count, but the Ministry responded that it is not the institution's job to supply medications, even though it has supplied the exact drug to others on certain occasions. In finding for the petitioner, the court appealed to the basic principle that "health is a legally-protected right intimately linked to life, to the physical, moral, and psychological integrity of a subject, to her/his quality of life, and to the development of his/her individuality. Before all, the right to health implies that a human being has a right to an [sic] adequate professional care, to care for it, to prevent illness, to find a place to be treated and to receive the necessary treatment for their recovery" (VI). The court's decision relied on the testimony of the petitioner's physician that Cetuximab was the only drug the petitioner needed to contain and treat his disease, as well as other expert evidence that went un-challenged. The court also recognized that the drug was endorsed nationally and internationally and was approved by the Ministry of Public Health for commercial use in 2009. Importantly, in making its decision, the court relied on the prior case No. 169/2011, another *amparo* case that raised the same claim.

3.1.7c Hernandez Edward v. Fondo Nacional de Recursos, No. 393/2011 (2011)

2nd Chamber of the Court of Civil Appeals

The court upheld the lower court's decision in granting the petitioner access to Nexavar-Droga Sorafenib for his renal cancer, as the differentiation that the drug was included on the Therapeutic Drug Roster for another cancer and not general oncological treatment had "no logical or scientific basis whatsoever." They considered that the drug was covered for one type of cancer but not the other to be "a technicality." The court placed emphasis on the physician's decision, considering that "prescriptions and therapies chosen by the physician cannot be dictated by politicians and administrative authorities…If administrative authorities are permitted to tell doctors what to do, this would be putting patients in the hands of political powers…" They further argued that "the medical profession must be governed by the principle of discretion, which manifests itself in the physician's

choice of drug for a patient's treatment, with his or her knowledge of the particularities of the case and the fact that all consumers have the right to a treatment that causes the least problems or dangers to them, in light of all scientific advantages that medicine can put at the patient's disposal."

3.1.7d Fontes Braida, Oscar v. State—Executive Branch—Ministry of Health, No. 3/2011 (2011),

3rd Chamber of the Court of Civil Appeals

Mr. Fontes Braida brought legal action against the Ministry of Public Health for failing to provide him with Cetuximab for his colon cancer. When the Canelones Medical Cooperative refused to cover the drug, Braida began self-funding the treatment with excellent results. When he ran out of money, he applied to the National Health Fund (for high cost specialized treatments), which denied coverage because the drug was not on the therapeutic drug form. He subsequently applied to the Ministry of Public Health for coverage. The Ministry of Public Health claimed that it was not its responsibility to provide the drug, and the drug was not on the therapeutic form, even though the Ministry had covered the same drug for others in the past.

Hearing the issue as to whether or not the drug should have been included on the therapeutic drug form, the court denied the Ministries argument in favor of the technical and regulatory annual procedure for updating the therapeutic form (FTM). The court held that "equal access to the necessary treatment in accordance with each individual's state of health, and, particularly, the right to access necessary medication" is fundamental to his or her right to health. The court further noted that the "annual review" time frame of updating the FTM is insufficient where medical technology advancements are fast moving. The annual review "should never be interpreted as a limiting factor for the inclusion of a new drug on the roster". Finally, in upholding the lower court's decision, the court found that the Ministry's argument that it is not in charge of providing the medication is flawed, and it is discriminatory that they have provided the medication to some and not to others.

3.2 Eastern Europe

3.2.1 Latvia

Latvia established its constitution in 1922. It was last amended in 2014. Article 111 of the constitution states, "The State shall protect human health and guarantee a basic level of medical assistance for everyone." The following decision by the Latvian District Court of Administrative Cases recognizes that governments have limited resources with which to cover healthcare services, and that the government may act within those limits without denying the State's responsibility to guarantee a basic level of medical assistance, so long as those limits are just and proportional.

3.2.1a Case No. 42755708 (2010)

District Court of Administrative Cases

The Plaintiff sought reimbursement for 13 packs of Sprycel that he had purchased throughout the year. Medical professionals felt the drug was required for his survival. According to Regulation No. 899 adopted on the grounds of the Pharmaceutical Law, medications on the reimbursable medication list to treat chronic, life-threatening illnesses or illnesses causing permanent disability receive full compensation. Medicines not on the list could be reimbursed up to LVL 10,000 for 12 months. This compensation cap applied to Sprycel as it was not listed on the reimbursable medication list. The Plaintiff claimed that his case was not typical, due to the fact that Sprycel was very effective for treating his illness; he asked the court to administer an administrative act to require the Ministry of Health to fully compensate his 13 packs of Sprycel, amounting to over LVL 77,000.

The court declined to issue an administrative act to require the Ministry of Health to cover the Plaintiff's Sprycel, reasoning that Resolution No. 899 did not conflict with the provision in Article 111 of the Constitution requiring a fixed amount of health care services to be paid by the State. It stated that within the State's funds, the maximum amount granted to compensate an individual for a drug not on the reimbursable medicines list was LVL 10,000 for 12 month.

It does note, however, that if an institution applied correct legal norms but the effect resulted in a restriction on an individual too severe juxtaposed against the benefit society would gain, such result would violate the "proportionality principle." In these cases, the fault would lie with the legislation, and the court could correct this Legislator's error. An atypical case "complies with all judicial requirements for legal norms, however, additional circumstances are indissolubly related to it and they are significantly altering the character of that care." The court

identified different age groups, a lack of money, and a high-priced medication as typical cases that would be subject to the LVL 10,000 compensation cap.

The Court also recognized that the Legislator did not expect LVL 10,000 to sufficiently cover the cost of all medications not on the reimbursable list. Rather, the Court noted, the Cabinet created the LVL 10,000 cap with the understanding of budget constraints and with the intention that the State funding allocation "would be sufficient enough for the largest number of patients possible requiring medication purchase costs compensation."

In discussing the right to health, the Court argued, "objectively the State cannot be liable for [sic] person's illness and natural consequences caused by it." The court distinguished between the phrase "maintaining life functions" in Regulation No. 899 and the phrase "specific and urgent life threat" in Article 2 of the European Convention on Human Rights. The court stated that no law or regulation could guarantee a specific number of life years for an individual. The Court also noted that the Plaintiff had alternative sources from which to seek medication funding aside from the State.

3.2.2 Macedonia

Macedonia (formerly the Republic of Yugoslav) established its constitution in 1991 and last revised it in 2011. Article 39 of the constitution states, "Every citizen is guaranteed the right to health care. Citizens have the right and duty to protect and promote their own health and the health of others."

3.2.2a Stamen Filipov and Biljana Zhivkovska to the Constitutional Court, 109/2009-0-1 (2010)

Constitutional Court

Petitioners challenged a provision of the Law on Health Insurance excluding coverage of certain health services. While specialist care was included in Article 9 of the law to be paid for under the compulsory health insurance scheme administered by the Health Insurance Fund, "specialist consultative and hospital health services without referral from the chosen doctor or provided health services in health care facilities where the Fund had not provided health service at its own expense" were excluded under Article 10.

In an earlier case (U.No.45/2006), the Constitutional Court determined that the Fund was required to buy services from health providers if those items were listed in Article 9, regardless of whether the Fund had a contract with a specific provider.

Before the ruling, the Fund was only covering Article 9 services provided by providers with whom the Fund had a contract. Article 10 was added in response to this case.

The petitioners argued that the new exclusion added in Article 10 violated Articles 34, 35, and 39 of the Constitution—right to social protection and security, social justice, and health and health care, respectively. They asserted that Article 10 restricted their access to secondary care to those providers contracted with the Fund, leaving persons seeking care from other providers to pay out of pocket, and violating their health and social security rights.

The court repealed the provision, holding that it did violate the constitution. The court found that this exclusion in Article 10 restricted access to services that individuals were already supposed to have access to through Article 9. The effect was to restrict access to basic services that the Law guaranteed access to. The Law then no longer acted as health insurance, but instead discretionary coverage. The exclusion violated the right of health services users to choose a doctor and violated the constitutional level of legal regulation of health insurance rights and obligations. It stated "not only is the right of the users of health services to choose a doctor infringed, but it also essentially infringes the constitutional level of lawful regulation of the rights and obligations from health insurance."[6]

4. COMMON LAW

Judges play an active role in developing the law in common law systems. While statutes are important, and the legislature continues to play a leading role in the development of the law, judicial cases are supreme. A statute may delineate the elements of the law, but the case law (legal decisions) determines how those elements will be interpreted. Because the judicial branch plays such a critical role in determining the law, it relies on precedent to maintain consistency between cases—also known as the principle of *stare decisis*. Past judgments act as a guide to inform the court as to how it should decide the case before it (Economist, 2013). Common law cases are therefore distinguished from civil law cases by making decisions based on past judgments and to act as precedent for future ones. Contrarily, each civil law case stands on its own. The largest common law countries include: United States, England, India, and Canada (Washington University Law Blog).

4.1.1 Israel

[6] Recall that social insurance is considered a constitutional right.

The Israeli constitution was established in 1958 and last amended in 2013. It does not include a right to health, and so the rights to life, human dignity, and bodily integrity are used to infer a right to health. The constitution is made up of a number of Basic Laws, one of which is on Human Dignity and Liberty. The fourth provision of this Law states that, "all persons are entitled to protection of their life, liberty, and integrity" (Basic Law, 2007). *Gila Louzon's* reliance on prior judgments (both national and international) exemplifies the common-law method of relying on precedent for decision-making.

4.1.1a Gila Louzon v. Government of Israel, HCJ 4013/05 (2005)

Supreme Court

Petitioners sought legal remedy from the Supreme Court to instruct the government to cover medications not included in the health basket, as they struggled to purchase the medications specifically. They argued that omitting the medications violated their constitutional rights—considering that the right to life, bodily integrity, and human dignity as conferred in Basic Law: Human Dignity and Liberty includes the right to health—and that by extension they had a right to receive publically funded medical treatment. They also challenged the way in which the Committee decided what would be included in the health basket. They asserted that "by not including Erbitux in the health services basket, appropriate weight was not assigned to the value of saving human life, and this constituted discrimination against the petitioners in relation to other patients whose required medications were included in the basket" (13). The State responded that the court should take care not to derive a general constitutional right to health and medical care, and that the prioritization of ranking medical technologies was a complex decision, subject to budgetary restrictions; the medication that petitioners sought (Erbitux) was new with unknown effects on improving symptoms of colon cancer and improving lives. They argued "the Committee was entitled to give it a lower priority than other medications that had been proven to be life-prolonging" and that the "recommendation was adopted after a thorough, informed, and in-depth decision making process, legally conducted" (3).

The court responded by first stating that the petitioner's assertion about a constitutionally protected right to health was far too broad. The right to health included "the right to preservation of a patient's privacy" as well as "the right not to be discriminated against with respect to access to medical treatment" (15). The petition was actually focused around a right to receive publicly funded medical treatment, which inarguably was not guaranteed as a basic human right. In fact, past legislative attempts to confer constitutionally protected status on social rights such as the right to health had failed.

The Court determined that prior case law had established that the right to basic health services was conferred in the right to human dignity, but had never determined which basic health services were protected, and whether the right should extend beyond protecting the basic level of services required to protect human existence.

The Court recognized the heavy conflict between offering to citizens any health treatment that may have any life saving potential, and appreciating the limited resources of the health care system. It noted that its policy was to be cautious about getting involved in economic policy where the legislature and executive had made decisions. Reviewing the ICESCR, to which Israel is a signatory, the court noted that the convention recognized the necessity of accounting for budgetary constraints when securing population health ("Section 2 of the Covenant adds that each Party State will take steps "…to the maximum of its available resources…").

Concluding that the medication did not need to be constitutionally provided, the court recognized that a lack of consensus on the effectiveness of the drug and "experimental innovative medication[] would not fall within the rubric of the *basic* health services required for minimal human existence in society" (22).

In holding that access to Erbitux did not fall under the legal right to public health services in Israel, the court cited a number of legislative articles, the National Health Insurance Law, and the Patient's Rights Law (as well as court cases such as *Soobramoney*) to distinguish instances in which a legal right to public health services had been conferred. Quoting a previous judicial decision, the court reiterated "the Health Law establishes a basket of services. It does not purport to provide all of the medical services that are or may be required by those insured by the Sick Funds…the existence of a health system is dependent upon its financial balance, and the existing financial sources do not guarantee the provision of all the possible medical services" (28). *Macabbi Health Services v. Minister of Finance* found that "the right to extend the health services basket beyond the basic basket is a…'budget-dependent right[]'" (29).

The court discussed whether or not the components of the health basket were legally determined. Under the National Health Insurance Law, any additional medication or technology added to the health services basket must come with a suitable funding source to cover the additional costs, and any decisions about additions to the basket that would involve additional cost required a decision by the Health Minister agreed upon by the Minister of Finance and the approval of the Government. The process for expanding the basket included a public appeal for requests for new services or technologies on which data was collected and professional evaluation was conducted. A Committee then evaluated the

technologies with the provided information based on a budgetary framework. The Committee's recommendations were sent to the Health Council, and then the Minister of Health. The court recognized the structure, accountability, and professionalism of the committee, and would not dispute the Committee's decisions so long as the correct process was followed and the appropriate framework was used. In rejecting the petitioner's argument that the committee acted inappropriately, the court stated that according to settled case law, public authorities were entitled to take budgetary constraints into consideration. The Health Law required an additional funding source for new additions to the health basket, making budget considerations legally mandated. In reviewing the process that the Committee used to determine the inclusion of Erbitux and the information that it took into consideration, the court found the committee decision reasonable.

4.1.1b Victoria Yisraeli v. Health Basket Committee, HCJ 2974/06 (2006)

Supreme Court

Petitioners requested that the National Health Law be amended so that adults suffering from bilateral deafness and requiring a cochlear implant would be exempted from the 70% "payment of participation" required (alternatively, petitioner requested that the participation rate be reduced so that the implant was available to those in need). The petitioners argued that the rate was too high and made the procedure unaffordable for all but the wealthiest. They argued that the basic right to health insurance guaranteed in the Health Insurance Law was part of human dignity, and that while some participation might be justified for cost of medication and treatments, 70% was unreasonable and not proportionate. The State, Ministers of Health and Finance, and Health Basket Expansion Committee responded by showing the necessity for a new funding source if a new technology was to be added. The Committee had evaluated whether or not to include the implant in the covered technologies but decided against it, offering coverage to higher priority technologies. They also claimed that a socio-economic right was not necessarily a part of the right to human dignity in Basic Law: Human Dignity and Liberty. Clalit Health Services wrote separately to argue that while it agreed on the humanitarian issue faced by the petitioners, it believed the issue was one for the legislature. It took no independent stance.

While the court found for the government, it drew attention to the potentially unfair level of participation that a 70-80% participation rate requires. Looking to formal definitions, participation required some participation from either party, no matter how large. Colloquially, the court found that participation signified an *additional* contribution, not a *majority* contribution. However, it found that this rate had been established by the legislature, commonplace for many years, and continued to have support from the legislature.

The court concluded that the Health Basket Committee held a well-devised scheme for priority setting, that resource allocation was essential in a health care system, and that that system would not be disputed. It said specifically "in a world in which medicine and technology are rapidly changing, often beyond recognition, but in which the costs of the technology and medications are high, there is no escaping the need to establish priorities." Even recognizing the life-restoring level and quality of the cochlear implant for adults, the court would not overturn the well-devised Health Law of the Israeli government.

5. MIXED LAW

Countries utilizing principles of both civil and common law are classified as having mixed legal systems.

5.1 Africa

5.1.1 South Africa

The South African constitution was established in 1996 and revised in 2012. It contains Section 27 specifically addressing "Health Care, Food, Water and Social Security" rights. Those rights include access to healthcare services (including reproductive health care). Children specifically also have the right to "basic nutrition, shelter, [and] basic healthcare services and social services" under Section 28.

In a case hailed for upholding fair and equitable access to care for South African citizens, the Constitutional Court decided *Minister of Health v. Treatment Action Campaign* in 2002. The South African government had developed a public health program to offer free nevirapine to HIV-positive pregnant women. However, the program was limited to pilot sites and failed to identify a timeline for national expansion of the program. The Court determined that the government must take reasonable steps to progressively realize Section 27 rights. It further found that, while it was reasonable to limit the program to pilot sites to determine its scalability and the drug's efficacy, the government could not wait until it had identified the most perfect program to scale up. Doing so, the Court reasoned, would unfairly deny women and children nevirapine access. *Soobramoney* offers another example of the Constitutional Court balancing the reasonableness of provision of services with the right to health.

5.1.1a Soobramoney v. Minister of Health, Case CCT 32/97 (1997)

Constitutional Court of South Africa

Appellant Mr. Soobramoney had diabetes, ischemic heart disease, and cerebro-vascular disease. When his kidneys failed in 1996, he was diagnosed with irreversible, chronic renal failure and he requested to be placed on the dialysis program of Addington State Hospital. Because of the hospital's limited resources and capacity, it was unable to offer dialysis to all of those in chronic renal failure. As a result, it followed the strict policy that only those patients with acute renal failure who could be treated and remedied were given automatic access. Also according to the hospital's policy, only those with chronic renal failure eligible for a kidney transplant would be given dialysis. Mr. Soobramoney was not eligible for a kidney transplant as a result of his ischaemic heart and cerebro-vascular diseases.

The appellant claimed that the hospital was required to make dialysis treatment available to him to comply with sections 27(3) and 11 of the 1996 Constitution, providing that no one may be refused medical treatment, and everyone has a right to life, respectively. In deciding in favor of Addington hospital, the court held that section 27 of the Constitution was dependent upon the resources available to offer resources to the public. The court reviewed the Department of Health in KwaZulu-Natal budget and found that, as it stood, the Department did not have sufficient funds to cover the services already publicly provided. It recognized that the State was not currently able to fulfill an unqualified obligation to housing, health care, food, water, and social security needs.

The court also found that while the phrase "emergency medical treatment" could be open to a broad interpretation, the court would expect a positive and specific statement of an alternate interpretation if anything other than the phrase's ordinary meaning were intended. If section 27 were construed as the Appellant desired, it would be substantially more difficult for the State to provide health care services to "everyone" given its limited resources. It would also have the effect of always prioritizing treatment for terminal illness over that of preventative care or non-life-threatening illnesses. The court found that such specific interpretations would need to be more specifically stated in section 27 to justify such a conclusion. Dialysis for chronic renal failure did not qualify as "emergency medical treatment," where such emergency treatment was defined as an emergency requiring "immediate remedial treatment."

The court held that if dialysis for chronic renal failure were provided to the Appellant, it would have to be provided to all individuals in the same condition—an impossible endeavor given the available funding and resources.

Recognizing that an unqualified right to human life cannot be granted to all persons, the court reasoned:

> "The State has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society" (19).

The court concluded that the responsibility for making difficult decisions about allocating the health care budget should lie with the political and medical authorities, and that it would not be quick to interfere if the decisions were made rationally and in good faith. It recognized the reality that limited healthcare resources must be maximized.

5.1.2 Kenya

The Kenyan constitution boasts an entire section on economic and social rights, Article 43 of which reads "every person has the right…to the highest attainable standard of health, which includes the right to health care services, including reproductive health." The constitution was newly established in 2010. The youth of the constitution is embodied in its comprehensive right to health references.

5.1.2a Okwanda v. Minister of Health and Medical Services and Ors., No. 94 (2012)

High Court of Nairobi

The petitioner sought urgent medical attention for his life-threatening terminal illness, Benign Hypertrophy. He claimed his fundamental social and economic rights under Article 43 of the Kenyan Constitution, as well as the special protections for older members of society ensured in Article 57. He asserted that his requests for free treatment were not unreasonable, as the constitution specifically intended to protect those poor and marginalized members of society. In response, the State argued that the petitioner did not set out a clear violation, did not clearly identify the constitutional violation, and did not offer a reasonable cause of action. It stated that Article 43 secured a progressive realization of social and economic rights within confined resources.

In interpreting Article 43, the court also referred to Article 20(5) in which the constitution directs that:

> In applying any right under Article 43, if the State claims that it does not have the resources to implement the right, a court, tribunal or other authority shall be guided by the following principles—

(a) it is the responsibility of the State to show that the resources are not available;
(b) in allocating resources, the State shall give priority to ensuring the widest possible enjoyment of the right or fundamental freedom having regard to prevailing circumstances, including the vulnerability of particular groups or individuals; and
(c) the court, tribunal, or other authority may not interfere with a decision by a State organ concerning the allocation of available resources, solely on the basis that it would have reached a different conclusion

The court also referenced Article 21 under which the State must act to progressively realize Article 43 rights, and Article 2(6) under which international legal instruments such as the International Covenant on Civil and Political Rights, the International Covenant on Economic and Social Rights, the Universal Declaration of Human Rights, and the Africa Charter on Human and People's Rights are incorporated into Kenyan law.

The court echoed the importance of incorporating economic and social rights into the constitution, as expressed by the petitioner. It identified the issue in determining whether or not the State had fulfilled those obligations of Article 43 as read with Article 21. The court had addressed this issue previously, interpreting Articles 43 and 21 to say that progressive realization implied "the state must begin to take steps, and…be seen to take steps, towards realization of these rights." The court concluded, therefore, "even where rights are to be progressively achieved, the State has an obligation to show that at least it has taken some concrete measures or is taking conscious steps to actualize and protect the rights in question."

The court turned to address whether or not the petitioner had established a state failure to "observe, respect, promote, and fulfill the rights and fundamental freedoms in the Bill of Rights." The court concluded that the petitioner did not offer evidence that the State had breached its constitutional duty. The state provided healthcare to the petitioner (even if provided at a cost). Again, the State only has an obligation to ensure that "every person has the right to the highest attainable standard or health". The questions of whether or not the cost was prohibitive and progressive realization of the right to health required free treatment was not explored in the depositions, and the judge did not answer them as a result.

The court concluded with addressing that there are clear health afflictions not sufficiently contained and treated that required attention, but that doing so was a matter of public policy within the constitutional framework, and not the courts.

6. DISCUSSION

The differences between the civil and common law systems promote variability in the way that the courts handle priority-setting cases. The lack of *stare decisis* in civil law systems leads courts to offer less consistent rulings and less deference to legislation and regulation. Most decisions do not hold the binding authority that results from common law judgments. As a result, one decision is not rooted in the reasoning of another, and decisions in right to health cases can vary greatly on a case-by-case basis.

6.1 Scaling back tutela or amparo action in civil law systems

Latin American courts play a prominent role in considering, and sometimes overturning, priority-setting decisions. For example, the Uruguayan cases identified above represent a strong propensity for the courts to disagree with coverage prioritization and to rely heavily on the recommendations of the prescribing physician. Language in the decisions—such as identifying the differentiation of certain drugs for certain cancer types as a "technicality"—signals a potential fissure between the medical and scientific, legislative, and judicial communities.

As discussed, many Latin American courts have aimed to develop strategic approaches to hearing priority setting cases, but they have been largely unsuccessful. The Brazilian Supreme Court outlined the duties that citizens are allowed to demand of the healthcare system, and, recognizing the realities of limited resources, the instances in which the court can force the healthcare system to grant a previously denied technology: (1) the safety, efficiency, and quality of the treatment is recognized by the Brazilian National Health Surveillance Agency (excluding experimental treatments); (2) the treatment is already included in the public health priorities; (3) the petition can prove that no treatment is offered to her or the treatments already offered are not appropriate; and, (4) the non-included treatment has been used for a long time by patients who can afford it but the inclusion of the treatment in official lists and guidelines is very slow (Wang, 2013). However, in making its decisions, the court has ruled that a scarcity of resources (and a lack of scientific evidence) is insufficient to deny care. Thus, the courts continue to grant access to medications for which a cheaper, but equivalent, version may already be accessible.

Similarly, the Colombian Constitutional Court set guidelines whereby citizens may appeal to the Court to hear actions of *tutela* if the case complies with four requirements: (1) a fundamental right must be threatened; (2) the procedure or treatment cannot be replaced by another medication covered by the health care

system and boasting the same effectiveness; (3) the patient must be unable to afford the cost of the medication or treatment plan required and must be unable to access health care through an alternative system; and, (4) the medication, procedure, or treatment plan must be prescribed by a doctor affiliated to the Health Promoting Entities to which the applicant is insured. However, lacking adequate knowledge about comparative effectiveness, courts often ignore or overlook whether or not a case complies with the above requirements (ISPOR, 2015). Thus, the court may make inconsistent decisions based on poorly defined standards, such as determining that access to labiaplasty would be granted if it were important to living a life with dignity in *Morrigan* (Colombia).

Governments could rely on past judgments to predict the future reasoning of the courts, and to prepare to defend their methods for priority setting accordingly. If using greater representation on behalf of priority setting, governments could utilize greater legal and medical representation to defend their prioritization methods. They could also turn to the rationalization of other courts in order to support their own arguments. In *Ana Carina*, Argentina interpreted Article 2, Section 1 of ICESCR to require states to use the maximum of their total resources, whereas Israel interpreted that same Section to demand utilization of resources up to a reasonable level in *Louzon* (Israel). Governments could pull from examples from other cases to argue how their present case should be decided. They could also aim to pool cases into collective claims, encouraging courts to better see the scarcity of available resources.

In addition to utilizing greater legal and medical representation in the courts to support the government priority setting decisions, courts could utilize solutions presented in the decisions of other country cases. For example, Latvia's proportionality principle, which it applies to ensure that the patient's suffering will never outweigh the benefit society will gain, could be applied to determine access to technologies in other countries. Rather than offering blanket approval for access to technologies that have been strategically denied by the government, the courts could apply a more standardized, formulaic principle like that of proportionality. Doing so would also require strong legal and medical representation in order to determine the threat to the patient and the harm to society.

However, identifying and strategically responding to past reasoning of the courts or utilizing the reasoning in other countries' judgments may offer limited benefit. While utilizing and relying on past examples could help in the decision making process, civil law courts have no obligation to follow the reasoning, or final decisions, in prior cases. Thus, a reduction in *tutelas* will require that the healthcare system better provide the healthcare access it guarantees—and not only that the government's decision-making is better defended. Priority setting methods, and

associated legislation, must also be appropriately strengthened to account for cost- and clinical-effectiveness, the social values of the population, marginalized or vulnerable groups, and other important features. To do so, policymakers may benefit from reviewing the reasoning courts offer for granting coverage and adapting legislation to what has been deemed constitutionally appropriate by the courts. Concurrently, the legislature and judiciary must work together to ensure that priority setting is adequately conducted to protect the right to health, and the judiciary feels comfortable to, and willingly agrees to, provide deference to such appropriate methods. This is especially true for countries with a deep history of judicial social policy making (Rueda, 2010). Judgments such as *T-760* (Colombia) signal the judiciary's desire to be able to yield to a fair and functional healthcare system.

6.2 Differentiating common law systems

Common law systems fundamentally differ from civil law systems, and their decisions in priority setting cases often reflect these differences. Relying on precedent, courts will reference prior decisions made by their own courts or foreign courts. *Louzon* (Israel) references past decisions when drawing its own conclusions. *Soobramoney* (South Africa) distinguishes itself from the Supreme Court of India's decision in *Paschim Banga Khet Mazdoor Samity and others v. State of West Bengal and another*. In *Samity,* the patient suffered a brain injury and serious hemorrhage after falling off of a train but was not offered the immediate medical attention and emergency services he required. *Soobramoney* utilizes *Samity* to define "emergency medical treatment" and determine that it did not apply in the present case.

Further, the influence of common law courts makes them more deferential to law and policy makers. Mixed legal systems applying common law principles in their courts appear equally differential. *Soobramoney* notes that it would not be quick to interfere with decisions made by medical authorities rationally and in good faith. *Okwanda* recognizes health afflictions requiring further attention, but finds that public policy, and not the courts, has the responsibility for doing so. This deference is pervasive across Africa. *Center for Health Human Rights and Development (CEHURD) v. Attorney General* in 2012 found that other branches of government are responsible for implementing health policies. It refused to intervene when petitioners claimed that the lack of basic health maternal commodities the Ugandan government offered to expectant mothers violated the constitution.

6.3 Striking a new balance between the legislature and judiciary in priority setting

Importantly, courts often overturn priority-setting decisions that have denied critical coverage or access to care. In doing so, they provide essential access to life saving, effective, and appropriate treatments. *T-760* (Colombia) denounced the government inefficiencies and insurance failures that were preventing individuals from gaining access to their guaranteed health coverage. Priority setting decisions should not be supported when they, for example, deny cost-effective, clinically effective treatments to a large and vulnerable patient group, such as denying antiretroviral therapy to persons living with HIV/AIDS. Priority setting must be conducted appropriately and strategically to ensure that patients can access true essential services. Thus, courts play a fundamental role ensuring that priority setting does not in fact conflict with a population's right to health. However, such deep judicial engagement in defining healthcare coverage and overturning priority-setting decisions could also be problematic.

As examined earlier, legal fees may be self-funded to employ private attorneys or paid by an unfamiliar NGO—pharmaceutical companies seeking coverage for their drugs may fund these NGOs. The heavy representation of certain physicians and attorneys suggests that the legal and medical professions might also have direct or indirect relationships with the pharmaceutical companies (Wang, 2013; Roseman & Gloppen, 2011; Afonso da Silva & Terrazas, 2011; Lopes et al., 2010). This relationship between NGOs, patients, physicians, and attorneys complicates the trust that courts place in physician recommendations. The Costa Rican Court, for example, has argued that a prescription from a physician outweighs the technicalities of an essential drugs list. Uruguayan courts may rely heavily on the scientific opinion of the physician as the main criterion for decision-making.

The government seems to consistently miss opportunities to offer equally strong medical representation on the opposing side. Where courts rely ultimately on the opinion of a physician, they must also hear evidence in support of priority setting from other trustworthy medical professionals. Efforts must be made to expose unethical relationships between NGOs, physicians, attorneys, and pharmaceutical companies. Fighting for access to a medication or service that is produced by the pharmaceutical funder is a clear violation of ethical principles and a physician's commitment to offer the best available care to his or her patients. In fact, Latin American courts often reject government arguments in favor of priority setting due to resource constraints out of a concern that such priority setting could actually be rooted in inefficiencies or corruption. More must be done then, to expose equally worrisome corruption in regards to patient representation.

A new balance between the judiciary and legislature will require transparent, explicit, and accountable priority setting in conjunction with the courts' greater reliance on those priority setting methods. Health technology assessment (HTA), a method of priority setting accounting for clinical- and cost-effectiveness, and social values, could be promoted to (1) ensure that proper, transparent, informed decisions about coverage are made, and (2) comfort courts with evidence that decisions have been made intentionally and rationally. Adopting an explicit, transparent method such as health technology assessment, the healthcare system could also incorporate an appeals process to challenge its coverage decisions. As a result, priority-setting decisions would be made methodically according to well-supported processes. Invested parties could appeal the decision to an appeals panel and again to the courts when and where they had a claim. (Dittrich, Cubillos, Gostin, Chalkidou & Li, 2016).

HTA, or a similarly explicit and transparent method for priority setting, and a subsequent process for appeals, would promote the greatest level of accountability to proper prioritization and adequate adherence to the right to health.

The National Institute of Health and Care Excellence (NICE), the priority-setting institution from England and Wales, offers a prime example of an organization held to this level of accountability. The initial priority setting process is clear, explicit and transparent, and it involves strong stakeholder engagement. However, when disagreement arises over technology appraisals and highly specialized technologies, the decision may be appealed on two grounds: (1) that in making its assessment, NICE failed to act fairly or exceeded its powers, or (2) that the recommendation is unreasonable in light of the evidence submitted to NICE (National Institute for Health and Care Excellence). In the case of further disagreement, individuals or organizations can seek legal redress where they believe that NICE's methodology was procedurally unfair.

For example, *Eisai Limited versus the National Institute for Health and Clinical Excellence* (2007) resulted from NICE's determination that the drug Aricept should not be covered for patients with early-stage Alzheimer's disease. The pharmaceutical company Eisai Ltd. appealed, and then sought judicial review to challenge the appeal panel's decision—and NICE's subsequent guidance—that Aricept not be funded as procedurally unfair, discriminatory, and irrational (Jackson, 2013). The Court of Appeal did not determine that NICE's guidance was wrong, but it did decide that restricting Eisai's access to NICE's economic modeling of the drug was procedurally unfair. In another example, a group of breast cancer patients challenged the funding scheme for Herceptin (for breast cancer) authorized by the Pharmaceutical Management Agency (Pharmac) in New Zealand in *Walsh v. Pharmaceutical Management Agency* (2008). While the Court found that

Pharmac's decision was procedurally fair and reasonable, it did have a duty to consult widely on the issue with breast cancer and women's health groups (which it had not done).

This method of explicit priority setting, opportunity for appeal, and judicial review, promotes a high level of accountability to fair decision-making, determination of the fairness of prioritization by an impartial, informed arbitral body, and maintains the opportunity for legal redress (Dittrich et al., 2016). It places an arbitral body as the frontline decision maker, but upholds the opportunity for judicial review where an informed appeals body has been inadequate.

6.2 Limitations

While this paper aims to offer a broad idea of international case law based on priority setting and the right to health, it is by no means comprehensive. The paper is limited by the case law available on the Global Health and Human Rights Database, and those cases that have been translated into English. Because, in some countries, thousands of right to health-based cases are heard each year, the cases identified do not necessarily represent the broader opinion of the judicial system or the trend in how cases are decided. Instead, each judgment offers an example in judicial decision-making that can be used to understand right to health cases, to predict future outcomes (when and where appropriate), to devise future research, and to develop future policy.

6.3 Future Research

This paper begins to explore the judicialization of the right to health and discusses methods for promoting a new balance between the judiciary and legislature in priority setting. With great hope, future research will explore the methods by which the lessons from past right to health judgments could be converted into effective legislation on health coverage priority setting. It will hopefully examine how to strengthen the communication between the judiciary and policymakers, and it will explore techniques for integrating an appeals process in order to improve accountability and maximize the transparency and fairness of priority setting.

6.4 Related Work

This working paper provides extensive background on priority-setting related court decisions. The ethicality and equitability of the judicialization of the right to health, and the potential solutions explored in section 6.3—striking a new balance

between the legislature and judiciary in priority setting—are explored in depth in: The International Right to Health: What Does it Mean in Legal Practice and How Can it Affect Priority Setting for Universal Health Coverage? The publication is part of the Health Systems & Reform 2016 Prince Mahidol Award Conference Special Issue, written by Rebecca Dittrich, Leonardo Cubillos, Lawrence Gostin, Kalipso Chalkidou and Ryan Li.

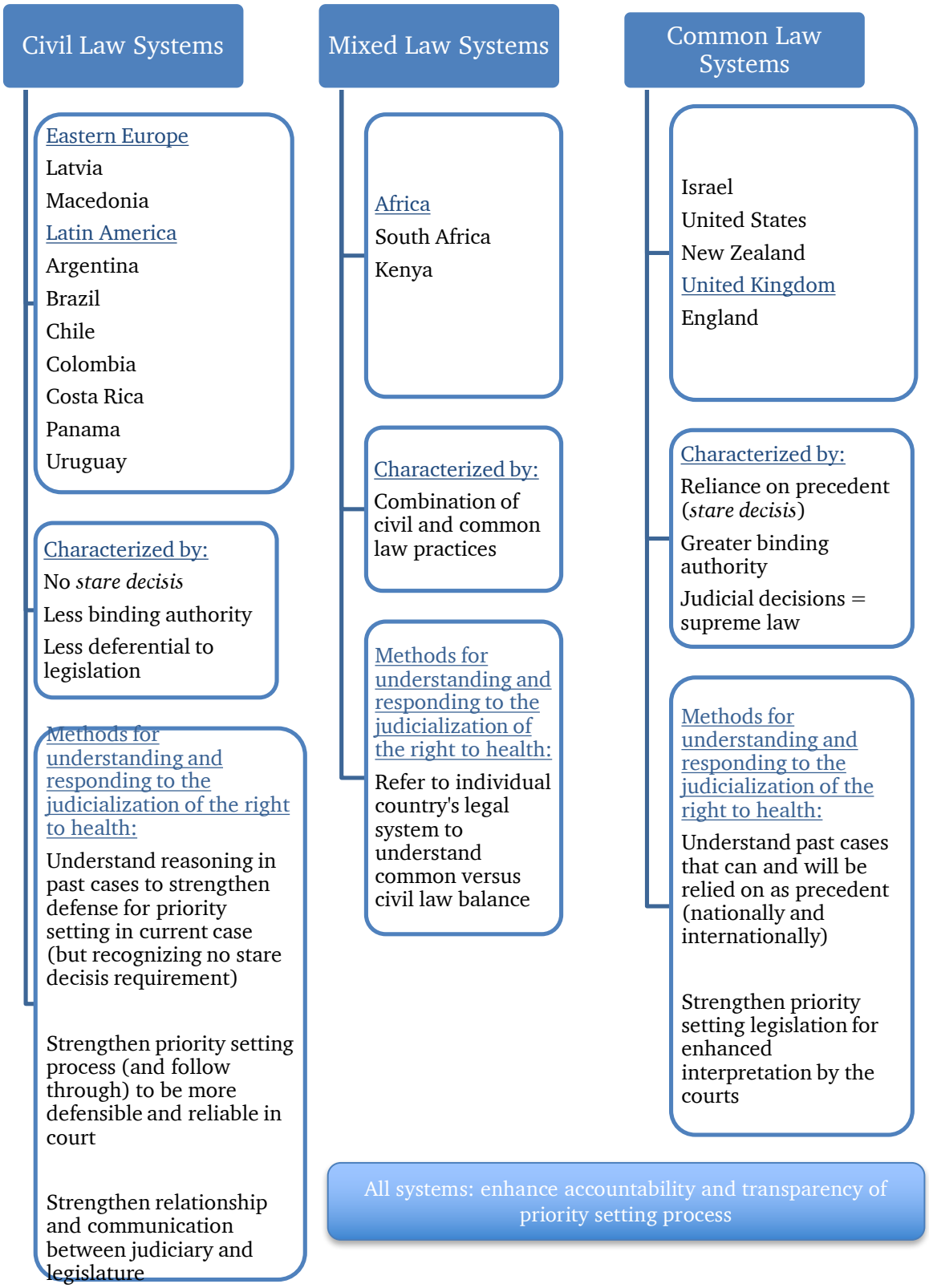
It can be found at: http://dx.doi.org/10.1080/23288604.2016.1124167.

7. APPENDIXES

7.1 Appendix A: Codification of Cases

Case	Country	Denial of technology contradicts RtH	Denial of technology contradicts law	Health law contradicts RtH	Priority setting method unfair
Ana Carina	Argentina	X			
Susana Beatriz	Argentina	X			
Mato Grosso	Brazil	X			
Espirito Santo	Brazil	X			
Caxias do Sul	Brazil	X			
N.R.V.	Chile	X			
Mr. X	Colombia	X			
T-760	Colombia	X			
Morrigan	Colombia	X			
Navarro	Costa Rica	X			
Ricardo Lachman	Panama	X			
Gerardo	Uruguay	X			
Hernando Gonzalez	Uruguay	X			
Hernandez Edward	Uruguay	X			
Fontes Braida	Uruguay		X		
42755708	Latvia	X			
Stamen Filipov	Macedonia			X	
Gila Louzon	Israel	X			
Victoria Yisraeli	Israel			X	
Soobramoney	South Africa	X			
Treatment Action Campaign	South Africa	X			X
Okwanda	Kenya				
Walsh	New Zealand				X
Eisai	England				X
Samity	India	X			
CEHURD	Uganda	X			

7.2 Appendix B: The judicialization of the right to health in varying legal systems



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